Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

POLAND

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PHIS

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Executive Summary

The legal framework for hospitals, medicines in the in-patient sector and their reimbursement are:

- The Act of 30 August 1991 on healthcare providers (Journal of Laws 2007 No.14, item 89 with further amendments);
- the Pharmaceutical Law of 6 September 2001 (Journal of Laws 2004 No. 53 item 553);
- the Act of 27 August 2004 on healthcare services financed through public funds (Journal of Laws 2008 No. 164 item 1027 with further amendments);
- the Act of 5 July 2001 on prices (Journal of Laws 2001 No. 97 item 1050 with further amendments);
- the Public Procurement Law of 29 January 2004 (Journal of Laws 2007 No. 223 item 1665 with further amendments).

The Polish legal system defines the healthcare provider (zakład opieki zdrowotnej, ZOZ) as an organisationally separated complex of people and material resources established and maintained to provide healthcare services and to promote health. The hospital is a health-care provider which is obliged to supply in-patients with healthcare services, medicines and medical devices as well as room and food according to the medical status of the patient.

The regulation of pharmaceutical prices in the in-patient sector is heterogeneous. Most of the medicines are acquired via public procurement which is the main cost-containment method used. Parts of the medicines used in the in-patient sector have statutory maximum prices listed in the regulations of the Minister of Health. The President of the National Health Fund (NHF) in his orders regulates the price which is paid by the NHF for active substances used in chemo treatment and in therapeutic health programs.

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, immediate help). Pharmacotherapy for these patients is reimbursed by the NHF to all entities contracted to provide such services.

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AHTAPol	Agencja Oceny Technologii Medycznych / Agency for Health Technology Assessment
ATC	Anatomic Therapeutic Chemical classification
CIVAS	Centralized Intravenous Admixtures Service
DDD	Defined Daily Doses
DG SANCO	Health and Consumer protection Directorate General
EU	European Union
GDP	Gross Domestic Product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital Pharmaceutical Formulary
HTA	Health Technology Assessment
DRG	Jednorodne Grupy Pacjentów, JGP / Unified Groups of Patients
Mio.	Million
NCU	National Currency Unit
NHF	Narodowy Fundusz Zdrowia / National Health Fund
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OTC	Over-The-Counter medicine
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project

PRP	Pharmacy Retail Price
SIMAP	Information System for Public Procurement (Système d'Informations sur lesMarchés Publics)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health organisation
ZOZ	Zakład opieki zdrowotnej / Health care provider

Introduction

PHIS research project

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

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

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

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

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

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

SUKL is the WP leader of Hospital Pharma.

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

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

PHIS Hospital Pharma

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

The survey is divided in two phases:

- Phase 1: General survey

Country reports on medicines in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the in-patient sector in the EU Member States (spring 2009)

- Phase 2: Case studies

A specific survey, including a price survey, provided by means of case studies, in a limited number of hospitals in a few countries (autumn 2009).

The final PHIS Hospital Report, covering information from the general survey (phase 1) and the case studies (phase 2), is scheduled for February 2010.

Methodology of the general survey

The production of the country-specific PHIS Hospital Pharma Reports is based on three steps:

1. Development of a uniform PHIS Hospital Pharma Report Template

The PHIS Hospital Pharma Report Template offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in-patient sector of a country. The Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in the EU Member States. Members of the PHIS network received the draft Template for feed-back, and had an opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Hospital Pharma Report

The country-specific PHIS Hospital Pharma Reports were written by members of the PHIS network. In order to get the needed information and data, hospital experts were contacted and involved in several countries. They provided information and data in written form and during telephone conservations and personal talks. In some countries the reports (or parts of it) were written by hospital experts. In several countries, the preparatory work for drafting the PHIS Hospital Pharma Reports also included study visits of the authors to hospitals and hospital pharmacies. Information on persons and institutions involved can be found in the

“Acknowledgements” at the beginning of this PHIS Hospital Pharma Report and in section 8 “References and data sources”, listing “Literature and documents” (section 8.1) and “Contacts” (section 8.2).

3. Editorial process

The draft PHIS Hospital Pharma Reports were submitted to the project management for review, which was undertaken by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template and terminology (PHIS Glossary). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for rephrasing and change and clarified open and/or misunderstanding points.

1 Background

1.1 Definition and scope

The Polish legal system defines a healthcare provider (zakład opieki zdrowotnej, ZOZ) as an organisationally separated complex of people and material resources established and maintained to provide healthcare services and to promote health. The basic legal act concerning healthcare organisation is the Act of 30 August 1991 on healthcare providers (Journal of Laws 2007 No.14, item 89 with further amendments). This general term refers to:

- hospitals, nursing homes, sanatoria and other facilities for people whose health requires whole day care or daylong healthcare services in appropriately equipped permanent premises;
- out-patient clinics (independent, not part of hospitals), health centres and other clinics;
- emergency departments;
- medical diagnostic laboratories;
- orthodontic and dental clinics;
- nurseries;
- emergency departments of military units, the Police, the Boarder Guard, the State Fire Service, the Government Protection Bureau and the Prison Service;
- sanitary-epidemiological stations;
- military facilities of preventive medicine;
- units of national blood services;
- other facilities meeting the requirements included in the law.

In general the name of healthcare providers gives an indication of which service they provide.

The hospital itself is a healthcare provider which is obliged to supply in-patients with healthcare services, medicines and medical devices as well as room and food according to the medical status of the patient. Hospitals per definition are committed to in-patient services. There are hospital out-patient departments in some hospitals for accidents and emergency services.

Currently hospitals are only being divided by specialisations or patients treated. In practice the old scheme of voivodeship and poviat (larger and smaller territorial units) hospitals remained. In principle, poviat hospitals offered 4 basic specialties: internal medicine, general surgery, pediatrics, obstetrics and gynecology (sometimes other departments as well). In

every voivodeship (49 in the 60-70' of XX century) were larger hospitals with more specialties.

According to the Polish legal system hospital treatment (lecznictwo zamknięte) only refers to the following healthcare providers: hospitals, nursing homes, sanatoria, and other facilities for people whose health requires day care in appropriately equipped permanent premises.

1.2 Organisation

Healthcare providers in Poland (including hospitals) are established under the Act of 30 August 1991 on healthcare providers (Journal of Laws 2007 No.14, item 89 with further amendments).

Healthcare providers (including hospitals) may be established by:

- The Minister of Health or central governmental administration organ;
- a local governmental administration body (voivoda);
- a self-government unit (poviat, gmina);
- a public medical university or public academy teaching and researching in the field of medicine;
- the Medical Centre of Postgraduate Education;
- a church or religious union;
- an employer;
- a foundation, trade union, trade self-government or association;
- other national or foreign legal entity or natural person other than an independent public healthcare provider; or
- a partnership without legal personality.

All healthcare providers are obliged to be registered in registers provided either by voivodas in each voivodaship (the largest administrative units in Poland) or by the Minister of Health. The latter also applies to public hospitals. Registration of the hospital is mandatory and requires meeting the technical requirements which are supervised by the Chief Sanitary Inspectorate.

There are both public and private hospitals in Poland. The majority of hospitals are public although there are governmental incentives for commercialisation nowadays. Only a small number of private hospitals were established originally as such. Most private hospitals were established by transforming public ones. The commercialisation and privatisation is a very sensitive topic in Poland and no consensus on a planned act governing these processes was reached in Parliament in November 2008 (the Act itself was vetoed by the President). This has resulted in the faster growth of the number of original (not transformed) private hospitals as companies find it harder the other way.

In 2007 517 out of 578 public hospitals were established by self-government units (the number has dropped from 530 in 2006). Only 19 were established by the Minister or other central organ of the governmental administration and 42 by a public medical university or public academy teaching and researching in the field of medicine.

Table 1.1: Poland – Key data on in-patient care, 2000 and 2004–2008

In-patient care	**2000**	**2004**	**2005**	**2006**	**2007**	**2008**
No. of hospitals[1]	n.a.	n.a.	831	742	748	n.a.
Classified according to ownership						
- thereof public hospitals	n.a.	n.a.	661	589	578	n.a.
- thereof private hospitals	n.a.	n.a.	170	153	170	n.a.
- thereof other hospitals (please specify)	n.app.	n.app.	n.app.	n.a.	n.a.	n.a.
Classified according to subtypes[1]						
- thereof general hospitals	719	790	781	n.a.	n.a.	n.a.
- thereof mental health and substance abuses hospitals	n.a.	n.a.	50	n.a.	n.a.	n.a.
- thereof speciality (other than mental health and substance abuse) hospitals	n.app.	n.app.	n.app.	n.a.	n.a.	n.a.
No. of acute care beds	190,952	183,280	179,493	n.a.	175,023	n.a.
- thereof in the public sector	189,378	175,631	171,278	n.a.	164,819	n.a.
- thereof in the private sector	1,574	7,649	8,215	n.a.	10,204	n.a.
Average length of stay in hospitals	8.9	6.9	n.a.	n.a.	6.2	n.a.
No. of hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof no. of hospital pharmacies that serve out-patients	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

n.a. = not available, n.app. = not applicable

Note: Data are indicated as of 31 December

[1] according to OECD definition and its subtypes

Source: Statistical Yearbook of Poland 2007, Central Statistical Office (for years 2000–2005) and Statistical Bulletin of the Ministry of Health 2008 (for year 2006 and 2007)

Table 1.2: Poland – Medicines, 2000 and 2005–2009

Number of medicines	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**
Authorised medicines in total	n.a.	8,089	n.a.	n.a.	n.a.	n.a.
- thereof hospital-only medicines	517	657	655	n.a.	n.a.	n.a.

n.a. = not available

Source: IMS Data View 03/2007,© 2007 IMS Health Incorporated or its affiliates. All rights reserved

All pharmacies are regulated by the Pharmaceutical Law of 6 September 2001 (Journal of Laws 2004 No. 53 Item 553). Hospital pharmacies are obligatory in hospitals which have more than 150 acute care beds and allowed in all other hospitals. They are not allowed to serve medicines to out-patients (only to hospital departments and other healthcare providers which do not have their own pharmacy according to the concluded agreement) but hospitals are allowed to establish a community pharmacy if their statute permits.

Hospital pharmacies provide pharmaceutical services such as:

- preparation of medicines for parenteral and enteral nutrition;
- preparation of infusion fluids, daily doses of medicines (also citostatics);
- organisation of the hospital pharmaceutical and medical devices supplies;
- participation in pharmaceuticals adverse reaction monitoring;
- participation in clinical trials done in the hospital;
- participation in the promotion of rational use of medicines as well as pharmaceuticals and medical devices management in the hospital.

Hospital pharmacies are also responsible for the records of clinical trial samples, acquiring donations in pharmaceuticals and medical devices as well as setting procedures for supplying pharmaceuticals to hospital departments. Hospital pharmacies and their heads are obliged to meet requirements mentioned in the Pharmaceutical Law. Hospital pharmacies are supervised by the Chief Pharmaceutical Inspectorate.

Hospital pharmacies purchase medicines from producers or wholesalers. This is mainly done through procurement (cf. section 2.2.1).

1.3 Funding

All public, general hospitals negotiate their budgets annually with the National Health Fund (NHF). The local branches of the NHF are responsible for the transaction of the budget to each hospital. Each hospital receives their budget depending on the population the hospital has to serve. Hence, all medicines acquired by hospitals are paid through sources contracted from the NHF.

Hospitals are remunerated based on agreements concluded between the hospital and the NHF. There are multiple types of agreements differed by the type of treatment:

- Payment for the whole procedure (e.g. “hospital treatment”)

- Payment per dispensed medicine (e.g. therapeutic health program).

The treatment in hospitals is free of charge for patients if pertaining in the scope of agreements concluded between the hospital and the NHF (this includes both services and dispensed medicines) thus the main payer is the NHF. The NHF’s sources are raised from social insurance contributions deducted from the employees’ salaries. Hence, there is no out-

of pocket payment is, although it is also possible to undergo hospital treatment on the patient's own cost.

Furthermore, some of the hospitals receive additional funding from their owners (local authorities, the Ministry of Health or Universities) but this additional funding can usually not be spent on health services, but rather for renovation of buildings, technical equipment purchasing, etc.

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

Expenditure (in million PLN)	**2000**	**2004**	**2005**	**2006**	**2007**	**2008**
Total health expenditure (THE)	n.a.	57,357	n.a.	79,495	n.a.	n.a.
- thereof THE public (in %)	70	68.6	n.a.	62.3	n.a.	n.a.
thereof THE private (in %)	30	31.4	n.a.	37.7	n.a.	n.a.
THE in hospitals (HOSHE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical expenditure (TPE)	12,355	16,099	17,245	n.a.	n.a.	n.a.
- thereof TPE public (in %)	34.2	35.0	35.1	n.a.	n.a.	n.a.
- thereof TPE private (in %)	65.8	65.0	64.9	n.a.	n.a.	n.a.
Pharmaceutical expenditure in hospitals (HOSPE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

Note: Data are indicated as of 31 December.

Source: IMS Data View 03/2007,© 2007 IMS Health Incorporated or its affiliates. All rights reserved and The Budget Act

2 Pricing

2.1 Organisation

2.1.1 Framework

In general, there is free pricing for medicines used in the in-patient sector. Nevertheless, the regulation on pharmaceutical prices in the in-patient sector is heterogeneous and foresees two exemptions:

- List of hospital drugs with statutory prices

  The legal basis is the Act of 5 July 2001 on prices and the following Regulations:

  - Regulation of the Minister of Health of 30 November 2006 on the list of medicines and medical devices which are acquired by hospitals for a statutory wholesale price;
  - Regulation of the Minister of Health of 6 December 2006 on the list of statutory wholesale prices of medicines and medical devices acquired by hospitals (it is not legally binding anymore).

The former Regulation contains the list of 28 active substances for which the maximum wholesale price is set. The list was set by the Minister of Health in consultation with the Minister of Finance taking into account the balance between the consumers' and producers' interests and financial capability of the National Health Fund (NHF). It contains medicines and medical devices with major shares of expenditure of public payer. This list is not relevant for the out-patient sector.

At the moment there are no statutory prices fixed for these drugs hence the list has no practical importance. At the moment the Ministry of Health is collecting information from pharmaceutical companies required to prepare a new list of hospital drugs and their statutory prices.

- Prices for chemo-therapy and therapeutic health programs set by NHF

  The president of the NHF in his orders regulates the price which will be paid by the NHF for active substances used in chemo treatment and in therapeutic health programs. These prices are set in course of negotiations between the Ministry of Health and industry which is based on the Act of 27 August 2004 on healthcare services financed from public funds.

  According to the latest decisions of the Minister of Health prices set for chemo-therapy and the health programs will be included as statutory prices in the above mentioned regulation.

All medicines are acquired through public procurement announced by hospitals which state the maximum sum they will pay for the supplies and what is needed – pharmaceuticals, doses, number of packages. These procedures are being conducted by the subordinated

entity responsible. The legal basis for the procedure is the Public Procurement Law of 29 January 2004 (Journal of Laws 2007 No. 223 Item 1665 with further amendments).

In general, hospital expenditure on pharmaceuticals is covered by hospitals themselves but is reimbursed according to the concluded agreements on performing the healthcare services. Expenses for these medicines are calculated in the cost of special procedures and the payer rather covers the complete hospital treatment then the price of the medicine itself (cf. section 1.3).

There are extra budgets covered by the NHF for abovementioned anti-cancer pharmaceuticals and other very expensive medicines (used in treatment of rare diseases or chronic diseases).

The pricing criteria are set in the Act on prices only for the hospital pharmaceuticals which have the statutory price. According to the Act the Pharmaceutical Management Team (the advisory body to the Minister of Health which makes recommendations on pharmaceuticals prices) has to take into consideration:

- prices in countries with similar GDP per capita (typically neighbour countries – Czech Republic, Slovakia etc.; although pharmaceutical companies are obliged to provide information on prices in all EU countries by law);
- price competitiveness;
- the influence of the price on the global costs of healthcare system;
- production costs;
- the amount of supply before the application and after it;
- proven therapeutical efficiency;
- pharmaceutical's role in combating civilization and epidemiological diseases;
- national payers' financial capability.

2.1.2 Hospital prices

The major pricing policy in the in-patient sector is procurement. All public hospitals purchase their medicines through procurement. There is no official scheme for setting the prices of medicines in the in-patient sector.

The hospital price is the ex-factory price with wholesale mark-ups and value added tax (VAT). All medicines are taxed in Poland with 7% VAT. The prices of the medicines sold to the hospitals include mark-ups imposed by wholesalers. Mark-ups are not regulated and the percentage is unknown to the hospitals and the national payer. Hospital pharmacies do not receive any additional mark-ups because they are subordinated units within the hospitals. The Ministry of Health usually gets the data on prices from public hospitals from their invoices.

There are no legal regulations of compulsory discounts for hospitals. There is a possibility of giving discounts, but it depends on bilateral agreements between the manufacturer and the hospital. Usually discounts are granted within a 2-10 per cent range.

There is no general rule regarding the compared prices in the in-patient and out-patient sector (as shown in Table 2.1). The Ministry of Health is planning to include a provision in the future Act on reimbursement stating that the hospital price cannot be higher than the out-patient price.

Table 2.1 Poland - Comparison of prices on the positive reimbursement lists and statutory prices for in-patient sector

Pharmaceutical name	Wholesale price for the in-patient sector in PLN (according to the regulation of Minister of Health)	Wholesale price for the out-patient sector in PLN (according to the open reimburse-ment lists)	Retail price for the out-patient sector in PLN
Amotaks Dis (Amoxicillinum) 750 mg – 16 tab.	10.25	9.39	11.34
Duomox (Amoxicillinum) 125 mg – 20 tab.	4.97	4.97	6.46
Ospamox (Amoxicillinum) 0,125g/5ml (60ml) granulated mass	3.86	4.28	5.72

Source: Regulations of the Minister of Health on prices

Data availability varies between medicines priced on different basis:

Statutory prices are published by way of regulation and thus publicly available. Prices negotiated by the Ministry of Health are not disclosed to the public at the moment but with the new regulation on statutory prices for hospital drugs this is likely to change (although it would include official prices and not the full details of concluded risk-sharing schemes). Prices of medicines used in chemo-therapy are published in the orders of the President of the National Health Fund (NHF). These prices are available at the NHF website.

In case of procurement everyone can ask to have insight into offers considered by the hospital to be advantageous, as well as the rest of the offers to find out what prices were suggested by individual wholesalers.

Neither the Ministry of Health nor the National Health Fund has any information on sharing information on prices of purchased medicines between hospitals.

2.2 Pricing policies

2.2.1 Procurement

The main legal act concerning public procurement is the Public Procurement Law of 29 January 2004. There are a few regulations based on this Act which were issued by the Prime Minister:

- Regulation of the Prime Minister of 19 December 2007 on average exchange rate PLN/EUR used in public procurements;
- Regulation of the Prime Minister of 19 May 2006 on documents which may be demanded by the contracting party from the contractor and forms in which the documents may be submitted;
- Regulation of the Prime Minister of 16 October 2008 on protocol of public procurement procedure;
- Regulation of the Prime Minister of 16 October 2008 on templates of announcements placed in the Public Procurements Bulletin.

Public procurement is the only pricing policy for all medicines used in public hospitals as it is mandatory in the majority of cases. All entities listed in the Public Procurement Law are obliged to run public procurement procedures. Among others this includes public hospitals and other healthcare providers (cf. section 1.2).

Public procurement is limited in two cases, when maximum prices are set for the 28 active substances and when the maximum prices are negotiated for chemo-therapy and therapeutic health programs. Private hospitals are also an exemption. The Public Procurement Law allows even more exceptions (e.g. the total value of contract is not higher than € 14,000), but most of them do not refer to medicines.

Most public procurement procedures are run by single hospitals, joint procurements are not common. Hospitals are allowed by law to let their own subordinate unit or external agency run the procedures as a proxy. Using external agencies (law firms, brokers) is not common. According to the Public Procurement Law the director of the hospital is responsible for the procurement and decides on the offers although s/he can assign the performance of the procurement (also her/his privileged responsibilities) to other people. In some cases (with high value of the contract) it is mandatory to establish a tendering commission which is responsible for evaluation of offers. The commission may be established for all or only specific procedures.

The main criterion in public procurements is the price. It can be the only criterion or combined with other related to the subject of the procedure. Evaluation criteria cannot be related to the contractor (e.g. financial, technical, economical credibility).

Mostly the procedures are to contract either medicines or medical devices although it is common that it is a group of products of given type (e.g. a few different medicines) which allows better pricing. Procedures are conducted as soon as the previous agreements on

certain products have expired according to the public procurement plans for the given year. Both manufacturers and wholesalers are invited to take part as contractors.

Information on the procedure depends on its type. Either it is an unlimited or limited tender procedure (the second one has 2 stages instead of one, at first the group of bidders capable of performing the contract is chosen; any of these procedures may be used in every case). In case of unlimited tender the contracting party is obliged to make the information available on the internet, in the publicly available place in its registered office and in the Public Procurement Bulletin via the Publications Office of the European Union in the SIMAP portal[1] (in the latter if the value of the contract exceeds € 133,000 in case of the public healthcare providers and € 206,000 in case of non-public healthcare providers owned by self-government organs).

Information on the chosen offer, rejected offers and excluded bidders is sent to the bidders and published on the internet and in the registered office of the contracting party as soon as the choice is made. Afterwards, when the agreement is concluded, the information on the agreement is published in the Public Procurement Bulletin or in the SIMAP portal.

Neither the National Heath Fund nor the Ministry of Health have information on exchange of information on the course and results of the procurement procedures between hospitals.

2.2.2 Others

There are no other pricing policies besides procurement in public hospitals.

Private hospitals may negotiate their pharmaceutical prices or also use procurement. They are allowed under the freedom of contract to conclude agreements with suppliers which will rule the purchase of medicines and medical devices. No details of such contracts are available.

3 Reimbursement

3.1 National hospital reimbursement procedure

The reimbursement of medicines in the in-patient sector is based on the Act of 27 August 2004 on healthcare services financed from public funds. According to its Article 35 all hospitalised beneficiaries receive medicines (and medical devices) free of charge. This regards to patients that are treated in hospitals, by day care providers or entities that are allowed to provide healthcare services (make diagnosis, rehabilitation, treatment, immediate help). Pharmacotherapy of these patients is reimbursed by the National Health Fund (NHF) to all

[1] www.simap.europa.eu

public hospitals contracted to provide such services. There are no positive or negative reimbursement lists for this type of treatment, but rather annually budgets for each hospital.

The medicines administered in these cases are reimbursed as:

- "hospital treatment procedures" via Unified Groups of Patients (Jednorodne Grupy Pacjentów, JGP). Each treatment procedure receives certain points to be reimbursed by the NHF (a DRG system);
- therapeutic health programs;
- chemotherapy;
- services on payers permission;
- direct import.

These procedures are varying widely and are used in different kinds of treatment. In particular drugs reimbursed via the DRG (diagnosis related group) system are not reimbursed for each dispensed package but rather with flat rate set for the whole procedure. In the course of the treatment (accounted via DRG) the physician is allowed to prescribe and administer any type of medicine which s/he will find suitable for the patient's needs.

In case of some very expensive oncology procedures it is possible to obtain reimbursement for a hospital drug on individual consent of the NHF regional branch's director. The detailed procedure is described in the Regulation of the Minister of Health of 30 August 2009 on healthcare services in the scope of health programs – this is so-called "non-standard chemotherapy".

In case of medicines which have no market authorization it is possible to obtain import consent and reimbursement in case of live-saving or health-saving if no similar drug is available in Poland. The consent for so-called direct import is given by the Minister of Health based on application submitted by a doctor or hospital if it is supported by a regional or national consultant in a given field of medicine. In case the drug is imported under consent, it is possible to apply for reimbursement to the President of the National Health Fund.

As explained above, all medicines in the in-patient sector are fully reimbursed in Poland by the National Health Fund. Although there are no positive reimbursement lists in general in practice there are separated budgets for particular diseases – therapeutic health programs mostly for oncology, rare and ultra rare diseases and in case of individual permission of the National Health Fund.

3.2 Hospital pharmaceutical formularies

There are no obligatory hospital pharmaceutical formularies (HPF). Only some hospitals have introduced formularies (so-call 'receptariusz') for economic reasons. These are based on the demand submitted by departments and decided by the Pharmaceutical and Therapeutic Committees working in hospitals. Even if a HPF is in place the doctor is allowed to de-

mand for another medicine which is required for the patient's treatment. The decision is being made by the hospital's director and the medicine is purchased by the hospital pharmacy.

4 Consumption of pharmaceuticals

Table 4.1 Poland – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in pharmacies						
in packs (in Mio.)	n.a.	n.a.	382.5	402.4	423.5	439.0
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses, please specify)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual pharmaceutical consumption for chemo-therapy and therapeutic health programs						
in packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (mg, jm)	n.a.	n.a.	n.a.	n.a.	3,912,655,386	1,706,580,438

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

Source: Business Object 6.5

Data on pharmaceuticals consumption is not widely available in Poland. It is possible to obtain some figures on the number of dispensed medicines in the out-patient sector as they are reimbursed by the National Health Fund (NHF) directly to pharmacies per pack sold.

Full data on pharmaceuticals consumption in the in-patient sector is not available due to the fact, that in case of hospital treatment accounted via the “hospital treatment procedures of the Unified Groups of Patients” the NHF has little information on pharmaceuticals administered only on the undergone procedures. Full data on pharmaceuticals consumption in therapeutic programs is available to the NHF.

Neither the Ministry of Health nor the NHF have any detailed information on consumption data at the hospital level although, as mentioned in section 5.1, the hospital pharmacist is obliged by law to collect data on medicines which were dispensed to patients in the wards.

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

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure
1	CAPECITABINUM - O - (ORAL, PER MOUTH) - 1 MG	1	TRASTUZUMABUM - P - (PARENTERAL) - 1 MG
2	FLUOROURACILUM - P - (PARENTERAL) - 1 MG	2	IMATINIB - O - (ORAL,) - 1 MG
3	IMATINIB - O - (ORAL) - 1 MG	3	DOCETAXELUM - P – (PARENTERAL) - 1 MG
4	CYCLOPHOSPHAMIDUM - P - (PARENTERAL) - 1 MG	4	OXALIPLATIN - P - (PARENTERAL) - 1 MG
5	RIBAVIRINUM - O - (ORAL) - 1 MG	5	RITUXIMABUM - P - (PARENTERAL) – 1 MG
6	GEMCITABINUM - P - (PARENTERAL) - 1 MG	6	PEGINTERFERONUM ALFA-2A - P - (PARENTERAL) - 0,001 MG
7	LAMIVUDINUM - O - (ORAL) - 1 MG	7	GEMCITABINUM - P - (PARENTERAL) - 1 MG
8	MITOTANUM - O - (ORAL) - 1 MG	8	ETANERCEPTUM - P - (PARENTERAL) - 1 MG
9	MESNUM - P - (PARENTERAL) - 1 MG	9	INTERFERON BETA-1B - P - (PARENTERAL) - 0.3 MG
10	IFOSFAMIDUM - P - (PARENTERAL) - 1 MG	10	IMIGLUCERASUM - P - (PARENTERAL) - 1 J.M.

Source: Business Object 6.5

5 Evaluation

5.1 Monitoring

There is no monitoring of the pharmaceutical consumption, hospital expenditure and prices of medicines in the in-patient sector. Exceptions are the targeted import and therapeutic programs. In the first case the individual decisions are made by the Ministry of Health who is in possession of such data and in the second case the National Health Fund (NHF) monitors patients in the therapeutic programs to verify meeting the inclusion and exclusion criteria set for each program.

Since 2004, the higher education speciality of hospital pharmacist exists in Poland. The tasks of the hospital pharmacists are described in section 1.2. Some of the specific tasks of the hospital pharmacists include:

- control of therapeutic and pharmaco-chemic compliance of pharmaceutical ingredients in the mixed pharmaceuticals;
- participation in pharmaceutical adverse reaction monitoring;
- data collection on dispensed medicines (for the needs of the hospital), in particular strong and psychotropic medicines;
- monitoring the expiry dates of medicines stored in the hospital pharmacy.

5.2 Assessment

The Agency for Health Technology Assessment (Agencja Oceny Technologii Medycznych, AHTAPOL) was established in 2005 to provide HTA reports for the Minister of Health. The Consultation Council within the Agency prepares recommendations on pharmaceuticals effectiveness based on the Minister's demand. The Consultation Council may recommend to reimburse the medicine, not to reimburse or reimburse in case of achieving better price (meeting the cost-effectiveness level based on the WHO standard 3 times GDP per capita). These recommendations are used by the Ministry of Health to choose pharmaceuticals for the therapeutic health programs and chemo schemes and as an argument in price negotiations with the industry.

The Ministry of Health has no information on savings achieved by hospitals thanks to procurement procedures as in most of the cases medicines are reimbursed under the DRG system (cf. section 3.1).

6 Developments and outlook

Nowadays hospitals are encouraged by the government to change their legal status from public to private. This transition period however does not affect pricing and reimbursement regulation and policies of medicines directly.

In a few months the Minister of Health will issue a new regulation on statutory prices of medicines used in hospitals changing the regulations mentioned in the 2006' Regulations. The regulation is currently being prepared by the Pharmaceutical Policy and Pharmacy Department of the Ministry of Health. The Ministry of Health requested pharmaceutical companies to submit information on 3 groups of drugs:

- included in the previous Regulations;
- included in the health programs;
- included in the chemotherapy schemes under the Regulation of the Minister of Health.

Another major change will be introduced in the Act on reimbursement which is due in fall 2010. The new Reimbursement Act will unify the reimbursement procedures for pharmaceuticals in the out-patient sector and the health programs in the in-patient sector. The company will apply for reimbursement to the Ministry of Health which will decide on the manner of reimbursement of the medicines. Also the statutory prices of the out-patient drugs will be automatically binding as maximum prices for procurements in the in-patient sector.

7 References and data sources

7.1 Literature and documents

No literature was used in course of answering the survey.

7.2 Contacts

In case of queries related to the Polish PHIS Survey please contact:

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Appendix 1

The list of active substances of drugs with statutory price according to the Regulation of the Minister of Health of 30 November 2006

1. Abciximabum
2. Acidum clavulanicum + Ticarclllinum
3. Amoxicillinum
4. Amoxicillinum + Acidum clavulanicum
5. Cefuroximum
6. Dalteparinum natricum
7. Darbepoetinum alfa
8. Docetaxelum
9. Enoxaparinum natricum
10. Erythropoietinum
11. Gemcitabinum
12. Imatinibum
13. Iopromidum
14. Irinotecanum
15. Lamivudinum
16. Meropenemum
17. Metamizolum natricum
18. Mofetili mycophenolas
19. Nadroparinum calcicum
20. Parnaparinum natricum
21. Peginterferon alfa-2a
22. Peginterferon alfa-2b

23. Reviparinum natricum

24. Rituximabum

25. Somatropinum

26. Tacrolimusum

27. Trastuzumabum

28. Zidovudinum