



## Pharmaceutical Health Information System

# PHIS Hospital Pharma Report 2009

## BULGARIA

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



# PHIS

**Pharmaceutical Health Information System**

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**PHIS Hospital Pharma Report**

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# Executive Summary

According to the Health Establishment Act (HEA) (OJ 62/1999, last amended OJ 110/ 2008.), a health establishment for hospital care is a treatment facility whereat doctors, with the assistance of other specialists and auxiliary personnel shall carry out all or some of the following activities: diagnostics and treatment of diseases when the treatment goals cannot be achieved in the conditions of out-patient care; natal care; rehabilitation; diagnostics and consultations requested by a doctor or a dentist or by other medical-treatment facilities; transplantation of organs, tissues and cells; collecting, storing, supply of blood and blood components, transfusion supervision; medical cosmetic services; clinical trials of medicines and medical equipment pursuant to Bulgarian Law; teaching and scientific activity.

Health establishments for hospital care are hospitals for active treatment; hospitals for further treatment and continuous treatment; rehabilitation hospitals; hospitals for further treatment, continuous treatment and rehabilitation.

Hospitals are also classified as (1) multi-profile hospitals, which should have at least four departments or clinics of different medical specialties, and (2) specialised hospitals.

Depending on the type of the territorial unit of serviced population, the hospitals are:

**district** - when the hospital provides treatment to resident of the same, or of neighbouring municipalities;

**regional** - when the hospital provides treatment to residents of municipalities within one region;

**inter-regional** - when the hospital provides treatment to residents of different regions;

**national** - when units within its structure carry out diagnostic and medical activities and scientific and research work on the implementation of modern medical technologies unique for the country, or carry out tasks on the development and implementation of the national health policy. They are determined by the Council of Ministers at the proposal of the Minister of Health.

University hospitals are multi-profile or specialised hospitals, determined by the Council of Ministers, whereat except the treatment activities, clinical training of students and doctoral students in medicine, dentistry and pharmacy, clinical training in health care, as well as training of students from all types of medical colleges and post graduate training of doctors, dentists, pharmacists, health care professionals and persons, graduated from medical colleges are also carried out.

A specific type of medical establishment is a **dispanser**, whereat doctors, with the assistance of other personnel, actively find, diagnose, treat and periodically observe patients with a specified disease. Beds for diagnosis and treatment may be opened at a dispanser. In 2008, there were 48 dispansers in the country with 4,154 beds. The average length of stay in 2008 in dispansers was 9.8 days<sup>1</sup>.

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<sup>1</sup> NCHI 2009

In Bulgaria, the HEA (Art. 8, para. 2) gives the possibility for some medical establishments for out-patient care which are medical centres and diagnostic consultative centres that are open up to 10 beds for in-patient care for a period up to 48 hours. After this period the patient should be transferred to a hospital. The same rights apply to the dental faculties of the Medical Universities.

As per the HEA, the medical establishments in Bulgaria are founded by the state, by the municipalities and by other legal or physical entities. The hospitals have a legal status of limited liability or joint stock companies. They are with equal status regardless of their ownership, which means that after contracting hospitals have the right to receive public financing from the national health insurance fund (NHIF).

The planning and the distribution of the medical establishments are carried out through the National Health Map and the Regional Health Maps, through which the national health policy is implemented. The National Health Map is created by the Ministry of Health and is voted by the Parliament.

A hospital has the right to carry out medical activities only after fulfilling certain criteria and receiving a permission that is issued by the Minister of Health.

The hospitals are subject to accreditation (Art. 86 of HEA). The accreditation is obligatory and is carried out by a specialised body for accreditation at the Ministry of Health. The hospital subject to accreditation is assessed for individual medical activities, for its entire medical activity, as well as for the education of students and specialists. The accreditation is made for a period of one to five years.

The health establishments for in-patient treatment provide health care services by the virtue of a contract between them and the NHIF units – Regional Health Insurance Funds (RHIF). RHIF pay the health establishments for health care they have provided to insured persons at predetermined process. The main obligations of the contract parties, the prices, payment method and procedures are determined in the **National Framework Contract**, which is signed between NHIF and representatives of the professional organisations of medical doctors and dentists. The particular contracts are signed between each health establishment and RHIF. Some hospitals sign contracts with a number of the 21 voluntary health insurance companies operating in the country.

Payment for in-patient care is made on the grounds of an agreement with the NHIF by groups of diseases defined as clinical pathways. Medicines are part of the treatment process and are part of the clinical pathways. Some medicines for treating particular diseases in hospitals are paid for through the state budget. Patients without active health insurance rights, which are estimated to around 1,020,000 people, pay the costs of their treatment, including medicines. When hospitalised patients with chronic diseases, for which they receive medicines for out-patient care from the NHIF, are supposed to carry the already prescribed medicines with them.

The delivery chain for pharmaceuticals for hospitals is quite simple. Any wholesaler licensed by the Bulgarian Drug Agency (BDA) is allowed to deliver medicines to hospital. The particu-



lar choice of a wholesaler is made usually after a public procurement process for the public hospitals and open tender or negotiation process for the private hospitals. The pharmaceutical manufacturers can also sell medicines to hospitals; however only those which they produce.

Pricing of medicines in Bulgaria in the in-patient sector is the same as in the out-patient sector. It is made according to the Pricing Regulation, which:

- defines the terms for regulation of the prices of the pharmaceuticals, included in the positive list of pharmaceuticals and paid with public funds;
- regulates the ceiling prices of the prescription-only medicines (POM), out of the positive list. These medicines are not included in the positive list and are on the free market.
- registers the prices of over-the-counter (OTC) medicines.

At manufacturer level, the price is determined based on the methodology of external price referencing, and at wholesale and pharmacy level statutory regressive maximum mark-ups and value added tax (VAT) are applied for POM.

Licensed wholesalers supply hospitals with pharmaceuticals after procurement in public hospitals or negotiation in private hospitals. Wholesalers are not allowed to sell pharmaceuticals to hospitals exceeding the manufacturer price plus the maximum mark-ups including VAT for a wholesaler.

Annually each public hospital organises public procurement for pharmaceuticals. Information about the procurement process is published in an official journal (OJ) and at least one other newspaper as well as it is sent to the Public Procurement Agency (PPA). The PPA maintains a Public Procurement Register (PPR), where the information requested by the PPA is published.

Evaluation of the offers is based primarily on the supplier's price, but can also include payment terms, discounts and delivery schedules. Private hospitals are usually provided pharmaceuticals after a negotiation process. Each hospital organises the negotiation process by itself. The hospital has the right to invite a selected number of wholesalers and to negotiate the price of each pharmaceutical.

Public hospitals are only allowed to purchase medicines if they are included in the positive list. The Council of Ministers defines by regulation the criteria, the rules and the procedure for including the medicines in the positive list of the country. As per Art. 262 of Medicinal Products in Human Medicine Act (MPHMA), the positive list includes POM, which are necessary to cover the health care needs of the population and are paid from the budget of the NHIF, from the national budget outside the scope of the obligatory health insurance, and from the budget of the public in-patient health care establishments. In the positive list medicines are included by pharmacological groups with the respective international non-proprietary names, (INN) the respective defined daily doses (DDD), reference price (value) for the DDD, and level of payment. For pharmaceuticals which have no DDD, a therapeutic course and reference value are determined.

The medicines in the positive list are selected according to evidence of efficacy, therapeutic effectiveness, safety, and analysis of pharmaco-economic indices. The decision of the Positive Drug List Committee (PDLC) might be appealed in front of the Transparency Committee (TC). The TC is subordinate to the Council of Ministries and includes representatives from the MoH, BDA, NHIF, Bulgarian Medical Union, the Dentists Union and the Union of Pharmacists in Bulgaria. The pharmaceuticals in the positive list 2009 are grouped in four parts - annexes:

1. medicines for the treatment of diseases reimbursed by the NHIF. The level of payment is determined according to the budget of NHIF for the corresponding year.
2. medicines paid by the budget of the in-patient public medical establishments;
3. medicines proposed for treatment of diseases out of range of Law for Health Insurance, paid through the budget of MoH;
4. medicines intended for treatment of rare diseases, AIDS, and infectious diseases.

Each hospital in Bulgaria has the choice and the right to create its own medicine policy, respectively its own list of preferred medicines or a hospital pharmaceutical formulary (HPF). The HPF is created by a hospital pharmaceutical and therapeutic committee (PTC) and approved by the director of the hospital. It is usually based on data from previous years, but updated according to the current positive list. The number of pharmaceuticals included in the HPF depends on the budget of the hospital, the type of the hospital and the dominating morbidity of the population. The public procurement of the hospital pharmacy is according to the hospital formulary.

In Bulgaria official information and data on consumption (utilisation) of pharmaceuticals in hospitals at a national level is not available. Each hospital monitors its consumption, but this information is not shared publicly.

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

Hospital expenditure has been rapidly growing, e.g. the average expenditure per hospitalisation increased from BGN 106 / € 54.19 in 2000 to BGN 443 / € 226.5 in 2007. In 2007 on average one out of five people in Bulgaria were hospitalised<sup>2</sup>. One of the obvious reasons for these facts is the system of reimbursement in hospitals meaning that patients do not need to co-pay for their treatment. The admissions to hospitals do not follow the typical movement, but are generated directly by the general practitioners (28%) or are a result of self directing

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<sup>2</sup> Sanigest Solutions 2008

from the side of the patients (16%). Despite the increasing expenditure, the quality of the provided services has not much improved.

This development requires a better interface management in general and with regards to medicines as well.

For a relatively young and still reforming health care system like the Bulgarian system, there is still a lot to be done. The existing National Health Map is from 1999 and is not considering main socio demographic, infrastructural, communicational, personnel, etc. characteristics. So far, in the past few years three National Health Map projects have started. None of them were accepted by the Parliament. In the National Health Strategy 2008-2013 the creation of a National Health Map is foreseen, which will be obligatory in terms of restructuring the medical establishment network and rationalising the system.

Another challenge is the optimisation of the multi-profile hospitals network and its internal restructuring, narrow specialisation and introduction of the one day surgery. The hospital managers should follow adequate investment policies for a progressive development and reach the required high technology state of medical establishments.

A process of improving the interaction between the out-patient and in-patient sector has to be developed as well as introducing the mechanisms allowing the information exchange of information between the in- and out-patient sectors.

Concerning medicines in the hospital sector, a few points are also planned for development, such as promotion of rational use of medicines and improvement of knowledge of health professionals; creating a system for monitoring of pharmaceutical consumption and system for qualitative and quantitative measurement of the consumption; the development of information links between the MoH, BDA, NHIF as well as the development of their own information systems in line with the legally regulated activities.

These are some of the points that are regularly entering in the public attention. What will be achieved in reality will depend of the results of the parliamentary elections in July 2009 and the political will of the new government.

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## List of abbreviations

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic Therapeutic Chemical classification
BDA	Bulgarian Drug Agency
BMG	Austrian Ministry of Health
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
HA	Health Act
HE	Health Expenditure
HEA	Health Establishment Act
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
NCHI	National Center for Health Informatics
NHIF	National Health Insurance Fund
NHS	National Health Service
MPHMA	Medicinal Products in Human Medicine Act
Mio.	Million
MoH	Ministry of Health
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute

OECD	Organisation for Economic Co-operation and Development
OJ	Official journal
OPD	Out-patient department(s)
OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals
PC	Pricing Committee
PDLC	Positive Drug List Committee
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPA	Public Procurement Agency
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parities
PPR	Public Procurement Register
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
RHIF	Regional Health Insurance Fund
SHI	Social Health Insurance
SOP	Standard operative procedure
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
TC	Transparency Committee
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
VHIF	Voluntary 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 conversations 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 re-phrasing and change and clarified open and/or misunderstanding points.



# 1 Background

## 1.1 Definition and scope

According to the Health Establishment Act (HEA) (OJ 62/1999, last amended OJ 110/ 2008), Art. 19, a health establishment for hospital care is a treatment facility whereat doctors, with the assistance of other specialists and auxiliary personnel shall carry out all or some of the following activities:

- diagnostics and treatment of diseases when the treatment goals cannot be achieved in the conditions of out-patient care;
- natal care;
- rehabilitation;
- diagnostics and consultations requested by a doctor or a dentist or by other medical treatment facilities;
- transplantation of organs, tissues and cells;
- collecting, storing, supply of blood and blood components, transfusion supervision;
- medical cosmetic services;
- clinical trials of medicines and medical equipment pursuant to Bulgarian Law;
- teaching and scientific activity;

As per Art. 9 of the HEA, health establishments for hospital care are the following types:

1. **Hospitals for active treatment** - treatment is provided to patients with acute diseases, traumas, aggravated chronic diseases, conditions requiring operative treatment at hospital conditions, as well as natal care and medical cosmetic services.
2. **Hospitals for further treatment and continuous treatment** - for persons needing long recovery of health and persons with chronic diseases requiring care and sustenance of satisfactory corporal and psychological condition.
3. **Rehabilitation hospitals** - for persons needing physical therapy, motor and psychic rehabilitation, balneological, climatological and thalassotherapy.
4. **Hospital for further treatment, continuous treatment and rehabilitation** - for persons needing long recovery of health and persons with chronic diseases requiring care and sustenance of satisfactory corporal and psychological condition and those needing physical therapy, motor and psychic rehabilitation, balneological, climatological and thalassotherapy.

Hospitals are also classified as **multi-profile hospitals**, which should have at least four departments or clinics of differing medical specialties and **specialised hospitals**, whereat departments or clinics have been established which fulfil one of the following requirements:

1. one basic medical or dental specialty;
2. one or more profiled specialties, derived from the basic one under item 1 above;
3. more than one profiled specialty, derived from the different basic medical specialties, in the cases when the hospital is appointed for the treatment of diseases within one and the same group.

Depending on the type of the territorial unit of serviced population, the hospitals are:

- **district** - when the hospital provides treatment to residents of the same, or of neighboring municipalities;
- **regional** - when the hospital provides treatment to residents of municipalities within one region;
- **inter-regional** - when the hospital provides treatment to residents of different regions;
- **national** - when units within its structure carry out diagnostic and medical activities and scientific and research work on the implementation of modern medical technologies unique for the country, or carry out tasks on the development and implementation of the national health policy. They are determined by the Council of Ministers at the proposal of the Minister of Health.

University hospitals are multi-profile or specialised hospitals, determined by the Council of Ministers, whereat activities shall be carried out for:

- clinical training of students and doctoral student in medicine, dentistry and pharmacy;
- clinical training in health care, as well as training of students from all types of medical colleges;
- post graduate training of doctors, dentists, pharmacists, health care professionals and persons, graduated from medical colleges.

Specific type of medical establishment is a **dispanser**, whereat doctors, with the assistance of other personnel, actively find, diagnose, treat and periodically observe patients with a specified disease. Beds for diagnostic and treatment may be opened at a dispanser. In 2008, there were 48 dispansers in the country with 4,154 beds. The average length of stay in 2008 in the dispanser was 9.8 days<sup>3</sup>.

In Bulgaria, the HEA (Art. 8, para. 2) gives the possibility for some medical establishments to provide out-patient care. Medical centers and diagnostic consultative centers can open up to 10 beds for in-patient care for period up to 48 hours. After this period the patient should be transferred to a hospital. Dental faculties of the medical universities have the same right.

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<sup>3</sup> NCHI 2009

In general the OECD definition for hospitals and its subtypes is relevant in Bulgaria. Additionally clinical trials and education process for students and post graduate specialisation for medical staff are carried out in some hospitals.

Pricing, reimbursement and monitoring of medicines in hospitals is mostly relevant for public hospitals.

## 1.2 Organisation

As per HEA, the medical establishments in Bulgaria are founded by the state, by the municipalities and by other legal or physical entities. The hospitals have a legal status of limited liability or joint stock companies. They are with equal status regardless of their ownership which means that after contracting they have the right to receive public financing from the National Health Insurance Fund (NHIF).

The medical establishments for hospital care and the dispensers are planned and distributed on a territorial principle on the basis of the needs of the population for accessible and timely medical care. The planning and the distribution of the medical establishments are carried out based on the National Health Map and the Regional Health Maps, through which the national health policy is implemented. The National Health Map is created by the Ministry of Health and is voted by the Parliament.

A hospital has the right to carry out medical activities only after receiving permission, issued by the Minister of Health, and after fulfilling certain criteria.

The hospitals are subject to accreditation (Art. 86 of HEA). The criteria, the indications and the methodology for accreditation are determined by Regulation No 18 of the Minister of Health. The methodology for accreditation contains the rules for the activity of the body - which carries it out - and a standard protocol for decisions. The criteria and the indications for accreditation should be updated every five years.

The accreditation is obligatory for both – private and public hospitals – and is carried out by a specialised body for accreditation of the Ministry of Health.

The hospital subject to accreditation is assessed for individual medical activities, for its entire medical activity, as well as for the education of students and specialists. The accreditation is granted for a period of one to five years.

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

In-patient care	2000	2004	2005	2006	2007	2008
<b>No. of hospitals<sup>1</sup></b>	249	257	262	270	292	305
<i>Classified according to ownership<sup>2</sup></i>						
- thereof public hospitals	211	208	207	206	205	205
- thereof private hospitals	18	40	45	54	71	85
- thereof institutional hospitals <sup>3</sup>	20	9	10	10	16	15
<i>Classified according to subtype<sup>2</sup></i>						
- thereof general hospitals	127	127	125	122	123	123
- thereof mental health and substance abuses hospitals	11	11	12	12	12	12
- thereof speciality (other than mental health and substance abuse) hospitals <sup>4</sup>	73	70	70	72	70	70
<b>No. of acute care beds</b>	45,408	34,038	33,387	32,298	33,056	32,879
- thereof in the public sector	45,174	33,342	32,505	31,019	30,850	29,901
- thereof in the private sector	234	696	882	1,279	2,206	2,978
<b>Average length of stay in hospitals</b>	11.5	8.2	7.9	7.2	6.9	6.6
<b>No. of hospital pharmacies</b>	149	151	151	154	157	n.a.
thereof no. of hospital pharmacies that serve out-patients	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

n.app. = not applicable

Note: Data are indicated as of 31 December

<sup>1</sup> according to definition and subtypes, explained in section 1.1.

<sup>2</sup> please note that sums of hospitals classified according to ownership and hospitals classified according to subtypes are different due to the methodology for collecting data, especially lack of information about the type of the private hospitals

<sup>3</sup> belonging to Ministry of Defence, Interior, Council of Ministers, etc. therefore also public hospitals

<sup>4</sup> there are only public mental health hospitals in Bulgaria

Source: National centre health informatics

As it is seen from Table 1.1, there is a slight trend of increase in the number of the hospitals in the country, which is mainly due to the opening of new private hospitals. The trend of decrease in the number of beds in public hospitals is connected with restructuring process that is going on in the public sector. The increase of beds in the private sector is connected with the increase of the number of private hospitals. A positive fact is that the hospitals have been decreasing the length of stay reaching the level of average length of stay in the EU Member States.

Nevertheless, public hospitals are the main actors and the main stakeholders of hospitals are the state and the municipalities. The number of private stakeholders is still small in comparison to the public owned ones.



The relative share of the private medical establishments for in-patient care in the EU Member States is averagely 20%<sup>4</sup>. In Bulgaria, despite the fact that many new private structures are opened, the share still remains very small and is around 1.3% from the public hospitals.

Some hospitals, on their own choice are members of some hospital associations like Association of the Bulgarian hospitals<sup>5</sup> and Regional association of hospitals "Stara Planina"<sup>6</sup>.

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

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
<b>Authorised pharmaceuticals in total<sup>1</sup></b>	7,497	5,830*	n.a.	n.a.	n.a.	n.a.
- thereof hospital-only pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

<sup>1</sup> as of 1 January, counted incl. different pharmaceutical forms, incl. different pack sizes, incl. different dosages

\*The number of authorised pharmaceuticals for 2005 is the estimation from the number authorised in 2004 plus the newly authorised products for 2005 as per the BDA report.

Source: BDA, IHIII

The classification of pharmaceuticals, as hospital-only medicines (HOM), in Bulgaria is made by the BDA during the process of marketing authorisation. Unfortunately there is no available information on how many HOMs are authorised or are on the market.

The delivery chain for pharmaceuticals for hospitals is quite simple. Any wholesaler licensed by the BDA is able to deliver medicines to hospitals. The particular choice of a wholesaler is usually made after a public procurement process for the public hospitals and open tender or negotiation process for the private hospitals. The pharmaceutical manufacturers can also sell medicines to hospitals; however only those which they produce.

As per Art. 222 of the Medicinal Products in Human Medicine Act (MPHMA) (OJ 31/2007 last amended OJ 23/ 2009), the medical facilities for in-patient care and the dispensaries may open pharmacies for satisfying their own needs. As it is shown in Table 1.1 the number of hospital pharmacies is much smaller than the number of hospitals. As it is prohibited to sell medicines, the hospital pharmacies have the right to provide medicines only for their needs and not for out-patients. The legislation gives a hospital without hospital pharmacy the opportunity to receive medicines from the closest licensed hospital pharmacy<sup>7</sup>. The hospital

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<sup>4</sup> Annual report 2008 of the Minister of Health, <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=420>

<sup>5</sup> <http://www.abh.bg>

<sup>6</sup> <http://www.veda.bg>

<sup>7</sup> Art. 38 of Regulation 28 for the terms and conditions of the work in the pharmacies and the nomenclature of the medicinal products – OJ 109/2008

pharmacies are licensed as per chapter 10 of the MPHMA also like the out-patient pharmacies, by the Minister of Health after the application from the side of the head of the hospital.

According to Art. 35 and 36 of Regulation 28 OJ 109/2008 the head of the hospital pharmacy is a member of the Medical Council of the hospital. As per Art. 75 of Health Establishments Act, the medical Council is a consultative body for the management of the hospital and consists of the head of the clinics and laboratories, head of the hospital pharmacy, the chairmen of the units of the Bulgarian medical union, dental union, the Bulgarian association for the professionals of health care and the chief nurse of the hospital. Other committees for the support of the management might be created as well. The head of the hospital pharmacy participates in the development of the medicinal policy of the hospital by:

- participating in pharmaco-therapeutic committees;
- developing practical prescription lists, based on the quality, safety and efficacy as well as pharmaco-economic evaluation of the medicinal products;
- participating in all activities connected with negotiations, supply and delivery of the necessary medicines;
- making propositions for the medicines budget;
- creating standard operative procedures (SOPs) for the activities in the hospital pharmacy;
- controlling the distribution, storage and accountability of the medicines in the wards and departments of the hospital;
- providing the necessary therapeutic information for the medical specialists.

In principle, when a hospital pharmacy is licensed to produce medicines, this is only for the need of the hospital. In practice few hospital pharmacies now are producing medicines ex-tempore.

### 1.3 Funding

At present the main financing institution for the hospitals is the National Health Insurance Fund (NHIF). The health establishments for in-patient treatment provide health care services by the virtue of a contract between them and the NHIF units of the Regional Health Insurance Funds (RHIF). RHIF pay to the health establishments for health care they have provided to insured persons at predetermined process. The main obligations of the contract parties, the prices, payment method and procedures are determined in the **National Framework Contract**, which is signed between NHIF and representatives of the professional organisations of medical doctors and dentists. The particular contracts are signed between each health establishment and RHIF. Some hospitals sign contracts with a number of the 21 voluntary health insurance companies operating in the country.

Payment for in-patient care is made on the grounds of an agreement with the NHIF by groups of diseases defined as clinical pathways. In 2008 NHIF financed 298 clinical path-

ways with 7,700 diagnoses (NHIF 2009). The doctors are employed by hospitals and their salaries are formed as percentage of hospital revenues, which might vary on a monthly basis. Although registered as corporations, hospitals get their funding at prices determined administratively by the NHIF. Once a year the NHIF and the branch organisations of doctors negotiate the specific amount of such prices, which are then included in the National Frame Contract. In case of over-expenditure in the NHIF budget the prices may be reconsidered on a 6-month basis. Every insured patient also pays a fee of 2% of the minimum salary for hospital treatment, for not more than 10 days during the year. This fee is due when a patient is actually treated in hospital. A small number of institutional hospitals are funded by the state; the municipalities are involved in the municipal hospital funding. The MoH can fund capital expenditure (infrastructural improvements and reparations) and expenditure for some actives like equipment for the hospitals with predominant State share. Hospitals, which are working with voluntary health insurance companies, are receiving funds from them as well.

In 2007, the NHIF contracted a total number of 377 medical establishments for in-patient care, thereof 142 multi-profile hospitals and 68 specialised hospitals (NHIF 2009).

There are some disadvantages in this way of financing hospital care. The “prices” of the clinical pathways are often not in line with the real expenditure as it can be underestimated or overestimated. Often the value of the clinical pathway is not connected with the severity of the disease, the accompanying diseases and the quality of the treatment. This leads to the opportunity for increasing the number of hospitalisations of more profitable clinical pathways, limited hospitalisation of old patients, multi-morbid and risky patients, and generating lots from hospitals that treat “heavy” or complicated cases.

The value of the pharmaceuticals, used in hospitals is part of the clinical pathway. Some medicines, for treating specific diseases – oncologic, HIV, after transplantation of organs, haemophilia, etc. – are paid from the state budget through the MoH. Patients without obligatory health insurance status (estimated around 1 mio. people, which is around 13% of the population) are charged by the hospitals for their treatment according to so called market prices.

Private hospitals are funded by the NHIF for the clinical pathways that are contracted, treatment fees paid by the patients admitted to hospital and cash payment of the patients, who are treated out of the NHIF scheme, as well as payments made by the voluntary health insurance companies.

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

Expenditure (in mio. BGN)	2000	2004	2005	2006	2007	2008
<b>Total health expenditure (THE)<sup>1</sup></b>	n.a.	948	1,073	1,006	1,111	n.a.
thereof THE public	n.a.	948	1,073	1,006	1,111	n.a.
thereof THE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>THE in hospitals (HOSHE)</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Total pharmaceutical expenditure (TPE)<sup>1</sup></b>	n.a.	289	330	298	334	n.a.
thereof TPE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof TPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Pharmaceutical expenditure in hospitals (HOSPE)</b>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSPE public	n.a.	289	330	298	334	n.a.
thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, NCU = national currency unit, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure

Note: Data are indicated as of 31 December

<sup>1</sup> Only public data

Source: National center of health informatics

Bulgaria still does not have official statistics to support certain information concerning health and pharmaceutical expenditure. Partial data is available, and the data indicated as total health or pharmaceutical expenditure, in fact are the public health and pharmaceutical expenditure.

The insufficient funding of in-patient care resulted in highly developed formal (with document) and informal (without document) payments. Some estimations of the out-of pocket payments per capita show an increase from € 50,- in 2006 to € 74.6 in 2007 (Sacheva 2008).

A report of the Open Society Institute, published in July 2008 states that in 2006 around BGN 38 mio. / € 19.4 mio. were formally paid by patients admitted to hospitals. From these, around 6% (BGN 4.5 mio. / € 2.3 mio.) are informal payments and were paid directly to doctors in the hospitals. Another study of “Alfa research” agency from July 2007 shows that around 50% of the hospitalised patients pay additionally for medicines and consumables. Over 42% of the patients give money for operations and additional attention from the side of the doctors and other medical staff.

## **2 Pricing**

### **2.1 Organisation**

#### **2.1.1 Framework**

Two of the main legal documents that have established the statutory pricing system in the country are the Medical Products in Human Medicine Act (MPHMA) and the Council of Ministers Decree N 295/ 2007 (OJ 104, 2007) for adopting a regulation on the terms and conditions for regulation and registration of the prices of pharmaceuticals (Pricing Regulation). Two committees are involved in the process: the Pricing Committee (PC) and the Transparency Committee (TC).

The Pricing Regulation defines the terms for regulation of the prices of pharmaceuticals, included in the positive list and paid with public funds, regulates the ceiling prices of the POM pharmaceuticals, out of the positive list and the registration of the prices of OTC medicines.

The price at which a medicine can be sold is the price approved by the PC and by the Minister of Health (MoH). The PC deals with all pharmaceuticals, whether publicly financed or not, whether prescription or over-the-counter (OTC) and whether in out-patient care or in hospitals. The manufacturers, wholesalers and pharmacies are not allowed to sell the pharmaceutical in excess of this price. The regulation approves the price at the different levels – at manufacturers, at wholesale and retail sale level for POM and elements – mark-up for each level and value-added tax (VAT) at each level is published in a register on the website of the MoH.

At manufacturer level, the price is determined based on the methodology of external price referencing, and at wholesale and pharmacy levels statutory maximum mark-ups are applied for POM.

The remuneration of the wholesalers and pharmacies is based on regressive mark-ups.

Once the price of POM is determined, it cannot be increased for the next 12 months. After this period the price can be changed, but with not more than the registered inflation. In the opposite way the price can be decreased at any time.

Pricing process for hospital pharmaceuticals is falling under the described rules. Wholesalers are not allowed to sell pharmaceuticals exceeding the manufacturer price plus the maximum mark-ups for a wholesaler with VAT to hospitals.

The main pricing policy in public hospitals is public procurement and negotiation policy in the private hospitals.

Summing up the pricing of pharmaceuticals in Bulgaria is the same for the out-patient and the in-patient sector. It is made according to the Pricing Regulation, which:

- defines the terms for regulation of the prices of the pharmaceuticals, included in the positive list and paid out of public funds;
- regulates the ceiling prices of the POM, not included in the positive list;
- registers the prices of OTC medicines.

At manufacturer level, the price is determined based on the methodology of external price referencing, and at wholesale and pharmacy levels statutory regressive maximum mark-ups and VAT are applied for POM.

The hospitals are supplied with pharmaceuticals through licensed wholesalers after procurement for public hospitals or negotiation for private hospitals. Wholesalers are not allowed to sell pharmaceuticals exceeding the manufacturing price plus the maximum mark-ups for a wholesaler with VAT to hospitals.

## 2.1.2 Hospital prices

Hospitals should purchase their medicines from wholesalers, thus the purchasing price should not be higher than defined in the pricing regulation. In practise the procured prices differ from case to case. The State Financial Control Agency is the body to monitor also this type of the activities of state and municipal hospitals and the MoH for the state hospitals.

Legally the Access to Information Act gives a possibility to ask for information about the prices in public hospitals, but often this information is difficult to be obtained.

The hospital price is the ex-factory price with the mark-ups for the wholesaler and incl. VAT. The standard VAT in Bulgaria is 20%. There is no exclusion or lower VAT for the pharmaceuticals. Periodically there are public discussions on the VAT, but changes are not envisaged at present.

The hospital pharmacy has no right to add its own mark-ups to the pharmaceuticals. There are no mandatory discounts to hospitals so far. During the negotiation process with the suppliers a hospital can obtain some discounts, usually connected with the higher purchased volume.

The expectations from the public about hospital prices are that they should be lower than in the out-patient sector. So far there is no official information about the actual prices of pharmaceuticals bought by hospitals. The public hospitals, which are acting under the Public Procurement Law are supposed to give information about the signed contracts to Public Procurement Register (PPR). From the PPR information about the contracted wholesaler and the total amount of the contract can be received, but not prices for particular pharmaceuticals.

## **2.2 Pricing policies**

### **2.2.1 Procurement**

Public procurement is the obligatory procedure for providing medicines paid from funds from the state or public budget. Legally it is defined by the Public Procurement Act OJ 28/2004, last amended OJ 24/2009. This act transposes the Directive 2004/17/EC and Directive 2004/18/EC and their amendments within the Bulgarian legislation.

The procurement procedures for all medicines, provided within the budget of the MoH and within the budgets of public hospitals fall within the scope of the Public Procurement Act. According to this each public hospital procurement has to be organised annually. As long as prices are not exceeding the price defined in the pricing regulation, they can be different. There is no experience in the country with public procurement/purchasing agencies, although the legislation gives such opportunity. Information about the procurement process is published in OJ and after that in one national or regional newspaper as well as it is sent to the Public Procurement Agency (PPA). The PPA maintains a Public Procurement Register (PPR), where the information requested by the PPA is published.

To evaluate the offers from the suppliers, an evaluation committee is appointed by the head of the hospital. The evaluation committee consists of a lawyer (as required by the PPA), and any or all of the following: a procurement expert (if the hospital has one, or hires one to serve on the committee); the hospital's deputy director (if the hospital has one); the hospital pharmacist; the hospital's heads of department and the head nurse. The committee must consist of at least three people, but some hospital evaluation committees have as many as 8 or 10 members.

Evaluation of the offers is based primarily on the supplier's price, but can also include payment terms, discounts and delivery schedules. The committee transmits its written decision to the hospital director for review prior to the hospital offering any contracts. The wholesaler ranked first is usually offered a contract for the delivery of the needed pharmaceuticals. It is possible for more than one wholesaler to obtain a contract, but each wholesaler supplies different groups of pharmaceuticals or medical consumables. The decision is taken by the director of the hospital, usually based on the decision of the evaluation committee.

### **2.2.2 Negotiations**

Private hospitals usually provide medicines after the negotiation process. Each hospital organises the negotiation process by itself. Some hospitals negotiate annually whereas some hospitals negotiate more often. The hospital has the right to invite a selected number of wholesalers to present their offers and then to negotiate the price of each pharmaceutical as well as other conditions (delivery terms, discounts, payment terms, etc.). Usually the most important criterion is the price of the medicine, but sometimes payment terms are also very importance. Hospitals might be in contact with manufacturers for their own products, but usually the negotiation process is with the suppliers because one supplier can offer the big

range of products used in the hospital unlike the local manufacturer who can offer only limited products, which are produced by itself.



## 3 Reimbursement

### 3.1 National hospital reimbursement procedure

Bulgaria established the first positive list for medicines in 2003. The present reimbursement system has undergone different developments. As per the Medical Products in Human Medicine Act (MPHMA) Art. 261, a Positive Drug List Committee (PDLC) is established, subordinate to the Council of Ministers. The PDLC reviews and decides on inclusion, change, and/or exclusion of medicines from the positive drug list (PDL). Its members have a mandate of 4 years and every two years half of the composition of the committee are renewed. It consists of representatives from the Ministry of Health (MoH), Ministry of Work and Social Policy, the National Health Insurance Fund (NHIF), Bulgarian Drug Agency (BDA), Bulgarian Medical Association and Bulgarian Dental Association. Additionally, medical specialists, lawyers, and economists with scientific achievements and/or practical experience in the field of medicines and in the respective spheres of their application can be appointed as members of the PDLC.

The Council of Ministers by regulation defines the criteria, the rules and the procedure for including the medicines in the PDL of the country. As per Art. 262 of MPHMA, the PDL includes prescription-only medicines (POM), which are necessary to cover the health care needs of the population and are paid from the budget of the NHIF, from the national budget outside the scope of the obligatory health insurance, and from the budget of the public in-patient health care establishments. In the PDL medicines by pharmacological groups with the respective international non-proprietary names (INN), defined daily doses (DDD), reference price (value) for the DDD, and level of payment are included. For pharmaceuticals which have no DDD, a treatment course and reference value are determined.

The medicines in the PDL are selected according to evidence of efficacy, therapeutic effectiveness, safety, and analysis of pharmaco-economic indications. The period for inclusion of medicines in the PDL is 90 days from the date of submission of a new application and 60 days for a change in the conditions for pharmaceuticals already included in the PDL. The decision of the PDLC might be appealed in front of the Transparency Committee (TC). The TC is subordinate to the Council of Ministries and includes representatives from MoH, BDA, NHIF, Bulgarian Medical Union, the Dentists Union and the Union of Pharmacists in Bulgaria. According to Art. 266 of MPHMA, the TC is the appeal body for the decisions of the Pricing Committee and the PDLC. The decisions of the TC could be appealed under the terms of the Administrative Procedure Act, but the appeal has no suspensive effect.

The medicines in the positive list in the year 2009 are grouped in four parts - annexes:

- medicines for treatment of diseases reimbursed by the NHIF. The level of payment is determined according to the budget of NHIF for the corresponding year.
- medicines paid by the budget of the in-patient public medical establishments;

- medicines proposed for treatment of diseases out of range of Law for Health Insurance, paid through the budget of the MoH. These are medicines, which are legally defined in a regulation under the Health Act (HA).
- medicines intended for treatment of rare diseases, AIDS, and infectious diseases.

The criteria and conditions for including pharmaceuticals in the PDL are specified in Section II of the Regulation on the criteria, conditions and rules for including medicines in the PDL of the Republic of Bulgaria. The inclusion in the PDL gives the right, the medicine to be reimbursed by the NHIF, MoH or public hospitals.

In 2009 PDL Annex 2 – medicines for in-patient care – 1,671 positions by brand name, including different pharmaceutical forms, dosages and pack size are included. They correspond to 513 INN. The level of reimbursement of the medicines, included in the Annex 2 is 100%. This means that theoretically the patient is not supposed to pay for them during hospitalisation. The medicines are included in the cost of the treatment as part of the medical activities carried out through clinical pathways. Some medicines for treating particular diseases in hospitals are paid for through the state budget. Patients without active health insurance rights (around 1 mio. people) pay the cost of their treatment, including medicines. Patients with chronic diseases, for which they receive medicines for out-patient care from the NHIF, are supposed to carry with them the already prescribed medicines when hospitalised. The Bulgarian PDL 2009 is published on the website of MoH<sup>8</sup>.

### **3.2 Hospital pharmaceutical formularies**

As per Art. 74 of the HEA, the head of the hospital can establish different committees and councils, according to the needs of the medical establishment, among which the pharmaceutical and therapeutic committee (PTC). In this committee the heads of the different departments in the hospital, the economic director, and the chief pharmacist usually participate. As per Art. 37 of Regulation 28 (OJ 109/ 2008) the PTC annually creates the hospital pharmaceutical formulary (HPF). The difference to the medical council is in the range of tasks and responsibilities. Members of the medical council might be members of the PTC and vice versa, e.g. the chief pharmacist in the hospital. Each hospital in Bulgaria has the choice and the right to create its own medicines policy, respectively its own list of preferred medicines HPF.

The PTC in public hospitals creates a HPF annually, with which the hospital pharmacy is operating. The formulary is approved by the director of the hospital. It is based usually on data from previous years, but updated according to the current PDL. The size range of the HPF depends on the budget of the hospital, the type of the hospital, and the dominating morbidity of the population. Public procurement of the hospital pharmacy is according to the

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<sup>8</sup> <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=384&categoryid=1355>

HPF. HPFs are available internally in the hospital and in most cases are mandatory for physicians in hospitals.

## 4 Consumption of pharmaceuticals

In Bulgaria official information and data on consumption (utilisation) of pharmaceuticals in hospitals at a national level is not available. Each hospital monitors its consumption, but this information is not shared publicly.

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

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
<b>Annual pharmaceutical consumption in total</b>						
in packs	165,271,912	152,816,461	157,367,105	n.a.	n.a.	n.a.
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Annual pharmaceutical consumption in hospitals</b>						
in packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

Source: BDA

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

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

## **5 Evaluation**

### **5.1 Monitoring**

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

Traceability of pharmaceuticals theoretically is possible, because the wholesalers are obliged to keep track of their sales, but in practice there is no aggregated data neither for individual hospitals nor generally for the in-patient sector.

As already explained in section 1.2. the chief hospital pharmacist is a member of the Medical Council of the hospital as well as member of the pharmaceutical and therapeutic committee (PTC). The head of the hospital pharmacy is a leading specialist in developing practical prescription lists, based on the quality, safety and efficacy as well as pharmaco-economic evaluation of medicines. He/she participates in all activities connected with negotiations, supply and delivery of the necessary medicines; makes proposals for the project of the budget, concerning medicines; creates standard operative procedures (SOPs) for the activities in the hospital pharmacy, incl. preparations of ex-temporal products; controls the distribution, storage and accountability of the medicines in the wards and departments of the hospital; interacts with other medical specialists, providing them with the drug information and recommendations for optimal drug therapy.

### **5.2 Assessment**

Health-economic analysis and particularly pharmaco-economic analysis still do not have a long history in the country. The only legal provision is in the regulation on the terms and conditions for including medicines in the positive list of the country. This provision is very general and is just mentioning that the pharmaco-economic analysis is considered for the inclusion of medicines in the positive list of medicines.

## 6 Interface management

Hospital expenditure has been rapidly growing, e.g. the average expenditure per hospitalisation increased from BGN 106 / € 54.19 in 2000 to BGN 443 / € 226.5 in 2007. In 2007 on average one out of five people in Bulgaria were hospitalised (Sanigest Solutions, 2008). One of the obvious reasons for these facts is the system of reimbursement of the hospitals meaning that treatments do not need to be paid by patients. The admissions to hospitals do not follow the typical movement, but are generated directly by the general practitioners (28%) or are a result of self directing from the side of the patients (16%). Despite the increasing expenditure, the quality of the provided services has not much improved.

This development requires better interface management in general and concerning medicines.

## 7 Developments and outlook

For a relatively young and still reforming health care system like the Bulgarian system, there is still a lot to be done. The existing National Health Map is from 1999 and is not considering main socio demographic, infrastructural, communicational, personnel, etc. characteristics. So far, in the past few years three National Health Map projects have started. None of them were accepted by the Parliament. In the National Health Strategy 2008-2013 the creation of a National Health Map is also foreseen, which will be obligatory in terms of restructuring of the medical establishment network and rationalising the system.

Another challenge is the optimisation of the multi-profile hospitals network and its internal restructuring, narrow specialisation and introduction of the one day surgery. The hospital managers should follow adequate investment policy for progressive development and reaching the required high technology state of the medical establishments.

The Bulgarian Privatisation law gives the opportunity for privatisation of the existing hospitals, except some particular hospitals with national importance, which are not allowed for privatisation. So far, there is no practice of privatisation or development of public-private partnership and implementation of the legislation.

A process of improving the interaction between the out-patient and in-patient sector has to be developed as well as introducing the mechanisms allowing the information exchange of information between the in- and out-patient sectors.

Concerning the pharmaceuticals in the hospital sector, few points are also planned for development:

- Promotion of rational use of medicines and the improving the knowledge of the health professionals;
- Creating a system for monitoring of pharmaceutical consumption and a system for qualitative and quantitative measurement of the consumption;
- Development of information links between the Ministry of Health, Bulgarian Drug Agency, National Health Insurance Fund as well as development of their own information systems in line with the legally regulated activities;
- More comprehensive disclosure of information in websites, annual reports, public forums concerning public procurement and other statistic information;
- An independent body for selection and procurement of medicines in all segments of the system was planned by the previous government;
- A system for professional development of personnel in the pharmaco-economic field;

Finally, these are some of the points, regularly entering in the public attention. What will be achieved in reality will depend on the results of the parliamentary elections in July 2009 and the political will of the new government.

## 8 References and data sources

Jelev, E., Ivanov L. (2008): The Health-Main Investment in the Future of the Country, annual report of the MoH. Sofia

MoH (2008): National Health Strategy 2008 – 2013.  
<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=419&home=true>

NHIF (2009): – Report Ten Years National Insurance Fund  
<http://www.nhif.bg/bg/default.phtml?w=1280&h=770>

Open Society Institute Sofia, (2008): Informal payment in the Healthcare system

Sacheva D.,IHHII (2008): Focus on Bulgaria, PMLive Intelligence online

Sanigest Solutions (2008): Report: Opportunities for improving the practices connected with the out-patient to in-patient treatments.

Semerdjiev, I. and others (2005): The Socio-Economic Environment in the Republic of Bulgaria in 2005, Paper, Sofia.