Pharmaceutical Pricing and Reimbursement Information

COUNTRY

Month 2009

PPRI

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Pharma Profile

Final version, Month 2009

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Acknowledgements

Executive Summary

BACKGROUND [0.3 Pages]

This section should give a very brief overview on the key characteristics of the health care system as of 2009.

- Indicate the organization of the health care system (National Health Service or Social Health Insurance), the underlying law/decree (on an optional basis) and the date that the current system was implemented.
- 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?
- Which are the main actors in the health care system and what are their roles in the health care system (e.g. the Ministry of Health, other ministries, insurance funds, local government or private service providers)?
- Indicate if the health care is organized in a decentralized or centralized way in the country?
- What is the level of coverage and are there any exemptions to the scheme e.g. due to income, age etc.
- How is outpatient health care organized? Does the outpatient doctor act as gatekeeper for specialist care? How are outpatient doctors remunerated? Which relevance does inpatient care have in the system? How are hospitals generally remunerated?

PHARMACEUTICAL SYSTEM [0.5 Page]

This section should provide an overview on the relevant actors and their role in the pharmaceutical system as well as introduce some key data as of 2009.

- Name the major laws/decrees (on an optional basis) that are relevant for the current pharmaceutical system and briefly describe the country's medicines' policy.
- Name the main actors in the pharmaceutical system and name their responsibility (e.g. market authorization, pricing, reimbursement)
- Please shortly describe the situation on national pharmaceutical manufacturing companies and international companies in your country.
- Give an overview on pharmaceutical distribution in your country: what is the total number of companies with wholesale license? How many pharmacies are there in your country? Are they public/private? Are pharmaceuticals dispensed from other than pharmacies (dispensing doctors, drug stores, hospitals outpatient dept. etc.)?
- Give the total expenditure on pharmaceuticals and the public and private share of pharmaceutical expenditure. Briefly describe the development in sales of pharmaceuticals in

the last decade and describe the role of the national pharmaceutical market, its size and influence on pharmaceutical policy.

PRICING [1.0 Page]

This section describes the pricing procedures at different price levels for pharmaceutical as of 2009.

- Who is/are the main actor(s) in pricing pharmaceuticals and what responsibilities do this/these actor(s) have?
- Describe the main pricing policy/ies (statutory pricing, price negotiation, free pricing and/or public procurement) in your country for pharmaceuticals – with regard to the different type of pharmaceuticals (prescription medicines / OTC, hospital pharmaceuticals, innovative pharmaceuticals, generics, reimbursable / non-reimbursable pharmaceuticals.
- Describe who is involved in the pricing procedure? At what level (ex-factory, wholesale level) is the price set?
- Which criteria are taken into account in the pricing decision? Insofar are prices of the product in other Member States (external price referencing) or the prices of similar pharmaceuticals in your country (internal referencing) considered?
- Describe how wholesalers and pharmacists are remunerated (mark ups/margins/contractual relationships?) Does a national law regulate this? If mark ups are used, are these linear, regressive, or other? Does the mark up/margin regulation cover all pharmaceuticals, or only the prescription / reimbursable segment?
- What is/are the VAT rate(s) on pharmaceuticals? Is this the standard VAT rate or does the VAT applied to pharmaceuticals differ from normal VAT?
- Briefly describe the pricing related cost-containment measures (most important) used in your country.

REIMBURSEMENT [1.0 Page]

This section describes the scope of reimbursement of pharmaceuticals and the procedure of access to reimbursement, as of 2009.

- Who is/are the main actor(s) in deciding the reimbursement of pharmaceuticals, and what is their role?
- Indicate if and, if yes, how the reimbursement procedure is linked to pricing of pharmaceuticals (e.g. pricing only for reimbursable pharmaceuticals, access to reimbursement only after having been granted a price)?
- Does your country have a/some positive list(s) and/or a/some negative list(s)? If yes, who determines which pharmaceuticals that 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 what law/decree underline these schemes and when was this implemented?
- Please state if you country has a reference price system. If yes, when was this introduced? How is the reference price calculated? How are the pharmaceuticals clustered? Who decides on clustering/setting the referencing prices and the inclusion of pharmaceuticals in the reference price system?
- Please describe the situation around co-payments. Is there a flat prescription fee (which amount?)? Is there, due to the reimbursement rate, a percentage charge?
- Is there any difference between reimbursement of pharmaceuticals in the inpatient sector (hospitals) and the outpatient sector? If yes, who pays for inpatient medicine: hospitals directly or via special government budget? Are the eligibility criteria for reimbursement of pharmaceuticals in the inpatient sector any different from the outpatient sector? If yes, please describe.
- Briefly describe the reimbursement related cost-containment measures (most important) used in your country.

RATIONAL USE OF PHARMACEUTICALS [0.5 Page]

- Do doctors have access to updated treatment guidelines and a national formulary?
- How is advertisement of pharmaceuticals regulated?
- Are there measures implemented to control the prescribing and use of pharmaceuticals? E.g. obligatory budget constrains for prescribing doctors set by third party payer?
- Describe the use of pharmaco-economic analysis e.g. if it is mandatory for the process of market authorization, pricing, reimbursement or other?
- Is generic substitution allowed/obligatory in your country and if yes, please explain. Is the use of generic substitution promoted?
- Is individual consumption data monitored? If yes, how? Is there an essential medicines policy in place?

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS [0.2 Page]

In one paragraph please describe the current challenges to the system e.g. escalating costs, limited access, lack of efficiency etc. In one sentence please describe any planned systemic changes (e.g. plans to introduce a reference price system, plans to change the reimbursement categories etc.)?

Table of content

List of tables and figures

List of abbreviations

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

ATC	Anatomic Therapeutic Chemical classification
BMGFJ	Austrian Ministry of Health, Family and Youth
DG SANCO	Health and Consumer protection Directorate General
GDP	Gross Domestic Product
GGE	General Government Expenditure
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
GP	General Practitioner
HE	Health Expenditure
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity

PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
SHI	Social Health Insurance
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organisation
WP	Work Package

PPRI Pharma Profile Update 2009

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of more than 50 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals (for the list of PPRI members see the PPRI website http://ppri.oebig.at → Network)

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, which are called “PPRI Pharma Profiles”, were produced (see http://ppri.oebig.at → Publications → Country Information. These PPRI Pharma Profiles refer, in general, to the year 2006/2007. The work was mainly under the responsibility of the WHO Regional Office for Europe assisted by the team of the Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute (GÖG/ÖBIG).

Despite of the official end of the research project in 2007, the PPRI network participants have agreed to continue the network and up-date the PPRI Pharma Profiles.

Outline

The PPRI Pharma Profile consists of six chapters, referring to the situation in 2009:

- Chapter 1 (Background) gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.

- Chapter 5 (Rational use of pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budgets, prescription guidelines, patient information, pharmaco-economics, generics and consumption.
- Chapter 6 (Current challenges and future developments) is a concluding chapter on the current challenges and future plans for developments in the pharmaceutical sector.

Further deliverables

Besides the PPRI Pharma Profiles and the PPRI network, the PPRI project produced further deliverables, among those:

- The **PPRI Glossary**, which is a unique glossary of pharmaceutical terms to establish a common "pharma" terminology within the EU. See http://ppri.oebig.at → Glossary
- The **PPRI Conference**, held in Vienna in June 2007. See http://ppri.oebig.at → Conferences → PPRI Conference
- The **Set of Core PPRI Indicators** to compare information of different pharmaceutical system. See http://ppri.oebig.at → Publications → Indicators
- A comparative analysis, based on the developed indicators, filled with real data from 27 PPRI countries. The PPRI comparative analysis is included in the **PPRI Report** and summed up in the concise report "**PPRI at a Glance**". See http://ppri.oebig.at → Publications → PPRI Report and http://ppri.oebig.at → Publications → Concise Information

Contact

The PPRI Secretariat is located at Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) which featured as the main partner of the PPRI research project.

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1 Background (10% / 4-6 pages)

This chapter provides an overview of the country and its health care system as of 2009.

Note:

- For every heading, please try to give a country-specific overview. The questions below the headings should be seen as a support while writing this section. This means that some of the questions are not applicable to your country and you should ignore these.
- For clarification of the used terms and definitions (e.g. Social Health Insurance, National Health Service, acute care beds, outpatient doctors), please consult the PPRI Glossary (http://ppri.oebig.at → glossary).
- Please insert cross-references to other sections / chapters if appropriate.
- Please do not delete rows in tables but rather state: not available (= data missing) or not applicable.
- Please note that there is also the possibility to only fill out the **Short List for chapter 1**.

Source:

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

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

1.1 Demography

Please write a section on the demographic situation in your country as of 2009, including:

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

Please provide an overview by completing Table 1.1.

Table 1.1: Country – Demographic indicators, 2000–2008

Variable	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total pop.									
Pop. density per km^2									
Pop. aged 0-14 (% of total)									
Pop. aged 15-64 (% of total)									
Pop. aged > 64 (% of total)									
L. e. at birth, total									
L. e. at birth, females									
L. e. at birth, males									

L. e. = life expectancy, Pop. = population

Source:

1.2 Economic background

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

Please complete the Table 1.2.

Table 1.2: Country – Macroeconomic indicators, 2000–2008

Variable (in NCU = ____ * or percentage)	2000	2001	2002	2003	2004	2005	2006	2007	2008
GDP in NCU									
GDP / capita[1] in NCU									
GDP / capita[1] in PPPa									
Annual economic growth rate in %[2]									
General government expenditure (GGE)									
GGE in % of GDP									
Exchange rate (NCU per €), annual rate									

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

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

[2] variance to previous year in %

* Please indicate in which currency the data are provided.

Source:

1.3 Political context

Please write a section on the political system as of 2009, covering the following questions:

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

1.4 Health care system

This section should provide an overview of the organisation of your country's health care system as of 2009 and also outline the main actors, their roles and their decision-making powers within the health care system.

1.4.1 Organisation

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

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

1.4.2 Funding

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

Please write a section describing:

- The main sources of funding, i.e. social health insurance contributions or national / regional taxes;
  Please explain all current health care funding schemes shortly and show their relevance (i.e. predominant sickness fund(s) in case there are several like in Germany or Austria).
  - SHI: State the percentage of contributions by employers, employees, government or other in terms of salary / income.
  - NHS: If tax is earmarked, please indicate the share in percentage of GDP.
- The relevant legal framework (laws, enactments).
- Secondary sources of funding, e.g. Voluntary Health Insurance (VHI) or Out-of Pocket Payments (OPP) of patients.
- Total Health Expenditure (THE) in National Currency Units and in % of GDP.
- The level of Public Health Expenditure (Public HE) in percentage of Total Health Expenditure.
- The level of Private Health Expenditure (Private HE) and the source for Private Health Expenditure i.e. Out-of Pocket Payments, VHI etc.

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

Table 1.3: Country – Health expenditure, 2000–2008

Health expenditure	2000	2001	2002	2003	2004	2005	2006	2007	2008
THE in NCU (in_____)*									
THE in % of GDP									
THE per capita[1] in NCU									
Public HE in % of THE									
Private HE in % of THE									

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

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

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

Source:

1.4.3 Access to health care

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

1.4.3.1 Outpatient care

Please write a section describing the following issues:

- How is outpatient care practised? In outpatient clinics (“ambulatories”), by independent General Practitioners (GPs), by specialists or other?
- Are some types of patients (e.g. children, oncology patients) traditionally treated in outpatient clinics (“ambulatories”) rather than by GP's or specialists?
- Is there free choice of outpatient doctor (i.e. GP or specialist)? How often may an outpatient doctor be changed?
- Does the outpatient doctor practise privately or publicly?
- Does the outpatient doctor act as a gate-keeper for access to specialists and inpatient care?
- How are outpatient doctors paid? Capitation fees, fee-for Service, flat rate per service or other?
- Are there any Out-of Pocket Payments applicable to outpatient care? If yes, are these charges fully / partly reimbursed or e.g. covered by Voluntary Health Insurance?
- Please complete Table 1.4 to indicate the evolution of the number of outpatient doctors and outpatient clinics (“ambulatories”).

Table 1.4: Country – Outpatient care, 2000–2008

Variable	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total no. of doctors[1]									
No. of doctors[1] per 1,000 inhabitants[2]									
Total no. of outpatient doctors									
of which GPs[3]									
of which dentists									
No. of outpatient doctors per 1,000 inhabitants[2]									
No. of outpatient clinics departments ("ambulatories")									

GPs = General practitioners, No. = number

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

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

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

Source:

1.4.3.2 Inpatient care

Please write a section describing the following issues:

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

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

Table 1.5: Country – Inpatient care, 2000–2008

Variable	2000	2001	2002	2003	2004	2005	2006	2007	2008
No. of inpatient doctors[1]									
No. of inpatient doctors per 1,000 inhabitants[2]									
No. of hospitals									
No. of acute care beds									
of which in private sector									
Acute care beds per 1,000 inhabitants[1]									
Average length of stay in hospital									

No. = number

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

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

Source:

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

This chapter provides an overview of the pharmaceutical system.

Note:

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

Sources:

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

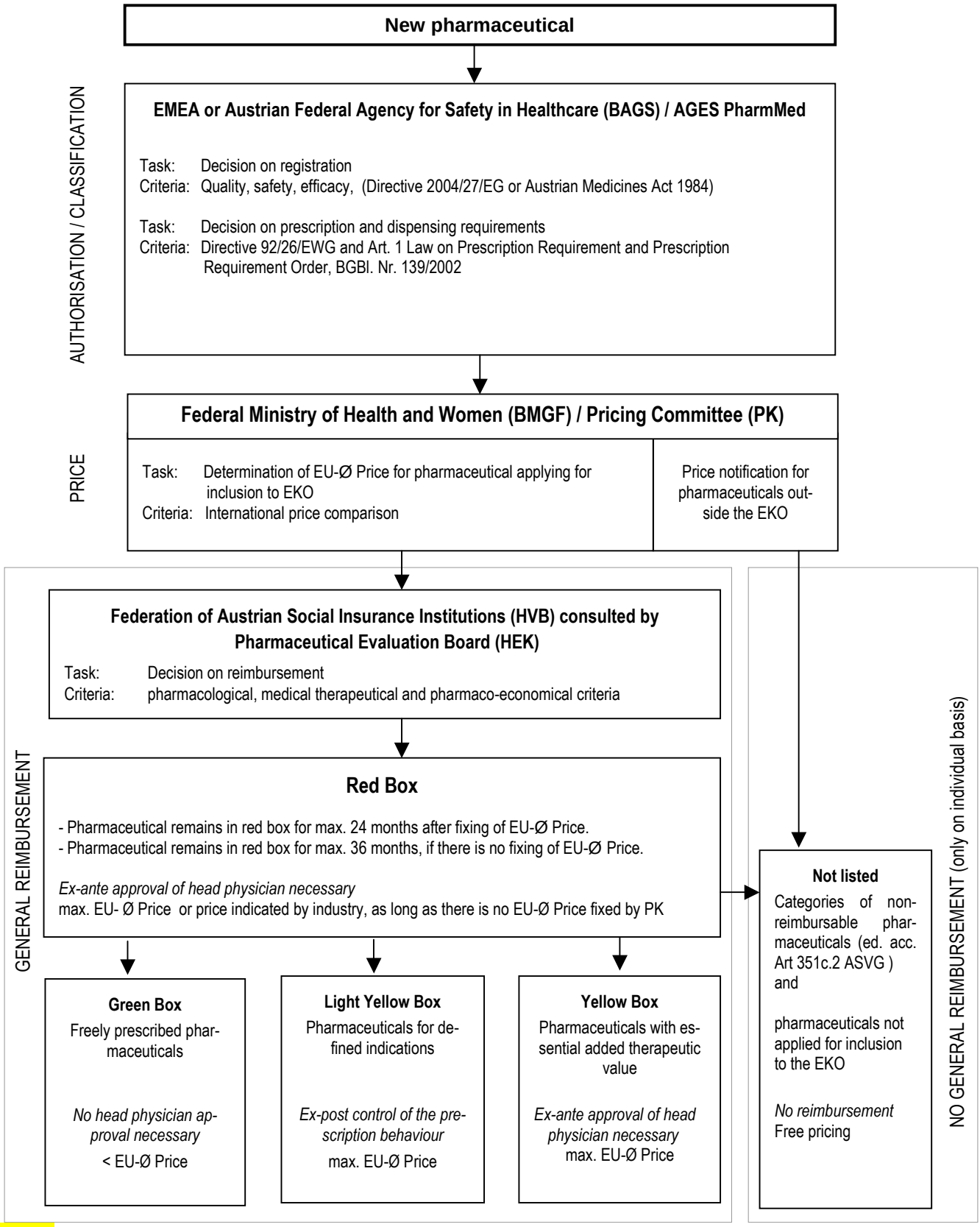
Please state for each table / figure which source, including the year, you have used.

2.1 Organisation

This section describes, on one hand, the regulatory framework (legal basis, main authorities and their tasks), and, on the other hand, the pharmaceutical market (data, key players) as of 2009. In case of relevant changes, please indicate here and in the relevant chapter/section.

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

Figure 2.1: Country – Flowchart of the pharmaceutical system (sample for Austria), 2009



Source:

2.1.1 Regulatory framework

This section includes a description of the legal framework for the pharmaceutical policy, the principal authorities and important players in this framework and their roles as of 2009.

2.1.1.1 Policy and legislation

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

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

Please inform if there have been the changes in the last two years.

2.1.1.2 Authorities

Please draw up a table, based on the example given in Table 2.1 that contains the relevant authorities and key regulatory actors (including Committees, Boards, etc. if relevant) as well as Third Party Payers as of 2009. For definitions please consult the PPRI Glossary.

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

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

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

How to complete the table:

- Description: please state if the actor is subordinate to another authority, the composition of a Committee and if it is an inter-ministerial Board, etc.
- Responsibility: please explain, for every authority (see example table from Germany):
  - What is the main role of the authority?
  - Which other roles does the authority have related to medicines?

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

Table 2.1: Germany – Authorities in the regulatory framework in the pharmaceutical system, 2009

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

Please include legends

Source:

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

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

In case there have been major structural and / or organisational changes in the last 3 years (e.g. establishment of a new authority, change in the competence of an authority, merger of

institutions, change in the composition of a Committee which gives certain actor more / less power), please note these.

2.1.2 Pharmaceutical market

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

2.1.2.1 Availability of pharmaceuticals

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

Be aware that the data is asked for as 1 of January. Indicate the method of counting e.g. active ingredient or active ingredient in a specific dosage form. Please also indicate what you count as a "generic". Please note that reimbursable pharmaceuticals are defined as those pharmaceuticals eligible for reimbursement (PPRI Glossary) and not those which are reimbursed.

Table 2.2: Country – Number of pharmaceuticals, 2000–2009[1]

Pharmaceuticals	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Authorised										
On the market										
POM										
Reimbursable										
Generics										
Parallel traded										
Hospital-only										
Others *(please include further lines if necessary)*										

POM = Prescription-Only Medicines

[1] as of 1 January

Please indicate method of counting:

– incl. / excl. different pharmaceutical form

– incl. / excl. different pack sizes

– incl. / excl. different dosages

Source:

Please write a section that explains / describes:

- Any particularities concerning a problematic situation with regard to availability, interesting developments, particular importance of a special group of pharmaceuticals.
- Differences between the number of pharmaceuticals registered and the number of pharmaceuticals on the market, and comment on possible reasons.
- The different classifications of pharmaceuticals, e.g.
  - Prescription-Only-Medicines (and possible sub-groups: prescriptions bound to certain specialities) and Over-The-Counter pharmaceuticals
  - Pharmaceuticals in the outpatient sector and Hospital-Only Medicines
  - Country-specific classifications (e.g. Eticas and Especialidadas Farmaceuticas Publicitarias in Spain)
  - Reimbursable and non-reimbursable pharmaceuticals (make a reference to the Reimbursement Chapter)
  - On-patent / off-patent pharmaceuticals and generics as well as parallel traded pharmaceuticals
- If there are special names / abbreviations in your language for these classifications, please indicate them.
- The actors deciding on these classifications and the criteria for decision
- Please write a few lines on switches (change from POM to OTC). Is there an overall policy on switches?

2.1.2.2 Consumption

Please fill out Table 2.3 and specify the definition of prescriptions (i.e. please the number of items which are allowed per prescriptions).

Table 2.3: Country – Annual prescriptions and consumption, 2000–2008

Consumption	2000	2001	2002	2003	2004	2005	2006	2007	2008
No. of annual prescriptions (in volume)									
No. of annual prescriptions in value (in NCU =____)*									
No. of annual consumption in packs									
No. of annual consumption in DDD									

DDD = Defined Daily Doses, No. = number

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

Source:

2.1.2.3 Market data

Please complete Table 2.4 and comment on it:

Table 2.4: Country – Market data, 2000–2008

In Million NCU = ____/€*	2000	2001	2002	2003	2004	2005	2006	2007	2008
Pharm. sales									
Sales at ex-factory price level									
Sales at wholesale price level									
Sales at PRP level									
Sales at hospitals									
Sales of generics									
Sales of parallel traded pharma-ceuticals									
Exports and imports									
Total pharm. exports **									
Total pharm. imports**									

NCU = national currency unit, pharm. = pharmaceutical, PRP = pharmacy retail price

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

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

Source:

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

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

Note: For definitions please consult the PPRI Glossary.

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

For Table 2.5, please list the top 10 best selling pharmaceuticals for 2008 or latest available year.

Table 2.5: Country – Top 10 best selling pharmaceuticals, by active ingredient, 2008 or latest available year

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

Source:

2.1.2.4 Patents and data protection

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

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

Under the recently adopted EU legislation authorities are also obliged to provide for data protection for an 8 + 2 + 1 year period. This provides for an additional protection period for patented drugs. Only after 8 years the medicines agency can process application for generic medicines under the EU Bolar amendment, which can then the marketed when the 10 year data protection period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and therewith delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

- With regard to access and public health issues, please comment if there is an explicit provision for compulsory licensing, parallel import and “government use” on patented products within the national legislation?

- Please also give some recent examples on court cases / lawsuits in relation to medicines patent protection? Describe any recent “ever greening” of patents (cases where companies seek extensions of market exclusivity by filing new patents on old drugs) or any other recent controversies around patent protection and / or data protection.

2.1.3 Market players

This section describes the key players in the pharmaceutical system except from the authorities which have been introduced in section 2.1.1.2 Authorities. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy making as of 2009.

2.1.3.1 Industry

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

- The different “branches” of pharmaceutical industry (research-oriented industry, generic manufacturers, biotechnology, raw materials). Please also name their interest associations.
- The usual distribution channel (e.g. via wholesale, direct distribution).
- The importance of industry to the economy of your country (with reference to data in Table 2.5)
- The role of industry in research and development, production, and as an employer.
- The relevance of local manufacturers versus international pharmaceutical companies
- The involvement of industry in pricing and reimbursement (e.g. framework agreements between industry and government, representation in Pricing Committees) and in particular in cost-containment (e.g. cap /”tax” on promotional expenditure, lower prices in return for reimbursement). Please cross-reference to section 5.3 Information to patients / doctors.
- The role of industry in policy making, e.g. industry initiatives on policy making?

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

Table 2.6: Country – Key data on the pharmaceutical industry, 2000–2008[1]

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total no. of companies									
– research-oriented									
– generic producers									
– biotech									
No. of persons employed[2]									

No. = number

[1] as of 1 January

[2] counted per head

Source:

2.1.3.2 Wholesalers

Please write a section on pharmaceutical wholesalers, including:

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

Please complete the table below:

Table 2.7: Country – Key data on pharmaceutical wholesale, 2000–2008[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total no. of wholesale companies									
Total no. of importers									
Total no. of outlets									

No. = number

[1] as of 1 January

Source:

2.1.3.3 Pharmaceutical outlets / retailers

Please write a section describing, as of 2009:

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

2.1.3.3.1 Pharmacies

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

- What regulations govern the pharmacies' activities, establishment and ownership? E.g., state if community pharmacies are privately or public owned and if ownership restrictions (e.g. only one pharmacy per owner) are applied?
- Are pharmacy chains allowed? Who are, generally speaking, the owners of the pharmacies? Give figures on number of pharmacies and type of ownership.
- What is the total share of pharmaceuticals dispensed in pharmacies in % of the total of consumed pharmaceuticals, indicated in both value and volume?
- What are the any important association of pharmacies / pharmacists? What is their role?
- Comment on the influence of the pharmacy association on policy making? If yes, at what level are the pharmacies involved in policy making?
- Comment on the remuneration of the pharmacies. Please indicate how pharmacists are paid: by profit margin per pharmaceutical dispensed capitation fee, a flat fee per prescription or a combination of these). Please cross-reference to section 3.5.2 Pharmacy remuneration.

- Are there any incentives for pharmacies to establish in rural areas? Is yes, please explain which. What regulations – if any – are there to guarantee a geographical spread of pharmacies across the country and therewith enhance the access to medicines?
- Please comment on the presence of POM dispensaries including branch pharmacies, dispensing doctors, and others such as university pharmacies (like in Finland), policlinic pharmacies (like in the Netherlands) and hospital pharmacies acting as community pharmacies.
- For community pharmacies and other POM-dispensaries, please indicate the total number and the number per 1,000 inhabitants. These numbers should be presented like in Figure 2.2.
- Please provide information on any potential vertical integration of wholesalers and pharmacies.
- Is distance selling, e.g. purchasing of pharmaceuticals via mail orders or internet allowed?
- Please comment on discounts / rebates given by industry and / or wholesalers to the pharmacies. Please cross-reference with section 3.6.1 Discounts / Rebates.

Please complete the table below:

Table 2.8: Country – Retailers of pharmaceuticals, 2000–2009[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
No. of community pharmacies[2]										
Thereof: No. of private pharmacies										
No. of public pharmacies										
No. of hospital pharmacies for outpatients										
No. of other POM disp.: ____										
Total no. of POM-dispensaries										
No. of internet pharmacies										
No. of OTC disp., like drugstores: _____										

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

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

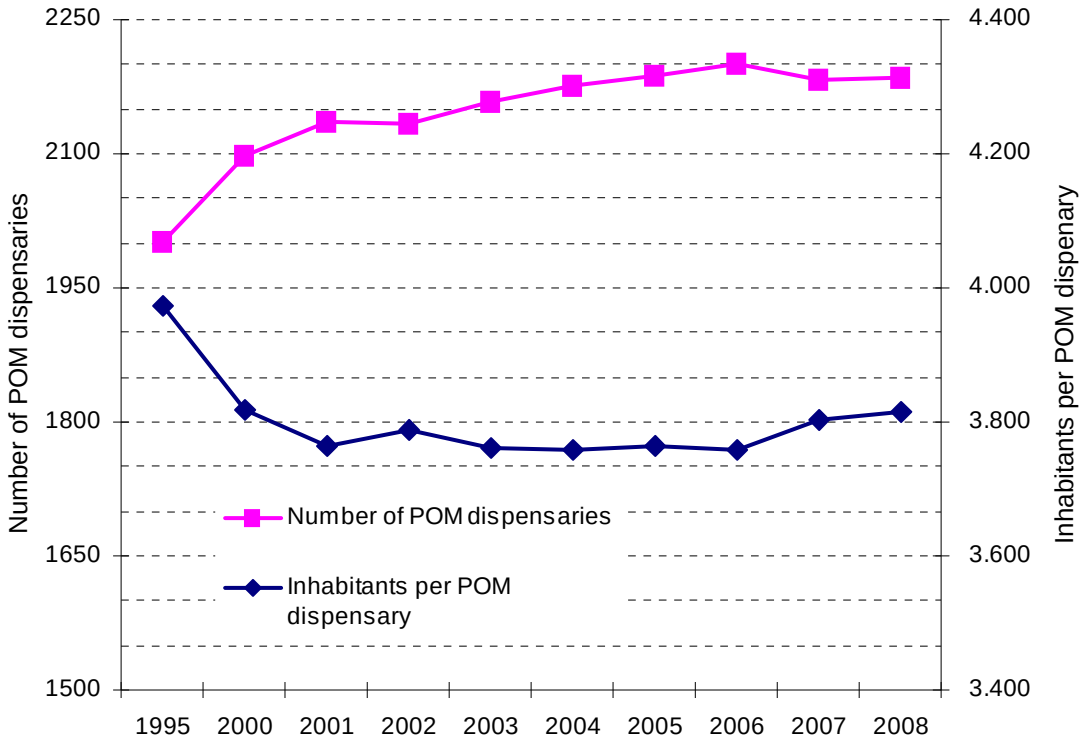
[1] as of 1 January

[2] incl. branch pharmacies

Source:

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

Figure 2.2: Austria – Number of retail pharmacies, prescription-only-medicines dispensaries and number of inhabitants per prescription-only-medicines dispensary, 1995 and 2000–2008



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

Source: Data gathering by GÖG/ÖBIG 2008

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

2.1.3.3.2 Other pharmacy outlets

Please briefly describe other pharmacy outlets:

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

2.1.3.3.3 Internet pharmacies

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

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

2.1.3.3.4 Dispensing doctors

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

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

Note: Information on e.g. dispensing doctors' specific reimbursement lists should be given in section 4.2.3 Reimbursement lists and specific mark up / margin schemes shall be added in section 3.5 Margins and taxes.

2.1.3.4 Hospitals

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

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

- Does the funding of hospital pharmacies (internal use / external use) differ from that of community pharmacies? (e.g. funding out of the hospital budget, different mark ups → please cross-reference to section 3.5.3 Remuneration of other dispensaries)

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

2.1.3.5 Doctors

Please write a section that:

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

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

2.1.3.6 Patients

Please write a section describing:

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

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

2.2 Funding

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

2.2.1 Pharmaceutical expenditure

In this section on pharmaceutical expenditure, please complete the Table 2.9 and comment in particular on:

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

Table 2.9: Country – Total pharmaceutical expenditure, 2000–2008

Pharmaceutical expenditure	2000	2001	2002	2003	2004	2005	2006	2007	2008
TPE in NCU = _____[1]									
TPE in % of THE									
TPE per capita[2] in NCU									
Public PE in % of THE									
Private PE in % of THE									

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

[1] Please indicate in which currency the data are provided. Please use preferably national currency.
[2] please use population data from Table 1.1 as basis for calculation.

Source:

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

2.2.2 Sources of funds

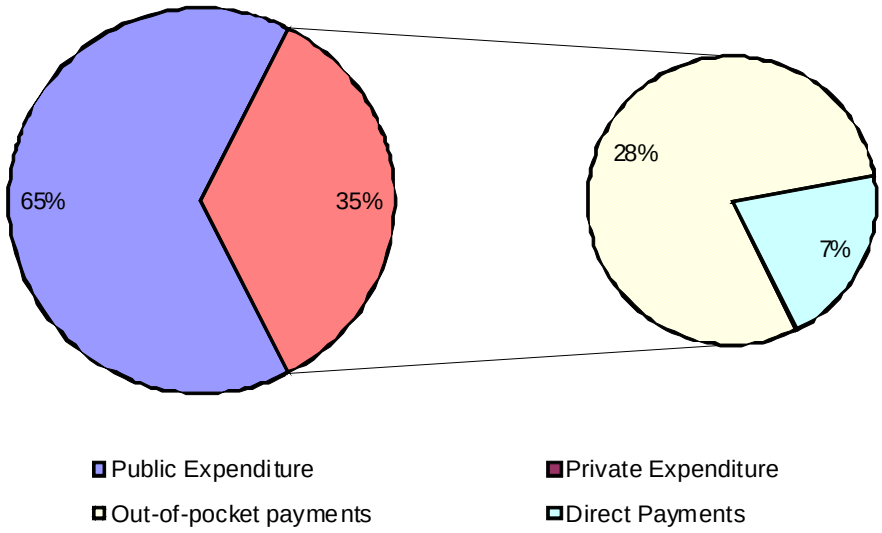
This section gives an overview of the funding of pharmaceuticals, in addition to the figures presented in Table 2.9. Please give information on:

- The main funding source(s) of public pharmaceutical expenditure (i.e. social health insurance contributions or national / regional taxes). Make a reference to health care funding in section 2.2 Funding. Please indicate the percentage of public pharmaceutical expenditure and comment on its development.
- Explain how private pharmaceutical expenses are made up:
  - Expenses for self-medication.

- Expenses for private health insurance funds (incl. voluntary supplementary insurances like Mutuelles).
- Out-of-Pocket Payments (percentage co-payment, fixed co-payment, deductibles, etc.)
- Expenses on non-reimbursed prescription medicines
- Informal payments

- If appropriate and possible draw a pie-chart showing the current relation of private to public pharmaceutical expenditure like shown in Figure 2.3.

Figure 2.3: Country – Share of private and public pharmaceutical expenditure, 2008 or latest available year



Source:

2.3 Evaluation

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

- What has been the main aim of implementing the above mentioned programmes?
- Which areas of the pharmaceutical policy are monitored? (e.g. medicines consumption, broken down in groups of drugs and by groups of patients; price trends of prescription medicines; development of co-payment levels per patient category; studies on outcomes of therapeutic interventions in defined clinical areas, regulatory action taken on quality of

medicines, or on medicines safety concerns, timing of reimbursement decisions and possible delays on market entry etc.)

- Is this routine monitoring or is this done through specifically commissioned studies?
- Which institution revises them? Government, universities, SHI research institutions, private industry / professional association research institutions? Many of these often produce annual reports, please provide the corresponding websites.
- Are there any specific indicators used? Please comment and provide examples.
- Have there been any written evaluations of the policies? If yes, are the reports publicly available? If so, please add a link to the publication and the institution behind the publication.

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

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

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

3 Pricing (20% / 8–12 pages)

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

Note:

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

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

Sources:

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

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

3.1 Organisation

This introductory section informs on the regulatory framework and organisational structure i.e. the main authorities and the legal background, as of 2009. Please cover the following:

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

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

3.2 Pricing policies

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

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

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

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

Table 3.1: Denmark – Ways of pricing of pharmaceuticals, 2009

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

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

Source:

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

- When was the current pricing system implemented?
- Do the price setting procedures differ depending on the type of pharmaceutical e.g. prescription-only pharmaceuticals, me-too products, generics, parallel traded pharmaceuticals?

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

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

- At what level are pricing decisions made? E.g. at manufacturer level, wholesale level, pharmacy level or other?
- Are price changes possible or is there a sort of price freeze / stop (please cross reference to section 3.6.3 Price freezes / Price cuts) in place?
- Explain if there are price ceilings / maximum prices and explain terms used in your country (e.g. “agreed prices” like in Bulgaria).
- Who may in which way and how often apply for price changes?
- Who decides on price changes?

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

3.2.1 Statutory pricing

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

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

3.2.2 Negotiations

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

- For which pharmaceuticals?
- At which price levels?
- Which authorities (incl. boards / committees) are involved?

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

3.2.3 Free pricing

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

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

3.2.4 Public procurement / tendering

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

3.3 Pricing procedures

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

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

Please complete Table 3.2 and comment on it:

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

Table 3.2: Country – Pricing procedures, 2009

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing			
External price referencing			
Cost-plus pricing			
Other, e.g. indirect profit control			

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

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

Source:

3.3.1 External price referencing

Please write a section that covers the following questions:

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

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

- Are there laws / decrees or other forms of formal rules for external price referencing (e.g. on the selection of countries for the country baskets)? If yes, please explain. If not, is this done as additional (informal) information?
- Which countries are included in the basket for external price referencing? Why were these countries chosen? Are there alternative countries in case there are no data from the selected countries? What happens if there are no data from the selected countries?
- Does the result of the price comparison directly influence pharmaceutical prices?

- How are the comparisons made? Please explain the methodological background answering questions like if the prices are adjusted according to purchasing power parity and what exchange rates that are used?
- Who provides the country price information? How is the data provided and in what way? In case a manufacturer provides the information, how does the authority check the information?
- What happens if the price in one of the reference countries changes (give details on price reviews in Section Price reviews and insert a cross reference)?

3.3.2 Internal price referencing

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

- Are there formal rules (e.g. on methodology) or laws / decrees on internal price referencing? If yes, please explain. If not, is this done as additional information?
- How are the reference pharmaceuticals that are to be compared defined (ATC level, formulation, pack size, availability etc.)?
- What type of information do companies have to deliver?
- Who undertakes the internal price referencing?

3.3.3 Cost-plus pricing

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

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

3.3.4 (Indirect) Profit control

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

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

3.4 Exceptions

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

3.4.1 Hospitals-only

Please describe - in a narrow sense:

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

3.4.2 Generics

Please describe:

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

3.4.3 Over-The-Counter pharmaceuticals

- Does the system for the pricing of OTC pharmaceuticals differ from the other pricing ways and procedures?
- If yes, in general or only in terms of reimbursement?

- Please name and explain the legal framework, procedures, if any.

3.4.4 Parallel traded pharmaceuticals

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

3.4.5 Other exceptions

Please state if other exceptions to the reimbursement scheme exist?

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy margin and mark ups, dispensing fees and sales taxes applied to pharmaceuticals, as of 2009.

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

Table 3.3: Country – Regulation of wholesale and pharmacy mark ups, 2009

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

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

Source:

3.5.1 Wholesale remuneration

This section, concerning wholesale remuneration as of 2009, should cover the following:

- How are wholesaler remunerated - via mark ups / margins or are there contractual relations between manufacturers and wholesalers?

- Are wholesale margins regulated by law / decree? If yes, which ones (please quote)? Please also indicate the date of latest update of regulations.
- Scope: which pharmaceuticals (e.g. all, only POM, only reimbursable pharmaceuticals) are covered?
- Is the government regulating the margins strongly as to limit the wholesaler's profit? If yes, is the type of regulation a linear margin or a regressive scheme?
- In case of a regressive scheme, please include a table with the scheme (cf. Table 3.4 with an example of the yellow and the green box of the Austrian Reimbursement Code).
- Please indicate the average wholesale margins for 2008 or the latest available year in terms of Pharmacy Purchasing Price (in total, and if possible for the reimbursable and the non-reimbursable market).
- Inform on planned changes in the margin system or refunding system for wholesalers.

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

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

Table 3.4: Austria – Wholesale mark up scheme, 2009

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

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

3.5.2 Pharmacy remuneration

Please describe in this section the pharmacy margins and other dispensing related remuneration applied to pharmaceuticals, including any potential differences according to the price of pharmaceutical or the type of pharmaceutical, as of 2009.

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

- How are pharmacists remunerated? Via mark ups / margins or via fee-for service or are there contractual relations between wholesalers and pharmacies?
- Are pharmacy mark ups / margins and / or fees regulated by law / decree? If yes, which ones (please quote)? Please also indicate the date of latest update of regulations.
- Scope: which pharmaceuticals (e.g. all, only POM, only reimbursable pharmaceuticals) are covered from
- Please indicate the average pharmacy margin for 2008 or the latest available year in terms of gross pharmacy retail price (in total, and if possible for the reimbursable and the non-reimbursable market).
- Inform on planned changes in the margin system or refunding system for pharmacists
- Show if margins or mark ups are different e.g. between reimbursable and non-reimbursable pharmaceuticals or between outpatient and inpatient use, please complete a table for both.

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

Table 3.5: Country – Pharmacy mark up scheme, 2009

Please provide a table – see example Table 3.4.

- Table 3.5 can be left out if not necessary, like for Greece, where a unilateral fixed flat percentage mark up is applied for all pharmaceuticals.

3.5.3 Remuneration of other dispensaries

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

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

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

3.5.4 Value-added tax

Please indicate the relevant VAT rates in 2009:

- Standard VAT
- VAT for pharmaceuticals (please specify if the VAT refers only to a group of pharmaceuticals and/or if there are split rates for different pharmaceuticals e.g. reimbursable / non-reimbursable)

- Please inform on changes in the VAT rates in the last few years (plus the reason for that) and on possible planned changes.

3.5.5 Other taxes

Are there, as of 2009, further taxes / fees on pharmaceuticals (e.g. a pharmacy fee per pharmaceutical dispensed or a general pharmacy tax like in Finland)?

3.6 Pricing related cost-containment measures

This section contains a description of the price control mechanisms currently used in your country in the last 5–10 years.

3.6.1 Discounts / Rebates

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

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

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

3.6.2 Margin cuts

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

3.6.3 Price freezes / Price cuts

- In case there is currently a price freeze applied in your country please explain the situation and name the involved stakeholders.

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

3.6.4 Price reviews

Please write a section answering the following questions:

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

Please cross-reference to section 2.3 Evaluation if appropriate.

4 Reimbursement (20% / 8–12 pages)

This chapter gives an overview of the reimbursement system, the reimbursement procedure and the regulation of reimbursement, as of 2009.

Note:

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

Sources:

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

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

4.1 Organisation

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities, as of 2009. Please write a section that answers the following questions:

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

- Can the reimbursement status of a pharmaceutical change? If yes, how?
  - If the patent runs out
  - If a competitor enters the market
  - If the price changes in your country
  - If the price changes in other countries has changed
  - Because of new evidence (EBM, Pharmaco-economics, etc.)?
  - Other, like switches
- What procedures precede a change in the reimbursement status?

4.2 Reimbursement schemes

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

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

4.2.1 Eligibility criteria

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

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

4.2.2 Reimbursement categories and reimbursement rates

Please describe the relevant reimbursement categories (e.g. fully reimbursed, partly reimbursed) and reimbursement rates in your country, as of 2009. Please complete Table 1.4 (add extra rows if necessary) and explain in detail:

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

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

Table 4.1: Country – Reimbursement of pharmaceuticals, 2009

Reimbursement category	Reimbursement rate	Characteristic of category

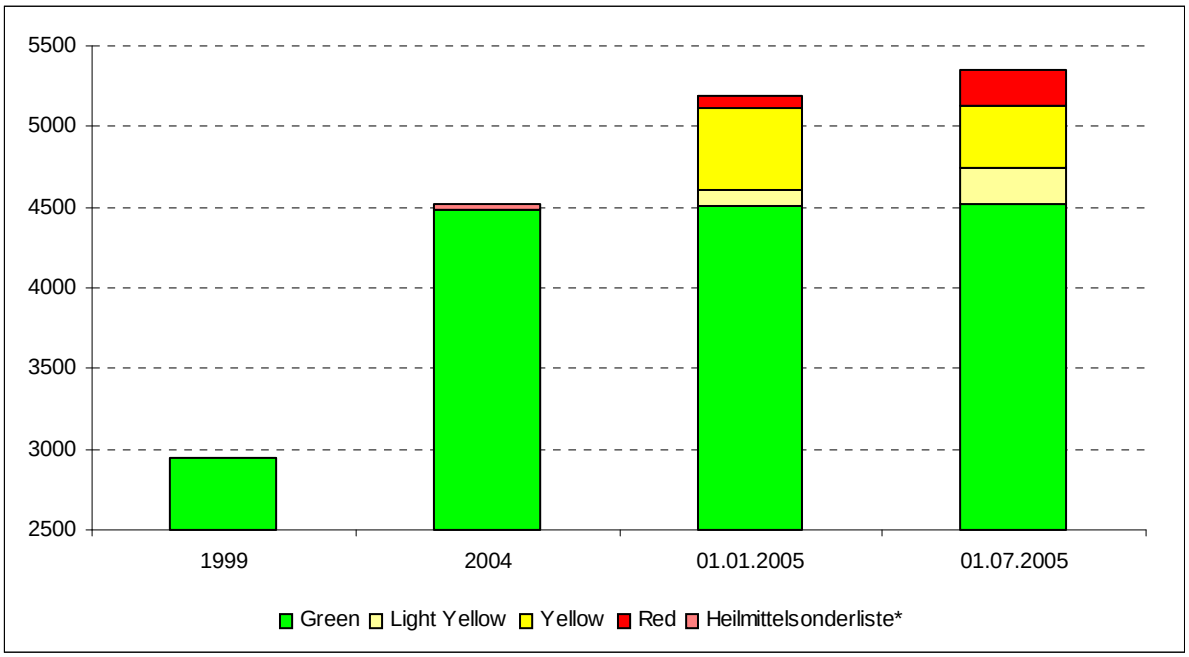
Source:

How to complete Table 4.1:

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

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

Figure 4.1: Austria – Development of pharmaceuticals in Reimbursement Code[1]



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

[1] Name of the Austrian positive list

* Pharmaceuticals being reimbursed under special conditions

Source: HVB 2005

4.2.3 Reimbursement lists

Please answer the following questions referring to the year 2009:

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

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

4.3 Reference price system

Please state if there is a reference price system in 2009? (Note: In case there is no reference price system applied in your country, please state it here (e.g. "*In Austria currently no reference price system is in place*:") Please state if there has been a reference price system in place in the past, like for example in Italy):

Please write a section covering the following questions:

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

4.4 Private pharmaceutical expenses

In this section, please describe with regard to the year 2009:

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

4.4.1 Direct payments

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

4.4.2 Out-of-pocket payments

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

Table 4.2: Denmark – Reimbursement rates and patient co-payment rates, 2009

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

1 before subtraction of reimbursement rate
2 A chronically ill patient in this context is defined as a patient who has a large consumption of prescribed medicine and accordingly large costs.
3 Includes all consumed pharmaceuticals (also not reimbursable pharmaceuticals prescribed by a doctor.

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

4.4.2.1 Fixed co-payments

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

4.4.2.2 Percentage co-payments

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

- Is there an annual or monthly out-of pocket maximum (ceiling)?

4.4.2.3 Deductibles

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

4.5 Reimbursement in the hospital sector

Please describe in this section how hospital pharmaceuticals are reimbursed in your country, as of 2009:

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

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

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

4.6 Reimbursement related cost-containment measures

Please write a section on reimbursement related cost-containment mechanisms currently implemented in your country in the last 5–10 years. For definitions please consult the PPRI Glossary.

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

4.6.1 Major changes in reimbursement lists

Please describe if there have been major changes in the reimbursement lists in the past 5 to 10 years.

State especially:

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

4.6.2 Introduction / review of reference price system

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

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

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

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

4.6.4 Claw-backs

Please describe:

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

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

4.6.5 Reimbursement reviews

Please write a section answering the following questions:

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

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

This chapter gives an overview of the current methods used to promote an equitable and efficient use of pharmaceuticals, as of 2009.

Note:

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

5.1 Impact of pharmaceutical budgets

Please describe the situation regarding pharmaceutical budgets as of 2009:

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

Please cross-reference to section 5.2 Prescription guidelines.

5.2 Prescription guidelines

Please describe the regulation of the prescription practice of doctors as of 2009, adding in any differences between outpatient and the inpatient sector. Please only explain the obligatory guidelines (legal framework) in more detail. It is sufficient to simply mention all indicative guidelines / recommendations and to insert links to these guidelines.

- Are measures implemented to control the prescribing and use of pharmaceuticals, like for example:
  - Treatment guidelines (i.e. guidelines on the prescribing of pharmaceuticals for a specific diagnosis):
    - When were these guidelines implemented?
    - Who is responsible for the implementation of the guidelines?
    - What is their content?
    - How is the adherence to these guidelines monitored? Are there any sanctions?
  - Monitoring of the sizes of the packages prescribed (in some countries family doctors prescribe smaller size packages, which leads to higher cost for patients)
    - Is this a known problem in your country? If yes, are actions taken to prevent this?
    - Are information systems used for monitoring prescribing patterns?
    - Do doctors receive the outcome of the monitoring?
- Is there a regular (e.g. annual) clinical audit of all doctors?
- Do doctors have access to information, like for example treatment guidelines, which helps them in selecting the pharmaceutical they want to prescribe?
  - Is this information available in a printed version and / or in an online database? Please explain.
  - By whom is this information being provided?
  - How often and in what way is the information updated, and who is responsible for this?
  - What is the role of national doctor's association in producing information?
  - Is information included about diagnostic limits, dose limits or duration limits for pharmaceuticals?

Please cross-reference to section 5.1 Impact of pharmaceutical budgets.

5.3 Information to patients / doctors

Please write a section on the regulation of the provision of information to patients and / or doctors as of 2009, answering the following questions:

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

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

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

5.4 Pharmaco-economics

Please describe the legal or regulatory use of health-economic analysis, as of 2009:

- Please state the legal national source for health-economic analysis.
- Is the provision of health-economic analyses necessary for obtaining market authorisation?
- Is the provision of health-economic analyses necessary in the decision on the price of a pharmaceutical?
- Is the provision of health-economic analyses necessary to obtain reimbursement status?
- Are health-economic evaluations necessary for type of pharmaceuticals (all, POM, OTC) and are there any differences?
- Since when are health-economic analyses applied?
- Who performs the health-economic analyses?
- Evaluation of pharmaco-economic guidelines:
  - Please give an overview of the content of the pharmaco-economic guidelines.
  - How often are the pharmaco-economic guidelines updated / revised?
  - Who is in charge of the evaluation of the pharmaco-economic guidelines?
- Does the country apply a maximum for what it is willing to pay for one QALY?

- Is the inpatient sector exempted from the application of these regulations?

Please cross-reference to section 4.6 Reimbursement related cost-containment measures if appropriate.

5.5 Generics

Please expand on the relevance of generics in your country.

Note: Pricing of generics is explained in section 3.4.2 Generics.

- Are there any legal regulations on the use of generics?
- Are generics mainly seen as cost-containment tool?
- Is the use of generics relevant in the inpatient sector?

Table 5.1: Country – Development of the generic market in the outpatient sector, 2000–2008

Generic market share	2000	2001	2002	2003	2004	2005	2006	2007	2008
Share of number of generic prescrip-tions as number of total prescriptions									
Share of expendi-ture for generics as percentage of total pharmaceutical ex-penditure									

Source:

In case that you have data on the "potential generic market" please include extra lines in the table. The "potential generic" market is the market where theoretically generics could be available because the patents have expired.

5.5.1 Generic substitution

Please give an overview of generic substitution in your country, as of 2009.

- Is generic substitution allowed in your country? If yes:
- Is generic substitution mandatory or voluntary? In case it is mandatory, please state the legal regulations for generic substitution.
- Are parallel imports included in the generic substitution system?
- Please explain if pharmacies are or allowed to substitute a generic for a branded pharma-ceutical (e.g. the originator)?

- Yes, but only if the doctor has written the prescription with its International Non-proprietary Name (INN).
- Yes, regardless if whether the doctor has prescribed a branded pharmaceutical or not.
- Yes, but with the doctor's explicit agreement.
- Yes, unless the doctor has explicitly indicated that the pharmaceutical should be substituted.
- Yes, but only with agreement of the patient (i.e. patient may oppose to substitution)
- Does opposition lead to consequences:
  - For doctors?
  - For patients? (e.g. higher co-payment)
  - For pharmacists?

- Are there incentives in place for generic substitution? If yes, please explain which?
  - Financial incentives?
  - Other incentives?
- Are pharmacies allowed to substitute therapeutically (i.e. dispense a pharmaceutical with equal therapeutic benefits (~ analogous substitution). Please explain.
  - Is this type of substitution obligatory?
- Are pharmacies allowed to substitute parallel imported pharmaceuticals? Please explain.
  - Is this type of substitution obligatory?

5.5.2 Generic prescription

Please give an overview of generic prescribing in your country, as of 2009.

- Are doctors obliged to write prescriptions generically? If yes, what happens if a doctor opposes to this?
- Does a doctor profit from prescribing generic pharmaceuticals? If yes, how?
- Do doctors have to prescribe by the International Non-proprietary Name (INN) or by a “brand” name?
- Is generic prescribing easily accepted by doctors?

5.5.3 Generic promotion

Please give an overview of generic promotion in your country, as of 2009.

- Is the use of generic pharmaceuticals promoted
  - Among patients?
  - Among doctors?
  - Among pharmacists?

- Why is the use of generic pharmaceuticals promoted? Reasons for this could be to ensure access of patients to a greater variety of pharmaceuticals, to enhance local generic manufacturers or for cost-containment reasons.

5.6 Consumption monitoring

Please describe the regulations of the consumption monitoring of pharmaceuticals, as of 2009. This section should also include an evaluation of the affordability and availability of pharmaceuticals in your country. Information on market data and sales are given in section 2.1.2.3 Market data.

- Is individual consumption data monitored? If yes,
  - How is this done?
  - Which authorities / institutions are responsible for monitoring consumption?
  - How is the information updated?
  - Is consumption of pharmaceuticals sold via internet also monitored?
- Is compliance data used in decisions regarding individual reimbursement? E.g. can a patient who has difficulties swallowing large tablets receive reimbursement for a more expensive pharmaceuticals (e.g. granules)?
- Is there an Essential Drug Policy in place? If yes, how many pharmaceuticals does it contain and how often is it updated?

6 Current challenges and future developments (max. 5% / 2 pages)

This chapter covers the most oppressing pharmaceutical challenges for the health care system and the future plans to meet these challenges.

6.1 Latest changes

Please sum-up the most important changes regarding the pharmaceutical system in the last 3–5 years (e.g. establishment of a Medicines Agency, change in the pricing methodology, change of reimbursement rates, introduction of a new form of out-of-pocket payment for pharmaceuticals, introduction of/change in a reference price system, generic substitution, etc.)

Table 6.1: Country – Changes in the pharmaceutical system, 2005–2009

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005			
2006			
2007			
2008			
2009			

Source:_____

6.2 Current challenges

Please write a section covering:

- An in-depth description of the main challenges that the pharmaceutical system currently faces.
  - Please state if this is your own view point or if this is a general opinion.

- Please provide sources and documentation if available.

Note: Please add sub-headings if necessary

6.3 Future developments

Please write a section covering:

- The long-term pharmaceutical policies which are:
  - Under negotiation
  - Already decided upon
  - Under implementation

Please describe the reasons for these pharmaceutical policies.

7 Appendixes

7.1 References

Please include key references to relevant (academic) publications relating to your country used as sources of information within the Pharma Profile. The template of the Pharma Profile uses the Harvard referencing system whereby citations are made within the text in parentheses, e.g. "(ÖBIG 2005)", and the full references are listed alphabetically in this section.

Examples:

Kutzin J (1998). The appropriate role for patient cost sharing. In *Critical challenges for health care reform in Europe*. R B Saltman, J Figueras and C Sakellarides (eds). Buckingham: Open University Press.

White Paper Caring for People: Community Care in the Next Decade and Beyond London: HMSO, 1989.

Witter S, Ensor T (1997). *An Intro to Health Economics for Eastern Europe and the Former Soviet Union*. Chichester, John Wiley & Sons.

World Health Organization (2002). WHO Traditional Medicine Strategy 2002–2005. Geneva: WHO, p. 7. Available at: http://www.who.int/medicines/library/trm/trm_strat_eng.pdf

7.2 Further reading

Please list any other relevant references for further reading on your country's pharmaceutical system.

7.3 Web links

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

7.4 Detailed description of authors

Please list the names of the authors who contributed to your country's PPRI Pharma Profile.