GÖG/ÖBIG

REPORT

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GÖG/ÖBIG

PPRI

REPORT

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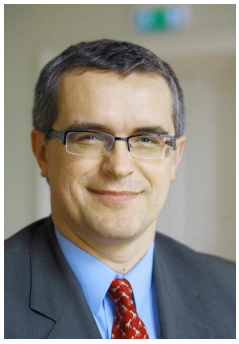


Foreword by Director Rys

Together with the Member States, the European Commission works to protect and promote the health of European citizens.

In this context, the Commission has been actively engaged in supporting Member States to cooperate, network and share information as regards pharmaceutical policy. Good information is essential for better, evidence-based decision-making and resource allocation, and paramount to avoid error and waste.

The Pharmaceutical Pricing and Reimbursement Information project was co-funded by the public health programme to increase the availability and transparency of information concerning pharmaceuticals in the Member States of the enlarged European Union. The project has contributed to an improved European Union framework for comparability of pharmaceutical pricing and reimbursement data, information and policies, developing a set of core indicators and undertaking comparative analysis based on country profiles, all of which are included in this report. Additionally, substantial input was given to develop an internationally-agreed glossary on pharmaceutical pricing and reimbursement.

The project has also put in place an active network of partners (competent authorities, third party payers in the field of pharmaceuticals, international institutions); in itself an example of the diversity of Europe and also of the shared needs, pooled expertise and common will to address a problem. The continued collaboration of the members of the project is a clear demonstration of its success as a network stemming from the teamwork during the project, providing the longer-term solutions that are needed whenever data collection and analysis are to be done on a sustained basis for the future.

Andrzej Rys

Director of Public Health
Health and Consumer Protection Directorate-General
European Commission

Foreword by Minister Dr. Kdolsky

For years, Austria has seen the need for in-depth information on pharmaceutical systems in other countries, in particular in fellow Member States of the European Union.

In order to gain knowledge in this field, the Austrian Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ) has, in the past 10 to 15 years, regularly commissioned the Austrian Health Institute ÖBIG to examine specific aspects of pharmaceutical systems in other countries.

Following this, the BMGFJ was pleased to hear that Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (successor of the Austrian Health Institute ÖBIG since August 2006) was commissioned by the European Commission, Health and Consumer Protection Directorate-General to take the lead in the PPRI project, which analyses pharmaceutical pricing and reimbursement in Europe. In order to demonstrate our support and commitment, the Austrian Ministry of Health, Family and Youth took the decision to co-fund the PPRI project.

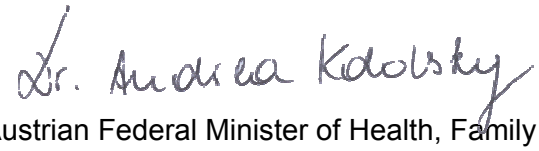
The PPRI project, aiming to improve knowledge on pharmaceutical pricing and reimbursement in Europe, is more than a research project. In fact, it filled the need for direct information-exchange and experience-sharing between policy-makers: The excellent PPRI management in the hands of Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, supported by the World Health Organisation (WHO), Regional Office for Europe, succeeded in establishing a network of competent authorities, third party payers, and further relevant institutions in the field of pharmaceuticals from 26 EU Member States, plus Albania, Canada, Norway, Switzerland, and Turkey, as well as European and international institutions (European Medicines Agency EMEA, European Commission, Enterprise Directorate-General, OECD, and the World Bank). I am proud that Austria has the lead in such a fruitful network.

In the course of the PPRI project, several deliverables were produced which are all of relevance for a successful European pharmaceutical policy. On the occasion of the PPRI Conference held in Vienna on 29 June 2007, which I had the pleasure to open, I was impressed to learn about the good practices in the PPRI member countries.

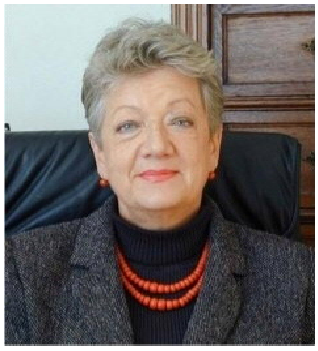
I would like to specifically mention one very important outcome of the PPRI project: Experiencing several misunderstandings between experts from all over Europe, the PPRI project management decided to establish the PPRI Glossary with relevant terms related to pharmaceutical pricing and reimbursement, in order to promote a common understanding and to develop a joint European language.

In this PPRI report, valuable results and recommendations are presented which give guidance in policy-making. Nonetheless, it is clear that challenges in pharmaceutical policies continuously need to be tackled, and that policy-supporting initiatives like PPRI should be carried on. Enhancing sustainability of the PPRI project, the Austrian Ministry of Health, Family and Youth highly appreciates a continuation of the successful work undertaken by the PPRI management and network. We consider PPRI as a model strategy for European pharmaceutical policy-advice in the 21th century.

Dr. Andrea Kdolsky



Austrian Federal Minister of Health, Family and Youth
November 2007



Foreword by General Manager Dr. Moritz

This report is one of the core results of the PPRI project that we, the Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, have conducted together with the WHO Regional Office for Europe in the last three years.

The project coordination under the lead of project manager Dr. Sabine Vogler, has more than a decade of experience in health care policy analysis and has published several reports on the pharmaceutical situation in Europe so far (cf. www.oebig.org → publications).

The PPRI Report offers a comprehensive overview of pharmaceutical pricing and reimbursement activities as well as information on the underlying health care systems in all EU Member States and further countries like Norway and Turkey. This comparative analysis is based on health care and pharmaceutical indicators which have guided the data collection.

However, the PPRI Report is only one of the many products of the PPRI project, others being:

- a **Needs Assessment Report**, exploring the expectations of more than 110 national and European institutions with regard to the information needs on pharmaceutical pricing and reimbursement,
- the **PPRI Website** (http://ppri.oebig.at) launched in summer 2005, containing an intranet for PPRI participants,
- 1-page **summaries** and **flowcharts** of the pricing and reimbursement framework in each PPRI country, offering information at a glance,
- a unique **glossary** of pharmaceutical terms to establish a common “pharma” terminology within the EU,
- a set of **21 core indicators** developed by an Indicators Task Force consisting of representatives from five EU Member States and international organisations with input from many stakeholders, completed by April 2007
- **22 Pharma Profiles** (country reports) of the PPRI countries, written by national experts, mostly from the institutions being responsible for pricing and reimbursement in the respective country, building the basis for the comparative analysis in this report,
- a variety of dissemination activities like a large scale **PPRI conference** in June 2007 in Vienna.

Nonetheless, to my opinion, the biggest and most sustainable achievement of the project is that GÖG/ÖBIG has managed to build up a strong **network** of pricing and reimbursement experts / officials from all but two EU Member States as well as further countries like Albania, Canada, Norway, South Africa, Switzerland and Turkey that will continue to meet even after the end of the research project on a bi-annual basis. Thus, allowing for a continuous exchange of information and lessons learned between official stakeholders being in charge of pricing and reimbursement in the enlarged European Union.

I want to thank the commissioners, the Austrian Federal Ministry of Health, Family and Youth (BMGFJ) and the European Commission, DG SANCO for their support during the project time.

Finally I'd like to congratulate the PPRI project team to this success and again want to express my thanks to all participants, especially our associate partner WHO Europe, for their efforts that made this project an overwhelming achievement.

Dr. Michaela Moritz

General Manager
Gesundheit Österreich GmbH

Foreword by Director Schmets

Well functioning health systems contribute to people's health; they should be responsive to people's expectations and the specific needs of all population groups; and they should be fair in the way that contributions to funding the system ensure that everyone has access to the health services. *The world health report 2000* introduced a common framework for analysing health systems and identified four major functions: governance/stewardship, financing, service delivery and resource generation. The resource generation function involves well trained people in the right places, health facilities and equipment, and products that are safe, accessible and appropriately used.

The WHO Regional Office for Europe's strategy on country support focuses on strengthening health systems on a country-by-country basis. Medicines play a crucial role in every country's health system as most medical interventions depend on the use of medicines, and because a sizeable part of health budgets is spent on medicines. Access to medicines depends on the country's financial capacity as well as on the efficiency of the supply system and the wider health system, but also on selection of the right medicines and their provision at affordable prices. Information about the regulation of pharmaceuticals and knowledge of other countries' experiences in this field can help improve the provision of medicines. The Pharmaceutical Pricing and Reimbursement Information (PPRI) project has assisted in improving the information and knowledge about the pharmaceutical systems in the European Union (EU) countries and beyond.

The PPRI project has also strengthened the networking between the countries of the EU and beyond, and their national pharmaceutical authorities and institutions. Its specific contribution is that it offers comprehensive country profiles for all EU member states, describing in detail their pharmaceutical systems and policies ("Pharma profiles"). In addition, the PPRI project has produced a comparative overview of the countries' pharmaceutical systems, allowing for analysis of aspects of pharmaceutical regulation within the context of the EU countries.

The information provided will undoubtedly contribute to greater transparency and a better understanding of the pharmaceutical systems, and this will, in turn, will assist countries in putting efficient provisional arrangements in place. It will also help them to further develop and improve their pharmaceutical systems and policies, on the basis of positive experiences in other countries.

Our main objective is to support WHO Member States in choosing the best possible investments in health on the basis of the available evidence and knowledge, and to build knowledge within the European Region. The PPRI has contributed to this task, and the WHO Regional Office for Europe is pleased to have been a part of the PPRI project and looks forward to continued collaboration with the network.

Gérard Schmets

Director a.i.
Division of Country Health Systems
WHO Regional for Europe

Abstract

PPRI (Pharmaceutical Pricing and Reimbursement Information) is a research project funded by the European Commission, Health and Consumer Protection Directorate-General (DG SANCO) and the Austrian Federal Ministry of Health, Family and Youth (BMGFJ). The project management is undertaken by the main partner Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) and the associated partner World Health Organisation, Regional Office for Europe (WHO Europe).

The objective of the PPRI project, which started in April 2005 and ended in October 2007, was to improve information and knowledge on the pharmaceutical systems in the Member States of the enlarged EU. This was mainly achieved by strengthening the network of relevant institutions in the field of pharmaceuticals and by compiling a comparative analysis, based on 21 core indicators for comparing pharmaceutical systems and on country specific reports (PPRI Pharma Profiles).

Within its time-frame of two and a half years, PPRI established a network of 52 institutions, mainly competent authorities and third party payers from a total of 31 countries. The PPRI network includes representatives from all 27 EU Member States except Romania, plus Albania, Canada, Norway, Switzerland, and Turkey. Additionally, European and international institutions (European Medicines Agency, OECD, WHO, World Bank) have been involved in the PPRI project.

The participating national representatives produced PPRI Pharma Profiles which provide in-depth information and data on pharmaceutical pricing and reimbursement in their country. At the end of the PPRI project, more than 20 Pharma Profiles have been finalised, and for the future annual up-dates of the profiles are planned.

The PPRI comparative analysis, which included 27 countries (the so-called “PPRI countries”), confirmed the existence of 27 different pharmaceutical pricing and reimbursement systems in Europe, though some identical key characteristics of pharmaceutical systems can be found in several PPRI countries. For instance, 24 of the 27 PPRI countries control the prices of pharmaceuticals (or of a group of pharmaceuticals, usually reimbursable pharmaceuticals). Pharmacy remuneration is regulated in all PPRI countries, and regulated wholesale mark-up schemes exist in 21 PPRI countries. All PPRI countries have reimbursement lists (national formularies) in place, of which positive lists, including pharmaceuticals that may be prescribed at the expense of a third party payer, are the most widespread (in 25 countries).

Some tools have become quite common in recent years. For example, at the end of the PPRI project, 18 of the 27 PPRI countries applied a reference price system, which implies that a maximum reimbursement amount has been defined for groups of interchangeable pharmaceuticals. Additionally, the methodology of external price referencing (international price

benchmarking), i.e. comparing to the prices of the same product in other countries, has become a widely-used methodology applied for pricing decisions in 22 PPRI countries.

Despite these similarities, each country features a specific pharmaceutical system, with its unique characteristics. PPRI offered the opportunity to learn about the systems of the fellow countries, including their experiences with reform measures. The PPRI participants have shown interest to follow-up with future developments in pharmaceutical pricing and reimbursement, and to devote on filling gaps in data availability and increasing comparability of pharmaceutical expenditure and consumption data.

Deliverables produced under the framework of the PPRI project, including the PPRI Pharma Profiles and the PPRI Glossary, are accessible through the PPRI website: http://ppri.oebig.at → Publications.

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	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. 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. 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).	2007
11	Pricing policies at distribution level	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. 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). In several PPRI countries statutory wholesale and pharmacy mark-ups cover all pharmaceuticals whereas in others OTC are excluded from regulations.	2007
12	Taxes on pharmaceuticals	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).	2007
		Reimbursement	
13	Positive/negative list	In all PPRI countries, reimbursement lists exists. 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.	2006/2007
14	Reference price system	18 of the 27 PPRI countries have introduced a reference price system (in one country it still has to be implemented).	2006/2007
15	Mechanisms for vulnerable groups	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).	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 date 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 interchangable (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 (PPPa), 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.

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ABPI	Association of the British Pharmaceutical Industry (United Kingdom)
AESGP	Association of the European Self-Medication Industry
AIFA	Agenzia Italiana del Farmaco / Medicines Agency (Italy)
AMIS	Arzneimittel-Informationssystem / Pharmaceutical Information System (Germany)
Art.	Article
ATC	Anatomic Therapeutic Chemical classification system
BMGFJ	Bundesministerium für Gesundheit, Familie und Jugend / Federal Ministry of Health, Family and Youth (Austria)
CDR	Common Drug Review (Canada)
CEE	Central and Eastern Europe
CNAMTS	Caisse Nationale d'Assurance Maladie des Travailleurs Salariés / National Sickness Fund for the Employees (France)
COPD	Chronic Obstructive Pulmonary Disease
CPB	Centraal Planbureau / Bureau for Economic Policy Analysis (Netherlands)
DAM	Délégués d'Assurance Maladie / Health Insurance Representatives (France)
DDD	Defined Daily Doses
DG	Directorate-General
DG ENTR	Directorate-General Enterprise and Industry of the European Commission
DG SANCO	Directorate-General Health and Consumer Protection of the European Commission
DoH	Department of Health (United Kingdom)
DP	Drug Payment scheme (Ireland)
EASP	Escuela Andaluza de Salud Pública / Andalusian School of Public Health
EC	European Commission / European Community
EEC	European Economic Community
EGA	European Generics Association
EHIF	Haigekassa / Health Insurance Fund (Estonia)
EMEA	European Medicines Agency
ESIP	European Social Insurance Platform
EU	European Union
EU-10	EU Member States as of the accession date of 1 May 2004
EU-15	EU Member States which acceded to the European Union before May 2004
EU-25	EU Member States as of the year 2006
EUROMEDSTAT	Name of a research project funded by DG SANCO
GDP	Gross domestic product
GMS	General Medical Services scheme (Ireland)
GÖG/ÖBIG	Gesundheit Österreich GmbH (GÖG), Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG) / Austrian Health Institute
HAS	Haute Autorité de Santé / High Authority for Health (France)
HEK	Heilmittel-Evaluierungskommission / Pharmaceutical Evaluation Board (Austria)
HILA	Lääkkeiden hintalautakunta / Pharmaceutical Pricing Board (Finland)

HiT	Health in Transition
HOM	Hospital-only medicine(s)
HPFB	Therapeutic Products Directorate of the Health Products and Food Branch (Canada)
HSE	Health Service Executive (Ireland)
HTMP	High Tech Medicinal Products scheme (Ireland)
HVB	Main Association of Austrian Social Security Institutions
ICER	Incremental Cost-effectiveness Ratio
IDTS	Indicative Drug Target scheme (Ireland)
IFPMA	International Federation of Pharmaceuticals Manufacturer Associations
IHHII	International Healthcare and Health Insurance Institute (Bulgaria)
INFARMED	Instituto Nacional da Farmácia e do Medicamento / Medicines Agency (Portugal)
Inh.	Inhabitant
INN	International Non-Proprietary Name
IRF	Institut for rationel farmakoterapi / Institute for Rational Pharmaco-Therapy (Denmark)
KELA	Kansaneläkelaitos / Social Insurance Institution (Finland)
LFN	Läkemedelsförmånsnämnden / Pharmaceutical Benefits Board (Sweden)
LSE	London School of Economics
LTI	Long Term Illness scheme (Ireland)
MA	Marketing authorisation
MEDEV	Medicine Evaluation Committee
Mio.	Million
MS	Member State(s)
n.a.	not available
n.appl.	not applicable
NAM	Lääkelaitos / Medicines Agency (Finland)
NHIF	National Health Insurance Fund (Bulgaria)
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence (United Kingdom)
NOC	Notice of Compliance (Canada)
NRT	Nicotine Replacement Therapy
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of Pocket Payment
OsMed	Osservatorio Nazionale sull'Impiego dei Medicinali / National Observatory for Pharmaceutical Use (Italy)
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical expenditure
PGEU	Pharmaceutical Group of the European Union
PMPRB	Patented Medicine Prices Review Board (Canada)
POM	Prescription-only medicine(s)
PPI	Pharmaceutical Price Information
PPP	Pharmacy Purchasing Price

PPPa	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information
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
PPRS	Pharmaceutical Price Regulation Scheme (United Kingdom)
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
ROC	Return on Capital
RPS	Reference price system
SD-doctors	Self-dispensing doctors
SFK	Stichting Farmaceutische Kengetallen / Foundation of Pharmaceutical Statistics (Netherlands)
SHA	System of Health Accounts
SHI	Social Health Insurance
SUKL	Štátny ústav pre kontrolu liečiv / Medicines Agency (Slovakia)
TÉB	Technológia Értékelő Bizottság / Technology Appraisal Committee (Hungary)
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value-added tax
WHO	World Health Organisation
WHO Europe	World Health Organisation, Regional Office for Europe
WP	Work package
ZCVA	Zāļu cenu valsts aģentūra / State Medicines Pricing and Reimbursement Agency (Latvia)

List of countries

AL	Albania
AT	Austria
BE	Belgium
BG	Bulgaria
CA	Canada
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HU	Hungary
IE	Ireland
IT	Italy
KZ	Kazakhstan
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
SE	Sweden
SI	Slovenia
SK	Slovakia
TR	Turkey
UK	United Kingdom
ZA	South Africa

List of curriences

BGN	Bulgarian lev
CZK	Czech koruna
CYP	Cyprus pound
DKK	Danish krone
EEK	Estonian kroon
EUR / €	Euro
GBP	Pound sterling
HUF	Hungarian forint
LTL	Lithunian litas
LVL	Latvian lats
MTL	Maltese lira
NOK	Norwegian krone
SEK	Swedish krona
SIT	Slovenian tolar
SKK	Slovak koruna
TRY	New Turkish lira

1 Introduction

PPRI (Pharmaceutical Pricing and Reimbursement Information) is a project commissioned by the European Commission, Health and Consumer Protection Directorate-General (DG SANCO) under the framework of the Public Health Programme 2003–2008, Health information and knowledge 2004.[1] The project is co-funded by the Austrian Federal Ministry for Health, Family and Youth (BMGJF). The PPRI project aims at providing and disseminating knowledge and information on pharmaceutical systems in the European Union.

The PPRI project is coordinated by the main partner Gesundheit Österreich GmbH (GÖG), Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG) / Austrian Health Institute (furthermore GÖG/ÖBIG), supported by the associated partner World Health Organisation, Regional Office for Europe (furthermore WHO Europe). In total, PPRI involves a network of 52 institutions from the field of pharmaceuticals. These institutions are national institutions, like Medicines Agencies, Ministries of Health, social insurance institutions and research institutes, as well as European and international institutions, such as the European Medicines' Agency (EMEA), OECD and World Bank.

The PPRI project started in April 2005 and ended in October 2007. Follow-up initiatives are under way.

1.1 PPRI objectives and rationale

The regulations of the European Union in the field of pharmaceuticals concern mainly the market authorisation and the distribution of pharmaceuticals. Pricing and reimbursement of pharmaceuticals are national affairs, though European regulations (e.g., the Transparency Directive) have induced changes in pharmaceutical policies in many EU Member States.

In reality, there are (meanwhile) 27 pharmaceutical pricing and reimbursement systems in the enlarged European Union which sometimes differ to a great extent. Some overviews of these systems have been made over the last years, both commercially as well as for authorities. Problems have often been the non-comparability of the information, incomplete information, invalid and not sufficiently detailed information, as well as out-of-date information.

Therefore, a network of authorities and institutions within the enlarged European Union to provide, exchange and analyse the pricing and reimbursement issues in the field of pharmaceuticals has been considered of great need. This was the starting point for PPRI and is reflected in the project objectives.

[1] http://ec.europa.eu/comm/health/ph_projects/2004/action1/action1_2004_05_en.htm

The general objectives of the PPRI project are defined as follows:

- to improve information and knowledge on the pharmaceutical systems in the Member States of the enlarged EU, thus contributing to increase transparency,
- to strengthen the networking of the relevant national authorities and institutions in the field of pharmaceuticals in the EU Member States,
- to facilitate a regular exchange of information and to allow a process of learning from each other,
- to develop indicators for analysing pharmaceutical pricing and reimbursement systems,
- to provide and disseminate information and advice for policy-makers at national and European Union level.

For the implementation of the general aims, specific objectives have been developed and assigned to the work packages (WP) of the project. The specific aims related to the PPRI project are:

1. Strengthening the networking of the relevant national authorities and institutions in the field of pharmaceuticals in the Member States (WP 1: “Coordination”)
2. Assessing the needs of EU and national administration and policy-makers with regard to knowledge and information transfer on pharmaceutical pricing and reimbursement (WP 3: “Needs Assessment”)
3. Developing a homogenous structure/template for country reports on pricing and reimbursement, the so-called “PPRI Pharma Profiles” (WP 4: “Survey”)
4. Developing indicators for a comparative analysis of pharmaceutical pricing and reimbursement information (WP 5: “Indicators”)
5. Systematic collection of relevant information and data on pharmaceutical pricing and reimbursement in the EU Member States and compilation of country reports (WP 4: “Survey”)
6. Analysing pharmaceutical pricing and reimbursement policies in the enlarged European Union (WP 6: “Comparative Analysis”)
7. Dissemination of the project results (WP 2: “Dissemination”)

The six work packages of the PPRI project will be described with regard to their objectives, tasks, methodology, and deliverables in chapter 2.

1.2 Structure of the PPRI Report

The aim of the PPRI Report is to present the deliverables and results of the PPRI project and to discuss the findings of the analysis.

The outline of the PPRI Report is as follows:

- Chapter 2 – PPRI project:

  Chapter 2 guides the reader through the different work packages of the project, with regard to their objectives, tasks, deliverables and outcomes. In that chapter, the various tools, papers and reports of the PPRI project are presented. Readers who are interested in further information can consult these deliverables.

- Chapter 3 – Comparative analysis:

  Chapter 3 presents the results on the comparative analysis, thus providing information and data on the underlying health care and pharmaceutical system, on pharmaceutical pricing and reimbursement policies as well as rational use of pharmaceuticals in the 27 PPRI countries. Additionally, country specific examples are displayed.

- Chapter 4 – Lessons learned:

  The concluding chapter 4, which can also be seen as a stand-alone document, highlights the key findings of the PPRI survey and analysis.

The PPRI Report will be accompanied by two annexes, which are, because of their size (about 2,000 pages), only available in electronic form (on a CD Rom and to be downloaded from the PPRI website):

- Annex I – PPRI Pharma Profiles:

  Annex I includes all reports on national pharmaceutical pricing and reimbursement policies. Within the framework of PPRI, 22 Pharma Profiles were produced.

- Annex II – PPRI tools and reports:

  Annex II is a compendium of all tools (e.g., the PPRI Pharma Profile Template, the PPRI Glossary), papers (e.g., the Set of Core PPRI indicators) and reports (e.g., the PPRI Needs Assessment Report) produced in the PPRI project.

The idea behind this set-up of the PPRI Report is to offer information and data at various levels of detail in order to serve the controversial interests of the different target groups. While the comparative analysis in chapter 3 of the PPRI Report might be too detailed for readers who wish to get a brief overview (and who are thus being advised to read the summary report “PPRI at a Glance” at the end of chapter 3), researchers interested in analysing a specific aspect of the pharmaceutical systems might consider the information offered in chapter 3 of the PPRI Report as a starting point, and make use of the PPRI Pharma Profiles for further in-depth investigation.

Policy-makers are recommended to read the key results and conclusions described in chapter 4 on “Lessons learned”.

The complete information (covering all documents of both annexes) is also accessible on the PPRI website, see http://ppri.oebig.at.

1.3 Terms and definitions

The PPRI Report is consistent with the terminology defined in the PPRI Glossary. As described in section 2.4.1, the PPRI Glossary was developed in order to guarantee the use of identical technical terms in the PPRI Pharma Profiles, written by authors from different countries. The use of the PPRI terminology is one approach to promote a common language regarding pharmaceutical policies in Europe.

In this report the term “PPRI countries” is used, referring to all countries whose representatives in the PPRI project provided input for the PPRI comparative analysis. These countries include all EU Member States, except Spain and Romania (not a Member State at the start of the PPRI project), plus Norway and Turkey. The number of “PPRI countries” exceeds the number of PPRI Pharma Profiles that have been submitted, since some countries only contributed to the comparative analysis, and opted not to write a Pharma Profile or were not able to finalise the Pharma Profile in time (cf. section 2.6.1). The non-EU Member States Albania, Canada and Switzerland have, at different points in time, decided to join in the PPRI network for gaining from and contributing to the sharing of experience, but are not included in the PPRI comparative analysis.[2]

Also, the group of the old EU Member States (so-called EU-15), i.e. those countries which acceded to the European Union before May 2004, is compared to the new EU Member States as of the accession date of 1 May 2004 (EU-10). The averages of these two groups of countries are compared to the total EU average (EU-25).

[2] Additionally, the PPRI Report offers a brief description of pharmaceutical pricing and reimbursement in Canada (cf. Box 4 in chapter 3).

2 PPRI project

The PPRI project aims at providing knowledge and promoting information-exchange on pharmaceutical pricing and reimbursement policies in the EU Member States.

This general objective is split up in seven specific objectives assigned to six work packages (see section 1.2). In the following, the tasks undertaken in these work packages are described, and their deliverables are presented. At the end of this chapter, the overview Table 2.4 provides a summary which deliverables have been produced in the PPRI project and how they are accessible.

2.1 PPRI network

The work package "coordination/network"[3] aims at strengthening the networking of the relevant national authorities and institutions in the field of pharmaceuticals in the EU Member States, thus filling the need for a better sharing of information and exchange of experiences.

2.1.1 Methodology

A major objective of PPRI was to establish a **network** of organisations in the field of pharmaceuticals, mainly national institutions, in the EU Member States. The international public health perspective was guaranteed by having WHO Europe on board as the associated partner.

PPRI participants initially contacted were competent authorities and further institutions which are in charge of pharmaceutical pricing and/or reimbursement decisions in their country (e.g., Medicines Agencies, ministries and social insurance institutions). It was planned to have as many of the then 25 EU Member States as possible represented by a national authority in the PPRI network. Additionally, the PPRI project management strived for the involvement of European and international institutions, projects and initiatives in the field in order to promote information-sharing and to avoid possible duplication of initiatives and projects.

Five **PPRI Coordination Meetings**[4] offered platforms for guaranteeing the flow of information and the coordination of the tasks between the PPRI participants. The PPRI Coordination

[3] The official name of this work package is "coordination". The authors decided to re-name the heading into "PPRI network" which is, in fact, the key outcome of this work package.

Meetings aimed not only at updating the participants on the progress of the project and at discussing and deciding on important tools (e.g., PPRI Pharma Profile Template, PPRI Glossary), but also at initiating and enhancing a dialogue between the PPRI participants. Therefore, specific aspects of pricing and reimbursement systems in PPRI countries, including reports on experiences with policies, were always on the agenda of the PPRI Coordination Meetings. Additionally, the PPRI participants were up-dated on the status of other relevant initiatives and projects, besides the PPRI project.

During the intervals between the PPRI Coordination Meetings, the **coordination and information-exchange** was guaranteed by regular e-mail and telephone conversations. Additionally, the PPRI management set up an **Intranet forum** where the PPRI participants had access to all relevant documents and could take part in discussions.

The PPRI project management considered it essential that all PPRI tools, papers and reports found the approval of the PPRI group. Thus, feed-back rounds were an integral part of the PPRI project (preferably at the PPRI Coordination Meetings, and, if necessary, additionally through e-mail correspondence). During the third and the fifth PPRI Coordination Meeting, the PPRI network members participated in an evaluation of the PPRI project.[5]

2.1.2 Results

In the course of the PPRI project, further interested institutions joined the network, so that in the end (October 2007) the **PPRI network consists of 52 institutions** which are listed in Table 2.1.

The **commissioning parties** are the European Commission, Health and Consumer Protection Directorate-General (DG SANCO) and the Austrian Federal Ministry of Health, Family and Youth (BMGJF).

The **project management** consists of the main partner Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute and the associated partner WHO, Regional Office for Europe.

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[4] The first and the fifth PPRI Coordination Meeting (1-2 September 2005 and 28 June 2007) were hosted by the main partner GÖG/ÖBIG in Vienna. The associated partner WHO Europe hosted the second PPRI Coordination Meeting in Copenhagen (27-28 April 2006). The third and fourth PPRI Coordination Meetings were hosted by PPRI participants (Polish Ministry of Health, Warsaw, 9-10 October 2006; Italian Medicines Agency, Rome, 1-2 March 2007).

[5] The results of this evaluation rounds are documented in the minutes of the PPRI Coordination Meetings (accessible at the Intranet Forum of the PPRI website). Based on this feed-back and on additional personal surveys undertaken by the project management, an evaluation of the report was undertaken (cf. section 2.1.3 and section 4.1).

40 of the participating institutions represent **national organisations**, mainly Medicines Agencies, ministries and third party payers. All EU Member States unless Spain[6] and the new Member State Romania are represented. In some countries, a second institution relevant for pricing and/or reimbursement decisions decided to join the network. Furthermore, PPRI transcended the EU borders: Albania, Canada, Norway, Switzerland and Turkey are also involved in the PPRI network. Furthermore, representatives from the Ministry of Health in South Africa attended the fifth PPRI Coordination Meeting, and an official of the Ministry of Health in Kazakhstan participated in the first network meeting after the end of the research project, held in Bratislava in November 2007.

The PPRI project management is pleased to also have the following **European and international institutions** participating in the PPRI network: the European Medicines Organisation (EMEA), the Enterprise Directorate-General of the European Commission, the Organisation for Economic Co-operation and Development (OECD), the WHO (WHO Europe as associated partner and WHO Geneva) and the World Bank.

Table 2.1: PPRI project – Participants of the PPRI network, as of October 2007

Country	Institution	Role
Project commissioners		
Luxembourg	European Commission, Health and Consumer Protection Directorate-General	EU Institution
Austria	Federal Ministry of Health, Family and Youth	Ministry
Project management		
Austria	Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute	Research institute
Denmark	World Health Organisation, Regional Office for Europe	International organisation
National stakeholders		
Albania	Health Insurance Institute	Third party payer
Austria	Main Association of Austrian Social Security Institutions	Third party payer
Austria	Chamber of Labour	Consumer association
Belgium	Ministry of Economic Affairs	Ministry
Belgium	Health Insurance Institute	Third party payer
Bulgaria	International Healthcare and Health Insurance Institute	Research institute
Canada	Health Canada	Federal government department within the Ministry of Health
Cyprus	Health Insurance Organisation	Third party payer

[6] No official authority from Spain is involved in PPRI. However, the Andalusian School of Public Health (EASP), which was commissioned with another EU project, is part of the PPRI network.

Country	Institution	Role
Cyprus	Ministry of Health	Ministry
Czech Republic	Ministry of Health	Ministry
Czech Republic	Medicines Agency	Medicines Agency
Czech Republic	Charles University	University
Denmark	Medicines Agency	Medicines Agency
Estonia	Ministry of Social Affairs	Ministry
Finland	Association of Finnish Pharmacies	Association of pharmacies
Finland	Ministry of Social Affairs and Health	Ministry
France	National Sickness Fund for Employees	Third party payer
France	University Claude Bernard Lyon 1	University
Germany	Institute for Medical Documentation and Information	Authority
Germany	Ministry of Health	Ministry
Greece	Institute for Pharmaceutical Research and Technology	Research institute
Hungary	National Health Insurance Fund	Third party payer
Ireland	Health Service Executive – Finance Shared Service – Primary Care Reimbursement Service, Medical Service Board	National Health Service
Ireland	National Centre for Pharmaco-economics, St. James Hospital	Research institute
Italy	Medicines Agency	Medicines Agency
Latvia	Medicines Pricing and Reimbursement Agency	Medicines Agency
Lithuania	Ministry of Health	Ministry
Luxembourg	Union of Sickness Funds	Third party payer
Malta	Medicines Agency	Medicines Agency
Netherlands	Ministry of Health, Welfare and Sport	Ministry
Norway	Medicines Agency	Medicines Agency
Norway	Ministry of Health and Care Services	Ministry
Poland	Ministry of Health	Ministry
Portugal	National Pharmacy and Medicines Institute	Medicines Agency
Slovakia	State Institute for Drug Control	Medicines Agency
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	Medicines Agency
Sweden	Pharmaceutical Benefits Board	Authority
Switzerland	Federal Office for Public Health	Authority
Turkey	Hacettepe University	University
United Kingdom	Medicines Pharmacy and Industry, Department of Health	Ministry

Country	Institution	Role
European / international stakeholders and representatives of projects		
Belgium	European Observatory on Healthcare Systems and Policies	Research institution
Belgium	European Commission, Directorate-General Enterprise and Industry	EU institution
France	Organisation for Economic Cooperation and Development, Health division	International organisation
Luxembourg	SOGETI	Research institute
Spain	Andalusian School of Public Health	University
Switzerland	World Health Organisation, Geneva	International organisation
UK	European Medicines' Agency	EU institution
USA	World Bank	International organisation

Source: PPRI

Furthermore, PPRI brought together several **projects** (e.g., Andalusian School of Public Health EASP, EUROMEDSTAT) **and initiatives** (e.g., Medicine Evaluation Committee MEDEV) in the field of pharmaceuticals.

The PPRI participants fulfilled not only successfully their tasks defined in the project framework (in particular, the drafting of the PPRI Pharma Profiles, cf. section 2.4), but have also contributed to a very **active communication between the network members**. For instance, in the face of an up-coming reform in their country, several PPRI participants addressed the group in order to learn from the experiences of their colleagues, which usually resulted in vivid discussions. Furthermore, the PPRI project management learned about bilateral meetings of PPRI representatives, in which they shared experiences with country specific measures.

Figure 2.1: PPRI project – The PPRI group at the fifth PPRI Coordination Meeting in Vienna, June 2007

Source: PPRI

For specific tasks, **sub-groups** were created: The staff of the PPRI project management (GÖG/ÖBIG and WHO Europe) was divided into country specific editorial teams reviewing the PPRI Pharma Profiles, and the PPRI Indicators Task Force worked on a proposal for the Set of Core PPRI indicators.

2.1.3 Excursus: Evaluation

An important objective of the PPRI project was the establishment of a network of competent authorities and further relevant institutions in the field of pharmaceuticals and to compile and share information and data on pharmaceutical pricing and reimbursement. Generally speaking, the PPRI network is by now being perceived by many European and international stakeholders as an important initiative, which is demonstrated by the quite large number of persons seeking contact to the PPRI management as well as by the numerous involved country representatives.

In addition to the external feedback the project was **internally evaluated** in two ways:

- Firstly, at **two PPRI Coordination Meetings** the PPRI participants were asked to give feedback on the PPRI process and the outcomes at that given time. It showed that the networking has been very fruitful and supportive for the PPRI participants, and in fact bridged the communication gap claimed in the PPRI needs assessment (cf. section 2.3.2 and PPRI Needs Assessment Report, Annex II). PPRI participants have expressed their

interest for a continuation of the networking after the end of the project. Some initiatives to guarantee sustainability and to follow-up with future tasks have already been launched. The findings of the qualitative evaluations are presented in more detail in section 4.1.

- Secondly, during summer 2007 a **survey**[7] on the outcome of the PPRI project was performed by means of an electronic questionnaire (response rate: 46 out of 70 persons addressed) and a hermeneutic analysis, accompanied by six qualitative interviews.

  This analysis also showed that PPRI has filled a gap: All respondents rated the usefulness of the PPRI Pharma Profiles (cf. section 2.4) as high and almost 90 percent of the authors considered the template for the PPRI Pharma Profiles as "good" or "very good".

  Likewise, 100 percent of the respondents stated that they plan to make use of the PPRI network in future, which was also demonstrated by the fact that more than 30 persons attended the first network meeting after the end of the research project[8]. On average, about two third of the PPRI participants took part in all network meetings held during the runtime of the project.

  The usefulness of the PPRI website (cf. section 2.2) and its intranet (the so-called SharePoint) was also considered as high: Almost all participants were familiar with the address of the website and about 70 percent of the respondents had used the SharePoint at least once.

2.2 PPRI dissemination

The work package "dissemination" aims at making PPRI and its results known.

2.2.1 Methodology

Dissemination primarily targets at the competent authorities and third party payers, who are directly addressed and involved in the PPRI network. Further **target groups** defined in the PPRI dissemination strategy cover European and international institutions (also involved in PPRI), research institutions/academia, patients/consumers, doctors, pharmaceutical industry, distribution actors, and specific media.

The key **dissemination principles** are as follows:

- As soon as information was quality-approved and accepted by the PPRI group, it was made available to the public (via the PPRI website).

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[7] Survey undertaken by a representative of the associated partner WHO Europe for a master thesis, not published

[8] The PPRI network meeting was kindly hosted by the Slovakian Medicines Agency SUKL, supported by the Slovakian Ministry of Health. It was held in Bratislava on 15–16 November 2007.

- From the beginning on, the PPRI project management took any possible opportunity to make PPRI known and encouraged the PPRI participants to follow this example.
- The PPRI participants have been considered to serve as “focal points” for their country. In this respect, they are not only competence centres regarding know-how on national pharmaceutical pricing and reimbursement policies, but they also act as an interface for dissemination in their country. National dissemination of PPRI is thus in the hands of the PPRI participants (e.g., some countries decided to have the PPRI Pharma Profile translated in their own language).
- The needs assessment process (cf. section 2.3), in which the PPRI participants addressed several stakeholders in their countries, was an excellent occasion in terms of making PPRI known.
- Information activities were supported by Corporate Identity measures (e.g., systematic use of the PPRI abbreviation or the PPRI logo, cf. Figure 2.2) and dissemination tools (e.g., the PPRI leaflet) designed by the project management for general use by PPRI participants.

Figure 2.2: PPRI project – Logo

Source: PPRI

2.2.2 Results

A key dissemination platform is the **PPRI website**, accessible at http://ppri.oebig.at, providing information on the framework and work plan of the PPRI project, the PPRI network and major dissemination activities (e.g. the PPRI Conference). At the PPRI website, key deliverables, such as the PPRI Glossary, the PPRI Pharma Profiles and further reports, are made available to the public.

The PPRI website has high rankings on search engines (e.g., first hit when searching on “PPRI” or “pharmaceutical pricing reimbursement” in the search machine like www.google.com), and is regularly visited. On weekdays, on average more than 60 people visit the PPRI website. The visitors come from about 65 different countries all over the world. The PPRI project management has received several requests for information from researchers and policy-advisers who had come across PPRI on the internet.

The **PPRI Conference** was a major dissemination event of the PPRI project. Situated in the baroque hall of the Austrian Society of Sciences in Vienna, the PPRI Conference brought together 250 delegates from 36 countries, representing national authorities, European and international institutions, specific media, academia and consultancy business, pharmaceutical industry and distribution actors. This one-day conference, which took place in the end phase of the project[9], allowed not only for the presentation of the objectives and deliverables of the project, but also offered a series of in-depth presentations of the results: National pricing and reimbursement systems[10] as well as a comparative analysis of pharmaceutical policies in the EU were presented.

As stated in section 2.2.1, the PPRI project was introduced at several occasions (e.g., meetings of policy-makers and scientific congresses). The PPRI project management was regularly invited to give **presentations** on the PPRI project. Furthermore, **articles** in scientific journals completed the dissemination strategy.[11]

A key dissemination tool is the present **PPRI Report**, which – together with all its annexes – offers the whole range of deliverables of the PPRI project.

The dissemination activities will continue after the official end of the project, de facto quite intensively with all results being available.

2.3 PPRI needs assessment

The work package "needs assessment" aims at assessing national and international stakeholders' information needs concerning pharmaceutical pricing and reimbursement. This assessment served as an important input for the development of the PPRI Pharma Profile Template (cf. section 2.4.1).

2.3.1 Methodology

Taking into account the requirements expressed by the PPRI participants at the first PPRI Coordination Meeting in September 2005 (**first needs assessment round**), a Needs Assessment Guide was developed.

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[9] The PPRI Conference was held on 29 June 2007. For further information see the PPRI website → Conference

[10] Some speakers gave presentations on selected aspects of pharmaceutical pricing and/or reimbursement in their countries (e.g., international price comparisons in Cyprus and the German "Festbetragssystem"/reference price system), whereas all PPRI participants explained their national system on posters.

[11] The complete list of presentations and the list of articles on PPRI can be found in Annex II.

The **Needs Assessment Guide** was structured as a mix of open questions for surveying which information the addressed persons/institutions were most interested in and leaving room for additional comments, and of requests on four specific priority areas (pricing, reimbursement, access/cost-containment and monitoring/evaluation).

The Needs Assessment Guide was the key tool for the PPRI project management and the PPRI participants to assess the information needs of different stakeholders. In their role as authorities, the PPRI participants themselves gave answers regarding the information needs of the institution which they represented and additionally, they addressed further stakeholders in their country. Furthermore, the PPRI project management undertook a survey among relevant European institutions.

The PPRI needs assessment was undertaken in autumn/winter 2005. In total, **115 institutions** participated in the PPRI needs assessment (thereof 101 national institutions and 14 European institutions).[12]

2.3.2 Results

Based on the assessment, specific information needs regarding **five priority areas** were identified. Table 2.2 provides a brief overview of the key areas of interest.[13] The issue of **access/cost-containment** featured as the top area of interest. Furthermore, many stakeholders showed a special interest in "background" information on the health care systems in spite of the fact that this was not a predefined theme in the Needs Assessment Guide. This indicates that there exists a great need for contextual information. Already at that early stage of the PPRI project, the importance of the sustainability of the project as well as the support of the decision-making stakeholders were mentioned.

[12] The 101 national institutions include 25 ministries, 14 third party payers (social insurance institutions and national health services), 25 public institutions (universities, public health institutes, etc.), 14 representatives of the pharmaceutical industry, 3 associations of pharmaceutical wholesale, 8 pharmacies' associations, 3 insurance companies, 3 doctors' associations and 6 patients' associations. The 14 European institutions were Directorates-General of the European Commission, European pharmaceutical industry associations, the European wholesale association, the European pharmacy association, OECD, and WHO. The complete list of participating institutions can be found in the PPRI Needs Assessment Report (Annex II).

[13] A detailed presentation and discussion of the results is provided in the PPRI Needs Assessment Report (Annex II).

Table 2.2: PPRI project – Most frequently mentioned information needs regarding pharmaceutical systems

1. Background	**4. Access/Cost-containment**
1.1 Organisation 1.2 Funding 1.3 Market authorisation and classification 1.4 Distribution	4.1 Policy 4.2 Price regulation 4.3 Volume regulation 4.4 Generics
2. Pricing	**5. Monitoring/Evaluation**
2.1 Price setting 2.2 Pricing procedure 2.3 Margins	5.1 Consumption and compliance 5.2 Method and indicators 5.3 Public Health
3. Reimbursement	
3.1 Criteria for reimbursement 3.2 Reimbursement procedure 3.3 Reimbursement rates/co-payment 3.4 Reference price system	

Source: PPRI

2.4 PPRI Pharma Profiles

The work package "survey/Pharma Profiles"[14] aims at producing reports on the national pharmaceutical pricing and reimbursement systems in Europe, drafted by the PPRI participants.

2.4.1 Methodology

A key deliverable of the PPRI project is the PPRI Pharma Profiles, which are reports on the pharmaceutical pricing and reimbursement systems in European countries. According to the concept of the PPRI project these reports were not to be written by researchers, but by the PPRI participants themselves, 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.

As a first step in this work package, the **PPRI Pharma Profile Template** was developed which should, on the one hand, guarantee the coverage of all relevant topics and, on the other hand, ensure a homogenous structure and content of the individual reports allowing for a comparative analysis of the results.

[14] The original name of this work package is "survey". The authors decided to re-name the heading into "PPRI Pharma Profiles" which is the well-known name for the reports on pharmaceutical pricing and reimbursement produced in the framework of this work package.

The development of the PPRI Pharma Profile Template was based on the long-time experience of the project management in this field[15], and took into consideration the results of the PPRI needs assessment (cf. section 2.3.2). The PPRI Pharma Profile Template was reviewed in several feed-back rounds internally within the PPRI group as well as externally. Moreover, the template was pre-tested by volunteering participants.[16]

In the course of the discussions on the PPRI Pharma Profile Template, the PPRI project management noticed misunderstandings on, sometimes key, concepts and terms related to pharmaceutical pricing and reimbursement among the PPRI participants, which are all well respected experts. Thus, seeing the need for a common language, the PPRI project management produced the **PPRI Glossary** based on definitions used in EUR-Lex and in publications of EGA, EMEA, ÖBIG, OECD, SOGETI, WHO and World Bank. The project management included experts from the National Centre for Pharmacoeconomics (Dublin), OECD, and SOGETI in the development of the PPRI Glossary, which was then approved by the PPRI group. However, the glossary is not a document carved in stone, but it is regularly monitored, adapted and enlarged, and any comments are most welcome.

Guided by the PPRI Pharma Profile Template and the PPRI Glossary, the PPRI participants drafted their Pharma Profiles, which were extensively **reviewed by an experienced editorial team**.[17] Before being acknowledged as final version, the draft versions of the PPRI Pharma Profiles were subject to at least two reviews. On the average, the production of a PPRI Pharma Profile, from the participant starting to write the first draft till the publication of the copy-edited final version accessible on the PPRI website, lasted six to nine months.

At the end of the PPRI project, the PPRI Pharma Profile Template was evaluated[18], and based on this assessment, a new template for producing updated Pharma Profiles referring to the year 2008 was distributed the PPRI group.[19]

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[15] For more than a decade, the main partner GÖG/ÖBIG, which is a well-known research institute, produced studies on pharmaceutical pricing and reimbursement issues in Austria and in the EU, while the associated partner WHO Europe is familiar with the experiences of the WHO Observatory gained in the compilation of the HiT (Health in Transition) Profiles.

[16] The PPRI Pharma Profile Template was sent to the PPRI participants for feed-back and was approved by the PPRI group at the 2nd PPRI Coordination Meeting in April 2006. Some participants volunteered for a pre-test, and at the 3rd PPRI Coordination Meeting in October 2006, representatives from Austria and Hungary informed on their experiences with the drafting of the Pharma Profile.

[17] For each Pharma Profile, an editorial team of 3 persons was determined: the editor-in-chief (WHO Europe), supported by two country experts (GÖG/ÖBIG).

[18] Already in the course of the PPRI project, minor adaptions had been undertaken in the PPRI Pharma Profile Template.

[19] Several PPRI participants have expressed their interest to up-date their Pharma Profiles after the end of the PPRI research project.

2.4.2 Results

In the course of the project **22 PPRI Pharma Profiles** were produced, thereof 21 have been made accessible on the PPRI website.

The PPRI Pharma Profiles offer **information and data** on

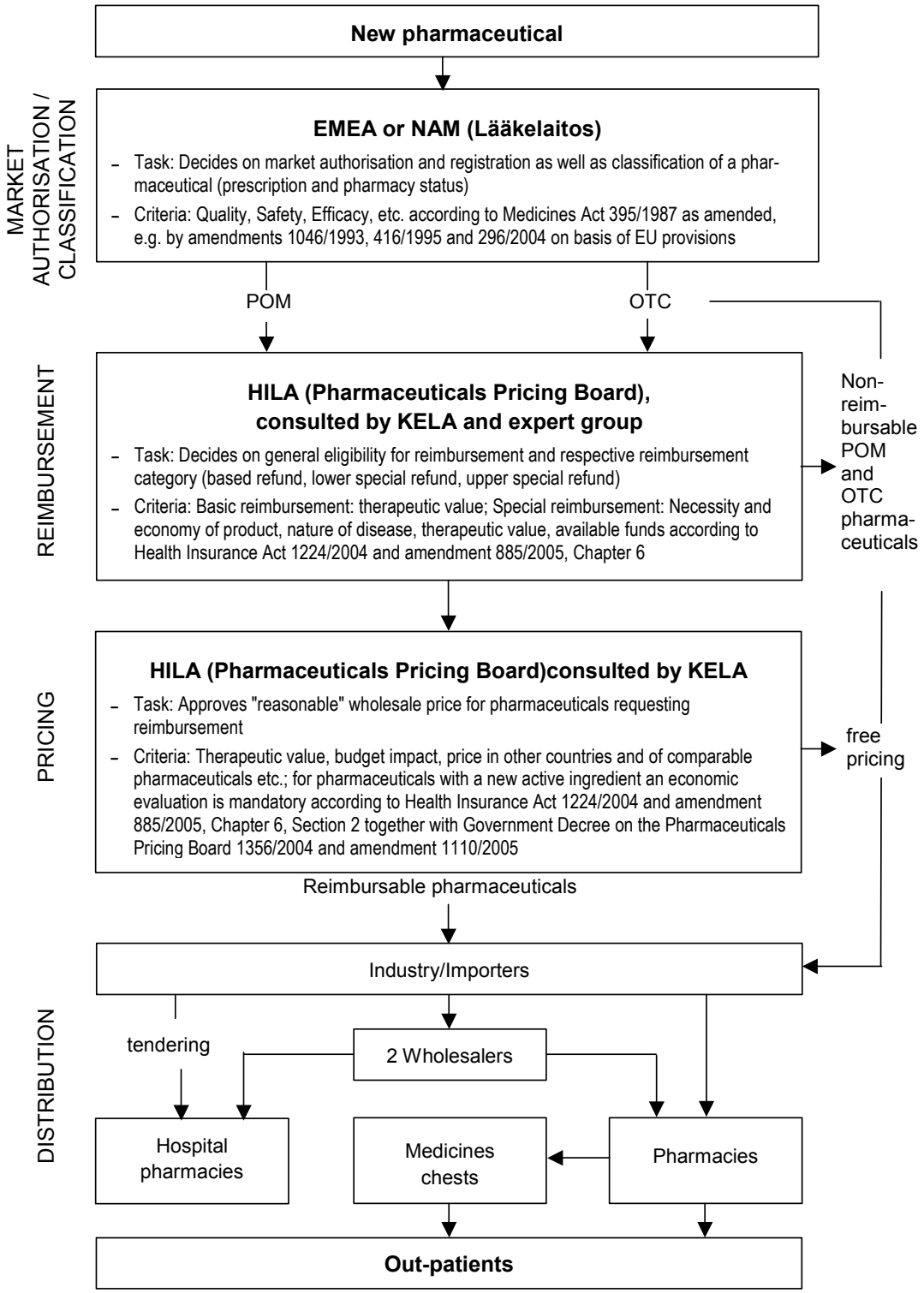
- the political and economic situation and the underlying health care system (e.g., the existence of a social health insurance system/national health service, health expenditure and its funding, provision of health care in the inpatient and outpatient sector)
- the pharmaceutical system (e.g., the regulatory framework, key authorities and institutions, the pharmaceutical market and distribution and pharmaceutical expenditure)
- pharmaceutical pricing (e.g., pricing policies like price control and free pricing for different kinds of pharmaceuticals, pricing procedures like international price comparisons, wholesale and pharmacy margins, taxes and cost-containment measures)
- reimbursement (e.g., reimbursement schemes and eligibility criteria, positive lists, reimbursement rates, reference price systems, out-of pocket payments and paybacks)
- rational use of pharmaceuticals (e.g., prescription monitoring and guidelines, pharmacoeconomics, generic substitution and promotion and information to doctors and patients)

The writing of the PPRI Pharma Profiles, including the extensive review process, was an enormous work-load for the authors, and the PPRI project management highly appreciates the motivation and time-investment of the PPRI participants in the Pharma Profiles. The content of the PPRI Pharma Profiles is based on the PPRI indicators (cf. section 2.5) which are needed for the comparative analysis (cf. section 2.6).

The PPRI Pharma Profiles cover all relevant aspects of pharmaceutical pricing and reimbursement in a country. On average, a PPRI Pharma Profile contains approximately 60 pages. In order to provide country specific information at a glance, PPRI offers, besides the Executive Summary within each Pharma Profile, two other overview tools:

- Each PPRI Pharma Profile includes a **flowchart** on the pharmaceutical system of that country (for a sample flowchart see Figure 2.3).
- At the PPRI Conference, the PPRI participants presented **posters** providing a brief summary of the pharmaceutical pricing and reimbursement framework (see http://ppri.oebig.at → Conferences).

Figure 2.3: PPRI project – Sample of a flowchart in the PPRI Pharma Profiles, example Finland



Source: PPRI Pharma Profile Finland 2007

Regarding the terminology, the **PPRI Glossary** has reached the status of a well-known terminology resource. Other study authors and institutions refer to the PPRI Glossary[20], which contributes to enhance a common language in this field.

2.5 PPRI indicators

The work package "indicators" aims at compiling a list of indicators to be applied for a comparative analysis (cf. section 2.6) of pharmaceutical pricing and reimbursement information.

2.5.1 Methodology

Parallel to the development of the PPRI Pharma Profile Template, first drafts of recommended pharmaceutical systems' indicators were developed, based on a comprehensive literature review and on the co-operation with further researchers in this field (e.g., OECD). The PPRI project management considered the at the time ongoing European **projects regarding pharmaceutical indicators**; these were, in particular, the SOGETI Pharmaceutical Indicators project[21] and the EUROMEDSTAT project[22] which both are represented in the PPRI network. In the course of this exploratory and cooperation-building effort, it was confirmed that indicators regarding the pharmaceutical sector, in particular indicators to assess systems and policies in this field, are not so common yet as other health care indicators.

A draft set of core PPRI indicators was presented at the PPRI Coordination Meeting in October 2006. As discussions showed diverging views of the PPRI participants on the importance of the various indicators presented, the PPRI group decided to appoint a **PPRI Indicators Task Force**. The PPRI Indicators Task Force included, besides the project management (GÖG/ÖBIG and WHO Europe), PPRI participants from France, Germany, Hungary and Italy, who are indicators experts and represent the different perspectives regarding the indicators development. The set of core PPRI indicators, which was decided on by the PPRI Indicators Task Force, was presented to and approved by the PPRI group at the following PPRI Coordination Meeting in March 2007.

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[20] The European Commission, Directorate-General Health and Consumer Protection disseminated the PPRI project and its glossary on its website: http://ec.europa.eu/health/ph_information/dissemination/hsis/hsis_17_en.htm. The report "Analysis of differences and commonalities in pricing and reimbursement systems in Europe" by the Andalusian School of Public Health (EASP 2007) for the Working Group on Pricing of the Pharmaceutical Forum also made use of the terms defined in the PPRI Glossary, http://ec.europa.eu/enterprise/phabiocom/docs/study_pricing_2007/andalusian_school_public_health_report_pricing_2007_incl_annexes.pdf

[21] http://ec.europa.eu/health/ph_information/indicators/docs/pharma_frep_en.pdf

[22] http://ec.europa.eu/health/ph_projects/2003/action1/action1_2003_29_en.htm

2.5.2 Results

The **21 pharmaceutical indicators** developed and approved in the PPRI project are listed in the document "**Set of Core PPRI Indicators**" (see Annex II). This paper discusses the PPRI indicators, giving evidence for their relevance as well as possible limitations.

Table 2.3: PPRI project – PPRI indicators

No.	Indicator	Category
1	Population age structure	Background
2	Gross domestic product per capita in € Purchasing Power Parities (PPPa)	
3	Public/private funding of health expenditure	
4	Total Health Expenditure per capita in € Purchasing Power Parities (PPPa)	
5	Regulatory framework for pharmaceutical policy	Pharmaceutical System
6	Key data on pharmaceutical industry	
7	Inhabitants per "Prescription-only medicines dispensary" (POM dispensary)	
8	Total pharmaceutical expenditure as percentage of total health expenditure	
9	Public/private funding of pharmaceutical expenditure	
10	Pricing policies at manufacturer level	Pricing
11	Pricing policies at distribution level	
12	Taxes on pharmaceuticals	
13	Positive/negative list	Reimbursement
14	Reference price system	
15	Mechanisms for vulnerable groups	
16	Share of generics in volume and value as percentage of outpatient market	Rational Use
17	Prescription guidelines	
18	Mandatory guidelines for decision-makers / role of pharmaco-economics	
19	Information to patients	
20	Monitoring of consumption	
21	Number of prescriptions per capita in volume and value	

Source: Set of Core PPRI Indicators

The developed indicators cover different aspects of the pharmaceutical systems, and are grouped according to the outline of the PPRI Pharma Profiles. The **PPRI Indicators Short List** offers an overview of the indicators at a glance (cf. Table 2.3).

2.6 PPRI comparative analysis

The work package "comparative analysis" aims at presenting and analysing information and data on the pharmaceutical systems in a comparative way.

2.6.1 Methodology

The PPRI comparative analysis makes use of the work undertaken in the course of the project, in particular of

- the PPRI Pharma Profiles providing all relevant data and information, which are referred to in the comparative analysis and
- the PPRI indicators for an outline and prioritisation of the PPRI comparative analysis.

The comparative analysis is a final step in the PPRI project, and forms the work package where everything comes together.

Even though the outline of the comparative analysis seems, at first sight, quite clear due to the underlying list of indicators, the PPRI project management had in-depth discussions especially on how to present information on qualitative indicators. A first **draft** of the PPRI comparative analysis was sent to the PPRI group in spring 2007. The PPRI participants were asked to comment on the outline of the comparative analysis and to check the data and information presented for their country. Furthermore, this **feed-back** round offered PPRI participants, who had not submitted a PPRI Pharma Profile by that time, the opportunity to deliver **inputs** and thus to participate in the comparative analysis.

The drafting of the comparative analysis was combined with a very thorough validation of the data, in order to guarantee data comparability as much as possible.

2.6.2 Results

The PPRI comparative analysis includes **27 countries** (so-called PPRI countries, cf. section 2.3), thus covering the EU-25 (except Spain, which is only included in some overview charts), plus Bulgaria, Norway and Turkey.

As the PPRI comparative analysis is one of the key deliverables of the PPRI project, the PPRI project management decided to give it enough room and include it in the **PPRI Report**. Therefore, the results of the comparative analysis are presented in the following chapter 3. In this analysis the authors did not limit themselves to analysing the 21 core PPRI indicators, but also considered further relevant information and data collected in the PPRI Pharma Profiles. Additionally, country specific examples of pharmaceutical policies and practises offer the reader an idea of the practical implementation.

For readers wishing to get a brief overview, the summary report "**PPRI at a Glance**", which is included at the end of chapter 3, but can also be seen a stand-alone document, provides in brief the results of the comparative analysis presented per PPRI indicator.

Table 2.4: PPRI project – Summary

No.	Work Package	Objective	Deliverables	Accessible at
1	Coordination	• Establish a network of relevant institutions in the field of pharmaceuticals in the EU Member States • Guarantee good communication and coordination in the PPRI network	• Network of 52 institutions from 26 EU Member States, plus Albania, Canada, Norway, Switzerland and Turkey. Involvement of DG ENTR, EMEA, OECD, WHO and World Bank. • Five PPRI Coordination Meetings of the PPRI network • PPRI Intranet Forum • Evaluation of the PPRI project • PPRI Interim Report • PPRI Report: the final report of the PPRI project, offering technical information on the project and its outcomes • Sustainability: Further networking and exchange of information planned, annual up-dates of the PPRI Pharma Profiles. First network meeting after the end of the project was held in November 2007	• Up-dated list of the PPRI participants: PPRI website • Minutes of the PPRI Coordination Meetings and internal information-exchange between PPRI participants: PPRI Intranet Forum • Evaluation: See excursus in section 2.1.3 and section 4.1 of this PPRI Report • PPRI Interim Report: PPRI website • PPRI Report: PPRI website
2	Dissemination	• Make PPRI and its results public	• PPRI website • PPRI Conference (Vienna, 29 June 2007): 250 delegates from 36 countries • Numerous presentations (e.g., at the Health System Working Party Meetings in April 2005 and June 2007, at OECD Experts Meetings on Pharmaceutical Pricing Policy in November 2006 and September 2007, Workshop on Medicines Pricing Policies in September 2006, IHHII conference in Sofia in November 2006) • Articles in scientific journals (e.g., in the Italian Journal of Public Health, spring 2006; in the Journal "Soziale Sicherheit" in October 2006) • PPRI Report	• PPRI website: http://ppri.oebig.at • Information on the PPRI Conference (incl. presentations and posters): PPRI website → Conference • List of presentations, personal contacts and articles: Annex II of the PPRI Report • PPRI Report: PPRI website

No.	Work Package	Objective	Deliverables	Accessible at
3	Needs Assessment	• Assess stakeholders' information needs regarding pharmaceutical pricing and reimbursement	• PPRI Needs Assessment Guide: a tool for undertaking the assessment • PPRI Needs Assessment Report: presenting the outcomes of the Needs Assessment at 115 stakeholders (101 national institutions, 14 European institutions)	• Needs Assessment Guide and Report: PPRI Interim Report and Annex II of the PPRI Report
4	Pharma Profiles	• Compile reports on pharmaceutical pricing and reimbursement in the EU Member States, drafted by the PPRI participants	• PPRI Pharma Profile Template: a guidance for authors, guaranteeing a homogenous structure and the survey of same kind of information and data (data comparability) • PPRI Glossary: defining all relevant terms on pharmaceutical pricing and reimbursement • 22 PPRI Pharma Profiles: country specific reports of pharmaceutical pricing and reimbursement • Flowcharts and posters, with brief information on the national pharmaceutical systems	• PPRI Pharma Profile Template: Annex II of the PPRI Report • PPRI Glossary: Annex II of the PPRI Report and a stand-alone deliverable at the PPRI website → Glossary • PPRI Pharma Profiles: presented in the Annex I of the PPRI Report and accessible at the PPRI website → Publications→ Country Information → Pharma Profiles; flowcharts are included in the PPRI Pharma Profiles • PPRI Posters: PPRI website → Conference
5	Indicators	• Create a list of relevant indicators for a comparative analysis of pharmaceutical pricing and reimbursement information	• Set of Core PPRI Indicators: 21 relevant pharmaceutical indicators, presented and discussed with regard to their evidence and limitations • PPRI Indicators Short List: the 21 PPRI indicators at a glance	• Set of Core PPRI indicators: Annex II of the PPRI Report and accessible at the PPRI website → Publications → Indicators • PPRI Indicators Short List: Annex II of the PPRI Report and accessible at the PPRI website → Publications → Indicators
6	Comparative Analysis	• Analyse in a comparative way the information and data on pharmaceutical systems	• PPRI comparative analysis: presenting, analysing and discussing the pharmaceutical pricing and reimbursement policies in the EU Member States • Summary Report "PPRI at a Glance": concise presentation of the comparative analysis per defined PPRI indicator	• PPRI comparative analysis: comprehensive presentation, analysis and discussion included in the PPRI Report (chapter 3) • PPRI at a Glance: stand-alone document, included at the end of chapter 3 in the PPRI Report

DG ENTR = European Commission, Enterprise Directorate-General, EMEA = European Medicines Agencies, IHHII = International Healthcare and Health Insurance Institute, OECD = Organisation for Economic Cooperation and Development, WHO = World Health Organisation

Note: The PPRI website is accessible at http://ppri.oebig.at. The PPRI Intranet Forum, which is accessible for the PPRI network (commissioning parties of the PPRI project, the project management and the PPRI participants), is hosted at the PPRI website → Members

3 Comparative analysis

This chapter provides an in-depth comparison of the pharmaceutical pricing and reimbursement systems in the EU. As stated in section 2.6.2, the PPRI comparative analysis is not limited to the 21 PPRI core indicators that were developed by the PPRI network (cf. section 2.5 for details), but offers further relevant pharmaceutical pricing and reimbursement information and data. The analysis includes examples of pharmaceutical policies in the PPRI countries (see the respective Boxes). At the end of this chapter 3, the overview table “PPRI at a Glance”, which can also be seen a stand-alone document, sums up the results of the comparative analysis presented per PPRI core indicator.

The major source of the presented data and figures are the PPRI Pharma Profiles that were written by the representatives of the participating countries. In addition, information and data which were provided by the PPRI participants in the course of the project, in particular when revising the PPRI Report, are included. Data are mainly based on national statistics. For OECD countries, in some cases data were either taken from or double-checked with the OECD Health Database 2006.

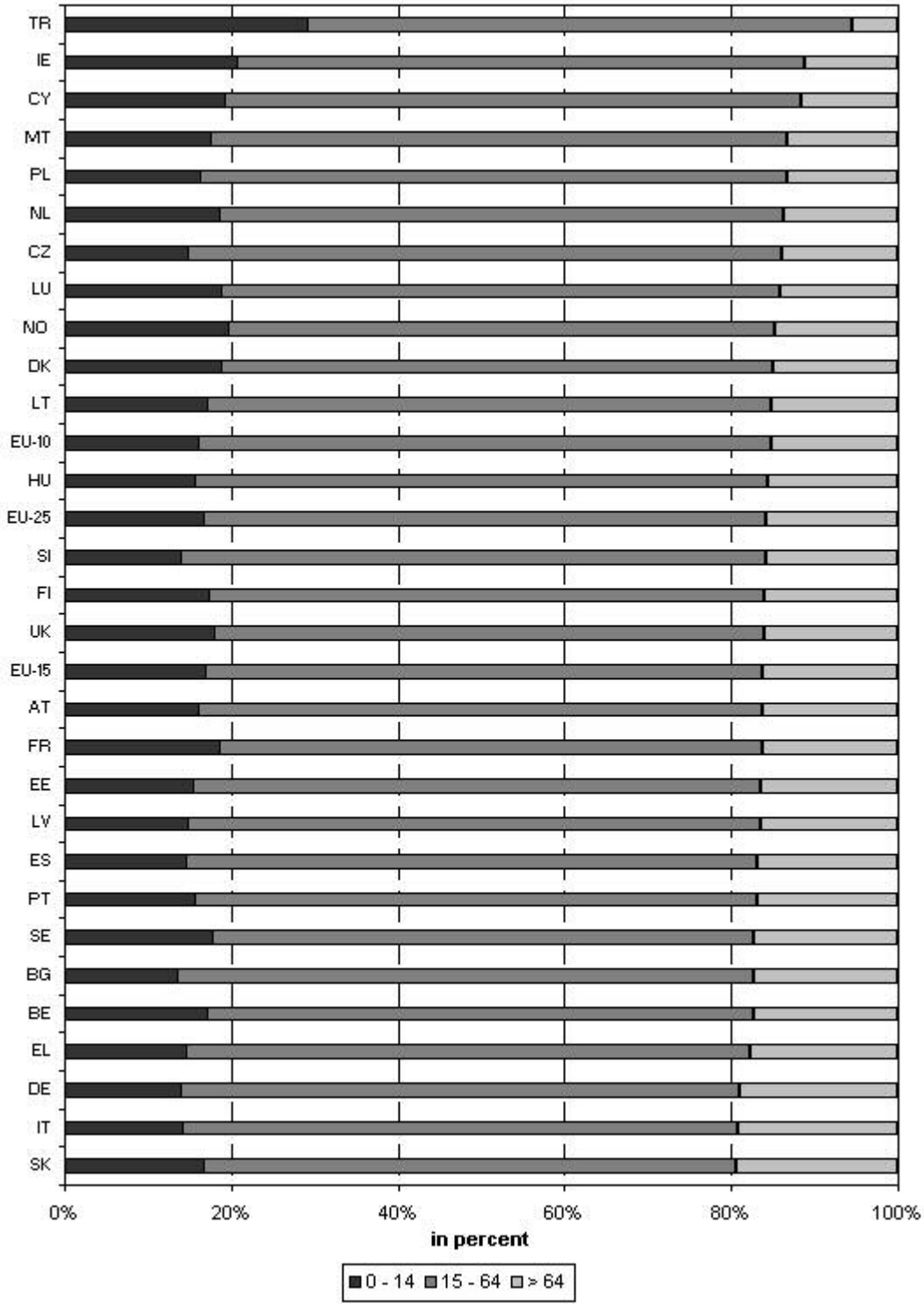
The countries included in the PPRI comparative analysis are basically the PPRI countries, i.e. all 27 EU Member States, excluding Spain and Romania, plus Norway and Turkey. Canada, Albania and Switzerland have also joined the PPRI network, but have not provided a PPRI Pharma Profile yet, therefore they are not included in the comparison. However, a brief overview on pricing and reimbursement in Canada will be provided in Box 4. Despite Spain not being a PPRI country, it was considered in the analysis when possible because of its status as an EU Member State. In the course of this chapter, we will talk of the 27 PPRI countries as well as of the EU-25, the EU-10 (new EU Member States which acceded to the EU on 1 May 2004) and the EU-15 (old Member States having acceded before May 2004), cf. also section 1.3.

3.1 Background

3.1.1 Demography

Many European countries face the challenge of an ageing population with its increasing need for health care as well as for pharmaceuticals. The demographic indicator for the population’s **age structure**, which is categorised into three groups (0–14 years, 15–64 years and above 64 years), is shown in Figure 3.1.

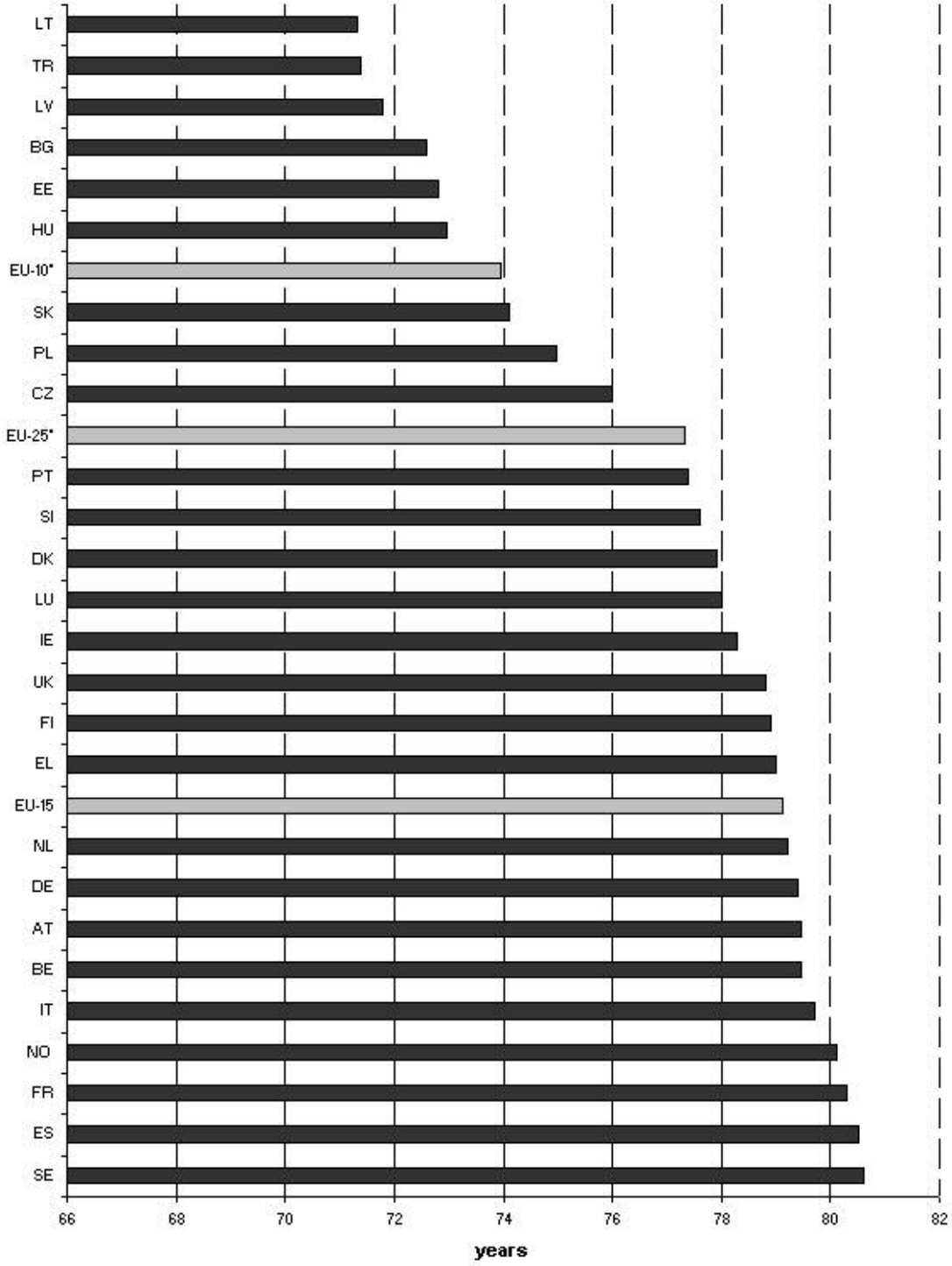
Figure 3.1: Comparative analysis – Population age structure 0–14, 15–64, > 64 years in percent of total population in the PPRI countries, 2005 or latest available year



2006: SI; 2004: CY, DK, EL, ES, FR, IT, LU, PT, SE; 2003: NL

Sources: PPRI Pharma Profiles 2006/2007; OECD Health Database 2006 for DK, ES, FR, LU, NL, PT, SE; EUROSTAT Yearbook 2006-2007 for MT; Institute of Health Information and Statistics of the Czech Republic 2005 for CZ

Figure 3.2: Comparative analysis – Life expectancy in the PPRI countries, 2005 or latest available year



* Excl. CY, MT

2004: BE, CY, DE, EL, ES, FR, NL, SK; 2003: HU, IE, IT, LU, PT; 2002: MT

Sources: PPRI Pharma Profiles 2006/2007; OECD Health Database 2006 for ES, IE, IT, LU, NL, PT; EUROSTAT Yearbook 2006-2007 for MT; Institute of Health Information and Statistics of the Czech Republic 2005 for CZ

Throughout Europe the largest part of the population (around 67%) is aged between 14-65 years (year 2005), building a solid ground for the working population. Considering the population above 65 years, there is not a significant difference between the EU-15 (16%) and the EU-10 countries (15%). Slovakia, Italy and Germany have the highest shares of elderly people (about 19 percent), meaning that approximately one sixth of the population represents elderly people with a higher need for health care and pharmaceutical resources, which may result in higher pharmaceutical consumption. Whereas Turkey has a significantly younger population, the rate of inhabitants aged 65 years and more being 5.4 percent.

Comparing the total **life expectancy** in the EU-15 countries (on average 79.1 years) with that in the EU-10 countries (on average 73.9 years), there is a considerable difference between the health status of the Western European countries and the Central and Eastern European countries. The Nordic countries Sweden and Norway as well as Mediterranean countries such as Spain, France and Italy have relatively high total life expectancies of around 80 years (cf. Figure 3.2), whereas Lithuania, Turkey and Latvia represent the lower ranked countries, with a total life expectancy of around 70 years. This means that the difference between the highest ranked country Sweden and the lowest ranked country Lithuania is 9.3 years (for males this gap is even higher, with 13 years).

Reasons for a lower total life expectancy could be a lack of investment in prevention programs, insufficient health care infrastructure and unhealthy life styles, such as smoking (Kaplan, W.; Laing, R. 2004).

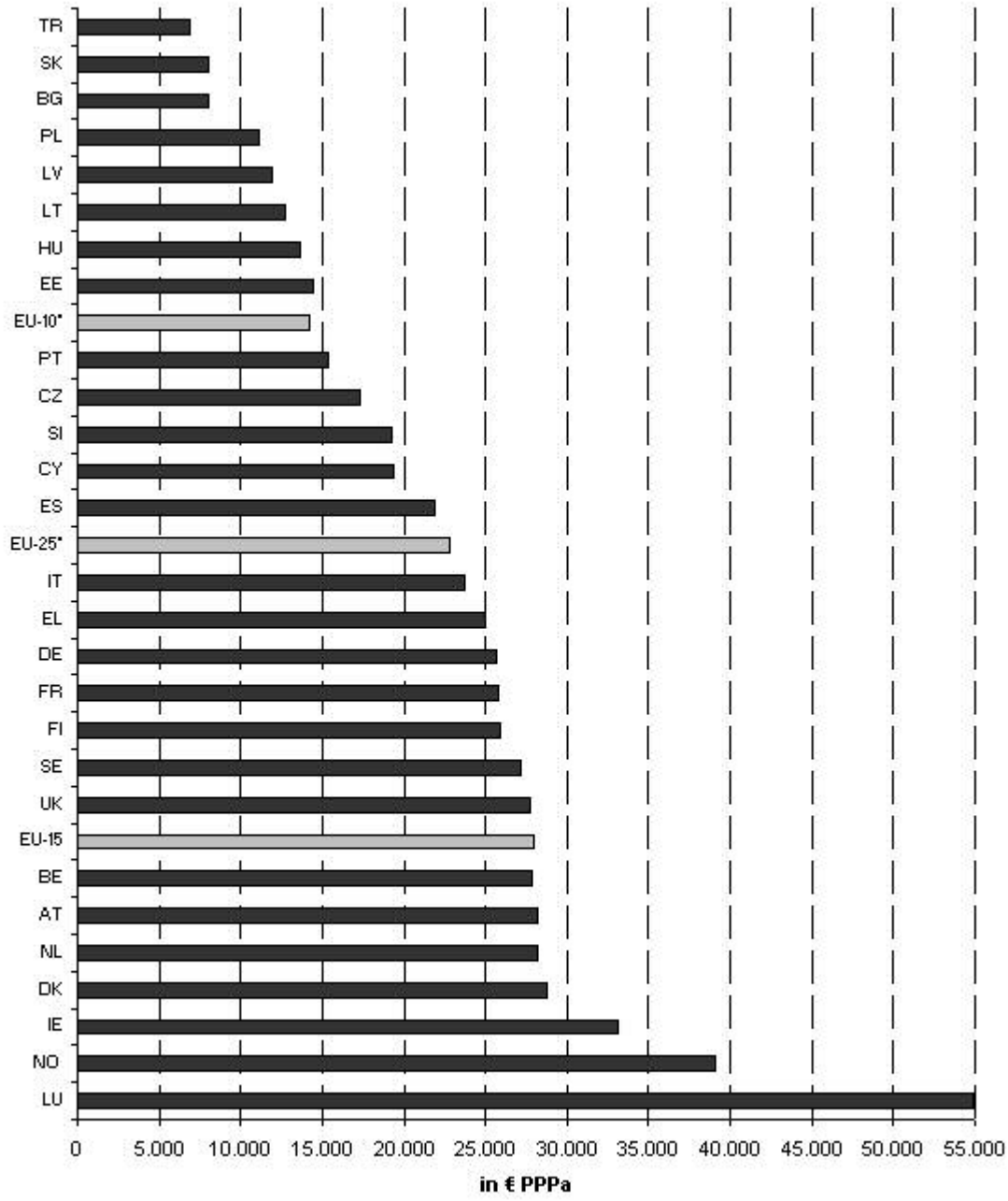
3.1.2 Economic background

Figure 3.3 illustrates the huge difference in the economic situation of the PPRI countries. The **gross domestic product** per inhabitant (GDP/capita) expressed in Euro Purchasing Power Parities (€ PPPa) in Luxembourg is eight times that of Turkey and almost seven times higher than in the fellow EU Member State Slovakia. However, the Luxembourgian situation is somewhat specific in Europe, as its GDP per capita is even 40 percent above the next country in line, Norway.

There appears to be an economic difference between the old Member States (EU-15) and the new ones (EU-10). The average GDP per capita in EU-15 countries (€ PPPa 27,942) is almost twice the EU-10 average (€ PPPa 14,193).

Being aware of this it is understandable that especially EU-10 countries have been struggling to contain their health care budgets. The existing economic gap plays an even more important role with regard to the restricted pharmaceutical budgets. Pharmaceuticals is an area in which local pharmaceutical prices reflect the international market prices as most of the products are imports. In addition, the prices of international brands, regardless of whether clothing, Mp3 players or pharmaceuticals are concerned, are less influenced by the local market and national economic power than by global marketing strategies (see also section 3.2.4).

Figure 3.3: Comparative analysis – Gross domestic product per capita in € PPPa in the PPRI countries, 2005



PPPa = Purchasing Power Parities

* Excl. MT

2004: AT, CY, ES, LU, NL, SI

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for ES, NL, PT; EUROSTAT Yearbook 2006-2007 for LU, MT; conversation rates by EUROSTAT

3.1.3 Health care system

3.1.3.1 Organisation

14 of the PPRI countries have a **social health insurance system**, whereas eleven countries operate a **national health service** (for definitions and a list by countries cf. Table 3.1). Historically, social health insurance systems have been in place in Austria, Belgium, Germany and France; in the 1990s the new EU Member States also introduced a social health insurance system. The "traditional" national health service is the NHS implemented in the UK; some Nordic countries (Denmark and Sweden) and some Mediterranean countries (e.g., Italy, Spain, Portugal) also operate a NHS-based health care system. Norway and Turkey define their health care system as mixed ones.

Table 3.1: Comparative analysis – Health care systems in the PPRI countries, 2006/2007

Country	Organisation of health care	Major reforms since 2000
AT	Social health insurance system	–
BE	Social health insurance system	–
BG	Social health insurance system	Promotion of the contractual rule and competition in health care in the last years
CY	Kind of national health service	Plans to introduce a social health insurance in 2008/09
CZ	Social health insurance system	–
DE	Social health insurance system	Health Care Reform 2007
DK	National health service	Local government reform 2007
EE	Social health insurance system	Reform of health insurance system 2002
EL	National health service	–
FI	National health service	–
FR	Social health insurance system	Key reform of the Health Insurance organisation 2004
HU	Social health insurance system	–
IE	National health service	–
IT	National health service	Shift of competences in health care to regions 2001
LT	Social health insurance system	–
LU	Social health insurance system	–
LV	National health service	–
MT	National health service	–
NL	Social health insurance system	New Health Insurance Act in 1/2006
PL	Social health insurance system	–
PT	National health service	Reorganisation of primary care; Pilot: private management of public health care institutions (mainly hospitals).
SE	National health service	–
SI	Social health insurance system	–

Country	Organisation of health care	Major reforms since 2000
SK	Social health insurance system	–
UK	National health service	–
NO	Mixed system (mostly national health service)	–
TR	Mixed system	–

Definitions: cf. PPRI Glossary, http://ppri.oebig.at → Glossary
National health service: This is a health care system which is usually financed through central or regional taxation and which usually covers all inhabitants/residents.
Social health insurance system: This is a type of health care provision which is often funded through insurance contributions by employers and employees as well as state subsidies.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

In all PPRI countries, there is a **private health care sector**, besides the public one. However, in Cyprus and Malta the private sector plays an important role, and the health care system is characterized by the two distinct sectors, the public and the private one. In the course of a planned health reform, Cyprus (cf. Box 1 for details) aims at a unification of the market and a coverage of all residents under the public sector.

As listed in Table 3.1, there have been major **reforms in health care** in the last few years; the most upcoming reform having been undertaken in Germany in the first half of 2007. Germany implemented reforms mainly focusing on introducing mandatory health insurance for all citizens, more competition among the sickness funds and a reform of the private insurances. The Netherlands also faced structural reforms in 2006 due to the introduction of the new Health Insurance Act which abolished statutory health insurance institutions. Now all residents of the Netherlands are obliged to take out health insurance at an insurance institution of their choice.

Box 1: Cyprus – Two distinct health care segments (public and private sector)

Cyprus finances its health care system (public sector) to a large extent through central taxation; it is organised as a kind of a national health service. Additionally, there is an important private sector in which patients have to pay out-of pocket for all health care services and pharmaceuticals.

Around 85-90% of the population is covered by the public sector by receiving either full reimbursement for health care services or by having to pay 50% out-of pocket, depending on their income. However, the majority of the population opts for the private system, and thereby hopes to receive higher quality care and better access to pharmaceuticals.

In 2001, a Law on the implementation of a General Health Care Scheme (which will imply a shift to a social health insurance system) was passed. The General Health Care Scheme is expected to be launched in 2008/2009 and should cover all Cypriot citizens living in Cyprus, irrespective of their level of income. It will be financed through contributions by employees.

Table 3.2 provides key data on **health infrastructure** such as the number of outpatient doctors and acute care beds per 1,000 inhabitants. In the EU average (EU-25), there are 2.71 outpatient doctors per 1,000 inhabitants, and 4.8 acute care beds per 1,000 inhabitants. There is a slightly lower ratio of outpatient doctors per 1,000 inhabitants in the new EU Member States compared to the old ones (EU-10: 2.66, EU-15: 2.75), whereas the number of acute care beds per 1,000 inhabitants is higher (EU-10: 5.1, EU-15: 4.5). Poland has the highest density of outpatient doctors per 1,000 inhabitants (5.1) and the Netherlands the lowest (1.0). With regard to acute care beds per 1,000 inhabitants Lithuania has the highest density (8.1) and Sweden the lowest (2.2).

Table 3.2: Comparative analysis – Number of outpatient doctors and acute care beds per 1,000 inhabitants in the PPRI countries, 2005 or latest available year

Country	Year	Outpatient doctors per 1,000 inhabitants	Acute care beds per 1,000 inhabitants
AT	2005	2.4	6.4
BE	2005	4.0 [1,2]	7.4
BG	2005	1.9	5.9
CY	2005	N.a.	N.a.
CZ	2005	2.9	6.4
DE	2005	2.4	6.4
DK	2005	3.4 [3]	3.8 [4]
EE	2004	1.6	4.26
EL	2003	2.5	4.7
ES	2003	3.8 [1]	2.8
FI	2004	3.0	3.0
FR	2004	3.4[1]	3.7
HU	2005	2.4	6.0
IE	2005	2.8 [1]	3.3
IT	2005	3.8 [1]	N.a.
LT	2005	N.a.	8.1
LU	2004	2.5 [1]	5.7
LV	2005	1.8	5.4
MT	2005	N.a.	N.a.
NL	2003	1.0	2.8
PL	2004	5.1	4.8
PT	2005	3.4	3.5
SE	2004	N.a.	2.2
SI	2005	2.3	4.8

Country	Year	Outpatient doctors per 1,000 inhabitants	Acute care beds per 1,000 inhabitants
SK	2004	2.5	N.a.
UK	2004	2.0	3.6
EU-10*	2005 or l.a.y.	2.7	5.1
EU-15**	2005 or l.a.y.	2.8	4.5
EU-25***	2005 or l.a.y.	2.7	4.8
NO	2004	3.7 [1]	3.1
TR	2004	N.a.	2.4

l.a.y. = latest available year, N.a. = not available

* Excl. CY, LT, MT (outpatient doctors); excl. CY, MT, SK (acute care beds)

** Excl. BE, ES, IE, IT, LU, SE (outpatient doctors); excl. IT (acute care beds)

*** Excl. BE, CY, ES, IE, IT, LT, LU, MT, SE (outpatient doctors); excl. CY, IT, MT, SK (acute care beds)

EU-averages exclude the countries with only practising doctors.

2004: DK (acute care beds), FI, FR, LU, PL, SK, UK, NO, TR (outpatient doctors and acute care beds); 2003: EL, ES, NL, SE (outpatient doctors and acute care beds); 2000: EE (outpatient doctors and acute care beds)

[1] Only practising doctors per 1,000 inhabitants

[2] Excl. dentists

[3] Incl. primary and hospital sector

[4] Incl. long term care

Sources: PPRI Pharma Profiles 2006/2007; OECD Health Database 2006 (total number of acute care beds) for ES, LU, NL, SK, UK, NO; Institute of Health Information and Statistics of the Czech Republic 2005 for CZ

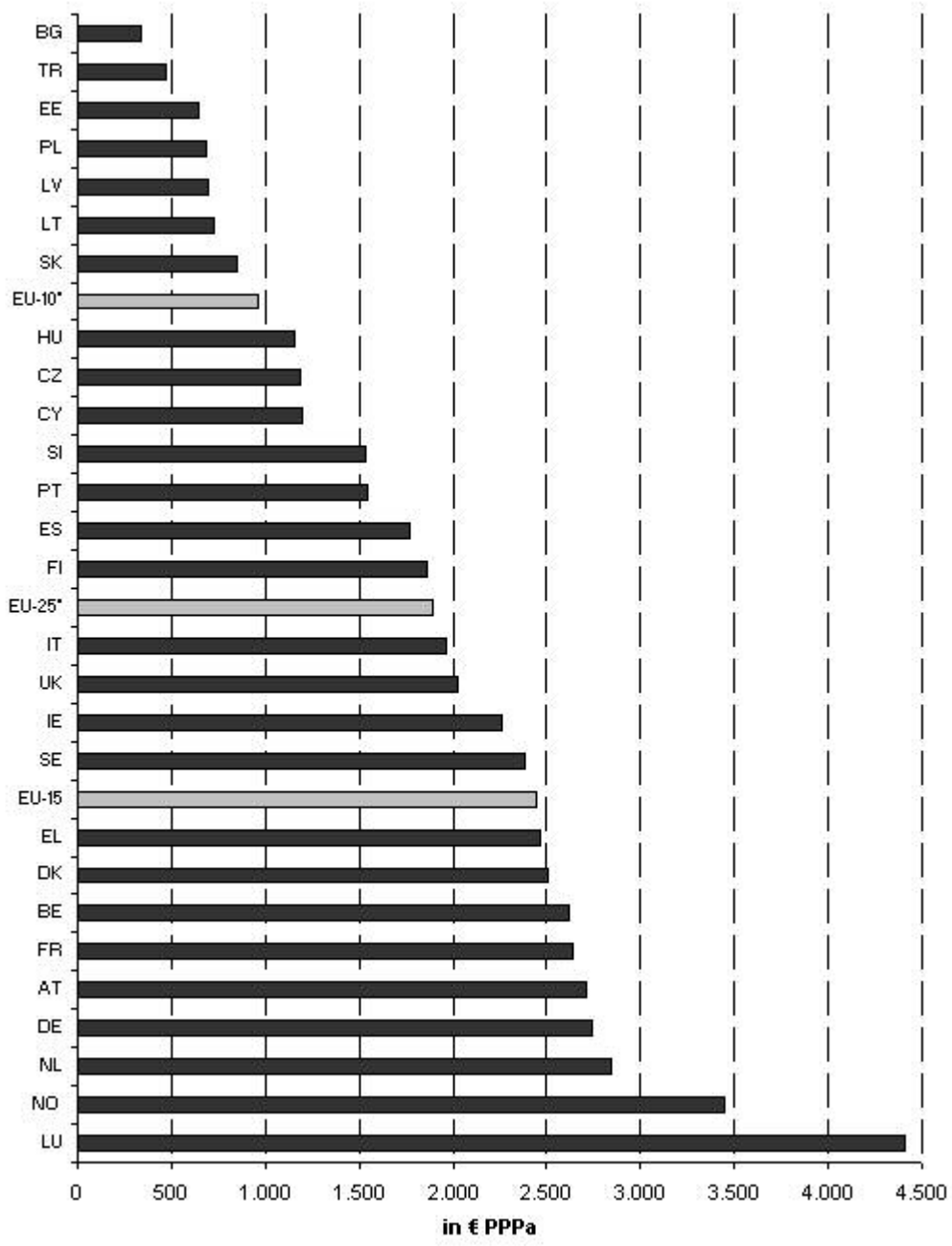
3.1.3.2 Funding

In 2005 (or 2004 respectively), all PPRI countries together spent a sum of about 1,000 billion Euro on health care: The **total health expenditure** (THE) includes inpatient care, outpatient care, pharmaceuticals, dental care, etc. In terms of PPPa (Purchasing Power Parities) this amounted to € PPPa 1,890.- per inhabitant in the European Union (EU-25 excluding Malta, cf. Figure 3.4).

When only those Member States which acceded to the EU in May 2004 (EU-10) are considered, this figure is € PPPa 965.- per inhabitant, whereas in EU-15 average the total health expenditure per capita amounted to about € PPPa 2,450.-, implying that EU-15 countries spent more than the 2.5-fold of health expenditure per capita in EU-10 countries. Bulgaria spent in 2004 € PPPa 335.- per inhabitant for health care, which is one third of the EU-10 average.

These data also reflect the fact that according to OECD two thirds of non-pharmaceutical or technology related health care expenses are labour costs, and the wages in EU-10 countries are significantly lower than in EU-15 countries (OECD 2004).

Figure 3.4: Comparative analysis – Total health expenditure per inhabitant in € PPPa in the PPRI countries, 2004



PPPa = Purchasing Power Parities

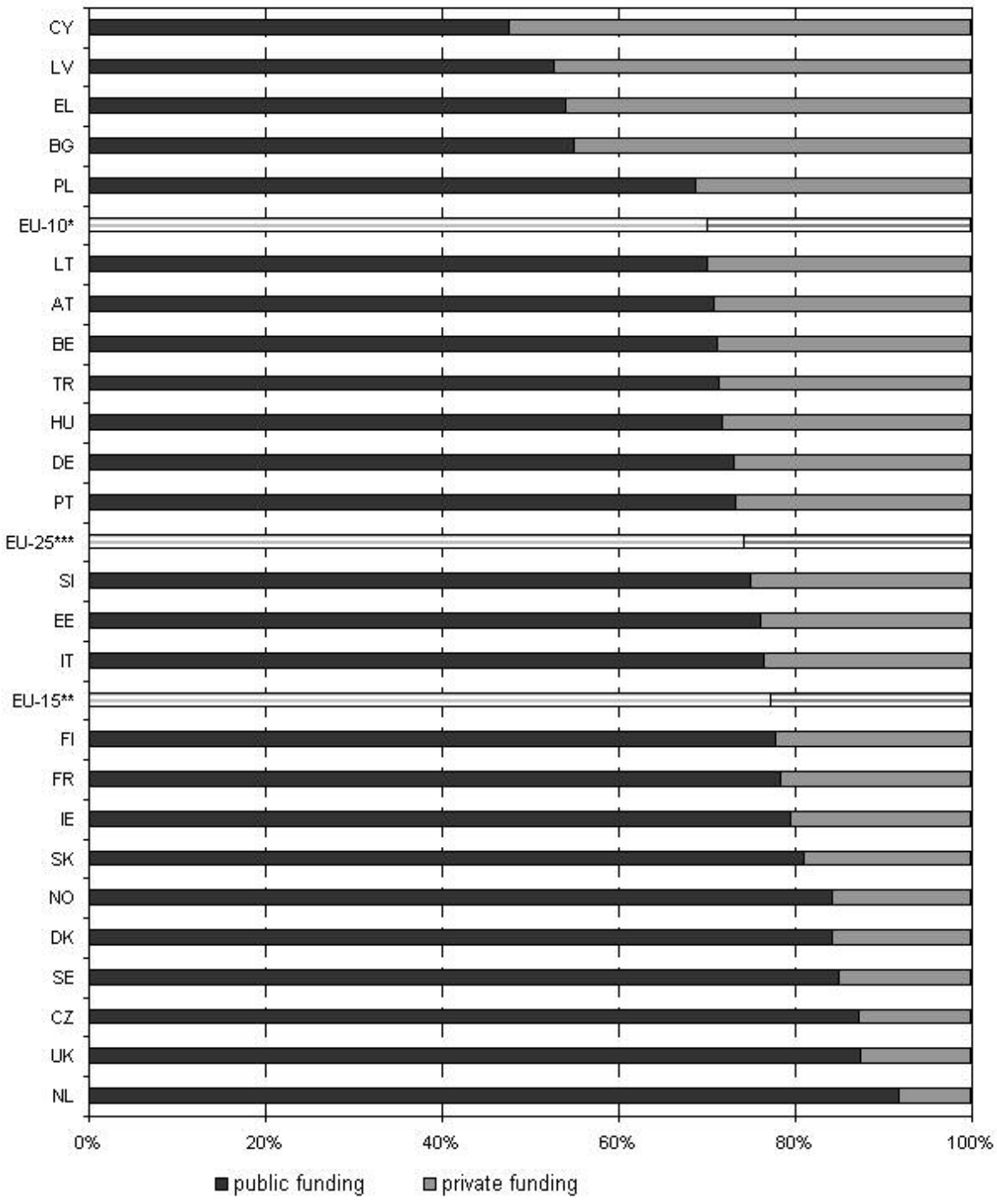
* Excl. MT

2005: DE, LT, NL, SK, IE (estimate)

FI: incl. inpatient + outpatient care, dental care, outpatient pharmaceuticals, medical devices and equipment, environmental health care, administration, public investments and reimbursements for travel expenses

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for CZ, ES, LU, PL, PT, CPB=Netherlands Bureau for Economic Policy Analysis for NL; conversation rates by EUROSTAT

Figure 3.5: Comparative analysis – Share of public / private funding of health expenditure in the PPRI countries, 2005 or latest available year



* Excl. MT; ** excl. ES, LU; *** excl. ES, LU, MT

2006: NO; 2004: AT, CY, EE (0.45% of funding from foreign sources), EL, FR, HU, IE, IT, PL, PT, SI; 2003: BE

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for PT; CPB=Netherlands Bureau for Economic Policy Analysis for NL

The data as displayed in Figure 3.4 need to be considered with caution, since some of the PPRI countries have already changed their national accounting system according to the new SHA ("System of Health Accounts") methodology[23] that was developed by OECD and EUROSTAT, whereas others still use the former national accounting concept from 1995. The major difference between the two is that the SHA concept also includes expenditure for long term and nursery care, whereas the former concept did not. In the future at least all OECD Member States will use the SHA concept in their national accounting systems, which will then allow for better comparisons.

Figure 3.5 displays the shares of public and private funding in terms of total health expenditure. The ratios for public health expenditure range from 47.6 percent in Cyprus to 91.7 percent in the Netherlands, with the EU-25 average of 74.2 percent. Among the new EU Member States, the Czech Republic has the highest public spending share (87.2% in 2005).

3.2 Pharmaceutical system

3.2.1 Organisation

3.2.1.1 Authorities

Key elements of a pharmaceutical system are market authorisation, pricing (for different price types), reimbursement, and distribution. In the PPRI Pharma Profiles (see section 2.4) the national authorities, the decision procedures and criteria (e.g., for reimbursement) are described in detail and displayed in flowcharts.

The competence for market authorisation is established at EU level, with the European Medicines Agency (EMEA) being the key authority, supported by national authorities. In many Member States, market authorisation lies in the hands of Medicines Agencies.

Pricing and reimbursement of pharmaceuticals lies in the **competence of the EU Member States**, which have to consider overall EU provisions such as the Transparency Directive. In several PPRI countries the Ministry of Health is in charge of pricing. In some countries, however, pricing of pharmaceuticals lies in the hands of the Ministry of Economy, Development or Finance (Belgium, Czech Republic, Greece, Luxembourg, Portugal). A few PPRI countries, in which the pricing and reimbursement processes are very much interlinked (cf. section 3.4.1), have established special institutions, which are in charge of both pricing and reimbursement. Examples of these are the Pharmaceutical Pricing Board (Lääkkeiden hintalautakunta, HILA) in Finland, the State Medicines Pricing and Reimbursement Agency (Zāļu cenu valsts aģentūra, ZCVA) in Latvia, and the Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN) in Sweden. In a small number of countries, the competence

[23] http://www.oecd.org/document/8/0,3343,en_2649_37407_2742536_1_1_1_37407,00.html

for pricing lies in the hands of the Medicines Agencies (see also Box 2 about the variety of the tasks of Medicines Agencies).

Box 2: The role of Medicines Agencies

In the vast majority of PPRI countries, Medicines Agencies have been established. In some countries, in particular in the Nordic states, the Medicines Agencies were established more than ten years ago whereas in others (e.g., Italy or Germany where it was set up in 2004 and 2007 respectively) the Medicines Agency is quite new. In the new Member States, Medicines Agencies were founded in the framework of the reforms of the pharmaceutical systems in the 1990s. Turkey is planning to establish one.

The key competence of a Medicines Agency includes usually market authorisation, pharmaco-vigilance, classification of pharmaceuticals and often also the licensing of manufacturers and distribution actors. As shown in Table 3.3, in some PPRI countries Medicines Agencies are also involved in pricing and reimbursement decisions.

A trend which could be observed over the past years is the increasing of the responsibilities of Medicines Agencies. Meanwhile, several Medicines Agencies are not only responsible for pharmaceuticals, but also for medical devices (e.g., France, Denmark, United Kingdom).

The fixing of distribution mark ups, another aspect of pricing, is often undertaken by Ministries of Health via statutory decisions.

Reimbursement decisions are usually in the competence of the social insurance (e.g., Austria, Hungary, Slovenia) or the Ministry of Health / Social Affairs (even in countries with a social insurance system, such as Czech Republic, Netherlands, Poland). As mentioned above, some countries (Finland, Latvia, Sweden) have specific institutions which are in charge of reimbursement; furthermore, reimbursement decisions may also be taken by a Medicines Agency (e.g., Denmark, Portugal).

Table 3.3 gives an overview of the national authorities that are in charge of market authorisation, pricing and reimbursement. Advisory bodies are also displayed in this table. In several countries, advisory bodies are internal committees or departments within the responsible institutions. Some countries have opted for the social health insurance to act as an advisory body in pricing and reimbursement decisions (e.g., Estonia, Finland). Further countries have set up expert groups, which evaluate several aspects (therapeutic benefit and relative improvement, economic advantage, etc.) of the pharmaceutical in question. Examples of such evaluation committees providing scientific evidence as a basis for the reimbursement decisions are the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission, HEK) in Austria and the Technology Appraisal Committee (Technológia Értékelő Bizottság, TÉB) in Hungary. In 2004, the French High Authority for Health (Haute Autorité de Santé, HAS) was set up specifically for evaluating on the therapeutic benefit and improvement of the therapeutic benefit as basis for pricing and reimbursement decisions.

Table 3.3: Comparative analysis – Authorities in the regulatory framework of the pharmaceutical system in the PPRI countries, 2006/2007

Country	Market Authorisation (at national level)		Pricing[1]		Reimbursement	
	Decision-making	Advising	Decision-making[2]	Advising	Decision-making	Advising
AT	Medicines Agency	–	Ministry of Health	Pricing Committee	Social Insurance	Evaluation Board
BE	Medicines Agency	–	Ministry of Economic Affairs	Two Pricing Committees	Ministry of Social Affairs	Reimbursement Committee
BG	Medicines Agency	–	Ministry of Health	Pricing Committee	Social Insurance	Positive List Committee
CY	Drugs' Council (acting as Medicines Agency)	–	Ministry of Health	Pricing Committee	Ministry of Health	Pharmaceutical Department of Ministry of Health
CZ	Medicines Agency	–	Ministry of Finance	–	Ministry of Health	Reimbursement Committee
DE	Medicines Agency[3]	–	–[4]	–	Ministry of Health/Federal Joint Committee/Federal Association of Sickness Funds[3]	–
DK	Medicines Agency	Marketing Authorisation Committee	–[4]	–	Medicines Agency	Reimbursement Committee
EE	Medicines Agency	Pharmaceutical Marketing Authorisation Committee	Ministry of Social Affairs	Pharmaceutical Committee and Estonian Health Insurance Fund	Ministry of Social Affairs	Pharmaceutical Committee, State Agency of Medicines and Estonian Health Insurance Fund
EL	Medicines Agency	–	Ministry of Development	Pricing Committee	Ministry of Health and Social Solidarity	Medicines Agency
FI	Medicines Agency	–	Pharmaceuticals Pricing Board	Social Insurance	Pharmaceuticals Pricing Board	Social Insurance, and Expert group within the Pharmaceuticals Pricing Board

Country	Market Authorisation (at national level)		Pricing[1]		Reimbursement	
	Decision-making	Advising	Decision-making[2]	Advising	Decision-making	Advising
FR	Medicines Agency	–	Pricing Committee	High Authority for Health	Ministry of Health and Social Affairs, Social Insurance	–
HU	Medicines Agency	–	(Ministry of Health)[5]	–	Social Insurance	Technology Appraisal Committee
IE	Medicines Agency	–	Department of Health and Children	–	National Health Service Unit	–
IT	Medicines Agency	–	Medicines Agency	–	Medicines Agency	–
LT	Medicines Agency	–	Ministry of Health	Department of Pharmacy	Ministry of Health	Reimbursement Committee
LU	Ministry of Health	–	Ministry of Economics	–	Social Insurance	Medical Control Committee of Social Insurance
LV	Medicines Agency	–	State Medicines Pricing and Reimbursement Agency	–	State Medicines Pricing and Reimbursement Agency	–
MT	Medicines Agency	–	–[4]	–	Ministry of Health	Drugs and Therapeutic Committee
NL	Medicines Agency	–	Ministry of Health, Welfare and Sport	Healthcare Insurance Board	Ministry of Health, Welfare and Sport	Healthcare Insurance Board
PL	Medicines Agency subordinate to Ministry of Health	–	Ministry of Health	Pharmaceutical Committee	Ministry of Health	Pharmaceutical Committee
PT	Ministry of Economic Affairs	–	Medicines Agency	–	Medicines Agency	–
SE	Medicines Agency	–	Pharmaceutical Benefits Board	–	Pharmaceutical Benefits Board	–
SI	Medicines Agency	–	Medicines Agency, Minister of Health	Expert groups nominated by Ministry of Health	Health Insurance Institute of Slovenia	Committee for Reimbursement of Pharmaceuticals

Country	Market Authorisation (at national level)		Pricing[1]		Reimbursement	
	Decision-making	Advising	Decision-making[2]	Advising	Decision-making	Advising
SK	Medicines Agency	–	Ministry of Health	Categorisation Committee	Ministry of Health	Categorisation Committee
UK	Medicines Agency	–	Department of Health	–	Department of Health	National Institute of Health and Clinical Excellence
NO	Medicines Agency	–	Medicines Agency	–	Medicines Agency	–
TR	Ministry of Health	–	Ministry of Health	–	Interministerial Reimbursement Committee	–

[1] Pricing refers to setting a price for a pharmaceutical at the thereby legally defined price level ("controlled price type"), often the manufacturer level (cf. section 3.3.3). The competence for fixing wholesale and pharmacy mark ups is not displayed in this table.

[2] In most PPRI countries this is only relevant for reimbursable pharmaceuticals

[3] Since 2007

[4] Free pricing at "controlled price type" (see Footnote 1)

[5] Pricing is much interlinked with reimbursement, statutory pricing criteria are in place for reimbursable pharmaceuticals (by Ministry of Health)

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Pricing Committees are usually as advisory bodies involved in pricing decisions (only in France the Pricing Committee itself undertakes the price negotiations). In general, Pricing Committees are inter-ministerial committees, in which the Ministry of Health/Social Affairs, the Ministry of Industry/Economy/Finance, and in a few countries also the social health insurance are represented. Manufacturers and distribution actors or patients' associations are seldom involved in Pricing Committees (e.g., the Cypriot Pricing Committee includes representatives from the pharmaceutical industry, the wholesale and pharmacy sector as well as from a patient and a consumer's association).

3.2.1.2 Policy and legislation

Whereas market authorisation is basically regulated at European Union level (Directive 2004/27/EC is a key legislation), pricing and reimbursement is mainly a competence of the EU Member States, taking overall EU provisions such as the "Transparency Directive" (Council Directive 89/105/EEC of 21 December 1988) into consideration.

As a consequence, complex regulatory pricing and reimbursement frameworks are in place that, on the one hand, have translated the EU stipulations into national legislation and, on the other hand, have been based on national objectives and policies.

Typical **legislation** in the context of pharmaceuticals include Medicines Acts, Pricing Acts, decrees on distribution mark ups, and Social Insurance Laws and Social Codes defining criteria for reimbursement. The acts are supplemented by executive orders, enactments and decrees for implementation. Table 3.4 provides per country an overview of the key regulatory framework for pharmaceutical pricing and reimbursement by listing relevant legislation.

Box 3: Ireland – No statutory framework for pharmaceutical pricing and reimbursement

Ireland has a long tradition of defining criteria and procedures by means of agreements between parties instead of regulating them via a statutory framework. There is no current legislation for deciding where pharmacies may be located, geographically or demographically.

The framework for pricing and reimbursement was contained in agreements between the State and the pharmaceutical industry. There is no parliamentary or delegated legislation applicable to price negotiations or reimbursement decisions. The current agreement is between the Health Service Executive (HSE), a State Agency, and the pharmaceutical industry: this agreement defines, among other matters, the pricing procedure, which includes external price referencing at the manufacturer/importer price level with a basket of nine EU Member States. It provides the formal rules, including methodological issues (e.g., if the pharmaceutical is not available in the reference countries, then the price has to be negotiated between the manufacturer/importer and the HSE).

The current Agreement, which was concluded in September 2006, is the latest in a line that has continued over decades.

In several countries **agreements** between the state and the manufacturers (usually industry associations) regulate certain aspects of the pharmaceutical system. These agreements usually cover pricing procedures, but also other issues may be determined in such agreements (e.g., timing of the access to the market, reward for innovation). PPRI countries with such (framework) agreements are France, Hungary, Ireland, Portugal and occasionally Denmark. Usually, the agreements apply for a predefined number of years. Negotiations for new agreements will start at the end of this period. In France, Hungary and Portugal parts of the stipulations of the agreements are then often put into legislation.

The fact that some countries prefer agreements, while others strongly rely on statutory rules, has to be seen in the context of the (legal) culture and tradition in a country (cf. Box 3).

To conclude: The PPRI countries have a complex regulatory framework, which aims at guaranteeing the provision of the population with safe, effective and high-quality pharmaceuticals. Despite of the efforts of the countries to fulfil this objective at its best, specifications in pharmaceutical legislation, in particular regarding pricing and reimbursement, often focus on cost-containment due to - sometimes considerable - budgetary restraints.

When several actors of controversial interests meet, law-suits might take place. With regard to pricing and reimbursement, pharmaceutical manufacturers from time to time charge EU Member States with allegedly breaching the EU Transparency Directive (e.g., Austria, Finland). The European Court in Strasbourg deals with these charges.

Table 3.4: Comparative analysis – Regulatory framework of pricing and reimbursement in the PPRI countries, 2006/2007

Country	Key statutory framework	Additional framework
AT	Medicines Act Price Act Social Insurance Act Decrees on Mark ups	Agreement between some social partners on pricing
BE	Medicines Act Decrees on Mark ups	Not applicable
BG	Medicines and Pharmacy Act Social Insurance Act Decrees on Mark ups Decree on Reimbursement	Not applicable
CY	Medicines and Pricing Act	Not applicable
CZ	Medicines Act Health Insurance Act Ministerial Decrees on Mark ups Ministerial Decrees on Maximum Prices Ministerial Decrees on Reimbursement Prices	Not applicable
DE	Medicines Act Pharmaceutical Price Ordinance Social Code Book V Decree on Pharmaceutical Care Pharmacy Act	Not applicable

Country	Key statutory framework	Additional framework
DK	National Health Security Act Executive Orders	Temporary agreement on pricing between the industry association and the Ministry of Health
EE	Health Insurance Act Governmental and Ministerial Regulations on Procedures regarding pricing and reimbursement of pharmaceuticals Medicines Act Governmental Regulation on the Mark ups of pharmaceuticals	Not applicable
EL	Several Acts	Not applicable
FI	Medicines Act Health Insurance Act Government Decrees	Not applicable
FR	Social Insurance Act Public Health Act	Framework Agreement between Pricing Committee and industry association
HU	Pricing Act Social Insurance Law Several Decrees	Agreement between government and industry association
IE	No specific law on pricing and reimbursement	Agreements between National Health Service and industry associations
IT	Acts and Enactments on Mark ups and procedures Budget Laws	Not applicable
LT	Governmental Decrees and Ministerial Orders	Not applicable
LU	Social Insurance Act Price Act Decree on Mark ups	Not applicable
LV	Ministerial Regulations	Not applicable
MT	Medicines Act	Not applicable
NL	Pricing Act Health Insurance Act and Decrees	Not applicable
PL	Pricing Act Health Insurance Act	Not applicable
PT	Several Acts and Enactments	Framework Agreement between Ministry of Health and industry association
SE	Pharmaceutical Benefits Act and Decrees and Regulations	Not applicable
SI	Medicinal Products Act Implementation Rule on Pricing of the Minister of Health Decision & Implementation Rule on the inclusion of certain pharmaceuticals in reimbursement lists Health Care and Health Insurance Act	Not applicable

Country	Key statutory framework	Additional framework
SK	Pricing Act and Decrees Act on Scope of Health Care Service	Not applicable
UK	Health Act	Not applicable
NO	Medicines Act Guideline on pricing issued by the Medicines Agency Social Insurance Act	Not applicable
TR	Medicines Act Decree on Pricing Decree on Reimbursement Budget Implementation Guide	Not applicable

Note: The proper names of the legislation (Medicines Act, Price Act, Social Insurance Act, Decree on Mark ups, etc.) were translated for an easier overview; see the respective PPRI Pharma Profiles for the name in local language and/or legal sources

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

The national frameworks presented in Table 3.4 concern regulation at federal level. In general, the PPRI countries have federal legislations and rules regulating the pharmaceutical system, which is reflected in the same pricing and reimbursement criteria applying for the whole country. The fact that in some countries (e.g., Estonia, Czech Republic and United Kingdom) pharmacy retail prices may differ between dispensaries is not an outcome of any regional or local legislation, but of the maximum wholesale and pharmacy mark ups, which are defined in national law, not being fully exhausted.

In most PPRI countries decision-making authorities are also situated at the federal level. In addition, in some countries (for instance Sweden, Italy and Canada) the provinces also play a major role.

However, Italy and Spain have undertaken a strong **decentralisation** in the health care sector, which resulted in regional legislation regarding the organisation and funding of health care. This also had an impact on the pharmaceutical system. In Italy, due to the regionalisation that started in 2001, different regional systems, having different co-payment rules, exist. Regions were allowed to re-introduce a prescription fee which had been abolished at central level, which, in fact, was implemented by some regions.

14 different pharmaceutical systems can be found in Canada, where each province has its own regulatory framework. Box 4 offers some information on the pharmaceutical systems in Canada, which is otherwise not reflected in the comparative analysis. Canada is participating in the PPRI network.

Box 4: Canada – Fourteen pharmaceutical systems

The roles and responsibilities for Canada's health care system are shared between the federal and provincial/territorial governments (total of 14 jurisdictions). Under the Canada Health Act, federal, provincial and territorial health insurance plans are required to provide coverage to their residents for all medically necessary hospital and physician services on a prepaid basis. Only pharmaceuticals provided in hospitals are covered under the Canada Health Act. Provinces and territories may also offer "additional benefits" under their respective health insurance plans, which may include prescription drug benefits (often only for specific populations). The scope of coverage varies between public plans.

Regulatory framework

In accordance with the Food and Drugs Act and related regulations, Health Canada is responsible for regulating the safety, efficacy and quality of pharmaceuticals. The Therapeutic Products Directorate of the Health Products and Food Branch (HPFB), a branch of the Department of Health (Health Canada), is in charge of reviewing new pharmaceuticals for licensing and labelling. At the end of the review process, Health Canada may grant a marketing authorisation or "Notice of Compliance (NOC)", which indicates that the pharmaceutical under review has met its safety, efficacy and quality requirements. An abbreviated procedure is used to assess generics.

Pricing

Since 1987, ex-factory prices of patented pharmaceuticals have been regulated at the federal level by the Patented Medicine Prices Review Board (PMPRB) to ensure that they are not "excessive". Prices of off-patent original products and generics are not federally regulated but may be regulated at the provincial/territorial level. Data suggest that Canadian price regulation of patented pharmaceuticals has had a dampening effect on relative price levels in Canada, bringing them closer to the median price paid in a selected set of countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). Canadian pharmacy retail prices for generics are substantially higher than those in a number of comparable countries.

Reimbursement

In Canada, the main purchasers of prescription-only medicines (POM) are third party payers, including publicly and privately-financed drug plans, patients and hospitals. Canadian hospitals operate under fixed budgets and/or payment per case, which they use to procure pharmaceuticals provided free-of-charge to their patients. Hospitals typically use group purchasing programs to establish group contracts for set prices. The hospital then buys directly from the manufacturer at the contract price. Private health insurance plans tend to act as passive payers, typically reimbursing plan members (who normally must pay out-of pocket first and then seek reimbursement) for the expenses of prescribed pharmaceuticals used by their enrolees that are included in a given plan's formulary, less any co-payment amount. Provincial, territorial and federal drug plans define reimbursement prices for pharmaceuticals covered under their formularies and, in some instances, use elaborate methodologies for determining reimbursement amounts. The reimbursed prices may differ from manufacturer's list prices. Public plans use different formulas to pay for POM purchases and distribution services. The Common Drug Review (CDR) is a centralized process that conducts evidence-based clinical and pharmacoeconomic review of new pharmaceuticals and new indications for old pharmaceuticals for potential coverage by participating drug benefit plans. Based on this review, the CDR recommends whether or not a drug should be listed on public drug plan formularies. Although federal, provincial and territorial drug plans each retain final authority to make listing decisions, approximately 90% of their listings are consistent with the CDR's recommendations.

3.2.2 Availability of pharmaceuticals

Table 3.5 provides data on the number of authorised pharmaceuticals and of pharmaceuticals on the market as well as on prescription-only medicines (POM) and reimbursable pharmaceuticals. However, these data have to be interpreted with caution, and cannot be considered comparable due to different counting approaches in the countries. The information on the counting methods is displayed in an extra column in Table 3.5. Regarding generics, their relevance in the pharmaceutical systems of the PPRI countries is discussed in section 3.5.4.

The number of **authorised pharmaceuticals** varies between the PPRI countries. This is, as discussed, a consequence of various counting methods, and might, in addition, be linked to the different market sizes (e.g., fewer pharmaceuticals in smaller markets such as Bulgaria, Cyprus and the Baltic States).

Table 3.5: Comparative analysis – Number of pharmaceuticals in the PPRI countries, as of 1 January 2006 or latest available year

C.	Year	Authorised	On the market	POM	Reimbursable	Comments/Counting
AT	2005	14,347	6,155	8,733[1]	3,926	Incl. different pharmaceutical forms, dosages, homeopathics, excl. different pack sizes
BE	2007	N.a.	N.a.	N.a.	5,061	N.a.
BG	2005	5,830[2]	4,481	N.a.	857[3]	Incl. different pharmaceutical forms, different pack sizes and different dosages. Only those ph. are indicated which are covered under the key reimbursement scheme (= NHIF reimbursement)
CY	2006	2,592	2,107	N.a.	700	Incl. different pharmaceutical forms, pack sizes and dosages; regarding reimbursable ph.: counted per active ingredients
CZ	2006	7,880	4,130	6,988	N.a.	Excl. different pack sizes and dosages
DE	2004	47,522[1]	N.a.	22,300[4]	N.a.	Ph. which are authorised according to Pharmaceutical Law 1978 incl. different pharmaceutical forms and dosages as well as parallel imports (11,634); excl. different pack sizes and homeopathics (incl. homeopathics the number would be 53,468).
DK	2006	9,142	4,346	7,393	3,987	Incl. different pharmaceutical forms and dosages; regarding POM and reimbursable ph. also incl. different pack sizes
EE	2005	2,907	4,078	2,441	1,612	Incl. different pharmaceutical forms and dosages, ex. different pack sizes
EL	2004	16,648	4,295	N.a.	N.a.	N.a.
FI	2006	7,071	4,672	4,163	2,581	Incl. different pharmaceutical forms and dosages; excl. different pack sizes[5]
FR	2005	14,990	8,650	5,000	6,100	Incl. different pharmaceutical forms, dosages, pack sizes excl. homeopathics
HU	2006	5,525	3,144	2,886	2,125	Excl. different dosages and pack sizes

C.	Year	Authorised	On the market	POM	Reimbursable	Comments/Counting
IE	2006	7,309	N.a.	N.a.	3,389	Incl. different pharmaceutical forms and dosages
IT	2006	33,490	13,070	28,630	9,567	Incl. different pharmaceutical forms, dosages and pack sizes
LT	2006	4,435	N.a.	3,054	1,565	Incl. different pharmaceutical forms and pack sizes; excl. different dosages
LV	2006	N.a.	3,660	2,477	261	Incl. different pharmaceutical forms and dosages, regarding reimbursable ph. counted per active substances
NL	2006	N.a.	N.a.	1,060	954	Counted per active ingredients
PL	2006	8,089[6]	4,275	2,749[7]	2,045	Incl. different pharmaceutical forms and pack sizes
PT	2005	36,432	10,637	34,717	8,777	Incl. different pharmaceutical forms and pack sizes
SE	2006	8,504	N.a.	7,844	5,126[8]	Incl. different pharmaceutical forms; excl. different dosages and pack sizes
SI	2006	2,791	N.a.	2,660	1,791	All presentations counted, herbals excluded
SK	2006	16,693	N.a.	17,804	4,804	Incl. different pharmaceutical forms, dosages and pack sizes
UK	2006	11,633	N.a.	8,204	N.a.	N.a.
NO	2006	6,829	3,579	6,245	N.a.	Incl. different pharmaceutical forms and dosages, excl. different pack sizes (except 2,874 ph. approved by centralised procedure, counted per different pack sizes), excl. natural remedies/herbal medicines, radiopharmaca and parallel imported ph.

Excl. = excluding, incl. = including, N.a. = not available, NHIF = National Health Insurance Fund, ph. = pharmaceuticals, POM = prescription-only medicines

[1] Excluding homeopathics

[2] Estimation based on the number of authorised pharmaceuticals in 2004 plus the newly authorised pharmaceuticals for 2005

[3] The reimbursement by the National Health Insurance Fund (NHIF) commenced in the second half of 2000. Before that, the reimbursement for outpatient treatment was regulated through other financial mechanisms and Regulation N2 (OJ 24, 1993) until 1997 and N12.

[4] Estimation

[5] Some pharmaceutical forms (asthma inhalation device package with asthma medicine / asthma inhalation medicine alone / single device package) differ in various statistics.

[6] Year 2005

[7] Including hospital-only pharmaceuticals

[8] Only reimbursed pharmaceuticals that have been sold during respective year are counted in the table. The data include different pharmaceutical forms and dosages but exclude different pack sizes.

Sources: PPRI Pharma Profiles 2006/2007, AMIS 2007, additional information provided by PPRI participants

In several PPRI countries the number of **pharmaceuticals** that are **available on the market** is lower than the number of authorised pharmaceuticals. Considerable differences are observed in Portugal, Greece and Austria. They result partly from the fact that pharmaceutical companies apply for a decentralised market authorisation without actually marketing the product in the country. A second reason is that consultancy businesses frequently submit multiple applications for the same product. After receiving the market authorisations, the consultancy firms sell these to generics companies. Thirdly, some companies do not market all presentations / pharmaceutical forms and pack sizes of the authorised product.

Regarding **reimbursable pharmaceuticals** (i.e. those which are eligible for reimbursement; not only the actually reimbursed pharmaceuticals) differences among the PPRI countries can be noticed. In some new EU Member States reimbursable pharmaceuticals tend to make up less than 50 percent of the pharmaceuticals on the market, whereas in some of the EU-15 countries (e.g., Finland) the respective share of reimbursable pharmaceuticals is higher.

In general, the percentage of **prescription-only medicines (POM)** is higher than the share of reimbursable pharmaceuticals.

3.2.3 Market players

Within Europe, commonalities in the distribution chains can be noticed: pharmaceuticals are either being locally produced or imported and subsequently distributed through wholesalers to community pharmacies, which dispense them to patients. Apart from that, hospitals or hospital associations, like the Danish AMGROS directly tender pharmaceuticals used in hospitals from producers, importers or wholesalers.

The EU-10 countries have historically a stronger focus on the production of generics than on innovative pharmaceuticals, and therefore in these countries local generic manufacturers still play an important role. This is particularly the case in Poland and Lithuania where twelve out of a total of 13 companies are generic producers. Since the 1990s the picture has been changing, in the sense that international **pharmaceutical industries** have been entering the markets of the EU-10 countries, although very often as branches. Having said that, the bio-tech industry has been increasingly established in Western European countries such as Germany (375 bio-tech companies) and Finland (20 bio-tech companies), cf. Table 3.6.

The pharmaceutical market in the EU-10 countries is characterised by a relatively high number of importers, which are very often the same companies as those having wholesale licenses. This might be due to the fact that some of these countries have a relatively small market size.

Table 3.6: Comparative analysis – Pharmaceutical industry and distribution in the PPRI countries, 2007 or latest available year

Country	Pharmaceutical industry	Wholesale	Pharmaceutical retail
AT	Approx. 200 companies	9 full-line wholesalers	Approx. 1,200 community pharmacies and 1,000 SD-doctors; 5 hospital pharmacies for outpatients
BE	Approx. 100 companies	Approx. 20 wholesalers	Approx. 5,224 community pharmacies
BG	23 research-oriented companies, 7 generic companies from CEE	Approx. 350 companies with wholesale licenses	Approx. 4,450 community pharmacies; sale of selected OTC products in drugstores
CY	5 companies, all of them local generic producers	Approx. 60 companies (incl. importers)	Approx. 470 community pharmacies, 8 hospital pharmacies for outpatients; very few SD-doctors
CZ	86 companies authorised to research and manufacture	220 companies with wholesale licences	2,360 pharmacies, 247 detached departments of pharmacies, 350 dispensaries of medical devices, 166 vendors of selected OTC pharmaceuticals
DE	975 companies, approx. 41 research-oriented companies and 375 biotech companies	Approx. 16 large wholesalers with nearly 130 outlets	Approx. 21,500 community pharmacies, approx. 490 hospital pharmacies, approx. 1,400 pharmacies have obtained an internet trade licence
DK	264 companies, thereof 189 manufactures and 10 parallel traders	3 leading full-line wholesalers	Approx. 320 community pharmacies incl. branches, approx. 140 pharmacy shops, 700 OTC outlets and 1,450 shops (supermarkets) licensed for limited OTC sale
EE	6 companies, all of them generic producers	54 companies with wholesale license (incl. wholesalers of veterinary products)	Approx. 320 community pharmacies, in total 524 pharmaceutical sales units
EL	Approx. 550 companies incl. 60 generic companies	130 wholesale outlets	Approx. 8,700 community pharmacies
FI	65 companies, thereof 20 bio-tech companies	2 wholesalers; single-channel	Approx. 800 community pharmacies; sale of selected OTC products in “medicine chests” (situated in grocery shops, post offices, etc.) in rural areas
FR	303 companies, thereof 12 generic producers	11, thereof 3 leading wholesalers	Approx. 22,600 community pharmacies, some (~ 120) SD-doctors, dispensing of selected pharmaceuticals by hospital pharmacies to outpatients
HU	58 companies	14 wholesalers	Approx. 2,700 community pharmacies, approx. 400 SD-doctors; 67 hospital pharmacies for outpatients
IE	76 companies	Approx. 140 wholesalers	Approx. 1,500 community pharmacies, approx. 140 SD-doctors
IT	229 companies	246 wholesale outlets	Approx. 17,400 community pharmacies approx. 300 OTC dispensaries

Country	Pharmaceutical industry	Wholesale	Pharmaceutical retail
LT	13 companies, thereof 12 generic producers	72 wholesalers	Approx. 1,400 community pharmacies, 60 hospital pharmacies for outpatients; approx. 1,000 health care centres
LV	14 companies	37 wholesale outlets	Approx. 810 community pharmacies plus approx. 100 branch pharmacies
MT	11 companies, all are local generic producers	90 wholesalers	Approx. 220 community pharmacies, 52 POM dispensaries (hospital pharmacies for outpatients, dispensaries in outpatient departments, health centres)
NL	125 companies	351 wholesalers, thereof 19 parallel traders	Approx. 1,800 community pharmacies, approx. 590 SD-doctors, 10 hospital pharmacies for outpatients, 4 internet pharmacies; approx. 4,000 OTC dispensaries (e.g., chemists)
PL	Approx. 300 companies	Approx. 600 wholesalers	Approx. 11,300 community pharmacies, dispensing by doctors only in exceptional cases
PT	Approx. 500 companies	Approx. 300 wholesalers	Approx. 2,700 community pharmacies
SE	Approx. 330 companies	2 wholesalers; single-channel	850 community pharmacies; 875 representatives, for example groceries, stocking a small amount of OTC and also allowed to deliver pre-ordered POM; 29 pharmacy shops for OTC products
SI	2 generic companies, 15 MA holders (small scale enterprise or importing wholesalers)	50 wholesalers	279 community pharmacies, 60 specialized stores dispensing herbals and selected OTC pharmaceuticals
SK	120 companies, thereof 77 local generic producers	Approx. 240 wholesalers	1,500 community pharmacies
UK	Approx. 80 companies	14 full-line wholesalers (more than 2,000 companies with wholesale license)	Approx. 11,600 community pharmacies, dispensing by doctors in specific cases; sale of selected OTC products in pharmacy shops and supermarkets
NO	178 companies	3 leading wholesalers	Approx. 530 community pharmacies, approx. 30 hospital pharmacies for outpatients, approx. 7,000 OTC dispensaries
TR	250 companies, thereof 200 generic producers	Approx. 490 wholesalers	Approx. 22,600 community pharmacies

approx. = approximately, CEE = Central and Eastern Europe, incl. = including, MA = marketing authorisation, POM = prescription-only medicines, OTC = Over-the-Counter, SD-doctors = self-dispensing doctors

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Pharmaceutical retailers, which dispense pharmaceuticals to outpatients, may be community pharmacies, self-dispensing doctors, hospital pharmacies, and also pharmacy outlets, drug stores, herbal shops or even supermarkets or petrol stations. The latter, however, are only allowed to dispense (a selected range of) OTC products.

In order to compare the provision of pharmaceuticals for patients in the outpatient sector, two indicators are analysed in Figure 3.6:

- Inhabitants per community pharmacy

  Throughout Europe pharmaceuticals are still mainly dispensed in **community pharmacies**. Community pharmacies are defined as health care facilities that dispense pharmaceuticals (POM and OTC, reimbursable and non-reimbursable pharmaceuticals) to outpatients and that are subject to pharmacy legislation (e.g., national legislation regarding establishment and ownership of pharmacies).

  The pharmacy density is higher in new EU Member States (EU-10: 3,360 inhabitants/ pharmacy; EU-15: 5,780 inhabitants/pharmacy) and is lowest in the Nordic countries (Denmark: 16,800 inhabitants/pharmacy, Sweden: 10,600 inhabitants/pharmacy) and in the Netherlands, where one community pharmacy serves on average 9,400 patients. Greece provides the highest number of often small-size pharmacies per citizen (approximately 1,280 inhabitants/pharmacy).

- Inhabitants per POM dispensary

  Apart from community pharmacies there are other retailers dispensing prescription-only medicines (POM), the most relevant being **hospital pharmacies serving outpatients** and **self-dispensing doctors**. For instance, there are 67 hospital pharmacies for outpatients in Hungary and 30 hospital pharmacies for outpatients in Norway. In addition, dispensing by self-dispensing doctors is noticeable in Austria (approx. 1,000), France (approx. 120), Hungary (approx. 400), Ireland (approx. 140), and the Netherlands (approx. 590).

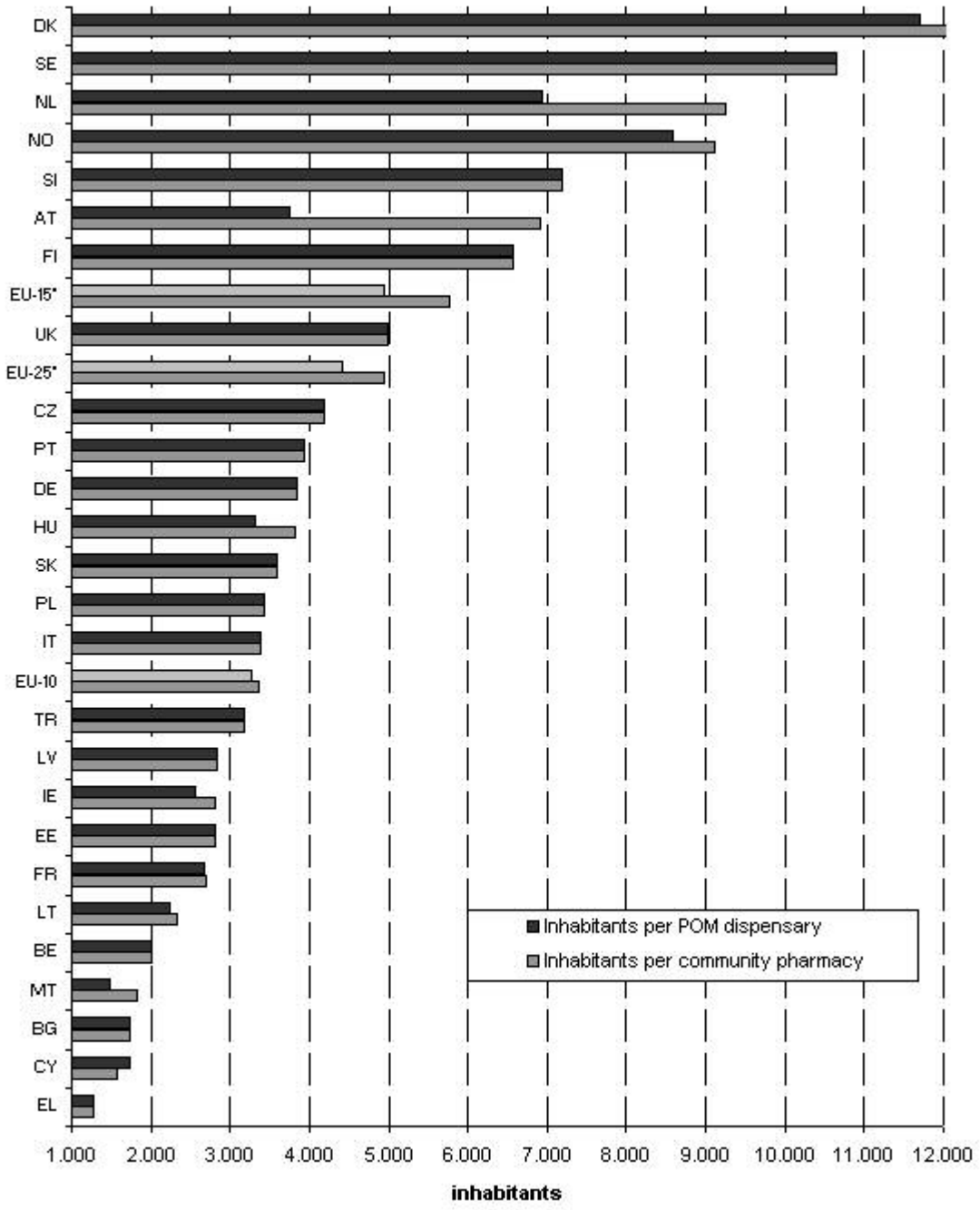
  Considering these dispensaries, Denmark still has the lowest retailer density (11,700 inhabitants/POM dispensary), and the highest ratio is again in Greece, even though no other POM dispensaries besides the community pharmacies are allowed.

In addition, in some countries (especially Nordic countries) a high number of **OTC dispensaries** has been observed. For example, Norway has 7,000, the Netherlands have 4,000 and Denmark has 700 OTC dispensaries.

Furthermore, the presence of **internet pharmacies** in the PPRI countries was explored, showing that in most of the countries Internet pharmacies are not allowed or at least not common. The Netherlands hosts four Internet pharmacies and about 1,400 German community pharmacies have obtained an internet trade licence.

Presently the retail market in some European countries (e.g., Netherlands, Norway, Slovenia) has been undergoing a liberalisation process, implying an abolishment of establishment rules and the rapid forming or expansion of pharmacy chains. Also Sweden is considering to abolish its state pharmacy monopoly currently officiated by the state-owned pharmacy organisation Apoteket.

Figure 3.6: Comparative analysis – Inhabitants per community pharmacy and per prescription-only medicines (POM) dispensary in the PPRI countries, 2005



* Excl. ES, LU

A POM dispensary is defined as a pharmaceutical retailer (e.g., pharmacy, self-dispensing doctor, hospital pharmacy) which is allowed to dispense prescription-only medicines (POM) to patients; cf. PPRI Glossary, http://ppri.oebig.at → Glossary

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.2.4 Funding

3.2.4.1 Pharmaceutical expenditure

In 2005 the PPRI countries together spent about € 156 billion on pharmaceuticals (EU-25 excl. Malta: € 153.8 billion). In terms of € PPPa **pharmaceutical spending** amounted to about € PPPa 360.- per capita in EU-15 countries, which is € PPPa 105.- more per inhabitant than in the EU-10 Member States (cf. Figure 3.7).

Concerning the **growth in pharmaceutical expenditure**, Figure 3.8 provides information for several PPRI countries (where data available) for the periods from 1995 to 2005 and from 2000 to 2005. The growth in pharmaceutical expenditure in the new EU Member States has been higher than in the old ones: between 2000 and 2005, the average annual growth rate in pharmaceutical expenditure was 11.6% in the EU-10, whereas it amounted to 7.3 % in the EU-15 (EU-25: 8.9%). In the last few years since 2000, some Western European countries have achieved to have relatively moderate growth rates (annual rates of about four to five percent). In the interpretation of the data, in particular those dating back to 1995, attention should be given to different starting levels as well as to inflation rates, which can make a difference regarding high growth in pharmaceutical expenditure in a country (e.g. Hungary).

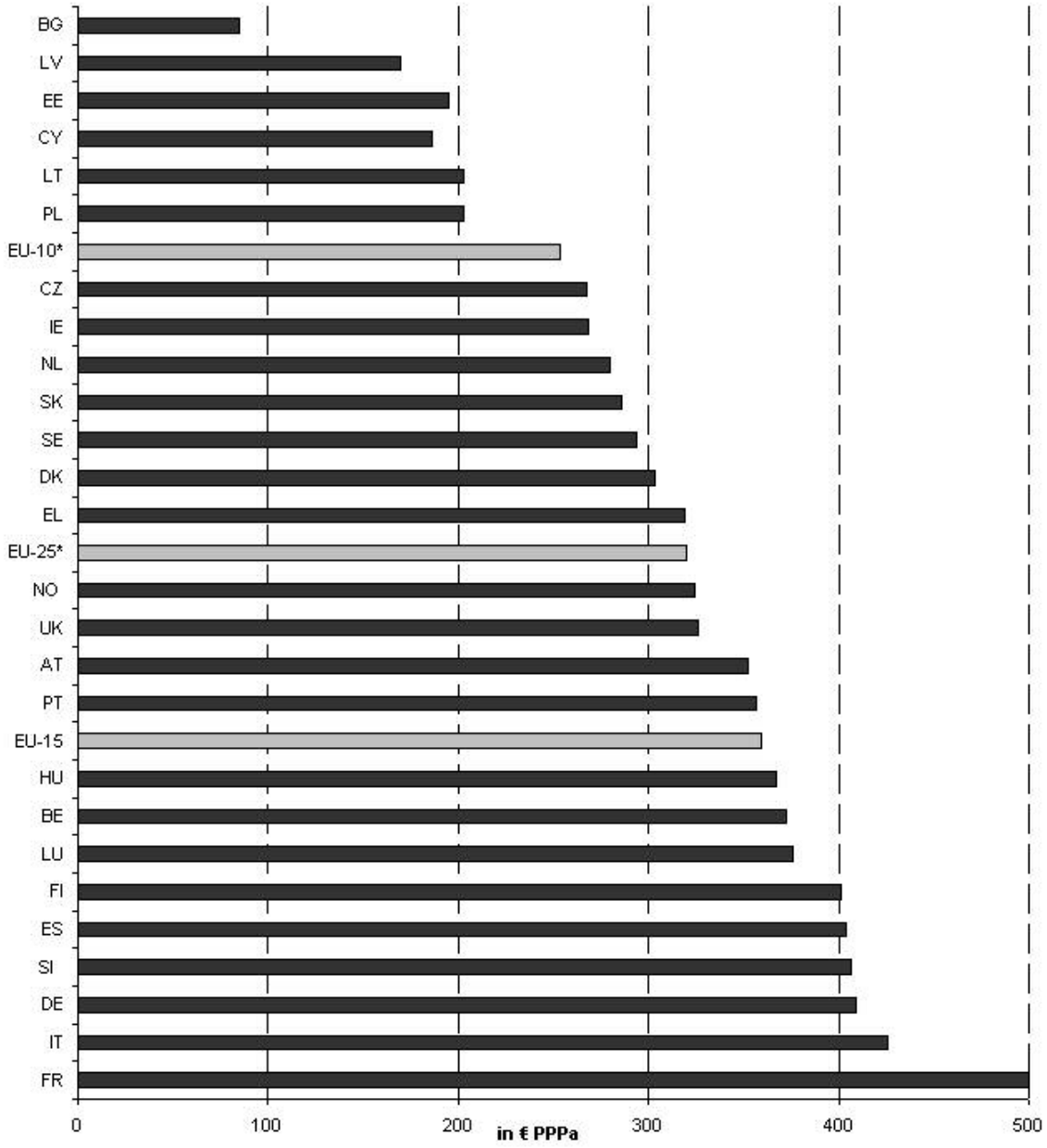
3.2.4.2 Health expenditure and pharmaceutical expenditure

In the European average, about **20 percent of health care funding goes to pharmaceuticals**. As Figure 3.9 demonstrates, the new EU Member States tend to use a greater share of their health care budget for the purchase of pharmaceuticals than the EU-15 Member States. Whereas Luxembourg spends 8.5 percent of the health budget on pharmaceuticals, Slovakia, on the other end of the scale, uses one third of total health expenditure.

As stated in section 3.1.3.2, in the EU-10 countries the prices of international brands are less influenced by the local market and national economic power than by global marketing strategies, which results in the prices of on-patent branded pharmaceuticals often being similar in EU-10 and EU-15 countries (ÖBIG PPI Service 2007).

In absolute terms, there is no relationship between the pharmaceutical expenditure per inhabitant and the health expenditure per inhabitant (R^2 = 0.2795, PPRI analysis for the PPRI countries except BG, MT, TR for the years 2004/2005).

Figure 3.7: Comparative analysis – Total pharmaceutical expenditure per inhabitant in € PPPa in the PPRI countries, 2005



PPPa = Purchasing Power Parities

* Excl. MT

2004 - AT, CY, DE, EL, ES, FR, IE, LU, PL, PT, SE, NO

BG: only public expenditure

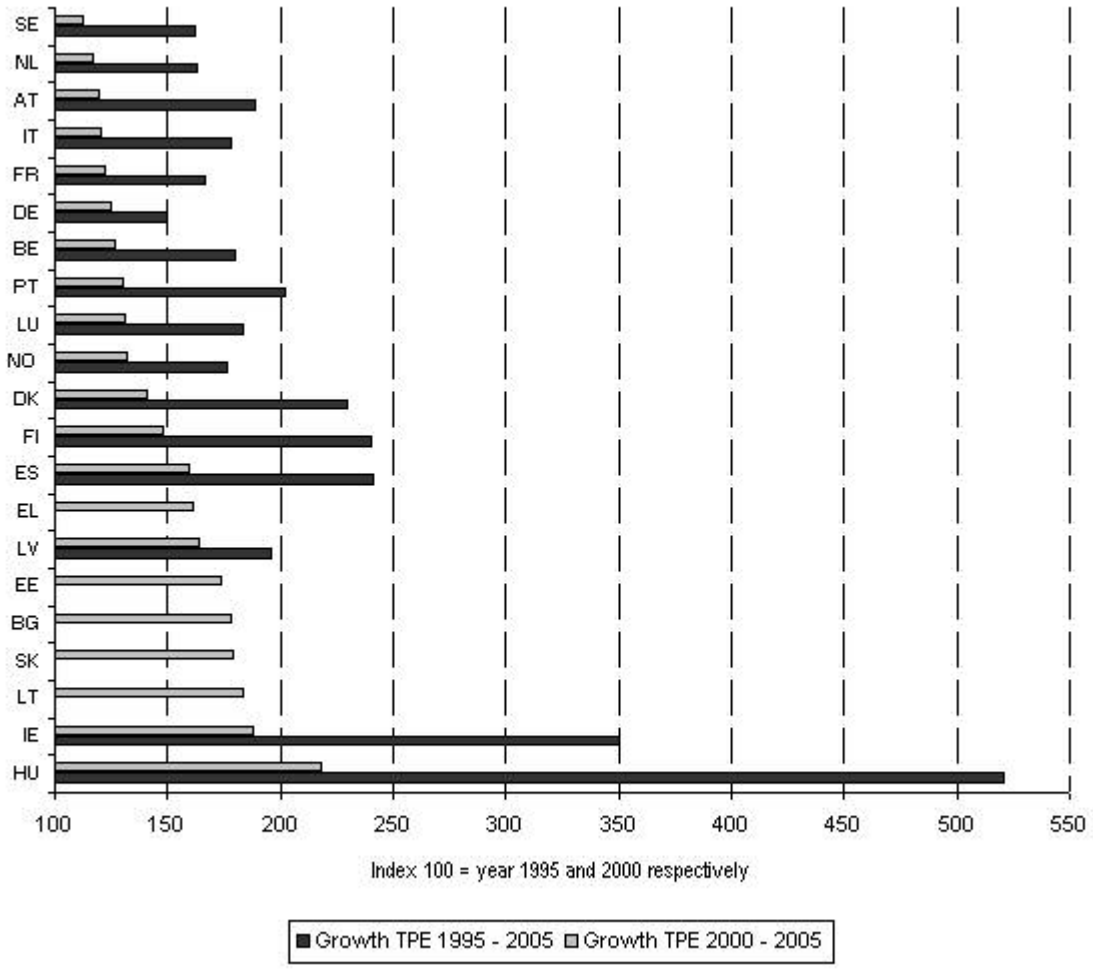
FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices

NL and SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for CZ, ES, IE, LU, PL; conversation rates by EUROSTAT

Figure 3.8: Comparative analysis – Growth in pharmaceutical expenditure in the PPRI countries, 1995–2005 and 2000–2005



TPE = Total pharmaceutical expenditure

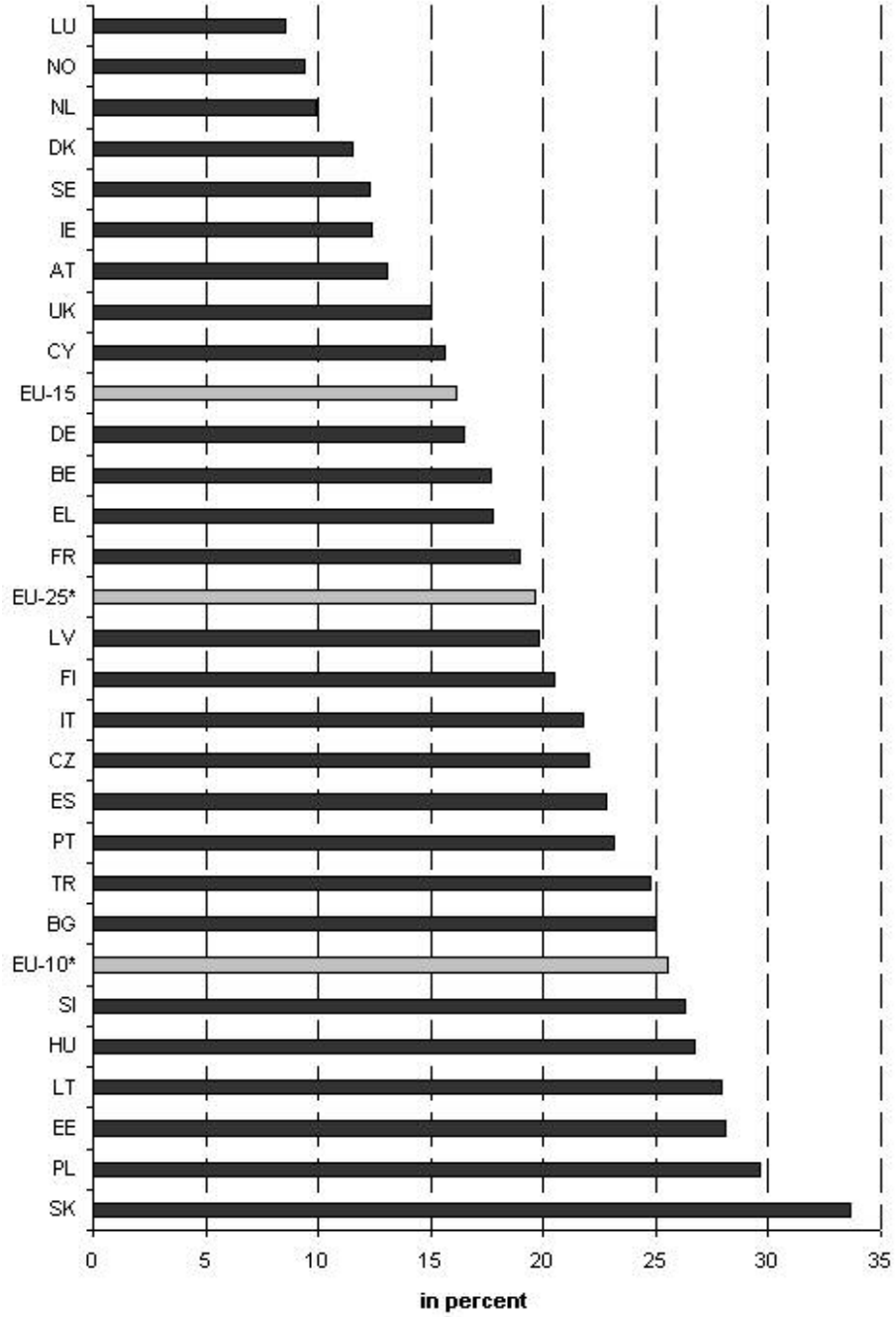
Growth from 1995 and 2000 respectively to 2004 – AT, EL, ES, FR, IE, LU, PT, SE

BG: only public expenditure
FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices
NL and SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for CZ, ES, IE, LU, PL; conversation rates by EUROSTAT

Figure 3.9: Comparative analysis – Share of pharmaceutical expenditure as percentage of total health expenditure in the PPRI countries, 2005 or latest available year



* Excl. MT

2006: BE; 2004: AT, CY, CZ, EE, EL, ES, FR, HU, IE, IT, LU, PL, PT, SE, NO; 2000: TR

BG: only public expenditure

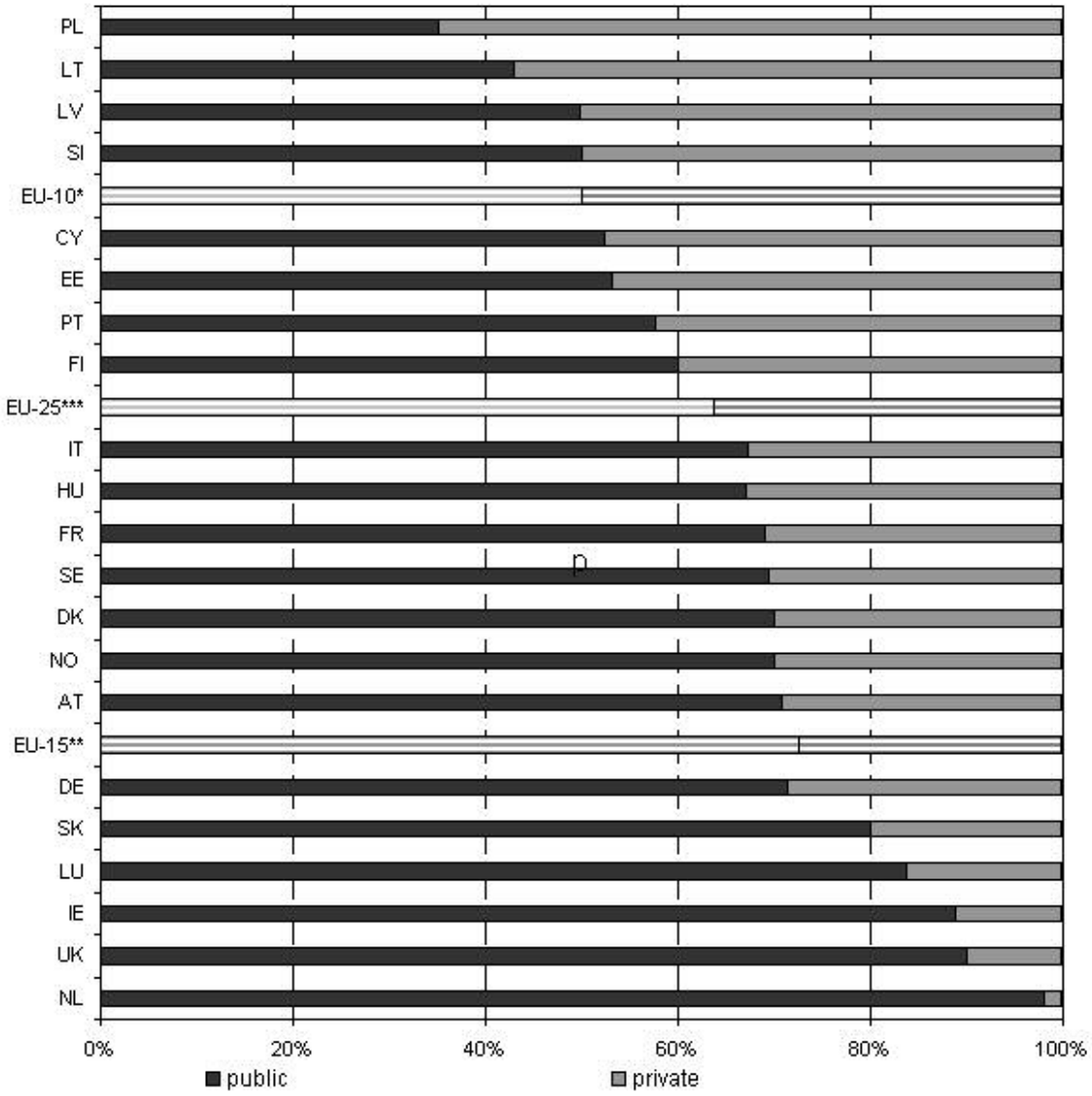
FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices

NL and SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI Pharma Profiles 2006/2007, OECD Health Database 2006 for CZ, ES, IE, LU, PT, NO

Figure 3.10: Comparative analysis – Share of public / private funding of total pharmaceutical expenditure in the PPRI countries, 2004/2005



* Excl. CZ, MT ** excl. BE, EL, ES, NL *** excl. BE, CZ, EL, ES, MT, NL

2005: DK, DE, LT, FI, FR, HU, LT, NL, UK, 2006: SI

FI: public - reimbursable and non-reimbursable prescription-only medicines (POM) + Over-the-counter (OTC) pharmaceuticals, incl. sales to hospitals, excl. social assistance paid to people with low incomes by the local municipal authorities and support paid to pensioners, children and people with disabilities
NL: only prescription-only medicines (POM) market (including Over-the-counter (OTC), the share of private expenditure would be approx. 42%, latest available figure of 2002)
SK: only prescription-only medicines (POM) market

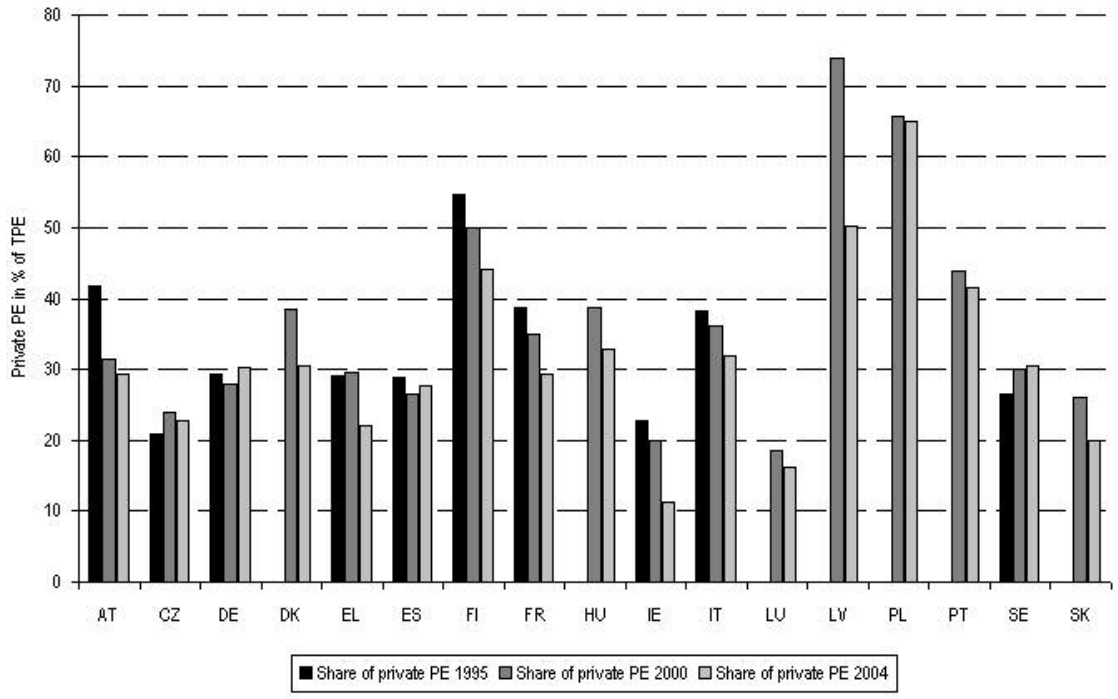
Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI Pharma Profiles 2006/2007; OECD Health Database 2006 for LU, IE

3.2.4.3 Public and private pharmaceutical expenditure

In the majority of the PPRI countries a great share of pharmaceutical expenditure, at least for prescription-only medicines (POM), is **covered by third party payers** (EU-25 average: approx. 64%, cf. Figure 3.10). The relatively low private expenditure share in Netherlands (2%) can be explained by the fact that this number refers only to the POM market. In the country with the second lowest private pharmaceutical expenditure, Great Britain, 90 percent of all pharmaceutical expenditure is covered by the National Health Service (NHS).

Figure 3.11: Comparative analysis – Development of the shares of private pharmaceutical expenditure in the PPRI countries, 1995–2004



PE = Pharmaceutical expenditure

Year 2004: 2002 – CZ, 2005 – HU
Year 2000: 2001 – HU, SK

SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI Pharma Profiles 2006/2007; OECD Health Database 2006 for IE, LU

Between 2000 and 2004, the increase in public pharmaceutical expenditure was higher than that in private expenditure in most PPRI countries.

This is in particular the case in the countries (except for Germany) which have managed to maintain growth in pharmaceutical expenditure at moderate rates (cf. section 3.2.4.1); here **public pharmaceutical expenditure increased at** considerably **higher rates** than private expenditure.

As a result, in some PPRI countries (especially those with relatively moderate growth in pharmaceutical expenditure, e.g. Austria, Italy), the share of private pharmaceutical expenditure in 2004 was lower compared to the years 2000 and 1995. None of the PPRI countries considered in this analysis (where data available) has shown a major increase in the share of private pharmaceutical expenditure between 1995 and 2004 (cf. Figure 3.11).

3.3 Pricing

3.3.1 Organisation

Pricing, like reimbursement, is mainly a national competence. As stated in section 3.2.1.1, in several PPRI countries the Ministry of Health is the **authority** in charge of pricing (i.e. regarding the "controlled price type", for a definition see the footnotes at Table 3.3), whereas in others the pricing of pharmaceuticals is in the hands of the Ministry of Economy/Development/Finance or of the Medicines Agency. In addition, some countries have established specific institutions which are in charge of pricing and reimbursement. This is especially the case in countries where the pricing and reimbursement process is interlinked. Furthermore, pricing also refers to the determining of distribution mark ups, which are often regulated by the state through the Ministry of Health.

As the findings in this section will show, there is, in general, a strong **connection between pricing and reimbursement**. This is, for instance, reflected by the fact that in most PPRI countries price control is only applicable for the group of reimbursable pharmaceuticals. The following sections will analyse pricing policies and procedures for different price types (manufacturer, wholesale and pharmacy), and thus investigate the elements that build the final pharmacy retail price (e.g., mark ups and taxes).

Please note that the information provided only refers to the outpatient sector unless explicitly stated otherwise.

3.3.2 Pricing policies

Pricing policies are defined as regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers (PPRI Glossary). Two key pricing policies are to be distinguished:

- Free pricing: In this pricing system pharmaceutical prices may be freely set by the manufacturers (or wholesalers, if the relevant controlled price type is the pharmacy purchasing price).
- Price control: Here pharmaceutical prices are determined by the authorities. In the outpatient sector, price control is usually exercised through statutory pricing or price negotiations, whereas in the inpatient sector public procurement is common (cf. Table 3.8).

In 24 of the 27 PPRI countries **prices are controlled for outpatient pharmaceuticals**. In the majority of these countries (e.g., in Finland, Italy and Poland), price control is limited to pharmaceuticals with reimbursement eligibility (= reimbursable pharmaceuticals), while for non-reimbursable pharmaceuticals, which are often OTC products, the manufacturer/importer may freely set the price. Seven countries (among which Greece, Luxembourg, and Turkey) regulate the prices of all pharmaceuticals, and three countries (Netherlands, Norway and Portugal) apply price control for prescription-only pharmaceuticals (cf. Table 3.7).

Denmark, Germany and Malta (in the private sector) are the only three countries where, technically speaking, no price control is exercised. However, in Denmark and Germany the prices of reimbursable pharmaceuticals (in particular the reimbursement prices) are indirectly influenced by the reimbursement system. This is different in Malta, where pharmaceuticals in the private sector are not reimbursed at all. In these three countries, there is free pricing at the ex-factory price level (Germany and Malta) or at the pharmacy purchasing price level (Denmark), but at the distribution levels, mark ups (wholesale and pharmacy mark ups in Germany and Malta, and pharmacy mark ups in Denmark) are regulated.

Within the framework of price control, **statutory pricing**, i.e. setting the price on a regulatory, unilateral basis, is the most common pricing policy. Statutory pricing is often based on external price referencing procedures (i.e. international price comparison) with the reference countries and other methodological issues being defined by statutory rules (cf. section 3.3.3). In a few countries prices are solely negotiated between the relevant actor (manufacturer or wholesaler) and the government authority (like the Medicines Agency in Italy). **Price negotiations** may be combined with statutory pricing (e.g., statutory pricing follows price negotiations in Estonia, Latvia and Poland, or is a back-up in case of the failure of negotiations in France). A particular case forms the UK which has no direct price control, but the prices of NHS pharmaceuticals are indirectly controlled through the PPRS scheme (see also Box 5).

Box 5: Pharmaceutical Price Regulation Scheme (PPRS) – Indirect price control in the UK

In the UK, the prices of branded prescription-only medicines sold to the National Health Service (NHS) are indirectly controlled in so far as the maximum profit that manufacturers are allowed to make on their sales to the NHS is regulated by the Pharmaceutical Price Regulation Scheme (PPRS).

The PPRS is a voluntary agreement between the Department of Health (DoH) and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI). However, the Health Act 1999 enables the state to impose statutory price and profit controls on those companies, which decide not to sign up to the voluntary scheme. There have been a series of voluntary agreements with the industry since 1957; the current PPRS started in January 2005 and is valid for five years. The 2005 PPRS incurred a price reduction of 7% on all products covered by the scheme from 1 January 2005 on.

On market entry, pharmaceutical companies have freedom of pricing for major new products, i.e. those introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Marketing Authority, while taking into consideration the allowed profit target. A company's profit is assessed based on the value of its sales of branded prescription-only medicines to the NHS, the company costs that would be appropriate for the NHS to bear (in particular the manufacturing cost), and capital employed by the company for delivering NHS sales. Where profits are assessed as exceeding the return on capital (ROC) target plus a margin (almost 30% of ROC), the excess has to be repaid to the DoH or prices reduced.

Where a new branded product has not been subject to a new active substance marketing authorisation, companies must seek the DoH's agreement for the price of the new product. In reaching a decision on the acceptability of the proposed price, the DoH may take into account factors such as the price of other presentations of the same pharmaceutical or comparable products, forecast sales and the effect on the NHS pharmaceutical expenditure or the clinical need for the product. The NHS list price of existing products may only be increased with the DoH's agreement if the criteria for price increases set out in the agreement are met.

The different pricing policies for pharmaceuticals in the PPRI countries are summed up in Table 3.7.

Table 3.7: Comparative analysis – Price control for pharmaceuticals in the outpatient sector in the PPRI countries, 2006/2007

Country	Scope of price control	Pricing policy	Controlled price type
AT	Reimbursable pharmaceuticals	Statutory pricing	Ex-factory price
BE	All pharmaceuticals	Statutory pricing	Ex-factory price
BG	All pharmaceuticals	Statutory pricing	Ex-factory price
CY	All pharmaceuticals (different procedures for imported and locally-produced pharmaceuticals)	Statutory pricing	Ex-factory price / pharmacy purchasing price[1]
CZ	All pharmaceuticals	Statutory pricing	Ex-factory price
DE	No price control (free pricing for all pharmaceuticals)	Obligatory price notification to Pharmacists Association	Ex-factory price
DK	No price control (free pricing for all pharmaceuticals)	Price notification to Medicines Agency	(Pharmacy purchasing price)
EE	Reimbursable pharmaceuticals	Statutory pricing after price negotiations	Ex-factory price
EL	All pharmaceuticals	Statutory pricing	Ex-factory price
FI	Reimbursable pharmaceuticals	Statutory pricing (pricing and reimbursement processes are combined)	Pharmacy purchasing price
FR	Reimbursable pharmaceuticals	Price negotiations; in case of failure statutory pricing	Ex-factory price
HU	Reimbursable pharmaceuticals	Price negotiations due to linkage with reimbursement system; in addition statutory pricing criteria	Ex-factory price
IE	Reimbursable pharmaceuticals and those supplied to the HSE (pharmaceuticals under price agreements)	Pricing based on an Agreement between HSE and industry; in case of non-availability of comparative data, price negotiations	Ex-factory price
IT	Reimbursable pharmaceuticals	Price negotiations	Ex-factory price
LT	Reimbursable pharmaceuticals	Statutory pricing (statutory price is base price for reimbursement)	Ex-factory price
LU	All pharmaceuticals	Statutory pricing	Pharmacy retail price
LV	Reimbursable pharmaceuticals	Statutory pricing after price negotiations	Pharmacy purchasing price
MT	No price control (free pricing for all pharmaceuticals)	–	Ex-factory price
NL	POM	Statutory pricing	Pharmacy purchasing price
PL	Reimbursable pharmaceuticals	Statutory pricing after price negotiations	Pharmacy purchasing price
PT	POM	Statutory pricing	Ex-factory price
SE	Reimbursable pharmaceuticals	Statutory pricing (pricing and reimbursement processes are combined)	Pharmacy purchasing price

Country	Scope of price control	Pricing policy	Controlled price type
SI	Reimbursable pharmaceuticals	Statutory pricing	2006: Pharmacy purchasing price, 2007: Ex-factory pr.
SK	Reimbursable pharmaceuticals	Statutory pricing	Pharmacy retail price
UK	NHS products, including branded POM and OTC	Indirect price control through profit control based on the Pharmaceutical Price Regulation Scheme (PPRS)	NHS list price[2]
NO	POM	Statutory pricing	Pharmacy purchasing price
TR	All pharmaceuticals	Statutory pricing	Ex-factory price

HSE = Health Service Executive (Irish NHS authority), NHS = National Health Service, POM = prescription-only medicines, PPRS = Pharmaceutical Price Regulation Scheme, OTC = Over-the-Counter
Definitions: cf. PPRI Glossary, http://ppri.oebig.at → Glossary
Statutory Pricing: Pricing system, where pharmaceutical prices are set on a regulatory basis (e.g., laws, enactments, decrees).
Price negotiations: A form of pricing procedure, where pharmaceutical prices are negotiated between the government and the manufacturers.

1 Control of ex-factory price for locally-produced pharmaceuticals, control of pharmacy purchasing price for imported pharmaceuticals

2 Corresponds to the pharmacy purchasing price, i.e. the price at which POM dispensaries are reimbursed

Note: This table refers to the outpatient sector and, where applicable (Cyprus, Malta, cf. section 3.1.3.1), to private systems.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Often, in the pricing procedure undertaken by the state the price is first set at the manufacturer level (cf. **controlled price type** in Table 3.7), and then further controlled through mark ups (cf. section 3.3.4). This is the case in 16 of the 27 PPRI countries (Cyprus not being included, since this method is applicable only for few products). Prices may also be controlled at the pharmacy purchasing (i.e. wholesale) price level. In fact, nine countries (Cyprus – for imported pharmaceuticals, Denmark, Finland, Latvia, Netherlands, Norway, Poland, Sweden and UK) set the price at wholesale level (year 2007). In seven of these nine countries, there is no statutory wholesale mark up and thus the ex-factory price is freely negotiated by the manufacturer and the wholesaler. In Luxembourg and in Slovakia prices are, in the first place, set at pharmacy retail level, but because of statutory wholesale and pharmacy mark ups the ex-factory and the pharmacy purchasing prices are indirectly fixed.

Additionally, from a third party payer's perspective and from the patients' perspective, the so-called reimbursement price (see also section 3.4.3) is of importance, which is the basis for reimbursement of pharmaceuticals, i.e. the maximum amount paid for by a third party payer.

In many systems the key criterion for a price to be either regulated or freely set is the reimbursement status of the product. This is also reflected in the respective pricing policies applied for specific types of pharmaceuticals, which are displayed for the 27 PPRI countries in Table 3.8. If in a country prices of reimbursable pharmaceuticals are controlled, then this also includes reimbursable generics, reimbursable OTC products as well as reimbursable

parallel-imported pharmaceuticals. In addition, in countries where price control applies for all pharmaceuticals (e.g., Belgium, Greece, Turkey), the prices of generics, OTC products and parallel-imported pharmaceuticals are also regulated.

Since **OTC products** are often not included in reimbursement, their price is in most countries freely set by the manufacturers or importers.

A specific type of pharmaceuticals is a **generic** (i.e. bioequivalent of a branded original pharmaceutical, whose patent on the active ingredient has expired, cf. PPRI Glossary). Whereas in the Central and Eastern European countries the generics share is already rather high (50% and more in volume, see Figure 3.13), other, particularly old EU Member States have seen the need to implement measures to boost their generics markets. Denmark, Germany, the Netherlands and Sweden, which started relatively early with fostering generic promotion, for instance through introducing a system of generic substitution (see section 3.5.4), have also reached a significant generics share (40%–55% in volume). Generic promotion will be further analysed in section 3.5.4.

Box 6: Mechanisms of generics pricing – Examples from Austria and Estonia

In **Austria**, specific pricing rules apply for generics which are to be included in the reimbursement list. The first generic is considered as economically efficient if the price is at least 48% (2006) below the price of the now off-patent original brand. Furthermore, economic efficiency is assumed if the second and each subsequent generic "follower" offer a sufficiently large price difference to the previous included generic. The price of the original has to be reduced by at least 30% within three months of the inclusion of the first generic follower in the positive list, in order to ensure the economic efficiency of the original product.

This means that the price of the first generic follower has to be 25.7% below the price of the discounted original product. This percentage was 20% in 2004 and 22.9% in 2005.

Estonia applies a similar pricing mechanism for reimbursable pharmaceuticals. If a generic first applies for reimbursement, the same pricing procedure is used as for the original product. In case that a new original product is added to the reimbursement list, which already includes one or more generic alternatives, the original product has to be cheaper than the previously added generic. If the original product is first in the positive list, the generic product has to be at least 30% cheaper than the original.

The next pharmaceutical to join the list has to be 10% cheaper than the valid reference price and the next two pharmaceuticals must be priced 5% below the reference price. All subsequently added pharmaceuticals must be cheaper than the previously added generic or below the reference price.

Concerning the pricing of generics, several PPRI countries (cf. Table 3.8) set the price of a generic considerably lower than that of the original product. Some countries provide mechanisms for reducing the prices of the second and further generics (see Box 6), which might result in lower prices of original products as well.

Table 3.8: Comparative analysis – Pricing policies for specific types of pharmaceuticals in the PPRI countries, 2006/2007

C.	Hospital-only ph.	Generics	OTC products	Parallel-traded ph.
AT	Price control; public procurement	Price control for reimbursable generics; at least 48% lower than price of original product in order to be cheapest for reimbursement (see Box 6)	Free pricing for non-reimbursable OTC products	No specific pricing policy
BE	Price control; direct negotiations between hospitals and manufacturers	Price control for all pharmaceuticals, thus also for generics	Price control for all pharmaceuticals, thus also for OTC products	Shorter period for pricing decision
BG	Price control; public procurement	Price control for all pharmaceuticals, thus also for generics	Simplified procedure (price notification), but still price control	Not applicable
CY	Price control; public procurement	Price control for all imported pharmaceuticals, thus also for generics. Specific procedure (cost-plus) for locally-produced generics	Price control for all imported pharmaceuticals, thus also for OTC products; specific procedure (cost-plus) for locally-produced OTC	Not applicable
CZ	Price control; direct negotiations between hospital pharmacists and manufacturers	Price control for all pharmaceuticals, thus also for generics	Price control for all pharmaceuticals, thus also for OTC products	Price control for all pharmaceuticals
DE	No price control; negotiations about discounts between hospital pharmacies and manufacturers	No price control, obligatory discount of 10% for sickness funds since 2006	Free pricing at manufacturer level	Free pricing
DK	Price control; public procurement mostly undertaken by hospital purchase consortium AMGROS	Free pricing. Price notifications to Medicines Agency	Free pricing. Price notifications to Medicines Agency for products restricted to pharmacy sale	Free pricing. Price notifications to Medicines Agency
EL	Price control; pharmacy purchase price is reduced by 13%	Price control for all pharmaceuticals, thus also for generics; at maximum 80% of price of original product	Price control for all pharmaceuticals, thus also for OTC products; no specific pricing policy for OTC products	Price control for all pharmaceuticals; no specific pricing policy
EE	No price control; public procurement by the hospitals. Regulated mark ups for wholesalers	Price control for reimbursable generics; 30% lower than price of original pharmaceutical for the first generic and lower prices of further generics (see Box 6)	Price control for reimbursable OTC and nutritional products sold in pharmacies	Price control for reimbursable parallel imports; 10% lower than the price of the original marketing authorisation holding product

C.	Hospital-only ph.	Generics	OTC products	Parallel-traded ph.
FI	Price control; public procurement	Price control for reimbursable generics	Free pricing for non-reimbursable OTC products	Price control for reimbursable parallel-traded pharmaceuticals
FR	Free pricing for most pharmaceuticals and public procurement. Exception for a few products (very costly): tariff control	Price control for reimbursable generics	Free pricing for non-reimbursable OTC products	No specific pricing policy
HU	Price control; public procurement	Price control for reimbursable generics; at least 30% lower than price of original product	Free pricing for non-reimbursable OTC products	No specific pricing policy
IE	Price control; public procurement	Price control for reimbursable generics and those supplied to the HSE and state-funded hospitals	Free pricing for non-reimbursable OTC products	Same as generics
IT	Price control; public procurement	Price control for reimbursable generics; at least 20% lower than price of original product	Free pricing for non-reimbursable OTC products	No specific pricing policy
LT	Price control; public procurement	Price control for reimbursable generics; at least 30% lower than price of original product	Free pricing for non-reimbursable OTC products	No specific pricing policy
LU	Price control: manufacturer price set by the Ministry of Economics	Price control for all pharmaceuticals, thus also for generics	Price control for all pharmaceuticals, thus also for OTC products	Not applicable
LV	Price control; public procurement	Price control for reimbursable generics	Free pricing	Price control for reimbursable parallel-traded pharmaceuticals
MT	Price control; public procurement	Free pricing for generics in the private sector	Free pricing for OTC products in the private sector	Not applicable
NL	Price control; public procurement	(Informal) price control for reimbursable generics (covenant); at least 40% lower than price of original product	Free pricing for OTC products	No specific pricing policy; for parallel-imported generics the policy on generics applies
PL	Price control; public procurement	Price control for reimbursable generics; at least 25% lower than price of original product	Free pricing for non-reimbursable OTC products	No specific pricing policy

C.	Hospital-only ph.	Generics	OTC products	Parallel-traded ph.
PT	Direct negotiations (centralised or by hospitals) with manufacturers. Recently introduction of price and budget control for new pharmaceuticals	Price control for generics (maximum price); at least 35% lower than price of original product	Free pricing for OTC products	Maximum price at least 5% lower than the authorised pharmaceutical
SE	Price control; public procurement	Price control; however a price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation	Free pricing for non-reimbursable OTC products	Price control; however a price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation
SI	Price control; public procurement. High-level decision-making for newer biologic pharmaceuticals	Price control with external referencing, algorithm is sensitive to minimum and maximum, prices of generics in the reference countries	Free pricing for non-reimbursable OTC products	No specific pricing policy
SK	Price control	Price control for reimbursable generics; at least 20–80% lower than price of original product	Free pricing for non-reimbursable OTC products	No specific pricing policy
UK	Price control; public procurement	Price control for most reimbursable generics (so-called category M)	Free pricing for non-reimbursable OTC products	No specific pricing policy
NO	Price control; public procurement	Price control through the “step-price system”	Free pricing for OTC products	Price control through the “step-price system”
TR	Price control; public procurement	Price control for all generics; maximum 80% price of original product	Price control	Not applicable

C. = country, HSE = Health Service Executive (Irish NHS authority), ph. = pharmaceutical(s), POM = prescription-only medicines, OTC = Over-the-Counter

Note: The information “price control / free pricing” in this table refers to the “controlled price type”, i.e. the level at which the price is first set (usually ex-factory or pharmacy purchasing price).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

In countries where there is an important share of **parallel imports** special pricing and reimbursement procedures for such pharmaceuticals may apply. This is, for instance, the case in the Nordic countries. In Denmark, parallel-imported pharmaceuticals are included in the reference price system (cf. section 3.4.4), and they are treated as alternatives, like generics. In Sweden, which abolished the reference price system in 2002, substitutable pharmaceuticals (including generics and parallel imported pharmaceuticals) are grouped together within the system of mandatory generic substitution, and a price which is lower than or equal to the highest price within a group of substitutable pharmaceuticals is accepted without further

investigation. A similar mechanism is noticeable in Norway, which also has no reference price system, but the so-called step-price system for off-patent pharmaceuticals (see Box 7) which is a kind of a reference price system.

A specific type of pharmaceuticals concerns those for hospital use. Normally, different pricing policies and reimbursement frameworks apply for these pharmaceuticals. In general, they are purchased by the hospitals (or groups of hospitals and/or hospital purchase associations) either via public procurement and/or direct negotiations with the manufacturers. In most countries the actual prices which the single hospitals or hospital groups negotiate are not known; however, prices of **hospital pharmaceuticals** are estimated to be much lower than those in the outpatient sector because of large-scale discounts. In general, the hospital sector has been analysed less than the outpatient sector, which results in some information gaps concerning pharmaceuticals in the inpatient sector.

Box 7: Step-price system in Norway

The so-called step-price model ("Trinnprismodellen") came into effect in Norway in January 2005. It applies for generics, parallel traded pharmaceuticals and the original products.

Under this scheme, a maximum reimbursement price is set for selected pharmaceuticals. The maximum price level is automatically reduced in stages (steps) following patent expiry. The size of the cuts depends on annual sales prior to the establishment of generics competition and time since competition was established. Pharmaceuticals added have to be cheaper than the last generic or reference price.

Based upon an evaluation of the system, the step-price system was modified. In 2007 the following steps and rates were applied:

- Sales over NOK 100 million / € 12.5 million: the maximum reimbursement price is cut by 30% when generic competition is established and by 75% after one year.
- Sales below NOK 100 million / € 12.5 million: the percentage decreases are 30% and 55%.

3.3.3 Pricing procedures

The most common pricing procedures among PPRI countries are external price referencing, internal price referencing, and, to a less extent, cost-plus pricing, as displayed in Table 3.9.

External price referencing, i.e. international price comparisons with various country baskets, is used by 22 of the 27 PPRI countries (all but Sweden, UK and in the three free pricing countries Germany, Denmark, and Malta). In most of the countries, external price referencing is undertaken for reimbursable pharmaceuticals, since these prices are usually controlled.

The methodology applied for external price referencing differs between the countries. For example, in Luxembourg, according to statutory rules, the referencing is done only to the prices in the country of origin, whereas in Italy the prices of the pharmaceutical in other, not

specified countries form one of the evaluation criteria. Furthermore, in Slovakia external price referencing is only supportive to other pricing procedures, in particular to the mechanism of "agreed prices" (see Box 9), whereas in Portugal it is a major decisive factor (see Box 8).

Table 3.9: Comparative analysis – Common pricing procedures for pharmaceuticals in the outpatient sector in the PPRI countries, 2006/2007

C.	External price referencing		Internal price ref.	Cost-plus
	Scope	Reference countries	Scope	Scope
AT	Reimburs. ph.	All other EU MS	Reimbursable ph.	–
BE	All ph.	All other EU MS	Me-too ph., generics, copy products, parallel imported ph.	–
BG	POM	Romania, Russia, CZ, SK, HU, PL, PT, ES, AT	Reimburs. ph. (only in reimbursement)	–
CY	Imported ph. (private sector)	SE (alternative: DK and DE), AT and FR (alternative: IT and BE), EL (alternative: ES and PT)	–	Locally-produced ph. (private sector)
CZ	All ph.	Not defined	Reimburs. ph.	–
DE	–	–	– [1]	–
DK	–	–	– [1]	–
EE	Reimburs. ph.	LV, LT, HU + country of origin	Reimburs. ph.	–
EL	All ph. (incl. OTC) except generics	Two EU-15 MS plus Switzerland and one EU-10 MS	Reimburs. ph.	Locally-produced ph.
FI	Reimburs. ph.	AT, BE, DK, FR, DE, EL, Iceland, IE, IT, LU, NL, NO, PT, ES, SE, UK	Reimburs. ph.	–
FR	Innovative ph.	DE, IT, ES, UK	Reimburs. ph.	–
HU	Reimburs. ph.– innovative ph.	FR, IE, DE, ES, PT, IT, EL, PL, CZ, SI, SK, BE, AT,one additional country	Reimburs. ph.	–
IE	POM	BE, DK, FR, DE, NL, ES, UK, FI, AT	–	–
IT	Reimburs. ph.	Countries not specified	Reimburs. ph.	–
LT	Reimburs. ph.	LV, EE, PL, CZ, SK, HU	Reimburs. ph.	–
LU	All ph.	Country of origin	–	–
LV	Reimburs. ph.	EE, LT	Reimburs. ph.	–
MT	– [2]	– [2]	– [2]	– [2]
NL	POM	BE, DE, FR, UK	– [1]	
PL	Reimburs. ph.	BE,UK, IE, FR, DE, NL, SE, DK, ES, PT, IT, EL, CZ, HU, LU, LT, Switzerland	Reimburs. ph.	–
PT	POM	ES, FR, IT and – since April 2007 – also EL	Reimburs. ph. (incl. authorised generics)	–

C.	External price referencing		Internal price ref.	Cost-plus
	Scope	Reference countries	Scope	Scope
SE	–	–	– [3]	–
SI	Reimburs. ph.	DE, FR, AT	Reimburs. ph.	–
SK	Reimburs. ph.	Country of manufacture, CZ, FR, HU, AT, DE, ES, IT, PL	Reimburs. ph.	Locally-produced ph.
UK	–	–	Some reimburs. ph.	Exceptionally, a few ph.
NO	POM	SE, FI, DK, DE, UK, NL, AT, BE, IE	Reimburs. ph. (only in reimbursement)	–
TR	All ph.	FR, EL, IT, ES, PT	Reimburs. ph.	–

C. = country, EU = European Union, EU-15 = EU Member States before May 2004, EU-10 = EU Member States having acceded on 1 May 2004, MS = Member States, ph. = pharmaceutical(s), POM = prescription-only medicines, OTC = Over-the-Counter, ref. = referencing, ref. c. = reference country, reimburs. = reimbursable

Definitions: cf. PPRI Glossary, http://ppri.oebig.at → Glossary
External price referencing (or international price comparison): The practice of comparing pharmaceutical prices across countries.
Internal price referencing: A method to compare prices of pharmaceuticals in a country with the price of identical pharmaceuticals (ATC 5 level) or similar products (ATC 4 level) or even with therapeutical equivalent treatment (not necessarily a pharmaceutical) in a country.
Cost-plus pricing: Pricing procedure which takes besides the production cost of a pharmaceutical other cost like promotional expenses and especially a profit margin into account.

1. The Danish, Dutch and German reference price systems are not applied as a tool for price regulation, but rather as a method to set reimbursement limits
2. No price control at the ex-factory price level
3. 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.

Note: This table refers to the outpatient sector and, where applicable (Cyprus, Malta, cf. section 3.1.3.1), to private systems.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

The number of **reference countries** varies between the PPRI countries reflecting historical links as well as geopolitical and economic considerations. For instance, the Baltic states have included the other Baltic states in their country baskets, and Central and Eastern European countries refer to other CEE countries. Furthermore, the average price level for pharmaceuticals is a criterion for being chosen as a reference country. Lower income countries tend to refer to other low-price countries, while more wealthy countries might define high-price states as reference countries. Some countries have created baskets with a mix of low- and high-price countries. This is the case for the country basket applied in Cyprus, containing one country with high prices (Sweden), two countries with medium prices (Austria and France), and one low-price country (Greece). In addition, for each of these three kinds of countries two alternative countries had been defined (see Table 3.9).

The majority of the PPRI countries that apply external price referencing have a range of around five reference countries; larger baskets are not common. Only Austria and Belgium refer to all other EU Member States. Some countries define in detail methodological issues, such as the calculation of the price, procedures in case of non-availability of the reference

pharmaceutical on the market or future price changes in the reference countries (see also Box 8 on Portugal).

Box 8: External price referencing in Portugal

In Portugal, prices of prescription-only medicines (POM) are statutorily fixed by the Ministry of Economy. The chosen procedure to calculate the ex-factory price of new pharmaceuticals is external price referencing: According to the methodology which was in place in 2006, the ex-factory price in Portugal was based on the lowest ex-factory price of identical or similar pharmaceutical specialities containing the same active ingredient, found in the three reference countries: France, Italy and Spain.

In principal, the active substance and pharmaceutical form must be identical; concerning both, the dosage and the pack size, the closest and smallest one should be considered.

Special rules apply if identical or similar pharmaceuticals are not on the market in the reference countries:

- If identical or similar pharmaceutical specialities exist in only one of the three reference countries, the lowest ex-factory price in that country is applied in Portugal.
- If identical or similar pharmaceutical specialities exist in two or three reference countries, either the lowest ex-factory price in those countries is applied, or if the difference between the average and the lowest ex-factory price is more than 30%, the lowest ex-factory price plus one third of the average of the two lowest ex-factory prices is applied.
- If no identical or similar speciality exists in the reference countries, whereas one does exist on the Portuguese market, then the highest pharmacy retail price applied at the time for this similar pharmaceutical in Portugal is taken.
- If an identical or similar speciality only exists in the country of origin, then the ex-factory price at the time that it was launched in that country is applied, but the situation will be reassessed annually.
- If an identical or similar speciality is subsequently marketed in any of the three reference countries, the Portuguese launch price will be revised towards this price (upwards or downwards) in 10% steps each year.

In spring 2007, the system of external price referencing was modified: Greece was added as a fourth reference country, and the calculation is no longer based on the lowest price, but on the average of the prices in the four reference countries.

Taking a price average is the most common method in external price referencing (for example applied in Austria, Ireland and the Netherlands), according to which the calculated price may not exceed the average of the prices in the reference countries. Some countries apply procedures taking the average as the basis for further calculation. For instance, in Slovenia (2006) the pharmacy purchasing price could, in general, not exceed 85 percent (96% in case of generics) of the average price determined by the price comparison, with an extra of 0.5 percent added for imported pharmaceuticals, and in Norway and Slovakia the price is set at the average of the three lowest prices (plus a mark up in Slovakia). A few countries set the price at the lowest price in the comparison (e.g., Bulgaria and Greece).

Table 3.10: Comparative analysis – External price referencing in the PPRI countries, 2006/2007

PPRI countries	Size of basket	PPRI countries	Ref. countries
AT, BE	> 20 ref. countries	BG, EE, HU, LV, LT, PT, SK; TR	Mostly low price c.
FI, HU, PL	10–20 ref. countries	IE; NO	Mostly high price c.
BG, IE, LT, SK; NO, TR	5–10 ref. countries	AT, BE, CY, EL, FI, FR, NL, PL, SI	Mix of low/high price c.
CY, EE, EL, FR, LU, LV, NL, PT, SI	< 5 ref. countries	CZ, IT, LU	Not attributable

C. = countries, ref. = reference

Note: countries (incl. number of countries) not specified – CZ, IT; respective countries of origin – LU

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

A further common pricing procedure is **internal price referencing**, which comprises an analysis of the prices of identical or similar pharmaceuticals within a country. Internal price referencing is always applied if a reference price system is in place, and may also be used when this is not the case. Internal price referencing is not only applied as a pricing procedure, but also, even more often, for reimbursement purposes. As a consequence, internal price referencing targets mostly reimbursable pharmaceuticals, but may also include other products (in particular off-patent products and/or parallel imported pharmaceuticals, for further details see section 3.4.4).

Box 9: Price competition for the "agreed prices" in Slovakia

Slovakia applies for reimbursable pharmaceuticals in the outpatient sector a specific pricing procedure, the so-called system of "agreed prices". This is a competitive system which is similar to tendering for the best price.

Price proposals for reimbursable pharmaceuticals, which can be submitted continuously, are published monthly on the website of the Ministry of Health. Two weeks after publishing, the pharmaceutical companies submit another price proposal, which can be the same as the first one or can offer a lower price. In a strategic move (for example as a reaction to competitors' price proposals) pharmaceutical companies very often decide to submit a lower price in their second proposal. After the second round, no further adjustments are allowed, and the "agreed prices" are fixed. Based on the agreed prices, the Categorisation Committee of the Ministry of Health sets the maximum pharmacy retail prices which correspond to the reimbursement prices.

The **cost-plus pricing** procedure takes the production cost, R&D cost and other cost, such as promotional expenses, into account when setting the price of a pharmaceutical. Often, cost-plus pricing is based on a proof of certain cost plus a granted mark up. Currently, cost-plus is no longer very common. It is used for the price setting of locally-produced pharmaceuticals in Cyprus (in the private sector), in Greece and in Slovakia as well as for some exceptional cases in the UK. However, production and other cost are also taken into consideration in the setting of a price in other countries (e.g., Finland), especially if – as stated above – these countries apply several pricing criteria.

Furthermore, some countries have developed specific pricing systems, such as the Pharmaceutical Pricing Regulation Scheme (PPRS) in the UK (see Box 5*),* the step-price system in the Norway (see Box 7) and the system of so-called "agreed prices" in Slovakia, which makes use of competitive elements (see Box 9).

3.3.4 Margins and taxes

Besides the pricing policies at manufacturer level, the pricing policies at distribution level (wholesale and retail), i.e. wholesale and pharmacy mark ups, are also of relevance. In the majority of PPRI countries **wholesale mark ups** are regulated. Pharmacy remuneration is regulated, at least for a selected group of pharmaceuticals, in all PPRI countries.

In 2006, seven out of the 27 PPRI countries (Cyprus - for imported pharmaceuticals, Denmark, Finland, Netherlands, Norway, Slovenia, and Sweden) had no statutory mark ups at the wholesale level. Since in these seven countries, the price of a pharmaceutical is set at the wholesale level (2006), the wholesale margin and thus the ex-factory price is the outcome of negotiations between the manufacturer and the wholesaler. Since April 2007, this has no longer been the case in Slovenia, where prices are now determined at the manufacturer level, and a statutory wholesale mark up was introduced.

Pharmacy margins are regulated, though to a different extent, in all 27 PPRI countries.

In most PPRI countries, the statutory mark up schemes cover all pharmaceuticals, whereas in some countries the mark up scheme is applied to a selected group of pharmaceuticals (e.g., for prescription-only medicines in Bulgaria and Portugal or for reimbursable pharmaceuticals in Italy and Poland). Some PPRI countries have different mark up schemes for the different kinds of pharmaceuticals (e.g., Germany and Slovakia). In Ireland, there are mark ups and dispensing fees, however, not on a statutory level (see Box 3).

Table 3.11 provides an overview of the pricing policies at the wholesale and pharmacy (i.e. retail) level. Statutory margins may take the form of linear mark ups or of a regressive scheme. The latter of these two is more common, particularly at the pharmacy level. In addition, besides pharmacy mark ups there are different forms of pharmacy remuneration, such as a fixed fee (in the Netherlands, and – in combination with a linear margin – in Germany) and a fee-for-service remuneration in Slovenia (see Box 10) and the UK.

Table 3.11: Comparative analysis – Pricing policies at distribution level in the outpatient sector in the PPRI countries, 2006/2007

Country	Statutory wholesale mark up		Statutory pharmacy mark up	
	Scope	Type	Scope	Type
AT	All ph.	2 regressive mark up schemes (depending on the reimbursement category)	All ph.	2 regressive schemes: 1 for "privileged customers" (e.g., sickness funds) and 1 for private customers
BE	All ph.	Regressive mark up scheme	All ph.	Regressive mark up scheme
BG	POM	Regressive mark up scheme	POM	Regressive mark up scheme
CY	Imported ph.	No statutory mark up	All ph.	Linear mark up
	Locally-produced ph.	Linear mark up		
CZ	All ph.	Combined regressive mark up for wholesale & pharmacy	All ph.	Combined regressive mark up for wholesale & pharmacy
DE	POM	Regressive mark up scheme	POM	Fixed pharmacy fee and linear mark up
	Reimb. OTC products	Regressive mark up scheme	Reimb. OTC products	Regressive mark up scheme
DK	No statutory mark up		All ph. except some OTC products[1]	Regressive mark up scheme, since April 2007 a linear mark up with variable elements
EE	All ph.	Regressive mark up scheme	All ph.	Regressive mark up scheme
EL	All ph.	Linear mark up	All ph.	Linear mark up
FI	No statutory mark up		All ph. except NRT [1]	Regressive mark up scheme
FR	Reimb. ph.	Regressive mark up scheme	Reimb. ph.	Regressive mark up scheme
HU	All ph.	Regressive mark up scheme	All ph.	Regressive mark up scheme
IE	Reimb. ph. [2]	Different linear mark ups, depending on Community Drug Scheme	Reimb. ph. [2]	Different linear mark ups and dispensing fees, depending on Community Drug Scheme
IT	Reimb. ph.	Linear mark up	Reimb. ph.	Linear mark up with regressive elements due to statutory discounts
LT	Reimb. ph.	Regressive mark up scheme	Reimb. ph.	Regressive mark up scheme
LU	All ph.	Linear and regressive mark up scheme	All ph.	Linear and regressive mark up scheme
LV	All ph.	2 regressive mark up schemes (1 for reimb. ph. and 1 for non-reimb. ph.)	All ph.	2 regressive mark up schemes (1 for reimb. and 1 for non-reimb. ph.)
MT	All ph.	Linear mark up	All ph.	Linear mark up
NL	No statutory mark up		POM	Fixed pharmacy fee
PL	Reimb. ph.	Linear mark up	Reimb. ph.	Regressive mark up scheme
PT	POM	Linear mark up	POM	Linear mark up

Country	Statutory wholesale mark up		Statutory pharmacy mark up	
	Scope	Type	Scope	Type
SE	No statutory mark up		All ph.	2 regressive mark up schemes (1 for POM and 1 for OTC products)
SI	No statutory mark up in 2006 / beginning of 2007; fixation of a wholesale mark up valid from April 2007 on		All ph.	Fee-for-service remuneration for ph. & pharmacy services
SK	All ph.	Different linear mark ups for different kinds of ph. (expensive ph., vaccinations, non-reimb. ph.)	All ph.	Different linear mark ups for different kinds of ph. (expensive ph., vaccinations, non-reimb. ph.)
UK	Reimb. ph.	Linear mark up with clawback, indirectly regulated by PPRS	Reimb. ph.	Fee-for service remuneration depending on patient or region
NO	No statutory mark up		All ph.	Regressive mark up scheme[3]
TR	All ph.	Regressive mark up scheme	All ph.	Regressive mark up scheme

NRT = nicotine replacement therapy, ph. = pharmaceuticals, POM = prescription-only medicines, PPRS = Pharmaceutical Price Regulation Scheme, OTC = Over-the-Counter, reimb. = reimbursable

[1] If also available for sale in other dispensaries than pharmacies

[2] For pharmaceuticals under the Community Drug Schemes (cf. Box 13). Wholesale and pharmacy mark up schemes are not statutory.

[3] No regulation of pharmacy mark ups within the step-price system. Pharmacists have a financial incentive to carry out generic substitution and dispense the less expensive product.

Note: This table refers to the outpatient sector and, where applicable (Cyprus, Malta, cf. section 3.1.3.1), to private systems.

Sources: PPRI Pharma Profiles 2006/2007, ÖBIG 2007, additional information provided by PPRI participants

The statutory wholesale and pharmacy margin schemes are implemented in general in the form of maximum mark ups. In several countries, the actual mark ups for pharmaceuticals correspond to the maximum mark ups as defined in the law. However, in some PPRI countries, in particular in Central and Eastern Europe, the maximum mark ups are sometimes not fully utilised, which may result in different pharmacy retail prices – especially in the OTC segment – between pharmacies throughout the country.

Box 10: Fee-for-service remuneration for pharmacies in Slovenia

Pharmacies in Slovenia are remunerated by the social insurance on a fee-for-service basis. This is based on a service-fee agreement which is negotiated annually between the pharmacy association, the social insurance and the Ministry of Health.

The pharmacies are assigned for each prescription a specific number of points, which reflect a certain amount of money. The fee-for-service system also covers OTC products, as well as pharmaceutical services like counselling and officinal preparations.

Finally, another important element of the final pharmacy retail price, which is paid by the patient, are the taxes, in particular the **value-added tax** (VAT).

As displayed in Figure 3.12, in most PPRI countries the VAT rate for pharmaceuticals is lower than the standard VAT rate. Exceptions to this are Austria, Bulgaria, Denmark, Germany, Norway and – in the last years before January 2007 – Slovakia , where, as a consequence, the VAT on pharmaceuticals is higher than in the other PPRI countries (e.g., 25% in Denmark and Norway). A few countries have split differential VAT rates for pharmaceuticals: for a specific group of pharmaceuticals, the VAT rate is lower (France) or no VAT is charged at all (Ireland, Sweden, UK).

Figure 3.12 shows that in several countries, especially in the new Member States in Central and Eastern Europe, the VAT for pharmaceuticals is set at 5 percent. There is no VAT on pharmaceuticals in Cyprus (except for diagnostic agents) and in Malta. However, Malta plans to introduce a 5 percent VAT on pharmaceuticals by 2010.

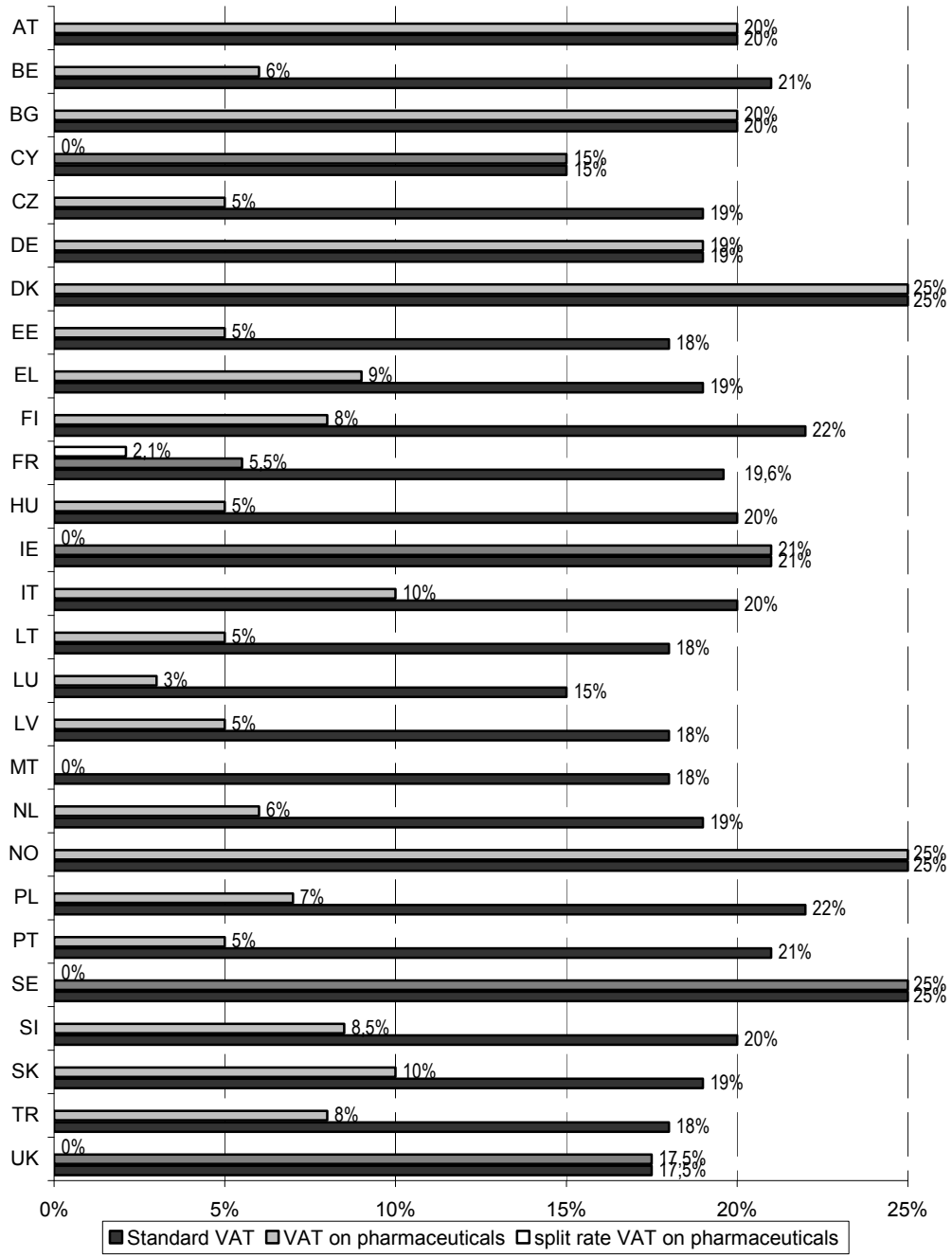
Additional taxes for pharmaceuticals are the INFARMED (Medicines Agency) tax of 0.4 percent of the net pharmacy retail price in Portugal and the pharmacy fees in Finland and in Norway (see Box 11 for details).

Box 11: Pharmacy taxes

In **Norway**, a pharmacy tax of 1.3% of the pharmacy purchasing price, corresponding to about 0.8% of the pharmacy retail price, is charged on all pharmaceuticals sold in pharmacies and other outlets allowed to sell OTC products. The fee is collected by the wholesalers, with a part of it being redistributed to the pharmacies as subsidies.

Finland also has introduced a pharmacy fee, which is a progressive, turnover-based, tax-like fee paid by the pharmacies to the state. In 2005, the pharmacy fee ranged from zero to € 1.18 million per pharmacy per year, amounting to an average pharmacy fee of 6.6 percent of the pharmacy's yearly turnover (the average in the course of time is about 7%). The rationale behind the pharmacy fee is to enable pharmacies of different sizes to sell pharmaceuticals at the same, medicine tariff based, prices, and to have smaller pharmacies getting to keep a greater share of the margin compared to the larger pharmacies. The pharmacy fee system ensures the operation of small pharmacies, as well as comprehensive pharmacy services in every part of the country.

Figure 3.12: Comparative analysis – VAT rates for pharmaceuticals in the PPRI countries compared to the standard VAT, 2007



VAT = value-added tax

CY: VAT of 15% for diagnostic agents; otherwise no VAT for pharmaceuticals

DE: from January 2007 on: standard VAT including VAT for pharmaceuticals has been increased to 19% (before 16%)

FR: split VAT rates on pharmaceuticals: 2.1% for reimbursable pharmaceuticals, 5.5% for non-reimbursable pharmaceuticals

IE: split VAT rates on pharmaceuticals: 0% for oral pharmaceuticals, 21% for others

SE: split VAT rates on pharmaceuticals: 0% for POM 25% for OTC products

SK: since January 2007 on: VAT on pharmaceuticals and medical devices has been reduced to 10% (before 19%)

UK: split VAT rates on pharmaceuticals: 0% for NHS pharmaceuticals, 17.5% for OTC products and hospital pharmaceuticals

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.3.5 Pricing related cost-containment measures

As shown in the PPRI Pharma Profiles and also confirmed by the EASP Report (EASP 2007), some pricing related cost-containment measures are quite common, whereas others are rather rarely implemented.

Price freezes have been documented in Denmark, Hungary, Ireland, the Netherlands and the UK as well as for non-reimbursable pharmaceuticals in Italy. In some of these countries price freezes have a long history. In the UK, a price freeze for generics has been in place since 1999, and in Hungary, a price stop was introduced in 2000, which was subsequently abolished and replaced by a limit for price increases up to the inflation rate. In Ireland, the current price freeze agreement started in September 2006, and the latest Danish price ceiling agreement commenced in January 2007.

More common cost-containment measures are **price and margin cuts**. Cuts of the pharmaceutical prices have been implemented in Cyprus, Finland, France, Italy, the Netherlands, Portugal, Slovakia, and the UK. Quite often, a price cut or a price freeze follows a price review. In fact, price reviews have been undertaken in Cyprus, Greece, France, Ireland, Italy, Norway, Sweden, Slovakia, and the UK in the past years.

The most common cost-containment measure with regard to pricing is the cutting of margins, which aims at limiting the profits of the distribution actors. In some countries, the reductions of allowed wholesale or pharmacy mark ups have not been so obvious, since the complete mark up schemes were changed. Margin cuts or changes of the distribution mark up schemes have been observed in Austria, Finland, France, Greece, Hungary, Lithuania, Norway, Poland, Sweden, Slovakia, and the UK. Additionally, Germany introduced statutory discounts to the social insurance for pharmaceutical actors (see Box 12), and Italy implemented statutory pharmacy discounts to be paid by the pharmacies to the national health service; both measures can be interpreted as sort of “hidden” margin cuts.

Cyprus is the only country which increased the distribution mark up; this measure was implemented in the course of the changing of the pricing system, which also included price cuts in order to keep the pharmacy retail prices stable.

Another cost-containment measure are the **statutory discounts**, which manufacturers or distribution actors have to grant to the third party payer. Statutory discounts have been implemented in Germany, France, Italy (however, implemented in the form of price cuts), the Netherlands and the UK. The latter two countries have implemented the statutory discounts in the form of a claw-back system (see section 3.4.7).

Box 12: Discounts in Germany

Discounts are frequently applied in Germany in order to contain pharmaceutical expenditure. Basically, there are two groups of statutory discounts.

The first group consists of so-called ”forced” or “collective” discounts, which are granted by pharmaceutical actors (manufacturers, wholesalers, pharmacies) to the sickness funds. They cover:

- the discount granted by manufacturers for pharmaceuticals which are not subject to the reference price system,
- the discount granted by pharmacies for prescription-only pharmaceuticals, which was € 2.00 per package until April 2007, then increased to € 2.30,
- the discount granted by pharmacies for OTC products, which is 5%, and
- the discount granted by manufacturers for generics, which is 10%.

While being obliged to grant discounts by law and being allowed to free pricing at the same time, manufacturers may avert the discounts by increasing the prices. Therefore, the discount policy targeting the manufacturers is strongly connected to price freezes. In 2005, discounts for the social insurance granted by manufacturers, wholesalers, and pharmacists amounted to € 1.7 billion or 6.2% of the pharmacy turnover.

The second group of law-based discounts includes those that are negotiated between individual sickness funds and a single or a group of pharmaceutical providers. Since 2004, sickness funds may negotiate various discount agreements with manufacturers, wholesalers, and pharmacies. Although these discounts have a legal basis, they are rather commercially negotiated discounts that may cover specific indications, individual pharmaceuticals, or all pharmaceuticals produced or supplied by a pharmaceutical provider.

In addition, there are commercial discounts negotiated between pharmaceutical providers and hospitals or between two pharmaceutical providers (e.g., discount granted by a wholesaler to a pharmacy or by a manufacturer to a pharmacy).

3.4 Reimbursement

3.4.1 Organisation

Reimbursement regulation is usually defined in Social or Health Insurance Law or Social Code with specific enactments and rules. As described in section 3.2.1, key **authorities** for reimbursement decisions are either social insurance institutions (e.g., Austria, Hungary, Slovenia) or Ministries of Health or Social Affairs (even in countries with a social insurance system, e.g., Czech Republic, the Netherlands, Poland). Some PPRI countries (Finland, Latvia and Sweden) have specific institutions which are in charge of pricing and reimbursement, whereas in other countries reimbursement decisions are taken by the Medicines Agency (e.g., Denmark, Portugal).

To understand how reimbursement functions in a country, it is important to assess if eligibility for reimbursement depends on the pharmaceutical product in question or on other criteria.

Therefore, the following section provides an overview on the different eligibility schemes in the PPRI countries. Key elements of pharmaceutical reimbursement, such as reimbursement criteria, positive lists, reimbursement rates and reference price systems, will be presented in sections 3.4.3 and 3.4.4. A special focus will be on the expenses by the patients, regarding their out-of pocket payments for pharmaceuticals (see section 3.4.5). The chapter on reimbursement concludes, following information on pharmaceuticals in hospitals, with a section on reimbursement-related cost-containment measures in the past years.

3.4.2 Reimbursement eligibility

In the PPRI countries, **four different reimbursement schemes** regarding the eligibility for reimbursement and the reimbursement rates can be identified. Please note that this information only refers to the outpatient sector.

3.4.2.1 Product-specific eligibility

Here eligibility for reimbursement and the reimbursement rates depend on the pharmaceutical in question: The product is considered either as reimbursable or as non-reimbursable. In case of product-specific eligibility, an evaluation of different aspects of the pharmaceutical (e.g., therapeutic benefit, comparison to alternative products, societal use, expected consumption, cost) plays an important role when the decision on the reimbursement status is taken (see also section 3.5.2).

This assessment, which generally involves experts, not only influences the decision on the inclusion of the pharmaceutical in the positive lists (cf. section 3.4.3), but also the reimbursement rates, which may vary according to the benefits proven in the pharmaceutical evaluation.

Product-specific eligibility is the **most common reimbursement scheme** in the European Union. It is the key criterion for eligibility of pharmaceuticals in 18 of the PPRI countries (e.g., Belgium, Czech Republic, Greece, Finland, Italy, the Netherlands, Poland, the UK).

Table 3.12: Comparative analysis – Eligibility for reimbursement in the PPRI countries, 2006/2007

Country	Key eligibility scheme	Further schemes
AT	Product-specific	Disease-specific
BE	Product-specific	Population-group-specific: higher reimbursement rate in a specific reimbursement category
BG	Product-specific	Disease-specific (12 diseases listed) Population-group-specific (veteran scheme)
CY	Population-group-specific	–
CZ	Product-specific	–

Country	Key eligibility scheme	Further schemes
DE	Product-specific	–
DK	Consumption-based and product-specific	Population-group-specific
EE	Disease-specific	Population-group-specific: higher reimbursement rate in a specific reimbursement category
EL	Product-specific	–
FI	Product-specific	Disease-specific (list of specified diseases): higher reimbursement rates
FR	Product-specific	Disease-specific (list with selected diseases)
HU	Product-specific	Disease-specific
IE	Population-group-specific	Product-specific (list of "high-cost" pharmaceuticals) Disease-specific (list of 15 specified diseases)
IT	Product-specific	–
LT	Disease-specific	Population-group-specific: Eligibility to one of the two positive lists due to social status
LU	Product-specific	–
LV	Disease-specific	–
MT	Population-group-specific	–
NL	Product-specific	In some cases disease-specific and/or population-group-specific criteria apply
PL	Product-specific	Population-group-specific: Higher reimbursement rates for war veterans and patients with severe diseases
PT	Product-specific	Population-group-specific: Higher reimbursement rates for pensioners with low income; for selected diseases 100% reimbursement
SE	Consumption-based	–
SI	Product-specific	–
SK	Product-specific	–
UK	Product-specific	–
NO	Product-specific	Consumption-based and population-group-specific: Higher reimbursement rates for children for low income pensioners and for patients having reached the co-payment ceiling; disease-specific criteria may also be applied
TR	Population-group-specific	–

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

Product-specific: Eligibility for reimbursement depends on the pharmaceutical in question (either a pharmaceutical is considered as reimbursable or as non-reimbursable).
Disease-specific: Eligibility for reimbursement is linked to the underlying disease which shall be treated.
Population-group-specific: Specific population groups are eligible for pharmaceuticals, while others are not.
Consumption-based: The level of reimbursement depends on the expenses for pharmaceuticals of a patient within a certain period of time (increasing reimbursement with rising consumption).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.4.2.2 Disease-specific eligibility

Under this scheme, eligibility for reimbursement and the reimbursement rates are linked to the underlying disease to be treated. The disease-specific reimbursement targets the reimbursement status and the reimbursement rate. One pharmaceutical may be reimbursed at different reimbursement rates for the treatment of different diseases.

The disease-specific reimbursement scheme is the key scheme in the three **Baltic states**, Estonia, Latvia, and Lithuania. In fact, the positive lists of these countries are actually "lists of reimbursable diseases". In Norway, the positive list regarding pharmaceuticals is based on a list of diseases or conditions for which pharmaceutical treatment can be reimbursed.

Elements of disease-specific reimbursement eligibility may also be found in other countries where there are lists of a limited number of diseases whose treatment is – in general 100 percent – reimbursed (e.g., France, Portugal). Important disease-specific sub-schemes can be found in Bulgaria, Hungary and Ireland (see also Box 13).

Box 13: Ireland – A mix of different reimbursement schemes

In Ireland, different reimbursement schemes, so-called Community Drug schemes, co-exist. The most important ones are the GMS and the DP scheme, under which specific population groups are eligible for reimbursement:

- The General Medical Services (GMS) scheme covers all residents over the age of 70 years as well as people below a certain income threshold.
- The Drug Payment (DP) scheme is applied for all Irish residents not covered by the GMS scheme.

In addition, there is in place a disease-specific reimbursement scheme, the Long Term Illness (LTI) scheme, covering 15 diseases or disabilities of a permanent or long term nature (e.g., epilepsy, diabetes mellitus, multiple sclerosis).

Another scheme is the High Tech Medicinal Products (HTMP) scheme, which lists a limited number of high tech (and usually expensive) pharmaceuticals supplied by community pharmacies, and is thus a product-specific reimbursement scheme.

The rules regarding reimbursement and co-payment rates are different in the various Community Drug schemes. Only people eligible under the GMS and the LTI scheme have full reimbursement of pharmaceuticals; patients eligible under the DP scheme have to pay a deductible of € 85.- per month (see section 3.4.5).

3.4.2.3 Population-group-specific eligibility

Under this eligibility scheme, specific population groups are eligible for reimbursement, while others are not. These may be for instance children, elderly persons, handicapped persons or people with low income. There might be an overlap between the disease-specific and population-group-specific eligibility, for example in case of elderly patients with specific long term diseases.

Population-group-specific reimbursement can be found in **Cyprus and Malta**, with a distinction between a public and a private health care sector (see also Box 1): While non-eligible persons have to buy health services and pharmaceuticals out-of pocket (private sector), eligible persons have access to publicly provided health care, including pharmaceuticals, purchased by the health authorities and dispensed in public health care facilities (public sector). In Malta all eligible persons have full access to health care and pharmaceuticals, whereas some of the Cypriot eligible patients are subject to co-payments (see section 3.4.5). Eligible are people with low income, patients with specific diseases, and people with specific professions (e.g., members of the police and army, civil servants).

In addition, the key eligibility schemes in **Ireland** are also population-group-specific (the GMS and DP scheme, see Box 13 for further information).

The Turkish system may also be classified as a population-group-specific reimbursement scheme. Though all people are granted access to reimbursable pharmaceuticals, there are different reimbursement rates for different groups in **Turkey**: Active workers and their dependants get pharmaceuticals 80 percent reimbursed, while retired persons and their dependants have their pharmaceuticals 90 percent and chronically ill 100 percent reimbursed.

In PPRI countries with product-, disease- or consumption-based reimbursement as the dominant scheme, population-group-specific eligibility elements may be quite common. For instance, higher reimbursement rates for specific population groups like poor and/or chronically ill persons can be applied (e.g. in Belgium, Estonia, cf. Table 3.15).

In Lithuania (see Box 15), one positive list covers pharmaceuticals which are reimbursed with regard to diseases, while a second positive list covers pharmaceuticals reimbursed for social reasons (e.g. retired persons).

3.4.2.4 Consumption-based eligibility

Under this eligibility scheme the level of reimbursement depends on the expenses for pharmaceuticals of a patient within a certain period of time (e.g. a year). As reimbursement coverage increases with the rising pharmaceutical consumption, this scheme favours patients in need for more pharmaceutical care (e.g. elderly people). The decision of the authorities / third party payers to grant reimbursement for a pharmaceutical is taken on a product level.

Consumption-based reimbursement is found in **Denmark and Sweden** (cf. Box 14).

Box 14: Consumption-based reimbursement in Denmark and Sweden

Before the patient is eligible for reimbursement she/he has to pay the full cost of her/his reimbursable medication up to a threshold of about € 64.- (Denmark) or € 97.- (Sweden) in a 12-month period. After passing this threshold, the reimbursement rate rises gradually.

- Denmark (adults):

Annual expenses below € 64.-	0% reimbursement,
between € 64.- and € 156.-	50% reimbursement
between € 156.- and € 366.-	75% reimbursement
over € 366.-	85% reimbursement

- Sweden:

Annual expenses below € 97.-	0% reimbursement,
between € 97.- and € 183.-	50% reimbursement
between € 183.- and € 356.-	75% reimbursement
between € 356.- and € 463.-	90% reimbursement, and
over € 463.-	100%

After passing a ceiling of € 463.- in Sweden all expenses for pharmaceuticals are 100% reimbursed in this period, the maximum co-payment within 12 months being € 194.-

In Denmark, there is 100% reimbursement only for chronically ill (passing a total consumption threshold of € 2,625.-, i.e. a maximum co-payment of € 472.-) and for terminally ill in any case, irrespective of their pharmaceutical consumption. Thus, the Danish system, which also provides different thresholds for children, has also included population-group specific elements.

3.4.3 Reimbursement lists and rates

All 27 PPRI countries have reimbursement lists defining which pharmaceuticals are included into reimbursement (positive lists) or which are excluded (negative lists).

Positive lists exist in 24 of the 27 PPRI countries. In general, **positive lists** contain those pharmaceuticals which are considered as reimbursable. Under disease-specific reimbursement schemes, there is usually a list of “reimbursable diseases”, based on which the pharmaceuticals are reimbursed or not (cf. section 3.4.2.2). Some countries have more than one positive list, due to different eligibility criteria and/or reimbursement rates (see Table 3.13 and, as an example, Box 15).

The criteria for a pharmaceutical being included in a positive list are usually medical-pharmacological, such as for example the therapeutic benefit, which is often analysed in terms of improvement compared to an alternative product.

Box 15: Positive lists in Lithuania

In the outpatient sector in Lithuania, pharmaceuticals are reimbursed according to a list of defined diseases (disease-specific eligibility, like in the other Baltic states), with the reimbursement rates linked to the severity of the disease. Besides this connection to the diseases, pharmaceuticals may be reimbursed for social reasons. This is reflected in the two parts (List A and List B) of the Lithuanian positive list:

List A covers pharmaceuticals, which are reimbursed with regard to the severity of the disease at:

- 100% (e.g., cancer, asthma, schizophrenia),
- 90% (a category introduced in 2002 after revision of the criteria for inclusion into the 100% reimbursement category),
- 80% (e.g., hepatitis B and C),
- 50% (e.g., osteoporosis).

Reimbursement under list A, which includes approximately 250 INN (International Non-Proprietary Names) accounts for approximately 85% of the total pharmaceutical reimbursement.

List B covers all pharmaceuticals, which are reimbursed because of social reasons at:

- 100% (treatment of children under the age of 18 and disabled people) or
- 50% (retired people and other social groups).

There is a tendency to include pharmaceuticals reimbursed for social reasons in List A as well; therefore the list B is progressively being reduced. List B covers approximately 80 INN.

In some PPRI countries, the positive list is updated in short intervals, for example on a monthly basis in Belgium, Finland and Ireland (for the GMS scheme), or every two weeks in Denmark.

The use of positive lists is more common than that of **negative lists**. Negative lists are found in a few PPRI countries (Germany, Hungary and the UK). In addition, Greece abolished its positive list at the end of 2005 and introduced a negative list for OTC products and life-style pharmaceuticals, which still has to be implemented. Also, in 2006 the Finnish Pharmaceuticals Pricing Board, which is the relevant pricing and reimbursement authority, was given the power to introduce a negative list, which, however, has not yet occurred.

Some countries, in general those with a smaller market, have also introduced the possibility of **individual reimbursement**. Thus, pharmaceuticals, which are not on the positive list, may be reimbursed after individual application (in general by a doctor) for a specific patient. Individual reimbursement is, for instance, possible in Austria, Denmark, Hungary and Lithuania.

With regard to access to and affordability of pharmaceuticals, the following two aspects are important:

- The number of reimbursable pharmaceuticals: From a patient's perspective, it is relevant how many pharmaceuticals (as percentage of the pharmaceuticals on the market, but also in absolute figures) are reimbursable, i.e. listed on a positive list and/or covered under another reimbursement instrument like a reference price system. Generally speaking, the number of reimbursable pharmaceuticals ranges from nearly 10,000 (France) to less than 1,000 (Bulgaria), cf. Table 3.5. However, the quality of the data available on this issue is insufficient for a thorough analysis, though most PPRI countries have advanced national pharmaceutical statistic systems. As explained in section 3.2.2, this is due to the method of counting of pharmaceuticals which differs between the PPRI countries.

- The reimbursement price: This price is the basis for the reimbursement of pharmaceuticals in a health care system, it is the maximum amount paid for by a third party payer. The reimbursed amount can either be the full reimbursement price or a percentage share of the reimbursement price. In a reference price system (see section 3.4.4) the reimbursement price can be lower than the pharmacy retail price of a pharmaceutical, in which case the patient has to pay the difference privately (or through complementary voluntary health insurance).

As shown in Table 3.13, most PPRI countries apply different **reimbursement rates**. Only in Austria, Germany, Italy, the Netherlands and the UK all pharmaceuticals considered as reimbursable are 100 percent reimbursed (further co-payments like prescription fees and/or due to a reference price system are possible, see section 3.4.5). In the rest of the PPRI countries, lower reimbursement rates exist for pharmaceuticals or for diseases which are considered as less relevant and/or comparatively too expensive given the therapeutic benefit. In addition, Ireland and Malta – countries with population-group-specific reimbursement as the dominant scheme – have 100 percent reimbursement for all people eligible for such reimbursement; however, in Ireland, other co-payments including a deductible in the Drugs Payment scheme exist (see Box 13). In Denmark and Sweden, the reimbursement rates are related to the consumption of pharmaceuticals (expressed in expenses by the patients) within a defined period (consumption-based reimbursement, see Box 14).

Usually, there are defined percentage rates (e.g., 100% for pharmaceuticals considered essential, 80% for pharmaceuticals for treatment of chronic diseases, and 60% for pharmaceuticals considered as having moderately improved therapeutic effect). In Bulgaria, in the Czech Republic and in Slovakia there are no such fixed percentage rates; here the reimbursement rates are individually defined per pharmaceutical in the course of the reimbursement decision process. In France, the standard reimbursement rates of 65 percent and 35 percent which are fixed by the Minister of Health may, at a single product level, be modified by the social insurance through adding or subtracting up to five percentage points.

Additionally, a higher reimbursement rate is applied for specific population groups (in general, vulnerable groups) in a few countries. This is, for instance, the case in Belgium (preferential reimbursement rate of 85% instead of 75%, for widows, orphans, retired, disabled

and low income persons, etc.) and Estonia (90% instead of 75% for children, disabled and retired people).

For some years Portugal had a 10 percent higher reimbursement rate for generics (compared to original products) in all reimbursement categories in order to promote generics; this measure was abolished in 2005.

Table 3.13 provides an overview of the reimbursement rates applied in the PPRI countries.

Table 3.13: Comparative analysis – Reimbursement lists and reimbursement rates in the outpatient sector in the PPRI countries, 2006/2007

Country	Reimbursement lists	Reimbursement rates
AT	Positive list	100%
BE	Positive list	100%, 75% (or 85% for vulnerable groups), 50%, 40%, 20%
BG	Two positive lists (one called positive list and one called reimbursement list)	No fixed reimbursement rates defined
CY	Positive list	100%, 50%[1]
CZ	Positive list	No fixed reimbursement rates defined
DE	No positive list Two negative lists	100%
DK	Positive list	100%, 85%, 75%, 50%, 0%[2]
EE	Positive list	100%, 75% (or 90% for vulnerable groups), 50%
EL	Negative list – not yet implemented	100%, 90%, 75%
FI	Positive list A negative list may be introduced – not yet implemented	100%, 72%, 42%
FR	Positive lists	100%, 65, 35%, 15%
HU	Positive list; Negative list	100%, 90%, 70%, 50%
IE	Positive lists	100%
IT	Positive list	100%
LT	Two positive lists	List A: 100%, 90%, 80%, 50% (disease-specific) List B: 100%, 50% (for social reasons)
LU	Positive list	100%, 80%, 40%
LV	Positive list	100%, 90%, 75%, 50%
MT	Positive list	100%
NL	Positive list	100%
PL	Positive lists	100%, 70%, 50%
PT	Positive list	100%, 95%, 70%, 40%, 20%[3]
SE	Positive list	100%, 90%, 75%, 50%, 0%[2]
SI	Two positive lists (one called positive list and another one is called intermediate list)	100% (limited to certain patient groups), 75% (positive list), 25% (intermediate list)

Country	Reimbursement lists	Reimbursement rates
SK	Positive list	100% and partial reimbursement, reimbursement rates depending on reference price system
UK	Two negative lists	100%
NO	Positive list	100%, 64%
TR	Positive list	100%, 90%, 80%[1]

[1] Patient-group-specific reimbursement: some patients have 100% reimbursement, other partial reimbursement

[2] Consumption-based reimbursement: reimbursement rate depending on the patient's pharmaceutical expenditure for reimbursable pharmaceuticals within a year

[3] Since 2007 reimbursement rates of 100%, 95%, 69%, 37% and 15% respectively

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.4.4 Reference price systems

In a reference price system (RPS), interchangeable pharmaceuticals are grouped (reference groups), usually at the ATC 5 or ATC 4 level. For these groups of pharmaceuticals, the social health insurance / national health service determines a maximum amount (= the so-called reference price) which is the basis for reimbursement. On buying a pharmaceutical under the reference price system, an insured patient must pay the difference between the reference price and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payments or percentage co-payment rates.

Currently, 18 of the 27 PPRI countries have implemented a reference price system (cf. Table 3.14). In 1989, Germany was the first to introduce a reference price system, the so-called "Festbetragssystem", which has meanwhile undergone several reforms (for the current organisation of the German reference price system see Box 16). The Netherlands, Denmark and Sweden also implemented a reference price system in the early 1990s. The Central and Eastern European countries introduced reference price systems during the reforms of their pharmaceutical systems in the course of the 1990s, the first country being Hungary, which had already prepared a legal basis for a reference price system in 1991. Some countries in Western and Southern Europe (Belgium, France, Italy, Portugal) launched reference price systems in the new millennium, after years of preparation. A challenge for these countries was to have enough similar products on the market (in general, generics) to build clusters (reference groups). In May 2006, Greece introduced a reference price system; by end 2007, its methodology still had to be fine-tuned.

Sweden is the only PPRI country which abolished its reference price system, after nearly a decade of existence. However, Sweden has established a system of obligatory generic substitution (see section 3.5.4), in which substitutable pharmaceuticals are clustered, and where prices not exceeding the highest price within such a group are de facto automatically accepted for reimbursement. Norway applies the so-called step-price system (see Box 7) which functions similar to a reference price system.

The authorities in charge of implementing the reference price system are usually the same ones as those responsible for reimbursement. As a consequence, in some countries the

social health insurance administers the reference price system (e.g., in Belgium, Hungary), while in other countries this is the task of the Medicines Agency (e.g., Denmark, Portugal). In a few PPRI countries, the responsibilities regarding the establishment of the reference groups and the determination of the reference prices are divided between two institutions (e.g. between the Medicines Agency and the social insurance in Slovenia; for Germany see Box 16).

The way how reference price systems are organised differs between countries. This is reflected in the composition of the clusters (reference groups), the kind of pharmaceuticals included in the reference price system and the methodology applied for determining the reference price.

Ten of the 18 RPS countries form the **reference groups** based on the substance (ATC 5) level. Four countries (Czech Republic, Germany, Hungary, and Slovakia) consider therapeutically similar pharmaceuticals as substitutable (ATC 4 level on therapeutic groups). For example, the Czech Republic defines that "reference groups are groups of medicinal products essentially therapeutically interchangeable with a similar efficacy and safety and with a similar clinical use" (Czech Public Health Insurance Act 2007 Art. 39c). In Latvia, the Netherlands and Poland the reference groups are determined on an even broader level, based on a mix of ATC 3, 4 and 5. For instance, the current definition of the reference groups in the Netherlands refers to the criterion of "mutual replaceability" (i.e. considering pharmaceuticals as mutually replaceable if they can be used for a similar field of application, are administered via a similar form of administration, and are generally intended for the same age category).

Products in a reference price system are, as stated above, pharmaceuticals regarded as interchangeable. Typically, off-patent alternatives are considered for being included in a reference price system; these are usually generics, but may also be copy products or me-too products. Some countries (e.g. Portugal) do not include copy products in the reference price system due to lacking bio-equivalency. In PPRI countries where parallel imported pharmaceuticals play an important role and have a considerable market share (e.g. in Denmark, Germany, the Netherlands), these pharmaceuticals are included in the reference price system. Additionally, Germany forms reference groups including on-patent brands, cf. Box 16.

Table 3.14: Comparative analysis – Reference price systems in the PPRI countries, 2006/2007

Country	RPS in place	Year of introduction	Clustering of reference groups
AT	No	N.appl.	N.appl.
BE	Yes	2001	ATC 5
BG	Yes	N.a.	ATC 5
CY	No	N.appl.	N.appl.
CZ	Yes	1995	Mix of ATC 4 and 5
DE	Yes	1989	Mix of ATC 4 and 5
DK	Yes	1993	ATC 5

Country	RPS in place	Year of introduction	Clustering of reference groups
EE	Yes	2003	ATC 5
EL	Yes	2006	*Methodology to be defined*
FI	No	N.appl.	N.appl.
FR	Yes [1]	2003	ATC 5
HU	Yes	1991 [2]	ATC 5 and from 2000 on also ATC 4
IE	No	N.appl.	N.appl.
IT	Yes	Since 2001	ATC 5
LT	Yes	Since 2003	ATC 5
LU	No	N.appl.	N.appl.
LV	Yes	2005	Mix of ATC 3, 4 and 5
MT	No	N.appl.	N.appl.
NL	Yes	1991	Mix of ATC 3, 4 and 5
PL	Yes	1998	Mix of ATC 3, 4 and 5
PT	Yes	2003	ATC 5
SE	No [3]	From 1993 to 2002	N.appl.
SI	Yes	2003	ATC 5
SK	Yes	1995	Mix of ATC 4 and 5 level
UK	No	N.appl.	N.appl.
NO	No [4]	2003 [4]	(ATC 5) [4]
TR	Yes	2004	ATC 5

ATC = Anatomic Therapeutic Chemical Code, N.a. = not available, N.appl. = not applicable, RPS = reference price system

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

ATC 3: Defines pharmaceuticals in the same pharmacological subgroup

ATC 4: Defines a therapeutic group within the anatomic therapeutic chemical classification system

ATC 5: Defines a single active ingredient or a fixed combination of active ingredients within the anatomic therapeutic chemical classification system

[1] For very few products (3.5% of the value of reimbursable pharmaceuticals)

[2] The legal basis was drafted in 1991 and specified in 1992 and 1995 respectively. The current reference price system started in 1997.

[3] However, 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 group of substitutable pharmaceuticals is accepted without further investigation.

[4] But there is a step-price system for off-patent pharmaceuticals and first-choice system for certain substances. The step-price system, introduced in 2003, has elements of a reference price system.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

The reference price systems are regularly **up-dated**, with regard to new generic alternatives on the market due to patent expiry. Some countries renew on a six-month basis (e.g., Belgium, Czech Republic), others quarterly (e.g., Estonia, Slovakia, Portugal). Italy updates monthly and Denmark every two weeks. Usually, these changes concern both the reference groups and the reference prices (except for the Netherlands: possibility for monthly modifications of the clusters, but no recalculation of the reimbursement limits).

Box 16: The "Festbetragssystem" / reference price system in Germany

The German reference price system, which is called "Festbetragssystem", was introduced in 1989 and has been subject to several changes in the course of the years. The current system is organised as follows:

In a first step, the Federal Joint Committee, in which the sickness funds and physicians are represented, undertakes the clustering of the pharmaceuticals. Prerequisite for the creation of a cluster is that the potential reference group will contain at least three different pharmaceuticals. Pharmaceuticals are classified into three levels (types) of groups:

- Type 1: Pharmaceuticals with the same active ingredient (e.g., an original product and its generic)
- Type 2: Pharmaceuticals with therapeutically and pharmacologically comparable active ingredients (e.g., a group consisting of the original product, its generics and related me-too pharmaceuticals and – if available – their generics)
- Type 3: Therapeutically and pharmacologically comparable pharmaceuticals with different active ingredients (a group may include on-patent pharmaceuticals if they are no novelties – meaning that the first active ingredient of the potential group is still on-patent – and if they provide no therapeutic improvement)

In a second step, the Federal Association of Sickness Funds determines the reference price for all package sizes and strengths. The reference price is strictly calculated through a mathematical formula and is not manually adjusted. Generally speaking, reference prices are set in a way that about one third of the pharmaceuticals in a given reference group are available at or below the reference price.

Reference price systems are not just reimbursement tools, but also instruments for a more rational use of pharmaceuticals (see section 3.5). Reference price systems have shown to limit the use of expensive pharmaceuticals (Aaserud M. et al. 2006) but have to be managed with caution as lower priced products tend to adjust their price towards to the reference price. In order to guarantee the effectiveness of a reference price system, it is advisable to combine it with other measures, in particular with obligatory generic substitution (cf. section 3.5.4).

3.4.5 Private pharmaceutical expenses

This section regards the share of pharmaceutical expenditure which is borne by the patients and/or consumers. Private pharmaceutical expenses is defined as direct payments including self-medication and out-of pocket payments, such as percentage co-payments, fixed co-payments and deductibles (cf. PPRI Glossary).

As displayed in Figure 3.10, the share of public and **private funding of pharmaceutical expenditure** varies considerably between the PPRI countries. While in EU-25 an average of 36 percent of pharmaceutical expenditure is financed by the private households, the share of private pharmaceutical expenditure is on average around 50 percent in the EU-10 countries and 28 percent in the EU-15 zone.

Direct payments refer to purchases of pharmaceuticals which are not reimbursed at all. Table 3.5 provides information on the number of the pharmaceuticals which are considered eligible for reimbursement (reimbursable pharmaceuticals), compared to the authorised pharmaceuticals as well as to pharmaceuticals on the market. Since there are differences in counting (even within a country), comparable figures on the share of non-reimbursable pharmaceuticals cannot be provided for the group of PPRI countries.

Besides direct payments patients may be required to **co-pay** for reimbursable pharmaceuticals:

- Fixed co-payments / prescription fees: This form of out-of pocket payments for pharmaceuticals is rather seldom. In seven countries (Austria, Estonia, Finland, Italy – in some regions, Poland, Slovakia, the UK) patients are charged a fixed fee for prescribed pharmaceuticals. Some countries (e.g., Finland, Poland) have a prescription fee for specific reimbursement categories, whereas in Estonia different prescription fees are applied in the different reimbursement categories (see Box 17).
- Percentage co-payments: The most common out-of pocket payment for pharmaceuticals is the percentage co-payment which results from different reimbursement rates on pharmaceuticals (see reimbursement rates in Table 3.13). One exemption is the percentage co-payment in Germany, amounting to 10 percent of the price of the pharmaceuticals, however within a range of fixed minimum and a fixed maximum. It is the follow-up of the fixed prescription fee which had been in place, in several variations, from 1977 to 2003.

  Percentage co-payments are applied in 21 of the 27 PPRI countries.
- Deductibles: This type of out-of pocket payment, consisting of a fixed amount which the patient has to pay for a defined period before the cost is fully or partially reimbursed, is found in the consumption-based reimbursement schemes in Denmark, Sweden, and in the Drug Payment Scheme in Ireland.
- Reference price systems: Patients have to co-pay the difference between the reimbursed amount (reference price) and the actual pharmacy retail price in a reference price system, which is in place in 18 PPRI countries (see section 3.4.4).

Table 3.15 offers an overview of out-of pocket payments for pharmaceuticals in the PPRI countries. It shows that in several countries different types of out-of pocket payments co-exist (see also Box 17 on Estonia).

Box 17: Out-of pocket payment model in Estonia

In Estonia, all pharmaceuticals on the positive list are, based on the underlying diseases, reimbursed at a rate of 100%, 75% (or 90% for vulnerable groups) and 50%. In the 75%/90% reimbursement category, the patient has to pay 25%/10% of the price of the pharmaceutical.

In the 50% category, if the price of a pharmaceutical exceeds € 3.20, 50% is covered by the Estonian Health Insurance Fund (EHIF) to an upper limit of € 12.80. The remaining part of the product's price has to be paid by the patient.

In addition to these percentage co-payments and to the co-payments resulting from the reference price system, patients have to pay a fixed co-payment (prescription fee) of € 1.28 in the 100% and 75%/90% reimbursement categories and of € 3.20 in the 50% reimbursement category.

Patients with private expenses for reimbursable pharmaceuticals between € 384.- and € 1,278.- per year qualify for supplementary benefits from the EHIF:

- If the overall sum of private pharmaceutical expenditure lies between € 384.- and € 639.- per year, the EHIF reimburses 50% of the sum above € 384.-.
- If the private pharmaceutical expenditure lies between € 639.- and € 1,278.- per year, the EHIF reimburses 75% of the sum above € 639.-. If pharmaceutical expenditure is above € 1,278.-, the additional benefit is limited to € 607.- per year.

Patients have to apply for this benefit only once in their lifetime and from then on the EHIF calculates and pays the benefits automatically on a quarterly basis. However, private expenses considered neither include the prescription fees and the sums paid above the reference price of the pharmaceuticals nor any self-medication.

From a public health perspective, the affordability of pharmaceuticals for the whole population is of great relevance. De facto all countries have introduced **mechanisms for vulnerable groups** who are, among others, ill (terminally ill, chronically ill) or handicapped persons, people of specific age groups (e.g. children, elderly people), and people with low income.

Typical examples of such mechanisms are a 100 percent reimbursement (e.g., Hungary, Portugal) or a higher reimbursement rate than the standard rate (e.g., Belgium, Estonia) as well as exemptions from prescription fees (e.g. Austria) for poor and/or chronically ill persons. Some countries have specific schemes for defined vulnerable groups (e.g., Denmark for terminally ill, Ireland for persons suffering from one of 15 defined diseases).

Another mechanism to guarantee the affordability of pharmaceuticals is to limit the co-payment, i.e. to introduce a maximum out-of pocket limit. This can be done

- by determining a maximum co-payment per prescription, like in Belgium and Germany,
- via annual limits for private expenses on pharmaceuticals and/or on health care respectively (i.e. co-payments are limited at a certain percentage of the income, e.g., in Germany and in Luxembourg) or
- by defining a maximum payable out-of pocket amount, i.e. a ceiling for a given time period, which is especially the case in systems with consumption-based reimbursement elements like in Sweden (cf. Table 3.12).

Table 3.15 shows the different arrangements to protect vulnerable groups from too high expenses.

Table 3.15: Comparative analysis – Out-of pocket payments for pharmaceuticals and mechanisms for vulnerable groups in the outpatient sector in the PPRI countries, 2006/2007

C.	Out-of pocket payments	Mechanisms for vulnerable groups
AT	Prescription fee of € 4.60 (2006) / € 4.70 (2007) for POM	Exemption from prescription fee for socially disadvantaged groups
BE	Percentage co-payment of 25%, 50%, 60% or 80% for specific pharmaceuticals Co-payment due to RPS	Reduced co-payment rates of 15% instead of 25% for patients with so-called preferential reimbursement status (widows, orphans, retired persons, disabled people, low income, etc.) Annual threshold for vulnerable groups (criteria: income, age, social status) and maximum co-payment per prescription of € 6.70 to € 26.10 in certain reimbursement categories
BG	Percentage co-payment of up to 90% for specific pharmaceuticals Co-payment due to RPS	Some exemptions for vulnerable groups
CY	Percentage co-payment of 50% for specific population groups granted reimbursement eligibility	Access to public health care (free pharmaceuticals or at reduced rate) for specific groups (criteria are profession, income, disease, medical conditions)
CZ	Different percentage co-payment rates due to RPS	No exemptions for vulnerable groups
DE	Percentage co-payment of 10% with a minimum of € 5.- and a maximum of € 10.- (however, pharmaceuticals priced 30% below their reference price are exempt from co-payments) Co-payment due to RPS	Children below age of 18 are excluded from co-payment Annual co-payment ceiling fixed at 2% of income or 1% of income (chronic conditions)
DK	Prescription fee of € 1.24 (reimbursable, already included in pharmacy retail price) Deductible of € 64.40 per 12 months. Percentage co-payment of 100%, 50%, 25%, 15% (decreasing with rising pharmaceutical expenditure). Co-payment due to RPS	Maximum limit of € 472.37 per 12 months for patients with a large consumption. Supplementary reimbursement schemes for disabled people and low income people and less co-payment for pensioners. Exemption from co-payment for terminally ill patients

C.	Out-of pocket payments	Mechanisms for vulnerable groups
EE	Prescription fee of € 1.28 (in reimbursement category of 100% and 75%/90%) and € 3.20 (in 50% reimbursement category). Percentage co-payment of 25% and 50% for specific pharmaceuticals. Full price in 50% reimbursement category for the price above € 12.80 per pack. Co-payment due to RPS.	Reduced co-payment rates of 10% instead of 25% for vulnerable groups In case of annual OPP above a limit of € 384.- per year social health insurance gradually may grant further reimbursement in addition to the normal reimbursement; this additional reimbursement is limited at a maximum of € 607.- per year (if total OPP is more than € 1,278.-).
EL	Percentage co-payment of 10% and 25% for specific pharmaceuticals. Co-payment due to RPS.	Reduced co-payment rate (10%) for low income pensioners.
FI	Prescription fee of € 3.- (in 100% reimbursement category). Prescription fee of € 1.50 per pharmaceutical purchase above maximum annual limit. Percentage co-payment of 28% and 58% for specific pharmaceuticals.	Annual maximum limit of co-payment in case of OPP for reimbursable pharmaceuticals above € 617.- (2006). Besides social insurance, further schemes to cover the patient's expenses for pharmaceuticals, e.g. social assistance paid to people with low incomes by the local municipal authorities and support paid to pensioners, children and people with disabilities.
FR	Percentage co-payment of 35%, 65% and 85% for specific pharmaceuticals. Co-payment due to RPS.	100% reimbursement for patients with a specified long-term illness (30 diseases) and socially-disadvantaged persons (income less than € 7,083.- annually).
HU	Percentage co-payment of 10%, 30% and 50% for specific pharmaceuticals. Co-payment due to RPS.	100% reimbursement for patients with a specified long-term illness and socially-disadvantaged persons.
IE	Deductible of € 85.- per month under one of the reimbursement schemes (Drug Payment Scheme).	Specific schemes with free access to pharmaceuticals (no co-payments) for people with low income (GMS scheme).
IT	Prescription fees in some regions. Co-payment due to RPS.	Some exemptions for vulnerable groups (e.g. by age, income or disease).
LT	Percentage co-payment of 10%, 20% and 50% for specific pharmaceuticals. Co-payment due to RPS.	Eligibility to one of the two positive lists due to social status (children, severely disabled people).
LU	Percentage co-payment of 20% and 60%	Annual maximum limit of co-payment for all health care services covered by social insurance fixed at 2.5% of annual contributable income.
LV	Percentage co-payment of 10%, 25% and 50% for specific pharmaceuticals. Co-payment due to RPS.	–
MT	No OPP in the public sector; however the private sector plays an important role.	Access to free pharmaceuticals for eligible persons (in the public sector).
NL	Co-payment due to RPS.	Fiscal compensatory arrangements for low income groups.
PL	Prescription fee of € 0.80 in some reimbursement categories. Percentage co-payment of 30% and 50% for specific pharmaceuticals. Co-payment due to RPS.	Reduced co-payment rates for war veterans and patients with severe diseases.

C.	Out-of pocket payments	Mechanisms for vulnerable groups
PT	Percentage co-payment rates of 5%, 30%, 60% and 80%. Co-payment due to RPS.	Special diseases (100% reimbursement) Pensioners with income below 14 times the minimum national wage (reimbursement rates are 15% higher than respective standard rates).
SE	Percentage co-payment rates, decreasing with rising pharmaceutical expenditure and no co-payment above a maximum limit Deductible of € 97.-.	Maximum limit of € 194.- per 12 months Children under 18 years of age within a family unit are considered as one beneficiary and their costs are pooled together.
SI	List-dependent percentage co-payment: amounting to 31% of reimbursable pharmaceuticals (in value, 2005), covered by supplementary voluntary insurance. Co-payment due to RPS.	Defined 100% reimbursement categories of patient age groups, certain diagnoses.
SK	Prescription fee of € 0.13. Different percentage co-payment rates due to RPS.	Limit of maximum co-payment for partially reimbursable pharmaceuticals.
UK	Prescription fee of € 9.70.	Large population groups exempted from prescription fees (criteria: age, illness, etc.). Limit of prescription fee by purchase of a four months prescription pre-payment certificate of € 48.80 or an annual prescription pre-payment certificate of € 134.25.
NO	Percentage co-payment of 36% for POM	Maximum limit of € 63.50 per prescription. Annual limit of € 205.- (in a calendar year). In case of private pharmaceutical expenses above € 152.-, the patient can claim reimbursement for 90% of all further expenses.
TR	Percentage co-payment of 20% on all pharmaceuticals for active working people and Green Card Holders (i.e. poor people) and 10% for pensioners.	Exemption from percentage co-payment for chronically ill people.

GMS = General Medical Service scheme (Ireland), OPP = out-of pocket payments, POM = prescription-only medicines, RPS = reference price system

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
Prescription fee: The patient has to pay a fixed fee for each prescription item dispensed on the expense of a third party payer, i.e. a form of 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 the a social health insurance / national health service.
Reference price system: On buying a pharmaceutical under the reference price system, an insured must pay the difference between the reference price and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payments or percentage co-payment rates.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.4.6 Reimbursement in the hospital sector

Regarding the pharmaceutical system and in particular the reimbursement framework, the **inpatient sector is quite different** from the outpatient sector in most PPRI countries. As displayed in section 3.3.2, also pricing policies differ between the outpatient and inpatient sector.

Inpatient pharmaceutical expenditure is in most countries covered by the hospital's budget, granting **100 percent reimbursement**, i.e. no co-payments on pharmaceuticals used for the treatment of inpatients. Thus, inpatient pharmaceutical expenditure is usually borne by the institutions that fund the hospitals. This may be the same payers as in the outpatient sector (this is especially the case in countries with a national health service, but is also e.g. in Hungary whose health care organisation is based on a social insurance system, cf. section 3.1.3.1), but in several PPRI countries the payers for inpatient and outpatient expenditure (e.g. in Austria) are different. In France, hospitals can claim reimbursement directly from the social insurance for those hospital pharmaceuticals which are dispensed in hospital pharmacies to outpatients.

Even though the hospital pharmaceutical market has been less analysed than the outpatient market it is of great relevance. Pharmaceuticals used in hospitals often influence the further treatment of the patient in the outpatient sector. Within the hospital a patient might be treated with an – expensive – original product. After hospital discharge, if the patient needs to continue treatment, she or he might prefer to take the same pharmaceutical, which can pose problems for the (outpatient) prescribing doctor.

In addition, hospital pharmaceuticals need to be considered from the perspective of access to pharmaceuticals. Even though it seems that in some countries the reimbursement list for outpatients is rather limited, several not listed pharmaceuticals are provided free of charge in the hospitals (e.g., in Poland, Austria).

3.4.7 Reimbursement related cost-containment measures

In the PPRI Pharma Profiles, five reimbursement related cost-containment measures (reimbursement lists, reference price systems, reimbursement review, claw-back/pay-back, and out-of pocket expenses) were described.

Changes in reimbursement lists have been observed in nearly all PPRI countries. Mostly, pharmaceuticals were withdrawn from reimbursement (~delisting), but also extensions of positive lists occurred (e.g., Bulgaria). A few countries have undertaken major changes, like Austria (introduction of the positive list called "reimbursement code" based on a new methodology), Greece (abolition of the positive list) or Finland (possibility to introduce a negative list). In some countries the modifications in the reimbursement lists were connected to changes in the reference price system (e.g., Latvia, Slovakia), whereas in other countries the changes were the result of an extensive reimbursement review (e.g., France, Sweden).

The section on **reference price systems** (cf. section 3.4.4) demonstrates that PPRI countries increasingly use this instrument. In the course of the years, some reference price systems were modified with regard to the kind of pharmaceuticals included and the clustering of the reference groups (e.g., in Belgium, Germany, Hungary, Poland).

Belgium, Denmark, France, Lithuania and Sweden are PPRI countries known to undertake **systematic reimbursement reviews** of several therapeutic classes or even of the whole system. France started the review of the reimbursement criteria “medical benefit” and “improvement of the medical benefit” for selected therapeutic groups in 1999, followed by further reviews in 2003, 2005, and 2006, which, in the end, resulted in a reduction of the reimbursement rates for specific pharmaceuticals. In Sweden, all reimbursable pharmaceuticals have been divided into 49 therapeutic groups. The Pharmaceutical Benefits Board has commenced to review one group after the other and investigates if the new criteria for reimbursement are fulfilled or not. By the year 2007 the reviewing of three therapeutic groups (migraine, stomach acid and asthma/COPD) had been completed.

Another reimbursement related cost-containment measure is the application of a **claw-back** 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. Claw-back systems are applied in Belgium, France, Hungary, the Netherlands (Box 18), and the UK.

Box 18: Claw-back system in the Netherlands

In 1998 the Netherlands introduced a claw-back rule obliging pharmacies to transform a part of the realised purchase benefits into a price benefit granted to the patients and to the health insurance companies. In 1998 this resulted in an effective discount rate of 2% on an annual basis, and in 1999, pharmacies were obliged to grant patients and health insurance companies an effective 3% discount on the list prices issued by the pharmaceutical manufacturers.

For the period between the beginning of 2000 and the end 2002, an agreement between the Ministry of Health and the Pharmaceutical Society provided for a phased increase of the prescription fee combined with an adjustment of the claw-back from 3% to effectively 6%. The claw-back formally increased to 6.82%, with a maximum of € 6.80 per dispensed prescription.

In 2003, a differentiated claw-back system was introduced: 8% of pharmacy reimbursement was clawed back for single-source pharmaceuticals (up to maximum of € 9.-), and 40% of the official pharmacy purchasing price for multi-source pharmaceuticals (up to a maximum of € 20.-). Single-source pharmaceuticals were defined as prescription-only medicines having been produced by one manufacturer (usually a pharmaceutical that is still patented), while pharmaceuticals that were supplied by more than one manufacturer were considered to be multi-source.

The differentiated claw-back was widely criticised and subject to legal challenges at the Trade and Industry Appeals Tribunal. In December 2003, the court ruled that it was unlawful, as the Ministry of Health had not put in place sufficient safety nets for pharmacies that were disproportionally disadvantaged. This was the end for the differentiated scheme. The original claw-back rule, according to which pharmacies were obliged to grant patients and health insurance companies a 6.82% discount on the list prices, with a maximum of € 6.80 per dispensed pharmaceutical, was reintroduced and still stands.

Reimbursement related cost-containment measures, which have been undertaken in several PPRI countries, have led to an increase of **out-of pocket payments**:

- New co-payments have arisen due to the introduction of a reference price system in some countries.
- Following modifications in the reimbursement lists (de-listings etc.), pharmaceuticals are no longer granted reimbursement status, and thus have to be paid out-of pocket.
- New reimbursement criteria or reimbursement reviews might have consequences on the reimbursement rates (often a decrease of reimbursement rates) and on the reimbursement price (which might be lowered).

3.5 Rational use of pharmaceuticals

3.5.1 Pharmaceutical budgets and prescription guidelines

In their function as prescribers, as communicators and as sort of "translators" to the patients, physicians play an important role in guaranteeing a rational use of pharmaceuticals. It is up to them to decide which pharmaceutical is prescribed – a decision for which also economic aspects could be taken into consideration if equivalent therapeutic alternatives are available (see also section 3.5.4).

As Table 3.16 shows, different instruments are suitable to (strongly) encourage physicians to promote a rational use of pharmaceuticals.

Table 3.16: Comparative analysis – Tools for rational use of pharmaceuticals addressing physicians in the PPRI countries, 2006/2007

C.	Prescription guidelines	Prescription monitoring	Budgets for physicians
AT	Compulsory guidelines on economic prescribing	Yes, but regularly only SHI/NHS contract doctors	No pharmaceutical budgets
BE	Obligation for physicians to prescribe a minimum of "cheap pharmaceuticals", see Box 19)	Yes	No pharmaceutical budgets
BG	No official guidelines; however regulation on terms of prescrib-ing/dispensing	N.a.	No pharmaceutical budgets
CY	Guidelines for physicians in the public sector	N.appl.	No pharmaceutical budgets
CZ	Indicative guidelines of the Medical Association	Yes, only SHI/NHS con-tract doctors	Pharmaceutical budgets (not enforced in reality)
DE	Compulsory guidelines	Yes, compulsory for SHI/NHS contract doctors	Practice-specific budgets for contract doctors
DK	Indicative guidelines	Yes, regularly through Ordiprax system[1]	No pharmaceutical budgets
EE	Indicative guidelines	Yes, only SHI/NHS con-tract doctors	No pharmaceutical budgets
EL	No prescription guidelines	Yes	No pharmaceutical budgets
FI	Indicative guidelines	Yes, for information pur-poses of SHI/NHS only	No pharmaceutical budgets
FR	Compulsory guidelines	Yes, only SHI/NHS con-tract doctors	No pharmaceutical budgets
HU	Compulsory guidelines	Yes, only SHI/NHS con-tract doctors	No pharmaceutical budgets
IE	No prescription guidelines	Yes, in IDTS[2]	Yes, Indicative Drug Target Scheme (IDTS)[2]

C.	Prescription guidelines	Prescription monitoring	Budgets for physicians
IT	Product-specific guidelines ("Notes")	Yes, only SHI/NHS contract doctors	No budgets for prescribers, but public pharmaceutical spending is limited to an allowed annual ceiling
LT	Rational pharmaco-therapy guidelines for several diseases	Yes	No pharmaceutical budgets (in place in 2002-2003)
LU	Internal prescription guidelines	Yes, for information purposes of SHI/NHS only	No pharmaceutical budgets
LV	Rational pharma-therapy guidelines	Yes	Pharmaceutical budgets with sanctions for unjustified overspending
MT	N.a.	N.a.	N.a.
NL	Indicative guidelines	Yes, by an electronic prescribing system	No pharmaceutical budgets
PL	Indicative guidelines	No	No pharmaceutical budgets
PT	No prescription guidelines	No	No pharmaceutical budgets
SE	Indicative guidelines	Yes	Pharmaceutical budgets, on different organisation level in different counties
SI	Indicative guidelines, statutory prescribing constraints per product	Yes, but regularly only SHI/NHS contract doctors	No pharmaceutical budgets
SK	Compulsory guidelines	Yes, but regularly only SHI/NHS contract doctors	Pharmaceutical budgets
UK	Indicative guidelines	Yes, but regularly only SHI/NHS contract doctors	Pharmaceutical budgets for NHS fund holders
NO	Compulsory guidelines	Yes	No pharmaceutical budgets
TR	Indicative guidelines	N.a.	No pharmaceutical budgets

C. = Country, IDTS = Indicative Drug Target Scheme, N.a. = not available, N.appl. = not applicable, SHI/NHS = social health insurance/national health service

[1] Ordiprax is an online statistical system where all doctors can compare own prescribing habits with that of their colleagues in the region.

[2] However, the Indicative Drug Target Scheme (IDTS) in Ireland has been officially suspended since 2005. The IDTS aimed to encourage general practitioners to prescribe economically by allowing them to invest savings made through more economic prescribing in practice development. The targets set, taking into account the age and gender of the patients and excluding certain specialist and expensive pharmaceuticals, may be considered as a kind of budgets. However, the scheme has been voluntary, there have been no sanctions in place for those who fail to meet their target.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Several PPRI countries have introduced **prescription guidelines** in order to promote an appropriate and economic prescribing of pharmaceuticals. In most countries, these guidelines are indicative; obligatory prescription guidelines are in place in Austria, Germany, Hungary, Norway and Slovakia. For instance, the "Guidelines on Economic Prescribing" in Austria, which apply for the outpatient sector, provide that in case of several similar therapeutic options being available a physician has to choose the most cost-effective one.

Additionally, the **prescription pattern is regulatory monitored** in nearly all PPRI countries (see Box 19 for Pharmanet in Belgium).

Another tool in this context are **pharmaceutical budgets for physicians,** which ex-ante fix the maximum amount of money to be spent on pharmaceuticals in a specific region or time period. In fact, most PPRI countries have not implemented pharmaceutical budgets for physicians. However, obligatory budgets for physicians are in place in Germany, Latvia, Sweden (some counties) and Slovakia. When calculating these budgets, different criteria, such as the number of patients, the age groups of the patients and their diseases, are taken into account. There have been experiences in countries, where financial sanctions for doctors overspending had been foreseen, but were not enforced, which resulted in the measures being futile.

Box 19: Systematic prescription monitoring in Belgium

In Belgium, the social insurance has established a large-scale database system, the **Pharmanet**, to monitor the consumption and prescription patterns.

Data about all reimbursable pharmaceuticals dispensed in pharmacies are collected by the Pharmanet system. Pharmacies submit their data monthly to an invoice office that in turn sends the data to the sickness fund. After anonymisation by a trusted third party the data are finally transmitted to the social insurance. The database is updated every three months. Based on these data, individual profiles of physicians can be created which are then used to give the physicians feedback about their prescribing patterns. The data are not used to monitor individual consumption of patients, which is impossible due to the anonymisation.

It is recommended that physicians use the feedback from the Social Insurance both for self-reflection and to discuss it with their peers in local groups. So far there has been feedback on prescribing of antibiotics and anti-hypotensive pharmaceuticals. The feedback reports are displayed on the website of the social insurance.

Since 1 April 2006, physicians have been obliged to prescribe a minimum percentage of “cheap pharmaceuticals”, which are defined as generics or original pharmaceuticals included in the reference price system, with a price equal to the reimbursement basis, and International Non-Proprietary Name (INN) prescribed pharmaceuticals.

A first evaluation of the “cheap pharmaceuticals” rule has revealed that most doctors reach their target, but a formal evaluation of its impact on both patients and social insurance expenditure has not yet been carried out at the time of the compilation of the respective Pharma Profile. Each doctor, including dentists, has to prescribe a minimum amount of these “cheap pharmaceuticals” – the exact percentage differs depending on the medical specialisation. If doctors do not comply with these percentage levels, they are asked to explain their actions. If the explanation is deemed unsatisfactory, the physician can be further monitored. If during the monitoring the physician’s prescribing pattern does not improve, doctors can either loose their accreditation and the accompanying higher fee-for-service payment(s) or are fined.

In most PPRI countries, prescription monitoring has been accompanied by an **information policy** of the third party payers to the physicians, on an individual basis (when giving feed-back on the prescription pattern) as well as at a group level (e.g., information campaigns for the use of generics or on specific therapeutic groups). The French Social Insurance has established a network of representatives to guarantee a regular information flow to the physicians (see Box 20).

A statistical analysis has shown no correlation between the number of outpatient doctors and the total pharmaceutical expenditure in the PPRI countries.

Box 20: France – Social Insurance representatives visit prescribing physicians

In 2003, the French Social Health Insurance (CNAMTS) has implemented a system of health insurance representatives, so-called "Délégués d'Assurance Maladie (DAM)". In 2006, the workforce consisted of about 700 DAM and this number is expected to double by 2009.

These representatives conduct face-to-face visits to professionals, which are mostly prescribing physicians, but also pharmacists (e.g. regarding generic substitution) and dentists. Their task is to inform the health professionals and to discuss specific themes with them, such as antibiotics, generic substitution, breast cancer screening, prevention, over-prescription or unmet goals according to the agreements of the physicians with the sickness fund.

The duration of each visit is about 30 minutes with a target of 150,000 visits per year, so a physician is visited by a DAM about three times per year. The health insurance representatives are professionals with medical training specific to campaigns. In 2006 each DAM attended about 25 days of training.

The preparation of the visits, including the evaluation of the preparedness of the DAM, takes about one training day per campaign. The DAM are provided with guidelines and specific documents to give to the professionals, including a report on her/his activity.

3.5.2 Pharmaco-economics

Pharmaco-economics continues to play an increasingly important role in decisions on pricing and, in particular, on reimbursement. De facto, all PPRI countries consider pharmaco-economic aspects when setting the prices and the reimbursement amounts of pharmaceuticals.

The extent of the application of **pharmaco-economic assessment** differs between the countries. For instance, the Netherlands, Sweden, the UK and the three Baltic states have adopted **guidelines** specifying rules for the conduction of pharmaco-economic analyses.

Box 21: The Baltic Guideline on Economic Evaluation of Pharmaceuticals

The Baltic Guideline for Economic Evaluation of Pharmaceuticals, which was approved by Estonia, Latvia and Lithuania in September 2002, specifies the main principles for performing pharmaco-economic analyses. These are:

1. Pharmaco-economic analyses shall be based on published clinical trial data or on meta-analysis or clinical trial data performed as a part of the pharmaceutical licensing process.

2. Pharmaco-economic analyses shall be performed from a health care perspective (incorporating only direct costs and benefits for health care); analyses from a societal perspective (including all costs and benefits outside the health care system) may be presented in addition, if considered relevant by the applicant.

3. Comparisons of costs and benefits shall be made between the new pharmaceutical and the most commonly used alternative pharmaceutical within the pharmaco-therapeutic group (if the new pharmaceutical belongs to an existing therapeutic group) or the most commonly used alternative pharmaceutical for the indication (if the new pharmaceutical belongs to a new pharmaco-therapeutic group).

4. The following economic evaluations can be conducted:

- Cost-minimisation analysis
- Cost-effectiveness analysis
- Cost-utility analysis (only in addition to the cost-effectiveness analysis).

5. The outcome indicator is the improvement in health resulting from the therapy. The final outcome is the change in the health status (prevention of death, reduced incidence of complications, reduced incidence of side-effects, incidence of well-controlled therapy symptoms, etc.).

6. To identify differences in the clinical effectiveness of the new pharmaceutical and comparative treatment, the absolute risk difference shall be calculated and used in the pharmaco-economic analysis.

7. A summary of the incremental analysis shall be reported, comparing the relevant alternatives. The costs per outcome unit of the new pharmaceutical and of the alternative treatment should be reported. To obtain evidence about the differences in costs for achieving an extra unit of benefits, the incremental cost-effectiveness ratio (ICER) shall be calculated. Budget impact and expected sales volumes shall be presented.

8. If the analysis cannot be performed otherwise, modelling techniques can be applied.

9. Economic analyses performed abroad can be applied to the local situation.

These guidelines must be followed so that the results of the analysis may be considered by the authorities in the reimbursement decision (for example, see Box 21 for the Baltic Guideline on Economic Evaluation of Pharmaceuticals). In addition, countries might focus on different aspects in their pharmaco-economic analyses: While the Baltic Guideline focuses on the health care perspective, Sweden applies a societal perspective for cost-effectiveness analyses.

Pharmaco-economic analyses are usually undertaken by the pharmaceutical companies and subsequently submitted to the reimbursement authorities.

The UK has set up the National Institute for Health and Clinical Excellence (NICE) which gives guidance to the NHS with regard to best clinical practice, for example through analysis of the clinical and cost-effectiveness of pharmaceuticals and other treatments (see Box 22).

Box 22: Cost-effectiveness assessment by NICE in the UK

The National Institute for Health and Clinical Excellence (NICE) provides independent professional advice on clinical and cost-effectiveness of pharmaceuticals and other therapeutic interventions. This guidance applies to both the hospital and the community setting.

The provision of health economic analyses is not necessary for obtaining market authorisation. In addition, health economic analyses are not required for the decision on the price or the reimbursement status of a pharmaceutical. Nevertheless, NICE may provide guidance on whether a product should be included in the NHS, where the price will have a bearing. This guidance is generally reviewed after five years.

In its assessment of clinical and cost effectiveness NICE makes use of health economic analyses and produces Quality Adjusted Life Year (QALY) data, on which it bases its recommendations. NICE has indicated that the threshold cost per QALY is in the range of GBP 20,000.- / € 27,753.- to GBP 30,000.- / € 41,629.-, but it will also take other factors into account.

3.5.3 Information to patients

With regard to patient information, the framework for pharmaceutical **advertising** is of relevance. Generally speaking, within the European Union, advertising to the general public is not allowed for prescription-only medicines, but companies may provide product-specific information if this information is personally requested by the patient. Under the Pharmaceutical Forum process, a Working Group is dedicated to the issue of patient information[24].

Information to patients is not only a matter of advertising and information provided by pharmaceutical companies, but includes also **information given to patients by health professionals** (e.g., doctors or pharmacists) **and authorities**. In some countries (e.g., Belgium, France) authorities have launched information campaigns to the general public, for instance, on specific pharmaceutical groups (antibiotics) or on generics, in order to give advice to the patients. As patient information has not been a focus of the PPRI project, there are not enough data on patient information available for a further analysis.

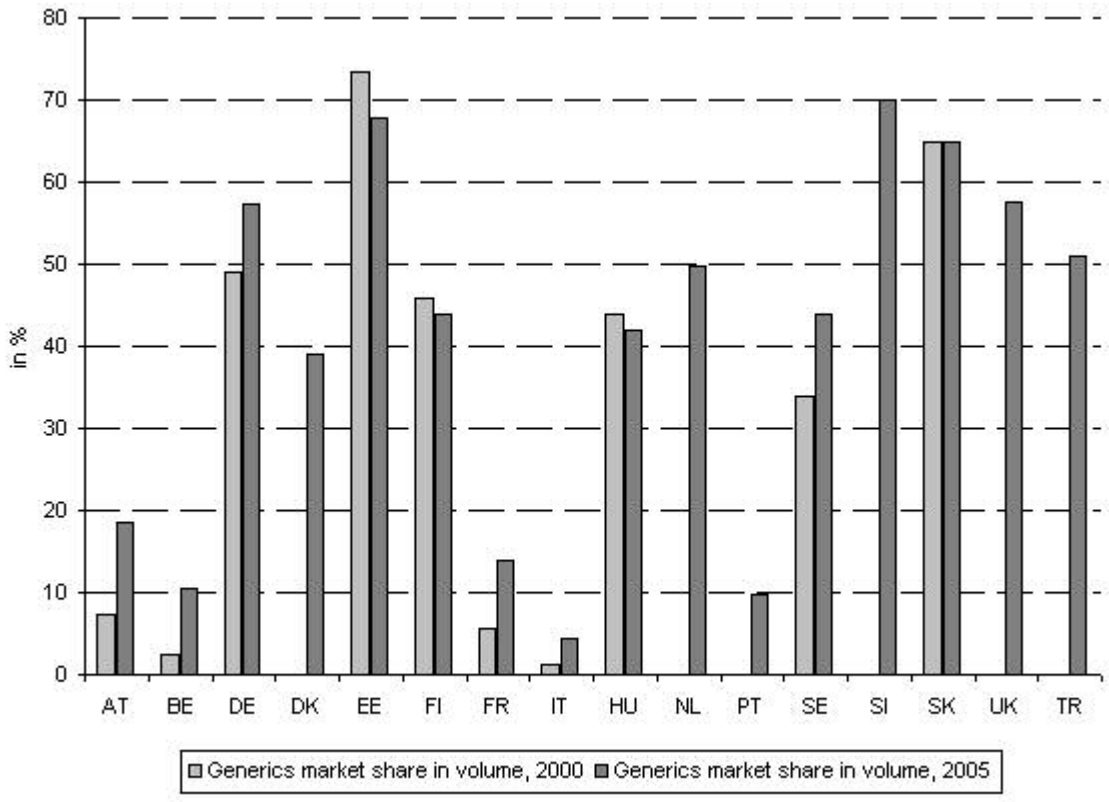
[24] http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/working_group_en.htm#1

3.5.4 Generics

Generics play an important role in cost-containment as well as in the rational use of pharmaceuticals. Based on savings made out of generic promotion higher prices for innovative pharmaceuticals might be granted.

The **generics shares** vary between the PPRI countries: The new Member States in Central and Eastern Europe have a tradition of a local production of generics and copy-products (and not of innovative pharmaceuticals). As a result, the market shares of generics have always been relatively high (around 50% and more in volume) in these countries. The old EU Member States have now seen the need to undertake initiatives to encourage the use of generics. Among those, some countries such as Germany, the Netherlands and the UK started a policy of generic promotion in the 1990s, which has resulted in considerable generics shares. In the last few years, further EU-15 countries have undertaken efforts to promote generics and consequently saw their generics shares rising. In the new Member States the generics shares in volume remained stable (e.g. Slovakia) or even decreased (Estonia, Hungary) in the past years.

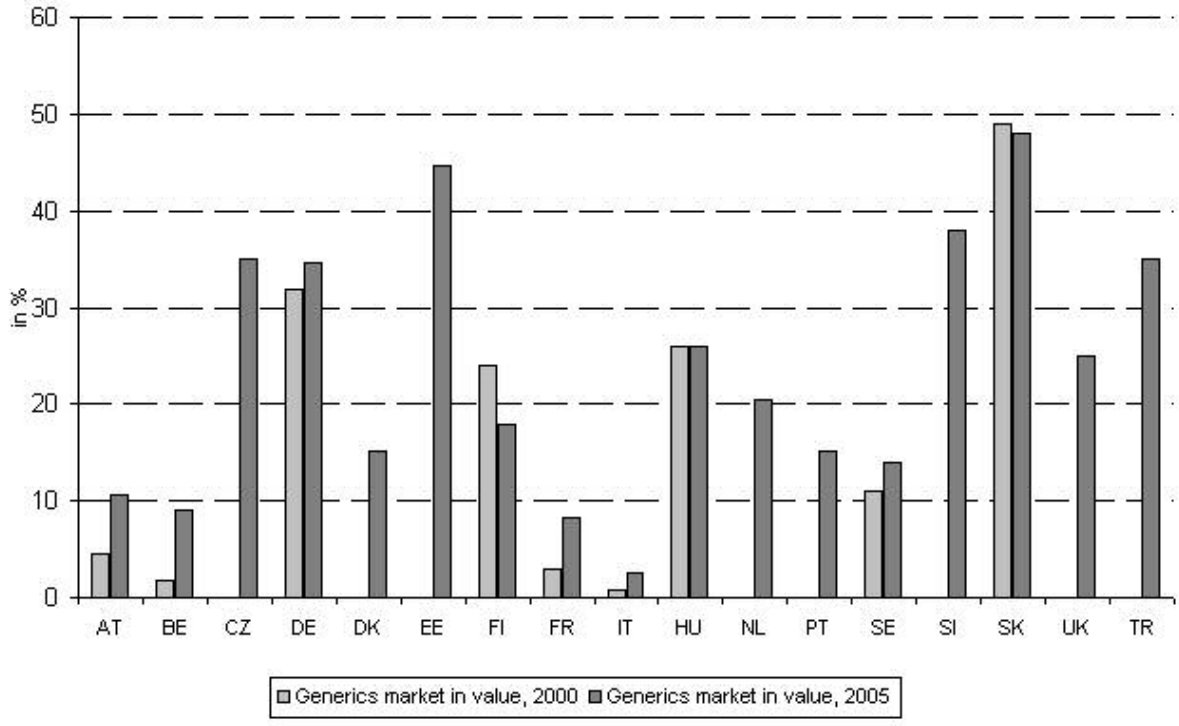
Figure 3.13: Comparative analysis – Generics shares in volume in the outpatient sector in the PPRI countries, 2000 and 2005



Generics market 2005: 2006 – AT, FI, PT, SE; 2004 – IT
Generics share, defined in number of prescriptions per year, expressed as percentage of the outpatient market
Note: For some countries it is likely that the data given are referring to the reimbursement market rather than to the total outpatient market.
Sources: PPRI Pharma Profiles 2006/2007; IMS Health for FI; SFK 2006 for NL

Figure 3.13 and Figure 3.14 display the generics shares in the outpatient markets in volume and in value. In most countries, due to the lower price level of generics, the generics share in value is, sometimes considerably, lower than the generics share in volume.

Figure 3.14: Comparative analysis – Generics shares in value in the outpatient sector in the PPRI countries, 2000 and 2005



Generics market 2005: 2006 – AT, FI, PT, SE; 2004 – IT
Note: For some countries it is likely that the data given are referring to the reimbursement market rather than to the total outpatient market.
Sources: PPRI Pharma Profiles 2006/2007; IMS Health for FI; SFK 2006 for NL

There are different tools for generic promotion, and they are sometimes used in parallel.

A key instrument is **generic substitution** which is allowed in 19 PPRI countries (see Table 3.17). Generic substitution can be indicative, i.e. pharmacists are allowed but not obliged to dispense generics; which is the case in thirteen PPRI countries. Six countries opted for obligatory generic substitution, obliging the pharmacists to substitute. However, even in systems of obligatory generic substitution, the possibility for prescribers to exclude generic substitution in specific cases is provided for.

Table 3.17: Comparative analysis – Tools for generic promotion in the PPRI countries, 2006/2007

C.	Generic prescribing	Generic substitution	Further generic promotion
AT	Not allowed	Not allowed	Information activities to prescribers by some sick funds
BE	Indicative INN prescribing	Not allowed	Recurrent campaigns to promote the use of generics, addressing both healthcare professionals (doctors and pharmacists) and patients
BG	N.a.	Not allowed	N.a.
CY	Not allowed in the private sector (only in the public sector)	Not allowed in the private sector (obligatory in the public sector)	N.a.
CZ	Indicative INN prescribing	Indicative generic substitution	N.a.
DE	Indicative INN prescribing	Obligatory generic substitution	Information activities to prescribers by some sick funds
DK	Not allowed	Obligatory generic substitution (also for non-reimbursable pharmaceuticals)	IRF and consultants from the Regions regularly promote generic substitution to general practitioners
EE	Obligatory INN prescription	Indicative generic substitution	Promotion through the reference price system
EL	Not allowed	Not allowed	N.appl.
FI	Indicative INN prescribing	Obligatory generic substitution	Information activities to patients by the Ministry of Social Affairs and Health and the Association of Finnish Pharmacies
FR	Indicative INN prescribing	Indicative generic substitution	Information activities by the government, sick funds; manufacturers and pharmacists to prescribers and patients Financial incentive for pharmacists to substitute
HU	Indicative INN prescribing	Indicative generic substitution	Information activities to prescribers by the government
IE	Indicative generic prescribing (INN or brand name)	Not allowed	Information activities to patients
IT	Indicative INN prescribing (INN, brand name and generic name)	Indicative generic substitution	Information activities to patients, prescribers and pharmacists
LT	Obligatory generic prescribing (writing of brand name only with justified reason)	Indicative generic substitution	Information activities to patients, prescribers and pharmacies

C.	Generic prescribing	Generic substitution	Further generic promotion
LU	N.a.	Not allowed	N.a.
LV	Indicative INN prescribing	Obligatory generic substitution	No special generic promotion activities
MT	N.a.	Indicative generic substitution	N.a.
NL	Indicative INN prescribing	Indicative generic substitution	Information activities targeting actors and public, electronic prescribing software supporting INN prescribing
PL	Indicative generic prescribing (INN, brand name or generic name)	Indicative generic substitution	Information activities to prescribers and pharmacies
PT	Obligatory INN prescribing	Indicative generic substitution	N.a.
SE	Not allowed	Obligatory generic substitution	No special generic promotion activities
SI	Indicative INN prescribing	Indicative generic substitution	N.a.
SK	Indicative INN prescribing	Obligatory generic substitution	Information activities to prescribers and pharmacies
UK	Indicative generic prescribing	Not allowed	Information activities to prescribers by Local Primary Care Organisation
NO	Indicative generic prescribing	Indicative generic substitution	Information activities to patients, prescribers and pharmacies
TR	Not allowed	Indicative generic substitution	No special generic promotion activities

C. = Country, INN = International Non-proprietary Name, IRF = Institute for Rational Pharmaco-Therapy (Denmark), N.a. = not available, N.appl. = not applicable
Definitions: cf. PPRI Glossary, http://ppri.oebig.at → Glossary
Generic prescribing: Physicians prescribing by International Non-proprietary Name (INN)
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).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Sometimes, as Table 3.17 shows, generic substitution goes hand in hand with the possibility (and sometimes obligation) for doctors to **prescribe by INN** (International Non-proprietary Name).

Additionally, generic substitution is quite often combined with a reference price system (see section 3.4.4), as displayed in Table 3.18.

Table 3.18: Comparative analysis – Reference price systems and generic substitution in the PPRI countries, 2006/2007

Generic substitution	Reference price system in place	No reference price system
Not allowed	BE, BG, EL	AT, (CY)[1], IE, LU, UK
Allowed	CZ, EE, FR, HU, IT, LT, NL, PT, PL, SI, TR	NO, MT
Obligatory	DE, DK, LV, SK	FI, SE[2]

[1] Generic substitution is not allowed in the private sector; in the public sector it is obligatory
[2] The reference price system was abolished in 2002

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

3.5.5 Consumption monitoring

In order to promote a more rational use of pharmaceuticals, some PPRI countries have established a **consumption monitoring system** (see Table 3.19). Usually, consumption monitoring is undertaken by Medicines Agencies or social health insurance institutions/national health services using the number of reimbursed prescriptions and/or the consumed Defined Daily Doses (DDD). The data are provided by wholesalers and/or pharmacies, which, in most cases, have a legal obligation to submit this information. Consumption is, in general, only monitored for the outpatient market, and often limited to the reimbursement segment. A few countries use individual consumption monitoring to analyse in more detail specific therapeutic groups which are of interest from a public health or a cost-containment perspective. The results of this monitoring are published in reports and/or give patients the opportunity to check their own consumption pattern (e.g., Sweden, Denmark).

Table 3.19: Comparative analysis – Consumption monitoring in the PPRI countries, 2006/2007

C.	Consumption monitoring	Additional comments
AT	Yes	Undertaken by sickness funds; only reimbursement segment
BE	Yes	Undertaken by Social Health Insurance; only reimbursement segment (Pharmanet system, see Box 19)
BG	N.a.	–
CY	N.a.	–
CZ	N.a.	–
DE	Yes	Undertaken by pharmacies with enlisted patients; only reimbursement segment
DK	Yes	Undertaken by Medicines Agency, reimbursement as well as non-reimbursement segment and hospital sector (www.medstat.dk)
EE	Yes	Undertaken by Health Insurance Fund (www.haigekasse.ee); only reimbursement segment
EL	Yes	Undertaken by Medicines Agency

C.	Consumption monitoring	Additional comments
FI	Yes	Undertaken by Medicines Agency; wholesaling to pharmacies and hospitals and by Social Health Insurance; only reimbursement segment
FR	Yes	Undertaken by sickness funds; only reimbursement segment
HU	No	Only individual reimbursement is monitored
IE	Yes	Undertaken by National Centre for Pharmaco-economics only for antibiotic consumption
IT	Yes	Undertaken by Medicines Agency through National Observatory for Pharmaceutical Use (OsMed): outpatient care. Monitoring in hospital sector started in 2006
LT	Yes	Undertaken by Medicines Agency; reimbursement segment as well as OTC products and internet sales
LU	N.a.	–
LV	Yes	Undertaken by Medicines Agency; only reimbursement segment
MT	N.a.	–
NL	N.a.	–
PL	Yes	Undertaken by Medicines Agency; only reimbursement segment
PT	N.a.	–
SE	Yes	Undertaken by the Centre of Epidemiology at the National Board of Health and Welfare and by Apoteket; only POM segment
SI	N.a.	–
SK	Yes	Undertaken by sickness funds; only reimbursement segment
UK	No	Only a limited number of cases in which individual patient consumption is monitored
NO	Yes	Undertaken by the Norwegian Institute of Public Health. Compliance data is used for decisions regarding individual reimbursement
TR	N.a.	–

C. = Countries, N.a. = not available, OTC = Over-the-Counter, POM = prescription-only medicines

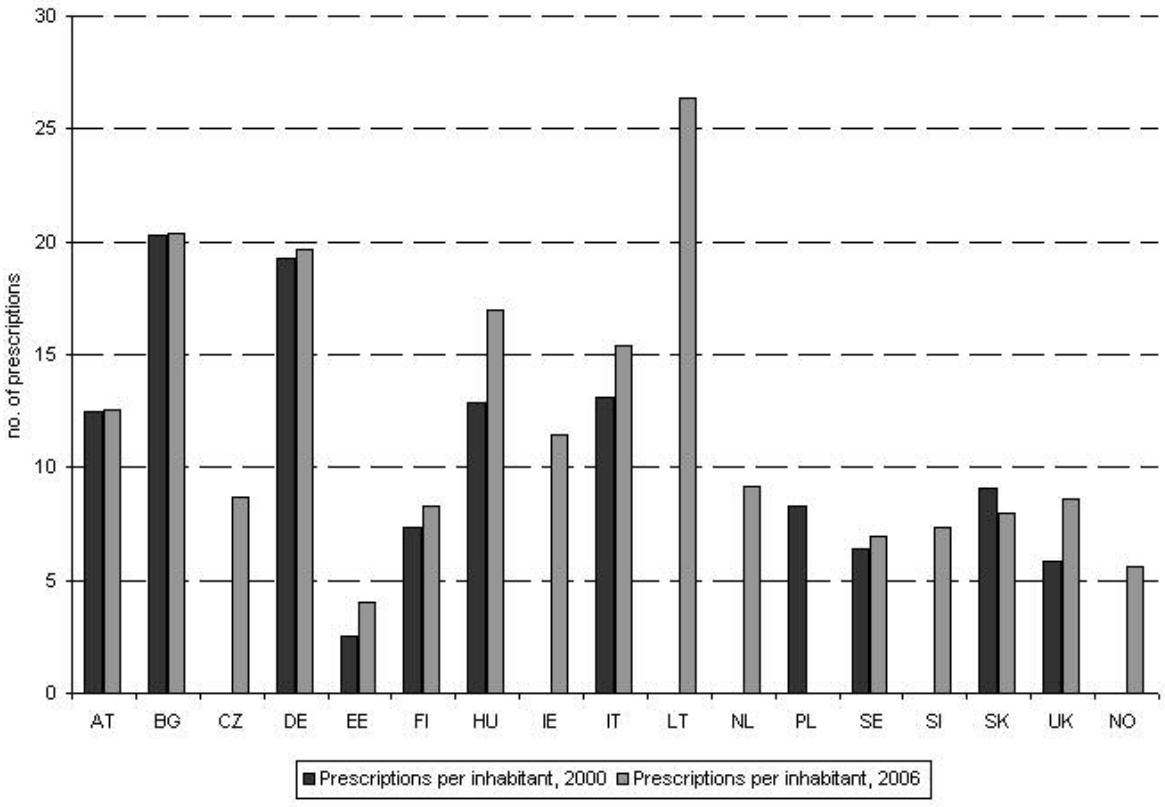
Note: In some cases (e.g. Austria, Hungary) the consumption is only monitored indirectly via a monitoring of the prescribing doctors.

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Consumption data which can be used for comparative analysis is mainly available only for the reimbursement and/or prescription segment. Since the number of pharmaceuticals consumed by patients is difficult to monitor on a large scale basis, the number of **prescriptions** was considered as best alternative and has been defined as a core PPRI indicator[25].

[25] See List of Core PPRI Indicators, Annex II (Indicator 21)

Figure 3.15: Comparative analysis – Number of prescriptions per inhabitant in the outpatient sector in the PPRI countries, 2000 and 2006



Year 2006: 2005 – AT, BG, DE, IT, LT SE, SK, UK 2004 – IE

CY: only public sector (1.8 prescriptions per inhabitant, year 2004), therefore not included in this figure

BG, IT, LT: volume in packs; EE: number of reimbursed prescriptions

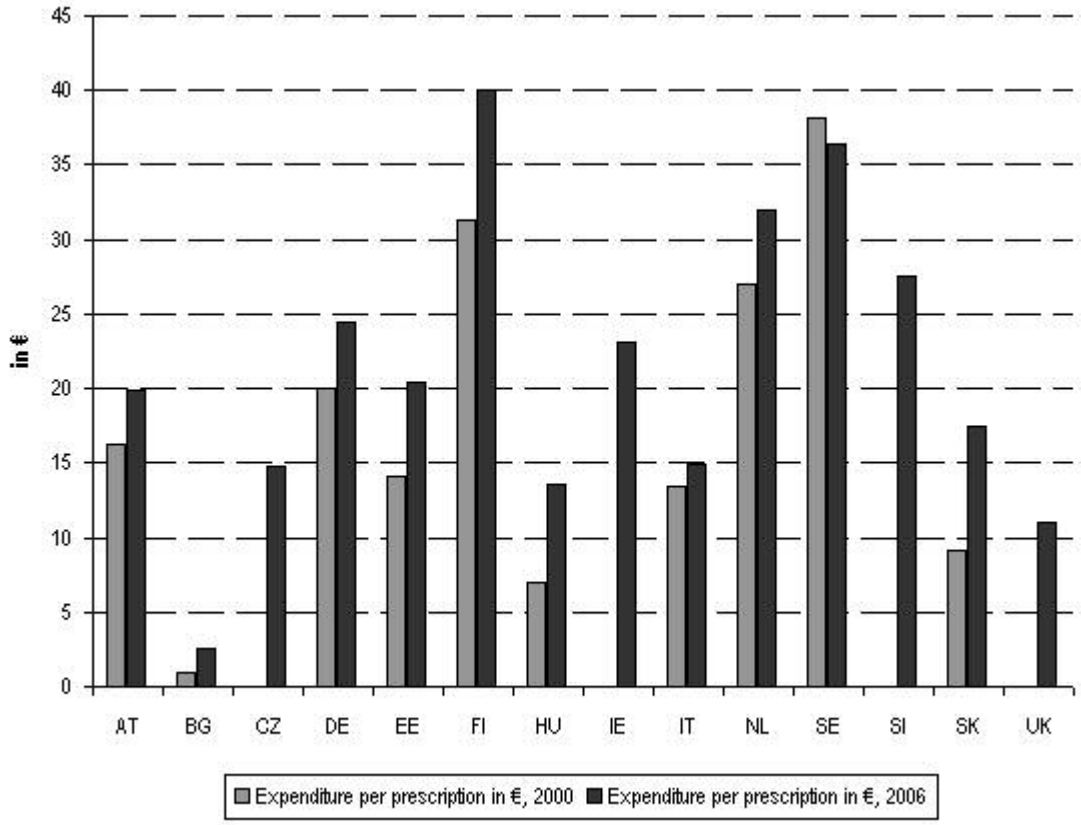
Note: Different methods for counting are applied in the PPRI countries (e.g. one prescription may include more than one pack or item).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants, ÖBIG 2007 for IE

Figure 3.15 shows the number of prescriptions per inhabitant for 2006 (or the latest available year), and, if available, also for the year 2000. On average, about 11.8 prescriptions were written per inhabitant in 2006, compared to 10.7 prescriptions per capita in 2000. Please note that this indicator has to be considered with caution, since the number of items or packs is counted in different ways (being counted as one or several prescriptions) throughout the PPRI countries. Furthermore, continuous prescriptions are not reflected in the data. The annual value of prescriptions (i.e. expenditure for prescriptions) is on average € 217.- per inhabitant.

The expenditure per prescription amounts to € 21.30 on average but varies considerably between the PPRI countries. Figure 3.16 displays the differences throughout the countries, for the year 2006 and, if available, also for 2000. This figure also must be interpreted with caution due to different counting methods regarding prescriptions in the PPRI countries.

Figure 3.16: Comparative analysis – Expenditure per prescription in € in the PPRI countries, 2000 and 2006



Year 2006: 2005 – AT, BG, DE, SE, SK, UK 2004: IE

Expenditure per prescription is calculated as the prescriptions in value (i.e. expenditure for prescriptions) divided by the number of prescriptions. See also Set of Core PPRI Indicators, Annex II of this report

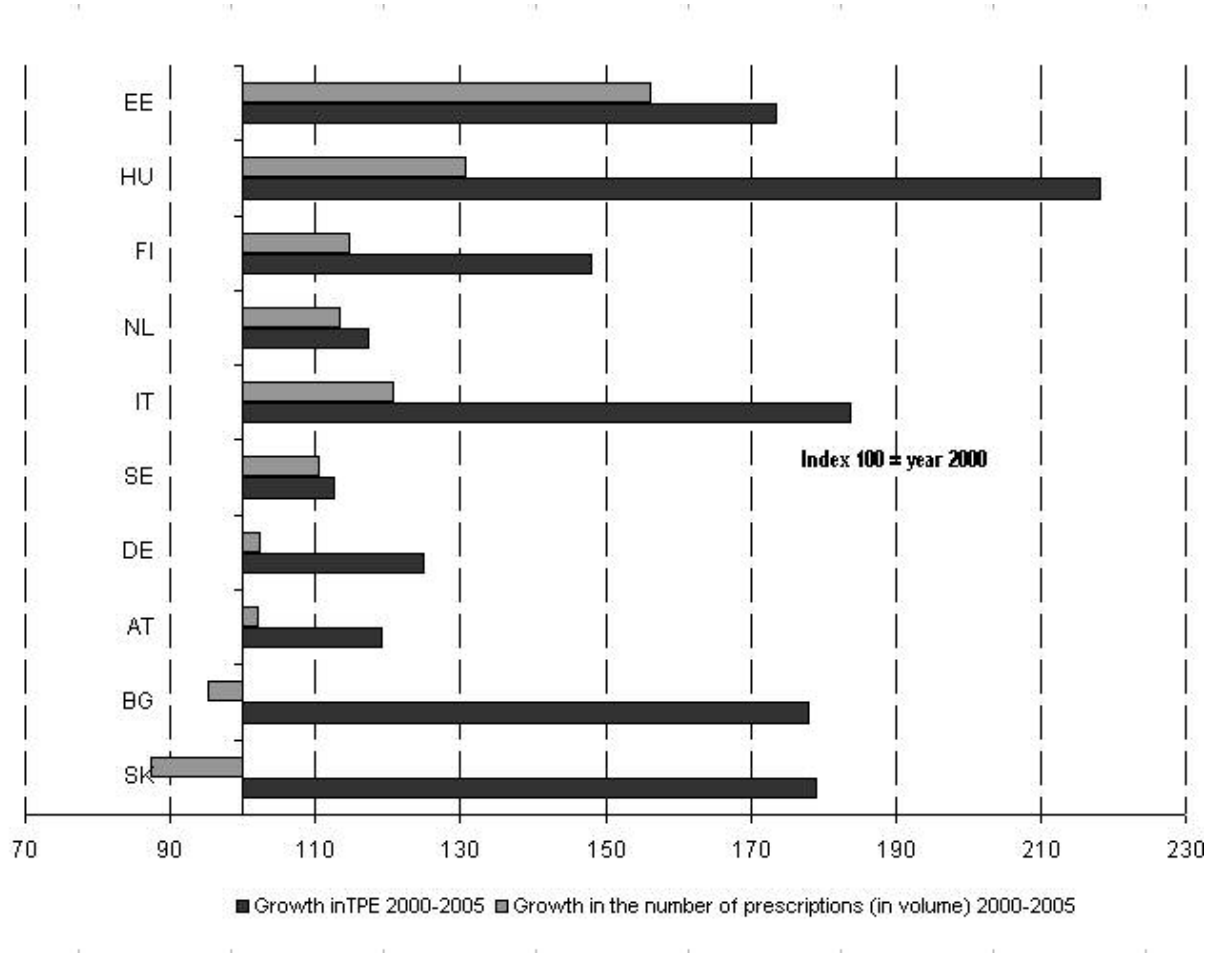
BG, IT: volume in packs; EE: volume in number of reimbursed prescriptions

Note: Different methods for counting are applied in the PPRI countries (e.g. one prescription may include more than one pack or item).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants, ÖBIG 2007 for IE

With regard to the development of the number of prescriptions, Figure 3.17 shows that in the last few years the growth in prescriptions in volume was less compared to the increase in pharmaceutical expenditure. This could be an effect of volume control measures, but it might also be an indication for the impact of value (price) component of pharmaceutical expenditure.

Figure 3.17: Comparative analysis – Cumulative growth in pharmaceutical expenditure and in prescriptions in volume in the PPRI countries, 2000–2005



TPE = Total pharmaceutical expenditure

Pharmaceutical Expenditure:

Growth 2000–2004: AT, SE

BG: only public expenditure

FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices

NL and SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Prescriptions (in volume):

Growth 2000–2006: EE, NL

BG, IT: volume in packs

EE: number of reimbursed prescriptions

Note: Different methods for counting are applied in the PPRI countries (e.g. one prescription may include more than one pack or item).

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Table 3.20: Comparative analysis – PPRI at a Glance: Results of the comparative analysis per core PPRI indicator, 2006/2007

Indicator	Objective	Results
Background		
1: Population age structure	To assess the age structure in order to analyse the effect on using health care/pharmaceutical resources	In the PPRI countries, the majority of the population (around 67%) is aged between 14–65 years (year 2005). Concerning the elderly population above 65 years, there are differences between the countries, but a systematic difference between the EU-15 (16%) and the EU-10 (15%) cannot be observed. Slovakia, Italy and Germany have the highest rates (over 19%) of people above 65 years, while Turkey has the youngest population. *Cf. section 3.1.1*
2: Gross domestic product per capita in € PPPa	To assess the economic situation in order to analyse the economic wealth of a country	With a gross domestic product (GDP) per capita of € PPPa 22,800.- in the EU-25 average (year 2004/2005), there appears to be a gap between the EU-15 (average: € PPPa 27,900.-) and the EU-10 (average: € PPPa 14,200.-). *Cf. section 3.1.2*
3: Public/private funding of health expenditure	To assess the main sources of health care funding in order to analyse the share of public funding vs. private funding of health care	The public/private funding shares of health expenditure differ between the PPRI countries. The share of public health expenditure varies from approximately 90% in the Netherlands (91.7%), UK (87.4%) and Czech Republic (87.2%) to about 50% in Greece (53.9%), Latvia (52.7%) and Cyprus (47.6%) (data for 2005 or latest available year). *Cf. section 3.1.3.2*
4: Total health expenditure per capita in € PPPa	To assess the expenditure on health per capita, per year in order to analyse the amount spent on health in a country	In 2005 (or 2004), all PPRI countries together spent about € 1,000 billion on health care. This amounts to € PPPa 1,900.- per inhabitant in the EU (EU-25). There tend to be considerable differences between the EU-15 (average: € PPPa 2,450.-) and the EU-10 (average: € PPPa 965.-) concerning health expenditure per capita. *Cf. section 3.1.3.2*
Pharmaceutical system		
5: Regulatory framework for pharmaceutical policy	To assess the legal context in order to analyse the national political framework for the provision of the population with effective pharmaceuticals	Pricing and reimbursement is a competence of the EU Member States, which have to comply with overall EU provisions, like the Transparency Directive. 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). Framework agreements between the state and the pharmaceutical industry have been concluded in Denmark, France, Hungary, Ireland and Portugal. *Cf. section 3.2.1.2.*

Indicator	Objective	Results
6: Key data on pharmaceutical industry	To assess the relevance of pharmaceutical manufacturers, distributors and retailers in order to analyse their impact on pharmaceutical policies and their role in research and development, production and distribution	Bio-tech industry is mainly situated in old EU Member States. The new EU Member States in Central and Eastern Europe are still characterised by a strong locally-producing (generics) industry, even though since the 1990s international pharmaceutical industries have been entering these markets. The pharmaceutical markets in the EU-10 countries have a relatively high number of importers, which are often companies that also hold a wholesale license. *Cf. section 3.2.3*
7: Inhabitants per "Prescription-only dispensary" (POM dispensary)	To assess the average number of inhabitants per retailer, that is allowed to dispense prescription-only pharmaceuticals (POM dispensary), in order to analyse the policies regarding dispensing of pharmaceuticals (e.g., access for patients)	POM dispensary is an umbrella term for facilities that are allowed to sell prescription-only medicines (POM) to outpatients: Besides community pharmacies, these are mainly self-dispensing doctors (e.g., in Austria, Hungary, Ireland, Netherlands) or hospital pharmacies serving outpatients (e.g., in Norway). The ratio of inhabitants per community pharmacy and of inhabitants per POM dispensary is higher in the new EU Member States (3,260 inhabitants per POM dispensary 2005) compared to the old Member States (4,950 inhabitants per POM dispensary). Greece has the highest retailer density (in terms of inhabitants per community pharmacy as well as of inhabitants per POM dispensary). *Cf. section 3.2.3*
8: Total pharmaceutical expenditure as percentage of total health expenditure	To assess and analyse the total expenditure on pharmaceuticals as a proportion of the total health expenditure	The share of health expenditure which PPRI countries spend on pharmaceuticals varies from 33.7% (Slovakia), 29.6% (Poland) and 28.1% (Estonia) to 9.9% (Netherlands), 9.4% (Norway) and 8.5% (Luxembourg). In general, the new Member States (EU-10 average: 25.5%) spend more of the health budget on pharmaceuticals than the old Member States (EU-15 average: 16.1%). In the EU-25, on average 19.6% of health expenditure is spent on pharmaceuticals (data for 2005 or latest available year). *Cf. section 3.2.4.2*
9: Public/private funding of pharmaceutical expenditure	To assess the main sources of pharmaceutical funding in order to analyse the amount of public funding versus private funding of pharmaceuticals	The ratios of public/private funding of pharmaceutical expenditure differ between the PPRI countries. The shares of publicly funded pharmaceutical expenditure vary from about 90% in the Netherlands (98%, however only referring to the prescription-only medicines market), UK (90%) and Ireland (88.7%) to less than 50% in Latvia (49.8%), Lithuania (43.0%) and Poland (35.0%) (data for 2005 or latest available year). *Cf. section 3.2.4.3*

Indicator	Objective	Results
Pricing		
10: Pricing policies at manufacturer level	To assess the different policies for pricing pharmaceuticals in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	In 24 of the 27 PPRI countries prices are controlled for outpatient pharmaceuticals. Generally speaking, Denmark, Germany and Malta exercise no price control at manufacturer level in the outpatient sector. However, in Denmark and Germany the prices of reimbursable pharmaceuticals (in particular the reimbursement price) are indirectly influenced by the reimbursement system. In the majority of the countries (e.g., in Finland, Italy, Poland), price control is limited to pharmaceuticals with reimbursement eligibility (= reimbursable pharmaceuticals), while for non-reimbursable pharmaceuticals, which are often OTC (Over-the-Counter) products, the manufacturer/importer may freely set the price. The most common price control policy is statutory pricing, which implies that authorities set the price on a regulatory, unilateral basis. In a few PPRI countries (e.g., Italy, France) pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the competent authority. A special case is the UK which has no direct price control, but the prices of NHS (National Health Service) pharmaceuticals are indirectly controlled through the profit-controlling PPRS (Pharmaceutical Price Regulation Scheme). A widely-used pricing procedure, which is applied by an increasing number of PPRI countries, is external price referencing (international price comparison). The pricing authority gathers the prices of the same product in other countries and takes these reference prices as guidance for their own pricing (and sometimes also reimbursement) decisions. 22 PPRI countries apply external pricing referencing, mostly referring to a basket of about five reference countries. A comparison with equivalent or similar products within the own country (so-called internal price referencing) as a basis for pricing or reimbursement decisions is usually undertaken for off-patent products (generics). In several PPRI countries, generics are priced, sometimes considerably, lower than original products. 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) control the pharmacy purchasing prices (wholesale prices) of pharmaceuticals, while two countries fix the pharmacy retail price. *Cf. sections 3.3.2 and 3.3.3*

Indicator	Objective	Results
11: Pricing policies at distribution level	To assess the different policies for pricing pharmaceuticals at the distribution level (wholesale, pharmacy) in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	At distribution level, six of the 27 PPRI countries (year 2007) have no statutory wholesale mark up. In these countries, the pharmacy purchasing price is controlled, and the ex-factory price is an outcome of negotiations between the manufacturer and the wholesaler. 21 PPRI countries have statutory wholesale mark ups, either a linear mark up or a regressive scheme. Pharmacy margins are regulated in all 27 PPRI countries. Usually, they also take the form of a regressive scheme or a linear mark up. Pharmacy remuneration consists of a fixed fee in the Netherlands and in Germany (together with a linear mark up), and pharmacists in Slovenia and the UK get a fee-for-service remuneration. In many PPRI countries, statutory wholesale and pharmacy mark ups cover all pharmaceuticals, whereas some countries apply the mark up schemes only to reimbursable pharmaceuticals (e.g., France, Lithuania) or to prescription-only medicines (e.g. Bulgaria, Portugal). *Cf. section 3.3.4*
12: Taxes on pharmaceuticals	To assess the different tax policies regarding pharmaceuticals in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	In most PPRI countries the VAT (value-added tax) rate for pharmaceuticals is lower than the standard VAT rate. Exceptions are Austria, Bulgaria, Denmark, Germany and Norway, where the VAT on pharmaceuticals equals to the standard VAT rate (e.g., 25% in Denmark and Norway). A few countries have split VAT rates, with a lower or even 0% rate for a specific group of pharmaceuticals (e.g., reimbursable pharmaceuticals). Additional taxes for pharmaceuticals include the INFARMED (Medicines Agency) tax of 0.4% of the net pharmacy retail price in Portugal and the pharmacy fees in Finland and in Norway. *Cf. section 3.3.4*
Reimbursement		
13: Positive/negative list	To assess if a country has implemented measures guaranteeing or limiting the access to pharmaceuticals which are, at least partially, funded by a third party payer	In all PPRI countries, reimbursement lists exists. Positive lists, which include pharmaceuticals that may be prescribed at the expense of a third party payer, are in place in 24 of the 27 PPRI countries (all but Germany, Greece and UK). Three countries (Germany, Hungary, UK) have introduced negative lists, and two countries (Greece and Finland) have foreseen the legal basis, but have not implemented the measure yet. *Cf. section 3.4.3*

Indicator	Objective	Results
14: Reference price system	To assess if a country has implemented a reference price system which is a common measure restricting the use of expensive pharmaceuticals while guaranteeing access to equivalent pharmaceuticals	In 2006/2007, 18 of the 27 PPRI countries had a reference price system in place (in one country it still had to be implemented). After nearly a decade, Sweden abolished its reference price system in 2002, but manages a system of obligatory generic substitution in which substitutable pharmaceuticals are grouped. Ten of the 18 reference price system countries (e.g., Denmark, Portugal) build the reference groups (i.e. groups of interchangeable pharmaceuticals) based on substance (ATC 5) level. Seven countries (e.g., Germany, Czech Republic) also consider therapeutically similar pharmaceuticals as interchangeable (ATC 4 level on therapeutic groups or even broader). Patients have to pay the difference between the reference price (base price for reimbursement) and the actual pharmacy retail price. *Cf. section 3.4.4*
15: Mechanisms for vulnerable groups	To assess the instruments and mechanisms in place for special vulnerable population groups in order to analyse the access to affordable pharmaceuticals	All PPRI countries have introduced mechanisms to protect vulnerable groups from too high out-of pocket payments. Specific 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 are exempted from prescription fees (e.g., in Austria). The total amount of co-payment may be limited: by a maximum co-payment per prescription (e.g., in Belgium) or annual ceilings for private expenses on pharmaceuticals and/or health care (e.g., in Germany and in Luxembourg). *Cf. section 3.4.5*
Rational use of pharmaceuticals		
16: Share of generics in volume and value as percentage of outpatient market	To assess the use of generics in order to analyse the efficiency of the pharmaceutical system	While the new EU Member States in Central and Eastern Europe have always had a relatively high share of generics, the old Member States have undertaken initiatives to encourage the use of generics. Among those, countries like Germany, the Netherlands or the UK have had a policy of generic promotion for a long period of time which has resulted in considerable generics shares. The generics share in volume is 50% or more in these “generic countries” of the EU-15 as well as in the new Member States, whereas it is below 20% in other old Member States which started later with generic promotion. Expressed in value, the generics shares are usually lower (due to the low prices of generics), ranging from around 20%–30% in the “generics countries” and about 10% in the others. *Cf. section 3.5.4*
17: Prescription guidelines	To assess the implementation of prescription guidelines in order to analyse their impact on rational use of pharmaceuticals as well as on cost-containment	The majority of PPRI countries introduced prescription guidelines to promote an appropriate and economic prescribing of pharmaceuticals. In most countries, the guidelines are indicative and usually only refer to the outpatient sector. *Cf. section 3.5.1*

Indicator	Objective	Results
18: Mandatory guidelines for decision makers / role of pharmaco-economics	To assess a country's policies regarding the decision making process in order to analyse the priorities in decision making on pricing, reimbursement and related issues regarding pharmaceuticals	Pharmaco-economics continues to play an increasingly important role in decisions on pricing and reimbursement. De facto all PPRI countries consider pharmaco-economic aspects when setting the prices and the reimbursement rates of pharmaceuticals. The extent of the application of pharmaco-economics differs between the countries. The three Baltic states, the Netherlands, Sweden and UK adopted guidelines specifying rules which have to be followed in pharmaco-economic analyses. *Cf. section 3.5.2*
19: Information to patients	To assess the actions undertaken to inform patients in order to analyse the impact on improving the rational use of pharmaceuticals	Within the EU, advertising to the general public is not allowed for prescription-only medicines (POM), however, companies may provide product-specific information if this information is personally requested by the patient. Currently, under the Pharmaceutical Forum process, a Working Group is dedicated to the issue of patient information. Information to patients is not only an issue of advertising and information provided by pharmaceutical companies, but also concerns information given to patients by health professionals (e.g., doctors or pharmacists) and by the authorities. Some countries (e.g., Belgium, France) have launched information campaigns to the general public (e.g., on specific pharmaceutical groups like antibiotics or on generics). *Cf. section 3.5.3*
20: Monitoring of consumption	To assess the actions undertaken to monitor the use of pharmaceuticals in order to analyse and improve methods for guaranteeing a more rational use of pharmaceuticals	Several PPRI countries have established consumption monitoring systems. Usually, consumption monitoring is undertaken by Medicines Agencies or social insurance institutions / national health services. The data are provided by wholesalers and/or pharmacies, which, in most cases, have a legal obligation to submit this information. Consumption monitoring is, in general, only done for the outpatient market, and in many cases limited to the reimbursement segment. A few countries use individual consumption monitoring to analyse in detail specific therapeutic groups, to publish reports and/or to give patients the opportunity to monitor their consumption pattern (e.g., Sweden, Denmark). *Cf. section 3.5.5*
21: Number of prescriptions per capita in volume and value	To assess the number of prescriptions per capita in order to analyse the utilisation in the prescription/reimbursement segment	Availability of comparable data concerning prescriptions is limited. On average in the PPRI countries (where data are available), about 11.8 prescriptions are written per inhabitant per year (year 2006), amounting to an average value of € 21.30 per prescription. This indicator has to be read with caution as the number of items or packs (as one or more prescriptions) is counted in different ways throughout the PPRI countries. The average annual expenditure for prescriptions in the PPRI countries amounts to € 217.- per inhabitant. *Cf. section 3.5.5*

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, PPRI countries = countries participating in the PPRI (Pharmaceutical Pricing and Reimbursement Information) project, which have contributed to the PPRI comparative analysis, these are EU-25 Member States except Spain, plus Bulgaria, Norway and Turkey
ATC = Anatomic Therapeutic Chemical Code, GDP = Gross Domestic Product, NHS = National Health Service, OTC = Over-the-Counter, POM = prescription-only medicines, PPPa = Purchasing Power Parities, PPRS = Pharmaceutical Price Regulation Scheme (UK), VAT = value-added tax

Sources: PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

4 Lessons learned

PPRI (Pharmaceutical Pricing and Reimbursement Information) is a research project funded by the European Commission, Health and Consumer Protection Directorate-General (DG SANCO) and the Austrian Ministry of Health, Family and Youth (BMGFJ) which aims at **providing knowledge and promoting information-exchange on pharmaceutical pricing and reimbursement policies** in Europe. PPRI is coordinated by the main partner Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), supported by the associated partner World Health Organisation, Regional Office for Europe (WHO Europe).

Within its time-frame of two and a half years, PPRI established a network of 52 institutions, mainly competent authorities and third party payers from a total of 31 countries. The core task of the participating countries was a commitment to exchange pricing and reimbursement related information and data between each other, thus increasing the transparency of their pharmaceutical systems.

This was mainly achieved by writing in-depth country profiles, the so-called PPRI Pharma Profiles[26], and by the exchange of information at network meetings. The PPRI countries plan to continue their network meetings and to up-date their PPRI Pharma Profiles after the end of the research project.

The following sections present the key findings of the research project, which have been discussed with the PPRI group.

4.1 Evaluation[27] of the PPRI project

The aim of the PPRI project was to establish a network of competent authorities and further relevant institutions in the field of pharmaceuticals and to compile and share information and data on pharmaceutical pricing and reimbursement. On their own, these two objectives had already been dealt with in previous initiatives and projects: Researchers (e.g. GÖG/ÖBIG, LSE, EASP) had surveyed and analysed pharmaceutical systems, and networking activities (e.g. under the auspices of WHO) had been undertaken. In addition, the Pharmaceutical Forum process was launched. The novel idea of PPRI was to combine the two objectives and to have country reports (so-called PPRI Pharma Profiles) written by the members of the PPRI network. Thus, in the field of pharmaceutical policies, PPRI was the **first network of such a dimension within the framework of a research project**.

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[26] Accessible to the public via the PPRI website, at http://ppri.oebig.at → Results

[27] The evaluation is based on the following methodology: In two PPRI Coordination Meetings group work yielded feedback on strengths and weaknesses of the PPRI process. For additional quantitative evaluation data please refer to section 2.1.3

This combination contributed to **awareness-raising** among authorities and academia. On the one hand, the PPRI network members personally experienced the limitations of scientific surveys, in particular regarding data availability and comparability. On the other hand, the PPRI project management together with its commissioners benefited from learning more about the approaches of authorities and their expectations on reporting and information-sharing. In this respect, the assessment of the **information needs**, which PPRI undertook with various stakeholders throughout Europe (more than 110 institutions involved in the PPRI needs assessment) before finalising the template for the survey of pharmaceutical pricing and reimbursement, was a good investment of time, because the template could be oriented to the actual information needs of the stakeholders.

A bias that became evident on several occasions during the preparatory work for the survey on pharmaceutical pricing and reimbursement, was the misunderstanding and different interpretation of aspects in the field of pharmaceuticals, which showed the need for an alignment regarding the terminology used. This was partly due to the fact that most PPRI experts have their national system with specific concepts in mind, and partly to terminology confusion and double meanings of some technical terms. Therefore, the project management considered it necessary to develop a glossary[28] which was binding for the authors of the PPRI Pharma Profiles. In the course of the PPRI project, we have increasingly experienced external interest for this **PPRI Glossary**: Other studies referred to it[29], and we have had encouraging and exciting discussions (e.g. external price referencing is quite a controversial term). Today, we see the PPRI Glossary not only as a tool for the PPRI Pharma Profiles, but as a long-term instrument for enhancing a common language in the EU. However, the Glossary is not carved in stone, and the PPRI network is pleased to receive comments and adapt or respectively expand it.[30]

A discussion point which has accompanied the PPRI project during its more than two years period concerned the **level of detail.** How detailed shall the Pharma Profiles (and consequently the underlying template) be? How much information shall the PPRI comparative analysis cover? And: How many indicators are considered necessary for assessing a pharmaceutical system? There is no final answer to these questions, as this depends on the different information needs of the respective readers. Even within the PPRI group, there have been controversial viewpoints with regard to this issue, though almost 90 percent of the authors considered the template as “good” or “very good” (cf. section 2.1.3). Thus, the PPRI project management, together with the PPRI participants, decided on a two-tier approach: In

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[28] PPRI website, http://ppri.oebig.at → Glossary

[29] The report “Analysis of differences and commonalities in pricing and reimbursement systems in Europe” by the Andalusian School of Public Health (EASP 2007) for the Working Group on Pricing of the Pharmaceutical Forum made use of the terms defined in the PPRI Glossary (see http://ec.europa.eu/enterprise/phabiocom/docs/study_pricing_2007/andalusian_school_public_health_report_pricing_2007_incl_annexes.pdf).

[30] We are pleased that the Directorate-General Health and Consumer Protection of the European Commission disseminated the PPRI project and the glossary on their website and invited for comments:
see http://ec.europa.eu/health/ph_information/dissemination/hsis/hsis_17_en.htm

general, PPRI deliverables (Pharma Profiles, comparative analysis presented in the PPRI Report) are based on a high level of detail; and some additional products provide brief summaries (e.g., flowcharts of the pharmaceutical system in the PPRI Pharma Profiles, posters at the PPRI Conference[31]).

At the end of the PPRI project, the dissemination activities were intensified. First results were made public at the PPRI Conference in Vienna at the end of June 2007. The PPRI Conference was attended by 250 delegates from 36 countries, representing competent authorities and third party payers, pharmaceutical industry and distributors, consulting institutions and academia as well as specific media, and it was rated a great success. In addition, the PPRI project management is considering ways of dissemination to patients and physicians, and has enlarged the **dissemination strategy** in order to also target these stakeholders. Furthermore, academia shall be addressed by actively inviting them to make use of the PPRI results and further analysing some of the collected data.

The involvement of competent authorities in the PPRI project allowed not only a sharing of information between the PPRI network members, but also the establishment of **national PPRI "focal points"**, contributing to a dissemination of PPRI and its results in their countries. The concept of the members of the PPRI group, doing networking in their own environment, shall be pursued in future initiatives.

To sum up, the outcomes of **PPRI exceeded the expectations** we had at the beginning of the project. We have established a network of 52 institutions – mainly Ministries of Health, Medicines Agencies, social insurance institutions from all EU Member States except Romania and Spain plus Albania, Canada, Norway, Switzerland, and Turkey, and international institutions like EMEA, OECD, WHO and World Bank. We have received contributions to the PPRI comparative analysis from 27 countries (EU Member States except Romania and Spain, plus Norway and Turkey). We have received 22 PPRI Pharma Profiles, which offer up-to-date, in-depth country information and are available for free on the PPRI website[32] and on some national websites. A few countries plan to have their Pharma Profile translated into their local language and distribute it to all Embassies. Further countries have addressed the PPRI project management to announce that they also plan to compile a PPRI Pharma Profile.

We attribute the success of PPRI to a competent, consistent project coordination and the active participation of motivated PPRI network members: Several participants decided to join in during the course of the project, when first results became available, thus acknowledging the added-value of this network. It took some time and several initiatives to make the PPRI network what it is today: An **active and self-dynamic network**, of which its members get into contact bilaterally or with the whole group if they need information or advice.

PPRI has filled a gap: The PPRI members wish to **keep the network alive and sustainable** and to **up-date the Pharma Profile** of their country **annually**, as information on pharmaceu-

[31] For download available at the PPRI website, http://ppri.oebig.at

[32] See http://ppri.oebig.at → Results

tical systems becomes out-dated soon. This commitment was demonstrated by the fact that more than 30 persons attended the first network meeting after the end of the research project in November 2007. For the future, the PPRI project management considers a secretariat to support the network participants as essential. Therefore, the great challenge at the end of the project is to convey PPRI to an on-going and sustainable project.

4.2 Overview on pharmaceutical pricing and reimbursement in Europe

Within the PPRI project country specific reports on pharmaceutical pricing and reimbursement, so-called Pharma Profiles (cf. http://ppri.oebig.at → Publications) were compiled. A survey and analysis of the pharmaceutical systems in the PPRI countries[33] brought the following results.[34]

4.2.1 Pricing

In 24 of the 27 PPRI countries **prices are controlled for outpatient pharmaceuticals**, whereas hospital pharmaceuticals are mostly purchased via public procurement.[35]

Denmark, Germany and Malta are the only three PPRI countries where, technically speaking, no price control at the manufacturer level is exercised in the outpatient sector. However, in Denmark and Germany the prices of reimbursable pharmaceuticals are indirectly influenced by the reimbursement system. A special case is the UK which has no direct price control, but where the prices of NHS pharmaceuticals are indirectly controlled through the PPRS (Pharmaceutical Price Regulation Scheme) allowing companies a predetermined maximum profit.

In the majority of the PPRI countries (e.g., in Finland, Italy, Poland), **price control is limited to pharmaceuticals with reimbursement eligibility** (= reimbursable pharmaceuticals), while for non-reimbursable pharmaceuticals, which are often OTC (Over-the-Counter) products, the manufacturer/importer may freely set the price.

The most common pricing policy for price-controlled pharmaceuticals is **statutory pricing**, where the authorities set the price on a regulatory, unilateral basis. In a few PPRI countries (e.g., Italy, France) pharmaceutical prices are negotiated between the manufacturer and the competent authority.

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[33] 22 participating countries submitted a PPRI Pharma Profile, and five further countries contributed input to the PPRI comparative analysis. The 27 PPRI countries, which are referred to in the following, are all EU Member States except Spain and Romania, plus Norway and Turkey.

[34] The information refers to the outpatient sector and to the years 2006/2007 unless stated differently.

[35] Please see for a definition of public procurement and other pharmaceutical terms the PPRI Glossary (http://ppri.oebig.at → Glossary) that was developed together with OECD and WHO Europe.

A widely-used pricing procedure, which has been introduced in more and more PPRI countries in the course of the past ten to 15 years, is **external price referencing** (international price comparisons or price benchmarking). National pricing authorities compare their prices to those of the same products in other countries and take these as a reference for their own pricing and sometimes also reimbursement decisions. Currently 22 PPRI countries apply external pricing referencing, mostly referring to a basket of around five reference countries.

Another common comparison tool is so-called **internal price referencing**: Here the prices of products in a given country are compared to their equivalents (~ generics) or similar products in the same country to have a basis for a pricing or reimbursement decision. In many PPRI countries, generics are priced, sometimes considerably, lower than original products.

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) control pharmacy purchasing prices (wholesale prices) of pharmaceuticals, whereas two countries determine the pharmacy retail price. However, in these two countries the ex-factory and pharmacy purchasing prices are indirectly controlled via regulated distribution margins.

At distribution level, six of the 27 PPRI countries (year 2007) apply no statutory wholesale mark up. In these countries the pharmacy purchasing price is controlled, and the ex-factory price is an outcome of negotiations between the manufacturer and the wholesaler. All other PPRI countries have **statutory wholesale mark ups**, either in the form of a linear mark up or a regressive scheme.

Pharmacy margins are regulated in all 27 PPRI countries. Usually, they also take the form of a regressive scheme or a linear mark up. Pharmacy remuneration is a fixed fee in the Netherlands and in Germany (together with a linear mark up), and pharmacists in Slovenia and the UK get a fee-for-service remuneration.

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

In most PPRI countries the **value-added tax** (VAT) for pharmaceuticals is lower than the standard VAT rate. Exceptions are Austria, Bulgaria, Denmark, Germany, Norway and – before 2007 – Slovakia, where the VAT on pharmaceuticals is the same as for other goods (e.g., 25% in Denmark and Norway). A few countries have split VAT rates, with a lower rate or 0% for a specific group of pharmaceuticals (e.g., prescription-only medicines in Sweden or NHS pharmaceuticals in the UK).

The most common pricing related cost-containment measures are 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.

4.2.2 Reimbursement

In most PPRI countries, **reimbursement eligibility** depends on the product in question: A pharmaceutical is considered either reimbursable, meaning that the purchasing cost are fully or partially covered by a third party payer (social health insurance / national health service), or non-reimbursable. This product-specific approach is applied in 18 of the PPRI countries (e.g., Belgium, Czech Republic, Greece, Finland, Italy, Netherlands, Poland, and UK).

Additionally, further eligibility for reimbursement can, for instance, be connected to certain diseases (e.g., in the Baltic States) or population groups (e.g., Ireland, Turkey). In Denmark and Sweden, reimbursement coverage increases with rising pharmaceutical consumption (i.e. pharmaceutical expenditure within a year), thus asking the patients to pay 100 percent of her/his medication in the beginning and offering full reimbursement after a certain out-of pocket spending threshold has been passed.

In six of the 27 PPRI countries (among those Austria, Italy, UK) all pharmaceuticals considered as reimbursable are 100 percent reimbursed, irrespective of any out-of pocket payments like prescription fees or co-payments due to a reference price system. In the other PPRI countries, **reimbursable pharmaceuticals may also be partially reimbursed**, i.e. a certain percentage of the price is covered by reimbursement.

In all PPRI countries, reimbursement lists exists. **Positive lists**, which include pharmaceuticals that may be prescribed at the expense of a third party payer, are very common and are in place in 24 of the 27 PPRI countries (all but Germany, Greece and United Kingdom). Three countries (Germany, Hungary, and UK) have negative lists, and two further countries (Greece, Finland) have provided a legal basis for negative lists, but have not implemented this measure yet.

At the time of writing (end of 2007), a **reference price system** was in place in 18 of the 27 PPRI countries. After nearly a decade of existence, the reference price system in Sweden was abolished in 2002, but the country manages a system of obligatory generic substitution in which substitutable pharmaceuticals are grouped. Ten of the 18 reference price system countries (e.g., Denmark, Italy, Portugal) build the reference groups (i.e. groups of interchangeable pharmaceuticals) based on substance (ATC 5) level. Seven countries (among those, Czech Republic, Germany and the Netherlands) also consider therapeutically similar pharmaceuticals as interchangable (ATC 4 level on therapeutic groups or even broader). 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 the reference price system, patients have 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 (in 21 of the 27 PPRI countries) is the percentage co-payment for reimbursable pharmaceuticals which are partially reimbursed.

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

In the past decade, typical measures of PPRI countries in the reimbursement segment included modifications of the reimbursement lists (listing and delisting of pharmaceuticals), the launch of systematic reimbursement reviews like in France or Sweden, and the introduction of reference price systems.

4.2.3 Rational use of pharmaceuticals

The majority of PPRI countries have introduced **prescription guidelines** to promote an appropriate and economic prescribing of pharmaceuticals. In most countries, these guidelines are indicative and refer only to the outpatient sector.

In all PPRI countries **prescription patterns are monitored**; however, the extent of supporting information technology (IT) solutions and the intensity of feed-back to the prescribers differs between the countries.

Pharmaceutical budgets for prescribers are rather rare; a few countries had established prescribing budgets, but never enforced them and/or eventually abolished them altogether (e.g., after negative court decisions).

Generic prescribing, i.e. the doctors prescribing by INN (International Non-Proprietary Name), is allowed in several PPRI countries; but it is often not used in practice.

Generic substitution, which implies that the pharmacist substitutes the product written on the prescription (usually an original product) by a generic (or a parallel-imported pharmaceutical), is allowed in 19 PPRI countries. Generic substitution can be indicative (in 13 PPRI countries) or mandatory (in six PPRI countries). However, even in case of mandatory generic substitution, patients and doctors may refuse generic substitution under certain conditions. Some countries do, even though generic substitution is mandatory, not sanction doctors when they unjustifiably prohibit generic substitution on a prescription.

4.2.4 Pharmaceutical expenditure

In 2005, the PPRI countries together spent about € 156 billion on pharmaceuticals. In terms of Euro Purchasing Power Parities (€ PPPa) this corresponds to **€ PPPa 320.- per EU-25 citizen**. There is a considerable spending difference between the old Member States (EU-15:

pharmaceutical expenditure of € PPPa 360.- per inhabitant) and the new ones (EU-10: € PPPa 250.- per inhabitant).

The **share of the health care budget spent on pharmaceuticals** is much higher in the new Member States (EU-10 average: 25.5%) compared to their fellow countries which have acceded to the EU earlier (EU-15 average: 16.1%). On EU-25 average, one fifth of the health budget is spent on pharmaceuticals.

In the majority of the PPRI countries, a large share of pharmaceutical expenditure (at least for prescription-only medicines) is **covered by third party payers** (EU-25 average: approximately 64%). In general, old Member States tend to finance a larger share of pharmaceutical expenditure publicly (EU-15 average: 71%) as compared to the new ones (EU-10 average: 50%).

Between the years 2000 and 2005 a few PPRI countries from the EU-15 zone, such as Sweden, the Netherlands or Italy managed to keep the **growth in pharmaceutical expenditure** below an annual average of five percent (EU-15 average: 7.0%). New EU Member States had higher average pharmaceutical expenditure growth rates (EU-10 average: 11.4%).

4.3 Key findings of the PPRI analysis

4.3.1 Investment in health and pharmaceuticals

The PPRI analysis has exposed considerable differences between PPRI countries concerning their economic situation and their spending on health care and pharmaceuticals.

There appears to be an economic difference between the old and the new Member States of the European Union, as the average **gross domestic product** (GDP) per inhabitant expressed in Euro Purchasing Power Parities (€ PPPa) in the EU-15 countries (average of € PPPa 27,942.-) is almost twice the EU-10 average (€ PPPa 14,193.-, year 2005).

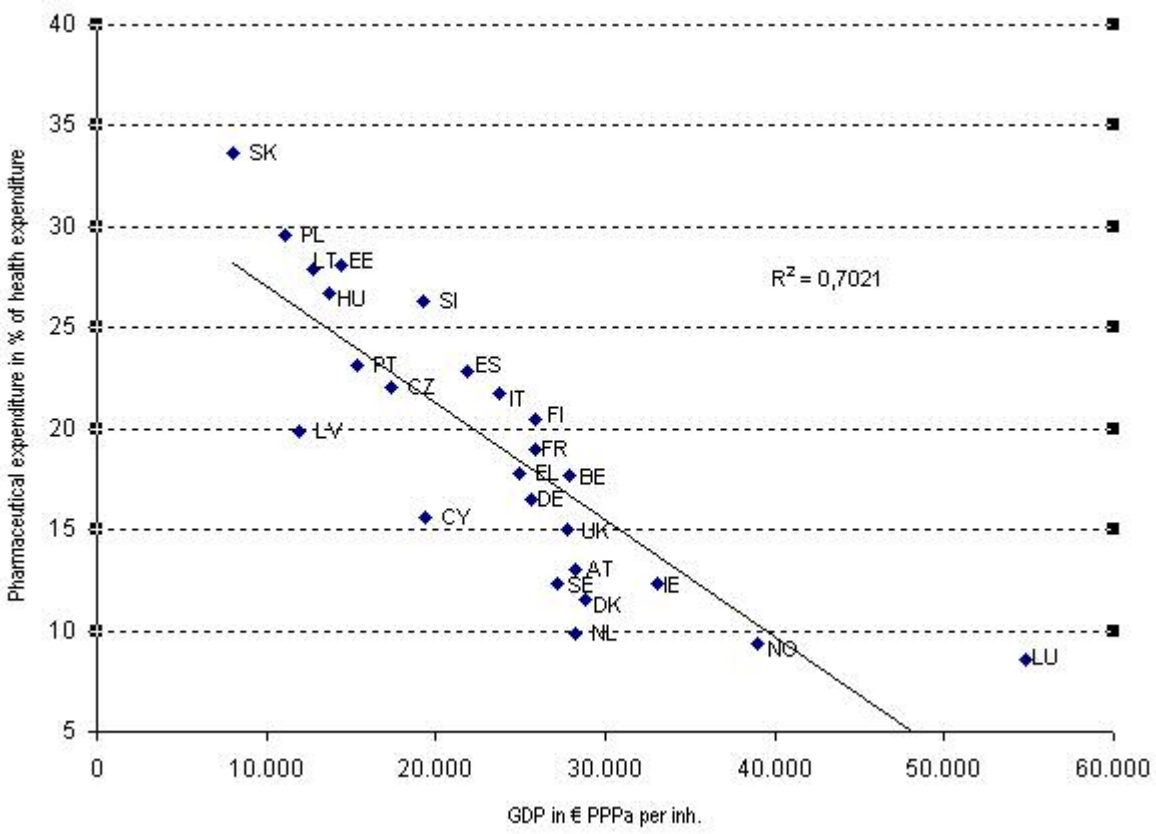
Regarding **health expenditure**, the new EU Member States spent on average € PPPa 965.- per inhabitant in 2004, whereas in EU-15 countries the average health expenditure per inhabitant amounted to about € PPPa 2,450.-. Thus, EU-15 countries spent per capita more than 2.5-fold on health than EU-10 countries.

The picture is similar with regard to **pharmaceutical expenditure**: In terms of € PPPa pharmaceutical expenditure amounted on average to about € PPPa 360.- per inhabitant in EU-15 countries, which is € PPPa 105.- more than in the new Member States (EU-10 average: € PPPa 254.-).

However, the **share of spending on pharmaceuticals within the health care budgets** tends to be, as the PPRI analysis has shown, higher in lower income countries (negative

correlation of R^2 = 0.7; cf. Figure 4.1). An explanation for this might be the relatively high prices of new pharmaceuticals throughout the EU (including the new Member States), whereas labour cost, which are linked with the economic wealth of a country and are consequently lower in new Member States, are a dominant factor of other – non-technology or non-pharmaceutical – related health expenditure (OECD 2004).

Figure 4.1: Lessons learned – Share of total pharmaceutical expenditure as percentage of total health expenditure in relation to GDP per inhabitant in the PPRI countries, 2005



GDP = Gross domestic product, inh. = inhabitant, PPPa = Purchasing Power Parities

GDP in € PPPa per inh. 2005: 2004 – AT, CY, ES, LU, NL, SI

Pharmaceutical expenditure in % health expenditure in 2005:
Year 2006 – BE; 2004 – AT, CY, CZ, EE, EL, ES, FR, HU, IT, LU, PL, PT, SE; NO

Pharmaceutical expenditure:
FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices
NL and SK: only prescription-only medicines (POM) market

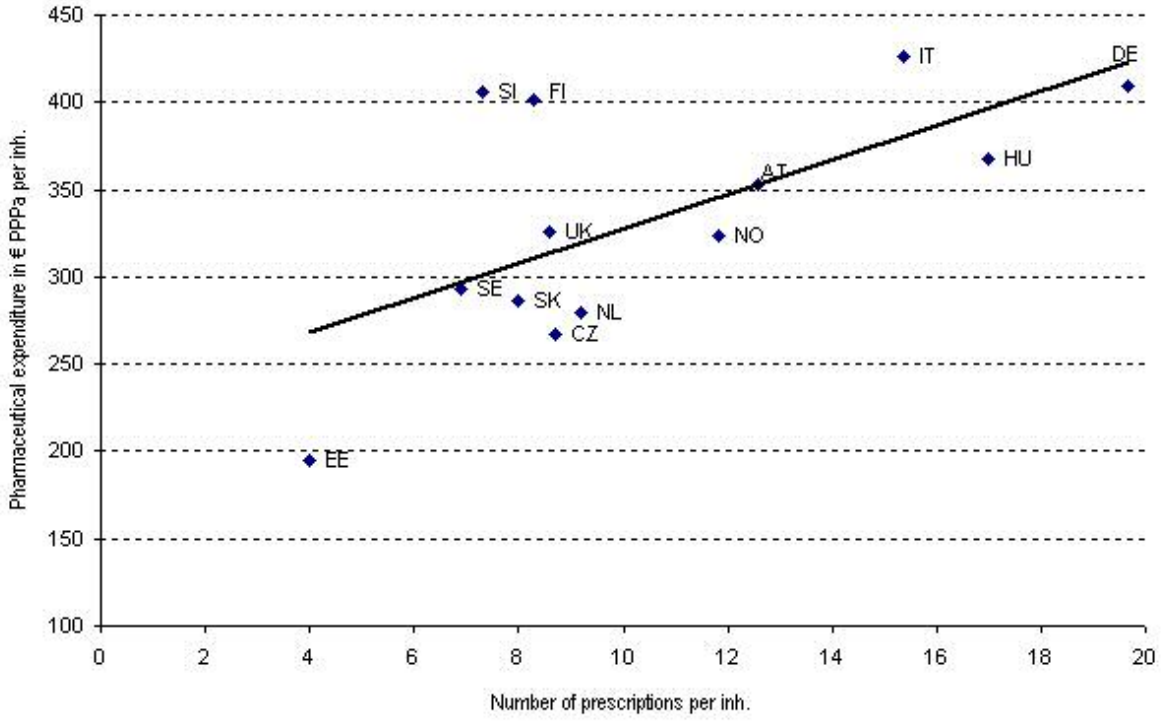
Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI analysis based on PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants, OECD Health Database 2006 for GDP in ES, NL, PT and for pharmaceutical/health expenditure in CZ, ES, IE, LU, PT, NO, EUROSTAT Yearbook 2006–2007 for GDP in LU; conversation rates by EUROSTAT

4.3.2 Pharmaceutical expenditure components

Pharmaceutical expenditure is the outcome of the price and volume component.

Figure 4.2: Lessons learned – Pharmaceutical expenditure per inhabitant in relation to the number of prescriptions per inhabitant in the PPRI countries, 2005



€ PPPa = Euro Purchasing Power Parities, inh. = inhabitant

Pharmaceutical expenditure:

2004 – AT, DE, SE; NO

FI: outpatient care at retail price with value-added tax (VAT) and sales to hospitals at wholesale prices
NL and SK: only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Prescription in volume:

Year 2006: 2005 – AT, DE, SE, SK, UK

CY: only public sector (1.8 prescriptions per inhabitant, year 2004), therefore not included in this figure
IT: volume in packs, EE: number of reimbursed prescription

Note: Different methods for counting (regarding counting the number items or packs as one prescription) are applied in the PPRI countries.

Sources: PPRI analysis based on PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants, OECD Health Database 2006 for pharmaceutical expenditure in CZ; conversation rates by EUROSTAT

Prices of international brands tend to be less influenced by the local market and national economic power than by manufacturers' global marketing strategies, which is also seen in the pharmaceutical sector. Price comparisons (e.g., ÖBIG PPI Service 2007) have shown that the prices of on-patent branded pharmaceuticals in the new EU Member States are often similar to those in the EU-15 countries.

The other part of the equation on pharmaceutical expenditure is consumption. There are considerable differences in **pharmaceutical consumption** between the PPRI countries. These result from differences in the age structure of the population, in country specific attitudes towards the use of pharmaceuticals (in general and on specific groups of pharmaceuticals, e.g. antibiotics, cf. EUROMEDSTAT 2004), the promotion of a rational use of pharmaceuticals in a country, and the extent of co-payments, which might pose a barrier to affordability.

In the PPRI project, the annual number of prescriptions per inhabitant was defined as a core indicator (see Set of Core PPRI Indicators, Annex II) to assess a country's pharmaceutical consumption in the prescription segment which is often similar to the reimbursement market. On average, in the PPRI countries nearly 12 prescriptions were issued per patient in 2006, with an average value of € 21.- per prescription.

Nonetheless, this indicator has to be read with caution as the number of items or packs is counted in different ways (being counted as one or several prescriptions) throughout the PPRI countries. Furthermore, continuous prescriptions is not reflected in the data presented. Figure 4.2. highlights differences in the number of prescriptions between the PPRI countries; in addition, it reveals the relevance of the volume component[36] in pharmaceutical expenditure.

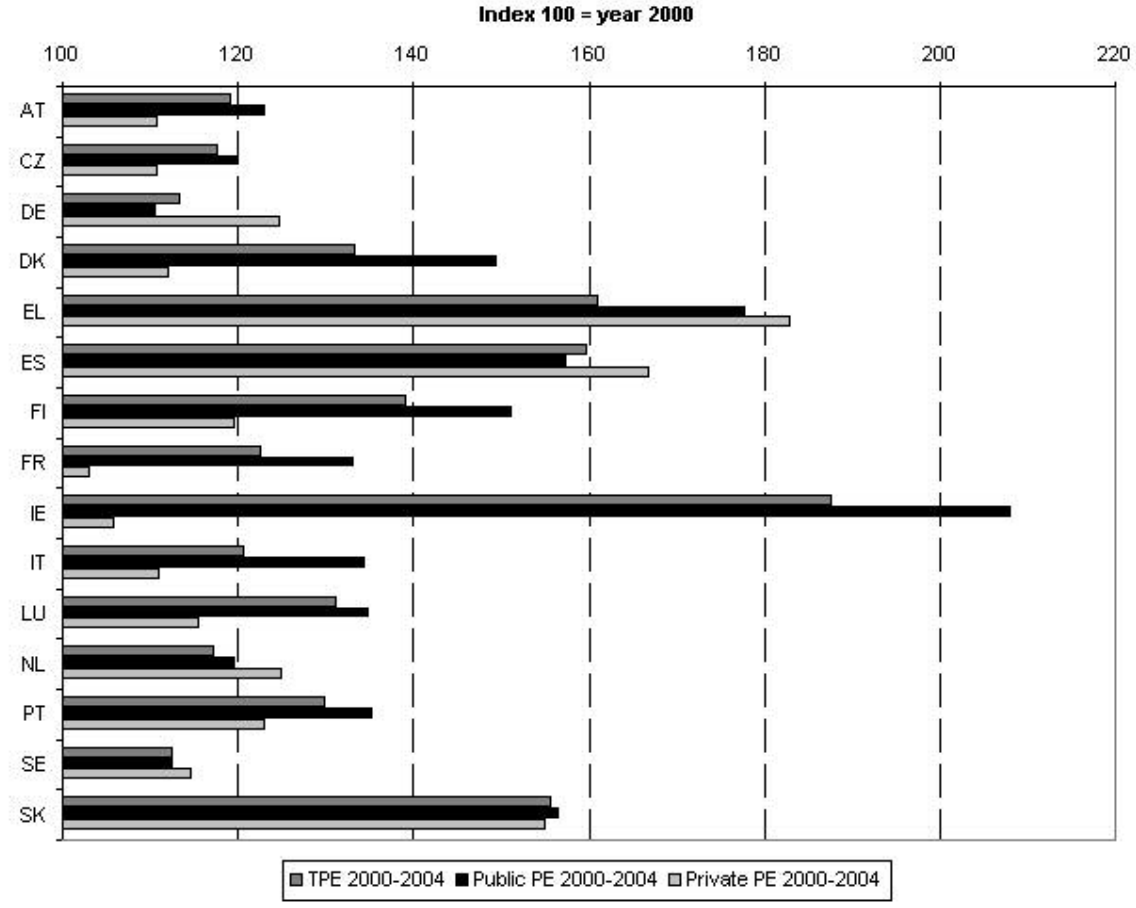
4.3.3 Growth of pharmaceutical expenditure by payers

In the new millennium (from 2000 to 2005), total pharmaceutical expenditure has grown at average annual growth rates of nine percent in EU-25 countries. A few countries in Western Europe have succeeded to keep their annual growth rates at about four to five percent, which is reflected in the average of EU-15 countries having lower growth rates (EU-15 average: 7.3%) compared to the new Member States (EU-10 average: 11.6%).

Total pharmaceutical expenditure has been increasing, as well as public pharmaceutical expenditure and private pharmaceutical expenditure. As Figure 4.3 displays, the growth in public pharmaceutical expenditure has been, sometimes considerably, higher than the increase in private pharmaceutical expenditure.

[36] Prescriptions are one, but not the only measurement of pharmaceutical consumption. Further indicators (however, not defined as core PPRI indicators) could be packages sold and/or utilisation measured in Defined Daily Doses (DDD).

Figure 4.3: Lessons learned – Growth in total, public and private pharmaceutical expenditure in the PPRI countries, 2000–2004



PE = Pharmaceutical expenditure, TPE = Total pharmaceutical expenditure

Growth rates of TPE, public and private PE: 2000–2002: CZ, 2000–2005: NL, 2000–2003: SK

IT: TPE – outpatient and inpatient sector; public and private PE – only outpatient sector

NL and SK: TPE, public and private PE – only prescription-only medicines (POM) market

Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical expenditure in some countries might still only refer to the outpatient sector.

Sources: PPRI analysis based on PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Despite of rising private, and total, pharmaceutical expenditure, the **share of private pharmaceutical expenditure as a percentage of the total pharmaceutical expenditure** has decreased in some PPRI countries, especially in those countries where pharmaceutical expenditure has grown at relatively moderate growth rates.

4.3.4 Cost-containment and rational use of pharmaceuticals

In the past ten and more years, PPRI countries have undertaken several cost-containment measures in the field of pricing (e.g., price and margins cuts) and reimbursement (e.g., increases in co-payments and de-listings) and have enhanced a more rational use of pharmaceuticals. Additionally, some institutional changes took place (e.g., establishment of Medicines Agencies or evaluation institutions).

Table 4.1 shows for five PPRI countries the most important characteristics and reforms regarding pricing, reimbursement and rational use. The selected countries are those which have had the lowest growth rates in pharmaceutical expenditure in the past five years.

Table 4.1: Lessons learned – Pharmaceutical policies in five selected PPRI countries, 2007

C.	Pricing	Reimbursement	Rational use
SE	• Linkage of pricing and reimbursement process • Prices of reimbursable ph. are evaluated as integral part of the cost-effective analysis • Simplified pricing procedure for generics to boost competition	• Positive list • Eligibility criteria for reimbursement: human value principle, need and solidarity principle, cost-effectiveness principle from a societal perspective • Consumption-based reimbursement[1], with an annual ceiling for private pharmaceutical expenditure • Drug committees at regional level • Systematic reimbursement reviews	• Prescription guidelines • Prescription monitoring and support for doctors by third party payers • Guidelines for pharmaco-economic analysis • Mandatory generic substitution, and clustering of substitutable pharmaceuticals
NL	• Statutory pricing for POM • External price referencing • Dispensing fee per prescription as pharmacy remuneration • Price cuts of generics (from 2004 on)	• Positive list • Reference price system • "Preference policy" by some health insurance institutions: reimbursement of least expensive ph. in a reference price group • Low co-payment (share of private funding of 2% of TPE in POM market) • Claw-back system for pharmacists	• Voluntary contracts between health insurance institutions and doctors on prescribing pattern • INN prescribing, supported by electronic prescription software • Indicative generic substitution, introduction was accompanied by information activities
AT	• Statutory pricing for reimbursable ph., based on external price referencing to all other EU Member States (EU average price system since 2004) • Prices of reimbursable generics have to be 48% lower than original product, price decreases for further generics • Regressive wholesale and pharmacy mark up schemes for all ph.	• New positive list since 2004 consisting of "boxes" (different rules concerning prescription procedure by doctors) • Negotiations between companies and social insurance on reimbursement price • All reimbursable ph. are reimbursed at 100% • Prescription fee, exemptions for vulnerable groups	• Guidelines for economic prescribing in the outpatient sector • Prescription monitoring and feed-back

C.	Pricing	Reimbursement	Rational use
IT	• Establishment of Medicines Agency in 2004, responsible for all aspects of pharmaceutical policy • Negotiation procedure for reimbursable ph. (since 2004) • Linear wholesale mark up and pharmacy mark up with regressive elements due to statutory discounts for reimbursable ph. • Several rounds of price cuts	• New positive list since 2003 • All pharmaceuticals on the positive list are reimbursed at 100% • Reference price system, extensively used in 2003 to cut prices • Prescription fee in some regions; exemptions for vulnerable groups	• Pharmacoeconomics (cost-effectiveness) started to play a role in the late 1990s
FR	• Statutory pricing for reimbursable ph. • Fast-track procedure based on external price referencing for innovative ph. • Regressive wholesale and pharmacy mark up schemes for reimbursable ph. • Lower VAT rate (2.1%) for reimbursable ph.; 5.5% on non-reimbursable ph. (standard: 19.6%) • Price reviews and price cuts	• High Authority of Health (HAS) for the assessment of ph. since 2004 • Positive list, covering 70% of all ph. on the market • Product-specific reimbursement, with reimbursement rates of 65%, 35% and 15% • 100% reimbursement for patients with long-term diseases and low income • Reference price system since 2003 • Systematic reimbursement reviews for years, having consequences on the reimbursement status and rates • Claw-back system for manufacturers	• Prescription monitoring and guidelines • Doctors are encouraged by agreement to prescribe by INN • Generic substitution with financial incentives for doctors and pharmacists • Social insurance representatives visiting doctors

C. = country, EU = European Union, INN = international non-proprietary name, ph. = pharmaceuticals, POM = prescription-only medicines, TPE = total pharmaceutical expenditure, VAT = value-added tax

[1] Consumption-based reimbursement: The level of reimbursement depends on the expenses for pharmaceuticals of a patient within a certain period of time (increasing reimbursement with rising consumption). Further eligibilty schemes are product-specific, disease-specific and population-group-specific reimbursement (for further information cf. PPRI Glossary, http://ppri.oebig.at → Glossary and section 3.3 of this PPRI Report)

Note: The assignment to the areas “pricing”, “reimbursement” and “rational use” was not always clearly possible. The selected countries are those which have had, among the PPRI countries, the lowest growth rates in pharmaceutical expenditure in the last five years.

Sources: PPRI analysis based on PPRI Pharma Profiles 2006/2007, additional information provided by PPRI participants

Initiatives for a more rational use of pharmaceuticals might contribute to cost-containment. The countries that have succeeded in keeping pharmaceutical expenditure at a rather moderate level are those countries, which rank above average with regard to economic wealth and which have constantly been engaged in the implementation of reform measures targeting both at price and volume.

Also in other PPRI countries a **policy of generic promotion** has shown to be an effective tool for accomplishing a more rational use of pharmaceuticals. In addition, generic policies have appeared to contribute to containing pharmaceutical expenditure. Often, generic substitution, which is allowed in 19 PPRI countries (thereof mandatory generic substitution in 6 countries) goes hand in hand with the existence of a reference price system (in 18 of the 27 PPRI countries).

4.4 Conclusions

There are 27 different pharmaceutical pricing and reimbursement systems in the 27 PPRI countries.

Pharmaceutical pricing and reimbursement policies have been and continue to be national issues. As the organisation of a pharmaceutical system is influenced by traditions and the prevailing political culture, national pharmaceutical policies allow for country specific traditional ways to tackle problems. Furthermore, national pricing and reimbursement policies are often customised for particular challenges in a country (e.g., age structure, lacking generic competition, high consumption).

Country specific challenges ask for country specific solutions. A lesson learned from the PPRI analysis is that “formulas for success” cannot simply be copied one-to-one from one country to the other; in order to be effective, policies have to be adapted to the country specific environment. Nonetheless, external price referencing has become quite popular among the 27 PPRI countries, as 22 are using this tool. Regarding reimbursement, 18 of the 27 PPRI countries feature a reference price system.

Initiatives for a dialogue and networking activities are appreciated by PPRI countries.

Network members are most interested to hear and learn from each other. The post-G10 process of the Pharmaceutical Forum achieved to bring pharmaceutical officials from all EU Member States together, and, at the same time, PPRI established an active network of representatives from pharmaceutical pricing and reimbursement authorities. The success of PPRI lies in the fact that, besides sharing knowledge, the PPRI group has produced a report containing information and data needed by the authorities and further stakeholders of the participating countries. Everybody has contributed with her/his country specific experience, and the PPRI network members have benefited from the inputs of the other countries.

Problems exist to understand each other. The fact of experts having their own national systems in mind and the ambiguous, though wide-spread, use of some technical terms could lead to confusion and misunderstandings. Within the framework of PPRI, this challenge was met by developing the PPRI Glossary guiding the about 30 authors from different countries and guaranteeing a common language in all PPRI deliverables. But at a general level, the problem continues to exist. PPRI endorses the need for a clear, uniform terminology regarding pharmaceuticals at EU level as this is an important prerequisite to understand each other.

The participating countries welcome the initiatives for a better communication and wish a continuation in a structured way. The launch of PPRI marked a turning point as the project brought together Competent Authorities and third party payers to compile national reports on pharmaceutical pricing and reimbursement. Nonetheless, besides PPRI there are other successful and comprehensive networks, and some (not all) PPRI network members are also involved in further groups and platforms (e.g., networking activities under the auspices of WHO, MEDEV group of the social insurance institutions, meetings of Heads of Agencies, cooperation of some of the neighbouring countries). As, not only in small countries, staff resources in authorities are restricted, officials wish to make best use of networking. In this respect, it is important to coordinate the post-PPRI process with the other initiatives[37] to avoid duplications.

Information on pharmaceutical pricing and reimbursement is needed by all stakeholders. There is a great need for information regarding pharmaceutical systems not only by the authorities, but also by patients and health professionals. Information on pharmaceutical pricing and reimbursement shall be directed to all stakeholders. Under the framework of the PPRI project, this was pursued by means of a comprehensive dissemination strategy, targeting all relevant stakeholders.[38] Additionally, the PPRI group discusses how to continue the network meetings, allowing an open dialogue between officials and experts sharing the same (non-profit) interest.

The rationale of reforms in the past years was not limited to cost-containment only, but also aimed at promoting a more rational use of pharmaceuticals.

Rational use of pharmaceuticals goes, to a great extent, hand in hand with cost-containment. In the 1990s, cost-containment was a key focus of reforms in the pharmaceutical sector. Since the new millennium especially in the richer EU-15 Member States, the rational use of pharmaceuticals, guaranteeing the correct provision to the individual patient (neither over-supply nor under-supply), increasingly gained importance. This covers generic promotion (i.e. prescribing by the INN name or generic substitution) and the quest for reasonable prescription patterns (including information to doctors and feed-back on prescription behaviour).

Lately, several PPRI countries have succeeded to contain pharmaceutical expenditure. The 1990s were characterised by several cost-containment measures, struggling with high growth rates in pharmaceutical expenditure. Between the years 2000 and 2005 some PPRI countries (e.g., Sweden, Netherlands) managed to keep the growth in pharmaceutical expenditure below an annual average of five percent.

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[37] PPRI has involved relevant initiatives and projects in the EU regarding pharmaceuticals. Thus, there was already a vivid exchange of information during the PPRI project (e.g., reporting on the status of other projects by representatives was on the agenda of all PPRI Coordination Meetings).

[38] Furthermore, the PPRI needs assessment addressed several stakeholders (ministries, third party payers and insurance companies, universities and public health institutes, representatives of the pharmaceutical industry, wholesalers and pharmacies; cf. section 2.3.2) on their information needs regarding pharmaceutical pricing and reimbursement.

Successful cost-containment does not necessarily mean shifting the burden to the patients. There has been evidence that in the 1990s the "success" of containing (public) pharmaceutical expenditure was achieved at the expense of patients which had to pay more. Now, a turning point of this trend can, at least for several EU-15 countries, be observed. In the new millennium, the share of private funding of pharmaceutical expenditure has, sometimes quite considerably, decreased in a number of European countries. The development of shrinking private funding was, in particular, observed in countries which have successfully contained pharmaceutical expenditure.

A global strategic approach versus single measures

In several countries, a set of well-defined strategies has proven to be effective in achieving cost-containment and a rational use of pharmaceuticals. Success factors for an effective pharmaceutical strategy, which contributes to keeping pharmaceutical expenditure at moderate growth rates and to guaranteeing affordability, equity and a rational use of pharmaceuticals, have to work at several fronts: Taking the national framework and culture into account, sometimes inter-depending measures should be combined: Pricing policies shall be accompanied by reimbursement strategies, and both, price and volume control, can be necessary.

A joint consensual policy environment tends to have a positive impact on the acceptance of decisions. The best reform is likely to fail if there is insecurity and lack of understanding among key stakeholders (in particular patients, prescribers, pharmacists and pharmaceutical industry) who consequently either ignore the measures or oppose them.

Investment in analysis and monitoring tools pays off. The PPRI group finds that it pays off to invest enough resources for information activities as well as the analysis and monitoring of policies. These are, in the first place, human resources, i.e. adequately staffed agencies and institutions, who are encouraged to introduce and follow-up processes of a, if necessary, critical and controversial dialogue with the stakeholders concerned. In this respect, regular monitoring of prescription behaviours, accompanied by feed-back to the doctors, is an effective measure. Additionally, well developed information technology (IT) systems as supporting tools for an in-depth analysis are an investment which definitely pays off – not only for the third party payer, but for the whole health care system.

Pharmaceutical policies are subject to a "pendulum effect". Policies may be effective in the short run, but after some time the stakeholders concerned will learn to find loop-holes. Therefore, measures need to be monitored and, if necessary and appropriate, be refined in a regular intervals.

Challenges

There are major data availability problems. In the process of compiling and reviewing the PPRI Pharma Profiles, gaps on data needed for the developed core indicators have become evident in several countries. This concerns, for instance, essential information such as consumption data (prescriptions) or the funding of pharmaceutical expenditure (private/public expenditure) which some countries could only deliver since a few years due to a change in

country-wide statistics. Therefore, adequate steps for enhancing an improvement in data availability, also regarding current up-to date information shall be initiated.

Furthermore, lacking data comparability limits drawing of conclusions. In addition to non-availability, cross-national definitions which differ considerably in some cases should be tackled. This regards, for instance, indicators like the generic market share, which may be expressed in prescriptions or packs and may relate to the total, the prescription or the reimbursement market. Not even a good picture on the number of pharmaceuticals in the EU Member States is available, due to differences in national counting methods. Quality problems and limited data comparability is not an academic issue of a few scientists, but has major consequences for the interpretation of analyses, thus biasing important decisions.

Pharmaceutical policies in the hospital sector need to be further investigated. The pharmaceutical service in the inpatient sector plays an important role and influences the provision of pharmaceuticals, and also pharmaceutical expenditure, in the outpatient sector. However, pricing policies and practices in the hospital sector have not been addressed by the PPRI project neither have they been the focus of other European research projects. There is a need for paying greater attention to the hospital sector with regard to the intramural rational use of pharmaceuticals and to the interface between the inpatient and the outpatient sector. Therefore, pharmaceutical policies in hospitals shall be surveyed, and, additionally, initiatives for a better cooperation between the inpatient and outpatient sector shall be promoted.

Information on pharmaceutical pricing and reimbursement needs to be regularly updated. In the course of the PPRI project, more than 20 Pharma Profiles were produced which provide in-depth information on country specific pricing and reimbursement frameworks and which offer a good basis for analyses in the near future. However, pharmaceutical systems are rapidly changing; there is at least one major change regarding pharmaceutical policies in each country every two to three years. PPRI participants have expressed their interest to up-date their Pharma Profiles in annual intervals after the end of the PPRI research project.

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Annex

All documents of Annex I and Annex II are included on the attached CD.

Annex I: PPRI Pharma Profiles

PPRI Pharma Profile Austria

PPRI Pharma Profile Belgium

PPRI Pharma Profile Bulgaria

PPRI Pharma Profile Cyprus

PPRI Pharma Profile Denmark

PPRI Pharma Profile Estonia

PPRI Pharma Profile Finland

PPRI Pharma Profile France

PPRI Pharma Profile Germany

PPRI Pharma Profile Greece

PPRI Pharma Profile Hungary

PPRI Pharma Profile Ireland

PPRI Pharma Profile Italy

PPRI Pharma Profile Latvia

PPRI Pharma Profile Lithuania

PPRI Pharma Profile Norway

PPRI Pharma Profile Poland

PPRI Pharma Profile Slovakia

PPRI Pharma Profile Sweden

PPRI Pharma Profile Turkey

PPRI Pharma Profile United Kingdom

Annex II: PPRI Tools and Reports

List of PPRI Participants

List of PPRI Dissemination Activities

PPRI Needs Assessment Report

PPRI Pharma Profile Template (version as of 2006, used by the PPRI Participants)

PPRI Pharma Profile – Executive Summary Template

PPRI Pharma Profile Template – Priority List for Chapter 1

PPRI Glossary

Set of Core PPRI Indicators

PPRI Indicators Short List