PPRI at a Glance

PPRI Secretariat
Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG)
Stubenring 6, 1010 Vienna, Austria
E-Mail: ppri@goeg.at
Dr. Sabine Vogler,PPRI Project Manager, E-Mail: vogler@goeg.at
Mag. Claudia Habl, Deputy Project Manager, E-mail: habl@goeg.at
Mag. Christine Leopold, MSc., PPRI Communication Officer, E-Mail: leopold@goeg.at
Romana Landauer, PPRI Assistant, E-Mail: landauer@goeg.at
Tel.: + 43-1-51561/262 (Ms. Landauer)
Fax.: +43 1 5138472
URL: http://ppri.oebig.at

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

Indicator	Objective	Results
Background		
1: Population age structure	To assess the age structure in order to analyse the effect on using health care/pharmaceutical resources	In the PPRI countries, the majority of the population (around 67%) is aged between 14–65 years (year 2005). Concerning the elderly population above 65 years, there are differences between the countries, but a systematic difference between the EU-15 (16%) and the EU-10 (15%) cannot be observed. Slovakia, Italy and Germany have the highest rates (over 19%) of people above 65 years, while Turkey has the youngest population.
2: Gross domestic product per capita in € PPPa	To assess the economic situation in order to analyse the economic wealth of a country	With a gross domestic product (GDP) per capita of € PPPa 22,800.- in the EU-25 average (year 2004/2005), there appears to be a gap between the EU-15 (average: € PPPa 27,900.-) and the EU-10 (average: € PPPa 14,200.-).
3: Public/private funding of health expenditure	To assess the main sources of health care funding in order to analyse the share of public funding vs. private funding of health care	The public/private funding shares of health expenditure differ between the PPRI countries. The share of public health expenditure varies from approximately 90% in the Netherlands (91.7%), UK (87.4%) and Czech Republic (87.2%) to about 50% in Greece (53.9%), Latvia (52.7%) and Cyprus (47.6%) (data for 2005 or latest available year).
4: Total health expenditure per capita in € PPPa	To assess the expenditure on health per capita, per year in order to analyse the amount spent on health in a country	In 2005 (or 2004), all PPRI countries together spent about € 1,000 billion on health care. This amounts to € PPPa 1,900.- per inhabitant in the EU (EU-25). There tend to be considerable differences between the EU-15 (average: € PPPa 2,450.-) and the EU-10 (average: € PPPa 965.-) concerning health expenditure per capita.
Pharmaceutical system		
5: Regulatory framework for pharmaceutical policy	To assess the legal context in order to analyse the national political framework for the provision of the population with effective pharmaceuticals	Pricing and reimbursement is a competence of the EU Member States, which have to comply with overall EU provisions, like the Transparency Directive. Complex statutory frameworks, usually including a Medicines Act, a Price Act and/or a Health Insurance Law are in place in 26 of the 27 PPRI countries (exception: Ireland). Framework agreements between the state and the pharmaceutical industry have been concluded in Denmark, France, Hungary, Ireland and Portugal.

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

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Pricing		
10: Pricing policies at manufacturer level	To assess the different policies for pricing pharmaceuticals in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	In 24 of the 27 PPRI countries prices are controlled for outpatient pharmaceuticals. Generally speaking, Denmark, Germany and Malta exercise no price control at manufacturer level in the outpatient sector. However, in Denmark and Germany the prices of reimbursable pharmaceuticals (in particular the reimbursement price) are indirectly influenced by the reimbursement system. In the majority of the countries (e.g., in Finland, Italy, Poland), price control is limited to pharmaceuticals with reimbursement eligibility (= reimbursable pharmaceuticals), while for non-reimbursable pharmaceuticals, which are often OTC (Over-the-Counter) products, the manufacturer/importer may freely set the price. The most common price control policy is statutory pricing, which implies that authorities set the price on a regulatory, unilateral basis. In a few PPRI countries (e.g., Italy, France) pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the competent authority. A special case is the UK which has no direct price control, but the prices of NHS (National Health Service) pharmaceuticals are indirectly controlled through the profit-controlling PPRS (Pharmaceutical Price Regulation Scheme). A widely-used pricing procedure, which is applied by an increasing number of PPRI countries, is external price referencing (international price comparison). The pricing authority gathers the prices of the same product in other countries and takes these reference prices as guidance for their own pricing (and sometimes also reimbursement) decisions. 22 PPRI countries apply external pricing referencing, mostly referring to a basket of about five reference countries. A comparison with equivalent or similar products within the own country (so-called internal price referencing) as a basis for pricing or reimbursement decisions is usually undertaken for off-patent products (generics). In several PPRI countries, generics are priced, sometimes considerably, lower than original products. In 16 of the 27 PPRI countries (year 2007) the controlled price type is the ex-factory price (manufacturer price). Nine PPRI countries (year 2007) control the pharmacy purchasing prices (wholesale prices) of pharmaceuticals, while two countries fix the pharmacy retail price.

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11: Pricing policies at distribution level	To assess the different policies for pricing pharmaceuticals at the distribution level (wholesale, pharmacy) in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	At distribution level, six of the 27 PPRI countries (year 2007) have no statutory wholesale mark up. In these countries, the pharmacy purchasing price is controlled, and the ex-factory price is an outcome of negotiations between the manufacturer and the wholesaler. 21 PPRI countries have statutory wholesale mark ups, either a linear mark up or a regressive scheme. Pharmacy margins are regulated in all 27 PPRI countries. Usually, they also take the form of a regressive scheme or a linear mark up. Pharmacy remuneration consists of a fixed fee in the Netherlands and in Germany (together with a linear mark up), and pharmacists in Slovenia and the UK get a fee-for-service remuneration. In many PPRI countries, statutory wholesale and pharmacy mark ups cover all pharmaceuticals, whereas some countries apply the mark up schemes only to reimbursable pharmaceuticals (e.g., France, Lithuania) or to prescription-only medicines (e.g. Bulgaria, Portugal).
12: Taxes on pharmaceuticals	To assess the different tax policies regarding pharmaceuticals in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals	In most PPRI countries the VAT (value-added tax) rate for pharmaceuticals is lower than the standard VAT rate. Exceptions are Austria, Bulgaria, Denmark, Germany and Norway, where the VAT on pharmaceuticals equals to the standard VAT rate (e.g., 25% in Denmark and Norway). A few countries have split VAT rates, with a lower or even 0% rate for a specific group of pharmaceuticals (e.g., reimbursable pharmaceuticals). Additional taxes for pharmaceuticals include the INFARMED (Medicines Agency) tax of 0.4% of the net pharmacy retail price in Portugal and the pharmacy fees in Finland and in Norway.
Reimbursement		
13: Positive/negative list	To assess if a country has implemented measures guaranteeing or limiting the access to pharmaceuticals which are, at least partially, funded by a third party payer	In all PPRI countries, reimbursement lists exists. Positive lists, which include pharmaceuticals that may be prescribed at the expense of a third party payer, are in place in 24 of the 27 PPRI countries (all but Germany, Greece and UK). Three countries (Germany, Hungary, UK) have introduced negative lists, and two countries (Greece and Finland) have foreseen the legal basis, but have not implemented the measure yet.
14: Reference price system	To assess if a country has implemented a reference price system which is a common measure restricting the use of expensive pharmaceuticals while guaranteeing access to equivalent pharmaceuticals	In 2006/2007, 18 of the 27 PPRI countries had a reference price system in place (in one country it still had to be implemented). After nearly a decade, Sweden abolished its reference price system in 2002, but manages a system of obligatory generic substitution in which substitutable pharmaceuticals are grouped. Ten of the 18 reference price system countries (e.g., Denmark, Portugal) build the reference groups (i.e. groups of interchangeable pharmaceuticals) based on substance (ATC 5) level. Seven countries (e.g., Germany, Czech Republic) also consider therapeutically similar pharmaceuticals as interchangeable (ATC 4 level on therapeutic groups or even broader). Patients have to pay the difference between the reference price (base price for reimbursement) and the actual pharmacy retail price.

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15: Mechanisms for vulnerable groups	To assess the instruments and mechanisms in place for special vulnerable population groups in order to analyse the access to affordable pharmaceuticals	All PPRI countries have introduced mechanisms to protect vulnerable groups from too high out-of pocket payments. Specific groups are granted a 100% reimbursement (e.g., in Hungary, Portugal), a higher reimbursement rate than the standard one (e.g., in Belgium, Estonia) or are exempted from prescription fees (e.g., in Austria). The total amount of co-payment may be limited: by a maximum co-payment per prescription (e.g., in Belgium) or annual ceilings for private expenses on pharmaceuticals and/or health care (e.g., in Germany and in Luxembourg).
Rational use of pharmaceuticals		
16: Share of generics in volume and value as percentage of outpatient market	To assess the use of generics in order to analyse the efficiency of the pharmaceutical system	While the new EU Member States in Central and Eastern Europe have always had a relatively high share of generics, the old Member States have undertaken initiatives to encourage the use of generics. Among those, countries like Germany, the Netherlands or the UK have had a policy of generic promotion for a long period of time which has resulted in considerable generics shares. The generics share in volume is 50% or more in these “generic countries” of the EU-15 as well as in the new Member States, whereas it is below 20% in other old Member States which started later with generic promotion. Expressed in value, the generics shares are usually lower (due to the low prices of generics), ranging from around 20%–30% in the “generics countries” and about 10% in the others.
17: Prescription guidelines	To assess the implementation of prescription guidelines in order to analyse their impact on rational use of pharmaceuticals as well as on cost-containment	The majority of PPRI countries introduced prescription guidelines to promote an appropriate and economic prescribing of pharmaceuticals. In most countries, the guidelines are indicative and usually only refer to the outpatient sector.
18: Mandatory guidelines for decision makers / role of pharmaco-economics	To assess a country’s policies regarding the decision making process in order to analyse the priorities in decision making on pricing, reimbursement and related issues regarding pharmaceuticals	Pharmaco-economics continues to play an increasingly important role in decisions on pricing and reimbursement. De facto all PPRI countries consider pharmaco-economic aspects when setting the prices and the reimbursement rates of pharmaceuticals. The extent of the application of pharmaco-economics differs between the countries. The three Baltic states, the Netherlands, Sweden and UK adopted guidelines specifying rules which have to be followed in pharmaco-economic analyses.
19: Information to patients	To assess the actions undertaken to inform patients in order to analyse the impact on improving the rational use of pharmaceuticals	Within the EU, advertising to the general public is not allowed for prescription-only medicines (POM), however, companies may provide product-specific information if this information is personally requested by the patient. Currently, under the Pharmaceutical Forum process, a Working Group is dedicated to the issue of patient information. Information to patients is not only an issue of advertising and information provided by pharmaceutical companies, but also concerns information given to patients by health professionals (e.g., doctors or pharmacists) and by the authorities. Some countries (e.g., Belgium, France) have launched information campaigns to the general public (e.g., on specific pharmaceutical groups like antibiotics or on generics).

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20: Monitoring of consumption	To assess the actions undertaken to monitor the use of pharmaceuticals in order to analyse and improve methods for guaranteeing a more rational use of pharmaceuticals	Several PPRI countries have established consumption monitoring systems. Usually, consumption monitoring is undertaken by Medicines Agencies or social insurance institutions / national health services. The data are provided by wholesalers and/or pharmacies, which, in most cases, have a legal obligation to submit this information. Consumption monitoring is, in general, only done for the outpatient market, and in many cases limited to the reimbursement segment. A few countries use individual consumption monitoring to analyse in detail specific therapeutic groups, to publish reports and/or to give patients the opportunity to monitor their consumption pattern (e.g., Sweden, Denmark).
21: Number of prescriptions per capita in volume and value	To assess the number of prescriptions per capita in order to analyse the utilisation in the prescription/reimbursement segment	Availability of comparable data concerning prescriptions is limited. On average in the PPRI countries (where data are available), about 11.8 prescriptions are written per inhabitant per year (year 2006), amounting to an average value of € 21.30 per prescription. This indicator has to be read with caution as the number of items or packs (as one or more prescriptions) is counted in different ways throughout the PPRI countries. The average annual expenditure for prescriptions in the PPRI countries amounts to € 217.- per inhabitant.

EU = European Union, EU-10 = new EU Member States having acceded to the EU in May 2004, EU-15: old EU Member States, having acceded before May 2004, EU-25 = EU Member States having acceded before January 2007, PPRI countries = countries participating in the PPRI (Pharmaceutical Pricing and Reimbursement Information) project, which have contributed to the PPRI comparative analysis, these are EU-25 Member States except Spain, plus Bulgaria, Norway and Turkey
ATC = Anatomic Therapeutic Chemical Code, GDP = Gross Domestic Product, NHS = National Health Service, OTC = Over-the-Counter, POM = prescription-only medicines, PPPa = Purchasing Power Parities, PPRS = Pharmaceutical Price Regulation Scheme (UK), VAT = value-added tax

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