PHIS Hospital Pharma Report

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

PHIS Hospital Pharma Report 2010

May 2010

Sabine Vogler (GÖG/ÖBIG)
Claudia Habl (GÖG/ÖBIG)
Christine Leopold (GÖG/ÖBIG)
Ján Mazag (SUKL)
Simone Morak (GÖG/ÖBIG)
Nina Zimmermann (GÖG/ÖBIG)

Assisted by:
Romana Landauer (GÖG/ÖBIG)

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

ISBN No. 13 978-3-85159-145-3

Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, A 1010 Vienna, Stubenring 6,
phone: +43 1 515 61-0, fax: +43 1 513 84 72, e-mail: name.surname@goeg.at

Foreword by Andrzej Rys

Together with the Member States, the European Commission works to promote and protect the health of European citizens.

In this context, the Commission has been actively engaged in supporting Member States to cooperate, network and share information as regards pharmaceutical policy. Medicines are one, but important, aspect of health policy.

The Pharmaceutical Health Information System (PHIS) was co-funded by the public health programme 2003-2008 in the priority area “health information”. Good information is an essential basis for better decision-making and resource allocation.

The PHIS Hospital Pharma Report is a major deliverable of the PHIS project, and it tackles an important field: the management of medicines in hospitals. This is an area on which several assumptions have been raised, but evidence-based information was little.

The European Commission is pleased that in this report the overwhelming majority of the 27 EU Member States are covered, which provides a good picture on the purchasing strategies, financing schemes and quality assurance mechanisms regarding medicines in hospitals across Europe. The additional case studies on selected countries provide clear and detailed information. We consider the PHIS Hospital Pharma Report as a valuable basis for decision-making.

We are aware of the fact that Hospital Pharma report is just one among several work packages of the PHIS project, which aims to provide comprehensive information about pharmaceutical policies on both the in-patient and out-patient sectors.

Andrzej Rys

Director Public Health and Risk Assessment

Health and Consumers Directorate General
European Commission

Foreword by Gernot Spanninger

Information on the pharmaceutical sector has usually been focused on the out-patient sector. Only little information was available on the hospital sector regarding medicines.

However, transparency needs to be comprehensive and has to cover both the out-patient and the in-patient sectors.

Therefore, the Austrian Federal Ministry of Health is pleased that Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (GÖG/ÖBIG) – Austrian Health Institute has initiated, together with the European Commission, the Pharmaceutical Health Information System (PHIS) project, which aims to provide information about pharmaceutical policies in the out-patient and hospital sectors. For achieving this objective, first-hand knowledge on the purchasing policies and financing strategies regarding medicines in the hospital sector had to be gained.

The results of the investigation of medicines management in hospitals are now available in the PHIS Hospital Pharma Report. The Austrian Federal Ministry of Health, which supports the PHIS project by co-funding, is in particular glad that this report surveyed and analysed, for the first time, the prices at which hospitals purchase medicines – compared to the prices in the out-patient sector.

We consider the PHIS Hospital Pharma Report as a pioneer's work in terms of transparency.

The outcomes of this report serve as an essential basis for the Austrian Federal Ministry of Health in decision-making. In future, both sectors – out-patient and hospital market – will be looked at when decisions about pharmaceutical policies are to be made.

Gernot Spanninger

Head of Department III/B/3

Austrian Federal Ministry of Health

Foreword by Kees de Joncheere

Over the last ten years there has been growing interest and action in networking on medicines pricing and reimbursement policies among the European countries, on initiative of countries themselves, and supported by the EU, WHO Europe and OECD. The PPRI Pharmaceutical Pricing and Reimbursement Information project, coordinated by then OEBIG (what is now Gesundheit Österreich) was a milestone: all participating countries wrote a comprehensive report on their pharmaceutical sector, and the project evolved into a sustainable network of policy makers who now regularly exchange information on pharmaceutical policy issues.

The PHIS project expands on this collaboration between the member states, as it focuses on the hospital medicines supply and it has brought in the expertise of the hospital sector, it widens the scope of the national pharmaceutical profiles, and it draws up a set of pharmaceutical policy indicators.

Medicines supply in hospitals is becoming increasingly important, both for patients as well as financially: hospital medicine use has effects on ambulatory care; hospital medicines are often difficult to manage and are used in complex clinical situations; and new hospital medicines often have high prices and have led to rapidly increasing costs.

This PHIS Hospital Pharma report is therefore a very needed and welcome addition to the growing information and evidence base on pharmaceutical policies for the European countries, as well as globally. It pulls together the information on the many different systems on medicines supply in hospitals, and - combined with the networking meetings and contacts - it supports countries in adjusting and improving their own systems based on best practices, evidence and experiences from other countries.

Kees de Joncheere

PHIS Advisory Board

Regional Adviser for Pharmaceuticals, WHO Europe

Foreword by Arno Melitopulos

Gesundheit Österreich GmbH (GÖG) has been established as a national research and planning institute for health care and a competence and funding centre of health promotion. Pharmaceutical policy research and analysis is a major area in the Health Economics department.

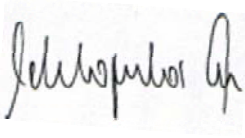
We are pleased that through the PHIS project GÖG continues its path as information provider and facilitator of pharmaceutical policies. The fact that the PHIS Hospital Pharma team pioneered in investigating medicines' management in hospitals, which is an area of little knowledge, was a challenge to us, and we are glad that we successfully completed this task.

As a Vienna based institute, GÖG is in an excellent position to build a bridge between the Western European countries and our neighbours in Central and Eastern Europe. Therefore, we are pleased that the PHIS project follows this tradition, by setting up a network of more than 60 institutions from 35 countries.

The novelty of the PHIS network is that it covers both the out-patient and the in-patient sectors. The PHIS network includes authorities being mainly in charge of out-patient pharmaceutical policies as well as hospital experts, hospital pharmacists and hospital associations. We were pleased to observe that during the project understanding for the interests and concerns of the representatives of "the other sector" and common trust could be built and strengthened.

One of GÖG's core values is to provide a neutral platform for stakeholders. In keeping the PHIS project and its network sustainable, we will continue promoting a dialogue and an exchange of information between representatives of the out-patient and hospital sectors in Austria as well as with further European countries.

Dr. Arno Melitopulos



General Manager

Gesundheit Österreich GmbH (GÖG)

Foreword by Jan Mazag

From the past, not only my country – the Slovak Republic – has seen a need for in-depth information on pharmaceutical systems in other countries, in particular in fellow Member States of the European Union.

Therefore a project like Pharmaceutical Health Information System (PHIS) not only offers information exchange in pharmaceutical policies but also the opportunity for networking between the countries of the EU territory and beyond. This enables us to introduce new and effective measures in pricing and reimbursement policies of medicines based on knowledge about practices in other countries.

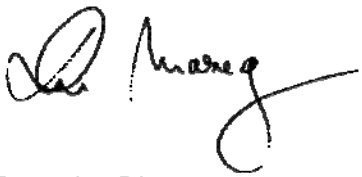
We welcome the objective of the PHIS project which is focusing on the in-patient pharmaceutical policies. We share the opinion that the in-patient sector plays a very important part of medicines policy. Therefore we appreciate our participation in PHIS project as active contributors for successful outcomes.

Even though I have already been involved in the PPRI project (cf. http://ppri.goeg.at) in the past, this time in PHIS I was directly responsible in my position as co-ordinator of the PHIS Hospital Pharma Work Package. Let me to express that when reading this report, you will find comprehensive information on pharmaceutical policies in the in-patient sector across EU countries together with the results from case studies for prices of selected medicines.

I want to thank the European Commission, the Austrian Federal Ministry of Health and the PHIS Advisory Board for their support. My special thanks go to colleagues from the Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG whom with I have had a chance to work in this project.

The information provided will undoubtedly contribute to a greater transparency and a better understanding of the pharmaceutical systems, and this will, in turn, assist countries in putting efficient provisional arrangements in place. It can also help us all to further develop and improve our pharmaceutical systems and policies especially in the in-patient sector, on the basis of positive experiences in other countries.

Dr. Jan Mazag



Executive Director
Coordinator of the Work Package Hospital Pharma
State Institute for Drug Control (SUKL)

Foreword by Roberto Frontini

Expenditures and reimbursement in hospitals across Europe are regulated in very different ways. There is no substantial transparency in the different use of medicines, in how the last are added to formularies and even whether hospitals limit the amount of drugs used. This lack of knowledge is detrimental in a time, where expenditures on drugs are increasing in all European countries and expensive innovations – whether real or deemed – are influencing budgets more and more.

Hospital pharmacists, as responsible for supply and distribution and together with the physicians for the choice of medicines in the formulary, will get from the Hospital Pharma Report relevant input in understanding the different models and this will help them to find out the best practice in their own hospital.

Different and no transparent prices in different countries as well as in the in- and outpatient sector reflect the national regulations. The most crucial point is to understand how formularies influence the expenditures in the primary care of the region. Being under high pressure to reduce drug costs in the hospital the pharmacist has to acknowledge his responsibility for the community choosing cost effective drugs in both in- and outpatient settings. To manage this important interface is not easy task. Very different models are in use across Europe and the overview provided by the Hospital Pharma Report is a valuable tool to understand best practices.

But in the future not only prices will influence decisions. Hospital pharmacists and doctors have to learn how to judge expensive medicines based on the evidence of trials. There is no longer place for high price drugs with little improvement of the outcomes. Health care professionals must deal with limited resources and find out the best for all patients and not only for few groups.

The most fascinating aspect of Europe is the diversity of cultures and how these are integrated in a continuous exchange of valuable experiences. The Hospital Pharma Report is an important piece of this experience.

Dr. Roberto Frontini

President
European Association of Hospital Pharmacists (EAHP)

Brief Summary

Information on medicines management in the in-patient sector has always been considered to be a “black box” compared to the knowledge available on pharmaceutical policies in the out-patient sector. In particular, prices of medicines used in hospitals are in general not known.

The work package Hospital Pharma of the PHIS (Pharmaceutical Health Information System) project, commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Federal Ministry of Health (BMG), aimed at bringing light into the black box of pharmaceutical procurement, distribution, pricing, financing and use in the in-patient sector.

This was achieved by country reports on medicines management in the in-patient sector (PHIS Hospital Pharma Reports), which were produced by representatives of the national competent authorities from 20 European countries, supplemented by concise country information by seven other EU Member States. In addition a survey, including a collection of prices, in hospitals of five case study countries was undertaken.

The present PHIS Hospital Pharma Report contains both a comparative analysis of medicines management in hospitals in 27 European countries and the findings of the case study survey.

A major result of the analysis presented in this report is the need expressed for an improved interface management between the in-patient and out-patient sectors, since the first treatment usually starting in hospital care influences the choice of medicines in the out-patient sector. There are, in particular in the Nordic countries, a few examples of cooperation regarding medicines management between the sectors (e.g. hospital pharmaceutical formularies coordinated with a list for the out-patient sector in Sweden). However there is still much room for improvement to achieve a well-functioning interface management.

Medicines used in hospitals are usually funded out of the hospital budget. They are included in the DRG or DRG-like system which exists as a remuneration scheme in many hospitals in Europe. Some European countries (e.g. France, the Netherlands) have introduced special financing schemes for some, usually very expensive, medicines used in hospital care. These medicines are not funded out of the hospital budget, but are either fully or partially paid separately by the social health insurance.

Medicines are normally supplied by the industry and wholesalers to the hospitals. Deliveries by hospital pharmacies or community pharmacies are possible and done in a few countries; this is especially the case if a hospital does not have a pharmacy of its own. In most European countries a relatively low share of hospitals is equipped with a hospital pharmacy. Even if in some countries (e.g. Czech Republic, France – for specified medicines, UK) hospital pharmacies may and do serve out-patients, the internal medicines management in a hospital is the primary task of the hospital pharmacy. Hospital pharmacists are among other things responsible for the rational use of medicines and they monitor the development of pharma-

ceutical consumption and expenditure in their hospitals. They are represented in the so-called Pharmaceutical and Therapeutic Committee and are thus involved in the decision about which medicines should be included in the hospital pharmaceutical formulary (HPF). Many hospitals have their own HPF which is a list specifying the medicines to be prescribed and used in hospitals. Other medicines may only be purchased on the basis of an extra justification by the prescribing doctor.

Medicines may be procured centrally by procurement agencies (e.g. AMGROS in Denmark and LIS in Norway which purchase for all public hospitals), by procurement groups (i.e. hospitals in a region and/or under the same management) or individually by hospitals. Different procurement methods are in place: tendering, competitive negotiations (e.g. so-called "market evaluation" in Slovakia) and direct procurement. In several countries there is a mix of different procurement policies. In eight European countries (Cyprus, Estonia, Italy, Latvia, Malta, Norway, Sweden, UK) all or the majority of medicines used in (public) hospitals are (centrally) tendered. In some further countries (e.g. Romania, Slovakia) some, rather expensive medicines (e.g. blood factors) are tendered at a centralised level, while further medicines are directly procured by negotiations of hospitals with suppliers. Individual negotiations at hospital level are carried out in many EU Member States, with a few countries (e.g. Austria, Germany) having individual negotiations as the major purchasing policy. But even those countries reported on an increase in tendering.

Prices achieved in the procurement process might be lower than the official list prices. This is attributable to the fact that in the in-patient sector discounts and rebates are common and their amount is not limited by law, as is the case for price reductions granted in the out-patient sector. As a result, discounts and rebates of up to 100% are possible and were reported for a few countries. In the European spectrum, discounts and rebates of 10%-20% are usual. Additionally, a few countries reported on the practice of medicines given cost-free to the hospitals while this practice is legally forbidden in other countries.

The results of the case studies analysing medicines management in a total of 25 hospitals in five countries (Austria, the Netherlands, Norway, Portugal, Slovakia) confirm the information provided by the European survey. A major focus of the case study survey was laid on collecting price data, as the actual prices which hospitals pay when procuring medicines are neither published nor shared among hospitals.

For the case study hospitals, the actual hospital prices were in fact lower, compared to the official hospital list prices and also to the out-patient prices. Discounts and rebates were granted, however the amount depended on the therapeutic class. If only an on-patent product was available on the market, then price reductions were less likely. In several cases hospitals paid a price equivalent to the official list price. Large price reductions could be achieved for products which were of strategic relevance for the suppliers (e.g. treatment of chronic diseases). These were also medicines which tended to be provided cost-free to the hospitals. In the case studies, cost-free medicines were a reality in Austria and Slovakia; and in Portugal some medicines were provided at very low prices, almost equalling to € 0.-.

Among the five countries of the case study price variations could be observed, with Norway having in general the lowest price level. However, within the countries the actual hospital prices of the medicines surveyed normally did not differ considerably between the hospitals.

Executive Summary

The PHIS (Pharmaceutical Health Information System) project, which was commissioned by the Executive Agency for Health and Consumers (EAHC) and is co-funded by the Austrian Federal Ministry of Health (BMG), 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 out-patient and the in-patient sectors.

One specific work package (WP) is PHIS Hospital Pharma, which has been managed by WP leader State Institute for Drug Control (SUKL), which is the Slovakian Medicines Agency, and the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG).

The aim of the WP PHIS Hospital Pharma was to gain knowledge on medicines management in hospitals in European countries. This objective was achieved by a two-tier approach:

- In a European survey, pricing and reimbursement strategies regarding medicines in the in-patient sector in the EU Member States and further volunteering countries were assessed. The policies are described in country reports (PHIS Hospital Pharma Reports) which were written by country representatives of the PHIS network (Ministries of Health, Medicines Agencies, social health insurance, hospital pharmacists). These country-specific PHIS Hospital Pharma reports are made accessible, after review at the PHIS website (http://phis.goeg.at).

- This general knowledge on medicines management in hospitals was deepened by case studies of several hospitals in five European countries. The case studies also include a collection of actual hospital prices for a selected number of medicines.

The present PHIS Hospital Pharma Report contains a comparative compilation of information and data of the European survey and the findings gained in the case studies.

European survey

In the European survey, results are provided for 27 European countries, thereof 25 EU Member States (all EU 27 except Greece and Luxembourg) plus two volunteering non-EU Member States (Norway and Turkey). These countries will be called PHIS countries. The information is based on the country reports (20 PHIS Hospital Pharma reports) and information and data provided by seven further countries.

Organisation

An official definition of a hospital exists in the majority of the PHIS countries. In de facto all countries the understanding of what is a hospital seems to conform to the OECD definition of hospitals, which is as follows: “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”.

The number of hospitals varies significantly among European countries. The relevant indicator of acute care beds per 1,000 inhabitants varies between 8.1 in Lithuania to 2.6 in the UK. On the whole, the number of acute care beds has decreased in European countries during the last years, as has the average length of stay.

Hospitals may either be general hospitals or specialised ones. Usually, the number of general hospitals outweighs – often considerably – the specialised hospitals.

In most European countries the public hospital sector is important whereas the relevance of the private sector is rather low. The majority of hospitals in Europe are in public ownership, with the states, regions or municipalities acting as major owner of hospitals. The dominance of the public sector is in particular reflected in the number of acute care beds where significantly more beds (about 90% of all acute care beds at European average) are in hospitals of public ownership or of non-profit private status (considered as part of the public sector) than in for-profit private hospitals.

Financing

In 14 of the 27 PHIS countries hospital care is predominantly funded through social insurance, whereas in the other countries hospital care is mainly funded by the state – mostly at federal level. Regions are the key payers of hospital care in Denmark and Italy. In Sweden, county councils fund hospital care. In 25 of the PHIS countries the funding institution(s) in the in-patient sector is/are the same as in the out-patient sector.

European hospitals are usually remunerated via a diagnosis-related group (DRG) system or a DRG-like system; with other remuneration schemes (e.g. fee-for-services) being additionally in place. However, the way the DRG-like systems are organised varies among the European countries. Patients usually do not need to pay out-of pocket for hospital care in the majority of PHIS countries.

On average 40% of total health expenditure in a country is spent on hospital care. Regarding pharmaceutical expenditure, which accounts for 19% of total health expenditure, less than one fourth of pharmaceutical expenditure is spent in the in-patient sector. However, these are rough averages based on a few countries, as national data collection and reporting on in-patient pharmaceutical expenditure is rather fragmentary in several European countries.

On European average, 75% of health expenditure is publicly funded, while this figure amounts to nearly two thirds regarding pharmaceutical expenditure. In general, the share of public funding appears to be higher in Western European countries than in Central and Eastern Europe.

Trastuzumab, rituximab, docetaxel, interferon beta-1a and etanercept are among the active ingredients which account for high expenditure in European hospitals. There is some, but not a remarkable pattern of different high-cost medicines used in hospitals in Western European compared to Central and Eastern European countries.

Delivery chain of medicines used in hospitals

16 European countries explicitly classify medicines for exclusive use in hospital care as hospital-only medicines (HOM). However, besides HOM a much greater variety of medicines may be used in hospitals, a fact which has an impact on the out-patient sector as the in-patient treatment influences the choice of medicines used in the consecutive out-patient treatment.

Medicines are usually supplied to hospitals either directly by the industry or through wholesalers. In a few countries (e.g. Latvia, Portugal and the UK) community pharmacies may also deliver medicines to hospitals. Parallel traders supply only in the Netherlands and the UK and are of minor relevance for the delivery to hospitals.

Not all hospitals in Europe are equipped with a hospital pharmacy. Whereas in France, Italy, Portugal, Romania and Sweden nearly all hospitals have their own pharmacy, this share is much lower in other European countries. Hospitals without a pharmacy of their own are normally supplied by other hospital pharmacies or community pharmacies.

The primary task of a hospital pharmacy is to serve in-patients. In fact hospital pharmacies exclusively serve in-patients in several countries. In some countries hospital pharmacies also serve out-patients, thus acting as community pharmacies. In a few countries, a second pharmacy for out-patients on the premises of the hospital is run by the hospital pharmacy.

Pricing framework

Pharmaceutical prices are regulated in nearly all EU Member States. In general, this price control is relevant for medicines on an overall level – whether the medicines are used in the out-patient sector or in hospitals. Denmark and Germany which have no price control at ex-factory price level in the out-patient do not apply it for the in-patient sector either.

Such a price regulation in the in-patient sector only targets the official hospital list price. It is a maximum price, often published in official journals or price lists. However, the actual hospital price achieved during the purchasing process might be lower as no limitations on discounts or rebates are in place in the in-patient sector (unlike the out-patient sector).

Procurement policies

Key policies for procuring medicines in the in-patient sector are tenders, which might be open or restricted, competitive negotiations and direct procurement (negotiations) between the supplier and purchaser.

In the PHIS countries medicines which are used in hospitals are mainly procured via tenders or direct negotiations. Procurement by competitive negotiations is the case in some countries (e.g. so-called “market evaluation” in Slovakia).

Many European countries apply a mix of different purchasing policies. There are a few countries where tendering is the sole or key policy for procuring medicines. In eight countries (Cyprus, Estonia, Italy, Latvia, Malta, Norway, Sweden, UK) all or the majority of medicines used in (public) hospitals are (centrally) tendered. For instance, in Denmark and Norway all medicines for public hospitals are procured at a centralised level by a national procurement

agency. Centralised procurement is usually carried out by Ministries of Health, social health insurance institutions or procurement agencies.

In some other countries (e.g. Romania and Slovakia) some medicines (mostly expensive products, e.g. blood factors) are tendered at a centralised level, while the remaining medicines are procured via direct negotiations between the hospitals and the pharmaceutical companies/wholesalers.

In countries where procurement both by tendering and by negotiations is carried out, the relevance of the policies differs between the countries. While several Western European countries reported on tendering being applied in a rather large number of acquisitions, direct negotiations by hospitals with suppliers (e.g. manufacturers or wholesalers) are the key purchasing policy in Austria, Germany and some EU Member States in Central and Eastern Europe. Tenders are only launched if required by EU legislation. Nonetheless, even these countries reported on an increased use of tenders.

In some countries direct negotiations might take place as a second step following (centralised) tenders. This allows hospitals to negotiate lower prices compared to the centrally procured prices.

Some countries have established regional procurement committees (e.g. Regional Therapeutic Committees in Italy or joint municipal authorities for primary health care in Finland), which are responsible for purchasing medicines for hospitals. Hospitals may join purchasing groups which procure together. Purchasing groups are formed by hospitals in the same region and/or under the same management.

Hospital prices

In some countries official hospital prices correspond to the ex-factory price or the net pharmacy purchasing price; however in the majority of PHIS countries they equal the gross pharmacy purchasing price, meaning that on the ex-factory price a wholesale mark-up plus a VAT rate is added. The wholesale mark-up for medicines used in hospitals might be the same as in the out-patient sector, but a few countries (e.g. Slovakia) have a specific hospital mark-up. Pharmacy mark-ups are irrelevant unless the hospital pharmacy serves out-patients or other pharmacies.

For the purchasers the actual hospital prices are of relevance, which might be lower due to different kinds of reductions granted in the procurement process. These might be discounts (i.e. price reductions under specific conditions), rebates (i.e. price reductions after the transaction has occurred), bundling (i.e. offering several products for sale as one combined product) or cost-free products (i.e. given to hospitals without payment). Apart from Italy, with the national health service asking for a 50% mandatory discount when public hospitals are supplied with medicines, no other obligatory price reductions are known for the in-patient sector in Europe. Commercial price reductions on a voluntary basis play an important role, ranging from above 0% to nearly 100%. In fact, discounts or rebates in the range from 10% to 20% are commonly applied in several European countries. The practice of providing

medicines cost-free to hospitals by manufacturers was only reported from five European countries. In some countries cost-free medicines are explicitly forbidden by law.

Information on hospital prices is only published regarding official or tendered prices. Actual hospital prices including discounts and rebates are neither publicly available nor shared among the hospitals.

Reimbursement

Although medicines are funded by the same payer in the in-patient and out-patient sectors in the majority of the European countries, the way they are reimbursed differs. Expenditure for medicines is normally covered out of the hospital budget which is based on a DRG or DRG-like payment scheme in many EU Member States. Additionally, some countries (e.g. France, the Netherlands) have introduced specific financing schemes for a group of medicines used in hospitals, in particular products accounting for high expenditure. These medicines are financed by separate budgets, their expenditure usually is borne by the social health insurance.

Medicines which are considered as reimbursable are included in a positive list. In some European countries the positive lists are only valid for the out-patient sector, but in a higher number of states the positive lists are also relevant for the in-patient sector (e.g. a specific part of the positive list is dedicated to medicines used in hospital care), or at least the out-patient list needs to be considered when deciding on the use of medicines in hospitals.

Additionally, in the majority of the European countries hospitals have hospital pharmaceutical formularies (HPF) to complement the national out-patient reimbursement list. These are mostly HPF applied in each hospital separately but joint HPF for hospitals within a hospital association are also possible. Denmark and Norway have HPF at regional level, and in France and Portugal a national HPF exists, which is supplemented by addendums at the level of the hospitals.

Usually, the decision about which medicines are included in the HPF is taken by the Pharmaceutical and Therapeutic Committee (PTC) or at least advised by this body. PTC are established in nearly all hospitals in the EU. They are normally composed of (chief) hospital doctors and (chief) hospital pharmacists plus the hospital management; in some countries further actors (e.g. chief nurse, representative of the primary care sector or social health insurance) are included. Besides the development and maintenance of the HPF, PTC might also be responsible for monitoring pharmaceutical expenditure and consumption in hospitals. Medicines which are not included in the HPF normally need a grounded reason by the prescribing doctor in order to be purchased.

Consumption

Country-wide data on pharmaceutical consumption in the in-patient sector is only available for a few countries, with methodological limitations due to different units of measurement among the countries. In the few countries having this kind of information available, in-patient pharmaceutical consumption ranges from 3% to 14% of total pharmaceutical consumption.

Active ingredients which account for the highest consumption in European hospitals include paracetamol, electrolyte, furosemide, acetylsalicylic acid, epoetin beta and albumin.

Evaluation

Monitoring of pharmaceutical consumption and expenditure is usually done at hospital level. Relevant data are usually prepared by the chief hospital pharmacist for discussion in the PTC.

Quite a number of countries reported on their monitoring of in-patient consumption and expenditure of medicines at national level. However complete and comparable country-wide data on in-patient pharmaceutical consumption and expenditure are missing for several countries.

Evaluations, including health technology assessments (HTA), on medicines used in hospitals are carried out in the European countries, but they range from well-established HTA structures and processes to evaluations being limited to only a few, mostly cost-intensive, products.

Interface management

The starting treatment in hospitals, often with expensive medicines, has a major impact on the out-patient sector as this influences the further choice of medicines prescribed after discharge of the patient. Due to the different remuneration systems in in-patient and out-patient health care the use of expensive medicines tends to be transferred from in-patient to out-patient sectors and the other way round.

The study showed a clear need for interface management which is defined as the mechanism of cooperation between the hospital and the out-patient sector. There are some examples of cooperation regarding medicines management between the sectors: hospital pharmaceutical formularies are coordinated with a list for the out-patient sector in Sweden, and a representative of social health insurance is included in the Pharmaceutical and Therapeutic Committees in some Austrian regions.

However, many European countries have not yet implemented specific interface management initiatives.

Case studies

The case studies were undertaken for a total of 25 hospitals in five countries (Austria, the Netherlands, Norway, Portugal, and Slovakia) and were mainly performed by study visits of GÖG/ÖBIG and SUKL staff and/or country representatives of the PHIS network (usually from the Ministry of Health or Medicines Agency).

For the price survey twelve active ingredients were selected based on defined criteria. Medicines which account for high expenditure in hospitals, but also products with available generic alternatives were included. The price survey aimed at comparing actual hospital prices achieved in the purchasing process for the same products in different hospitals and

compared to the official list prices, as well as showing possible differences in prices between the countries.

Price reductions

The price survey showed that the actual hospital prices of some products were lower compared to the official hospital list prices. This was due to price reductions granted by the suppliers to the purchasers (procurement agency, purchasing group, individual hospital) in the procurement process. A commonly applied form of price reductions is discounts at the time of buying medicines which were observed in a range from 1 to 100% for the case study hospitals. In Austria and Portugal retrospective rebates are granted to hospitals e.g. at the end of the year. The practice of providing medicines cost-free to Austrian hospitals was reflected in prices of € 0.- for some products.

The amount of price reductions considerably depends on the therapeutic class. In the case of just one on-patent product being available, price reductions are less likely. The survey showed, for instance, that for (mostly on-patent) oncologic medicines hospitals could not achieve any reductions and paid a price equivalent to the official list price. The availability of generics tended to result in lower price levels. Price reductions, including cost-free medicines, were observed for products which are of strategic relevance for manufacturers, i.e. medicines which are to be continued in the out-patient treatment. These are e.g. cardiovascular products for which price differences between the actual hospital prices and the official list prices were seen.

The same pattern regarding the amount of price reductions depending on the therapeutic class was reflected in the comparison of the actual hospital prices to the prices in the out-patient sector. For some products, a price difference of up to 30-50% between the in-patient and out-patient sector could be observed.

Intra-country and cross-country comparisons

In general, the actual hospital prices of the medicines surveyed did not differ considerably between the hospitals of a country. In some therapeutic classes (e.g. oncologic medicines), all case study hospitals in a country even reported the same price. Some price variations could be observed for immunomodulation and cardiovascular medicines.

The cross-country price comparison showed differences among the five countries selected for the case studies. In general, Norway tended to have the lowest price level.

Acknowledgements

First, we would like to thank our commissioners for providing a framework to undertake the PHIS project including the work package (WP) on PHIS Hospital Pharma which allowed us to gain insight into the "black box" of medicines management in the in-patient sector: We express our most sincere gratitude to the European Commission, European Agency for Health and Consumers (EAHC), represented by project officers Ms. Ann Thuvander and Ms. Jurgita Kaminskaite and to the Directorate General Health and Consumers (DG SANCO), represented by Mr. Jérôme Boehm, Mr. Artur Furtado, and Mr. Anders Lamark Tysse. Sincere thanks also go to the Austrian Federal Ministry of Health (BMG), especially to the Head of the Pharmacoeconomics Department, Mr. Gernot Spanninger.

The WP on PHIS Hospital Pharma was carried out by WP leader State Institute for Drug Control (SUKL) in Slovakia and project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG). The further members of the PHIS project management team (International Healthcare and Health Insurance Institute (IHHII) in Bulgaria, SOGETI Luxembourg SA. and the Italian Medicines Agency (AIFA)) were involved in discussions and reviews, and we want to thank them for their cooperation.

We express our appreciation for the continuous encouragement by the members of the PHIS Advisory Board:

- European Commission, Directorate General Health and Consumer Protection (DG SANCO): Mr. Jérôme Boehm, Mr. Artur Furtado and Mr. Anders Lamark Tysse
- European Commission, Directorate General Enterprise and Industry (DG Enterprise): Ms. Guilia del Brenna, Mr. Christophe Roeland and Mr. Stefaan van der Spiegel (till summer 2009)
- Executive Agency for Health and Consumers (EAHC): Ms. Ann Thuvander (till spring 2009) and Ms. Jurgita Kaminskaite
- Statistical Office of the European Communities (EUROSTAT): Ms. Dorota Kawiorska
- Organisation for Economic Co-operation and Development (OECD): Ms. Elizabeth Docteur (till spring 2009) and Ms. Valerie Paris
- World Health Organisation (WHO) Regional Office for Europe: Mr. Kees de Joncheere
- World Health Organisation (WHO) Headquarter: Mr. Richard Laing and Mr. Dele Abegunde

For the PHIS project management team, the PHIS Advisory Board served as primary contact for giving advice on methodology and content-related questions. Several times the PHIS Advisory Board members provided intensive feed-back on a range of papers and reports (among those, terminology clarifications, template of the country reports, methodology for the case studies). It was a pleasure to discuss crucial and challenging issues with them.

Furthermore, we would like to thank the members of the PHIS network, coming from over 60 institutions (competent authorities, social insurance institutions, hospital pharmacies and associations) in 35 countries for their endorsement of the project from the very beginning, by attending PHIS Network Meetings and the PHIS Hospital Pharma seminar, reviewing the documents sent out and providing feed-back. We are pleased that two associations, the European Hospital and Healthcare Federation (HOPE) and the European Association of Hospital Pharmacists (EAHP) are on board. Mr. Pascal Garel (HOPE) and Mr. Roberto Frontini (EAHP) provided valuable information and review.

In particular, we would like to thank the authors of the country-specific PHIS Hospital Pharma reports for doing research on medicines management in the in-patient sector in their country and for writing country reports on top of their existing work load. We also thank them for their patience in the review process and for providing and checking information in the course of the European survey.

Finally, we would like to thank the representatives of the countries in which the case studies were carried out. Besides Austria and Slovakia with the PHIS project management team being represented, these were:

- Ms. Margreet Schreurs and Mr. Harrie Storms of the Ministry of Health, Welfare and Sport, Netherlands;
- Mr. Torfinn Aanes of the Drug Procurement Cooperation (LIS), Norway and
- Ms. Isaura Vieira and Ms. Sonia Caldeira of the National Authority of Medicines and Health Products (INFARMED), Portugal.

PHIS network members of the case study countries supported us in organising the study visits, accompanied us to the hospitals and collected and validated information and data provided by hospitals. Without their help the case study survey could not have been undertaken.

A major contribution was provided by the hospital pharmacists and hospital management representatives of the 25 hospitals in Austria, Netherland, Norway, Portugal and Slovakia, which were chosen for the case studies. They offered us in-depth insight in medicines management in their hospitals and they shared price data with us. For guaranteeing anonymity, we cannot mention them by name here, but we would like to convey our sincere thanks to them.

Last but not least, we would like to highlight the contribution of our valuable assistant Ms. Romana Landauer at GÖG/ÖBIG for her continuous support and for layouting the report and of our copy-editor Ms. Marian Pink who safeguarded the high quality of this PHIS Hospital Pharma Report by proof-reading parts of it.

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ACSS	Administração Central do Sistema de Saúde / Central Administration of the Health System (Portugal)
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
AIP	Norwegian Pharmacy Purchase Price
ALOS	Average length of stay
APC	Area Prescribing and Medicines Management Committees (United Kingdom)
ATC	Anatomic Therapeutic Chemical classification
BGN	Bulgarian Lev
BMG	Bundesministerium für Gesundheit / Austrian Ministry of Health
CEE	Central and Eastern European Countries
CHNM	Código Hospitalar Nacional do Medicamento / National Hospital Code for Medicines (Portugal)
DBC	Diagnosis and Treatment Combination (The Netherlands)
DDD	Defined Daily Doses
DG Enterprise	Directorate General Enterprise and Industry
DG SANCO	Directorate General for Health and Consumer Protection
DRG	Diagnosis-related Group
€	Euro
EAHC	Executive Agency for Health and Consumers
EAHP	European Association of Hospital Pharmacists
EEA/EFTA	European Economic Area/European Free Trade Association
EKO	Erstattungskodex / Reimbursement List (Austria)
EMINet	European Medicines Network
EU	European Union
EUROSTAT	Statistical Office of the European Communities
FTE	Full Time Equivalent

GHPS	Government Health Procurement Services (Malta)
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HIV	Human Immunodeficiency Virus
HOM	Hospital-only Medicines
HOPE	European Hospital and Healthcare Federation
HOSPE	Hospital Pharmaceutical Expenditure
HPF	Hospital Pharmaceutical Formulary
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute (Bulgaria)
INN	International Non-proprietary Name
LVL	Latvian Lats
LIS	Norwegian Drug Procurement Cooperation
LKF	Leistungsorientierte Krankenanstaltenfinanzierung / Austrian DRG model
NCU	National Currency Unit
NHPF	National Hospital Pharmaceutical Formulary
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence (United Kingdom)
NIS	National Insurance Scheme
NOK	Norwegian Krone
NPC	National Prescribing Centre (United Kingdom)
NZa	Nederlandse Zorgautoriteit / Dutch Health Care Authority (The Netherlands)
Mio.	Million
MoH	Ministry of Health
MS	Multiple Sclerosis
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute

OECD	Organisation for Economic Co-operation and Development
OPP	Out-of Pocket Payments
PCT	Primary Care Trust
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
PPI	Pharma Price Information (a service offered by GÖG/ÖBIG)
PPP	Pharmacy Purchasing Price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PTC	Pharmaceutical and Therapeutic Committee
RHA	Regional Health Authorities
SFK	Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics (Netherlands)
SHA	System of Health Accounts
SHI	Social Health Insurance
SUCH	Serviço de Utilização Comum dos Hospitais / Common Use Service of Hospitals (Portugal)
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
TNF	Tumor Necrosis Factor
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
VsZP	Vseobecna zdravotna poisťovňa / General Health Care Insurance (Slovakia)
WHO	World Health Organisation
WP	Work Package
WS	Wholesaler
ZRIG	Hospital Pharmacists Rijnmond Purchasing Group (The Netherlands)

List of countries

AL	Albania
AT	Austria
BE	Belgium
BG	Bulgaria
CA	Canada
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IS	Iceland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
TR	Turkey
UK	United Kingdom
ZA	South Africa

1 Introduction

1.1 Objectives and framework of the PHIS project

Pharmaceutical Health Information System (PHIS) is a research project commissioned under the call for project proposals 2007 of the programme of Community Action in the field of public health (2003-2008) 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 is co-funded by the Austrian Federal 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 out-patient and the in-patient sectors.

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

- PHIS Terminology: in order to increase a common understanding and to support a common language in reports and communication, the PHIS Glossary (cf. Annex I) comprising terms on pharmaceutical policies was developed (accessible at the PHIS website, see below);
- PHIS Monitoring: an information system including up-dated country reports (as of 2010) on pharmaceutical pricing and reimbursement policies in the out-patient and in-patient sectors in the EU Member States and beyond (PHIS Library) will be established;
- PHIS Indicators: based on a set of indicators for pharmaceutical policies (PHIS Taxonomy is available and accessible at the PHIS website[1]) the PHIS Database will be developed and filled with data of the EU Member States; and
- PHIS Hospital Pharma.

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 BG), Bulgaria
- SOGETI Luxembourg SA., which is a service provider, and
- the State Institute for Drug Control (SUKL), Slovakia

[1] http://phis.goeg.at

The PHIS project management is supported by the PHIS Advisory Board which is comprised of the commissioning party EAHC, EU Commission services DG SANCO and DG Enterprise, EUROSTAT, OECD and WHO (WHO Headquarter and WHO Europe).

Another objective of the PHIS project is to build a network of EU Member States representatives who provide information and data on their countries and to disseminate information on the PHIS project and its outcomes. Currently, the PHIS network comprises 35 countries, including all 27 EU Member States plus eight volunteering countries (Albania, Canada, Croatia, Iceland, Norway, South Africa, Switzerland, and Turkey). The network covers representatives from competent authorities (Medicines Agencies, Ministries of Health) and social insurance institutions, which are in charge of out-patient pharmaceutical policies in most countries, as well as hospital pharmacists and experts. The associations HOPE (European Hospital and Healthcare Federation) and EAHP (European Association of Hospital Pharmacists) are also members of the PHIS network.

The PHIS project runs from September 2008 to April 2011 (32 months). Reports and deliverables are made available at the PHIS project website http://phis.goeg.at.

1.2 Objectives and deliverables of PHIS Hospital Pharma

The choice of medicines needed for treatment in hospitals has a major impact on the medicines supplied for the patients after their discharge. However, knowledge on medicines management in hospitals is rather poor outside the in-patient institutions. Analyses of pharmaceutical policies and descriptions of pharmaceutical systems usually focus on the out-patient sector, and the need for information on the in-patient pharmaceutical sector has been increasingly expressed (PPRI 2008).

Therefore, the PHIS project devotes a full work package (WP) to medicines management in hospitals. This PHIS Hospital Pharma WP was led by WP leader Slovak Medicines Agency, SUKL. Additionally, the aspect of in-patient pharmaceutical policies is a central issue for the whole PHIS project and is thus included in all the other work packages as well.

The aim of the PHIS Hospital Pharma WP was to gain knowledge on medicines management in hospitals in the European Union. This objective was achieved by a two-tier approach:

1. European survey:

   In a first step, pricing and reimbursement strategies regarding medicines in the in-patient sector were surveyed in the EU Member States and described in country reports (PHIS Hospital Pharma Reports) written by the country representatives of the PHIS network. The main issues covered were: the major purchasing strategies for medicines in hospitals, their funding, the role of hospital pharmacies / hospital pharmacists and of the Pharmaceutical and Therapeutic Committees (PTC), hospital pharmaceutical formularies and interface management.

2. Case studies:

   On the basis of the information gained in this European general survey, the knowledge was deepened by case studies of hospitals in some of the countries. The specific investigation included a price survey in order to analyse the level of prices of medicines in the in-patient compared to the out-patient sector.

The methodology for both surveys will be described in chapter 2.

This PHIS Hospital Pharma Report is the contractually agreed deliverable of the work package PHIS Hospital Pharma. As described in the next section, it summarizes the results of the European survey in a benchmarking exercise and presents the results of the case studies.

Further key deliverables of PHIS Hospital Pharma are the country-specific reports (PHIS Hospital Pharma Reports), which have been drafted for several countries and are, as soon as they are finalised, accessible on the PHIS website[2]. A PHIS Hospital Pharma Report template, as a basic outline for country reports on the in-patient pharmaceutical sector, was developed and is available at the website. By the end of May 2010 twelve country reports (Austria, Bulgaria, Cyprus, Denmark, Finland, Latvia, Malta, the Netherlands, Norway, Slovakia, Turkey, United Kingdom) have been published. The reports are included in the Annex of this PHIS Hospital Pharma Report (Annex V). The PHIS Hospital Pharma Report template was taken into account when developing the template for the PHIS Pharma Profiles covering both the in-patient and out-patient sector. Finally, a relevant deliverable produced in another work package is the PHIS Glossary (cf. Annex I), which contains relevant terms for the in-patient sector applicable for this report as well as for the hospital country reports.

As a dissemination activity the PHIS Hospital Pharma seminar was organised in Bratislava on 26 February 2010 where the results of the PHIS work package Hospital Pharma were shared and discussed with an interested audience.

1.3 Outline of the PHIS Hospital Pharma Report

Based on the two-tier approach of the PHIS Hospital Pharma work package, this report is divided in two major parts.

Following chapter 2 on the methodology for both the European survey and the case studies, chapters 3 to 8 will be devoted to the European overview. After a comprehensive introduction to the topic on hospitals (organisation of the in-patient sector, funding and expenditure, delivery chain for medicines), chapter 4 deals with the purchasing and pricing strategies for medicines. Chapter 5 on reimbursement explores funding mechanisms in hospitals and looks at pharmaceutical formularies and commissions. Further chapters provide information and data on pharmaceutical consumption in hospitals, evaluation and monitoring as well as interface management.

[2] http://phis.goeg.at

Chapters 9 and 10 discuss the results of the case studies, first for the five survey countries (Austria, the Netherlands, Norway, Portugal, Slovakia) individually and then in a comparative analysis.

Following a discussion of major findings in chapter 11 conclusions arising from the insights of medicines management in the in-patient sector will be drawn in chapter 12. Chapter 13 provides recommendations.

Interesting information on specific policies in single countries is provided in boxes in all chapters.

2 Methodology

The work on PHIS Hospital Pharma was led by the WP leader Slovak Medicines Agency SUKL, represented by Director Ján Mazag, and carried out in close coordination with the main partner GÖG/ÖBIG. As explained in the following sections, we involved all the associated partners of the project management, consulted with the PHIS Advisory Board and had feed-back rounds with the PHIS network.

2.1 European survey

The objective of the European survey was to gather information on medicines management, in particular purchasing strategies and funding mechanisms, in the in-patient sector in the European Union. We aimed to cover as many EU Member States as possible and also invited non-EU countries to join in the exercise.

The primary tool for collecting data and information were country reports on the in-patient pharmaceutical system, called PHIS Hospital Pharma Reports, which were to be provided by country representatives in the PHIS network.

In order to guarantee uniform reporting which would allow for a meaningful comparison, an outline, the PHIS Hospital Pharma Report template, was developed. This template (cf. Annex II), which is designed in the PHIS layout, defines at a very detailed level the content and the outline of the country reports. The development of this template was first based on a literature review, confirming that there is very little literature on this specific issue. We undertook the additional exercise of compiling the information and data from the PPRI Pharma Profiles[3] (PPRI 2007/2008/2009) which referred to the out-patient sector. We learned that at the same time a survey of hospital medicine prices had been commissioned by the Danish Ministry of Health and Prevention. However, its results were only to be available in summer 2009 (cf. COWI Report 2009). A reviewed draft based on the input of the whole project management was sent to the PHIS Advisory Board and PHIS network, and we took the opportunity of an informal meeting of the PPRI network in Berlin in February 2009, to put the draft template on the agenda and discuss it there. On the basis of the feed-back received from this round, we finalised the template.

The PHIS Hospital Pharma Report template is divided into seven chapters:

- Background: This chapter gives an introduction to the in-patient sector, with key structure data, including expenditure data, and information on the organisation and funding of this sector and the delivery chain of medicines.

[3] http://ppri.goeg.at

- Pricing: In this key chapter, the major policies of hospitals for purchasing medicines are described. Additionally, the authors are encouraged to explain the characteristics of hospital prices (e.g. role of VAT, discounts).
- Reimbursement: This is another major chapter which explores the national reimbursement schemes (informing if third party payers like social insurance institutions or national health services cover the expenses of – specific – medicines used in hospitals), the role of the Pharmaceutical and Therapeutic Committees (PTC) and the formularies applied in hospitals.
- Consumption: In-patient pharmaceutical consumption compared to total consumption is surveyed in this chapter.
- Evaluation: This chapter looks at monitoring mechanisms regarding pharmaceutical prices, consumption and expenditure and at assessment tools.
- Interface management: In order to highlight the importance of an improved interface management between the in-patient and out-patient sector, a chapter of its own is devoted to this issue.
- Developments and outlook: A concluding chapter informs about ongoing and future developments.

There were extensive discussions with the PHIS Advisory Board and PHIS network on the wording of “pricing” and “reimbursement”, as the terms “purchasing” and “funding” might be more appropriate in the context of the in-patient sector. However, with the view of combining the information on the in-patient and out-patient sectors in a next step (WP Monitoring), it was decided to use the terms “pricing” and “reimbursement” in the country reports, and we basically follow the decision in this report.

Another major discussion point around the template development was to reach a common understanding on what a hospital is and which definition we would like to apply. Both the WHO and the OECD definitions of a hospital seemed adequate; in the end, after consultation with the PHIS Advisory Board and the PHIS network, the OECD hospital definition was taken as reference. The specialisation of hospitals in the OECD definition which should be reflected in the OECD database was considered as one major reason for this decision. The authors were asked to check their national hospital definition, if available, on the conformity to the OECD definition.

Authors were asked to provide financial, e.g. expenditure, data in national currency. In a later step for performing the comparison the project management calculated all currencies into Euros based on the annual average exchange rates for the relevant years provided by the European Central Bank. To allow for comparability, the authors of national country reports were advised to use EUROSTAT-OECD-WHO Joint System of Health Accounts (SHA) collection when available as the preferred source. This is in full accordance with the preferred source for the PHIS Indicators as developed and approved by the EAHC in the PHIS Taxonomy (PHIS 2009w). However in some cases (e.g. average length of stay) for the benchmarking tables in this report data of OECD and WHO statistical databases were taken due to incomplete data provision by PHIS network members at the time of drafting this report.

Another issue of the “Guide for Authors” included in the PHIS Hospital Pharma Report template regarded terminology. The authors were invited to use the respective preferred terms of the PHIS Glossary (cf. Annex I). The PHIS Glossary was submitted in June 2009, now accessible at http://phis.goeg.at. However, the hospital terms had already been defined at the time when country representatives were asked to start writing their reports.

The drafting of the country reports started at the beginning of March 2009. The Austrian PHIS Hospital Pharma Report was finished first, and it served as a pilot giving orientation to the other authors.

The collection of the information and data proved a very difficult task for the members of the PHIS network, as most of them were experts for the out-patient pharmaceutical sector with little knowledge of hospitals. In most cases, the authors needed to contact hospital management, hospital pharmacists or other hospital experts to get the information. On the one hand, this delayed the process of writing, but on the other hand it supported the building of links between the out-patient and the in-patient sectors in the Member States.

For guaranteeing high quality of the reports, a review process was established. An editorial team was set up consisting of the editor-in-chief (GÖG/ÖBIG), a person from SUKL and one person with country-specific knowledge from GÖG/ÖBIG. The reports were reviewed with regard to content (consistency, contradictions and credibility), form (editorial requirements) and language. Good quality reports usually included two rounds of feed-back.

As of May 2010, (draft) reports have been produced by 20 countries. Thereof twelve country reports (Austria, Bulgaria, Cyprus, Denmark, Finland, Latvia, Malta, the Netherlands, Norway, Slovakia, Turkey, United Kingdom) have been published at the PHIS website, whereas five reports are currently in review and three draft versions were made available to the project management in order to contribute with information.

As the basis for the presentation of results in a comparative analysis to be included in this report, the information and data of the country reports was compiled in overview tables. In doing this, we paid heed to cover all in-patient relevant indicators of the PHIS taxonomy which had meanwhile been developed and finalised. A working document of this benchmarking exercise was sent to the PHIS network for review and checking for country data in December 2009, and nearly all authors took the opportunity to do so.

This also offered the opportunity to those Member States which had not submitted a report by that time to contribute to the European survey. Some countries used this option. In the end, the European survey covers 27 countries, called thereafter “PHIS countries”, 25 are EU Member States and two volunteering non-EU Member States.

2.2 Case studies

The exploration of the in-patient pharmaceutical system in European countries was accompanied by an in-depth investigation at hospital level to shed light on medicines management

in case study hospitals. As a key element of the case studies, a price survey was undertaken. Additionally, further information were collected in the hospitals surveyed which allowed to better understand and interpret the price data.

As a consequence, the case studies were divided into two parts: collection of information about the hospital (part 1), guided by a questionnaire, and a price survey, based on a price template (part 2). The information and data were gathered during study visits to the hospitals by staff of WP leader SUKL or the main partner GÖG/ÖBIG, usually accompanied by the members of the PHIS network in that country.

The methodology for the case studies, in particular for the price survey, was developed and discussed from June to September 2009 by SUKL and GÖG/ÖBIG and described in the PHIS Hospital Pharma Methodology Paper (PHIS 2009b). It was revised after a feed-back round with the project management and the PHIS Advisory Board and fine-tuned after the first study visits.

2.2.1 Selection of countries and hospitals

In line with the resources available, five countries with three to eight hospitals were chosen as an appropriate number of case studies which would allow for meaningful insight and interpretation.

Selection criteria for the countries were:

- “Old“ and “new” EU Member States as well as an EEA/EFTA country;
- An equal balance of countries with a social health insurance system and those with a national health service;
- An equal balance of countries with a centralised and with a decentralised purchasing policy for medicines used in hospitals;
- Countries with different purchasing power (a criterion of minor importance)

The readiness and cooperation of the country to be investigated was a further selection criterion. The availability of a national (draft) PHIS Hospital Pharma Report was an additional benefit as it helped the researchers to be better prepared for the study visits.

Selection criteria for the hospitals were:

- Type: focusing on general hospitals
- Size: a balance of large, medium and small hospitals
- Ownership: main focus on public hospitals; if possible: also a private one
- Both hospitals with a hospital pharmacy and those with a pharmaceutical depot, if appropriate and possible

In total, case studies were undertaken in 25 hospitals in five countries (Austria, the Netherlands, Norway, Portugal, Slovakia), see Table 2.1.

Table 2.1: Methodology – Number of participating hospitals per country

Country	Number of participating hospitals in PHIS case studies
AT	5
NL	3
PT	4
NO	2
SK	11[1]
In total	**25**

[1] Price data of eight hospitals were considered (four hospitals are under one management and have the same price data); organisational information was only available for 10 hospitals.

Source: PHIS case studies 2009

2.2.2 Survey on structure and process

As background information for the analysis, structure data and information on processes of the hospital surveyed were collected on the basis of a guided questionnaire (cf. Annex III). The major topics of this questionnaire are displayed in Table 2.2.

Table 2.2: Methodology – Key issues of the structure and process survey questionnaire for the case studies

1. Key parameters of the hospital
1.1 Geographic position (urban/rural)
1.2 Ownership
1.3 Type of hospital, specialisation
1.4. Hospital association
1.5 Statistics: Size of the hospital in terms of acute care beds, departments (which key departments), number of patients treated annually, number of staff, average length of stay)

2. Delivery chain and pharmaceutical provision
2.1 Major distribution actors
2.2. Hospital pharmacy (if yes: number of staff, task; if not: organisation of pharmaceutical provision)
3. Purchasing policies in hospitals (“Pricing” of medicines)
3.1 Major purchasing / pricing policies
3.2 Understanding pharmaceutical prices
3.3 Publication of pharmaceutical prices

4. Funding in hospitals (“Reimbursement” of medicines)
4.1 Funding of the hospital in general
4.2 Funding of medicines in the hospital
4.3 Relevance of the out-patient reimbursement scheme

4.4 Hospital pharmaceutical formulary (incl. pharmaceuticals on the list, setting the list, updates, decision-making process)
4.5 Health / pharmaceutical expenditure in the hospital
4.6 Top 10 medicines (by expenditure) in the hospital
5. Consumption
5.1 Data on pharmaceutical consumption in the hospital
5.2 Top 10 pharmaceuticals (by consumption) in the hospital
6. Monitoring and interface management
6.1 Monitoring of prices, consumption and expenditure in the hospital
6.2 Good practices of rational use, safety, evaluation in the hospital
6.3 Interface management (need, examples regarding for your hospital)
6.4 Changes (reforms with impact on your hospital, needed change)

Source: PHIS 2009b

2.2.3 Selection of products

The selection of products was one of the most crucial tasks of the price survey exercise. We considered the following criteria:

- In a first step, active substances were selected based on the compilation of the top 10 products in expenditure according to the national PHIS Hospital Pharma Reports.
- In a second step, we decided to focus on commonly used / standard therapeutic groups as well as on products of high diagnostic relevance. Account was also given to a few products (e.g. cardiovascular medicines) which have an impact on the out-patient sector due to the dual financing in some countries.
- The following groups were taken into consideration:
  - Cardiovascular medicines
  - Contrast media
  - Haematology medicines
  - Neurology medicines, especially for Multiple Sclerosis
  - Nutrition (electrolyte)
  - Oncology medicines (breast, colon, leukemia)
  - Orphan medicines
  - Transfusion medicines
- Additionally, therapeutic areas which have already been surveyed in other projects (e.g. COWI Report 2009 (cf. section 2.1), the INFOPRICE exercise[4], an orphan medicines sur-

[4] A voluntary price exchange exercise in the framework of the Transparency Committee.

vey[5] (cf. EMINet 2009a) within the EMINet[6] project were considered for a possible inclusion.

- A balance regarding patent-protected versus non-patent protected segments was considered.
- Products which are difficult to survey due to, for example, different dosage forms or bulk packages were deselected.
- Before the survey, we verified that the products of the selected active ingredients were on the market in the countries of the survey.
- If too many different brands of the same dosage/strength of the same active ingredient were used in the hospitals, then only the ones with the highest and the lowest price were chosen.

According to these criteria 20 products were selected in a first step. The complete list of active ingredients is available in the PHIS Hospital Pharma Methodology Paper (cf. PHIS 2009b). For organisational reasons (in order not to burden the cooperating hospitals too much) we decided to concentrate on the first twelve active ingredients during the price surveys (cf. Table 2.3).

Table 2.3: Methodology – Selection of products for the case studies

	Active ingredient	ATC Code
1	Trastuzumab	L01XC03
2	Docetaxel	L01CD02
3	Rituximab	L01XC02
4	Etanercept	L04AB01
5	Imatinib	L01XE01
6	Immunglobulin	J06BA02
7	Infliximab	L04AB02
8	Interferon beta-1a	L03AB07
9	Amlodipin	C08CA01
10	Simvastatin	C10AA01
11	Atorvastatin	C10AA05
12	Clopidogrel	B01AC04

Source: PHIS 2009b

[5] Quantitative survey with the objective to give a picture of the current state of art for pricing, reimbursement and use of selected orphan medicines in the European Union

[6] EMINet (European Medicines Information Network on Pricing and Reimbursement of pharmaceuticals) aims at supporting EU Member States, EEA-EFTA countries and the Commission by providing information, technical expertise and analysis on pharmaceutical pricing and reimbursement policies and related topics.

2.2.4 Price template

For performing the price survey, a template (cf. Annex IV) was prepared.

The following characteristics and limitations were considered.

Specification of the products

- As the trade names may vary between the countries, space for indicating information on the active substance and the ATC level was included.
- In case of off-patent medicines, where different products were available, only the most expensive (usually the original product) and the least expensive were surveyed.

Date of the price surveyed

- Requested date: 30 September 2009 (minor deviations were accepted).

Understanding the price and relevance of the product

- The price template asked both for information on the official "list" price as well as on the actual price (considering possible discounts of the list price).
- Being aware of existing aggregate prices an extra column for comments regarding discounts/rebates, special agreements or cost-free products was included in the price template.
- To allow a more robust analysis, we also asked for the underlying purchasing policy.
- The price template also included space for remarks (e.g. possible explanations for a rather high price; possible answer: product is new since 2009).
- The relevance of the product within the hospital pharmaceutical budget (ranking) was asked for.
- It was attempted to collect hospital expenditure for each product in national currency units (NCU) in 2008.

Indication of "unit price"

- The price template asked for the price (per pack usually); unit calculations were done later by SUKL and GÖG/ÖBIG.
- The price template also included space for adding the defined daily dose (DDD), asking for the WHO DDD and if necessary also for other (national) DDD definitions.

Problems were expected in the survey due to the existence of multiple pharmaceutical forms. These difficulties could be reduced to a great extent by pre-filling the price query template with the most common pharmaceutical forms.

2.2.5 Analysing hospital prices

Selecting comparable products

Twelve active ingredients were selected to be surveyed (see Table 2.3). Price data of all products were collected which were available at the hospital level. This automatically led to a wide variety of products of different strengths and package sizes per active ingredient. Hence for each active ingredient a specific product was chosen for a detailed analysis. For the comparison the following features were taken into consideration:

- Identical active ingredient
- Identical/similar strength
- Similar/comparable package size for the calculation of the unit prices
- Identical/similar pharmaceutical form
- Consideration of whether the price of an original brand or generic product was reported.

In most cases identical products could be considered for the cross country comparison. In exceptional cases a similar product or package size was taken into account (see notes to the figures in sections 9 and 10).

The price comparison was undertaken at the level of the main therapeutic indications for the selected medicines (e.g. oncology).

Defining price types for the analysis

Table 2.4 describes the price types (price levels) which were used for the PHIS price comparison in the different countries.

Table 2.4: Methodology – Price types compared in the case study

Price type	Definition	Which price does it refer to in the countries? Which sources are used to get the price information?				
		AT	NL	NO	PT	SK
Official hospital list price	*"The prices that purchasers display as the prices at which they are prepared to sell their products and/or regulated by legislation. The prices of products as quoted in the purchaser's price list, catalogue, internet site, advertisements, in a national price list/formulary etc. They are not necessarily actual transaction prices. Depending on the country and/or the product, they may or may not include delivery and installation costs, VAT*[1] *and other indirect taxes on products, discounts, surcharges and rebates, invoiced service charges and voluntary gratuities. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices. Also referred to as "Offer price".* (Source: PHIS 2009a). In the in-patient sector the official hospital list price is considered as the basis for the purchasing price of hospitals. Depending on the country the official hospital list price may or may not include wholesaler mark-ups, VAT etc. It is the maximum price where hospital purchasing bodies start to negotiate or procure cheaper prices.	Ex-factory price or pharmacy purchase price (net) for hospitals (Source: PPI[2])	Pharmacy purchase price (net) for hospitals (Source: Z-Index[3])	Maximum official pharmacy purchase price (net) – max. AIP[4] (Source: Norwegian Medicines Agency)	Official hospital purchasing price (Source: ACSS[5])	Maximum ex-factory price (Source: Slovakian Ministry of Health)
Actual hospital price	*"The price or amount paid by a hospital (or hospital pharmacy) in order to take delivery of certain unit of medicines. Often the hospital price corresponds to the pharmacy purchasing price. It may or may not include VAT."* (Source: PHIS 2009a). For the price comparison in this report VAT is excluded.	Actual (negotiated) price paid by the hospitals without VAT	Actual (negotiated) price paid by the hospitals without VAT	Actual price achieved by LIS[6] or actual negotiated price by individual hospitals without VAT	Actual (negotiated) price paid by the hospitals without VAT	Actual (negotiated) price paid by the hospitals without VAT
Out-patient price	*"The price charged by retail pharmacies to the general public. It includes any pharmacy mark-up or dispensing fee."* (Source: PHIS 2009a) For the price comparison VAT is excluded. This is the price the end consumer pays (either the patient or a third party payer).	Pharmacy retail price (net) or reimbursement price[7] (net) (Source: PPI[2], Warenverzeichnis)	Pharmacy retail price (net)[8] (Source: Z-Index)	Pharmacy retail price (net) (Source: Norwegian Medicines Agency)	Pharmacy retail price (net) (Source: INFARMED[9])	Pharmacy retail price (net) (Source: Slovakian Ministry of Health)

Legend and source: see next page

[1] VAT = Value Added Tax
[2] PPI = Pharma Price Information – a service offered by GÖG/ÖBIG
[3] Z-Index is a subsidiary of the Dutch Pharmacist Association
[4] AIP = maximum pharmacy purchase price (net)
[5] ACSS = Administração Central do Sistema de Saúde / Central Administration of the Portuguese Health System
[6] LIS = Norwegian Drug Procurement Cooperation
[7] Especially for the Austrian pharmaceutical market the so-called reimbursement price is of special relevance. This is the price the Austrian sickness funds pay for the medicine in the out-patient sector and which is lower than the pharmacy retail price (net).
[8] The public / retail price net 2009 is exclusive of the average € 7.28 flat rate service charge for pharmacists ("prescription fee"). This average fee could go up to a maximum of € 7.95 if the pharmacist and the insurer have a written agreement. In addition pharmacists have to pay a rebate ("claw-back") of 6.82% (maximum of € 6.80) over the public / retail prices listed. This rebate can also vary depending on the agreement that a pharmacist has with the insurer. Therefore the indicated price equals the pharmacy purchase price (net).
[9] INFARMED = Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. / National Authority of Medicines and Health Products, I.P. Portugal

Source: PHIS case studies 2009

For the in-patient sector, the hospital pharmacy purchase price (or "actual hospital price") was the most important price type as discounts achieved in the procurement process were considered if known. The actual hospital prices were then compared with:

- the official hospital list price and
- the out-patient public price.

As described in Table 2.4 the official hospital list price is regarded as the starting point for hospitals to achieve lower prices via their purchasing policy (e.g. tendering or negotiations). The official hospital list price may or may not include any add-ons (e.g. wholesale mark-up) which are due to the different purchasing systems in the countries (cf. Table 2.5). The reductions on the list price result in the actual hospital price. Price reductions may have different forms (as defined in the PHIS Glossary in the latest updated version, cf. PHIS 2009a):

"*Discount* is a price reduction granted to specified purchasers under specific conditions."

"*Rebate* is a payment to the purchaser after the transaction has occurred. Purchasers (either hospitals or pharmacies) receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time."

"*Bundling* is a marketing strategy that involves offering several products for sale as one combined product."

"*Cost-free medicines* are products which are given to hospitals/hospital pharmacies in the course of the delivery without need for payment (e.g. from wholesaler to hospitals/hospital pharmacies or pharmaceutical company to hospitals/hospital pharmacies."

All these forms of price reductions are considered in the price comparison. However expected rebates were considered as estimates (cf. section 9.4.2.2) or were not considered at all in some cases because the hospitals could not or did not specify them.

Table 2.5: Methodology – Overview of prices and add-ons used for comparison within case studies

		Wholesale mark-up	Pharmacy mark-up	VAT[1]
Official hospital list price	AT	-	-	-
	NL	√	-	-
	NO	√	-	-
	PT	-	-	-
	SK	-	-	-
Actual hospital price	AT	partly[2]	-	-
	NL	√	-	-
	NO	√	-	-
	PT	partly[3]	-	-
	SK	√	-	-
Out-patient public price	AT	√	√	-
	NL	√	-	-
	NO	√	√	-
	PT	√	√	-
	SK	√		-

√ an add-on is integrated in the price calculation

- the add-on is not applicable in the price calculation

[1] VAT is disregarded in this price comparison although national hospitals may have to pay VAT for their medicines.

[2] In general hospitals purchase directly from manufacturers. However in exceptional cases (e.g. if the hospital owner association has no hospital pharmacy or if small amounts of medicines are required where it is unattractive for hospital pharmacies to purchase directly from manufacturers) wholesalers are addressed. In case of cooperation with wholesalers, an individual mark-up is added on the ex-factory price or special discounted price and is charged to the hospitals. The mark-up regulation for the out-patient sector is seen as the maximum mark-up to be charged also in the in-patient sector.

[3] Possible rebates are disregarded in the price comparison as they were not applicable at the time of collecting the price data (granted in a retrospective way at the end of the year). Wholesale mark-ups for the in-patient sector are not particularly regulated; if applied, then usually the out-patient mark-up is used. In practice the mark-up is not for all hospitals or products of relevance, as hospitals normally directly purchase from manufacturers.

Source: PHIS case studies 2009

As the surveyed countries have different VAT rates on medicines, it was decided to disregard VAT in the price comparison. We are interested in a comparison of net prices without a bias due to different tax levels in Europe. Although hospitals in the PHIS case study countries have to pay VAT for the medicines they purchase, some are eligible to recapture expenditure on VAT (e.g. in Austria via special funds, etc.).

In a further step the average prices of the surveyed medicines were calculated per unit (e.g. vial, tablet, etc.) of all price types to make them internationally comparable.

The inclusion of mark-ups of the calculation of the different price types is displayed in Table 2.5.

Most of the surveyed products are hospital-only medicines. Hence the out-patient price has more a theoretic character but provides a comprehensive picture.

2.2.6 Price comparisons

After the price collection we compared and analysed the prices at two levels:

- Within the country (intra-country comparison) between the hospitals to see the differences between hospitals
- Between the countries (cross-country comparison) to analyse differences between the selected EU Member States.

Intra-country comparison

This comparison identified price variations within the surveyed countries. The dimension of the price variations was described per product. The results are made available in section 9.

The basis for the intra-country comparison is the prices delivered by the individual hospitals. However hospitals purchase different products depending on their service portfolio. Hence product and price data are in some cases not available for all sample hospitals per country.

A weighting of the prices on the basis of the consumption data could not be realised due to lack of data.

Cross-country comparison

The cross-country comparison delivers a picture of price differences of the same products in the participating countries. Cross-country comparisons of prices of medicines in the in-patient sector have rarely been undertaken so far.

Prices were compared in Euro. Norway is the only case study country which does not use the Euro. The Norwegian prices were converted to Euro by using the exchange rate of 30 September 2009 (the date of the collected prices): 1 Euro = 8.460 NOK[7].

For the surveyed products the mean prices per country were calculated. In some countries the nation-wide price variation to the mean value was considerable. As a consequence, the product price range is separately analysed in Figure 10.4.

[7] Source: European Central Bank, data of 30 September 2009

2.3 PHIS Hospital Pharma Report

The PHIS Hospital Pharma Report was written by members of the PHIS project management team, namely by staff of project leader GÖG/ÖBIG and Hospital Pharma WP leader SUKL. This report has undergone several rounds of feed-back and reviews.

European survey

As for the survey on medicines management in the PHIS countries, the PHIS network members were informed about the outline of the report including the key indicators according to the PHIS Taxonomy (PHIS 2009w) because they received the PHIS Benchmarking Table (PHIS 2009v) prefilled with country data. This table was sent out in November 2009 and allowed members to check information on their country and/or to include missing information (e.g. in case that they had not submitted a national PHIS Hospital Pharma report yet, cf. section 2.1).

When the authors drafted the European comparison, some missing information and misunderstandings became obvious. Issues which had seemed clear from a purely national perspective yielded incomplete and unclear in the comparison. A precise terminology proved very important.

While drafting and reviewing this PHIS Hospital Pharma Report, the authors got several times into contact with the PHIS network members for clarification. This also had an impact on the review of some national PHIS Hospital Pharma reports, which was under the way for several countries at that time.

The PHIS network members received a first draft of the European survey including the PHIS Hospital Pharma Report in February 2010 and were invited to comment on it, in particular with a view to checking their country. They could do so in writing or personally during the PHIS Network Meeting at the February 2010. After the Network Meeting a revised version of the PHIS Hospital Pharma Report was sent to the network for information and feed-back, and the final version submitted to the commissioning party was also forwarded to the PHIS network.

After the official submission of the PHIS Hospital Pharma Report at end of March 2010, there was another change in the European survey. Two EU Member States whose data had been missing provided relevant information for the European survey. Thus, the European overview now covers 27 PHIS countries, thereof 25 EU Member States. The main messages of the reports were not changed by the new information, but confirmed.

Case studies

As described in section 2.2, the methodology which was elaborated to allow a price survey and comparison of medicines in the in-patient sector was summarized in the Methodology Paper. This document was sent for feed-back to the Advisory Board and revised afterwards.

When writing about the results of the case studies, the authors were in regular contact with the targeted Member States (discussion of open points, sending texts for review).

In February 2010, the report part on the case studies was sent to the countries involved, and the PHIS project management team organised a meeting with the representatives of the case study countries during the Network Meeting at the end of February 2010. It was very valuable that hospital pharmacists from all countries and a representative of the European hospital pharmacy association were present at the meeting. Afterwards, written correspondence with further comments followed which was quite active.

An important quality safeguard was the inclusion of the Advisory Board members in the PHIS network. When sending the PHIS Hospital Pharma report to the network, the Advisory Board members also got it. The Advisory Board members gave very valuable comments on the conclusions and recommendations of the report.

EUROPEAN SURVEY

3 The hospital landscape

In order to gain insight into medicines management in hospitals in the European Union, it is important to have a comprehensive overview on the hospital landscape in the EU Member States as a first step. This includes information on the organisation of the in-patient sector as well as the financing of hospital care including medicines. In this and the following chapters (chapters 3 to 8) the results of a European survey on these key components of medicines management in hospitals are presented. As described in section 2.2.1, the results are provided for 27 European countries, 25 are EU Member States and two volunteering non-EU Member States (Norway and Turkey). The countries will be referred to as PHIS countries.

3.1 Definition and scope

Different definitions of hospitals at international and national level exist. Standard international definitions include definitions of a hospital provided by OECD and WHO. As explained in section 2.1, for the PHIS project and consequently also for the present PHIS Hospital Pharma Report the OECD definition of a hospital (cf. Box 3.1) was considered as an appropriate basis and decided on after consultation with the PHIS Advisory Board and feed-back from the PHIS network.

Box 3.1: European survey – 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."

Source: OECD 2000

In 18 (i.e. AT, BE, BG, CY, CZ, DE, EE, ES, FR, HU, IT, LV, PL, PT, RO, SI, SK, TR) out of the 27 PHIS countries an official hospital definition exists, whereas nine countries (DK, FI, IE, LT, MT, NL, NO, SE, UK) do not have an explicit official national definition. Nonetheless, in all but one country (Sweden) the understanding of what is a hospital is rather conform to the OECD definition as shown in Box 3.1.

In some of the PHIS countries, the understanding of a hospital comprises some particularities. This is attributable to differences in the organisation of the health systems as well as historical developments. For example in Austria independent out-patient health clinics ("Ambulatorien" such as X-ray clinics, dental care centres and similar facilities) are also formally covered by the term "hospital" but they are not considered as belonging to the in-patient

sector. In the UK a variety of subtypes of hospitals exists; each of which have a different status in terms of autonomy, strategic focus and funding. The hospital definition in Italy includes care for foreign citizens who are not mentioned in the OECD definition.

3.2 Organisation

3.2.1 Provision with hospitals

The number of hospitals varies significantly among European countries ranging from nine hospitals in Malta to 2,772 hospitals in France. In terms of hospitals per 1,000 inhabitants the range is between 6.51 (DK) and 0.89 hospitals (SE). This is due to the different role of primary care in the European countries.

Table 3.1 provides information on the number of hospitals in total and with regard to their specialisation as well as on the provision with acute care beds in the European countries.

Table 3.1: European survey – Hospitals and acute care beds in European countries, as of 31 December 2008 or latest available year

Country	Year	No. of hospitals[1]	Specialisation[2]		No. of acute care beds	No. of acute care beds per 1,000 inhabitants
			General hospitals[3]	Specialised hospitals[4] and other		
AT	*2007*	270	103	167	54,566	6.6
BE	*2007*	210	142	n.a.	70,444	6.7
BG	*2008*	305	123[5]	82[5]	32,879	4.3
CY	*2006*	24	23	1	2,864	3.7
CZ	*2008*	192	n.a.	n.a.	54,326	5.2
DK	*2008*	n.app.	n.a.	n.a.	15,789	2.9
DE	*2007*	2,087	n.a.	n.a.	507,000	6.2
EE	*2009*	68	n.a.	n.a.	5,163 (2008)	3.8
EL[6,7]	*2006*	317	n.a.	n.a.	43,965	4.0
ES	*2008*	804	498	306	160,981[8]	3.6
FI	*2008*	312	297	n.a.	34,097	6.4
FR	*2007*	2,772	1,618	828	222,194	3.5
HU	*2009*	179	109	70	44,308	4.4
IE[6]	*2007*	176	n.a.	n.a.	11,517 (2006)	2.8 (2006)
IT	*2007*	1,187	804	n.a.	232,103	3.9
LT	*2007*	165	75	90	27,476	8.1
LV	*2008*	88	65	23	11,847	5.2
MT	*2008*	9	5	4	1,102	2.7
NL	*2006*	206	n.a.	n.a.	49,715	3.0
NO[6]	*2008*	87	87	n.app.	13,553 (2007)	2.9 (2007)

Country	Year	No. of hospitals[1]	Specialisation[2]		No. of acute care beds	No. of acute care beds per 1,000 inhabitants
			General hospitals[3]	Specialised hospitals[4] and other		
PL	*2007*	748	n.a.	n.a.	175,023	4.6
PT	*2008*	189	139	50	30,209 (2007)	2.9 (2007)
RO[9]	*2006*	419	n.a.	n.a.	109,046	5.0
SE	*2007*	81	n.a.	n.a.	25,758 (2008)	2.8 (2008)
SI	*2008*	29	10	19	7,748	3.8
SK	*2007*	122	80	42	34,288	6.4
TR	*2007*	1,276	1,033 (2006)	130 (2006)	184,983	2.6
UK	*2007*	1,810[10]	n.a.	n.a.	144,867 (2006)	2.6

n.a. = not available, n.app. = not applicable, no. = Number
LU – no data available

1 All hospitals, not only for acute care.

2 The sum of no. of general hospitals and no. of specialised hospitals need not equal the total no. of hospitals

3 A general hospital is a licensed establishments primarily engaged in providing diagnostic and medical treatment (both surgical and non-surgical) to in-patients with a wide variety of medical conditions. These establishments may provide other services, such as out-patient services, anatomical pathology services, diagnostic X-ray services, clinical laboratory services, operating room services for a variety of procedures, and pharmacy services. (PHIS 2009a)

4 Specialised hospitals include mental health and substance abuse hospitals and speciality hospitals.
A mental health and substance abuse hospital is a licensed establishment primarily engaged in providing diagnostic and medical treatment, and monitoring services to in-patients who suffer from mental illness or substance abuse disorders. The treatment often requires an extended stay in an in-patient setting including hostelling and nutritional facilities. Psychiatric, psychological, and social work services are available at the facility. These hospitals usually provide other services, such as out-patient care, clinical laboratory tests, diagnostic X-rays, and electroencephalography services.
A speciality hospital is a licensed establishment primarily engaged in providing diagnostic and medical treatment to in-patients with a specific type of disease or medical condition (other than mental health or substance abuse). Hospitals providing long-term care for the chronically ill and hospitals providing rehabilitation, and related services to physically challenged or disabled people are included in this item. These hospitals may provide other services, such as out-patient services, diagnostic X-ray services, clinical laboratory services, operating room services, physical therapy services, educational and vocational services, and psychological and social work services. (PHIS 2009a)

5 Only public hospitals

6 No. of acute care beds were added from OECD Health Data 2009

7 No. of hospitals were added of country profiles provided by HOPE (European Hospital and Healthcare Federation) accessed online (http://www.hope.be).

8 Hospital beds in general

9 No. of acute care beds were added from WHO Health for All Database, Feb. 2010 - no validation by country / PHIS country representatives

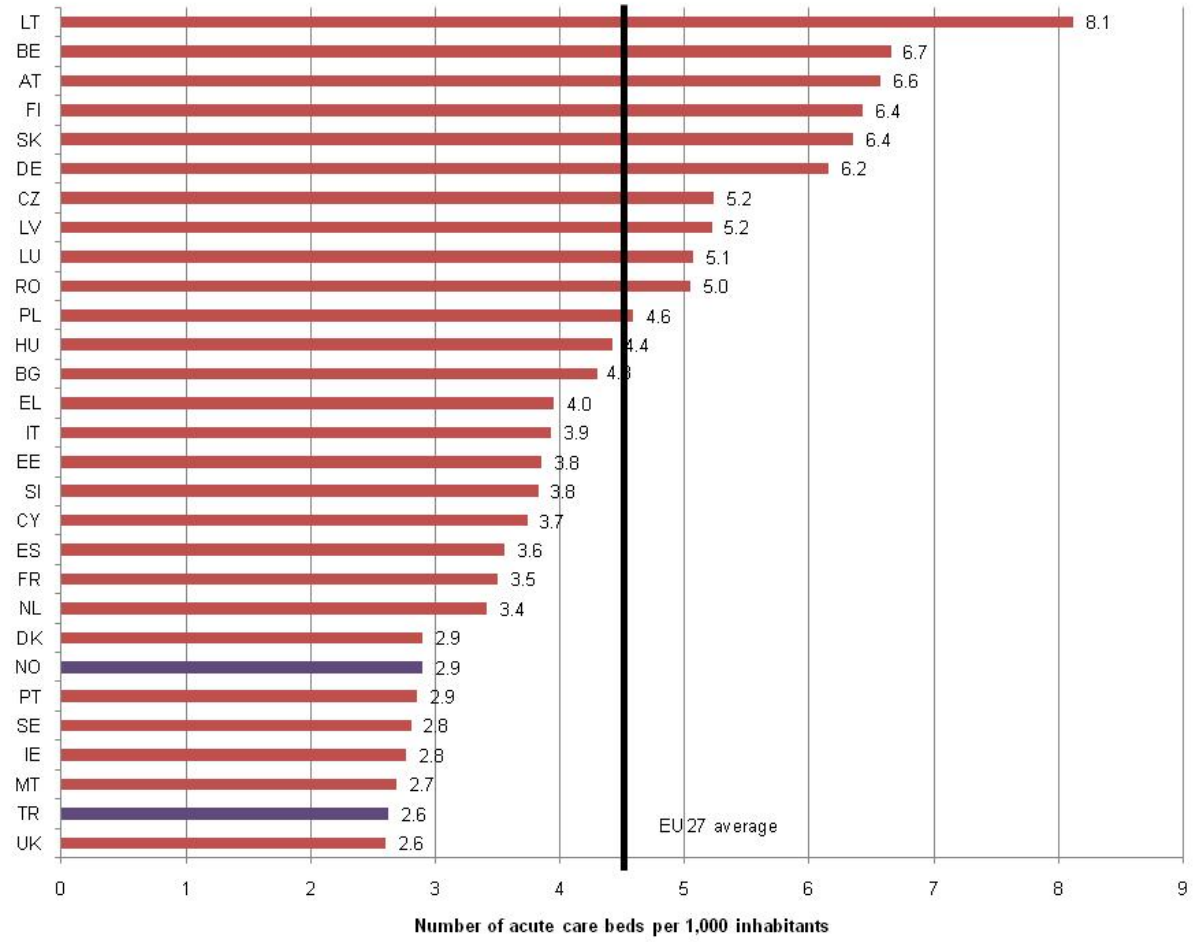
10 Public hospitals: 1,600; private hospitals: Independent acute medical/surgical hospitals.

Source: HOPE 2010, OECD 2009, PHIS 2009c-u, PHIS 2009v, WHO 2010

Numbers of general and specialised hospitals are not available for all countries. As a rule, in most countries (exemptions: AT, EE, LT, SI) there are more general hospitals than specialised hospitals. In some countries there are only a few more general hospitals than specialised hospitals (e.g. MT, HU), whereas in other countries general hospitals present the major-

ity (e.g. CY, ES, FI). In Turkey for example the number of general hospitals is more than twice as high as the specialised in-patient institutions. For the analysis of the medicines management in a country it is relevant to take account of the different organisation types of hospitals to determine possible differences.

Figure 3.1: European survey – Number of acute care beds per 1,000 inhabitants in European countries, as of 31 December 2008 or latest available year



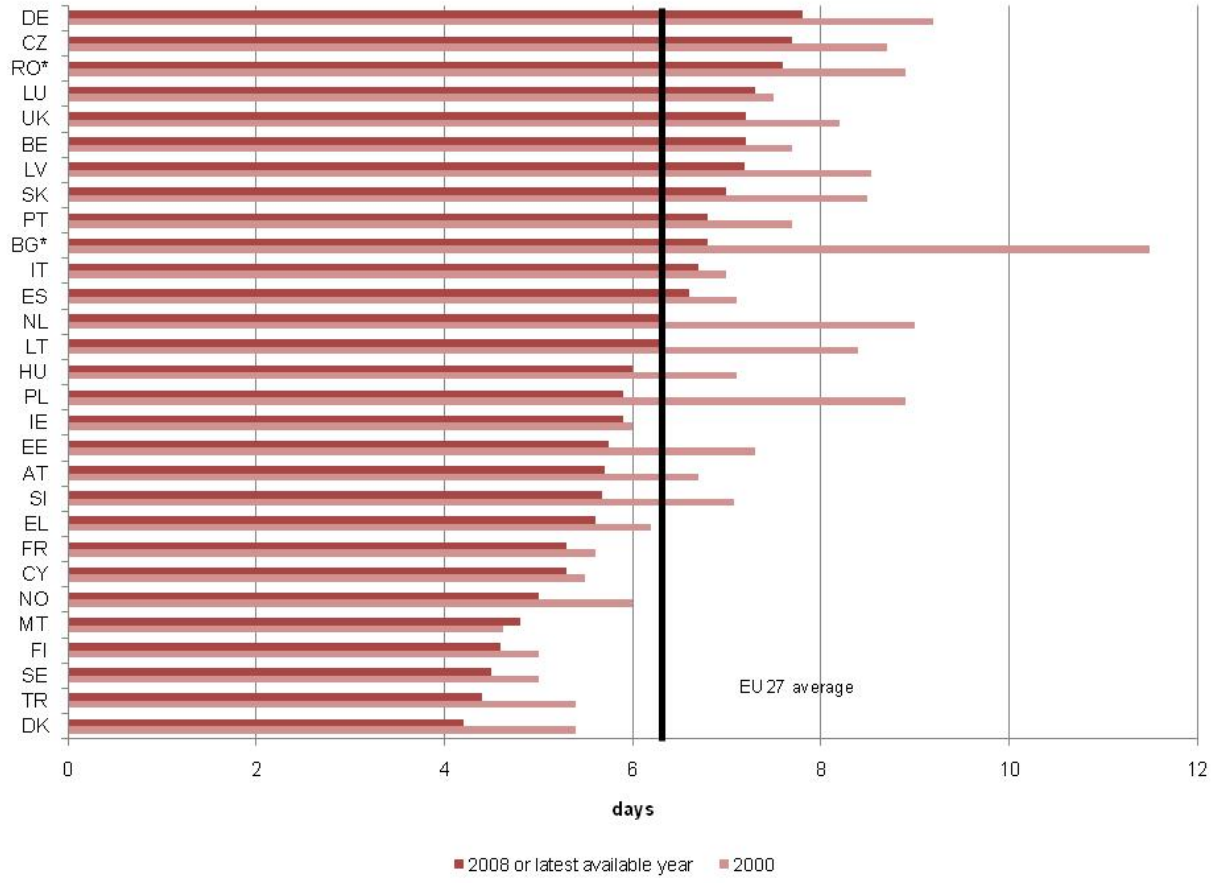
2004: LU
2006: CY, EL, IE, NL, RO
2007: AT, BE, DE, FR, IT, LT, NO, PL, PT, SK, TR, UK
2008: BG, CZ, DK, EE, ES, FI, LV, MT, SE, SI
2009: HU
EU 27 average – values of NO and TR were disregarded
Missing values for acute care beds were added from OECD Health Data 2009 (DK, EL, IE, LU, NL, NO, UK) and WHO Health for all Database (RO)
Population data of Eurostat

Source: PHIS 2009c-u, PHIS 2009v, Eurostat 2009, OECD 2009, WHO 2010

The number of acute care beds is also an important figure for characterising the in-patient sector. Speaking in absolute figures Germany has the highest number of acute care beds with more than 500,000. Figure 3.1 shows the number of acute care beds per 1,000 inhabi-

tants. The general picture shows that the number of acute care beds is below the EU 27 average in the majority of the European countries. With 8.1 beds Lithuania shows the highest number of acute care beds per 1,000 inhabitants in the PHIS countries whereas the lowest number of acute care beds (2.6 per 1,000 inhabitants) can be found in the UK and in Turkey.

Figure 3.2: European survey – Average length of stay in acute care in European countries, 2008 (or latest available year) compared to 2000



2005: EL
2006: BE, ES, IE, IT
2007: AT, CY, CZ, DE, FI, FR, HU, LU, NL, NO, PL, PT, SE, SK, TR, UK
2008: BG, DK, EE, LT, LV, MT, RO, SI
EU 27 average: values of NO and TR were disregarded
* ALOS of all hospitals and not only acute care.
Values of OECD Health Data 2009 (AT, BE, CZ, DE, EL, ES, FI, FR, HU, IE, IT, LU, NL, NO, PL, PT, SE, SK, TR, UK) and WHO Health for All Database 2010 (BG, CY, EE, LV, LT, MT, RO, SI) and PHIS Hospital Pharma Report Denmark 2009 (data of The National Board of Health (SST): http://www.sst.dk/)

Source: OECD 2009, WHO 2010, PHIS 2009h

The average length of stay (ALOS) in acute care is on average 6.2 days in the European Union, however there are wide variations among the countries (cf. Figure 3.2). There is a general trend in European countries to reduce the length of stay in hospitals. For example the ALOS in acute care in Poland decreased from nearly 9 days in the year 2000 to almost 6 days in 2007. Relevant reductions of ALOS in acute care have also been achieved in Bul-

garia, the Netherlands, and Germany. In Ireland, Cyprus and Luxembourg the ALOS only decreased slightly in comparison to 2000. In Malta the ALOS in acute care did even increase from 4.6 days in 2000 to 4.8 days in 2008. Compared to the USA where the ALOS in acute care is 5.5 days (OECD 2009), the EU 27 average is higher.

3.2.2 Ownership

In general, defining hospitals as “public” or “private” ones is rather difficult since among the European countries it is unclear if ownership, funding, or providing public health services (access for patients) is the key criterion. The HOPE report talks about “new boundaries between public and private” to describe the existence of “multiple statuses ... between public health establishments (managed by public authorities) and private health establishments” (HOPE 2009). Within the scope of the PHIS project, the first focus was put on the ownership criteria, however – in coordination with the countries concerned – we took a broader approach regarding the role of the hospitals in the public health care system. This approach is reflected in Figure 3.3 on the share of publicly owned acute care beds.

The role of the public and private sector with regard to in-patient care differs among the PHIS countries. What can be said on an overall level is that in most of the European countries the public hospital sector is important whereas the relevance of the private sector is rather low.

The majority of hospitals in Europe are in public ownership. In several European countries the state / NHS is the major owner of hospitals (e.g. BG, CY, EE, ES, HU, IE, IT, LT, LV, MT, NO, PT, RO, SK, TR, UK). Additionally regions (e.g. AT, CZ, DE, DK, ES, PL, SE, SK) and municipalities (e.g. BG, DE, EE, ES, FI, HU, LV) are major owners. Other hospital owners include church/fraternities (e.g. AT, DE, ES, PL), sickness funds (e.g. AT) and voluntary bodies (e.g. IE).

Regarding private ownership, there is, for instance, a strong presence of for-profit private establishments in France, both in the number of beds and the number of hospitals (HOPE 2009). However, private owners also play a role in some other countries (e.g. BE, CY, DE, FR, LV, NL, PT).

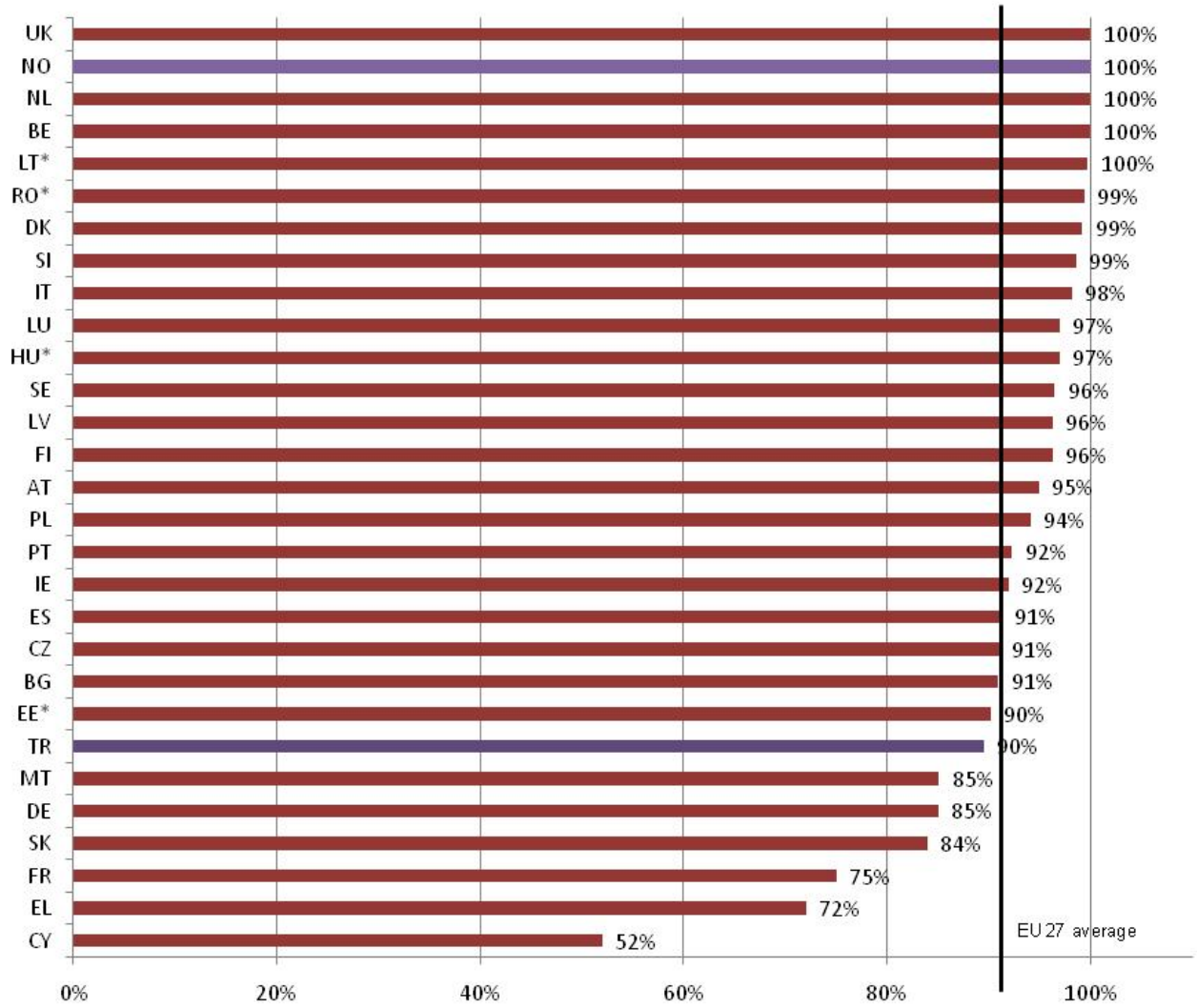
In the Netherlands hospitals are in the ownership of non-profit organisations which function in the public sector. Only a small number of private clinics in the private sector complement hospital care in the Netherlands. Many privately owned hospitals exist in Belgium, but health expenditure, including hospital expenses, are covered by social insurance. That means that a Belgium patient will have his or her hospital expenses reimbursed regardless of the hospital ownership, apart from some exceptions. In Austria a hospital can be defined as public or private with reference either to the legal status of a hospital (public law status) or to the responsible body involved. Within this framework, hospitals with public law status in private ownership exist as well as hospitals without public law status, owned and/or run by provincial or municipal hospital companies or sickness funds. In Italy besides public and private hospitals so-called “independent hospitals” exist which are publicly controlled and financed 100% by the government through the region. These hospitals have been established in order to

compete with private hospitals with the aim to create self-financing hospitals acting like private corporations. The resources produced by an independent hospital are very little and the government has to cover the exceeding expenditure.

In general, the number of public hospitals overweighs the number of private hospitals in the majority of the European countries. At EU average about 60% of all hospitals are public, however there are wide variations between the European countries. As explained, when analysing the ownership of hospitals in European countries, also the profit orientation of the owners has to be considered. Many hospitals have private owners but provide their services not-for profit (e.g. fraternities etc.). More meaningful than the number of hospitals is the number of beds provided. In Figure 3.3 the share of publicly owned and not-for-profit privately owned acute care beds as % of all acute care beds is shown.

In acute care the dominance of the public and private non-profit sector is evident. In the majority of the European countries, more than 90% of the acute care beds are in public hospitals or private hospitals which operate not-for-profit. In some countries (e.g. UK, NO) 100% of acute care health services are provided in public institutions or not-for-profit privately owned hospitals. In the Netherlands acute care beds are established in privately owned hospitals, which are not allowed to make any profit

Figure 3.3: European survey – Share of publicly owned and not-for-profit privately owned acute care beds as % of total number of acute care beds in European countries, 2008 or latest available year



EU 27 average: values of NO and TR were disregarded

* Share of public hospital beds and not only acute care beds; no. of public hospital beds were added from country profiles provided by HOPE (European Hospital and Healthcare Federation), accessed online (http://www.hope.be)

Source: HOPE 2010, OECD 2008-2009, PHIS 2009c, PHIS 2009e, PHIS 2009f, PHIS 2009i, PHIS 2009j, PHIS 2009l, PHIS 2009m, PHIS 2009p, PHIS 2009r, PHIS 2009s, PHIS 2009v

3.3 Financing

3.3.1 Funding hospital care

An important element for the analysis of the medicines management in European hospitals is the way how (acute care) hospitals are funded. In 14 of the PHIS countries hospital care is predominantly funded through social insurance, whereas in the other countries hospital care is funded by the state – mostly at federal level – either as only funding source or in addition to other funds. Regions are the key payers of hospital care in Denmark and Italy. In Sweden county councils fund hospital care (cf. Table 3.3). In 25 of the PHIS countries the payer in the in-patient sector is the same as in the out-patient sector. The only exceptions, meaning that there are different payers in the out- and in-patient sectors, are Austria and Norway.

Patients usually do not need to pay out-of pocket for hospital care in the majority of PHIS countries (i.e. CZ, DK, HU, IT, LT, MT, NL, NO, PL, RO, SI, SK, TR, UK), while in nine PHIS countries (i.e. AT, BE, DE, EE, FI, FR, LV, PT, SE) out-of pocket payments (OPP) for patients are charged. They range from daily fees (AT, BE, DE, LV, SE) via OPP for specific treatments and surgeries (LV), to hospital admission charges (PT). In France hospital care is covered by 80% by the social health insurance system. Coverage increases to 100% in case the length of stay of the patient lasts longer than 30 days, pregnancy, low income, long-term or major illness, hospitalised for an accident at work etc. There are also two fixed fees for patients in France that may be reimbursed by complementary health insurance. These fees account for € 18.- if the patient stays over 24 hours in hospital and € 18.- in case the treatment costs more than € 90.- excluding in-patient stays over 30 days, radiology, transport, etc. There is a specific situation in Cyprus and Malta where both sectors (public and private) are of high relevance. Certain population groups (e.g. specific professions, patients with special diseases) have access to public health care, while other patients need to pay out-of pocket for private hospital care unless this is covered by private health insurance.

Table 3.2: European survey – Key payers of hospital care in European countries, 2009

Key payers	Countries
Social insurance (sickness funds)	BE, BG, CZ, DE, EE, FR, HU, LT, NL, PL, RO, SI, SK, TR
State (NHS)	CY, ES, FI, IE, LV, MT, NO, PT, UK
Regions	DK, IT[1]
Municipalities (local level)	FI, RO
County councils	SE
Provincial Health Funds	AT[2]

Data not available for EL, LU

[1] NHS through regions

[2] Funded mainly by sickness funds, federal state, provincial and local governments

Source: PHIS 2009c-u, PHIS 2009v

Table 3.3 gives an overview about hospital remuneration systems in Europe. 16 European countries have a diagnosis-related group (DRG) remuneration system, a remuneration system similar to a DRG system or a DRG like system in combination with another remuneration system in place. A survey on DRG systems in 14 European countries was conducted by HOPE in 2006. The results of this survey showed that the usage of DRGs in the surveyed countries differs a lot. Reasons are the many different health systems in Europe as well as the cultural and political background and development of the countries (cf. HOPE 2006, HOPE 2009).

Table 3.3: European survey – Remuneration for hospital care in European countries, 2009

Remuneration	Countries
DRG or DRG-like system	AT, BG[1], CZ, DE, DK, FR, HU, IT, NL[2], SK[3]
Fee-for-service	FI, LT
More than one remuneration system is in place	BE[4], EE[5], HU[6], LV[7], NO[8], PL[9], PT[10], RO[11], SE[12], TR[13]
Separate public and private sector with different remuneration	CY[14], MT[15]
Other remuneration system	IE[16], SI[17], UK[18]

DRG = Diagnosis-related Groups, OPP = Out-of Pocket Payment, PCT = Primary Care Trust

Data not available for EL, ES, LU

1 National Framework Contract (once a year negotiated between National Health Insurance fund and doctors associations). Remuneration of patients by groups of diseases which are called clinical pathways

2 Diagnosis and Treatment Combination system

3 Capitation fee per patient (so-called "completed hospitalisation of an individual patient") - fee depending on medical specialisation and type of hospital

4 (1) Fixed annual budget (2) fee-for service funding for certain activities (3) part of the fees of doctors working in hospitals (4) profits made on medicines and medical devices (5) patient's out-of-pocket payments (OPP)

5 30% remunerated according to indicated health services, 70% by DRG system

6 DRG and fee-for service remuneration

7 DRG remuneration, payment for bed days, plus occasionally payments for particular diagnosis

8 All hospitals are remunerated by a mixture of ex-ante fixed budgeting (60%) and a DRG system (40%)

9 Might either be included in the "hospital treatments" or in other cases payment is per administered medicine ("therapeutic program")

10 Own revenues, global budgeting based on payment per level of activity or per service

11 DRG remuneration and fixed budgeting

12 Fixed prospective per-case payments (based on DRG) and complemented with price or volume ceilings and quality components

13 Remuneration from the government budget, by the public reimbursement agencies, private insurance companies and households. All public hospitals receive line-item budgets from either the Ministry of Health (state hospitals) or Ministry of Education (university hospitals). These allocations are made through the routine budget allocation process and mainly cover salary payments and other current and capital expenses. Public hospitals also have revolving funds where payments from third parties are pooled. Public social security system pays per case, per service and global budget.

14 Public: funded through budget allocated by Ministry of Health. Private: funded through out-of pocket payment from patients or their private health insurance

15 Public: funded through government budget allocation. Private: funded through out-of pocket payment from patients or their private health insurance.

16 Hospital funding is principally historical (last year's funding plus inflation and new developments) with some adjustment based on case mix

17 Global budgeting

[18] Department of Health allocates funding (from general taxation) to Primary Care Trusts (PCT). A weighted capitation formula determines each PCT's target share of available resources, to enable them to commission similar levels of health services for populations in similar need.

Source: PHIS 2009c-u, PHIS 2009v

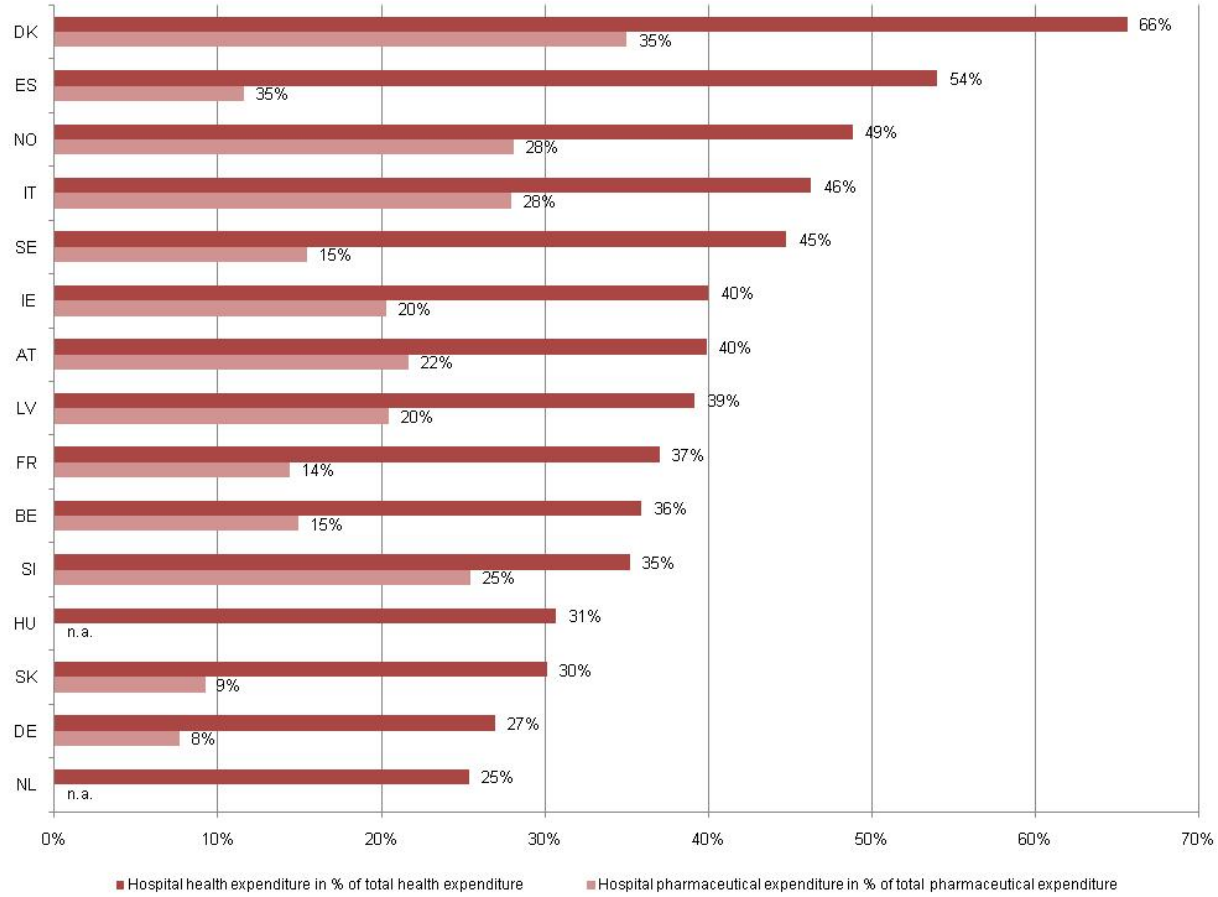
A mere fee-for-service remuneration can be found in Finland and Lithuania. In combination with other remuneration forms fee-for-service remuneration exists in Belgium, Hungary, Portugal and Turkey. Malta funds public hospitals through a fixed hospital budget.

In many European countries (BE, HU, LV, NO, PL, PT, RO, SI, SE, TR) a mixture of more than one remuneration systems is in place which often contains the DRG system.

3.3.2 Health and pharmaceutical expenditure

It was observed that expenditure data for in-patient care are not easily available in all PHIS countries. Possible reasons could be that hospital expenditure is either not monitored, only at hospital level or data are not publicly available. In Figure 3.4 the relevant hospital shares of total health expenditure (THE) and total pharmaceutical expenditure (TPE) are displayed.

Figure 3.4: European survey – Hospital health expenditure in % of total health expenditure and hospital pharmaceutical expenditure in % of total pharmaceutical expenditure in European countries, 2008 or latest available year



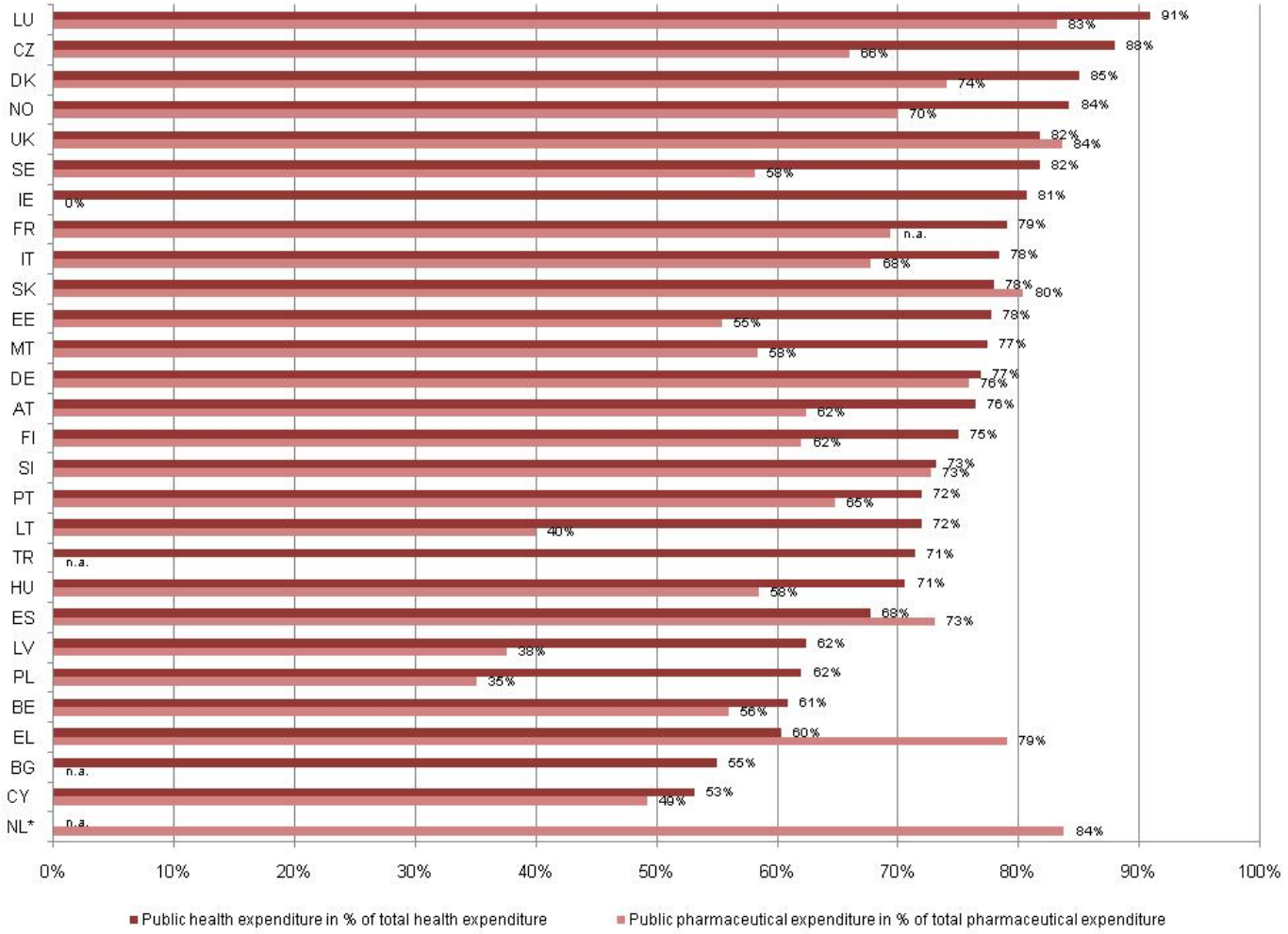
n.a. = not available
Data not available for BG, CY, CZ, EE, EL, FI, LT, LU, MT, PL, PT, RO, TR, UK
Only public health expenditure data are available in case of BE, NL, NO, ES
Only public pharmaceutical expenditure data are available in case of BE, NO, SI and SK (relates to hospital expenditure)
Data of 2006: LV
Data of 2007: AT, DE, ES, FR, HU, IT, SE
Data of 2008: BE, DK, IE, NL, NO, SK
Data of 2009: DK (hospital pharmaceutical expenditure in % of total pharmaceutical expenditure), SI

Source: OECD 2009, PHIS 2009c-u, PHIS 2009v, PPRI 2007/2008/2009

On average around 40% of total health expenditure of a country is spent on in-patient care. For pharmaceutical expenditure the picture is slightly different: Of the 19% of total health expenditure which is spent on medicines on average, less than one fourth of pharmaceutical expenditure account for the in-patient sector.

Regarding funding of health and pharmaceutical expenditure in the in- and out-patient sectors, Figure 3.5 provides an overview of available data on public expenditure.

Figure 3.5: European survey – Public health expenditure in % of total health expenditure and public pharmaceutical expenditure in % of total pharmaceutical expenditure in European countries, 2008 or latest available year



Legend and sources: see next page

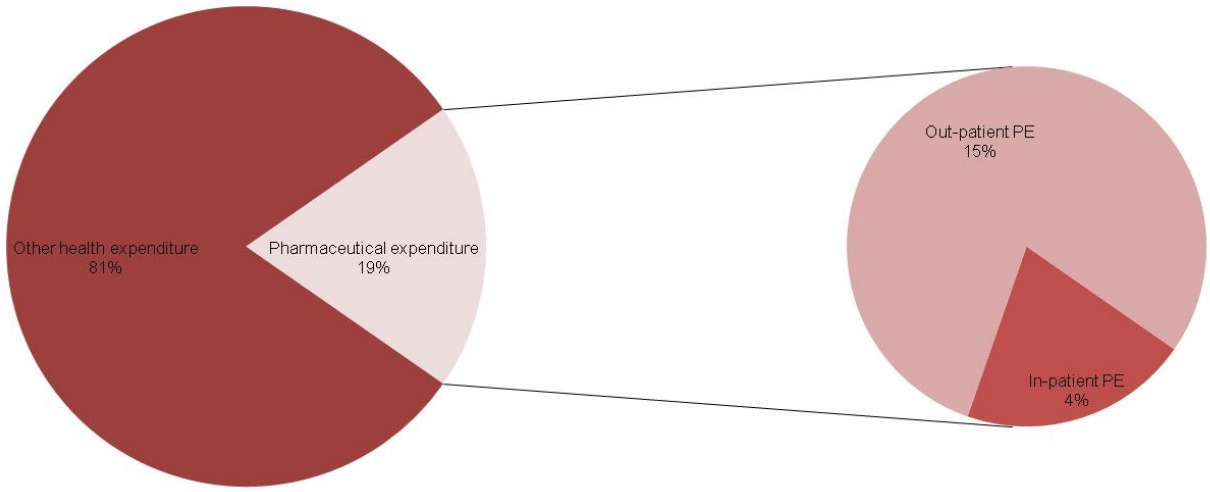
n.a. = not available
Data not available for RO
* only out-patient sector
Data of 2006: CZ, LU, LV, PL, PT, TR
Data of 2007: AT, BE, BG, CY, DE, EL, ES, FI, FR, HU, IT, LT, MT, SE, UK
Data of 2008: DK, EE, IE, NL, NO, SK
Data of 2009: SI

Source: OECD 2009, PHIS 2009c-u, PHIS 2009v, PPRI 2007/2008/2009

On average nearly 75% of health expenditure is covered by public payers. The same is true for pharmaceutical expenditure where almost two thirds are publicly funded. Variations in the countries can be explained by the different funding systems of health care in the countries. In general, the share of public funding in Western European countries, which tend to have a higher GDP per capita, appears to be higher than in the EU Member States in Central and Eastern Europe.

Detailed data are only fragmentarily available in many countries. Due to limited data availability (and probably also comparability) additional efforts at national and also international level seem necessary to develop a statistical framework. The availability of these data would allow a complete and meaningful picture of in-patient (pharmaceutical) expenditure and an analysis of funding in the in- and out-patient sectors. Figure 3.6 shows pharmaceutical expenditure data for the break-downs of the two sectors of health care for one country (Latvia) as example.

Figure 3.6: European survey – Pharmaceutical expenditure in Latvia, 2006



Total health expenditure: 776 Mio. Latvian Lats (LVL) = ~ € 1,115 Mio. (2006)
PE = Pharmaceutical Expenditure
Source: PHIS 2009l

Pharmaceutical expenditure in Latvia accounts for 19% of total expenditure on health; thereof 15% for out-patient care and 4% in-patient care.

Medicines are an essential component in hospitals but, in spite of their therapeutic importance, they usually play a rather minor role in the management of hospitals. This is mainly due to the fact that they often only represent less than 10% of total expenditure within a hospital (PHIS 2009c, PHIS 2009u). However, a few high cost medicines might account for a significant share of the hospital pharmaceutical budget. Trastuzumab, rituximab and docetaxel are among the top active ingredients accounting for high expenditure in European hospitals (cf. section 6).

3.4 Provision of medicines to hospitals

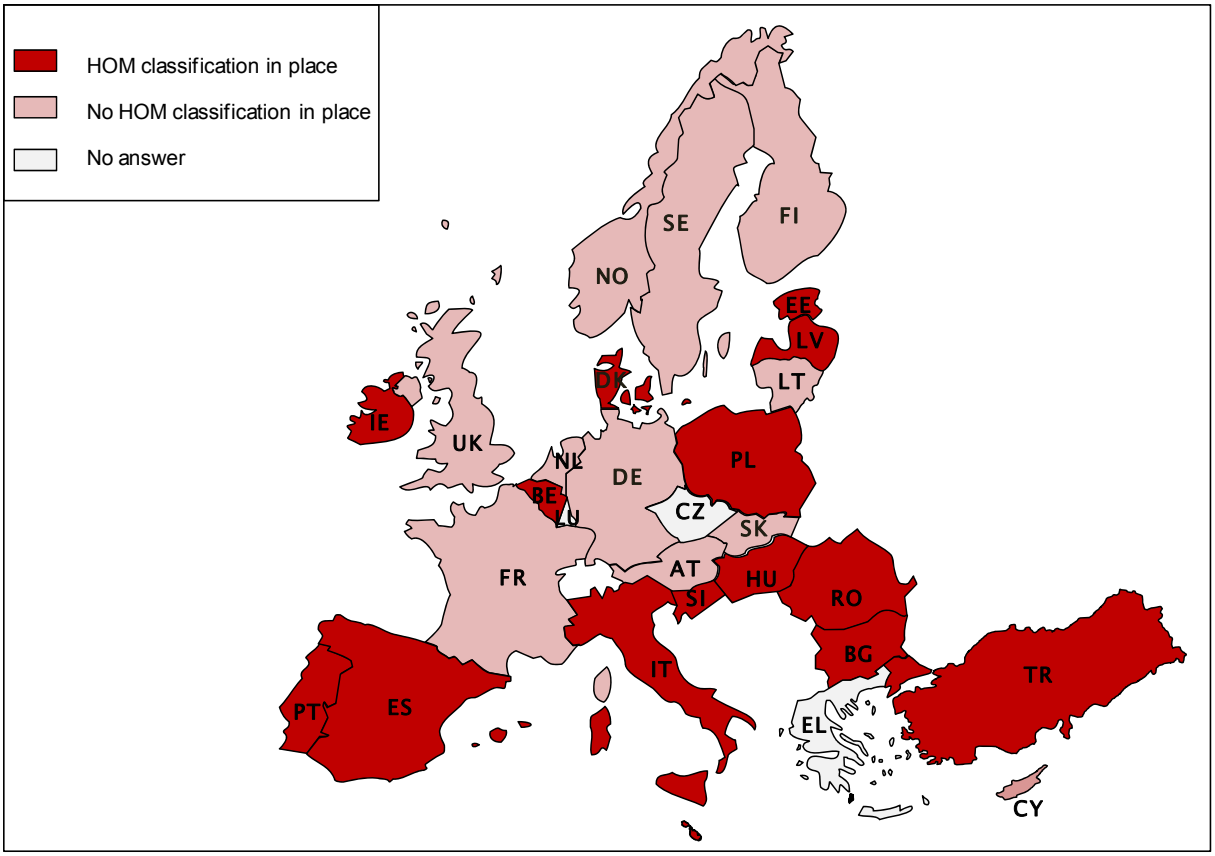
3.4.1 Medicines used in hospitals

In 15 European countries (i.e. BE, BG, DK, EE, ES, HU, IE, IT, LV, MT, PL, PT, RO, SI and TR) medicines for exclusive use in hospital care are classified as hospital-only medicines

(HOM). In Bulgaria the classification of medicines as HOM is made by the Bulgarian Medicines Agency during the process of marketing authorisation. In Denmark the HOM classification is connected to the dispensing status of prescription-only medicines meaning that medicines that fall e.g. in the group A § 4 BEGR (= limited) may only be dispensed in hospitals. However, in some of the countries (e.g. LV, MT) where a classification of HOM exists, this is not laid down in law. In 11 PHIS countries no official classification for HOM is in place i.e. AT, CY, DE, FI, FR, LT, NL, NO, SE, SK and UK.

Figure 3.7 shows which European countries classify HOM and those which do not. Having a classification of HOM might have consequences on e.g. pricing and reimbursement. In Italy, for instance, medicines of category H, which are hospital medicines, are a sub-type of medicines of category A, which defines 100% reimbursable medicines.

Figure 3.7: European survey – Classification of medicines as hospital-only medicines (HOM) in European countries, 2009



BE and TR: for reimbursement only
MT: only specific medicines however not regulated by law

Source: PHIS 2009c-u, PHIS 2009v

There is a tendency that in many cases hospital-only medicines comprise rather expensive medicines. The percentage rates of HOM range between 1% (LV) and 25% (MT). However, the number of medicines used in hospitals is considered much higher. No data or estimations on the share of authorised medicines or medicines on the market used in hospitals as per-

centage of total authorised medicines or medicines on the market could be provided by the countries. This study focuses on all medicines used in hospitals and is not limited to HOM.

3.4.2 Delivery chain

The way medicines are delivered is differently organised in the European countries. In the majority of the PHIS countries medicines are supplied to hospitals either directly by the industry or through wholesalers. This is the case e.g. in AT, CZ, DK, IE, LT, LV, NL, NO, PL, PT, RO, SK, TR and UK. In addition, parallel traders may deliver to hospitals in the Netherlands and the UK, however this delivery chain is rare even in those two countries. In Austria, Latvia, Portugal and the UK community pharmacies may deliver medicines to hospitals as well. In Norway pharmacies and wholesalers deliver medicines to hospitals. Hospitals in countries with only one delivery channel are either delivered directly by industry (i.e. BE, DE, ES, FR and IT) or by wholesalers (i.e. BG, EE, FI, HU, SE, SI).

In Cyprus and Malta distinct public and private health care sectors exist which are also characterised by different delivery chains: Whereas private hospitals are delivered by private suppliers (either industry or wholesalers), medicines for the public sector are centrally procured by tendering by a government unit and then distributed to public hospitals and any other relevant public entities (see Box 3.2).

Box 3.2: European survey – Delivery chain in Cyprus and Malta

The fact that the public and private health care sectors are separate in Cyprus and Malta is also reflected in different supply chains.

In Cyprus the marketing authorisation holder of a medicine delivers to the stores of the Pharmaceutical Services of the Ministry of Health which then delivers medicines to hospital pharmacies upon request. Private hospitals in Cyprus buy medicines through private pharmacies.

In Malta private wholesalers deliver pharmaceuticals to the Government Health Procurement Services (GHPS) stores. The GHPS is then responsible for the distribution of these medicines (using government transportation) to public hospital pharmacies and other public out-patient pharmacies. Wholesalers deliver hospital pharmacies in the Maltese private sector.

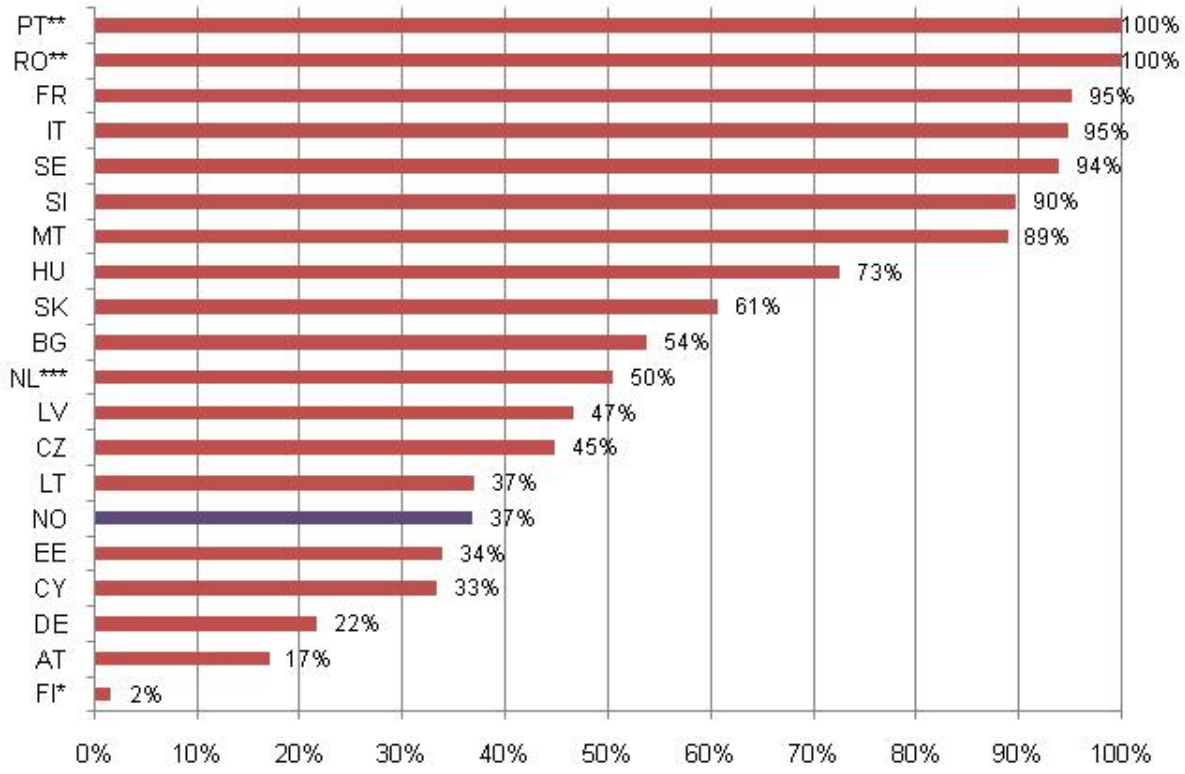
Source: PHIS 2009f, PHIS 2009m

In most of the European countries not all hospitals have a hospital pharmacy (for further information see section 3.4.3). Pharmaceutical provision in hospitals without a pharmacy (cf. Figure 3.8) is either assured via a pharmaceutical depot (i.e. AT, BE, ES) or by other hospital pharmacies which is the case in BG, DK, EE and HU. Another possibility for hospitals without a pharmacy is the delivery through other pharmacies, e.g. community pharmacies such as in DE, FI, FR and LV. In IE, SI, SK and the UK hospitals without a hospital pharmacy rely either on larger hospitals or local community pharmacies for supplies.

3.4.3 Hospital pharmacies

Not in all hospitals in Europe a hospital pharmacy is established. Figure 3.8 shows the percentage of hospitals within a country having a hospital pharmacy. The range goes from almost all hospitals per country having one (i.e. FR, IT, PT, RO, SE) to only 2% in Finland. Reasons for the different relevance of hospital pharmacies are traditions meaning that the historical role of hospital pharmacies differs between the countries as well as different national legal provisions.

Figure 3.8: European survey – Number of hospital pharmacies in % of number of all hospitals in European countries, 2009 or latest available year



* Pharmacies at University hospitals; the number of pharmacies in small hospitals or in dispensaries are unknown

** Only public hospitals (in PT de facto all public hospitals have a hospital pharmacy)

*** Applies only to general and speciality hospitals

2006: CY, NL

2007: AT, BG, DE, FR, IT, LT, SE, SK

2008: CZ, FI, LV, MT, NO, PT, SI

2009: EE, HU, RO

No data of BE, DK, EL, ES, IE, LU, PL, UK, TR

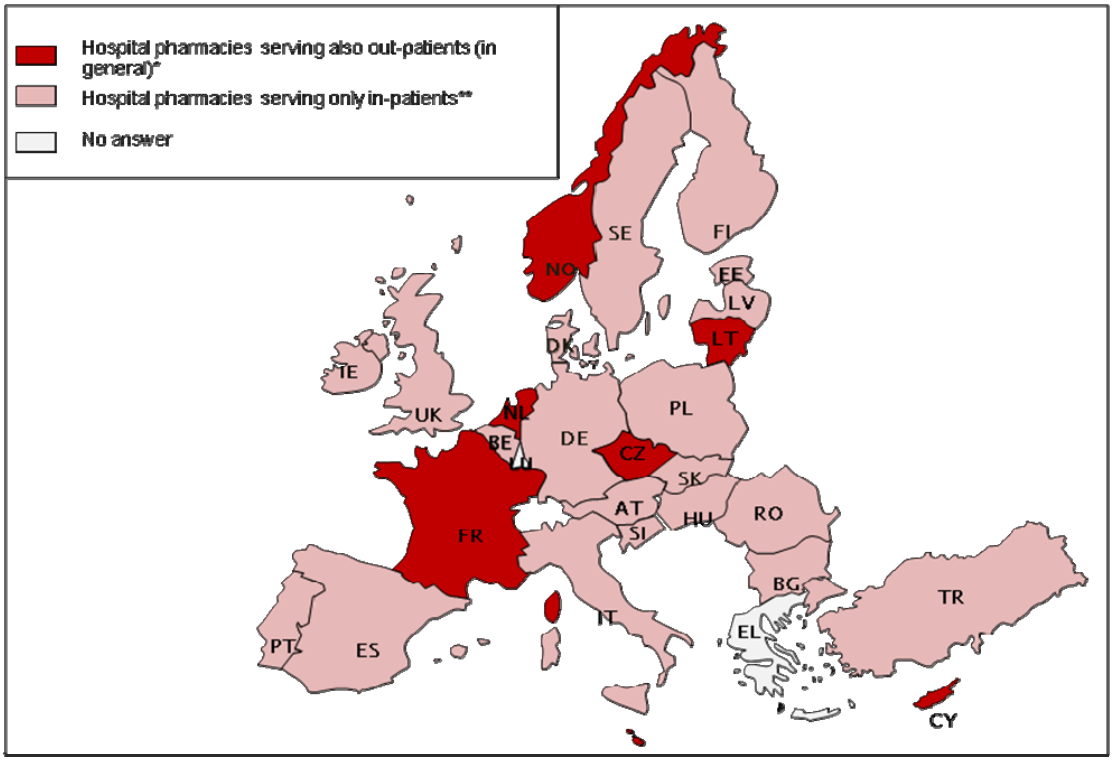
Source: PHIS 2009c-u, PHIS 2009v

The basic task of hospital pharmacies is to serve in-patients. It is confirmed by the information gathered in the European survey that in most countries hospital pharmacies exclusively or mainly serve in-patients. However, in some countries hospital pharmacies may also serve

out-patients, thus acting as community pharmacies. In a few countries, a second pharmacy for out-patients on the premises of the hospital is run by the hospital pharmacy (e.g. HU, NL, PL). Serving out-patients by hospital pharmacies may be limited for specific medicines (e.g. BE, FR), for specific patient groups (e.g. IE, PT), for medicines administered to out-patients in day clinics (e.g. BE) or in out-patient hospital departments (e.g. DE, UK). Hospital pharmacies serving out-patients may only be relevant for a few hospital pharmacies (e.g. AT) or a specific percentage (e.g. NL). For detailed information see the country-specific legend of Figure 3.9.

Hospital pharmacists play a crucial role within hospital pharmacies, being in charge of activities such as ordering, distribution and service production of medicines as well as quality control and clinical pharmacy. This aims at ensuring a rational and safe use of medicines. In most PHIS countries hospital pharmacists are part of the Pharmaceutical and Therapeutic Committee which are also in charge of hospital pharmaceutical formularies (cf. section 5.2). However, the role varies a lot among the PHIS countries.

Figure 3.9: European survey – Customers of hospital pharmacies in European countries, 2009



* i.e. acting as community pharmacy and/or running a community pharmacy on the hospital's premises

** as a general rule – minor exceptions (e.g. few hospitals, a limited number of defined medicines/patients) might be possible

AT: Only 10% of hospital pharmacies serve also out-patients due to historic reasons
BE: Only for out-patients in day-clinic and some special medicines like gonadotrophines
DE: Also serve out-patients at hospital out-patient departments if administered in the out-patient department
ES: Hospital pharmacies supply medicines for the first cycle of treatment for out-patients discharged from hospitals and hospital pharmacies serve HOM for out-patients as well
FR: Hospital pharmacies can serve out-patients for a list of reassigned ("rétrocession") medicines
HU: Some hospitals may get the license to serve out-patients
IE: Some hospitals have additional services across specific patient groups e.g. HIV positive patients, treatment of tuberculosis
IT: Hospital pharmacies supply medicines for the first cycle of treatment for out-patients discharged from hospitals
LT: In many hospitals community pharmacies dispense to out-patients
NL: No legal impediment for hospital pharmacies to dispense to out-patients - 55% of hospital pharmacies dispense to out-patients
NO: All hospital pharmacies have an out-patient department open for patients, families, hospital employees
PL: Some hospitals may get the license to establish community pharmacies to serve out-patients
PT: Only predefined medicines (e.g. HIV, renal failure, etc.) are dispensed to specific out-patients who had been treated as in-patient before (e.g. HIV/AIDS patients). Exemption: exceptional circumstances with social implications or for clinical reasons. Since 2006 a legal framework for establishing community pharmacies in NHS hospitals has been in place. Currently there are three community pharmacies in hospital facilities
RO: Some hospitals may get the license to establish community pharmacies to serve out-patients
SI: Mainly serving in-patients – two hospital pharmacies serve also out-patients
UK: Hospital pharmacies also serve out-patients who attend hospital for consultation or treatment without being admitted to a hospital as an in-patient

Source: PHIS 2009c-u, PHIS 2009v

4 Purchasing and pricing

4.1 Regulatory framework

For the out-patient sector there is a rather clear regulatory framework regarding pricing of medicines. In most of the European countries (24 of 27 EU Member States) prices of medicines are controlled (e.g. via statutory pricing); however in the majority of countries price control is limited to reimbursable medicines. Remuneration for distribution actors is also regulated (for wholesalers in the majority of the EU Member States, for pharmacies in all countries), and discounts granted to purchasers (either in the delivery chain or to patients) are either not allowed or regulated at a specific limit (PPRI 2008).

In general the framework regarding pricing in the public in-patient sector is similar to the one in the out-patient sector. In most PHIS countries pricing policies in the in-patient sector are linked to overall price regulations which are also valid in the out-patient sector (for country information see PHIS 2009c-u, PHIS 2009v). Often there is no distinction between medicines for out-patient care and hospital care. For instance in Bulgaria there is statutory pricing for all medicines at the ex-factory price level including medicines used in hospitals. Even in those 16 PHIS countries which classify specific medicines as HOM (cf. section 3.4.1) other medicines which are also applied in out-patient care are used in hospitals. Furthermore the out-patient mark-up scheme might also be valid for medicines used in the in-patient sector (cf. Table 4.3).

In a few countries there is no price regulation in the in-patient sector: Prices of medicines in hospitals are not regulated in Denmark and Germany which have no price control at ex-factory price level in the out-patient sector. In Poland hospital prices are in general not regulated. However, there are two exceptions including statutory pricing on wholesale level for 28 active ingredients set by the Ministry of Health and pricing negotiations by the National Health Fund for medicines in chemotherapy programmes.

However, price regulations only target the maximum hospital list price which might afterwards be reduced during the procurement process. In the in-patient sector no limitations on commercial discounts or rebates are in place in the PHIS countries, which might lead to (considerable) price reductions (see section 4.3.2). In general and in particular for specific indications, e.g. cardiovascular diseases, the actual hospital price, which is achieved in a procurement process, is considered much lower than the maximum hospital price. This assumption will be validated in the case studies (cf. sections 9 and 10).

4.2 Procurement of medicines for hospital use

There are a few different policies in place for the procurement of medicines used in hospitals. In general, procurement “is a complex process that involves many steps and many stake-

holders. It is also conducted within national and institutional policies, rules, regulations, and structures that may hinder or support the overall efficiency of the procurement process. An effective procurement process at any level must ensure that four strategic objectives are achieved:

- the procurement of the most cost effective medicines in the right qualities,
- the selection of reliable suppliers of high-quality products,
- procurement and distribution systems that ensure timely and undisturbed deliveries,
- processes that ensure the lowest possible total costs." (PHIS Glossary, PHIS 2009a, quoting WHO 2002b).

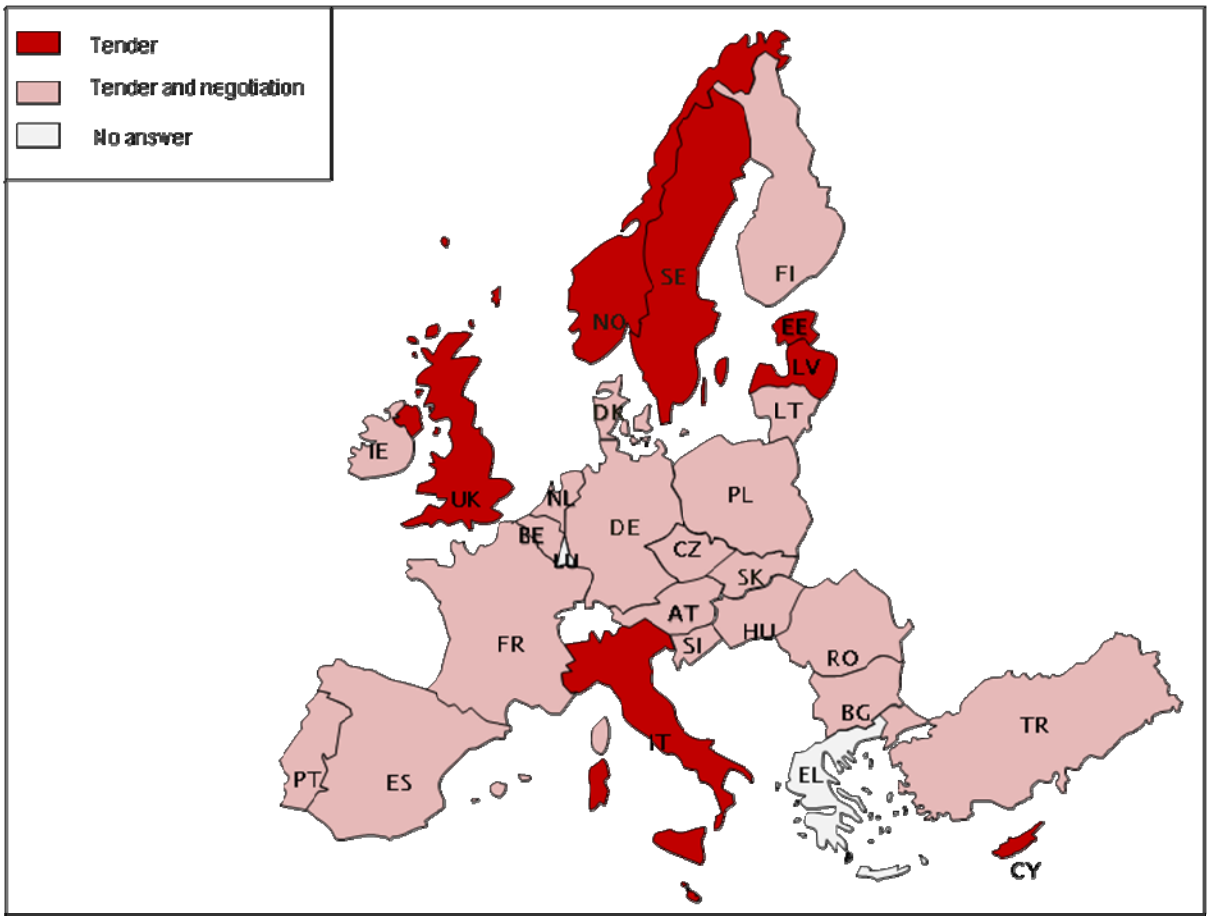
In the following section, the relevant procurement policies in the European countries are described, followed by information on the way procurement (independent of the procurement policy applied) is organised (cf. section 4.2.2) and which procedural issues play a role (cf. section 4.2.3).

4.2.1 Purchasing policies

Key policies for procuring medicines are tenders, which might be open or restricted, competitive negotiations (for further information see section 4.2.1.2) and direct procurement between the supplier and purchaser (PHIS Glossary, PHIS 2009a, quoting WHO 2002b).

In the PHIS countries medicines for hospital use are mainly procured by tenders or by negotiations.

Figure 4.1: European survey – Purchasing policies for medicines used in hospitals in European countries, 2009



Data not available for EL, LU

Source: PHIS 2009c-u, PHIS 2009v

Most countries apply a mix of these different purchasing policies (cf. Figure 4.1). However, there are a few countries where tendering is the key or sole policy for procuring medicines. For example in Norway all medicines for public hospitals are procured at a centralised level by a national procurement agency (see Box 4.3). In other PHIS countries where procurement both by tendering and by negotiations is carried out, the relevance of the policies differs among the countries. While several Western European countries reported on tendering being applied in a rather large number of acquisitions, direct procurement by negotiations of hospitals with suppliers is the key purchasing policy in Austria, Germany and some EU Member States in Central and Eastern Europe with tenders only being launched if required by EU legislation (cf. section 4.2.1.1). Nonetheless, even these countries reported on an increased use of tenders.

In line with EU requirements, usually rather expensive medicines are tendered (e.g. blood factors, this was reported by e.g. HU, SK), while the remaining medicines are procured via direct negotiations between the hospitals and the pharmaceutical companies/wholesalers.

In some countries (e.g. PL, PT) individual negotiations might take place as a second step following (centralised) tenders (cf. Box 4.1). This allows hospitals to negotiate lower prices compared to the centrally procured prices (cf. case studies, e.g. section 9.4.2.2 for viewing actual hospital prices achieved in Portugal).

Box 4.1: European survey – Two step procurement for medicines in hospitals in Portugal

In Portugal several policies for procuring medicines for hospitals are applied, including tendering at a centralised level by ACSS and acquisitions by hospitals (individually by hospitals and/or by associations of several hospitals).

For several medicines, a two step procurement process is applied involving direct negotiations by hospitals following centralised tendering. The common procurement policy is that the Central Administration of the Health System (ACSS) tenders a number of medicines which are then listed in a publicly accessible catalogue. The tender prices of these centrally procured medicines are displayed in the ACSS catalogue. In a second step, hospitals enter into negotiations with the companies for actually acquiring theses medicines. During the negotiations, price reductions might be agreed which are usually granted as rebates (so-called “rappel”) at the end of the year. Depending on the economic relevance of the medicines for the hospital budget, hospitals pharmacists start competitive negotiations asking four to five manufacturers to submit a proposal, while in case of low-priced medicines they might decide to refrain from negotiations and purchase the medicine at the ACSS price.

For those medicines which are not centrally procured, procurement is only carried out via negotiations of the hospitals.

Source: PHIS 2009q

4.2.1.1 Tendering

Procuring medicines for hospital use by tendering is a major purchasing policy in the in-patient sector. This is in contrast to the out-patient sector where tendering is mainly done for specific medicines or populations groups (ÖBIG FP 2008a) or as a reimbursement strategy (ÖBIG FP 2008b, EMINet 2009b).

In most PHIS countries tendering and negotiations are carried out in parallel. As shown in Figure 4.1, tendering is the sole purchasing policy in eight countries (CY, EE, IT, LV, MT, NO, SE, UK).

Tendering of public goods is regulated at EU level in Directive 2004/18/EC. It specifies the award criteria and the thresholds for which a tendering process needs to be initiated. The directive lays down the common procedure to ensure that tendering processes are conducted in a competitive manner across Europe.

The EU Member States have transposed this EU Directive into their national law. In addition, some EU Member States have implemented national guidelines and rules for tendering.

Besides national guidelines international organisations such as the World Health Organisation (WHO), the World Bank and the Organisation for Economic Co-operation Development (OECD) published different guidelines in the field of public pharmaceutical procurement by tendering.

4.2.1.2 Negotiations

In several PHIS countries negotiations between supplier and purchaser (the individual hospitals or hospital purchasing groups, see section 4.2.2) are a major way of acquiring medicines.

While competition is a characteristic feature of procurement by tendering (see definition at the beginning of section 4.2), negotiations might include a competitive component: Competitive negotiations mean approaching a few selected companies and requesting price offers. Only a few countries (e.g. SK see Box 4.2) explicitly reported that competitive negotiations are used in their countries. Besides, direct negotiations between purchaser and supplier are also a common purchasing policy for acquiring medicines for hospital use.

Box 4.2: European survey – Competitive negotiations called "market evaluation" in Slovakia

If a medicine accounts for an annual pharmaceutical expenditure of between € 15,000.- and € 30,000.- of the hospital budget, it must be purchased by the hospital through competitive negotiations which are called "market evaluation" in Slovakia.

The responsible person for procuring by market evaluation is the chief hospital pharmacist. S/he collects a minimum of three offers from different wholesalers for each medicine to be acquired. The criteria for selecting the wholesaler include among others the lowest price and the availability. In many hospitals this method is used for every individual medicine which is not publicly procured by tendering. Tendering is mandatory for a hospital if the total expenditure of a pharmaceutical (active substance) exceeds € 30,000 per year. The chief hospital pharmacist must document the reasons for her/his decision in a written form. In many hospitals the final decision is taken by the medical or economic director of the hospital, and the chief pharmacist has an advisory role.

Normally there are 5–30 medicines in a hospital which must be procured by tenders, all other medicines are purchased by the method of market evaluation or by direct negotiations with the manufacturer or wholesaler. In these cases it is the responsibility of a purchasing committee or medical/economic director or the chief hospital pharmacist.

Source: PHIS 2009s

4.2.2 Organisation of procurement

Procurement of medicines for hospital use may be organised at different levels: It may be done at a centralised level, in purchasing groups or individually by hospitals. Different ways

of organising procurement may be done in parallel; e.g. a hospital can be part of a purchasing group which procures specific, usually more expensive, medicines, while it individually acquires other needed medicines directly from the suppliers. An overview of different ways how procurement might be organised is provided in Table 4.1.

Table 4.1: European survey – Organisation of procurement for medicines in hospitals in European countries, 2009

Procurement	Countries
Centralised (e.g. MoH, SHI, national purchasing agency)	CY[1], DK, HU[2], LV, MT[1], NO, PT[2], RO[2], SK[2], UK
Purchasing groups (e.g. committees at regional/district/county level, joint hospital groups)	AT, DE, FI, FR, IE, IT, NL, PT, SE, UK
Directly by hospitals	AT, BE, BG[3], CY, DE, EE, ES, FI, FR, HU, IE, LV, NL, PL, PT, RO, SI, SK, TR, UK

MoH = Ministry of Health, SHI = Social health insurance institution

Data not available for EL, LU

[1] CY and MT only relevant for the public sector

[2] HU, PT, RO, SK: centralised tendering for some medicines, often followed by individual negotiations of hospitals

[3] private hospitals

Source: PHIS 2009c-u, PHIS 2009v

A procurement group and/or a hospital may apply different procurement methods for different acquisitions. Again, specific medicines might be acquired via tendering (e.g. due to legal requirements or for gaining a stronger bargaining position), while other medicines may be procured by negotiations. Usually, when medicines are centrally procured in the PHIS countries, this is usually done via tendering.

In a few countries (e.g. CY, IT, MT, NO, UK) all or the majority of medicines used in (public) hospitals are centrally procured. In some other countries (e.g. RO and SK) specific, usually expensive medicines (e.g. blood factors) are procured at centralised level.

Centralised procurement by tendering is carried out by Ministries of Health, social health insurance institutions or national procurement agencies. In Denmark, for example, the national purchasing agency AMGROS is responsible for providing all public hospitals with medicines (for a description see Box 4.3).

Box 4.3: European survey – Procurement agencies AMGROS in Denmark and LIS Norway

In **Denmark** medicines are purchased via public tendering and price negotiations carried out by AMGROS, which is a procurement agency owned by the five regions. The decision about which medicines to use in a hospital is taken at hospital level. All public hospital pharmacies order and buy medicines via the AMGROS' electronic purchasing system. AMGROS holds tenders under the EU rules and signs contracts for almost all medicines at ATC 5 level.

Tenders are organised 60-70 times a year and are published at the website of AMGROS (www.amgros.dk). Contracts are usually set for around one to two years and the contract price is fixed for this period. Hospitals are delivered directly from industry without the involvement of AMGROS.

In **Norway** the Norwegian Drug Procurement Cooperation (LIS) procures for all publicly funded hospitals. This is done on a yearly basis and includes all medicines financed by the hospitals. The only exceptions are solutions and x-ray contrasts where the procurement process takes place every second year. All suppliers, manufacturers and wholesalers are addressed by LIS and the Public Procurement Law is applied, which is in line with the European Union procurement law. Due to legal provision the tenders are published in the Doffin (http://www.doffin.no) and TED (http://ted.europa.eu) database.

Source: PHIS 2009h, PHIS 2009o

Some PHIS countries have established regional procurement committees, e.g. in Italy the Regional Therapeutic Committees or in Finland the joint municipal authorities for primary health care are the responsible authorities for purchasing medicines for hospitals. Hospitals may join purchasing groups which procure together specific medicines: This is done by individual hospitals in the same region (for instance the Hospital Pharmacists Rijnmond Purchasing Group, ZRIG, cf. Box 4.4) and/or under the same management.

Box 4.4: European survey – Sole source commitment policy by a regional purchasing group in the Netherlands

The Hospital Pharmacists Rijnmond Purchasing Group (ZRIG) in the Netherlands includes 15 hospitals. This purchasing group procures on average one third of the medicines needed in the hospitals of that region. All members of the regional purchasing group have to agree on the medicine. As soon as a contract with a manufacturer or wholesaler is set, the hospitals of the regional hospital purchasing group have to use the purchased medicine. This is called a “sole source commitment”.

Source: PHIS 2009n

Additionally, in the majority of all PHIS countries medicines are acquired by the hospitals from the suppliers. This is often done directly with manufacturers or wholesalers. At least 18 of the 27 PHIS countries reported to do so (as indicated in the European survey). Even though individual hospitals might not have the same bargaining power as national purchasing groups due to smaller volumes and direct negotiations are considered as less favourable for achieving lower prices (WHO 2002b), it might still be a possibility for hospitals to get price reductions and maintain their individuality. As information on the actual hospital price is neither publicly available nor shared with other hospitals (cf. section 4.3), it is difficult for individual hospitals to know if their procured price is really lower as compared to other hospitals.

4.2.3 Procurement procedures

Usually, when medicines for hospital use are procured, the contracts are valid for a specific period of time. Usual time-frames which were reported range from one year to up to three years. Some countries (AT, CZ, PL, RO, SK, TR) reported that new procurement procedures are initiated when needed; they did not specify time-frames.

In the procurement process – whether done by tendering or negotiations – the price is certainly a key award criterion in all 27 PHIS countries. Nonetheless, further factors, such as storage, supply conditions, payment terms, frequency of delivery, packaging, are considered when the decision on awarding the contract is taken. In several countries (e.g. DE, DK, FI, FR, LT, NL, SE, SK, UK) an emphasis is put on quality, medical and therapeutic benefits and needs when assessing the offers.

Table 4.2: European survey – Award criteria and duration of contracts in procuring medicines for hospitals in European countries, 2009

Award criteria[1]	Countries
Price	AT, BE, BG, CY[2], CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LV, MT[2], NL, NO, PL, PT, RO, SE, SI, SK, TR, UK
Quality, medical and therapeutic benefits/needs	DE, DK, FI, FR, LT, NL, SE, SK, UK
Further qualitative factors like storage, supply conditions, payment terms, frequency of delivery, packaging	AT, BE, BG, CZ, DK, ES, HU, IE, IT, NL, NO, SI
Frequency[3]	**Countries**
Annually	BG, DK, FR, HU, IE (frequently), LV, NL, NO (medicines), SI (2 or more), SE, UK (frequently)
Every two / three years	CY[1], DE, FI, IT, MT[1], NL, NO (solutions and x-rays), PT
When needed	AT, PL, RO, SK, TR

Data not available for CZ, EL, LU

[1] Several criteria may be applied

[2] CY and MT only relevant for the public sector

[3] No information on the frequency: BE, EE, ES, LT

Source: PHIS 2009c-u, PHIS 2009v

4.3 Understanding hospital prices

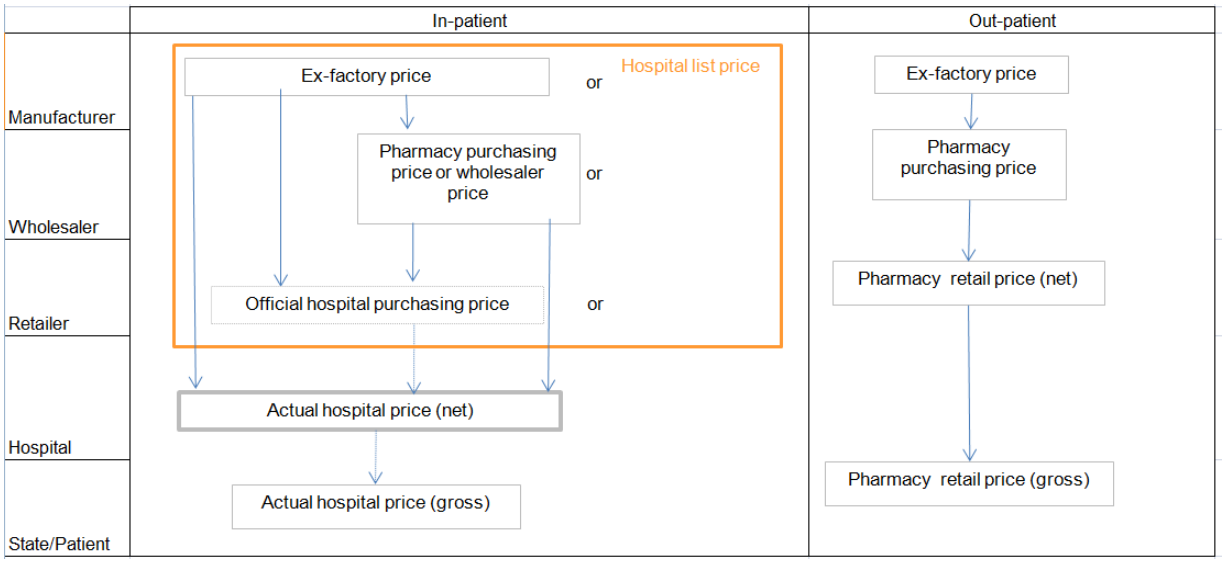
4.3.1 Price types

Understanding the prices applied for medicines in hospitals is even more difficult than for the out-patient sector. As explained in section 4.1, in the out-patient sector prices are regulated

at all levels in most countries (price control of the ex-factory or pharmacy purchasing price plus regulation of the remuneration of the distribution actors). In the in-patient sector several countries regulate the maximum list price, which is the ex-factory price or the pharmacy purchasing price (cf. Table 4.3). The maximum list price builds the basis for the actual hospital price which is achieved during the procurement process (by tendering or by negotiations). Whereas discounts and rebates are usually forbidden or limited by regulation in the out-patient sector (cf. section 4.1), different forms of price reductions without any limitations may be granted in the in-patient sector.

To visualise the price types in the in-patient sector compared to the out-patient sector, a schematic overview is given in Figure 4.2.

Figure 4.2: European survey – Build-up of medicine prices in the in-patient compared to the out-patient sector, 2009



Source: Developed by PHIS Hospital Pharma (GÖG/ÖBIG, SUKL) 2010

In many PHIS countries (BE, BG, CZ, DE, EE, LT, NL, NO, PL, RO, SK, TR, UK) the hospital price includes a fixed mark-up and a VAT rate.

Table 4.3: European survey – Understanding hospital prices in European countries, 2009

Hospital price corresponds to ...	Countries
Ex-factory price	AT, DE, ES, FR, IT, PT
PPP net	(AT), CY[1], DK, FI, HU, IE, LV, MT, SI, SE
PPP gross	BE, BG, CZ, DE, EE, LT, NL, NO, PL, RO, SK, TR, UK (NHS)
Add-ons (wholesale mark-ups, fees and VAT)	**Countries**
Out-patient WS mark-up applicable	(AT), BG, CZ, HU, LV, RO, TR
WS mark-up not regulated	CY[1], DK, FI, LT, NL, NO, PL, SE
Fixed hospital WS mark-up	BE (21.746%), DE (6%), IE (17.66%), SK (9%)
VAT	BE (6%), BG (20%), CZ (10%), DE (19%), EE (9%), LT (5%), NL (6%), NO (25%), PL (7%), PT (5%), RO (9%), SK (10%), TR (8%), UK (17.5%)

NHS = National Health Service, PPP = Pharmacy Purchasing Price, VAT = Value Added Tax, WS = Wholesale

Data not available for EL, LU

[1] Only valid for public hospitals; private hospitals PPP plus 20% administration costs

Source: PHIS 2009c-u, PHIS 2009v

As shown in Table 4.3, in six countries (AT, DE, ES, FR, IT, PT) the hospital price corresponds to the ex-factory price; in nine other countries (CY, DK, FI, HU, IE, LV, MT, SI, SE) the official hospital price is the net pharmacy purchasing price. Hence, in the majority of countries the hospital price corresponds to the gross pharmacy purchasing price, meaning that on the ex-factory price a wholesale mark-up plus a VAT rate is added to the price. The wholesale mark-up for medicines used in hospitals might be the same as in the out-patient sector, but might also not be regulated at all. Four countries (BE, DE, IE, SK) have specific hospital wholesale mark-ups. They range between 6% in Germany and 21.7% in Belgium. (for further specific information see Box 4.5).

Box 4.5: European survey – Wholesale mark-up schemes for medicines in hospitals in Austria, Belgium, Germany, Ireland, Portugal and Slovakia, 2009

In **Austria** hospital prices are usually set at ex-factory price level. However, several hospitals do not have a hospital pharmacy and therefore they are obliged by law to be supplied by other (hospital) pharmacies. Hence, the hospital price for medicines in those hospitals corresponds to the net pharmacy purchasing price (incl. e.g. wholesale mark-ups). The price build-up in Austria is explained in more detail under section 9.1.1.

In **Belgium** the official maximum hospital price is the gross pharmacy purchasing price, which is calculated by adding a 21.746% wholesale mark-up as well as 6% VAT rate on the ex-factory price.

In case a medicine is delivered through a wholesaler in **Germany**, a fixed mark-up of 6% is added on the ex-factory price. Hospital prices in Germany include 19% VAT.

In general, hospital prices in **Ireland** include a wholesale mark-up of 17.66% if hospitals are supplied by wholesalers (direct delivery by industry are also possible). However, under nationally agreed arrangements public hospitals are exempt from the wholesale mark-up if their individual orders reach pre-defined thresholds. In fact, most hospitals can avoid the wholesale mark-up due to a substantial proportion of their purchases.

In **Portugal** the hospital price corresponds to the ex-factory price including 5% VAT. In practice wholesale mark-ups are not relevant in the in-patient sector due to direct deliveries from industry. Wholesale mark-ups for the in-patient sector are not regulated, but when applied usually the out-patient mark-ups are taken. The price build-up of medicines used in hospitals in Portugal is explained in more detail in section 9.4.1.

In **Slovakia** hospital prices include a linear wholesale mark-up of 9%, in contrary to the out-patient sector, where a regressive wholesale mark-up scheme is applied. Prices of medicines used in hospitals include 10% VAT. The price build-up of medicines used in hospitals in Slovakia is explained in more detail in section 9.5.1.

Source: PHIS 2009c, PHIS 2009d, PHIS 2009q, PHIS 2009s, PHIS 2009v

In contrary to the out-patient sector, there is no pharmacy mark-up applied in the in-patient sector. This is linked to the distribution system in the in-patient sector where hospitals are mainly delivered by industry and wholesalers (cf. section 3.4). Should a hospital pharmacy dispense medicines to out-patients, then a specific remuneration might be applied (e.g. in Belgium where the hospital pharmacy receives a fee of up to € 7.11 per package).

Hospital prices in 14 of 27 PHIS countries include VAT rates. The VAT rates vary between 5% in Portugal and 25% in Norway. The VAT rates for medicines used in the hospital sector are the same as for medicines applied in the out-patient sector.

4.3.2 Discounts/rebates and cost-free medicines

One key element of successful procurement is to get reasonable prices (see PHIS Glossary, PHIS 2009a, quoting WHO 2002b in the introductory section 4.2 on procurement policies). This can be achieved by e.g. discounts, rebates, bundling or cost-free medicines. These forms of price reductions are defined as followed (PHIS Glossary in its latest version, PHIS 2009a):

"*Discount* is a price reduction granted to specified purchasers under specific conditions prior to purchase."

"*Rebate* is a payment to the purchaser after the transaction has occurred. Purchasers (either hospitals or pharmacies) receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time."

"*Bundling* is a marketing strategy that involves offering several products for sale as one combined product."

"*Cost-free medicines* are products which are given to hospitals/hospital pharmacies in the course of the delivery without need for payment (e.g. from wholesaler to hospitals/hospital pharmacies or pharmaceutical company to hospitals/hospital pharmacies)."

Usually, price reductions granted to hospitals in the European countries are provided on a voluntary basis (commercial discounts/rebates). There is the possibility that suppliers are required by law to provide price reductions if they deliver to specific costumers. For the hospital sector, this is the case in Italy where pharmaceutical manufacturers need to grant mandatory discounts of 50% to the national health service when supplying public hospitals.

(Commercial) discounts/rebates (i.e. granted by the suppliers to the purchasers on a voluntary basis) are rather common. The extent of the price reductions differs considerably, ranging from above 0% to 100% in Europe. It strongly depends on the bargaining power of the purchasing group or the hospital or the willingness of the pharmaceutical company. However, discounts/rebates in a rather low range of 10% to 20% seem to be common practice in several European countries (cf. Table 4.4).

Table 4.4: European survey – Price reductions and cost-free products in hospitals in European countries, 2009

Discounts/rebates	Countries
Mandatory	IT (50%)
Voluntary (commercial)	AT (0-99%), BG, CY, CZ, DE (10-20%, 0% for innovators), DK (~20%), EE, ES, FI, FR, HU, IE[2], IT (33.35%), LT, MT, NL (~31%), NO (25-40%), PL (2-10%), PT, RO, SE, SI (1-10%), SK (1-10%), TR, UK (~12%)
Cost-free medicines[1]	AT (10% of all medicines), CY, EE (1-2%), FR (included in negotiation process), IE, SK

Data not available for EL, LU

[1] Legally not allowed: DE, DK, HU, IT, LT, UK

[2] Under national agreements public hospitals are exempt from wholesale mark-up if individual orders reach predefined thresholds.

Source: PHIS 2009c-u, PHIS 2009v

According to the information from the PHIS Hospital Pharma Reports, cost-free medicines are not very common. Six countries (AT, CY, EE, FR, IE, SK) informed that hospitals may receive medicines directly from pharmaceutical industry without having to pay for it. Hospital experts in Austria estimate that cost-free medicines account for 10% of all medicines purchased in hospitals. In France, cost-free medicines are reported to be part of the negotiation processes, meaning that the contract with the wholesaler or the manufacturer is concluded for a specific volume, which might include some cost-free medicines.

Some countries (DE, DK, HU, IT, LT, UK) explicitly stated that cost-free medicines are legally not allowed. In the Netherlands cost-free medicines are not forbidden by law, but many hospitals do not accept cost-free medicines.

Information on bundling could not be gathered in the European survey. In a few countries (e.g. AT), it was reported that this practice is not applied in the hospitals in order to maintain transparency.

4.3.3 Price information

Knowledge on hospital prices is weak in the European countries, as this information is not publicly available. What is published, these are the maximum list prices of medicines used in hospitals. This information is available in several countries, provided that the maximum prices are regulated (cf. section 4.1).

According to the tendering provisions by the European Union, prices of tendered medicines need to be published. This is done in the European TED[8] and in national databases (e.g. Doffin[9] database in Norway).

As a result, for example in Portugal, the maximum prices of new medicines used in hospitals are published on the INFARMED website and the prices of tendered medicines by ACSS on the ACSS website.

The actual discounted or rebated hospital prices are not publicly available. Additionally, they are normally not shared between the pharmacies. However, during research for the European survey, we learned that some pharmacists have an idea about the prices achieved by the other hospitals (PHIS 2009c).

The lack of transparency regarding hospital prices was highlighted several times by high-level speakers and panellists at the PHIS Hospital Pharma seminar in Bratislava in February 2010 (PHIS 2010).

The level of competitiveness of the hospital market (e.g. price variations between the hospitals) is analysed in the case studies in section 9.

[8] http://ted.europa.eu

[9] http://www.doffin.no

5 Reimbursement

5.1 National hospital reimbursement

Funding of hospital care (cf. Table 3.2) as well as financing medicines used in hospital care differs among the PHIS countries. In most of the PHIS countries in-patient and out-patient care is funded by the same payers with the only exceptions being Austria and Norway (cf. section 3.3.1).

With regard to funding of medicines the situation is the following in the PHIS countries: Generally speaking, in the majority of the PHIS countries the main payer of medicines is the same in the in-patient and out-patient sectors. However, regarding remuneration of expenditure the situation differs in PHIS countries. This fact can lead to problems at the interface between the in-patient and out-patient sectors, with transferring high cost treatments from one to the other sector (cf. section 8).

Table 5.1: European survey – Positive lists for the in-patient sector in the European countries, 2009

Positive list	Countries
Relevant only for the out-patient sector	DK, EE, FI, FR, NO, LT, LV, NO, PT, SI
Also relevant for the in-patient sector	AT[1], BE[2], BG[3], CY[2], CZ[4], HU[2], IT[2], MT[5], NL[4], PL[4], SE, SK[4], TR

Data not available for EL, ES, IE, LU

No positive list in place: DE, UK
In FR, LV and PT separate national positive lists for the in-patient sector (cf. section 5.2)
RO: not included, as hospitals need to provide all medicines needed by patients for free

1 The reimbursement list used in the out-patient sector needs to be considered at the time of discharging the patient
2 The same list for in-patient and out-patient medicines
3 One annex of the positive list is for medicines in in-patient care
4 Basis for discussion during the procurement process
5 Same list but subdivided into out-patient formulary and hospital formulary

Source: PHIS 2009c-u, PHIS 2009v

Medicines which are considered as reimbursable are included on positive lists. In ten PHIS countries the positive lists are only valid for the out-patient sector, whereas for the in-patient sector other lists (hospital pharmaceutical formularies, cf. section 5.2) exist. In 13 PHIS countries the positive list is relevant for both the out-patient sector and the in-patient sectors. This is the case for example in Bulgaria where one specific annex of the positive list contains medicines for in-patient use. In some countries (e.g. CZ, NL, PL) the positive list is relevant for the in-patient sector by means of being the basis for discussion during the procurement process. In Malta the positive list is subdivided into an out-patient formulary and a hospital formulary. In Romania no specific lists exist but hospitals need to provide all medicines for in-patients need free of charge. France, Latvia and Portugal have separate positive lists for the in-patient sector (cf. section 5.2).

In most PHIS countries (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, LV, MT, NL, NO, PL, PT, RO, SI, SK, UK) medicines are included in the hospital remuneration, often in the DRG system. In Latvia medicines are included in the fees of medical services and in Sweden the County Councils fund medicines used in in-patient care. In Cyprus the Department of Pharmaceutical Services within the Ministry of Health, which procures medicines by tendering for public hospitals (cf. section 4.2.1.1), has its own pharmaceutical budget which is not linked to the budget of the individual hospital. However, it is part of the total budget of the Ministry of Health which is the main payer of hospital medicines in the public hospital sector in Cyprus.

In Table 5.2 countries with specific financing models for medicines used in hospitals are presented. Some countries have introduced specific financing schemes meaning that some – usually high-cost – medicines are not financed out of the hospital budget, but they are paid separately, either fully or party, usually by the social health insurance. The idea of such (supplementary) financing by another payer or remuneration scheme for expensive medicines is to ensure equitable access to these high cost medicines which could cause considerable variations in the distribution of DRG costs, either because of their very expensive nature, or because the marginal number of patients being treated. The reason why in a few countries social health insurance “co-pays” and does not fully cover these expenses is that hospitals should be made aware and accountable, at least partly, for the expenditure incurred due to these medicines.

Table 5.2: European survey – European countries with specific funding schemes for medicines used in hospitals, 2009

Countries	Targeted medicines	Medicine funding schemes
AT	Oncologic medicines, high-cost medicines	General funding: Medicines are integrated in the lump sums which can be generated for the procedures and diagnosis-oriented case groups in hospitals. Specific funding: In at least two provinces in Austria (Styria, Carinthia) some medicines (e.g. oncologic medicines) used in hospitals are funded differently. In these provinces the main public hospital owner organisations have concluded agreements with the regional sickness funds stating that the expenditure of oncologic medicines will be covered by the sickness fund even if they are dispensed in the in-patient sector.
BG	Medicines for particular diseases	General funding: Payment for in-patient care is made on the grounds of an agreement with the National Health Insurance Fund by groups of diseases defined as clinical pathways. Medicines are part of the treatment process and are part of the clinical pathways. Specific funding: Some medicines for treating particular diseases in hospitals are paid for through the state budget.
DE	High-cost medicines	General funding: Medicines are integrated in the DRG system. Specific funding: For expensive medicines additional reimbursement based on the documentation of their use (“Zusatzentgelte”).
FR	High-cost medicines; “reassigned medicines” (dispensed to out-patients)	General funding: Medicines used in hospitals are integrated in the activity-based costing system. Basically, they are included in the lump sums which can be generated for reimbursement of the procedure and DRG in hospitals. Specific funding: A supplementary list, “liste en sus” or “non T2A” medicines, of costly medicines excluded from the DRG system (particularly anti-cancer medicines, blood products, orphan medicines and some treatments for rheumatoid arthritis) has been developed. Medicines on this list are reimbursed up to 70-100% separately by the social health insurance. Another list of reassigned medicines which may be dispensed to out-patients by hospitals is reimbursed by the sickness fund.
HU	Specific medicines	General funding: Medicines used in hospitals are paid by the National Health Insurance Fund and are part of the hospital budget. Specific funding: Anti-coagulant factors are centrally procured products.
LV	High-cost medicines	General funding: Hospitals (including medicines) are financed from the State budget for health care services using the following types of payment: (1) occasional payments for a particular medical diagnosis or group of medical diagnoses, (2) occasional payments for a particular medical diagnosis or group of medical diagnoses in cases of short-term surgical treatment, (3) payments for diagnoses included in disease profiles, (4) payments for bed days and (5) payments for in-patient forensic medical examinations and treatment in compulsory treatment departments. Specific funding: Certain high-cost medicines are either covered by hospital budget in case the hospital budget is high enough or state budget. In case a certain high cost medicine is not available patients may be transferred to another hospital.
NL	Orphan medicines; high-cost	General funding: Medicines in in-patient care are paid out of the hospital budget. A hospital will fill its budget in the course of the year using the DBC system which is similar to the DRG system; DBC tariffs are paid for

Countries	Targeted medicines	Medicine funding schemes
	medicines	by the health insurer. The DBC tariffs cover the costs of most medicines, though these medicines are not earmarked within DBCs. Specific funding: Orphan medicines on the orphan medicine list and expensive medicines on the list of high-cost medicines (both lists set up by the Dutch Health Care Authority) are not covered by DBCs, but are reimbursed by the health social insurance: 100% for orphan medicines, while 80% for expensive medicines – the rest is borne by the hospitals.
PL	Highly specialised services	General funding: All hospitalised beneficiaries receive medicines (and medical devices) free of charge. This regards patients that are treated in hospitals, by day care providers or entities that are allowed to provide healthcare services (make diagnosis, rehabilitation, treatment, and immediate help). Pharmacotherapy for these patients is reimbursed by the National Health Fund to all entities contracted to provide such services. Medicines are part of the annual hospital budgets. Specific funding: Highly specialised services (e.g. grafting, incl. pharmaceutical treatment) are funded by the state budget (however, only of minor relevance).
SI	Orphan medicines; some high-cost medicines	General funding: Medicines in in-patient care are paid out-of the hospital budget: Specific funding: High-cost medicines (e.g. infliximab, rituximab, alemtuzumab, docetaxel) are not part of the hospital budget. The Health Committee evaluates on a case per case basis high-cost medicines and prepares the proposal whether to financed for in-patient treatment (i.e. financing of certain indications for a determined number of patients by a certain scheme in a specific hospital e.g. university hospital, specialised hospital). The final decision of financing of high-cost medicines for hospital use is made by agreements between representatives of hospitals, the Health Insurance Institute and the Ministry of Health. On the basis of these annual agreements, the Health Insurance Institute finances the specific high-cost medicine for a specific hospital.[1]
SK	Growth factors; beta-interferons	General funding: The health insurance company reimburses the hospitals by a fixed fee for „completed hospitalisation" of every in-patient. The portion reimbursed differs for every medical specialisation (e.g. internal medicine, oncology, surgery, anaesthesiology, etc.) and also differs depending on the type of hospital. Every health insurance company makes its own contract with a hospital and therefore the remuneration for individual hospitals can vary. Hospital remuneration also includes medicines. Specific funding: Some medicines like growth factors or beta-interferons are purchased by sickness funds directly in case medicines are used in special limited centres in hospitals.

DBC = diagnosis and treatment combination, DRG = diagnosis-related groups
No specific funding schemes: CY, CZ, DK, EE, ES, IT, IE, LT, MT, NO, PT, RO, SE, TR, UK
No information available: EL, LU

[1] The high-cost medicines financing scheme is valid until the end of the year 2010, due to envisaged changes of hospital medicines financing regulations. The financing decision of high-cost medicines for hospital use will then be made within the reimbursement process for medicines used in the out-patient sector.

Source: PHIS 2009c-u, PHIS 2009v

Besides general out-of pocket payments (OPP) for hospital care (cf. section 3.3.1) in a few countries patients need to additionally pay out-of pocket for medicines used in hospitals. For

example in Belgium € 0.62 per patient per hospital day is charged for reimbursable medicines and non-reimbursable medicines are fully charged. In Bulgaria OPP for medicines depend on whether the patient is insured or not (i.e. insured patients do not have to pay out-of pocket for medicines whereas patients without health insurance have to pay for medicines used in hospitals). In Cyprus patients that fall under a certain reimbursement category (category B – which includes all patients with annual income less than € 20,500.- or € 37,500.- for a family) need to partially co-pay medicines in the public sector and 100% in the private sector. OPP need to be paid unless patients have private health insurance. In the Maltese private health sector private health insurance is needed for the remuneration of medicines used in hospitals. In Norway OPP related to medicines are only due for treatments in hospital out-patient departments and in Germany for treatment in ambulatories.

5.2 Hospital pharmaceutical formularies

All PHIS countries except five (CY, MT, RO, SE, TR) have hospital pharmaceutical formularies (HPF) in addition to a national out-patient reimbursement list (cf. section 5.1). A HPF is a list of medicines that may be prescribed and applied by physicians in a hospital (PHIS 2009a). Table 5.3 shows that most HPF are applied at hospital level, only a few countries (DK, NO) use HPF at regional level. In France, Latvia and Portugal a national HPF is in place and additionally HPF exist in the hospitals.

Table 5.3: European survey – Hospital pharmaceutical formularies in European countries, 2009

HPF	Countries
HPF at national level	FR[1], LV[1], PT[1]
HPF at regional level	DK, NO
HPF at hospital level	AT[2], BE, BG[3], CZ, DE, EE, ES, FI[4], FR, HU, IE[5], IT, LT, LV, NL[5], PL[6], PT, SI[3], SK, UK[4]
No HPF in place (other than national reimbursement list)	CY, MT, RO, SE, TR

HPF = hospital pharmaceutical formulary

Data not available for EL, LU, SI

1 National HPF for all public hospitals, plus additional lists in all hospitals
2 Each hospital or hospital owner organisation
3 Each hospital has the right to create a HPF
4 Single or joint HPF in place
5 Nearly all hospitals have their own HPF
6 For some medicines, not obligatory

Source: PHIS 2009c-u, PHIS 2009v

The number of medicines (indicated either by trade name or active ingredient) on a HPF varies from region to region (e.g. in DK) or from hospital to hospital. In Austria between 1,500 and 2,500 medicines are on a HPF whereas in Belgium the number is lower ranging from

750 to 1,000 medicines. In Slovakia around 500 to 900 active substances are included and in Finland the number of medicines ranges from 100 in small hospitals to 1,100 in large hospitals. In Italy around 1,000 active ingredients are on a HPF, in the case study hospitals in the Netherlands (cf. section 9.2) between 800 and 1,000 active substances are on the HPF. In the UK the number of items on each HPF varies significantly. As a minimum, medicines which are approved by the National Institute for Health and Clinical Excellence (NICE) are on this list.

In all PHIS countries but Hungary, Malta and Turkey the Pharmaceutical and Therapeutic Committee (PTC) (cf. section 5.3) is either the decision taking or advisory body when it comes to the inclusion of medicines into the HPF. In Hungary the hospital pharmaceutical purchasing committee has this role.

Box 5.1: European survey – Process of inclusion of medicines into the hospital pharmaceutical formulary in European countries

The process of inclusion of medicines in the HPF differs among PHIS countries. In **Norway** the PTC produces a list of medicines based on specific criteria that include price, functional characteristics such as durability and ability to blend, packages such as unit-dose, labelling (readability, strength specification), generic name (according to European Pharmacopoeia), package varieties (unity), product variety such as administration form, formulation, strength varieties, service such as training (product knowledge) and help with medical enquiries and delivery. In **Belgium** the PTC need to base the selection of the medicines on evidence based medicine. In the process of setting up the HPF the purpose and the services of the hospital have to be considered to guarantee the provision of the required medicines to the patient. In **Denmark** an important inclusion criterion is the impact on the out-patient sector meaning not to choose a product which is cheap in the in-patient sector, but expensive in the out-patient sector.

Source: PHIS 2009c-u

As not all medicines are on a HPF sometimes exceptions need to be made in order to grant the patient access to a specific medicine. For these specific cases approval mechanisms are in place in the majority of PHIS countries. For example an approval by the chief hospital pharmacist (e.g. DE, EE), by the prescribing doctor (e.g. BE, DE, IT, NL, NO, PL, UK), by the chief doctor of the respective department (e.g. SK), by the director of the PTC (e.g. BG, EE) or by the hospital management (e.g. CZ) is needed. Exemptions are possible, if justified, e.g. in Finland, France, Hungary, and Portugal.

In Austria, for example, in case of a required use of a medicine which is not included in the formulary, the prescribing doctor officially needs to request it by using a standardised form. The filled form stating the reasons and the necessity of the use of the special medicine has to be authorised by the respective responsible hospital pharmacist in consultation with chief doctors. In Spain the decision to administer a medicine that is not on the HPF needs to be properly justified on clinical grounds and be approved by the chief hospital pharmacist and by the hospital clinical manager.

5.3 Pharmaceutical and Therapeutic Committees

As already mentioned in section 5.2, in all but three (HU, MT, TR) PHIS countries the Pharmaceutical and Therapeutic Committee (PTC) takes the decision or advices on the decision about the inclusion of medicines into the HPF.

PTC are either established in (nearly) all hospitals in a country (e.g. BE, CZ, EE, NL, LT, SK) or by each county council like in Sweden. Joint PTC for hospital associations are common in Austria. The members of the PTC usually are (chief) hospital doctors and (chief) hospital pharmacists. In some countries (e.g. AT, DK, BG, LT, SK) a representative of the hospital management is also part of the PTC. In Austria and Belgium also the chief nurse is a PTC member. Furthermore representatives from the primary care sector (DK), specialists in procurement (NO) or representatives from the sickness funds (AT) are possible members of a PTC.

Two case examples (on Belgium and on UK) are displayed in Box 5.2 and Box 5.3.

Box 5.2: European survey – Hospital pharmaceutical formulary and Pharmaceutical and Therapeutic Committee in Belgium

The organisation of a PTC and the use of a HPF are a legal obligation in Belgium. Belgian hospitals are obliged to establish a PTC, which meets at least once a year. The members of the PTC are the head of the hospital pharmacy, the chief doctor, the chief nurse and some physicians representing the medical team. The defined tasks of the PTC includes the organisation and decision-making on the articles of association as well as the compilation and update of the HPF (reimbursed or not) that are purchased by the hospital. In general, each hospital draws up its own HPF, which includes 750-1,000 medicines.

When doing this the PTC has to consider guidelines. On the one hand the selection of the medicines has to be done on the basis of evidence based medicine and on the other hand in the process of the developing the HPF the purpose and the services of the hospital have to be considered to guarantee the provision of the required medicines to the patients.

Source: PHIS 2009d

In many PHIS countries the PTC have a similar role including tasks like setting, developing and updating the HPF or national reimbursement list (e.g. AT, BE, BG, CY, DK, LV, NL, NO, PT, SK, UK). Furthermore in several countries the PTC's tasks also include monitoring of expenditure and consumption development (e.g. CZ, DK, LV). Also the formulation of guidelines on purchasing and handling of medicines (e.g. AT, UK) might be covered by a PTC. For instance, in Latvia the PTC additionally organises the purchase of medicines and medical devices, promotes the effective use of medicines and monitors side-effects caused by medicines.

Box 5.3: European survey – Hospital pharmaceutical formulary and Pharmaceutical and Therapeutic Committee in the UK

In the UK HPF have been in place in the majority of hospitals for many years; they have also been developed by primary care organisations and, more recently, some hospitals have developed joint HPF with primary care trusts. Organisations also share them between several NHS bodies. Each hospital will normally have their own formulary of active substances, and as a result, the number of items on each list will vary significantly. However, as a minimum medicines which are approved by NICE are on this list. Generic substitution is normally practiced with these lists, with the exception of products with narrow therapeutic indices and variable bioavailability. The formularies are continually updated, and depending on hospital policy, they are overhauled between every 1 to 2 years. Some hospitals allow specialists to override these lists; others only allow such an override in specially approved circumstances. Formularies are developed locally and may be made available in paper and electronic forms. Electronic copies may be available only on intranets for organisational use or on the publicly accessible internet.

The role of PTC (known as drugs and therapeutic committees in the UK) varies – some are advisory, others are decision makers. Most usually, the PTC oversees the formulary system and members of the pharmacy team update the documentation/electronic system.

The membership of PTC varies but comprises a multi-professional group with a mix of doctors, pharmacists, nurses and others. For an area PTC, general practitioners are also represented, as are pharmacists working in primary care organisations. The PTC manages entry to the formulary but also supports safe and effective prescribing – often with oversight of guidelines, medicines documentation and so on. The National Prescribing Centre has produced helpful guidance on prescribing committees (further information available at www.npc.co.uk). The topics discussed in building HPF will normally include issues around cost and clinical-effectiveness, safety, efficacy, and whether there are benefits compared to existing medicines on the HPF.

Source: PHIS 2009t

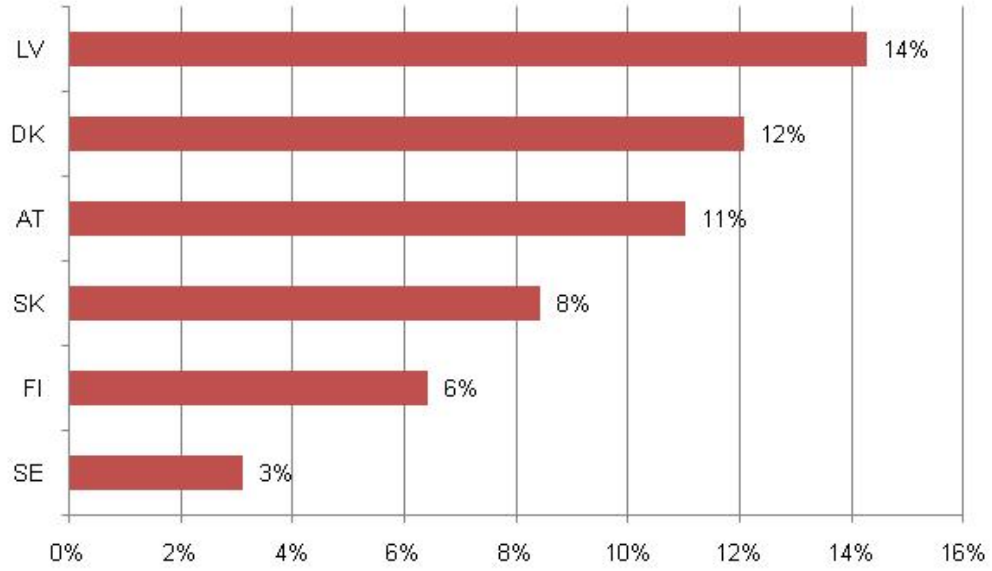
6 Consumption

Data on pharmaceutical consumption as it is available for many European countries is often limited to the out-patient sector. The picture of in-patient consumption is however fragmentary. Different units for measuring consumption are used in the out-patient sector but also in European hospitals which complicates comparisons in this field. Units used in the in-patient sector are: packs, DDD, units of administration and others like weight in mg. For some countries the values for in-patient consumption could be gathered:

- In packs: AT, DK, IT, LV, SK, UK
- In DDD: FI, SE, SI
- Units of administration and other: BE, PL, PT.

Figure 6.1 shows in-patient consumption as share of the total pharmaceutical consumption. It reflects the limited data availability.

Figure 6.1: European survey – In-patient pharmaceutical consumption in % of total pharmaceutical consumption in European countries, 2008 or latest available year

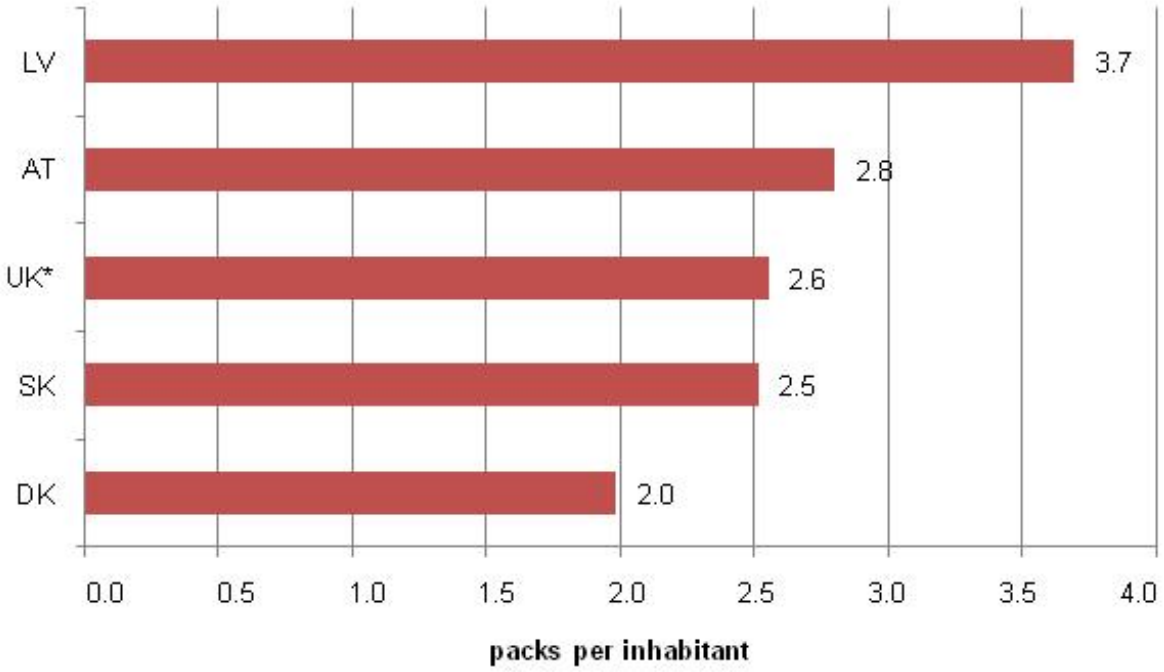


Data of 2006: AT (in packs)
Data of 2008: DK (in packs), FI (in DDD), LV (in packs), SE (in DDD)

Source: PHIS 2009c-u, PHIS 2009v

For those countries which indicate consumption in packs, pharmaceutical consumption per inhabitant in the in-patient sector can be calculated. As Figure 6.2 displays, in-patient consumption ranges between 2 and 3.7 packs per inhabitant in the countries where this measurement is applied and data are available.

Figure 6.2: European survey – In-patient pharmaceutical consumption in European countries – dispensed packs per inhabitant, 2008 or latest available year



National data sources for consumption data in packs. The unit "packs" was not standardised.
* Data refer to England only
Data of 2006: AT
Data of 2008: DK, LV, SK, UK (England only)

Source: PHIS 2009c-u, PHIS 2009v

As shown in Table 6.1 and Table 6.2 the top 10 active substances with regard to consumption differ considerably from the top 10 medicines ranked according to expenditure. Whereas paracetamol is the leading active substance with regard to consumption, it is trastuzumab in terms of expenditure. Thus there is not necessarily a correlation between dispensed volume and expenditure.

Table 6.1: European survey – Top 10 active ingredients by consumption in hospitals in European countries, 2007

Position	Top 10 active ingredient used in hospitals, ranked with regard to consumption	Main indication
1	Paracetamol	Analgesic (nervous system)
2	Electrolyte	Solution affecting the electrolyte balance
3	Furosemide	Diuretic (cardiovascular system)
4	Acetylsalicylic Acid	Antithrombotic agent Analgesics (nervous system)
5	Epoetin beta	Antianemic preparation (blood and blood forming organs)

Posi-tion	Top 10 active ingredient used in hospitals, ranked with regard to consumption	Main indication
6	Albumin	Blood substitute and plasma protein fraction (blood and blood forming organs)
7	Omeprazol	Proton pump inhibitor (medicines for acid related disorders)
8	Ranitidine	H2-receptor antagonist (medicines for acid related disorders)
9	Prednisolone	Corticosteroids (alimentary tract and metabolism, dermatological, respiratory system)
10	Coagulation Factors IX, VII and X	Blood coagulation factors (blood and blood forming organs)

Based on data by: BE, CY, DK, FI, FR, IT, LT, LV, MT, PL, PT, SE, SK, UK

Source: PHIS 2009c-u, PHIS 2009v

Eight (DK, FI, FR, MT, PT, SE, BE, UK) of 14 countries, where data were available, indicated paracetamol as one of the top active ingredients accounting for high consumption.

Regarding electrolyte (such as natrii chloridum, calcii chloridum dihydricum, sodium chloride, kalii chloridum), which is ranked second at European average, Latvia, Portugal and Slovakia reported it as the active substance with the highest consumption in hospitals in their country; whereas furosemide is the top 1 consumed active ingredient in Denmark, Finland and Italy, on position three in France, on four in Sweden and five in Portugal.

The top 10 active ingredients with regard to expenditure, as listed in Table 6.2, represent the cost-drivers in hospitals. As explained in more detail under section 5.2 (see also Table 5.2) some countries have specific funding schemes, usually for expensive medicines.

The ranking of the 10 top active ingredients which account for high expenditure used in hospitals showed a very clear picture: 14 out of 17 countries, where data were available, listed trastuzumab among the top 10 active substances in hospitals. In Cyprus, France, Poland and UK trastuzumab is on the first position. However, trastuzumab is not ranked among the top 10 active substances used in hospitals in Latvia, Malta and Slovakia.

Eleven countries listed rituximab and docetaxel among the top ten active substances with regard to expenditure. No clear trend on whether those two active substances are more frequently used in Western European countries or CEE countries could be identified. However, rituximab is not listed among the top 10 high cost active substances in hospitals in Belgium, Denmark, Latvia, Malta, Portugal and Slovakia.

As for Interferon beta-1a (position four at European average), more Western European countries list Interferon beta 1-a among the ten active substances accounting for high expenditure (Denmark, Italy, Norway) than for example Malta and Poland.

Table 6.2: European survey – Top 10 active ingredients by expenditure in hospitals in European countries, 2007

Position	Top 10 active ingredient used in hospitals, ranked with regard to expenditure	Main indication
1	Trastuzumab	Monoclonal antibody (antineoplastic and immunomodulating agent)
2	Rituximab	Monoclonal antibody (antineoplastic and immunomodulating agent)
3	Docetaxel	Taxane (antineoplastic and immunomodulating agent)
4	Interferon beta-1a	Monoclonal antibody (antineoplastic and immunomodulating agenty)
5	Etanercept	Tumor necrosis factor alpha (TNF-α) inhibitor (antineoplastic and immunomodulating agent)
6	Epoetin alfa	Antianemic preparation (blood and blood forming organs)
7	Imatinib	Protein kinase inhibitor (antineoplastic and immunomodulating agent)
8	Oxaliplatin	Platinum compound (antineoplastic and immunomodulating agent)
9	Adalimumab	Tumor necrosis factor alpha (TNF-α) inhibitor (antineoplastic and immunomodulating agent)
10	Bevacizumab	Monoclonal antibody (antineoplastic and immunomodulating agent)

Based on data by: AT, BE, CY, CZ, DK, FI, FR, IT, LV, MT, NL, NO, PL, PT, SE, SK, UK

Source: PHIS 2009c-u, PHIS 2009v

7 Evaluation

7.1 Monitoring

In many countries monitoring of consumption and expenditure in hospitals is done at hospital and/or national level (cf. Table 7.1). In two countries (HU, TR) no monitoring system is in place.

Table 7.1: European survey – Monitoring of consumption and expenditure in hospitals in European countries, 2009

Monitoring	Countries
Done at hospital level	AT[1], BG[2], CY[3], DE[1], DK, EE, FI, FR, IE, IT, LT[2], LV, MT, NL[4], PL, PT, SE, SI[4], SK, UK
Done at national level	BE, CY, DK[3], FI, FR, IT, LV, MT[5], NL[4], NO, PL[6], PT, SE, SI, SK, UK

Data not available for CZ, EL, LU

[1] Or by hospital owner organisation

[2] Only consumption monitoring

[3] Only expenditure monitoring

[4] Only for high-cost medicines

[5] Only for public hospitals

[6] Only for specific therapeutic programmes

Source: PHIS 2009c-u, PHIS 2009v

For example in Slovakia monitoring of in-patient pharmaceutical consumption and prices at national level is obligatory. Wholesalers need to regularly report prices and the amount of medicines delivered to hospitals. Monitoring of medicines in the in-patient sector in France and Finland is part of the nation-wide compiled statistics. In Italy a regularly updated database including data on expenditure and consumption exists. In Belgium monitoring is also done at national level by means of submitting an internal audit report to the Insurance Committee of the National Institute for Health and Disability Insurance. In public hospitals in Cyprus the pharmacy department of the Pharmaceutical Services (Department of the Ministry of Health) monitors pharmaceutical expenditure and consumption.

In Lithuania consumption monitoring is done at national level. However, there is no monitoring system of pharmaceutical consumption in hospitals.

In the Netherlands expenditure, prices and consumption of medicines on the list of high-cost medicines of the Dutch Health Care Authority are monitored at national level by the Foundation for Pharmaceutical Statistics by collecting data via surveys at hospitals, and reports annually on this issue.

Boxes Box 7.1Box 7.2 show country specific examples with regard to monitoring of expenditure and consumption.

Box 7.1: European survey – Monitoring of expenditure and consumption in Denmark

Monitoring of the in-patient sector in Denmark is done by Amgros (hospital purchasing agency) on a regular basis. Every quarter Amgros makes a market monitoring report, which contains the development of total pharmaceutical expenditure in hospitals and the expenditure per region, per ATC code and per diagnosis. The report is not publicly available.

At hospital level the hospital pharmacists monitor the prescriber's choice of medicines: The medicines have been included in the medicine module of the digital patient files' as so-called standard prescriptions, which makes it easy for the doctor to select the (economically) most advantageous medicines. The hospital pharmacy often runs the procedure and at the same time assists the wards by directly substituting with the recommended cheaper generic product that has been purchased by Amgros. In case where the ward orders a medicine therapeutically equivalent to the one already on the recommended list, the hospital pharmacy will contact the ward in order to make a possible change to the recommended medicine. In spite of this procedure it is still possible for the ward to order an expensive medicine, as long as the total consumption of the ward is within the budgetary limits.

Source: PHIS 2009h

In many PHIS countries hospital pharmacists have an important monitoring role such as in France or Finland where pharmacists are responsible for monitoring pharmaceutical consumption. In the UK hospital trusts' expenditure on medicines are monitored closely which is usually led by the Chief Pharmacist and her/his team. Monthly monitoring is the usual approach but process and extent vary between organisations. In Slovakia hospital pharmacies have by law the obligation to quarterly report prices and consumption of medicines to the National Centre for Health Information. Hospital pharmacists can monitor expenditure, however cannot interfere or control the budget as monitoring is on national level as mentioned above.

In the majority of PHIS countries an IT system for monitoring purposes is in place in hospitals; such as in Latvia where hospital pharmacies use computer software to summarise the information on pharmaceutical expenditure. Since computer registration of medicines has been introduced, which is done either by the hospital pharmacist or by the physician in the Netherlands, monitoring the use of a single medicine is possible within a hospital. However, since these computer systems are generally not compatible between hospitals, it is not possible to do this at national level. An IT system is currently being installed in public hospitals in Cyprus. The rationale is to connect all health care providers in order to track down prescribed and dispensed products.

Box 7.2: European survey – Monitoring of expenditure and consumption in Bulgaria

In Bulgarian hospitals the evaluation of pharmaceutical policies and consumption has not been regularly monitored. The Bulgarian Drug Agency (BDA) on national level generally analyses consumption of medicines on the market, broken down by groups of medicines. It seems that this is still not a routine process and it is uncertain whether this information will ever be used in connection with pharmaceutical policy decisions. Occasionally the Ministry of Health requests information from the public hospitals, but this is usually connected with price considerations and not for therapeutic or pharmaco-economic purposes.

Traceability of medicines is theoretically possible, because the wholesalers are obliged to keep track of their sales, but in practice aggregated data are neither for individual hospitals nor generally for the in-patient sector available.

Source: PHIS 2009e

7.2 Assessment

The situation with regards to evaluation and health technology assessments (HTA) varies in the PHIS countries. In the Netherlands for example only for medicines on the list of high-cost medicines and on the list of orphan medicines (cf. section 5.1) assessments take place at national level. For these medicines (the hospital receives reimbursement from the social health insurance), therapeutic value and cost-effectiveness are taken into account. In Belgium besides rapid assessments for medicines also evaluation reports of newly reimbursed medicines, as well as the semi-annual Monitoring of Reimbursement Significant Expenses report are available. In Finland HTA is done, however for technologies in hospitals only and not for medicines. In Austria HTA reports for medicines are available however only considered in a few cases. Furthermore independent scientific reports and analyses (e.g. in international journals) are regularly considered in decisions on the use and purchase of medicines. In countries such as Denmark, France and Sweden HTA is well established. Italy has developed a risk sharing and payment scheme by result procedures based on national monitoring registries. This procedure allows the track of pharmaceutical expenditure on innovative medicines, in particular anti-cancer, cardiovascular, anti-diabetic and ophthalmologic medicines. HTA for medicines has been established in some regions in Italy. In Poland assessments for medicines are undertaken and in the UK NICE's role is to determine, on the basis of the best available evidence and free from political interference, whether a treatment is sufficiently clinically and cost effective to justify the cost. This guidance is then provided to the NHS. If the guidance is positive, the NHS Constitution stipulates that patients have the right to these treatments if their doctor says they are clinically appropriate for the patient. NICE appraisals are not given to all medicines, and so hospitals will often have to make decisions on clinical and cost effectiveness without NICE guidance. No HTAs are made e.g. in Lithuania or Latvia. In Cyprus several measures such as implementation of guidelines are in place. In Norway cost-effectiveness reports are done by Norwegian Knowledge Centre for Health Services.

8 Interface management

The starting treatment in hospitals, often with expensive medicines, has a major impact on the out-patient sector as it influences the further choice of medicines prescribed after discharge of the patient.

Due to the different remuneration systems in the in-patient and out-patient sector (cf. section 5.1) in several countries, expensive medicines tend to be shifted between the sectors. This was for example reported for Austria, Germany, Finland, the Netherlands and Sweden.

Several countries (e.g. BG, MT, FR) have expressed a need of implementing interface management which is defined as the mechanism of cooperation between the hospital and the out-patient sector (cf. PHIS 2009a). However, some of them have not implemented specific initiatives yet, while in other countries (in particular in the Nordic countries) several initiatives have been launched.

Box 8.1: European survey – Interface management Austria

In Austria coordination problems between the out-patient and in-patient sector are reported. The separated financing system of the in-patient and out-patient sectors might lead to a shifting of expensive treatments to the other sector. The first use of a medicine is often realised in the in-patient sector whereas the follow-up prescription is done by out-patient doctors. At the time of first prescription of a medicine an extensive medical observation may be required which can only be offered in the in-patient sector.

The positive list in the out-patient sector, the Reimbursement Code, is also valid for the in-patient sector.

A starting point for interface management is that representatives of a sickness fund are members of the Pharmaceuticals and Therapeutic Committees in hospitals in some Austrian regions. But the degree of participation and the role of the out-patient sector representatives within these committees differ among the Austrian provinces.

In the Austrian province Tyrol a pilot project ("Medicines at the interface") initiated by the Tyrolean sickness fund is running which exactly deals with such shifts of expensive pharmaceutical treatments (oncologic and rheumatologic medicines) between the in-patient and out-patient sectors. One of the main aims is to realise an adequate financial approach for reimbursing these services in the sector where those medicines are applied.

Source: PHIS 2009c

In some countries (e.g. DK, ES, SE) Pharmaceutical and Therapeutic Committees (PTC) try to tackle this problem of transfer of patients and medical treatments between the sectors by coordinating hospital pharmaceutical formularies with the positive list for the out-patient sector. The aim is to avoid starting treatment with an expensive medicine in the hospital which might result in a continuation in the out-patient care although alternative treatments

are available. In the UK hospitals have been asked to take into account the impact of their prescribing on primary care and joint Pharmaceutical and Therapeutic Committees within primary care were established to support this. There are examples of hospitals switching and controlling specific medicines to support cost-effective prescribing in primary care.

The boxes in this sector describe country examples with regard to interface management problems or initiatives.

Box 8.2: European survey – Interface management Norway

Interface management between the in-patient and out-patient sector in Norway exists with regard to specific medicines as hospitals pay for medicines that patients need after discharge of the hospital. These medicines include tumor necrosis factor (TNF) medicines and medicines for the treatment of Multiple Sclerosis. The funding of these products was transferred from the budget of the National Insurance Scheme (NIS) to hospital budgets in 2006 and 2008 respectively. This was mainly due to the fact that some products in this field were financed by the NIS and some products were financed by the hospital. This created the economic incentive for hospitals to prescribe products funded by NIS. Also it was an aim to achieve more competition in the area and lower prices.

The Pharmaceutical and Therapeutic Committee provides mandatory prescribing recommendations. For example for TNF medicines the first and second choice of medicine in 2008 switched places in 2009. This means that doctors follow the prescribing recommendations on interface management.

Source: PHIS 2009o

In Latvia the interface idea is guaranteed by the Centre of Health Economics, which elaborates both the list of medicines used in out-patient care and the one in hospitals. Hospitals provide treatment recommendations for primary care and general practitioners usually follow those treatment recommendations.

In Finland improving cooperation between in-patient and out-patient sector continues to be a challenge. Currently there are many ongoing local development projects and experiments concerning municipal services (for example increasing cooperation between municipalities, between primary and secondary care services and between municipalities and the private sector). However, they are not well coordinated from the national level, probably leading to increasing regional diversities in structures.

Box 8.3: European survey – Interface management United Kingdom

Health economy prescribing committees (sometimes referred to as Area Prescribing and Medicines Management Committees (APCs)) whose “member” organisations are primary and secondary care commissioners (purchasers) and providers work together to ensure a consistent health community approach to medicines management. Many were established to manage more effectively the entry of new medicines into the NHS. Now, however, the functions and forms of many APCs go far beyond this original remit.

In particular, they can be used as forums to resolve issues around medicines safety and usage across the care interfaces, for example from primary to secondary care.

There are clear benefits to patients and organisations of having an effective and influential APC, for example, an APC can:

– promote co-operation and consistency of approach in the commissioning process

– prevent duplication of professional and managerial effort by ensuring local joint working

– ensure that robust standards and governance underpin community wide decision making

– enable key stakeholders, working in the NHS locally, to exert an influence on the prioritisation, improvement and development of healthcare delivery

– co-ordinate the safe and effective use of medicines across a health community.

Source: PHIS 2009t

CASE STUDIES

9 Country-specific results

9.1 Austria

9.1.1 Introduction

Five hospitals in Austria were surveyed in detail as PHIS hospital case studies. The selected hospitals differ with regard to geographic location (each is situated in a different region of Austria), by the services they offer and by the hospital owners. All hospitals are part of hospital associations of different owners (ranging from three to 25 hospitals, on average eleven hospitals), whereof four belong to provinces of Austria. One hospital is owned by a private religious congregation but operates as a public hospital. In all cases the hospital owners established out-sourced holding structures which manage one or more hospitals.

The selected hospitals have all public law status according to Austrian law meaning that they are non-profit and have to meet certain requirements indicated by the Austrian Federal Hospitals Act. Furthermore, they are eligible for receiving funds by the Austrian Provincial Health Funds, which reimburse the services offered on the basis of a diagnosis related reimbursement system – the Austrian DRG model (Leistungsorientierte Krankenanstaltenfinanzierung, LKF). All selected hospitals are basically general hospitals but they all offer additional specialties. One hospital is a University hospital providing medical services in all medical disciplines according to the state of the art as well as teaching and research. The number of acute care beds has remained rather stable in the last years in the surveyed hospitals.

Four hospitals provide a hospital pharmacy, while the fifth hospital has a pharmaceutical depot instead. As this hospital is integrated within a hospital owner organisation which has no hospital pharmacy at all, medicines are mainly purchased from a wholesaler with an affiliated pharmacy. In Austria, pharmaceutical depots, which are very common for the provision of medicines in Austrian hospitals (83% of hospitals without a hospital pharmacy have a depot, see section 3.2.1) are only allowed to purchase the required medicines from licensed pharmacies in the European Economic Area (EEA). The hospital with a pharmaceutical depot selects the wholesaler via an open tender. In the selected hospital pharmacies (disregarding the University hospital) on average 16 people are employed, thereof 25-40% are pharmacists.

The case study hospitals do not dispense medicines to out-patients. One hospital has a community pharmacy within the building of the hospital but this pharmacy is separated from the hospital pharmacy serving in-patients. In total only five of the hospital pharmacies in Austria act as community pharmacies by virtue of holding long-established rights (cf. section 3.4.3 and PHIS 2009c).

Hospitals in Austria – and this is also true for the case study hospitals – are mainly directly delivered by pharmaceutical companies. Wholesalers and other (hospital) pharmacies only

play a minor role as supplier. They are contacted in case very small quantities of a specific medicine should be needed or if the products required are not provided by pharmaceutical companies. In one of the surveyed hospitals, a wholesaler is the main medicines supplier due to the circumstances described in the paragraph above. Nonetheless even in that hospital prices are directly negotiated with the pharmaceutical industry. In general, regulations regarding maximum mark-ups in the out-patient sector are also applicable for the in-patient sector. However, in that particular hospital mainly delivered by a wholesaler, the pharmacy purchase price is seen as the absolute maximum price to be achieved.

Direct negotiations with pharmaceutical industry are mainly carried out by hospital pharmacies at individual hospital level, but for special medicines (e.g. of which a high quantity is needed) centralised purchasing by the hospital owner organisation is performed. In such cases a designated hospital purchasing body (a responsible person in the management of the hospital owner organisation, the chief hospital pharmacist of the owner organisation or a designated hospital pharmacist) is established for negotiating the prices for a selected product basket. Hospitals which are organised in hospital owner organisations usually cooperate to achieve a higher bargaining power in the negotiation process with the pharmaceutical company. Networking and informal exchange between hospital pharmacists of different hospitals – in fact a relatively small group in Austria – is of high importance. In most cases the chief hospital pharmacist leads the price negotiations, which are conducted in most of the hospitals. Market surveillance and price observation are the main strategies of the persons involved to achieve good negotiation results.

Tendering of medicines is only applied in very rare cases. However a rising trend can be observed. According to the practical experiences reported by the hospital pharmacists tendering at ATC 5 level is judged as problematic, complex, time consuming and often not successful with regard to the expected results (regarding cost savings).

The surveyed hospitals achieve prices at and below the ex-factory price. Discounts and rebates granted by pharmaceutical companies are very common for medicines in a competitive market situation (e.g. several generics on the market). For innovative medicines which do not face competition, in general no discounts are granted. For approximately 25-30% (data of two hospitals) of the medicines purchased by hospitals special conditions and discounts (ranging from 1% to 99% of the price) can be negotiated by the leading hospital purchasing body. Around 15% by volume of the medicines required in a hospital are provided cost-free (data of one hospital). The prices achieved in all hospitals are not made public.

Furthermore, it was reported by one hospital pharmacist that the expenditure on medical devices even overtake pharmaceutical expenditure.

Reimbursement of medicines is integrated in the diagnosis oriented case groups (DRG reimbursement). Expenditure for medicines is part of the lump sums calculated, each eligible hospital can bill to the Provincial Health Funds. An exemption to this model regards around 50 pre-defined fees for service, where the concrete use of medicines (mostly oncologic medicines) is separately refunded (see also section 3.3.1). However it was reported that the lump sums are not considered as cost-effective and therefore may lead to budgetary problems of hospitals. Despite the billing of hospital services (including pharmaceutical expendi-

ture) to the Provincial Health Funds hospitals have defined separate internal budgets for medicines (mostly at service unit level).

The basis for the reimbursement of a medicine is its inclusion in the hospital pharmaceutical formulary (HPF). Each of the selected hospitals has its own individual formulary, while similar formularies exist within one hospital owner organisation. The medicines included in the hospital pharmaceutical formulary depend on the medical services the hospital offers – therefore individual and flexible solutions for the formularies are preferred. Around 1,500 brand names or 900 active ingredients (data of two hospitals) can be found on the lists. Medical and economic criteria (evidence based process) are considered in the decision process for inclusion of medicines in the HPF. The reimbursement status of a medicine in the out-patient sector does not imply its inclusion in the HPF (only one hospital reported to consider the reimbursement status in the out-patient sector). Most of the interviewed persons confirmed that medicines which are needed in the hospital are usually integrated in the hospital pharmaceutical formulary. In such case it is sufficient that the need of the medicine is documented and proven by the doctor requesting it.

By law each hospital (or hospital owner association) has to establish a Pharmaceutical and Therapeutic Committee (PTC). The composition of the PTC is regulated differently among the Austrian provinces. In some provinces also representatives of regional sickness funds are asked to participate; this is true for all case study hospitals but in some cases only have a consultative role.

Due to the separated financing system of the in- and out-patient sector all hospitals reported a high need for interface management.

Table 9.1 provides an overview of the qualitative results of the PHIS Hospital Pharma case study in Austria.

Table 9.1: Case studies – PHIS Hospital Pharma case study Austria, 2009

Parameter	Case Study Hospitals	Country-wide
Key characteristics		
Number of hospitals	5	266 (Dec. 2008)
Type of hospitals and geographic distribution	All are general hospitals; 1 in Vienna, 1 in the South East of Austria, 1 in the South, 1 in the North Western part, 1 in the biggest province of Austria	The Austrian in-patient sector is characterised by a large number of small hospitals. 38% of all hospitals were general hospitals (2007).
Ownership	All are public hospitals; 4 are owned by Austrian provinces, 1 belongs to a non-profit religious congregation.	Around 60% of hospitals are public.
Size of hospitals	4 are big hospitals (> 500 acute care beds); One hospital is middle sized (between 400 and 500 acute care beds)	Total number of acute care beds in the public sector: ~52,000 (2007).
Pharmaceutical expenditure in % of total hospital expenditure	Around 7% of the hospital expenditure account for medicines.	Expenditure on medicines accounts for 9% of expenditure in hospitals.
Delivery chain and distribution actors		
Hospital pharmacy	4 hospitals have a pharmacy; 1 hospital has a pharmaceutical depot which is delivered by a wholesaler with an affiliated pharmacy (Pharmaceutical depots are only allowed to purchase the required medicine from another licensed pharmacy in the EEA)	17% of all hospitals have a hospital pharmacy (2008). The other, often smaller hospitals are equipped with a pharmaceutical depot.
Dispensing to outpatients	The hospitals only serve in-patients.	Only 5 out of all hospital pharmacies also serve as a community pharmacy. However a separated community pharmacy may be run at the premises of a hospital.
Key suppliers	The majority of the hospitals are directly supplied by pharmaceutical companies. Wholesalers or other pharmacies (hospital and community pharmacies) only play a minor role. The one hospital with the pharmaceutical depot mainly purchases the medicines via a wholesaler with an affiliated pharmacy as there is no other hospital pharmacy within the hospital owner association.	Same situation: mainly industry. Wholesalers and pharmacies are only considered in exceptional cases. Pharmaceutical depots are usually supplied by other hospital pharmacies within the same owner association.
Purchasing policies in hospitals		
Level of decentralisation	Decentralised purchasing (purchasing at hospital level or at the hospital owner level)	Same situation for all hospitals

Parameter	Case Study Hospitals	Country-wide
Tendering	Minor importance at hospital level for 4 hospitals; 1 hospital commissioned the wholesaler following a tendering process.	Same situation for all hospitals – tendering of medicines is only done in rare cases, but a rising trend can be observed
Negotiations	Key purchasing policy at hospital level	Same situation for all (public) hospitals
Main award criteria	Mainly price; Medical/therapeutic benefit; Safety of medicines (e.g. danger of confusion); Delivery/payment conditions	Same situation for all (public) hospitals
Understanding the actual hospital price		
Price level	Hospital prices are at maximum at the ex-factory price level (excl. VAT) or in one case at the pharmacy purchase price level (incl. wholesale mark-ups)	Same situation for all hospitals
Wholesale add on	For one hospital relevant The maximum mark-ups are regulated for both the in- and out-patient sector.	Same situation for all hospitals
VAT	10% (hospitals have to pay VAT, but get it refunded)	Same situation for all hospitals
Discounts/ Rebates	Discounts are quite common for medicines in a competitive environment (discount range: 0-100% of the price); valid for 25-30% of the medicines; around 15% are provided cost-free; rebates at the end of the year are granted but could not be exactly stated at the time of case study data collection.	Same situation for all hospitals
Publication of prices	Actual hospital prices are not published. (Hospitals are afraid of losing their bargaining power.)	Same situation for all hospitals
Funding in hospitals		
Funding of hospitals and remuneration	Austrian DRG model (Leistungsorientierte Krankenanstaltenfinanzierung, LKF)	Same situation for all hospitals, which receive funds out of the Provincial Health Funds
Funding of medicines	Medicines are integrated in the lump sums of the LKF system which can be generated for the procedures and diagnosis-oriented case groups in hospitals. Exception: about 50 defined single medical procedures (Medizinische Einzelleistungen, MEL) exist within the system where explicitly the dispensing of a specific oncological pharmaceutical is reimbursed.	Same situation for all hospitals, which receive funds out of the Provincial Health Funds. Exceptions exist in some provinces for specific medicines (cf. Table 5.2)
Co-payments for medicines	No	Same situation for all hospitals

Parameter	Case Study Hospitals	Country-wide
Hospital formulary	All 5 hospitals have an individual hospital pharmaceutical formulary.	Hospitals have either their own hospital formulary or one hospital formulary is applicable in all hospitals of the same owner association.
Criteria for inclusion	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; Safety of medicines	Similar situation for all hospitals
Updates and publication	Different up-date procedures: Up-dated on ad-hoc basis (3 hospitals) Quarterly (1 hospital) Yearly (1 hospital) The hospital pharmaceutical formularies are not published, but are internally available.	Same situation for all hospitals
Monitoring & Interface management		
Pharmaceutical and Therapeutic Committee (PTC)	The PTC can consist of people of different professions and functions within the provinces. The main task of the PTC is the drafting and maintenance of the HPF.	Same situation for all hospitals
Monitoring	Monitoring of prices, consumption and expenditure by the chief hospital pharmacist or pharmacist in charge of purchasing – done on regular basis, results only for internal use	Same situation for all hospitals
Interface management	Need for interface management expressed due to the separated financing of the in- and out-patient sectors; several ongoing projects	Same situation for all hospitals

DRG = Diagnosis Related Groups, HPF = Hospital Pharmaceutical Formulary, INN = International Non-Proprietary Name, PTC = Pharmaceutical and Therapeutic Committee

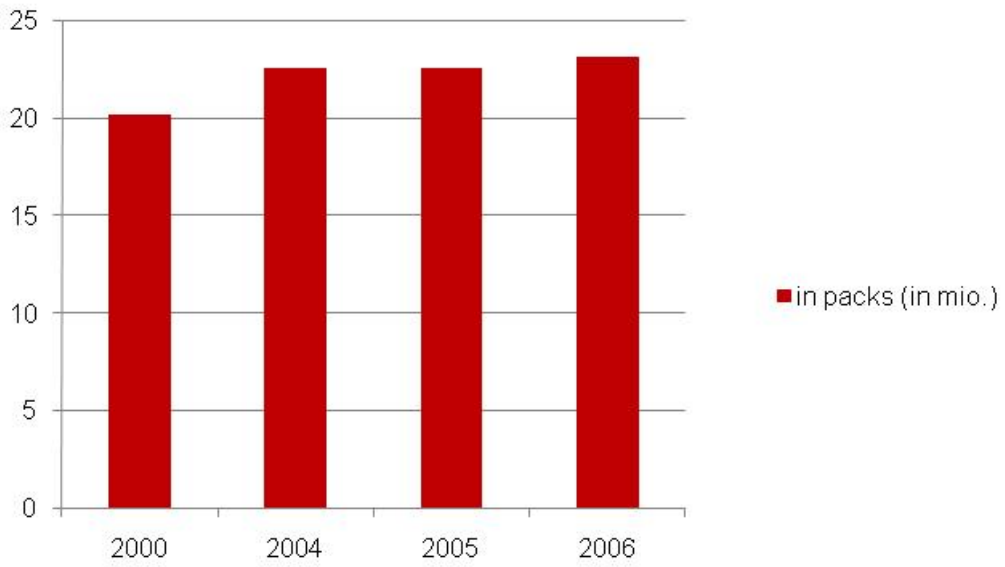
Source: PHIS 2009c, PHIS case studies 2009

9.1.2 Results

9.1.2.1 Consumption

In Austria total annual pharmaceutical consumption in hospitals has been steadily growing for years (cf. Figure 9.1). Consumption is measured by supplied packs. Hospital experts estimate the growth in pharmaceutical expenditure in the last years as ranging from “enormous increases” to “of minor relevance” as increases (e.g. in the expenditure on oncologic medicines) are balanced by decreases (e.g. due to the use of generic medicines). No uniform picture can be drawn which is also due to the differences in the health services provided.

Figure 9.1: Case studies – Annual pharmaceutical consumption in hospitals in Austria, 2000 and 2004–2006



Source: PHIS 2009c (data of PHARMIG 2008)

The hospitals participating in the PHIS case studies monitor pharmaceutical consumption primarily by analysing expenditure data. Consumption data in volume is not provided in Daily Defined Doses (DDD) – except for antibiotics – but in different units (e.g. grams, m³, packs, tabs etc.). Therefore an overall comparison of consumption data in volume is not possible.

The top 5 active ingredients listed in Table 9.2 caused the highest expenditure country-wide in Austrian hospitals. A comparison of findings among three case study hospitals (where data available) shows some deviations. Rituximab and trastuzumab are ranked in two hospitals on first and second position. Further active substances among the top 5 medicines in value in the case study hospitals are: bortezomib, cetuximab, meropenem, docetaxel and caspofungin.

Table 9.2: Case studies – Top 5 active substances used in hospitals by pharmaceutical expenditure in Austria, 2008

Position	Top active substances used in hospitals ranked with regard to expenditure[1] – country-wide[2]
1	Erythrocyte concentrates
2	Bevacicumab
3	Pemetrexed
4	Rituximab
5	Trastuzumab

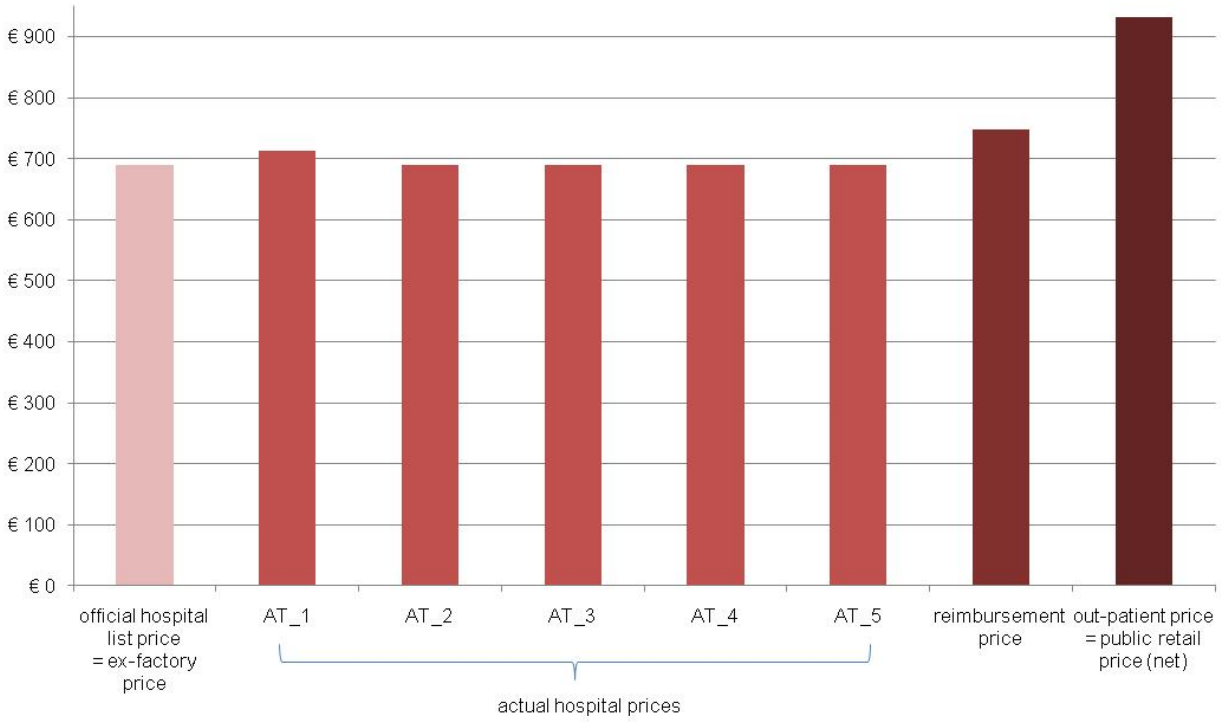
[1] Data refer to a ranking of the top medicines (brand names) with regard to expenditure
[2] Data gathered by GÖG/ÖBIG on the basis of data provided by a big hospital owner organisation

Source: PHIS 2009c

9.1.2.2 Prices

The price comparison of an oncologic medicine shows that the actual prices paid by the hospitals almost equal the official hospital list price which is the maximum ex-factory price in Austria. The ex-factory price is basically not controlled in Austria, but it needs to be properly notified to the authorities. However, medicines that are included in the Austrian positive list (i.e. out-patient reimbursement list EKO) are subject to external price referencing with 24 EU Member States (PPRI 2009). Consequently the ex-factory price is used as basis for price negotiations of these hospitals with the suppliers. Still the reimbursement price of the oncologic medicine paid by the sickness funds in the out-patient sector is about 8% higher than the ex-factory price, whereas the out-patient price (including wholesale and pharmacy mark-ups, see section 2.2.5) is indeed higher.

Figure 9.2: Case studies – Comparison of hospital and out-patient prices per unit of an oncologic medicine in Austria, 2009



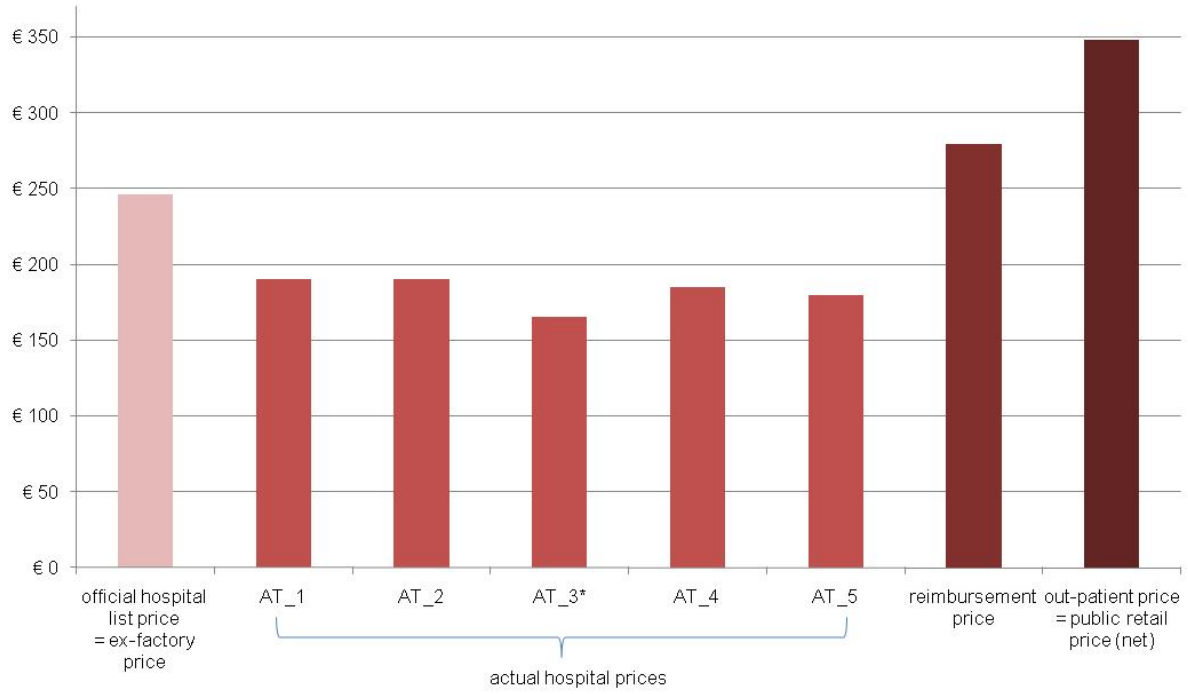
AT_1, AT_2, AT_3, AT_4, AT_5 = different Austrian hospitals participating in the PHIS Hospital Pharma case studies
Reimbursement price = this price is the basis for the reimbursement of medicines in the out-patient sector, it is the maximum amount paid for by the Austrian sickness funds.

Source: PHIS case studies 2009

Interviewed hospital pharmacists stated that due to lacking competition for some oncologic medicines (original brands with no generic alternatives) no discounts to the list price can be achieved. However, in some cases pharmaceutical companies offer rebates on the final invoice billed by the company, usually at the end of the year depending on the quantity or type of medicines purchased. These possibly expected rebates cannot be estimated in advance and are not part of the price negotiations.

Figure 9.3 shows the price differences between the actual hospital prices and the official hospital list price of a medicine for immunomodulation. For this medicine the hospital purchasing bodies usually negotiate the prices per gram. In this case different prices between the hospitals could be achieved due to their different bargaining power. The actual hospital price lies on average 26% below the hospital list price (range: 23-33%).

Figure 9.3: Case studies – Comparison of hospital and out-patient prices per unit of a medicine for immunomodulation in Austria, 2009



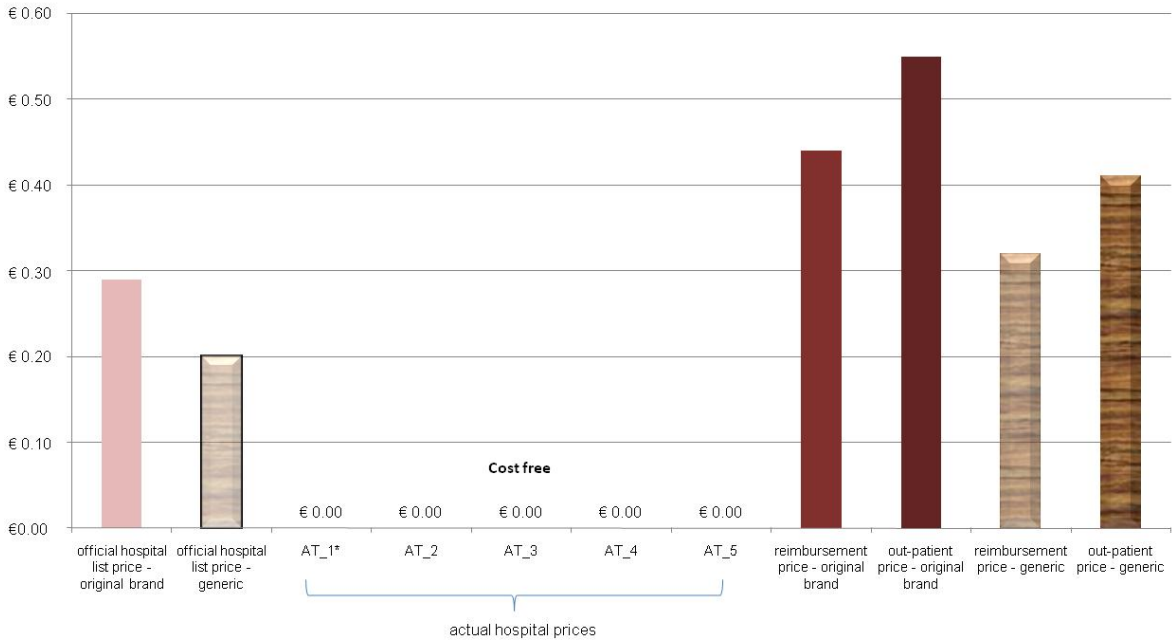
AT_1, AT_2, AT_3, AT_4, AT_5 = different Austrian hospitals participating in the PHIS Hospital Pharma case studies
Reimbursement price = this price is the basis for reimbursement of medicines in the out-patient sector, it is the maximum amount paid for by the Austrian sickness funds.
AT_3* = different brand than the other presented medicine but the same strength

Source: PHIS case studies 2009

Additionally, hospital pharmacists reported that for immunomodulation several different medicines of different companies are used to prevent potential shortcomings arising from supply difficulties.

Figure 9.4 shows that the Austrian hospitals participating in the PHIS case studies receive some cardiovascular medicines cost-free. This is a common practice in the in-patient sector in Austria. Whereas four hospitals receive the original brand cost-free, one hospital gets the generic medicines at no costs.

Figure 9.4: Case studies – Comparison of hospital and out-patient prices per unit of a cardiovascular medicine (original product and generic) in Austria, 2009



AT_1, AT_2, AT_3, AT_4, AT_5 = different Austrian hospitals participating in the PHIS Hospital Pharma case studies
reimbursement price = this price is the basis for reimbursement of medicines in the out-patient sector, it is the maximum amount paid for by the Austrian sickness funds.
AT_1* = generic medicine

Source: PHIS case studies 2009

This example shows that although generic medicines are available, hospitals still tend to prioritise the original brand if expenditures equal for both medicines. All hospital pharmacists of the surveyed case study hospitals are aware of the fact that the choice of a medicine in the in-patient sector has consequences on the out-patient sector. However this knowledge is usually disregarded due to economic considerations, and hospitals grant the supply contracts to the pharmaceutical company which lays the best offer. The separate funding of the in- and out-patient sector in Austria is another factor contributing to this behaviour.

9.2 Netherlands

9.2.1 Introduction

In the course of the study visits in the Netherlands, three hospitals were visited. All three case study sites are general hospitals; two of them in a metropolitan area and one in a small town. All three hospitals are located in the West / South West region of the Netherlands. Two of them are medium sized hospitals with around 450 acute care beds and the other one is a small sized hospital.

All three hospitals have a hospital pharmacy. Two hospitals employ around 40 full time equivalents (FTE), thereof are six full time equivalent pharmacists. In the smaller hospital around 20 FTE are employed, around 2.5 FTE are pharmacists.

High-quality treatment with medicines in hospitals is standard in the Netherlands. According to the PHIS Hospital Pharma Report from the Netherlands (PHIS 2009n) most hospitals in the Netherlands have a hospital pharmacy which is part of the hospital, but some have in addition separate pharmacies serving the out-patient sector. One hospital pharmacist explained that having a separate out-patient pharmacy in his hospital has helped him understand better the problems of discharged patients in terms co-payment and availability of medicines. However, having a separate out-patient pharmacy demands a lot on logistics (e.g. separate storage rooms, different labelling etc.), but, as confirmed by the hospital pharmacist, it also generates more revenues.

Wholesalers are the main suppliers (approximately 80%) of medicines of the three case study hospital pharmacies. In certain cases the wholesaler may not deliver to the hospital pharmacies e.g. when the proposed wholesale margin or the delivery volume is too high. In the last couple of years direct delivery by the manufacturer has increased, especially for expensive medicines (e.g. raninizumab, trastuzumab, rituximab, bevacuzimab) where no or little competition exists. In these cases hospital pharmacies do not have the possibility to achieve any discounts in the negotiation due to monopolistic market situations. In emergency situations the hospital pharmacies may receive medicines from other hospital pharmacies.

Tendering is the major purchasing policy in the three case study hospitals, representing the country-wide pattern. Centralised procurement by tendering is done through regional purchasing groups, combining around fifteen hospitals from the region of the tree case study hospitals, which decide which medicines to procure; examples are cytotoxic medicines, intravenous analgesia and anaesthetics, intravenous antibiotics and immunoglobulines. The case study hospitals reported that they are obliged to use these medicines purchased by the regional purchasing groups for the contracted period which could be one to three years (“sole source commitment”). This mechanism may not allow reacting ad-hoc to emerging needs.

In addition, the case study hospitals may individually negotiate with the pharmaceutical industry. One hospital pharmacist explained that he uses the maximum pharmacy purchasing price listed in the “taxe” (which is the positive list for the out-patient sector) as an upper limit and then collects offers from different wholesalers. Due to good cooperation with certain wholesalers, he knows where to achieve the best price for the needed amount of medicines. Contracts are usually valid for up to three years.

All three hospital pharmacists interviewed emphasised that cost-free products are not allowed in their hospitals. As soon as they should find out that doctors in their hospital had accepted cost-free medicines from a manufacturer, their use was no longer allowed. However, large discounts (up to 95%) compared to the out-patient sector were reported for some medicines.

In each case study hospitals the chief hospital pharmacist is in charge of selecting the medicines, in line with the decision of the Pharmaceutical and Therapeutic Committee (PTC) regarding the inclusion of medicines in the reimbursement list. Each hospital has its own hospital pharmaceutical formulary. It used to be a little paper booklet, but nowadays the

formulary is only available electronically (only for internal use). The medicines included in the hospital formulary are paid for out of the hospital budget.

In addition, the Dutch Health Care Authority (Nederlandse Zorgautoriteit, NZa) issues two lists: one for high-cost medicines and one for orphan medicines (cf. section 5.2). Both lists were introduced to help hospitals in financing expensive medicines. The list of orphan medicines is not relevant for the case study hospitals, as the seven orphan medicines included in that list are only used in university hospitals. However, the medicines on the list of high-cost medicines, including 32 medicines (by generic name), are of increasing concern for the three case study hospitals. For these medicines 20% of the expenditure is paid out of the hospital budget while the remaining 80% is financed complementarily by the social health insurance. Because of the increasing use of these high-cost medicines and the continuing introduction of new ones, these medicines have a high impact on hospital expenditure.

The chief hospital pharmacist, assisted by the PTC, also approves good prescription guidelines/protocols which are mandatory for all doctors in the hospital. S/he is also in charge of quality assurance.

Each hospital in the Netherlands monitors prices, expenditure and consumption of medicines used in hospitals. The three case study hospitals mentioned that they regularly monitor prices, expenditure and consumption. Regarding medicines included in the list of high-cost medicines issued by the NZa expenditure, prices and consumption are monitored at national level by the Foundation for Pharmaceutical Statistics (Stichting Farmaceutische Kengetallen, SFK). SFK collects these data by means of surveys at hospitals, and reports annually on this issue.

All interviewed hospital pharmacists emphasized the importance of interface management. In the Netherlands this is particularly important due to the preference policy in the out-patient sector which also has an influence on the in-patient sector. The preference policy allows insurers to indicate a preferred generic medicine for reimbursement (GÖG/ÖBIG 2006) when a choice exists between different generic varieties of the same active pharmaceutical compound. Tendering is carried out for certain medicines within classes organised by each private insurer (e.g. every six months). The company offering the lowest price wins the market of that insurer. Therefore, the preference policy has had a high impact on the use and prices of generics in the out-patient sector.

The medicine used in the out-patient sector (e.g. as a result of the preference policy) might be different from the medicine used within the hospital (which might for example get a large discount on an on-patent medicine). A problem mentioned in respect with interface management is that when a patient comes to a hospital with medicine A, he/she is not allowed to continue it in the hospital. Hence, the equivalent medicine, which might be medicine B, is given to the patient. But when the patient is discharged the general practitioner of the patient either prescribes him/her the “old” medicines A or continues with medicine B which might not be cost-effective. It might lead to the complex situation that the patient takes medicine A and B. Hence, this problem demands for a sophisticated solution to better coordinate prescribing patterns in the out-patient and the in-patient sectors.

Table 9.3: Case studies – PHIS Hospital Pharma case study Netherlands, 2009

Parameter	Case Study Hospitals	Country-wide
Key characteristics		
Number of hospitals	3	206
Type of hospitals and geographic distribution	All 3 general hospitals 2 in a metropolitan area, 1 in a small town in the Western part of the Netherlands	Almost half of the total number of hospitals are general hospitals (96 general hospitals, 100 mental and substance abuse hospitals)
Ownership	3 public hospitals	All hospitals (206) function in the public sector (non-profit)
Size of hospitals	2 medium sized hospitals (< 500 acute care beds) and 1 small hospital	Total number of acute care beds in public (not-for profit) hospitals: ~ 46,500
Pharmaceutical expenditure in % of total hospital expenditure	In 2 case study hospitals medicines account for 4.6% and 3.5% of the total hospital expenditure	Expenditure on medicines accounts for 4.3% of expenditure in hospitals (2006)
Delivery chain and distribution actors		
Hospital pharmacy	All 3 hospitals have a hospital pharmacy	De facto all public hospitals have a hospital pharmacy
Serving out-patients	Yes, serving in-patients, but also serving specific out-patient institutions, including nursing homes and a detention centre	Approximately 55% of all hospital pharmacies serve out-patients
Key suppliers	Majority of supplies by wholesalers, around 20% are deliveries by industry, by other hospital pharmacies only in emergency cases	Same situation: mainly industry, wholesale and pharmacies are possible
Purchasing policies in hospitals		
Level of decentralisation	Regional purchasing in purchasing groups; decentralised purchasing by individual hospitals	Same situation for all public hospitals
Tendering	Key purchasing policy by regional purchasing groups	Same situation for all hospitals
Negotiations	Additional purchasing policy at hospital level	Same situation for all hospitals
Main award criteria	Mainly price; Medical/therapeutic benefit; User friendliness (e.g. packaging, labelling)	Same situation for all hospitals
Understanding the actual hospital price		
Price level	Hospital prices correspond to the pharmacy purchasing price (gross)	Same situation for all hospitals
Wholesale mark-up	Wholesale mark-ups for in- and out-patient sector not regulated	Same situation for all hospitals

Parameter	Case Study Hospitals	Country-wide
VAT	6%	Same situation for all hospitals
Discounts/ Rebates	No mandatory discounts Voluntary discounts on average ~ 30%	Same situation for all hospitals
Publication of prices	Maximum prices for all medicines (in- and out-patient sector) are published in the *taxe*. No information on actual hospital prices	Same situation for all hospitals
Funding in hospitals		
Funding of hospitals and remuneration	DRG system	Same situation for all hospitals
Funding of medicines	Out of hospital budget, 100% funding through SHI, but for orphan medicines 80% by SHI and 20% by hospitals for high-cost medicines	Same situation for all hospitals
Co-payments for medicines	No	Same situation for all hospitals
Hospital pharmaceutical formulary	All 3 hospitals have an individual hospital pharmaceutical formulary including between 800 – 1,000 INN	No legal obligation to have a HPF
Criteria for inclusion	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	Same situation for all hospitals
Updates and publication	Up-dated on an ad-hoc basis; not published	Continuous updates in all hospitals
Monitoring & Interface management		
Pharmaceutical and Therapeutic Committee (PTC)	PTC consists of chief pharmacist and physicians and decides to add new medicines on the HPF	Same situation for all hospitals
Monitoring	Monitoring of prices, consumption and expenditure – results only for internal use For medicines included in the list of high-cost medicines issued by the NZa expenditure, prices and consumption are monitored at national level by the Foundation for Pharmaceutical Statistics	Same situation for all hospitals
Interface management	Need for interface management expressed; especially due to preference policy; first analysis have been initiated	Same situation for all hospitals

DRG = Diagnosis Related Groups, HPF = Hospital Pharmaceutical Formulary, INN = International Non-Proprietary Name, NZa = Dutch Health Care Authority (Nederlandse Zorgautoriteit), PTC = Pharmaceutical and Therapeutic Committee, SHI = Social Health Insurance

Source: PHIS 2009n, PHIS case studies 2009

9.2.2 Results

9.2.2.1 Consumption

In the Netherlands no nation-wide information on annual consumption of medicines in hospitals is available. However, two of the case study hospitals could report on annual pharmaceutical consumption – the one hospital expressed it in packs and the other one in DDD - for the year 2008. In one of the hospitals the consumption was 179.000 packs and in the other hospital 1,634.242 DDD.

The top 5 active ingredients which accounted for highest expenditure in hospitals in the Netherlands are listed in Table 9.4. This country-wide list is indeed very similar to the situation in the case study hospitals. In addition, the following active substances were mentioned by the case study hospitals: omalizumab, pemetrexed and bevacizumab.

Table 9.4: Case studies – Top 5 active substances used in hospitals by pharmaceutical expenditure in the Netherlands, 2008

Position	Top active substances used in hospitals ranked with regard to expenditure – country-wide
1	Infliximab
2	Trastuzumab
3	Rituximab
4	Oxaliplatin
5	Docetaxel

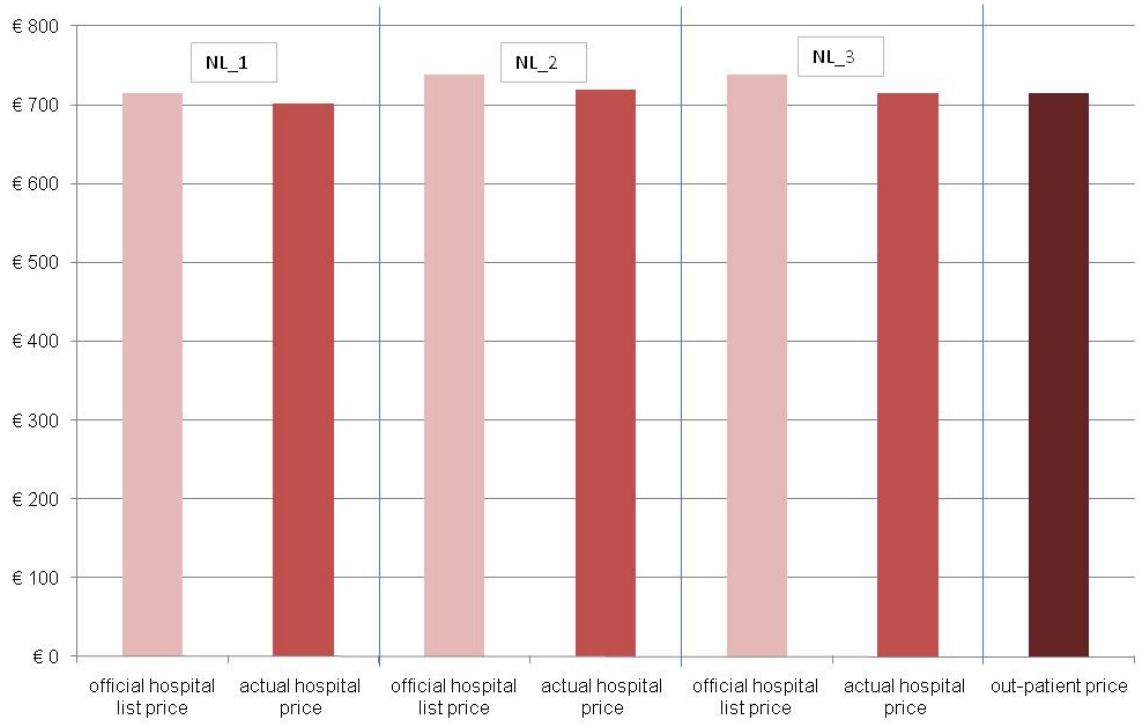
Source: PHIS 2009n

9.2.2.2 Prices

For out-patient medicines, an official price list is available which is updated every month, the *taxe*. Hospital pharmacists also use this price list as a reference (upper limit). Prices indicated in the *taxe* are pharmacy purchasing prices. When purchased from a wholesaler, medicines are sold to hospitals including a wholesale mark-up. There is no regulation on these wholesale mark-ups.

The actual hospital prices for an oncologic medicine differ between the hospitals (cf. Figure 9.5). The out-patient price in this case is almost at the same level as the actual hospital price, as the indicated out-patient price presents the pharmacy purchasing price (net). Hence, the informative value of comparing the hospital price with the indicated out-patient price is limited.

Figure 9.5: Case studies – Comparison of hospital and out-patient prices per unit of an oncologic medicine in the Netherlands, 2009



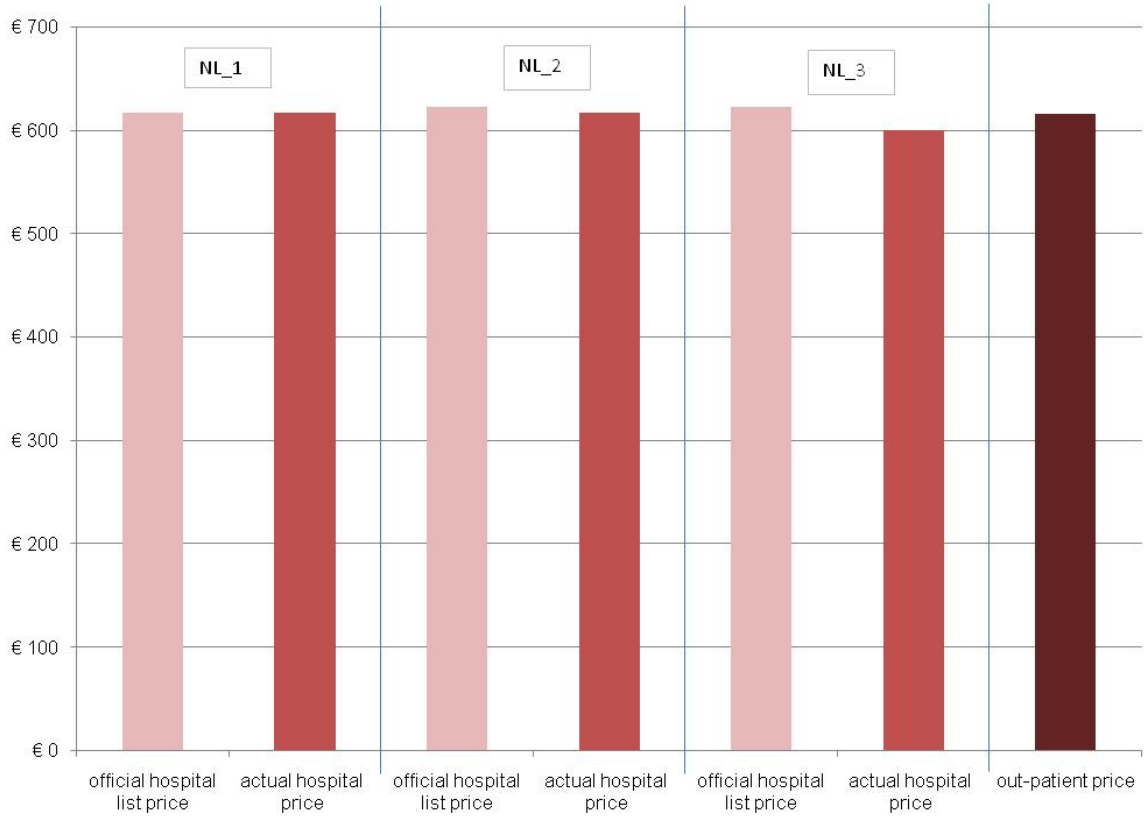
NL_1, NL_2, NL_3 = different Dutch hospitals participating in the PHIS Hospital Pharma case studies

Out-patient price: The public / retail price net 2009 is exclusive of flat rate service charge of € 7.28 on average for pharmacists ("prescription fee"). This average fee could go up to a maximum of € 7.95 if the pharmacist and the insurer have a written agreement. In addition pharmacists have to pay a rebate ("claw-back") of 6.82% (maximum of € 6.80) over the public / retail prices listed. This rebate can also vary depending on the agreement that a pharmacist has with the insurer. The indicated price equals the pharmacy purchasing price (net).

Source: PHIS case studies 2009

Figure 9.6 shows slight differences between the actual hospital prices paid by the three surveyed hospitals in the Netherlands. One hospital achieved a price which is 3% lower than the other two hospitals. Prices for this specific product achieved by individual negotiations on hospital level in the Netherlands are in general equal or below the official list price. The bargaining power is rather narrow.

Figure 9.6: Case studies – Comparison of hospital and out-patient prices per unit of an anti-inflammatory medicine in the Netherlands, 2009



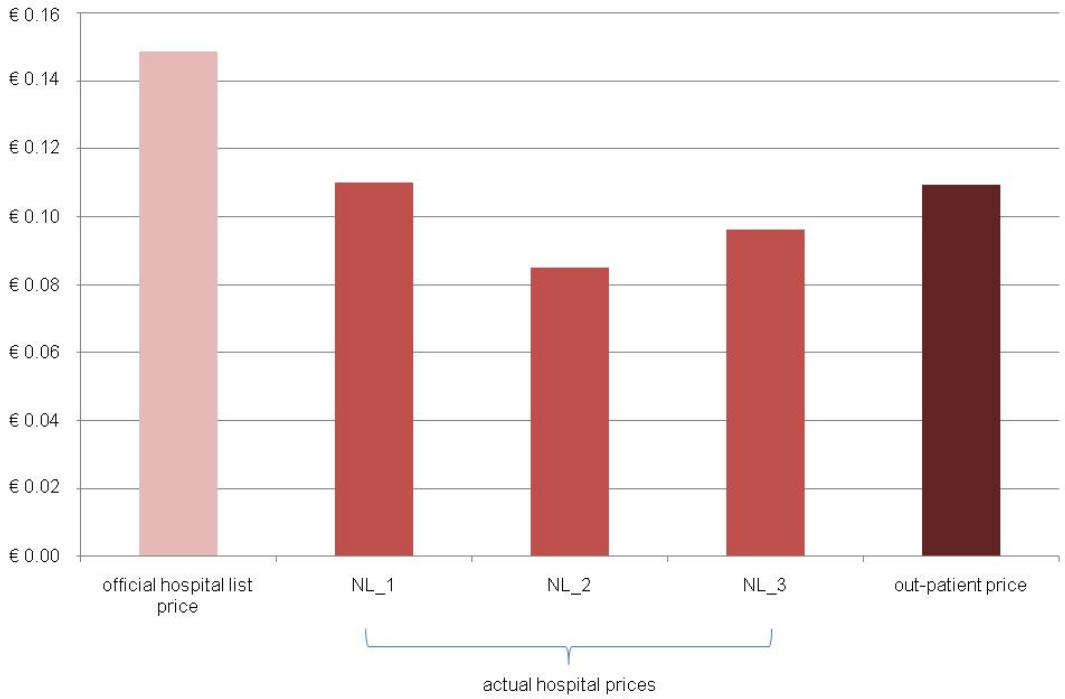
NL_1, NL_2, NL_3 = different Dutch hospitals participating in the PHIS Hospital Pharma case studies

Out-patient price: see legend of Figure 9.5.

Source: PHIS case studies 2009

While cardiovascular medicines are often received cost-free in Austria, hospitals in the Netherlands pay between € 0.09 and € 0.11 per unit for a surveyed cardiovascular medicine. These are the actual negotiated prices, and they are approximately 35% lower than the official list prices. For the surveyed active ingredient of the cardiovascular system the case study hospitals in the Netherlands reported only prices of generic medicines.

Figure 9.7: Case studies – Comparison of hospital and out-patient prices per unit of a cardiovascular medicine (only generics) in the Netherlands, 2009



NL_1, NL_2, NL_3 = different Dutch hospitals participating in the PHIS Hospital Pharma case studies

Out-patient price: see legend of Figure 9.5.

Source: PHIS case studies 2009

9.3 Norway

9.3.1 Introduction

Two hospitals participated in the PHIS hospital case study. One hospital is situated in a county in the South and one hospital is located in Oslo. The county hospital has faced larger changes in the previous years (bed capacity and staff reduction). This hospital is currently rebuilt and a project is being realised to put a focus on primary care. In the case of the hospital in Oslo, in fact four hospitals are integrated in a joint hospital organisation, but only one hospital which came out of a fusion of two of them, provided data for the PHIS Hospital Pharma case study. In 2008 180,000 in-patients were treated by hospitals integrated in this hospital organisation.

In both participating hospitals hospital pharmacies are established which are owned by the Health Regions and which besides serving in-patients act as community pharmacies (mainly delivering medicines to patients being discharged from hospital, families, visitors and hospital

employees). About a third of the employees in the hospital pharmacies are hospital pharmacists. They play a crucial role in the in-patient pharmaceutical system.

The main suppliers of the hospital pharmacies are other (hospital) pharmacies and wholesalers.

An important body in the in-patient pharmaceutical system is the Norwegian Drug Procurement Cooperation (LIS), which is responsible for the purchasing and pricing of medicines in all Norwegian public hospitals which account for around 90% of all hospitals (cf. Table 9.5). Pharmaceutical procurement in the in-patient sector is mainly realised by tendering. Three employees at LIS work full time in the procurement department and maintain official contacts to the Norwegian regions (Regional Health Enterprises). The regions are also members of the boards. In meetings with all management organisations of Norwegian hospitals the active ingredients which should be procured are usually decided on. A scoring system for ranking medicines is used before granting the tender. The three wholesalers in Norway have a negotiated margin with LIS (1.5%) but no margin at the level of hospital pharmacies is applied. Discounts are given in financial terms. The interviewed hospital experts consider the Norwegian model as transparent, as decisions are not taken by LIS but approved independently by every single hospital as result of open processes conducted by PTC in form of meetings and other efforts. The purchasing decisions are reflected in the prescribing guidelines, meaning that the selected medicines are recommended for the doctors. For a better promotion of the prescribing guidelines, leaflets are produced which can be put into the pocket of the doctor's overall.

However, some medicines used in hospitals are not procured by LIS and thus are within the limits of maximum regulated prices.

Pharmaceutical expenditure is covered within the hospital financing system by global budgeting in combination with a DRG oriented system. Patients do not have to provide co-payments for medicines applied in the in-patient sector.

Table 9.5: Case studies – PHIS Hospital Pharma case study Norway, 2009

Parameter	Case Study Hospitals	Country-wide
Key characteristics		
Number of hospitals	2	87 (2008)
Type of hospitals and geographic distribution	Both are general hospitals; 1 in Oslo and 1 in a big town in the South of Norway	All 87 hospitals are general hospitals
Ownership	Both are public hospitals	About 90% of hospitals are public

Parameter	Case Study Hospitals	Country-wide
Size of hospitals	1 big hospital (> 500 acute care beds; fusion of 2 hospitals) and 1 hospital of middle-size (400-500 acute care beds)	Approx. 50% of hospitals in Norway are small (<100 beds), 30% are medium size (100-300 beds) and 20% are large (>300 beds). This is measured by the number of beds in somatic care. Total number of acute care beds in public hospitals: ~ 11,850
Pharmaceutical expenditure in % of total hospital expenditure	2% and 5% respectively	3.8% (in public hospitals)
Delivery chain and distribution actors		
Hospital pharmacy	In both hospitals hospital pharmacies are established which are owned by Regional Health Enterprises.	Hospital pharmacies are established in 32 out of 78 public hospitals.
Serving out-patients	The hospital pharmacies also act as community pharmacies.	All hospital pharmacies have an out-patient department mainly serving patients, families, hospital employees and visitors.
Key suppliers	Wholesalers and other hospital pharmacies are the key suppliers.	Pharmacies (all medicines), wholesalers (medicines of a specific list) deliver medicines to hospitals.
Purchasing policies in hospitals		
Level of decentralisation	LIS negotiates centrally the pharmacy purchasing price (PPP). Regional Health Enterprises or hospitals decide on or negotiate the pharmacy mark-up. The wholesale mark-up is subject to a separate tender.	Same situation for all public hospitals
Tendering	Key purchasing policy	Same situation for all public hospitals
Negotiations	However those medicines which are not centrally procured by LIS are purchased directly by the hospitals at the maximum (official) price.	Of no relevance in the in-patient sector
Main award criteria	Mainly price, but also the medical/therapeutic benefit; Delivery/payment conditions	Same situation for all public hospitals
Understanding the actual hospital price		
Price level	Hospital prices correspond to the pharmacy purchasing price.	PPP + pharmacy mark-up + 25% VAT

Parameter	Case Study Hospitals	Country-wide
Wholesale mark-up	Hospital prices include wholesale mark-ups, tendered by LIS.	The wholesale mark-up is subject to a tender by LIS, usually determined for a period of three years.
VAT	25%	Same situation for all hospitals
Discounts/ Rebates	LIS tenders have resulted in a 24% price reduction for the hospitals, compared to the statutory maximum prices.	Other discounts than the one given in the tendering process are prohibited.
Publication of prices	The prices for the medicines tendered by LIS are available, but there is no legal obligation for the hospital pharmacies to publish the prices.	Same situation for all public hospitals
Funding in hospitals		
Funding of hospitals and remuneration	By the State and Regional Health Enterprise on the basis of global budgeting and a DRG system	Same situation for all public hospitals
Funding of medicines	Pharmaceutical expenditure is part of the hospital budget.	Pharmaceutical expenditure in publicly funded hospitals is covered by the hospital budgets
Co-payments for medicines	No	Same situation for all public hospitals
Hospital formulary	Both hospitals have a regional hospital pharmaceutical formulary.	Hospital pharmaceutical formularies are developed by Pharmaceutical and Therapeutic Committees.
Criteria for inclusion	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; Safety of medicines (1 hospital)	Same situation for all public hospitals
Updates and publication	The HPF are annually up-dated and published in the intranet of the hospitals and made available in form of a leaflet.	Same situation for all public hospitals
Monitoring & Interface management		
Pharmaceutical and Therapeutic Committee (PTC)	At all hospitals PTC are established which work on the list of preferred products/suppliers (HPF).	22 PTC are established by hospitals.
Monitoring	Monitoring of prices, consumption and expenditure – results only for internal use	Same situation for all public hospitals; the total national consumption is monitored by LIS

Parameter	Case Study Hospitals	Country-wide
Interface management	No specific interface management initiatives are realised.	Interface management exists with regard to specific medicines as hospitals pay for medicines that patients need after discharge from the hospital (e.g. Tumor Necrosis Factor and MS medicines)

DRG = Diagnosis Related Groups, HPF = Hospital Pharmaceutical Formulary, LIS = Norwegian Drug Procurement Cooperation, MS = Multiple Sclerosis, PPP = Pharmacy Purchasing Price, PTC = Pharmaceutical and Therapeutic Committee, VAT = Value Added Tax

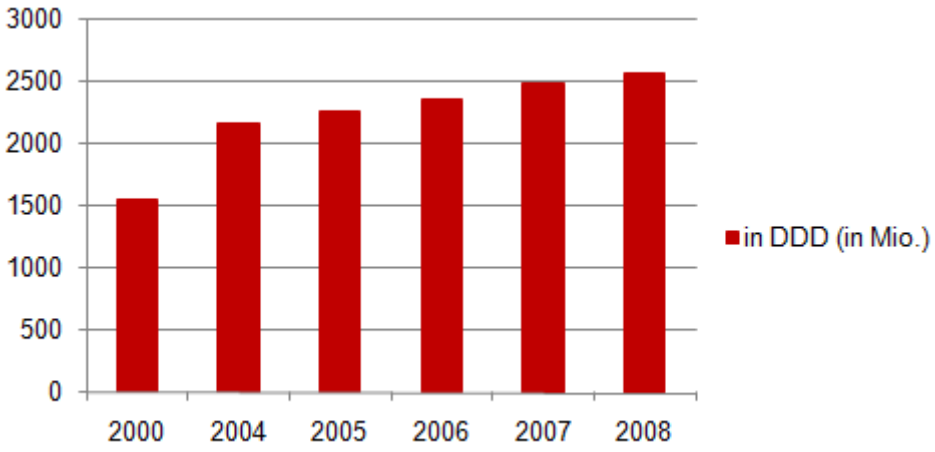
Source: PHIS 2009o, PHIS case studies 2009

9.3.2 Results

9.3.2.1 Consumption

Total annual pharmaceutical consumption in Norway has been growing over the last couple of years, as it is shown in Figure 9.8. Annual consumption is expressed in DDD. Unfortunately no data on country-wide pharmaceutical consumption in hospitals are available. But the two case study hospitals reported on the annual pharmaceutical consumption in their hospitals for the year 2008. The annual pharmaceutical consumption is in one hospital around 1,669,000 DDD and in the other hospital (fusion of two hospitals) it is approximately 2,594,600 DDD.

Figure 9.8: Case studies – Annual pharmaceutical consumption in hospitals in Norway, 2000 and 2004-2008



Source: PHIS 2009o

The picture regarding the top 5 active substances causing the country-wide highest expenditure in Norwegian hospitals is similar to that in other European countries. A few of the Top 5

substances (cf. Table 9.6) e.g. trastuzumab are also reflected under the Top 5 substances in the two case study hospitals. Several additional active substances e.g. bortezomib, caspofungin and meropenem, were mentioned by the case study hospitals as the top cost-drivers in their hospitals.

Table 9.6: Case studies – Top 5 active substances used in hospitals by pharmaceutical expenditure in Norway, 2008

Position	Top active substances used in hospitals ranked with regard to expenditure – country-wide
1	Etanercept
2	Infliximab
3	Adalimumab
4	Trastuzumab
5	Rituximab

Source: PHIS 2009o

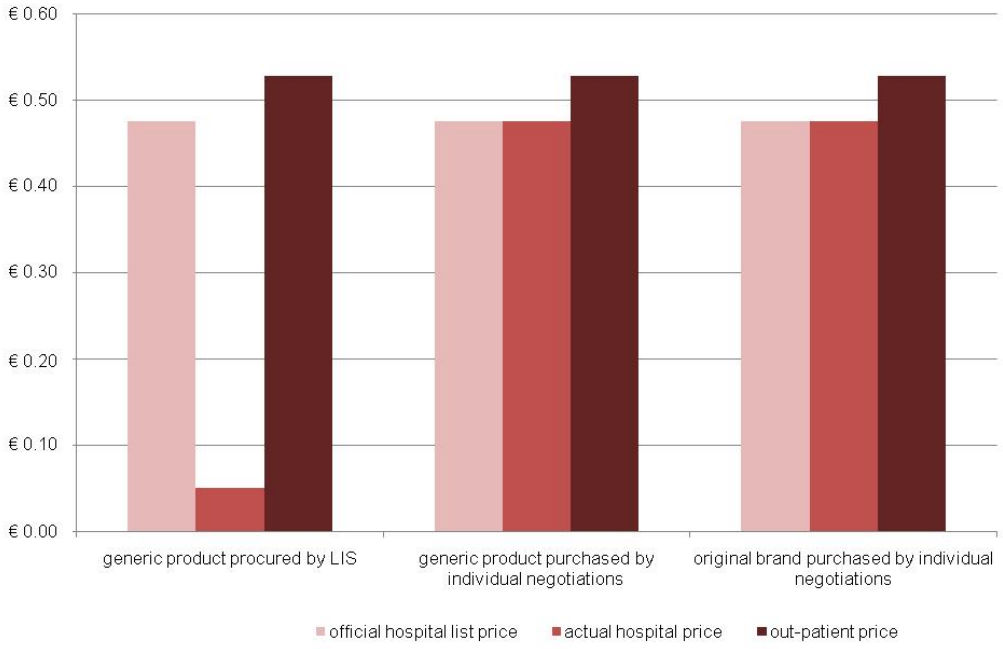
9.3.2.2 Prices

LIS negotiates the pharmacy purchasing price (PPP). Delivery costs are included in the PPP. The wholesale mark-up is subject to a separate tender. One wholesaler is selected for providing distribution services to the hospitals, usually for a period of three years. This tender is carried out by the Regional Health Enterprises, on behalf of the four regional health authorities. Other discounts than the ones given in the tendering process are prohibited.

Due to the reasons explained above price comparisons between Norwegian hospitals are of minor relevance as hospitals pay the same price.

In the hospitals participating in the case study certain medicines are individually purchased. The actual prices achieved by different purchasing policies for original and generic cardiovascular medicines are displayed in Figure 9.9. The price procured by LIS is almost 90% lower than the prices of the same original and even generic medicine.

Figure 9.9: Case studies – Comparison of hospital and out-patient prices per unit of a cardiovascular medicine per purchasing policy in Norway, 2009

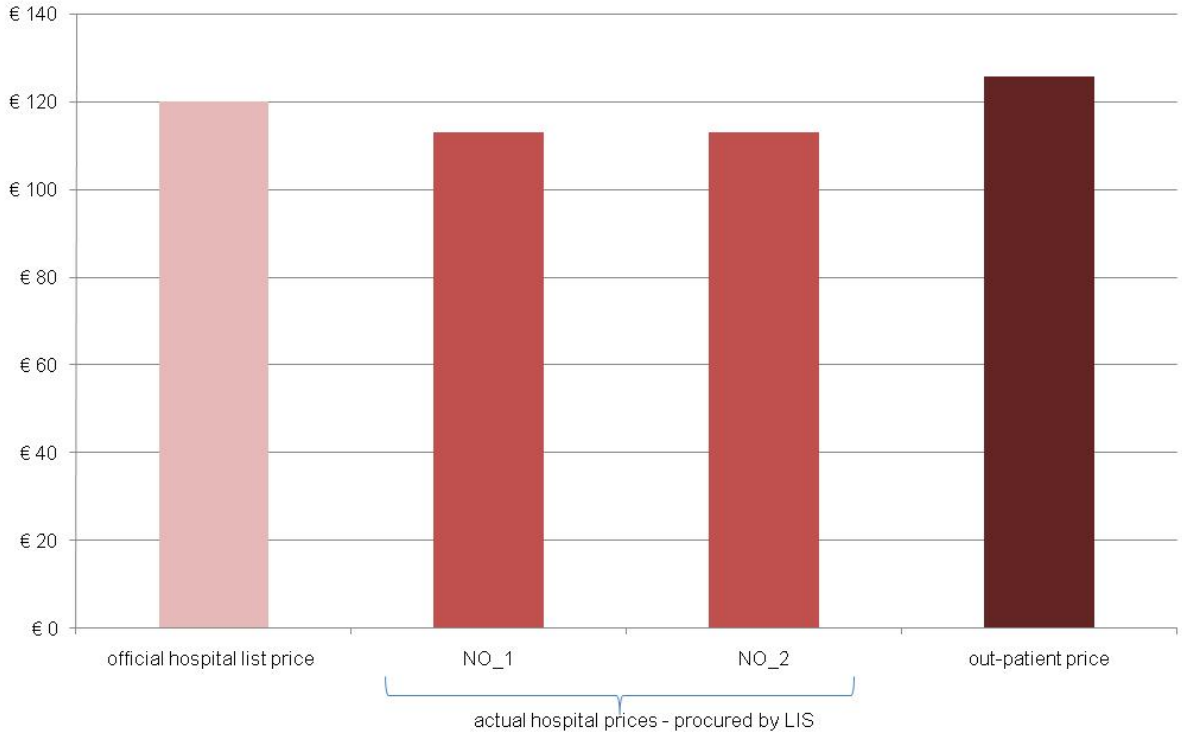


LIS = Norwegian Drug Procurement Cooperation

Source: PHIS case studies 2009

As described, hospitals in Norway have the same prices due to centralised procurement by tendering carried out by the Norwegian Drug Procurement Cooperation, as Figure 9.10 shows. Depending on the medicine and the active ingredient actual hospital prices for centrally procured for publicly funded hospitals are on average 45% lower than official hospital list prices.

Figure 9.10: Case studies – Comparison of hospital and out-patient prices per unit for a medicine for oncology/rheumatoid arthritis in Norway, 2009



LIS = Norwegian Drug Procurement Cooperation
NO_1, NO_2 = two different Norwegian hospitals participating in the PHIS Hospital Pharma case studies

Source: PHIS case studies 2009

9.4 Portugal

9.4.1 Introduction

In Portugal, four hospitals were surveyed during the case study. All these hospitals were large general hospitals, one of them in a big town in the North, another one in a big town in the centre of Portugal, while the other two hospitals were both in Lisbon, however situated in different districts and even regions. One of the hospitals in Lisbon is in charge of the whole Southern region down to the Algarve, being the first hospital centre in the region (e.g. with regard to oncology and neurology treatment) offering as such out-patient services for around 5,000 people per year from the whole region.

All four case study hospitals have a hospital pharmacy, however, in one of the hospitals the hospital pharmacy serves besides this own hospital two additional hospitals which were consolidated to the same hospital centre comprising three hospitals. In the last years, there has been a re-structuring of hospitals with a merging of several hospitals into “hospital centres” with one joint management and usually one central pharmacy (PHIS 2009q).

In the case study hospital pharmacies around 50-90 staff work, thereof around 30% to 35% are pharmacists. In two of the four hospitals hospital pharmacists also work on the ward.

In Portugal, hospital pharmacies are not allowed to dispense medicines to out-patients unless in case of exceptional circumstances (e.g. social and clinical reasons) defined in law. This is the case for two of the four surveyed hospitals where HIV patients, who had been treated as in-patients, come after discharge to the hospital pharmacy to get their medication.

Medicines deliveries to hospital pharmacies, including those of the case study, mainly come from pharmaceutical industry (up to 99%), while wholesalers and community and/or hospital pharmacies are rare suppliers (only in case of emergencies). One hospital pharmacist reported during the interview that purchases from wholesale are not welcome as they once made the experience that a wholesaler charged a wholesale margin. This is not illegal since there is no explicit regulation on the wholesale margin for the in-patient sector (cf. Table 9.7).

When hospitals purchase medicines, they usually enter into negotiations with pharmaceutical industry. Tendering by hospitals is rather rare. However, direct purchasing by hospitals is in many cases only the second step: For several medicines, ACSS (Central Administration of the Health System) fixes the maximum prices of medicines via tendering and lists those centrally tendered medicines in a catalogue. If hospitals wish to achieve a lower price and/or if medicines are not in the ACSS catalogue, they enter into negotiations with the companies. According to an interviewed hospital pharmacist, “for peanuts” negotiations are not considered as cost-effective and medicines are bought at the ACSS price, but for other medicines hospitals “go to market” and ask four to five manufacturers to submit a proposal. For generics price reductions of around 20% are usually asked.

A purchase contract between a hospital and a manufacturer is normally valid for one year. A common procedure, which is also in place in the four surveyed hospitals, is a system of retrospective rebates which hospitals receive if their sales with a company (covering generally all medicines of that manufacturer) exceed a certain threshold within a year. Therefore only at the end of the year hospitals know their exact rebates.

The hospital pharmacy is in charge of deciding on the selection of the supplier based on their price proposals, in line with the decision of the PTC regarding the inclusion of medicines in the reimbursement list. The technical handling of the purchase is usually done by a purchasing unit in the hospitals.

In 2007, Portugal introduced a reimbursement evaluation for new medicines for hospital use where the pharmaceutical companies have to demonstrate via economic evaluation studies the added therapeutic value and economic advantage compared to other medicines. If the Medicines Agency decides in favour of reimbursement, public hospitals are free to decide on the acquisition, if a medicine is not evaluated or not reimbursed, public hospitals cannot purchase it. The maximum price is settled – under the supervision of the Ministry of Health – by INFARMED and displayed on the INFARMED website.

Portugal has been operating a National Hospital Pharmaceutical Formulary (NHPF) for years (currently in its 9th edition), which is mandatory for all public hospitals. The national formulary is regularly reviewed and updated by a committee including experts from the Medicines Agency. In general, public hospitals should only use medicines on that formulary, but exceptions (e.g. for clinical reasons) are allowed. If a medicine not included in the NHPF is needed for in-patient treatment, the Pharmaceutical and Therapeutic Committee (PTC) of a hospital will decide if this medicine should be included in the hospital-specific addendum to the NHPF. In fact, all public hospitals do have their own addendum in place supplementing the NHPF, thus also the surveyed hospitals.

A key task of the PTC is to guarantee the compliance with the NHPF and its addendum. PTC members usually meet once a month. The PTC is additionally in charge of monitoring consumption and expenditure of medicines used in its hospital. The results of their evaluation are only internal. The PTC also approves good prescription guidelines which are mandatory in the hospital. In general, hospital pharmacists act as quality assurance: in one of the surveyed hospitals the Intranet validation system was shown to the interview team: When a hospital doctor prescribes, the prescription is – before being filled – validated (e.g. with regard to possible adverse drug reactions etc., considering disease pattern, age and further characteristics) by a hospital pharmacist who might need to contact the prescribing doctor in case of possible risks for the patient.

All interviewed hospital pharmacists expressed an urgent need for interface management which has not been developed by now. Additionally, a closer cooperation between hospitals was also seen as necessary. One interview partner stressed that the evaluation which has been undertaken for new medicines for hospital use by INFARMED since 2007 is of great support for the hospitals. Before 2007 this task was done by the hospitals themselves, which was rather time-intensive and difficult in particular for smaller hospitals.

Table 9.7: Case studies – PHIS Hospital Pharma case study Portugal, 2009

Parameter	Case Study Hospitals	Country-wide
Key characteristics		
Number of hospitals	4	189, thereof 92 public hospitals (2008)
Type of hospitals and geographic distribution	All are general hospitals; 2 in Lisbon (however, 2 different health districts), 1 in a big town in the North, 1 in a big town in the centre of Portugal	73% of all hospitals (77% of all public hospitals) are general hospitals Out of the public hospitals (disregarding military/ prison hospitals), 24 are Central and 57 regional hospitals. Regional hospitals are distributed country-wide, Central hospitals (the biggest ones) are located mainly in Porto, Lisbon and Coimbra.
Ownership	All are public hospitals	92 public hospitals (thereof 11 military and prison hospitals) Around 50% of hospitals are public (bed capacity is more than 50%)
Size of hospitals	All 4 of big hospitals (> 500 acute care beds)	The beds per 1,000 inhabitants are 2.9 (North), 3.4 (Centre), 4.1 (Lisbon), 2.4 (South).
Pharmaceutical expenditure in % of total hospital expenditure	13%, 19% and 22% respectively (data for three hospitals available) of the hospital expenditure account for medicines	N.a.
Delivery chain and distribution actors		
Hospital pharmacy	All 4 hospitals have a hospital pharmacy	De facto all public hospitals have a hospital pharmacy (due to consolidation “hospital centres” with a central pharmacy)
Serving out-patients	Basically serving in-patients, but also serving specific out-patients (e.g. HIV patients who had been treated in hospital care before and special groups of patients or pathologies by special regime) in 2 of the 4 hospitals	Hospital pharmacies may only deliver to out-patients under exceptional circumstances defined by law.
Key suppliers	Majority of deliveries directly by industry, wholesalers or pharmacies (hospital and community pharmacies) are exemptions (e.g. in case of stock ruptures)	Same situation: mainly industry, wholesale and pharmacies are possible

Parameter	Case Study Hospitals	Country-wide
Purchasing policies in hospitals		
Level of decentralisation	Both centralised (for maximum prices) and decentralised purchasing (direct purchasing at hospital level)	Same situation for all public hospitals
Tendering	Centralised procurement by tendering by a NHS agency Minor importance at hospital level	Same situation for all (public) hospitals[1]
Negotiations	Key purchasing policy at hospital level	Same situation for all (public) hospitals[1]
Main award criteria	Mainly price and medical/therapeutic benefit; Delivery/payment conditions (minor importance)	Same situation for all (public) hospitals[1]
Understanding the actual hospital price		
Price level	Hospital prices correspond to the ex-factory price incl. VAT.	Same situation for all hospitals
Wholesale mark-up	In practice not relevant due to direct deliveries from industry; wholesale mark-up for the in-patient sector are not regulated, but when applied usually the out-patient mark-ups are taken	Same situation for all hospitals
VAT	5%	Same situation for all hospitals
Discounts/ Rebates	Usually rebates at the end of the year if a certain sales amount is reached with a company	Similar situation for all hospitals
Publication of prices	Maximum prices are published on Medicines Agency's website and ACSS tendering published on their website. But no information on actual prices	Same situation for all hospitals
Funding in hospitals		
Funding of hospitals and remuneration	NHS (ACSS - Central Administration of the Health System) funding, administrated by regions and ACSS DRG system, payment by service and own revenues (hospital admission charges)	Same situation for all (public) hospitals[1]
Funding of medicines	Part of hospital budget	Same situation for all (public) hospitals[1]
Co-payments for medicines	No	Same situation for all (public) hospitals[1]
Hospital formulary	All 4 hospitals have an addendum to the National Hospital Pharmaceutical Formulary (NHPF).	NHPF mandatory for (public) hospitals[1], addendums are possible and common
Criteria for inclusion	Medical and therapeutic benefit; Economic criteria like cost-effectiveness; Budget impact; Disease specific criteria like severity of illness; Patient specific criteria like chronically or terminally ill patient	Same situation for all (public) hospitals[1]

Parameter	Case Study Hospitals	Country-wide
Updates and publication	Up-dated on a monthly basis (2 hospitals) and ad-hoc basis (1 hospital) or every 2 to 3 weeks or whenever needed (1 hospital) NHPF accessible on Medicines Agency's website, addendums not published	Continuous updates in all (public) hospitals[1] Conc. publication same situation country-wide
Monitoring & Interface management		
Pharmaceutical and Therapeutic Committee (PTC)	Guaranteeing compliance with NPHF and hospital addendum, monitoring and good prescribing	Same situation for all (public) hospitals[1]
Monitoring	Monitoring of prices, consumption and expenditure – results only for internal use	Same situation for all (public) hospitals[1]
Interface management	Need for interface management expressed; no concrete initiatives	Same situation for all (public) hospitals[1]

ACSS = Central Administration of the Health System, DRG = Diagnosis Related Groups, HIV = Human Immunodeficiency Virus, HPF = Hospital Pharmaceutical Formulary, NHPF = National Hospital Pharmaceutical Formulary, NHS = National Health System, PTC = Pharmaceutical and Therapeutic Committee, VAT = Value Added Tax

[1] Only information on the public sector (covering nearly 50% of hospitals) is available based on the PHS Hospital Pharma Report Portugal

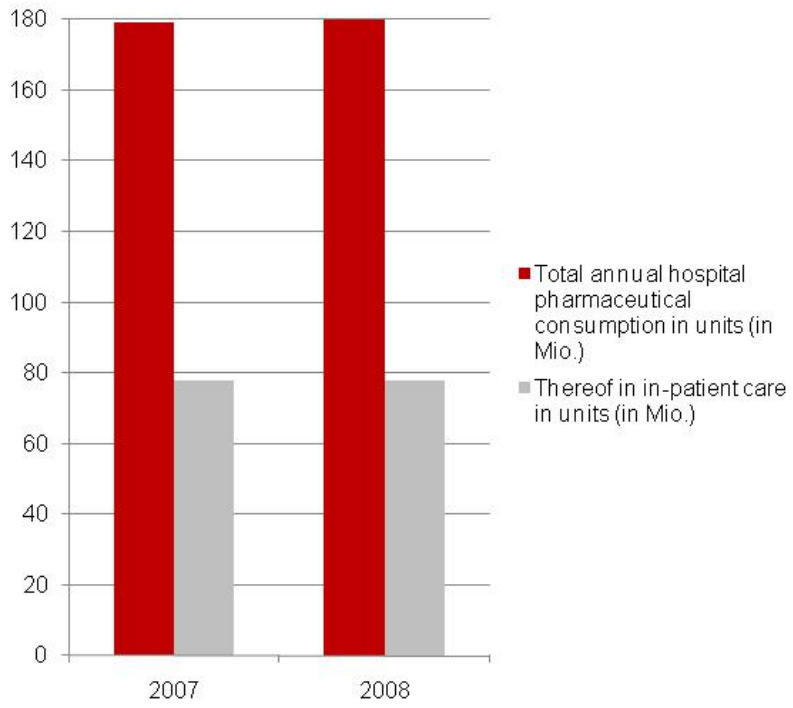
Source: PHIS 2009q, PHIS case studies 2009

9.4.2 Results

9.4.2.1 Consumption

Total pharmaceutical consumption in hospitals has increased in the last years, as shown in Figure 9.11. A comparison to the case study hospitals is difficult, as only one hospital reported on the annual pharmaceutical consumption (5,864,734 measured in units). In Portugal pharmaceutical consumption in hospitals is always measured and indicated in units.

Figure 9.11: Case studies – Annual pharmaceutical consumption in hospitals in Portugal, 2007–2008



Source: PHIS 2009q

Data available refer to consumption of medicines covered by the CHNM (Código Hospitalar Nacional do Medicamento / national hospital code for medicines) which is a classification system attributed by the Medicines Agency INFARMED to medicines used in hospitals and refer to 59 national health service hospitals, which represent about 77% of the public hospital pharmaceutical expenditure (HOSPE).

The top 5 active substances used in hospitals ranked according to pharmaceutical expenditure, as listed in Table 9.8, follow similar trends as in other countries. The case study hospitals have additionally reported tenofovir, lopinavir and ritonavir among their top 5 medicines. The reason for this particularity is that in Portugal hospital pharmacies may in specific cases, such as for HIV patients and special groups of patients or pathologies by special regime, also serve out-patients which is the case in the surveyed hospitals.

Table 9.8: Case studies – Top 5 active substances used in hospitals by pharmaceutical expenditure in Portugal, 2008

Position	Top active substances used in hospitals ranked with regard to expenditure – country-wide
1	Trastuzumab
2	Docetaxel
3	Human normal Immunoglobulin
4	Meropenem
5	Sodium Chloride

Source: PHIS 2009q

9.4.2.2 Prices

In general the "hospital price" in Portugal corresponds to the maximum ex-factory price plus value added tax (VAT). For the price comparison the VAT is excluded (cf. section 2.2.5). In general most of the medicine purchases are directly made with industry, so no mark-up is applicable (in case of a purchase from a wholesaler, the out-patient mark-up might be applied, see section 9.4.1).

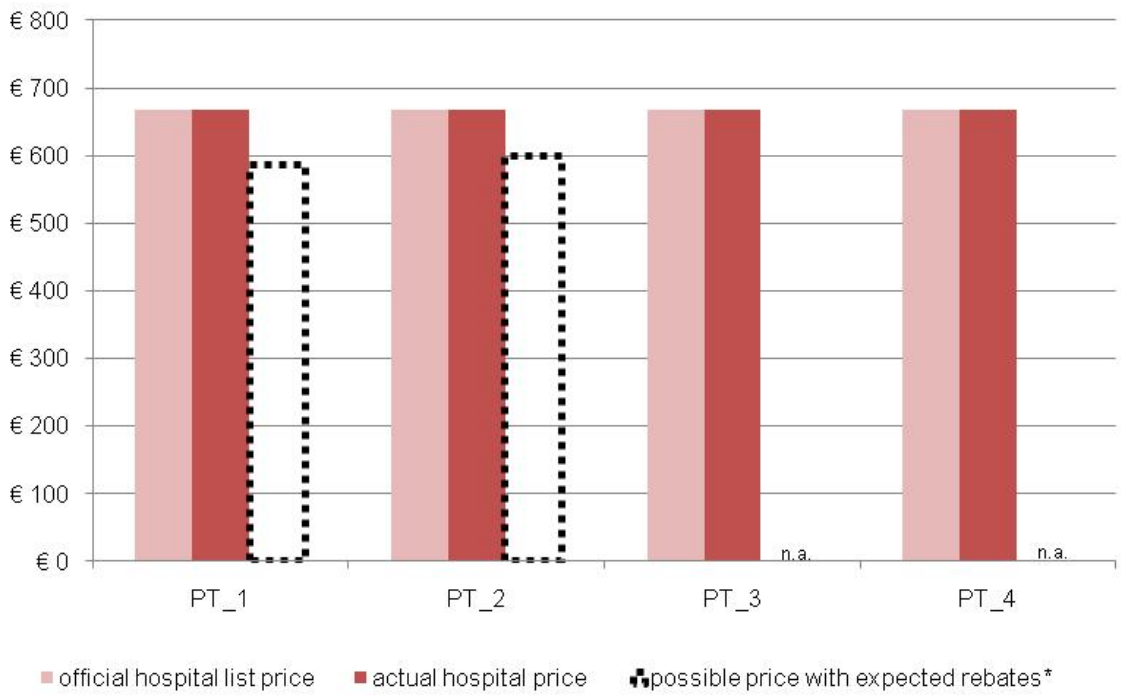
In purchasing medicines various scenarios are possible in Portugal, with a combination of centralised procurement by tendering and individual acquisitions.

- public procurement process by tendering (centrally purchased by ACSS);
- central purchasing by Serviço de Utilização Comum dos Hospitais (SUCH) / Common Use Service of Hospitals;
- acquisition by an association of several hospitals;
- acquisition by each hospital individually.

Additionally pharmaceutical companies offer rebates ("rappel") usually granted at the end of the year if the hospital purchases a certain quantity or type of medicines.

In Figure 9.12 possible rebates for an anti-inflammatory medicine are displayed in comparison to the official hospital list price and the actual hospital price which equal in this case because the medicine was tendered by ACSS. In these cases 10-12% rebates on the final bill had been offered the year before by pharmaceutical company. In general up to 20% rebates are possible. The out-patient price was disregarded in this price comparison as the focus laid on in-patient prices and rebates.

Figure 9.12: Case studies – Comparison of hospital prices per unit of an anti-inflammatory medicine in Portugal, 2009



PT_1, PT_2, PT_3, PT_4 … different Portuguese hospitals participating in the PHIS Hospital Pharma case studies

n.a. = not available

* Possible estimated rebated price: Possible rebates (e.g. a credit at the end of the year) are granted by pharmaceutical companies to hospitals, if a certain amount of purchased medicines is reached ("rappel"). Amount of rebates is based on the year before.

Source: PHIS case studies 2009

Medicines of (minor) relevance for a hospital are usually purchased at the prices tendered by ACSS, as the workload for the individual negotiation of the hospital would not seem to pay off (see section 9.4.1). However, even in case of an oncologic medicine (cf. displayed in Figure 9.13) all hospitals participating in the PHIS case studies purchase this medicine at the level of the price tendered by ACSS.

Figure 9.13: Case studies – Comparison of hospital and out-patient prices per unit of an oncologic medicine in Portugal, 2009

PT_1, PT_2, PT_3, PT_4 … different Portuguese hospitals participating in the PHIS Hospital Pharma case studies

Source: PHIS case studies 2009

9.5 Slovakia

9.5.1 Introduction

In Slovakia, ten out of 80 general public hospitals participated in the case study. These hospitals are evenly distributed around Slovakia, situated in small towns as well as in metropolitan cities including the capital Bratislava. One hospital is a specialised hospital and another one a military hospital. Four hospitals are under one central management.

All case study hospitals have a hospital pharmacy. Since 1 January 2009 hospital pharmacies have been forbidden by law to serve out-patients. Exemptions are possible for specific prescription-only medicines. Four case study hospitals established a separate community pharmacy with specific requirements for staff and storage of medicines. In one hospital concern was expressed that they might no longer be able to run the community pharmacy as in the last six years hospital pharmacies had to be closed due to high staff and maintenance costs. Hospitals without hospital pharmacies directly purchase their medicines from community pharmacies, which is much more expensive due to different mark-up schemes in the out-patient sector (cf. section 4.3).

There are wide variations in the number of pharmacists and total staff working in the case study hospital pharmacies. The number of pharmacists ranges between one to nine pharmacists and of the staff members from five to up to 25. Additional staff is required if there is a separate community pharmacy serving out-patients.

Hospital pharmacists are mainly involved in the counselling of doctors, preparation of magistral medicines, guaranteeing pharmaceutical safety and monitoring of pharmaceutical expenditure and consumption. In most case study hospitals the hospital pharmacist is a member of the Purchasing Committee and of the Pharmaceutical and Therapeutic Committee.

Medicines are mainly delivered by wholesalers to the hospitals. However, especially for high priced medicines the General Health Care Insurance (Vseobecna zdravotna poisťovňa, VsZP) centrally tenders those medicines, e.g. blood derivatives. Direct deliveries by manufacturers or by other community pharmacies are of minor importance.

Market evaluation, which is a kind of competitive negotiation, is an important purchasing policy of the hospitals in Slovakia. Market evaluation is applied if annual expenditure for a specific medicine is between € 15,000.- and € 30,000.-. The chief hospital pharmacist, who is responsible for market evaluation, collects a minimum of three offers from different wholesalers for the needed medicines. The criteria for selecting a wholesaler include among others the lowest price and the availability of medicines. The chief hospital pharmacist has to justify the reasons for his/her decision in written form, and the medical or administrative director of the hospital then takes the final decision.

In all ten hospitals the purchase contracts are usually valid for one year. However, they can be adjusted on an ad-hoc basis. These purchase contracts include commercials discounts granted by the wholesalers or industry as a result of the negotiations. Some hospitals receive discounts in kind (cost-free medicines) from industry, but in the majority of cases discounts are granted on the maximum purchasing price. Discounts usually range between 1-10% (cf. Table 9.9). Negotiations are based on the official list price, which is the maximum ex-factory price published by the Ministry of Health. As explained in the European survey (cf. section 4.3) in Slovakia, wholesale mark-ups for medicines used in hospitals are regulated at 9%. In addition, prices of medicines in hospitals include a 10% VAT.

All case study hospitals have their own hospital pharmaceutical formulary which is only available in paper format and only for internal use. The size of the hospital formularies of the case study hospitals ranges from 590 to 1,500 trade names (at country average: 500 to 900 active substances, cf. section 5.2). Slovakia has no national hospital pharmaceutical formulary. The Pharmaceutical and Therapeutic Committee (PTC), including the medical and administrative director as well as the chief pharmacist, is responsible for setting, developing and updating the hospital pharmaceutical formulary.

Table 9.9: Case studies – PHIS Hospital Pharma case study Slovakia, 2009

Parameter	Case Study Hospitals	Country-wide
Key characteristics		
Number of hospitals	10	122 in total
Type of hospitals and geographic distribution	9 general hospitals; 1 specialised hospital 3 hospitals are located in small towns and 7 are in different metropolitan cities incl. the capital	80 general hospitals, thereof 40 specialised; even spread of hospitals
Ownership	All are public hospitals (1 military and 2 faculty hospitals)	87 (public)
Size of hospitals	7 big hospitals (> more than 400 acute care beds) 3 small hospitals (< than 200 acute care beds)	9 large hospitals (> more than 400 acute care beds) 18 middle sized hospitals (200-400 acute care beds) 30 small hospitals (< than 200 acute care beds) 21 university hospitals
Pharmaceutical expenditure in % of total hospital expenditure	13% and 10% (data only from two hospitals)	Pharmaceutical expenditure in hospitals accounts for 11% of total expenditure in hospitals
Delivery chain and distribution actors		
Hospital pharmacy	All 10 hospitals have a hospital pharmacy	De facto all public hospitals have a hospital pharmacy (exemptions: very small hospitals)
Serving out-patients	Basically serving in-patients; exemptions are made for specific prescription-only medicines and in hospital out-patient clinics 4 hospitals run separate community pharmacies on the premises of the hospital	According to law hospital pharmacies may only serve in-patients; community pharmacies may be separately established
Key suppliers	Almost 100% of deliveries by wholesalers; only a very small portion delivered directly by industry or centrally tendered by SHI	Same situation: majority of deliveries by wholesalers
Purchasing policies in hospitals		
Level of decentralisation	Centralised tendering for specific medicines by health insurance, otherwise decentralised purchasing	Same situation for all public hospitals
Tendering	One of several purchasing policies	Same situation for all public hospitals

Parameter	Case Study Hospitals	Country-wide
Market evaluation (competitive negotiations)	Key purchasing policy at hospital level: If the annual expenditure is below € 30,000.- but higher than € 15,000.- the active substance must be purchased by the hospital through competitive negotiations called “market evaluation” by collecting a minimum of three offers from different wholesalers for every medicine.	Same situation for all public hospitals
Main award criteria	Mainly price; Medical/therapeutic benefit; Delivery/payment conditions	Same situation for all public hospitals
Understanding the actual hospital price		
Price level	Hospital prices correspond to the pharmacy purchasing price incl. VAT	Same situation for all hospitals
Wholesale mark-up	Statutory linear maximum wholesale mark-up of 9% in the in-patient sector	Same situation for all hospitals
VAT	10%	Same situation for all hospitals
Discounts/ Rebates	No mandatory discounts; commercials discounts range between 1-10%	Same situation for all public hospitals
Publication of prices	Maximum ex-factory price is published by the Ministry of Health; but no public information on actual negotiated prices, only for internal use	Same situation for all hospitals
Funding in hospitals		
Funding of hospitals and remuneration	Majority of hospitals receive 100% of funds from SHI; the military hospital receives 30% of funds by the federal state; additional funds might come through commercial activities of the hospital DRG system, fee for and own revenues (hospital admission charges)	Same situation for all hospitals
Funding of medicines	Part of hospital budget and cost borne by SHI; High-cost medicines are purchased directly by SHI	Same situation for all hospitals
Co-payments for medicines	No	Same situation for all public hospitals
Hospital formulary	All 10 hospitals have their own hospital formulary, no national hospital pharmaceutical formulary	Same situation for all public hospitals
Criteria for inclusion	The main criteria are the medical and therapeutic benefit and economics criteria like cost-effectiveness or budget impact	Same situation for all public hospitals
Updates and publication	All hospitals up-date the hospital formulary annually, and two hospitals additionally on an ad-hoc basis All hospitals do not publish their hospital pharmaceutical formularies	Continuous updates in all public hospitals Conc. publication same situation country-wide

Parameter	Case Study Hospitals	Country-wide
Monitoring & Interface management		
Pharmaceutical and Therapeutic Committee (PTC)	Responsible for setting, developing and updating the HPF, monitoring and good prescribing	Same situation for all (public) hospitals
Monitoring	Monitoring of prices, consumption and expenditure – results only for internal use	Same situation for all public hospitals
Interface management	Not specified	Is needed

DRG = Diagnose-related groups; HPF = Hospital Pharmaceutical Formulary; PTC = Pharmaceutical and Therapeutic Committee; SHI = Social Health Insurance, VAT = Value Added Tax

Source: PHIS 2009s, PHIS case studies 2009

9.5.2 Results

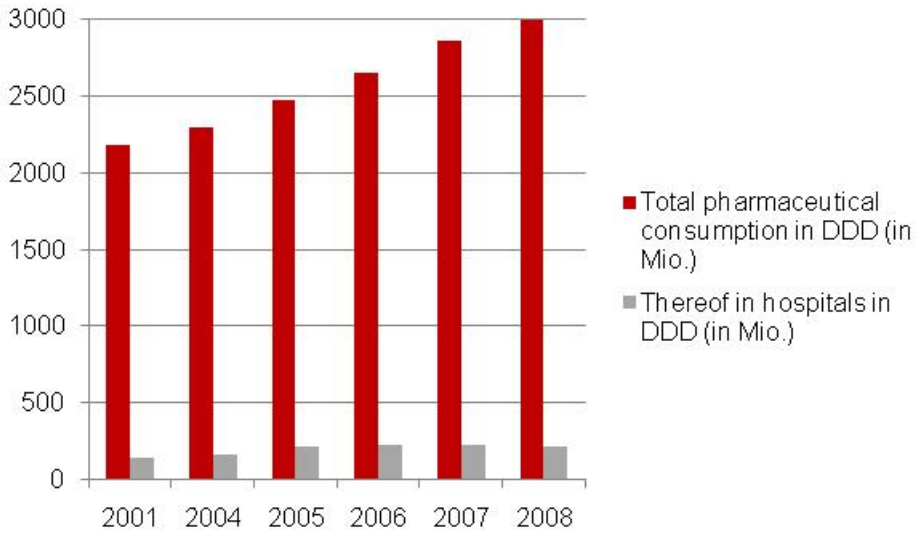
9.5.2.1 Consumption

According to information from the PHIS Hospital Pharma Report Slovakia (PHIS 2009s), hospitals are legally obliged to quarterly report prices and consumption of medicines used to the Slovakian National Centre for Health Information. Additionally, wholesalers have to report quarterly the maximum ex-factory prices (discounts of tendering process not included in price) or pharmacy purchasing prices and the amount of medicines delivered to hospitals to the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, SUKL). Therefore Slovakia has very good data availability on pharmaceutical consumption.

As in other case study countries, total pharmaceutical consumption has been growing over the last couple of years. As illustrated in Figure 9.14 total pharmaceutical consumption amounted to 2,179 Mio. DDD in 2001 and in 2008 it increased to 3,068 Mio. DDD. However, the trend is a bit different for pharmaceutical consumption in hospitals. In-patient pharmaceutical consumption declined from 226 Mio. DDD in 2007 to 212 Mio. DDD in 2008.

As reported by the case study hospitals pharmaceutical consumption varies among the surveyed hospitals from under 500,000 packs per year to over 1,600,000 packs per year, depending on the size of the hospital.

Figure 9.14: Case studies – Annual pharmaceutical consumption in hospitals in Slovakia, 2001 and 2004–2008



Source: PHIS 2009s

In Table 9.10 the top 5 active substances used in hospitals with regard to expenditure and consumption are listed in a country-wide overview. The case study hospitals have mentioned additionally other active substances with regard to expenditure: metamizolum, elforan and glucose.

Comparing the active ingredients used in hospitals causing the highest expenditure in Slovakia to the top 10 active substances at European level (see outcomes of the European survey, cf. Table 6.2), very expensive active substances such as trastuzumab, rituximab and interferon beta-1a are not included in the Slovakian top 5 list. This is linked to the tendering system in Slovakia (cf. section 4.2). The Vseobecna zdravotna poisťovňa / General Health Care Insurance (VsZP) centrally tenders some expensive medicines, such as interferon beta-1a. The VsZP directly pays for these active substances and the delivery is done by the manufacturers. Those centrally tendered medicines such as interferon beta-1a do not result in any cost for hospitals (cf. section 9.5.2.2).

Table 9.10: Case studies – Top 5 active substances used in hospitals by pharmaceutical expenditure and consumption in Slovakia, 2008

Position	Top active substances used in hospitals ranked with regard to expenditure – country-wide	Top active substances used in hospitals ranked with regard to consumption – country-wide
1	Electrolytes	Electrolytes
2	Docetaxel	Glucosum
3	Irinotekan	Ciprofloxacin
4	Ciprofloxacin	Hydrocortison
5	Paclitaxel	Sodium + sacharides

Source: PHIS 2009s

9.5.2.2 Prices

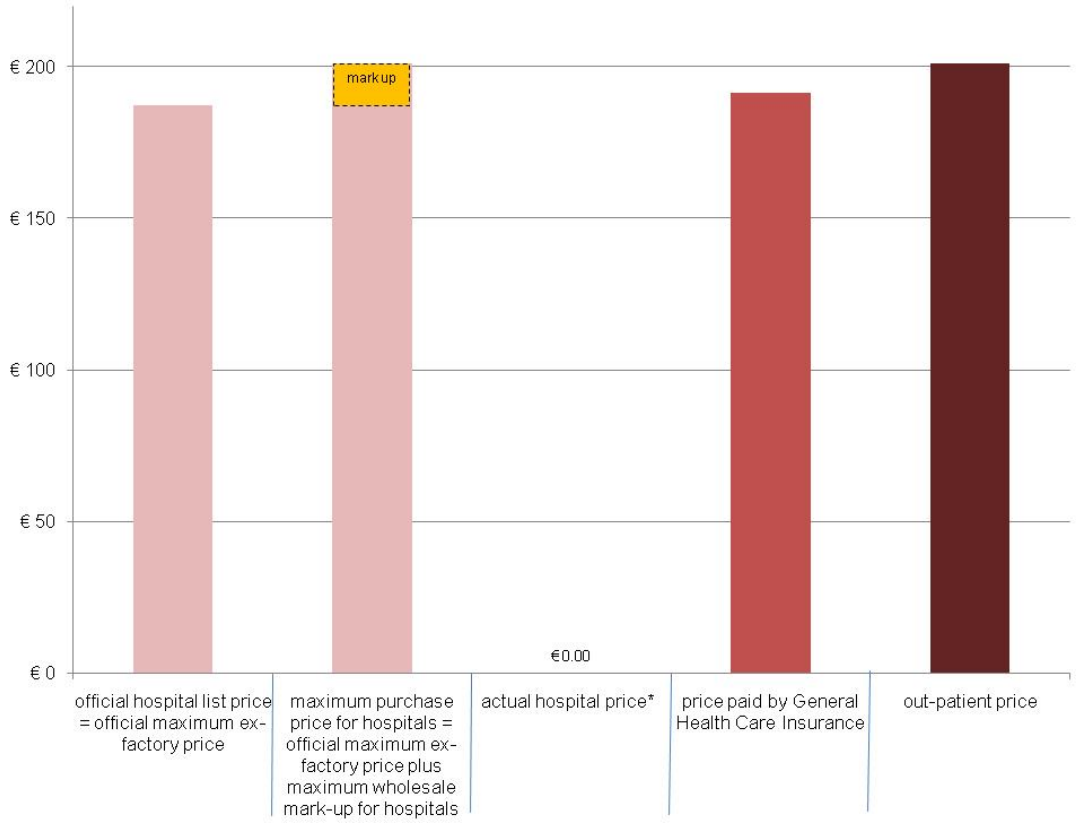
In general hospital prices correspond to the gross pharmacy purchasing price. Thus, the prices for hospital medicines equal the maximum ex-factory price plus the wholesale mark-up (9%) and a 10% value added tax (VAT). No pharmacy mark-ups are applied. For the price comparison in this report the VAT is excluded (cf. methodology reflection in section 2.2.5). As described in section 9.5.1, hospitals might be granted commercial discounts ranging from 1-10% of the pharmacy purchasing price (wholesale price) of a medicine depending on the volume of the medicines purchase and payment terms.

The pharmacy purchasing prices of hospital medicines, which are purchased with a maximum wholesale mark-up of 9%, can be lower (for not very expensive medicines) or higher (for very expensive medicines) than prices in the out-patient sector. The reason is that regressive wholesale mark-ups are applied in the out-patient sector, while in the in-patient sector a fixed maximum mark-up of 9% is in place (cf. section 4.3).

Price data of eight hospitals were considered in the price comparison (in one case four hospitals have the same management and therefore have the same prices – they are regarded in the following as one hospital).

Figure 9.15 compares the official hospital list price (maximum ex-factory price) and the maximum purchasing price for hospitals, which equals the list price plus the maximum wholesale mark-up of 9%, for a medicine used for neurology and/or the treatment for Multiple Sclerosis. The medicine is centrally tendered by Vseobecna zdravotna poisťovňa / General Health Care Insurance (VsZP). Hence costs for these products in hospitals are borne by the General Health Care Insurance and the actual hospital price is indicated within the hospitals as € 0.-. The centrally achieved price is about 5% lower than the maximum hospital purchase price.

Figure 9.15: Case studies – Comparison of hospital prices per unit of a medicine for neurology/for the treatment of Multiple Sclerosis in Slovakia, 2009

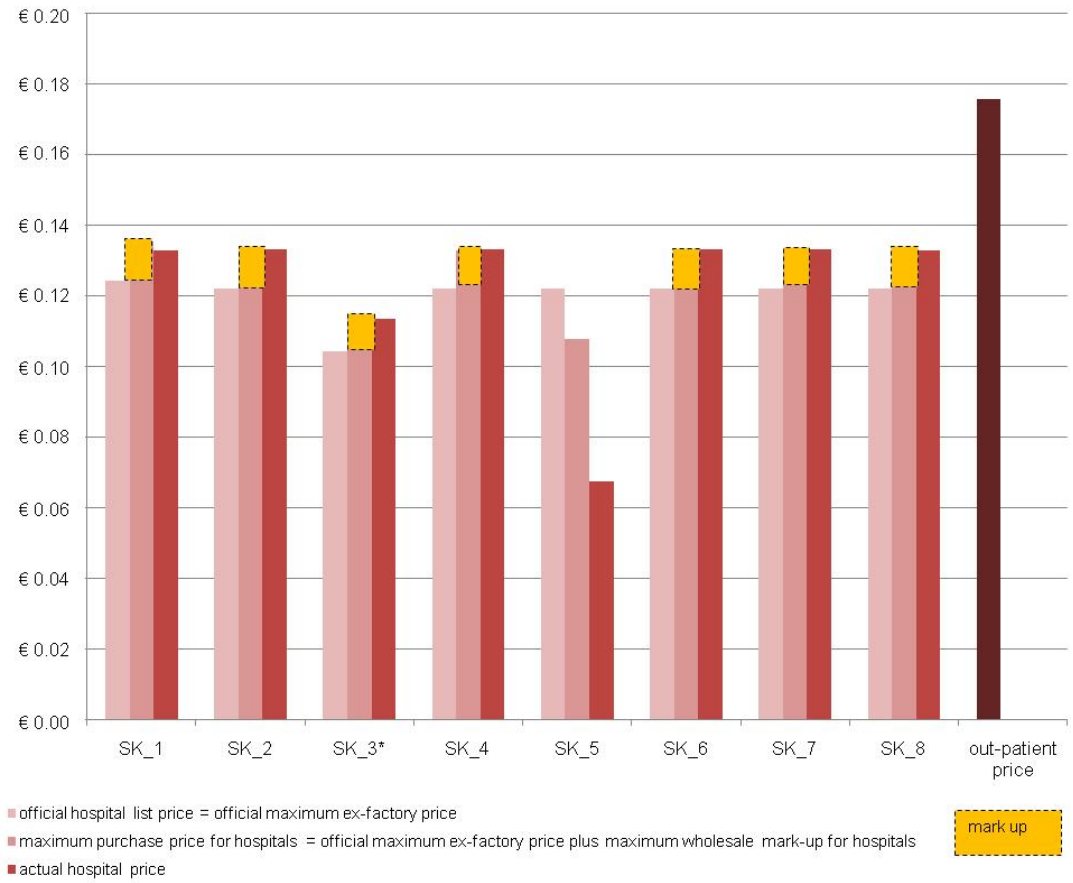


* Medicines are centrally purchased and financed by the General Health Care Insurance (Vseobecna zdravotna poisťovňa, VsZP) and are not charged to the hospitals

Source: PHIS case studies 2009

The price comparison regarding a cardiovascular medicine shows clear differences between the surveyed hospitals in Slovakia (cf. Figure 9.16). In seven hospitals the actual hospital price lies above the list price and equals the maximum purchase price for hospitals (including the maximum wholesale mark-up for hospitals). Only one hospital achieved a price which is 45% lower than the official list price. The low price in this hospital was achieved for a new generic medicine that had just entered the market. This approach was not applied in the other hospitals. The other case study hospitals rather purchased different generics, thus not taking advantage of a generic newcomer in the market. Market evaluation (cf. section 4.2) was indicated as the major purchasing policy for this medicine. For this medicine only generics are applied in the surveyed Slovakian hospitals.

Figure 9.16: Case studies – Comparison of hospital prices per unit of a cardiovascular medicine (only generic medicines) in Slovakia, 2009

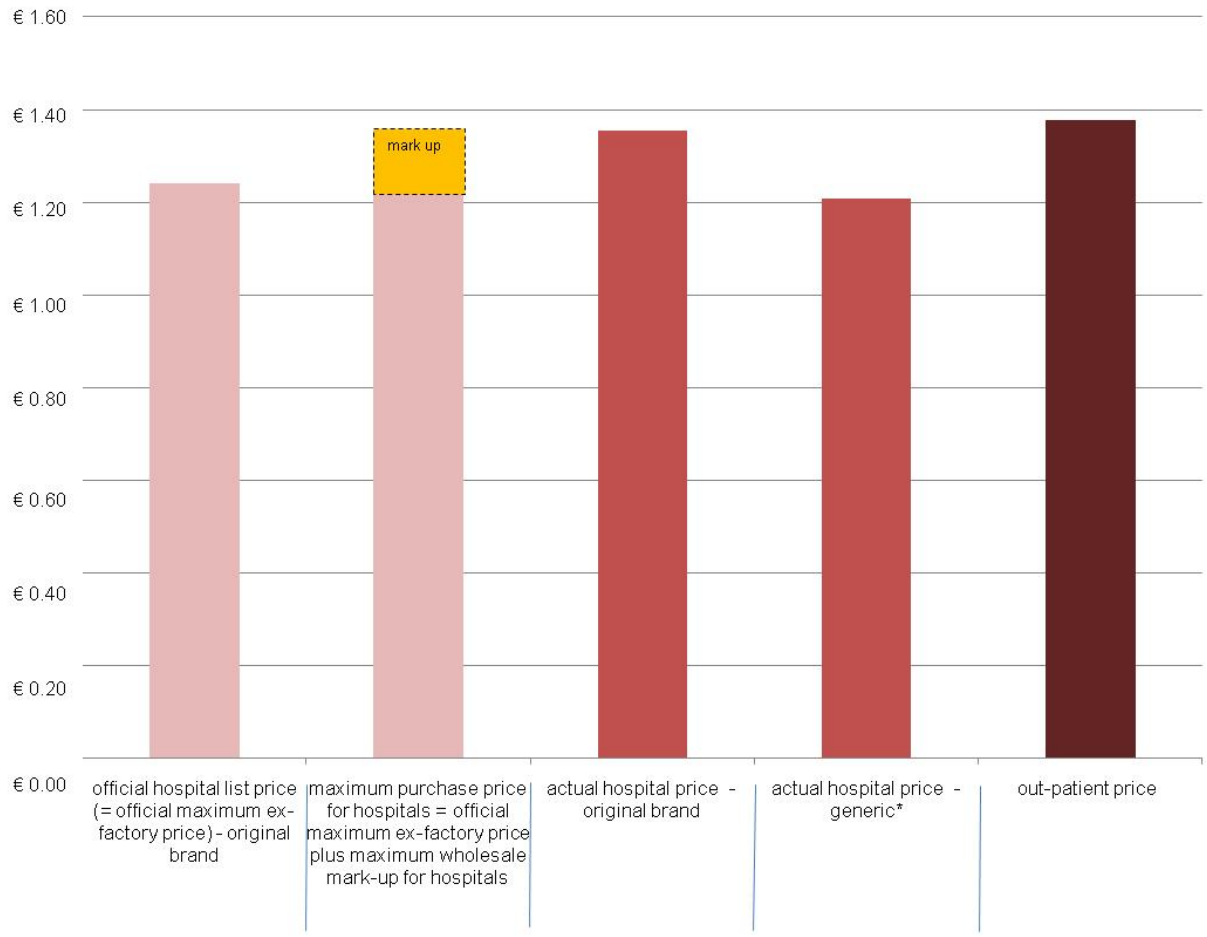


SK_1, SK_2, SK_3, SK_4, SK_5, SK_6, SK_7, SK_8 … different Slovak hospitals participating in the PHIS Hospital Pharma case studies
SK_3* = different pack size

Source: PHIS case studies 2009

Also in the case of a thrombozyte inhibitor a new generic medicine has just entered the Slovakian market. Only one of the ten case study hospitals already used this generic medicine; this hospital could achieve an actual hospital price of 11% below the actual hospital price of the original medicine. The other hospitals still purchased the original medicine and paid a price equal to the maximum purchase price (cf. Figure 9.17).

Figure 9.17: Case studies – Comparison of hospital and out-patient prices per unit of a thrombocyte inhibitor in Slovakia, 2009



Actual hospital price – generic*: a new generic medicine entered the market

Source: PHIS case studies 2009

10 Cross-country analysis

10.1 Introduction

The objective of the cross-country comparison was to assess differences of prices achieved for medicines used in hospitals between the case study countries. The analysis focuses on the actual hospital prices, which might contain possible add-ons (i.e. distribution mark-ups, cf. Table 2.5) but are often lowered by discounts, rebates and other price reductions. The actual hospital prices include partly (in AT, PT) or always (NL, NO, SK) wholesale mark-ups. VAT was disregarded in the cross-country analysis.

The cross-country analysis was undertaken for a total of twelve medicines. For each of the twelve surveyed active ingredients (cf. section 2.2.3) one medicine was selected. The medicines were chosen according to their data availability in the hospitals (i.e. the analysed medicines are those for which most data regarding countries, hospitals and prices were provided). Usually the same brands were compared, in some cases a comparison of the original medicine and its generic alternative(s) was undertaken (see notes below the figures).

For some medicines price data could not be gathered because these medicines were not used in the surveyed hospitals. This was attributable to the fact that the indications of these medicines are, in general, not in the scope of the surveyed hospital. For other indications alternative medicines are available and used.

As in the intra-country analysis in section 9, the medicines will not be indicated by the trade names, but by their main indication or therapeutic area. For comparability reasons all prices are given per unit (i.e. ml, tablet, etc.). The methodology of the price comparison is explained in detail in section 2.2.5.

As differences between the prices reported by the participating hospitals within one country may occur, as demonstrated by the results presented, for the cross-country comparison average hospital prices per country were calculated. However, as shown in chapter 9 prices do not differ significantly between hospitals.

10.2 Results by indications

10.2.1 Oncologic medicines

Figure 10.1 shows the average actual hospital prices of four oncologic medicines (all are on-patent medicines) in the five participating countries. Almost all medicines are available at least in one of the case study hospitals per country.

For product A the difference between the average actual hospital prices of the least (NO) and the most expensive product (PT) was € 227.-, meaning that the medicine costs 29% less in Norway. On average € 665.- per unit are spent on this medicine in the selected European hospitals. Prices of product B lie in the same price range but the difference between the highest (NL) and the lowest average actual hospital price (SK) is less than € 175.- (- 25%).

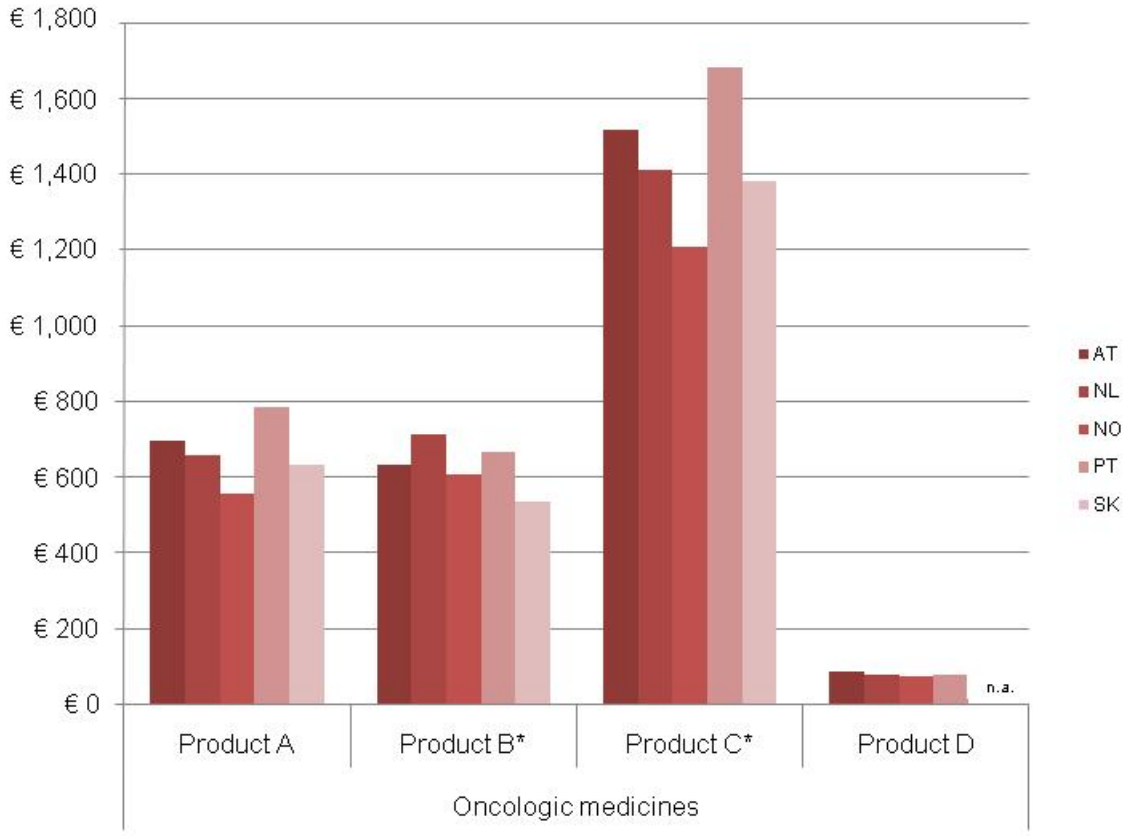
The comparison for product C shows a similar picture to product A – again Norway reported the lowest price level, whereas Portugal displayed the most expensive average actual hospital prices. Here the range is about € 475.-, meaning that Portugal paid almost 40% more for the same medicine.

For product D Austria reported the highest average hospital prices, and again Norway had the lowest.

Overall the following observations can be made for the four surveyed oncologic medicines:

- Three of the four surveyed medicines are available in all countries.
- Differences to the average actual hospital prices are observed among the countries (on average 30% between the least and most expensive medicine).
- Norway has the lowest average prices in three of four selected medicines.

Figure 10.1: Case studies – Cross-country comparison of actual hospital prices per unit of oncologic medicines in five European countries, 2009



n.a. = not available
* NL: same medicine but with a slightly different strength
Product A: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals, SK – price in 1 hospital;
Product B: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals, SK – average of prices in 6 hospitals;
Product C: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals, SK – price in 1 hospital;
Product D: AT – average of prices in 4 hospitals, NL – price in 1 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals

Source: PHIS case studies 2009

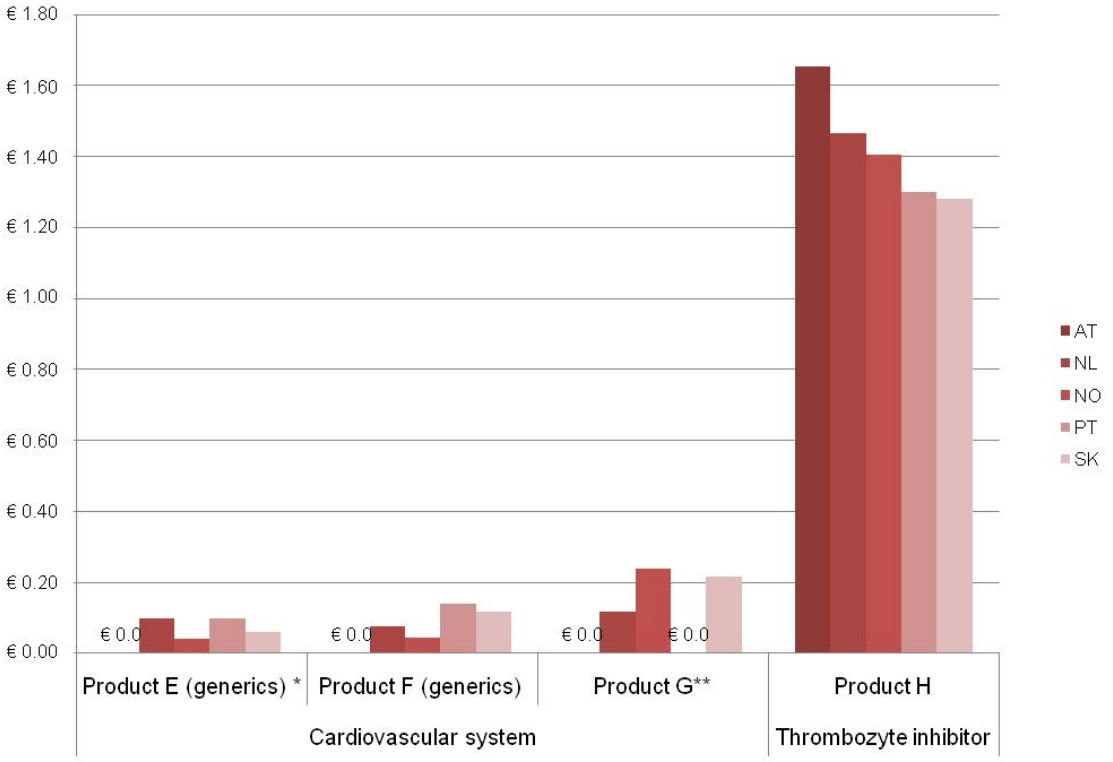
10.2.2 Cardiovascular medicines

In the group of cardiovascular medicines prices of three products were surveyed. All participating Austrian hospitals receive these three medicines free of charge from pharmaceutical companies, whereas in Portugal one of the three products is provided almost cost-free (due to rebates hospitals pay almost € 0.-, therefore the price in Figure 10.2 is displayed as € 0.0). In all other countries hospitals pay on average between € 0.04 and € 0.24 per tablet for the selected medicines in this therapeutic class.

The analysis of cardiovascular medicines was mainly based on generics, which are used by hospitals. However in the case of one of the medicines (product G) most case study hospitals still use the original brands.

As the prescription of these cardiovascular medicines is likely to be followed by lifelong use of these, the decision as to which medicine is chosen for first treatment might probably have long term implications for out-patient treatment and – as a result – expenditure.

Figure 10.2: Case studies – Cross-country comparison of actual hospital prices per unit of cardiovascular medicines and a thrombocyte inhibitor in five European countries, 2009



€ 0.00 = hospitals receive the medicines free of cost (AT) or at a price which – considering ex-post rebates – corresponds to € 0.00 (PT)
* NL: prices of the same active ingredient but a different package size
** original brand except for NO and SK (generic medicines)
Product E: AT – price in 1 hospital, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 3 hospitals, SK – average of prices in 8 hospitals;
Product F: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 3 hospitals, SK – average of prices in 5 hospitals;
Product G: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – price in 1 hospital, SK – average of prices in 7 hospitals;
Product H: AT – average of prices in 5 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals, SK – average of prices in 3 hospitals

Source: PHIS case studies 2009

The following trends regarding cardiovascular medicines in the in-patient sector can be observed:

- All surveyed cardiovascular medicines are available in almost all case study hospitals in the five countries.
- Generics are available for the selected cardiovascular medicines in most hospitals.
- The availability of generics resulted in lower price levels for cardiovascular medicines in hospitals. In most countries this is also the case in the out-patient sector, as generic pric-

ing policies are applied in many countries (e.g. as soon as a generic enters the market, the price of the original medicine has to be lowered, PPRI 2008).

- Some cardiovascular medicines are provided cost-free to Austrian and to some Slovakian hospitals, and at a price of nearly € 0.- to Portuguese hospitals.

10.2.3 Other indications

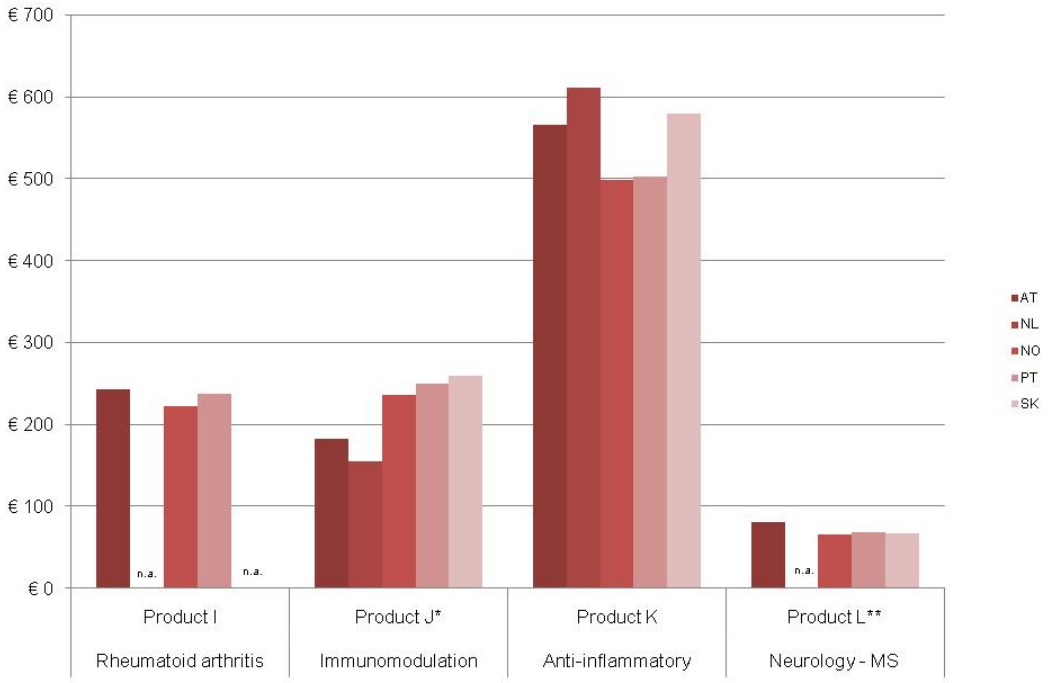
Average actual hospital prices of further medicines were analysed:

- a thrombozyte inhibitor,
- a medicine for the treatment of rheumatoid arthritis,
- a medicine for immunomodulation,
- an anti-inflammatory medicine,
- a medicine for neurology / treatment of Multiple Sclerosis (MS).

As displayed in Figure 10.2 and Figure 10.3, in some cases the picture is different from the oncologic and/or cardiovascular medicines:

- For an on-patent thrombozyte inhibitor (product H) Austrian hospitals pay on average almost 30% more than Slovakian hospitals.
- Product I (for the treatment of rheumatoid arthritis) was only available in three countries. The differences between the prices was about € 20.- (less than 10%), with Austria reporting the highest price level and Norway the lowest.
- The average actual hospital prices of a medicine for immunomodulation (product J) rank between € 155.- in the Netherlands (however, with a different strength) and € 259.- in Slovakia, despite competitors being on the market.
- The analysis for an anti-inflammatory medicine (product K) revealed that the lowest price level (NO) is on average about 20% lower than the highest price (NL).
- For product L (neurology/Multiple Sclerosis) only four countries reported price data: The prices of Norway, Portugal and Slovakia are very similar, whereas the Austrian average hospital price is about 25% higher.

Figure 10.3: Case studies – Cross-country comparison of actual hospital prices per unit of selected medicines for rheumatoid arthritis, immunomodulation, anti-inflammatory, for neurology/treatment of Multiple Sclerosis (MS) in five European countries, 2009



MS = Multiple Sclerosis
n.a. = not available
* NL: prices of the same active ingredient but a different brand and strength
** SK: prices paid by the general health insurance company in tendering (the actual price for the hospitals is € 0.-)
Product I: AT – price in 1 hospital, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals;
Product J: AT – average of prices in 5 hospitals, NL – price in 1 hospital, NO – average of prices in 2 hospitals, PT – price in 1 hospital, SK – average of prices in 6 hospitals;
Product K: AT – average of prices in 3 hospitals, NL – average of prices in 3 hospitals, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals, SK – price in 1 hospital;
Product L: AT – price in 1 hospital, NO – average of prices in 2 hospitals, PT – average of prices in 4 hospitals; SK – price in the general health insurance company

Source: PHIS case studies 2009

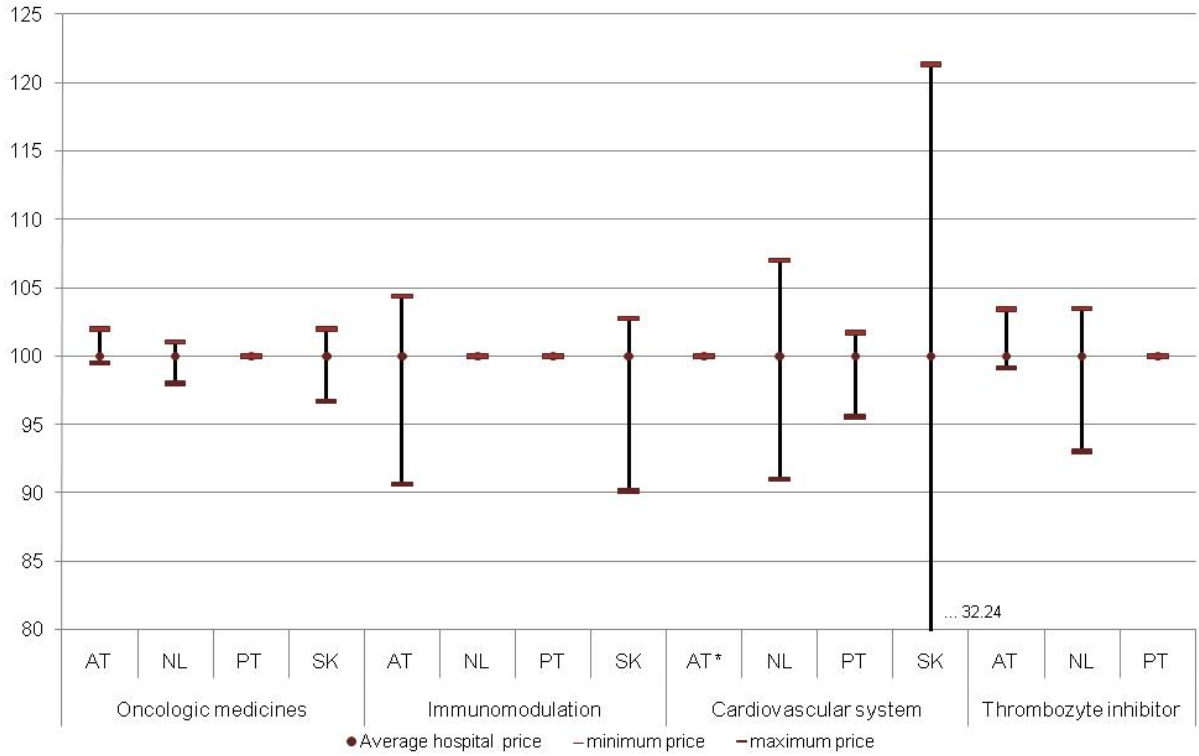
For these medicines for different indications, the collected price data show a more heterogeneous picture than for oncologic medicines. No commonalities could be observed except that Norwegian hospitals again reported the lowest prices for three of the five medicines.

10.3 Price range analysis

Figure 10.4 displays the price range within a country for the selected medicines. Norway was excluded from this range analysis as the prices reported for the two case study hospitals were the same. The figure illustrates that the price differences for oncologic medicines are

rather small within all five countries (average price = 100), whereas the price variations of the immunomodulation medicine mainly concern Austria and Slovakia, indicating a considerable price range in these countries. The price range for cardiovascular medicines is considerable in the Netherlands and Slovakia: In Slovakia one hospital gets the products free of charge whereas other Slovakian hospitals have to pay on average € 0.22 per tablet. It shows clearly that the national-wide price differences are lowest in Portugal (disregarding Austria and – as explained – Norway).

Figure 10.4: Case studies – Range of actual hospital prices for selected medicines (average price per country = 100) per unit in five European countries, 2009



100 = average price per country
Data for Norway was disregarded for this figure, as the price data provided was identical for the two participating hospitals.
* no variation as all five surveyed hospitals receive products free of charge

Source: PHIS case studies 2009

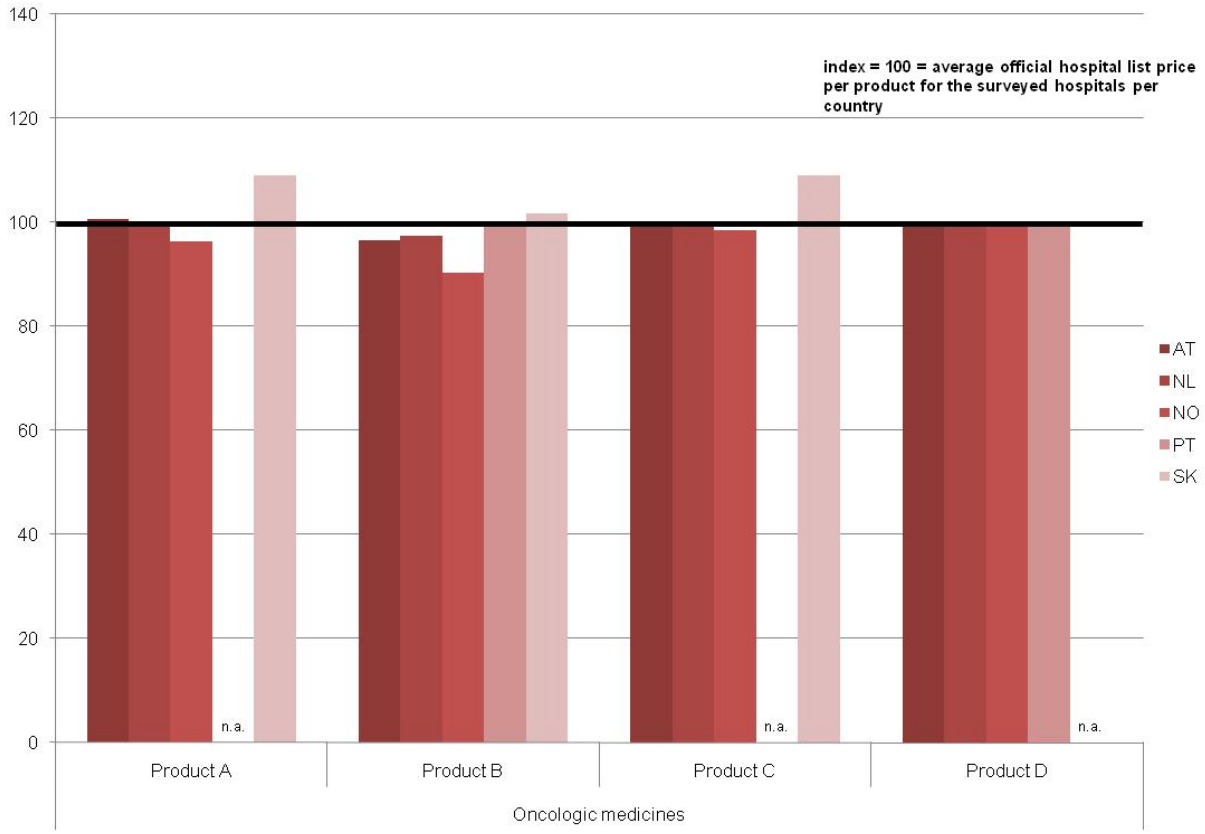
The official hospital list price is regarded as the starting point for hospitals to achieve lower prices during their purchasing process (e.g. tendering or negotiations). Figure 10.4 shows the potential for procuring at competitive prices within and among the selected five countries:

- For oncologic medicines (mostly on-patent products), price ranges are rather small which seems to indicate limited bargaining power. This finding demonstrates the strategy of pharmaceutical companies to establish a rather narrow price band for brands without therapeutic alternatives in each country.

- Potential to procure at better prices seems to exist with immunomodulation products and cardiovascular medicines, where some case study hospitals receive the products free of charge, whereas others have to pay for them.

An analysis of the differences reported between the official hospital list prices and the actual hospital prices (cf. Figure 10.5 to Figure 10.7) yields a similar picture. The index 100 represents the calculated average list price within the countries. When interpreting Figure 10.5 to Figure 10.7, it should be borne in mind that the actual hospital prices might contain some distribution add-ons.

Figure 10.5: Case studies – Difference between the average official hospital list prices and the average actual hospital prices (index = 100 = average official hospital list price) of oncologic medicines in five European countries, 2009

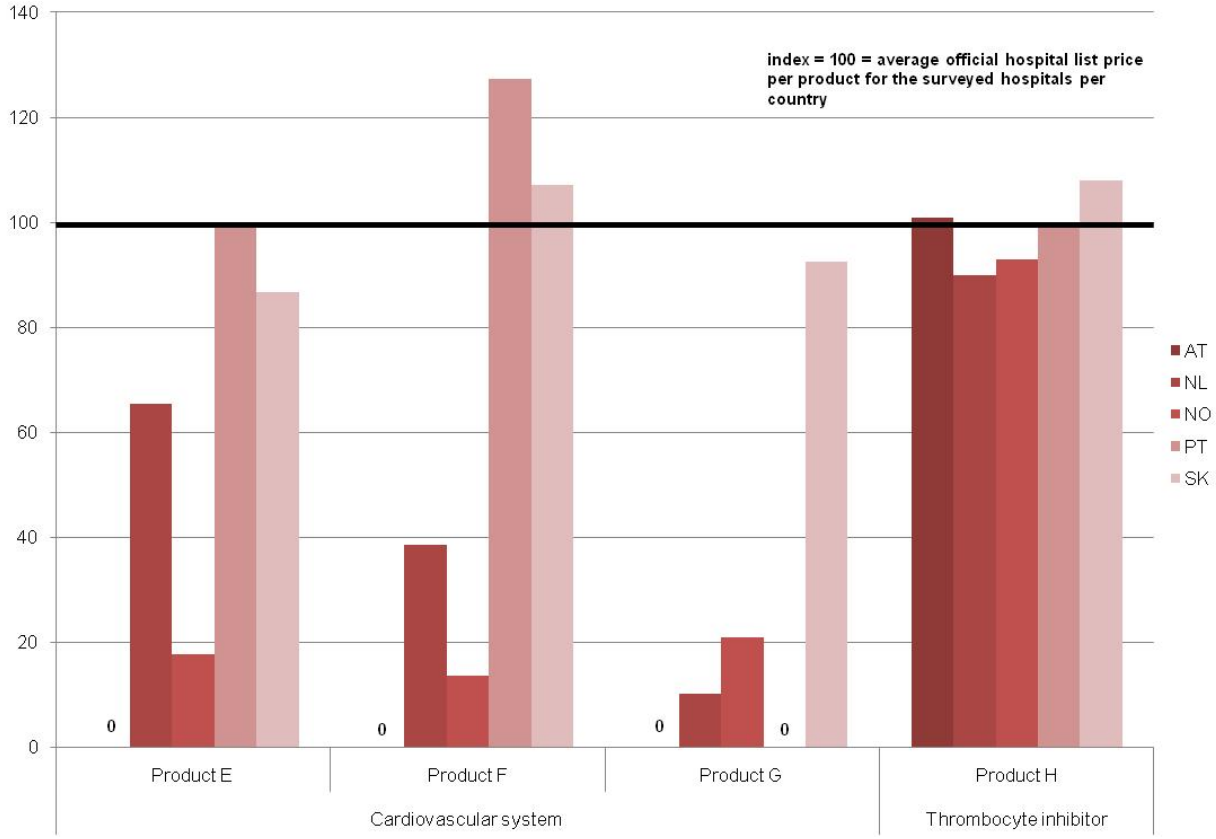


n.a. = not available

Source: PHIS case studies 2009

Figure 10.5 shows that for oncologic medicines hardly any discounts may be achieved in all countries. All hospitals purchase oncologic (and often on-patent) medicines almost at the level of the list price indicating little bargaining power for this group of medicines.

Figure 10.6: Case studies – Difference between the average official hospital list prices and the average actual hospital prices (index = 100 = average official hospital list price) of selected cardiovascular medicines and a thrombocyte inhibitor in five European countries, 2009

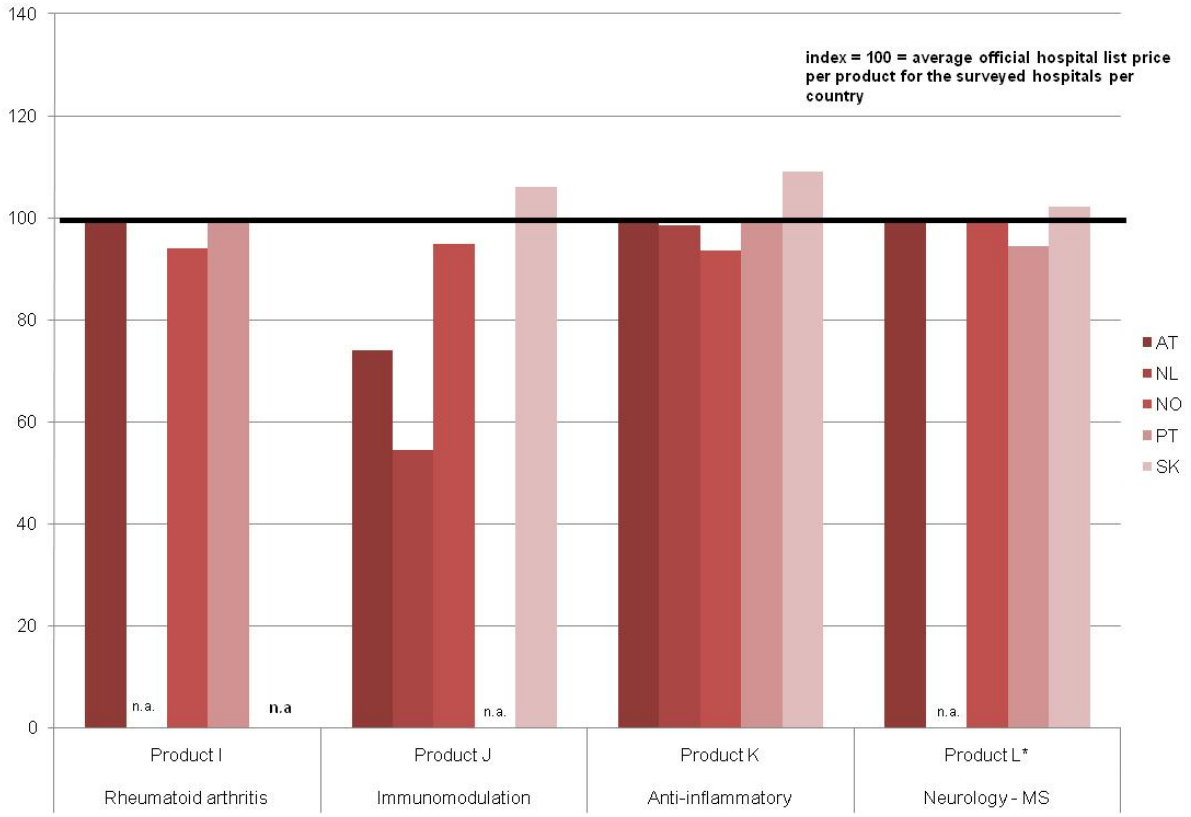


0 = hospitals receive this products free of charge/cost-free (€ 0.-)

Source: PHIS case studies 2009

For the group of cardiovascular medicines an enormous difference between the hospital list price and the actual hospital price can be observed in countries where products are provided free of charge.

Figure 10.7: Case studies – Difference between the average official hospital list prices and the average actual hospital prices (index = 100 = average official hospital list price) of selected medicines in five European countries, 2009



n.a. = not available

* SK: prices paid by the general health insurance company in tendering (the actual price for the hospitals is € 0.-)

Source: PHIS case studies 2009

As displayed in Figure 10.7, the differences between the average list price and the average actual hospital prices for immunomodulation medicines show higher bargaining power to receive discounts/rebates for this group of medicines when used in hospitals.

11 Discussion

During 2009 the PHIS project management under the lead of work package leader SUKL (Slovak Medicines Agency) and PHIS project leader GÖG/ÖBIG (Austrian Health Institute) carried out a survey and an analysis on hospital medicines management in European countries including case studies in a few selected countries.

High demand for a hospital medicines survey

As the need for gathering information on the in-patient pharmaceutical system has been expressed on a number of occasions, the PHIS project management addressed this demand by devoting a work package on Hospital Pharma.

An initial desk-top literature review confirmed that little has been published on the in-patient pharmaceutical sector in Europe. Pharmaceutical policy research is mainly limited to the out-patient sector.

Clear terminology is needed

Based on the experiences in similar projects the PHIS management team was aware of the fact that precise and clear terminology is crucial for a successful analysis. Thus the PHIS team made sure to include relevant terms regarding the in-patient sector in the PHIS Glossary (cf. PHIS 2009a).

It was also essential to clearly define the scope of research: How are hospitals defined; which institutions are considered as elements of the in-patient sector? We considered it important to take an established international definition as a reference against which the national specific definitions on hospitals should be checked with regard to conformity.

The PHIS project management team found both the definition of a hospital by OECD and WHO meaningful and applicable for further use. For practical reasons (the OECD definition includes specifications on the specialization of hospitals which are also reflected in the OECD database) we decided to opt for the OECD definition of a hospital after consultation with the PHIS Advisory Board and feed-back from the PHIS network.

Developing a glossary with specific hospital terms proved to be a successful strategy because 1) it gave the national authors of the PHIS Hospital Pharma country reports clear guidance and 2) it helped them to explore the in-patient pharmaceutical sector. We are pleased to have provided enough time for clarifications and dissemination of definitions, and we are glad to have organised a training session on the PHIS Glossary, with a specific part on Hospital Pharma, for the authors of the country reports as it certainly improved the quality of the reports.

It was quite a challenge to understand the different ways of “procurement” (e.g. by tendering, competitive negotiations) and to make it understandable in the report. Another critical terminology issue concerned the different manners of price reductions (e.g. discounts, rebates, bundling) as well as products which are provided free to the hospitals (“cost-free products”).

We are aware that both in research and in the dissemination of the results a clear wording is essential.

Developing the methodology

Due to this being a rather new research field with only limited scientific research so far, key methodology issues needed to be resolved.

A template for the country reports on the in-patient sector was developed allowing both a description of the national particularities as well as a comparability of different systems. In doing so, we followed the model of the out-patient pharmaceutical system wherever possible and appropriate. This could be achieved at the level of chapters, but for the more detailed description a totally different approach had to be followed. As the review process yielded only a few misunderstandings, we are optimistic that the PHIS Hospital Pharma Report template is a good basis which can be used in future similar work.

A major challenge concerned the development of a methodology for the price survey in the case studies. Key topics in this context were the selection of the products, the development of a survey instrument for collecting prices and a framework for the analysis of the prices. The focus of the price survey was to identify the actual hospital prices, thus taking into consideration discounts and other forms of benefits (e.g. products provided cost-free to the hospitals). The comparison to the out-patient sector ("which price does the hospital price correspond to in the out-patient care?") and in a cross-country analysis (with the underlying health care systems organised in different ways) required specific methodological approaches. Nonetheless, it was obvious from the start that only a primary quantitative survey in hospitals could deliver valid results.

The methodology work was time-intensive and demanded a considerable level of effort. The PHIS project team had to shift some tasks to spend enough time for the development of an appropriate methodology, in particular for the price survey.

We are happy to see that the chosen methodology was suitable for the survey, and consider it as a valuable basis for further work in this field – either by PHIS members or other researchers.

Hospital survey helped to build and strengthen links to the in-patient sector and to improve cross-sectoral cooperation

The idea of the European survey was to provide information and data in the framework of national PHIS Hospital Pharma Reports based on a uniform outline (PHIS Hospital Pharma Report template). Based on the experience gained in another project (PPRI / Pharmaceutical Pricing and Reimbursement Information), representatives of the PHIS network acted as authors of the reports. They had the advantage of having direct access to the national data sources. An additional benefit was that the country perspective expressed by the authors was matched by a system perspective of the reviewers taking into consideration comparative analysis elements. This has led to fruitful discussions and a better understanding on both sides (PPRI 2008). Therefore we decided to follow this approach. We were aware of the

limitation that the participants of the PHIS network write the reports on a purely voluntary basis, without any compensation, on the top of their usual work load. Knowing that as the project management team we could not provide any financial incentives in order to promote the submission of the country reports, we are very grateful that the PHIS network participants nonetheless were willing to participate actively.

However, the majority of the representatives of the PHIS network (mainly competent authorities like Medicines Agencies and Ministries of Health and third party payers such as social insurance institutions), did not have direct access to the information to be included in the country reports as they usually are responsible for the regulation and implementation of pharmaceutical policies in the out-patient sector.

This required that the country authors got into contact with the hospital experts. It implied extra work since in some countries these contacts first needed to be established. In several cases the research for the country reports was the starting point for an improved cooperation between the out-patient and in-patient sector and as a consequence hospital pharmacists from some countries joined the PHIS network. Additionally, the PHIS project management team succeeded in involving two hospital associations at European level and could thus broaden the scope of the PHIS network.

Thus the technical research work for the national PHIS Hospital Pharma Reports supported the establishment of sustainable cooperation structures. The PHIS project team noticed bilateral follow-up activities between representatives of the authorities and hospital pharmacists, and we have observed that a better understanding by staff of the two sectors for the problems of the other sector was created.

Valuable support by well connected and motivated hospital pharmacists

Since the PHIS project management team was not as well known in the hospital sector as it is in the out-patient sector, trust needed to be built in the beginning and the aim and the added value of PHIS had to be explained to the hospital experts. In the course of time we were able to build an excellent cooperation with hospital pharmacists who were of great help for our research.

We learned that hospital pharmacists are fully aware of the impact that hospital medicines have on long-term treatment and consequences for the full health care system. But they have to manage their own budgets as they are not granted any incentives to change their purchasing behaviour (e.g. by rejecting cost-free medicines).

In general, hospital pharmacists are well connected. In spite of the fact that actual hospital prices are not published or shared, we learned that some hospital pharmacists know the marketing and price situation in other hospitals.

Case studies as a second review process

As a quality assurance measure all PHIS Hospital Pharma country reports were reviewed by an experienced editorial team. This helped to remove possible misunderstandings and guaranteed the use of the agreed Glossary terms.

The second step of the in-depth analysis in the case studies proved of great importance as we could gather additional information and improve understanding. In fact, the case studies served as a sort of another review process as we could dig deeper, identifying some contradictory information which we had to resolve afterwards.

Additionally, the comparative exercise of the European survey was another quality safeguard, since during the compilation of the overview the authors were motivated to critically review the statement and information provided in the national reports.

Coordinated approach involving all work packages

Gaining knowledge of the in-patient sector was not only the aim of the survey in one specific work package, but was considered as a cross-cutting topic for all the other core work packages (e.g. regarding terminology, indicators and database, library of PHIS Pharma Profiles). The integrated approach proved necessary and successful.

Strong expectations from the outside

The work package on Hospital Pharma is one of five core work packages of the PHIS project. Nonetheless, it is the one which raised the most attention both internally within the PHIS network as well as with people not directly involved in the project.

This might have been triggered by this being a rather new research area with little information published. Another reason might be the strong and sometimes conflicting interests of the various stakeholders (either directly involved in the hospital supply chain or indirectly targeted, e.g. payers in the out-patient sector).

In some cases people expressed their scepticism and predicted that we would fail with PHIS Hospital Pharma, in particular by not succeeding to gather price data from the in-patient sector.

We are pleased that we could fully meet the objectives of PHIS Pharma Hospital as agreed with the commissioning parties. It is very satisfying in particular if we take into consideration that information and data were provided by EU Member States representatives and hospital pharmacists on top of their normal work load. The writing of the country reports of the in-patient pharmaceutical sector has been a voluntary exercise of members of the PHIS network. Thus, having 20 (draft) national PHIS Hospital Pharma Reports produced within the short time alloted is most impressive.

12 Conclusions

The PHIS Hospital Pharma exercise produced a number of interesting results. Some outcomes were rather surprising, while others (in particular the price survey) confirmed generally held assumptions.

Procurement by tendering is a major purchasing policy for medicines in the in-patient sector, but other policies are also applied.

When acquiring medicines for the in-patient sector, European countries apply a limited number of purchasing policies, among those tendering and negotiations. A few countries (e.g. Italy, Norway, Sweden, UK) procure medicines only by tenders in a centralised procedure (e.g. via the procurement agency LIS in Norway). Further purchasing policies include procurement by competitive negotiations (e.g. so-called “market evaluation” in Slovakia) or direct negotiations between manufacturers, wholesalers and hospitals. There is a mix of different policies in several countries. In a few countries (e.g. Austria, Germany) hospitals or hospital associations mainly purchase by direct negotiations with pharmaceutical companies.

For high-cost medicines in hospitals some countries have introduced specific financing schemes.

Usually, medicines used in hospitals are funded out of the hospital budgets which are allocated by their owners (e.g. states, regions, municipalities). In several European countries medicines for the out-patient sector are funded by social health insurance which leads to a dual financing system for the in-patient and out-patient sectors. This is one reason for the trend that the use of expensive medicines is being shifted between the different sectors. Some countries have thus introduced specific financing schemes meaning that some – usually high-cost – medicines are not financed out of the hospital budget, e.g. on a DRG basis, but they are remunerated separately by the social health insurance. This is for instance the case in France or in the Netherlands (e.g. for orphan medicines 100% coverage by the social insurance and 80% for other expensive medicines). The reason why in a few countries social health insurance does not fully cover these expenses is that hospitals should be made aware and accountable, at least partly, for the expenditure incurred due to these medicines.

Activities to promote the rational use of medicines have been implemented in hospitals in several countries.

In several countries the use of generics has been encouraged and applied in hospitals for a longer time than in the out-patient sector. Hospitals usually have their own hospital pharmaceutical formulary (HPF), which are administered by the Pharmaceutical and Therapeutic Committees (PTC). The PTC, which are normally composed of hospital pharmacists, doctors and the hospital management, decide on the inclusion of medicines in the HPF. As a rule, medicines which are not on the HPF usually need an extra justification by the doctor asking for these medicines. In general, in the European countries the PTC seem to be rather strong bodies which contribute to a more rational use of medicines.

Besides their work in the PTC, hospital pharmacists play a key role with regard to quality assurance from a therapeutic point of view (e.g. prescription validation concerning possible side-effects and adverse drug reactions in some countries). Another important task of the hospital pharmacists is the monitoring of pharmaceutical expenditure, consumption and prices in the hospitals (see below).

An urgent need for interface management has been expressed by several stake-holders. While some good practice examples exist, they are rather few.

Medicines used in hospitals have an important impact on the out-patient sector as the first treatment in hospitals influences the further choice of medicines prescribed and applied when the patient is discharged. Interface management addresses measures which ensure a better cooperation between the hospital and out-patient sector, including raising awareness for the difficulties and challenges in both sectors. Interface management measures with regard to medicines include the representation of policy and decision makers of the out-patient sector in the PTC (e.g. in some regions in Austria) and hospital pharmaceutical formularies which are coordinated with the medicines list for the out-patient sector (e.g. in Sweden).

While monitoring of prices, expenditure and consumption is common in hospitals, a lack of data on the break-downs of hospital expenditure and consumption at national level is evident.

Pharmaceutical prices, expenditure and consumption are monitored at the level of hospitals in several European countries – a task usually performed by hospital pharmacists with data being discussed in PTC meetings. While a rather high number of countries stated that they undertake expenditure and consumption monitoring at national level, these data are only available for a few countries – and often only partially.

The availability of the selected products proved to be quite good. Country-specific differences regarding the use of products exist.

Hospital pharmaceutical formularies are rather restricted compared to the reimbursement lists of the out-patient sector. The choice of the products for the survey was, among others, based on the top 10 active ingredients with regard to expenditure in 14 European countries, in order to ensure the selection of relevant products. The actual use of medicines in hospitals might be different, but in fact most medicines were on the list in the surveyed hospitals. Some differences regarding the top 10 products in expenditure and consumption exist among the European countries. In particular a pattern regarding geographic regions (e.g. similarities between Central and Eastern European countries, Nordic countries) was observed.

Prices of medicines used in hospitals are usually not published – if so, only the maximum list prices are available.

The majority of the surveyed European countries control the prices of medicines used in hospitals. However, the price regulation only addresses the maximum official list prices, while the actual prices achieved are neither published nor shared between hospitals: They remain in a “black box”.

The actual hospital prices are usually less than the maximum list prices although the amount varies by therapeutic class of medicines.

The actual achieved prices are the relevant prices to be considered for analyses and comparisons. Suppliers might offer a wide range of price reductions, either as discounts, rebates or other forms like bundling. The majority of countries reporting on discounts stated discounts of 25% to 40%. But discounts might range from 1% to up to 100%, and in five countries medicines are provided cost-free to hospitals.

The actual prices of medicines do not differ considerably between the hospitals in the five surveyed PHIS case study countries (Austria, the Netherlands, Norway, Portugal, and Slovakia). However, variations between the countries could be observed, with Norway having in general the lowest price level for the medicines surveyed. Norway attributes its low prices to the transparent tendering process by the procurement agency LIS with 15 years experience and synergy effects of hospitals working together as well as the cooperation of experts in medicine, pharmaceuticals and purchasing.

Discounts are less likely to be provided where there is only an on-patent product available.

For these medicines the bargaining power of the hospitals is rather weak. These on-patent products (e.g. some oncology medicines, orphan medicines) where no competition is possible often account for an important portion of the hospital pharmaceutical budget. However, as soon as therapeutic alternatives are available considerable room for discounts may exist.

For some “strategic” products prices in the hospital sector are considerably lower than in the out-patient sector.

The actual hospital prices of the surveyed medicines are less than in the out-patient sector. For specific products (e.g. for chronic diseases) which are most likely to be followed up in the out-patient treatment and thus are economically very relevant for the pharmaceutical companies, the price range between in-patient and out-patient sector is considerable.

13 Recommendations

Based on the experiences and expertise gained during the work package on Hospital Pharma the PHIS project management team has come up with the following recommendations:

1. **The pharmaceutical dialogue between the in-patient and out-patient sector should be strengthened, and further interface management activities be launched.**

   The work on PHIS Hospital Pharma resulted in a closer cooperation between the out-patient and in-patient sector, as hospital experts have been involved and/or were addressed for input and feed-back. The momentum which PHIS has generated should be maintained. In particular concrete interface management activities for which an urgent need was expressed by several parties should be started and/or continued. An example could be to develop a list of preferred medicines to be jointly used in the in- and out-patient sectors. The participation of social insurance representatives in Pharmaceutical and Therapeutic Committees (PTC) could serve as another good-practice model.

2. **The PHIS project could be seen as a starting point for further analyses.**

   In the PHIS project several pace-setting tasks were undertaken. Nonetheless, this PHIS Hospital Pharma Report has to be precise and cannot expand on all details. The country reports, which are and continue to be made available at the PHIS website after review, offer a large spectrum of information and data which could be used for further studies. This option may be used by academic researchers (e.g. for cross-country comparisons) as well as by policy makers and officials. Furthermore, the case studies include a variety of price data which may be used for further analyses.

3. **Knowledge on the in-patient pharmaceutical sector needs to be widely spread.**

   In surveying intensively the in-patient pharmaceutical sector throughout Europe the PHIS project management team has gained in-depth knowledge which was shared with the experts of the PHIS Advisory Board and the PHIS network where involved representatives also gained new insights during the research in their countries. This expertise should be disseminated at a broader level. The PHIS project management sees the dissemination of the results as part of the wider PHIS communication strategy. Key elements of the dissemination plan of the PHIS Hospital Pharma work package are this PHIS Hospital Pharma Report, which is also made available at the PHIS website and the country reports, also accessible at the PHIS website. In February 2010, the PHIS Hospital Pharma seminar was held in Bratislava in order to present and discuss first outcomes. Further dissemination of the results at conferences and in publications is planned by the PHIS project management team. The PHIS Advisory Board and network members are strongly encouraged to contribute to the dissemination of the PHIS project outputs.

4. **Statistics for surveying expenditure and consumption at national level should be further developed.**

   Monitoring of prices, expenditure and consumption is usually performed by hospital pharmacists at the level of their hospital. Some European countries do not collect hospital expenditure and consumption data at national level, and those which do so have still difficulties to provide comparable data. The national reporting and statistical systems should be elaborated – with a view to guarantee international comparability. Future reporting systems should allow for a break-down of the hospital data as part of total pharmaceutical expenditure and consumption in the National Health Accounts.

5. **The in-patient pharmaceutical system is different. Policy-makers should consider its particularities.**

   Research on medicines management and policies in hospitals confirmed that the in-patient pharmaceutical system differs significantly in several areas from the out-patient sector. A comprehensive health care policy approach should thus take into account these particularities and not try to copy pharmaceutical policies which proved successful in the out-patient sector and transfer them to the hospital sector. The in-patient sector requires specific policy options, and based on knowledge gained in reports like this one and expertise by hospital pharmacists and other hospital staff, appropriate policy options need to be developed.

6. **Each system has its own characteristics at a country-specific level and cannot be easily changed.**

   Historical developments, traditions and culture have a large influence on the way health systems are organised in a country. Thus, the out-patient and in-patient pharmaceutical systems are the outcome of country-specific characteristics and habits. Cross-country surveys are important instruments which allow learning about the challenges and solutions in other countries. Good-practice examples should be identified and studied with a view to adapting such measures in one's own country. However, these case examples are models and cannot be copied identically, but need to be translated into policy options which take the country-specific framework into consideration. Each health care system and pharmaceutical system covered in this study has its beneficial and rather unfavourable characteristics: policy changes should target specific deficiencies but should not challenge the system on the whole.

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15 Annex

In order to save the environment, the print version of the PHIS Pharma Hospital report contains no annexes. All documents of the Annex are included in the electronic version of the report.

Annex I PHIS Glossary. June 2009. Latest updated version as of May 2010

Annex II PHIS Hospital Pharma Report template

Annex III PHIS Hospital Pharma Case Study – Questionnaire

Annex IV PHIS Hospital Pharma Case Study – Price Query Template

Annex V Published versions of the country PHIS Hospital Pharma Reports

PHIS Hospital Pharma Report Austria

PHIS Hospital Pharma Report Bulgaria

PHIS Hospital Pharma Report Cyprus

PHIS Hospital Pharma Report Denmark

PHIS Hospital Pharma Report Finland

PHIS Hospital Pharma Report Latvia

PHIS Hospital Pharma Report Malta

PHIS Hospital Pharma Report Norway

PHIS Hospital Pharma Report Slovakia

PHIS Hospital Pharma Report The Netherlands

PHIS Hospital Pharma Report Turkey

PHIS Hospital Pharma Report United Kingdom