Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

CZECH REPUBLIC

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

PHIS

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PHIS Hospital Pharma Report

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Executive Summary

- **Background**

Hospitals in the Czech Republic can be founded by the state, region or municipality as well as by a physical person or other legal body.

Until the end of 2002 all hospitals in the Czech Republic were state-owned, beginning with January 2003, a lot of them were transferred into non-state organisations.

In the Czech Republic we distinguish “classical hospitals” and separate Special Therapeutic Institutes (e.g. psychiatric institutes, institutes for long-term patients).

At the end of 2008, there were 192 hospitals in the Czech Republic, with 63,263 beds (of that 85.9% acute care beds). Divided according to the founder, there were 20 hospitals directly run by the Ministry of Health (11 university hospitals), 24 hospitals run by the region and 18 hospitals run by the city or municipality. There were 122 private health establishments - 102 hospitals and 20 nursing after-care hospitals. The founder of 3 hospitals is the Church, 5 hospitals fall within the duty of the Ministry of Defense and Justice.

Hospitals directly run by Ministry of Health provide specialized and highly specialized healthcare to the most demanding patients (e.g. transplantology, oncology).

In 2008 there were 153 specialised therapeutic institutes in the Czech Republic (68 institutes for long-term patients, 19 psychiatric institutes, this category includes also hospices and convalescent homes).

The structure of the network of hospitals is relatively stabilised in the Czech Republic. Primary out-patient care is stagnant in long terms. An ongoing decrease of acute-care bed capacity in hospitals, gradual decrease of bed capacity of the nursing after-care hospital departments and institutes for long-term patients, can be observed probably in connection with assignment of beds to provision of social services according to the new Act of Social Services.

Only pharmacies can supply -- hospitals with medicines - only pharmacies with specialised workplaces (not the basic ones) can deliver medicines to bed establishments. Infusion solutions and vaccines can be supplied directly to hospital´s wards by the wholesalers.

Pharmacies purchase medicines from the manufacturers or wholesalers. The hospital pharmacy often purchases the most expensive medicines (such as oncologic medicines, lowmoleculer heparins etc.) from the manufacturers.

In 2007 (as well as in the previous years), the major part of health service expenditure was funded by the system of public health insurance, which covered 78.4% of expenditure. The stated total expenditure presented 6.7% of the Gross Domestic Product (GDP) in 2007. Among all providers of healthcare, hospitals enjoy the dominant position. Settlements from health insurance companies, which represented 81% of all hospital revenues in 2007, are the main source of hospital incomes.

- **Pricing**

In the Czech Republic the purchasing of medicines and the setting of their prices in hospitals is decentrally organized, it depends on the hospital owner (state hospitals, others). There is no special tendering system for medicines, but according the Act on Public Procurement, public institutions and facilities are obliged to declare tender when buying pharmaceuticals exceeding a certain financial volume, mostly they are costly medicines and pharmaceuticals with high consumption – according to the focus of the individual hospital.

Medicines used in state hospitals (founded by Ministry of Health) have to be included in a hospital pharmaceutical formulary which has to be authorised by pharmaceutical commission. Hospitals have to purchase medicines exclusively from the pharmacies.

There is no legal framework in place which regulates the setting of the prices of medicines in hospitals. The price of a medicine is the result of a procurement or of a negotation procedure between the hospital and the manufacturer or wholesaler.

In general, purchase prices of medicines in hospital pharmacies are lower than those in community pharmacies – due to higher purchasing volumes, the manufacturer or wholesaler provides a major discount and other convenient purchasing conditions (very similar principle as in realised tenders). Prices in the hospital sector are considerably lower than in the out-patient sector, but the availability and transparency of pharmaceutical prices in the in-patient sector is misty, these informations are not publicly available.

- **Reimbursement of pharmaceuticals in hospitals**

Since 2008 the State Institute for Drug Control is the only institution involved in decisions on the level and conditions of reimbursement. Decisions about reimbursement (as well as setting the maximum ex-factory price) are made in individual administrative proceedings with the possibility to appeal to the Ministry of Health against the decision made by SUKL CZ. Only medicines with defined maximum ex-factory price are eligible for reimbursement. If a new pharmaceutical is authorized first the maximum price is appointed and then the level and conditions of reimbursement could be designated.

Prices of non-reimbursable medicines can be set freely.

There are not special pricing procedures for Hospital-Only Medicines or medicines used in hospitals in the Czech Republic.

There are two ways in which medicines are remunerated in the in-patient sector: Hospitals agree with sickness funds on a particular lump sum which involves also costs of medicines or they can charge pharmaceuticals provided to a specific patient directly to sickness fund (separately charged pharmaceuticals (ZULP)).

- **Consumption of pharmaceuticals**

The highest consumption of drugs in 2007 measured by numbers of packages was in groups of medicines for treatment of cardiovascular diseases (22.1 %), diseases of the nervous system (18.4 %), of the digestive tract and metabolism (12.9 %) and of the respiratory system (10.1 %).

Total expenditure on medicines in 2007 calculated with the methology of SUKL CZ was 67.16 thousand million CZK, which represented again an increase in accord with the long-term trend, after a singular decrease in 2006. The number of distributed packages increased by 7.22%, the financial value (calculated using SUKL CZ methodology) increased by 13.89 %. In 2008 317.7 million packages of pharmaceuticals were distributed.

- **Expenditure**

The trend on the evolution of public expenditure shows their steady growth.Total expenditures of hospitals in 2007 increased by 5.7 % from the preceding year. In 2007 approximately 8.6 % of public expenditure was from public budgets and 91.4 % was expenditure from public health insurance. The healthcare expenditure of health insurance companies increased from 2006 by 6.7 %. The large increase was in hospital care 8.8 %, the lowest increase was in costs of medicines and medical device (0.3 %).

- **Evaluation**

Checking of medicines used in hospital care differs depending on the founder of the hospital. State hospitals are obliged to comply with valid legal regulations and follow the Act on Public Procurement when purchasing medicines (when reaching a certain annual turnover, a tender needs to be carried out), moreover, doctors are obliged to use predominantly those medicines stated in PPL (pharmaceutical formulary) when providing healthcare. In other hospitals (especially in private establishments), medicines are purchased by hospital management for the prices taken from suppliers (wholesalers) who offer the most convenient trading conditions (usually on the basis of an agreement on a purchase price or special promotions, discounts, etc. during the year).

In the Czech Republic, there is no legal obligation of establishing a system of securing quality in healthcare facilities. In spite of this fact, there is a steady rise of hospitals which implement systems of quality management – usually through accreditation of healthcare facilities (focused especially on medical and nursing care) or ISO certification (particularly for laboratories, hospital pharmacies, etc.). Their aim is to ensure standardized and quality care in healthcare facilities.

Hospital pharmacies usually provide pharmaceutical care to hospitalized patients, patients released from healthcare facilities, out-patients and patients in the system of home care.

- **Developments and outlook**

The expenditures of medicines increase year by year in the Czech Republic, as well as in other countries. It is mainly due to the ageing of population and the availability of new medical proceedings and high-quality, but of course very expensive pharmacotherapy for more patients.

In the last years, there has been a reform of Czech Health Service carried out, bringing – among others – a major change in establishing the so-called regulation fees. Although this is a step bringing a lot of finances into the budget, it has met with a grudge in many places (both from the patients and political parties). So far there have been several changes suggested to reduce or cancel them completely, but none of the suggestions have been approved of by the parliament of the Czech Republic so far. It is likely that it would happen after setting up the new government – following the parliamentary elections, which will be held in autumn 2009.

On December 31 2008 the SUKL CZ began to operate the Central electronic prescription repository (CU) , as stipulated by the Act on Pharmaceuticals. Communication via the CU will result in the development of a system of electronic patient records, it will significantly enhance the effectiveness of communication among doctors, pharmacies and patients.

Table of content

List of tables and figures

List of abbreviations

AAC	The Associated Accreditation Committee
AH CZ	The Association of Hospitals in the Czech Republic
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic Therapeutic Chemical classification
BMG	Austrian Ministry of Health
CIVAS	Centralized Intravenous Admixtures Service
CZK	Czech crowns
CMA JEP	The Czech Medical Association of Jan Evagenlista Purkyně
CU	Central Electronic Prescription Repository
DDD	Defined Daily Doses
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
EU	European Union
GDP	Gross Domestic Product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital Pharmaceutical Formulary
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute
NCU	National Currency Unit
NHS	National Health Service
NRC	The National Reference Centre
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute

OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient department(s)
OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals
pcs.	Pieces
PE	Pharmaceutical Expenditure
PHE	Public Health Establishment
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
PZLU	Medicines and foods for special medical purposes
SHE	Specialised Health Establishment
SHI	Social Health Insurance
SHP CZ	The Section of Hospital Pharmacists in the Czech Republic
SUKL	Statny Ustav pre Kontrolu Lieciv / State Institute for Drug Control (Slovakia)
SUKL CZ	Statni Ustav pro Kontrolu Leciv / State Institute for Drug Control (Czech Republic)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UZIS	Institute of Health Information and Statistics of the Czech Republic
VAT	Value Added Tax
VZP	General Health Insurance Fund
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 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 pharmaceuticals,
- 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 pharmaceuticals 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 Act [1)] on Healthcare of Citizens defines the term of Hospital as a health establishment providing out-patient and in-patient basic and specialized diagnostic and medical care, which also includes the necessary preventive measures.

The Act [2)] on Public Non-profit Health Establishments for bed care defines the term Public non-profit health establishment (PHE), the main agenda of which is providing healthcare especially in the form of in-patient care, but also in the form of out-patient care. They are non-profit health establishments, the total profit of which must be used to manage their agenda.

Health establishments providing healthcare must be equipped professionally, rationally and technically for a specific kind and extent of healthcare - as requested by Public Notice [3)].

- Classical hospitals (in-patient and out-patient care) can be divided into university hospitals, hospitals and nursing after-care hospitals.

University hospitals – establishments for bed care and education founded by Ministry of Health. Its specialised facilities are educational bases of medical and pharmaceutical faculties and of post-gradual education of physicians and pharmacists. They provide out-patient care, acute bed care, health care in specialised and higly specialised branches (disciplines). Exceptionally they also may provide subsequent and nursing care.

Acute care hospitals – establishments for bed care. They provide out-patient care, acute bed care as well as subsequent and nursing care in specialised and highly specialised branches (disciplines).

Hospitals of nursing after-care – establishments for bed care. They provide out-patient care and bed care consisting only in nursing and subsequent care following acute care that had been provided to the patient in another establishment.

- Specialised Therapeutic Institutes, which are specialized usually according to the kind of illnesses. Their care is consequential with the care provided by hospitals and policlinics. Specialised Therapeutic Institutes are e.g. institutes for treatment of TB and respiratory diseases, psychiatric institutes, rehabilitation institutes and other special therapeutic institutes and sanatoria.

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1) The Act No. 20/1966 Coll., as amended, on Healthcare of Citizens

2) The Act No. 245/2006 Coll., as amended, on Public Non-profit Health Establishments for bed care

3) The Public Notice No. 49/1993 Coll., as amended, on Material and Technical Equipment

There are in the UZIS Statistics [4)] rank among the specialised therapeutic institutes also institutes for log-term patients and hospices.

Institutes for long-term patients – health establishments for bed care, they provide specialised bed care focused mainly on nursing care and rehabilitation, mostly to persons suffering from long-standing illness (prevalently to elderly and chronic patients).

Hospices – health establishments for bed care. Care is based on palliative therapy provided to patients in high or terminal stages of disease when the therapy leading to cure is no more possible. Its purpose is to alleviate the patient´s pain and create conditions for quiet and respectful death.

The division of hospitals is possible according to their founder - state, region, city or municipality and private facilities.

It is possible to claim that the definition of activities providing in hospitals (health establishments) is similar to the OECD definition. But the subtypes of hospitals are slightly different, we distinguish “classical” hospitals (university hospitals, hospitals and nursing after-care hospitals) and separately Special therapeutic institutes (e.g. psychiatric institutes, institutes for long-term patients) and others (emergency service, day clinics, balneologic institutes et al.). Also the UZIS statistics [4)] rank specific therapeutic institutes separately from hospitals.

1.2 Organisation

Until the end of 2002 all hospitals in the Czech Republic were state-owned, beginning with January 2003, a lot of them were – in compliance with the Act [5)] – transferred into the region´s competences as non-state allowance organisations and during the following years, some of them were transformed into trading companies whose sole stockholder is the region (city). The main reason for the transformation was high indebtedness of formerly regional hospitals. In 2006, there were 34 hospitals – trading companies with a 100% share of public property, in 2008 there were 51 these hospitals.

Health establishments in the Czech Republic can be founded by state, region or municipality as well as physical person or other legal body. They can be also owned by more founders.

The Act [2)] states that the founders approve of the budget of the healthcare facility which they have founded. The Public Health Establishment (PHE, see 1.1.) is obliged to observe regulations of public procurement (tender) when purchasing goods and services. It is obliged to publish (in a manner allowing for remote access) the conditions and results of contractual proceedings and all offers including costs. PHE manages the property deposited by the founder and property gained by its own activities. All its incomes must be used for management and development of this facility.

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4) Institute of Health Information and Statistics of the Czech Republic (UZIS)
http://www.uzis.cz/news.php?mnu_id=1100

5) The Act No. 290/2002 Coll., on change over of items, power and engagement to regions and municipality

PHE is obliged to publish regularly (in a manner allowing for remote access) the complete list of all its suppliers together with the specification of purchased goods and services. The regular inspection of its management is carried out by the founder and Ministry of Health. The facility makes all arrangements in compliance with its budget approved by the founder. The revenues of PHE are particularly the finances from public health insurance, grants from public budgets, support of research and projects and settlements for providing services to citizens in compliance with the public interest.

The network of health establishments must be structured in a way that all subregional territories of PHE within the region are consequential and the availability of healthcare is ensured.

The Act on Healthcare in Non-state Health Establishments [6)] states that they can be run by either a physical person or other legal body to do so according to the above-mentioned Act. Non-state Health Establishments are obliged to provide healthcare to the extent and kind as stated in the Dictum on Registration issued by the respective regional authority according to the place of operation.

At the end of 2008, there were 192 hospitals in the Czech Republic, with 63,263 beds (of that 3.4 % newborns´cots, 10.7 % nursing care beds and 85.9% acute care beds). Divided according to the founder, there were 20 hospitals directly run by the Ministry of Health - out of this number, there were 11 university hospitals and 9 hospitals. There are 24 hospitals run by the region (14.9% of all beds) and 18 hospitals run by the city or municipality (6.3% of all beds). There were 122 private hospitals - 102 hospitals and 20 nursing after-care hospitals (other legal body as founder – 48% of all beds). These private health establishments include 51 hospitals – trading companies with the 100% share of public (regional or munticipal) property. These facilities present almost 70% of private bed capacity of hospitals. The founder of 3 hospitals is the Church, five facilities fall within the Ministry of Defense and Justice (2.3% of all beds) [4)].

The number of beds includes acute-care beds, new-born beds and after-care beds.

The bed capacity of university hospitals (11 facilities) represents 25.5% of all beds, after-care hospitals (28 facilities) represent 3.7%.

By the end of 2008 there were 14,479 beds for nursing after-care in the Czech republic, of that 6,756 beds were in hospitals, 7,194 in institutes for long-term patients, 366 beds in hospices and 163 beds in other specialised therapeutic institutes.

In 2008 there were 153 specialised therapeutic institutes in the Czech Republic (68 institutes for long-term patients, 19 psychiatric institutes, this category including also hospices and convalescent homes). Beds in psychiatric institutes presented 42% of the total bed capacity, beds in institutes for long-term patients presented almost 33% [4)].

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6) The Act No.160/1992 Coll., as amended, on Healthcare in Non-state Health Establishments

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

In-patient care	2000	2004	2005	2006	2007	2008
No. of hospitals [1)]	**211**	**197**	**195**	**191**	**192**	**192**
hospitals + spec.therap.instit.	n.a.	***363***	***358***	***353***	***345***	***346***
Classified according to ownership						
- thereof public hospitals (state, region, city and municipality)	n.a.	114	100	93	70	70
- thereof private hospitals (physician person, other legal body, church)	n.a.	83	95	98	122	122
- *other hospitals* [2)] *(specialised therapeutic institutes)*	n.a.	*166*	*163*	*162*	*153*	*154*
No. of acute care beds - hospitals	60,349	56,694	56,111	55,296	54,903	54,326
- thereof in the public [3)] sector	n.a.	n.a.	42,113	39,479	29,748	29,204
- thereof in the private sector	n.a.	n.a.	13,998	15,817	25,155	25,122
No. of beds – spec. therap.instit.	*22,667*	*23,189*	*22,874*	*22,714*	*22,191*	*22,005*
Average length of stay in hospitals – acute care beds	n.a.	7.4	7.2	7.1	7.0	6.7
Average length of stay in hospitals	8.6	8.1	8.0	7.8	7.7	7.4
No. of hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	86
thereof no. of hospital pharmacies that serve out-patients	n.a.	n.a.	n.a.	n.a.	n.a.	83

[1)] only "classical" hospitals - without Specialised Therapeutic Institutes [2)], [3)] Founders: Ministry of Health, region, city, municipality
n.a. – not available

Source: UZIS, SUKL CZ

The acute-care beds´ numbers have decreased significantly in comparison with 2007 – by 577 pcs. (from 54,903 to 54,326 beds); on the contrary the bed capacity of the nursing after-care has increased – by 183 beds (from 6,573 to 6,756). The number of acute-care in-patients has decreased by 1.2% in comparison with 2007, on the contrary the number of in-patients of the nursing after-care has increased by 3.7%. However, the usage of bed capacity has decreased both in case of acute-care beds and beds of nursing after-care. The reason is not only the limited finances in consequence of the increase of costs for services, but also quickly developing medical processes (techniques) shortening the stay of in-patients on the acute-care beds; another possible reason is the implementation of regulation fees for staying in hospital. The decrease in provided acute care is probably also influenced by the Act of Social Services [7)] which enables the individuals dependent on the help of another individual to draw a financial contribution (according to the level of dependence). We can also presume that a significant part of provided nursing after-care has shifted to the beds of social hospitalization, which are not figured into the hospital bed fund (social hospitalisation represented the increase by 57% in 2008).

7) The Act No. 108/2006 Coll. of Social Services

According to the capacity of beds (bed fund), “classical” hospitals can be divided as follows: less than 100 beds there are total of 48 hospitals, 18 of them are hospitals with nursing after-care where more than a half of beds is devoted to nursing care. With 100-300 beds there are 73 hospitals and with more than 300 beds there are 71 hospitals, more than 1,000 beds out of this amount 12 hospitals (10 of them are university hospitals).

State health establishments: Founders: Ministry of Health - 20 establishments (28% of all hospital beds) and Ministry of Defence and Justice – 5 establishments (2.3% of all hospital beds)

Non-state health establishments: Founders:

PUBLIC: region - 24 establishments (14.9% beds), city, municipality - 18 establishments (6.3% beds),

PRIVATE: the Church - 3 establishments (0.6%), other legal body - 122 establishments (48% of all hospital beds).

In 2008 there were 192 hospitals with 63,263 beds in the Czech Republic; 54,326 – 85.87% of them being acute-care beds (the average length of stay was 6.7 days), 2,181 – 3.4% of them being new-born beds (the average length of stay was 5 days) and 6,756 – 10.7% of them being beds of follow-up nursing care (the average length of stay was 42.3 days).

Hospitals directly run by Ministry of Health provide specialized and highly specialized health-care to the most demanding patients (e.g. transplantology, oncology). In the last years, the focus has been to centralize this highly specialized healthcare in well-chosen, best-equipped health establishments. Currently there are 13 accredited Comprehensive Oncologic Centers (KOC) to which the most complicated and the cost-intensive health care of oncologic patients was moved. Some hospitals traditionally specialize for treatment of specific diseases such as for example the Masaryk Memorial Cancer Institute in Brno specializes for treatment of malignant diseases or the Institute of Clinical and Experimental Medicine in Prague which is specialised in treatment of cardiovascular diseases, transplantations and disorders of metabolism.

The structure of the network of health establishments is relatively stabilised in the Czech Republic. Primary out-patient care is stagnant in long terms. An ongoing decrease of acute-care bed capacity in hospitals, gradual decrease of bed capacity of the nursing after-care hospital departments and institutes for long-term patients, has probably to be seen in connection with assignment of beds to provision of social services according to the new Act [7)].

The hospital pharmacy is a part of a health establishment providing in-patient care. Currently there are 86 hospital pharmacies in the Czech Republic, whose founder is the hospital (only 21 of them are state-owned). In case of the other hospital pharmacies the founder is different. Hospital pharmacies in the Czech Republic are allowed to dispense to out-patients. Apart from few exceptions, dispensing of medicines to out-patients is a part of the agenda of these pharmacies. On the contrary, the hospitals of nursing after-care, institutes for long-term patients, hospices and psychiatric institutes rarely have their own pharmacy.

In 2007 there were on average 6 pharmacists and 7 pharmaceutical assistants working in a hospital pharmacy. In pharmacies of large hospitals (mainly university hospitals), there are approximately 10 - 15 pharmacists and 20 - 30 pharmaceutical assistants.

The range of medicines in hospital pharmacies also includes special expensive medicines – the average value of pharmaceuticals included in one prescription in a hospital pharmacy in 2007 was approximately 2.6 times higher than the one in a community pharmacy [4)].

Implementary regulation of the Act on Pharmaceuticals [8)] – Public Notice on Proper Pharmaceutical Practice and Conditions of Dealing with Pharmaceuticals in Health Establishments [9)] states that only pharmacy can supply (both in-patient and ou-tpatient) health establishments with medicines. Only infusion solutions and vaccines can be supplied by the wholesalers. Only pharmacies with specialised workplaces (not the basic ones) can deliver pharmaceuticals to hospitals (bed establishments) [3)]. Pharmacies purchase pharmaceuticals from the manufacturers or wholesalers. In 2007 there were 224 companies with wholesale license. However there are only 4 major full line wholesale companies – Gehe Pharma Praha, Phoenix, Alliance Healthcare and Pharmos. They are associated in the Association of Wholesalers (Asociace velkodistributorů – AVEL). The four major wholesalers support the majority of the pharmaceutical market and of supply hospital pharmacies. The hospital pharmacies often purchase the most expensive medicines (such as oncologic medicines) from the manufacturers.

Table 1.2: Czech Republic – Medicines, 2000 and 2005–2009

Number of medicines	2000	2005	2006	2007	2008	2009
Authorised medicines in total [1)]	16,022	30,841	38,596	47,179	50,408	n.a.
- thereof hospital-only medicines	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1)] on the 31.12. of each year

– incl. different pharmaceutical form, different pack sizes and different dosages (only for human use, not included homeopathic products)

Source: State Institute for Drug Control (SUKL CZ)

According to type of defined symbol of reimbursement and form of remuneration (in competency of SUKL CZ by the Act [10)] and Notice [11)]) we can define several categories of medicines which are in use within the scope of hospitals (in-patient care) or occasionally within the scope of out-patient care. We have e.g. categories with prescribing limitation ("L"), with indication limitation ("P"), with increased remuneration ("V"), medicines administered in out-patient care ("A"), pharmaceuticals administered in specialised health establishments ("S") and others.

8) The Act No. 378/2007 Coll., as amended, on Pharmaceuticals

9) The Public Notice No. 84/2008 Coll., on Proper Pharmaceutical Practice and Conditions of Dealing with Pharmaceuticals in Health Establishments

10) The Act No. 48/1997 Coll., as amended, on Public Health Insurance

11) The Public Notice No. 92/2008 Coll., on assesment list of reference basket states and reimbursement of pharmaceuticals

There is a list of Specialised health establishment (SHE) [12)] on the internet website of General Health Insurance Fund (Vseobecna zdravotni pojistovna, VZP). SHE are centers with special contracts with health insurance funds, VZP appoints special reimbursed mechanismes for medicines with the ymbol “S”. There is a list of ATC codes which can be prescribed by each mentioned health establishment (e.g. these are hematoncologic and oncologic medicines - monoclonal antibodies, medicines for Crohn´s disease, ulcerative colitis, rheumatoid arthritis, hard psoriasis and others).

There is category of medicines, which are remunerated to a contractual healthcare facility of in-patient care from health insurance in a form of a pharmaceutical lump-sum. When being prescribed, they are not remunerated by health insurance. These medicines are marked with H in the column “LIM1” of the Czech medicine pricelist. They are mostly infusion solutions, infusions of proteins, lipids and other nutrients.

The Association of Hospitals in the Czech Republic (AH CZ) was established in 1993 as an interest group of in-patient healthcare facilities, medical institutions and research institutes in the Czech Republic, to organize and support mutual help and cooperation and implement other interests of its members. The main target is the development and improvement in providing healthcare services, extension of scientific and research knowledge in healthcare facilities´ operations and establishing cooperation with similar foreign institutions. The internet websites [13)] of AH CZ contain the address list of registered teaching hospitals, other hospitals and specialized medical institutions. AH CZ has been a corporate member of HOPE since 2004.

Public organisations (including state hospitals) in the Czech Republic have statutory duty to provide for data of activities in a previous calendar year via Annual Report [14)] .

Out-patient care

Citizens of the Czech Republic have a right of free choice of out-patient doctors (GPs, dentists, gynaecologists or other specialists). Although it is recommended, there is no need to have a referral from GPs if specialist care is needed. This might be one of the factors that lead to over-use of primary health care. At the beginning of 2008 fixed regulatory fees were introduced to limit patient´s visits at the doctors (CZK 30 for a regular visit and CZK 90 for emergency visit). Regulatory fees are paid out-of pocket. First surveys show a decrease in visit rate of ambulatory specialists by 28% compared to the same period in 2007.

Doctors in primary care are generally private. They can work either alone (most commonly) or within out-patient clinics that provide primary health care in addition to specialist care. Out-patient doctors working as ambulatory specialists in the state hospitals are usually hospital staff.

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12) http://www.vzp.cz/cms/internet/cz/Lekari/Informace-pro-praxi/Seznam_ZZ_03_09.xls

13) http://www.ancr.cz/

14) The Act No. 106/1999 Coll., as amended, on free access to information

1.3 Funding

The Czech health care system is based on mandatory health insurance that is also the main source of funding. Insurance composes of contributions from individuals, employers and state. Health care is co-financed by state or municipal budgets and out-of-pocket payments.

Currently there are 10 health insurance funds with predominant position of the General Health Insurance Fund (VZP). VZP was established by law [15)] in 1991. It is the dominant one, covering 70% of the population. In order to start a new insurance fund, an application must be submitted to the Ministry of Health and the Ministry of Finance. The conditions are laid down in Act [16)].

Public expenditures are considered to be the state budget, regional and municipal budget expenditures as well as the expenditures of public health insurance.

In 2007 (as well as in the previous years), the major part of health expenditure was funded by the system of public health insurance, that covered 78.4% of the expenditure. The state and regional budget covered 7.4% of the total expenditure and private expenditure covered 14.2%. The mutual proportion of the above-mentioned individual sources of financing has remained roughly the same in the last few years. The stated total expenditure presented 6.7% of the Gross Domestic Product (GDP) in 2007 [4)].

Among all providers of healthcare, hospitals enjoy the dominant position. Settlements from health insurance funds, which represented 81% of all hospital revenues in 2007, are the main source of hospital incomes.

The significant share of expenditure is represented by the expenditure of medicines. The total financial expenditure in 2007 amounted to 67.16 mld. CZK, which means an increase by 13.9% in comparison with the previous year [4)].

Conditions for providing healthcare and its payments are defined by the Act on Public Health Insurance [10)]. The health insurance fund is obliged to conclude a Contract of providing healthcare and its payments with a public non-profit healthcare facility registered among the public healthcare facilities.

The list of medical performances together with their points evaluation is issued by Ministry of Health´s Public Notice [17)]. Health insurance funds cover the costs of medicines to the health establishments using a lump-sum, its value is dealt with in the Contract (united for in-patient and out-patient care in the hospital). The health insurance fund covers the costs of medicines which exceed the given lump-sum as stated in the Supplement of the Act [10)] such a way of covering the costs is decided over by the SUKL CZ.

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15) The Act No. 551/1991 Coll., on the General Health Insurance Fund

16) The Act No. 280/1992 Coll, on department, occupational, business and other health insurance funds

17) The Public Notice No. 464/2008 Sb. , on assesment point price and remuneration healthcare

Table 1.3: Czech Republic – Health and pharmaceutical expenditure, 2000 and 2004-2008

Expenditure (in million CZK)	2000	2004	2005	2006	2007	2008 *
Total health expenditure (THE)	146,835	209,270	218,774	226,810	241,935	259,245
- thereof THE public [1)]	132,962	184,825	191,356	197,027	206,565	219,119
thereof THE private	13,873	24,445	27,418	29,783	35,370	40,126
THE in hospitals (HOSHE)	62,967	84,694	89,451	97,254	103,734	112,089
thereof HOSHE public	58,761	72,816	74,507	76,835	76,010	73,274
thereof HOSHE private	4,206	11,878	14,944	20,419	27,724	38,815
Total pharmaceutical expenditure (TPE)	38,4	57,0	64,9	59,0	67,2	72,75
- thereof TPE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof TPE private [2)]	*7,612*	*10,144*	*11,089*	*12,067*	*13,902*	*15,154*
Pharmaceutical expenditure in hospitals (HOSPE)	5,434	6,519	6,749	8,099	11,778	13,317
- thereof HOSPE public	5,190	5,810	5,875	6,784	9,631	10,203
- thereof HOSPE private	0,244	0,709	0,874	1,315	2,147	3,114

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

1) state and territorial budgets + health insurance corporations

2) direct cash expenditure of population in pharmacies (OTC + supplementary payments on prescriptions)

Source: UZIS, Ministry of Health * preliminary data (will be specify in 4Q 2009)

In 2008 health care in hospitals in the Czech Republic was provided to 79,068 foreigners with total costs of the respective health care 555 million CZK. Out of this number 40,189 treated foreigners were of EU citizenship. The most frequently treated patients were persons originating from Slovakia, Ukraine, Germany and Vietnam. The most frequent way of payment for health care provided to foreigners in respect of value was cash and utilization of foreign health insurance. Outstanding debts after due date for health care provided to foreigners reached 44 million CZK at the end of 2008 [4)].

As for the payments for healthcare provided to foreigners in hospitals, the biggest share is made up by cash payments. Expressed by the amount of people, cash payments were carried out in 48.1% of the patients.

2 Pricing

2.1 Organisation

2.1.1 Framework

In the Czech Republic the purchasing of medicines and the setting of their prices in hospitals is decentrally organized, it depens on the hospital owner (state hospitals, others). There is no special tendering system for medicines, but according the Act [18)] on Public Procurement, public institutions and facilities are obliged to declare tender when buying medicines exceeding a certain financial volume, mostly they are costly medicines and pharmaceuticals with high consumption – depending on the focus of the individual hospital.

Medicines used in state hospitals (founded by Ministry of Health) have to be included in a hospital pharmaceutical formulary which has to be authorised by a pharmaceutical commission. Pharmaceutical formularies were put into operation in hospitals founded by Ministry of Health in a directive way in 2005. Pharmaceutical formulary is available to the doctors through computer nets (hospital IT-system) at the hospital. Each hospital founded by Ministry of Health disposes of its own hospital pharmaceutical formulary.

Pharmaceutical committees are established in state hospitals, which are in charge of the purchase and procurement of medicines. These committees are mostly comparised of the chief of the hospital pharmacy, the management of the hospital, the managing doctors of the wards and other hospital experts.

The hospitals are obliged to purchase medicines exclusively from pharmacies [9)]. Only pharmacies with specialised workplaces (not the basic ones) can deliver medicines to hospitals (bed establishments) [3)]. Infusion solutions and vaccines can be supplied directly to hospital´s wards by the wholesalers.

There is no legal framework in place which regulates the setting of the prices of medicines in hospitals. The price of a medicine is the result of a procurement procedure or of a negotiation between the hospital (hospital pharmacy) and the manufacturer or wholesaler.

Primarily state hospitals have their own pharmacies (hospital pharmacies) which buy pharmaceuticals based on the results of the public procurement or negotiations. It is the objective to agree on the lowest possible purchase price.

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18) The Act. No. 137/2006 Coll. , on Public Procurement Act

Hospitals without their own pharmacy can buy medicines from community pharmacies.Usually these pharmacies offer medicines to hospitals at lower prices (lowered mark-up) due anticipated higher purchase volumes. There is competition between community pharmacies to cooperate with hospitals in the Czech Republic.

Provided that the owner of more hospitals is one private subject (e.g. legal body), not all its hospitals have their own pharmacies. Very often it is only a community pharmacy for out-patient services which delivers medicines to the hospitals. The hospital management purchases centrally in one of its pharmacies with specialised working places, which is allowed to deliver medicines to the hospitals and supply all their hospitals centrally.

In general, cost intensive medicines and pharmaceuticals with high consumption are bought from the manufacturers, other common medicines are usually purchased from wholesalers. In most cases negotiations between the hospital pharmacy (or hospital management) and wholesalers are take place.

In general, purchase prices of medicines in hospital pharmacies are lower than those in community pharmacies – due to higher purchasing volumes, the manufacturer or wholesaler provides a major discount and other convenient purchasing conditions (very similar principle as in realised tenders).

After being released from the hospitals, the patients receive prescriptions for medicines, which had been prescribed to them during their hospitalization. Doctors prescribe medicines using their brand name. Also medicines prescribed by out-patient doctors are often chosen by tenders and doctors are thus obliged to prescribe them preferentially (medicines with high consumption and financial expenditures). The main intention of hospitals is dispensing the medicines to pateints directly in a hospital pharmacy. patients usually do not pay any additional fees for them, since hospital pharmacies reduce these fees to a minimum so that patients do not have a reason to collect them elsewhere.

2.1.2 Hospital prices

In general hospitals buy pharmaceuticals via hospital pharmacies directly from manufacturers at the ex-factory price or a special price, which can be lower then the official ex-factory price (e.g. rebates in cash). Due to the high pharmaceutical consumption in hospitals substantial discounts can be reached during the purchasing process.

In state hospitals (they have their own pharmacies) the “hospital price” corresponds to pharmacy purchase price - ex-factory price or lower price + VAT 9%, from manufacturers ex-factory price + wholesaler mark-up + VAT 9%. These prices are charged to the hospitals.

Community pharmacies supplying the non-state hospitals are allowed to add their own mark-up, these medicines are regulated according to generally true order (maximum ex-factory price and regressive mark-up scheme).

There is no mandatory system of discounts or rebates applied to pharmaceutical industry, wholesalers or pharmacies.

In general, prices in the hospital sector are considerably lower than in the out-patient sector, but the availability and transparency of pharmaceutical prices in the in-patient sector is misty, these informations are not publicly available.

In the Czech Republic there is no legal obligation to report prices of medicines used in hospitals. The information of the prices of the hospital pharmaceuticals are not available for the general public.

The Act of Advertisement [19)] allows using a small amount of medicines supplied as free samples for doctors (in-patient and out-patient).

2.2 Pricing policies

It is the main objective of hospitals to receive the lowest price for the medicines needed.

2.2.1 Procurement

The hospitals (all health establishments) have to purchase medicines (excluding the infusion solution and vaccines) only from pharmacies.

There is no special tendering system for medicines in the Czech Republic, but according to Act.[18)] public institutions and facilities are obliged to declare tender when buying products and services exceeding a certain financial volume.

The results of the procurement procedure are available on-line and this information is accessible to the participants of this procedure.

Pharmaceutical committees in the state hospitals are in charge of purchasing medicines and the procurement (tendering). The committees are mostly comparised of the chief of hospital pharmacy, the management of the hospital and the main doctors. They are involved in the pharmaceutical policy – the pharmaceutical committee, the hospital pharmacy, the economic section and in some cases the antibiotic centre and the workplace of the clinical pharmacology.

19) The Act No. 40/1995 Coll., as amended, on advertisement

2.2.2 Negotations

Negotiations are the important way to purchase pharmaceuticals in hospitals. In case of medicines with identical active substance (original vs generics) the selection of the provider is most often dependent on the best offer (the lowest price). If the direct comparison of the medicines is not feasible, further decision criteria are: efectiveness, medical and therapeutic criteria, etc.If there are no alternative medicines – the hospital pharmacy (hospital management) tries to achieve a special discounted price for these medicine.

It often happens during the year that pharmaceutical companies propose hospital pharmacies to bargain offers for certain pharmaceuticals (e.g. for reasons of short expiry dates). This purchase can be implemented if this offer is not in defiance of binding agreements (e.g. it is a deal to the result of public procurement).

2.2.3. Other – price competition

As a complement to the general pricing system there is an instrument called Price Competition [10)]. If requested by health insurance companies or by manufacturers / wholesalers, SUKL CZ is authorised to announce competition for the lowest retail price of the medicine in specific reference group (group of different active substances with similar effect). If the bid from one of the manufacturers is lower then valid reimbursement amount the price is accepted. The manufacturer (winner) with the lowest price is obliged to supply the market with the pharmaceutical for a certain time period (12 month). The basic reimbursement amount for this reference group is revised according to the new lowest price [20)].

20) § 39e of The Act No. 48/1997 Coll., as amended, on Public Health Insurance

3 Reimbursement

3.1 National hospital reimbursement procedure

Eligibility criteria for reimbursement are the same for both in-patient and out-patient sector.

Since April 2008 SUKL CZ has been processing and publishing on its website the List of reimbursed medicines and foods for special medicinal purposes, which is SUKL CZ´ obligation of Act [10)]. The list is processed on the basis of decisions about maximum prices and conditions and levels of reimbursements which, since 2008, have been issued by the SUKL CZ Price and Reimbursement Branch in the form of administrative procedures. Other sources for this List are, in particular, the SUKL CZ Database of medicines, and overview of agreed prices provided to the SUKL CZ by the General Health Insurance Company (VZP), producer price reports for products excluded from the maximum price regulation and data provided by the marketing authorization holders in compliance with the Act [8)] (placement on the market / discontinuation of supplies of medicines).

The list is being published both in the xml format intended for reading and in the txt format intended for downloading. In August 2008 the SUKL CZ, furthermore, took over the area of determining of allowable additional payments which was originally within the powers of the Ministry of Health.

SUKL CZ furthermore publishes a list of medicines which are not reimbursed from the health insurance as a supplement to the SUKL CZ Index and to the List of reimbursed pharmaceuticals and foods for special medical purposes. This publication is not SUKL CZ´s statutory duty, but an initiative to facilitate the needs of healthcare professionals. The purpose of the list is to provide medical doctors with an overview of medicines not covered by the health insurance which may be prescribed. The list is restricted to medicines which are currently on the market and it does not include products which actually cannot be prescribed for out-patients (such as radiopharmaceuticals, infusion solutions). [21)]

Since 2008 the State Institute for Drug Control is the only institution involved in decisions on the level and conditions of reimbursement. Decisions about reimbursement (as well as setting the maximum ex-factory price) are made in individual administrative proceedings with the possibility to appeal to the Ministry of Health against the decision made by SUKL. The Act [10)] and the Public Notice [11)] issue clear rules for setting reimbursement. Only medicines with defined maximum ex-factory price are eligible for reimbursement. If a new medicine is authorized first the maximum price is appointed and then the level and conditions of reimbursement could be designated. Prices of non-reimbursable medicines can be set freely.

21) Annual Report 2008 SUKL CZ

SUKL CZ issues and periodically up-dates a list of reimbursed medicines (positive list). Up-dates are done once a month. There is also a list of therapeutic substances designated for supportive and complementary treatment issued by the Ministry of Health in a Public Notice [22)].

Medicines are either appointed a certain level of reimbursement or not. No reimbursement categories are applied. There is also a possibility to appoint two levels of reimbursement to one pharmaceutical depending on different indication.

Revision of the reimbursement system must be done at least once a year and it is the responsibility of SUKL CZ. Subject to the revision are: fulfilling of expected outcomes of pharmacotherapy, suitability of reference groups, level and conditions of basic reimbursement, assessment of cost and clinical effectiveness in comparison with original objectives of pharmacotherapy.

There are two ways in which medicines are remunerated in in-patient sector. Hospitals agree with sickness funds on a particular lump sum which involves also costs of medicines or they can charge pharmaceuticals provided to a specific patient directly to sickness funds - medicines are covered in the lump sum of hospitals or as separately charged pharmaceuticals (ZULP).

Patients do not pay for medicines used during their hospitalization.

In connection with providing remunareted in-patient care, the patients are obliged to pay a regulation fee to the health establishments – for each day spent in hospital (60 CZK). The regulation fee is the income of the healthcare establishment. The health establishment is obliged to inform health insurance companies on collected regulation fees. The Act [10)] defines which exceptions from paying regulation fees exist.

On health fees there has been a heavy political pressure almost since the implementation of this instrument in 2008. So far there have been several changes suggested to reduce or cancel them completely, but none of the suggestions has been approved by the parliament of the Czech Republic so far. It is likely that it would happen after setting up the new government – following the parliamentary elections, which will be held in autumn 2009.

22) The Publice Notice No. 385/2007 Coll., on assesment list of active substances for supportive and complementary therapy

3.2 Hospital pharmaceutical formularies

The development of the policy regarding medicines was influenced especially by establishing drug (pharmaceutical) committees and introducing pharmaceutical formularies *(in czech we say „pozitivní lékové listy" – positive pharmaceutical lists*). The condition of existence and functioning of formularies are a part of accreditation standards and criteria for quality assessment of hospital care.

Hospital Pharmaceutical Formularies (HPF) were put into operation in hospitals run by Ministry of Health in a directive way in 2005. They are a list of medicines available in a healh establishment without any further limitation, which must be kept in stock at a hospital pharmacy. Drug (pharmaceutical) committees are responsible for drafting and updating of HPF- they are available to the doctors through computer nets at the hospitals.

The majority of larger hospitals has a so-called pharmaceutical formulary, which contains the selection of medicines predominantly used for in-patients. These HPF usually contain medicines which have been chosen within the procurement process (tender). They can also be – depending on the turnover (financial volume) – made for medicines prescribed in outpatient´s care. HPF are based both on the choice of active substance (from a certain ATC group) and on the choice of a particular medicine (competition of manufacturers, generics). If a physician need to use other medicines, not represented in the HPF, they need to have this exception approved by the hospital management.

The hospitals which implemented HPF usually have efficient drug (pharmaceutical) committees, compound of representatives of the physicians from individual wards, hospital management and pharmacy representatives, usually a clinical pharmacist or a head of pharmacy. HPF – as well as procurement (tender) – are updated approximately once a year.

Pharmaceutical committees were established in all hospitals directly run by Ministry of Health in 1995, their establishment was motivated by the effort to ensure smooth functioning of HPF and the reduction of expenditures of medicines. This committee is the advisory body of the hospital´s director. Further on, the drug (pharmaceutical) committees are supposed to solve essential problems regarding rational pharmacotherapy, observe the development of expenditures of medicines as well as their consumption.

4 Consumption of medicines

Evaluation of deliveries of distributed medicines based upon the reporting from entities authorized to distribute medicines in the Czech Republic was, in 2008, like in previous years, conducted on a quarterly basis. Reports were received on deliveries of medicines to pharmacies and other healthcare facilities. In addition to the authorized medicines, also products included in special therapeutic programmes and non-authorised products supplied on medical prescription to a specific patient were included in the evaluation. Following an agreement with The Czech Ministry of Health and the AVEL wholesaler association, also regular monthly reporting by wholesalers associated in the AVEL has been introduced in addition to the quarterly reporting of supplies of medicines from all wholesalers. These data are processed for the internal purposes of SUKL CZ and Czech Ministry of Health to whom the data from the reports are forwarded.

Data on the volumes of distributed medicines (in number of packages), in financial volumes (in CZK), and in DDD/1,000 inhab./day were evaluated. Data on the financial volumes were calculated as the upper estimate of expenditure for final consumers and were based upon ex-factory prices increased by the maximum mark-up stipulated by the Price Ruling of the Ministry of Health or by the Price Regulation of the Ministry of Health and VAT 9%. The calculation disregarded of situations where mark-up was lower than the permitted maximum, and the resulting data hence do not represent actual costs of pharmaceuticals, but the maximum possible costs, which are in fact overestimated. The wholesalers and pharmacies may however decide to charge lower margins for reasons of competition, higher sales volume or introduction of new drugs, etc.

The regular quarterly evaluation of supplies of distributed products has been, since 2008, newly supplemented on the website of the SUKL CZ, with a table showing consumption for each active substance.

Total expenditure on medicines in 2007 calculated with the methology of SUKL CZ was 67.16 thousand million CZK, which represented again an increase in accord with the long-term trend, after a singular decrease in 2006.
In 2008 317.7 million packages of medicines were distributed, which corresponds to approx. 5,210 million DDD.The value of these deliveries did not exceed 72.75 million CZK (calculated with the maximum mark-up).

The highest consumption of medicines measured by numbers of packages was in groups of pharmaceuticals for treatment of cardiovascular diseases, antineoplastics, diseases of the nervous system, of the digestive tract and metabolism and of the respiratory system.

There is not implemented unit dose application system in any hospital in the Czech Republic. The main reason is lack of financing.

Table 4.1 Czech Republic – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption [1)]	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in packs (million)	n.a.	327	369	320	343	317
in million DDD	n.a.	4,800	5,900	5,500	8,045	5,210
In other measures units (million CZK)	n.a.	55,850	64,570	59,000	67,154	72,748
Annual pharmaceutical consumption in hospitals						
in packs (million)	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 (e.g. unit doses, please specify	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

[1)] Deliveries of distributed medicines (to pharmacies and health establishments)

Source: SUKL CZ

Table 4.2 Czech Republic – Top 11 pharmaceuticals by pharmaceutical expenditure and consumption 2008 in hospitals

Position	Top pharmaceuticals used in hospitals indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals indicated by active ingredient ranked with regard to expenditure
1	electrolytes	1	trastuzumab
2	saccharides solutions	2	rituximab
3	n.a.	3	interferon beta-1a
4	n.a.	4	imatinib
5	n.a.	5	infliximab
6	n.a.	6	enoxaparin
7	n.a.	7	electrolytes
8	n.a.	8	erythropoetin
9	n.a.	9	docetaxel
10	n.a.	10	somatropin
11	n.a.	11	bevacizumab

Source: SUKL CZ

5 Evaluation

5.1 Monitoring

Checking of used medicines in hospital care differs depending on the founder of the hospital. State hospitals are obliged to comply with valid legal regulations and follow the Act on Public Procurement [19)] when purchasing pharmaceuticals (when reaching a certain annual turnover, a tender needs to be carried out), moreover, doctors are obliged to use predominantly those medicines stated in PPL (pharmaceutical formulary) when providing healthcare. In other hospitals, medicines are purchased by hospital management for the prices taken from suppliers (wholesalers) who offer the most convenient trading conditions (usually on the basis of an agreement on a purchase price or special promotions, discounts, etc. during the year).

Nevertheless, there is still a certain resentment among the doctors in the Czech Republic toward these regulations, since they are constantly under pressure and lobbying of pharmaceutical companies, which push forward preferential usage of their medicines. However, this is mainly the issue of out-patient care. Very often, the issue is also the position of original medicines and their generics as for giving priority to one of them.

System of quality assurance

In the Czech Republic, there is no legal obligation of establishing a system of securing quality in healthcare facilities. In spite of this fact, there is a steady rise of hospitals which implement systems of quality management – usually through accreditation of healthcare facilities (focused especially on medical and nursing care) or ISO certification (particularly for laboratories, hospital pharmacies, etc.). Their aim is to ensure standardized and quality care in healthcare facilities.

For example, AAC (The Associated Accreditation Committee) is an interest group of other legal bodies, which were established by The Association of Hospitals in the Czech Republic in 1998. The main agenda of AAC is stable improvement of quality and safety of healthcare in the Czech Republic by means of accredited healthcare facilities, coucelling services and publication activities. AAC releases national accreditation standards for healthcare facilities including detailed methodology, helps healthcare facilities with accreditation process preparations, organizes educational events focused on the issue of healthcare quality and safety of patients. AAC cooperates with agencies of public administration and agencies of general government in healthcare. AAC disposes of its own consultants and inspectors of the accreditation process. Accreditation and auditing are focused especially on medical and nursing proceedings, although dealing with pharmaceuticals is not omitted either (particularly from the point of view of ensuring safe pharmacotherapy). The accredited healthcare facilities also carry out (besides external auditing carried out by AAC) their own internal auditing on a regular basis, the aim of which is eliminating the observed drawbacks, carry out corrective measurements and establish features ensuring improvement of the quality of healthcare.

Apart from accreditation and ISO audits, there are also other external checks carried out in hospitals – especially by SUKL CZ – handling medicines in healthcare facilities (both in in-patient and out-patient departments), handling medical devices. Newly, since 2008, SUKL CZ inspectors have got the right to carry out price checks, especially observing the maximum ex-factory price and the maximum mark-up for wholesaler and pharmacy at regulated medicines – earlier it used to be fully in the competences of the Ministry of Finance.

Role of hospital pharmacies

The Czech Medical Association of Jan Evagenlista Purkyně (CMA JEP) is an independent voluntary association of individuals – doctors, pharmacists and other medical workers as well as workers in associate professions. The individual specialized medical sections of CMA JEP release – on the basis of the latest clinical findings – guidelines, which contain information and proceedings for the best possible treatment of the individual diseases, including rational pharmacotherapy. The Section of Hospital Pharmacists [23)] (SHP) is a specialized section of the Czech Pharmaceutical Society of JEP. SHP associates mainly pharmacists from hospital pharmacies and other experts which are interested in hospital pharmaceutical service. SHP is a member of EAHP and takes part in its events. SHP has held regular specialized events (congresses of hospital pharmaceutical service) once a year since 1996. A major impact is put on oncological pharmacy (a Working Group of oncological pharmacy has been set up) and on the issues of clinical assessment (pharmacies provide pharmaceutical service for clinical assessment – input, ouput, preparation, registration of assessed pharmaceuticals within clinical assessment).

Hospital pharmacies provide pharmaceutical care to hospitalized patients, patients released from healthcare facilities, out-patients and patients in the system of home care.

Hospital pharmacies prepare sterile medicines containing cytostatics, or their pre-medications, radiopharmaceuticals, solutions for parenteral nutrition, or other parenteral solutions. Hospital pharmacies also include providing clinically oriented care on the level corresponding to the needs of a hospital, directly cooperating with other experts in a multidisciplinary clinical team (the doctor, pharmacist, nurse, psychologist, etc.), such as:

- in a nutrition team following the preparation of parenteral and enteral nutritive mixtures
- in an oncological team following the centralized preparation of cytostatics
- observing and evaluation of quality and efficiency of pharmacotherapeutic interventions and their usage in pharmaceutical policy of a hospital
- in the work of commissions dealing with the policy of pharmaceuticals (pharmaceutical, antibiotic, ethic commission, etc.)
- ensuring pharmaceutical service when dealing with pharmaceutical clinical studies
- collecting pharmacoepidemiologic data and their processing into pharmacoeconomic outputs
- evaluating individual prescription in case of hospitalized patients

23) The Section of Hospital Pharmacists http://www.nemlek.cz/

In many hospitals (especially university hospitals and hospitals providing specialized care) there is the antibiotic policy carried out, the aim of which is to minimize the risks of resistance and control over the usage of “costly” antibiotics – by carrying out the sensitivity tests of found bacterial strains to these pharmaceuticals.

However, it is necessary to remark that the position of a clinical pharmacist among other specialists, especially doctors, is very complicated, and that is why there are very few well-qualified clinical pharmacists in the Czech Republic, and their enforcement and inclusion into specialized teams is so far very difficult.

In the Czech Republic, the system of postgraduate education encompasses an independent specialized branch Hospital pharmaceutical service and Clinical Pharmacy; in the latest draft to the amendment of act, there is a newly stated specialization (among others) - Pharmaceutical Assistant for Hospital Pharmaceutical Service (so far it has only been a common branch Pharmaceutical Service).

5.2. Assessment

Data about cost – effectiveness of treatments of various diseases is possible to be found in professional journals, where pharmaco-economic studies with confrontation of different medical treatment and using expensive medicines or innovative products are published. These results are also presented in professional conferences and congresses for healthcare experts.

Professional associations issue guidelines, that involving recommended procedures enabling safety, quality and efficiency therapy and rational use of medicines.

In the Czech Republic HTA system is employed only in some cases in reimbursement of some medicines for now – e.g. for comparison interchangeability of similar medicines. Meanwhile is not employed with comparisons of unpharmacological methods.

6 Interface management

In general, purchase prices of medicines in hospital pharmacies are lower than those in public pharmacies. Due to higher purchase volumes, the manufacturer or wholesaler provides a major discount and other convenient business conditions when purchasing them (very similar principle as in realized tenders).

After being released from the hospitals, the patients receive prescriptions for medicines, which had been prescribed to them during their hospitalization. Doctors prescribe medicines using their brand name. Also pharmaceuticals prescribed by out-patient doctors are often chosen in hospitals by tenders and doctors are thus obliged to prescribe them preferentially (pharmaceuticals with high consumption and financial expenditure).

The Czech regulations allow a generic change of medicines on conditions stated by the public notice [9)] – simply, if the doctor does not indicate the brand name of a medicine on a prescription with ®, the pharmacist can eventually offer cheaper generics. However, the patient needs to agree with this change. All major changes (similar active substance, e.g. because of non-availability of the prescribed one) can be made only after being approved of by the doctor.

The new feature in 2009 is launching the Central Electronic Prescription Repository (CU) established by SUKL according to the law as one of its organizational units, which has - thanks to data assembly on prescribed, or dispensed medicines – made it possible to keep a record of the medicines the patients have used. It is available to concrete patients and, after their approval, also to their doctor and pharmacist. CU will collect data on all dispensed medicines (prescribed both on “classic” paper prescriptions and on electronic prescriptions). The main aim in the future is to make this current system improved in a way that it will be possible to prevent excessive prescription of medicines (thanks to the opportunity to check the record). It should also prevent duplicated usage of medicines, reveal the prospective interaction of medicines, observe the compliance of a patient, etc. The system could also enable mutual sharing of information on prescribed medicines among the individual hospitals and doctors from out-patient departments. Nevertheless, this agenda will be a matter of complex negotiations and it will also be necessary to make some arrangements in legal regulations.

In the Czech Republic, there is a limitation stated for certain medicines depending on the specialization of doctors in specialized out-patient departments (neurology, ophthalmology, oncology, allergology, psychiatry, cardiology, etc.); these medicines cannot be prescribed (in consideration of health insurance companies) by doctors with the other specializations, or general practitioners (GPs).

The National Reference Centre (NRC) was established in 2003 as an interest group of individuals. All of its members are health insurance companies in the Czech Republic, the Association of Hospitals in the Czech Republic, the Association of Private Hospitals in the Czech Republic, the Association of Out-patient Specialists in the Czech Republic, etc. The

articles of NRC enable membership to other professional associations of healthcare providers as well.

Because of the long-lasting problems of the Czech health service – non-existence of generally accepted and used methodology of allocating expenditure in case of hospitalization and its components, there are several projects currently running in the Czech Republic dealing with this issue (such as the NRC projects).

The Expert Forum was established as the advisory body of Ministry of Health and health insurance companies. The coordinator of the Expert Forum is NRC. The main target of the Expert Forum is making recommended procedures – setting the standards of healthcare and defining the conditions of concentration of the chosen expensive higly specialized care. The Expert Forum assesses and sets the standards of healthcare, recommends the types of healthcare, which is rational due to the quality and efficiency of concentration, and suggests special requirements (methodology and criteria) for running highly specialized workplaces (cardiology, neurology) - www.odborneforum.cz.

The main target NRC is making and developing of the classification systems for the purposes of documentation and the payments for healthcare services on the national level. Among the main aims, there are the support of the sector of acute in-patient care togehter with broader implementation of DRG as the payment mechanism, the revision of the list of medical performances, making use of the data from health insurance companies to follow the quality of provided healthcare etc. Deeper cooperation between NRC and Ministry of Health is desirable.

NRC collects and analyses the data from all health insurance companies, information is processed on the basis of the respective statements of expenses, which were shown by the hospitals for their hospitalized patients (via the DRG system). NRC evolved special software for active working with the database of the List of Medical Performances with their points evaluation, which is intended for free-of-charge distribution to the institutions associated in NRC and the Ministry of Health. It is a local application which enables browsing through, looking up and sorting out in the database of the List of Medical Performances, e.g. the prices of medicines and medical supplies.

There are also NRC data portals available, such as: www.brix.nrc.cz – it provides the members of NRC with an application for achieving reference values in cases of acute in-patient care. It provides reference values for the following indicators: expenditure, lenght of stay, number of points for a certain case etc. The database includes more than 2.5 mil. cases of hospitalization. www.jaksekdeleci.cz for both expert and lay users, provides basic statistic information on the chosen types and parametres of treatment in Czech hospitals (currently it contains two sections – childbirths and total joint endoprosthesis). The output of the application is statistic comparison of indvidual hospitals especially in the following parametres: frequency of the chosen performances, average length of stay etc.

NRC has created also an internet portal www.czdrg.cz for its members, where basic information on the DRG system is summarised. The comparison of statistic results and other para-

metres of treatment in individual hospitals are provided to the expert public (the database contains more than 8 million cases of hospitalization).

Every year NRC releases an annually report which is commonly available on its website.

The Notice [17)] uses the DRG classification for assessing hospital production. In the next years, the extension of the volume of production assessed through DRG is presumed, as it is common in the countries of the European Union.

7 Developments and outlook

The expenditures of medicines increase year by year in the Czech Republic, as well as in other countries. It is mainly due to the ageing of population and the availability of new medical proceedings and high-quality, but of course very expensive pharmacotherapy for more and more patients.

In the last years, there has been a reform of Czech Health Service carried out, bringing – among others – a major change in establishing the so-called regulation fees (as mentioned earlier). Although this is a step bringing a lot of finances into the budget, it has met with a grudge in many places (both from the patients and political parties). So far there have been several changes suggested to reduce or cancel them completely, but none of the suggestions have been approved of by the parliament of the Czech Republic so far. It is likely that it would happen after setting up the new government – following the parliamentary elections, which will be held in autumn 2009.

On December 31 2008 the SUKL CZ began to operate the Central electronic prescription repository (CU), as stipulated by the Act [8)]. Communication via the CU will result in the development of a system of electronic patient records, it will significantly enhance the effectiveness of communication among doctors, pharmacies and patients, and it will restrict its risks. At the same time, it will allow for the dispensing of medicines in the new restricted OTC category (currently medicines with pseudoefedrin). By the end 2009 most pharmacies should be connected to the CU. Afterwards, further two stages of development will follow: connecting doctors and providing patients with access to medication records. Although doctors do not have the statutory duty to connect to the CU, the repository will provide them with the opportunity to avail of electronic prescription, to eliminate the risk of contraindications and overdosage where medicines are prescribed by several doctors at the same time and to check for patient´s compliance in respect of the prescribed therapy. Last but not least the roll-out of online access to medication records for patients is being planned. Patients who have no access to the internet should have the option to obtain a printout of their personal medication record via the Czech Point service. The medication record will include complete and up-to-date information about prescription-only and restricted OTC medicines dispensed to the patient, including their reimbursement from the health insurance and the amount of additional payments allowable in respect of the protective limit. Access to this unique set of data will mean a significant enhancement of information provided to citizens. The implemen-

tation of these two stages of the e-prescription project will result in the interest in the use of other components of the e-health system by all of its stakeholders.

8 References and data sources

8.1 Literature and documents

Czech Laws

The Act No. 20/1966 Coll., as amended, on Healthcare of Citizens

The Act No. 245/2006 Coll., as amended, on Public Non-profit Health Establishments for bed care

The Act No. 290/2002 Coll., on change over of items, power and engagement to regions and municipality

The Act No.160/1992 Coll., as amended, on Healthcare in Non-state Health Establishments

The Act No. 108/2006 Coll. of Social Services

The Act No. 378/2007 Coll., as amended, on Pharmaceuticals

The Act No. 48/1997 Coll., as amended, on Public Health Insurance

The Act No. 106/1999 Coll., as amended, on Annual Reports

The Act. No. 137/2006 Coll. , on Public Procurement Act

The Act No. 551/1991 Coll., on the General Health Insurance Fund

The Act No. 280/1992 Coll, on department, occupational, business and other health insurance funds

The Act No. 40/1995 Coll., as amended, on advertisement

The Public Notice No. 49/1993 Coll., as amended, on Material and Technical Equipment

The Public Notice No. 92/2008 Coll., on assesment list of reference basket states and reimbursement of pharmaceuticals

The Public Notice No. 84/2008 Coll., on Proper Pharmaceutical Practice and Conditions of Dealing with Pharmaceuticals in Health Establishments

The Public Notice No. 464/2008 Sb. , on assesment point price and remuneration healthcare

The Publice Notice No. 385/2007 Coll., on assesment list of active substances for supportive and complementary therapy

Publications

Annual Report 2007 State Institute for Drug Control, Czech Republic

Annual Report 2008 State Institute for Drug Control, Czech Republic

Web links

Institute of Health Information and Statistics of the Czech Republic (UZIS) http://www.uzis.cz/news.php?mnu_id=1100

The Association of Hospitals in the Czech Republic http://www.ancr.cz/

General Health Insurance Fund http://www.vzp.cz/cms/internet/cz/Lekari/Informace-pro-praxi/Seznam_ZZ_03_09.xls

The Section of Hospital Pharmacists http://www.nemlek.cz/

The National Reference Centre (NRC) Data portals www.brix.nrc.cz, www.jaksekdeleci.cz, www.czdrg.cz

The Expert Forum www.odborneforum.cz

8.2 Contacts

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