PPRI Pharma Profile

Country 2018

PPRI Pharma Profile Country

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.

# Acknowledgements

Please add text.

# 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).

# 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**. Please, do not answer with yes and no. **Questions will be deleted for the final version.** Please insert cross-references to other sections / chapters if appropriate.
* Please fill the information for yellow marked sections.

*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.
* Please also note that for some tables we ask you to fill in OECD data.

*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.

*Tables / Figures*

* Please provide data preferably in national currency unit (NCU) in the tables – and indicate the name of the currency used in the tables. 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 is not available give estimation wherever possible (e.g. share in %)
* Please do not delete rows in tables but rather state: not available (= data cannot be provided) or not applicable (= data do not exist).
* Please state for each table / figure which source, including the year, you have used.
* Please have a look at the notes below the table 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.

*Citation*

* Please use the Harvard Referencing System whereby citations are made within the text or as source under the tables in parentheses e.g. (GÖG 2010) and the full references listed alphabetically in the section Bibliography.
* For legislations please use a short title when writing the text. The long title should be mentioned in the bibliography

*Abbreviation*

* Please include all the abbreviations used in the PPRI Pharma Profile in the list of abbreviations. Please use abbreviations only when it approves readability of the text.

**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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# List of abbreviations

*Please add abbreviations used in this PPRI Pharma Profile and delete those you did not use!*

ATC Anatomic therapeutic chemical classification

BMG Bundesministerium für Gesundheit / Austrian Ministry of Health

DG SANCO Health and Consumer Protection Directorate General

DRG Diagnosis related group

EAHC Executive Agency for Health and Consumers

INN International Non-proprietary Name

GDP Gross domestic product

GÖG/ÖBIG Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG /   
Austrian Public Health Institute

GP General practitioner

HTA Health technology assessment

HE Health expenditure

HiT Health systems in transition

HOM Hospital-only medicine

HPF Hospital pharmaceutical formularies

NCU National currency unit

NHS National health service

NMEs New molecular entities

Mio. Million

OECD Organisation for Economic Co-operation and Development

OPP Out-of-pocket payment

OTC Over-the-counter medicine

PHIS Pharmaceutical Health Information System

PE Pharmaceutical expenditure

POM Prescription-only medicine

PPP Purchasing power parities

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

# Health care system

This section gives a brief introduction to the demographic and economic situation of the country as well as on the access to the health care system as 2018.

## Population and age structure

Please complete [Table 1.1](#Table11) and comment on the trends regarding population and age structure as well as health status.

Table 1.1: Country – Demographic indicators 2000, 2010, 2015, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Demography | 2000 | 2010 | 2015 | 2017 |
| Total population |  |  |  |  |
| Population aged 0-14 |  |  |  |  |
| Population aged 15-64 |  |  |  |  |
| Population aged > 64 |  |  |  |  |
| Life expectancy at birth |  |  |  |  |
| Life expectancy at age 65 |  |  |  |  |

Note: Preferred sources: EUROSTAT, OECD, WHO

Data as of 31 December

Source:

## Organisation of the health care system

* Indicate the organisation of the health care system by indicating the type of health care system (National Health Service or Social Health Insurance), the main actors, the coverage and the main underlying law/decree.
* How is out-patient and in-patient health care organised?
  + How is primary out-patient care practised? In out-patient clinics (“ambulatories”), by independent General Practitioners (GPs), by specialists or other?
  + How is in-patient care organised? Are private (profit or non-profit) or public hospitals dominating the system?
* 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.

## Health expenditure

* Please complete Table 1.2 and comment on the trends regarding health expenditure (HE) in total by sector (out-patient and in-patient) and funding (private and public).

Table 1.2: Country – Health expenditure 2000, 2010, 2015, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Health expenditure  in NCU = \_\_\_\_\_\_\_1 | 2000 | 2010 | 2015 | 2017 |
| GDP |  |  |  |  |
| THE |  |  |  |  |
| *- thereof public HE* |  |  |  |  |
| *- thereof private HE* |  |  |  |  |
| HE in the out-patient sector |  |  |  |  |
| *- thereof public* |  |  |  |  |
| *- thereof private* |  |  |  |  |
| HE in the in-patient sector |  |  |  |  |
| *- thereof public* |  |  |  |  |
| *- thereof private* |  |  |  |  |
| *Exchange rate (NCU per* €) |  |  |  |  |

GDP = gross domestic product, HE = health expenditure, NCU = national currency unit, THE = total health expenditure

1 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.

Note: Preferred sources: EUROSTAT, OECD, WHO or respectively for expenditure data EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources  
For the international comparison please indicate which expenditure is included in the stated figures. Please state any limitation of the expenditure data.

Source:

## Sources of funding

* 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 the gross domestic product (GDP) and what is the public and private share of total health expenditure? What is the share for out-patient and in-patient health expenditure?
* Secondary sources of funding, e.g. voluntary health insurance (VHI) or out-of pocket payments (OPP) of patients. What is the role of VHI in your country? Please specify how much (in percentage) of the funds are financed through these secondary sources.

# 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 as of 2018.

## Organisation of the pharmaceutical system

* Please describe the pharmaceutical system in your country as of 2018 and briefly explain the pharmaceutical policy in the in-patient and the out-patient sector. Please provide a flowchart of the pharmaceutical system following the model in Figure 2.1. If possible, develop a flow-chart integrating the in-patient sector, or providing two charts.

Figure 2.1: Country – Flowchart of the pharmaceutical system (sample for Austria), 2018



Source:

* Please fill out Table 2.1 giving information on the relevant authorities and key regulatory actors (including committees, boards, etc.) and third party payers as well as market actors and their interest associations as of 2018.

Table 2.1: Country – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2018

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Fields | Legal basis | Scope (in-patient, out-patient sector) | Authorities in English  (local name,  local abbreviation) | Activity / responsibility in the pharmaceutical system | Actors and interest associations in English  (local name,  local abbreviation) |
| Market authorisation | e.g. Austrian Medicines Law | In- and out-patient sector | Federal Office for Safety in Health Care and AGES Medizinmarktaufsicht – Austrian Medicines and Medical Devices Agency (Bundesamt für Sicherheit im Gesundheitswesen (BASG) / AGES Medizinmarktaufsicht) | Responsible for marketing authorisation of medicinal products in Austria and assessment of medicinal products and medical devices which are already on the market regarding efficacy, adverse reactions, production, shipment and storage. | e.g. pharmaceutical companies  Interest associations: Pharmig – pharmaceutical industry association, FOPI (Forum der forschenden phamazeutischen Industrie) – association of research oriented manufacturers, Österreichischer Generikaverband (ÖGV) - generics industry associations |
| Pricing / Purchasing |  |  |  |  |  |
| Reimbursement |  |  |  |  |  |
| Promotion |  |  |  |  |  |
| Distribution |  |  |  |  |  |
| Vigilance |  |  |  |  |  |

Source:

* Please comment on the table.

## Availability of and access to medicines

* Please comment on the developments of availability of medicines in your country (e.g. number of authorised and medicines available on the market).
* Please fill in Table 2.2 and comment on the developments of prescriptions. Provide explanations, if available, on trends (e.g. rising prescriptions in value due to new medicines, decreasing number of prescriptions due to rational use). Please note that the data only refer to the out-patient sector. Should this not be the case in your country (e.g. total market) please indicate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Prescriptions | 2000 | 2010 | 2015 | 2017 |
| No. of prescriptions (in volume) |  |  |  |  |
| Prescriptions in value  (in NCU = \_\_\_\_) |  |  |  |  |

le 2.2: Country – Annual prescriptions in the out-patient sector 2000, 2010, 2015, 2017

Prescription in volume = number of items prescribed.  
Prescription in value = public expenditure of prescribed medicines.

Should you use different definitions, please indicate.

Source:

* What is the average time between marketing authorisation and patient accessibility defined as the medicines actually being available on the market? Please consider and comment on the different phases (time till having a price / granting reimbursement, time between reimbursement approval and actual launch of the product by the market authorisation holder).
* Please state the number of new molecular entities (NMEs) launched per year for the time frame 2005 – 2015 and 2010 – 2017 (if possible). Please fill out Table 2.3.

Table 2.3: Country – Number of new molecular entities, 2005-2017

|  |  |  |
| --- | --- | --- |
| New molecular entities | 2005 – 2015 | 2010 – 2017 |
| Number of new molecular entities |  |  |

Source:

## Development of the pharmaceutical sales

* Please give information about the development of the pharmaceutical sales and the share of the out-patient, in-patient and parallel traded market.

## Pharmaceutical consumption

* Please complete Table 2.4 and comment on it and explain the trends in the total pharmaceutical consumption and the consumption in the out-patient and in-patient sectors.
* Please especially comment on the common measurement for consumption (packs, DDD) in your country (out-patient, in-patient) and possible limitations. If there are limitations in surveying / collecting of consumption data, which measures are undertaken to overcome them? What is the legal basis?
* Please also comment on the availability of a system for statistic management of consumption data in the country for medicine in the out-patient and in-patient sector? When was it introduced and commissioned? Who manages and runs it? Is there an obligation to deliver the data? Can (all) hospitals provide consumption data? Is it possible to quantify pharmaceutical consumption by every department? Is it possible to link up pharmaceutical consumption with the patient (i.e. a given unit with a given patient or by an ATC code)? Is there a monitoring possibility?

Table 2.4: Country – Annual pharmaceutical consumption 2000, 2010, 2015, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Consumption | 2000 | 2010 | 2015 | 2017 |
| Total pharmaceutical consumption | | | | |
| In packs |  |  |  |  |
| In DDD |  |  |  |  |
| Pharmaceutical consumption in the in-patient sector | | | | |
| In packs |  |  |  |  |
| In DDD |  |  |  |  |
| Pharmaceutical consumption in the out-patient sector | | | | |
| In packs |  |  |  |  |
| In DDD |  |  |  |  |

DDD = defined daily doses

Source:

## Generics

* Please complete Table 2.5 and comment on the relevance of generics in your country in general and particularly in the in-patient sector regarding the following questions:
  + Are there any legal regulations regarding generics especially with regard to market authorisation and to pricing and reimbursement?
  + Please comment on the relevance of the generic uptake/use in the in-patient sector with regard to the out-patient sector?

Table 2.5: Country – Development of the generic shares in volume and value, 2005, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Generic share | Volume1 | | Value2 | |
| 2005 | 20173 | 2005 | 20173 |
| Shares in % of total market (in-patient/ out-patient) |  |  |  |  |
| Shares in % of total out-patient market |  |  |  |  |
| Shares in % of out-patient reimbursement market |  |  |  |  |
| Shares in % of out-patient off-patent market |  |  |  |  |
| Shares in % of the in-patient market |  |  |  |  |

1 Expressed in number of prescriptions (if you have another measure for volume e.g. medicines/packs dispensed or sold please specify)

2 Expressed in expenditure (if you have another measure for value e.g. sales, please specify)

3 If you provide data before 2017, please indicate the year

Source:

## Top 10 medicines

* Could you please fill in and comment on Table 2.6 and Table 2.7 indicating the Top 10 active ingredients (indicating their ATC code in a separate column) in volume and in value for your country.

Table 2.6: Country – Top 10 active ingredients in value and volume in the out-patient sector, 2017

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Position | Top active ingredients used in the out-patient sector, ranked with regard to consumption | | Position | Top active ingredients used in the out-patient sector, ranked with regard to expenditure | |
| 1 |  |  | 1 | B03XA01 | Erythropoietin |
| 2 |  |  | 2 |  |  |
| 3 |  |  | 3 |  |  |
| 4 |  |  | 4 |  |  |
| 5 |  |  | 5 |  |  |
| 6 |  |  | 6 |  |  |
| 7 |  |  | 7 |  |  |
| 8 |  |  | 8 |  |  |
| 9 |  |  | 9 |  |  |
| 10 |  |  | 10 |  |  |

Source:

Table 2.7: Country – Top 10 active ingredients in value and volume in the in-patient sector, 2017

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Position | Top active ingredients used in the in-patient sector, ranked with regard to consumption | | Position | Top active ingredients used in the in-patient sector, ranked with regard to expenditure | |
| 1 | B05BB01 | Sodium | 1 |  |  |
| 2 |  |  | 2 |  |  |
| 3 |  |  | 3 |  |  |
| 4 |  |  | 4 |  |  |
| 5 |  |  | 5 |  |  |
| 6 |  |  | 6 |  |  |
| 7 |  |  | 7 |  |  |
| 8 |  |  | 8 |  |  |
| 9 |  |  | 9 |  |  |
| 10 |  |  | 10 |  |  |

Source:

## Market players

* Please give an overview on the market players, including the pharmaceutical industry, wholesalers, and retailers.
* Who is allowed to dispense medicines? E.g. community pharmacies, dispensing doctors, mail-order / internet pharmacies, other dispensaries (e.g. drug stores, supermarkets).
* Which products are the various dispensaries allowed to dispense? Full assortment of medicines (POM and OTC)? Other products (under what regulations)? Only selected range of OTC?
* Please complete Table 2.8 and comment on it, and describe the role of community pharmacies in the delivery chain in your country with regard to ownership (privately/publicly owned), allowance of chains, potential vertical integration of wholesalers and pharmacies, different distribution chains (pharmacy outlets, POM dispensing doctors, hospital pharmacies dispensing to out-patients etc.) For community pharmacies and other POM dispensaries, please indicate the total number and the number per 1,000 inhabitants.

Table 2.8: Country – Retailers of medicines 2000, 2010, 2015, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Retailers | 2000 | 2010 | 2015 | 2017 |
| No. of community pharmacies1 |  |  |  |  |
| * *Thereof: No. of private pharmacies2* |  |  |  |  |
| * *Thereof: No. of public pharmacies* |  |  |  |  |
| No. of hospital pharmacies for out-patients |  |  |  |  |
| No. of dispensing doctors |  |  |  |  |
| No. of other POM disp.,  *please specify* |  |  |  |  |
| **Total no. of POM dispensaries** |  |  |  |  |
| No. of internet pharmacies |  |  |  |  |
| No. of OTC disp., like drugstores |  |  |  |  |

Disp. = dispensaries, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (Glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://whocc.goeg.at>).

1 hospital pharmacies dispensing to out-patients are not included in this figure (according to the Glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://whocc.goeg.at>).

2 Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

Data as of 1 January

Source:

* Please shortly explain the role of hospital pharmacies: Do all hospitals have a pharmacy? Do they only serve patients inside the hospital or are they allowed to dispense medicines to out-patients? Do hospital pharmacies also run a community pharmacy for out-patients on the hospital’s premises, or are community pharmacies separate from the hospital pharmacy allowed to be established on the premise of the hospital?

## Pharmaceutical expenditure

* Please complete Table 2.9 and comment in particular on status and trends regarding pharmaceutical expenditure in total and by payer (public/private) in the in-patient and the out-patient sector:

Table 2.9: Country – Total pharmaceutical expenditure 2000, 2010, 2015, 2017

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pharmaceutical expenditure | 2000 | 2010 | 2015 | 2017 |
| TPE in NCU = \_\_\_\_\_\_\_1 |  |  |  |  |
| * *thereof public* |  |  |  |  |
| * *thereof private* |  |  |  |  |
| PE in the out-patient sector |  |  |  |  |
| * *thereof public* |  |  |  |  |
| * *thereof private* |  |  |  |  |
| PE in the in-patient sector |  |  |  |  |
| * *thereof public* |  |  |  |  |
| * *thereof private* |  |  |  |  |

NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure

1 Please indicate in which currency the data are provided. Please use national currency.

Please provide, wherever possible, absolute figures; if not possible, you can provide the estimated share of public/private funding.

Data as of 31 December

Note: Preferred sources: EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources.

For the international comparison please indicate which expenditure is included in the stated figures (e.g. if expenditure data cover just medicines or also medical durables and non durables). Please state any limitation of the expenditure data.

Source:

## Sources of funding

* Give an overview of the sources of funding (public and private) of medicines in the out-patient and in-patient sector.

# Pricing, reimbursement and volume control in 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.

## Organisation of the out-patient sector

* What is the legal framework in 2018 and who are the main actors in pricing of medicines and what responsibilities do these actors have?

## Pricing of medicines

### Pricing policies

* 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). For definitions please consult the Glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://whocc.goeg.at>.
* Fill in Table 3.1 and please specify for which medicines the pricing policies are valid. Feel free to insert more rows, e.g. on “Price-Volume Agreements” or “Price Notification”.

Table 3.1: Country – Ways of pricing of medicines at manufacturer level, 2018

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Pricing policies | (Non) prescription market | | (Non) reimbursement market | | Specific groups of medicine | | |
| POM | OTC | Reimbursable | Non-reimbursable | Generics | Parallel traded | Others, specify: e.g. biosimilars |
| Free pricing |  |  |  |  |  |  |  |
| Statutory pricing |  |  |  |  |  |  |  |
| Price negotiations |  |  |  |  |  |  |  |
| Tendering |  |  |  |  |  |  |  |
| Others – specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |  |  |  |

POM = prescription-only medicine, OTC = over-the-counter medicines

How to fill in the table: Please fill in “Yes” or “No”, if this policy is applied. Feel free to add for further specifications, e.g. POM – yes, but only if reimbursable

Source:

### Pricing Procedures

* Please complete [Table 3.2](#Table32) and comment on it:
  + Which pricing procedures are currently used?
  + Are these enforced by law? Who is involved in the pricing procedure?
  + Have there been major changes in the pricing procedures in the past few years?

Table 3.2: Country – Pricing procedures, 2018

| Pricing procedure | In use: yes / no | Price type1 | Scope2 |
| --- | --- | --- | --- |
| External price referencing |  |  |  |
| Internal price referencing |  |  |  |
| Cost-plus pricing |  |  |  |
| Indirect profit control |  |  |  |
| Price/volume agreements |  |  |  |
| Other managed-entry agreements, pls. specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| Others, specify: \_\_\_\_\_\_\_\_ |  |  |  |

1 Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

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

Source:

* Which criteria are taken into account in the pricing decision? Are there laws or other regulations for the different pricing procedures?
* If possible, please explain the pricing procedures in detail e.g.:
  + External price referencing:
    - 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?
    - How are prices set? Please, explain the methodological background on how are prices set (at the average of all prices, the lowest price of the basket). Have there been changes in the methodology?
    - 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?
  + Internal price referencing:
    - Are there formal rules (e.g. on methodology) or laws / decrees on internal price referencing? If yes, please explain.
    - At which level (ATC 5 or below) are prices compared? Is there therapeutic referencing in your country? Have there been any changes in the methodology in the course of time?
  + Cost-plus pricing
    - Are there formal rules (e.g. on methodology) or laws / decrees on cost-plus pricing? If yes, please explain.
    - Which evidence / information is required from the industry in the pricing procedure? E.g. information on production cost, expected sales, price of the medicine in other countries, the therapeutic value, cost effectiveness analysis, any other information.
  + (Indirect) profit control
    - Are there formal rules (e.g. on methodology) or laws / decrees on cost-plus pricing? If yes, please explain.
  + Tendering
    - Do you apply tendering? If yes, please explain (for which medicines, procedural issues).
  + Value-based pricing
    - Do you apply value-based pricing as an integrated pricing and reimbursement policy? If yes, please elaborate how it work?
    - If you do not use value-based pricing, please elaborate whether and how you include value-based elements in your pricing decisions?
  + Managed-entry agreements
    - Do you have managed-entry agreements? If yes, could you please elaborate: on the type of the agreement (performance-based, financial agreement, type of agreement, for which medicines), refer to section 3.4.5
  + Others
    - If there are other pricing procedures, that play a role in the out-patient sector, please describe them.

### Specific pricing policies

Please write a section whether you have specific pricing policies

* For high-cost medicines: If yes, please elaborate (which is the definitions for the high-cost medicines, which pricing policies do you apply, specific procedural issues). Could you have any data on the impact on these policies (e.g. evaluations on savings).
* For generic and biosimilar medicines: Do you apply a generic price link (generic must be priced a specific percentage below the originator), or do have competition work (e.g. tendering)? Do your pricing policies differ for biosimilars from generics?

### Discounts / rebates

Please write a section on discounts and rebates, including the following points:

* Are there mandatory discounts in your country?
* If yes, for which medicines (e.g. medicines in the public interest)?
* Who is obliged to grant those mandatory discounts (e.g. manufacturer, distributor and other actors)?
* To whom (e.g. Social Insurance) have mandatory discounts to be granted?
* Which is the legal basis for granting mandatory discounts?
* Please state the amount of the mandatory discounts (for the different segments, to different actors, for different medicines) to be granted?
* Are all types of discounts / rebates allowed (or only cash discounts or also discounts in kind)?
* Are there specific rules (e.g. limitations) regarding commercial discounts / rebates (e.g. maximum limits for specific medicines, for specific actors)?
* In case of commercial discounts, please give the average for the different segments.

### Remuneration of wholesalers and pharmacists

* 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? Do you have fee-for-service remuneration, e.g. for pharmacists? Could you please share the scheme with us?
* Please complete Table 3.3 and provide an overview of remuneration of wholesalers and pharmacists.

Table 3.3: Country – Regulation of wholesale and pharmacy mark-ups, 2018

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Wholesale mark-up | | | Pharmacy mark-up | | |
|  | Regulation | Content | Scope\* | Regulation | Content | Scope\* |
| *Example* | *Yes* | *Regressive mark-ups* | *All  medicines* | *Yes* | *Regressive mark-ups* | *All medicines* |
| *Your country* |  |  |  |  |  |  |

\* Regulations concerning mark-ups do not always apply to all medicines, it may also target only POM or reimbursable medicines

Source:

### Taxes

* 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? Please indicate the relevant VAT rates in 2018: Standard VAT/VAT on medicines.
* Please specify if the VAT refers only to a group of medicines and/or if there are split rates for different medicines 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.
* Are there, as of 2018, further taxes / fees on medicines (e.g. a pharmacy fee per medicine dispensed or a general pharmacy tax like in Finland)?

## Reimbursement of medicines

### Reimbursement policies

* 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?
* Please describe the general reimbursement scheme and, in case there are some, specific schemes (e.g. for specific patient groups or expensive medicines) by giving answers to the following points: What is the name of the current scheme? When was it introduced? What is the legal framework for this scheme? Who is covered by this scheme (coverage of population)? Who is excluded from this scheme (e.g. asylum seekers)?

### Reimbursement procedure

* 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? If yes, how is this administered? Do(es) the list(s) contain active ingredients or medicines by trade name? How many active ingredients or medicines included in the list(s)? Are the lists published? If yes, please insert source. How often is (are) the list(s) updated? How often are changes in the list(s) made? How are these changes communicated to doctors, pharmacists and patients? Which evaluations are undertaken?.
* Please elaborate further on the use of pharmaco-economics as criteria for inclusion and / or exclusion of medicines on the reimbursement list, if appropriate.
* Please explain the role and the composition of the responsible body. Who decides on the inclusion of medicines into reimbursement? 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 were the regulations implemented?

### Reference price system

* Is there a reference price system in your country? When was the reference price system implemented?
* What is the scope (covering all products, limited rage)? Which products are covered? How many active substances and brands are included? Are parallel traded medicines included in reference groups?
* Which criteria are used to group medicines in categories (e.g. ATC 5 level, ATC 4 level, indication / disease)? Please explain in detail at what price type medicines are compared? How many reference groups are included? How often are reference price groups reviewed/updated and evaluated? What happens, if there are no matching medicines to compare with available in your country?
* How is the reference price calculated?
* As the lowest priced medicine 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 medicines, etc.)?
* What happens if a doctor prescribes a medicine above the reference price? Is the doctor allowed to do so? Does the patient have to pay the difference between the actual price and the reference price?
* Have there been major changes in the reference price system?

### Private pharmaceutical expenses

* 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?
* If possible, please insert a table showing the system out-of-pocket payment in your country as shown in Table 3.2..

Table 3.4: Country – Out-of-pocket payments for medicines, 2018

|  |  |  |
| --- | --- | --- |
| Out-of-pocket payments | Amount | Vulnerable groups |
| Fixed co-payments |  |  |
| Percentage payments |  |  |
| Deductibles |  |  |
| Reference price system |  |  |

Source:

## Volume control

* 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 generic policies are applied in your country? Are they mandatory or voluntary? How they are promoted?

### Generic substitution

Please elaborate on the developments and trends regarding generic substitution in your country as of 2018:

* Is generic substitution allowed in your country? Since when is generic substitution allowed in your country?
* Is generic substitution mandatory or voluntary? In case it is mandatory, please state the legal regulations for generic substitution.
* Is there a historic relevance of generics in your country?
* How is the public perception of generics in your country? Are doctors allowed to exclude generic substitution? If yes, under which prerequisites? Are pharmacists allowed to substitute a branded medicine (e.g. the originator) with a generic? Please explain the prerequisites for pharmacists to substitute e.g. it is mandatory or only allowed when the doctors has written the prescription with its International Non-proprietary Name (INN).
* Are there incentives in place for generic substitution? If yes, please explain which (e.g. financial incentives). In case of non-adherence, are there sanctions? Are pharmacists allowed to substitute therapeutically (i.e. dispense a pharmaceutical with equal therapeutic benefits (~ analogous substitution). Is this type of substitution obligatory? Are pharmacists allowed to substitute parallel imported medicines? Is this type of substitution obligatory?

### INN prescribing

Please elaborate on the developments and trends regarding INN prescribing in your country as of 2018:

* Are doctors allowed to prescribe generically? Do doctors receive an evaluation of their prescribing habits? Is it mandatory, i.e. Do doctors have to prescribe by the International Non-proprietary Name (INN)? What happens if a doctor opposes to this?

### Other generic promotion

Please elaborate on the developments and trends regarding other generic promotion policies in your country as of 2018:

* Is the use of generic medicines promoted (e.g. among patients, doctors, pharmacists)? If yes, how and which measures are implemented (e.g. information campaigns).
* Are there special procedures to promote the use of generics such as lower prescription fees for generics or fast track pricing and reimbursement decision or faster launch?
* Why is the use of generic medicines promoted? Reasons for this could be to ensure access of patients to a greater variety of medicines, to enhance local generic manufacturers or for cost-containment reasons.

### Claw-backs

Please elaborate on the developments and trends regarding claw-backs / pay backs in your country as of 2018:

* Are claw-backs allowed in your country? If yes, please explain. When was it introduced? What is the legal basis? At which actors are the claw-backs targeted? What administrative arrangements and sanctions underpin these arrangements?

### Managed-entry agreements

Please elaborate on the developments and trends regarding risk-sharing schemes / managed entry agreements in your country in your country as of 2018:

* Do you have managed-entry agreements in your country? Are they common, or only applied in a few cases? (pls. provide some examples) Which types of MEA (financial schemes, performance-based agreement) do you have? What is the legal basis? Which actors / active ingredients / products /sectors (out-patient only or also in-patient?) are covered? Are results / evaluations available?

## Evaluation

* 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?
* Please describe briefly the evaluation measures in your country as of 2018. When writing this paragraph, please consider the following points:
* Are health-economic evaluations necessary for type of medicines (all, POM, OTC) and are there any differences? 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?
* Please provide a rough estimation on possible savings achieved from pricing, rational use or cost-containment strategies in medicines? Do you know other achievements concerning medicines (e.g. better compliance) due to these strategies?
* Do medicine shortages occur in your country? If yes, which products, sectors are concerned? What are the reasons for shortages and how do you deal with them in your country?

### Prescription monitoring

Please describe the developments and trends regarding prescription monitoring in your country as of 2018:

* Are there prescription guidelines (such as treatment guidelines) in your country in place? When was this measure implemented? Which authority / institution is in charge of the implementation? (E.g. government, universities, third party payers, research institutions, private industry / professional association research institutions? Many of these often produce annual reports, please provide the corresponding websites).
* What is the frequency of monitoring this measure? Are the results published? Please insert the link. 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.

### Pharmaceutical consumption monitoring

Please describe the developments and trends regarding monitoring of pharmaceutical consumption in your country as of 2018:

* Is pharmaceutical consumption monitored in your country (e.g. per region, per patient, per diagnosis)? When was this measure implemented?
* Which authority / institution is in charge of monitoring pharmaceutical consumption? (E.g. government, universities, third party payers, research institutions, private industry / professional association research institutions? Many of these often produce annual reports, please provide the corresponding websites). What is the frequency of monitoring this measure? Are the results published? Please insert link. 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.
* Are there computerised tracking systems for prescriptions in place? Are individual sizes of prescribed packages monitored? (Since in some countries physicians prescribe smaller size packages, which leads to higher cost for patients). Is the adherence to treatments monitored by monitoring the share of medicines actually dispensed

### Decision making tools

Please describe briefly the tools that are used in the decision-making process regarding medicines in your country as of 2018. When writing this paragraph, please consider the following points:

* Please state the legal national source for pharmaco-economic analyses. Since when are pharmaco-economic analyses applied? Who performs them? Is the provision necessary for obtaining market authorisation/ for the pricing decision/ to obtain reimbursement status?
* Are there Heath Technology Assessments (HTA) performed in your country? Are they used as a base for decision making?
* Are external audit reports available?
* Is your country involved in pre-launch activities, such as horizon scanning and forecasting? If yes, please elaborate (who is involved? Is there a systematic procedure e.g. with regard to reporting? Are the results published?

# 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.

## Organisation of the in-patient sector

* 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?

## Pricing and purchasing policies

* 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 an 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?
* Please describe the major purchasing policies (e.g. tendering or negotiations) used in the in-patient sector in your country as of 2018. If different purchasing policies are applied in your country (in parallel or one following the other one), please comment on their relevance. Should one purchasing policy follow another one (e.g. first central tendering, then direct purchases of hospitals) please indicate.
* 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?
* Do you have managed-entry agreements in your country in hospitals? Are they common, or only applied in a few cases? (pls. provide some examples) Which types of MEA (financial schemes, performance-based agreement) do you have? What is the legal basis? Which actors / active ingredients / products /sectors (in-patient only or also out-patient?) are covered? Are results / evaluations available?

## Procurement

* 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?

## Reimbursement

Please describe in this section how medicines used in hospitals are financed in your country as of 2018. Specify if the financing/reimbursement system is applied country-wide or for a majority of hospitals (e.g. public hospitals). When describing the system, please consider the following points:

* Does financing/reimbursement in the in-patient sector differ from the out-patient sector? Which legal provisions (e.g. Social Insurance Law) are relevant for reimbursement in the hospital sector?
* Who is the main “payer” of medicines in hospitals (e.g., NHS / SHI, state, owner of hospital, community / region)? Is funding of medicines covered by hospital budgets? Which budgets cover reimbursement for medicines in in-patient care?
* Are there co-operative funding ways for the reimbursement of medicines (e.g. does NHS / SHI pay a share of the medicines used in hospitals like in the Netherlands)? If yes, please give an example for specific illnesses or medicines. Are there specific budgets provided for specific medicines used in hospitals (e.g. for orphan drugs, for specific diseases, for high cost medicines)?
* At what level are medicines covered by hospital budgets for in-patient care (fully or partly reimbursed)?
* Are the criteria for funding of medicines in the hospital sector any different from the general sector?
* Are positive and/or negative list(s) applied in the out-patient sector also relevant for the in-patient sector?

If medicines are partly reimbursed, please answer the following questions:

* Do patients have to co-pay for medicines received during the treatment in hospitals?
* If yes: Do all patients have to co-pay? Are there exemptions for vulnerable groups?
* Which are the prerequisites? Note:
* How much do they have to co-pay? And in which form?

### Hospital pharmaceutical formularies

Please describe if there are hospital pharmaceutical formularies in your country as of 2018. When describing the system, please consider the following points:

* Are there separate hospital pharmaceutical formularies for each hospital?
* Do hospitals (which? – all public hospitals, hospitals of the same owner?) have joint hospital pharmaceutical formularies?
* Are there country-national hospital and regional hospital pharmaceutical formularies, possibly accompanied by individual hospital formularies?

### Pharmaceutical and Therapeutic Committees

* What is the role of the hospital pharmacists and the pharmaceutical and therapeutic committees – advisory or decision taking?

## Volume Control in the in-patient sector

* 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?

### Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policies and system in the in-patient sector, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prices, pharmaceutical expenditure and consumption.

* Are prices in the in-patient sector regularly monitored? If yes, by whom?

Please describe the developments and trends regarding monitoring of pharmaceutical expenditure in your country as of 2018:

* Is pharmaceutical expenditure monitored in the in-patient sector in your country (e.g. per region, per patient, per diagnosis)? Is this monitoring done for each hospital or for groups of hospitals? (Please specify in which hospitals, e.g. public hospitals, hospitals of a specific owner)? Is it possible to quantify the expenditure of pharmaceuticals for a given disease, for instance via a DRG.
* When was this measure implemented?
* Which authority / institution is in charge of monitoring prices? (E.g. the individual hospital, the government, universities, third party payers, research institutions, private industry / professional association research institutions? How many of these often produce annual reports, please provide the corresponding websites. Are the results presented and discussed (in meetings of hospital pharmacists and the hospital management)?
* What is the frequency of monitoring this measure? Are the results published? Please insert the link.
* What is the role of the hospital pharmacists with regard to rational use and monitoring?
* 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.
* Are there any generic promotion policies in place?
* Do medicine shortages occur in your country? If yes, which products, sectors are concerned? What are the reasons for shortages and how do you deal with them in your country?

### Decision-making tools

Please describe briefly the tools that are used in the decision-making process regarding medicines in the in-patient sector in your country as of 2018. When writing this paragraph, please consider the following points:

* 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 analyses also applied in the in-patient sector?
* Who performs the pharmaco-economic analyses?
* Is your country involved in pre-launch activities, such as horizon scanning and forecasting? If yes, please elaborate (who is involved? Is there a systematic procedure e.g. with regard to reporting? Are the results published?)

### Evaluation of measures

Please describe briefly the evaluation measures relevant in the in-patient sector in your country as of 2018. When writing this paragraph, please consider the following points:

* Are pharmaco-economic evaluations necessary for types of medicines (all, POM, OTC) and are there any differences?
* 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?

### Reports and results

Please describe briefly the evaluation / assessment reports relevant in the in-patient sector in your country as of 2018. When writing this paragraph, please consider the following points:

* Are there Health Technology Assessments (HTA) performed in your country? Are the HTA published? Do the HTA build the basis for decision-making?
* Are external audit reports available?

# Interface management and developments

This concluding chapter covers information about the interface management and the most important pharmaceutical developments for the health care system.

## Interface management

Please describe the relevance of interface management (i.e. mechanisms of co-operation between in-patient and out-patient sector) considering the following issues:

* Need for interface management: Please comment on the impact of pharmaceutical use in hospitals on the out-patient sector.
* Interface management: In terms of pharmaceutical care, how is interface management (in-patient/out-patient care) organised? Please provide some examples (good practice) of interface management?

## Developments

Briefly explain the most important changes 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.

# Bibliography

## Literature

Please include key references to relevant (academic) publications relating to your country used as sources of information within the PPRI Pharma Profile. The template of the PPRI 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:

*Studies / Books:*

HiT 2004  
European Observatory on Health Care Systems and Policies 2004  
Health Care Systems in Transition. Cyprus 2004

ÖBIG 2006  
Interface management of pharmaceuticals. Comparison of Austria and the Netherlands. Vienna: ÖBIG

PPRI 2008a  
Pharmaceutical Pricing and Reimbursement Information. PPRI Pharma Profile Austria 2008.  
Vienna: ÖBIG. In online: http://ppri.goeg.at/

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

*Journal articles:*

Vogler S, Espin J, Habl C,. Pharmaceutical Pricing and Reimbursement Information (PPRI) – New PPRI analysis including Spain. Pharmaceutical Policy and Law 2009;11(3):213-34

Vogler S, Zimmermann N, Habl C, Piessnegger J, Bucsics A. Discounts and rebates granted to public payers for medicines in European countries. Southern Med Review. 2012;5(1):38-46

*Book chapter:*

Rosian, I.; Habl, C.; Vogler, S.:  
Innovation im Arzneimittelmarkt. Frankreich, Großbritannien, Italien: In: Klauber, J. ; Schröder, H; Selke G.W. (Ed.): Innovation im Arzneimittelmarkt, Berlin / Heidelberg 2000

## Legislation

Please list any legislation that is relevant for the PPRI Pharma Profile regarding your country’s pharmaceutical system.

## Web links

Please list any relevant web links for further reading on your country’s pharmaceutical system.