Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

SLOVAKIA

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

Slovakia

PHIS Hospital Pharma Report

Final Version, April 2009

PHIS Network Participants
State Institute for Drug Control, SUKL: Jan Mazag, Barbara Bilančíková

PHIS Hospital Pharma Report – Author
State Institute for Drug Control, Bratislava, Slovakia, Dr. Jan Mazag

PHIS Hospital Pharma Report – Editorial Team
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, Austria:
Simone Morak (Editor-in-Chief), Christine Leopold, Sabine Vogler

Responsible for the PHIS Hospital Pharma Report Template
State Institute for Drug Control SUKL, Slovakia (Leader of Work Package 7: Hospital Pharma): Jan Mazag, Barbara Bilančíková
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, Austria: (PHIS Project Leader): Sabine Vogler, Christine Leopold

Acknowledgements

The author of the report consulted with representatives of the following institutions/persons:

- Slovak Association of Hospitals,
- Slovak Association of Faculty Hospitals,
- Slovak Association of Hospital Pharmacists,
- Insurance companies representatives and
- the hospital pharmacy in the Oncological Institute in Bratislava (personal visit).

The following national hospital experts contributed to the realisation of this report:

PharmDr. Dominik Tomek (SZP, Bratislava), PharmDr. Krc-Jediná (VsZP, Bratislava), MUDr. Ján Masaryk (SZP, Bratislava), MUDr. Lesáková (VsZP, Bratislava), MUDr. Kafková (ZP Union, Bratislava), MUDr. Janeková (NZZ, Bratislava), MUDr. Ottinger (Associácia nemocníc, Bratislava), MUDr. Petko (Asociácia nemocníc, Bratislava), MUDr. Šajty (Asociácia fakultných nemocníc, Košice), MUDr. Šálek (Onkologický ústav, Bratislava), MUDr. Msoli (SUSCH, Bratislava), Doc. PharmDr. Sýkora (Asociácia nemocničných lekárnikov, Bratislava), MUDr. Kausitz (NOU, Bratislava), PharmDr. Foltánová (FaF, UK), MUDr. Haško (FNsP, Bratislava).

Executive Summary

Background

The official definition of hospitals and hospital care in Slovakia is laid down in the respective law, Act on Health Care Services and related Services No. 576/2006, as amended.

In § 7 of this respective Act types of health care services are defined: outpatient services and specialised services where hospital care is defined as health care service which requires more than 24 hours of care for patients. Services related to health care service are also defined in this Act. Besides others these services are mainly related to accommodation and providing food for patients.

Another relevant Act of the Ministry of Health is the Act on defining signs of types of health care facilities, No. 770/2004, as amended. It defines day care clinics, facilities for providing health care services for more than 24 hours and hospitals, general hospitals and specialised hospitals. Other health care facilities as mental health, nursery houses or hospices are also defined with clear differentiation from hospitals, general hospitals or specialised hospitals. Moreover a classification for hospitals based on ownership is in place.

Hospital pricing, reimbursement and monitoring in this PHIS Hospital Pharma Report refer to the majority of hospitals in Slovakia. There are some differences among individual hospitals but principles and major policies are applied for all hospitals in Slovakia.

Basically, the competence on accreditation, establishment, supervision on running and budget for hospitals is under state regulation defined in respective Acts and ownerships. Practically this means that state regulation bodies (Ministry of Health and Territory Regional Units[1]) are the bodies that have competences with regard to accreditation of hospitals and owners are responsible for the supervision of hospitals, including their management and budgets. In the case of state ownership these bodies are the Ministry of Health and Territory Regional Units, in the case of private ownership (private companies or joint owners) these bodies are private companies and Territory Regional Units.

Since 2000 the Ministry of Health has been aiming at reducing the number of acute care beds to 5 beds per 1,000 inhabitants, the number of chronic care beds to 1 bed per 1,000 inhabitants and the number of psychiatric care beds to 1 bed per 1,000 inhabitants. In the year 2004 the number of acute care beds slightly increased but the aim of the Ministry of Health could not be reached. Most beds were reduced in internal, gynaecology, chirurgic and paediatric departments.

The financing of hospitals is specified in the Decree No. 07045-7/2004 of the Ministry of Health and following directives, which regulate prices for health care services. In this Decree maximum prices for health care services (prices for so called „completed hospitalisation of an individual patient“) provided to an individual inpatient by a specific hospital department are

[1] Slovakia is divided in 6 regions - the Territory Regional Units

listed. The health insurance company reimburses the hospitals by a fixed fee-for „completed hospitalisation" of every inpatient. The amount reimbursed of it differs for every medical specialisation (e.g. internal medicine, oncology, surgery, anaesthesiology, etc.) and also differs with regard to the type of hospital. For example, the maximum price of completed hospitalisation for an individual patient at the department of internal medicine is about € 300–2,000, psychiatry € 1,000, clinical oncology € 1,500, surgery € 600–1,000, anaesthesiology €°5,000, etc. Every health insurance company makes its own contract with a hospital and therefore the prices for individual hospitals can vary. Hospital remuneration also includes medicines.

Pricing

The maximum ex-factory price of hospital medicines is regulated by the Ministry of Health. According to the Decree No. 577/2004 on Price Regulation the maximum ex-factory price of a medicine must not exceed the average of the lowest prices in 6 reference countries. Every 3 months the Ministry of Health publishes a list of maximum ex-factory prices of medicines in the Decree on Price Regulation. Apart from the regulated maximum ex-factory prices hospitals can have public tenders or negotiations with the manufacturer or wholesaler to achieve a lower price than the maximum ex-factory price listed in the Decree on Price Regulation or than the maximum purchase price of the medicine of the wholesaler to the hospital. Medicines for hospitals are normally purchased from wholesalers at the maximum wholesale mark up of 9%. Value added tax for hospital medicines is 9% which is the same as in the outpatient sector. There is no pharmacy margin applied in hospitals. In the outpatient sector degressive wholesale and pharmacy margins are applied. Therefore, normally, the price of the same medicine in hospital is lower than in a community pharmacy. There is no direct reimbursement of medicines in hospitals by health insurance companies.

It is mandatory for a hospital to have procurement if the total expenses of a medicine exceed € 30,000 per year. In case annual expenses are below € 30,000 the medicine (active substance) must be purchased by the hospital through "market evaluation" or direct negotiation with manufacturer or wholesaler.

Reimbursement of pharmaceuticals in hospitals

Pharmaceuticals used in hospitals are reimbursed from the hospital budget. Patients do not have to pay extra.

The hospital reimbursement is organised at national level and is totally separate from the outpatient sector. Therefore the decision on reimbursement of hospital medicines (decision on which products will be purchased and used in hospital) is of importance especially for the economic director and the medical director of a hospital. Besides medicines the hospital budget also covers other expenses needed for running the hospital (e.g. salaries for doctors, operational costs, etc.).

Hospital pharmaceutical formularies (HPF) are standard in hospitals. No country-wide positive or negative list for the inpatient sector exists. HPF may differ from the positive list of the outpatient sector. Every hospital has its own specific hospital pharmaceutical formulary.

Normally once a year every medical specialisation or individual doctor can make proposals for the inclusion or deletion of a medicine to or from the HPF. The most important criteria for adding a pharmaceutical to the HPF are medical and therapeutic benefit, economic criteria like cost-effectiveness and budget impact. The pharmaceutical and therapeutic committee (PTC) then decides about the inclusion in or deletion of a medicine from the HPF.

In general the HPF only lists active substances. However, in many formularies additionally the names of the pharmaceutical specialties are listed as information for doctors.

Consumption of pharmaceuticals in hospitals

Monitoring and evaluating medicine consumption as well as comparing the planned expenditure of departments (including medicines) and real spending is done by each department. The pharmaceuticals represent approximately 20-30% of total expenditure of the hospital. Therefore the monitoring of direct expenditure of pharmaceuticals is a very frequent tool. In fact only specialised hospitals (e.g. oncology or cardiovascular institute) analyse consumption data on an individual level per patient in case it is related to expensive treatment (e.g. antibiotics, growth hormones, expensive medicines for oncology treatment, etc.).

Evaluation

Medicines used in hospitals are included in the total hospital budget. There is no co-payment for patients. Therefore evaluation, monitoring of prices, expenditure and consumption of pharmaceuticals is of interest for the hospital management.

According to the Act No. 140/1998 on Pharmaceuticals and Medical Devices concerning the monitoring of prices and consumption of medicines and medical devices in hospitals there are two legal obligations:

1. The prices and consumption of medicines used in hospitals can be monitored quarterly by regular reports from wholesalers to the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, SUKL). Every wholesaler has to report the maximum ex-factory prices or pharmacy purchasing prices as well as the consumption of pharmaceuticals delivered from the wholesaler to the hospitals.

2. All hospital pharmacies and community pharmacies delivering pharmaceuticals and medical devices have by law the obligation to report prices and consumption of pharmaceuticals and medical devices quarterly to the National Centre for Health Information.

Data on prices and consumption are publicly available at the SUKL and National Health Information Centre upon request.

In every hospital expenditure and consumption of medicines on hospital as well as department level is monitored and assessed by the pharmaceutical and therapeutic committee (PTC). When needed the PTC creates general or specific guidelines and recommendations for the use of medicines in hospitals (e.g. guidelines and regulation of albumin use, antibiotic prophylaxis in surgery, centralised antibiotic policy in the hospital, rational use of Novoseven in anaesthesiology, etc.).

Interface management

According to the legislation the hospital has to provide the patient with pharmaceuticals for 3 days after discharge from the hospital. This is the responsibility of the doctor. In hospitals the doctor and the nurse are involved in the interface management of medicines. There is no direct involvement of hospital pharmacists.

Developments and outlook

Insufficient resources to fully cover the generous scope of services, financial limitations in the contracts with health care providers and the debts outstanding from the health insurance funds resulted in debts reaching € 268 mio. mainly in specialised hospitals in the period 2007. The government, in particular the Ministry of Health, are planning to solve this issue by helping selected hospitals to cover the debts based on submitted applications from the hospital management. These applications need to include a clear management plan provided from hospitals in order to indicate and guarantee good operational running of hospitals including managing operational expenditure and rational use of medicines.

Table of content

List of tables and figures

List of abbreviations

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic Therapeutic Chemical classification
BMG	Austrian Ministry of Health
CIVAS	Centralized Intravenous Admixtures Service
DDD	Defined Daily Doses
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
EU	European Union
GDP	Gross Domestic Product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital Pharmaceutical Formulary
HPI	Health Policy Institution
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute
IMS	Institute for Medical Statistics
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPD	Outpatient department(s)
OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals

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

Introduction

PHIS research project

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

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

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

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

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

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

SUKL is the WP leader of Hospital Pharma.

Further key stakeholders 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 inpatient 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 pharmaceuticals in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the inpatient 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 inpatient 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 official definition of hospitals and hospital care in Slovakia is laid down in the respective law, Act on Health Care Services and related Services **No. 576/2006** as amended.

In § 7 of this respective Act types of health care services are defined:

a. outpatient services and

b. specialised services where hospital care is defined as health care service which requires more than 24 hours of care for patients. Services related to health care service are also defined in this Act. Besides others these services are mainly related to accommodation and providing food for patients.

Another relevant Act of the Ministry of Health is the Act on defining signs of types of health care facilities**, No. 770/2004,** as amended. It defines the following services:

a. in § 3: day care clinics are defined (basically specialised services for patients within 24 hours),

b. in § 9: facilities for providing health care services for more than 24 hours are defined followed by

c. § 10: where hospitals, general hospitals and specialised hospitals are defined. Other health care facilities as mental health, nursery houses or hospices are also defined with clear differentiation from hospitals, general hospitals or specialised hospitals (these definitions correspond with the OECD definition)

Basically subtypes of hospitals are defined in the respective Act on Health Care Providers, Medical Workers, and Professional Organisations in the Health Service of the Ministry of Health, **No. 578/2004,** as amended. In § 7, section 3, the types of hospitals are defined as general hospital and specialised hospital.

These types of hospitals are then described in more detail in § 10 of the respective Act on Defining Signs of Types of Health Care Facilities of the Ministry of Health, **No. 770/2004,** as amended:

1. Hospital as health care facility providing non-selective health care service for patients, special health care service including following accompanied outpatient health care services and pharmaceutical services.
2. General hospital as health care facility providing inpatient service in various health care speciality fields.
3. Speciality hospital as health care facility providing inpatient service in one speciality field and/or other fields closely connected with the main field of speciality (cardiovascular special hospitals or oncological institutes, etc).

Moreover a classification for hospitals is in place based on ownership: Basically three sub-types based on ownership could be defined (cf. section 1.2).

a. Hospitals with state ownership (Ministry of Health)
b. Hospitals with private ownership (limited companies)
c. Non-profit hospitals (ownership transformed to non-profit organisations under the organisation of Territory Regional Units).

Hospital pricing, reimbursement and monitoring in this Hospital Pharma Report refer to the majority of hospitals in Slovakia. There are some differences among individual hospitals but principles and major policies are applied for all hospitals in Slovakia.

1.2 Organisation

Basically, the competence on accreditation, establishment, supervision on running and budget for hospitals is under state regulation defined in respective Acts and ownerships. Practically this means that state regulation bodies (Ministry of Health and Territory Regional Units) are the bodies that have competences with regard to accreditation of hospitals and owners are responsible for supervision on running and budget for hospitals. In the case of state ownership these bodies are the Ministry of Health and Territory Regional Units, in the case of private ownership (private companies or joint owners) these bodies are private companies and Territory Regional Units.

The legal framework for establishing and running hospitals is regulated in the following Acts:

a. Act No. 576/2004 Coll. on Health Care and Health Care-related Services
b. Act No. 578/2004 Coll. on Health Care Providers, Medical Workers, Professional Organisations in the Health Service
c. Act. No. 580/2004 Coll. on Health Insurance
d. Act No. 581/2004 Coll. on Health Insurance Companies and Supervision
e. Act No. 302/2004 Coll. on Territory Regional Units
f. Act No. 416/2001 Coll. on Transforming Respective Responsibilities from Central State Organisations to Territory Regional Units

Based on the respective Act of the Ministry of Health on Health Care Providers, Medical Workers, Professional Organisations in the Health Service, No. 578/2004, as amended, the Ministry of Health published the Decree No. 640/2008, on Public minimal network for Health Care providers, where the minimum number of inpatient health care providers is defined. Practically this means that a minimum number of acute care beds, a minimum number of chronic care beds and beds for medical speciality are set which have to be financed by social health insurance. In other words this decree defines a minimum number of hospital beds in Slovakia which are divided to Territory Regional Units in order to be financed through public sources (i.e. social health insurance).

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

Inpatient care	2000	2004	2005	2006	2007	2008
No. of hospitals[1]	133*	132*	125	121	122	n.a.
*Classified according to ownership**						
- thereof public hospitals	133*	132*	94 (75%)	86 (71%)	87 (71%)	n.a.
- thereof private hospitals	0	0	12 (10%)	19 (16%)	20 (16%)	n.a.
- thereof other hospitals (non-profit)	0	0	19 (15%)	16 (13%)	15 (13%)	n.a.
Classified according to subtypes[1]						
- thereof general hospitals	95	91	83	79	80	n.a.
-thereof mental health and substance abuses hospitals	6	5	n.a.	n.a.	n.a.	n.a.
-thereof speciality (other than mental health and substance abuse) hospitals	32	36	42	42	42	n.a.
No. of acute care beds	36,820*	36,124*	35,891	34,324	34,288	n.a.
-thereof in the public sector	36,820	36,124	90%	84%	84%	n.a.
-thereof in the private sector	0	0	10%	16%	16%	n.a.
Average length of stay in hospitals	n.a.	9,1	8,9	8,8	8,7	n.a.
No. of hospital pharmacies	133*	81	n.a.	74*	n.a.	51*
thereof no. of hospital pharmacies that serve outpatients	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 the Slovak definition and its subtypes general and specialty hospitals. A general hospital usually runs departments like internal medicine, surgery, paediatric, gynaecology, but a hospital is also considered as a general hospital in case it operates with fewer than all these departments.

* SUKL estimation based on information from personal communication, data from 2007

Source: Statistical Yearbook 2000-2008, Bratislava, Slovakia

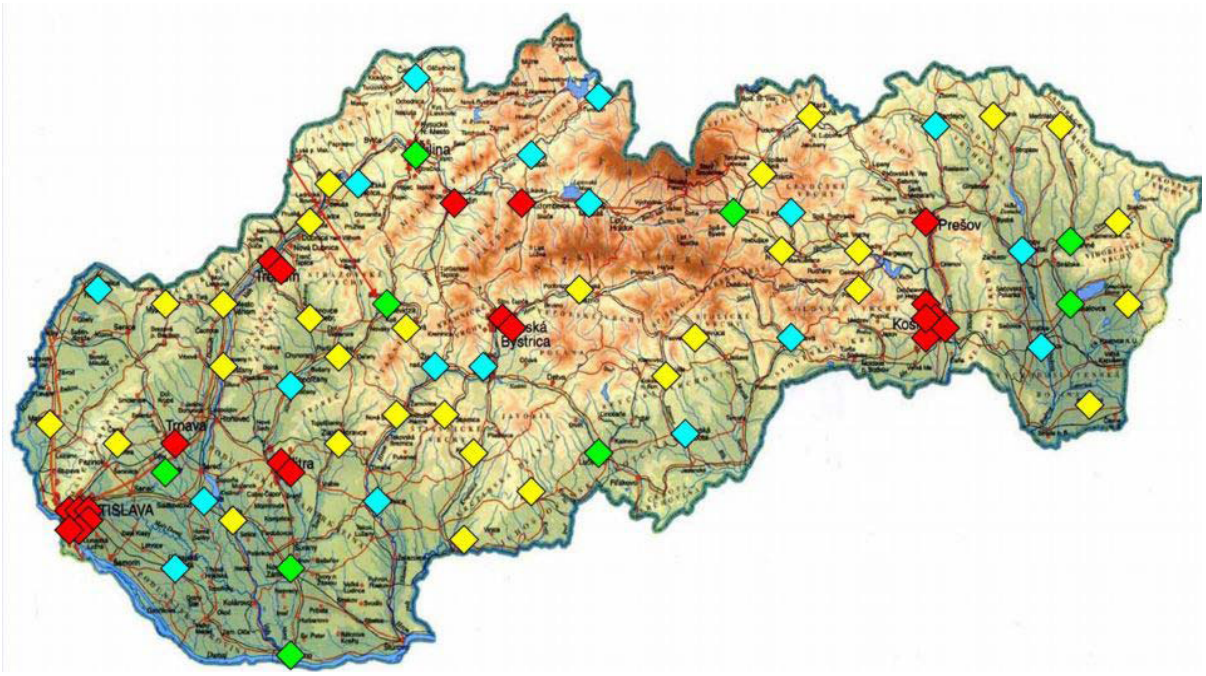
From the year 2000 the strategy of the Ministry of Health has been to reduce the number of acute care beds to 5 beds per 1,000 inhabitants, the number of chronic care beds to 1 bed per 1,000 inhabitants and the number of psychiatric care beds to 1 per 1,000 inhabitants. In the year 2004 the acute care bed number slightly increased but the aim of the Ministry of Health could not be reached. Most beds were reduced in internal, gynaecology, chirurgic and paediatric departments.

Despite the growing financial problems in the health care sector, the number of highly specialised hospitals has increased in comparison to 2000. In recent years highly specialised health care facilities have been extensively built as the government has prioritised programmes for dialysis, plasmapheresis, cardiovascular diseases and cancer. These specialised hospitals are in charge of a selection of diseases, e.g. the National Institute of Cardiovascular Diseases takes care of all cardiovascular diseases and transplantations at national level. There are also psychiatric specialised hospitals, hospitals for tuberculosis and respira-

tory diseases, etc. The aim is to have a county hospital in every region, and specialised institutions spread evenly, one for two or three regions (although some of them also operate at national level, such as the National Institute of Oncology).

The following figure shows the distribution of hospitals as well as the number of hospitals in Slovakia with regard to size. There are 30 small hospitals with less than 200 acute care beds, 18 middle size hospitals with 200-400 acute care beds and 9 large hospitals with more than 400 acute care beds. The 21 university hospitals are indicated in red.

Figure 1.1: Slovakia - Distribution of hospitals, 2007



up to 200 acute care beds, 200–400 acute care beds, more than 400 acute care beds, university hospitals

Source:

http://www.health.gov.sk/redsys/rsi.nsf/0/650E3DBCE94B4E0DC1257310003A9EF2/$FILE/priloha3.pdf

Since 2007 a classification of hospitals based on ownership has been in place. Basically three types of ownership are distinguished (for figures please cf. Table 1.1):

a. Hospitals with state ownership: Those public hospitals were established by the Ministry of Health. In the year 2002 the accountability for some public hospitals has been transferred from the Ministry of Health to Territory Regional Units and became non-profit organisations. In 2007 71% of the total number of hospitals were public hospitals.

b. Hospitals with private ownership: Those hospitals are either established by limited companies (10 hospitals) or via a joint establishment with Territory Regional Units with a majority of private ownership (10 hospitals). Hospitals which offer postgraduate education are represented in the Association of Faculty Hospitals. In the year 2007 16% of the total number of hospitals were in private ownership.

c. Non-profit hospitals: The ownership of those non-profit hospitals has been transferred to the organisation and funding of Territory Regional Units at a regional administrative level. 15 non-profit hospitals existed in 2007.

Provision of pharmaceuticals in hospitals

All authorised medicines that are used in hospitals are funded through the hospital budget. In Slovakia, medicines are not specifically authorised for hospital use. Practically, the hospital pharmacy can order and buy all pharmaceuticals authorised. The majority of medicines used in hospitals are related to inpatient use (e.g. parenteral use), but also oral medicines. Due to budgetary limits, the use of medicines in hospitals amounts to approximately 10% of the total hospital budget and doctors tend to push the use of medicines to the outpatient sector.

Table 1.2: Slovakia – Pharmaceuticals, 2000 and 2005–2009

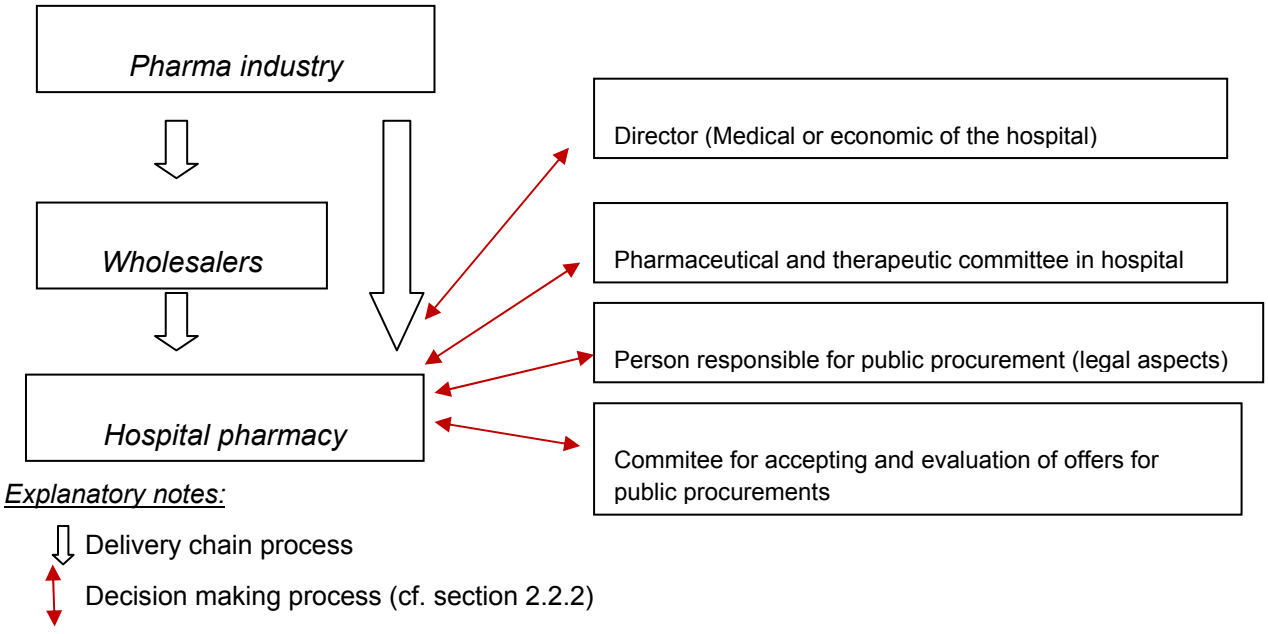
Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total	14,012	14,459	19,927	24,265	28,047	29,929
thereof hospital-only medicines	Up to 20% from total					

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

Data reflect the number of pharmaceuticals excluding homeopathic;
Data include different pharmaceutical forms, pack sizes and different dosages

Source: State Institute for Drug Control, Bratislava, Slovakia

Figure 1.2: Slovakia – Schematic flow chart of pharmaceutical provision in inpatient care, 2009



Source: own illustration (SUKL)

For the majority of cases medicines are delivered to hospitals by wholesalers through tenders. In some cases industry representatives are licensed to deliver pharmaceuticals directly to hospitals (e.g. in specific fields of medicine, for example cardiology or oncology etc.). In the year 2008, 11 wholesale companies dominate the market (95% of pharmaceutical sales). Major wholesalers include Phoenix, Unipharma and Med-Art. Phoenix, the outcome of a merger between Fides, Biama and Drugimpex in October 2004, trades more than 10,000 products in five centres around the country. Unipharma, ranking second on the wholesale market, is a joint stock company whose stakeholders are mostly practising pharmacists. Specific wholesalers focusing on delivery to hospitals only operate in Slovakia. These specific wholesalers either have a contract directly with insurance companies for so called “direct delivery upon decision of insurance companies” to select hospitals for selected group of medicines (growth hormones, erythropoietin, interferon, etc.) or contracts with hospitals themselves. At present parallel trade is not of interest in Slovakia.

The majority of hospitals (up to 70%) have hospital pharmacies. In case of smaller hospitals, due to economic reasons (e.g. if no hospital pharmacy can be established or maintained in a hospital) there is a possibility to order pharmaceuticals from other hospital pharmacies or from a community pharmacy. The decision is based on the economic balance of delivery costs of pharmaceuticals as this is paid from the hospital budget. In case a community pharmacy delivers medicines to hospitals the pharmacy mark ups should not exceed the 9% wholesale mark up.

Hospital pharmacies are part of the organisation of hospitals, and the main role and responsibilities of hospital pharmacies are:

a. to prepare sterile products and non-sterile products;
b. to organise purchasing and delivering of medicines to hospitals in cooperation with the hospital management;
c. to organise clinical services for doctors including pharmaceutical information and formulary services. Direct recommendation of a hospital pharmacist to optimise medicine therapy for the individual patient is very rare.
d. The main communication tool of hospital pharmacists is the membership in many hospital committees (Pharmaceutical and Therapeutic Committee, Antibiotic Committee, Committee for Nosocomial (Hospital Acquired) Infections, Ethic Committee, Committee for Parenteral Nutrition, etc.)

Hospital pharmacies are operated directly by hospitals and form an integrated part of hospitals. The ownership depends on the status of the hospital. In general hospital pharmacies are obliged to have 3 departments where at least 3 pharmacists (University graduated) should work. The hospital pharmacy team usually consists of pharmacists, pharmacy technicians, administrative personnel and scrub nurses.

Hospital pharmacy departments are defined in the Decree No. 198/2001 of Ministry of Health on Good Pharmaceutical Practice as:

a. department of clinical pharmacy;

b. department for preparing medicines;

c. department of medical devices.

According to § 34 part 3 Act No.140/1998 on Medical Products and Medical Devices hospital pharmacies are only allowed to dispense medicines for inpatients. However, hospitals can establish a hospital pharmacy and a public pharmacy with specific requirements for personnel, material and other requirements based in the Act on pharmaceuticals.

Annual reports are produced by hospitals. These are available mainly on the website of every hospital.

1.3 Funding

Since the introduction of the health insurance scheme in the year 1994 hospitals´ remuneration systems changed several times, mostly reflecting changes in government. In 1993, the points-based fee-for-service system (similar to that used in the German outpatient care sector) was introduced for inpatient care in Slovakia. It was replaced by a combined system of payment by bed-days and points, but this was abolished after two months.

In July 1994 the performance-based system was introduced which foresees reimbursement for services according to bed-days. For selected hospital types a daily charge for a bed-day was defined. The rates were defined after negotiations between the Ministry of Health, the Ministry of Finance, health insurance companies and hospitals. The Ministry of Finance then issued a decree on bed-day prices and hospitals invoiced the health insurance companies for their services.

In 1999 the retrospective system of payment for hospital services was replaced by a system of prospective total budgets for hospitals. The Ministry of Health based these calculations mainly on historical cost and also other indicators were considered. The prospective budget was divided among the different health insurance companies based on the number of insured individuals treated in a given hospital over the previous months and on the volume of services provided to the insured. While this controlled the expenditure of health insurers, unstructured contracts encouraged health care providers to choose priorities that frequently did not correspond with overall health policy aims. In response to this situation, in December 2001 a new reimbursement mechanism was introduced. This system, which could be described as a form of diagnosis-related groups (DRGs), is based on a fee-for service system for inpatient care delivered with payments classified according to the type of hospital and specialty. Health insurance companies are obliged to have structured contracts with health care providers and to monitor their performance.

The new system includes incentives for shortening the average length of hospital stay as well as certain incentives to implement day-treatment procedures, some of which are reimbursed on a fee-for service basis. Nonetheless, insufficient resources to fully cover the generous scope of services, financial limitations in the contracts with health care providers and the debts outstanding from the health insurance companies resulted in health care providers' areas reaching € 268 mio. debts in 2007.

Currently the legal basis for remuneration is specified in the Decree of the Ministry of Health No. 07045-7/2004 and following directives, which regulate prices in health care services. In

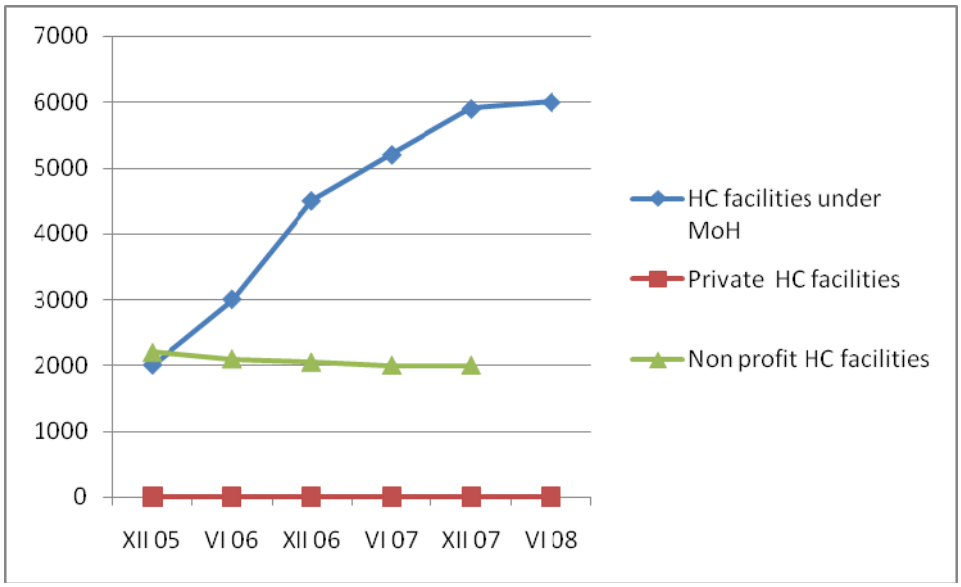
this Decree maximum prices of health care services (prices for so called „completed hospitalisation of an individual patient“) provided to an individual inpatient by a specific hospital department are listed. The health insurance companies reimburse hospitals by a fixed fee for „completed hospitalisation” of every inpatient. The amount reimbursed for a “completed hospitalisation” is different for every medical specialisation (e.g. internal medicine, oncology, surgery, anaesthesiology, etc.) and differs also with regard to the type of the hospital. For example, the maximum price of completed hospitalisation for an individual patient at the department of internal medicine is about € 300-2,000, psychiatry € 1,000, clinical oncology €°1,500, surgery € 600–1,000, anaesthesiology € 5,000, etc. Every health insurance company makes its own contract with a hospital and the prices for individual hospital can vary.

Table 1.3: Slovakia – Balance sheet of revenues and expenses for hospitals

Basic Balance sheet splitting	Type	Note
Revenues of hospitals:	income from insurance companies - based on length of hospital stay - special diagnostic and examination services (X-rays, MRI, laboratory,..)	90% of revenue
	income from rent of part of buildings (canteene, health care related services, other purposes)	
	sell-out of unnecessary/useless building or part of buildings	no regular income
	payments from patients	minor importance
Expenses of hospitals:	Pharmaceuticals and special medical devices	20-30% from total expenditure
	Salaries for employers of hospitals	35-40% from total expenditure
	Operational costs	20-25% from total expenditure
	Investments	25-50% from total expenditure

Source: Personal communication with members of Slovak Association of Hospitals

Figure 1.3: Slovakia – Evolution of debts (unpaid invoices) in hospitals displayed according to type of ownership in mio. SKK, 2005–2008



HC = Health Care, MoH = Ministry of Health

Source: Ministry of Health documents for government from 2009, http://www.health.gov.sk/redsys/rsi.nsf/vdb_Sections?OpenView&ID=PAR404513675766&TYPE=S&LANGUAGE=S&LENGTH=S&MNU=MNU860150877770

Table 1.4: Slovakia – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million €)	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)	2,169.9	2,999.2	3,326.4	3,369.2	3,421.1	3,502.0
- thereof THE public	1,851.6	2,317.5	2,504.3	2,516.9	2,655.7	2,728.8
- thereof THE private	318.4	669.7	822.1	852.3	765.4	773.2
THE in hospitals (HOSHE)	661.1	895.4	928.1	995.8	1,027.4	1,054.6
- 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)	508.8	765.8	930.6	1,092.1	1,113.6	1,273.3
- thereof TPE public	508.8	671.2	752.0	882.3	892.2	1,023.5
- thereof TPE private	0	94.6	178.6	209.8	221.4	249.8
Pharmaceutical expenditure in hospitals (HOSPE)	76.5	97.2	99.4	107.8	115.7	117.4
- thereof HOSPE public	76.5	97.2	99.4	107.8	115.7	117.4
- thereof HOSPE private	0	0	0	0	0	0

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, NCU = National Currency Unit, THE = Total Health Expenditure, TPE = Total Pharmaceutical Expenditure

Note: Data are indicated as of 31 December.

Source: National Health Information Centre, Bratislava, Slovakia for 2000 – 2005 (in 2004 TPE private not for total period during 2004), HPI for 2006-2008 est.

Out-of pocket payments by inpatients

Co-payments in hospitals are marginal. Patients only have to pay for some extra services like special accommodation, gynaecologic and obstetrics (epidural analgesia, individual gynaecologist assistance by the delivery). The patient has an option to decide on the respective doctor who will treat her/him. In most cases this is a surgeon, anaesthesiologist, gynaecologist, etc. The prices for extra care are set in advance and must be public and freely accessible. Private expenses are actually not known.

Reimbursement of medicines in hospitals for patients from abroad is based on local prices and managed by the insurance of the patient from abroad.

2 Pricing

2.1 Organisation

2.1.1 Framework

The legal framework with regard to pricing is set in two legislative acts:

1. Act No. 577/2004 concerning the scope of health care services reimbursed by public health insurance. The law determines how the ex-factory price of a pharmaceutical in the Slovak Republic is set up.
2. The Decree of the Ministry of Health No. 07045-27/2009-OL where changes are listed to Decree of the Ministry of Health of Slovak Republic No. 07045/2003 on scope of regulation of prices in health care services. The Price Decree is published every 3 months. It is a list of maximum ex-factory prices of pharmaceuticals.

The prices of medicines in hospitals are regulated. According to Act No. 577/2004 the maximum ex-factory price of a medicine must not exceed the average of the lowest prices of this pharmaceutical in 6 reference countries.

The Ministry of Health, Department of Categorisation and Pricing has the power and responsibility to decide on the prices of medicines.

In the legislation process the competent authorities or third party payers (health and social insurance institutions) can comment on the proposal of the Decree on prices. The Ministry of Health can accept or reject their comments.

The maximum ex-factory price of pharmaceuticals for hospitals is regulated by the Ministry of Health. The hospital can have public tenders or negotiations with the manufacturer or wholesaler to achieve a lower price than the maximum ex-factory price or maximum pharmacy purchasing price.

Decision making in hospitals

Hospitals can decide on the prices through public tenders or direct negotiations with manufacturers or wholesalers but the results of tenders or direct negotiations may not exceed the maximum listed prices.

1. When the medicine is purchased through public tendering there is always a hospital committee for the evaluation of offers.
2. In case the pharmaceutical is not purchased through public tendering but by market evaluation, direct negotiations with manufacturers or wholesalers, the final decision falls under the responsibility of the medical or economic director of the hospital. The chief hospitals pharmacist has an advisory task and in some hospitals in some situation also a decision making role.

The chief hospital pharmacist has a decision making role under certain circumstances. This is the case when the sum of purchased medicines for a day does not exceed a certain amount in € (the amount is hospital specific and is set up by the hospital e.g. €°1,000 per day). The chief hospital pharmacist undertakes a market analysis for every medicine which was not purchased through public tender. From three offers for a pharmaceutical the chief hospital pharmacist chooses the pharmaceutical with the lowest price and documents this in a written form. But in many hospitals the chief hospital pharmacist has only an advisory role. Her/his proposal must be confirmed by medical or economic director of the hospital and only then the tender can be rewarded to the wholesaler. In Slovakia pharmaceuticals for the use in hospitals are directly delivered and purchased via wholesalers. Manufacturers that have a wholesale licence can also directly deliver medicines to hospitals.

Major pricing policies in hospitals are (cf. section 2.2.):

1. Market evaluation (choosing the lowest price from three offers)
2. Direct negotiation with manufacturer or wholesaler
3. Public tenders

Most relevant criteria for setting a price of medicines are:

1. Medical and therapeutic benefits,
2. Prices of other similar products,
3. Budgetary and financial limitations in relation to type and scope of the contract of the hospital with health insurance companies.

The most relevant exception is the need to purchase a medicine immediately from a wholesaler at a higher price as the hospital would achieve through public tendering or market evaluation. Possible reasons could be that the pharmaceutical is not on stock in the hospital pharmacy or is not included in the hospital pharmaceutical formulary (HPF) but this specific pharmaceutical is essential for an individual patient.

To sum it up the maximum ex-factory price of medicines for hospitals is regulated by the Ministry of Health. According to the Decree No. 577/2004 on Price Regulation the maximum ex-factory price of a pharmaceutical must not exceed the average of the lowest prices in 6 reference countries. Every 3 months the Ministry of Health publishes a list of maximum ex-factory prices of medicines in the Decree on Price Regulation. Apart from the regulated maximum ex-factory prices hospitals can have public tenders or negotiations with the manufacturer or wholesaler to achieve a lower price than the maximum ex-factory price listed in the Decree on Price Regulation or maximum pharmacy purchasing price of the pharmaceutical of the wholesaler to the hospital. The prices and reimbursement of pharmaceuticals for the outpatient sector are set by the Categorisation Committee of the Ministry of Health. Medicines for hospitals are normally purchased from wholesalers with the maximum wholesale mark-up of 9%. There is no pharmacy margin applied in hospitals. In the outpatient sector degressive wholesale and pharmacy margins are applied. Therefore, normally, the price of the same medicine in hospital is lower than in a community pharmacy. There is no direct reimbursement of pharmaceuticals in hospitals by health insurance companies. Pharmaceuticals for outpatients are directly reimbursed (fully or partially) by health insurances.

2.1.2 Hospital prices

In general hospital prices correspond to the pharmacy purchasing price. In order to calculate the prices for hospital medicines the maximum wholesale mark up (9%) and 10% value added tax (VAT) is added to the ex-factory price. No pharmacy mark ups are applied. The calculation scheme for hospital medicines is: maximum ex-factory price + maximum wholesaler mark up + value added tax (VAT) of 10%. The same VAT rate applies for pharmaceuticals in the outpatient sector. The standard VAT in Slovakia is 19%.

Discounts to hospitals from the suppliers are not mandatory. However, it is possible to receive voluntary discounts. Voluntary discounts may be granted ranging from 1–10% of the pharmacy purchasing price (wholesale price) of a medicine depending on the volume of medicines and payment terms.

The pharmacy purchasing prices of many hospital medicines which are purchased from wholesalers at a maximum ex-factory price with a maximum wholesaler mark up of 9% can be lower (for not very expensive pharmaceuticals) or higher (for very expensive pharmaceuticals) than prices in the outpatient sector. The reason for that is that degressive wholesale mark ups are applied in the outpatient sector and in the inpatient sector there is a fixed mark up of 9%. Hospitals can decrease prices of medicines by purchasing the them through tenders or direct negotiations with manufacturers or wholesalers. The examples can be found and calculated from Decree No. 07045-27/2009-OL on Price Regulation for hospitals and from the “Categorisation list of pharmaceuticals” for outpatient care.

In general there is only information on total pharmaceutical consumption (cf. section 4) in hospitals, there are no detailed price surveys on pharmaceuticals in the hospital sector.

On ex-factory price level, there is full transparency on official prices due to the public access to the Decree No. 07045-27/2009-OL on price regulation issued by the Ministry of Health. The information on prices of medicine through public tenders are not that transparent, since they are not publicly accessible. There is no legal obligation for hospitals, for hospital groups or hospital owners either to publish the medicine prices or to notify the price to a competent authority. Public information on maximum ex-factory prices for medicines for hospitals are officially available and can be accessed through the website[2] of the Ministry of Health. This price information is for free and covers all medicines used in hospitals. The price list is updated every 3 month.

Usually hospitals do not share information on purchasing medicines. Hospitals do only cooperate in case more hospitals are owned by the same owner (e.g. public hospitals in some regions of Slovakia, where the owner is a Territory Regional Unit). The exchange of information is mainly organised by the Territory Regional Unit.

[2] www.health.gov.sk

2.2 Pricing policies

2.2.1 Procurement

It is mandatory for a hospital to have procurement if the total expenditure of a pharmaceutical (active substance) exceeds € 30,000 per year. The conditions for public procurement are laid down in the Act No. 25/2006. According to this Act, the procurement documents have to include (example is given in brackets):

- specifications of the subject of public procurement (*alteplasum – medicine for blood and blood organs)*
- anticipated quantities (*620 original packages/2 years)*
- anticipated costs (*€165,600)*
- and the time period of contract *(2 years*)

Responsible for the organisation and evaluation of public procurement is always the "capable person for public procurement". This person passed an examination and is regularly trained by the Office for Public Procurement which is a state organisation. The person is also officially listed in the list of "capable persons for public procurement", which is published by the Office for Public Procurement. This person can be an employee of the hospital or can be appointed by the hospital on contract base. The director of the hospital nominates a committee for accepting the offers for public procurement and a committee for the evaluation of the offers of public procurement. There are mainly 3–6 persons in these committees consisting of the chief hospital pharmacists, pharmacologists and physicians (e.g. specialists, etc.). The announcement and results of public procurements are published in the official "Business bulletin"[3] which is published by the Office for Public Procurement.

Contracting the agencies from hospitals is an option, but the practice is that hospitals are organising procurement by themselves. In hospital groups owned by Territory Regional Units joint procurement is used.

The most relevant criteria for accepting a tender which could cover single medicines or a bundle of products covering separately the medicines and medical devices are:

- price of the pharmaceutical
- its medical benefit and
- therapeutic benefits.

Mostly wholesalers are concerned with procurement, not manufacturers. It is not common that hospitals share information about the procurement prices.

[3] http://www.uvo.gov.sk/

As already mentioned in section 2.1.2 the end prices of hospital pharmaceuticals are usually lower than prices in the outpatient sector because there is no pharmacy mark up added. Also due to the mechanisms of public tenders, market evaluation and direct negotiations with manufacturers and wholesalers, lower prices can be achieved. When the hospital does not use any pricing policy it is possible that the pharmacy purchasing prices in hospital pharmacy and community pharmacy for a pharmaceutical are very similar.

2.2.2 Others

Other pricing policies are: e.g. negotiations, market evaluation and direct negotiations with manufacturers and wholesalers.

In case annual expenditure are below € 30,000 but higher than € 15,000 the medicine (active substance) must be purchased by the hospital through “market evaluation”. The responsible person for market evaluation is the chief hospital pharmacist. The chief hospital pharmacist collects a minimum of three offers from different wholesalers for every medicine. The criteria for selecting the wholesaler include: e.g. the lowest price, availability of packages. In many hospitals this method is used for every individual pharmaceutical which is not purchased by public procurement. The chief hospital pharmacist must document the reasons for his/her decision in a written form. In many hospitals the final decision is made by the medical or economical director of the hospital and the chief pharmacist has an advisory role. Normally there are 5–30 pharmaceuticals in a hospital which must be purchased in form of public procurements, all other pharmaceuticals are purchased by the method of market evaluation or by direct negotiation with manufacturer or wholesaler. In these cases this is the responsibility of purchasing committees or medical/economic director or chief hospital pharmacist.

3 Reimbursement

3.1 National hospital reimbursement procedure

The legal framework of the reimbursement of medicines is laid down in the Decree of the Ministry of Health of Slovak Republic No. 07045-7/2004 and following directives which regulate prices of health care services. In this Decree maximum prices of health services (prices for so called „completed hospitalisation of an individual patient“, cf. section 1.3) provided to an individual inpatient by a specific hospital department are listed. The health insurance companies reimburse hospitals by a fixed fee for „completed hospitalisation” of every inpatient. The amount reimbursed for “completed hospitalisation” is different for every medical specialisation (e.g. internal medicine, oncology, surgery, anaesthesiology, etc.) and also differs from the type of hospital. For example, the maximum price of completed hospitalisation for an individual patient at the department of internal medicine is about € 300-2,000, psychiatry € 1,000, clinical oncology € 1,500, surgery € 600–1,000, anaesthesiology € 5,000, etc.

Every health insurance company makes an own contract with the hospitals and the prices for individual hospitals can vary. This is the only payment (reimbursement) that a hospital receives from a health insurance company. The expenditure of all pharmaceuticals provided to patients in hospitals are included in the reimbursement of the completed hospitalisation. Only in case the price of a medicine exceeds the price of the completed hospitalisation, the health insurance company may reimburse also the difference.

Medicines used in hospitals are financed through the hospital budget. There are no extra co-payments for patients. Therefore the decision on reimbursement (decision on which products will be purchased and used in hospital) is important also for the economic director and medical director of hospital. Besides medicines other expenses such as salaries for doctors, operational costs etc. need to be covered from the total hospital budget. The main share is covered by health insurance funds. There are few specific budgets provided for specific hospital pharmaceuticals, e.g. for growth hormone for children.

3.2 Hospital pharmaceutical formularies

In Slovakia specific hospital pharmaceutical formularies (HPF) are used as a standard tool with regard to reimbursement in hospitals. No country-wide positive or negative lists exist for the inpatient sector and HPF may differ also from the positive list for outpatient sector. Every hospital has one specific HPF and no joint HPF exist.

The pharmaceutical and therapeutic committee (PTC) is the responsible body for setting, developing and updating the HPF and is appointed by medical director of every hospital. A purchasing committee only exists in case medicines are purchased through public procure-

ment. Normally the medical director, the economic director and the chief hospital pharmacist are responsible for purchasing medicines for the hospital.

According to the legislation the hospital pharmacist is a decision taking member of the PTC of the hospital and usually holds the function of the secretary. The number of members of a PTC differs in each hospital and amounts to 5–7 members. A medical doctor is always the chairman of the PTC. Other members represent the most important medical specialisations of the hospital (e.g. internal medicine, anaesthesiology, surgery, etc.).

Normally once a year every medical specialisation or individual doctors can make proposals for the inclusion or deletion of a medicine to/from the HPF. The most important criteria for adding a medicine to the HPF are medical and therapeutic benefit, economic criteria like cost-effectiveness and budget impact. The PTC then decides on the inclusion or deletion of a pharmaceutical to/from the HPF. There are no financial restrictions for an exclusion of a pharmaceutical from the hospital formulary. In Slovakia the clinical pharmacologist is always a doctor. Only a few hospitals (less than 1% of all hospitals in Slovakia) have a clinical pharmacologist. In these hospitals the clinical pharmacologist is the chairman of a PTC. The clinical pharmacologist is especially involved in antibiotic therapy in the hospital, therapeutic drug monitoring and clinical trials.

In general only active substances are listed in the HPF. However, in many formularies there are also medicine specialities listed which is for information of medical doctors only. According to a survey performed in Slovakia in 2005 the average number of active substances in a hospital formulary is between 500 and 900 medicine specialities.

According to the legislation the Decree of the Ministry of Health No. 198/2001, on requirements of Good Pharmacy Practice, hospital formularies should by updated at least once a year. The HPF is published in a print form or is accessible electronically upon request in hospital pharmacy.

Hospital formularies are mandatory for doctors in hospitals. They may also choose other medicines for treatment under certain criteria e. g. for patients admitted to hospital and already treated with pharmaceuticals which are not on the HPF and are not interchangeable. In these cases doctors must clearly document the therapeutic need and benefit of this pharmaceutical for an individual patient which is not listed in HPF.

4 Consumption of pharmaceuticals

Basically the management of each hospital monitors and evaluates the pharmaceutical consumption of every department and compares the planned expenditure and real spending for each department (including medicines). The pharmaceuticals represent approximately 20-30% of the total hospital expenses, therefore monitoring of direct spending on pharmaceuticals is a very frequent tool. An analysis of pharmaceutical consumption linked to individual patients is mainly done in specialised hospitals (e.g. oncology institute or cardiovascular institute) and is related to expensive treatment (e.g. antibiotics, growth hormones, expensive medicines for oncology treatment, etc.).

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

Pharmaceutical consumption	2001	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in packs	148,748,950	139,097,499	144,760,887	149,377,432	158,292,641	161,125,064
in DDD	2,179,167,968	2,298,729,478	2,475,057,304	2,651,674,187	2,860,722,577	3,068,920,433
Value / EUR	633,193,928	655,596,174	713,095,539	827,583,493	950,252,897	1,063,918,197
Annual pharmaceutical consumption in hospitals						
in packs	10,991,818	11,015,257	11,663,910	11,859,657	13,903,646	13,589,633
in DDD	136,879,256	156,300,039	208,746,532	221,362,994	226,660,655	212,333,447
Value / EUR	67,029,228	72,101,752	77,533,170	94,058,227	117,102,557	118,707,786

DDD = Defined Daily Doses, EUR = Euro

Differences to pharmaceutical expenditure data indicated in table 1.4 are due to different sources. In table 1.4 National Health Information Center and HPI (Health Policy Institution estimation) is used where in table 4.1 the mean from 3 different local private sources is used. Nevertheless, differences are minor and trends are equal in both tables.

Source: Meean from 3 local sources, SUKL Bratislava-MCR, Pharmadata, IMS

Table 4.2 Slovakia – Top 10 pharmaceuticals by pharmaceutical consumption in hospitals - comparison of two data sources, 2008

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	A Unit (original packs)	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	B Unit (original packs)
1	B05BB01 – Sodium	5,231,128	1	B05BB01 - Sodium	6,907,023
2	B05BA03 – Glucosum	983,570	2	B05BA03 - Glucose	1,747,062
3	J01MA02 – Ciprofloxacin	397,637	3	A12BA - Potassium	713,551
4	H02AB09 – Hydrocortison	357,761	4	A12AA03 - Calcium	551,423
5	B05BB02 – Sodium + sacharides	306,144	5	H02AB09 - Hydrocortisone	377,220
6	N02BB02 – Metamisol natrium	225,035	6	J01MA02 - Ciprofloxacin	375,771
7	J01DD01 – Cefotaxim	184,799	7	N02BB02 - Metamizole sodium	314,432
8	N01BB – Amid	178,500	8	B05BB02 - Glucose 1-phosphate	263,939
9	A12CC02 – Magnesium	150,718	9	A12BA - Magnesium	263,139
10	V07AB – Infundibilia	150,188	10	A07FA01 - DL-Lactic acid	243,531

Source: A: SUKL reports from wholesalers, MCR, Bratislava; B: IMS, Bratislava

Table 4.3 Slovakia – Top 10 pharmaceuticals by pharmaceutical expenditure in hospitals - comparison of two data sources, 2008

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure	A € (thousands)	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure	B € (thousands)
1	B05BB01 – Sodium	6,412.82	1	B05BB01 - Sodium	7,640.94
2	L01CD02 – Docetaxel	4,636.68	2	L01CD02 - Docetaxel	4,793.96
3	L01XX19 – Irinotekan	3,968.02	3	L01XX19 - Irinotecan	4,286.04
4	J01MA02 – Ciprofloxacin	3,963.86	4	V08AB05 - Iopromide	4,125.47
5	L01CD01 – Paclitaxel	3,839.39	5	L01XA03 - Oxaliplatin	3,454.11
6	L01XA03 – Oxaliplatina	3,388.00	6	L03AB07 - Interferon Beta-1A	3,445.23
7	B01AB06 – Nadroparin	3,303.27	7	B01AB06 - Nadroparin calcium	3,278.93
8	B05AA01 – Albumin	2,943.93	8	L01CD01 - Paclitaxel	3,153.41
9	L03AB07 – Interferon beta-1a	2,793.51	9	L01BC05 - Gemcitabine	2,718.75
10	L01BC05 – Gemcitabin	2,634.28	10	A12BA - Potassium	2,450.73

Source: A: SUKL reports from wholesalers, MCR, Bratislava; B: IMS, Bratislava

5 Evaluation

5.1 Monitoring

Medicines used in hospitals are included in the total hospital budget. There is no co-payment for patients. Therefore evaluation, monitoring of price, expenditure and consumption of pharmaceuticals is of interest for the hospital management. Expenditure, prices and/or consumption of hospital pharmaceuticals are monitored in every hospital.

According the Act No. 140/1998 on Pharmaceuticals and Medical Devices concerning the monitoring of prices and consumption of pharmaceuticals and medical devices in hospitals there are two legal obligations:

1. The prices and consumption of pharmaceuticals used in hospitals can be monitored quarterly by regular reports from wholesalers to the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, SUKL). Every wholesaler has to report maximum ex-factory prices (rebates of tendering process not included in price) or pharmacy purchasing prices and the amount of pharmaceuticals delivered from the wholesaler to the hospital.
2. All hospital pharmacies and community pharmacies delivering pharmaceuticals and medical devices have by law the obligation to report quarterly to the National Centre for Health Information prices and consumption of pharmaceutical and medical devices.

This Act guarantees a very good traceability of medicines in Slovakia, concerning the monitoring of prices and consumption of pharmaceuticals and medical devices.

The data are publicly available at SUKL and the National Health Information Centre upon request.

At the time of writing there is no DRG system in place in hospitals in Slovakia. Some hospitals monitor medicines and medical devices expenditure as part of their overall evaluation of some specific financially very expensive procedures (e.g. in surgery, anaesthesiology, oncology, neurology, transplantation, etc). The results of this evaluation serve the hospital management as a basis for negotiations with health insurance funds for reimbursement of these specific procedures.

In every hospital there is a computerised tracking system for purchase orders, inventory control and stock-taking for medicines. The purchasing and delivering of medicines to hospital departments are computerised. A unit dose delivery system of medicines does not exist.

Clinical services of hospital pharmacies include medicines information and formulary services – preparing and diluting pharmaceuticals mainly for oncology patients in respective department. Direct recommendations of a hospital pharmacist to optimise medicines therapy for the individual patient are very rare.

The main communication tool of hospital pharmacists is the membership in many hospital committees (Pharmaceutical and Therapeutic Committee, Antibiotic Committee, Committee for Nosocomial (hospital acquired) Infections, Ethic Committee, Committee for Parenteral Nutrition, etc.)

There is an excellent collaboration between manufacturers, wholesalers, SUKL (coordinates all these activities), Health Offices of Territory Regional Units (municipal pharmacist) and hospital and community pharmacies. Any medicine can be withdrawn from the Slovak market very quickly.

5.2 Assessment

There are no special cost-effectiveness tools or external audit reports (e.g. HTA reports) concerning medicines in hospital settings.

In every hospital the expenditure and consumption of pharmaceuticals at hospital or department level are monitored and assessed by the Pharmaceutical and Therapeutic Committee (PTC). When needed the PTC creates general or specific guidelines and recommendations for the use of medicines in the hospital (e.g. guidelines and regulation of albumin use, antibiotic prophylaxis in surgery, centralised antibiotic policy in the hospital, rational use of Novoseven in anaesthesiology, etc.).

Rough estimations on possible savings achieved through pricing, rational use or cost-containment strategies with regard to medicines in hospital (e.g. guidelines and regulation of albumin use, antibiotic prophylaxis in surgery, centralised antibiotic policy in the hospital, rational use of Novoseven in anaesthesiology, etc.) are about 5–10% of expenditure of specific procedures or pharmaceuticals.

6 Interface management

According to the legislation hospitals have to provide the patient with medicines for 3 days after discharge. This is the responsibility of the doctor. In the hospital doctors and nurses are involved in interface management of medicines. There is no direct involvement of hospital pharmacists.

Moreover pharmaceutical consumption in hospitals may induce consumption in outpatient sector due to free pharmaceutical samples provided at the beginning of a therapy. Therefore sampling is regulated by law and limited to 3 samples of pharmaceuticals per doctor per year. It is not easy in practice to control the real practice.

A therapy in the inpatient sector especially in modern therapy (advanced therapy, oncology, etc.) starts with expensive treatment. Very often initiating treatment starts from offered samples from pharmaceutical companies as „starter packs". Continuation of therapy should be realised in the outpatient sector.

When patient are discharged from hospital, doctors provide patients with detailed description of the diagnosis, treatment in hospital sector and recommendations for continuation of the treatment in the outpatient sector. Doctors in the outpatient sector have an option but it is not obliged to follow the recommendations. In the majority of cases the recommendation for treatment is followed in the outpatient sector if this is in line with the reimbursement eligibility of medicines in the outpatient sector.

7 Developments and outlook

Insufficient resources to fully cover the generous scope of services, financial limitations in the contracts with health care providers and the debts outstanding from the health insurance funds resulted in debts reaching € 268 Mio mainly in specialised hospitals in the period of 2007. The Ministry of Health and the government are planning to solve this issue by helping selected hospitals to cover the debts based on submitted applications from the hospital management. These applications need to include a clear management plan provided from hospitals in order to indicate and guarantee good operational running of hospitals including managing operational costs and rational use of medicines.

The Ministry of Health of the Slovak Republic is preparing a new “Catalogue of Health Procedures” for the years 2010/11. Every health procedure in the catalogue will be described in detail and the maximum price (including medicines and medical devices) will be also defined and determined.

8 References and data sources

8.1 Literature and documents

Association of Insurance companies Slovakia (2007). Basic Frames for Health Care policy for years 2007–2011. Bratislava

Faculty Hospital (2008). Hospital Pharmaceutical Formulary. Bratislava

Health Policy Institute (2005). Sources in Health Care system. Bratislava

Institute for Health Information Centre (2005). Health Statistics Yearbook of the Slovak Republic 2004. Bratislava

Institute for Health Information Centre (2006). Health Statistics Yearbook of the Slovak Republic 2005. Bratislava

Institute for Health Information Centre (2007). Health Statistics Yearbook of the Slovak Republic 2006. Bratislava

Institute for Health Information Centre (2008). Health Statistics Yearbook of the Slovak Republic 2007. Bratislava

Jednotný automatizovaný systém právnych predpisov, JASPI Web (2009). Ministerstvo spravodlivosti. Slovenská republika, Source for respective Acts in Slovak republic. Bratislava

Kaló Z, Docteur E and Moïse P (2008). Pharmaceutical pricing and reimbursement policies in Slovakia. OECD health working paper N0. 31. OECD

Mazag J (2007). PPRI Pharma Profile: Slovakia, Pharmaceutical Pricing and Reimbursement Information project. Bratislava

Správa o činnosti Sekcie nemocničných lekárnikov SleK za rok (2008). Farm obzor, 10-11, 227–229

Stratégia liekovej politiky 2007-2010 (2007). Ministerstvo zdravotníctva. Bratislava

Web links

In this publication web link references to authorities and web addresses where information was obtained are made directly in the text.

A sample list of active substances as part of a hospital pharmaceutical formulary from the Faculty Hospital in Bratislava, 2008 can be asked for directly from Jan Mazag at

mazag@sukl.sk

8.2 Contacts

The author of the report received information from the Slovakian hospital inpatient sector by contacting the following institutions/persons:

- Slovak Association of Hospitals,
- Association of Faculty Hospitals, Slovakia,
- Slovak Association of Hospital Pharmacists,
- Insurance companies representatives and
- the hospital pharmacy in the Oncological Institute in Bratislava (personal visit).

The following national hospital experts contributed to the realisation of this report:

PharmDr. Dominik Tomek (SZP, Bratislava), PharmDr. Krc-Jediná (VsZP, Bratislava), MUDr. Ján Masaryk (SZP, Bratislava), MUDr. Lesáková (VsZP, Bratislava), MUDr. Kafková (ZP Union, Bratislava), MUDr. Janeková (NZZ, Bratislava), MUDr. Ottinger (Associácia nemocníc, Bratislava), MUDr. Petko (Asociácia nemocníc, Bratislava), MUDr. Šajty (Asociácia fakultných nemocníc, Košice), MUDr. Šálek (Onkologický ústav, Bratislava), MUDr. Msoli (SUSCH, Bratislava), Doc. PharmDr. Sýkora (Asociácia nemocničných lekárnikov, Bratislava), MUDr. Kausitz (NOU, Bratislava), PharmDr. Foltánová (FaF, UK), MUDr. Haško (FNsP, Bratislava).