



Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

TEMPLATE

COUNTRY

Commissioned by the European Commission, Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health (BMG)

PHIS

Pharmaceutical Health Information System

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PHIS Hospital Pharma Report

Version 1.0, Month 2009

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Acknowledgements

Please list the institutions and persons who have supported you in drafting the PHIS Hospital Pharma Report, by providing information and data.

Executive Summary

Please sum up the major issues regarding pharmaceuticals in hospitals (in particular pricing and reimbursement):

- Background (defining what is a hospital, information on organisation and funding of hospitals)
- Pricing (purchasing of pharmaceuticals in hospitals and setting their price)
- Reimbursement of pharmaceuticals in hospitals (national inpatient reimbursement procedure and hospital pharmaceutical formularies)
- Consumption of pharmaceuticals in hospitals
- Evaluation (monitoring of prices, expenditure and consumption of pharmaceuticals used in hospital and assessment)
- Interface management (linkage between inpatient and outpatient sector)
- Developments and outlook

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List of abbreviations

Please add abbreviations used in your country and delete those you did not use!

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic Therapeutic Chemical classification
BMG	Austrian Ministry of Health
CIVAS	Centralized Intravenous Admixtures Service
DDD	Defined Daily Doses
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
EU	European Union
GDP	Gross Domestic Product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital Pharmaceutical Formulary
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute
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
OPD	Outpatient department(s)
OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals

PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
SHI	Social Health Insurance
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WP	Work Package

Introduction

PHIS research project

PHIS (Pharmaceutical Health Information System) is a research project commissioned under the call for proposals 2007 in the priority area “health information” of the European Commission, DG SANCO. It has been commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project aims at increasing knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union (EU) Member States, covering both the outpatient and the inpatient sector.

This will be done via different work packages (WP) resulting in the following deliverables:

- the PHIS Glossary with key terms related to pharmaceuticals,
- the PHIS Library offering country specific information on outpatient and inpatient pharmaceutical pricing and reimbursement for the EU Member States
- the PHIS Indicators and the PHIS Database, containing major data for the developed indicators in the Member States,
- the PHIS Hospital Pharma Report with information on pharmaceutical policies in the inpatient sector in the EU Member States, including a price survey

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), which is a research institute situated in Vienna, Austria, and four associated partners:

- the Italian Medicines Agency (AIFA)
- the International Healthcare and Health Insurance Institute (IHHII), Bulgaria
- SOGETI Luxembourg SA., which is a services provider, and
- the State Institute for Drug Control (SUKL), Slovakia

SUKL is the WP leader of Hospital Pharma.

Further key stakeholders of the PHIS project management are the PHIS Advisory Board covering EU Commission services and agencies and other international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project runs from September 2008 to April 2011 (32 months). Further information and all deliverables will be made available at the PHIS project website <http://phis.goeg.at>

PHIS Hospital Pharma

The aim of the work package “Hospital Pharma” is an in-depth investigation of the inpatient sector, as the current knowledge of pharmaceutical policies in this sector is rather poor.

The survey is divided in two phases:

Phase 1: General survey

Aim and description: Country reports on pharmaceuticals in hospitals (“PHIS Hospital Reports”), written by the country representatives of the PHIS network, based on a uniform outline, the “PHIS Hospital Report Template”

Time-line:

- Sending the draft PHIS Hospital Report Template to the PHIS network members for feedback – beginning of February 2009
- Sending the final PHIS Hospital Report Template to the PHIS network members allowing them to start working on it – end of February 2009
- Drafting of the country hospital reports by the PHIS network members – March to mid-April 2009
- Editorial process on the country hospital reports – mid-April to June 2009
- Presentation of results of the country hospital reports – PHIS Network Meeting on 8/9 June 2009

Phase 2: Case studies

Aim and description: A specific survey, including a price survey, provided by means of case studies, undertaken by the PHIS project management (in particular WP leader SUKL) in a limited number of hospitals in a few countries

Time-line: development of methodology in spring/summer 2009, undertaking the survey from September to November 2009

The deliverable, the PHIS Hospital Report, including reports of the general survey (phase 1) and the case studies (phase 2), will be provided by the WP leader SUKL in February 2010.

Methodology in the development of the PHIS Hospital Pharma Template

The PHIS Hospital Pharma reports are designed to describe specific pharmaceutical policies in the inpatient sector in the EU Member States.

The PHIS Hospital Pharma Report Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in EU Member States.

A review of available information from other projects included the following studies:

- ÖBIG FP 2008: Tendering of Pharmaceuticals in EU Member States and EEA countries, June 2008, Vienna
- ÖBIG 2006: Nahtstellenmanagement bei Arzneimittel, Vienna, September 2006
- McKee, M. and Healy, J.: Hospitals in a changing Europe, European Observatory on Health Care systems Series, WHO 2002
- Review of information from PPRI Pharma Profiles regarding hospital sector, and

personal communication with local stakeholders, and internet research with regard to the hospital sector.

Guide for authors

This is the PHIS Hospital Pharma Report Template for describing the pharmaceutical pricing and reimbursement system in the inpatient sector. Though the Template is based on a list of bullet points with questions and explanatory remarks, it is important, however, to write a **full descriptive text**.

In using this template for the PHIS Hospital Pharma Report please consider the following points:

- Please use the standard Word format of this Template as basis for writing your country profile.
- The authors are kindly asked to use the terms and concepts as defined in the PHIS Hospital Pharma Glossary, which will be provided by the PHIS project management, in particular by the Italian Medicines Agency AIFA (WP leader of the work package Terminology). Additional terms may be found in the PPRI Glossary (<http://ppri.oebig.at> → Glossary).

Note: Some definitions provided in the Glossary may be different than those used in your country. If possible, we ask you to use the preferred terms from the glossary.

- Please provide data using national / local sources (e. g. local health statistical yearbooks, annual hospital reports.) if available. You might also find relevant information in WHO HiT Profiles or in some sections of the PPRI Pharma Profiles.
- Please provide data preferably in NCU (National Currency Unit) in the tables – and indicate the name of the currency used in the tables. If you provide data in EURO €, use the relevant exchange rates for the respective years as listed at the website of the European Central Bank, see <http://sdw.ecb.int/browseSelection.do;jsessionid=D0BEF91C695DA4380A45E6C72484269A?DATASET=0&FREQ=A&node=2018794>
- Please use the Harvard Referencing System whereby citations are made within the text or as source under the Tables in parentheses e. g. (Taylor 1996) and the full references listed alphabetically in the References Section 8.

- Please include all the abbreviations used in the PHIS Hospital Pharma Report in the list of abbreviations.

The PHIS Hospital Pharma report on your country should be around 20 pages.

Contact

If you have any questions, please do not hesitate to contact SUKL, Slovakia (Work Package leader on PHIS Hospital Pharma) or GÖG/ÖBIG (PHIS project leader).

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Deadline

Please send the PHIS Hospital Pharma Report on your country to mazag@sukl.sk and phis@goeg.at in CC **by 17 April 2009**.

THANK YOU VERY MUCH FOR YOUR CO-OPERATION!

Dr. Jan Mazag
 WP Leader of PHIS Hospital Pharma
 Bratislava, Slovakia

Dr. Sabine Vogler
 PHIS Project Manager
 Vienna, Austria

1 Background

1.1 Definition and scope

This section starts by defining the key term hospital because it is crucial to have a clear and common understanding on the term hospital as there are differences among and within countries.

Please address the following points:

- Definition of a hospital: Does an official definition of hospitals and hospital care (e.g. laid down in law) exist in your country? Does this definition correspond to the OECD definition¹? If not, which are the major differences? Could you briefly comment on the role of hospital "ambulatory" services like ambulatory surgery for minor interventions, previously performed on a hospital basis.
- Definition of subtypes of hospitals: Are the subtypes of hospitals defined by OECD² also relevant in your country? Do you have instead or in a complementary way another relevant classification for hospitals in place (e.g. classification by ownership, cf. also section 1.2)?
- Scope and relevance: Is the definition of the term hospital and its subtypes relevant and applied for the description in the following sections of this country-specific PHIS Hospital Pharma Report? Does the description on hospital pricing, reimbursement and monitoring in this Hospital Pharma Report refer to all hospitals in your country? If not, could you please mention which hospitals are not covered and briefly explain the difference.

¹ OECD definition of a hospital: „This item comprises licensed establishments primarily engaged in providing medical, diagnostic, and treatment services that include physician, nursing, and other health services to in-patients and the specialised accommodation services required by in-patients. Hospitals may also provide out-patient services as a secondary activity. Hospitals provide in-patient health services, many of which can only be provided using the specialised facilities and equipment that form a significant and integral part of the production process. In some countries, health facilities need in addition a minimum size (such as number of beds) in order to be registered as a hospital.” Please be aware that nursing homes, which primarily provide long term care services particularly for the elderly, would not normally be considered as “hospital” of the purpose of this PHIS Hospital Pharma Report Template.

² a. general hospitals, b. mental health and substance abuse hospitals, c. speciality (other than mental health and substance abuse) hospitals; for a definition see the Glossary

1.2 Organisation

Please describe the organisation of the inpatient sector in your country, addressing the following points:

- Competence/legal framework: Who has the competence on accreditation, establishment, supervision on running and budget for hospitals? Is it regulated at federal, regional, district level? Please list and comment on the legal framework for hospitals and the most relevant Laws/Acts.
- Number of hospitals: Could you please provide data in Table 1.1 and comment on possible developments.

Table 1.1: **Country** – Key data on inpatient care, 2000 and 2004–2008

Inpatient care	2000	2004	2005	2006	2007	2008
No. of hospitals¹						
<i>Classified according to ownership</i>						
- thereof public hospitals						
- thereof private hospitals						
- thereof other hospitals (please specify)						
<i>Classified according to subtypes¹</i>						
- thereof general hospitals						
- thereof mental health and substance abuses hospitals						
- thereof speciality (other than mental health and substance abuse) hospitals						
No. of acute care beds						
- thereof in the public sector						
- thereof in the private sector						
Average length of stay in hospitals						
No. of hospital pharmacies						
thereof no. of hospital pharmacies that serve outpatients						

By filling in the Table, please indicate the correct numbers. Only in case that these numbers were not available, a percentage estimation could be indicated. In case that data on acute care beds are not available, you could also indicate hospital beds in general, but please specify.

Note: Data are indicated as of 31 December

Please be aware that, apart from hospital pharmacies, the data of this table are asked for the years 2000 to 2008 in Table 1.5 of the PPRI Pharma Profile Template 2009. Table 2.8 of PPRI Pharma Profile Template 2009 asks for the number of hospital pharmacies for outpatients (see <http://ppri.oebig.at> → Publications → Country Information)

¹ according to OECD definition and its subtypes **If you use another definition/classification, please specify.**

Source: _____

- Number of acute care beds: Could you please provide data in Table 1.1 and comment on possible developments (e.g. reduction in hospital acute care beds)? Could you please state in the text how many hospitals out of the total number of hospitals in your country are large hospitals (more than 300 acute care beds), how many are middle-sized hospitals (100 to 300 acute care beds) and how many are small hospitals (fewer than 100 acute care beds)? If you do not have the exact number, could please give an estimation or a percentage of the total number of hospitals?
- Ownership: Who are the main owners of hospitals? Are public hospitals (at federal, regional, district level) or private (profit or non-profit) dominating the system? Are there other ownership constructions (e.g. public ownership but having a private status)? Could you please provide some figures (at least for one year) regarding the number of hospitals and acute care beds in Table 1.1.
- Subtypes / specialisation: Is there a sort in specialisation of hospitals or is there a sort of hierarchy (e.g. only university hospitals taking care of severe diseases)? Are hospitals evenly spread throughout the country? Could you please provide some figures (at least for one year) in Table 1.1.
- Hospital stakeholders: Who are the main hospital stakeholders (national hospital association, hospital “cooperations” / hospital agencies)? Could you please name them? Please describe which kind of hospitals are organised in hospital associations?

Table 1.2: **Country** – Pharmaceuticals, 2000 and 2005–2009

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total						
- thereof hospital-only pharmaceuticals						

Note: In contrast to other tables, in Table 1.2 data are asked for as of 1 January, as this refers to administrative data.

Please be aware that the data for pharmaceuticals and hospital-only pharmaceuticals are asked for the years 2000 to 2009 in Table 2.2 of the PPRI Pharma Profile Template 2009.

Please indicate method of counting:

– incl. / excl. different pharmaceutical form

– incl. / excl. different pack sizes

– incl. / excl. different dosages

Source: _____

Please describe briefly the relevance of pharmaceuticals in hospitals and the role of hospital pharmacies (Note: The role of hospital pharmacists in pricing and reimbursement will be addressed at the relevant sections.)

- Hospital pharmaceuticals: Could you please inform us on the share/relevance of hospital pharmaceuticals and hospital-only pharmaceuticals? If possible, provide some figures (at

least for one year) in Table 1.2. For the definition of hospital pharmaceuticals and hospital-only pharmaceuticals see the Glossary.

- Delivery chain: Which distribution actors (industry, wholesaler, parallel traders, community pharmacies) are allowed to deliver pharmaceuticals to hospitals? Is there a difference in the delivery chain if a hospital has a hospital pharmacy or not? Which distribution actors deliver in practice to the hospitals? Maybe you could provide a flow-chart on the delivery chain.
- Hospital pharmacies: Do all hospitals have a pharmacy? Please provide the data (at least for one year) in Table 1.1. Please comment on the role and function of hospital pharmacies. How many staff usually work in a hospital pharmacy? Do private pharmacies operate in public hospitals? Do hospital pharmacies only serve inpatient or are they allowed to dispense to outpatients (like a community pharmacies)?
- Publications: Do hospitals produce annual reports? If yes, please indicate them in section 8 References and data sources.

1.3 Funding

Please describe the funding of the inpatient sector in your country, addressing the following points:

- Payers: Who are the main payers of funding hospitals in general and funding pharmaceuticals in hospitals (e.g. NHS / SHI, state, owners of hospitals, community / region)?
- Remuneration: How are hospitals remunerated? (e.g. payment per day, payment per case like the diagnosis-related group (DRG) system, line-item budgeting, payment based on procedure or service, global budgeting)?
- Hospital expenditure: Please fill in Table 1.3 and comment the data and developments. If it is not possible to fill out all years, please provide data for at least for one year.

Table 1.3: **Country** – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million NCU)	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)						
- thereof THE public						
thereof THE private						
THE in hospitals (HOSHE)						
thereof HOSHE public						
thereof HOSHE private						
Total pharmaceutical expenditure (TPE)						
- thereof TPE public						
- thereof TPE private						
Pharmaceutical expenditure in hospitals (HOSPE)						
- thereof HOSPE public						
- thereof HOSPE private						

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, NCU = National Currency Unit, PE = Pharmaceutical Expenditure, THE = Total Health Expenditure, TPE = Total Health Expenditure

Note: Data are indicated as of 31 December.

Please indicate in which currency the data are provided. Please use preferably national currency, please indicate the name of your currency.

Please fill in the exact data in NCU. Should it be not available, please provide an estimate in %.

If there are any specifications or limitations regarding expenditure data, could you please specify them in the notes under the Table.

Please be aware that the data for health expenditure and pharmaceutical expenditure are asked for the years 2000 to 2008 in Table 1.3 and Table 2.9 of the PPRI Pharma Profile Template 2009.

Source: _____

- Out-of pocket payments (OPP): Which OPP do patients have to pay for inpatient treatment?
- Cross-border care: How is the funding of pharmaceuticals being organised for patients from abroad?

2 Pricing

2.1 Organisation

2.1.1 Framework

This section presents the organisational structure and framework for purchasing pharmaceuticals in hospitals and setting their prices in the inpatient sector. Please describe the system for hospitals in general – in case that there should be too many differences (regional, due to the ownerships of hospitals), comment on them and try to present the most common ones.

In your description please address the following points:

- Legal framework: Is there a legal framework regarding pricing of hospital pharmaceuticals? If yes, could you please list the most relevant Laws/Acts indicating the date of their last revision.
- Price regulation: Are prices of pharmaceuticals in hospitals regulated? If yes, could you please describe how? (e.g. maximum prices)
- Decision-taking bodies/persons and process: Who has the power and responsibility to decide on the prices of pharmaceuticals? Are competent authorities or Third Party Payers (social insurance institutions) involved? Is pricing the responsibility of the owners of the hospitals? Can hospitals themselves decide on the prices? At hospital level and within hospitals, who is in charge of deciding on the prices of pharmaceuticals? Are there specific institutions (e.g. hospital purchasing / procurement agencies), specific bodies (purchasing committees), or specific persons (e.g. hospital management, clinical pharmacologist, hospital pharmacists, main physician in the respective field)? What is the role of hospital pharmacists (decision-taking or advisory)? Could you briefly describe the process of setting the price?
- Pricing policies: Which are the major pricing policies (e.g. procurement, negotiations). Please list them briefly and refer to section 2.2. where they will be discussed in further detail.
- Criteria: Which are the most relevant criteria for setting a price of pharmaceuticals? Possible criteria: Budgetary and financial limitations, prices of other similar products, medical and therapeutic benefits, health economics considerations etc.
- Exceptions: In case that there are relevant exceptions (e.g. for certain products, diseases, for private hospitals) could you please quote them?
- Summing up: Please conclude in a paragraph how pharmaceutical pricing in hospitals is organised, and which are the differences to the outpatient sector? (*This paragraph can be copied in the Executive Summary.*)

2.1.2 Hospital prices

As the prices might be difficult to understand, interpret and compare, could you please explain the structure of hospital prices:

- Type of price: Which type of price (ex-factory price, pharmacy purchase price, pharmacy retail price) does the “hospital price” correspond to? Is there an official price calculation scheme for hospital pharmaceuticals (maximum ex-factory price + maximum mark up + VAT)?
- VAT: Are pharmaceuticals sold to hospitals subject to VAT? If yes, at which VAT rate? Is there a difference to the VAT for other pharmaceuticals? If yes, does the “hospital price” include VAT?
- Mark ups: Are mark ups relevant for hospital pharmaceuticals? Are pharmaceuticals sold to hospitals including a wholesale mark up? Are hospital pharmacies allowed to add their own mark up when purchasing pharmaceuticals? If yes, is there any regulation on the (maximum) mark up; please explain and describe possible schemes.
- Discounts: Are there any mandatory discounts to hospitals from the suppliers? Are there voluntary discounts? Please describe and give – if possible – an estimation.
- Summing up: Please conclude which elements the “end price of hospital pharmaceuticals” consists of (ex-factory price, wholesale mark, VAT)? *(This paragraph can be copied in the Executive Summary.)*

In the general discussion, prices in the hospital sector are considered as considerably lower than in the outpatient sector. Could you please comment on the level of pharmaceutical prices in the hospitals:

- Level of hospital prices: Are the prices of hospital pharmaceuticals lower, equal and higher than pharmacy retail prices?
- Examples: In case that you should have any evidence for that at hand (e.g. a publication), could you please mention it here.
- Price survey: In case that you know of price surveys undertaken, could you please quote them (and if possible also sum up the key results), and indicate if these surveys were published (publicly available).

Could you please comment on the availability and transparency of pharmaceutical prices in the inpatient sector:

- Legal obligation: Is there any legal obligation for hospitals (e.g. for specific hospitals, e.g. public hospitals), for hospital groups or hospital owners either to publish the pharmaceutical prices or to notify the price to a competent authority? If yes, please quote the legal provision and briefly sum up its content? If yes, at which intervals the prices need to be published/notified?
- Public information: Is public information available on prices for pharmaceuticals in hospitals? If yes, could you please quote the source? If so, is the information freely available?

Which scope (which hospitals, which products, etc.) does the information cover? How often is it updated?

- Exchange of information: Do hospitals share among themselves the information on purchasing pharmaceuticals? If yes, which hospitals cooperate (e.g. hospitals of the same owner)? Who organises the exchange of information? (if necessary, please cross-reference to section 4.2).

2.2 Pricing policies

2.2.1 Procurement

Please comment the pricing policy of procurement, discussing in particular the following points:

- Legal framework: Which legal provisions at EU and national level (e.g. regarding obligation for procurement, publication provisions, mandatory discounts) need to be complied when purchasing pharmaceuticals via procurement?
- Scope: Is procurement the key / sole pricing policy? For which products, diseases, etc. is procurement mandatory or very common?
- Organisation: Do hospitals carry out their own procurement? Is there joint procurement for a group of hospitals used in practice? Is procurement done at the level of hospital purchasing / procurement agencies? Which suppliers (manufacturer, wholesaler) are addressed?
- Process: Who is involved in the procurement process? E.g. specific bodies (purchasing committees), the hospital pharmacy, main physician in the respective field)? Who has an advisory and who has a decision-taking role in the procurement process?
- Criteria: Which are the most relevant criteria for accepting a tender? Possible criteria could be: price of the offered product, budgetary and financial limitations, medical and therapeutic benefits, health economic considerations etc. Does a tender usually cover only one pharmaceuticals or a bundle of products (both pharmaceuticals and medical devices)?
- Frequency: How often does a procurement process take place?
- Publication: Where and how is the tender published? Are the results of the tender also published (due to a legal provision)? Are hospitals sharing information about the procurement process and its results?
- Information on prices: Do you have any information on the prices reached in procurement – in particular compared to the outpatient sector or other pricing policies used in hospitals? If yes, could you please give some examples. Which role do discounts play?

2.2.2 Others

If there are other pricing policies (e.g. negotiations, unilateral pricing) that play a role in the inpatient sector, could you please describe them, using a similar outline as for section 2.2.1. Please change the heading replacing “others” by the name of the pricing policy. If there are no other pricing policies, please state that explicitly: “There are no other pricing policies besides procurement.”

3 Reimbursement

3.1 National hospital reimbursement procedure

Please describe how reimbursement is organised at a national level. Please specify if the reimbursement system is applied country-wide or for a majority of hospitals (e.g. public hospitals). Please inform in particular regarding the following points:

- Legal framework: Which legal provisions (e.g. Social Insurance Law) are relevant for reimbursement in the hospital sector?
- Payers: Who pays for pharmaceuticals which inpatients receive when they are treated in hospitals? Reimbursement for pharmaceuticals in inpatient care is covered out of which budgets? Are there some cooperative ways of funding (e.g. the National Health Service / Social Health Insurance pays for parts of hospital pharmaceutical expenditure)?
- National reimbursement lists: Are positive and/or negative list(s) applied in the outpatient sector also relevant for the inpatient sector? Are there country-wide positive and/or negative list(s) specific for hospital use in place? If yes, could you please describe these lists with regard to
 - Number of pharmaceuticals on the list(s),
 - Involved actors and bodies in the decision-making process on the inclusion / exclusion of pharmaceuticals in the list(s),
 - Criteria for the inclusion / exclusion of pharmaceuticals in the list(s)– e.g. medical and therapeutic benefit, economics criteria like cost-effectiveness, budget impact, disease specific criteria like severity of illness, patient specific criteria like chronically or terminally ill patient
 - Intervals of updating these lists?
 - Is/Are the list(s) published? If yes, where? (please provide the link, if possible)
- Co-payments for pharmaceuticals in hospital care: At which level are pharmaceuticals used in inpatient care covered (fully or partly reimbursed)? Are there any other out-of-pocket payments for inpatients for pharmaceuticals (e.g. fixed co-payments, deductibles)?

- Specific budgets: Are there specific budgets provided for specific hospital pharmaceuticals (e.g. for orphan drugs, for specific diseases, for high cost pharmaceuticals).
- Hospital pharmacies: Are there any exceptions – e.g. in case of hospital pharmacies acting as community pharmacies for outpatients or for patients in day care, in outpatient departments (OPD)?
- Summing up: Please conclude in a brief paragraph how pharmaceutical reimbursement in hospital reimbursement is organised at national level, and if it is totally separate from the outpatient sector or if there are some common elements (joint positive lists)? (*This paragraph can be copied in the Executive Summary.*)

3.2 Hospital pharmaceutical formularies

Please describe pharmaceutical reimbursement at specific hospitals, in particular hospital pharmaceutical formularies (HPF):

- Scope: Are specific hospital pharmaceutical formularies common in your country (in all hospitals)? Do they exist in addition to country-wide positive / negative lists? Are they different from the country-wide positive / negative lists, or do they contain the same substances/pharmaceuticals? Are there separate hospital formularies for each hospital? Do hospitals (which? – all public hospitals, hospitals of the same owner?) have joint hospital formularies?
- Payers: Who pays for pharmaceuticals on hospital pharmaceutical formularies?
- Decision-taking bodies/persons and process: Who is responsible for setting, developing and updating HPF? Are there specific bodies (purchasing committees) or specific persons (e.g. hospital management, clinical pharmacologist, hospital pharmacists, main physician in the respective field)? What is the role of hospital pharmacists and Pharmacy and Therapeutic Committees (decision-taking or advisory)? Are pharmacists involved in setting rebates?
- Pharmacy and Therapeutic Committees: Who is involved in these Committees? Please describe their tasks and responsibilities. How much are they involved in setting up the hospital formularies?
- Process and criteria: How is the process of the decision on the inclusion of pharmaceuticals on the HPF going on? Which are the criteria (e.g. medical and therapeutic benefit, economics criteria like cost-effectiveness, budget impact, disease-specific criteria like severity of illness, patient-specific criteria like chronically or terminally ill patient)? Are there certain criteria / threshold which lead to the exclusion of the pharmaceuticals from the hospital formulary?

- Pharmaceuticals on hospital formularies: Could you please describe the HPF in case that this is possible at such a general level.
 - Are there one or several hospital formularies in hospitals?
 - Are pharmaceutical specialities or active substances listed? In case of pharmaceutical specialities, may they be replaced (decision by physicians or pharmacists?) by generics or other interchangeable pharmaceuticals? Could you please comment on the role of clinical pharmacologists and possible interactions with physicians in inpatient care?
 - How many pharmaceuticals or active substances are on the (different) lists?
- Updates: How often are the hospital formularies updated?
- Publications and binding character: Are they published – internally in the hospital and/or accessible for the publication? Are hospital formularies mandatory for physicians in hospitals, or may they also choose other pharmaceuticals for treatment (under certain criteria)?

4 Consumption of pharmaceuticals

This section provides information and data on consumption (utilisation) of pharmaceuticals in hospitals at a national level and informs on data availability at hospital level:

- Consumption data on a national level: Could you – if possible – fill out the following table. If you do not have the data, please state them and fill “n.a.” in the table. If you need to comment, to specify, please feel free to do so by adding comments in the legend.
- Consumption data at hospital level: Can (all) hospitals provide consumption data? Is it possible to quantify pharmaceutical consumption by every department? Is it possible to link up pharmaceutical consumption with the patient (i.e. a given unit with a given patient or by a ATC code)?
- Could you please fill in Table 4.2 indicating the Top10 pharmaceuticals in hospital use by consumption and by expenditure?

Table 4.1 **Country** – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in packs						
in DDD (Defined Daily Doses)						
In other measures units (e.g. unit doses, please specify)						
Annual pharmaceutical consumption in hospitals						
in packs						
in DDD						
In other measures units (e.g. unit doses, please specify)						

DDD = Defined Daily Doses, n.a. = not available

Please be aware that annual pharmaceutical consumption in total for the years 2000 to 2008 is also asked for in Table 2.3 of the PPRI Pharma Profile Template 2009.

Please fill out the measure units which are available in your country; preferably the data should be filled in for both packs and DDD.

Source: _____

Table 4.2 **Country** – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption 2007 or latest available year in hospitals

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	
7		7	
8		8	
9		9	
10		10	

Source: _____

5 Evaluation

5.1 Monitoring

Please describe the internal management and monitoring system and processes regarding consumption of pharmaceuticals:

- Monitoring in the inpatient sector on a country-wide, regional or other global level: Are expenditure, prices and/or consumption of pharmaceuticals used in hospitals monitored (e.g. per region, per patient, per diagnosis)? Is this done on a regular basis? Who does it? Are data/results publicly available (please provide the link) or only to a limited group (to whom)?
- Monitoring at hospital level: Are expenditure, prices and/or consumption of hospital pharmaceuticals monitored in some hospitals or groups of hospitals (please specify in which hospitals, e.g. public hospitals, hospitals of a specific owner)? Is it possible to quantify the expenditure of pharmaceuticals for a given disease, for instance via a DRG? Who in the hospitals is in charge of undertaking the monitoring process? Which indicators are applied? Are the results presented and discussed (in meeting of hospital pharmacists and the hospital management)? Is this a regular process or done occasionally? How is the relation between treatment guidelines and the hospital formulary?
- IT support: What is the level of computerized tracking systems in supply and use? In particular, which are the main aspects involved? (purchase order, inventory control, stock-taking, units of care supplies, record systems?)
- Role of hospital pharmacists: Describe the role of hospital pharmacists, in particular with regard to rational use and monitoring. Regarding the role of hospital pharmacists in the price setting and reimbursement process, please cross-reference to relevant sections in Chapter 2 Pricing and Chapter 3 Reimbursement. Please consider the following aspects:
 - Product services include preparation of sterile products, non-sterile products and Centralized Intravenous Admixtures Service (CIVAS)
 - Support services include purchasing, supply of drugs to ward and or to patient, education and training of personnel and patient, computer services, research and development
 - Clinical services include drug information, formulary services and recommendation of optimal drug therapy for the individual patient
 - Communication and interaction with other professionals, e.g. possible interactions of clinical pharmacologists with physicians in hospitals
- Traceability / tracking of pharmaceuticals: Could you please comment on traceability possibilities and possible projects for tracking pharmaceuticals in the inpatient sector in your country, in particular information on hospital sale (in volume and prices) for individual hospitals or generally for inpatient sector.

5.2 Assessment

- Cost-effectiveness / HTA reports: Are there special cost-effectiveness tools concerning pharmaceuticals in hospital settings (e.g. HTA reports)? If used, please describe briefly.
- Audit reports: Are external audit reports available?
- Cost-containment: Have there been cost-containment measures regarding pharmaceuticals taken in hospitals. If yes, which ones and when, and in which hospitals? With which results?
- Savings and other benefits: Could you – if possible – provide a rough estimation on possible savings achieved from pricing, rational use or cost-containment strategies in pharmaceuticals? Do you know other achievements concerning pharmaceuticals (e.g. better compliance) due to these strategies?

6 Interface management

Please describe the relevance of interface management (i.e. mechanisms of cooperation between inpatient and outpatient sector) considering the following issues:

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

7 Developments and outlook

Please provide comments on recent, currently on-going and planned initiatives, reforms, measures for the hospital sector:

- Recent and current changes: Have there recently been any reforms / initiatives / measures in the hospital sector? (at regulatory level and regional level)
- Outlook: Are there any reforms / initiatives / measures in the hospital sector planned in the near future? (at regulatory level and regional level)

8 References and data sources

8.1 Literature and documents

Please include key references to relevant (academic) publications relating to your country used as sources of information within the PHIS Hospital Pharma Report. The template of the PHIS Hospital Pharma Report uses the Harvard referencing system whereby citations are made within the text in parentheses, e.g. “(ÖBIG 2008)”, and the full references are listed alphabetically in this section.

Examples:

McKee M, Healy J (eds) (2002). Hospitals in a changing Europe. Buckingham: Open University Press

ÖBIG (2008): Tendering of Pharmaceuticals in EU Member States and EEA countries. Results from the country survey. Vienna

8.2 Contacts

Please indicate who helped you in compiling the report.

Were visits made to hospitals to collect data? Please indicate the hospitals and contact persons?

Additionally, people and institutions who/which provided information and data for this PHIS Hospital Pharma report should be mentioned under “Acknowledgements” (at the beginning of the Template).