

## Pharmaceutical Pricing and Reimbursement Information (PPRI): a European Union project

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### Abstract

**Background:** In the European Member States, the systems for pharmaceutical pricing and reimbursement differ significantly. Amongst the administration and policy-makers at both national and European levels there is a lot of interest in the different pharmaceutical systems of the Member States as a means of learning from their experiences in pricing and reimbursement.

**Objectives:** The general objective of the PPRI-Project – started in April 2005 - is to develop a network of authorities and institutions in order to improve information and knowledge on the pharmaceutical systems in the enlarged European Union. This network should facilitate a regular exchange of information and allow a process of learning from each other.

**Project description:** The PPRI project team consists of the main partner (ÖBIG), an associated partner (WHO-EURO) and a network of partners and observers which represent national stakeholders from almost all EU Member States and a number of international stakeholders. The information on pharmaceutical pricing and reimbursement will be collected and summarised in country reports (“Pharma Profiles”) which follow a homogenous structure. The individual country’s information will be analysed and compared on the basis of a set of indicators (benchmarks).

**Deliverables:** The main deliverables of the project are:

- Pharma Profiles,
- a benchmarking report, in which pharmaceutical pricing and reimbursement in the Member States is compared,
- a website containing information on the project and on pricing and reimbursement in the Member States, and
- a conference at the end of the project during which the study results will be disseminated.

*Key words: pharmaceuticals, pricing, reimbursement, Europe, PPRI*

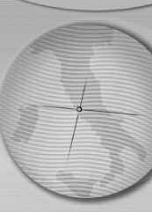
### Background

Over the past years pharmaceutical expenditure within EU member states has continued to increase. Considering the causes of these increases, which are mainly demographic factors (population increase and ageing) and a trend towards the use of new and expensive pharmaceuticals, the increase in pharmaceutical expenditure is expected to continue in the years to come. The pricing and reimbursement of pharmaceuticals are important tools to control pharmaceutical expenditure and therefore have been receiving increased attention at national and international levels.

On an international level, the European Union provides a framework for pricing and reimbursement of pharmaceuticals. This framework is primarily constituted of the “Transparency Directive” (Council Directive 89/105/EEG of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal

products for human use and their inclusion in the scope of national health insurance systems). The requirements of Directive 89/105/EEC do not affect national policies on price setting and the determination of social security schemes. Its objective is to attain transparency in pricing and reimbursement procedures. In order to comply with Directive 89/105/EEC, all the criteria on which pricing and reimbursement decisions are based should be objective and verifiable. The Directive also adopts time limits: Within 90 days after a request has been posed the national authorities must determine the price of the pharmaceutical and decide whether or not to include the pharmaceutical in the list of reimbursable pharmaceuticals (often called “positive list”). Altogether the pricing and reimbursement process is allowed to take a maximum of 180 days.

The definition of the pharmaceutical system remains the task of the individual member states. Consequently, there are 25 different pharmaceutical systems in the European Union.



The responsible authority for decisions concerning the pricing and the reimbursement of pharmaceuticals is in general the ministry of health, the ministry of social affairs or those responsible for social insurance. The authorities are often supported by special committees which include deputies of the pharmaceutical industry, physicians and other stakeholders of the pharmaceutical market. In some countries decisions on the reimbursement of a pharmaceutical can only be made after the price of the pharmaceutical has been set. In other countries decisions on the reimbursement of pharmaceuticals are made first.

Criteria for reimbursement of pharmaceuticals are often based on medical appraisals (therapeutic benefit, alternative treatments) and economic considerations, such as the price of the new pharmaceutical. For example, the price of the new pharmaceutical can be compared to that of similar pharmaceuticals that are already available within the country, or to the prices of the same pharmaceutical in other countries. These reference countries for price comparisons are mostly neighbouring countries or other EU member states which are known to have relatively low pharmaceutical prices. The so called "Reference Pricing Systems" are often applied to predefined clusters of pharmaceuticals. The forming of the clusters is mainly based on the active components of the pharmaceuticals. Within each cluster a reference price is determined. This price is exactly what is reimbursed for the pharmaceuticals within this cluster. In most cases where a pharmaceutical costs more than the predetermined price the patient has to pay the difference.

The prices of pharmaceuticals are basically determined by three methods. The prices can be 1) fixed by the state, 2) negotiated between the pharmaceutical companies and the state or social insurance or 3) determined by the pharmaceutical companies themselves. This generally concerns the pharmaceutical's price at the level of the manufacturers and of the wholesalers. The margins for the wholesalers and for the pharmacies are often determined by the state or in some cases negotiated between the actors in the distribution process of the pharmaceuticals. When deciding on the price of a pharmaceutical the authorities on the one hand look at the prices of similar pharmaceuticals that are already available within their country, and on the other hand consider the prices of the pharmaceutical in question in a number of reference countries.

As the pricing and reimbursement of pharmaceuticals is a national affair, there are

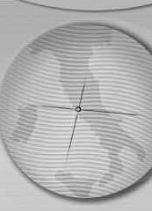
currently 25 pharmaceutical pricing and reimbursement systems within the enlarged European Union, which sometimes differ to a great extent. In addition, the increasing level of pharmaceutical expenditure in all member states has resulted in the governments taking cost containing measures. These cost-containment measures may be distinguished by whether they are aimed at influencing the prices and/or the consumption of pharmaceuticals. Examples of the first are price freezing, price cuts, and the promotion of the use of generic. Measures influencing the consumption of pharmaceuticals are, for example, the reclassification of pharmaceuticals (e.g. switch from prescription-only to OTC, or de-listing from the so called "positive-list", which are lists of pharmaceuticals which may be prescribed at the expense of the National Health Service or social insurance fund) and the introduction or increasing levels of patient co-payments. Due to these measures, the pharmaceutical pricing and reimbursement systems have been, and still are, changing continuously.

Numerous overviews of national pharmaceutical pricing and reimbursement systems have been made, both commercially, as well as for and by authorities.

ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen) / the Austrian Health Institute has published several studies in which pharmaceutical systems (pricing, reimbursement, co-payment, distribution) were surveyed and analysed [1-4]. These studies revealed the great interest of public authorities and policy-makers to learn about the pharmaceutical systems and the experiences made in other countries. ÖBIG also introduced the Pharmaceutical Pricing Information (PPI) service [5] which provides the prices of pharmaceuticals in the EU Member States.

Under the G10 process overviews of pharmaceutical markets were produced and are available on the web. [6] WHO has also worked on overviews on prices, reimbursement systems and conditions in a networking arrangement with the national authorities in Europe [7].

DG SANCO sponsored projects (Euro-Medicines [8], EURO-MED-STAT [9]) that mapped out existing databases on medicines in Europe, including the reimbursement status and pricing issues. Problems in these studies have often been the non-comparability, incompleteness, invalidity and an insufficient level of detail of the information. In addition, due to the frequent reforms in pricing and reimbursement systems, these studies may no longer be up-to-date.



For these reasons, a network of authorities and institutions within the enlarged Union to provide, exchange and analyse the pricing and reimbursement issues in the field of pharmaceuticals is of great importance. This has led to the initiation of the Pharmaceutical Pricing and Reimbursement Information Project (PPRI).

**Objectives of the PPRI Project**

The general objective of the PPRI-Project is to develop a network of authorities and institutions in order to improve information and knowledge on the pharmaceutical systems in Europe. This network should facilitate a regular exchange of information as well as a process of learning from each other.

Specific aims of the PPRI project are as follows:

- the strengthening of the networking between the national authorities and institutions in the field of pharmaceuticals in the EU Member States
- the assessment of the needs of the European Commission and national administration and policy-makers with regards to knowledge and information transfer on pharmaceutical pricing and reimbursement
- the systematic collection, reporting and analysis of relevant information and data on pharmaceutical pricing and reimbursement in the Members States
- the development of indicators for the comparative analysis of pricing and reimbursement
- the benchmarking of pharmaceutical pricing and reimbursement in the enlarged European Union
- the dissemination of the project results.

**Organisation of the project**

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Austrian Federal Ministry for Health and Women's Issues.

The main partner in the PPRI project, ÖBIG / Austrian Health Institute, is in charge of the overall coordination of the project and will act as the main contact both within and outside the project.

The associated partner, WHO-EURO is also in charge of managerial tasks and has take the lead in two of the work packages (see below). In addition the project team consists of a network of partners from almost all of the Member States of the enlarged Europe Union and Bulgaria.

These partners (mainly Ministries of Health, Medicines Agencies, Social Insurances, or research institutes) represent the relevant authority of their Member State. Of the EU-countries which do not have a partner involved in the project, as well as

Norway, an observer who is also an expert in pharmaceutical pricing and reimbursement participates in the project. Some countries are represented in the project by more than one institution, and therefore are represented by a partner as well as an observer. In addition, a number of international and European stakeholders, such as the European Medicines Agency (EMA) and the Organisation for Economic Co-operation and Development (OECD), are represented by observers.

In the course of the project the entire project team, including all partners and observers, will have four coordination meetings. The first of these meetings took place in September 2005 in Vienna and the second meeting took place in April 2006 in Copenhagen the thrid meeting will take piace on 9 and 10 october 2006 in Warsaw, Poland.

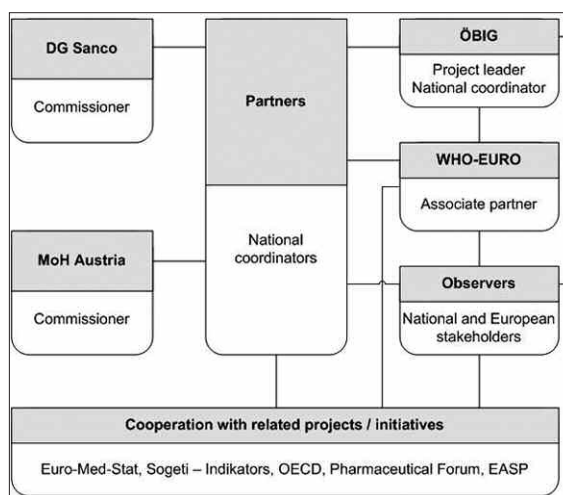
In addition to these meetings, ÖBIG will coordinate a continuous flow of information and communication between the project partners, which will mainly take place through a non-public sharing point on the internet.

The PPRI project has a strong relationship with the EURO-MED-STAT project [8], which is also funded by DG Sanco. The EURO-MED-STAT project aims to perform an inventory of data sources for pharmaceutical prices and expenditures and to survey the available data in the EU member states. ÖBIG is acting as a partner in the EURO-MED-STAT project, and the Italian Medicines Agency (AIFA), which has the scientific responsibility of the EURO-MED-STAT project, is acting as a partner in the PPRI project. (Figure 1)

**Description of the project**

The PPRI project is split into six work packages: 1) Coordination, 2) Dissemination, 3) Assessment,

**Figure 1. Organisation chart of the Pharmaceutical Pricing and Reimbursement Information (PPRI) project**



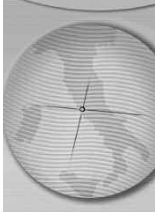


Table 1. Overview of the aims of the PPRI project and the corresponding work packages (WP) and deliverables

Specific aim:	Work package(s):	Deliverables:
Strengthening the networking	WP 1 'Coordination'	good communication and cooperation in the project, achieving the objectives of the project in good quality and according to the time-table
	WP 2 'Dissemination'	a website and a conference at the end of the project (Spring 2007)
Assessing the needs	WP 3 'Assessment'	questionnaire to be used in the interviews, list of key information to be surveyed
Collection and re-reporting of information	WP 4 'Survey'	Pharma Profiles (=country reports) of the EU Member States
Developing indicators	WP 5 'Developing of comparable indicators'	a list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report
Dissemination of project results	WP 2 'Dissemination'	International publications and organisation of a conference at the end of the project (Spring 2007)

4) Survey, 5) Development of comparable indicators (benchmarks) and 6) Comparative analysis (benchmarking). Below is a description of each of the Work Packages. In addition, Table 1 provides an overview of the aims of the project and their corresponding work packages and deliverables.

#### Work package 1: Coordination (lead partner: ÖBIG)

ÖBIG / Austrian Health Institute takes the lead in the overall coordination of the PPRI project. In this role ÖBIG acts as the contact person both within and outside the project team, thus guaranteeing good communication within the project and an understanding of the objectives.

In addition, ÖBIG is responsible for the preparation (organisation and content) of the large-scale conference at the end of the project.

#### Work package 2: Dissemination (lead partner: ÖBIG)

A key work package is dissemination. This concerns the project, its objectives, the set of indicators (benchmarks) developed, the information and data on pricing and reimbursement in the individual Member States and the comparative analysis; and does not only take place at the end, but during stages of the project.

Important products of this work package are a (conference) hosted in Vienna at the end of the project and a public website (<http://ppri.oebig.at>) with information on the project, its objectives, its partners, its European value, and pharmaceutical pricing and reimbursement information per country. Apart from these two key deliverables regular national and international publications and presentations are planned. In addition the main partner, the associated partner and the participants in the project are devoted to make the project widely known in their countries.

#### Work package 3: Assessment (lead partner: WHO)

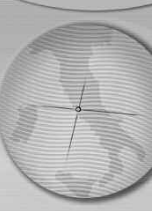
The first step of this work package, which started in September 2005 and completed in December 2005, was to assess which kind of pricing and reimbursement information is of interest to policy-makers and stakeholders at both national and EU levels. There may be, for example, interest in the functioning and structuring of the reference price systems which some Member States have introduced, there may be the need for further information on the handling of reimbursement decisions (formal, economic and medical criteria applied, guidelines, etc.) or there may be the urge to know more about the different models of generic promotion in the Member States and the experiences that the Member States had with these models.

The needs assessment was made up of two parts. In the first part the partners and observers who attended the 1st coordination meeting on 1 and 2 September 2005 were asked to express their most urgent information needs both verbally and in writing. In the second part an open questionnaire was developed which was used by the partners and some of the observers in the project to systematically assess the information needs of other relevant stakeholders in their country. In addition, this questionnaire was used during interviews with representatives from a number of international organisations at a European level, such as the European Commission and several interest groups (e.g. pharmaceutical industry, pharmacists, and patients). The results of all interviews have been documented and analysed.

This resulted in a list of pricing and reimbursement information to be surveyed and reported upon.

#### Work package 4: Survey (lead partner: WHO)

The key research work in the PPRI-project will



be the survey of information on pricing and reimbursement in the Member States, and the documentation of this information in so-called "pharma profiles". The information collected will meet the needs identified in work package 3 as much as possible, and the reporting in the "pharma profiles" will follow a homogenous structure, which is currently under development. The partners in the PPRI network (including the main partner ÖBIG as a representative of Austria) will each draft a "pharma profile" on pharmaceutical pricing and reimbursement in her/his country.

**Work package 5:** Development of comparable indicators (lead partner: ÖBIG)

To compare the pharmaceutical pricing and reimbursement information of the individual.

Member States, indicators ("benchmarks") have to be developed. The main partner in the project, ÖBIG, will draft a list of indicators guaranteeing the comparability of the information and data of the different Member States.

**Work package 6:** Comparative analysis (lead partner: ÖBIG).

Based on the work done in the previous work packages, pharmaceutical pricing and reimbursement in the Member States will be benchmarked. The results of the comparative analysis will be drafted in a report by ÖBIG.

#### **Running time of the project**

The PPRI project started on the 1st of April 2005 and is designed to run for 24 months until the summer of 2007. At the end of the project, ÖBIG will organise a conference which will take place in Vienna. During this conference the results of the PPRI study will be disseminated. As

mentioned previously the pharmaceutical systems in the Member States are subject to frequent changes and reforms. This means that descriptions of the current system might be out of date within a few years. It is therefore important that during the course of the PPRI project plans are made for the continuation of the information sharing process.

#### **Funding**

The PPRI project, which is described in this article, is funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Austrian Ministry of Health and Women's Issues.

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