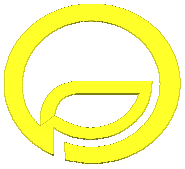

PPRI

Pharmaceutical Pricing and Reimbursement Information

A project funded by
European Commission, Directorate-General Health and Consumer Protection and
Federal Ministry of Health and Women's Issues, Austria

INTERIM REPORT

Vienna, May 2006

PPRI

Pharmaceutical Pricing and Reimbursement Information

TECHNICAL INTERIM REPORT

delivered by the main beneficiary

ÖBIG / Austrian Health Institute

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Abbreviations

AIFA	Italian Medicines Agency
BMGF	Austrian Federal Ministry of Health and Women's Issues (Österreichisches Bundesministerium für Gesundheit und Frauen)
DG Entr	Directorate-General Enterprise and Industry of the European Commission
DG Sanco	Directorate-General Health and Consumer Protection of the European Commission
EC	European Commission
EGA	European Generics Association
EMEA	European Medicines Agency
ESIP	European Social Insurance Platform
EU	European Union
FASII	Austrian Federal Association of Social Insurance Institutions
IFPMA	International Federation of Pharmaceuticals Manufacturer Associations
LSE	London School of Economics
MEDEV	Medicine Evaluation Committee
MS	Member States
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
PGEU	Pharmaceutical Group of the European Union
WHO	World Health Organisation
WHO Europe	World Health Organisation - Regional Office for Europe
WP	Work Package

Technical Fact sheet

Project	Pharmaceutical Pricing and Reimbursement Information (PPRI)
Project No.	Agreement Number - 2004125
Programme	Public Health Programme 2003-2008; Health information and knowledge 2004
Action	Improving information and knowledge for the development of public health
Start Date of Project	April 2005
Duration	24 months extension to summer 2007 planned
Objectives	Improvement of information and knowledge on the pharmaceutical systems in the enlarged Europe, thus • contributing to increase transparency, • providing information and advice for policy-makers on national and European levels, • and facilitation a regular exchange of information and allowing a process of lessons learning from each other.
Tasks/Work packages	WP 1 Coordination WP 2 Dissemination WP 3 Assessment WP 4 Survey WP 5 Development of comparable indicators (benchmarks) WP 6 Comparative analysis (benchmarking)
Commissioners	• European Commission – Health & Consumer Protection Directorate General • Austrian Ministry of Health and Women's Issues
DG SANCO Representative	Mr. Daniel Mann successor of Ms. Zinta Podniece
Austrian BMGF Representative	Mr. Gernot Spanninger
Main Beneficiary	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (ÖBIG)
Associate Beneficiary	World Health Organisation – Regional Office for Europe (WHO Europe)
Partners	• Ministry of Economy Affairs, Belgium • International Healthcare and Health Insurance Institute, Bulgaria • Health Insurance Organisation, Cyprus • Ministry of Health, Cyprus • Ministry of Health, Czech Republic • Medicines Agency, Denmark • Ministry of Social Affairs, Estonia • Association of Finnish Pharmacies, Finland • University Claude Bernard Lyon 1, France • Institute for Medical Documentation and Information,

	Germany • Institute for Pharmaceutical Research and Technology, Greece • National Health Insurance Fund, Hungary • HSE-Shared Services-Primary Care, Ireland • Medicines Agency, Italy • Ministry of Health, Lithuania • Ministry of Health, Welfare and Sport, Netherlands • Ministry of Health, Poland • State Institute for Drug Control, Slovakia • Agency for Medical Products, Slovenia • Pharmaceutical Benefits Board, Sweden
Institutions involved as Observers	National stakeholders • Federal Association of Social Insurance Institutions, Austria • Health Canada, Canada • Ministry of Health, Cyprus • Charles University, Czech Republic • Ministry of Social Affairs and Health, Finland • National Sickness Fund for Employees, France • National Centre for Pharmaco-economics St. James Hospital, Ireland • Medicine's Pricing and Reimbursement Agency, Latvia • Ministry of Economic, Luxembourg • Union of Sickness Funds, Luxembourg • Ministry of Health, Health Division, Malta • Medicines Agency, Norway • Ministry of Health and Care Services, Norway • National Pharmacy and Medicines Institute, Portugal • Ministry of Health and Consumer Affairs, Spain • Andalusian School of Public Health, Spain • Medicines Pharmacy and Industry, United Kingdom European / International Institutions • Health Division, OECD • European Medicines Agency, EMEA • European Observatory on Healthcare Systems and Policies • European Commission, DG Enterprise • SOGETI

1 Introduction

This report is the Interim Technical Report on Implementation on the Pharmaceutical Pricing and Reimbursement Information project (PPRI), delivered by the main beneficiary ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute) to the commissioner Directorate-General Health and Consumer Protection of the European Commission.

The project is co-funded by the Austrian Federal Ministry of Health and Women's Issues (Österreichisches Bundesministerium für Gesundheit und Frauen, BMGF).

As stipulated in the Reporting Requirements (Annex III) in the Grant Agreement for an Action (Agreement Number - 2004125), the Interim Technical Report on Implementation

- provides information on the results obtained to-date and
- gives an outlook to the work programme to be performed.

According to Article I.5.2 of the Grant Agreement, the beneficiary authorises the Commission to disseminate, communicate or publish the report concerning the action.

Additionally, the main beneficiary has submitted a consolidated financial statement on the first period (taking into account expenditure until April 2006) to the commissioner.

According to Article I.5.1 of the Grant Agreement, the Interim Technical Implementation Report should cover the period from 1 April 2005 (start of project) to 31 March 2006. The main beneficiary has decided to expand the reporting period to the end of April 2006, as on 27 and 28 April 2006 the second project co-ordination meeting took place and its outcomes were to be included into the report.

2 Overview on PPRI project

2.1 Background

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

In reality, there are 25 pharmaceutical pricing and reimbursement systems in the enlarged Union which sometimes differ to a great extent. Several overviews have been made over the last years, both commercially as well as for and by authorities. Problems have often been the non-comparability of the information, lack of completeness, issues on validity and sufficient level of detail to make it meaningful, as well as information not being up to date.

Therefore, 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 has been considered of great need.

The PPRI project under the lead of the main beneficiary Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (furthermore ÖBIG) and the associate beneficiary World Health Organisation, Regional Office for Europe (furthermore WHO Europe) aims, together with a network of relevant stakeholders in pharmaceutical policy at national level from all EU Member States, Bulgaria and Norway, to produce comprehensive country reports on pharmaceutical pricing and reimbursement ("Pharma Profiles") and to benchmark these information and data in a comparative analysis.

2.2 Objectives

2.2.1 General Objectives

The general objectives of the PPRI project are as follows:

- to improve information and knowledge on the pharmaceutical systems in the Member States of an enlarged Europe, thus contributing to increase transparency,
- strengthening the networking of the relevant national agencies and institutions in the field of pharmaceuticals in the EU Member States,
- facilitating a regular exchange of information and allowing a process of lessons learning from each other,

- developing indicators for benchmarking pharmaceutical pricing and reimbursement systems,
- providing information and advice for policy-makers on national and European Union level.

2.2.2 Specific Objectives

The specific aims related to this project are:

1. Strengthening the networking of the relevant national authorities and institutions in the field of pharmaceuticals in the Member States
2. Assessing the needs of EU and national administration and policy-makers with regard to knowledge and information transfer on pharmaceutical pricing and reimbursement
3. Developing a homogenous structure/template for the country reports on pricing and reimbursement ("pharma profiles")
4. Developing indicators (benchmarks) for the comparative analysis of the pharma profiles
5. Systematic collection of relevant information and data on pharmaceutical pricing and reimbursement in the Member States, clear reporting (the pharma profiles, to be kept on national websites as living documents) and in-depth analysis
6. Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe
7. Dissemination of the project results

2.3 Commissioners

The PPRI project is commissioned by the Directorate-General Health and Consumer Protection of the European Commission (furthermore DG Sanco) under the framework of the Public Health Programme 2003-2008, Health information and knowledge 2004.[1]

The Austrian Ministry of Health and Women's Issues (Österreichisches Bundesministerium für Gesundheit und Frauen, BMGF), co-funding PPRI, acts as second commissioning party.

2.4 Project Co-ordination

The PPRI project is co-ordinated by the main beneficiary ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute) located in Vienna (Austria) in cooperation with the associate partner WHO Europe located in Copenhagen (Denmark). WHO Europe takes the lead in two work packages (work package 3: assessment and work package 4: survey) whereas ÖBIG takes the lead in the four other work packages (cf. Table 2.2 for details).

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

At ÖBIG, a broad team of experts is committed to the PPRI project, some of them involved in a "core team" and some working as consultants on selected parts of the project. Table 2.1 lists the ÖBIG staff contributing to the PPRI project.

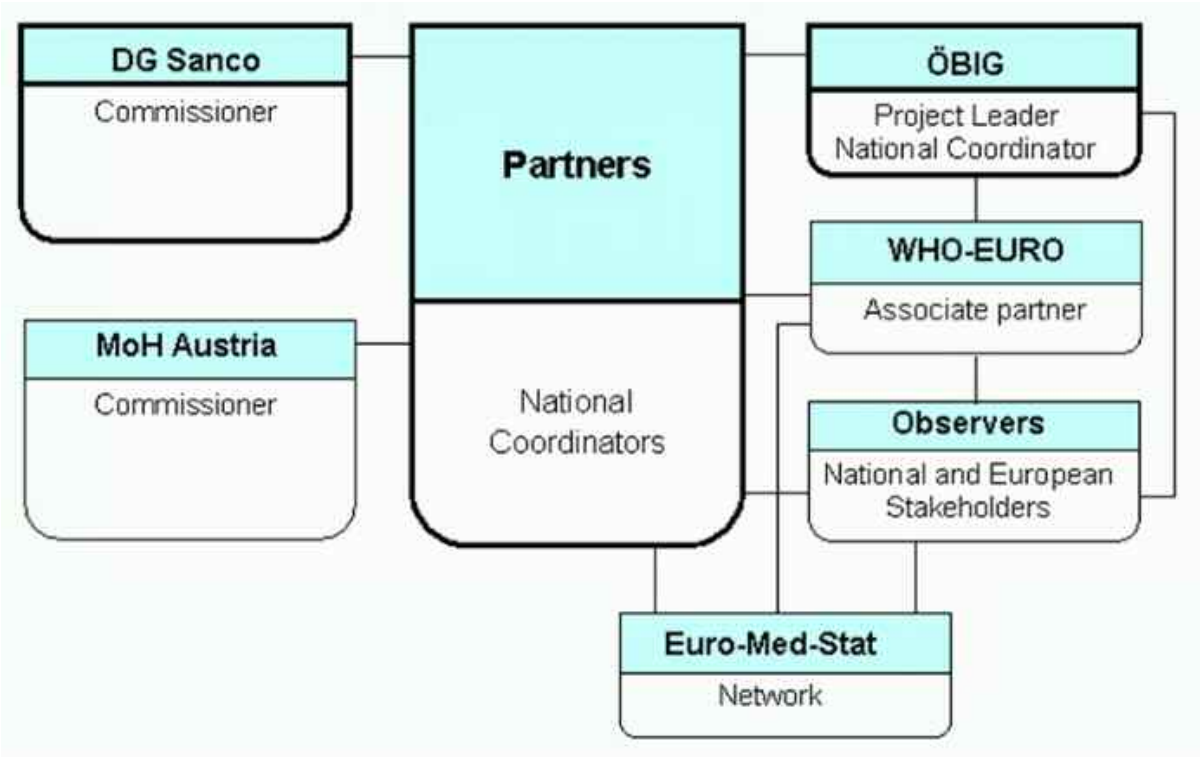
Table 2.1: Overview - PPRI team at ÖBG

ÖBIG PPRI core team	ÖBIG PPRI consultants and support
• Sabine Vogler (project coordinator) • Claudia Habl (deputy project coordinator) • Ingrid Rosian-Schikuta (deputy project coordinator) • Danielle Arts • Barbara Fröschl • Christine Leopold • Reinhard Lehner (IT) • Romana Landauer (Assistant)	• Katja Antony • Heidi Stürzlinger • Marion Weigl • Gerhard Hofstätter • Brigitte Juraszovich • Karin Kopp • Philipp Mold • Zdenka Soucek • Ference Schmauder • Renate Weidenhofer

Source: PPRI

At WHO Europe, Mr. Kees de Joncheere, Ms. Trine Lyager Thomsen, Ms. Marie-France Wargniez and further support staff (e.g. IT-expert) work on the PPRI project.

Figure 2.1: Overview - Project organisation



Source: PPRI

The PPRI project co-ordination may be contacted directly through the e-mail address ppri@oebig.at, which is read by ÖBIG PPRI team members and Ms Trine Lyager Thomsen from WHO Europe. The following Figure 2.1 allows an overview of the project organisation.

2.5 Tasks and Deliverables

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study. Table 2.2 provides an overview of these work packages with their key deliverables.

Table 2.2: Overview - Objectives, work packages and deliverables

Specific objective of PPRI project	Work package(s)	Deliverables
Strenghtening the networking of institutions in the field of pharmaceuticals in Member States and Dissemination of project results	WP 1 'Co-ordination'	Good communication and co-operation within the project, for delivering a project of high quality on time; fulfilling of administrative tasks like reporting and documentation
	WP 2 'Dissemination'	A website (http://ppri.oebig.at), international presentations and publications and organisation of a conference at the end of the project (foreseen for summer 2007 in Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected; provision of results in written form
Collection, reporting and analysis of information on pricing and reimbursement in Members States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Deleveloping indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged EU	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report

In the following sections 3 to 8, each work package will be described in detail with regard to its tasks and deliverables. Each section will

- start with an overview of the work package (lead partner, partners involved, tasks, current status of deliverables, additional outcome),
- continue with a presentation on the task performed and the results obtained in the reporting period, and finally
- give an outlook on the work programme planned for the second year of the PPRI project.

Deviations from the initial work programme outlined in the PPRI project proposal will be indicated.

The PPRI project co-ordination is pleased to report that even more tasks and deliverables have been performed than originally planned (e.g. the network of PPRI participants has been enlarged by further observers, cf. 3.2.1, and as support tool for drafting the pharma profiles a PPRI glossary of relevant terms of pharmaceutical policy, cf. 6.2.3 was developed), which will be outlined in the respective sections on the work packages.

2.6 Time-table

The PPRI project started in April 2005 and has, according to the project proposal, a planned duration of 24 months. However, the project co-ordination assumes that the PPRI project will probably end in summer 2007 as especially the project partners have suggested to separate the 4th coordination meeting and the final conference which was in the origin planned to be at one date.

The PPRI conference (cf. 4.3.3), which will be one of the last deliverables, is planned for end of June 2007.

Table 2.3 informs on the time-table for the 6 work packages of the PPRI project from a current perspective.

Table 2.3: Overview - Time-table on PPRI project

WP No.	Work package (WP)	Time-table
1	Co-ordination	Is performed during the whole duration of the PPRI project
2	Dissemination	Is performed during the whole duration of the PPRI project
3	Assessment	Is completed
4	Survey	Has started, will probably be completed at the end of 2006
5	Development of comparable indicators	Has started, will probably be completed by January 2007
6	Comparative analysis; benchmarking	Will start after completion of work package 4 and 5, will be performed in 2007

Source: PPRI

3 Work package 1: Co-ordination

3.1 Overview

Work Package 1	Coordination
Lead Partner	Main Beneficiary: ÖBIG
Partners involved	All
Tasks	• Assuring that the defined objectives of the PPRI project are reached correctly according to the timetable as well as that the expectations of DG SANCO, the participants and other parties interested are met. • Acting as the contact for DG Sanco, for all participants (partners and observers) and for all external requests (e.g. other Commission representatives) • Guaranteeing a good communication and co-operation in the project team • Providing for the technical, administrative and organisational concerns during the project • Organisation of coordination meeting and workshops • Drafting the mid-term and final report • Setting up the project website
Current Status on Deliverables	• D 1.1: Minutes from the 1st Co-ordination Meeting - performed (cf. Annex II) • D 1.2: Minutes from the 2nd Co-ordination Meeting - performed (cf. Annex IV) • D 1.3: Minutes from the 3rd Co-ordination Meeting - due in October 2006 • D 1.4: Minutes from the 4th Co-ordination Meeting - due in spring/summer 2007 • D 1.5: Interim report to DG SANCO - performed • D 1.6: Final technical and financial report to DG SANCO - due after completion of project in summer 2007
Additional Outcome	• Integration of further relevant national and European/international stakeholders in the project on an observatory basis • Ensuring communication between the participants via the establishment of an intranet platform (members-only site) on the project website

3.2 Tasks Performed

3.2.1 Network of Partners and Observers

Work package 1 aims at strengthening the network of institutions in the field of pharmaceuticals among the participating countries. Thus, this work package is relevant throughout the whole

project (cf. Table 2.3), however work has already been done in this context before the official start of the project.

Already in the proposal several partners who have committed themselves to participate in the project have been named. The project co-ordination is pleased to report that in the course of the project further partners and observers could be added to the project.

Besides the associate beneficiary WHO Europe (cf. 3.2.2), the partners represent relevant national stakeholders in the field of policy making on pricing and reimbursement of pharmaceuticals. The partners represent mainly Ministries of Health or Third Party Payers (i.e. National Health Services or Social Health Insurance Institutions).

By now, all 25 EU Member States, plus Bulgaria and Norway, are included in the PPRI project, at least on an observatory basis. In March 2006 also Canada has requested to take part as an observer and was invited to do so. The distinction between partners and observers is purely administrative, meaning that partners receive compensation for their expenses and observers participate on a voluntary basis.

In addition to the national stakeholders from Member States, ÖBIG is pleased to have also included European/supranational institutions, such as the European Medicines Agency (EMEA) and the Organisation for Economic Co-operation and Development (OECD). Furthermore it is the intention of the project team to closely co-operate with on-going European pharmaceutical projects like:

- OECD 'Pharmaceutical Pricing Policy project' (project manager: Ms. Elizabeth Docteur / OECD Health Division)
- DG Enterprise project 'Analysis of differences and communalities in Pricing and Reimbursement Systems in Europe' (project manager: Mr. Jaime Espin / Andalusian School of Public Health)
- DG Sanco project 'Euro-Med-Stat (database)' (project manager: Mr. Pietro Folino-Gallo / AIFA)
- DG Sanco project 'Development of public health impact performance indicators for the pharmaceutical sector' (project manager: Ms. Sophie Lopes / Sogeti)

As of May 2006, the PPRI project integrates a total of 20 partners and 21 observers, who are listed in Table 3.1.

Table 3.1: Work package 1 - Partners and observers participating in the PPRI project, as of May 2006

Country	Institution	Role	Status in PPRI
Project Coordination			
Austria	Austrian Health Institute	Research Institute	Main beneficiary
Denmark	WHO Europe	International Organisation	Associate beneficiary
National Stakeholders			
Austria	Federal Association of Social Insurance Institutions	Third Party Payer	Observer
Belgium	Ministry of Economy Affairs	Ministry	Partner
Bulgaria	International Healthcare and Health Insurance Institute	Research Institute	Partner
Canada	Health Canada	Research Institute	Observer
Cyprus	Health Insurance Organisation	Third Party Payer	Partner
Cyprus	Ministry of Health	Ministry	Partner
Czech Republic	Ministry of Health	Ministry	Partner
Czech Republic	Charles University	University	Observer
Denmark	Medicines Agency	Medicines Agency	Partner
Estonia	Ministry of Social Affairs	Ministry	Partner
Finland	Association of Finish Pharmacies	Association of Pharmacies	Partner
Finland	Ministry of Social Affairs and Health	Ministry	Observer
France	University Claude Bernard Lyon 1	University	Partner
France	National Sickness Fund for Employees	Third Party Payer	Observer
Germany	Institute for Medical Documentation and Information	Authority	Partner
Greece	Institute for Pharmaceutical Research and Technology	Research Institute	Partner
Hungary	National Health Insurance Fund	Third Party Payer	Partner
Ireland	HSE-Shared Services-Primary Care, Medical Service Board	Third Party Payer	Partner
Ireland	National Centre for Pharmaco-economics, St. James Hospital	Research Institute	Observer
Italy	Medicines Agency	Medicines Agency	Partner
Latvia	Medicine's Pricing and Reimbursement Agency	Medicines Agency	Observer
Lithuania	Ministry of Health	Ministry	Partner
Luxembourg	Ministry of Economics	Ministry	Observer
Luxembourg	Union of Sickness Funds	Third Party Payer	Observer
Malta	Ministry of Health	Ministry	Observer
Netherlands	Ministry of Health, Welfare and Sport	Ministry	Partner
Norway	Medicines Agency	Medicines Agency	Observer

Country	Institution	Role	Status in PPRI
Norway	Ministry of Health and Care Services	Ministry	Observer
Poland	Ministry of Health	Ministry	Partner
Portugal	National Pharmacy and Medicines Institute	Medicines Agency	Observer
Slovakia	State Institute for Drug Control	Medicines Agency	Partner
Slovenia	Agency for Medical Products	Medicines Agency	Partner
Spain	Ministry of Health and Consumer Affairs	Ministry	Observer
Spain	Andalusian School of Public Health	University	Observer
Sweden	Pharmaceutical Benefits Board	Authority	Partner
United Kingdom	Medicines Pharmacy and Industry, Department of Health	Ministry	Observer
European / International Stakeholders			
Belgium	European Observatory on Healthcare Systems and Policies	Research Institution	Observer
Belgium	European Commission, DG Enterprise	EU Institution	Observer
France	OECD, Health division	International Organisation	Observer
Luxembourg	SOGETI	Research Institute	Observer
UK	EMEA	EU Institution	Observer

Source: PPRI

The main beneficiary ÖBIG as well as the associate partner WHO Europe are constantly in contact with the project participants. On a regular basis information on the co-ordination meetings as well as the achievements of the project are sent out to the partners and observers of the project. In the course of the implementation of the intranet platform on the PPRI website the communication with the project partners as well as between the project partners will be facilitated (cf. 3.2.4)

3.2.2 Co-operation between main and associate beneficiary

Though the main beneficiary ÖBIG is taking the lead in WP 1, 2, 5 and 6 and the associate partner WHO Europe in WP 3 and 4 it is intended to perform all tasks in close cooperation. To guarantee such a close cooperation there are weekly wrap-up telephone conferences, that are supported by a regular (most daily) exchange of information via email.

In addition, Ms. Lyager Thomsen visits ÖBIG on a regular basis for several days for team meetings and consultation (cf. 6.2.1).

On top of that, there are also regular workshops held with the full project team (cf. 2.4). These meetings were held so far in May 2005, in September 2005, in October 2005 and in March 2006.

Furthermore, the 2nd PPRI co-ordination meeting on 27-28 April 2006 was held in Copenhagen, hosted by WHO Europe and was prepared in joint cooperation of the main and associate beneficiary (cf. 3.2.3.2).

3.2.3 Co-ordination meetings

For the PPRI project, four co-ordination meetings with all participants (partners and observers) are planned. Two of the meetings already took place.

3.2.3.1 Vienna Meeting

The first PPRI co-ordination meeting took place at ÖBIG on 1-2 September 2005. 42 persons, representing 29 institutions participated in this first meeting. The list of participants is attached to this Interim Technical Implementation Report (cf. Annex I).

The agenda covered

- getting to know each other and learning from the experiences and challenges in the field of pharmaceutical policy (work package 1)
- a presentation of the PPRI project website (work package 2)
- a first assessment on the needs of the partners and observers with regard to pharmaceutical pricing and reimbursement (work package 3)

The activities and outcomes of the first PPRI co-ordination meeting are in detail described in the minutes of the meetings, which are attached to this Interim Technical Implementation Report (cf. Annex II).

3.2.3.2 Copenhagen Meeting

WHO Europe hosted the second co-ordination meeting from 27-28 April 2006. 51 persons, representing 39 institutions participated in the second meeting. The list of participants is attached to this Interim Technical Implementation Report (cf. Annex III).

The agenda of the second co-ordination meeting covered

- an introduction of other relevant European projects in the field of pharmaceutical pricing and reimbursement (work package 2)
- a presentation of the PPRI website and intranet (work package 2)
- a presentation of the results of the needs assessment (work package 3)
- introduction of the template as well as the first experiences of countries in writing the template (work package 4)
- and a presentation of the PPRI glossary (work package 4).

In addition to the presentation of the template a group work on the different chapters of template was performed. The project participants could then in an open forum ("market place" technique) look at the results of the various groups and add their comments. The second co-ordination meeting ended with summing up the results of the group works as well as of the open forum

and an outlook on the third co-ordination meeting that is due for 9-10 October 2006 and will be hosted by Poland.

The activities and results of the second PPRI co-ordination meeting are in detail described in the minutes of the meetings, which are attached to this Interim Technical Implementation Report (cf. Annex IV).

3.2.4 PPRI Intranet Platform

For guaranteeing a good information flow between the main and associate beneficiary and the partners as well as observers of the PPRI project, ÖBIG has established an intranet platform for internal communication on the PPRI project website (cf. 4.2.3), which was presented at the 2nd co-ordination meeting in Copenhagen on 27-28 April 2006 (cf. 3.2.3.2).

The intranet ("members-only site") can be entered through the PPRI website (http://ppri.oebig.at). In order to log-in all project participants have received an individual password. Please find below a screenshot of the intranet.

The intranet platform is structured into the following sections:

- Contact details
- Meetings
- Discussion forum
- Documents
- Country information

Each section has a subsection, where all the relevant documents are available. The participants were encouraged to use the discussion forum and to up-load further documents.

For an easier handling of the intranet, ÖBIG has developed a manual, which is attached to this Interim Technical Implementation Report (cf. Annex V).

3.2.5 Forum of EU funded projects on pharmaceuticals

The PPRI project intends to encourage the co-operation of experts working in the same field. Thus, the project co-ordination has established the contact to the leaders of projects on pharmaceuticals funded by the European Commission.

At the 2nd co-ordination meeting on 27-28 April 2006 representatives of all relevant EU / European projects and initiatives were present:

- Pietro Folino-Gallo (AIFA) presented the „EURO-MED-STAT (db)" project, commissioned by European Commission DG Sanco
- Stefaan van der Spiegel (DG Enterprise and Industry) presented the "Pharmaceutical Forum and the Working Group on Pricing" as the follow up project to the G10 process.
- Kees de Joncheere (WHO Europe) presented the WHO networking initiatives with the competent authorities on pricing and reimbursement policies in Europe.
- Jaime Espin (Andalusian School of Public Health) presented the project: "Analysis of Differences and Commonalities in Pricing and Reimbursement Systems in Europe" commissioned by the Directorate-General Enterprise and Industry of the European Commission
- Elisabeth Docteur (OECD) presented the "OECD Pharmaceutical Pricing Policy Project" commissioned by OECD Health Division.
- Sophie Lopes (SOGETI) presented the project "Development of Public Health Performance Indicators for the Pharmaceutical Sector" commissioned by European Commission DG Sanco.
- Peter Wieninger (FASII) presented the MEDEV (Medicine Evaluation) committee, which is a pharmaceutical policy cooperation hosted by the European Social Insurance Platform (ESIP).

3.3 Work Programme Planned

3.3.1 Further co-ordination meetings

The third PPRI co-ordination meeting will take place on 9-10 October in Warsaw. The meeting will be hosted by the Polish PPRI partner, the Ministry of Health. ÖBIG will assist in the organisation of the meeting, besides being fully responsible for the content of the meeting.

The agenda is planned to focus on

- the experiences in the drafting of the reports of the national pharmaceutical pricing and reimbursement systems ("Pharma Profiles", cf. 6.3.1; work package 4)
- fixing the time table for completion and editing of the country profiles
- a discussion of a first proposal of indicators for the benchmarking (work package 5)

The fourth PPRI co-ordination meeting shall take place in the spring 2007.

3.3.2 Regular communication

The good communication flows between the main and the associate partner on the one hand, and to all PPRI participants is planned to be continued as hitherto (cf. 3.2.2).

The intranet platform (cf. 3.2.4) is considered to act as an important tool to facilitate the exchange of information between the partners.

3.3.3 Reporting

As for the minutes of the first 2 co-ordination meetings, the project co-ordination will also submit the minutes of the further meetings as well as the final report to its commissioners.

4 Work package 2: Dissemination

4.1 Overview

Work Package 2	Dissemination
Lead Partner	Main Beneficiary: ÖBIG
Partners involved	All
Tasks	• Setting up a project website • Regular contacts to DG SANCO and, if appropriate, to member of the G10-post process • Large-scale workshop/conference • Regular information on the PPRI project in journals
Current Status on Deliverables	• D 2.1: PPRI project website - performed, to be regularly up-dated • D 2.2: PPRI conference - due in spring/summer 2007 • D 2.3: Publications - performed, to be continued
Additional Outcome	• Several presentations on the PPRI project in international conferences • PPRI project is known to relevant stakeholders at national and supranational level in Europe • PPRI logo

4.2 Tasks Performed

4.2.1 Logo

For dissemination purposes, a logo was developed for the PPRI project. The PPRI logo, which is displayed in Figure 4.1, shall be used in all publications on PPRI.

Figure 4.1: Work package 2 - PPRI Logo

Source: PPRI

4.2.2 Information Leaflet

Shortly after the start of the project, a leaflet with key information on PPRI was designed. The information leaflet, which was presented to the PPRI participants in the 1st co-ordination meeting in Vienna, has meanwhile been sent to numerous persons being interested in the PPRI project.

The information leaflet, which can also be downloaded from the PPRI website (cf. 4.2.3), is attached to this Technical Interim Report in Annex IX.

4.2.3 Website

A key dissemination tool is the PPRI website which was set up in summer 2005 and presented to the PPRI participants at the 1st co-ordination meeting.

The URL of the website is: http://ppri.oebig.at . Please find below a screenshot of the starting page of the intranet.

The website is structured as follows:

- General information: displaying the objectives and the duration of the project as well as the information leaflet, links, contact details and a disclaimer. There is also a news section on the right side of the webpage, where all the relevant happenings in the field of pricing and reimbursement in the Member States are presented.

- Project organisation: giving information on DG Sanco, the Austrian Ministry of Health and Women's Issues, ÖBIG, WHO Europe, the project partners and observers.
- Work plan: giving an overview of the 6 work packages.
- Dissemination: stating all the dissemination activities that have been preformed so far.
- Glossary: defining all relevant terms in the field of pharmaceutical pricing and reimbursement.
- PPRI Members: special intranet platform for all project participants.

In addition to the publicly available parts of the PPRI website, a intranet platform was created (cf. 3.2.4) which allows PPRI participants to communicate between each other and which provides information for drafting the pharma profiles (work package 4, cf. 6.3.1).

4.2.4 Communication to commissioning parties

The PPRI project co-ordination has been committed to a good communication to the commissioning parties, the Directorate-General Health and Consumer Protection of the European Commission and the Austrian Ministry of Health and Women's Issues.

Representatives from both the Directorate-General Health and Consumer Protection of the European Commission and the Austrian Ministry of Health and Women's Issues have been present at the two PPRI co-ordination meetings which took place by now.

In addition, PPRI project team members of ÖBIG participated in the meeting of the Working Party on Health Systems on 26 April 2005 in Luxembourg and presented the PPRI project. In June 2005, ÖBIG held a meeting with representatives of the Austrian Ministry of Health and Women's Issues in order to inform in-depth on the PPRI meeting.

Furthermore, representatives of the commissioning parties are included in all relevant e-mail conversation which the PPRI project co-ordination has the group of participants.

4.2.5 Communication to stakeholders

The PPRI participants, who represent key institutions in the field of pharmaceutical policy at national level (cf. 3.2.1), are considered to act as "focal points" in their country. Besides undertaking the needs assessment (work package 3) at national level and drafting the pharma profile on their country (work package 4), dissemination activities in their country are mainly up to them.

The needs assessment proved to be a good opportunity to get into contact with several stakeholders. As described in section 5.2.3, representatives from the public sector (ministries, medicines' agencies, social insurance funds, etc.) as well as from the private sector (association of the pharmaceutical industry, wholesale, pharmacies, doctors and patients) were contacted in the course of the second half of 2005. The needs assessment at European level, predominantly undertaken in October 2005, contributed to the dissemination of the PPRI project at European stakeholders in pharmaceutical policy.

4.2.6 Presentations at international conferences

The PPRI project was also made known at international conference, where at least a part of the presentation was devoted to the PPRI project.

Table 4.1 gives an overview of the dissemination activities of the main beneficiary ÖBIG and the associate beneficiary WHO Europe at national and international conferences during the first year of the PPRI project in chronically order.

Table 4.1: Work package 2 - Presentations on PPRI until beginning of May 2006

Date	Place	Conference / Audience	Title of the presentation	Hosting Institution	Presenting institution
1/2005	Paris, France	Conference "Global Pricing and Reimbursement"	Presentation "Pricing and Reimbursement in the New Member States - Update on selected countries"	IIR	ÖBIG
3/2005	Vienna / Graz, Austria	Best-of-Biotech Workshop	Presentation "Health economics of innovative medicines"	Austrian Economic Service	ÖBIG
3/2005	Vienna, Austria	Annual International Conference "Pharmaceutical Markets in Russia and CIS"	Presentation "Pharmaceutical systems in Eastern Europe - an overview"	Marcus Evans	ÖBIG
4/2005	Luxembourg, Luxembourg	4th Meeting of Health System Working Party (representatives from Commission, Member States and academic and public institutions)	Presentation "PPRI. Pharmaceutical Pricing and Reimbursement Information"	European Commission, DG SANCO	ÖBIG
5/2005	Brussels, Belgium	Conference "Pricing, Reimbursement, and Parallel Trade"	Presentation "Pharmaceutical systems in Europe - an overview"	Jacob Fleming	ÖBIG
5/2005	Vienna, Austria	Meeting with Representatives from the Austrian Federation of Social Insurance Institutions	Presentation of the outline of the PPRI project	Austrian Federation of Social Insurance Institutions	ÖBIG
5/2005	Rome, Italy	1st Meeting of the project "EURO-MED-STAT (db)", commissioned by the European Commission, DG SANCO	Presentation of the PPRI project	Euro-Med-Stat group, managed by Pietro Folino-Gallo	ÖBIG
6/2005	Stegersbach, Austria	UNISYS Meeting	Presentation "Kosten versus Nutzen innovativer Arzneimittel"	UNISYS	ÖBIG
6/2005	Lisbon, Portugal	Meeting of Representatives of European Third Party Payers	Presentation of the PPRI project	MEDEV / ESIP	Austrian Federation of Social Insurance Institutions
6/2005	Vienna, Austria	Meeting with Representatives from the Austrian Federation of Social Insurance Institutions	Presentation of the PPRI project	Austrian Ministry of Health and Women's Issues	ÖBIG

Date	Place	Conference / Audience	Title of the presentation	Hosting Institution	Presenting institution
6/2005	Beirut, Lebanon	High Level Workshop with Stakeholders from Lebanese Pharmaceutical System (Ministry of Health, Order of Pharmacists, Importers' Organisation, Industry), World Bank and WHO	Presentation "Pharmaceutical pricing systems in Europe - an overview"	World Bank	ÖBIG
9/2005	Oslo, Norway	Meeting with Mr. Audun Håga from the Norwegian Ministry of Health	Presentation of the PPRI project, acquisition of further partners	Norwegian Ministry of Health	ÖBIG
9/2005	Vienna, Austria	1st Annual International Third Party Payer's Conference	"PPRI project outline"	Federal Association of Social Insurance Institutions	ÖBIG
9/2005	Izmir, Turkey	Conference of the Turkish Pharmacological Society	Presentation on Pharmaceutical policies in Europe	Turkish Pharmacological Society	WHO Europe
10/2005	Budapest, Hungary	CEE Pharmaceutical Challenges	Presentation "Pharmaceutical systems in Eastern Europe"	Jacob Fleming	ÖBIG
10/2005	Riga, Latvia	Annual Meeting of EuroPharm Forum	WHO medicines programme presentation	EuroPharm Forum (Pharmaceutical associations of 34 countries in Europe	WHO Europe
11/2005	Geneva, Switzerland	Meeting of all WHO personnel working in the area of medicines	Update on WHO Europe programme	WHO Geneva	WHO Europe
11/2005	St. Pölten, Austria	Health Care Best Practice Workshop with high level Bulgarian and Lower Austrian Government representatives as well as World Bank representatives	"Pricing and Reimbursement in Austria from an international perspective"	Austrian Ministry of Health and Women's Issues	ÖBIG
11/2005	Paris, France	2nd Eurohealth Forum	Presentation on Pharmaceutical policies in Europe	Societé Francaise d' Economie de Santé	WHO Europe
11/2005	Berlin, Germany	Annual Meeting of European Generic Manufacturers Association	Generic policies in Europe	EGA	WHO Europe
11/2005	Geneva, Switzerland	Meeting on Priority Medicines for Europe and the World	Discussion on reimbursement systems in Europe and other OECD countries	WHO Geneva	WHO Europe
11/2005	Brussels, Belgium	PGEU General Assembly	"Community Pharmacies in Europe"	PGEU	ÖBIG
12/2005	Paris, France	OECD meeting of experts on pharmaceutical pricing policy	Discussion on reimbursement systems in Europe and other OECD countries Presentation of the PPRI project and establishment of cooperation with OECD pharmaceutical impact project	OECD	ÖBIG and WHO Europe
1/2006	Barcelona, Spain	Conference "Global Pricing and Reimbursement"	Presentation "Central & Eastern Europe"	IIR	ÖBIG

Date	Place	Conference / Audience	Title of the presentation	Hosting Institution	Presenting institution
2/2006	Sarajevo, Bosnia Herzegovina	South East Europe Pharmaceutical Conference	Presentation "Pricing and Reimbursement in the European Union"	WHO	ÖBIG and WHO Europe
3/2006	Geneva, Switzerland	Workshop on "Pharmaceutical Consumption Measurement" (attendees: Pharmaceutical Industry Representatives, WHO, EFPIA)	Introduction to PPRI project	IFMPA	ÖBIG
4/2006	Copenhagen. Denmark	Euro-Med-Stat (db) coordination meeting	Progress report on PPRI project	Euro-Med-Stat Group	ÖBIG and WHO Europe
5/2006	Vienna, Austria	Meeting with the Permanent Secretary of the Ministry of Health of Cyprus	Presentation of the Austrian pharmaceutical system in brief, highlighting PPI and PPRI project	Austrian Ministry of Health and Women's Issues	ÖBIG

Source: PPRI

4.2.7 Articles

The PPRI project shall also be made public via articles in journals. However, these dissemination activities are planned to be set mainly at the end of project, when results can be presented.

The articles published by now (written by PPRI participants and external journalists, cf. Table 4.2) thus provided more a general description of the objectives, tasks and the project organisation.

Table 4.2: Work package 2 - Articles on PPRI until beginning of May 2006

Date	Place	Journal	Article	Author
January, 2006	Brussels; Belgium	kma	EU-Arzneimittelpolitik: "Nicht vor und nicht zurück"	ÖBIG
February, 2006	Cambridge, UK	PPR Magazine of IMS Health	PPRI Round-Up and introduction of Pharmaceutical Policy in New EU Member States	ÖBIG
May, 2006	Rome, Italy	Italian Journal of Public Health	Pharmaceutical Pricing and Reimbursement Information (PPRI): A European Union project	ÖBIG

Source: PPRI

4.3 Work Programme Planned

4.3.1 Communication and presentations

The dissemination activities will, of course, continue. To give two concrete examples:

- The PPRI project co-ordination will provide an up-date on the PPRI project at the next meeting of the Working Party on Health Systems in 20-21 June 2006, hosted by the Directorate-General Health and Consumer Protection of the European Commission in Luxembourg.

- The PPRI project will be introduced during a presentation on pharmaceutical pricing and reimbursement in Central and Eastern Europe in a conference in 12-13 June 2006, held in Budapest.

4.3.2 Publications

The PPRI report, including the pharma profiles (work package 4) and a comparative analysis on pharmaceutical pricing and reimbursement (work package 6), is scheduled for the end of the project. It is planned to be published on the PPRI website as well as on national websites of PPRI participants.

At stated in section 4.2.7, articles in journals on the outcome of the PPRI project will mainly be published at the end of project, when results can be presented. For the next month, an article in an Italian journal (called “About Pharmacy”) is intended. Several participants have already announced that they will publish some of the findings in peer-reviewed magazines like the Journal of Health Economics. On the last coordination meeting it was agreed, that publications of the PPRI participants basing on the results of the project are very much welcomed, provided that the articles are reviewed by either ÖBIG or WHO and that the PPRI project is mentioned as the basis of the article.

4.3.3 PPRI Conference

A highlight of the PPRI project will certainly be the conference at the end of the project.

As outlined in the project proposal, the outcome of the PPRI project will be presented and discussed. The conference, which is planned to take place in Vienna, is intended to be high-level: Representatives from the European Commission, the Pharmaceutical Forum, national administration, Third Party Payers (Social Insurance, National Health Service, etc.) and other stakeholders and interested parties, including industry and distribution chain representatives as well as academics shall be invited to the PPRI conference.

Most probably, the conference will take place in June 2007, which is a deviation from the PPRI proposal. Thus, the project co-ordination herewith officially requests the European Commission for an extension of the PPRI project, due to end in April 2007, till summer 2007.

5 Work package 3: Assessment

5.1 Overview

Work Package 3	Assessment
Lead Partner	Associate Beneficiary: WHO
Partners involved	All
Tasks	• Assessment of the information that is particular important for policy makers on national and EU level • Establishment of a list with the key needs of the EU Member States in the field of pharmaceutical pricing and reimbursement
Current Status on Deliverables	• D 3.1: Questionnaire to be used in the interviews (“Needs Assessment Guide”) - performed • D 3.2: Summary of the results of the assessment - performed • D 3.3: List of key information to be surveyed - performed
Additional Outcome	• Dissemination of the project (cf. 4.2.4)

5.2 Tasks Performed

5.2.1 First Assessment Round

As a kick-off for the work package 3, a first needs assessment round was undertaken during the 1st PPRI co-ordination meeting in Vienna on 1-2 September 2005. In a brainstorming session the participants in the meeting were asked to identify the most “burning needs” with regard to pharmaceutical pricing and reimbursement information for their countries from a public health perspective.

A total of 28 stakeholders from EU Member States, Bulgaria, Norway and European stakeholders participated in the first round of the needs assessment. The following priority areas with regard to pharmaceuticals were identified:

- Reimbursement
- Pricing
- Regulation
- Distribution
- Monitoring/Surveillance
- Access
- Affordability

In addition, the participants specified very detailed needs under these headings (e.g. which countries are in the basket in case of external price referencing). A preliminary list of key information to be surveyed was identified in this first needs assessment round and was included in the minutes of 1st co-ordination meeting and in the report on the needs assessment ("Intermediate Report", see section 7.4 and 7.5) which is enclosed to this Technical Interim Report (Annex VI a Intermediate Report of WHO).

5.2.2 Needs Assessment Guide

On the basis of the results of the first needs assessment, a questionnaire to be used in the interviews (the "Needs Assessment Guide") was developed under the lead of WHO team which is responsible for this work package. The needs assessment guide was completed in September 2005.

The questions in the Needs Assessment Guide were structured around three main areas:

- What information are you most interested in? (= background information for pharmaceutical pricing and reimbursement)
- Pricing, Reimbursement, Access/Cost-containment, Monitoring/Evaluation
- Additional comments

The Needs Assessment Guide can be found in section 7.6 of the report on the needs assessment ("Intermediate Report") enclosed to this Technical Interim Report (Annex VI a).

5.2.3 Needs Assessment

The actual needs assessment (the so-called second round of the needs assessment) was undertaken in autumn/winter 2005 and was divided into two strands:

- The needs assessment at national level

  Besides outlining their own needs, the participants involved in the PPRI project (partners and observers) addressed relevant stakeholders in their country (regulatory bodies such as ministries and/or medicines' agencies; third party payers like social insurance institutions and/or national health service; pharmaceutical industry, wholesale, pharmacy, doctors' and patients' associations) to assess their wishes concerning transparent information on pharmaceutical pricing and reimbursement.

  At national level, 101 institutions were assessed, which represent different actors:

  - 25 ministries
  - 14 third party payers (social insurance institutions and national health services)
  - 25 public institutions (universities, public health institutes, etc.)
  - 14 representatives of the pharmaceutical industry
  - 3 representatives of the pharmaceutical wholesale
  - 8 pharmacies' associations

- 3 insurance companies
- 3 doctors' associations
- 6 patients' associations

- The needs assessment at European level

  This part of the needs assessment was carried out by WHO and ÖBIG in form of interviews with relevant stakeholders from 14 European institutions (European pharmaceutical industry associations, European pharmacy association, Directorates-General of the European Commission, OECD, WHO). A side-effect of the needs assessment round at European level was that the PPRI project was made known to the European stakeholders.

A detailed list of all stakeholders involved is provided in section 7.1 (PPRI participants), section 7.2 (further national stakeholders) and section 7.3. (European stakeholders) of the report on the needs assessment ("Intermediate Report"), which is enclosed to this Technical Interim Report (Annex VI a).

5.2.4 Needs Assessment Report

The results of the needs assessment are displayed in detail in the "Intermediate report" by the WHO. The report gives information on the methodology and the outcome of the needs assessment and discusses and analyses the results. The report plus a summary is provided in Annex VI a and VI b of this Technical Interim Report.

The key information to be surveyed is listed in the following Table 5.1.

Table 5.1: Work package 3 - Overview of the key results of the needs assessment

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

Source: PPRI

5.3 Work Programme Planned

The work package 3 “Assessment” has been concluded with the provision of the “Intermediate Report” (Annex VI a), which was also presented in the 2nd co-ordination meeting in Copenhagen on 27-28 April 2006. Its results were the basis for the drafting of the template to be used when writing the pharma profiles (cf. chapter 6).

6 Work package 4: Survey

6.1 Overview

Work Package 4	Survey
Lead Partner	Associate Beneficiary: WHO
Partners involved	All
Tasks	• Development of a template for the Pharma Profiles according to the identified needs in the needs assessment • Description of the pharmaceutical systems of the EU Member States, Bulgaria and Norway
Current Status on Deliverables	• D 4.1: Homogeneous structure for country report ("Template") - performed • D 4.2: "Pharma profiles" - will be drafted in the course of the year 2006
Additional Outcome	• PPRI glossary • Involvement of European experts with expertise on country profiles (European Observatory, LSE, OECD) • Style sheet for drafting the pharma profiles

6.2 Tasks Performed

6.2.1 Template

Work package 4 is of key relevance and asks for major contributions by all PPRI participants: With its completion, identical country reports on the pharmaceutical system (the so-called "Pharma Profiles") will be provided for the European Member States and other participating countries like Bulgaria or Norway.

In order to guarantee

- that all relevant information is included and
- that the report are structured identically

a homogenous structure (the so-called "Template") was developed by WHO Europe with the support of ÖBIG and other experts (see below).

The headings of the pharma profiles are displayed in the following Table 6.1.

Table 6.1: Work package 4 - Headings of the pharma profiles, as foreseen in the template[1]

[1] Version as of 24 May 2006

Source: PPRI

The template was developed by the PPRI project team under the lead of WHO Europe on the basis of the Needs Assessment (c.f. Needs Assessment Report in Annex VI a and VI b).

Experiences by HiT (Health in Transition) profiles of WHO Observatory and by ÖBIG of similar pharma reports were taken into account. Furthermore, Mr. Elias Mossialos of the London School of Economics (LSE) reviewed the template and gave brief feed back on it.

In the beginning of February 2006, Ms. Trine Lyager Thomsen from WHO Europe stayed at ÖBIG for a week, and together with the ÖBIG team revised the template. After an additional workshop on 1 March 2006 between the main beneficiary ÖBIG and the associate beneficiary WHO Europe, the template was reviewed again by ÖBIG and then was sent to selected project participants (from Denmark and the Netherlands) for testing purposes.

This version of the template (see also Annex VIII) was then sent to the PPRI participants for feed back to be given during the 2nd PPRI co-ordination meeting on 27-28 April 2006. At the meeting 5 out of 6 chapters of the template ("background", "pharmaceutical system", "pricing", "reimbursement" and "rational use of pharmaceuticals") were discussed in detail in 5 work

template will be given to the PPRI participants for drafting the pharma profiles and will be available on the intranet site of the PPRI website (cf. 4.2.3).

The development of the template has taken longer than foreseen in the proposal (planned to be completed within 6 months after the project start), which is due to the several reviews as explained before. This delay also has consequences on the time-table for the completion of the pharma profiles (cf. 6.3.1).

The outcome of this thoroughgoing process of drafting and revising the structure of the pharma profiles is an extensive template which is considered as standard for further country reports on pharmaceutical pricing and reimbursement beyond the PPRI project. For each heading, the template states which information and data shall be included and gives hints on the way of presentation (e.g. sample tables are included). The template of the PPRI pharma profiles is provided in Annex VIII.

6.2.2 Style sheet

To facilitate the task of writing the country profiles for the national authors and to reduce the time needed for editing ÖBIG has produced a style sheet (".dot format") for the pharma profiles in order to guarantee an identical layout. The PPRI participants drafting the pharma profiles are asked to used the style sheet.

6.2.3 Glossary

As a support tool for the authors of the pharma profiles, an extensive glossary on pharmaceutical pricing and reimbursement terminology was established, which should guarantee the same understanding of technical terms by all PPRI participants.

The glossary has been developed by ÖBIG in co-operation with WHO Europe, the SOGETI indictors group, the OECD, the National Centre for Pharmacoeconomics (Ireland) and the WHO Observatory. The definitions in the glossary are based on existing ones of WHO, OECD, SOGETI, EGA, EMEA, World Bank as well as EURLEX terms and have been adapted by the ÖBIG team. In order to receive valuable feed back, the PPRI team sent the glossary to a couple of experts in the field of pharmaceutical pricing and reimbursement in the EU Member States as well as to the SOGETI indicators group, the OECD and WHO Observatory. In addition, the glossary was presented and discussed with the PPRI participants at the 2nd co-ordination meeting at end of April 2006.

The exhaustive feed-back rounds should assure that professionals of pharmaceutical pricing and reimbursement have agreed on these definitions of pharmaceutical terms. In addition to being a support tool for drafting the pharma profiles, the PPRI glossary is furthermore planned to develop as a standard instrument for all staff working in the field of pharmaceutical pricing and reimbursement.

The glossary was up-dated after the 2nd coordination meeting and now contains 142 terms (as "preferred terms", complemented by "synonym terms" and abbreviations). It is attached to this Technical Interim Report in Annex VII and is also available on the PPRI website (cf. 4.2.3).

6.2.4 Editorial Team

To provide support to the authors of the pharma profiles (cf. 6.3.1) and to guarantee high-quality editorial work on the pharma profiles, an editorial team, consisting of staff of the main and the associate beneficiary, was set up.

The key contact for technical issues is Ms Trine Lyager Thomsen from WHO Euro, which is assisted by PPRI team members of ÖBIG and WHO with country-specific expertise. For each country, two experts were nominated to help the authors in case of advice when writing and to review the respective pharma profiles.

The list of the members of the editorial team was made known to the PPRI participants in the 2nd co-ordination meeting on 27-28 April 2006 and is available to the participants on the intranet.

6.3 Work Programme Planned

6.3.1 Drafting of the Pharma Profiles

As already stated in section 6.2, work package 4 is of major relevance, and this is due to the country reports on the pharmaceutical pricing and reimbursement systems (the so-called "Pharma Profiles").

As outlined in the project proposal, the pharma profiles will be provided by the PPRI participants. This was one of the reasons why relevant stakeholders, active in the pharmaceutical pricing and reimbursement, were chosen to be included as partners and observers in the PPRI network (cf. 3.2.1). The PPRI participants may draft the pharma profile on their country themselves, or may outsource sections of the report to other national institutions, but finally, it is in their responsibility to deliver the national pharma profile. The editorial team set up by project members of ÖBIG and WHO will assist with advice (cf. 6.2.4).

As the intensive work on the template has taken longer than set out in the PPRI project proposal (cf. 6.2.1), the start of the writing of the pharma profiles has also been delayed. However, this has the advantage that more up-to-date data (e.g. pharmaceutical expenditure of the year 2005) can be included. The drafting of the pharma profiles is planned to take place in summer 2006. As decided at the 2nd co-ordination meeting on 27-28 April 2006, the PPRI participants will send their first draft of the pharma profile to the project co-ordination by end of September 2006.

6.3.2 Review of the Template

Based on the experiences in drafting the pharma profiles, which the PPRI participants will report on during the 3rd co-ordination meeting on 9-10 October 2006, and on the review of the pharma profiles by the editorial team, the template may be revised so that a multiple-tested version will be available for future work beyond the PPRI project.

In the course of the revision of the template, the glossary may also - if necessary - be modified.

6.3.3 Editorial Work

The pharma profiles will be reviewed by an editorial team, consisting of country experts, who has already been set up (cf. 6.2.4). The editors will assess the text with regard to consistency and comprehensibility and may look for any misunderstandings.

Furthermore all participating countries were encouraged to involve national experts in writing their pharma profiles and to have their text proof read before providing it to WHO Europe.

7 Work package 5: Development of comparable indicators

7.1 Overview

Work Package 5	Development of comparable indicators
Lead Partner	Main Beneficiary: ÖBIG
Partners involved	All
Tasks	• Defining indicators to compare the pharmaceutical systems of the individual countries • Discussion of the proposed indicators, development and common decision on indicators by the network of PPRI participants
Current Status on Deliverables	• D 5.1: Set of benchmarks - to be delivered by January 2007
Additional Outcome	• Close co-operation with EU-funded projects on indicators

7.2 Tasks Performed

7.2.1 Co-operation forum with indicators experts

Since December 2005, preliminary activities have been undertaken to develop a set of benchmarks to compare the pricing and reimbursement information provided in the pharma profiles.

In particular, there has been an ongoing close co-operation with the SOGETI indicators group who is also working on pharmaceutical indicators. The SOGETI indicators group has established a draft of indicators in the field of health care with a section on pharmaceuticals. This draft was revised by European health experts as well as, from the PPRI perspective, by ÖBIG. There have been several telephone conferences and two meetings with SOGETI representatives in Brussels. The SOGETI project manager Ms. Sophie Lopes also participated in the 2nd PPRI co-ordination meeting in Copenhagen.

Additionally, there has been discussion on indicators proposed by the EURO-MED-STAT group. Furthermore, the EURO-MED-STAT group had developed pharmaceutical indicators with a special focus on utilisation/expenditure and price. Based on these outcomes, the follow-up EURO-MED-STAT group will carry on to work on the utilisation/expenditure and price indicators. ÖBIG has been and still is a member of the EURO-MED-STAT group, and the EURO-MED-STAT project leader, Mr. Pietro Folino, is part of the PPRI network.

7.3 Work Programme Planned

7.3.1 Identification and discussion of indicators

The preliminary work on identification of indicators, which has been performed in co-operation with other EU-funded project teams working on indicators, as well as other published indicators pertaining to the pharmaceutical system, will continue and will result in a draft set of indicators.

When setting up this list of indicators, it has to be taken into consideration that the PPRI indicators have, to a great extent, be developed for benchmarking qualitative information instead of "hard" data. Indeed, based on previous projects, the ÖBIG team has experience on establishing such indicators.

The draft set of indicators will undergo some reviews. It is planned to ask the SOGETI indicators group and OECD for feed-back, and a proposed set of benchmarks will presented and discussed with the PPRI participants in a co-ordination meeting.

7.3.2 Final Set of Benchmarks

After revisions rounds the final set of benchmarks will be provided and shall be used for the comparative analysis of the pharmaceutical pricing and reimbursement information (work package 6). It is expected to complete the work package by January 2007, which is a deviation to the work programme outlined in the proposal.

8 Work package 6: Comparative analysis

8.1 Overview

Work Package 6	Comparative analysis
Lead Partner	Main Beneficiary: ÖBIG
Partners involved	All
Tasks	• Benchmarking of the pharmaceutical systems on the basis of the comparable indicators • Analyses of the results
Current Status on Deliverables	• Set of comparable pharmaceutical pricing and reimbursement information - to be delivered in the next period of the PPRI project • Analysis of pharmaceutical pricing and reimbursement in the enlarged Europe - to be delivered in the next period of the PPRI project
Additional Outcome	• Cannot not be estimated by now

8.2 Tasks Performed

Work package 6 can only be performed after completion of work package 4 (provision of the pharma profiles) and after a draft set of benchmarks has been developed and agreed upon by the project group. As outlined in the PPRI project proposal, it is thus planned for the last months of the PPRI project.

Therefore no tasks under work package 6 have been performed by now. The PPR project co-ordination expects to start this work package earliest in December 2006.

8.3 Work Programme Planned

By now, there are no deviations to the work programme of work package 6 as outlined in the Grant Agreement, Annex I, Section 4.3.

Annex

Annex I: 1st Co-ordination Meeting, list of PPRI Participants

Annex II: Minutes of the 1st Co-ordination Meeting, Vienna (1-2 September 2005)

Annex III: 2nd Co-ordination Meeting, list of PPRI Participants

Annex IV: Minutes of the 2nd Co-ordination Meeting, Copenhagen (27-28 April 2006)

Annex V: Manual PPRI Intranet

Annex VI a: Needs Assessment Report ,“Intermediate Report”

Annex VI b: Summary of Needs Assessment Report

Annex VII: PPRI Glossary

Annex VIII: Template of the PPRI Pharma Profiles

Annex IX: PPRI Information Leaflet

Annex I
1st Co-ordination Meeting, list of PPRI Participants

1st Co-ordination meeting, list of PPRI Participants

Name	Institution	Country
Zinta Podniece	European Commission, DG Sanco	Luxembourg
Hubert Hrabcik	Ministry of Health and Woman's Issues	Austria
Doris Kohl	Ministry of Health and Woman's Issues	Austria
Main Beneficiary		
Michaela Moritz	Austrian Health Institute	Austria
Sabine Vogler	Austrian Health Institute	Austria
Claudia Habl	Austrian Health Institute	Austria
Danielle Arts	Austrian Health Institute	Austria
Romana Landauer	Austrian Health Institute	Austria
Christine Leopold	Austrian Health Institute	Austria
Associate Beneficiary		
Kees de Joncheere	WHO, Regional Office	Denmark
Trine Lyager Thomsen	WHO, Regional Office	Denmark
Partners		
Marie-Thérèse Peeters	Ministry of Economic Affairs	Belgium
Mireille Pierlet	Ministry of Economic Affairs	Belgium
Gergana Andre	International Healthcare and Health Insurance Institute	Bulgaria
Athos Tsinontides	Ministry of Health	Cyprus
Pynelopi Valsamisová	Ministry of Health	Czech Republic
Elisabeth Thomsen	Medicines Agency	Denmark
Katrin Pudersell	Ministry of Social Affairs	Estonia
Sirpa Peura	Association of Finish Pharmacies	Finland
Eric van Ganse	University Claude Bernard Lyon 1	France
Hans-Peter Dauben	Institute for Medical Documentation and Information	Germany
Vardica Areti	Institute of Pharmaceutical Research and Technology	Greece
Gábor Lengyel	National Health Insurance Fund	Hungary
Deirdre Elliott	HSE-Shared Services-Primary Care	Ireland
Gerald Byrne	HSE-Shared Services-Primary Care	Ireland
Pietro Folino	National Research Institute	Italy
Gita Krukiene	Ministry of Health	Lithuania
Tomas Alonderis	Ministry of Health	Lithuania
Petra Jansen	Ministry of Health, Welfare and Sport	Netherlands
Piotr Blaszczyk	Ministry of Health	Poland
Stanislav Primozic	Agency for Medicinal Products	Slovenia
Thord Redman	Pharmaceutical Benefits Board	Sweden

Name	Institution	Country
Observers		
Anna Bucsics	Federal Association of Social Insurance Institutions	Austria
Axel Heilig	Federal Association of Social Insurance Institutions	Austria
Elizabeth Docteur	OECD	France
Christian Marty	National Sickness Fund for Employees	France
Lesley Tilson	National Centre for Pharmaco-economics St. Jame's Hospital	Ireland
Daiga Behmane	Medicine's Pricing and Reimbursement Agency	Latvia
Daniel Palnoch	Department of Health	United Kingdom
Göran Isaksson	EMEA	United Kingdom

Annex II
Minutes of the 1st Co-ordination Meeting, Vienna
(1-2 September 2005)

ÖBIG

PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION (PPRI)

MINUTES

First meeting

Vienna 1 - 2 September 2005
Venue: ÖBIG mezzanine, Stubenring 6, 1010 Vienna

Participants to the project: *see attachment 1*

Thursday, 1st September 2005

Registration 9:30-10:00

Morning session, 10.00 - 13.00: Welcome and Introduction *(chair: Sabine Vogler, ÖBIG)*

The morning session of the 1st day was dedicated to the introduction of all participants in the 1st Coordination meeting of the PPRI project:

- Michaela Moritz (General Manager of ÖBIG) welcomed the participants of the meeting and gave a short overview of the organisation and work of ÖBIG (Austrian Health Institute) and of the PPRI Project.
- Hubert Hrabcik (Austrian Federal Ministry of Health and Women's Issues, Director General of Public Health, MoHW) gave an introductory speech presenting the activities of the Austrian Federal Ministry of Health and Women's Issues in the field of pharmaceuticals (e.g. the average EU pricing, supported by the ÖBIG Pharma Price Information (PPI) service).
- Zinta Podniece (European Commission, DG Sanco) informed on the activities of DG Sanco and on projects funded by DG Sanco (*see attachment 2*).
- Sabine Vogler (Project leader, ÖBIG) introduced the ÖBIG PPRI project team and their roles.
- Kees de Joncheere (Associate partner, WHO) introduced the team at WHO and gave a presentation of the work of WHO Euro in terms of international cooperation in the field of pharmaceuticals (*see attachment 3*). He emphasized that different activities and initiatives in pharmaceuticals are going on in parallel, and that the PPRI project will make sure not to duplicate/copy efforts already undertaken by others.
- Introductory round: Each participating institution in the PPRI project (Partners and Observers) introduced themselves, presented the challenges in their national pharmaceutical

pricing and reimbursement system and specified their expectations on the PPRI project (*see attachments 4-24)*.

Presentations were given by Belgium (Marie-Thérèse Peeters), Bulgaria (Gergana Andre), Cyprus (Athos Tsinontides), Czech Republic (Pynelopi Valsamisová), Denmark (Elisabeth Thomsen), Estonia (Katrin Pudersell), Finland (Sirpa Peura), France (Eric van Ganse and Christian Marty), Germany (Hans-Peter Dauben), Greece (Vardica Areti), Hungary (Gábor Lengyel), Ireland (Deirdre Elliott and Gerald Byrne), Italy (Pietro Folino-Gallo), Latvia (Daiga Behmane), Lithuania (Gita Krukiene), Netherlands (Petra Jansen), Poland (Piotr Blaszczyk), Slovenia (Stanislav Primozic), Sweden (Thord Redman), United Kingdom (Danny Palnoch), EMEA (Göran Isaksson) and OECD (Elizabeth Docteur).

- Additionally, in the afternoon, Anna Bucsics (Austrian Federation of Social Insurance Institutions) gave her presentation on the challenges in the Austrian pharmaceutical system and expectations on the PPRI project and announced the 3rd Party Payers Conference in Vienna on 15-16 September 2005 (*see attachment 25*).

The session closed with questions and a discussion on cost-control measures taken by countries and their experience with them (e. g. prescribing habits - incentives vs. control), on the patent protection and transition periods of new Member States and on other projects (e. g. HTA-Network).

Afternoon session, 15.00 - 18.00: Presentation of PPRI *(chair: Kees de Joncheere, WHO)*

The afternoon session of the 1st day was devoted to the objectives, work packages, deliverables and tasks in the PPRI Project.

Presentation of the objectives and work packages of the PPRI project

In the first part of the afternoon session, Sabine Vogler (ÖBIG) gave a presentation on the PPRI project (*see attachment 26*). First she presented the field of activity “Pharma@ÖBIG” (international studies and cooperation, provision of pharmaceutical prices in the Member States through the PPI service). Having highlighted the rationale which lead to the project (need for up-to-date information on pharmaceutical pricing and reimbursement from a Public Health perspective; need for networking between the Member States), she described the general objectives (improving information and knowledge on the pharmaceutical systems in the enlarged Europe, increased transparency, providing information and advice for policy-makers on national and European levels, facilitating a regular exchange of information and allowing a process of lessons learning) and the specific objectives of the PPRI project as outlined in the project approved by DG Sanco and co-funded by the Austrian MoHW:

- Strengthening the **networking** of the relevant national authorities and institutions in the field of pharmaceuticals in the Member States
- **Assessing** the need of EU and national administration and policy-makers with regard to knowledge and information transfer on PPRI
- Country reports on pharmaceutical pricing and reimbursement ("**pharma profiles**")
- Developing **indicators** (benchmarks) for the comparative analysis
- **Benchmarking** pharmaceutical pricing and reimbursement in the enlarged Europe
- **Dissemination** of the project results

In the following, the expectations in the project expressed by the participants in the introductory round in the morning session were discussed:
Expectations could be summarised as: networking, cooperation and information sharing needs, learning from the experience of other countries, gaining information on pricing and reimbursement systems in other Member States, access to information and data, creating a database, developing benchmarks, and undertaking a comparative analysis. Sabine Vogler made clear that PPRI does neither aim to build a database of registered medicines (like the EMEA and the "EURO-MED-STAT db" project plan to establish) nor provide a database of pharmaceutical prices (which is already provided by the PPI service offered by ÖBIG). Finally, Sabine gave an overview of the work packages in the project:

- Coordination (WP 1, lead: ÖBIG): Overall coordination and communication between the main partner ÖBIG, the associate partner WHO, all partners and observers in the PPRI project and the commissioning parties
- Dissemination (WP 2, lead: ÖBIG): Making the project public (e. g. PPRI website, conference)
- Assessment (WP 3, lead: WHO): Assessing which information on pharmaceutical pricing and reimbursement is needed by the Member States and European stakeholders
- Survey (WP 4, lead: WHO): Country reports ("Pharma Profiles") with data and information on the national pharmaceutical systems (focus on pricing and reimbursement) in the EU Member States
- Comparable indicators (benchmarks) (WP 5, lead: ÖBIG): Development of indicators to compare the pharmaceutical systems
- Comparative analysis (benchmarking) (WP 6, lead: ÖBIG): Benchmarking of the pharmaceutical systems on the basis of the indicators in a comparative report

Discussion of the objectives and work packages of the PPRI project

In the following discussion, Sabine Vogler and Kees de Joncheere stressed that the focus of this project is on pricing and reimbursement. To meet the needs for information of the policy-makers, there will be a special work package (WP 3, "Assessment"), so that each country can express the required information on pricing and reimbursement.

There was a discussion on prices vs. pricing, some participants expressed the need for price information. Sabine Vogler pointed out that the aim of the project is not to build a database of European pharmaceutical prices but to share information on pricing (process, institutions,

criteria, fixed vs. negotiated pricing, distribution margins) and reimbursement. Prices without system information can be misinterpreted; besides, there are many methodological questions on how prices shall be compared. Furthermore, Member States needing information on pharmaceutical prices already established information services for their purpose (e.g. the ÖBIG PPI service for Austria).

It was agreed that links to country specific prices, if available, can be offered. The „EURO-MED-STAT (db)" project which aims to establish a database of licensed medicines was briefly presented by Pietro Folino (Italy).

Presentation of the tasks of the participants in the PPRI project

The second part of the afternoon session was dedicated to organisational and administrative matters of the PPRI Project (*see attachment 27*). Claudia Habl (ÖBIG) introduced the organisation in the project matrix (Commissioners, Partners, Project Leader, Associate Partner, Observers and related projects). She then talked about the tasks of the participants, administrative matters (communication, information flow) and the overall timetable.

She concluded her presentation with the next steps to be taken:

- Submission of the minutes of the 1st Coordination Meeting to the Partners/Observers of the PPRI project (20th September 2005, ÖBIG)
- Submission of the Need Assessment Guide (WP 3) to the Partners/Observers of the PPRI project (End September 2005, WHO)
- Needs Assessment carried out by the Partners/Observers of the PPRI project (October 2005), results sent to WHO by beginning of November 2005
- Consultation meetings of ÖBIG and WHO with the European Commission (October 2005)
- Development of a Pharma Profile template for the country profiles by WHO together with ÖBIG (till November 2005)
- Feed-Back Partners/Observers of the PPRI project on the Draft Pharma Profile Template (Winter 2005/2006)
- 2nd Coordination Meeting in Copenhagen (April 2006→ cf. Outlook of meeting)
  Preliminary Agenda:
  - Presentation of Results of Work Package 3
  - Approval of Final Pharma Profile Template
  - Discussion of indicators on the basis of the indicator draft paper

Communication

The participants were asked to use the e-mail address **ppri@oebig.at** for communication.

The List of Participants (address, e-mail,…) can be provided by ÖBIG on request.

Friday, 2nd September 2005

Morning session, 10.00 - 13.00: WP 3 "Assessment" *(chair: Claudia Habl, ÖBIG)*

The morning session was devoted to Work Package 3 "Assessment".

Presentation of the WP 3 ("Assessment)

Kees de Joncheere presented the key points of WP 3 (*see attachment 28*) in which WHO takes the lead:

- Assessment of the needs and expectations of the relevant stakeholders at Member State and European level with regard to pharmaceutical pricing and reimbursement information
- "Pharma Profiles" will be based on the results of the needs assessment as well as on various already existing material and literature
- First round of needs assessment in a brainstorming session in the first Coordination Meeting in Vienna
- Second round of needs assessment: done by the partners/observers in the project (acting as national focal points) with contacts to relevant national stakeholders; done by ÖBIG and WHO with contacts to the stakeholders at European level

Brainstorming Session of WP 3 ("Assessment")

The participants in the PPRI project were asked to formulate issues of interest for the PPRI project and then to present one major point. Key headings were as follows:

- Reimbursement
- Pricing
- Regulation
- Distribution
- Monitoring/Surveillance
- Access
- Affordability

Attachment 29 provides the results of the session as written down on flipcharts.

Next steps to be undertaken

On the basis of the results in the brainstorming session (summed up and attached to the minutes in the above mentioned *Attachment 29*), a **Needs Assessment Guide** will be developed by WHO and ÖBIG. Partners and observers will be invited to give feed-back and to re-assess their needs in the PPRI project. A key task of WP 3 is that participants in the project, acting as national focal points in the project, are asked to contact relevant stakeholders in their Member State to assess their needs on the basis of the Need Assessment Guide that will be sent to them. The main partner ÖBIG and the associate partner WHO will do the need assessment with the stakeholders at European level. The Needs Assessment should take place in October 2005.

The Needs Assessment is one of the pillars to develop a template for the "Pharma Profiles". As Kees de Joncheere stressed, the balance between details on the system and a manageable portion should be kept. He repeated that there should be linkages to other projects such as EURO-MED-STAT as to avoid overlapping work.

Afternoon session, 14.00 - 16.00: **WP 2 "Dissemination"** *(chair: Claudia Habl, ÖBIG)*

Presentation of work package 2 „Dissemination" (Sabine Vogler, ÖBIG)

Sabine Vogler presented the objectives, tasks, deliverables and the timetable of WP 2 "Dissemination" (*see attachment 30*). The aim of this WP is, on the one hand, the dissemination of the results of the project and, on the other hand, giving information on the on-going project itself. Key deliverables are a PPRI Information Leaflet (to be updated regularly), the PPRI website, presentations and articles, and a conference at the end of the project.

Sabine Vogler stressed that, besides ÖBIG and WHO, all partners and observers are asked to participate in the dissemination process. Consulting national institutions, for example, may also be a way of informing them about the PPRI project. They may use the PPRI Information Leaflet (*see attachment 31)* which is made available at the PPRI website.

Presentation of PPRI website (Danielle Arts, ÖBIG)

A key dissemination instrument is the PPRI website (http://ppri.oebig.at), which was set up by ÖBIG and went on-line on 1 September 2005. The website is primarily designed as an information source on the project accessible to the public. There are plans that in the future there will also be a restricted member area for the participants of the project that can only be accessed by password.

One important section of the website is the News section. For example, news on regulatory changes in Member States and announcements of events may be presented there. These news should be sent to the general PPRI-E-Mail-address (ppri@oebig.at), with a clear hint in the "subject" that the e-mail refers to news concerning the website. There is also a section for the announcement of dissemination activities, e.g. articles, presentations, etc. undertaken by all partners and observers. ÖBIG asked to be informed on articles published in country-specific journals and to receive a copy of it (even if not in English). The Hungarian partner already kindly delivered a presentation on the system in Hungary which will be published on the website. Concerning documents on the legal basis as well as laws to be published on the website, the participants agreed that they should be provided through links rather than downloads.

In the discussion it was proposed to establish a FAQ section or even a forum on the website. This may be open to the public (as to obtain feedback from outside) as well as in the restricted area (as a tool for interaction).

Outlook and closing of the meeting

Final discussion

One key point in the discussion was the challenge of a constant update of the information after the year of 2007. This will be an issue for which a solution should be found in the course of the project. Kees de Joncheere made clear that this lies mainly in the responsibility of the Member States. ÖBIG expressed its interest to continue to take the lead in a follow-up project if funding were provided.

Participants expressed concern who should take over the organisational responsibility for the numerous flows of information (e.g. with regard to the website). Sabine Vogler confirmed that this task is performed by ÖBIG as the main partner, being in charge of the overall coordination of the PPRI project.

Finally, regarding organisational questions asked by participants, it was made clear that in case of a job change, partners are obliged to inform ÖBIG about a successor (as stated in the "Memo of Common Understanding" signed by the partners).

Summing up of key results of the meeting (Sabine Vogler, ÖBIG)

At the end of the meeting Sabine Vogler summarised the key results of the 1st Coordination Meeting of the PPRI project (*see attachment 32*).

The date of the second Coordination Meeting was commonly decided on and fixed for **27 and 28 April 2006**. It will be hosted by WHO Euro and take place in **Copenhagen**.

On behalf of the main partner ÖBIG, Sabine Vogler thanked all participants for their active participation and cooperation and closed the 1st Coordination meeting of the PPRI project.

Annex III
2nd Co-ordination Meeting, list of PPRI Participants

2nd Co-ordination meeting, list of PPRI Participants

Name	Institution	Country
Daniel Mann	European Commission, DG Sanco	Luxembourg
Gernot Spanninger	Ministry of Health and Woman's Issues	Austria
Main Beneficiary		
Claudia Habl	Austrian Health Institute	Austria
Barbara Fröschl	Austrian Health Institute	Austria
Christine Leopold	Austrian Health Institute	Austria
Associate Beneficiary		
Kees de Joncheere	WHO, Regional Office	Denmark
Trine Lyager Thomsen	WHO, Regional Office	Denmark
Partners		
Marie-Thérèse Peeters	Ministry of Economic Affairs	Belgium
Mireille Pierlet	Ministry of Economic Affairs	Belgium
Gergana Andre	International Healthcare and Health Insurance Institute	Bulgaria
Athos Tsinontides	Health Insurance Organisation	Cyprus
Xenia Ashikales	Ministry of Health	Cyprus
Pynelopi Valsamisová	Ministry of Health	Czech Republic
Elisabeth Thomsen	Medicines Agency	Denmark
Katrin Pudersell	Ministry of Social Affairs	Estonia
Sirpa Peura	Association of Finish Pharmacies	Finland
Eric van Ganse	University Claude Bernard Lyon 1	France
Hans-Peter Dauben	Institute for Medical Documentation and Information	Germany
Vardica Areti	Institute of Pharmaceutical Research and Technology	Greece
Gábor Lengyel	National Health Insurance Fund	Hungary
Tamas Attila Kovacs	National Health Insurance Fund	Hungary
Szabolcs Szigetti	National Health Insurance Fund	Hungary
Deirdre Elliott	HSE-Shared Services-Primary Care	Ireland
Gerald Byrne	HSE-Shared Services-Primary Care	Ireland
Pietro Folino	Medicines Agency	Italy
Gita Krukiene	Ministry of Health	Lithuania
Tomas Alonderis	Ministry of Health	Lithuania
Petra Jansen	Ministry of Health, Welfare and Sport	Netherlands
Alex van Exel	Ministry of Health, Welfare and Sport	Netherlands
Piotr Blaszczyk	Ministry of Health	Poland
Jan Mazag	State Institute for Drug Control	Slovakia
Stanislav Primozic	Agency for Medicinal Products	Slovenia
Thord Redman	Pharmaceutical Benefits Board	Sweden
Magnus Köping-Höggard	Pharmaceutical Benefits Board	Sweden

Name	Institution	Country
Observers		
Peter Wieninger	Federal Association of Social Insurance Institutions	Austria
Susanne Grosse-Tebbe	European Observatory for Healthcare Systems and Policies	Belgium
Stefaan van der Spiegel	European Commission, DG Enterprise	Belgium
Wayne Critchley	Health Canafa	Canada
Lenka Praznovcova	Charles University	Czech Republic
Sinikka Rajaniemi	Ministry of Social Affairs and Health	Finland
Elizabeth Docteur	OECD	France
Christian Marty	National Sickness Fund for Employees	France
Lesley Tilson	National Centre for Pharmaco-economics St. James Hospital	Ireland
Anita Viksna	Medicine's Pricing and Reimbursement Agency	Latvia
Sophie Lopes	SOGETI	Luxembourg
Tor Frostelid	Medicines Agency	Norway
Jaime Espin-Balbino	Andalusian School of Public Health	Spain
Daniel Palnoch	Department of Health	United Kingdom
Göran Isaksson	EMEA	United Kingdom

Annex IV
Minutes of the 2nd Co-ordination Meeting, Copenhagen (27-28 April 2006)

ÖBIG

BUNDESMINISTERIUM FÜR GESUNDHEIT UND FRAUEN

PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION (PPRI)

MINUTES of the Second meeting

Copenhagen 27 - 28 April, 2006
Venue: WHO Regional Office for Europe, Scherfigsvej 8, 2100 S, Copenhagen, Denmark

Participants: 50 persons attended the meeting, cf. the Attendance list on the Member site of the PPRI website

Thursday, 28th April 2006

Morning session, 10.00 - 13.00 (chair: de Joncheere/WHO)

The morning session of the first day was dedicated to an introduction of all participants in the 2nd Coordination Meeting of the PPRI project and a brief update on the PPRI project including a presentation by project managers from other major European or global projects on pharmaceuticals. It then continued with a presentation of the PPRI website and the Needs Assessment report.

In order to download all the presentations that were given we invite you to visit the Members-only site of our PPRI website (http://ppri.oebig.at) under 2nd Coordination Meeting → select Documents. Here you find all presentations by the name of the speakers.

You should have received your password by now, if not please contact Ms. Danielle Arts at ÖBIG (for contact details see below).

Introduction:

- Gerard Schmets (Director of the Division of Country Health Systems Support, DCS / WHO Regional Office for Europe) welcomed the participants of the meeting and gave a short overview of the organisation and work of the DCS. Furthermore he presented the plans for the Ministerial Health Systems Conference in 2008 led by WHO Regional Office for Europe.
- Kees de Joncheere (Associate partner / WHO Regional Office for Europe) welcomed the participants of the meeting and presented the work in WHO Health Technologies and Pharmaceuticals, gave a short overview of the EU funded projects on pharmaceutical policy and presented the proposals and aims of the Networking agreements with the MEDEV Group.
- Tour de table: Participants introduced themselves, their country and their organisation.
- Daniel Mann (European Commission / DG Sanco) briefly explained the importance of the PPRI project in relation to public health.

- Gernot Spanninger (Austrian Ministry of Health and Women's Issues) presented the importance of the PPRI project and the role of ÖBIG in international pharmaceutical research.

Update and presentation of other project on pharmaceuticals

Claudia Habl (Deputy Project leader / ÖBIG) explained briefly the content of the work that has been carried out since the 1st coordination meeting in Vienna in September, 2005. This involved Work Package 3: Needs Assessment carried out by the associate partner WHO, with all project participants and European stakeholders in order to elaborate what indicators should be included in the template (cf. download on PPRI website). She thanked all the participants for their input and great effort that they have put into the needs assessment and explained the central role that these needs assessment have played in generating the template. Finally, Claudia Habl introduced the project leaders from other current pharmaceutical projects:

- Pietro Folino-Gallo (AIMA) presented the „EURO-MED-STAT (db)" project, commissioned by European Commission DG Sanco.
- Stefaan van der Spiegel (DG Enterprise and Industry) presented the "Pharmaceutical Forum and the Working Group on Pricing" which is the follow up to the G10. It has three working groups: pricing, relative effectiveness and information to patients.
- Jaime Espin (Andalusian School of Public Health) presented the project: "Analysis of Differences and Commonalities in Pricing and Reimbursement Systems in Europe" commissioned by European Commission DG Enterprise and Industry.
- Elisabeth Docteur (OECD) presented the "OECD Pharmaceutical Pricing Policy Project commissioned by OECD Health Division.
- Sophie Lopes (SOGETI) presented the project "Development of Public Health Performance Indicators for the Pharmaceutical Sector" commissioned by European Commission DG Sanco.

Website and the members-only area

Christine Leopold (Project member / ÖBIG) introduced the website and the members-only area, see http://ppri.oebig.at. The website gives general information on the PPRI project (objectives, duration, contacts, project organisation and dissemination activities). Ms. Leopold requested all participants to keep ÖBIG updated on any news in the field of pricing and reimbursement in their country and invited to send information to ÖBIG for publication on the website (e.g. changes in legislation, up-coming events, etc.).

The member-only area is based on the Microsoft Sharepoint software. The members-only area is limited to the participants in the PPRI-project (instructions for the log-in will be provided latest end of May) and their associates. The members-only area is designed to facilitate the work of writing up the Pharma Profile and to ease the exchange of information. The following menus can be found:

- "Contact details" including contact details of all participants on a voluntary basis.
- "Meetings" including all documents from all meetings, e.g. presentations, statements, etc.

- “Discussion forum” which we invite you to use ("How to use" manual is available on the website).
- “Documents” where you can find the final Needs Assessment report, the latest template in .dot version, the glossary, the approved interim report to DG Sanco (due for July 2006) and PPRI related articles or presentations.
- “Country information” where you can upload or download articles, statistics and any other data in English or in your native language.

The core asset of the Member-only site is, that it allows all participants to down- and up-load documents and statements in a data protected surrounding.

Main contact for specific website/share point questions is Danielle Arts (Arts@oebig.at) Tel.:0043-1-515 61 294

The Needs Assessment report

Trine Lyager Thomsen (Project member / WHO Regional Office for Europe) presented the final results of WP 3, the Needs Assessment report. The main objective of the Needs Assessment was, to elaborate the key interests of policy-makers of the EU Member States, Bulgaria and Norway as well as of other European stakeholders.

A total of 28 institutions participated in the first part of the Needs Assessment (Brainstorming-session/Vienna) and 111 institutions contributed to the second part (based on the Needs Assessment Guide). Of the 45 European stakeholders (e.g. EFPIA, PGEU, IAPO, etc.) that the project team contacted, 36 replied, giving a respond rate of 80%. The Needs Assessment Guide was structured around the following questions:

1) “What information are you most interested in?”

2) “Key areas of interest in relation to the following areas”
    a) Background
    b) Pricing
    c) Reimbursement
    d) Access/Cost-containment
    e) Monitoring/Evaluation

The main results are the following:

- The issues that were brought up in the first question “What information are you most interested in“? all relates to the 5 specified key priority areas: “Background”, “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation”,
- The issues expressed in the second question of the Needs Assessment: “Key areas” showed that there was a high interest in the 5 key areas: Background, Pricing, Reimbursement, Access/Cost-containment, Monitoring/Evaluation

- The issues mentioned in the third question of the Needs Assessment “Additional comments” mostly related to the 5 key priority areas identified, the process of the PPRI project and EU related issues, such as the Transparency Directive or the post-G10 process.

In the analysis, the sub-groups i.e. National Stakeholders vs. European Stakeholders; EU-15 + Norway vs. EU10 + Bulgaria and the various sectors within the European Stakeholders all expressed issues of interests that reflected their institution. However, the difference was only marginal. Furthermore, the European Stakeholders explicitly stated that biocide products, medical devices and borderline products should not be further explored in the PPRI project and that the focus should remain at the investigation of the pricing and reimbursement systems of pharmaceuticals in the EU Member States

Afternoon session, 14.00 - 17.30 (chair: Claudia Habl/ÖBIG)

The afternoon session of the first day was devoted to 1) a presentation of the draft template, the glossary, feedback from sample countries (Denmark and the Netherlands) as well as presentation of the experience of the European Observatory on the Health Care in Transition Profiles (HiT) and 2) a discussion on the template in five working groups, each led by a appointed group manager.

Template

Trine Lyager Thomsen (Project member / WHO Regional Office for Europe) presented the template, developed by WHO and ÖBIG (under the lead of WHO) on the basis of the Needs Assessment results.

The main objective of the presentation was to give an overview of the structure of the template and to give advice on how to write the country profile by using the template. The latest version of the template is available on the member-only site of PPR website.

The presentation initiated a number of specific questions to each chapter, which will be adapted directly into the final template. The more general questions and remarks are presented below.

Question	Answer/general agreement
What happens if the template changes?	The changes we discuss now will be integrated in the template by 31 May 2006, afterwards the template is not due to changes from May to October, 2006. In case of urgently necessary changes these will be highlighted in the template
Do I have to answer all the questions in the template	The questions below the headings should be seen as a support while writing a section. This means that it is not necessary to answer each question (especially if they are not applicable in your country), but to give a country-specific overview acc. to each heading.
Why shall I use the style sheet (.dot version)	To guarantee a consistency of the single country profiles and to reduce the editing and layout work for you and the editorial team at WHO and ÖBIG
How should the summary be structured?	In general it should be based on the list of content. ÖBIG and WHO will draft a summary basing on 1 or 2 country profiles for the next coordination meeting in autumn 2006.
Is there a review process?	So far there have only been pilots drafted by Denmark, the Netherlands and Austria so no review process has taken place until now. However, all participants are encouraged to consult with local experts and preferable have the country profile proof read. Finally all country profiles will be reviewed by WHO and ÖBIG.
Shall I send you a .doc (Word) or a .pdf (Adobe) version of my profile	Both ways are possible, but the editors at WHO and ÖBIG would prefer to receive a .doc (Word) version to ease the editing process. In case of large documents you could also send it as .zip file.
Shall the country profiles include graphs and tables or not?	Graphs, figures and tables are very much welcome as the template shows. The tables may be either included directly into the profile and sent as extra document.
Whom shall I contact in case of questions	For general questions the first person to contact is Trine Lyager Thomsen. Furthermore each country was appointed 2 project team members, either from ÖBIG or WHO, to be the first contact persons. The list of these "Country editors" may be obtained from the member-site of PPRI website.
Is it okay to publicly publish on the basis of data collection?	Yes, but the articles should be peer-reviewed by ÖBIG and WHO and the PPRI project has to be mentioned as the basis of the article.
Remark on contact journals	Susanne Grosse-Tebbe suggested to contact journals and make a series of Pricing and Reimbursement in EU MS publications. This was encouraged by the commissioner Mr. Mann and several participants.
Should there not be more information on pricing and reimbursement of pharmaceuticals in the hospital sector?	ÖBIG and WHO will include more explicit questions regarding the pricing and reimbursement of pharmaceuticals in hospitals. Should be explicitly stated

Glossary

Barbara Fröschl (Project member / ÖBIG) introduced the glossary which is available on the members-only site as well as on the public website (http://ppri.oebig.at). The glossary consists of preferred terms, synonym terms and abbreviations. The purpose of the glossary is to assist authors in writing up the Pharma Profile. The main source of the glossary are the Ob-

servatory's glossary, WHO, ÖBIG and OECD. The glossary has been reviewed by several international experts. Furthermore, the glossary is constantly being updated and suggestions to the glossary are welcome and should be send to Barbara Fröschl, Fröschl@oebig.at

There was a remark made on the glossary, that it would be difficult to ask contributors to use the glossary when writing up the profiles. It was therefore decided that the main purpose of the glossary should be to assist authors in understanding the points to be covered when writing the template and that the task of streamlining the use of words in the Pharma profile should be done by ÖBIG and WHO.

Feedback from sample countries and European Observatory

- Elisabeth Thomsen (Danish Medicines Agency) presented her experience with the template. Main suggestions were to extend the list of words in the glossary, to include more explicit questions on the hospital sector, to include more explanation to some of the figures and to make minor variations in layout. Conclusion so far is that the task of completing the Pharma Profile is time consuming and involves many people, but that it is worth the time and effort.
- Petra Jansen (Dutch Ministry of Health, Welfare and Sports) presented her experience with the template. Ms. Jansen provided specific recommendations for each chapter that will be included in the template and she concluded that the workload should not be underestimated but could involve interns or students.
- Susanne Grosse-Tebbe (European Observatory on Health Systems) presented the European Observatory on Health Systems, see www.observatory.dk and the Health in Transition (HiT) Country Profiles. Ms. Grosse-Tebbe also showed the Observatory's glossary and shared the experience of the Observatory in producing the HiT Country Profiles. She explicitly encouraged the participants to get in touch with local HiT authors and kindly offered to provide PPRI participants with an up-dated listed of approved and ongoing HiT profiles by country. This list will also be available on the members-only area of PPRI website.

Discussion on the template in working groups with group managers

The rest of the afternoon was devoted to discussions on the template in working groups with group managers. All participants where asked to join a group to discuss the content of one of the chapters in the template.

Chapter to be discussed	**Group manager**
Background	Susanne Grosse-Tebbe/European Observatory
Pharmaceutical system	Stanislav Primozic/Slovenian Medicines Agency
Pricing	Gergana Andre/Bulgarian IHHI
Reimbursement	Thord Redman/Swedish Pharmaceutical Benefits Board
Rational Use of Pharmaceuticals	Eric van Ganse/University Claude Bernard Lyon 1

Friday, 28th of April 2006

Morning session, 10.00 - 13.00 (chair: de Joncheere/WHO)

The morning session was firstly devoted to an open space forum ("marketplace") where the participants could leave their group and could walk around to ask questions to group managers of the other groups and discuss/endorse the proposed changes of the template . Secondly, the group managers presented the results of the group discussion; and last there was a summing up of key results of the meeting, next steps, timeframe and tasks to be undertaken.

The following listing represents the presentations of the group discussions by the five group managers and comments by the plenum. It only includes the discussion surrounding general questions, since the more specific questions will be adapted directly into the final template.

On the member-only site of the PPRI website you may have a look at the summary of the flip charts, that were written during the workgroup and presented on the market place.

1) Background (Susanne Grosse-Tebbe / European Observatory)

Three options were presented:

- Keep the template as it is and use international sources such as WHO Health For All Database or OECD Health Database.
- Revise the content of the chapter and copy/paste information from HiT Country Profile Summaries http://www.euro.who.int/observatory/Hits/20020525_2
- Include only 10 indicators on health systems and contextual factors and make a link to http://www.euro.who.int/observatory/Hits/TopPage

In the group there was further discussions on the trade-off between quantity, quality and sustainability of information, problems with consistency of data/information, whether to use national or international sources, whether to include international comparisons or not and the issue of resources for updates.

Discussion

The group considered the second option as the best, though Claudia had concerns because Hit Summaries are not available for all participating countries. Susanne offered to draft a table indicating which HiT summaries are available, their publishing year and planned future HiTs. There was a general agreement that a standardised way of presenting the data is good. It was agreed that ÖBIG and WHO would revise the chapter in assistance with Susanne Grosse-Tebbe for the second draft and possibly reduce the number of topics to be covered. ÖBIG offered to help countries stating a need for assistance by filling out the tables in the background chapter for the first version of the Pharma Profile. Furthermore the group decided that the project leaders should provide exchange rates to be used for conversion of, e.g. expenditure dates from National Currency to Euro in the template.

2) Pharmaceutical system (Stanislav Primozic / Slovenian Medicines Agency)

The chapter was recognised to be well-written and well-structured. It provides an appropriate frame in which all important characteristics of the national pharmaceutical systems are reflected. The group had the following general remarks:

- More questions regarding the regulation of promotional activities (advertising, etc.)
- Questions regarding the regulation of post marketing studies should be included
- Data and patent protection-related questions should be included
- Questions regarding hospital procurement and pricing should be included
- Questions regarding the impact of stakeholders (the industry, the patients' organisations etc.) on policy making should be more explicit
- Questions regarding vertical integration, internet sales and self-service should be included
- A list of top 10 pharmaceuticals (by terms of value per year, and DDD/100.000 population consumption) should be included but could also be covered in chapter 5.
- The term dispensary shall be replaces by pharmaceutical retailer.

Discussion

It was decided to include more questions regarding the regulation of promotional activities,, monitoring of post marketing studies, the hospital sector and the impact of stakeholder organisations on policy making. The suggestion to include Data and patent protection-related topics was challenged by some participants, as these are very complex and a coverage of such questions would be time consuming. Claudia and Kees explained that such general topics might also be covered in the final benchmarking report.

Furthermore, there was a wish to include more questions related to internet sale, but due to the potentially large size of this area, it was agreed to limit this section to a max. 1 page. A wish to include a top 10 of the most often sold pharmaceuticals was also expressed and it was agreed to include such a table on a voluntary basis as some participants noted that they couldn't include it due to data protection legislation.

3) Pricing (Gergana Andre / IHHI)

The comments on Chapter 3 were divided into "general" and "specific" comments. The general comments were as follows

- Give more information in the beginning of each chapter & explain the words that are used.
- More cross-references needed.
- Clearly differ between "Not applicable" and "Missing data".

Specific comments were:

- Challenges in public procurement should be included.
- Discounts/rebates section should be deleted.
- Rename ways of pricing to pricing policy

It was agreed to include more explanations on the words used in the template and include more definitions (e.g. maximum price into the glossary). It was also agreed that authors should write „Not available" (= data missing) or not applicable and to include more cross references. The specific comments were endorsed by the plenum. However, the project leaders asked not to delete the discount section but to shorten it.

4) Reimbursement (Thord Redman / Swedish Pharmaceutical Benefits Board)

There was a general discussion on the wording in Section 4.2: Dominant vs. sub-dominant and in section 4.3: Reimbursement categories vs. Reimbursement rates. Additionally, some suggestions for the glossary were made. The following suggestions were made:

Restructure the list of content as follows:

Option 1	**Option 2**
4.2 Reimbursement Scheme	4.3 Reimbursement categories
4.2.1 Dominant Scheme	4.3.1 Dominant Scheme
4.2.1.1 Reimbursement rate	4.3.2. Sub-dominant scheme
4.2.1.2 Reimbursement list	4.4 Reimbursement list
4.2.2. Sub-dominant scheme	4.3.1 Dominant Scheme
4.2.1 Dominant Scheme	4.3.2 Subdominant Scheme
4.2.1.1 Reimbursement rate	
4.2.1.2 Reimbursement list	

Discussion

Mr. Redman reported that the terms dominant and sub-dominant scheme are considered to be confusing. It became obvious that the participants were interested in the decision criteria for inclusion/exclusion of pharmaceuticals in reimbursement. In the discussion it was agreed that ÖBIG and WHO would revise the structure of the chapter and revise the glossary

5) Rational Use of Pharmaceuticals (Eric van Ganse / University Claude Bernard Lyon 1)

This group had a discussion about the headings of the chapter and the corresponding questions. In general, the headings were not precise enough and a general need to revise the headings was expressed. The group expressed a need for more cross-references and as well as add links to websites. Furthermore, additional questions that explain the use of other economic methods used in cost-containment should be included.

Discussion

There was a general agreement to include the above issues into the template and the glossary.

Summing up of key results of the meeting and next steps

At the end of the meeting Claudia Habl summarised the key results of the 2nd PPRI Coordination Meeting. The suggested date for the 2nd Coordination Meeting was in the end of September, 2006, but a general concern was expressed by all participants about the limited time to complete the first draft of the Pharma Profile, so the date for the **2nd Coordination Meeting was commonly decided on and fixed for the 9 and 10 of October 2006 in Warsaw, Poland.** It kindly will be hosted by Piotr Blaszczyk from the Drug Policy Department of the Ministry of Health in Poland.

Claudia Habl concluded her summery with the next steps to be taken:

- Submission of the minutes of the 2nd Coordination Meeting to the participants of the PPRI project (May 2006, WHO&ÖBIG)
- Submission of the final PPRI Template to the participants (End May 2006, WHO)
- Upgrading of the Glossary (continuously/ÖBIG)
- Participants of the PPRI project may begin drafting the Pharma Profile with assistance of the country-specific editors (please find the list of the country specific editors on the members-only site under Pharma Profiles/Template).
- Submission of the interim report to DG Sanco (1 June 2006, ÖBIG)
- Participants send the first draft of the Pharma Profile to ppri@oebig.at (latest end September 2006,ÖBIG)
- 3rd Coordination Meeting in Warsaw, Poland the 9-10 of October 2006. Preliminary Agenda:
    - Presentation of the experiences of writing the Country Pharma Profiles by the participants
    - Update on the project
    - Update on other EU pharmaceutical projects e.g. Pharmaceutical Indicators project, Euro-Med-Stat II

On behalf of ÖBIG and WHO, Kees de Joncheere gave best regards from Sabine Vogler (Project leader / ÖBIG) who could not attend the meeting and thanked all participants for their active participation and cooperation.

Afternoon session, 14.00 - 16.00: *(chair: Elisabeth Thomsen, Danish Medicines Agency)*

The participants had the chance to visit the Danish Medicines Agency, where 5 presentations in two parallel work strings were given. The presentations were uttermost interesting and stimulated a lively discussion among the attendees. We like to tha

In order to download all the presentations of the Danish Medicines Agency, we invite you to visit the members-only site (http://ppri.oebig.at) under 2nd Coordination Meeting/Documents.

Annex V
Manual PPRI Intranet

PPRI-Member-site Manual

General aim of the PPRI-member-site: To provide PPRI project participants with information, e.g. contact details of project participants, details on meetings and a number of relevant documents, and to give them the opportunity to share information and have online discussions.

Contents of the different sections of the PPRI-member-site:

Contact details (read-only): Contains contact information of project coordinators (ÖBIG & WHO) and of all involved national and international stakeholders. Note: You are not able to change or add contact details. In case your contact details have changed, please send an email to ppri@oebig.at.

Meetings (read-only): Contains information on past and future meetings, such as the agenda and the venue of the meeting, a list with suggested hotels, documents for preparation of the meeting, minutes of the meeting and slides of presentations that have been held.

Discussion forum: The discussion forum can be used for all kinds of (PPRI-related) discussions and information exchange. *Please find details on how to use the discussion forum below.*

Documents (read-only): Contains several documents for download.

- **Needs assessment**: Report and summary report of the main findings of the NA
- **Pharma Profiles**: Pharma Profile Template and (when available) Sample Pharma Profiles
- **Glossary:** Print version (pdf) and link to the online version of the PPRI-glossary
- **Interim Report:** Interim report of the PPRI project, from June 2006
- **Dissemination**: Presentations and journal articles presenting the PPRI-project

Country information: Contains documents providing information on pharmaceutical pricing and reimbursement on **country, EU and international** level.
Please feel free to add relevant documents to this section!! For instructions, see below.

Settings: Provides the possibility to change your password. Note: in case you have forgotten your password and/or username, please send an email to ppri@oebig.at

How to use the PPRI-discussion forum.

1.	Choose view:	Press “Expand/Collapse” to change the view
2.	Start a new discussion:	Press “New Discussion” Type in Subject and Text Press “Attach File” to upload a document (not required) Press “Save and Close” To change your message, press “Edit Message”
3.	Reply on a message:	Press the message on which you want to reply Press “Post Reply” Type in Text Press “Attach File” to upload a document (not required) Press “Save and Close” To change your message, press “Edit Message”

How to upload documents in the “Country information” section.

1. Provide the document with a clear, descriptive name.
2. Select the folder to which the document belongs: If the report concerns one specific country, select the folder of the country in question under ‘Countries’. If more countries or non-European countries are described in the document choose “International” or “EU” (only for papers from the EU).
3. upload the document: Press “upload document”, select the document to be uploaded and press “save and close”.

You may also create a new document within a folder by pressing “New document”. This will open an empty Word file (.doc), which you can edit. If you do not have Word 2003, the document must first be saved on your hard disk, and can then be uploaded through the same procedure as described above. If you use Word 2003, the document can be saved directly in the member-site.

If desired, one may create a new folder within an existing Documents-folder, by pressing “New folder”. We suggest to restrict the amount of newly created folders as much as possible!

How to receive alerts.

You can choose to receive alerts in your email inbox for each of the single items in the member-site. On each page (relating to one “item”) within the member-site you can press “alert me” in the light blue column on the left site of your screen. If you enable this function you will receive an email in case something has been added, changed or deleted within the item in question.

In case of questions, please contact ppri@oebig.at or +43 1 515 61 294 (Ms. D. Arts)

Annex VI a
Needs Assessment Report, “Intermediate Report”

Pharmaceutical Pricing & Reimbursement Information project

Intermediate report

Trine Lyager Thomsen

Kees de Joncheere

Health Technology and Pharmaceuticals

WHO Regional Office for Europe

February 2006

In cooperation with ÖBIG – Austrian Health Institute

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1 Introduction

1.1 Pharmaceutical Pricing & Reimbursement Information project

The Pharmaceutical Pricing & Reimbursement Information project (PPRI-project) is a 2-year project commissioned by the European Commission's Health and Consumer Protection Directorate General (DG SANCO) and the Austrian Federal Ministry of Health and Women's Issues. The project is executed by the main partner ÖBIG – Austrian Health Institute, the associate partner WHO Regional Office for Europe together with EU Member States, Bulgaria and Norway.

The *objective* of the PPRI-project is to improve information and knowledge on the pharmaceutical pricing and reimbursement systems in the enlarged European Union, contributing to increased transparency, providing information and advice for policy-makers on national and European levels. The product of the PPRI-project will be on one hand country profiles i.e. "Pharma Profiles" written by the countries themselves and a on the other hand the project team will develop indicators allowing for a comparative analysis of the systems and resulting in a benchmarking study of the pricing and reimbursement policies of all EU Member States and other participating countries. The results will be "living documents" that continuously will be updated and will also be available on the internet (http://oebig.ppri.at). The project builds on ÖBIG's and WHO's knowledge and on the knowledge of the EU Member States as well as other participating countries and institutions. The PPRI-project is structured around 6 Work Packages (WP), displayed in Table 1:

Table 1: Overview of the PPRI-project

Lead partner	Work Packages (WP)
ÖBIG	WP 1 Coordination: Communication between leading partner ÖBIG, associate partner. WHO Regional Office for Europe and the EU Member States and other participating countries, organisation of meetings, administrative work
ÖBIG	WP 2 Dissemination: Making the project and its results known by setting up a webpage (http://ppri.oebig.at) and by writing articles and presentations
WHO	WP 3 Assessment: Assessing the needs and expectation of the EU Member States, and other participating countries and European Stakeholders in terms of pharmaceuticals
WHO	WP 4 Survey: Development of a template for the country profiles to assist the EU Member States and other participating countries in writing up the country profiles, which is part of WP 4
ÖBIG	WP 5 Development of comparable indicators (benchmarks): Setting up a draft paper for the indicators to compare the pharmaceuticals system of the EU Member States and other participating countries.
ÖBIG	WP 6 Comparable analysis (benchmarking): Benchmarking the pharmaceutical systems on the basis of the selected indicators and publishing the report.

1.2 WP 1 & WP 2: Coordination & Dissemination

WP 1 (coordination) aims at establishing a network of public institutions and third party payers in charge of pharmaceuticals in the European Union. Therefore the leading partner ÖBIG – Austrian Health institute and the associated partner WHO Regional Office for Europe establish and strengthen contacts to the stakeholders of EU Member States and other interested countries like Norway and Bulgaria. This resulted in 25 contact institutions in the different countries, excluding Luxembourg and Spain, since no contact institution could be found so far. The contact institutions are differentiated into partners and observers for administrative purposes only, meaning that partners are receiving compensation for their cooperation in the project and observers are participating on a voluntary basis. Countries are still being invited to participate as observers.

The purpose of WP 2 (dissemination) is to make the project and its results known to all the relevant stakeholders in the field of pharmaceutical pricing and reimbursement in the European Union and associated countries. Therefore a 1st project coordination meeting was organised in the beginning of September 2005 in Vienna. 3 more coordination meetings are planned, the next one being held on 27th & 28th April 2006 in Copenhagen.

Furthermore presentations are being held at different pharmaceutical congresses throughout Europe. Additionally articles are written and submitted to European Journals in the field of

pharmaceutical pricing and reimbursement. One major intention is to set up an internet-based information platform where the planned country profiles (see WP 4) will be presented. The website (http://ppri.oebig.at) was launched in September 2005.

The PPRI project is designed to run from April 2005 to early summer 2007. The final results will be disseminates during the last conference in spring 2007 in Vienna.

1.3 WP 3: Needs Assessment

WP 3 (Assessment) consists of a Needs Assessment with the intention to analyse which areas in relation to pricing and reimbursement of pharmaceuticals Member States and European Stakeholders are interested in. The main objective of the Needs Assessment is to identify these areas, which will then create the basis for the development of the template for the country profiles and the development of the benchmarks in WP 5. The Needs Assessment is an essential part of the PPRI-project, since it ensures that the key areas of interest of the participating institutions are included in the country profiles.

The Needs Assessment was carried out in several stages during the 1st of September, 2005 to the 16th of December, 2005, and can be divided in to two main parts:

In the first part, the participants in the 1st coordination meeting of the PPRI-project were given a preliminary chance to express their needs of information regarding pricing and reimbursement.

In the second part of the Needs Assessment, participating institutions were given the chance to expand on their ideas, express their most urgent needs and take in more long term structural issues of interest as well. Furthermore, in the second part of the Needs Assessment, the participating institutions were asked to collect the needs of relevant National Stakeholders and to share this information with the PPRI project team. The participating institutions will be introduced in the next section.

1.4 Definitions

This report describes the assessed needs and interest of the EU Member States as well as these of Bulgaria and Norway. Additionally the project team decided to include several European Stakeholders in the survey. To facilitate the understanding of the groups of coun-

tries that are dealt with in this report, the following definitions have been developed, please see Table 2.

Table 2: Definitions

Name	Definitions
All EU Member States, Bulgaria and Norway	All the countries that were invited to participate in the Needs Assessment i.e. Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia ,Spain, Sweden and United Kingdom. This group is referred to as countries.
Project participants	The institutions from EU Member States, Bulgaria and Norway and the European Stakeholders, that participated in the Needs Assessment.
National Stakeholders	The countries that participated in the Needs Assessment, in the text referring to either the first or the second part of the Needs Assessment.
Assessed institutions	The institutions that were interviewed by the National Stakeholders in the second part of the Needs Assessment.
EU 15 Member States + Norway (EU 15 + Nor.)	All the countries from the EU 15 Member States* + Norway that participated in the Needs Assessment i.e. Austria, Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Netherlands, Norway, Sweden and United Kingdom (no Needs Assessment from France, Luxembourg, Spain, Portugal)
EU 10 Member States + Bulgaria (EU 10 + Bul.)	All the countries from the new EU 10 Member States* + Bulgaria that participated in the Needs Assessment i.e. Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia (no Needs Assessment from Malta)

* EU 15 Member States refers to the countries that joined the EU before May 2004 and New EU 10 Member States refers to the countries that joined the EU after May 2004

1.5 Objectives

This report on WP 3 (Needs Assessment) will:

- Describe which issues EU Member States, Bulgaria and Norway and European Stakeholders (project participants) wish to include in the country profiles.
- Identify key areas of interest expressed by project participants.
- Analyse differences and similarities between the areas of interest 1) in the first and the second part of the Needs Assessment and 2) by EU Member States, Bulgaria and Norway and European Stakeholders.
- Discuss the areas of interests and provide recommendation for how these areas can be used to develop both the template for the country profiles and the benchmarks in WP 4 and WP 5.

1.6 Structure

This report is divided into 7 chapters. The introduction is followed by a description of the participating institutions in the Needs Assessment (Chapter 2) and a chapter on the methodology (Chapter 3). The results of the Needs Assessment are presented in Chapter 4, the analysis in Chapter 5 and the report ends with a discussion of the results (Chapter 6). Annexes are displayed in Chapter 7.

All chapters are divided into sub-sections relating to either the first or the second part of the Needs Assessment, or relating to either the National Stakeholders or the European Stakeholders. This analysis focuses on the second part of the Needs Assessment as this involved not only the project partners but further national and international stakeholders.

2 Participating institutions

2.1 Participating institutions

In the 1st project coordination meeting, in September 2005, in Vienna a total of 28 institutions from EU Member States, Bulgaria, Norway and European Stakeholders participated. As already mentioned, during this meeting the participants had a first chance to explain the needs of their countries. Due to the method of data collection (described in Chapter 3), it was not possible to link the needs expressed during the first part of the Needs Assessment to the participating institutions. Therefore the first part of the Needs Assessment will not be analysed according to institutions. The results will be presented in Section 4 and discussed in Section 6.

A total of 45 institutions were in the second part of the Needs Assessment invited to participate. As a result of the contacts, 36 institutions participated in the second part of the Needs Assessment. The following sections describe these participating institutions split into National Stakeholders and European Stakeholders.

2.1.1 National Stakeholders

Besides all PPRI-project participants also Spain and Luxembourg were invited to take part in the Needs Assessment (see annex 7.1).

By the end of the Needs Assessment, 22 National Stakeholders had replied. These 22 National Stakeholders assessed the needs of 79 institutions, leading to a total of 101 Assessed Institutions (see annex 7.2). The 101 institutions cover the following 2 main sectors and 8 sub-sectors:

- Governmental Organisations: Ministries *(e.g. Ministry of Health, Ministry of Social Affaires)*, Third party payers i.e. Social Health Insurance Funds/National Health Services (SHI/NHS) and Public Organisations[1]
- Private Organisations: Pharmaceutical Industry, Associations of Wholesalers, Association of Pharmacists, Associations of Doctors and Patient Associations.

[1] Public organisation covering the following: National Organisations funded by the government, research institutes and universities.

2.1.2 European Stakeholders

A total of 18 European Stakeholders were invited to participate in the Needs Assessment, of which 14 gave feed-back (see annex 7.3) The European Stakeholders cover the following 2 sectors and 8 sub-sectors.

- Private Organisations at European level: Pharmaceutical Industry, Associations of Wholesalers, Association of Pharmacists, Patient Associations.

- European Institution: European Commission (General Directorates and EFTA Surveillance Authority), Organisation for Economic Co-operation and Development (OECD) and European Observatory for Health Systems - WHO.

3 Methodology

3.1 Data collection

The first part of the Needs Assessment was conducted in Vienna on the 2nd of September 2005 as part of the 1st project coordination meeting that brought together most of the PPRI-project participants (see annex 7.1 and 7.3). The purpose of the first part of the Needs Assessment was to identify the needs concerning information on pricing and reimbursement of pharmaceuticals. The participating institutions expressed their preliminary needs in a brainstorming session (see annex 7.4). Furthermore, the participating institutions were asked to indicate the most immediate issues in writing. The issues raised during the brainstorming session and those provided in written form were summarised in the document "Result of the first part of the Needs Assessment" (see annex 7.5). This document was used as a basis to develop the "Needs Assessment guide", for the second part of the Needs Assessment (see annex 7.6).

The second part of the Needs Assessment took place between the 26th of September, 2005 and 19th of January, 2006. The following two sub-sections will in detail describe the data collection process for the second part of the Needs Assessment.

3.1.1 National Stakeholders

On 26th of September, 2005, an email with an introduction to the PPRI-project, the Needs Assessment guide and the result of the first part of the Needs Assessment was sent out to all EU Member States, Bulgaria and Norway[1] (see annex 7.5 and 7.6). The accompanying letter requested the EU Member States, Bulgaria and Norway to carry out three tasks; first, to expand on their needs and expectations of the PPRI-project; second, to assess the needs of National Stakeholders and third, to create a comprehensive report on the basis of these consultations and return it to the WHO Regional Office for Europe. The deadline for the Needs Assessment was set as the 1st of November, 2005.

The project team encouraged the National Stakeholders to contact all relevant stakeholders in their country; however it was suggested to concentrate on public health institutions. The means to include the National Stakeholders (e.g. interviews, emails, surveys, questionnaires)

[1] Norway was included later and received the email on 30th of September, 2005

was left to the discretion of the PPRI-project participants. ÖBIG – Austrian Health Institute and WHO Regional Office for Europe, however, provided a structured list of questions (Needs Assessment guide) to assist the project partners in this task. In most cases the National Stakeholders opted not only to include their ideas in the Needs Assessment but also to integrate the views of other relevant stakeholders in their country.

3.1.2 European Stakeholders

The European Stakeholders were identified and contacted by ÖBIG – Austrian Health institute and WHO Regional Office for Europe. One European Stakeholder (EFTA) was not contacted by the project team but participated in the Needs Assessment on its own intent. The Needs Assessments were collected both by personal interviews and emails. During a visit to Brussels from the 10th to the 12th of October, 2005, 6 interviews were carried out; a seventh was carried out in Brussels on the 21st of November, 2005. Further emails were sent to 10 European Stakeholders on the 31st of October, 2005 including an accompanying letter, an introduction to the PPRI-Project, the Needs Assessment guide and the results of the first part of the Needs Assessment, (see annex 7.5 and 7.6). The deadline was set to the 15th of November, 2005.

Several reminder calls and emails were carried out by WHO Regional Office for Europe between the 21st of November, 2005 and the 13th of December, 2005. The Needs Assessment ended on the 19th of January, 2006. Please see Table 3 for an overview of the data collection process.

Table 3: Timetable

Date	**Activity**
1st – 2nd September 2005	First part of the Needs Assessment: brainstorming session on issues of interest
26th of September 2005	Second part of the Needs Assessment sent by email to National Stakeholders
10th - 12th of October 2005	Interview with European Stakeholders
26th of October 2005	Reminder sent to National Stakeholders by email
31st of October 2005	Second part of the Needs Assessment sent by email to European Stakeholders
1st of November 2005	Deadline for National Stakeholders
15th of November 2005	Deadline for European Stakeholders
21st of November – 16th of December 2005	Reminder calls and emails to National Stakeholders and European Stakeholders
19th of January 2006	End of Needs Assessment

3.2 Statistics

This following section presents the statistics from the second part of the Needs Assessment.

3.2.1 Response rate

Twenty-two out of the 27 National Stakeholders (EU Member States, Bulgaria and Norway) and 14 out of 18 European Stakeholders, a total of 36 out of 45 institutions contributed to the Needs Assessment. It is not know how many institutions that the National Stakeholders contacted during the second part of the Needs Assessment, and it is therefore not possible to calculate the total respond rate. For the National Stakeholders and the European Stakeholders, it has been possible to calculate the respond rate, please see Table 4.

Table 4: Response rate

	National Stakeholders			**European Stakeholders**			**All**		
Method of contact	**Email**	**Inter-views**	**Sum**	**Email**	**Inter-views**	**Sum**	**Email**	**Inter-views**	**Sum**
Total contacts	27	0	**27**	12	6	**18**	39	6	**45**
Responses	22	0	**22**	8	6	**14**	30	6	**36**
Missing responses	5	0	**5**	4	0	**4**	9	0	**9**
Response rate	**81%**	**100%**	**81%**	**67%**	**100%**	**78%**	**77%**	**100%**	**80%**

3.2.2 The participating institutions

The 115 participating institutions on National and European level cover a total of 12 sub-sectors. The 22 institutions from the National Stakeholders are Governmental Organisations i.e. Ministries, Social Health Insurance Funds/National Health Services (SHI/NHS) and Public organisations and one Association of Pharmacies. The 79 National Institutions assessed by the National Stakeholders were both Government Organisations and Private Organisations. Of the 79, 55 were assessed by EU-15 + Nor.) and 24 by EU-10 + Bul. Table 5 gives an overview of the participating institutions.

Table 5: The participating institutions

	National Stakeholders	Assessed Institutions	European Stakeholders	Total
N =	**22**	**79**	**14**	**115**
Governmental Organisations	**21**	**43**	**0**	**64**
Ministries	*11*	*14*	*0*	*25*
SHI/NHS	*2*	*12*	*0*	*14*
Public organisations	*8*	*17*	*0*	*25*
Private Organisations	**1**	**36**	**6**	**43**
Representatives of Pharma-ceutical Industry	*0*	*14*	*2*	*16*
Associations of Pharmacies	*1*	*7*	*1*	*9*
Associations of Wholesalers	*0*	*3*	*1*	*4*
Insurance Companies	*0*	*3*	*0*	*3*
Associations of Doctors	*0*	*3*	*0*	*3*
Patient Associations	*0*	*6*	*2*	*7*
European Institutions	**0**	**0**	**8**	**8**
European Commission	*0*	*0*	*6*	*6*
OECD	*0*	*0*	*1*	*1*
WHO	*0*	*0*	*1*	*1*

3.3 Data analysis

The data from the first part of the Needs Assessment consist of both the issues mentioned during the brainstorming session and the written information provided by the participating institutions. During the brainstorming the following seven fields of interests were identified:

1) “Background”
2) “Pricing”
3) “Reimbursement”
4) “Distribution”
5) “Monitoring”
6) “Regulation”
7) “Access/Affordability”.

By carefully analysing the data from the brainstorming and by deleting overlaps 5 key areas were identified:

1) “Background”
2) “Pricing”
3) “Reimbursement”
4) “Access/Cost-containment”
5) “Monitoring/Evaluation”

The purpose of identifying these areas was to include them as key areas in the Needs Assessment guide. However, we did not include “Background” on the indication that the indicators for issues related to background information would be provided by the authors of the template.

The data collected during the second part of the Needs Assessment was analysed in the same way as the first part of the Needs Assessment. This was done to ensure that no new areas of interest were overlooked. By reading through all the issues expressed by the participating institutions, 5 key areas and 21 sub-categories were identified, which will be described in the next chapter.

4 Results

This chapter presents the results of the Needs Assessment. Section 4.1 is an overview of the areas identified in the first and the second part of the Needs Assessment. Section 4.2 shows the results of the second round of the Needs Assessment for all the participating institutions. The results are presented following the succession of questions in the Needs Assessment guide except information on “Background” which was added to the key priority areas. The results are presented in the following order:

1) “What information are you most interested in?”
2) Key priority areas: “Background”, “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation”
3) “Additional comments”.

4.1 First and second part of the Needs Assessment

The results from the Needs Assessment consist of issues of interest in the form of questions or comments, listed by the participating institutions. More issues were mentioned during the second part of the Needs Assessment than during the first and on the basis of these issues 5 key priority areas and 21 sub-categories were identified. However, the key areas of interest identified on the basis of these issues during the first and the second part of the Needs Assessment areas are equal. The differences between the first to the second part of the Needs Assessment have merely led to a restructuring of the categories: “Distribution” has become part of “Background”; “Access/Affordability” and “Monitoring” has been renamed to “Access/Cost-containment” and “Monitoring/Evaluation”, respectively; and “Regulation” has been integrated into existing areas, please see Table 6.

Table 6: Areas of interest

First part of the Needs Assessment	Second part of the Needs Assessment	
1. Background **2. Pricing** **3. Reimbursement** **4. Regulation** ***5.* Distribution** **6. Monitoring** **7. Access/ Affordability**	**1. Background**	**4. Access/Cost-containment**
	1.1 Organisation *1.2 Funding* *1.3 Market authorisation and classification* *1.4 Distribution*	*4.1 Policy* *4.2 Price regulation* *4.3 Volume regulation* *4.4 Generics*
	2. Pricing	**5. Monitoring/Evaluation**
	2.1 Price setting *2.2 Pricing procedure* *2.3 Margins*	*5.1 Consumption and compliance* *5.2 Method and indicators* *5.3 Public Health*
	3. Reimbursement	
	3.1 Criteria for Reimbursement *3.2 Reimbursement procedure* *3.3 Reimbursement rates/co-payment* *3.4 Reference price system*	

The areas of interest identified covers a vast amount of actual suggestions for the template, which due to lack of space cannot be displayed here. However, in the following the areas of interest will be explained briefly:

“Background” refers to data on the organisation and funding of the pharmaceutical sector and also includes information on the pharmaceutical market i.e. market authorisation processes and distribution issues.

“Pricing” is related to pricing policy, and where “Price setting” refers to the criteria for pricing e.g. free pricing or reference pricing, then “Pricing Procedure” refers to the regulation of pricing. “Margins” refers to information on the margins applied to pharmaceuticals at the various levels e.g. pharmacy margins/mark-ups.

“Reimbursement” is related to reimbursement policy and here the same explanations apply as for “Pricing”. “Reference price system” includes information on how a country calculates reimbursement rates on the basis of a comparison with other pharmaceuticals and/or countries, if such methods are applied.

"Access/Cost-containment" includes methods to curb pharmaceutical expenditure and regulate the consumption of pharmaceuticals. It also describes the overall policy and the share of generics.

"Monitoring/Evaluation" includes data on consumption and compliance, methods and indicators used to monitor pharmaceuticals and data on the effect of the pharmaceutical policy on public health.

Comments that could not be included in the other categories were classified as "Additional comments".

4.2 Second part of the Needs Assessment

4.2.1 What information are you most interested in?

Of the 36 participating National and European Stakeholders, 28 institutions (78%) answered the first question: "What information are you most interested in?". These respondents were primarily the National Stakeholders (61%) and the issues mentioned were mostly related to the five key priority areas: "Background", "Pricing", "Reimbursement", "Access/Cost-containment" and" Monitoring/Evaluation". Table 7 displays the results of the first question in the Needs Assessment guide. The issues mentioned are listed according to the type of participating institution and according to what area of interest the issue reflects.

Table 7: What information are you <u>most</u> interested in?

1. Background	**Issue**	**Participating institution**
1.1 Organisation	What is the role of patients in pricing and reimbursement decisions?	Patient Associations
	Who is responsible for pricing and reimbursement?	European Commission EU-15 + Nor. EU-10 + Bul. Pharmaceutical Industry
1.2 Funding	What is the structure of the funding system is there e.g. voluntary private health insurance?	EU-15 + Nor. EU-10 + Bul.
1.3 Market authorisation and classification	Process time for pharmaceuticals	Pharmaceutical Industry EU-15 + Nor. Associations of Pharmacy
1.4 Distribution	Parallel trade Pharmaceutical sale via the Internet	European Commission Pharmaceutical Industry EU-15 + Nor.
	Distribution of pharmaceuticals	Pharmaceutical Industry EU-15 + Nor.
2. Pricing	**Issue**	**Participating institution**
2.1 Price setting	Price setting mechanisms	European Commission Associations of Wholesalers Pharmaceutical Industry EU-15 + Nor. EU-10 + Bul.
2.2 Pricing procedure	Regulation of pricing	European Commission EU-15 + Nor. EU-10 + Bul. Pharmaceutical Industry
	Frequency of changes	EU-15 + Nor.
2.3 Margins	Wholesale/Pharmacy margins	Pharmaceutical Industry EU-15 + Nor. EU-10 + Bul.
3. Reimbursement	**Issue**	**Participating institution**
3.1 Criteria for reimbursement	What criteria exist for reimbursement? Is added therapeutical value used to decide upon reimbursement decisions?	European Commission Associations of Wholesalers EU-15 + Nor. EU-10 + Bul.
	The use of pharmaco-economics in reimbursement	EU-15 + Nor.

3.2 Reimbursement procedure	Regulation of reimbursement	European Commission EU-15 + Nor. EU-10 + Bul. Pharmaceutical Industry
	Frequency of changes	EU-15 + Nor.
3.3 Reimbursement rates/co-payment	Reimbursement rates Co-payment rates	EU-15 + Nor. EU-10 + Bul.
3.4 Reference price system	Identify the reference price systems within Europe	Patient Associations EU-15 + Nor. EU-10 + Bul.
4. Access/Cost-containment	**Issue**	**Participating institution**
4.1 Policy	What local policies influence innovation? Policies for orphan drugs	European Commission EU-15 + Nor. EU-10 + Bul.
	What is the purpose of the current policy?	European Commission EU-15 + Nor.
	Access and availability	European Commission Patient Associations EU-15 + Nor.
	Policy for preventive pharmaceuticals	EU-15 + Nor.
	EU Transparency directive	Association of Pharmacies
4.2 Price regulation	Affordability	Patient Associations EU-15 + Nor. EU-10 + Bul.
	Cost-containment policies	EU-15 + Nor. EU-10 + Bul.
4.3 Volume regulation	Regulation of parallel trade	Pharmaceutical Industry EU-15 + Nor.
	Cost-containment policies	EU-15 + Nor. EU-10 + Bul.
4.4 Generics	Generic prescribing practice	Pharmaceutical Industry
	Role of generic products Generic substitution	European Commission EU-15 + Nor. EU-10 + Bul.
5. Monitoring/Evaluation	**Issue**	**Participating institution**
5.1 Consumption and compliance	What data exists on consumption and compliance? What data on pharmacotherapy exists?	EU-15 + Nor. EU-10 + Bul.
5.2 Method and indicators	Monitoring of competition	Pharmaceutical Industry EU-15 + Nor.
5.3 Public health	Consequences for public health	European Commission EU-15 + Nor.

Regarding the National Stakeholders, the interest expressed by EU-15 + Nor. covered almost all areas, where as EU-10 + Bul. mostly only mentioned issues directly related to "Pricing" and "Reimbursement". Regarding the European Stakeholders, the distribution of issues was as follows:

The issues listed by the Pharmaceutical Industry were:

- processing time,
- parallel trade,
- margins/mark-ups,
- generic prescribing,
- monitoring of competition.

The issues listed by the Associations of Pharmacies were:

- processing time,
- the transparency directive.

The issues listed by the Associations of Wholesalers were:

- criteria for pricing and reimbursement.

The issues listed by the Patient Associations were:

- access of pharmaceuticals
- availability of pharmaceuticals,
- affordability of pharmaceuticals.

4.2.2 Key priority areas

The results of the second question in the Needs Assessment guide, which aimed to identify "Key priority areas", are displayed in Table 8. The table does not display the interest expressed by the individual European Stakeholders. Even though "Background" was not part of the four key areas of the Needs Assessment guide, this area was identified in the analysis and is therefore included in the results.

Interest in "Background" information was expressed by more than two thirds (69%) of the participating institutions. The interest in "Background" was higher among the National Stakeholders, (77%) than among the European Stakeholders (57%) and a lot higher among EU-15

+ Nor. (92%) compared to EU-10 + Bul. (60%). Of the sub-categories, “Market authorisation and classification” was the most frequently named.

Of the key priority areas, “Access/Cost-containment” was stated by most stakeholders (94%); however the most frequently listed sub-category was “Criteria for reimbursement” (89%) under “Reimbursement”.

National Stakeholders were especially interested in “Pricing” and “Access/Cost-containment” focusing on sub-categories “Price setting”, “Criteria for reimbursement” and “Reference price system”.

The most frequently listed areas of interest for European Stakeholders were “Reimbursement” and “Access/Cost-containment” with the sub-category “Criteria for reimbursement”. Among the European Stakeholders who commented on the key priority areas, all indicated interest in all the topics. The interest varied slightly by e.g. the Pharmaceutical Industry being very interested in “Margins”, where the Patient Associations showed no interest.

Of the National Stakeholders, the most frequently listed areas of interest for EU-15 + Nor. (EU-15 + Norway), were all the first five categories and a number of sub-categories. The most frequent listed areas for EU-10 + Bul. was also quite widely spread with the most frequent categories being “Pricing”, “Reimbursement” and “Access/Cost-containment and also here a number of sub-categories.

Table 8: Key Priority Areas

Key Priority Areas	Total	National Stake-holders (NS) and European Stakeholders (ES)		EU-15 + Nor. and EU-10 + Bul.	
	All	NS	ES	EU-15 + Nor.	EU-10 + Bul.
N =	36	22	14	12	10
1. Background	**69%**	**77%**	**57%**	**92%**	**60%**
1.1 Organisation	39%	55%	14%	67%	40%
1.2 Funding	31%	50%	0%	42%	60%
1.3 Market authorisation and classifi-cation	50%	55%	43%	75%	30%
1.4 Distribution	42%	45%	36%	58%	30%
2. Pricing	**92%**	**100%**	**79%**	**92%**	**100%**
2.1 Price setting	86%	95%	71%	83%	100%
2.2 Pricing procedure	83%	91%	71%	75%	100%
2.3 Margins	61%	86%	21%	92%	80%
3. Reimbursement	**92%**	**95%**	**86%**	**92%**	**100%**
3.1 Criteria for Reimbursement	89%	95%	79%	92%	100%
3.2 Reimbursement procedure	69%	77%	57%	75%	80%
3.3 Reimbursement rates/co-payment	78%	91%	57%	83%	100%
3.4 Reference price system	81%	95%	57%	92%	100%
4. Access/Cost-containment	**94%**	**100%**	**86%**	**92%**	**100%**
4.1. Policy	69%	73%	64%	75%	70%
4.2 Price regulation	78%	91%	57%	92%	80%
4.3 Volume regulation	64%	73%	50%	92%	50%
4.4 Generics	75%	86%	57%	75%	100%
5. Monitoring/Evaluation	**86%**	**91%**	**79%**	**92%**	**80%**
5.1 Consumption and compliance	42%	50%	29%	50%	50%
5.2 Method and indicators	81%	86%	71%	92%	70%
5.3 Public Health	47%	55%	36%	58%	50%
6. Additional comments	**53%**	**50%**	**57%**	**58%**	**40%**
6.1 Other issues	17%	18%	14%	33%	0%
6.2 On the process	33%	36%	29%	42%	30%
6.3 EU related issues	19%	14%	29%	17%	10%

4.2.3 Additional comments

The third question in the Needs Assessment guide gave the participating institutions a chance to express issues related to other topics than the four key areas. The collected comments were divided into three groups: “Other issues”, which were suggestions for the template, “Process”, which were suggestions for the process of the PPRI-project and “EU related issues”, which covered an interest in the EU transparency directive and follow up of the G10-process. In total, 53% of the project participants answered this question.

Regarding the sub-category “Other issues”, 17% of the participating institutions came up with suggestions. The issues mentioned were the following: “Include the hospital sector in the country profile”, “Analyse and compare how adequate supply is guaranteed”, “Create a forum for policy makers”, “Focus on public health issues”, “Innovation”, “Orphan drugs”, “Parallel trade” and “Share experience with the use of compliance data in reimbursement decisions”. These issues were brought up by EU-15 + Nor. and European Stakeholders, i.e. European Commission and Association of Pharmacies.

Regarding the sub-category “Process”, 33% of the institutions commented on this, stressing the importance of ensuring the sustainability of the project and providing recommendations for which European Stakeholders to further include. These issues were brought up by the National Stakeholders, the European Commission and The European Observatory for Health Systems – WHO.

19% of the institutions commented on the sub-category “EU related issues”. The issues mentioned related to the EU Transparency Directive and the Post G10 process. The interest in “EU related issues” was expressed by National Stakeholders and Associations of Pharmacies, Associations of Wholesalers, Patient Associations and the OECD.

5 Analysis

In this chapter, the results described in Chapter 4 are analysed. Section 5.1 is an analysis of the first and the second part of the Needs Assessment. Section 5.2 is an analysis of the results of the second part of the Needs Assessment for all the participating institutions. The analysis is presented according to the areas of interest, i.e. in the same way as in Chapter 4: 1) "What information are you most interested in?" 2) Key priority areas: "Background", "Pricing", "Reimbursement", "Access/Cost-containment", "Monitoring/Evaluation" and 3) "Additional comments".

5.1 First and the second part of the Needs Assessment

A vast amount of topics were expressed during the first and the second part of the Needs Assessment. These issues merged to allow identifying targets for EU pharmaceutical policy from a public health perspective. The issues mentioned in the first and the second parts of the Needs Assessment were in general coinciding. However the areas identified in the second part of the Needs Assessment contributed to a greater understanding of the issues of interest, a précising and a regrouping of the areas identified in the first part of the Needs Assessment.

5.2 Second part of the Needs Assessment

5.2.1 Priority points of interest

The analysis of the data shows that the issues mentioned in the first question "What information are you most interested in?" all relate to the five specified key priority areas. The greater part of the participating institutions listed several issues covering more than one area, so it appears that the participating institutions used this question to describe their overall interest more than the most urgent matter in relation to pricing and reimbursement. However, the result of the first question could also indicate that the most oppressing areas are the 5 key areas identified during this needs assessment.

On a more detailed level, it shows that the National Stakeholders, EU-15 + Nor. were interested in all areas, whereas EU-10 + Bul. mostly listed issues related to "Pricing" and "Reimbursement". The reason for this is not to be found in the data but it signifies that the EU-10 +

Bul. are less preoccupied with "Cost-containment" and "Monitoring/Evaluations" issues, however they said that they had specific interest in funding/budgeting issues.

The European Stakeholders showed an interest in most of the key areas. On a more detailed level, the issues mentioned by the different participating institutions reflects the nature of the institution responding: For example, the issues listed by the Pharmaceutical Industry are issues of importance for the production and the sale of pharmaceuticals like processing time for reimbursement decisions for new pharmaceuticals, the relevance of the parallel trade market, the margins applied to pharmaceuticals, the guidelines for generic prescribing and the regulation of competition. Other examples are the topics stated by the Patient Associations, which all relate to patient access to pharmaceuticals, i.e. free access, availability and affordability of pharmaceuticals.

5.2.2 Key priority areas

In general the results showed that there is a great interest in the areas identified during the analysis (see Table 8). Surprisingly many project participants mentioned issues related to "Background". It was explicitly written in the Needs Assessment guide that "Background" issues would be included in the final template for the country profiles but 69% still chose to comment on this area.

Regarding "Background", "Market authorisation and classification" was the most often mentioned sub-category by the participating institutions, except EU-10 + Bul., who showed more interest in "Funding". EU-15 + Nor., even adjusted for their high respond rate, were the ones who expressed most interest in "Market authorisation and classification", but also the European Stakeholders, especially the Pharmaceutical Industry, the Associations of Wholesalers, The European Commission and the OECD indicated a deepened interest in this issue.

"Distribution" was also an explicitly named by the EU-15 + Nor. and the European Stakeholders. However, of the latter, mainly the European Commission expressed interest in "Distribution". The issues mentioned naturally reflects the nature of the institution responding. This is seen for example by the above mentioned institutions' interest in "Market authorisation and classification". These institutions have a special interest in this issue for commercial or policy reasons, whereas the Patient Associations for example do not share that interest, probably because "Market authorisation and classification" do not have an obvious direct impact on patient access to pharmaceuticals. The increased interest in "Funding" issues

expressed by EU-10 + Bul. might signify that the pharmaceutical expenditure is a pressing issue for some of these countries. The high number of participating institutions commenting on “Background” can be an indication for a large need for “Background” information of the pharmaceutical sector such as “Organisation”, “Funding”, “Market authorisation and classification” and “Distribution”. This is also one of the reasons the European Commission recognised the necessity of the PPRI-project proposal.

The main area of interest of the 5 key priority areas was “Access/Cost-containment”. This interest was most significant among EU-15 + Nor. and less significant among the European Stakeholders. Looking into the subcategories of the areas, the results showed that the interest was generally high among most sub-groups of participants. There were only a few exceptions. One of the exceptions was found in the sub-category “Margins” in the key area “Pricing”, in which the European Stakeholders showed a significant low interest (21%). Within the area “Monitoring/Evaluation”, “Methods and indicators” was the most important sub-category, especially expressed by EU-15 + Nor. EU-15 + Nor. was generally more interested in “Monitoring/Evaluation” than the European Stakeholders and especially EU-10 + Bul. Again, the reason for this is not to be found in the data, but it could be that parts of EU-10 + Bul. have other interests.

In general the results and the analysis show that there is a high interest in the areas and subcategories identified, but that the interests differ between the participating sub-groups.

5.2.3 Additional comments

More than half of the participating institutions used the chance to give further inputs. The points given mostly related to the key areas included, suggestions for the framework of the country profiles and future corporation between policy makers. However, a few new issues were mentioned such as to include the hospital sector in the country profiles. The pricing and reimbursement of pharmaceuticals in the hospital sector is somewhat of a “black box” in many European countries, which is why this would be important to include.

The National Stakeholders, the European Commission and the European Observatory for Health Systems - WHO all gave relevant and valuable suggestions on how the process of the PPRI-project should continue, especially with regard to making the country profiles sustainable, whereas sustainability being a crucial point for the long term impact of the project. Regarding “EU related issues”, the Transparency Directive was the most listed single point,

probably because many of the participating institutions are directly influenced by the Transparency Directive.

European Stakeholders explicitly stated that biocide products, medical devices and borderline products should not be further explored in the PPRI project. The focus should remain at the investigation of the pricing and reimbursement systems of pharmaceutical products in the Member States.

6 Discussion

6.1 Results

1) In the first part of the needs assessment, the National and European Stakeholders listed a number of issues in relation to pricing and reimbursement, which were grouped into seven areas of interest

Table 3: Result of the first part of the Needs Assessment

1. Background	5. Monitoring
2. Pricing	6. Regulation
3. Reimbursement	7. Access/Affordability.
4. Distribution	

2) These seven areas of interest created the basis for the Needs Assessment guide used in the second part of the Needs Assessment that included three questions:

   a. "What information are you most interested in?"

   b. Key priority areas: What areas are you interested in relation to "Pricing", "Reimbursement", "Access/Cost-containment" and "Monitoring/Evaluation""

   c. "Additional comments".

3) From the issues mentioned during the second part of the Needs Assessment, 5 key areas of interest were identified. Furthermore 21 sub-categories were identified, all displayed in Table 4.

Table 4: Result of the second part of the Needs Assessment

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

4) The areas of interest expressed during the first and second part of the Needs Assessment were in general coinciding.

5) The issues that were brought up in the first question "What information are you most interested in"? all relates to the 5 specified key priority areas: "Background", "Pricing", "Reimbursement", "Access/Cost-containment" and "Monitoring/Evaluation",

6) The issues expressed in the second question of the Needs Assessment: "Key areas" showed that there was a high interest in the 5 key areas: "Background", "Pricing", "Reimbursement", "Access/Cost-containment" and "Monitoring/Evaluation". The main key area of interest of the 5 key priority areas was "Access/Cost-containment", but the level of interests differs between the participating sub-groups".

7) Surprisingly many stakeholders showed a special interest in "Background", in spite of the fact that this was not asked for, but this indicates a large need for information on these issues among the participating institutions.

8) The issues mentioned in the third question of the Needs Assessment "Additional comments" mostly related to the following:

    a. The 5 key priority areas identified

    b. The process of the PPRI project

    c. EU related issues, such as the Transparency Directive or the post-G10 process.

Table 4 displays the issues mentioned.

Table 5: """Additional comments" *mentioned in the second part of the Needs Assessment*

Other issues	Include the **hospital sector** in the country Profile, Analyse and compare how **adequate supply is guaranteed,** Create a **forum for policy makers, Focus on public health issues, Innovation, Orphan drugs, Parallel trade, Share experience** with the use of compliance data in reimbursement decisions
Process Issues	Several **process issues,** Stressing importance of **sustainability**, **Recommendations** for which European Stakeholders to further include
EU related Issues	**EU Transparency Directive** **Post G10 process**

9) The sub-groups i.e. National Stakeholders vs. European Stakeholders; EU-15 + Norway vs. EU10 + Bulgaria and the various sectors within the European Stakeholders all expressed issues of interest that reflected their institution. However, the difference was only marginal

10) European Stakeholders explicitly stated that biocide products, medical devices and borderline products should not be further explored in the PPRI project and that the focus should remain at the investigation of the pricing and reimbursement systems of pharmaceutical products in the EU Member States.

6.2 Methodology

The overall response rate of the Needs Assessment is very high i.e. 78%. When leaving out the personal interviews, the response rate of National Stakeholders and European Stakeholders is 74%. The high respond rate could be an indication of the participating institutions being highly motivated to contribute to the success of this project and/or and indication of the great need for information in this field. Furthermore 14 out of 22 National Stakeholders assessed further institutions, in total 79 assessed institutions resulting in an average of more than 5 institutions per Member State. These institutions represent a wide range of sectors, which together with the high respond rate and the high number of assessed institutions add to the extraordinary high validity of this study.

The purpose of the second part of the Needs Assessment was furthermore to identify the most oppressing issues of interest within the 5 target areas. However, most of the participating institutions contributed more issues than identified during the first part of the Needs Assessment.

The Needs Assessments carried out by National Stakeholders were often longer and included more questions. However, the identification of key priority areas was not based on quantitative measures (i.e. who listed which issue), but rather on the qualitative parameters i.e. if the issue related directly to pricing and reimbursement of pharmaceuticals. If the selection of issues were based on quantitative measures, from the Needs Assessment, this could lead to a bias. The analysis of the data was qualitative and the purpose was to identify issues or questions that should be answered in the planned country profile. The number of participating institutions that mentioned a given area was only weighted to assess which needs were significant for which groups. The selection of issues for the country profile will not be

based on how many Stakeholders that mentioned a given issue, but based on the overall results and on the discretion of the PPRI project participants. The final country profile contents will be discussed in the next coordination meeting, scheduled for the 27th – 28th of April, 2006.

It could have been interesting to see if there were any differences according to whether the issues were expressed by Governmental Organisations or by Public Organisations, but due to the method of data collection, this was not possible. It might have been possible to analyse the data on a more country specific level, but the team decided not to do so because the analysis by now has shown a general interest in the key priority fields. To identify the country-specific differences, the analysis would have had to be done by comparing the specific issues of interest expressed by the assessed institutions in the single countries on a more qualitative basis.

Several institutions expressed that they were very pleased to participate in the Needs Assessment. Their endorsement was due to the fact that they were given the chance to express viewpoints and the chance to contact and assess the needs of fellow National Stakeholders.

6.3 Conclusion

In conclusion, this report has mainly described, analysed and discussed the results of the Needs Assessment of National Stakeholders and European Stakeholders in relation to the PPRI-project. Additionally the report has shown that there is a great need for information on pharmaceutical policy in the various European countries. This need is mainly expressed for the areas “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation” albeit with small variations between the participating institutions. The issues listed are all relevant and important, but much too plentiful to all be included in the country profiles. The Needs Assessment will therefore be used to guide the selection process of issues that will be included in the template for writing up the country profiles. This process will be performed by ÖBIG – Austrian Health Institute and WHO Regional Office for Europe in close cooperation with the project partners and observers. The template and the glossary will be developed by WHO Regional Office for Europe and ÖBIG – Austrian Health Institute and the final approval of the template and the glossary will take place during the 2nd PPRI Coordination Meeting on 27th & 28th of April, 2006.

7 Annex

7.1 List of countries invited to participate in Needs Assessment

Countries	Sector	Participants		Contact persons	Address	Country
		1st part	2nd part			
Austrian Federal Association of Social Insurance Institution	SHI/NHS	YES	YES	Peter Wieninger Anna Bucsics	Kundmanngasse 22 1030 Vienna	Austria
Austrian Health Institute - ÖBIG	Public organisation			Sabine Vogler, Claudia Habl, Ingrid Rosian	Stubenring 6 1010 Vienna	
Austrian Federal Ministry of Health and Women's Issues	Ministry			Gernot Spanninger	Radetzkystr. 2 1030 Vienna	
Ministry of Economic Affairs of Belgium	Ministry	YES	YES	Marie-Thérèse Peeter, Mireille Pierlet	Boulevard Roi Albert II 16 1000 Bruxelles	Belgium
International Healthcare and Health Insurance Institute	Public organisation	YES	YES	Gergana Andre	57 Tsar Simeon Str. 3rd Floor 1000 Sofia	Bulgaria
Ministry of Health of Cyprus	Ministry	YES	YES	Athos Tsinontides	7. Larnacos Avenue 1475 Lefkosia	Cyprus
Ministry of Health of Czech Republic	Ministry	YES	YES	Pynelopi Valsamisová	Palackého nám. 4 128 01Praha 2	Czech Republic
Danish Medicines Agency	Public organisation	YES	YES	Elisabeth Thomsen	Axel Heides Gade 1 2300 Copenhagen S	Denmark
Ministry of Social Affairs of Estonia	Ministry	YES	YES	Katrin Pudersell	Gonsiori str 29 15027 Tallinn	Estonia
Association of Finnish Pharmacies	Association of Pharmacies	YES	YES	Sirpa Peura	Pieni Roobertinkatu 14C 120 Helsinki	Finland
University Claude Bernard Lyon 1	Public organisation	YES	NO	Eric van Ganse	43 boulevard du 11 novembre 1918 69622 Villeurbanne cedex	France
French National Sickness Fund for Employees - CNAM-TS	SHI/NHS			Christian Marty	26-50, avenue de Professeur André Lemierre 75986 Paris Cedex 20	

German Institute for medical documentation and information (DIMDI)	Public organisation	YES	YES	Hans-Peter Dauben	Waisenhausgasse 36-38a 50676 Köln	Germany
Institute of Pharmaceutical Research and Technology	Public organisation	YES	YES	Vardica Areti	18th km Marathonos Ave. 153 51Pallini Attiki	Greece
National Health Insurance Fund Administration	SHI/NHS	YES	YES	Gábor Lengyel	Vaciut ut 73/A 1139 Budapest	Hungary
HSE-Shared Services-Primary Care Reimbursement Service	SHI/NHS	YES	YES	Gerald Byrne, Deidre Elliott	Exit 5, M 50 North Road Finglas, Dublin	Ireland
National Centre for Pharmacoeconomics St Jame's Hospital	Public organisation			Lesley Tilson	St James Hospital Jame's St Dublin 8	
Italian Medicines Agency - AIFA	Public organisation	YES	YES	Pietro Folino-Gallo	Via Sierra Nevada 60 00144Roma	Italy
Medicine's Pricing and Reimbursement Agency	Public organisation	YES	YES	Daiga Behmane	72 Brivibas iela 1011Riga	Latvia
Department of Pharmacy, Ministry of Health	Ministry	YES	YES	Tomas Alonderis, Gita Krukiene	Traku str. 14 2001Vilnius	Lithuania
Ministry of Health, Direction of Health of Luxembourg	Ministry	NO	NO	Mariette Backes-Lies	Villa Louvigny, Allée Marconi, 2120 Luxembourg	Luxembourg
Health Division	Ministry	NO	NO	Patricia Vella-Bonanno	BMW Building, 198, Rue d'Argens, Gzira GZR03	Malta
Ministry of Health, Welfare and Sport	Ministry	YES	YES	Petra Jansen	Postbus 20350 2500 EJ Den Haag	Netherlands
Ministry of Health and Care Services of Norway	Ministry	NO	YES	Audun Haga	Einar Gerhardsens pl. 3 0030 Oslo	Norway
Ministry of Health of Poland	Ministry	YES	YES	Piotr Blaszczyk	Miodowa 15 00-952 Warszawa	Poland
The National Pharmacy and Medicines Institute	Public organisation	NO	NO	Jesus Maria Vasco, Isaura Vieira	Av. do Brasil 53 1749-004 Lisboa	Portugal
Ministry of Health of Slovakia	Ministry	NO	YES	Jan Mazag	Kevntá 11 825 08 Bratislava	Slovakia
Agency for Medical Products of the Republic of Slovenia	Ministry	YES	YES	Stanislav Primozic	Mali TRG 6 1000 Ljubljana	Slovenia

Ministry of Health and Consumer Affaires of Spain	Ministry	NO	NO	José Martinez Olmos	Paseo del Prado 18-2028071 Madrid	Spain
Swedish Pharmaceutical Benefits Board	Public organisation	YES	YES	Thord Redman	Sundbybergsvägen 1 Box 55 171 11 Solna	Sweden
Department of health, Medicines Pharmacy and Industry	Ministry	YES	YES	Danny Palnoch	Skripton House, 80 London Road, SE1 6LH London	United Kingdom

7.2 List of nationally assessed institutions

Institution	Country	List of assessed institutions	Total
Austrian Health Institute - ÖBIG	Austria	Ministries (2): Austrian Ministry of Health and Women, Ministerial Office; Dept. of Health Economics Pharmaceutical Industry (1): Association of the Austrian Pharmaceutical Industry Association of Pharmacists (1): Austrian Chamber of Pharmacists Association of Wholesalers (1): Association of the Austrian Pharmaceutical Wholesalers Association of Doctors (1): Austrian Physicians' Association SHI/NHS (1): Association of Austrian Social Insurances Public Organisations (1): Austrian Chamber of Labour	8
Ministry of Economic Affairs of Belgium	Belgium	Pharmaceutical Industry (1): Association Belge de l'Industrie pharmaceutique (pharma.be) SHI/NHS (1): Association Nationale des Mutualités socialistes Public Organisation (1) Coordinateur des experts internes de la Commission de Remboursement des Médicaments (INAMI)	3
International Healthcare and Health Insurance Institute	Bulgaria	SHI/NHS (1): National Health Insurance Fund Association of Wholesalers (1): Association of Wholesalers Association of pharmacies (1) he Bulgarian Pharmaceutical Union,	3
Ministry of Health of Czech Republic	Czech Republic	Public Organisations (1): Czech Medical Association Ministries (2): Appellate Committee of the Pharmaceutical Categorization Committee of the Ministry of Health;	3

		Drugs and Medical Devices Policy Department	
Danish Medicines Agency	Denmark	Ministries (1): Ministry of Interior and Health Public Organisations (2): Association of County Councils, Danish Competition Authority	3
Ministry of Social Affairs of Estonia	Estonia	SHI/NHS (1): Health Insurance Fund	1
Association of Finnish Pharmacies	Finland	Patient Associations (1): The Diabetes Association Ministries (1): Ministry of Health Public Organisations (1): Association of Communities Pharmaceutical Industry (1): The Pharmaceutical Industry Association Association of Pharmacists (1): The Pharmacists Association	5
German Institute for medical documentation and information (DIMDI)	Germany	Ministries (1): Federal Ministry of Health SHI/NHS (2): Several German Social Health Insurance Institutions	3
Institute of Pharmaceutical Research and Technology	Greece	Ministries (3): Ministry of Health and Social Solidarity; Ministry of Development – Commercial Section; Ministry of Employment and Social Protection SHI/NHS (4): Social security for private employees; Social security for public servants; Social security for commercial navy personnel; Social security for farmers Public Organisations (2): National Organization for Medicines; University of Thessaly (Department of Health Economics and Social Policy) Pharmaceutical Industry (1): Hellenic Association of Pharmaceutical Companies Association of Pharmacists (1): Hellenic Association of Pharmacists	11
National Health Insurance Fund Administration	Hungary	Industry (2): VÉFE–Védőoltás Forgalmazók Egyesülete (Association of Manufacturers of Vaccinations), MAGYOSZ Magyarországi Gyógyszergyártók Országos Szövetsége (Hungarian Pharmaceutical Manufacturers Association) Patient associations (1): Patient-representative body (haemophilia patients) SHI/NHI (1): OEP–Országos Egészségbiztosítási Pénztár – National Health Insurance Fund.	3
HSE-Shared Services-Primary Care Reimbursement Service	Ireland	Association of Doctors (1): Irish Medical Organisation Pharmaceutical Industry (3): Irish Pharmaceutical Union; Irish Pharmaceutical Healthcare	12

		Association; Association of Pharmaceutical Manufacturers in Ireland Insurance Companies (3): VHI Healthcare; BUPA Ireland Ltd.; Vivas Insurance Ltd. Ministries (1): Department of Health and Children Public Organisations (4): National Centre for Pharmaco-economics in Ireland; Irish Medicines Board; Interim Health Information Quality Authority; HSE community Care Pharmacists Group	
Medicine's Pricing and Reimbursement Agency	Latvia	Ministries (1): Ministry of Health of Latvia Pharmaceutical Industry (2): Association of International Research-based Pharmaceutical Manufacturers; Association of Generic Manufacturers Association of Pharmacists (1): Society of Pharmacists of Latvia	4
Department of Pharmacy, Ministry of Health	Lithuania	Public Organisations (1): The State Patient Fund	1
Ministry of Health, Welfare and Sport	Nether-lands	SHI/NHS (1): Healthcare Insurance Board Public Organisations (1): Nivel (research institute) Ministries (1): Ministry of Health	3
Agency for Medical Products of the Republic of Slovenia	Slovenia	SHI/NHS (1): Health Insurance Institution (ZZZS) Pharmaceutical Industry (2): The pharmaceutical industry association (FORUM); the association of the manufacturers of medicinal products of Slovenia (ZPZS) Ministries (1): Chamber of Economy Association of Wholesalers (1): Section of wholesalers of medicinal products Association of Pharmacists (1): Pharmacy Chamber of Slovenia Association of Doctors (1): The Medical Chamber of Slovenia Patient Associations (2): EuropaDonna; The international oncology patient organization.	9
Swedish Phar-maceutical Benefits Board	Sweden	Public Organisations (3): The Swedish Council on Technology Assessment in Health Care; The Swedish Medical Products Agency; The Swedish Academy of Pharmaceutical Sciences Association of pharmacists (1): The Swedish Pharmaceutical Association; Pharmaceutical Industry (1): The Swedish Association of the Pharmaceutical Industry	7

		Patient Associations (2): The Swedish Association for Senior Citizens; The Swedish National Pensioners' Organisation	
Total	**15**		**79**

7.3 European Stakeholders

European Stakeholder	Sector	Participants		Contact persons	Address	Country
		First part	Second part			
Association of the European Self-Medication Industry - AESGP	Pharmaceutical Industry	NO	NO	Hubert Cranz	7 Avenue de Tervuren, 1040 Brussels	Belgium
European Association of Euro-Pharmaceutical Companies - EAEPC	Pharmaceutical Industry	NO	YES	Heinz Kobelt	Ave. Parmentier 24 1150 Brussels	Belgium
European Federation of Pharmaceutical Industries - EFPIA	Pharmaceutical Industry	NO	NO	Brendan Barns	Rue du Trone 18 1050 Brussels	Belgium
European Generic Medicines Association - EGA	Pharmaceutical Industry	NO	YES	Greg Perry, Ana Wisse Teixeira	Rue d'Arlon 15 1050 Brussels	Belgium
European Association of Pharmaceutical Wholesalers - GIRP	Association of Wholesalers	NO	YES	Monika Derecque-Pois	13b, avenue de Tervuren 1040 Brussels	Belgium
Pharmaceutical Group to the European Union - PGEU	Association of Pharmacies	NO	YES	Monica Alfaro	Rue du Luxembourg 19-21 Box 6 1000 Brussels	Belgium
European Patient's Forum	Patient Association	NO	YES	Christoph Thalheim	Nieuwland 23 3090 Overijse	Belgium
Eurordis - European Organization for Rare Diseases	Patient Association	NO	YES	Michele Lipucci de Paola	Rue didot 102 75014 Paris	France
International Alliance of Patients' Organizations - IAPO	Patient Association	NO	NO	Jo Harkness	703 The Chandlery, 50 Westminster Bridge Road SE1 7QY London	United Kingdom
European Observatory for Health Systems - WHO	WHO	NO	YES	Susanne Grosse-Tebbe Suzsy Lessof	Rue de l' Autonomie 4 1070 Brussels	Belgium
Health Division – OECD	OECD	YES	YES	Elizabeth Docteur	2, rue André Pascal 75775 Paris Cedex 16	France
DG Competition	European Commission	NO	YES	Nicola Schelling	200 rue de la loire, G/70 04/179 1040 Brussels	Belgium

DG Enterprise	European Commission	NO	YES	Christian Siebert, Stefaan van der Spiegel, Nils Behrndt	45, Avenue d'Auderghem 1049 Brussels	Belgium
DG Research	European Commission	NO	YES	Irene Norstedt	200 rue de la loire CDMA 02/180 1040 Brussels	Belgium
DG Sanco	European Commission	YES	YES	Zinta Podniece, Marianne Takki	45, Avenue d'Auderghem 1049 Brussels	Belgium
European Medicines Agency - EMEA	European Commission	YES	NO	Göran Isaksson	7 Westferry Circus, Canary Wharf, London E14 4HB	United Kingdom
EURO-MED-STAT[1]	European Commission	YES	YES	Pietro Folino-Gallo	Via Sierra Nevada 60 00144Roma	Italy
EFTA	European Commission	NO	YES	Elisabethann Wright	Rue Belliard 35 1040 Brussels	Belgium

[1] The Needs Assessment for the EURO-MED-STAT project has been included in the same Needs Assessment of Italy by Mr. Folino-Gallo

7.4 Results of brainstorming session

Questions of interest expressed by the partners and the observers of PPRI at the 1st project coordination meeting in Vienna 1st & 2nd of September 2005

Background

- What is the overall aim of the current policy
- Outline of the health care system

Reimbursement

- Reimbursement criteria / guidelines for Over-The-Counter pharmaceuticals, Prescription pharmaceuticals and Innovative products
- Categories / groups of reimbursement
- Essential list
- Decision-making process
- Who are the responsible committees or authorities in the decision-making reimbursement procedure?
- Role of cost-effectiveness
- Grouping of pharmaceuticals for reference pricing
- Generics and new products
- Officinal preparations like dietary mixtures
- Special reimbursement systems for medical devices
- Reimbursement of orphan drugs
- Which therapeutic guidelines do Member States have?

Pricing

- Wholesale and pharmacy margins / mark-ups
- Cost structure
- Taxes
- Decision making process
- Grouping of pharmaceuticals for reference pricing
- How do Member States assess the cost-effectiveness of products?
- Strength and weaknesses of reference price systems → comparisons with all MS
- Sources for price referencing → comparisons with all MS
- Selection of basket countries (why and which)
- Health Economic Evaluation – Pharmaco-economic guidelines
- Claw-backs, rebates, discounts (for which products?, transparency level official versus unofficial)
- Pharmaceutical prices in hospitals and nursing homes

- Parallel trade
- Generic pricing → influence on prices of brand products
- Pricing of orphan drugs
- Price components of innovative pharmaceuticals (costs of R&D)

Regulation

- Consequences (positive / negative) of regulation
- Legal basis for pricing and reimbursement
- Financing of system / budgetary aspects
- Switches from prescription to Over-The-Counter pharmaceuticals
- Promotion of generic medicines

Distribution

- Who is entitled to dispense pharmaceuticals?
- Prescribing systems (Who are allowed to prescribe?)
- Scope of products sold outside of pharmacies
- Generic substitution
- Discounts
- Medicines via internet

Monitoring / Surveillance

- Pharmaceutical consumption
- Compliance
- How do MS monitor these?
- Demand regulation
- Supply regulation
- Prescription habits of doctors
- How does other countries regulate?
- Does the system in your country work well?

Access

- Expenditure on pharmaceuticals
- Pharmaceuticals available
- Generic share
- Parallel imports
- Orphan drugs
- Pharmaceutical lists
- Influence of pricing and reimbursement decision of access of the population
- Pharmaceuticals via the internet.
- Cross-border acceptance of prescription
- Public purchasing of e.g. anti-tuberculosis therapy (tenders?)

Affordability

- Burden of disease
- Value for money
- Cost-containment
- How to check the “reasonability of a price”?
- Benchmarking of pricing and reimbursement systems → influence on outcome
- Co-payment → influence on patient
- Outcome measurement → output
- Household expenditure for pharmaceuticals
- Are there studies on consumption?
- Is there a system on consumption?

7.5 Results of the first part of the Needs Assessment

<table>
<tr><th colspan="2">Background</th></tr>
<tr><td colspan="2">
- The organisation of regulation and pricing of pharmaceuticals
- The legal framework for regulation and pricing of pharmaceuticals
- The financing of pharmaceuticals
- Statistics
  o Pharmaceutical expenditure % total health expenditure
  o Pharmaceutical expenditure
  o Pharmaceutical expenditure
  o Public/private spending
  o VAT
  o Annual budget
- Glossary/definition
  o Positive list
  o Innovative medicine
</td></tr>
<tr><th>Pricing</th><th>Reimbursement</th></tr>
<tr><td>
– System of pricing
– Experience with pricing of
  o Medicines
  o Medical devices
  o Dietary pharmaceuticals
– What are the criteria for grouping of medicines for price?
– How often are price changes made?
– Generic price setting system
– How is innovative medicines dealt with when they loose patent?
– Pricing of parallel import
– Retail price
– The role of pharmaco-economics in pricing
– Discounting/rebates
– Pricing in nursing homes/hospitals?
– Distribution margins on wholesale pharmacies?
</td><td>
– The overall structure of the reimbursement system/level of co-payment
– The actors involved in pharmaceutical reimbursement decisions?
- What are the criteria for grouping of medicines for reimbursement?
- On what basis are pharmaceuticals reimbursed? Age, diagnosis, social class?
- Are lifestyle pharmaceuticals reimbursed?
- What is the timeframe for decisions on reimbursement of pharmaceuticals?
- Is there a system for re-assessing the reimbursement list?
- What are the guidelines for reimbursement of innovative medicines?
- Criteria for the positive/negative list
- The role of pharmaco-economics in reimbursement decisions
- Reimbursements effect on quality of care, equity of access
- Analyse of market entry delays (administrative procedures, completeness of information submitted)
</td></tr>
<tr><th>Distribution</th><th>Monitoring</th></tr>
<tr><td>
– How and by whom are pharmaceuticals distributed?
– Parallel import
</td><td>
– Is there a system to monitor pharmaceutical consumption/compliance?
– Is there an existing integrated evaluation of the reimbursement system?
– What outcome measures are used?
</td></tr>
</table>

Regulation	Access/Affordability
– Experience with pricing and reimbursement in countries that negotiates price – Regulation of pharmaceutical sale/information on the Internet, – Criteria for positive/negative list – Guidelines for rational use of medicine – Regulation of marketing of medicine – Regulation to increase competition and decrease price – Innovations on cost-control – How do new pharmaceuticals enter the market? – How does government/state inform doctors about good prescribing? – Use of and guidelines for pharmaco-economics – The system of generic substitution? – Experience with mechanisms to regulate demand and supply of pharmaceuticals	– How does innovation, Access/Cost-containment interact in the system? – Is there access to orphan drugs – How does pricing and reimbursement decisions influence access? – What is the influence if the prescribing system on access to pharmaceuticals? – Market share of generics and parallel imported pharmaceuticals – Cost-containment measures – How is value for money evaluated? – Co-payment – Level of patient information – Household expenditure on pharmaceuticals

7.6 Needs Assessment guide

Organisation	
Name	
Country	
Date	

Please answer the following questions

Question 1) What information are you most interested in?

Please list issues or questions that you would like to know about the Member States of the European Union regarding pricing and reimbursement of medicines. These issues or questions should reflect the issues that you think are the most oppressing or relevant issues nationally or international level.

_____

_____

_____

Question 2) Key priority areas

Pricing:

What would you like to know about pricing of medicines? e.g.

- Decision making process of pricing medicines
- Methodology used for external price referencing/price comparison e.g. country basket, price levels

_____

_____

_____

Reimbursement:

What would you like to know about reimbursement of medicines? e.g.

- The role of pharmaco-economics in reimbursement decisions
- Experience with the co-payment systems used in the country

_____

_____

_____

Equality of Access/Cost-containment

What would you like to know about cost containing measures and equality of access? e.g.

- Consequences of cost-containment measures for e.g. public health
- Promotion of generics in order to favour most expensive/innovative medicines

_____

_____

_____

Monitoring/Evaluation

What would you like to know about Monitoring/Evaluation of policies for pricing and reimbursement of medicines? e.g.

- Indicators used to monitor the effect of the price and reimbursement system
- Techniques used to evaluate the pricing and reimbursement system e. g. pharmaco-economic analysis/evaluation

_____

_____

_____

Part 3) Additional Comments

If you have any additional comments to the PPRI project, please comment.

_____

_____

Thank you very much for your help!

Annex VI b
Summary of Needs Assessment Report

Intermediate report

Summary

Trine Lyager Thomsen and Kees de Joncheere

Health Technology and Pharmaceuticals

WHO Regional Office for Europe

In cooperation with ÖBIG – Austrian Health Institute

Introduction

This report summarises the result of Work Package 3 (Needs Assessment) of the PPRI-project. The purpose of WP 3 is to analyse which areas in relation to pricing and reimbursement of pharmaceuticals that EU Member States, Bulgaria, Norway and European Stakeholders are interested in.

The main objective of this Needs Assessment is to:

- Describe which issues EU Member States, Bulgaria and Norway and European Stakeholders (project participants) wish to include in the planned country profiles that are to be written by the participating institutions during Work Package 4, i.e. "Pharma Profiles".
- Identify key areas of interest expressed by project participants.
- Analyse differences and similarities between the areas of interest 1) in the first and the second part of the Needs Assessment and 2) by EU Member States, Bulgaria and Norway and European Stakeholders.
- Discuss the areas of interests and provide recommendation for how these areas can be used to develop both the template for the Pharma Profiles and the benchmarks in WP 4 and WP 5.

The Needs Assessment was carried out in two main parts.

The first part took place during the 1st coordination meeting of the PPRI-project on the 1st and 2nd of September, 2005, where a brainstorming session was carried out. The data from the first part of the Needs Assessment was summarised in the document "Result of the first part of the Needs Assessment". This document was used as a basis to develop the "Needs Assessment guide", for the second part of the Needs Assessment, in which the following three questions were asked:

1) "What information are you most interested in?"
2) Key priority areas: What areas are you interested in relation to "Background", "Pricing", "Reimbursement", "Access/Cost-containment" and "Monitoring/Evaluation"
3) "Additional comments".

The second part took place from the 26th of September, 2005 to the 19th of January, 2006, where the participating institutions in the PPRI-project were asked to; first, to expand on their needs and expectations of the PPRI-project; second, to assess the needs of National Stakeholders and third, to create a comprehensive report on the basis of these consultations and return it to the WHO Regional Office for Europe.

Participating institutions

A total of 28 institutions from EU Member States, Bulgaria and Norway and European Stakeholders participated in the first part of the Needs Assessment. A total of 115 institutions from national and international institutions participated in the second part of the Needs Assessment, please see Table 1.

Table 1: The participating institutions

	National Stakeholders	Assessed Institutions	European Stakeholders	Total
N =	**22**	**79**	**14**	**115**
Governmental Organisations	**21**	**43**	**0**	**64**
Ministries	*11*	*14*	*0*	*25*
SHI/NHS	*2*	*12*	*0*	*14*
Public organisations	*8*	*17*	*0*	*25*
Private Organisations	**1**	**36**	**6**	**43**
Representatives of Pharmaceutical Industry	*0*	*14*	*2*	*16*
Associations of Pharmacies	*1*	*7*	*1*	*9*
Associations of Wholesalers	*0*	*3*	*1*	*4*
Insurance Companies	*0*	*3*	*0*	*3*
Associations of Doctors	*0*	*3*	*0*	*3*
Patient Associations	*0*	*6*	*2*	*7*
European Institutions	**0**	**0**	**8**	**8**
European Commission	*0*	*0*	*6*	*6*
OECD	*0*	*0*	*1*	*1*
WHO	*0*	*0*	*1*	*1*

*Assessed by National Stakeholders, ** Public organisation covering the following: National Organisations funded by the government, research institutes and universities.

The respond rate was extraordinary high (80%), see table 2, which indicating a widespread need for information on pricing and reimbursement of pharmaceuticals. The response rate is based on the National Stakeholders and the European Stakeholders. It has not been possible to calculate the respond rate for the institutions assessed by the National stakeholders.

Table 2: Response rate

	National Stakeholders			European Stakeholders			All		
Method of contact	**Email**	**Interviews**	**Sum**	**Email**	**Interviews**	**Sum**	**Email**	**Interviews**	**Sum**
Total contacts	27	0	**27**	12	6	**18**	39	6	**45**
Responses	22	0	**22**	8	6	**14**	30	6	**36**
Missing responses	5	0	**5**	4	0	**4**	9	0	**9**
Response rate	**81%**	**100%**	**81%**	**67%**	**100%**	**78%**	**77%**	**100%**	**80%**

Main findings

1) In the first part of the needs assessment, the National and European Stakeholders listed a number of issues in relation to pricing and reimbursement, which were grouped into seven areas of interest

Table 3: Result of the first part of the Needs Assessment

1) "Background"	5) "Monitoring"
2) "Pricing"	6) "Regulation"
3) "Reimbursement"	7) "Access/Affordability".
4) "Distribution"	

2) These seven areas of interest created the basis for the Needs Assessment guide used in the second part of the Needs Assessment that included three questions:

   a. "What information are you most interested in?"

   b. Key priority areas: What areas are you interested in relation to "Pricing", "Reimbursement", "Access/Cost-containment" and "Monitoring/Evaluation"

   c. "Additional comments".

3) From the issues mentioned during the second part of the Needs Assessment, 5 key areas of interest were identified. Furthermore 21 sub-categories were identified, all displayed in Table 4.

Table 4: Result of the second part of the Needs Assessment

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

4) The areas of interest expressed during the first and second part of the Needs Assessment were in general coinciding.

5) The issues that were brought up in the first question “What information are you most interested in“? all relates to the 5 specified key priority areas: “Background”, “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation”,

6) The issues expressed in the second question of the Needs Assessment: “Key areas” showed that there was a high interest in the 5 key areas: “Background”, “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation”. The main key area of interest of the 5 key priority areas was “Access/Cost-containment”, but the level of interests differs between the participating sub-groups”.

7) Surprisingly many stakeholders showed a special interest in “Background”, in spite of the fact that this was not asked for, but this indicates a large need for information on these issues among the participating institutions.

8) The issues mentioned in the third question of the Needs Assessment “Additional comments” mostly related to the following:

    a. The 5 key priority areas identified
    b. The process of the PPRI project
    c. EU related issues, such as the Transparency Directive or the post-G10 process.

Table 4 displays the issues mentioned.

Table 5: ““Additional comments” *mentioned in the second part of the Needs Assessment*

Other issues	Include the **hospital sector** in the country Profile, Analyse and compare how **adequate supply is guaranteed,** Create a **forum for policy makers, Focus on public health issues, Innovation, Orphan drugs, Parallel trade, Share experience** with the use of compliance data in reimbursement decisions
Process Issues	Several **process issues,** Stressing importance of **sustainability**, **Recommendations** for which European Stakeholders to further include
EU related Issues	**EU Transparency Directive** **Post G10 process**

9) The sub-groups i.e. National Stakeholders vs. European Stakeholders; EU-15 + Norway vs. EU10 + Bulgaria and the various sectors within the European Stakeholders all expressed issues of interest that reflected their institution. However, the difference was only marginal

10) European Stakeholders explicitly stated that biocide products, medical devices and borderline products should not be further explored in the PPRI project and that the focus should remain at the investigation of the pricing and reimbursement systems of pharmaceutical products in the EU Member States.

Conclusion

In conclusion, the study showed that there is a great need for information on pharmaceutical policy in the various European countries. This need was mainly expressed within the areas “Pricing”, “Reimbursement”, “Access/Cost-containment” and “Monitoring/Evaluation” albeit with small variations between the participating institutions. The issues listed were all relevant and important, but much too plentiful to all be included in the Pharma Profile template.

The next step in the PPRI project is to create a template on the basis of the results of the Needs Assessment and the development of a glossary to assist the template. The template will be developed by WHO Regional Office for Europe and ÖBIG - Austrian Health Institute in close cooperation with the project partners and observers. The template and the glossary will be discussed during the 2nd PPRI Coordination Meeting on 27th & 28th of April, 2006.

Annex VII

PPRI Glossary

ABBRE	Preferred term	Synonym term	Definition/Description
	Access		The ability to obtain health care, as determined by factors such as the availability and affordability of goods and services.
	Active Ingredient	**(Active) Substance, Compound**	The primary chemical substance or compound contained in a pharmaceutical. Some **pharmaceuticals** contain more than one active ingredient (**combination product**).
	Affordability		Financial accessibility of goods and services.
	Analogous Substitution		Dispensation of a **pharmaceutical** (often **generic**) by the pharmacist with a different **active ingredient** (or **combination product**) but the same therapeutical effect instead of the product prescribed by the doctor. Cf. also **generic substitution**.
ATC	**Anatomic Therapeutic Chemical classification system**	**Anatomic Therapeutic Chemical Code**	In this classification system **pharmaceuticals** are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.
	ATC 4 level		Defines a therapeutic group within the **anatomic therapeutic chemical** classification system.
	ATC 5 level		Defines a single **active ingredient** or a fixed combination of active ingredients within the **anatomic therapeutic chemical classification system**.
	Benchmarking		A process of measuring another organisation's product or service according to specified standards in order to compare it and improve one's own product or service.
	Bioavailability		The amount of an **active ingredient** that is absorbed by the organism and the speed at which this occurs when introduced in a given dosage form.
	Bioequivalence		Two **pharmaceuticals** are bioequivalent if they are pharmaceutically equivalent (cf. **pharmaceutical equivalence**) and their **bioavailability** (rate and extent of availability) - after administration in the same moral dose - is similar to such a degree that their effect can be expected to be essentially the same.
	Brand Name		The trade or marketing name of a **pharmaceutical.** Also **generics** may have a brand name.
	Branded Generic		Cf. **generic.**
	Capitation		A remuneration method for **general practitioners** applied by some **social health insurance / national health service.** The remuneration is based on a fixed monthly amount for each enrolled/listed patient.
CIP	**Carriage and Insurance Packaging**	**Carriage and Insurance Paid To**	A type of price quotation, indicating the delivery of goods including cargo insurance to the named place of destination at seller's expense. In an export the quotation indicates the place of destination (discharge) after the acronym CIP, for example CIP Athens.
	Central Taxation		Taxes collected through central government.
	Centralised Procedure		Way of approval of **pharmaceuticals** valid in all Member States.The Centralised Procedure is administered by the European Medicines Agency (EMEA) in London. It consists of a single application which, when approved, grants **market authorisation** for all markets within the European Union. This procedure is available to all new, innovative pharmaceuticals, and is obligatory for 1. biotechnology-derived products, 2. new active ingredients for treating AIDS, cancer, diabetes and "neuro-degenerative illnesses" as well as 3. **orphan drugs**. Under certain conditions the centralised authorisation can be limited for one year. If the pharmaceutical is important for public health (especially therapeutic innovations) the appraisal period can be abbreviated.
	Claw-back		A system allowing **third party payers** to recoup (part of the) discounts/rebates granted in a reimbursement system between various stakeholders, e.g. wholesalers and pharmacists.
	Combination Product		A **pharmaceutical** that contains more than one **active ingredient**.
	Compulsory Health Insurance	**Obligatory Health Insurance**	Health Insurance under an obligatory scheme basing on a legal act, usually with income-related contributions. See also **social health insurance** and **voluntary health insurance.**

ABBRE	Preferred term	Synonym term	Definition/Description
	Contribution		Money paid by or on behalf of insured persons to a **social health insurance** to purchase the coverage of a defined range of services (the benefit package).
CIF	**Cost, Insurance and Freight**		The cargo insurance and delivery of goods to the named port of destination (discharge) at the seller's expense. Buyer is responsible for the import customs clearance and other costs and risks.
	Cost-Containment		Measures like **price freezes** taken to reduce expenditure or the rate of growth of expenditure, or the unit cost of services.
	Cost-Effectiveness Analysis		Compares the cost per unit of outcome of alternative therapies with the aim of identifying the most efficient therapy. Determines the cost incurred to obtain an increase in health benefit.
	Cost-plus Pricing		**Pricing procedure** which takes besides the production cost of a **pharmaceutical** other cost like promotional expenses and especially a profit margin for fixation of the price into account. This share is usually expressed as a percentage of the cost.
	Decentralised Procedure		The Decentralised Procedure came into operation in late 2005. It is applicable in cases where a **market authorisation** does not yet exist in any of the EU Member States. Identical dossiers be submitted to all Member States where a **market authorisation** is sought. A Reference Member State, selected by the applicant, will prepare draft assessment documents within 120 days and send them to the Concerned Member States. They, in turn, will either approve the assessment or the application will continue into arbitration procedures. The new Decentralised Procedure will involve concerned Member States at an earlier stage of the evaluation than under the **MRP** in an effort to minimise disagreements and to facilitate the application for **market authorisation** in as many markets as possible.
	Deductible		**Out-of-pocket payment** 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 a **social health insurance / national health service**, then all or a percentage of the rest of the cost is covered.
DDD	**Defined Daily Dose**		Technical unit developed in the early 1970's used to measure the consumption of pharmaceuticals in a comparable way. The DDD is the assumed average maintenance dose per day for a **pharmaceutical** used for its main indication in adults.
	De-listing		Exclusion of a **pharmaceutical** from a pharmaceutical list (e.g. **positive list**), often resulting in exclusion from **reimbursement**.
DRG	**Diagnosis Related Group**		A way of categorising patients according to diagnosis and intensity of resources required, usually for the period of one hospital stay.
	Direct Payments		Payments for goods and services which are not covered by a **social health insurance / national health service** or a v**oluntary health insurance** (including self-medication).
	Discount	**Rebate**	A price reduction granted to specified purchasers of a **pharmaceutical**.
	Dispensing fee		Payment of the pharmacist for the service of dispensing a **pharmaceutical**.
	Distance Selling		Dispensing of **pharmaceuticals** via internet or posting services.
	Distributors		Distributors rather sell products under a licence obtained from original manufacturers but most likely do not produce it by themselves.
	Effectiveness		The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do. Clinical trials that assess effectiveness are sometimes called management trials. Cf. also **pharmacoeconomic evaluation** and **cost-effectiveness analysis.**
	Efficacy		The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate. Cf. also **pharmacoeconomic evaluation** and **cost-effectiveness analysis**.

ABBRE	Preferred term	Synonym term	Definition/Description
	Efficiency		Efficiency measures whether health care resources are being used to maximise value for money.
	Essential Drug Policy		Essential pharmaceuticals satisfy the **primary care** needs of a population and are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. An essential drug policy shall guarantee that such pharmaceuticals are available within the context of the respective health care systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and at a price the individual and the community can afford.
	Ex-factory Price	**Manufacturer Price, Procurement Price, List Price**	The **manufacturer**'s posted price, in some countries also referred to as list price. This price does not include any **discounts** or other incentives offered by manufacturers.
	External Price	**Cross Country Referencing,**	The practice of comparing **pharmaceutical** prices across countries. There are various methods applied and different
	Fee-for Service		Payments to a provider (for example a **general practitioner**) for each act or service rendered.
	Fixed Co-payment	**Co-payment**	A **out-of-pocket payment** in the form of a fixed amount (like for example a **prescription fee**) to be paid for a service, a **pharmaceutical** or a medical device. See also **deductible** and **percentage co-payment.**
	Framework Agreement		This is an agreement between representatives of stakeholders, which serves as a base for individual agreements (this is for
	Free Pricing		Pricing system, where **pharmaceutical** prices may be freely set.
G10	**G 10 Medicines Group**		The G 10 Medicines Group (consisting of then Commissioner Liikanen and then Commissioner Byrne, a number of European health and industry ministers, as well as leaders of the pharmaceutical and health insurance industry and patient representatives) was set up in 2001 with the aim to discuss the major issues relevant to the right balance of health objectives and industry competitiveness in Europe. In May 2002 a report was published containing recommendations on how to improve the competiveness of industry while meeting public and social health objectives. The results were followed-up in the so-called "Post G 10"-process and are in 2006 discussed in the EU Pharmaceutical Forum. Still a lot of the recommendations are waiting for implementation.
	Gatekeeper		A health care person, most likely a **general practitioner** (but also paediatrician or gynaecologist), who is responsible for overseeing and coordinating all the medical needs of a patient. The gatekeeper has to authorise any referral of the patient to **secondary care** (specialist) or **tertiary care** (hospital). Referral exemptions are possible in emergencies or in some systems if patients accept higher **out-of-pocket payments**.
GP	**General Practitioner**	**Family Doctor, Primary Care Physician**	A general doctor, who is the first point of contact with the health services for all non-emergency cases. See also **gatekeeper**.
	Generic		**Bioequivalent** of a branded original **pharmaceutical**, whose patent on the **active ingredient** has expired (also called **off-patent** or multi-source pharmaceutical). By law, a generic product must contain an identical amount of the same active ingredient(s) as the branded product. There are **branded generics** and **unbranded generics** on the market. Branded generics also have a specific trade name, whereas unbranded generics use the **international non-proprietary name** and the manufacturer's name.
	Generic Substitution	**Original Substitution**	Practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s). Generic substitution may be performed by prescribers (doctors) and in some countries also by dispensers (pharmacists).
GDP	**Gross Domestic Product**		GDP is the value of goods and services provided in a country by residents and non-residents without regard to their allocation among domestic and foreign claims. This corresponds to the total sum of expenditure (consumption and investment) of the private and government agents of the economy during the reference year.

ABBRE	Preferred term	Synonym term	Definition/Description
HTA	**Health Technology Assessment**		HTA is a multidisciplinary process of systematically reviewing existing evidence and providing an evaluation of the effectiveness, cost-effectiveness and impact, on both patient health and on the health care system, of medical technology and its use.
	Hospital Price		The price of a **pharmaceutical** in hospital use.
HOM	**Hospital-Only Medicines**		Type of classification; **pharmaceuticals** that may be only administered in hospitals (**inpatient care** and **outpatient care**).
	Human Pharmaceutical		1. Any **active ingredient** or combination of active ingredients presented as having properties for treating or preventing
	Inpatient care		Medical procedures that require a stationary hospital stay (perhaps of only one day).
	Internal Price Referencing	**Therapeutic Referencing**	A method to compare prices of **pharmaceuticals** in a country with the price of identical **pharmaceuticals** (**ATC 5 level)** or similar products (**ATC 4 level**) or even with therapeutical equivalent treatment (not necessarily a pharmaceutical) in a country. Often performed in the course of a **reference price system**.
INN	**International Non-proprietary Name**	**Generic Name**	A **pharmaceutical** is normally identified by either its chemical or "generic" name, which often is referred to as INN or its **brand** name, which is the trade or marketing name.
	Magistral Formula		Magistral Formula is any **pharmaceutical** prepared in a pharmacy in accordance with a prescription for an individual patient.
	Manufacturer		Pharmaceutical companies who produce pharmaceuticals and very often also search for and develop new chemical entities, i.e. **active ingredients.**
	Market Authorisation	**Licensing**	A licence issued by a medicines agency approving a **pharmaceutical** for market use based on a determination by authorities that the **pharmaceutical** meets the requirements of quality, safety and efficacy for human use in therapeutic treatment. There are four application procedures possible in the EU: "**centralised procedure**" or "**mutual recognition procedure**" (MRP), "**decentralised procedure**" and "**national procedure**". For homeopathic pharmaceuticals and **medical devices** no authorisation but a registration procedure is necessary.
	Maximum Price		This term is used in a different way in different countries: e.g. in some countries it is the maximum amount which is reimbursed (cf. **reference price system**), in others it is the maximum share that is refunded by **social health insurance / national health services** expressed as percentage of the reimbursment basis.
	Medical Device		Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - investigation, replacement or modification of the anatomy or of a physiological process, - control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. This term defines a wide spectrum of products, ranging from spectacles and clutches to highly sophisticated implantable devices.
	Me-too Pharmaceutical		A me-too **pharmaceutical** is one that is approved after a pioneering drug and which is defined as comparable or similar and is not clinically superior.

ABBRE	Preferred term	Synonym term	Definition/Description
MRP	**Mutual Recognition Procedure**		The MRP is the most common market authorisation procedure in the EU. It states that the marketing authorisation granted in one EU Member State (the so-called "Reference Member State") being "mutually recognised" as valid in other Member State (the "Concerned Member State") upon request. The legal basis is Directive 2001/83/EC, as amended by Directive 2004/27/EC, and further guidance is given in the Notice to Applicants, which forms Chapter 2 of the Rules Governing Medicinal Products in the EU.
NHS	**National Health Service**	**Beveridge System, Semashko System**	The system of social security and health services arising out of the Beveridge report in England and Wales, first published in 1943. A NHS System is financed through **central taxation** or **regional taxation**, usually covering all inhabitants/residents. The scope of services rendered is identical for every person covered and most services are offered by public institutions. In some countries people may opt for a complementary VHI (see **voluntary health insurance)** for services, which are not covered through the NHS.
	National Procedure		Independent national **market authorisation** procedures are still applicable during the initial stage of the **mutual recognition procedure** in the country that is to act as reference Member State (RMS). They are also applicable in situations in which the mutual recognition procedure is not compulsory, namely: - Bibliographical applications for **pharmaceuticals** with a well-established medicinal use for which no reference product is available in the EU. - Line extensions of nationally registered pharmaceuticals for which no harmonised product information is available within the EU. Although some changes to dossiers for nationally registered pharmaceuticals (such as a change in the strength, pharmaceutical form or route of administration) require the submission of a new **market authorisation** application, these changes are considered as variations to a nationally issued market authorisation.
	Negative List		List of **pharmaceuticals** which cannot be prescribed at the expense of the **social health insurance/ national health service**.
	Officinal Formula		Officinal Formula is any **pharmaceutical** which is prepared in a pharmacy in accordance with the prescriptions of a **pharmacopoeia** and is intended to be supplied directly to the patients served by the pharmacy in question (To distinguish from **Magistral Formula**).
	Off-patent Pharmaceutical	**Off-patent Product, Multi-source Pharmaceutical**	(Branded) **original product**, whose patent has expired as opposed to **on-patent** pharmaceuticals. Multisource products may be marketed either under the approved **international non-proprietary name** or under a brand (proprietary) name.
	On-patent pharmaceutical	**On-patent Product**	A pharmaceutical that is protected by a patent or a **supplementary product certificate** (SPC); i.e. a branded **original product**.
	Original Product	**Originator, Original Preparation**	The first version of a **pharmaceutical**, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 15 years. A original product has a unique trade name for marketing purposes, its so-called **brand** name.
	Orphan Drug		A **pharmaceutica**l which only has a limited target population or which treats a rare disease thus limiting its commercial and financial potential.
	Out-of Pocket Maximum		The maximum amount (e.g. a certain percentage of income) that an insured person has to pay for all covered healthcare services for a defined period (often a year), cf. **Out-of pocket payments**.
OPP	**Out-of Pocket Payments**		The amount a person has to pay for all covered healthcare services for a defined period (often a year). It includes: *** fixed co-payments,**
	Outpatient care	**Out-Of-Hospital Care**	Medical procedures that do not require a hospital stay. They typically occur in the ambulatory of a hospital (~ outpatient clinic) or a doctor's practice. Cf. also **primary care** and **secondary care.**

ABBRE	Preferred term	Synonym term	Definition/Description
	Over prescribing		If a doctor prescribes more **pharmaceuticals** than comparable doctors (e.g. with similar patient groups or in the same region). The measure of over prescribing is of particular importance if the doctor has been approved a **pharmaceutical budget.**
OTC	**Over-The-Counter Pharmaceutical**	**Non-prescription medicine, Over-The-Counter medicine**	**Pharmaceuticals** which may be dispensed without a doctor's prescription being submitted and which are in some countries available via self-service in pharmacies a/o other retail outlets (e.g. drug stores). Selected OTC may be reimbursed for certain indications in some countries.
	Parallel Trade	**Parallel Distribution**	Parallel trades are products imported into one Member State from another (the "export" country) and placed on the market in the destination Member State, outside the manufacturer's or its licensed **distributor**'s formal channels.
	Parapharmaceuticals		Parapharmaceuticals are substances or compounds which do not correspond to the legal definition of a **pharmaceutical**. They are in any event products which, by virtue of their composition, utilisation or presentation, are compatible with the dignity of the profession of pharmacist.
	Percentage Co-payment	**Co-insurance**	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.
	Pharmaceutical	**Medicine, Drug, Medicinal Product**	Any **active ingredient** or **combination product** presented for treating or preventing disease in human beings or animals. Any **active ingredient** or **combination product** which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a pharmaceutical.
	Pharmaceutical Budget		Pharmaceutical budgets are a cost-containment measure of **third party payers**. The maximum amount of money to be spent on **pharmaceuticals** in a specific region or period of time is fixed ex-ante.
	Pharmaceutical Equivalence		**Pharmaceuticals** are pharmaceutical equivalents if they contain the same amount of the same **active ingredient**(s) in the same dosage form; if they meet the same comparable standards; and if they are intended to be administered by the same route. However, pharmaceutical equivalence does not necessarily imply therapeutic equivalence as differences in the excipients and/or the manufacturing process can lead to differences in product performance.
	Pharmaceutical Form		The pharmaceutical- technological form in which an **active ingredient** is made available. **Pharmaceuticals** may be administered in sold form (e.g. tablets, powders), in semi-liquid form (e.g. ointments, pastes), in liquid form (e.g. drops, infusions) or in gaseous form (inhalation).
	Pharmaceutical Retailer	**Dispensary**	Umbrella term for facilities that dispense/sell pharmaceuticals (POM and OTC) to out-patients, e.g. pharmacies, **self-dispensing doctors**, hospital pharmacies, pharmacy outlets, medicine chests, drugstores, supermarkets etc. In most countries the dispensation of pharmaceuticals is regulated by law, e.g. stating that supermarkets or pharmacy outlets may only sell a limited range of **OTC**.
	Pharmacoecomic Evaluation	**Pharmacoeconomics, Pharmacoeconomic Guidelines**	The comparative analysis of alternative courses of action in terms of both their costs and consequences.
	Pharmacological Class		**Pharmaceuticals** that have similar therapeutic effects and similar safety and tolerability, both in nature and extent; cf. **therapeutic group**
	Pharmacopoeia		Pharmacopoeia (literally, the art of the drug compounder), in its modern technical sense, is a book containing directions for the identification of samples and the preparation of **combination products,** and published by the authority of a government or a medical or pharmaceutical society.

ABBRE	Preferred term	Synonym term	Definition/Description
	Pharmacovigilance		Pharmacovigilance is the ongoing surveillance of product safety occurring throughout the product life cycle. The EU legislation definition is "The collection and scientific evaluation of adverse drug reactions (ADR), under normal conditions of use, for regulatory purposes. It includes collection of data on drug consumption as well as misuse and abuse".
	Pharmacy Margin		The gross profit of pharmacies expressed as a percentage of the **pharmacy retail price**.
	Pharmacy Mark Up		The gross profit of pharmacies expressed as a percentage of the **pharmacy purchasing price**.
PPP	**Pharmacy Purchasing Price**	**Wholesale Price, Pharmacy Purchase Price**	The price charged by wholesalers to the retailers (usually pharmacies). It includes any **wholesale mark-up**.
PRP (gross)	**Pharmacy Retail Price (gross)**	**Gross Pharmacy Selling Price**	The price charged by retail pharmacists to the general public. It includes any **pharmacy mark-ups** or **dispensing fees** and **VAT**.
PRP (net)	**Pharmacy Retail Price (net)**	**Net Pharmacy Selling Price**	The price charged by retail pharmacists to the general public. It includes any **pharmacy mark-ups** or **dispensing fees** and does not include **VAT** (see also **pharmacy retail price (gross**).
	Positive List	**Formulary**	List of **pharmaceuticals** that may be prescribed more or less without further conditions at the expense of a **social health insurance / national health service**. Cf. **negative list**.
	Prescription Fee	**Prescription Charge**	The patient has to pay a fixed fee for each prescription item dispensed on the expense of a **third party payer**, i.e. a form of **fixed co-payment.**
POM	**Prescription-Only-Medicines**		**Pharmaceuticals** that may be dispensed only on a doctor's prescription.
	Price Cap	**Price Ceiling**	A **cost-containment** measure which fixes ex-ante the maximum price of **pharmaceutical**, e.g. taking into consideration inflation rates and production cost. Companies are allowed to choose any price below this threshold and in exchange authorities refrain from further control of company data (profit margins, sales etc.).
	Price Freeze		A popular **cost-containment** method. The price of a **pharmaceutical** is fixed at a given level, mostly for a predetermined period of time. Price freezes are sometimes based on agreements between pharmaceutical industry and authorities but in most cases it is done by law.
	Price negotiations		A form of **pricing procedure**, where **pharmaceutical** prices are negotiated.
	Price-Volume Agreement		Like a **framework agreement**, a volume control tool. The price of a pharmaceutical is agreed between public authorities and a manufacturer on the basis of a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the **pharmaceutical** is usually reviewed downwards.
	Pricing	**Price Setting**	The act of setting a price for a **pharmaceutical**.
	Pricing Policies		Regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers (e.g. **free pricing**, **statutory pricing, price negotiation**).
	Pricing Procedure		There are several methods of determining the price of a **pharmaceutical**: **internal price referencing**, **external price referencing**, **cost-plus pricing** and profit control.
	Primary Care		Primary care is provided by health care persons (mainly **general practitioners**, but also family nurses, gynaecologist or paediatrics) trained for and skilled in comprehensive first contact and continuing care for persons with any undiagnosed sign, symptom, or health concern not limited by problem origin (biological, behavioural, or social), organ system, or diagnosis. Primary care includes health promotion, disease prevention, health maintenance, counselling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings. Specialist care and hospital care are also referred to as **secondary care** and **tertiary care**.

ABBRE	Preferred term	Synonym term	Definition/Description
	Private Pharmaceutical Expenses	**Household Expenses**	This term includes all forms of - **out-of pocket payments (OPP):** *** percentage co-payment,** *** fixed co-payment,** *** deductibles** as well as - **direct payments**.
	Public Procurement		General term for buying goods, e.g. **pharmaceuticals** via a public tendering procedure.
QALY	**Quality-adjusted-life year**		A QALY is a measure of the value of health outcomes. Since health is a function of length of life and quality of life, the QALY was developed as an attempt to combine the value of these attributes into a single index number. The change in utility value induced by the treatment is multiplied by the duration of the treatment effect to provide the number of QALYs gained.
	Reference Price		cf. **reference price system.**
RPS	**Reference Price System**		The **social health insurance / national health service** determines a maximum price (= Reference Price) to be reimbursed for certain **pharmaceuticals**. On buying a pharmaceutical for which a fixed price (~ the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price and the actual **pharmacy retail price** of the pharmaceutical in question, in addition to any **fixed co-payment** or **percentage co-payment** rates. Usually the reference price is the same for all pharmaceuticals in a given **ATC 4 level** and/or **ATC 5 level** group.
	Regional Taxation		Taxes collected/generated through single municipalities/communities or provinces/regions.
	Registration		Simplified licensing procedure (instead of **market authorisation**) that is foreseen for herbal **pharmaceuticals**.
	Reimbursement		Reimbursement is the percentage of costs (for a service or a **pharmaceutical**) which the **social health insurance / national health service** pays. So 100% reimbursement means that the social health insurance/national health service accept 100% of the costs for a **pharmaceutical** or service.
	Reimbursement Category	**Reimbursement Group**	**Pharmaceuticals** eligible for **reimbursement** are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different **reimbursement rates** are determined for different reimbursement categories.
	Reimbursement Price	**Public Price**	This price is the basis for **reimbursement** of **pharmaceuticals** in a health care system, i.e. the maximum amount paid for by a **third party payer.** The reimbursed amount can either be the full reimbursement price (like e.g. Austria) or a percentage share of the reimbursement price (e.g. in Denmark). In a **reference price system** the reimbursement price is lower than the full price of the **pharmaceutical**, leaving the patient to pay the difference privately (or through complementary **voluntary health insurance**).
	Reimbursement Rate		The percentage share of the price of a **pharmaceutical** or medicinal service, which is reimbursed/subsidised by **social health insurance / national health service**. The difference to the full price of the pharmaceutical or medicinal service is paid by the patients **(out-of-pocket payment)**.
	Reimbursement Scheme	**Key Reimbursement Scheme, General Reimbursement**	The reimbursement system which covers the majority of residents in a country, in some countries also referred to as "general" reimbursment.
	Risk-sharing Agreement		An agreement between public authorities and one **manufacturer** which links the price of a **pharmaceutical** to a defined risk. The risk can be a risk of inappropriate use (over-prescription compared to targeted population or prescription of inappropriate dosages) or can be related to the cost-effectiveness claimed by the **manufacturer**.

ABBRE	Preferred term	Synonym term	Definition/Description
	Sales/Pharmacy Tax		A tax - other than **VAT** - levied by a state or city on the **pharmacy retail price** of an item, collected by the retailer.
	Secondary Care	**Specialist Care, Ambulant Care**	Summarizes all types of specialised medical treatment. In many countries specialist treatment is offered not only in ambulatory care but also in **out-patient** departments of hospitals (sometimes called 'Policlinics'). Free access for patients is often only possible with referral from **primary care** services, otherwise patients are charged with **out-of-pocket payments.**
SD-doctors	**Self-Dispensing Doctor**	**Dispensing Doctor**	Physicians who have been granted the right to dispense **pharmaceuticals** to their patients.
	Self-Medication		Self-Medication refers to **pharmaceuticals** purchased without prescription.
	Sickness Fund	**Social Insurance Institution**	A single **social health insurance** institution. In some countries there are several sickness funds operating (Austria) or even competing each other (Germany). Some sickness funds are operating on a regional basis whereas others are limited to specific professional groups like farmers or self-employed persons.
SHI	**Social Health Insurance**	**Health Insurance, Bismarck System**	Social health insurance is a type of health care provision, often funded through insurance **contributions** by employers and employees as well as state subsidies. In many countries there are obligatory schemes for *(employed)* persons whose income does not exceed a certain amount/limit (= insurance obligation) in place. Social health insurance is often organised in different **sickness funds** - in some countries allowing the patient to select a sickness fund (Germany) whereas in others the membership is determined mandatory, e.g. depending on the type of occupation (e.g. Poland, Austria). In some Social Health Insurance countries persons with higher income as well as self-employed persons may opt for **substitutive private health insurance**. In addition to social health insurance in some countries **voluntary health insurance**, covering e.g. co-payments or allowing for free choice of doctors, is very popular.
	Statutory Pricing		**Pricing** system, where **pharmaceutical** prices are set on a regulatory basis (e.g. law, enactment, decree).
	Substitutive Private		Cf. **voluntary health insurance**.
SPC	**Supplementary Protection Certificate**		SPC gives **original products** a complementary period of market exclusivity beyond patent expiry to compensate for delays of marketing in the **pharmaceutical** sector. SPC are available in EU countries but such complementary protection exists in other countries.
	Switch		Reclassification of **prescription-only-medicines** to **over-the-counter pharmaceuticals** .
	Tertiary Care		Tertiary care services are provided by specialised hospitals or departments that are often linked to medical schools or teaching hospitals. They treat patients with complex conditions who have usually been referred by other hospitals or specialist doctors.
	Therapeutic Benefit		The effect conveyed on a patient following administration of a **pharmaceutical** which either restores, corrects or modifies a physiological function(s) for that patient.
	Therapeutic Group		**Pharmaceuticals** from the same **pharmacological class**, such as statins. See also **ATC 4 level**.
	Therapeutically Interchangeable		An interchangeable pharmaceutical is one which is therapeutically equivalent to a **original product**, i.e. meaning that the two molecules both deliver a similar **therapeutic benefit** to patients.
	Third Party Payer		Any organisation, public or private, that pays or insures health care expenses for beneficiaries at the time at which they are patients, e.g. **social health insurance** or **national health service** or Communities.
TD	**Transparency Directive**		Directive 89/105/EEC (of 21 December 1988) relates to the transparency of measures regulating the pricing of **pharmaceuticals** for human use and their inclusion in the scope of National **social health insurance** systems / **national health service**.

Annex VIII

Template of the PPRI Pharma Profile

ÖBIG

Pharmaceutical Pricing and Reimbursement Information project

Pharma Profile Template

For comments and suggestions please email

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I.I Foreword

The Pharmaceutical Pricing and Reimbursement Information project (PPRI) Pharma Profiles Template is developed to assist National stakeholders in writing up profiles on pricing and reimbursement policies of their country i. e. Pharma Profiles. The Pharma Profiles will be written by National stakeholders in collaboration with the Austrian Health Institute (ÖBIG) and WHO Regional Office for Europe (WHO) as project leaders.

The PPRI Pharma Profile Template has been developed by WHO and ÖBIG in collaboration with the PPRI partners (EU Member States, Bulgaria and Norway), but is available for other countries to be used as well. The template provides detailed guidelines and specific questions, definitions and examples needed to compile the Pharma Profiles. A standardised profile may not be able to capture all details, because the pharmaceutical pricing and reimbursement policy differ across countries. However, a standardised profile offers advantages, because it raises similar issues and questions. If the template is used in a flexible way, it is likely that differences will still be seen across the Pharma Profiles in content and comprehensiveness, but the country situations they will still be comparable.

Compiling the Pharma Profiles poses a number of methodological problems: It will not be possible to collect data from uniform sources on pricing and reimbursement in all EU Member States and because there are also great differences in the way the health care systems and the pharmaceutical systems are structured. We acknowledge that data collection methods and definitions may vary, and we encourage the National Stakeholders to provide feedback on those.

We have not been able to accommodate all needs of National and International Stakeholders as expressed in the Needs Assessment, that was performed between September 2005 and January 2006 and we understand that this type of exercise in which we try to address several aspects of the pharmaceutical pricing and reimbursement system has limitations. Some of the issues that have not been included are issues regarding medical devices, borderline pharmaceuticals, elicited drugs, orphan drugs, pharmaceutical price comparisons and biocide products.

Following the 2nd Coordination Meeting held in Copenhagen on the 27-28th of April, several partners mentioned a need to include more indicators on the use of pharmaceuticals in the hospital sector and evaluation of the prevailing methods used in pricing and reimbursement. These two areas have been included in every chapter, as sub-sections, and in the end of every chapter, respectively.

Comments and suggestions for the further development and improvement of the template are most welcome, please send them to: ppri@oebig.at. Please also keep up-dated on any news regarding the project on http://ppri.oebig.at

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- Cyprus: Athos Tsinontides (Health Insurance Organisation), Xenia Ashikales (Ministry of Health of Cyprus)
- Czech Republic: Pynelopi Valsamisová (Ministry of Health of Czech Republic), Lenka Prazno-cova (Charles University)
- Denmark: Elisabeth Thomsen (Danish Medicines Agency)
- Estonia: Katrin Pudersell (Ministry of Social Affairs of Estonia)
- Finland: Sirpa Peura (Association of Finnish Pharmacies)
- France: Eric van Ganse (University Claude Bernard Lyon), Christian Marty (French National Sickness Fund for Employees - CNAM-TS)
- Germany: Hans-Peter Dauben (German Institute for Medical Documentation and Information - DIMDI)
- Greece: Vardica Areti (Institute of Pharmaceutical Research and Technology)
- Hungary: Gábor Lengyel, Szabolcs Szigeti (National Health Insurance Fund Administration),
- Ireland: Deidre Elliott, Gerald Byrne (HSE-Shared Services-Primary Care Reimbursement Service), Lesley Tilson (National Centre for Pharmacoeconomics St Jame's Hospital)
- Italy: Pietro Folino-Gallo (Italian Medicines Agency - AIFA and EURO-MED-STAT)
- Latvia: Daiga Behmane, Tomas Alonderis (Medicine's Pricing and Reimbursement Agency)
- Lithuania: Gita Krukiene (Department of Pharmacy, Ministry of Health)
- Netherlands: Petra Jansen (Ministry of Health, Welfare and Sport)
- Norway: Audun Håga (Ministry of Health and Care Services of Norway), Tor Frostelid (Medi-cines Agency)
- Poland: Piotr Blaszczyk (Ministry of Health of Poland)
- Slovak Republic: Jan Mazag (State Institute for Drug Control)
- Slovenia: Stanislav Primozic (Agency for Medical Products of the Republic of Slovenia
- Sweden: Thord Redman (Swedish Pharmaceutical Benefits Board)
- United Kingdom: Danny Palnoch (Department of Health, Medicines Pharmacy and Industry)
- European Commission: Daniel Mann, Zinta Podniece, Marianne Takki (DG SANCO), Stefaan van der Spiegel (DG Enterprise)

- European Stakeholders: Göran Isaksson (European Medicines Agency - EMEA), Elias Mossialos (London School of Economics - LSE), Susanne Grosse-Tebbe, Suzsy Lessof (European Observatory for Health Systems - WHO), Sophie Lopes (SOGETI)
- OECD: Elizabeth Docteur, Valerie Paris (Health Division - OECD)

Further thanks is dedicated to:

- European Commission: Christian Siebert, Nils Behrndt (DG Enterprise), Nicola Schelling (DG Competition), Irene Norstedt (DG Research)
- European Stakeholders: Heinz Kobelt (European Association of Euro-Pharmaceutical Companies - EAEPC), Greg Perry, Ana Wisse Teixeira (European Generic Medicines Association - EGA), Monika Derecque-Pois (European Association of Pharmaceutical Wholesalers - GIRP), Monica Alfaro (Pharmaceutical Group to the European Union - PGEU), Christoph Thalheim (European Patient's Forum), Michele Lipucci de Paola (Eurordis - European Organization for Rare Diseases), Elisabethann Wright (EFTA)

Table of content

I.III Introduction

The Pharmaceutical Pricing and Reimbursement Information project (PPRI-project) is a 2-year project commissioned by the European Commission's Health and Consumer Protection Directorate General (DG SANCO) and the Austrian Ministry of Health and Women's Issues (BMGF). The project is executed by the main partner Austrian Health Institute (ÖBIG), the associate partner WHO Regional Office for Europe, the EU Member States, Bulgaria and Norway. The objectives of the PPRI-project are to improve information and knowledge on the pharmaceutical pricing and reimbursement systems in the European Union countries, contributing to increased transparency, providing information and advice for policy-makers on national and European levels. The product of the PPRI-project will be on one hand a report for every country that contains a description of the pricing and reimbursement policies i. e. "Pharma Profiles" a benchmarking study of the pricing and reimbursement policies of all EU Member States, Norway and Bulgaria and other interested countries. The project builds on ÖBIG's and WHO's knowledge in the field of pricing and reimbursement at the European level, and on the knowledge of policy makers in the field of pharmaceutical policy in the EU Member States, Bulgaria and Norway.

The template is part of the work package 4 (WP 4: Survey) of the PPRI-project. The purpose of the survey is for the EU Member States, Norway and Bulgaria to collect information regarding pricing and reimbursement systems of pharmaceuticals and transform this information into a Pharma Profile.

I.IV Notes for National Stakeholders

The template consists of seven chapters including an appendix: the first chapter gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system. This is followed by a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system. The following two chapters cover the price setting system and reimbursement system. The chapter on pricing (Chapter 3) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures. The chapter on reimbursement (Chapter 4) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures. Chapter 5 is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption. Chapter 6 is a concluding chapter on the current challenges and future plans for developments in the pharmaceutical sector and Chapter 7 are a list of the appendixes.

In using this template for the Pharma Profile please consider the following points:

- All National Stakeholders will be appointed two country specific contact persons from the editorial team to assist with country-specific questions (cf. http://ppri.oebig.at).
- Please use the standard word format (.dot), that we have uploaded on the share point of the PPRI-website (http://ppri.oebig.at) as basis for writing your country profile.
- Please include all the abbreviations used in the country profile in the list of abbreviations.
- Check the glossary for definitions of terms and concepts used in this template. The glossary is available on the PPRI-website (http://ppri.oebig.at → glossary).
  Note: Some definitions provided in the glossary of this template may be different than those used in your country. If possible, we ask you to use the preferred terms from the glossary.
- If you are unclear about any of the questions raised or definitions used in the template, please consult the glossary and if further discussion or clarification is needed, please contact your country specific contact person from the editorial team (http://ppri.oebig.at → Pharma Profiles→ Template).
- Please make cross reference to chapters and sections when appropriate.
- Please provide data using national / local sources (e. g. local health statistical yearbook) if available. If not, please seek advice from your country specific contact persons from the editorial team.
- Please use in the tables, where you provide data in NCU and in EURO €, the exchange rates that we have provided for you on the PPRI-website (http://ppri.oebig.at).
- Please use the Harvard Referencing System whereby citations are made within the text in parentheses e. g. (Taylor 1996) and the full references listed alphabetically in the References Section 7.1 Reference list (see appendix).
- The final Pharma profile should be between 40-60 pages and the summery should be no longer than 5 pages.
- Each chapter is provided with a percentage rate and an indication of the number of pages that the chapter should have. The percentage indicates the size of the chapter i.e. if a chapter indicates 10%, the chapter should be between 4-6 pages.

The template is built on a list of questions for every section and sub-sections, but it is important to keep in mind that it is not the intention that all countries should answer all questions. Some of the questions may simply not be available or may not be relevant to the individual country. However, even though all questions might not be answered, it is advised that National Stakeholders follow the structure of the template and complete all chapters and sections, even if the answer is as short as “No”, to ensure consistency in the presentation of the profiles. It is likely that National Stakeholders might wish to add points or headings on issues that might not be included in the template, but the National Stakeholders should consult the editor with their proposed changes.

General questions regarding the template should be addressed to:

Contact details for editors:

Ms. Trine Lyager Thomsen

WHO Regional Office for Europe

Health Technologies and Pharmaceuticals

Scherfigsvej 8, 2100 Copenhagen, Denmark

Tel.: + 45 3917 1565

Email: ppri@oebig.at or tlt@euro.who.int

When the Pharma Profile is completed, it should be returned to Ms. Trine Lyager Thomsen, WHO Regional Office for Europe, for review and editing.

I.V Abbreviations

Please add abbreviations used in your country Pharma profile and delete those you didn't use

ATC	Anatomic Therapeutic Chemical classification
BMGF	Austrian Ministry of Health and Women's Issues
DG SANCO	Health and Consumer protection Directorate General
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year

SHI	Social Health Insurance
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organisation
WP	Work Package

I.VI List of tables and figures

Executive summary (5 pages)

This section should provide an outline of the content of the Pharma Profile following the key headings included in the profile; Background, Pharmaceutical system, Pricing, Reimbursement, Rational use of pharmaceuticals and current challenges and future developments.

Following the 2nd coordination meeting in Copenhagen it was decided that OEBIG and WHO would draft a sample version of the summary, based on the Danish or Austrian Pharma profile. The result of this work will be presented at the 3rd coordination meeting in Warsaw, Poland in October, 2006.

1 Background (10% / 4-6 pages)

This chapter provides an overview of the country and its health care system.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions, please consult the glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.
- Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.

Sources:

For the statistical data please use standardised sources, preferable Eurostat data or OECD data to allow for easier comparison. Alternatively we would like you to use national sources, like the Statistic Yearbook of your country.

Please state for each table / figure which source, including year, you have used.

For the descriptive data, please use national sources, but alternatively use the HiT profiles from the Observatory (www.observatory.dk).

1.1 Demography

Please write a section on the demographic situation in the country, including:

- The total population.
- The population density, i. e. inhabitants per km2. Also, please explain if population is evenly distributed throughout the country or if there are specific rural or sparsely populated areas.
- The distribution of age according to the three age-groups (cf. Table 1.1), indicating if the population is ageing and also if there is a national strategy tackling the problems related to an ageing population.
- The average life expectancy at birth for total population, and also for men and women, respectively. In case of a noticeable development please expand a little on it.
- The main causes of mortality and morbidity. Please indicate the three leading causes for your country.
- Relevant population trends. In case life expectancy is decreasing, please explain why.

Please provide an overview by completing Table 1.1.

Table 1.1: Country - Demographic indicators 1995, 2000, 2003 and 2005

Variable	1995	2000	2003	2005 or latest available year
Total population				
Population density per km^2				
Population aged 0-14 (in % of total)				
Population aged 15-64 (in % of total)				
Population aged > 64 (in % of total)				
Life expectancy at birth, total				
Life expectancy at birth, females				
Life expectancy at birth, males				

Please indicate sources: _____

1.2 Economic background

- Gross Domestic Product (GDP) in total and also per capita in National Currency Units (NCU) and preferably also in Purchasing Power Parities (PPPa).
- Economy growth rates in your country.
- Government spending (i. e. General Government Expenditure (GGE)) in NCU and as ratio (i. e. GGE in % of GDP). The text could be as follows "In terms of total government spending as a percentage of GDP, Sweden stands with 65.1% alone at the top, followed by fellow Nordic countries Denmark (58.2%) and Finland (56.8%)".
- A short assessment of the economic development and the future outlook in your country (e. g. are there major privatisation trends in general and / or in the health care sector).

Please complete the Table 1.2.

Table 1.2: Country - Macroeconomic indicators 1995, 2000 - 2005

Variable (in NCU or percentage)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU							
GDP / capita[1] in NCU							
GDP / capita[1] in PPPa							
Growth rate from 1995-2000							
Growth rate from 1995-2005[2]							
General government expenditure (GGE)							
GGE in % of GDP							
Exchange rate (NCU per €), annual rate							

GDP = Gross Domestic Product, GGE = General government expenditure, NCU = National Currency Unit, PPPa = Purchasing Power Parity

[1] please use population data from Table 1.1 as basis for calculation

[2] or latest available year

Please indicate sources: _____

1.3 Political context

Please write a section on the political system, covering the following questions

- Is the political system federal or does it contain significant mesolevel governments (regional or local) and what are the competencies of the different levels of government?
- In federal systems or where mesolevel governments operate, do states or regional / local governments have legislative or tax-raising powers or do they have to operate within a national framework?
- What is the ruling party configuration of the present government?
- Are there any major contextual factors contributing to the current political structure (e. g., wars, independence, joining of a regional grouping)?

1.4 Health care system

This section should provide an overview of the organisation of your country's health care system and also outline the main actors, their roles and their decision-making powers within the health care system.

1.4.1 Organisation

This section describes the scope of the system, the regulatory framework and the main authorities. Please write a section covering:

- The type of health care system i. e. National Health Service (NHS) or Social Health Insurance (SHI) or other. i. e.
- For SHI:
  - Is there free choice of sickness fund for all patients or for a selected group of patients (e. g. all above a defined income threshold)?
  - Is membership mandatory according to e. g. income, location and / or other?
- The level of coverage (depending on income level, social factors, age) and exceptions to the insurance schemes, e. g. due to income, age, type of employment etc.
- The laws / acts leading to the implementation of the current health care system and the year in which the current health care system was implemented?
- The organisation of the system i. e. if the sickness funds are self-governing bodies and if they have the power to determine the amount of social insurance contributions by themselves.
- The main authorities and relevant bodies in the health care system at central level and at decentralised level.
- Describe if the governance mechanisms are decentralised in your country. If yes, to what extent?
- Which powers and financial responsibilities are transferred to decentralised governance actors? (For example, transfer of full or partial responsibility for regulation, provision and financing).
- Have there been major changes in the system in the last decade (i. e. introduction of co-payments or gate keeping)? If yes, please state the main reason for changing the system.

1.4.2 Funding

This section gives an overview of the health care expenditure and the sources of funding health care. More detailed information on the funding of pharmaceuticals should be provided in section 2.2 Funding.

Please write a section describing:

- The main sources of funding, i. e. social health insurance contributions or national / regional taxes;
  Please explain all current health care funding schemes shortly and show their relevance (i. e. predominant sickness fund(s) in case there are several like in Germany or Austria).
  - SHI: State the percentage of contributions by employers, employees, government or other in terms of salary / income.
  - NHS: If tax is earmarked, please indicate the share in percentage of GDP.

- The relevant legal framework (laws, enactments).
- Secondary sources of funding, e. g. Voluntary Health Insurance (VHI) or Out-of Pocket Payments (OPP) of patients.
- Total Health Expenditure (THE) in National Currency Units and in % of GDP.
- The level of Public Health Expenditure (Public HE) in percentage of Total Health Expenditure.
- The level of Private Health Expenditure (Private HE) and the source for Private Health Expenditure i. e. Out-of Pocket Payments, VHI etc.

Please provide an overview of the health expenditure by completing Table 1.3:

Table 1.3: Country- Health expenditure, 1995, 2000 - 2005

Health expenditure	1995	2000	2001	2002	2003	2004	2005
THE in NCU							
THE in % of GDP							
THE per capita[1] in NCU							
Public HE in % of THE							
Private HE in % of THE							

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure, NCU = National Currency Unit

[1] Please use population data from Table 1.1 as basis for calculation

Please indicate source: _____

1.4.3 Access to health care

This section describes the level of access to health care that the statutory health care system provides. For definitions please consult the glossary.

1.4.3.1 Outpatient care

Please write a section describing the following issues:

- How is outpatient care practised? In outpatient clinics ("ambulatories"), by independent General Practitioners (GP's), by specialists or other?
- Are some types of patients (e. g. children, oncology patients) traditionally treated in outpatient clinics ("ambulatories") rather than by GP's or specialists?
- Is there free choice of outpatient doctor (i. e. GP or specialist)? How often may an outpatient doctor be changed?
- Does the outpatient doctor practise privately or publicly?
- Does the outpatient doctor act as a gate-keeper for access to specialists and inpatient care?

- How are outpatient doctors paid? Capitation fees, fee-for Service, flat rate per service or other?
- Are there any Out-of Pocket Payments applicable to outpatient care? If yes, are these charges fully / partly reimbursed or e. g. covered by Voluntary Health Insurance?
- Please complete Table 1.4 to indicate the evolution of the number of outpatient doctors and outpatient clinics ("ambulatories").

Table 1.4: Country - Outpatient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Total number of doctors[1]					
Number of doctors[1] per 1,000 inhabitants[2]					
Total number of outpatient doctors					
thereof General Practitioners[3]					
thereof dentists					
Number of out patient doctors per 1,000 inhabitants[2]					
Number of out-patient clinics departments ("ambulatories")					

[1] please exclude retired and non-practising doctors or indicate the exact composition of the number

[2] please use population data from Table 1.1 as basis for calculation

[3] if exact number is not available please give a percentage estimation

Please indicate source: _____

1.4.3.2 Inpatient care

Please write a section describing the following issues:

- How is inpatient care organised? Are private (profit or non-profit) or public hospitals dominating the system?
- Is there a sort of specialisation of hospitals or is there a sort of hierarchy (e. g. only university hospitals taking care of severe diseases) and are hospitals evenly spread throughout the country?
- Are Out-of Pocket Payments applied for inpatient care? If yes, are these charges fully / partly reimbursed?
- Are doctors employees of the hospitals or are they paid e. g. on a Fee-for Service basis or do they act as fund holder?
- How are hospitals – generally speaking – remunerated: through annual fixed budgets (ex-ante or ex-post?), DRG, fee-for-service, direct cost compensation?
- By whom are hospitals funded: Central or regional governments, NHS, SHI, patients?

Please complete Table 1.5 showing the evolution of the number of doctors, hospitals, acute care beds etc.

Table 1.5: Country - Inpatient care 1995, 200, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Number of inpatient doctors[1]					
Number of inpatient doctors per 1,000 inhabitants[2]					
Number of hospitals					
Number of acute care beds					
thereof in private sector					
Acute care beds per 1,000 inhabitants[1]					
Average length of stay in hospital					

[1] please exclude retired and non-practising doctors or indicate the exact composition of the number

[2] please use population data from Table 1.1 as basis for calculation

Please indicate source: _____

2 Pharmaceutical system (25% / 10-15 pages)

This chapter provides an overview of the pharmaceutical system.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions, please consult the glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.
- Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.

Sources:

For the statistical data please use national sources, like the Statistical Yearbook of your country. Alternatively we would like you to use standardised sources, preferable Eurostat or OECD data.

Please state for each table / figure which source, including the year, you have used.

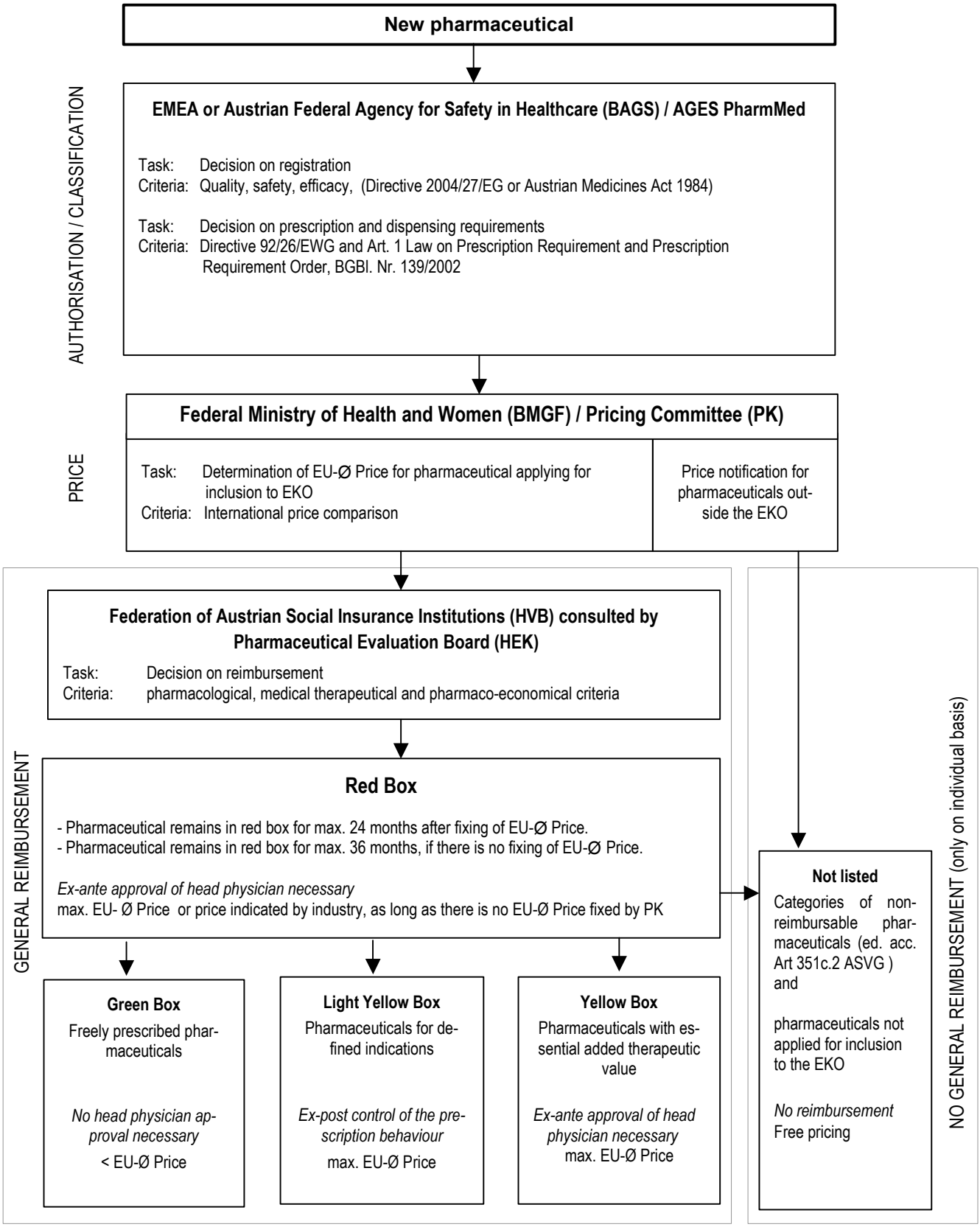
For the descriptive data, please use national sources, but alternatively use the HiT profiles from the Observatory (www.observatory.dk).

2.1 Organisation

This section describes, on one hand, the regulatory framework (legal basis, main authorities and their tasks), and, on the other hand, the pharmaceutical market (data, key players). For definitions please consult the glossary.

Please provide a flowchart of the pharmaceutical system, following this model:

Figure 2.1: Country - Flowchart of the pharmaceutical system (sample for Austria)



Source:

2.1.1 Regulatory framework

This section includes a description of the legal framework for the pharmaceutical policy, the principal authorities and important players in this framework and their roles.

2.1.1.1 Policy and legislation

Please indicate the major laws, enactments and ministerial decrees that are relevant for the pharmaceutical sector, e. g. Medicines Law. Preferable please include relevant Internet links and refer to these laws in the respective chapters / sections.

Please indicate if the country has adopted and implemented a comprehensive policy in the medicines area, or is there a set of policies and legislation that govern together the pharmaceutical sector. Please refer to policy document and / or legislation. Does this policy refer to the Essential Medicines or does it specifically indicate mechanisms to select medicines for reimbursement?

2.1.1.2 Authorities

Please draw up a table, based on the example given in Table 2.1 that contains the relevant authorities and key regulatory actors (including Committees, Boards, etc. if relevant) as well as Third Party Payers. For definitions please consult the glossary.

Other market players in the field of pharmaceuticals will be described in section 2.1.3 Market players.

The table should include the relevant players in the fields of:

1. Overall pharmaceutical policy
2. Market authorisation / licensing
3. Possible classifications (e. g. concerning prescription status, hospital-only or not)
4. Public procurement / tendering of pharmaceuticals
5. Pricing procedures
6. Reimbursement decisions
7. Assessment and evaluation of pharmaceuticals
8. Vigilance and security concerns
9. Monitoring (e. g. of consumption)
10. Distribution

How to complete the table:

- Description: please state if the actor is subordinate to another authority, the composition of a Committee and if it is an inter-ministerial Board, etc.

- Responsibility: please explain, for every authority (see example table from Germany):
  - What is the main role of the authority?
  - Which other roles does the authority have related to medicines?

Please characterise the type of relationships between the authorities (e. g. hierarchical, contractual).

Table 2.1: Germany - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Bundesministerium für Gesundheit (BMG)	Ministry of Health	Regulatory body	Overall planning and legislative authority In charge of the reimbursement legislation/decision
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	Federal Institute for Drugs and Medical Devices	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation, classification, vigilance
Gemeinsamer Bundesausschuss (G-BA)	Joint Federal Committee	Association of doctors, sickness funds, and patients	Reference price system (e. g. grouping of pharmaceuticals in reference groups)
Spitzenverbände der Krankenkassen	Head Association of Sickness Funds	Third Party Payers	In charge of setting the reference prices and of the reimbursement of pharmaceuticals

Please include legends

Please indicate source: _____

- Please describe the policy and decision-making processes and the interaction of the various entities therein.
- Describe the process of market authorisation and average time it takes.
- Have measures been implemented (or are planned to be undertaken) to shorten this time period?
- In case that there is a public discussion on this topic (e. g. by the pharmaceutical industry), inform us about this discussion.

Note: There is no need to write about the European procedure (centralised and decentralised authorisation) and the EMEA. For definitions please consult the glossary.

In case there have been major structural and / or organisational changes in the last 5 years (e. g. establishment of a new authority, change in the competence of an authority, merger of institutions, change in the composition of a Committee which gives certain actor more / less power), please note these.

2.1.2 Pharmaceutical market

This section gives an overview on the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

Please complete Table 2.2 indicating the number of pharmaceuticals available in your country. In case that there are no exact data available for certain sub-groups, please give an estimate. If necessary, please include further rows to the table.

- Please specify method of counting:
  - incl. / excl. different pharmaceutical form
  - incl. / excl. different pack sizes
  - incl. / excl. different dosages
- Be aware that the data is asked for as 1 of January. Indicate the method of counting e.g. active ingredient or active ingredient in a specific dosage form. Please also indicate what you count as a "generic"

Table 2.2: Country - Number of pharmaceuticals 1995, 2000 - 2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised								
On the market								
POM								
Reimbursable								
Generics								
Parallel traded								
Hospital-only								
Others *(please include further lines if necessary)*								

POM = Prescription-Only Medicines

[1] as of 1 January

Please indicate source: _____

Please write a section that explains / describes:

- Any particularities concerning a problematic situation with regard to availability, interesting developments, particular importance of a special group of pharmaceuticals.
- Differences between the number of pharmaceuticals registered and the number of pharmaceuticals on the market, and comment on possible reasons.
- The different classifications of pharmaceuticals, e. g.
  - Prescription-Only-Medicines (and possible sub-groups: prescriptions bound to certain specialities) and Over-The-Counter pharmaceuticals

- Pharmaceuticals in the outpatient sector and Hospital-Only Medicines
- Country-specific classifications (e. g. Ethicas and Especialidadas Farmaceuticas Publicitarias in Spain)
- Reimbursable and non-reimbursable pharmaceuticals (make a reference to the Reimbursement Chapter)
- On-patent / off-patent pharmaceuticals and generics as well as parallel traded pharmaceuticals

- If there are special names / abbreviations in your language for these classifications, please indicate them.
- The actors deciding on these classifications and the criteria for decision
- Please write a few lines on switches (change from POM to OTC). Is there an overall policy on switches?

2.1.2.2 Market data

Please complete Table 2.3 and comment on it:

Table 2.3: Country - Market data 1995, 2000 - 2005

Pharmaceutical industry in million NCU / €	1995	2000	2001	2002	2003	2004	2005
Pharmaceutical sales							
Sales at ex-factory price level							
Sales at wholesale price level							
Sales at pharmacy retail price level							
Sales at hospitals							
Sales of generics							
Sales of parallel traded pharmaceuticals							
Exports and imports							
Total pharmaceutical exports *							
Total pharmaceutical imports*							

* Please indicate if this is finished products and / or raw material

Please indicate source: _____

On the basis of the data in the table please write a section that discusses:

- The development of the pharmaceutical market / sale
- The share of the generics and parallel trade market of the pharmaceutical market / sale
- The development of pharmaceutical export and import

Note: For definitions please consult the glossary.

In addition, comment on pharmaceutical consumption (give the number of packages sold per year or DDD consumption for the latest available year, see also Section 5.6 Consumption.

For Table 2.4, please list the top 10 best selling pharmaceuticals for 2005 or latest available year.

Table 2.4: Top 10 best selling pharmaceuticals, by active ingredient, 2005 or latest available year.

Position	Pharmaceutical, by active ingredient
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

Please indicate source: _____

2.1.2.3 Patents and data protection

This section briefly describes the patent and data protection issues. Please write maximum 1 page on the issue of data protection in your country covering the major institutions involved and the below mentioned areas.

Patent protection is harmonized under the European Patent convention and ensures original pharmaceuticals market protection for 20 years. Under EU legislation there is a possible extension for 5 more years under a Supplementary protection certificate.

Under the recently adopted EU legislation authorities are also obliged to provide for data protection for an 8 + 2 + 1 year period. This provides for an additional protection period for patented drugs. Only after 8 years the medicines agency can process application for generic medicines under the EU Bolar amendment, which can then the marketed when the 10 year data protection

period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and therewith delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

- With regard to access and public health issues, please comment if there is an explicit provision for compulsory licensing, parallel import and “government use” on patented products within the national legislation?
- Please also give some recent examples on court cases / lawsuits in relation to medicines patent protection? Describe any recent “ever greening” of patents (cases where companies seek extensions of market exclusivity by filing new patents on old drugs) or any other recent controversies around patent protection and / or data protection.

2.1.3 Market players

This section describes the key players in the pharmaceutical system except from the authorities which have been introduced in section 2.1.1.2 Authorities. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy making.

2.1.3.1 Industry

Please write a section on the pharmaceutical industry and give information on:

- The different “branches” of pharmaceutical industry (research-oriented industry, generic manufacturers, biotechnology, raw materials). Please also name their interest associations.
- The usual distribution channel (e. g. via wholesale, direct distribution).
- The importance of industry to the economy of your country (with reference to data in the Table 2.4)
- The role of industry in research and development, production, and as an employer.
- The relevance of local manufacturers versus international pharmaceutical companies
- The involvement of industry in pricing and reimbursement (e. g. framework agreements between industry and government, representation in Pricing Committees) and in particular in cost-containment (e. g. cap /”tax” on promotional expenditure, lower prices in return for reimbursement). Please cross-reference to section 5.3 Information to patients / doctors.
- The role of industry in policy making, e.g. industry initiatives on policy making?

In the description, please also comment on major developments (such as emergence of research-based industry, involvement of industry in pricing and reimbursement through influence or representation in Pricing Committee or negotiations of framework agreement, new distribution forms like direct distribution to patients, etc.).

Table 2.5: Country - Key data on the pharmaceutical industry 1995 - 2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies							
- research-oriented							
- generic producers							
- biotech							
Number of persons employed[2]							

[1] as of 1 January

[2] counted per head

Please indicate source: _____

2.1.3.2 Wholesalers

Please write a section on pharmaceutical wholesalers, including:

- The number of wholesalers (companies and average number of outlets); if possible, number of staff employed; comment on size of wholesale companies and ownership.
- The role of wholesale in distribution to pharmacies, hospitals, etc. (multi-channel or single channel).
- Information on logistics: full wholesaler, average numbers of item on stock; number of deliveries per day.
- Comment on the presence and importance of parallel trade wholesalers.
- Wholesale associations and their role / importance (if given) in the pharmaceutical system.
- Comment on wholesalers role and influence on policy making through their trade organisation.
- Comments on important developments (e. g. merging of wholesalers, bankruptcy of wholesale companies, debts to / of wholesale companies).

Please complete the table below:

Table 2.6: Country - Key data on pharmaceutical wholesale 1995 - 2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies							
Total number of outlets							

[1] as of 1 January

Please indicate source: _____

2.1.3.3 Pharmaceutical outlets / retailers

Please write a section describing:

- Who is allowed to dispense pharmaceuticals? E. g. community pharmacies, dispensing doctors, mail-order / internet pharmacies, other dispensaries (e.g. drug stores, supermarkets)
- Legal prerequisites for the functioning of other dispensaries than community pharmacies, if allowed (e. g. if there are no community pharmacies in the area).
- What are the various dispensaries allowed to dispense? Full assortment of pharmaceuticals? Other products (under what regulations)? Only selected range of OTC?

2.1.3.3.1 Pharmacies

Please describe the role of pharmacies in dispensing pharmaceuticals, commenting on:

- What regulations govern the pharmacies' activities, establishment and ownership? E. g., state if community pharmacies are privately or public owned and if ownership restrictions (e. g. only one pharmacy per owner) are applied?
- Are pharmacy chains allowed? Who are, generally speaking, the owners of the pharmacies? Give figures on number of pharmacies and type of ownership.
- What is the total share of pharmaceuticals dispensed in pharmacies in % of the total of consumed pharmaceuticals, indicated in both value and volume?
- What are the any important association of pharmacies / pharmacists? What is their role?
- Comment on the influence of the pharmacy association on policy making? If yes, at what level are the pharmacies involved in policy making?
- Comment on the remuneration of the pharmacies. Please indicate how pharmacists are paid: by profit margin per pharmaceutical dispensed capitation fee, a flat fee per prescription or a combination of these). Please cross-reference to section 3.5.2 Pharmacy remuneration.
- Are there any incentives for pharmacies to establish in rural areas? Is yes, please explain which. What regulations –if any - are there to guarantee a geographical spread of pharmacies across the country and therewith enhance the access to medicines?
- Please comment on the presence of POM dispensaries including branch pharmacies, dispensing doctors, and others such as university pharmacies (like in Finland), policlinic pharmacies (like in the Netherlands) and hospital pharmacies acting as community pharmacies.
- For community pharmacies and other POM-dispensaries, please indicate the total number and the number per 1,000 inhabitants. These numbers should be presented like in Figure 2.2.
- Please provide information on any potential vertical integration of wholesalers and pharmacies.
- Is distance selling, e.g. purchasing of pharmaceuticals via mail orders or internet allowed?
- Please comment on discounts / rebates given by industry and / or wholesalers to the pharmacies. Please cross-reference with section 3.6.1 Discounts / Rebates.

Please complete the table below:

Table 2.7: Country - Retailers of pharmaceuticals 1995, 2000 - 2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies[2]								
No. of private pharmacies								
No. of public pharmacies								
Number of hospital pharmacies for outpatients								
Number of other POM dispensaries: _____								
Total number of POM-dispensaries[1]								
No. of internet pharmacies								
No. of OTC dispensaries, like drugstores: _____								

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number

POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

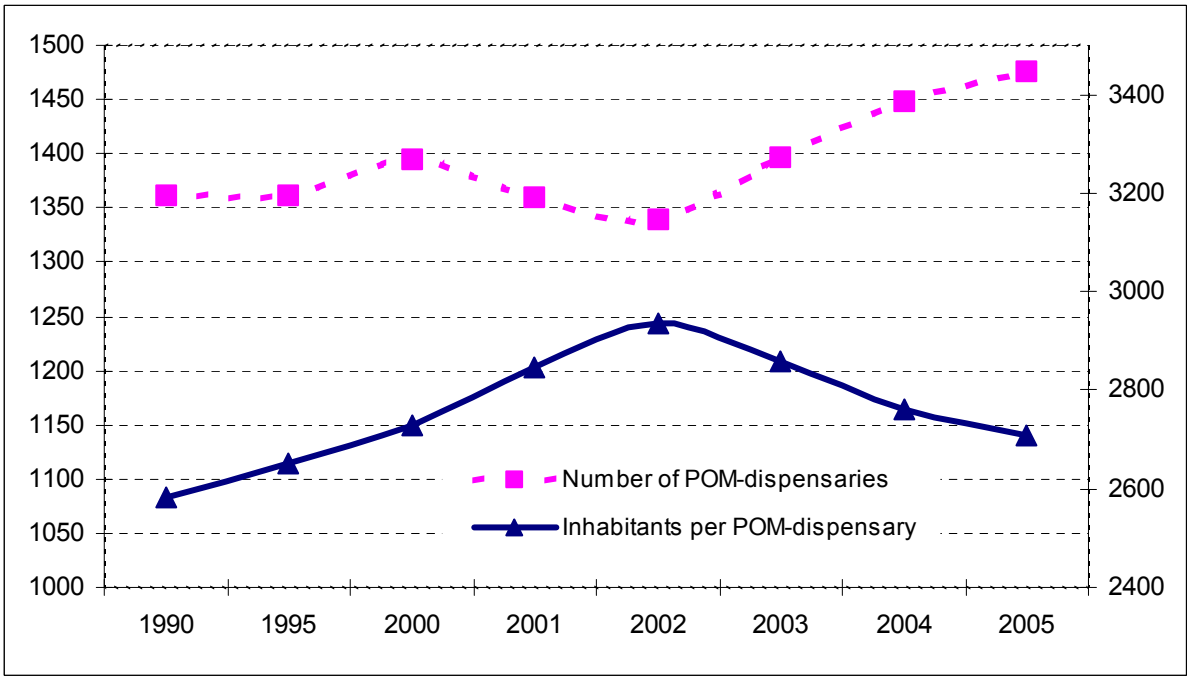
[1] as of 1 January

[2] incl. branch pharmacies

Please indicate source: _____

Please create a figure like the one shown below. Please use the number of inhabitants from Table 1.1.

Figure 2.2: Country - Number of retail pharmacies, POM-dispensaries and number of inhabitants per POM-dispensary 1990, 1995 and 2000 - 2006



POM = prescription-only medicines; All POM-dispensaries = including branch pharmacies, SD-doctors, and other university pharmacies, policlinic pharmacies and hospital pharmacies acting as community pharmacies

Note for Figure 2.2: An additional line only for pharmacies is welcome.

2.1.3.3.2 Other pharmacy outlets

Please briefly describe other pharmacy outlets:

- Is it allowed for others to dispense medicines? If yes, which medicines are they allowed dispensing? POM? OTC?
- Are these other pharmacy outlets regulated? If yes, how?
- Is the licensing, requirement for professional staff etc the same for these other pharmacy outlets as for normal pharmacies?

2.1.3.3.3 Internet pharmacies

Please write maximum 1 page on the existence and use of internet pharmacies operating in your country.

- Do you have any nationally based internet pharmacies? If yes, please state their approximate number.
- Are these regulated? If yes, how?
- Is the licensing, requirement for professional staff etc the same for internet pharmacies as for normal pharmacies?

2.1.3.3.4 Dispensing doctors

This section refers only to dispensing doctors (GP's, specialists etc.) in outpatient care!

- Which doctors are allowed to dispense pharmaceuticals? All doctors or only out-patient doctors or e. g. only contracting doctors of SHI / NHS? How many doctors are licensed to dispense medicines?
- Does the dispensing-doctor profit from dispensing pharmaceuticals?
- Please also state here if other persons besides doctor like family nurses are allowed to dispense (selected) pharmaceuticals, e. g. contraceptives.

Note: Information on e. g. dispensing-doctors' specific reimbursement lists should be given in section 4.2.3 Reimbursement lists and specific mark-up / margin schemes shall be added in section Margins and taxes.

2.1.3.4 Hospitals

Please explain in this section the role of hospitals distribution / dispensing of pharmaceuticals,

- Comment on the number and type of hospital pharmacies? Do they only serve for internal use, or are they allowed to dispense pharmaceuticals to outpatients?
- Do the hospitals work with a limited list of medicines pharmaceuticals? Are these drugs part of the national reimbursement list or is every hospital autonomous to purchase drugs that may not be on the national list? How is this list generated and used? Describe the composition and functioning of the hospitals committees (cross-reference with section 4.5 Reimbursement in the hospital sector).
- How do the purchasing and procurement mechanisms work? Normally hospitals are budgeted and within that budget they purchase medicines according to public procurement regulations, please comment (cross reference with section 3.2.4 Public procurement / tendering and 3.4.1 Hospitals-only). Please comment on the influence of pharmaceutical companies to include new drugs onto the hospital list, as a way of enhancing primary care prescribing of that drug.
- Does the funding of hospital pharmacies (internal use / external use) differ from that of community pharmacies? (e. g. funding out of the hospital budget, different mark-ups → please cross-reference to section 3.5.3 Remuneration of other dispensaries)

Note: Information on e. g. hospital specific reimbursement lists should be given in section 4.5 Reimbursement in the hospital sector. The number of hospital-only pharmaceuticals shall be added in Table 2.2.

2.1.3.5 Doctors

Please write a section that:

- Comments on the role and importance of the doctors associations and their impact on pharmaceutical policy making.

- Are they in any way officially involved in policy-making (e.g. government-doctors association's contracts on % of generic prescribing)?
- Are there any special arrangements around the doctor's role in prescribing?

Please cross-reference with section 5.2 Prescription guidelines if appropriate.

2.1.3.6 Patients

Please write a section describing:

- Any special features around the patient's role in deciding which medicines will be prescribed / dispensed (e.g. co-payment mechanisms, professional programmes on patient involvement).
- Are medicines prices the same in every pharmacy or are patients encouraged to "shop around" for pharmaceuticals?
- How do patients receive information on pharmaceuticals and their prices?
- The patients' role in pharmaceutical policy-making (please comment on patients' groups and their lobby; please comment on industry funding for patient groups; name the most important consumers / patients organisations with regard to pharmaceuticals)

Please cross-reference to section 5.3 Information to patients / doctors if appropriate.

2.2 Funding

This section provides an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

In this section on pharmaceutical expenditure, please complete the Table 2.8 and comment in particular on:

- Total Pharmaceutical Expenditure (TPE)
- Trends in Total Pharmaceutical Expenditure
- The public and the private share of Total Pharmaceutical Expenditure (Public PE / Private PE)
- Please discuss the total expenditure of pharmaceuticals as a share of GDP and Total Health Expenditure (THE) and compare this share to that in other EU Member States.

Table 2.8: Country - Total pharmaceutical expenditure 1995, 2000 - 2005

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in NCU							
TPE in % of Total Health Expenditure							
TPE per capita[1] in NCU							
Public PE in % of THE							
Private PE in % of THE							

NCU = National Currency Unit, GDP = Gross Domestic Product, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

[1] please use population data from Table 1.1 as basis for calculation

Please indicate source: _____

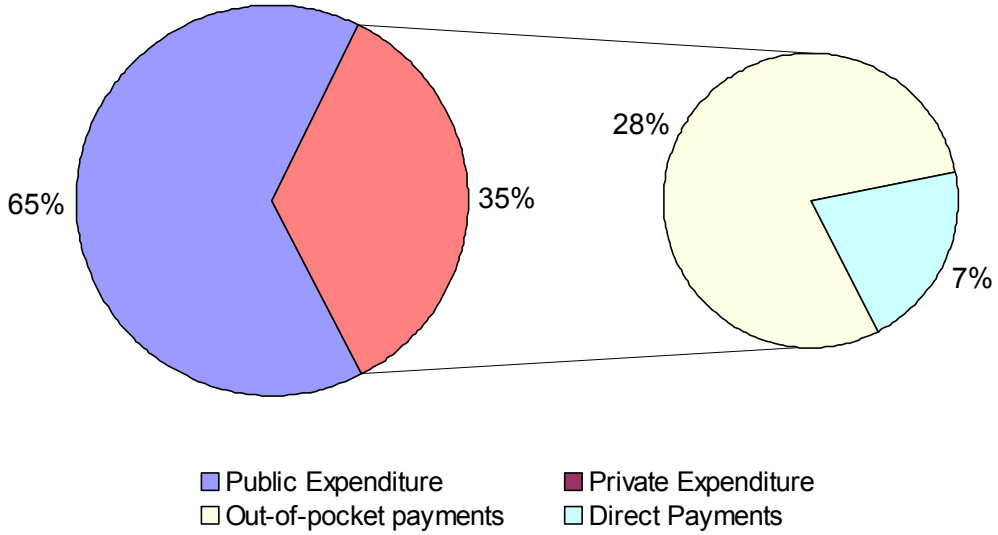
Note: If you prefer to display the development of pharmaceutical expenditure in a graph or figure (e. g. TPE / Total Health Expenditure in %) please do so.

2.2.2 Sources of funds

This section gives an overview of the funding of pharmaceuticals, in addition to the figures presented in Table 2.8. Please give information on:

- The main funding source(s) of public pharmaceutical expenditure (i.e. social health insurance contributions or national / regional taxes). Make a reference to health care funding in section 2.2 Funding. Please indicate the percentage of public pharmaceutical expenditure and comment on its development.
- Explain how private pharmaceutical expenses are made up:
  - Expenses for self-medication.
  - Expenses for private health insurance funds (incl. voluntary supplementary insurances like Mutuelles).
  - Out-of-Pocket Payments (percentage co-payment, fixed co-payment, deductibles, etc.)
  - Expenses on non-reimbursed prescription medicines
  - Informal payments
- If appropriate and possible draw a pie-chart showing the current relation of private to public pharmaceutical expenditure like shown in Figure 2.3.

Figure 2.3: Country - Share of private and public pharmaceutical expenditure 2005



Please indicate source: _____

2.3 Evaluation

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policy and the system, and its impact on health, access to medicines, and cost-containment. Please write a section that describes these programmes, and the institutions responsible for evaluating / monitoring the impact of the pharmaceutical policy. Please refer here to:

- What has been the main aim of implementing the above mentioned programmes?
- Which areas of the pharmaceutical policy are monitored? (e.g. medicines consumption, broken down in groups of drugs and by groups of patients; price trends of prescription medicines; development of co-payment levels per patient category; studies on outcomes of therapeutic interventions in defined clinical areas, regulatory action taken on quality of medicines, or on medicines safety concerns, timing of reimbursement decisions and possible delays on market entry etc.)
- Is this routine monitoring or is this done through specifically commissioned studies?
- Which institution revises them? Government, universities, SHI research institutions, private industry / professional association research institutions? Many of these often produce annual reports, please provide the corresponding websites.
- Are there any specific indicators used? please comment and provide examples
- Have there been any written evaluations of the policies? If yes, are the reports publicly available? If so, please add a link to the publication and the institution behind the publication.

With regard to EU legislation, please describe any recent problems or developments around the transposition of EU legislation or adherence to the EU Directives (especially the Transparency directive).

- Which authority normally would deal with these issues?
- Please indicate if there have been recent official cases / legal action with regard to possible non-compliance of EU legislation. Are data on this easily accessible? Please provide web-sites

Please cross-reference with section 3.6.4 Pricing reviews and section 4.6.5 Reimbursement reviews if appropriate.

3 Pricing (20% / 8-12 pages)

This chapter gives an overview of the pricing system by describing the process and the regulation of the pricing of pharmaceuticals.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions, please consult the glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.

Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.

Sources:

For the statistical data please use national sources, like the Statistical Yearbook of your country. Alternatively we would like you to use standardised sources, preferable Eurostat or OECD data.

Please state for each table / figure which source, including the year, you have used.

For the descriptive data, please use national sources, but alternatively use the HiT profiles from the Observatory (www.observatory.dk).

3.1 Organisation

This introductory section informs on the regulatory framework and organisational structure i.e. the main authorities and the legal background. Please cover the following:

- Please describe the legal framework in your country with regard to pricing of pharmaceuticals.
- Who determines the pricing criteria for pharmaceuticals?
- Which authorities are in charge of pricing decisions for single pharmaceuticals?
  - Is there a "price committee"? If yes, describe its role in the pricing decision with regard to the authorities, its composition, and its way of working e. g. number of meetings.
- How are pricing and reimbursement decisions interlinked?
  - Is it the same institution responsible for pricing and reimbursement?
  - Are decision on pricing and reimbursement one procedure?
  - In case one institution / agency (e.g. Pricing Board) approves or determines a price, does the Third party payer (SHI or NHS) accept this price for reimbursement or is there another pricing round?

- How long is the process of pricing on average?
- At what stage in the process does pricing take place (before, after and together with the reimbursement decision)? Please refer to Flowchart (Figure 2.1 in Chapter 2).
- Have there been major changes / development in the legal framework and organisation of pricing (e. g. strengthening the role of the Pricing Committee, shortening the time period for pricing)?

3.2 Pricing policies

There are, basically, four ways of pricing (for definitions please consult the glossary):

- Statutory Pricing.
- Price negotiations
- Free Pricing.
- Public procurement.

In many countries, these ways of pricing co-exist, for different kinds of pharmaceuticals.

- Please fill out a table, explaining the pricing policies for different types of pharmaceuticals (on-patent and off-patent (i.e. generic), POM, HOM and OTC, reimbursed vs. non-reimbursable pharmaceuticals, etc.) like the example for Denmark shows
- Feel free to insert more rows, e.g. on "Price-Volume Agreements" (as relevant in France) or "Price Notification" (as relevant for manufacturer level in Austria)
- In case there are further / different groups of pharmaceuticals (which then should also be added in section 2.1.2.1 Availability of pharmaceuticals) with particular pricing policies, please adjust the table accordingly, e. g. differentiation between oral and non-oral pharmaceuticals like in Ireland.

Table 3.1: Denmark - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all products set by the manufacturer/ importer, cf. below. Public procurement for all pharmaceuticals *used* in hospitals (not only HOM but also for others)		Free pricing for OTC sold outside pharmacies[1]

[1] The pricing of OTC pharmaceuticals which are not limited to distribution from pharmacies is free and subject to local competition.

Statutory Pricing	Not applied, but price of reimbursable pharmaceuticals (POM and OTC) may be indirectly influenced via the reimbursement system (reimbursement price)		Reimbursable pharmaceuticals (POM and OTC) via a regressive mark-up[2] scheme, that is negotiated every 2 years between IM and the Pharmacists Association
Price Negotiations	Manufacturers and wholesalers negotiate their share of the wholesale price (which is set by the manufacturer/importer, cf. above).		Not applied
Discounts / rebates	Yes, cost related discounts	Yes, cost related discounts	Yes, 1,72% in 2005 to the National Health Service
Public Procurement	➢ Mainly relevant for products used in hospitals (performed by AMGROS) ➢ Not relevant in out-patient sector, except for vaccinations and certain blood products		
Institution in charge of pricing	➢ Hospital Purchasing Agency AMGROS ➢ IM for pharmacy mark-up scheme ➢ (DMA on behalf of IM for reimbursement price)		
Legal Basis	➢ Lov om offentlig sygesikring (National Health Security Act) No. 311 of 9 June 1971, latest amended by LF No. 1431 of 22 December 2004 ➢ BEK om ændring af bekendtgørelse om beregning af forbrugerpriser på apoteksforbeholdte lægemidler samt ikke apoteksforbeholdte håndkøbslægemidler m.v. (Executive Order BEK No. 237) of 24 March 2006, Art. 1		

DMA = Lægemiddelstyrelsen, HOM = Hospital-only Medicines, IM = Indenrigs- og Sundhedsministeriet, POM =Prescription-Only Medicines, OTC = Over-The-Counter pharmaceutical

Please indicate source: _____

Please explain in the text accompanying Table 3.1 the scope of the pricing system and the methods of monitoring and evaluation, covering the following questions:

- When was the current pricing system implemented?
- Do the price setting procedures differ depending on the type of pharmaceutical e. g. prescription-only pharmaceuticals, me-too products, generics, parallel traded pharmaceuticals?
- At what level are pricing decisions made? E. g. at manufacturer level, wholesale level, pharmacy level or other?
- Are price changes possible or is there a sort of price freeze / stop (please cross reference to section 3.6.3 Price freezes / Price cuts) in place?
- Explain if there are price ceilings / maximum prices and explain terms used in your country (e.g. "agreed prices" like in Bulgaria)
- Who may in which way and how often apply for price changes?
- Who decides on price changes?

[2] The mark-up is negotiated with the IM every 2 years and is calculated from the wholesale price.

Hospital: Please comment explicitly on the pricing of Hospital-only Medicines and the pricing of pharmaceuticals used in in-patient treatment in section 3.4.1 Hospitals-only.

3.2.1 Statutory pricing

Please sum up the main information (even if already mentioned) on statutory pricing of pharmaceuticals, giving answers to:

- For which pharmaceuticals?
- At which price levels?
- Which authorities (incl. boards / committees) are involved?
- Which pricing procedure / method (cf. section 3.3 Pricing procedures) is used? Which criteria are applied?
- When was the current system implemented?
- What is the legal framework?
- Are there mechanisms for enforcement?
- Is statutory pricing written in law, and replaced by other ways of pricing in reality?
- Please provide procedural information (e. g. timeframe for applications and decisions, which information has to be provided in which way by applicants, etc.).

3.2.2 Negotiations

Please sum up the main information (even if already mentioned) on price negotiations for pharmaceuticals, giving answers to:

- For which pharmaceuticals?
- At which price levels?
- Which authorities (incl. boards / committees) are involved?
- Who are the negotiating parties, that are representing government / Third Party Payers on the one hand and manufacturers on the other hand (e. g. individual manufacturers or Industry Associations, local or central bodies)?
- Which pricing procedure / method (cf. section 3.3 Pricing procedures) is used? Which criteria are applied?
- When was the current system implemented?
- What is the legal framework (e. g. framework agreement as basis)? If appropriate, please add subheadings.
- What is the usual procedure?
- What happens if negotiations fail?
- Are there compromises?

3.2.3 Free pricing

Please sum up the main information (even if already mentioned) on free pricing for pharmaceuticals, giving answers to:

- For which pharmaceuticals?
- At which price levels?
- When (which year) was this current way of pricing introduced?

3.2.4 Public procurement / tendering

- Is there tendering in your country? If yes, is there only tendering for a specific segment like hospitals? Please cross reference to section 3.4.1 Hospitals-only.
- What is the relevance of tendering procedures?
- For which type of pharmaceuticals is it performed?
- Share your experiences with the results of tendering procedures - did they lead to the prices that were expected?

3.3 Pricing procedures

There are, basically, four pricing procedures / methods (for definitions, see glossary under http://ppri.oebig.at):

- Internal price referencing.
- External price referencing.
- Cost-plus pricing.
- (Indirect) Profit control.

Please complete Table 3.2 and comment on it:

- Which pricing procedures are currently used?
- Are these enforced by law?
- Have there been major changes in the ways of pricing in the past few years?

Table 3.2: Country - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing			
External price referencing			

Cost-plus pricing			
Other, e. g. indirect profit control			

[1] Level of pricing = at what stage of the pricing process does the pricing take places (e. g. at the retail price level)

[2] Scope = A pricing procedure does not always refer to all pharmaceuticals: e. g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for Over-The-Counter pharmaceuticals there is free pricing.

Please indicate source: _____

3.3.1 External price referencing

Please write a section that covers the following questions:

- For which pharmaceuticals (e. g. POM, OTC, and generics) is external price referencing applied?
- At which price level(s) (e. g. pharmacy retail price level) is external price referencing applied?

Explain if external price referencing is the only procedure or just one criterion. Describe the procedure of external price referencing, and give, in particular, an answer to the following questions:

- Are there laws / decrees or other forms of formal rules for external price referencing (e. g. on the selection of countries for the country baskets)? If yes, please explain. If not, is this done as additional (informal) information?
- Which countries are included in the basket for external price referencing? Why were these countries chosen? Are there alternative countries in case there are no data from the selected countries? What happens if there are no data from the selected countries?
- Does the result of the price comparison directly influence pharmaceutical prices?
- How are the comparisons made? Please explain the methodological background answering questions like if the prices are adjusted according to purchasing power parity and what exchange rates that are used?
- Who provides the country price information? How is the data provided and in what way? In case a manufacturer provides the information, how does the authority check the information?
- What happens if the price in one of the reference countries changes (give details on price reviews in Section Price reviews and insert a cross reference)?

3.3.2 Internal price referencing

State for which pharmaceuticals and at what price level internal price referencing is applied. Explain if internal price referencing is the only procedure or just one criterion. Describe the procedure of internal price referencing, and give, in particular, an answer to the following questions:

- Are there formal rules (e. g. on methodology) or laws / decrees on internal price referencing? If yes, please explain. If not, is this done as additional information?

- How are the reference pharmaceuticals that are to be compared defined (ATC level, formulation, pack size, availability etc.)?
- What type of information do companies have to deliver?
- Who undertakes the internal price referencing?

3.3.3 Cost-plus pricing

Please state for which pharmaceuticals and at which price levels cost-plus criteria are applied and if it is the only relevant criterion. Please expand especially on the following points:

- What evidence is needed from the industry in the pricing procedure?
  - Information on production cost?
  - Expected sales?
  - Price of the pharmaceutical in other countries?
  - The therapeutic value?
  - Cost effectiveness?
  - Other?
- How is information from companies validated?
- What happens if a company refuses to accept the price set by the regulator? For example, is the pharmaceutical excluded from the list of pharmaceuticals reimbursed? Is the pharmaceutical reimbursed at the regulated price but the patient must pay the difference if he wants the pharmaceutical?
- What happens if the evidence changes (e. g. if a pharmaceutical is subsequently shown to be more (or less) effective than originally assessed)?

3.3.4 (Indirect) Profit control

Please explain in this section if indirect profit control is applied in your country (which is – as the PPRI team assumes - most likely not the case).

This section is especially applicable to the British PPRS scheme (→ add further subheadings if necessary).

3.4 Exceptions

Please explain in the following subsections any potential exemptions to pricing techniques / procedures for the following groups of pharmaceuticals: hospitals use only (HOM), parallel trade, generics, OTC and orphan drugs.
If necessary please cross-reference to other sections of the country profile.

3.4.1 Hospitals-only

Please describe - in a narrow sense:

- Does the system for determining pharmaceuticals' prices in hospitals differ?
  - Do hospitals carry out their own procurement?
  - Are there (hospital) purchasing / procurement agencies?
  - In practice, do they achieve lower prices than those in the outpatient sector?
- Are the price-changes monitored and evaluated?
- Is information available on prices for pharmaceuticals in hospitals?
- Please name and explain any legal foundation, procedure rules, etc.

3.4.2 Generics

Please describe:

- Does the system for the pricing of generics differ from the other pricing ways and procedures?
- If yes, in general or only in terms of reimbursement?
- Please name and explain any legal bases, procedure rules, etc.

3.4.3 Over-The-Counter pharmaceuticals

- Does the system for the pricing of OTC pharmaceuticals differ from the other pricing ways and procedures?
- If yes, in general or only in terms of reimbursement?
- Please name and explain the legal framework, procedures, if any.

3.4.4 Parallel traded pharmaceuticals

- Does the system for the pricing of parallel traded pharmaceuticals differ from the other pricing ways and procedures?
- If yes, in general or only in terms of reimbursement?
- Are parallel traded pharmaceuticals treated like generics?
- Please name and explain any legal bases, procedure rules, if any.
- Please insert a cross reference to section 3.4.2 Generics if relevant.

3.4.5 Other exceptions

Please state if other exceptions to the reimbursement scheme exist?

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy margin and mark-ups, dispensing fees and sales taxes applied to pharmaceuticals.

In Table 3.3, please list the methods for regulating the wholesale and pharmacy mark-ups.

Table 3.3: Country - Regulation of wholesale and pharmacy mark-ups 2005

	Wholesale mark-up			Pharmacy mark-up		
	Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
Example	Yes	Regressive mark-ups	All pharmaceuticals	Yes	Regressive mark-ups	All pharmaceuticals
Your country						

* Regulations concerning mark-ups do not always apply to all pharmaceuticals, e. g. in the example the pricing procedure does only refer to reimbursable pharmaceuticals. For OTC there is free pricing.

Please indicate source: _____

3.5.1 Wholesale remuneration

This section, concerning wholesale remuneration, should cover the following:

- How are wholesaler remunerated - via mark-ups / margins or are there contractual relations between manufacturers and wholesalers?
- Are wholesale margins regulated by law / decree? If yes, which ones (please quote)? Please also indicate the date of latest update of regulations.
- Scope: which pharmaceuticals (e. g. all, only POM, only reimbursable pharmaceuticals) are covered?
- Is the government regulating the margins strongly as to limit the wholesaler's profit? If yes, is the type of regulation a linear margin or a regressive scheme?
- In case of a regressive scheme, please include a table with the scheme (cf. Table 3.4 with an example of the yellow and the green box of the Austrian Reimbursement Code).
- Please indicate the average wholesale margins for 2005 in terms of Pharmacy Purchasing Price (in total, and if possible for the reimbursable and the non-reimbursable market).
- Inform on planned changes in the margin system or refunding system for wholesalers.

Note: Please be precise in talking about margins (in % of the pharmacy purchase price) or mark-ups (in % of the ex-factory price) (For definitions please consult the glossary).

Please provide a table based on the structure of the Austrian example in the following table, if possible.

Table 3.4: Austria - Wholesale mark-up scheme 2006

Ex-Factory Price in €	Maximum Mark-up in % of Ex-factory price	Wholesale price in €
0.00 - 6.06	15.5%	-
6.07 - 6.22	-	7.00
6.23 - 12.11	12.5%	-
12.12 - 12.32	-	13.62
12.33 - 53.78	10.5%	-
53.79 - 54.77	-	59.43
54.78 - 181.68	8.5%	-
181.69 - 184.22	-	197.12
184.23 - 339.14	7.0%	-
Over 339.15	Fixed amount € 23.74	

Source: Enactment of the BMGF on Maximum Wholesale Mark-ups for Pharmaceuticals 2004

3.5.2 Pharmacy remuneration

Please describe in this section the pharmacy margins and other dispensing related remuneration applied to pharmaceuticals, including any potential differences according to the price of pharmaceutical or the type of pharmaceutical.

Please be precise in talking about margins (in % of the pharmacy retail price) or mark-ups (in % of the pharmacy purchase price). For definitions please consult the glossary.

- How are pharmacists remunerated? Via mark-ups / margins or via fee-for service or are there contractual relations between wholesalers and pharmacies?
- Are pharmacy mark-ups / margins and / or fees regulated by law / decree? If yes, which ones (please quote)? Please also indicate the date of latest update of regulations.
- Scope: which pharmaceuticals (e. g. all, only POM, only reimbursable pharmaceuticals) are covered from
- Please indicate the average pharmacy margin for 2005 in terms of gross pharmacy retail price (in total, and if possible for the reimbursable and the non-reimbursable market).
- Inform on planned changes in the margin system or refunding system for pharmacists
- Show if margins or mark-ups are different e. g. between reimbursable and non-reimbursable pharmaceuticals or between outpatient and inpatient use, please complete a table for both.

Please complete a table, based on the structure of the following Table 3.5, if possible.

Table 3.5: Country - Pharmacy mark-up scheme 2006

Example		Your country	
Pharmacy purchase price (PPP) from … to… in NCU / €	**Pharmacy mark-up coefficient in % of PPP**	**Pharmacy purchase price (PPP) from … to… in NCU/€**	**Pharmacy mark-up coefficient in % of PPP**
Up to NCU / € 2	20%		
From NCU / € 2 - NCU / € 4	15%		
From NCU / € 4 - NCU / € 8	10%		
From NCU / € 8 - NCU / € 12	7%		
From € 12	5%		
Average mark-up	10%		

NCU = National Currency Unit

Please indicate source: _____

- Please modify Table 3.5, e. g. if in your country a "fixed amount" is paid rather than a percentage.
- Table 3.5 can be deleted if not necessary, like for Greece, where a unilateral fixed flat percentage mark-up is applied for all pharmaceuticals.

3.5.3 Remuneration of other dispensaries

Please state here specific margin or fee-for-service agreements, e. g. for

- Self-dispensing doctors
- Hospitals
- Drugstores and other non-pharmacy outlets

Note: Information on claw backs should be included in section 4.6.4 Claw-backs.

3.5.4 Value-added tax

Please indicate the relevant VAT rates:

- Standard VAT
- VAT for pharmaceuticals (please specify if the VAT refers only to a group of pharmaceuticals and/or if there are split rates for different pharmaceuticals e. g. reimbursable / non-reimbursable)
- Please inform on changes in the VAT rates in the last few years (plus the reason for that) and on possible planned changes.

3.5.5 Other taxes

Are there further taxes / fees on pharmaceuticals (e. g. a pharmacy fee per pharmaceutical dispensed or a general pharmacy tax like in Finland)?

3.6 Pricing related cost-containment measures

This section contains a description of the price control mechanisms currently used in your country.

3.6.1 Discounts / Rebates

Please write a section regarding any potential discounts or allowances granted in your country:

- Are all types of discounts allowed (or only cash discounts or also discounts in kind)?
- Is there a legal basis on granting discounts or are there rather “commercial” discounts, e. g. allowances for payments in time?
- Are statutory discounts applied, e. g. in some segments like the hospital sector or in the reference price system? In case of such discounts, please give the average.
- Is there information on the discounts that hospitals receive from wholesalers and manufacturers? If yes, please explain.
- Are there sales based ex-post discounts in place, i. e. a sort of "solidarity contributions"?

Note: there is a specific paragraph on claw back in the section on reimbursement, cf. 4.6.4 Claw-backs).

3.6.2 Margin cuts

- Please write a short paragraph on the changes / cuts of wholesale respectively pharmacy mark-ups or margins in your country.
- In case there are no pharmacy margins but rather fee-for-service refunding applied for pharmacists, please state changes in this system also here.

3.6.3 Price freezes / Price cuts

- In case there is currently a price freeze applied in your country please explain the situation and name the involved stakeholders.
- What has been the main aim of using this mechanism? Has the effect been monitored and / or evaluated? If yes, how? Please cross-reference to section 2.3 Evaluation if appropriate.
- Especially state if it is a statutory freeze or if it is rather based on an agreement with the industry. Which administrative arrangements and sanctions underpin these arrangements?
- Since when is the current price freeze in place?
- Is there a history of price freezes in your country (like e. g. in Denmark?)
- May pharmaceuticals apply for price increases irrespective of the price freeze?
- Have there been price cuts in your country, e. g. in a specific segment like generics?

3.6.4 Price reviews

Please write a section answering the following questions:

- Are the ways of pricing and the pricing procedures reviewed and evaluated on a regular basis in your country?
- If yes, how, by whom and how often?
- According to which criteria are the procedures reviewed?
- What is the basis of these criteria? Is it a legal framework or other?
- Who may ask for a review of the pricing procedures?
- Has the results of the reviews been published yet ?
- If yes, please add a link to the publication and the institution that published the review.

Please cross-reference to section 2.3 Evaluation if appropriate.

4 Reimbursement (20% / 8-12 pages)

This chapter gives an overview of the reimbursement system, the reimbursement procedure and the regulation of reimbursement.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions, please consult the glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.
- Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.

Sources:

For the statistical data please use national sources, like the Statistical Yearbook of your country. Alternatively we would like you to use standardised sources, preferable Eurostat or OECD data.

Please state for each table / figure which source, including the year, you have used.

For the descriptive data, please use national sources, but alternatively use the HiT profiles from the Observatory (www.observatory.dk).

4.1 Organisation

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities. Please write a section that answers the following questions:

- Please describe the legal framework surrounding the reimbursement policy making.
- State the general scope of pharmaceuticals included in the reimbursement scheme, i. e. if some, e. g. OTC, are exempt from reimbursement in general?
- Does the policy cover the whole country and all institutions or does it vary e. g. between county to country or between pharmaceuticals dispensed in pharmacies and hospitals?
- Who has the decision-making power in deciding whether or not a pharmaceutical is reimbursed?
- Which organisations and institutions can potentially influence the reimbursement decision?
- Is the reimbursement process linked to the pricing?
- What is needed from a company to apply for reimbursement status of a pharmaceutical?
- Can the reimbursement status of a pharmaceutical change? If yes, how?

- If the patent runs out
- If a competitor enters the market
- If the price changes in your country
- If the price changes in other countries has changed
- Because of new evidence (EBM, Pharmaco-economics, etc.)?
- Other, like switches

- What procedures precede a change in the reimbursement status

4.2 Reimbursement schemes

Please describe in the following the general reimbursement system and, in case there are some, e.g. individual other ways (e. g. for specific patient groups, or particular illnesses), other schemes (Note: Relevant in e.g. Ireland, Denmark, etc.)

- What is the name of the current scheme and when was it introduced?
- What is the legal framework for this scheme?
- Scope of the scheme: Who is covered by this scheme (e. g. percentage of population or share of prescriptions reimbursed under the scheme)?
- How long does is take for a pharmaceutical to obtain reimbursement (please discuss adherence to Transparency Directive in detail in section 2.3 Evaluation).

4.2.1 Eligibility criteria

Please write a section presenting the factors that determine whether a pharmaceutical qualifies for reimbursement or not.

- Please describe criteria for reimbursement eligibility.
  - Product specific criteria (e. g. essential drug policy, medical & therapeutic value, safety, lack of alternative therapies, prescription status, patent status)
  - Economic criteria (e. g. cost-effectiveness, reference price, budget impact)
  - Patient specific criteria(e. g. age, sex, chronically or terminally ill patient)
  - Disease specific criteria (e. g. severity of illness, special medical needs)
- Which institution or authority decides on the reimbursement category of a single pharmaceutical?
- Show how these criteria have an impact on reimbursement and / or out-of-pocket payments (Note: Please insert cross references to the relevant sections).
  - Please describe the appeal procedure for companies if pharmaceutical is denied reimbursement.

4.2.2 Reimbursement categories and reimbursement rates

Please describe the relevant reimbursement categories (e. g. fully reimbursed, partly reimbursed) and reimbursement rates in your country. Please complete Table 1.4 (add extra rows if necessary) and explain in detail:

- Who has determined these categories?
- What is the basis for the reimbursement categories (e. g. legal basis, tradition, other)?
- Explain how categories and reimbursement rates are interlinked (e. g. based on pharmaceutical, disease, patient status (chronically ill, age, income), profession, region where pharmaceutical is dispensed, etc.); Note: A cross reference to 4.2.1 Eligibility criteria is useful.
- Is a specific / fixed reimbursement price a prerequisite for inclusion of the pharmaceutical in reimbursement system or are the reimbursement categories somehow connected with a reference price system (if one exists)? → Note the possible connection to the reference price system as stated in section 2.3 Evaluation. Please make a cross-reference.
- Is there an appeal procedure for patients / doctors in place for individual pharmaceuticals, e.g. may they apply for reimbursement with an individual procedure?

Note: Table 4.1 might not be possible to complete. Instead of trying to compete the table, make sure that you have explained the reimbursement categories / rates thoroughly above.

Table 4.1: Country - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category

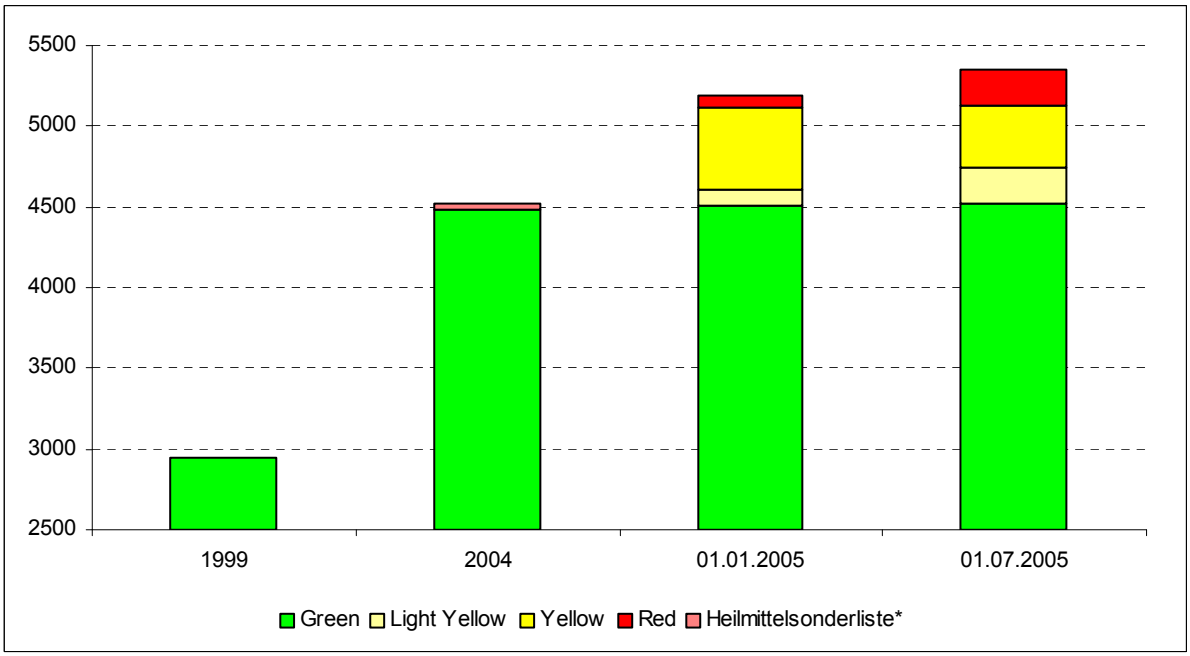
Please indicate source: _____

How to complete Table 4.1:

- Reimbursement category: Please indicate the reimbursement categories / groups applied in your country.
- Reimbursement rate: Please indicate the reimbursement rates equivalent to the reimbursement categories in your country.
- Characteristic of category: Please state which types of pharmaceuticals belong to this group and why, i. e. please explain the inclusion criteria for the various groups. If possible please also give the number of pharmaceuticals / substances in a group. Please be aware that the single reimbursement lists should be explained in detail in 4.2.3 Reimbursement lists.

If possible, please also add a graph like the one in Figure 4.1 (example from Austria).

Figure 4.1: Country - Development of pharmaceuticals in Reimbursement Code[1]



Please note that the number of packs is higher than the number of reimbursable packs as many pharmaceuticals are sold in several pack sizes

[1] Name of the Austrian positive list

* Pharmaceuticals being reimbursed under special conditions

Source: HVB 2005

4.2.3 Reimbursement lists

Please answer the following questions:

- Does your country have a positive and / or a negative list, indicating reimbursable and non-reimbursable pharmaceuticals?
- If yes, how is this administered? Please explain the role and the composition of the responsible body.
- How often is (are) the list(s) updated?
- What are the criteria for inclusion and / or exclusion in the list(s)?
- How often are changes in the list(s) made? How are these changes communicated to doctors, pharmacists and patients?
- What procedures are in place in order to add pharmaceuticals, which do not completely fulfil the inclusion criteria, to the list?
- Are specific reimbursement conditions / systems in place for pharmaceuticals used in hospitals or nursing homes?

Please cross reference to section 5.4 Pharmaco-economics to elaborate further on the use of pharmaco-economics as a criteria for inclusion and / or exclusion of pharmaceuticals on the reimbursement list, if appropriate.

4.3 Reference price system

Please write a section covering the following questions (Note: In case there is no reference price system applied in your country, please state it here (e. g. "*In Austria currently no reference price system is in place*:") Please state if there has been a reference price system in place in the past, like for example in Italy):

- Which authority is in charge of the reference price system?
- What is the basis of this system? Is it a legal framework or other?
- When was the reference price system implemented?
- Which criteria are used to group pharmaceuticals in categories (e. g. ATC 5 level, ATC 4 level, indication / disease)? Please explain in detail, for example at what price level and if the pharmaceuticals are compared?
- How are reference price groups reviewed and evaluated?
- What happens if there are no matching pharmaceuticals to compare with available in your country?
- How many pharmaceuticals are included in a reference price group? If possible, please give the number of pharmaceuticals per reference group.
- Are parallel trade pharmaceuticals included in reference groups?
- How is the reference price calculated?
    - As the one of the lowest priced pharmaceutical in a group, as the average, as the average plus 10%, or as something else?
    - How is the "dose-equivalency" determined?
    - Does your country have a reference price system where the reimbursement rate for all interchangeable substances (e. g. statins) is calculated from the lowest price or a computed price (like e. g. the average of the two cheapest pharmaceuticals, etc.)?
- What happens if a patient opts for another pharmaceutical than the one, which is priced at (or below) the reference price level? (e. g. does the patient have to pay the difference between the actual price and the reference price)
- What happens if a doctor prescribes a pharmaceutical above the reference price? Is the doctor allowed to do so?
- Please make a cross reference to generic substitution (cf. 5.5.1 Generic substitution).

4.4 Private pharmaceutical expenses

In this section, please describe:

- Who is responsible for making decisions regarding Private Pharmaceutical Expenses?
- If possible, please state the relative contribution of private pharmaceutical expenses in terms of pharmaceutical expenditure.
- Are mechanisms in place to protect vulnerable groups of people (e. g. reduced rates, exemptions, ceilings (caps) on private pharmaceutical expenses, tax relief, discounts for pre-paid charges, substitution of cheaper (generic) pharmaceuticals by pharmacists)?
- Are mechanisms applied in order to promote rational consumption of pharmaceuticals, which are aimed at the patients?
- Do the cost sharing policies have explicit objectives? These objectives might include raising the revenue for the health sector, reducing the inappropriate demand, containing the costs, or encouraging the responsibility of the consumers.
- In recent years, have there been any changes (decreases or increases) in the level of private pharmaceutical expenses? In what areas? Explain why there have been changes over time.

4.4.1 Direct payments

Please describe any pharmaceuticals where patients are faced with direct payments. If such pharmaceuticals, especially besides self-medication, exist please state the amount of money paid in average for such a pharmaceutical.

4.4.2 Out-of-pocket payments

Please describe the system in place for out-of pocket payments of patients (co-payments / deductibles). If possible / appropriate please insert a table showing your out-of-pocket payment system, like the one in Table 4.2 (example from Denmark).

Table 4.2: Denmark - Reimbursement rates and patient co-payment rates, 2006

Annual expenses for patients in terms of reimbursement price in DKK/ €[1]	Co-payment rate in %	Reimbursement rate in %
Adults		
DKK 0-480 / € 0-64.41	100%	0%
DKK 480-1,165 / € 64.41-156.34	50%	50%
DKK 1,165-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / € 366.35	15%	85%
Children up to 18 years		
DKK 0 - 1,165 / € 156.34	50%	50%
DKK 1,165-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / 366.35	15%	85%
Chronically ill[3]		
DKK 0-18,105 (adults) or 19,705 (<18 yrs) / € 0-2,625.8 (adults) or 2,858.4 (<18 yrs)	Co-payment rates and reimbursement rates as stated above	
> DKK 18,105 or 19,705 / € 2,625.8 or 2,858.4	0%	100%
Terminally ill[4]		
DKK / € 0	0%	100%

[1] before subtraction of reimbursement rate

Source: Sundhedsloven (Health Act) No. 546 of 24 June 2005 as amended

4.4.2.1 Fixed co-payments

- If fixed co-payments, e. g. prescription fees are used, please describe how (especially concerning the predominant reimbursement scheme).
- If relevant (like for example in Ireland), please also describe fixed co-payments in other reimbursement schemes.
- Is there a monthly or annual out-of pocket maximum (ceiling)?

[3] A chronically ill patient in this context is defined as a patient who has a large consumption of prescribed medicine and accordingly large costs.

[4] Includes all consumed pharmaceuticals (also not reimbursable pharmaceuticals prescribed by a doctor.

4.4.2.2 Percentage co-payments

- If percentage co-payments are in place, please describe how (especially concerning the predominant reimbursement scheme).
- If relevant (like e. g. in Ireland), please also describe percentage co-payments in other reimbursement schemes.
- Is there a minimum co-payment (threshold)?
- Is there an annual or monthly out-of pocket maximum (ceiling)?

4.4.2.3 Deductibles

- If deductibles are used, please describe how (especially concerning the predominant reimbursement scheme).
- If relevant please also describe deductibles in other reimbursement schemes.
- Is there a minimum co-payment (threshold)?
- Is there an annual or monthly out-of pocket maximum (ceiling)?

4.5 Reimbursement in the hospital sector

Please describe in this section how hospital pharmaceuticals are reimbursed in your country:

- Does the reimbursement in the inpatient sector differ from the outpatient sector?
- Who is the main "payer" of pharmaceuticals in hospitals (e.g., NHS / SHI, state, owner of hospital, community / region)?
- Are there cooperative funding ways for the reimbursement of pharmaceuticals (e.g. does NHS / SHI pays a share of the pharmaceuticals used in hospitals like in the Netherlands)?
    - If yes, please give an example for specific illnesses or pharmaceuticals
- At what level are pharmaceuticals reimbursed for inpatient care (fully or partly reimbursed)?
- Are the criteria for reimbursement of pharmaceuticals in the hospital sector any different from the general sector? Please cross-reference to Section 4.2.1 Eligibility criteria if appropriate.
- If yes, please describe these criteria:
    - Product specific criteria (e. g. essential drug, safety, lack of alternative therapies, prescription status, patent status)
    - Economic criteria (e. g. cost-effectiveness, reference price, therapeutic value, budget impact)
    - Patient specific criteria (e. g. age, sex, chronically or terminally ill patient.)
    - Disease specific criteria (e. g. severity of illness, special medical needs)

If pharmaceuticals are only partly reimbursed please answer the following questions:

- What kind of out-of pocket payments are used in hospital sector (percentage or fixed co-payments, deductibles)?

4.6 Reimbursement related cost-containment measures

Please write a section on reimbursement related cost-containment mechanisms currently implemented in your country. For definitions please consult the glossary.

Note: The area of Pharmaco-economics should be covered in section 5.4 Pharmaco-economics. If appropriate, please cross-reference.

4.6.1 Major changes in reimbursement lists

Please describe if there have been major changes in the reimbursement lists, like for example in Germany the past 5 to 10 years.

State especially:

- If new lists have been introduced
- If lists have been abolished

4.6.2 Introduction / review of reference price system

Please describe major changes in the system during the last 5 to 10 years like for example:

- The expansion of reference groups, e. g. by taking the ATC 4 level into account
- Changes in reference pricing procedures
- The inclusion of parallel traded pharmaceuticals in the reference price system

4.6.3 Introduction of new / other out-of-pocket payments

Please describe major changes in the system of out-of pocket payments during the last 5 to 10 years.

4.6.4 Claw-backs

Please describe:

- Are claw-backs used in your country? If yes, please explain.
- What administrative arrangements and sanctions underpin these arrangements?
- What has been the main aim of using this mechanism?

- Has the effect of the mechanism been monitored and / or evaluated? If yes, please describe the measured effect?

4.6.5 Reimbursement reviews

Please write a section answering the following questions:

- Are reimbursement decisions reviewed / evaluated on a regular basis?
- If yes, by whom and how often?
- According to which criteria are the reimbursement decisions reviewed?
- What is the basis of these criteria? Is it a legal framework or other?
- Who may ask for a review of a reimbursement decision (e. g. pharmaceutical companies, patients, Third Party Payers)?
- Have the results of the reviews been published yet ? Sweden has for example published a review of pharmaceuticals that work against diseases caused by stomach acid.
- If yes, please add a link to the publication and the institution that published the review.
- Please cross-reference to section 2.3 Evaluation if appropriate.

5 Rational use of pharmaceuticals (20% / 8-12 pages)

This chapter gives an overview of the current methods used to promote an equitable and efficient use of pharmaceuticals. For definitions please consult the glossary.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions, please consult the glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.
- Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.

5.1 Impact of pharmaceutical budgets

- Are there (obligatory or indicative) budgetary constraints for prescribing doctors set by third party payers or the state? If yes, please state the extent and the use of the budgetary constraints.
- Are these budgetary constraints applied on a national or a regional level?
- How are the budgetary constraints enforced and by whom? Please explain possible sanctions and state if they have ever been commonly applied.
- Do doctors receive an evaluation of their prescribing habits?
- Are there special prescribing procedures (different from the outpatient sector) in the inpatient sector?
- In case of special prescribing procedures for the inpatient sector, does this influence the prescribing habits of doctors in the outpatient sector?

Please cross-reference to section 5.2 Prescription guidelines.

5.2 Prescription guidelines

Please describe the regulation of the prescription practice of doctors, adding in any differences between outpatient and the inpatient sector. Please only explain the obligatory guidelines (legal framework) in more detail. It is sufficient to simply mention all indicative guidelines / recommendations and to insert links to these guidelines.

- Are measures implemented to control the prescribing and use of pharmaceuticals, like for example:

- Treatment guidelines (i. e. guidelines on the prescribing of pharmaceuticals for a specific diagnosis):
  - When were these guidelines implemented?
  - Who is responsible for the implementation of the guidelines?
  - What is their content?
  - How is the adherence to these guidelines monitored? Are there any sanctions?
- Monitoring of the sizes of the packages prescribed (in some countries family doctors prescribe smaller size packages, which leads to higher cost for patients)
  - Is this a known problem in your country? If yes, are actions taken to prevent this?
  - Are information systems used for monitoring prescribing patterns?
  - Do doctors receive the outcome of the monitoring?

- Is there a regular (e. g. annual) clinical audit of all doctors?
- Do doctors have access to information, like for example treatment guidelines, which helps them in selecting the pharmaceutical they want to prescribe?
  - Is this information available in a printed version and / or in an online database? Please explain.
  - By whom is this information being provided?
  - How often and in what way is the information updated, and who is responsible for this?
  - What is the role of national doctor's association in producing information?
  - Is information included about diagnostic limits, dose limits or duration limits for pharmaceuticals?

Please cross-reference to section 5.2 Prescription guidelines.

5.3 Information to patients / doctors

Please write a section on the regulation of the provision of information to patients and / or doctors, answering the following questions:

- Are the" Marketing directives" as stated in Directive 2001/83/EC implemented in your country? Please state the national legal foundation.
- Who is responsible for the implementation of these directives (acts, laws, regulations)?
- Is direct advertising of OTC pharmaceuticals to patients allowed?
- Is advertising of pharmaceuticals on the internet allowed? If yes, how is it regulated?
- Are measures implemented in order to restrict or control promotional spending of manufactures? If yes, are there:
  - Budget ceiling or taxes on promotional expenditure? If yes, please explain.
  - Audits of the sales promotion material sent to doctors and on advertisements in journals? If yes, please explain.
  - Other measures? If yes, please explain.

- Are there regulations or restrictions on the activities of representatives of pharmaceutical companies who visit doctors? If yes, please explain the type of regulation or restriction and how it is executed.
- Are there restrictions on sending of pharmaceuticals samples to doctors? If yes, please explain the kind of restrictions that are in place.
- Is there any control over the quantity of sales promotion activities undertaken by pharmaceutical companies? If yes, please explain the kind of control.
- Are actions taken to inform patients on the rational use of pharmaceuticals? If yes, by whom are they taken (by the state, third party payers, doctor's association, others?).
    - Is this information available in a printed version and / or in an online search engine? Please explain.
    - Is this information provided by pharmacist? If yes, please explain.
- Are there any specific regulations for information to patients in the inpatient sector?

Please cross-reference to section 2.1.3.1 Industry and / or 2.1.3.6 Patients if appropriate.

5.4 Pharmaco-economics

Please describe the legal or regulatory use of health-economic analysis:

- Please state the legal national source for health-economic analysis.
- Is the provision of health-economic analyses necessary for obtaining market authorisation?
- Is the provision of health-economic analyses necessary in the decision on the price of a pharmaceutical?
- Is the provision of health-economic analyses necessary to obtain reimbursement status?
- Are health-economic evaluations necessary for type of pharmaceuticals (all, POM, OTC) and are there any differences?
- Since when are health-economic analyses applied?
- Who performs the health-economic analyses?
- Evaluation of pharmaco-economic guidelines:
    - Please give an overview of the content of the pharmaco-economic guidelines.
    - How often are the pharmaco-economic guidelines updated / revised?
    - Who is in charge of the evaluation of the pharmaco-economic guidelines?
- Does the country apply a maximum for what it is willing to pay for one QALY?
- Is the inpatient sector exempted from the application of these regulations?

Please cross-reference to section 4.6 Reimbursement related cost-containment measures if appropriate.

5.5 Generics

Please expand on the relevance of generics in your country.

Note: Pricing of generics is explained in section 3.4.2 Generics.

- Are there any legal regulations on the use of generics?
- Are generics mainly seen as cost-containment tool?
- Is the use of generics relevant in the inpatient sector?

Table 5.1: Country - Development of the generic market in the out-patient sector, 2000 - 2005

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)						
Value						

Please indicate source: _____

5.5.1 Generic substitution

Please give an overview of generic substitution in your country.

- Is generic substitution allowed in your country? If yes:
- Is generic substitution mandatory or voluntary? In case it is mandatory, please state the legal regulations for generic substitution.
- Are parallel imports included in the generic substitution system?
- Please explain if pharmacies are or allowed to substitute a generic for a branded pharmaceutical (e. g. the originator)?
  - Yes, but only if the doctor has written the prescription with its International Non-proprietary Name (INN).
  - Yes, regardless if whether the doctor has prescribed a branded pharmaceutical or not.
  - Yes, but with the doctor's explicit agreement.
  - Yes, unless the doctor has explicitly indicated that the pharmaceutical should be substituted.
  - Yes, but only with agreement of the patient (i. e. patient may oppose to substitution)
  - Does opposition lead to consequences:
    - For doctors?
    - For patients? (e. g. higher co-payment)
    - For pharmacists?
- Are there incentives in place for generic substitution? If yes, please explain which?
  - Financial incentives?

- Other incentives?

- Are pharmacies allowed to substitute therapeutically (i. e. dispense a pharmaceutical with equal therapeutic benefits (~ analogous substitution). Please explain.
  - Is this type of substitution obligatory?
- Are pharmacies allowed to substitute parallel imported pharmaceuticals? Please explain.
  - Is this type of substitution obligatory?

5.5.2 Generic prescription

Please give an overview of generic prescribing in your country.

- Are doctors obliged to write prescriptions generically? If yes, what happens if a doctor opposes to this?
- Does a doctor profit from prescribing generic pharmaceuticals? If yes, how?
- Do doctors have to prescribe by the International Non-proprietary Name (INN) or by a "brand' name?
- Is generic prescribing easily accepted by doctors?

5.5.3 Generic promotion

Please give an overview of generic promotion in your country.

- Is the use of generic pharmaceuticals promoted
  - Among patients?
  - Among doctors?
  - Among pharmacists?
- Why is the use of generic pharmaceuticals promoted? Reasons for this could be to ensure access of patients to a greater variety of pharmaceuticals, to enhance local generic manufacturers or for cost-containment reasons.

5.6 Consumption

Please describe the regulations of the consumption of pharmaceuticals. This section should also include an evaluation of the affordability and availability of pharmaceuticals in your country. Information on market data and sales are given in section 2.1.2.2 Market data.

- Is individual consumption data monitored? If yes,
  - How is this done?
  - Which authorities / institutions are responsible for monitoring consumption?
  - How is the information updated?
  - Is consumption of pharmaceuticals sold via internet also monitored?

- Is compliance data used in decisions regarding individual reimbursement? E. g. can a patient who has difficulties swallowing large tablets receive reimbursement for a more expensive pharmaceuticals (e. g. granules)?
- Is there an Essential Drug Policy in place? If yes, how many pharmaceuticals does it contain and how often is it updated?

6 Current challenges and future developments (max. 5% / 2 pages)

This chapter covers the most oppressing pharmaceutical challenges for the health care system and the future plans to meet these challenges.

6.1 Current challenges

Please write a section covering:

- An in-depth description of the main challenges that the pharmaceutical system currently faces.
  - Please state if this is your own view point or if this is a general opinion.
  - Please provide sources and documentation if available.

Note: Please add sub-headings if necessary

6.2 Future developments

Please write a section covering:

- The long-term pharmaceutical policies which are:
  - Under negotiation
  - Already decided upon
  - Under implementation

Please describe the reasons for these pharmaceutical policies.

7 Appendixes

7.1 References

Please include key references to relevant (academic) publications relating to your country used as sources of information within the Pharma Profile. The template of the Pharma Profile uses the Harvard referencing system whereby citations are made within the text in parentheses, e. g. "(ÖBIG 2005)", and the full references are listed alphabetically in this section.

Examples:

Kutzin J (1998). The appropriate role for patient cost sharing. In *Critical challenges for health care reform in Europe*. R B Saltman, J Figueras and C Sakellarides (eds). Buckingham: Open University Press.

White Paper Caring for People: Community Care in the Next Decade and Beyond London: HMSO, 1989.

Witter S, Ensor T (1997). *An Intro to Health Economics for Eastern Europe and the Former Soviet Union*. Chichester, John Wiley & Sons.

World Health Organization (2002). WHO Traditional Medicine Strategy 2002-2005. Geneva: WHO, p. 7. Available at: http://www.who.int/medicines/library/trm/trm_strat_eng.pdf

7.2 Further reading

Please list any other relevant references for further reading on your country's pharmaceutical system.

7.3 Web links

Please list any relevant web links for further reading on your country's pharmaceutical system.

7.4 Detailed description of authors

Please list the names of the authors who contributed to your country's Pharma Profile.

Annex IX

PPRI Information Leaflet

Pharmaceutical Pricing and Reimbursement Information

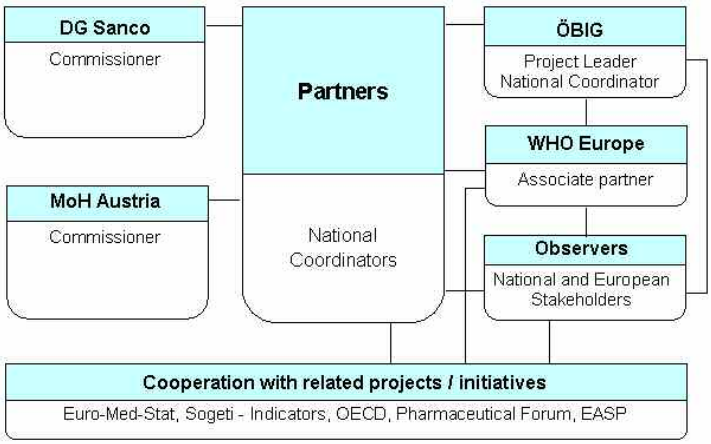
PPRI project

The pricing and reimbursement of pharmaceuticals is a national issue. Consequently there are 25 pharmaceutical pricing and reimbursement systems in the enlarged European Union which often differ greatly. Therefore, the objective of the PPRI project is to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe, by providing comprehensive country reports on the Member States and a comparative analysis.

Project organisation

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Federal Ministry for Health and Women's Issues, Austria. The project team consists of the main partner (ÖBIG / Austrian Health Institute), an associate partner (WHO Regional Office for Europe) and a network of 20 partners and 21 observers from a large range of EU Member States and other countries such as Bulgaria and Norway.

The PPRI project is designed to run from April 2005 to summer 2007. The results will be disseminated during a **summer 2007 conference in Vienna**.



Project description

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study.

Specific objective of the PPRI project:	Work package(s):	Deliverables of the PPRI project:
Strenghtening the networking of institutions in the field of pharmaceuticals in Member States	WP 1 'Coordination'	Good communication and cooperation within the project, for delivering a project of high quality on time
	WP 2 'Dissemination'	A website (http://ppri.oebig.at) and a conference at the end of the project (Summer 2007, Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected
Collection, reporting and analysis of information on pricing and reimbursement in Members States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Deleveloping indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe	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 the summer 2007 conference

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