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Pharmaceutical Pricing and Reimbursement Information (PPRI) – New PPRI analysis including Spain

Sabine Vogler[a,*], Jaime Espin[b] and Claudia Habl[a]
[a]*Health Economist at the Austrian Health Institute GÖG/ÖBIG, Vienna, Austria*
[b]*Professor at the Andalusian School of Public Health (EASP), Granada, Spain*

The EU-funded project Pharmaceutical Pricing and Reimbursement Information (PPRI) offers country specific information on pricing and reimbursement for numerous EU Member States and indicators for a comparative analysis. This article presents relevant pharmaceutical pricing and reimbursement information in a comparative analysis for 28 countries and also a detailed description about the Spanish pricing and reimbursement system.

1. Introduction: European initiatives and networks on pharmaceutical policies

The last three years have been very productive in pharmaceutical policies in creating platforms for an exchange of information between the stakeholders and in collecting, analyzing and benchmarking information.

An important initiative has been the Pharmaceutical Pricing and Reimbursement Information (PPRI) project.[1] It built up a network of competent authorities and provided a comparative analysis of pharmaceutical pricing and reimbursement systems. PPRI project management has always been committed to knowing about other relevant projects and initiatives and to cooperating with them. In this context, the involvement of the PPRI project leaders as technical experts to the Working Group on Pricing of the Pharmaceutical Forum has been of great importance.

The Pharmaceutical Forum[2] was launched as political initiative by DG SANCO and DG Enterprise Commissioners with the aim of improving the performance of the pharmaceutical industry in terms of its competitiveness and contribution to social and public health objectives. The Forum has brought together Ministers from all European Member States, representatives of the European Parliament, the pharmaceutical industry, health care professionals, patients and insurance funds. Three were the Working Groups (Information to Patients, Pricing and Relative Effectiveness)

*Corresponding author: Sabine Vogler, GesundheitÖsterreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen (GÖG/ÖBIG), Stubenring 6, A 1010 Vienna, Austria. Tel.: +43 1 51561/147; E-mail: vogler@goeg.at.

[1]http://ppri.oebig.at.

[2]http://ec.europa.eu/pharmaforum/.

that were established as support to a Steering Committee. On 2nd October 2008, the Pharmaceutical Forum agreed on some conclusions and recommendations [1].

During this process, some interested products have been developed. To mention are the "toolbox" [2], a comprehensive instrument where some pharmaceutical policy practices are collected in summary templates, with set-up conditions, risks and benefit of there practices are described; or the "Guiding principles for good practices implementing a pricing and reimbursement policy" [3] based on a report by Andalusian School of Public Health (Escuela Andaluza de Salud Pública – EASP) [4].

In this article, we will describe the objectives, organisation and outcomes of the PPRI project. One key PPRI deliverable is the national country reports on pharmaceutical pricing and reimbursement, known as PPRI Pharma Profiles. To illustrate the structure and the main indicators of such a national report, a brief version of a Spanish Pharma Profile will be produced for the first time. The comparative analysis which follows is thus not only based on the 27 PPRI countries, but also includes Spain.

2. What is PPRI?

Originally, PPRI was 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 was undertaken by the main partner called Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) in cooperation with the associated partner World Health Organisation, Regional Office for Europe (WHO Europe).

The PPRI project, which started in April 2005 and ended in October 2007, aimed at improving 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 and compiling a comparative analysis based on 21 core indicators and on country specific reports (PPRI Pharma Profiles).

Today, PPRI is a sustainable network of authorities and institutions allowing for a quick exchange of information. The network members launch and answer ad-hoc queries and they meet regularly.

2.1. PPRI network

In the initial stages of the project, the PPRI project management planned to build a network consisting of one relevant authority from each EU Member State. In fact, as the PPRI network and its benefits for the participating countries became better and better known several additional institutions joined.

Currently, the PPRI network includes 56 institutions from a total of 31 countries (all EU Member States except Romania, plus Albania, Canada, Norway, Switzerland, and

Turkey). The majority of the participating institutions are national authorities, mainly Ministries of Health, Medicines Agencies and Social Insurance institutions. In addition, European and international institutions (European Medicines Agency, OECD, WHO and World Bank) and representatives of related initiatives (e.g. Medicine Evaluation Committee) and projects (e.g. Andalusian School of Public Health/EASP) joined the network.

2.2. PPRI pharma profiles

The increase in transparency was achieved by the exchange of information at network meetings and in answering internal network queries and also by the compilation of in-depth country profiles, known as PPRI pharma profiles [5].

In order to guarantee readability and comparability of the data and information, the PPRI Pharma Profiles follow a uniform, homogenous outline, the PPRI Pharma Profile Template. The development of the Template was based on the outcome of a large-scale needs assessment, involving 101 national stakeholders and 14 European and international institutions.

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 (approximately 60 pages each) offering in-depth information on the pharmaceutical pricing and reimbursement systems as of 2006/2007 were published.

2.3. PPRI Glossary

During the development of the PPRI Pharma Profile Template, misunderstandings and differences in the interpretation of technical terms became evident among the national PPRI participants. Therefore, an additional deliverable, the PPRI Glossary covering key terminology regarding pharmaceutical pricing and reimbursement, was developed and is considered as binding for the authors of the PPRI Pharma Profiles.

Today, the PPRI Glossary [6], 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.

2.4. Set of core PPRI indicators and comparative analysis

In order to compare information, indicators were developed. The final set comprises 21 indicators for comparison of “hard” quantitative figures like pharmaceutical

expenditure and prescriptions as well as qualitative information on pricing and reimbursement [7]. Based on these indicators, a comparative analysis was undertaken and included in the PPRI Report [8].

All PPRI deliverables (PPRI Pharma Profiles, PPRI Glossary, PPRI Indicators, PPRI Comparative Analysis, etc.) are accessible on PPRI website, see http://ppri.oebig.at.

3. Case study: Pharmaceutical pricing and reimbursement system in Spain

As yet, Spain is not among the 22 countries which have provided a PPRI Pharma Profile yet. However, in this article we give a brief description on the current pharmaceutical pricing and reimbursement system in Spain.

3.1. The National Health Service

In 1986, the General Health Law established a National Health Service (NHS) in Spain. It is a universal health care management decentralised system, with universal coverage and finance from general taxation. There are 17 Autonomous Communities which have complete competence regarding public health, healthcare services planning and full control of budgets. Health care is provided free of charge except for pharmaceuticals.

In November 2004, the Spanish Minister of Health presented a Strategic Pharmaceutical Policy Plan (*Plan Estratégico de Política Farmacéutica para el Sistema Nacional de Salud Español*) which should guide the Spanish Health Administration for the following four years. The key lines of this plan were laid down in a package of 67 policy measures in order to achieve a more rational use of medicines and specially in order to contain public spending on pharmaceuticals. Now a new Strategic Pharmaceutical Policy Plan is under elaboration.

In 2006, a new pharmaceutical law was approved and got in force in July: the Law of "Guarantees and the Rational Use of Medicines and Health Products, Law 26/2006". The new law replaced the Spanish Medicines Law of 1990 and, among others, introduced a modified reference price system. The new law also incorporated into Spanish Law the European Directive 2004/27/CE on the Community code relating to medicinal products for human use and Directive 2004/28/CE on the Community code relating to veterinary medicinal products.

3.2. Pricing

In Spain the reimbursement decision precedes the price decision, since only reimbursable products have a regulated price.

The pricing of reimbursable prescription-only pharmaceuticals is carried out by the Interministerial Commission on Pharmaceutical Prices operating under the Ministry

of Health, which is made up of representatives of the Ministry of Health, the Ministry of Finance and the Ministry of Industry. The Interministerial Commission on Pharmaceutical Prices decided on the maximum ex-factory price, but the final decision is formally undertaken by the Directorate General of Pharmacy and Health Products of the Ministry of Health. The Interministerial Commission will take into account, according to the new Pharmaceutical Law, the therapeutic utility reports provided by the Spanish Agency for Medicines and Health Products, which will cooperate with a team of external experts to be proposed by the Autonomous Regions. Until this procedure is settled, these reports are made by the technical unit of the General Directorate of Pharmacy.

Manufacturers are free to set the price of non-reimbursable pharmaceuticals. However, final prices still need to be approved, though it is simply an administrative procedure.

There are two types of non-prescription medicines in Spain, with pricing regulations varying:

- Non-advertisable OTC: they have to follow the same pricing process as other pharmaceuticals and can be reimbursed if prescribed.
- Advertisable OTC (Especialidades Farmaceuticas Publicitarias, EFPs): prices are not regulated at the manufacturer level but the retail price has to be the same in all pharmacies - except for an optional discount of up to 10% (including VAT) that pharmacists are permitted to offer.

Generics (Especialidades Farmacéuticas Genéricas, EFG) follow the same pricing procedure as other reimbursable prescription medicines without the therapeutic utility report. According to Article 93.3 of Pharmaceutical Law, generics included in the reference price system must be priced at, or below, the reference price level.

3.2.1. Manufacturer price

The manufacturer price of all prescription-only medicines is set by the Interministerial Commission on Pharmaceutical Prices. In the pricing process, the criteria that are assessed are the same that for reimbursement (Art. 89 of the Pharmaceutical Law); in addition, the methodology of European average price comparison (external price referencing) is applied. (Art. 90: Price fixing: "*2. Within the framework of the procedure for the financing of pharmaceuticals with public funds, referred to in Article 89 of the present Law, it corresponds to the Interministerial Commission on Pharmaceutical Prices, dependent on the Ministry of Health, to fix, on the basis of reasoned and objective criteria, the maximum industrial price for pharmaceuticals and medical devices that are to be included in the pharmaceutical provision of the National Health Service, for the account of public funds, and dispensed, under an official prescription, within the national territory. In addition to the criteria set forth in the Art 89.1, there will also be taken into account the average price for the pharmaceutical in the member States of the European Union which, without being subject to exceptional or transitory policies in relation to industrial property would*

Table 1
Spain – Pharmaceutical pricing system, 2008

Pricing	Manufacturer level	Wholesale level	Pharmacy level
Free Pricing	Non-reimbursable pharmaceuticals, parallel exported pharmaceuticals	Non-reimbursable pharmaceuticals, parallel exported pharmaceuticals	Non-reimbursable products, parallel exported pharmaceuticals
Statutory Pricing	Reimbursable pharmaceuticals	Reimbursable pharmaceuticals, regulated via fixed margins (with maximums)	Reimbursable pharmaceuticals, regulated via fixed margins (with maximums)
Price/volume agreements, discounts/rebates	Payback to NHS according to annual company sales (up to 3 million € 1.5%; from 3 million € 2%)	Not applied	Discount from wholesales to pharmacies (volume, cash sales). On OTC products a 10% discount for patients is allowed
Institution in charge of pricing	Interministerial Commission on Pharmaceutical Prices (Comision Interministerial de Precios de los Medicamentos)		
Basis	Ley 29/2006, de 26 de julio, del Medicamento (Pharmaceutical Law) Royal Decree 2402/2004		

Source: GÖG/ÖBIG, EASP and Spanish Health Ministry 2008.

have incorporated the corresponding European Community legislation into their own legal system.")

Manufacturers receive a preliminary note regarding the Interministerial Commission's proposed price. Manufacturers can appeal in case of disagreement, but they can also choose to launch the product unreimbursed.

The price which was fixed may be revised at the administration's initiative or at the request of the manufacturers. In this case, the process is similar to that for obtaining an initial price, although companies also have to submit an application for modification of the price and a document justifying why the price should be increased. Apart from the cases previously determined, the price of a pharmaceutical can be modified when changes in the economic, technical or health circumstances or in the assessment of their therapeutic utility make it necessary (Art 91).

Generic manufacturers are legally obliged to price their products at or below the reference price. For competitive reasons most of them opted for cutting their prices to a level below the reference price.

Regarding hospital pharmaceuticals, public tender procedures are common (for example, generics). Where there is no competence, negotiations on prices are used (even some risk-sharing agreements were signed).

3.2.2. Wholesale price

The wholesale margin is a statutorily fixed rate of 7.6% of the wholesale price if the manufacturer price for a pharmaceutical is below €91.63 (Table 2). If the

Table 2
Spain – Wholesale and pharmacy margins, as from August 2008 on

Manufacturer price in € (excl. VAT)	Wholesale margin	Pharmacy margin
0.00–91.63	7.6% of the wholesale price	27.9% of pharmacy retail price
> 91.63	€7.54	€38.37

Source: Royal Decree 823/2008.

Table 3
Spain – Pharmacy claw-back levels, 2008

Total sales (pharmacy retail price incl. VAT) up to €	Deduction	Rest up to	Percentage
32,336.12	0	43,583.47	8.00
43,583.47	899.79	58,345.61	9.4
58,345.61	2,287.43	120,206.01	10.9
120,206.01	9,030.21	208,075.90	13.5
208,075.90	20,892.64	295,242.83	14.5
295,242.83	33,531.85	Forward	15

Source: Royal Decree 823/2008.

manufacturer price is higher than €91.63, the wholesale margin is a fixed sum of €7.54, as of August 2008.

These margins apply to all pharmaceuticals – reimbursable and non-reimbursable pharmaceuticals, branded pharmaceuticals and generics, and OTC.

3.2.3. Pharmacy retail price

The pharmacy margin for pharmaceuticals with a manufacturer price below €91.63 is statutorily fixed at 27.9% of the pharmacy retail price as of August 2008. If the manufacturer price is higher than €91.63, the pharmacy margin is a fixed sum of €38.37 per pack (Table 2). The pharmacy margins also apply to all pharmaceuticals.

A pharmacy clawback system has been in place since August 2000, with pharmacies making payments based on a percentage of their annual sales of reimbursable pharmaceuticals at manufacturer prices. Changes to the operation of the system came into effect in 2004, in February 2005 and May 2008 (cf. Table 3).

3.2.4. Value Added Tax (VAT)

The standard VAT rate is 16% and the VAT rate for pharmaceuticals is 4%.

3.3. Reimbursement

Once a pharmaceutical is authorized and registered, the Ministry of Health decides, upon grounded resolution, before it is launched on the market, on the inclusion into the pharmaceutical coverage of the National Health Service (Art. 89 of Pharmaceutical Law – Public financing procedure). The decision on inclusion into reimbursement

lays in the competence of the Directorate General of Pharmacy and Health Products of the Ministry of Health.

There are four reimbursement categories, resulting co-payment rates:

1. 100% reimbursement for hospital pharmaceuticals
2. 90% reimbursement for pharmaceuticals for the management of chronic illnesses such as epilepsy, asthma and diabetes (price up to €2.64)
3. 60% reimbursement for the majority of prescription-only pharmaceuticals (70% for civil servants in mutualities as MUFACE)
4. 0% reimbursement for pharmaceuticals on the negative lists

In Spain, the National Health Service covered 94% of the cost of all pharmaceutical prescriptions in 2007 and 100% of cost of the pharmaceuticals prescribed in hospitals. Hospital pharmaceuticals are for free for inpatients and outpatients (for example, patients that receive ARV pharmaceuticals).

3.3.1. Selection criteria

The following criteria are considered when the Ministry of Health makes reimbursement decisions (Art. 89 of Pharmaceutical Law – Public financing procedure):

a) The severity, duration and sequels of the different pathologies for which they are indicated
b) The specific necessities of certain groups of people
c) The therapeutic and social usefulness of the pharmaceutical
d) The rationalization of the public expenditure addresses to the pharmaceutical
e) Existence of pharmaceuticals or other alternatives for the same diseases
f) The degree of innovation of the pharmaceutical

3.3.2. Positive list

The majority of reimbursable pharmaceuticals are prescription-only medicines. Several non-prescription pharmaceuticals are reimbursed under the condition that they are prescribed by a doctor.

In Spain, nearly 12,000 pharmaceutical products (counted including different pharmaceutical forms, dosages, and pack sizes) have a market authorization. 75% of these pharmaceuticals are prescription-only medicines, so they account for the core business in a pharmacy. 73% of all pharmaceuticals are reimbursable.

3.3.3. Negative lists

In Spain, if a pharmaceutical falls into a therapeutic group which is excluded from reimbursement, it is automatically excluded from public financing. This results in an out-of pocket payment of 100% of the price of the pharmaceuticals. The Spanish government used this policy for the first time in 1993, and in 1998 and in 2003 the list of excluded groups was modified.

The Spanish 1993 Royal Decree had two main objectives: (1) to prioritise public financing for those pharmaceuticals whose need or the severity of the illnesses for

Table 4
Spain – Pharmaceuticals on the market, 2000–2007

Pharmaceuticals[1]	2000	2001	2002	2003	2004	2005	2006	2007
ph. with market authorization	11,806	11,094	12,775	11,137	11,157	11,783	10,706	11,998
POM	9,226	9,403	10,181	9,056	9,119	10,074	8,030	9,058
EFP	1,241	1,238	1,253	1,152	1,163	1,127	n.a.	n.a.
Reimbursable ph.	8,922	8,756	9,580	8,348	8,474	9,569	7,898	8,790
Generics	580	857	1,211	1,669	1,675	2,202	2,782	3,608

EFP = Especialidades Farmaceuticas Publicitarias, n.a. = not available, ph. = pharmaceuticals, POM = Prescription-only medicines.
[1]Data per 1 January. Pharmaceuticals for human use, excluding magistral or officina formula, counted including different pharmaceutical forms, dosages, pack sizes.
Source: GÖG/ÖBIG, EASP and Spanish Ministry of Health 2008

which they were used was greater, and (2) to exclude from public financing those pharmaceuticals with low therapeutic value. This led to the development of the first negative list. The government introduced a second list of excluded medicines in 1998 (834 products corresponding to 39 therapeutic groups). The second list was not accepted by some Autonomous Communities (Andalucia and Navarra, for example), which decided to finance the consumption of excluded medicines with funds from its own budget. The last Royal Decree excluded 98 therapeutic groups.

Prescription-only to OTC switches are uncommon in Spain. A list of active ingredients suitable for switching is published. All pharmaceuticals containing these active ingredients may have their status changed if the manufacturer applies for the switch to the Spanish Agency for Medicines and Health Products, although not many companies choose to do so. Only around three to four products are switched from prescription-only to OTC each year. In all cases, switching to EFP status leads to a loss of reimbursement.

3.3.4. Reference price system

The reference price system, first introduced in 2000, was radically modified in 2004 and 2006.

Reference price groups include all pharmaceuticals with the same active substance and route of administration (ATC 5). Although each group must contain at least one generic version, there is no bio-equivalence requirement. This means that pharmaceuticals with the same active ingredient but different doses, as well as corresponding copy products, are included in the same group. Original branded products, with no generic equivalent available, are not included in the reference price system.

The reference price for each group is calculated as the arithmetic mean of the three lowest costs per treatment and day of the pharmaceutical presentations included in the group, for each route of administration, calculated in accordance with the defined daily dose. The three products selected must be produced by three different companies. Products with a manufacturer price below €2.- are excluded. Reference prices can be revised on an annual basis (or twice a year, according to a new proposal).

The latest reference price system was introduced with the new Pharmaceutical Law (Art. 93), specified by a Royal Decree .Under the new system, the price of generics must be reduced to or below the reference price of the reference group which they were assigned to in the within two months after the legislation had come into force.

In May 2004, 200 pharmaceuticals were added to the reference price system. After these changes were made, the reference price system covered 2,270 presentations, 72 active ingredients and 94 groups. In 2006, the reference price system covered 4,237 presentations, 119 active ingredients and 136 groups; in 2007 it has been added 169 presentations, 14 active ingredients and 14 groups. In 2008 a new updated will be made to the reference system. With this update, nearly half of the reimbursement market will fall under the reference prices system.

It is important to understand that the current Spanish reference price system is different from the system applied in other European countries, mainly because it works as a maximum price system for those pharmaceuticals included in the homogeneous groups. In addition, patients do not have the option of paying the difference between the reference price and the pharmacy retail price of the pharmaceuticals.

3.3.5. Out-of pocket payments

In Spain, there is a percentage co-payment. There is neither a prescription fee nor a deductable. Exemptions from co-payment are for retired people (0% co-payment) or people with chronic disease (10%).

3.4. Rational use

3.4.1. Prescription monitoring

As from January 2003 on, all 17 Spanish regions have full responsibility for defining their own health budgets. The Law of Cohesion and Quality of the National Health Service sets a common legal framework and guarantees a minimum level of health services to be provided by all regions.

As a tool to target physicians' prescribing habits, some regions use incentives for doctors to stick to a specified budget. Prescribing controls were implemented at a regional level in line with the regions' autonomy in health matters. The regions are currently experimenting with budgets and incentives for GPs to reduce pharmaceutical expenditure and increase awareness of prescribing costs. Andalusia, for example, offer doctors financial incentives to prescribe pharmaceuticals with high therapeutic effectiveness and prescribe by active ingredients, by addressing GPs to set targets regarding both efficiency and quality of their prescribing practices.

Some of the Autonomous Regions launched electronic prescription monitoring systems to verify physicians' prescribing habits and to help combat fraud. National and regional authorities implemented further prescribing controls in an attempt to contain pharmaceutical expenditure. A number of pharmaceuticals fall under a national prior inspection visa system (*visados previos de inspección*), which aims to ensure that products are used for the right indications. Under the scheme, a

prescription can only be dispensed after confirmation of the regional inspection services that the product is used correctly. Regional evaluation committees were also established to increase the quantity and quality of information available to doctors, as well as raising their awareness of the price differences between similar pharmaceuticals.

3.4.2. Pharmaco-economics

Pharmaco-economic studies are beginning to be used in several decision making contexts, although their submission is neither mandatory nor is it clear to what extent they actually influence the outcome of price and reimbursement decisions. A Spanish proposal for methodological standardisation of economic analysis of health technologies and programs was compiled in 1995, and a new proposal has been recently published. Although these proposals have been sponsored by the Ministry of Health they never got an official/mandatory status.

Providing pharmaco-economic evidence is not mandatory but companies normally submit a pharmaco-economic report showing the pharmaceutical's budgetary benefits along with the pricing dossier. Although the previous Strategic Plan mentioned that pharmaco-economics studies would be used as criteria to determine the price of pharmaceuticals (joint to therapeutic value studies), the new Pharmaceutical Law does not explicitly state it. According to Art. 92 pharmaceutical companies are asked to provide, for the pricing procedure the Ministry of Health with all information on technical, economic and financial aspects.

3.4.3. Generics

The 1990 Medicines Act was modified in 1996 and in 1997 in order to pave the way for the introduction of generic pharmaceuticals within the Spanish health care market. In July 1997, the first generic brands were authorized for commercial distribution.

In Spain generic substitution is allowed unless it is specifically excluded by the prescriber. It is mandatory for pharmaceuticals under the reference price system when the generic has the lowest price. In such a case the pharmacist must dispense the pharmaceutical having a lower price and, should the price be the same, a generic one (Art 93.4c of the Pharmaceutical Law).

For pharmaceuticals under the reference price system when the generic has the lowest price it is mandatory unless it is specifically excluded by the prescriber. When the prescription is made by active ingredient subject to reference price, the pharmacist must dispense the pharmaceutical having a lower price and, should the price be the same, a generic one (Art 93.4c of the Pharmaceutical Law)

The new Pharmaceutical Law promotes the prescription by International Non-proprietary Name (INN). In this sense, Art 85 states that "The health Authorities shall encourage the prescription of pharmaceuticals identified by their active ingredient in the prescription. In cases where the prescribing person merely indicates an active ingredient on the prescription, the pharmacist shall dispense the pharmaceutical having the lowest price and, should the price be the same, the generic one, if available".

The new Law has also introduced the so called "Bolar Provision" which allows manufacturers of generic products to carry out the necessary studies to show that the products meet the definition of a "generic medicine" and all other necessary activities to apply for marketing authorization before the expiry of the patent, "although the EU harmonized period of data exclusivity for the innovation is guaranteed by establishing that the pharmaceutical may not be commercialized until ten years have elapsed, or eleven years if it obtains an additional indication with a significant clinical benefit in comparison with existing therapies".

In 2004 generics represented 4.96% of total prescription medicines sales by value and 9.13% by volume. In June 2008, generics represent 8.82% of total prescription medicines by value (an increase of 50%) and 21.46% by volume (more than a 100% increase).

Spain is one of the lowest priced markets in the European Union and, as a consequence, one of the leading parallel exporters of pharmaceuticals. However, during the last years parallel import started to play a role in Spain because the new Member States have lower prices than Spain.

4. Comparative analysis

22 participating countries submitted a PPRI Pharma Profile, and five further countries contributed input to the PPRI comparative analysis. In the PPRI report, these 27 countries have been referred to as PPRI countries. The PPRI countries include all EU Member States except Spain and Romania, plus Norway and Turkey. As this article contains also information on Spain, we present in the following an adapted comparative analysis covering 28 countries, hence forward referred to as "the countries" and "the group". Please note that the information refers to the outpatient sector and to the year 2008 unless stated differently.

4.1. Indicators for the comparative analysis

As stated in Section 2.4, PPRI developed a set of 21 core indicators. In the following analysis, we will focus on the indicators for pricing (three indicators: pricing policies at manufacturer level, pricing policies at distribution level, taxes on pharmaceuticals), for reimbursement (three indicators: positive/negative list, reference price system, out-of pocket payments / mechanisms for vulnerable groups) and a few indicators regarding rational use (prescription guidelines, prescription / consumption monitoring).

4.2. Pricing

In 25 of the 28 countries of the group prices are controlled for outpatient pharmaceuticals, whereas hospital pharmaceuticals are mostly purchased via public procurement. Denmark, Germany and Malta are the only three countries of the group

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 countries (e.g. in Finland, Italy, Poland), price control is limited to pharmaceuticals with reimbursement eligibility (i.e. reimbursable pharmaceuticals), while for non-reimbursable pharmaceuticals, which are often OTC (Over-the-Counter) products, the manufacturer/importer is free to 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 countries (e.g. Italy, France) pharmaceutical prices are negotiated between the manufacturer and the competent authority.

A widely-used pricing procedure, which was introduced in several 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 23 countries of the surveyed group apply external price referencing, mostly referring to a basket of around five reference countries. Another common comparison tool is what we know as internal price referencing: Here the prices of products in a given country are compared to their equivalents 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 17 of the 28 countries analyzed the controlled price type is the ex-factory price (manufacturer price). Nine countries 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, but effectively controlled via regulated distribution mark ups.

At distribution level, six of the 28 countries surveyed apply no statutory wholesale mark ups. 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 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 28 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 also in Germany but with a linear mark up, and pharmacists in Slovenia and the UK get a fee-for-service remuneration.

In several 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).

Table 5
Pharmaceutical pricing in the outpatient sector in 28 European countries, 2008

C.	Price control	Pricing policy	Methodology		Controlled price type
			Ext.	Int.	
AT	Reimb. ph.	Statutory pricing	Y	Y	Ex-factory price
BE	All ph.	Statutory pricing	Y	Y	Ex-factory price
BG	All ph.	Statutory pricing	Y	Y	Ex-factory price
CY	All ph.	Statutory pricing	Y	N	Ex-factory price / pharmacy purchasing price[1]
CZ	All ph.	Statutory pricing	Y	Y	Ex-factory price
DE	No control	Price notification	–	–[2]	Ex-factory price
DK	No control	Price notification	–	–[2]	(Pharmacy purchasing price)
EE	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Ex-factory price
EL	All ph.	Statutory pricing	Y	Y	Ex-factory price
ES	Reimb. ph.	Statutory pricing	Y	Y	Ex-factory price
FI	Reimb. ph.	Statutory pricing (pricing & reimbursement is combined)	Y	Y	Pharmacy purchasing price
FR	Reimb. ph.	Price negotiations	Y	Y	Ex-factory price
HU	Reimb. ph.	Price negotiations, statutory pricing criteria	Y	Y	Ex-factory price
IE	Reimb. ph.	Pricing based on agreement between state and industry	Y	N	Ex-factory price
IT	Reimb. ph.	Price negotiations	Y	Y	Ex-factory price
LT	Reimb. ph.	Statutory pricing	Y	Y	Ex-factory price
LU	All ph.	Statutory pricing	Y	N	Pharmacy retail price
LV	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Pharmacy purchasing price
MT	No control	–	–	–	Ex-factory price
NL	POM	Statutory pricing	Y	(N)[2]	Pharmacy purchasing price
PL	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Pharmacy purchasing price
PT	POM	Statutory pricing	Y	Y	Ex-factory price
SE	Reimb. ph.	Statutory pricing (pricing & reimbursement is combined)	N	(N)[3]	Pharmacy purchasing price
SI	Reimb. ph.	Statutory pricing	Y	Y	Ex-factory price[4]
SK	Reimb. ph.	Statutory pricing	Y	Y	Pharmacy retail price
UK	NHS ph.	Indirect price control through profit control (PPRS)	N	Y	NHS list price[5]
NO	POM	Statutory pricing	Y	Y	Pharmacy purchasing price
TR	All ph.	Statutory pricing	Y	Y	Ex-factory price

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, Y = yes.

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

[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]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.

[4]In 2007, the controlled price type changed from the pharmacy purchasing price to the ex-factory price.

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

Sources: PPRI Report [8], PPRI at a Glance [9], GÖG/ÖBIG surveys, EASP information.

Table 6
Wholesale and pharmacy mark ups and VAT rates in 28 European countries, 2008

C.	Statutory mark up		VAT	
	Wholesale	Pharmacy	on ph.	Standard
AT	Y, all ph.	Y, all ph.	20%[1]	20%
BE	Y, all ph.	Y, all ph.	6%	21%
BG	Y, POM	Y, POM	20%	20%
CY	N, imported[2]	Y, all ph.	0% in general 15% for diagnostic agents	15%
CZ	Y, all ph.	Y, all ph.	9%	19%
DE	Y, POM and reimb. OTC	Y, POM and reimb. OTC	19%	19%
DK	N	Y, all but some OTC[3]	25%	25%
EE	Y, all ph.	Y, all ph.	5%	18%
EL	Y, all ph.	Y, all ph.	9%	19%
ES	Y, all ph.	Y, all. ph.	4%	16%
FI	N	Y, all. ph.[4]	8%	22%
FR	Y, reimb. ph.	Y, reimb. ph.	2.1% on reimb. ph. 5.5% on non-reimb. ph.	19.6%
HU	Y, all ph.	Y, all ph.	5%	20%
IE	Y, reimb. ph. (not statutory)	Y, reimb. ph. (not statutory)	0% on oral ph. 21% on others	21%
IT	Y, reimb. ph.	Y, reimb. ph.	10%	20%
LT	Y, reimb. ph.	Y, reimb. ph.	5%	18%
LU	Y, all ph.	Y, all ph.	3%	15%
LV	Y, all ph.	Y, all ph.	5%	18%
MT	Y, all ph.	Y, all ph.	0%	18%
NL	N	Y, POM	6%	19%
PL	Y, reimb. ph.	Y, reimb. ph.	7%	22%
PT	Y, POM	Y, POM	5%	20%
SE	N	Y, all ph.	0% on POM 25% on OTC	25%
SI	N (2006) Y, all ph. (2007)	Y, all ph.	8.5%	20%
SK	Y, all ph.	Y, all ph.	10%	19%
UK	Y, reimb. ph.	Y, reimb. ph.	0% on NHS ph. 17.5% on OTC	17.5%
NO	N	Y, all ph.	25%	25%
TR	Y, all ph.	Y, all ph.	8%	18%

C. = Countries, N = no, ph. = pharmaceuticals, OTC = Over-the-Counter, POM = prescription-only medicines, reimb. = reimbursable, VAT = value-added tax, Y = yes.
[1]Reduction of VAT on pharmaceuticals from 20% to 10% is planned.
[2]No statutory wholesale mark up for imported pharmaceuticals, a statutory linear wholesale mark up for locally-produced pharmaceuticals.
[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.
Sources: PPRI Report [8], PPRI Pharma Profiles [5], PPRI at a Glance [9], GÖG/ÖBIG surveys, EASP information.

In most countries the value-added tax (VAT) for pharmaceuticals is lower than the standard VAT rate. Exceptions are e.g. Denmark, Germany and Norway 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).

4.3. Reimbursement

In most countries, reimbursement eligibility depends on the product in question: A pharmaceutical is considered either reimbursable, meaning that the purchasing costs are fully or partially covered by a third party payer (either a social health insurance institution or a national health service), or non-reimbursable. This product-specific approach is applied in 19 of the 28 countries of the survey group (e.g. Belgium, Czech Republic, Greece, Finland, Italy, Netherlands, Poland, and UK).

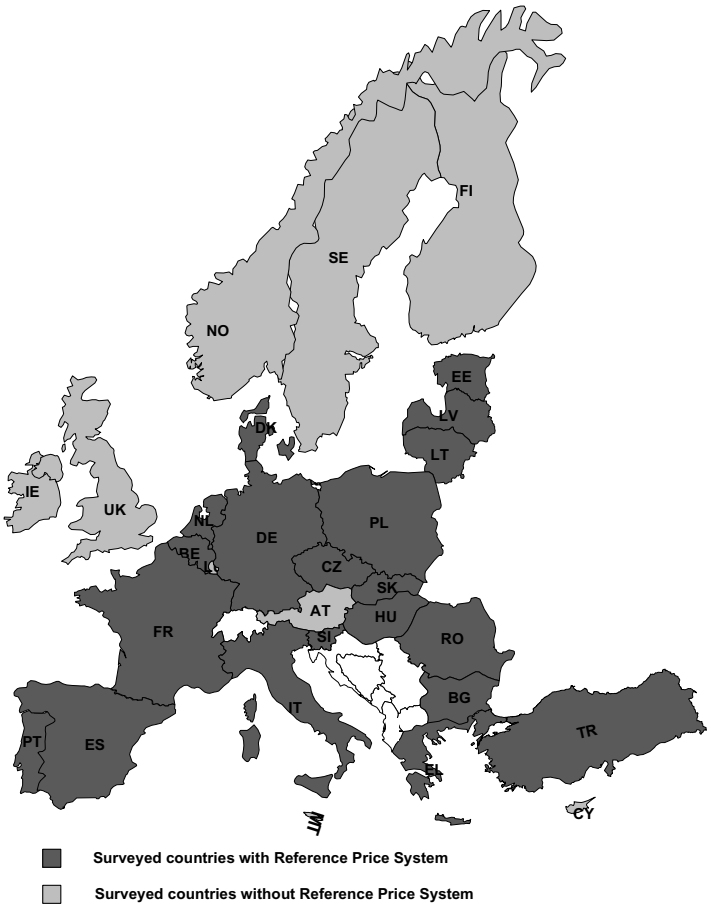
Additionally, further eligibility for reimbursement can, for instance, be connected to certain diseases (e.g., in the Baltic States) or population groups (e.g., Ireland, Turkey). In Denmark and Sweden, reimbursement coverage increases with rising pharmaceutical consumption (i.e. pharmaceutical expenditure 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 28 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 countries of the group, reimbursable pharmaceuticals may also be partially reimbursed, i.e. a certain percentage of the price is covered by reimbursement.

In all countries of the analysis, 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 countries (all but Germany, Greece, Spain and United Kingdom).

Four countries (Germany, Hungary, Spain 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.

A reference price system is in place in 19 countries of the group. 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. Eleven of the 19 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).



Sources: PPRI Report [8], PPRI at a Glance [9], GÖG/ÖBIG surveys, EASP information

Fig. 1. Reference price systems in European countries, 2008.

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 22 countries) is the percentage co-payment for reimbursable pharmaceuticals which are partially reimbursed.

De facto all countries have mechanisms in place 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

Table 7
Pharmaceutical reimbursement in the outpatient sector in 28 European countries, 2008

C.	Lists		Reference price system		Out-of pocket payment		
	Pos.	Neg.	Introduction	Clustering	Fixed	%	Deduct.
AT	Y	N	N	N.appl.	Y	N	N
BE	Y	N	Y, since 2001	ATC 5	N	Y	N
BG	Y	N	Y	ATC 5	N	Y	N
CY	Y	N	N	N.appl.	N	Y	N
CZ	Y	N	Y, since 1995	Mix of ATC 4 and 5	N	Y	N
DE	N	Y	Y, since 1989	Mix of ATC 4 and 5	N	Y[1]	N
DK	Y	N	Y, since 1993	ATC 5	N	Y	Y
EE	Y	N	Y, since 2003	ATC 5	Y	Y	N
EL	N	(Y)[2]	Y, since 2006	Methodology to be defined	N	Y	N
ES	N	Y	Y, since 2000	ATC 5	N	Y	N
FI	Y	(Y)[2]	N	N.appl.	Y	Y	N
FR	Y	N	Y, since 2003	ATC 5 [3]	N	Y	N
HU	Y	Y	Y, since 1991	ATC 5 and from 2000 on also ATC 4	N	Y	N
IE	Y	N	N	N.appl.	N	N	Y
IT	Y	N	Y, since 2001	ATC 5	Y[4]	N	N
LT	Y	N	Y, since 2003	ATC 5	N	Y	N
LU	Y	N	N	N.appl.	N	Y	N
LV	Y	N	Y, since 2005	Mix of ATC 3, 4 and 5	N	Y	N
MT	Y	N	N	N.appl.	N	N	N
NL	Y	N	Y, since 1991	Mix of ATC 3, 4 and 5	N	N	N
PL	Y	N	Y, since 1998	Mix of ATC 3, 4 and 5	Y	Y	N
PT	Y	N	Y, since 2003	ATC 5	N	Y	N
SE	Y	N	N (it existed from 1993 to 2002)	N.appl.	N	Y	Y
SI	Y	N	Y, since 2003	ATC 5	N	Y	N
SK	Y	N	Y, since 1995	Mix of ATC 4 and 5 level	Y	Y	N
UK	N	Y	N	N.appl.	Y	N	N
NO	Y	N	N	(ATC 5)[5]	N	Y	N
TR	Y	N	Y, since 2004	ATC 5	N	Y	N

ATC = Anatomic Therapeutic Chemical Code, C. = countries, Deduct. = deductible, Neg. = negative list, N = no, n.a. = not available, n.appl. = not applicable, 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.

ATC 3: Defines pharmaceuticals in the same pharmacological subgroup.

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

Table 7, continued

ATC 5: Defines a single active ingredient or a fixed combination of active ingredients within the anatomic therapeutic chemical classification system.
[1]Prescription fee as percentage of price, with absolute minimum and maximum.
[2]Legal basis for negative list, not yet implemented.
[3]For very few products (3.5% of the value of reimbursable pharmaceuticals).
[4]Prescription fees in some regions.
[5]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 Report [8], PPRI at a Glance [9], GÖG/ÖBIG surveys, EASP information.

expenses on pharmaceuticals and/or health care may be in place (e.g., in Germany and Luxembourg).

4.4. Rational use of pharmaceuticals

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

In general, prescription patterns are monitored; however, the extent of supporting information technology applications and the intensity of feed-back to the prescribers differs among 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 countries; but it is often not used in practice. Generic substitution (i.e. the pharmacist substitutes the product written on the prescription, usually an original product, by a generic or a parallel-imported pharmaceutical), exists in 20 of the 28 countries. Generic substitution is indicative (in 13 countries) or mandatory (in seven 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.

5. Conclusions

Pharmaceutical pricing and reimbursement is a national competence. Therefore, there are 27 different pharmaceutical pricing and reimbursement systems in the European Union. Though specific tools (e.g. external price referencing) have become quite common in the European Union, country specific challenges ask for country specific solutions. Nonetheless, Member States are most interested in learning from each other. Therefore, initiatives like the PPRI project are appreciated by the Member

States. There is common understanding that PPRI contributed to improve the exchange of information between the Member States. In this respect, the PPRI glossary is an important additional deliverable supporting a promotion of a joint language regarding pharmaceutical policies among the EU Member States.

PPRI Pharma Profiles [5] and further EU-funded studies analyzing pharmaceutical policies and their impact in the EU Member States (e.g. the EASP study [4]) show a clear picture: It is seen that certain practices get out-dated and are only rarely used (e.g. cost-plus pricing), whereas some "popular" tools seem to be increasingly used in the Member States. International price comparisons (external price referencing) are a pricing practice applied in 23 of the 28 countries analyzed in this article. Concerning reimbursement instruments it is observed that the implementation of reference price systems being in place in 19 of the countries surveyed. Pharmaceutical industry reacts to these practices (e.g. launching pharmaceuticals first in high price market) and as a result some tools risk losing their impact which they have shown in the first few years (e.g. regarding cost-containment). Additionally to these traditional tools, new practices will arise and be applied in a growing number of countries. Such a new practice is, for instance, the risk-sharing schemes.

PPRI contributed to an increase of knowledge in several fields, but it also disclosed gaps and limitations. For instance, data availability problems became evident. This regards not only the difficult area of pharmaceutical prices – thus rendering external price referencing difficult –, but also essential information like consumption data (prescriptions) or the funding of pharmaceutical expenditure (private/public expenditure) which some countries can only deliver for a few years due to a change in country specific statistics. In addition to non-availability, national definitions differ considerably making correct and meaningful comparisons difficult. 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. Thus, there is a need to continue to work on it (e.g. by standardizing definitions).

Finally, we also have to take into consideration the pharmaceutical service in the inpatient sector which influences, to a major extent, the pharmaceutical provision and expenditure in the outpatient sector. However, pricing policies and practices in the hospital sector have neither been addressed by the PPRI project nor have they been the focus of other European research projects. Therefore, pharmaceutical policies in hospitals should be surveyed, which, in fact, will be done in the frame-work of the recently launched PHIS (Pharmaceutical Health Information System) project.[3] PHIS

[3] http://phis.goeg.at.

will provide a survey on pharmaceuticals in hospitals. In addition, initiatives for a better cooperation and interface management between the inpatient and outpatient sector should be promoted.

To conclude it can be said that we are facing numerous challenges for the European pharmaceutical systems in future and initiatives like the PPRI follow-up or the PHIS project will continue contributing with options for solutions.

Authors

Sabine Vogler is a senior researcher at the Austrian Health Institute (GÖG/ÖBIG). She is a health economist with in-depth knowledge on the European countries with regard to pharmaceutical pricing/prices, reimbursement and distribution, as well as cost-containment reforms, access and affordability issues. Sabine Vogler is the project leader of the Pharmaceutical Pricing and Reimbursement Information (PPRI) project (http://ppri.oebig.at) and the Pharmaceutical Health Information System (PHIS) project (http://phis.goeg.at), both including networks of competent authorities from the whole EU.

Jaime Espin is professor in the Andalusian School of Public Health (EASP – Escuela Andaluza de Salud Pública). He is lawyer in training and health economist and has been involved in many international projects, especially focused on pharmaceutical pricing and reimbursement systems in Europe. He has been external independent expert in the Working Group of Pricing in the Pharmaceutical Forum and has been teaching and giving conferences about P&R systems during the last years. He is co-author of the EU-funded report "Analysis of differences and commonalities in pricing and reimbursement systems in Europe".

Claudia Habl is senior health economist at the Austrian Health Institute (GÖG/ÖBIG), involved in a great number of international pharmaceutical projects like the Austrian Pharmaceutical Price Information Service and works as a consultant for, e.g., the European Union and World Bank. She is author of a number of international publications in the field of pharmaceuticals and other topics like gender-health and Health Technology Assessment. In addition she heads the Austrian Medical Devices Register and is Member of the Austrian Independent Pharmaceutical Commission (UHK).

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