Short PPRI Pharma Profile

Country 2018

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Template

Update: 2018

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**Disclaimer**
The data provided in this document by the members of the PPRI network and other authors represent the current situation. The data have no legally binding value and are meant especially for the information of PPRI network members who are committed to sharing information on pharmaceutical pricing and reimbursement.

# Introduction

**PPRI Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement**

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian Public Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) and the World Health Organization (WHO) developed the so-called “PPRI Pharma Profiles” as a tool for understanding, collecting and analysing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles was that the Profiles were written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions) represented in the PPRI network and that they were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

As a further development, information on the in-patient sector was integrated: The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. 19 PHIS Hospital Pharma reports and 5 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at <http://whocc.goeg.at/Publications/CountryReports>.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre’s website at <http://whocc.goeg.at/Publications/CountryPosters>.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were matched and were made available to the authors. In the course of the years, the templates for the comprehensive profiles (in 2015 the “PPRI/PHIS Pharma Profiles were renamed again to “PPRI Pharma Profiles”) were revised, further developed and updated.

The PPRI Pharma Profile 2018 is designed to comprise up-to-date information as of 2018 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

**Templates and glossaries**

All PPRI Pharma Profiles are based on a template which provides a homogenous outline for reporting. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI Pharma Profiles.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre’s website at <http://whocc.goeg.at/Glossary/About>. Authors of the PPRI Pharma Profiles are requested to adhere to the Glossary.

**PPRI, PHIS, and WHO Collaborating Centre**

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was performed from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 80 institutions: These are public authorities and third party payers from 46 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, WHO (HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including updates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme’s National Focal Points (NFP) and the Directorate General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (<http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf>).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Health Economics Department of the Austrian Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated in 2014. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre’s explicit tasks is to develop the tool for for describing and analysing national pharmaceutical pricing and reimbursement systems ("Pharma Profiles"). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the “PPRI Pharma Profiles” for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to our findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: <http://whocc.goeg.at>. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

Since Sept. 2016 the Centre is located at the Pharmacoeconomics Department of the Austrian Public Health Institute (GÖG).

**About this short profile**

This short profile aims at providing a concise overview of the pharmaceutical system of the given country. The report is structured in 6 sections:

1. Health care system
2. Pharmaceutical system
3. Pricing, reimbursement and volume control in the out-patient sector
4. Pricing, reimbursement and volume control in the in-patient sector
5. Interface management and developments
6. Pharmaceutical data fact sheet

# Guide for authors

When completing the PPRI Pharma Profile template, please consider the following points:

*General*

* For every heading, please give a country-specific overview. The questions below the headings should be seen as a writing support. In case that some of the questions are not applicable to your country, you can ignore them.
* Though the template is based on a list of bullet points with questions and explanatory remarks, **it is important to write a full descriptive text**. **The questions are deleted in the final version of the country report.** Please, do not answer with yes and no. Please insert cross-references to other sections / chapters if appropriate.

*Data source*

* Please provide data using national / local sources (e.g. local health statistical yearbooks, annual reports). Alternatively please use standardised sources, preferably EUROSTAT or OECD data.
* You might also find relevant information in WHO HiT Profiles or in some sections of the PPRI Pharma Profiles, PHIS Hospital Pharma reports or PHIS Pharma Profiles.

*Glossary*

* The authors are kindly asked to use the terms and concepts as defined in the glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://whocc.goeg.at> 🡪 Glossary.
* Note: Some definitions provided in the Glossary may be different than those used in your country. Please use the preferred terms from the glossary or describe the meaning of the term used in your country.

**Contact**

If you have any questions, please do not hesitate to contact the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Austrian Public Health Institute (GÖG/ÖBIG).

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# Health care system

This section gives a brief introduction to the demographic and economic situation of a country as well as on the access to the health care system.

* Please comment on the trends regarding population and age structure of your country as of 2018 or the latest available year.
* Indicate the organisation of the health care system by mentioning the type of health care system (National Health Service or Social Health Insurance), the main actors, the coverage and the main underlying law/decree.
* Please comment on the developments of the health expenditure in total and for out-patient and in-patient sectors.
* What is the main source of funding i.e. social health insurance contributions or general taxation? What is the current health expenditure as a percentage of GDP and what is the public and private share of total health expenditure?
* How is out-patient and in-patient health care organised? How are out-patient doctors remunerated?
* Who are the main payers in the in-patient sector? In general, how are hospitals remunerated? Are private (for-profit/ non-profit) or public hospitals dominating the system?
* Give the trends in the evolution of number of doctors and pharmacists and discuss if it is sufficient to cover the country needs.

# Pharmaceutical system

This section provides a description of the pharmaceutical system; its organisation, regulatory framework and authorities, the market players and the funding of the system for the out-patient and the in-patient sectors.

* Please describe the pharmaceutical system in your country as of 2018 and briefly explain the medicines’ policy in the in-patient and the out-patient sector.
* Please name the main actors in the pharmaceutical system and their responsibilities.
* Please comment on the developments of availability of medicines in your country (e.g. number of authorised and available on the market medicines and the access to medicines.
* Please give information about the development of the pharmaceutical sales and the share of the out-patient, in-patient and parallel traded market.
* Briefly explain the trends in the total pharmaceutical consumption and the consumption in the out-patient and in-patient sectors.
* Briefly elaborate on the emergence of high-cost medicines in recent years, their impact in your country (e.g. on pharmaceutical expenditure) and possible reactions?
* Do you have pre-launch activities such as horizon scanning and forecasting in your country?
* What is the relevance of generics and biosimilars in your country in general and particularly in the in-patient sector?
* Please give an overview on the market players, including the pharmaceutical industry, wholesalers, and retailers.
* Give the trends of total pharmaceutical expenditure, including the public and private share of pharmaceutical expenditure both in hospitals and in the out-patient sector.
* Give an overview of the sources of funding of medicines in the out-patient and in-patient sector.
* Please try to draw an overview chart of the pricing and reimbursement system in your country. See example below.

Example of an overview chart of the Austrian pharmaceutical pricing and reimbursement policies



# Pricing, reimbursement and volume controlin the out-patient sector

This section covers a description of the organisation of the pricing system and policies. It describes also the organisation of the reimbursement system, the reimbursement schemes, reference price system, private pharmaceutical expenses and the volume control mechanisms in the out-patient sector as of 2018.

* What is the legal framework and who are the main actors in pricing of medicines and what responsibilities do these actors have?
* Describe the main pricing policies for medicines (free pricing, statutory pricing, price negotiations) in your country – with regard to the different types of medicines (prescription medicines / OTC, hospital medicines, innovative medicines, generics, reimbursable / non-reimbursable medicines).
* Which pricing procedures are currently used? Who is involved in the pricing procedure? At which level (ex-factory, wholesale, pharmacy retail price level) is the price set and which scope of medicines is targeted (e.g. reimbursable medicines only, prescription only medicines)?
* Please elaborate on major pricing policies applied in your country, such as external price referencing (e.g. basket of reference countries, updates)? Do you use tendering? Which role do value-based pricing elements play?
* Which criteria are taken into account in the pricing decision? Are there laws or other regulations for the different pricing procedures?
* Do you specific pricing or reimbursement policies for high-cost medicines?
* Do you have specific pricing policies for generics? (e.g. generic price link, tendering) Are the same pricing policies applied for biosimilars as for generics?
* Describe how wholesalers and pharmacists are remunerated (mark-ups / fee-for service)? Is this regulated by law? If mark-ups are applied, are these linear, regressive, or other? Does the mark-up/mark-up regulation cover all medicines, or only the prescription / reimbursable segment?
* What is the VAT rate on medicines? Is this the standard VAT rate or does the VAT applied to medicines differ from the normal VAT?
* Describe the legal framework for the reimbursement policies? Who are the main actors in deciding the reimbursement of medicines, and what is their role? Which medicines (scope, e.g. also OTC products) are included in the reimbursement scheme?
* How the reimbursement procedure is linked to pricing of medicines (e.g. pricing only for reimbursable medicines, access to reimbursement only after having been granted a price)?
* Does your country have positive or negative lists? Who determines which medicines enter these lists? Describe the criteria / factors that determine whether or not a pharmaceutical is eligible for reimbursement.
* Describe the relevant reimbursement categories and the reimbursement rates in your country. Who is in charge of defining these categories and which laws define and enforce these schemes? When are the regulation implemented?
* Please state if your country has a reference price system. When was this introduced? How is the reference price calculated? How are the medicines clustered? Who decides on clustering/setting the referencing prices and the inclusion of medicines in the reference price system?
* Which role do managed-entry agreements play – if yes, could you please elaborate on the use (for which medicines)?
* Please describe the situation around the private pharmaceutical expenses. Which out-of-pocket payments (fixed co-payments, percentage payments, deductibles, etc.) are applied in your country? Explain which mechanisms and exemptions are in place for vulnerable groups?
* Briefly describe the volume control measures in your country. Are there measures implemented to control the prescribing and use of medicines? E.g. obligatory budget constraints for prescribing doctors set by third party payer?
* Which policies to promote generics uptake are applied in your country (e.g. generic substitution, INN prescribing)? Are they mandatory or voluntary? How they are promoted?
* Are claw-backs allowed in your country? What is the legal basis and which actors are targeted?
* Briefly describe the methods used to evaluate the pharmaceutical prices, expenditure, prescriptions and consumption? If applicable, describe when these tools were implemented? Who is in charge of the monitoring process and at which frequency? Are there any written evaluations available?
* Which tools are used in decision making process regarding medicines in your country? Describe the use of pharmaco-economic analysis e.g. if it is mandatory for the process of market authorisation, pricing, reimbursement or other? Who performs them?
* Are there Health Technology Assessments (HTA) performed in your country? Are they used as a base for decision making?

# Pricing, reimbursement and volume control in the in-patient sector

This section describes the organisation of the pricing system and policies in the hospital sector. It covers the reimbursement and the volume control and the reimbursement related cost-containing measures in the in-patient sector as of 2018.

* What is the legal framework regarding pricing of medicines used in hospitals and who are the main actors in pricing of medicines and what responsibilities do these actors have?
* At hospital level, who is in charge of deciding if and which price medicines are purchased? Are there specific institutions, bodies or persons involved in the process? What is the role of the hospital pharmacists?
* Which price type does the hospital price correspond to (ex-factory, pharmacy purchasing price, pharmacy retail price)? Is there official price calculation scheme for medicines used in hospitals?
* Are medicines sold to hospitals subject to VAT and at which rate?
* Are mark-ups relevant for medicines used in hospitals? Please, describe the possible schemes. What is the legal basis?
* Are there any mandatory or voluntary (commercial) discounts, rebates or other price reductions granted to the hospitals?
* Describe the main purchasing policies (tendering, negotiations, etc.) used in the in-patient sector. Which legal provisions on national and EU level need to be complied with?
* Do hospitals carry out their own procurement or is there joint procurement for a group of hospitals? Is there a national / regional procurement agency in your country? How often does procurement take place?
* Who is involved in the procurement process? Who has advisory and who has decision taking role in the procurement process? Which are the most relevant criteria for deciding if a medicine is purchased?
* Are there other purchasing policies (besides tendering and negotiations) that play a role in the in-patient sector? What are the legal provisions for these? Who is involved and which are the most relevant criteria?
* Is there any difference between reimbursement (financing) of medicines in hospitals and the out-patient sector? Which legal provisions are relevant for reimbursement in the in-patient sector?
* Who is the main payer for in-patient medicines (e.g. NHS/ SHI, state, hospitals directly or via special government budget)?
* Are there co-operative funding ways for the reimbursement of medicines? Give examples of specific medicine or disease. Are there specific budgets for specific medicines?
* At what level are the medicines covered and are the eligibility criteria for reimbursement of medicines in the in-patient sector different from the out-patient sector? If yes, please describe. Are positive / negative lists applied in the out-patient sector also relevant for the in-patient sector?
* Do patients have to co-pay for medicines in the in-patient sector? In which case, who and how much has to be paid?
* Are there separate hospital formularies for each hospital? Who pays for the medicines on the hospital formulary? Who creates, develops, and updates the formulary? How is the process of inclusion/exclusion of medicines going on?
* What is the role of the hospital pharmacists and the pharmaceutical and therapeutic committees – advisory or decision taking?
* Briefly describe the methods used to evaluate the pharmaceutical prices, expenditure, prescriptions and consumption? If applicable, describe when these tools were implemented? Who is in charge of the monitoring process and at which frequency? Are there any written evaluations available?
* Concerning consumption monitoring, are there computerised tracking systems for prescriptions in place? Please, comment on the traceability possibilities.
* What is the role of the hospital pharmacists with regard to rational use and monitoring?
* Which tools are used in decision making process regarding medicines in the in-patient sector? Describe the use of pharmaco-economic analysis? Who performs them?
* Are pharmaco-economic evaluations asked for? How often pharmaco-economic guidelines updated?
* Are there Health Technology Assessments (HTA) performed in the in-patient sector in your country? Are they used as a base for decision making?

# Interface management and developments

This section describes the interlinkage between the out-patient and in-patient sectors as well as information on the current plans and foreseen developments in the pharmaceutical sector.

* Please describe the relevance of the interface management (linkage between in-patient and out-patient sector). How is interface management of pharmacotherapy organised?
* Briefly explain the most important changes in recent times in the out-patient and the in-patient sectors as well as the foreseen pharmaceutical reforms. Please, describe the systemic changes under implementation and those still under discussion.

# Pharmaceutical data fact sheet: Country

Please include the requested data for your country.

|  | 2017 | 2016 | 2015 | Source  | Notes |
| --- | --- | --- | --- | --- | --- |
| Demography |
| Population  | total |  |  |  |  | Note: Preferred sources: EUROSTAT, OECD, WHOData as of 31 December |
| 0-14 years |  |  |  |  |
| 15-64 years |  |  |  |  |
| > 64 years |  |  |  |  |
| Life expectancy  | at birth |  |  |  |  |
| at age 65 |  |  |  |  |
| Economic data in \_\_\_\_\_\_ (Euro or National Currency Unit – please indicate) |
| Gross domestic product |  |  |  |  | Please indicate in which currency the data are provided.Please provide, wherever possible, absolute figures; if not possible, you can provide the estimated share of public/private funding. Preferred sources: EUROSTAT, OECD, WHO or respectively for expenditure data EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources |
| Health expenditure | total |  |  |  |  |
| public |  |  |  |  |
| private |  |  |  |  |
| Health expenditure in the out-patient sector | total |  |  |  |  |
| public |  |  |  |  |
| private |  |  |  |  |
| Health expenditure in the in-patient sector | total |  |  |  |  |
| public |  |  |  |  |
| private |  |  |  |  |
| Prescriptions |
| No. of prescriptions  | in volume |  |  |  |  | Prescription in volume = number of items prescribed. |
| Prescriptions  | in value |  |  |  |  | Prescription in value = public expenditure of prescribed medicines. |
| **Pharmaceutical consumption** |
| Total | In packs |  |  |  |  | DDD = defined daily doses |
| In DDD |  |  |  |  |
| Out-patient sector | In packs |  |  |  |  |
| In DDD |  |  |  |  |
| In-patient sector | In packs |  |  |  |  |
| In DDD |  |  |  |  |
|  | 2017 | 2016 | 2015 | Source  | Notes |
| Generic shares |
| Shares in % of total market (in-patient/ out-patient) | In volume |  |  |  |  | Volume: Expressed in number of prescriptions Value: Expressed in expenditure |
| In value |  |  |  |  |
| Shares in % of total out-patient market | In volume |  |  |  |  |
| In value |  |  |  |  |
| Shares in % of out-patient reimbursement market | In volume |  |  |  |  |
| In value |  |  |  |  |
| Shares in % of out-patient off-patent market | In volume |  |  |  |  |
| In value |  |  |  |  |
| Shares in % of the in-patient market | In volume |  |  |  |  |
| In value |  |  |  |  |
| Retailers of medicines |
| No. of community pharmacies | private |  |  |  |  | Data as of 1 JanuaryHospital pharmacies dispensing to out-patients are not included in this figure |
| public |  |  |  |  | Data as of 1 JanuaryPrivate pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership. |
| No. of hospital pharmacies for out-patients |  |  |  |  | Data as of 1 January |
| No. of dispensing doctors |  |  |  |  | Data as of 1 January |
| No. of other POM disp., please specify |  |  |  |  | Data as of 1 January |
| Total no. of POM dispensaries |  |  |  |  | Data as of 1 January |
| Pharmaceutical expenditure \_\_\_\_\_\_ (Euro or National Currency Unit – please indicate) |
| Pharmaceutical expenditure | Total |  |  |  |  | Data as of 31 DecemberNote: Preferred sources: EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources |
| Public  |  |  |  |  |
| Private |  |  |  |  |
| Pharmaceutical expenditure in the out-patient sector | Total |  |  |  |  |
| Public  |  |  |  |  |
| Private |  |  |  |  |
| Pharmaceutical Expenditure in the in-patient sector  | Total |  |  |  |  |
| Public  |  |  |  |  |
| Private |  |  |  |  |

Guide for filling the data fact sheet:

* Please provide data preferably in national currency unit (NCU) in the table – and indicate the name of the currency used in the table. In the text of the profile, please provide data in NCU and Euro (NCU / €) and use the relevant exchange rates for the respective years as listed at the website of the European Central Bank, see: <http://sdw.ecb.int/home.do> --> exchange rates.
* If possible, always provide absolute figures. However, if data are not available, provide an estimation wherever possible (e.g. share in %).
* Please do not delete rows in the table but rather state: not available (= data cannot be provided) or not applicable (= data do not exist).
* Please state which source you have used.
* Please have a look at the notes if data at a given point in time should be provided at 31 December or 1 January. Annual data (e.g. prescription, consumption, sales) cover the whole year.

# References