



Lessons learned

PPRI Secretariat

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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 Profiles¹, 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.

This short report presents the key findings of the research project, which have been discussed with the PPRI group. The lessons learned are also included in Chapter 4 of the PPRI Report.

1 Evaluation² 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**.

¹ Accessible to the public via the PPRI website, at <http://ppri.oebig.at> → Results

² 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.

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 glossary¹ 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 it², 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.³

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”. Thus, the PPRI project management, together with the PPRI participants, decided on a two-tier approach: In general, PPRI

¹ PPRI website, <http://ppri.oebig.at> → Glossary

² 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).

³ 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

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., flow-charts of the pharmaceutical system in the PPRI Pharma Profiles, posters at the PPRI Conference¹).

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 website² 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 pharmaceutical systems becomes out-dated soon. This commitment was demonstrated by the fact that

¹ For download available at the PPRI website, <http://ppri.oebig.at>

² See <http://ppri.oebig.at> → Results

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.

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 countries¹ brought the following results.²

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.³

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.

¹ 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.

² The information refers to the outpatient sector and to the years 2006/2007 unless stated differently.

³ 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.

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 exist. **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 interchangeable (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.

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.

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%).

3 Key findings of the PPRI analysis

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).

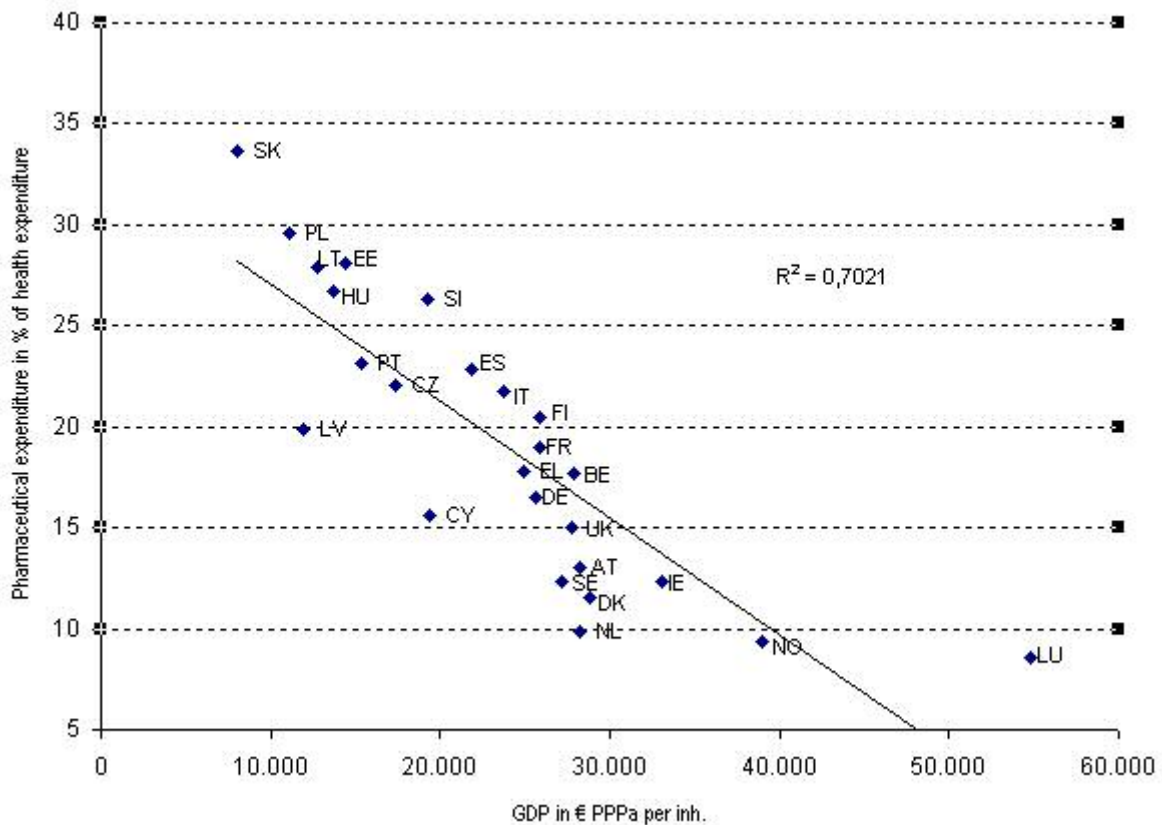
Regarding **health expenditure**, the new EU Member States spent on average € PPPa 965.- per inhabitant in 2004, whereas in EU-15 countries the average health expenditure per inhabitant amounted to about € PPPa 2,450.-. Thus, EU-15 countries spent per capita more than 2.5-fold on health than EU-10 countries.

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 $R^2 = 0.7$). 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 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

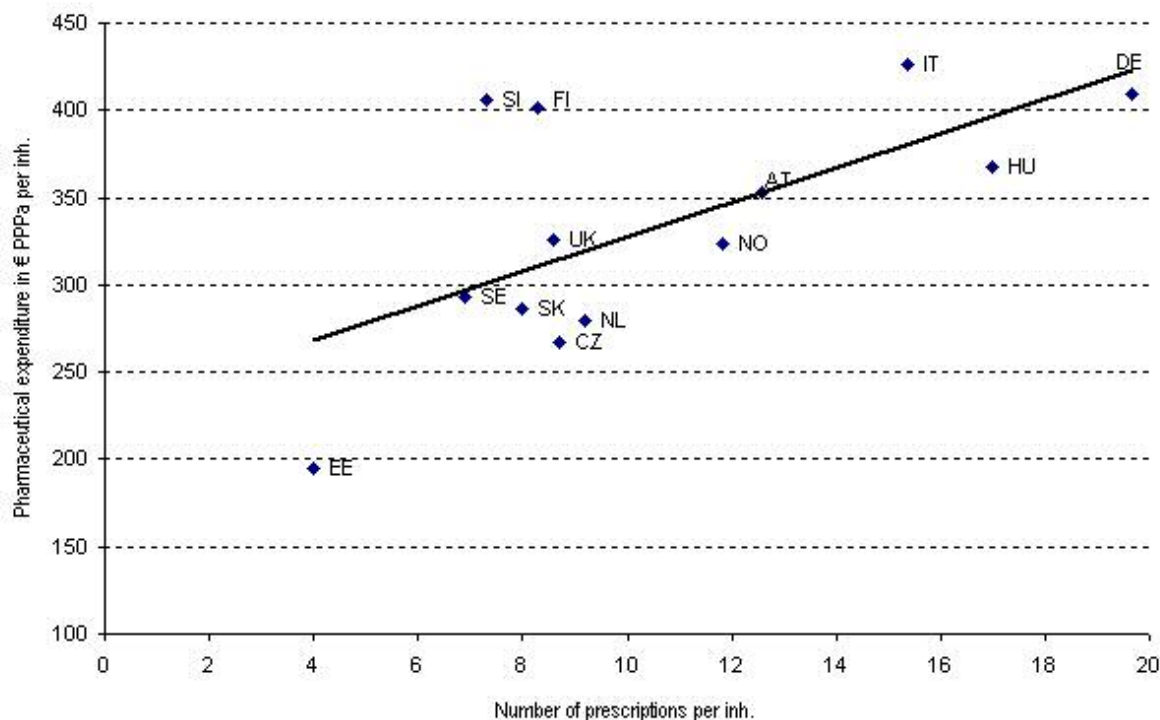
Note: In the PPRI project, total pharmaceutical expenditure has been defined as covering both the outpatient and inpatient sector (cf. Set of Core PPRI Indicators, Annex II of the PPRI Report). Data were double-checked with regard to this definition where possible. Despite of that, data on pharmaceutical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

3.2 Pharmaceutical expenditure components

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

Figure 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 2 highlights differences in the number of prescriptions between the PPRI countries; in addition, it reveals the relevance of the volume component¹ in pharmaceutical expenditure.

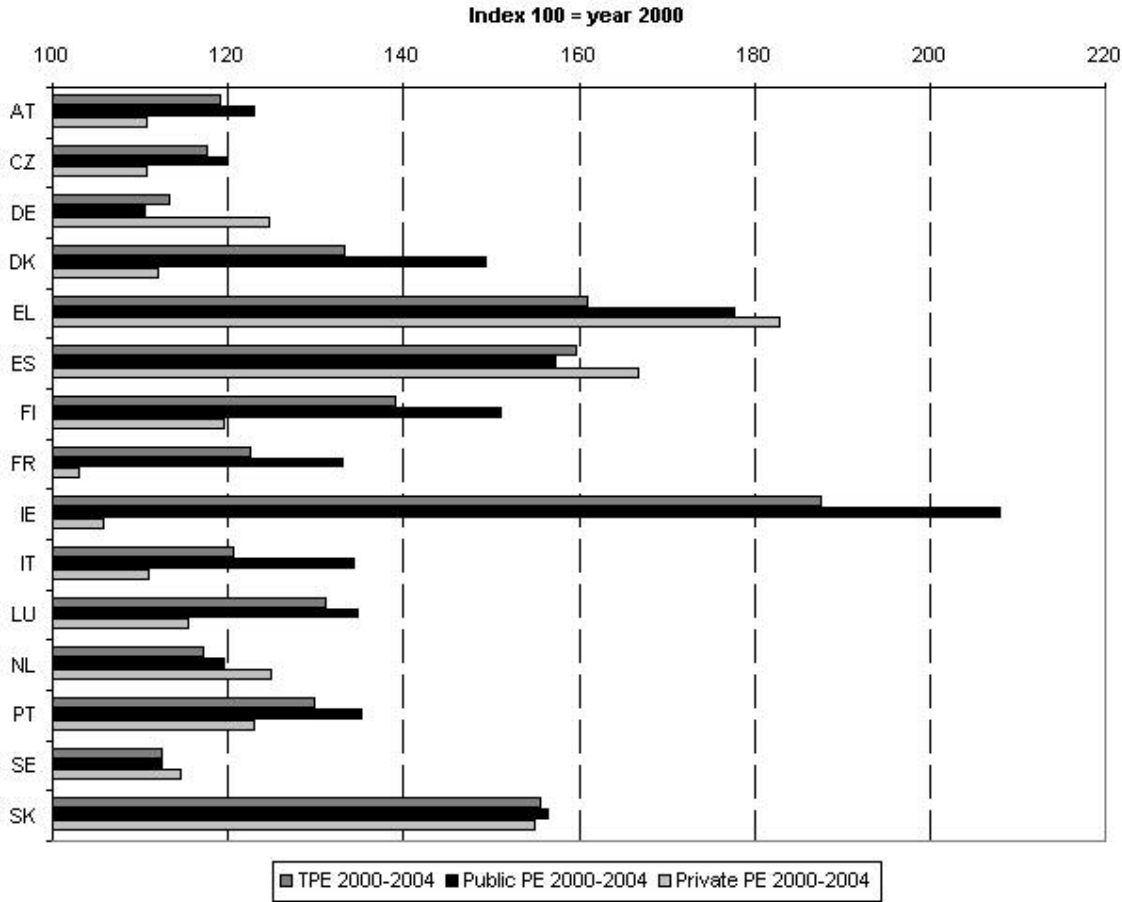
3.3 Growth of pharmaceutical expenditure by payers

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 3 displays, the growth in public pharmaceutical expenditure has been, sometimes considerably, higher than the increase in private pharmaceutical expenditure.

¹ 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 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.

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

C.	Pricing	Reimbursement	Rational use
SE	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Positive list • Eligibility criteria for reimbursement: human value principle, need and solidarity principle, cost-effectiveness principle from a societal perspective • Consumption-based reimbursement¹, with an annual ceiling for private pharmaceutical expenditure • Drug committees at regional level • Systematic reimbursement reviews 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Statutory pricing for POM • External price referencing • Dispensing fee per prescription as pharmacy remuneration • Price cuts of generics (from 2004 on) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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

C.	Pricing	Reimbursement	Rational use
AT	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Guidelines for economic prescribing in the outpatient sector • Prescription monitoring and feed-back
IT	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Pharmacoeconomics (cost-effectiveness) started to play a role in the late 1990s
FR	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 eligibility 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 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 initiatives¹ 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.² 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 reason-

¹ 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).

² 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.

able 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.

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-dependending 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 update their Pharma Profiles in annual intervals after the end of the PPRI research project.