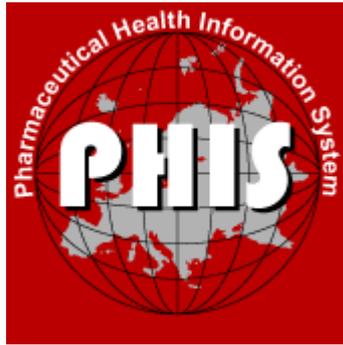




PHIS Pharma Profile

Bulgaria

2010



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Executive Summary

Health care system

At the beginning of the 21st century the population of Bulgaria follows a trend of decrease and as of December 31, 2001, when the last official census was carried out, there were 7,932,984 people living permanently in the country. As compared to the previous census conducted in 1992, the population decreased by 544,333. This trend is expected to continue reaching by the end of 2010 approximately 7,362,300 people living in Bulgaria.

Population is aging because of unfavourable trends in demographic processes in the past four decades. In 2001, the share of population under age 15, as compared to the 1992 census, decreased to 15.2% of the total population and the share of persons over 64 increased to 17.4% of the population. In 2009 1,026,200 people aged 0-14, or 13.56% of the total population, 5,211,619 people aged 15-64 (68.90% of the total population) and 1,325,891 people aged over 65 (17.52% of the total population) lived in Bulgaria. The changes in the age composition of the population affect both cities and villages. The average life expectancy increased in 1995 - 2008 from 70.50 to 73.00; the declining birth rates, emigration flow, reduction of persons of working age and the increase of people over working age cause major **changes in the population age structure** in Bulgaria, which can be defined as **demographic aging**, i.e. increase the absolute number and proportion of older people.

By a health reform starting in 1999, Bulgaria implemented many beneficial elements of the positive structural and functional solutions of the healthcare systems of social security type, combined with some elements of the national health services. This is a new and increasingly implemented model by various countries, defined as a **Public-private mix**. Thus, the Bulgarian healthcare covers, in varying degrees and ranges, the governmental, insurance (public and corporate) and private sectors, each of which has its perimeters of action, rights, and responsibilities.

The reforms initiated in 1999 in the field of medical healthcare were radical and extremely serious. They and the newly established **NHIF** (National Health Insurance Fund) regulated and defended the rights of citizens concerning the healthcare system, patients' rights to medical care rendered in hospitals and the rights of medical professionals performing medical and health care. The medical healthcare reform started with the adoption by the National Assembly of several new structural laws for the health system until 2000 and another one concerning mainly the public health, which was adopted in 2004: Law on Safety and Health at Work (LSHW) - in 1997; Health Insurance Act (HIA) - in 1998; Law for the NHIF budget from 2000 until now]; National Framework Agreement- NFA (concluded each year between the NHIF and branch organizations of physicians and dentists) - from 2000 until now; Law on the professional organizations of physicians and dentists (LPOPD) - in 1998; Health Establishments Act (HEA) - in 1999; Law on Pharmaceuticals and Pharmacies in Human Medicine (LPPHM) - in 2000; Health Law - in 2004.

These basic structural laws and the NFA regulate the structure, operation, organization, and management of medical, dental, and pharmaceutical activities and their funding.

The health care system is administered by the Ministry of Health, which has 28 units - Regional Healthcare Centres. Social health insurance is represented by the NHIF, which has a separate budget determined on annual basis by the National Assembly.

The funding of healthcare for insured citizens (health insurance in Bulgaria is mandatory) is done by **the National Health Insurance Fund**. When a person is also insured by a voluntary health insurance company, depending on the insurance contract, the expenses for his/her treatment are covered also by the relevant insurance company. If a person goes to a health establishment at his own will (without referral from the general practitioner or a specialist) he/she pays him-/herself the treatment expenses. In addition to the insurance contribution, the obligatorily insured persons pay a customer fee for each primary visit to a doctor or a dentist at the rate of 1% of the minimum salary and for each day of hospital treatment (but not more than 10 days a year) at the rate of 2% of the minimum salary. Some population groups are exempt from payment of customer fees.

The range of income for which the 8% mandatory health insurance contribution is applied varies from 2 to 10 times the minimum insured income. At present, the employer pays 60% of the contribution and the employee pays 40%

The state represented by the MoH and municipalities, via the consolidated state budget, provide financing from taxes for the activities of the public healthcare institutions, which are public property- *Regional Inspectorates for Public Health Control; Emergency healthcare centres; Centres for transfusion haematology; Healthcare establishments for stationary psychiatric care; Homes for medical and social care designated for medical monitoring and specific care for children; Healthcare establishments at the Council of Ministers and healthcare establishments of governmental departments.*

The public healthcare expenditure in 2009 reached up to 348 BGN/177.93 € per capita that is almost triple increase compared to the year 2000. Presented as a percentage of the GDP the public healthcare expenditures are steadily positioned at about 4% for the past ten years. Based on expert assessments of the WHO, for the same period the private healthcare financing gradually caught up with the public financing, whereby presents 35 – 40% of the public financing. A large part of the private financing is not legally regulated, to the detriment of the best practices.

The choice of a healthcare provider is regulated in a Regulation of the Ministry of Health. In the primary healthcare, the choice of a general practitioner is fully liberal and every citizen is entitled to change his/her choice once in every 6 months.

General practitioners are paid based on per capita principle with additional payment for certain activities. GPs are the "doorkeepers" to specialized care. Specialists in out-patient care are paid in the form of a fixed fee per visit. Highly specialized diagnostic services are paid in the form of fee per service.

All hospitals for active treatment, post-surgery treatment and rehabilitation, as well as hospices were transformed in 2000 into public limited liability companies or joint stock companies. So far, none of them has been privatized. Before 2010, payment of hospital care was based on a contract with NHIF by groups of diseases, defined as "clinical pathways". Since 2010, hospital funding has changed and is done through the so-called "delegated budgets", which are a form of global budgets with a fixed framework for a one-year period.

Each hospital has the right to sign a contract for funding with the existing 21 companies for voluntary health insurance. Doctors in hospitals are employed based on an employment contract. Although hospitals are registered as corporations, they receive their funding based on administrative prices set by the NHIF. Once a year there are negotiations between the NHIF and the professional organizations of doctors with regard to the specific amount of these prices, which are then described in the National Framework Agreement, but with recent changes in the NFA 2010, this period was increased to 3 years. Each insured person also pays for hospital care a user fee amounting to 2% of the national minimum wage but not for more than 10 days a year. The minimum wage is 240 BGN.

In late 2009 there are 27,988 practicing doctors having their main employment contract in the medical and healthcare establishments in the country.

Among all specialties, in the end of 2009 the largest proportion is of GPs - 4,949 or 17.7% of all practicing doctors in the country. Specialists of internal diseases are 1,496 or 5.3%. Next within the structure of doctors by specialties are Obstetrics and Gynaecology (1,387 or 5.0%) and Paediatrics (1,381 or 4.9%).

Depending on the health establishments, where they have their main employment contract, the healthcare specialists in the country are divided as follows: In establishments for hospital care, (hospitals and dispensaries) there are 13,999 practicing physicians. 11,226 practicing physicians have their main employment contract with establishments for out-patient care. At the end of 2009 the coverage with medical doctors is 37.0 per 10,000 people.

According to data of the Bulgarian Medical Association on average 500 medical doctors are leaving the country annually. There is no data on their age, speciality or country of migration, however it is considered that they mostly go to other European countries.

Pharmaceutical system

Since the beginning of 2007 as Bulgaria became a Member of the European Union the Bulgarian pharmaceutical legislation is corresponding to the European legislation, with only minor fluctuations in the duration of some procedures and still needs fine tuning to some regulations, e.g. those defining the market access (pricing + reimbursement decision + actual reimbursement) and this is one of the areas in which the pharmaceutical legislation in Bulgaria should improve.

According to art. 14 of the Law on Pharmaceutical Products in Human Medicine (LPPHM), the policy in the pharmaceutical sector in Bulgaria is executed by the Ministry of Health (MoH).

The Ministry of Health is in charge of the overall pharmaceutical policy planning, as the executing and controlling authority. The Ministry also issues licences for retail pharmacies and provides by means of public procurement some medicines for treating of specific diseases, obligatory vaccinations and some health programmes, such as tuberculosis, AIDS, oncology treatment, etc.

As per article 17 of LPPHM, the Bulgarian Drug Agency (BDA) is the specialised body to the MoH for the quality, safety and efficacy of medicines.

Various Committees are established - Pricing Committee (PC), Transparency Committee (TC), Positive Drug List Committee (PDLC) to support and implement the pricing and reimbursement policy of the government.

Since 2007 we are working according the Law on Pharmaceutical Products in Human Medicine, which is already 9 times amended by the time of writing this profile. Parallel to the Law on Pharmaceutical products in Human Medicine, the sector is also regulated by the Control of Narcotics and Precursors Act, the Health Act, the Health Establishments Act, and the Health Insurance Act, as well as the regulations for their implementation.

The secondary legislation on the implementation of the key laws for the sector, the LPPHM and the Control of Narcotics and Precursors Act, consists of over 50 regulations and other bylaw acts (regulations, orders, tariffs, etc.) for both (25 already issued and 5 still pending at the time of writing the profile, concerning the LPPHM and over 20 concerning the Control of Narcotics and Precursors Act).

Despite several attempts through the years to do so, on the part of the Ministry of Health (MoH), in the country there is still no officially adopted National Drug Policy Paper. This leads to the lack of middle and long term vision and sustainability of the development of the pharmaceutical sector and even worse, it gives the possibility each new leading team in the Ministry of Health constantly to make changes in the pharmaceutical environment.

A slightly decreasing trend in the number of medicines on the market for the last year is observed, but at the time of writing this report is still early to have a definite explanation for it. Possible reason of this trend might be the pharmaceutical companies' policy, to withdraw some medicines from the market due to the restrictive pricing procedures or not attractive market conditions.

There are few examples of switches from POM to OTC, but it is not possible to follow this process closely, again due to lack of chronological information about the POM and OTC medicines.

Concerning the parallel traded (PI) medicines, still there is no experience in the country. One of the possible reasons might be the fact that there is a formal procedure, but in practise there are legislative and administrative obstacles for the PI medicines to enter the reimbursement system, e.g. it is required the wholesaler/parallel Importer to be authorised by the holder of marketing authorisation in order to be included in the reimbursement list of NHIF for the PI medicines to enter the reimbursement system.

The average time between marketing authorisation and patient accessibility varies according to the type of medicines – reimbursed or not, POM or OTC. For the medicines, included in the Positive list, the duration is 45 days for price + 90 days for reimbursement decision = 135 days after the marketing authorisation. Then medicines reimbursed by the NHIF need two more months to become effectively available for the patients. Those medicines, supposed to be reimbursed by MoH have further to be included in another regulation in order to be able to be included in the annual public procurement process. POM, which do not have reimbursement pretensions theoretically reach the market within 45 days after receiving the marketing authorisation.

The OTC products are reaching the market within 30 days after receiving marketing authorisation.

An increasing tendency of pharmaceutical sales is observed. For the last five years from 2005 to 2009 there is more than 71% increase of the total sales. The increase in % in the out-patient sector is higher than the % increase in the hospital sector. Possible reasons are the restricted and limited hospital budgets for medicines versus the increased resources for out-patient medicines of the NHIF, as well as the slightly increasing budget for public procured medicines by the MoH.

As the pharmaceutical sales are growing, the consumption is growing as well – total consumption in DDD has grown by around 29% in the last five years period. For the same period the consumption in DDD in the out-patient sector grows faster than the consumption in the hospitals.

Data concerning consumptions in Bulgaria is available only for that part of prescriptions, which are reimbursed – fully or partially by the NHIF. There is no regulatory obligation to monitor the prescriptions in the rest of out-patient or in-patient sector.

Steady trend of increase in both volume and value is observed. Some of the reasons are connected with the increased number of medicines, especially “the expensive ones”, included in the reimbursement list of the NHIF as well as the increased budget of NHIF for medicines throughout the years. Other reasons are the fact that during the years more and more people are getting informed and benefit from the compulsory insurance as well as the increasing morbidity of the aging population. Budget of the NHIF for medicines was also steadily growing through the years.

The delivery chain for medicines for both - out-patient sector and hospital sector - is quite simple. Any wholesaler licensed/registered by the BDA is able to buy from manufacturers and deliver medicines to other wholesalers, out-patient pharmacies and hospital pharmacies.

In Bulgaria manufacturing is regulated by Chapter 5 of the LPPHM and Regulation N15 on conditions for authorization of the manufacture/ import and the principles and requirements of GMP for all types of medicines, incl. those for clinical trials and active ingredients (OJ 38, 2009)

Manufacturers may supply medicines that they have produced themselves, wholesale traders, other manufacturers, only if necessary for the production activities, hospitals, Ministry of Health (MoH) – with vaccines, toxins and serums necessary for the fulfilment of the vaccination calendar of the Republic of Bulgaria, as well as in emergency epidemic situations.

Local producers classify themselves as generics manufacturers. Till 2005 the BDA was publishing data in volume and value about the medicines sold by the local and foreign manufacturers, but at present official data is not published any longer.

Several associations of manufacturers are established in the country. Each of them is very active concerning the regulatory environment in the sector.

The wholesalers' activities are regulated by Chapter N9 of the LPPHM and Regulation No 39 of 13.09.2007 on the principles and requirements for Good Distribution Practice (OJ 77, 2007). Authorisation is granted for an indefinite period by the Bulgarian Drug Agency (BDA). The procedure of authorisation takes three months. For the wholesalers, who has license issued by a regulatory body of a member state, the Executive Director of the BDA shall issue a certificate for registration within 15 days of submission of the documentation.

Data from IMS Bulgaria shows that in 2009 the 80% of the sales on wholesale market level is made by 5 wholesalers. Each of the top two wholesalers has around 21 % and the fifth one has 2.3% of the market.

The legislation in Bulgaria allows medicines to be sold at retail level only by pharmacies and drugstores. Exceptionally doctors and dentists may sell medicines only in places/regions without a pharmacy.

A pharmacy by definition is a health facility where the following activities are performed: storage, preparation, packaging, control, consultation, dispensing of POM or OTC medicinal products, as well as medical devices, diet foods for special medical purposes and foods for breast-fed children and transitional foods, food supplements, cosmetic and hygienic products.

Chapter ten of the LPPHM provides detailed information about the requirements, procedures and obligations of the pharmacies. Art. 222 states that the right to carry out retail trade can be granted to a physical or legal person who is registered as a trader in accordance with the Bulgarian legislation or in accordance with the legislation of a Member State if he has concluded a labor contract or a contract for management of the pharmacy with a qualified pharmacist or, in the cases laid down in the law, with a pharmacist assistant. Such person is authorized to open up to 4 pharmacies on the territory of Bulgaria. The qualified pharmacist or a pharmacist assistant may be the manager of only one pharmacy and must work within the pharmacy. This person cannot be employed on a labor contract or participate in another company involved in the manufacture, import, wholesale or retail sale of medicines, neither can work in other companies of related persons in accordance with the Trade Law.

In an area, where no other pharmacy is available, the right to open a pharmacy might be granted to a person who has concluded a labor contract or a contract for management of the

pharmacy with a pharmacist assistant or a qualified pharmacist even with experience less than a year.

To motivate opening of pharmacies in locations with less than 10 000 inhabitants a separate specific form and 5 times reduced fees are introduced.

To open a pharmacy which dispenses and sells medicines containing narcotic substances, the provisions under the Narcotic Substances and Precursors Control Act must also be followed, e.g. a second licence should be obtained.

The municipalities and the medical establishments for hospital care can register a pharmacy fulfilling their own needs under same procedure as the other pharmacies. The pharmacist is the licence holder for these types of pharmacies and he cannot open a private pharmacy.

Not all of the registered pharmacies can work with the National Health Insurance Fund. They need to meet NHIF's requirements in terms of record-keeping software and monthly reporting, and they are inspected by the National Health Insurance Fund and the Bulgarian Drug Agency. The contracts between Pharmacies and NHIF are renewed annually.

It is forbidden to sell POM by internet.

The main funding sources for public pharmaceutical expenditure in the country are social health insurance contributions via the National Health Insurance Fund and the state budget via the Ministry of Health and the Municipalities, incl. the contributions to pharmaceutical funding for a very limited group of medicines for war veterans and victims and military disabled persons.

Private pharmaceutical expenses are made up of expenses for out-of-pocket payments for the reimbursed medicines; expenses for non-reimbursed prescription medicines; self-medication expenses paid to Voluntary Health Insurance Funds and informal payments.

Pricing, reimbursement and volume control in the out-patient sector

Two of the main legal documents that have established the statutory pricing system in the country are the LPPHM 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 medicines (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 medicines, included in the positive list and paid with public funds, regulates the ceiling prices of the POM medicines not included in the positive list and the registration of the prices of OTC medicines. When a medicine will apply later for inclusion in the Positive List, both applications – for price and for reimbursement price - can be filed at the same time. The reimbursement price will be effective from the moment of inclusion of the medicine in the positive list.

The price, at which a medicine can be sold, is the price approved by the PC. 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 medicine in excess of this price.

For POM the price is determined at manufacturer level based on the methodology of external price referencing, and at wholesale and pharmacy levels statutory maximum mark-ups are applied. The remuneration of the wholesalers and pharmacies is based on regressive mark-ups. The regulation approves the price for POM at each level – at manufacturer, at wholesale and retail sale level with all elements, e.g. from the ex-factory price, the mark-up for each level and value-added tax (VAT) at each level.

The pricing procedure is the second step towards market access for the medicine. In an ideal scenario the procedure for prescription-only medicine(s) (POM) lasts 45 days.

After the pricing decision, medicines seeking to be included in the reimbursement lists are subject to the next stage in the process which is the application to the Positive Drug List (PDL). Medicines not seeking reimbursement are ready to be sold on the free market. Standard value-added tax (VAT) in Bulgaria is 20%. There is no exclusion or lower value-added tax for medicines.

Several legislative acts are structuring the reimbursement system in the country in 2010. The Health Insurance Act (OJ 70/1998, last amended OJ 62/2010) is an act, which frames the overall structure and functioning of the national health insurance system. It regulates the signing of the National Framework Agreement (NFA) between NHIF and the professional associations of health care providers – doctors and dentists. The NFA provides for the parameters and procedures related to the functioning of the health insurance system as a whole. It defines the order, content and the payment of the health care activities and services to be provided to the insured population. Aside from the Health Insurance Act, the regulative framework of the reimbursement system is determined by several other main laws – the Health Act (OJ 70, 2004), the LPPHM (OJ 31/2007), and the War Veterans Act (OJ 152, 1998), Military disabled and war victims Act (OJ27/2005) as well as the regulations related to their application.

Regulation N38/2004 is defining the list of diseases, for which medicines for out-patient treatment are paid fully or partially by the NHIF. To be covered by the existing mechanisms for reimbursement, the medicines should be included in the PDL. The regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee are adopted by the Council of Ministers Decree N311/2007. The reimbursable medicines for out-patient sector are in the Annex 1 of the four annexes of the Positive Drug List.

A Positive Drug List Committee (PDLC) is established at the Council of Ministers after a proposal of the Minister of Health. The decisions of the PC and the PDLC might be appealed in front of the Transparency Committee, set up by the Council of Ministers.

For the first time in 2003, a PDL was introduced in Bulgaria. Currently, the Council of Ministers Decree N311/2007 adopts the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List as well as the conditions for the functioning of the Positive drug list Committee.

Article 262 of LPPHM states that the PDL includes POMs, which cover the health needs of the population and are reimbursed by the budget of the NHIF, the state budget out of the scope of obligatory health insurance and by the budgets of the in-patient public medical facilities. The Positive Drug List is a list of medicinal products showing their trade name, drawn by pharmacological groups with the relevant international non-proprietary names, defined daily dosage, defined prices by the PC, reference value for a defined daily dosage, price calculated on the basis of the reference value and level of reimbursement. At present, the PDL consists of 4 Annexes.

The medicines in the Positive Drug list are included on the basis of evidence for efficacy, therapeutic efficiency, safety and analysis of the pharmaco-economic indicators. The procedure for inclusion of medicinal products in the PDL is 90 days from the submission of valid documentation and 60 days for a change in the conditions for medicines already included in the PDL.

The decision for the inclusion/exclusion or change of the medicines in the PDL is made by a Positive Drug List Committee, which is established at the Council of Ministers after a proposal of the Minister of Health.

Reimbursement categories and rates are determined by the PDLC and are set according to the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee. Currently there are 3 reimbursement categories in the out-patient sector, based on INN and pharmaceutical form of the medicines, included in the PDL. These are medicines for the treatment of chronic diseases, which lead to severe disturbance of the quality of life or disability and requiring prolonged treatment – reimbursement up to 100 percent; medicines for chronic diseases occurring with high prevalence of disease – reimbursement up to 75 percent; medicines for diseases other than those under the previous points - reimbursement up to 50 percent.

A reference price system is applied for all the medicines included in the Positive List. A detailed explanation is given medicines fully or partially reimbursed by the National Health Insurance Fund. As parallel traded medicines are not part of the reimbursement system, they are not included in the reference group. Generally, the reference price is made at ATC 5 level. The methodology is described in details in the Positive Drug List Regulation.

There are percentage co-payments which vary for each medicine. Besides the category of fully reimbursed medicines, for the others which are partially reimbursed, the patients actually make the co-payment. There some medicines, which are reimbursed only 10% and in these cases the co-payment might reach 90%.

For many years the creation and implementation of overall generic policy is discussed among the interested parties, but no practical legislative steps have been taken so far. In 2010, still generic substitution is not allowed in Bulgaria. Regulation № 4/2009 on the terms and conditions for prescribing and dispensing of medicinal products OJ (21/2009), article 8 gives the possibility to the physicians to prescribe under INN together with the right to prescribe by brand names. INN is not mandatory and thus very rare.

Health economics analysis and particularly pharmacoeconomic analysis do not have a long history in Bulgaria. The one legal provision in this field is in the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee. This provision is very general and it simply states that pharmacoeconomic analysis is taken into consideration when medicines are evaluated for inclusion in the Positive Drug List.

Pricing, reimbursement and volume control in the in-patient sector

Pricing in the in-patient sector is organised in the same way and is regulated by the same legislation acts like the pricing in the out-patient sector. It is by nature statutory pricing and is determined by the state according the LPPHM.

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

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 not more than the registered inflation. In the opposite way the price can be decreased at any time.

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

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% for all types of medicines, incl. the hospital ones. The hospital pharmacy has no right to add its own mark-ups to medicines. 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 hospitals are supplied with medicines through licensed wholesalers after procurement for public hospitals or negotiation or tendering for private hospitals. There is no specific institution involved with the decision of the purchasing process. In each hospital a commission is appointed by the manager of the hospital for purchasing of medicines.

Public procurement is the obligatory procedure for providing medicines paid from funds from the state or public budget. This applies for procurement procedures for medicines for the Ministry of Health and for public hospitals.

Legally procurement 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 value of the medicines, used in hospitals is part of the clinical pathway. Thus medicines for the in-patients should be fully covered by the hospital budget. Patients with chronic diseases, for which they receive medicines for out-patient care from the NHIF, are supposed to carry the already prescribed medicines when hospitalised with them.

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.

Bulgaria established the first positive list (Positive Drug List, PDL) for medicines in 2003. At that time it was only for medicines for the out-patient sector. The present reimbursement system has undergone different developments and the hospital medicines now are part of the PDL.

As per art. 37 of Regulation 28 (OJ 109/ 2008) the Pharmaceutical and Therapeutic Committee (PTC) annually creates the hospital pharmaceutical formulary (HPF) in public hospitals, 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 range of medicines included in the HPF depends on the budget of the hospital, the type of the hospital, and the dominating morbidity of the population.

As per article 74 of the Health Establishments Act (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). These are internal for the hospital structure. Usually the pharmaceutical and therapeutic committee (PTC) comprises the heads of the different departments of the hospital, the economic director, and the chief pharmacist.

Since many years the Monitoring and Evaluation are weak points in the Bulgarian pharmaceutical sector. There is no institution on central or regional level in the sector, which is obliged to collect and analyse data.

On national level, price monitoring is still not a routine process. Occasionally the MoH is monitoring prices of public hospitals under its supervision, obtained after the public procurement, but data is not publicly available.

There is lack of complete, actual and reliable statistic data about medicines in hospitals on regional and on national level, which might be used for analytical and decision making purpose. This represents an important obstacle for decision making.

Interface management and developments

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 was 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 improved much.

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

For a relatively young and still reforming health care system like the Bulgarian, there is still a lot to be done in both healthcare and especially in the pharmaceutical sector. Some of the points, regularly entering in the public attention and still looking for its decision are connected with:

- Introducing legal requirements for monitoring of pharmaceutical consumption, prices, expenditures on national and regional level for both out- and in-patient sector.
- 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;
- Creating a system for monitoring of pharmaceutical consumption and a system for qualitative and quantitative measurement of the consumption
- Promotion of rational use of medicines and improving the knowledge of the health professionals;
- A system for professional development of personnel in the pharmacoeconomic field
- More comprehensive disclosure of information in websites, annual reports, public forums concerning public procurement and other statistic information;

To improve the overall organisation and management of the pharmaceutical sector, numerous changes in the structural, pricing and reimbursement aspects are planned from the side of MoH and available on <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=393¤tPage=2&categoryid=3381>

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List of abbreviations

AIDS	Acquired immune deficiency syndrome
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ARPharM	Association of Research-based Pharmaceutical Manufacturers
ASA	Association of Owners of pharmacies
ATC	Anatomic therapeutic chemical classification
BDA	Bulgarian Drug Agency
BDU	Bulgarian Dentists Union
BGfarmA	The Bulgarian Generic Pharmaceutical Association
BGN	Bulgarian lev
BMG	Bundesministerium für Gesundheit
BMU	Bulgarian Medical Union
BPU	Bulgarian Pharmaceutical Union
DDD	Defined daily dose
DG SANCO	Health and Consumer Protection Directorate General
DRG	Diagnosis related group
EAHC	Executive Agency for Health and Consumers
GDP	Gross domestic product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
GP	General Practitioner
HIA	Health Insurance Act
HTA	Health technology assessment
HE	Health expenditure
HEA	Health Establishments Act
HIA	Health Insurance Act

HiT	Health systems in transition
HOM	Hospital-only medicine
HPF	Hospital pharmaceutical formularies
IHHI BG	International Healthcare and Health Insurance Institute BG
INN	International Non-proprietary Name
LPPHM	Law on Pharmaceutical Products in Human Medicine
LPOPD	Law on Professional Organisation of physicians and Dentists
LSHW	Law on Safety and Health at Work
Mio.	Million
MoF	Ministry of Finance
MoH	Ministry of Health
NCU	National currency unit
NFA	National Framework Agreement
NHIF	National Health Insurance Fund
NHM	National Health Map
NMEs	New molecular entities
OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient departments
OPP	Out-of-pocket payment
OTC	Over-the-counter medicine
PAP	Professional Association of Pharmacists
PC	Pricing Committee
PDL	Positive Drug List
PDLC	Positive Drug List Committee
PE	Pharmaceutical expenditure

PHIS	Pharmaceutical Health Information System
PI	Parallel imported medicines
POM	Prescription-only medicine
PPP	Purchasing power parities
PPR	Public Procurement Register
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
PTC	Pharmaceutical and Therapeutic Committee
QALY	Quality adjusted life year
RHC	Regional Health Centre
RHIF	Regional Health Insurance Fund(s)
RIPCPH	Regional Inspection for Protection and Control of the Public Health
SHI	Social health insurance
SUKL	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control
SOGETI	SOGETI Luxembourg SA
SOP	Standard operative procedure
TC	Transparency Committee
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
VHI	Voluntary health insurance
VHIF	Voluntary Health Insurance Fund(s)
WHO	World Health Organisation
WP	Work package

Introduction

The Pharmaceutical Health Information System (PHIS) project is a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) a research institute situated in Vienna, Austria, and four associated partners: the Italian Medicines Agency (AIFA), Italy, the International Healthcare and Health Insurance Institute - (IHHI), Bulgaria, SOGETI Luxembourg SA., Luxembourg and the State Institute for Drug Control (SUKL), Slovakia. Further key stakeholders of the PHIS project management are the PHIS advisory board covering EU Commission services and agencies and 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 aims to increase the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This will be achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

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 Monitoring

The aim of the work package “Monitoring” is to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States.

The country-specific information is compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sector written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sector (also part of the PHIS Pharma Profile)
- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (<http://phis.goeg.at>) and is constantly updated.

PHIS Pharma Profile

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

1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sector. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template is based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria¹) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

¹ IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – www.zdrave.net – which is an online arena of information exchange and debates in health reaching at daily average 5, 000 people acting in health and pharmaceutical system.

2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conversations and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRI report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHII, Bulgaria (Work Package leader of “Monitoring”) 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, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feedback on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Health care system

This chapter provides an overview of the country's health care system as of 2010.

1.1 Demography

Table 1.1: Bulgaria – Demographic indicators 2000, 2005–2009

Demography	2000	2005	2006	2007	2008	2009
Total population	8,149,468	7,718,750	7,679,290	7,640,238	7,606,551	7,563,710
Population aged 0-14	1,266,427	1,047,051	1,031,915	1,023,409	1,021,594	1,026,200
Population aged 15-64	5,551,417	5,343,220	5,322,628	5,293,641	5,261,118	5,211,619
Population aged > 64	1,331,624	1,328,479	1,324,747	1,323,188	1,323,839	1,325,891
Life expectancy at birth	71.70	72.60	72.60	72.70	73.00	73.4
Life expectancy at age 65	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Data as of 31 December

Source: National Statistical Institute; National Health Information Centre; EUROSTAT

At the beginning of the 21st century the population of Bulgaria follows a trend of decrease and as of December 31, 2001, when the last official census was carried out, there were 7,932,984 people living permanently in the country. As compared to the previous census conducted in 1992, the population decreased by 544,333. This trend is expected to continue reaching by the end of 2010 approximately 7,362,300 people living in Bulgaria.

The territory of Bulgaria is 111 thousand square kilometres, in which lived 7,563,710 people as of December 31, 2009. Population is aging because of unfavourable trends in demographic processes in the past four decades. In 2001, the share of population under age 15, as compared to the 1992 census, decreased to 15.2% of the total population and the share of persons over 64 increased to 17.4% of the population. In 2009 1,026,200 people aged 0-14, or 13.56% of the total population, 5,211,619 people aged 15-64 (68.90% of the total population) and 1,325,891 people aged over 65 (17.52% of the total population) lived in Bulgaria. In 2001 working age population in absolute numbers decreased to 5,382,804 people; in 2009, it was only 5,211,619 people. The greatest reduction by 2010 is expected for the population below working age, whose share is expected to reach 13.5% percent of the population (1.7% less than its share in 2001). The number of people over working age is expected to grow by 10.9% and their share is expected to increase by 3.3 points to reach 20.7% of the population.

The changes in the age composition of the population affect both cities and villages. In 2009, 555,681 people living in villages were over 65. The share of the elderly in the cities is 770,210. Internal migration in recent years is characterized by an increase of older people in urban areas. The migration process, however, mainly affects people of working age and is

oriented mainly from the country to abroad and to a much lesser extent - from villages to cities.

Demographic and health characteristics of the population have an integrating effect on one of the main synthetic indicators for the population health, which is *the estimated life expectancy*. This indicator in Bulgaria showed a downward trend in the period 1980 - 1995 and reached its lowest values in 1995 - 1996, going to 70.50 (67.10 for men and 74.30 for women). After this period, the negative trend was broken in and the average life expectancy increased in 2000, reaching a total of 71.70 (68.15 for men and 75.34 for women). In 2008 this indicator was 73.00 in total, whereas ***the estimated average life expectancy in 2010 is 73.50 in total***. This is one proof that healthcare reform from 1999 in Bulgaria was necessary and that its implementation had a positive effect on some basic health indicators of the country. The average life expectancy increased in 1995 - 2008 from 70.50 to 73.00; the declining birth rates, emigration flow, reduction of persons of working age and the increase of people over working age cause major ***changes in the population age structure*** in Bulgaria, which can be defined as ***demographic aging***, i.e. increase the absolute number and proportion of older people. Since older people are carriers of more than one chronic disease (average 3.3 chronic diseases in Bulgaria per 1 person over 64), the demographic aging significantly alters the structure of healthcare needs of the population and carry higher demands on managing requirements.

Registered morbidity in hospitals over the past 10 years is relatively constant. An analysis of the disease classes shows significant prevalence of respiratory diseases (about 40%), followed by diseases of the nervous system and sensory organs (about 12%), diseases of the circulatory system, injuries and poisoning, diseases of the urinary-genital system, skin and subcutaneous tissue disorders and diseases of the digestive system. These classes of diseases represent over 86% of the total morbidity. There is some specificity in the nosological structure of diseases resulting in disability, depending on the severity of disability. For people with more than 90% lost working ability, leading diseases are those of the circulatory system, followed by neoplasms, diseases of the nervous system and sensory organs, diseases of the bones, the muscular system and connective tissue, etc. For persons with disability from 71 to 90%, most common diseases are also those of the circulatory system, followed by diseases of the musculoskeletal system and connective tissue disorders, neoplasms, diseases of endocrine glands, nutrition, metabolism and immunity disorders, diseases of the nervous system and sensory organs, etc., while for people with disabilities from 50 to 70% the most common diseases after the diseases of the circulatory system diseases are the musculoskeletal system and connective tissue, diseases of the nervous system and sensory organs, diseases of endocrine glands, nutrition, metabolism and immunity disorders, etc.

Causes of death maintain a relatively stable structure for more than a decade. In the last 10 years about 2/3 of all deaths are due to diseases of the circulatory system (over 64.7% - 2009), the second place of the death causes is held by neoplasms (about 16.4% - 2009), followed by the diseases of the respiratory system (about 4.0%) and injuries and poisoning (also about 4.0%), i.e. nearly 89% of all deaths in Bulgaria are due to these four groups of diseases. In the recent years, due to the upward trend and the increasing incidence of

deaths, particular attention is paid in Bulgaria to road traffic accidents. In the last 20 years there is an increase of deaths due to suicide; however the trend starts to be broken at the beginning of 21st century and currently the overall number of deaths due to suicide decreases.

The total mortality due to diseases in Bulgaria over the last 10 years is about 14 people per 1000, whereas the mortality of men is 12% higher than mortality of women. Mortality by age groups is as follows: about 8 per 1000 people are aged under one year, about 1 per 1000 are aged up to 20 years, 1.2 per 1000 - from 20 to 40, 6.8 per 1000 - from 40 to 60, about 20 per 1000 are from 60 to 70 years old and about 79 per 1000 are over the age of 70. The mortality rate for diseases of the circulatory system is about 970 per 100,000 inhabitants, and the intensity is higher among men - 1004 per 100,000 men and 940 per 100,000 women. The most frequent deaths from diseases of the circulatory system are caused by cerebrovascular disease and ischemic heart disease with mortality about 277 and 262 per 100,000 inhabitants, respectively.

The second place of the causes of death is held by neoplasms, where the mortality of men is higher again - about 240 per 100,000 men against 163 per 100,000 women. Over one third of all men who died from malignant neoplasms had their neoplasms located in digestive organs and the peritoneum - about 37%, and the neoplasms of about 31% are located in the respiratory system. Women deaths from malignant neoplasms are due most frequently to breast neoplasms - about 17%, and to uterus, cervix and ovary neoplasms - about 16%.

1.2 Organisation

Until 1999, Bulgaria's healthcare system was organized similarly to the Soviet system **Se-mashko**, which is characterized by tax funding and public offering of health services. Through the health reform started in 1999, Bulgaria implemented many beneficial elements of the positive structural and functional solutions of the healthcare systems of social security type, combined with some elements of the national health services. This is a new and increasingly implemented model by various countries, defined as a **Public-private mix**. Thus, the Bulgarian healthcare covers, in varying degrees and ranges, the governmental, insurance (public and corporate) and private sectors, each of which has its perimeters of action, rights, and responsibilities. The most specific feature of the public-private model in Bulgaria is that all health activities with separable effect are in the sphere of private services and are funded mainly publicly, with lesser private funding. As a term "separable effect" is used in Bulgaria to describe every medical care provided by a medical doctor received by the individual himself. From this classic market segment only those health services are excluded where the consumer is supposed to be unable to take independent decisions - for example, emergency medical care, in-patient psychiatric care, hemotransfusiology and others. Meanwhile, health activities with a non-separable effect (the nonseparable effect is used for healthcare services that are provided simultaneously to many people as result of prevention interventions – e.g. salt treatment with iodine) such as the state healthcare supervision, the programs addressing socially significant diseases e.g. cardiovascular diseases which in Bulgaria are 60% death cause in the last years, mandatory treatment, epidemiology and

other anti-epidemic measures, remain in the area of public financing and predominantly public and less private production of relevant services.

The reforms initiated in 1999 in the field of medical healthcare were radical and extremely serious. They and the newly established **NHIF** (National Health Insurance Fund) regulated and defended the rights of citizens concerning the healthcare system, patients' rights to medical care rendered in hospitals and the rights of medical professionals performing medical and health care. The medical healthcare reform started with the adoption by the National Assembly of several new structural laws for the health system until 2000 and another one concerning mainly the public health, which was adopted in 2004:

- *Law on Safety and Health at Work (LSHW) - in 1997*
- *Health Insurance Act (HIA) - in 1998*
- *Law for the NHIF budget - from 2000 until now.*
- *National Framework Agreement- NFA (concluded each year between the NHIF and branch organizations of physicians and dentists) - from 2000 until now.*
- *Law on the professional organizations of physicians and dentists (LPOPD) - in 1998*
- *Health Establishments Act (HEA) - in 1999*
- *Law on Pharmaceuticals and Pharmacies in Human Medicine (LPPHM) - in 2000*
- *Health Law - in 2004.*

These basic structural laws and the NFA regulate the structure, operation, organization, and management of medical, dental, and pharmaceutical activities and their funding.

The other important feature of the change in medical aid was the regulation of the **contractual principle** in the relations between medical facilities and the funding authorities represented by the National Health Insurance Fund (NHIF). All Bulgarian citizens are mandatory covered by a certain package of medical care that is paid by the NHIF. Medical care is provided by hospitals by virtue of a contract between them and the divisions of the NHIF, the Regional Health Insurance Funds (RHIF). They are as a result of the NFA and individualise the terms in accordance with the subject of activity of individual hospital, types of medical services it provides, etc. RHIFs pay to the hospitals for the medical care provided by them to insured people, at certain prices. The main responsibilities of the parties under this contract, the prices, terms of payment and procedures, are defined in the **National Framework Agreement**, signed between the NHIF and representatives of professional organizations of physicians and dentists in the country. Specific contracts are signed also among hospitals and RHIFs, as well as with the 21 companies for voluntary health insurance existing in the country.

The third major feature is the granting, since 2000, to the consumer of a **right to choose** a practitioner for both medical and dental primary out-patient care, a hospital for specialized out-patient care and, from January 1, 2004 for hospital care. This limited considerably the administrative compulsion, which before had been substantially restrictive towards the rights

of citizens to choose the specialists or facilities to provide medical care. The legally established management, legal and economic autonomy of the actors in the field of medical care - hospitals and funding bodies-, together with the introduction of contractual relations and the right of free choice by the user, are key prerequisites of the formation of the **medical services market** and **competition** in the in-patient and out-patient sector.

The health care system is administered by the Ministry of Health, which has 28 units - Regional Healthcare Centres. Social health insurance is represented by the NHIF, which has a separate budget determined on annual basis by the National Assembly. Hospitals for out-patient and in-patient care have legal status as business companies *with limited liability or joint stock companies*.

In 2010 some changes to existing health laws introduced a number of innovations that re-centralized the decision making in health care and significantly restricted the opportunities for self-government by the hospitals. The most important changes in this respect are listed below:

- *"Nationalization" of the NHIF by eliminating the self-governance authorities, like the Assembly of Representatives, the Management Board and the Controlling Board, and replacing them with the **Supervisory Board** appointed by the government. The current position of Director of the NHIF, who was elected by the Management Board through a competitive process, is now called a **Governor** who is elected by the National Assembly by a majority voting;*
- *Change in the method of payment to hospitals - from payment by clinical pathways (activities by diagnoses), the so-called **delegated budget** (a fixed global annual budget) was introduced;*
- *Introduction of higher requirements for the number of specialists practicing in hospital wards, which resulted in a number of hospitals undergoing changes in their scope of activities and having their budgets reduced.*

The planned additional changes that the government already declared, is expected to lead to an even stronger administrative interference in medical healthcare. Because of such interference, the population access to healthcare is seriously deteriorated, corruption practices will increase as well as the number of physicians leaving the country.

1.3 Funding

This section gives an overview of the health care expenditure and the sources of funding health care.

1.3.1 Health expenditure

Table 1.2: Bulgaria – Health expenditure 2000, 2005–2009

Health expenditure in Mio., in NCU = BGN	2000	2005	2006	2007	2008	2009
GDP	26,753	42,797	49,361	56,520*	66,728*	66,256*
THE ¹	1,524.1	3,294.9	3,549.1	4,149.7	4,844.4	2,634.4
- thereof public HE	977.7	2,008.6	2,022.5	2,373.3	2,830.8	n.a.
- thereof private HE	546.4	1,286.3	1,526.6	1,776.4	2,013.6	n.a.
HE in the out-patient sector	209.6	502.8	533.3	634.3	697.4	n.a.
- thereof public	97.5	304.3	318.8	358.2	401.9	n.a.
- thereof private	112.1	198.5	214.5	276.1	295.5	n.a.
HE in the in-patient sector	n.a.	1,322.5	1,371.6	1,611.4	1,956.5	n.a.
- thereof public	n.a.	1,160.1	1,160.6	1,375.5	1,665.0	n.a.
- thereof private	n.a.	162.4	211.0	235.9	291.5	n.a.
Exchange rate (NCU per €)	n.a.	1,9558	1,9558	1,9558	1,9558	1,9558

GDP = gross domestic product, HE = health expenditure, n.a. = not available, NCU = national currency unit, THE = total health expenditure

*2007, 2008, 2009 – preliminary data

¹ - THE include also other expenditures that are made by the state such as prevention, long term care, rehabilitation, emergency service, screening programs, etc. and that's why the sum of HE in the out-patient and HE in the in-patient does not add up to the THE.

Source: Data provided by MoH with letter dated 23 June 2010

1.3.2 Sources of funds

The funding of healthcare for insured citizens (health insurance in Bulgaria is mandatory) is done by **the National Health Insurance Fund**. When a person is also insured by a voluntary health insurance company, depending on the insurance contract, the expenses for his/her treatment are covered also by the relevant insurance company. If a person goes to a health establishment at his own will (without referral from the general practitioner or a specialist) he/she pays him-/herself the treatment expenses. In addition to the insurance contribution, the obligatorily insured persons pay a customer fee for each primary visit to a doctor or a dentist at the rate of 1% of the minimum salary and for each day of hospital treatment (but not more than 10 days a year) at the rate of 2% of the minimum salary. Some population groups are exempt from payment of customer fees.

The social health insurance in the Republic of Bulgaria, administered by the National Health Insurance Fund, does not provide for any exception from the obligatory insurance system. The following persons are to be insured:

- All Bulgarian citizens who are not citizens of any other country.
- Bulgarian citizens who are citizens of another country and live permanently in the territory of the Republic of Bulgaria.

- Foreign citizens or persons without citizenship who have permits for long-term residence in the Republic of Bulgaria, unless otherwise provided for by an international agreement to which the Republic of Bulgaria is a party.
- Persons with the status of refugees or with granted right of refuge.

The range of income for which the 8% mandatory health insurance contribution is applied varies from 2 to 10 times the minimum insured income. At present, the employer pays 60% of the contribution and the employee pays 40%; in future, these percentages will be equalled. There are certain penalty mechanisms for persons who have not paid the contributions due for health insurance for the last 36 months from their entering in a hospital for treatment – they lose their right of insurance and have to pay themselves for any medical care at market prices. When the health insurance contributions are paid, the insurance rights are reinstated. The non-payment of insurance contributions due to the fault of the employer does not deprive a person from the right of insurance and the amounts possibly paid by such person for medical care are subject to refunding. There are no differences in the insurance and access to medical care based on gender, religious, ethnic, racial or any other reason. However, in practice certain groups of population-farmers, Roma, minorities fail to take enough advantage of the benefits guaranteed by the social health insurance because of some educational, cultural or other reasons.

The state represented by the MoH and municipalities, via the consolidated state budget, provide financing from taxes for the activities of the public healthcare institutions, which are public property:

- Regional Inspectorates for Public Health Control;
- Emergency healthcare centres;
- Centres for transfusion haematology;
- Healthcare establishments for stationary psychiatric care;
- Homes for medical and social care designated for medical monitoring and specific care for children;
- Healthcare establishments at the Council of Ministers and healthcare establishments of governmental departments.

Occupational health services are financed by the **respective companies** and the school health offices by **the municipal councils**.

The public healthcare expenditure in 2009 reached up to 348 BGN/177.93 € per capita that is almost triple increase compared to the year 2000. Presented as a percentage of the GDP the public healthcare expenditures are steadily positioned at about 4% for the past ten years. Based on expert assessments of the WHO, for the same period the private healthcare financing gradually caught up with the public financing, whereby presents 35 – 40% of the public financing. A large part of the private financing is not legally regulated, to the detriment of the best practices.

Voluntary healthcare in Bulgaria is underdeveloped and has an insignificant share of the healthcare financing. In 2009 in Bulgaria, 21 licensed voluntary health insurance corporations operate with annual income of BGN 38.2 million in total. The expenditures of the voluntary health insurance funds for health insurance payments for the same period amount to total BGN 21.7 million. The government announced some planned reforms to commence in 2011, where the voluntary health insurance funds will be entitled to manage public funds up to 2% of the mandatory health insurance contributions, which are about BGN 500 million annually. These funds will be allocated for competitive management based on registers of health insured persons, who have voluntarily chosen to be insured by a health insurance fund of their choice. At this stage, the planned reforms are being discussed by the parliamentary healthcare commission of the National Assembly, but are not yet formalized in a legislative instrument. Levels of informal payments have been regularly researched by experts and according to media publications¹ in the period of 2001 – 2008 their amount is varying between 1 bln, BNG and 75 mln, BGN. A report² of the Open Society Institute _ Sofia and the International Healthcare and Health Insurance Institute published in 2008 on the informal payments in the health system³ states that the average volume of out-of – pocket payments annually amount at 160 mln. BGN and this amount does not include dental care, pharmaceuticals and medical aids. The survey was held nationwide among 1,447 respondents in July 2007. Dynamics of informal payments however is quite high and strongly dependent on the overall health system management and organization.

1.3.3 Out-patient care

General practitioners are paid based on per capita principle with additional payment for certain activities. GPs are the "doorkeepers" to specialized care. Specialists in out-patient care are paid in the form of a fixed fee per visit. Highly specialized diagnostic services are paid in the form of fee per service.

1.3.4 In-patient care

All hospitals for active treatment, post-surgery treatment and rehabilitation, as well as hospices were transformed in 2000 into public limited liability companies or joint stock companies. So far, none of them has been privatized. Before 2010, payment of hospital care was based on a contract with NHIF by groups of diseases, defined as "clinical pathways". Since 2010, hospital funding has changed and is done through the so-called "delegated budgets", which are a form of global budget with a fixed framework for a one-year period. Each hospital has the right to sign a contract for funding with the existing 21 companies for voluntary health insurance. Doctors in hospitals are employed based on an employment contract. Although hospitals are registered as corporations, they receive their funding based on administrative prices set by the NHIF. The prices of clinical pathways are set, the hospitals receive their payments in accordance with them, but within global budgets. Once a year there are negotia-

² Media Monitoring Data Base of the IHHII, <http://mediamonitoring.zdrave.net/>, visited 2nd April 2011.

tions between the NHIF and the professional organizations of doctors with regard to the specific amount of these prices, which are then described in the National Framework Agreement. With recent changes in the NFA 2010, this period was increased to 3 years. Each insured person also pays for hospital care a user fee amounting to 2% of the national minimum wage but not for more than 10 days a year. The minimum wage is 240 BGN. It changes according to the state economic indicators. There is no fixed period for its amendments.

A small number of departmental hospitals are funded by the state; municipalities have no function related to hospital funding.

1.4 Access to health care

1.4.1 Health care professions

Table 1.3: Bulgaria – Doctors and pharmacists development 2000, 2005–2009

Health professionals	2000	2005	2006	2007	2008	2009
Total no. of doctors ¹	27,526	28,197	28,111	27,911	27,470	27,988
- of which GPs	4,870	5,262	5,321	5,474	5,224	4,949
- of which work in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	11,226
- of which work in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	13,999
No. of pharmacists	5,210 ²	n.a.	n.a.	n.a.	n.a.	5,559 ³
- of which work in community pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in hospital pharmacies	373	220	225	233	231	n.a.

GP = general practitioner; n.a. = not available
Data as of 31 December

¹ practicing doctors. Dentists are not included.

² Petrova G. Model of the reform of the pharmaceutical sector in the Balkan region - analysis of the application of the theoretical concepts. Doctor of Science Dissertation, Medical University in Sofia, 2004

³ OJ N 73/2009 - Register of the pharmacists, which have the right to work as a pharmacist, e.g. are members of the Bulgarian Pharmaceutical Union.

Source: National Health Information Centre;

In late 2009 there are 27,988 practicing doctors having their main employment contract in the medical and healthcare establishments in the country. 6,493 dentists are practising in Bulgaria. Medical care professionals amount to 48,099 persons, of which 31,961 are nurses. Other staff with non-medical background in medical and healthcare establishments with

³ http://www.osf.bg/downloads/File/Neform_plashtania_Report.pdf

employment contract is 37,664 persons. According to the practiced specialty the doctors in the medical and healthcare establishments are distributed as follows:

- Specialties with predominant therapeutic focus - 11,297 doctors;
- Specialties with predominant surgical focus - 5,581 doctors;
- Specialties with predominant clinical and diagnostic focus - 2,178 doctors;
- Specialties with other focus - 1,283 doctors;
- Individual practices for primary and specialized medical care, which have signed a contract with the NHIF - 7,649 doctors.

Among all specialties, in the end of 2009 the largest proportion is of GPs - 4,949 or 17.7% of all practicing doctors in the country. Specialists of internal diseases are 1,496 or 5.3%. Next within the structure of doctors by specialties are Obstetrics and Gynaecology (1,387 or 5.0%) and Paediatrics (1,381 or 4.9%).

Depending on the health establishments, where they have their main employment contract, the healthcare specialists in the country are divided as follows:

- In establishments for hospital care, (hospitals and dispensaries) there are 13,999 practicing physicians and 38 dentists. Medical health care professionals are 28,938, of which 20,772 are nurses.
- 11,226 practicing physicians and 6,152 dentists have their main employment contract with establishments for out-patient care. This includes all doctors (7,649) and dentists (5,865), working in individual and group practices under a contract with the NHIF. Of the other out-patient care establishments, the largest proportion of doctors is working under a main employment contract in the diagnostic and consultation centres (1,684) and medical centres (1,584). At the end of 2009, 239 doctors work at private medical and diagnostic laboratories.
- As of 31 December 2009 2,742 physicians and 303 dentists work in other medical and health establishments (including nursery schools and school health offices) under a main employment contract work. 21 doctors work in sanatoria establishments.

At the end of 2009 the coverage with medical doctors is 37.0 per 10,000 people. The coverage with dentists amounts to 8.6 per 10,000 people.

When analyzing the data about population coverage with medical care by districts, the following peculiarities of medical services should be taken into account. Health establishments are not only related directly to servicing the population of a city or municipality and the access to medical care is free. Many establishments service the population of a district or group of municipalities, and specialized establishments service the population of several districts. Establishments with national scope, regardless of their location, service the population of the entire country. The indicator for coverage with medical doctors by districts varies from 23.7 to 47.3 per 10,000 persons. The highest coverage of the population with medical doctors is in the main cities of which have medical universities and university hospitals.

Values of this indicator above the country average have the districts of Varna (47.3), Sofia (capital) (45.4), Pleven (44.9), Plovdiv (41.6) and Stara Zagora (40.7). The lowest values of this indicator are in the districts of Razgrad (23.7 per 10 000 inhabitants), Silistra (25.0) and Kardjali (26.0).

The coverage with general practitioners in the end of 2009 is 6.5 per 10,000 people. For 12 districts out of 28 districts, the indicator is higher than the country average. The highest coverage with general practitioners is in the districts of Pleven (7.9), Kyustendil (7.5) and Dobrich (7.4). The lowest coverage with general practitioners is in the districts of Razgrad and Targovishte - 4.7 and Ruse - 4.9.

The distribution of pharmacies is uneven. The highest number of pharmacies are logically located in the big cities. For example in Sofia, where around of 19% of the population is living are registered more than 26% of the pharmacies of the country.

Differences between districts exist due to a number of reasons linked to the overall economic and social development of the region, the structure of the population (e.g. minorities, elderly people, etc.). The National Health Insurance Fund pays additional funds to medical doctors who agree to work in remote or mountain areas, but still the overall policy for alleviating these differences is insufficient and not comprehensive.

According to data of the Bulgarian Medical Association at average 500 medical doctors are leaving the country annually. There is no data on their age, speciality or country of migration, however it is considered that they mostly go to other European countries.

1.4.2 Out-patient care

The choice of a healthcare provider is regulated in a Regulation of the Ministry of Health. In the primary healthcare, the choice of a general practitioner is fully liberal and every citizen is entitled to change his/her choice once in every 6 months. The choice of a dentist may be changed every day. The patient, together with the general practitioner (family doctor) chooses an out-patient specialist or health establishment.

All doctors in the out-patient sector are registered as legal entities under the Companies Act and HEA and are private practitioners. The territorial layout and coverage of country's healthcare network, as well as the planning of its development are regulated by the developed **National and Regional Health Maps**, which should be updated every 5 years. They contain the number of the various health establishments in the different regional units /district and municipalities/. These health establishments sign contracts with the Regional Health Insurance Funds for the provision of health care to the population. The legislation regulates **the equality** (in terms of rights to receive funding from public sources such as the National Health Insurance Fund) of public /state and municipal/ and private health establishments.

The National Health Map (NHM) was introduced in the Health Establishments Act, first adopted on 5th July 1999. According to its art. 32 amended in 2010, the NHM consists of regional health maps defining the number of emergency healthcare centers, blood transfu-

sion centers, psychiatric clinics, oncological healthcare establishments, etc., national health priorities, hospitals which had to be contracted by the NHIF annually, minimum and maximum active treatment beds incl. the ones for long term care and rehabilitation, a list of healthcare establishments which will not be privatised. NHM does not include any quality criteria.

Since the beginning of 2010, major changes are planned on the basis of the National Health Map, which foresees changes in the sense that it would include only selected health establishments, which will be entitled to public funding. This approach is imposed by the intentions of the Government to reduce public health costs by about BGN 1 billion compared to 2009.

The main feature of the healthcare reform from 1999 (introduction of the health insurance model in Bulgaria) is the radically changed legal status and the complete legal, financial, and economic autonomy of health establishments:

- The individual practices for primary and specialized medical and dental care have to be registered by and are property of the respective medical doctors and dentists;
- The group practices for specialized medical and dental care, medical, dental and medical and dental centres, diagnostic and consultation centres, independent medical diagnostic and medical technical laboratories and hospices are established as companies or holdings and if necessary may be established as limited liability companies or joint stock companies by the state and municipalities - either independently or jointly with other persons;
- Health establishments for in-patient care, homes for medical and social care and dispensaries are established by the state and municipalities, by legal entities and natural persons, as companies or cooperatives;
- The following remain property and responsibility of the state: emergency medical care centres, centres for transfusion haematology, healthcare establishments for stationary psychiatric care, healthcare establishments for medical monitoring and care for children, as well as the healthcare establishments with some Ministries (the Ministries of Defense, of Interior, of Transport and of Justice).

As of 31 December 2009 before the implementation of the planned changes, there were 4,949 registered GPs and 2,700 autonomous practices for specialized out-patient care, 1,715 health establishments for specialized out-patient care, of which 115 are diagnostic and consultation centres with 283 beds for short stays up to 48 hours, 590 medical centres with 541 beds for short stays, 49 dental centres, 33 medical and dental centres, 928 medical diagnostic and medical technical laboratories, of which 291 are medical diagnostic and 637 are medical-technical laboratories in the out-patient sector. Compared to 2008, the beds in out-patient care establishments have decreased by 10.9%, due to the reduced number of beds in medical centres

The population's access to the infrastructure for medical care by doctors and dentists is legally based on the free choice of the patient. This access is regulated by the state and does not depend on the financial and property status of the person. Upon provision, the

healthcare service is “free” for the patient, since its value is covered by the National Health Insurance Fund or the state budget. Officially patients pay only the so called consumers’ fee which is 1% of the minimum wage in the country for the out-patient care visit and 2% from the minimum wage in the country for hospital stay per day, not more than 10 days. If the patient is not using the services of the NHIF, he/she pays market prices. The National Health Map defines the standards of territorial coverage with health establishments and the number of specialists necessary depending on the population's needs of healthcare. So far, in Bulgaria there are no regulated or actual waiting lists with very few exceptions related to heart surgeries, valve prosthetics, transplants, and joint prosthetics.

1.4.3 In-patient care

Table 1.4: Bulgaria – In-patient care 2000, 2005–2009

In-patient care	2000	2005	2006	2007	2008	2009
No. of hospitals	249	262	270	292	305	306
<i>Classified according to ownership</i>						
– thereof public hospitals	231	217	216	221	220	203
– thereof not-for-profit privately owned hospitals	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.
– thereof for-profit private hospitals	18	45	54	71	85	93
<i>Classified according to subtypes</i>						
– thereof general hospitals	127	125	122	123	123	122
No. of acute care beds	45,408	33,387	32,298	33,056	32,879	34,041
– thereof in the public sector	45,174	32,505	31,019	30,850	29,901	n.a.
– thereof in not-for-profit privately owned sector	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.
– thereof in for-profit private hospitals	234	882	1,279	2,206	2,978	n.a.
Average length of stay (acute care) in days	n.a.	6.9	6.2	5.9	5.6	5.3
No. of hospital pharmacies	149	151	154	157	n.a.	168*

No. = number, n.a. = not available

Data as of 31 December

Source: National Health Information Centre and *MoH web site from 20 August 2010
<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=387>

Hospital within the meaning of the Health Establishments Act (HEA) is a health establishment for hospital healthcare, where doctors with the help of other specialists and auxiliary staff perform all or some of the following activities:

- Diagnosis and treatment of diseases where the treatment purpose cannot be achieved by out-patient care;
- Maternity care;

- Rehabilitation;
- Diagnosis and consultations requested by a doctor or dentist or other health establishments;
- Medical and cosmetic services;
- Clinical trials of medicines and medical devices in accordance with the existing legislation in the country;
- Teaching and research.

Coverage with hospital beds (beds in hospitals and dispensers) in Bulgaria in 2009 is 661.6 per 100,000 people. Dispenser is a specific type of medical establishment, 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 dispenser.

Several types of health establishments for hospital care are in place: public property registered only under HEA, state/municipal private property (registered as legal entities under the Companies Act and HEA) and privately owned (registered as legal entities under the Companies Act and HEA). The latter may work for profit.

The country's healthcare network as of 31 December 2009 has 352 in-patient health establishments with 50,041 beds. Of these 306 are hospitals with 45,906 beds, and 46 dispensers with 4,135 beds. There are 4 sanatoria establishments operating in Bulgaria with 740 beds, but they are not considered as hospitals. **The in-patient health establishments** include hospitals and dispensers. In accordance with the Health Establishments Act, the two types of hospitals are multi-profile and specialized. Multi-profile hospitals are 122 with 27,779 beds, and specialized hospitals are 69 with 8,105 beds.

In 2009, 40% of hospitals are public multi-profile and concentrate 60.5% of beds of all hospitals in the country. The number of beds in these establishments varies widely from 30 to 1,345 beds, where the highest number is in university hospitals.

69 specialized hospitals for active treatment offer 8,105 beds. 6 specialized hospitals for post-surgery treatment and long-term treatment are in place having 356 beds. By the end of the year 2009 12 specialized hospitals for post-surgery treatment, long-term treatment, and rehabilitation operate with 840 beds and 22 specialized rehabilitation hospitals with 3,293 beds.

State psychiatric hospitals are 12 with 2,685 beds.

Depending on their ownership, the hospitals are state-owned, municipal, and private local or private under foreign control. By the end of 2009, hospitals with private ownership are 93 with 5,291 beds. Compared to 2008 the number of beds in these establishments has increased by 30%, which was the logic market behaviour, connected with the need of such establishments and the access to public financial resources.

In-patient care establishments include hospital dispensers with stationary, which, upon registration, have reported as their core activity hospital care. The number of these establishments remains unchanged compared to 2008 - 48 with 4,135 beds in 2009. Dispansers' distribution by types is as follows:

- Dispanser for Pulmonary Diseases - 12 establishments with 762 beds;
- Skin-venereal dispensers - 10 establishments with 218 beds;
- Oncology dispensers - 12 establishments with 1,625 beds;
- Psychiatric dispensers - 12 establishments with 1,530 beds.

The **other treatment and health establishments** include centres for emergency medical care, the Regional Inspectorates for Protection and Control of Public Health, Regional Health Centres, Homes for Medical and Social Care for Children (HMSCC), hospices, national centres and dispensaries without beds. In the end of 2009, their number was 189 with 5,258 beds. The change in their number is due to the change in number and beds in hospices. In 2008, these establishments were 49 with 418 beds. In the end of 2009, there are 59 hospices with 659 beds in the country.

From 2005 to 2009 a general decreasing tendency in the hospital beds can be observed, although it is not steady through the years. This is mainly due to the increase of the beds in the private hospitals and the decrease of the beds in the public hospitals.

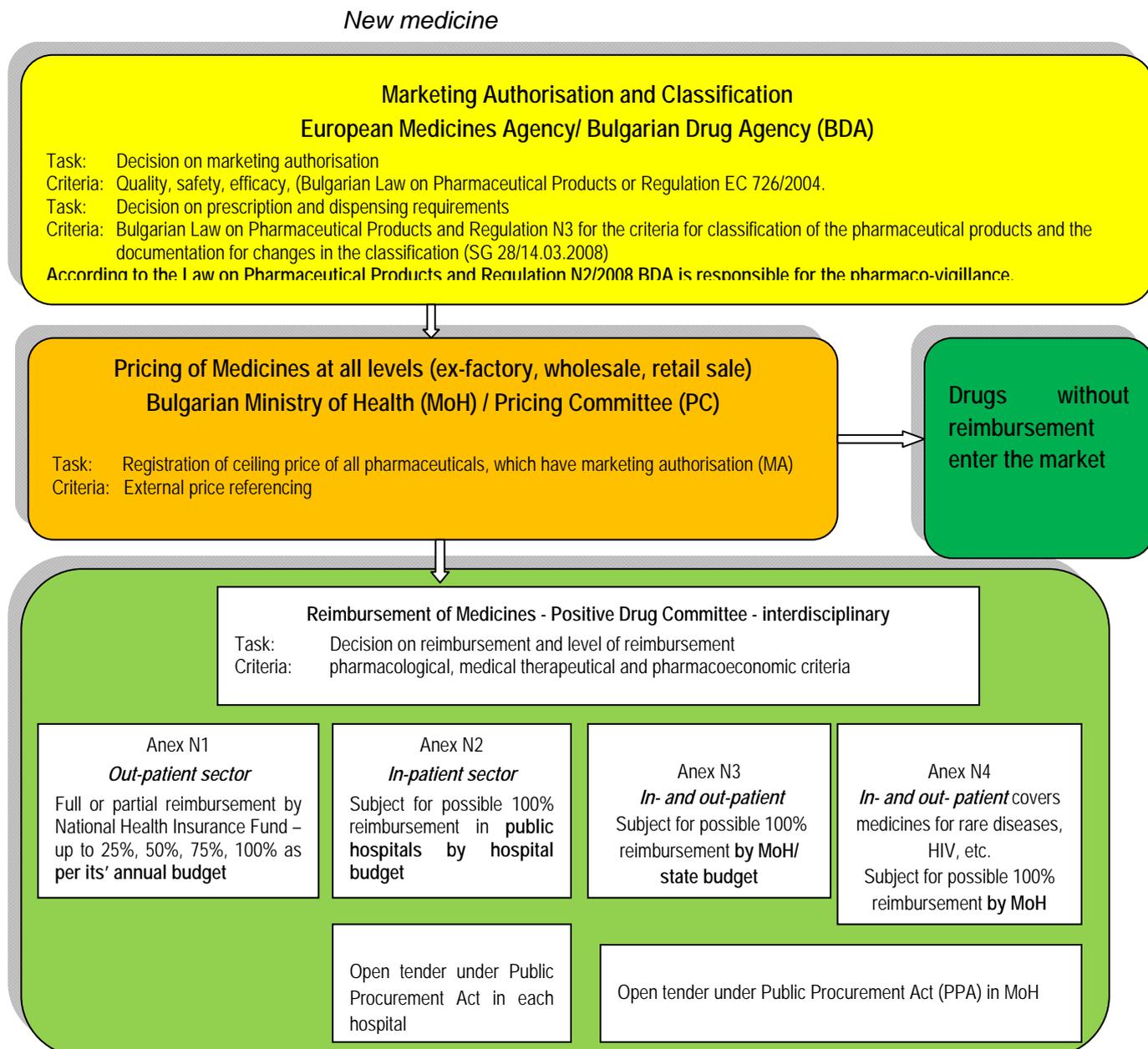
Until 2003, it was possible to choose freely a hospital only within the district of patient's residence. Since 01 January 2004, patients and treating doctors are free to choose the appropriate hospital for free hospital care throughout the country without any restrictions. The free choice of a particular treating doctor or a team in the preferred hospital, however, are considered as a personal choice and health care received after the personal choice shall be paid by the patient at prices determined by the hospital based on market principle.

2 Pharmaceutical system

This chapter gives an introduction to the pharmaceutical system, including organisation, key statistic data, market players, and funding.

2.1 Organisation

Figure 2.1: Bulgaria – Flowchart of the pharmaceutical system, 2010



Source: Law on Pharmaceutical Products in Human Medicine OJ 31, 2007, last amended OJ 59, 2010

2.2 Regulatory framework

Since the beginning of 2007 as Bulgaria became a Member of the European Union the Bulgarian pharmaceutical legislation is corresponding to the European legislation, with only minor fluctuations in the duration of some procedures and still needs fine tuning to some regulations, e.g. those defining the market access (pricing + reimbursement decision + actual reimbursement) and this is one of the areas in which the pharmaceutical legislation in Bulgaria should improve.

Before to reach this state of harmonisation, since the early 1990s the Bulgarian pharmaceutical sector has undergone radical changes. It has been transformed from state-owned and centralised governance and management to a fully decentralised and privately owned system.

The first in the series of new pharma legislation was the Law on Pharmaceutical Products in Human Medicine, voted by the Parliament in 1995. Since its enforcement, more than 30 regulations have been worked out, intending to synchronise Bulgarian pharmaceutical legislation with the European Directives and Good Practices. In this way a complete specific pharmaceutical legislation has been implemented in Bulgaria. It regulates the process of market authorisation, classification, clinical trials, manufacturing, registration of ceiling prices, the process of granting a reimbursement status, wholesale and retail sales, importing, exporting, prescribing, dispensing and advertising of medicines, as well as what standards are required in terms of quality, efficacy and safety of the medicines. Via an order by the Minister of Health, the European Pharmacopoeia came into act in 1995.

The Law on Pharmaceuticals and Pharmacies in Human Medicine of 1995 had been amended more than 20 times throughout the years. Since 2007 we are working according the Law on Pharmaceutical Products in Human Medicine, which was since then already amended 9 times by the time of writing this profile.

Parallel to the Law on Pharmaceutical products in Human Medicine, the sector is also regulated by the Control of Narcotics and Precursors Act, the Health Act, the Health Establishments Act, and the Health Insurance Act, as well as the regulations for their implementation.

The secondary legislation on the implementation of the key laws for the sector, the Law on Pharmaceutical Products in Human Medicine (LPPHM) and the Control of Narcotics and Precursors Act, consists of over 50 regulations and other bylaw acts (regulations, orders, tariffs, etc.) for both (25 already issued and 5 still pending at the time of writing the profile, concerning the Law on Pharmaceutical Products in Human Medicine and over 20 concerning the Control of Narcotics and Precursors Act).

Despite several attempts through the years to do so, on the part of the Ministry of Health (MoH), in the country there is still no officially adopted National Drug Policy Paper. This leads to the lack of middle and long term vision and sustainability of the development of the pharmaceutical sector and even worse, it gives the possibility each new leading team in the Ministry of Health constantly to make changes in the pharmaceutical environment.

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Table 2.1: Bulgaria – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2010

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Market authorisation	Law on Pharmaceutical Products in Human Medicine and the respective Regulation N 27/2007 on marketing authorization	In- and out-patient sector	Bulgarian Drug Agency (BDA) Изпълнителна агенция по лекарствата (ИАЛ)	In charge of market authorisation, classification, advertising and promotion of medicines, vigilance, producers' licensing, clinical trials, wholesalers licensing, import permissions, registering drug-stores and the control of all above-mentioned activities.	Pharmaceutical companies, Bulgarian Generic Pharmaceutical Association (Българска генерична фармацевтична асоциация - БГФарМА), Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (Асоциация на научно изследователските фармацевтични производители в България- ARPharM)
Pricing / Purchasing	Law on Pharmaceutical Products in Human Medicine and the respective Regulation on pricing of medicines.	In- and out-patient sector	Ministry of Health* (MoH) Министерство на здравеопазването (МЗ) Transparency Committee (TC) Комисия по прозрачност Pricing Committee (PC) Комисия по цени на ЛП	Overall health, including pharmaceutical policy planning, as the executing and controlling authority. Issuing licences for retail pharmacies and providing some pharmaceuticals for specific diseases. The Minister is approving the prices of medicines. TC – decisions of the PC may be appealed. PC - Registering ceiling prices of pharmaceuticals.	Pharmaceutical companies; Bulgarian Generic Pharmaceutical Association (Българска генерична фармацевтична асоциация - БГФарМА); Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (Асоциация на научно изследователските фармацевтични производители в България- ARPharM)

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Reimbursement	Law on Pharmaceutical Products in Human Medicine and the respective Regulation for the Positive Drug List; Health Insurance act; Regulation N10 for the NHIF; Health Act;	In- and out-patient sector	Positive Drug List Committee (PDLC) Комисия по позитивен списък Transparency Committee (TC) Комисия по прозрачност; National Health Insurance Fund (NHIF) Национална здравноосигурителна каса (НЗОК) Third-party payer – the sole compulsory insurance body	In charge of the reimbursement decision. TC – decisions of the PDLC may be appealed.	Pharmaceutical companies and their associations; Pharmaceutical wholesalers; Bulgarian Medical Union- (Български лекарски съюз БЛС); Bulgarian pharmaceutical union-(Български фармацевтичен съюз – БФС);
Promotion	Law on Pharmaceutical Products in Human Medicine and the respective Regulation for the Promotion of medicines	In- and out-patient sector	Bulgarian Drug Agency- (Изпълнителна агенция по лекарствата -ИАЛ)	In charge of market authorisation, classification, approving and control of advertising and promotion of medicines, vigilance, producers licensing, clinical trials, wholesalers licensing, import permissions, registering drugstores and the control of all above-mentioned activities.	Pharmaceutical companies
Distribution	Law on Pharmaceutical Products in Human Medicine and the respective Regulation for the Good Distribution Practice and Regulation for the pharmacies	In- and out-patient sector	Bulgarian Drug Agency (Изпълнителна агенция по лекарствата -ИАЛ)	As mentioned above	Pharmaceutical wholesalers;

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Vigilance	Law on Pharmaceutical Products in Human Medicine and the respective Regulation for the Marketing Authorization as well as Regulation N2 for pharmaco-vigilance	In- and out-patient sector	Bulgarian Drug Agency (Изпълнителна агенция по лекарствата -ИАЛ)	As mentioned above	Pharmaceutical companies
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* The Ministry of Health (MoH) also operates through its regional structures, such as regional health centres (RHCs) and the Regional Inspection for Protection and Control of the Public Health (RIPCPH), which are the regional structures of MoH.

MoH = Ministry of Health, NHIF = National Health Insurance Fund

Source: Law on Pharmaceutical Products in Human Medicine; Health Insurance act; The Health Act; Data gathering by IHHII 2010

According to Art. 14 of the Law on Pharmaceutical Products in Human Medicine (LPPHM), the policy in the pharmaceutical sector in Bulgaria is executed by the Ministry of Health (MoH).

The Ministry of Health is in charge of the overall pharmaceutical policy planning, as the executing and controlling authority. The Ministry also issues licences for retail pharmacies and provides by means of public procurement some medicines for treating of specific diseases, obligatory vaccinations and some health programmes, such as tuberculosis, AIDS, oncology treatment, etc.

As per article 17 of LPPHM, the Bulgarian Drug Agency (BDA) is the specialised body to the MoH for the quality, safety and efficacy of medicines. The market authorisation of a medicine is issued by the Director of the Bulgarian Drug Agency.

Within 30 days of the date of submitting the marketing authorisation application the BDA verifies whether all parts of the dossier accompanying the application are complete and comply with the requirements for issuing a marketing authorization or a certificate for registration. In case of completeness of the documentation the BDA notifies the applicant in writing for the validity of the documentation. The procedure for granting a marketing authorization or a registration for medicinal products starts from the date identified in the notification and have to be finalized within 210 days. It is ending either with granting of the market authorisation or a motivated refusal. Within 5 more days, it should be entered into Register of authorized medicines and comes into force from the date of entering into the Register.

The BDA, together with the specialized committees, assess the quality, safety and efficacy of the medicinal product. These specialized committees are established as consultative bodies to the Executive Director of the BDA.

The classification of the medicine, e.g. prescription-only medicine(s) (POM), over-the-counter (OTC), etc., is decided during the assessment process and is part of the market authorisation and is set according to Regulation N3 (harmonised with the Directive 2001/83) for the criteria for classification of medicines and the documentation for changes in the classification.

After receiving market authorisation, a medicine has to apply to the Pricing Committee (PC) for a ceiling price (cf. 3.1.1 Organisation of pricing). According to article 259 of the Law on Pharmaceutical Products in Human Medicine, the Pricing Committee is settled by the Council of Ministers, but is subordinate to the Minister of Health. The Pricing Committee includes representatives from the Ministry of Health, the Ministry of Finance, the Ministry of Economy and Energy, the Bulgarian Drug Agency, and the National Health Insurance Fund. Members' mandate is 4 years, but each two years half of the members have to be changed according to the legislative requirements.

For over-the-counter (OTC) medicines and those POMs, intended to be sold on the free market, the administrative procedure is finished at this point. For the rest of the medicines, as soon as they receive the price, they are supposed to apply to the Committee for the Positive Drug List (PDL) for a reimbursement status.

According to article 264, of the Law on Pharmaceutical Products in Human Medicine, the Council of Ministers defines by regulation the criteria, rules and procedure for including the medicines in the Positive Drug List (PDL). As per article 262 of the same Law, 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 reimbursement. For medicines which have no DDD, a therapeutic course and a reference value are determined.

The medicines in the positive list are selected according to evidence of efficacy, therapeutic effectiveness, safety, and analysis of pharmacoeconomic 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 Bulgarian Pharmaceutical Union. The medicines in the positive list 2010 are grouped within 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, also paid through the budget of MoH.

Out of the Positive List POM, which are needed in case of major circumstances like epidemics, pandemics, chemical or biological agents or nuclear radiation (paragr. 8 article 262 of the LPPHM) are paid from the state budget as well.

A Transparency Committee (TC), subordinate to the Council of Ministers, is involved in the described process. According to article 266, of the LPPHM, the decisions of the PC and PDLC may be appealed.

Membership of the Transparency Committee is defined by the Council of Ministers and includes representatives from the Ministry of Health, the Bulgarian Drug Agency, the National Health Insurance Fund, the Bulgarian Medical Union, the Bulgarian Dentists Union, the Bulgarian Pharmaceutical Union, Patients' organisations and representatives of the pharma industry.

2.3 Statistics

This section gives an overview on the number of medicines as well as on market figures and consumption.

2.3.1 Availability of medicines

2.3.1.1 Market authorisation

Table 2.2: Bulgaria – Number of medicines 2000, 2005–2010

Medicines	2000	2005	2006	2007	2008	2009	2010	Method of counting
Authorised	n.a.							
On the market	2,291	1,959	2,029	2,076	2,130	2,138	1,943	Counted by brand/generic name, excl. different pharmaceutical form, different pack sizes, different dosages
POM	n.a.	1,442	1,497	1,536	1,598	1,627	1,457	Counted by brand/generic name, excl. different pharmaceutical form, different pack sizes, different dosages
Reimbursable ¹	n.a.	388	452	516	583	644	638	Counted by INN, excl. different pharmaceutical form, different pack sizes, different dosages
Generics	n.a.	1,437	1,500	1,541	1,572	1,565	1,483	Counted by brand/generic name, excl. different pharmaceutical form, different pack sizes, different dosages
Parallel traded	n.a.							
Hospital-only ²	n.a.	478	491	507	525	515	443	Counted by brand/generic name, excl. different pharmaceutical form, different pack sizes, different dosages

POM = prescription-only medicines, n.a. = not available

Data as of 1 January

¹ reimbursed just by the NHIF (which is actually Annex 1 of the PDL) and counted by INN

² However no list of medicines which are ONLY allowed to be used in the in-patient sector exists.

No data is available for the medicines eligible for reimbursement.

Source: IMS Bulgaria, April 2010;

Publicly accessible information about the authorized medicines in the country is available on website of the Bulgarian Drug Agency under the section Registry http://www.bda.bg/index.php?option=com_content&view=section&layout=blog&id=6&Itemid=59&lang=bg. At the website of BDA a link to the European Medicines Agency for the centrally authorized medicines and another link for medicines authorized in Bulgaria can be found. At present the BDA is not able to provide the needed annual information about the number of authorized medicines, possible sub-groups - HOM, POM, generics, etc. due to different reasons, among which are lack of legal requirement, capacity, and resources.

A slightly decreasing trend in the number of medicines on the market for the last year is observed, but at the time of writing this report is still early to have a definite explanation for it. Possible reason of this trend might be that some medicines are still in renewal of MA procedure as in 2005 or the pharmaceutical companies' policy, to withdraw some medicines from the market due to the restrictive pricing procedures or not attractive market conditions.

There are few examples of switches from POM to OTC, but it is not possible to follow this process closely, again due to lack of chronological information about the POM and OTC medicines. There is no obvious or officially announced policy on switches.

Concerning the parallel traded medicines, still there is no experience in the country. One of the possible reasons might be the fact that there is formal procedure, but in practise there are legislative and administrative obstacles for the PI medicines to enter the reimbursement system, e.g. it is required the wholesaler/parallel Importer to be authorised by the holder of marketing authorisation in order to be included in the reimbursement list of NHIF, for the PI medicines to enter the reimbursement system.

2.3.1.2 Access to medicines

The average time between marketing authorisation and patient accessibility varies according to the type of medicines – reimbursed or not, POM or OTC. For the medicines, included in the Positive list, the duration is 45 days for price + 90 days for reimbursement decision = 135 days after the marketing authorisation. Then medicines reimbursed by the NHIF need two more months to become effectively available for the patients. Those medicines, supposed to be reimbursed by MoH have further to be included in another regulation in order to be able to be included in the annual public procurement process. POM, which do not have reimbursement pretensions theoretically reach the market within 45 days after receiving the marketing authorisation.

The OTC products are reaching the market within 30 days after receiving marketing authorisation.

Table 2.3: Bulgaria – Number of new molecular entities, 1999-2009

New molecular entities	1999 – 2009	2004 – 2009
Number of new molecular entities	n.a.	n.a.

n.a. = not available, No official data available about the number of new molecular entities (NMEs).

2.3.2 Prescriptions

Data concerning prescriptions in Bulgaria is available only for that part of prescriptions, which are reimbursed – fully or partially by the NHIF. There is no regulatory obligation to monitor the prescriptions in the rest of the out-patient or in-patient sector.

Table 2.4: Bulgaria – Annual prescriptions 2000, 2005–2009

Prescriptions	2000	2005	2006	2007	2008	2009
No. of prescriptions ¹ (in volume)	n.a.	15,909,316	17,512,327	18,015,177	18,469,778	18,576,829
Prescriptions in value ² BGN (in NCU = 1.9558 Euro)	n.a.	249,082,842	274,026,197	279,602,103	311,182,860	327,370,949

n.a. = not available

¹ is the number of the prescriptions (not the number of items prescribed). One prescription may consists of up to three items

² The value of prescriptions consists of the value for medicines, medical devices and medical food at the moment of the real consumption, e.g. the moment of dispensing by the pharmacy.

Source: NHIF, letter dated May 2010

Steady trend of increase in both volume and value is observed. Some of the reasons are connected with the increased number of medicines, especially “the expensive ones”, included in the reimbursement list of the NHIF as well as the increased budget of NHIF for medicines throughout the years. Other reasons are the fact that during the years more and more people are getting informed and benefit from the compulsory insurance as well as the increasing morbidity of the aging population. Budget of the NHIF for medicines was also steadily growing through the years.

2.3.3 Sales

Table 2.5: Bulgaria – Pharmaceutical sales 2000, 2005 –2009

Sales, in Mio EURO	2000	2005	2006	2007	2008	2009
Sales at ex-factory price level	186	359	420	472	555	615
– Sales in out-patient sector	151	277	336	380	450	493
– Sales at hospitals	35	82	84	92	105	121
Sales of parallel traded medicines	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Data as of 31 December

Source: IMS Bulgaria, April 2010

An increasing tendency of pharmaceutical sales is observed. For the last five years from 2005 to 2009 there is more than 71% increase of the total sales. The increase in % in the out-patient sector is higher than the % increase in the hospital sector. Possible reasons are the restricted and limited hospital budgets for medicines versus the increased resources for out-patient medicines of the NHIF, as well as the slightly increasing budget for public procured medicines by the MoH.

2.3.4 Consumption

Table 2.6: Bulgaria – Annual pharmaceutical consumption 2000, 2005–2009

Consumption, in Mio.	2000	2005	2006	2007	2008	2009
<i>Total pharmaceutical consumption</i>						
In packs	180	192	217	235	251	249
In DDD	n.a.	1,797	2,063	2,257	2,452	2,522
<i>Pharmaceutical consumption in the in-patient sector</i>						
In packs	40	30	39	43	45	46
In DDD	n.a.	50	49	53	54	57
<i>Pharmaceutical consumption in the out-patient sector</i>						
In packs	140	162	179	192	206	202
In DDD	n.a.	1,747	2,014	2,205	2,398	2,465

DDD = defined daily doses, n.a. = not available

Source: IMS Bulgaria, April 2010

As the pharmaceutical sales are growing, the consumption is growing as well – total consumption in DDD has grown with around 29% in the last five years period. For the same period the consumption in DDD in the out-patient sector grows faster than the consumption in the hospitals.

A serious problem is the lack of an integrated system for statistical management of consumption data in the country for medicines in the out-patient and in-patient sector. Occasionally there are discussions among the public actors, but so far there is no legal basis for the establishment. The NHIF has a system for monitoring the consumption only for the out-patient medicines which are reimbursed by the NHIF. However, at the time of writing the country profile such data is not publicly available.

There are some attempts following art. 4, paragraph 15 of the regulation N 39 on the principles of the GDP (OJ 77, 2007) to collect data from wholesalers. The wholesalers are obliged by law to provide information to the Ministry of Health annually (until 30 January each year) regarding their sales to other wholesalers, pharmacies and hospitals in terms of volume and price. Based on the data, provided by the wholesalers, the BDA analysed the pharmaceutical market in 2009. The analysis has some limitations and is available in Bulgarian language on: http://www.bda.bg/images/stories/documents/analiz_pazar/analiz_proajbi_2009.pdf (September 2010).

No official data is available in the country on the sales of generics and of parallel traded medicines.

2.3.5 Generics

Table 2.7: Bulgaria – Development of the generic shares 2000, 2005–2009

Generic share	Volume		Value	
	2005	2009	2005	2009
Shares in % of total market (in-patient/ out-patient)	n.a.	n.a.	n.a.	n.a.
Shares in % of total out-patient market	n.a.	n.a.	n.a.	n.a.
Shares in % of out-patient reimbursement market	n.a.	n.a.	n.a.	n.a.
Shares in % of out-patient off-patent market	n.a.	n.a.	n.a.	n.a.
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.

n.a. = not available

As it was mentioned before there is no official data concerning sales of generics. Besides, there is no specific generic policy in the country. In the Positive drug list regulation, some attention to the generics was paid, but after some amendments of this regulation in April 2010, the only difference for generics is that they do not have to present data from clinical trials if their referent product is already included in the Positive drug list. Regulatory changes, mainly concerning the procedure and the required documentation, are envisaged concerning the pricing of the generics, which are still under discussion at the time of writing.

2.3.6 Top 10 medicines

Table 2.8: Bulgaria – Top 10 active ingredients in value and volume in the out-patient sector, 2009

Position	Top active ingredients used in the out-patient sector, ranked with regard to <u>consumption</u>		Position	Top active ingredients used in the out-patient sector, ranked with regard to <u>expenditure</u>	
1	A01AD05 B01AC06 N02BA01	ACETYLSALICYLIC ACID	1	C09AA02	ENALAPRIL
2	N02BB02	METAMIZOLE SODIUM	2	N02BE01	PARACETAMOL
3	C09AA02	ENALAPRIL	3	C03AA03	HYDROCHLOROTHIAZIDE
4	N02BE01	PARACETAMOL	4	G01AD03 S01XA15 A11GA01	ASCORBIC ACID
5	G01AD03 S01XA15 A11GA01	ASCORBIC ACID	5	A01AD05 B01AC06 N02BA01	ACETYLSALICYLIC ACID
6	C03AA03	HYDROCHLOROTHIAZIDE	6	A10AC01	INSULIN HUMAN ISOPHANE
7	A10AC01	INSULIN HUMAN ISOPHANE	7	A10AE	INSULIN HUMAN BASE
8	C07AB02	METOPROLOL	8	N02BB02	METAMIZOLE SODIUM
9	C07AB07	BISOPROLOL	9	C03BA11	INDAPAMIDE
10	C03BA11	INDAPAMIDE	10	J01CA04	AMOXICILLIN

Source: IMS Bulgaria, April 2010

Among the top 10 INN both – in volume and value - 4 OTC products are present. All the rest are included in reimbursement list of NHIF and are covered fully or partially by it.

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Table 2.9: Bulgaria – Top 10 active ingredients in value and volume in the in-patient sector, 2009

Position	Top active ingredients used in the in-patient sector, ranked with regard to <u>consumption</u>		Position	Top active ingredients used in the in-patient sector, ranked with regard to <u>expenditure</u>	
1	A12CA01 B05CB01 B05XA03	SODIUM	1	A12CA01 B05CB01 B05XA03	SODIUM
2	A12AA07 B05XA07 G04BA03	CALCIUM	2	L01XC03	TRASTUZUMAB
3	A12BA01 B05XA01	POTASSIUM	3	L01XX28	IMATINIB
4	B05CX01 V04CA02 V06DC01	GLUCOSE	4	B02BD02	FACTOR VIII
5	N02BB02	METAMIZOLE SODIUM	5	M05BA08	ZOLEDRONIC ACID
6	D07AA01 D10AA02 H02AB04	METHYLPREDNISOLONE	6	B03XA	EPOETIN BETA
7	J01DA13	CEFTRIAXONE	7	L01XC02	RITUXIMAB
8	C03CA01	FUROSEMIDE	8	A12AA07 B05XA07 G04BA03	CALCIUM
9	G01AD03 S01XA15 A11GA01	ASCORBIC ACID	9	A12BA01 B05XA01	POTASSIUM
10	C01BB01 C05AD01 N01BB02 R02AD02 S01HA07 S02DA01	LIDOCAINE	10	L02BG04	LETROZOLE

Source: IMS Bulgaria, April 2010

The top INN, used in hospitals in both volume and value is Sodium. Together with it, there are 3 other infusion solutions. The highest part in terms of expenditure is for medicines, which are supplied to hospitals by the budget of MoH (as per Regulation N34).

2.4 Market players

The delivery chain for medicines for both - out-patient sector and hospital sector - is quite simple. Any wholesaler licensed/registered by the BDA is able to buy from manufacturers and deliver medicines to other wholesalers, out-patient pharmacies and hospital pharmacies.

The particular choice of a wholesaler in the out-patient sector is made based on the market assessment. For the hospital supply of medicines, the choice of the 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 directly; however only those which they produce.

2.4.1 Industry

In Bulgaria manufacturing is regulated by Chapter 5 of the Law on Pharmaceutical Products in Human Medicine and Regulation N15 on conditions for authorization of the manufacture/import and the principles and requirements of GMP for all types of medicines, incl. those for clinical trials and active ingredients (OJ 38, 2009).

The manufactures of all types of medicinal products, incl. those for clinical trials, of active ingredients, can operate in Bulgaria after receiving manufacturing authorisation issued by the Director of the Bulgarian Drug Agency. Such authorization is required also for production of medicines intended for export. A manufacturing authorisation is required as well for persons who perform simultaneously or separately total or partial manufacture, various processes of dividing up, packaging, re-packaging, labelling, quality control and batch release of medicinal products or medicines intended for a clinical trial.

Manufacturing authorisation shall be provided after spot-check which is performed to establish compliance with the actual manufacturing conditions, control and storage of the medicines with the presented documentation and the requirements of Good Manufacturing Practice regulations.

Within 90 days of receipt of the valid application, the Executive Director of the BDA shall either issue an authorisation for manufacture or make a motivated refusal. BDA has the obligation to forward to the European Medicines Agency a copy of the manufacturing authorizations for including that information in the Community database.

Article 158 (1) of LPHM oblige the Bulgarian Drug Agency to maintain a register of the issued manufacturers' authorizations. Data from this register should be available on the web page of the BDA http://www.bda.bg/images/stories/documents/registers/register_158_new.pdf as of October 2010.

Table 2.10: Bulgaria – Key data on the pharmaceutical industry 2000, 2005–2010

Pharmaceutical industry	2000	2005	2006	2007	2008	2009	2010
Total number of companies	n.a.						
– research-oriented	n.a.						
– generic producers	n.a.						
– biotech	n.a.						
Number of persons employed	n.a.						

There is no official data in the need format about the pharmaceutical industry in the country.

According to article 196, paragraph 1 of LPPHM, Bulgarian manufacturers may carry out wholesaling activities only with medicines manufactured by them, under the manufacturing licence.

Manufacturers may supply with medicines that they have produced themselves, wholesale pharmaceuticals traders, other manufacturers, only if necessary for the production activities, hospitals, Ministry of Health (MoH) – with vaccines, toxins and serums necessary for the fulfilment of the vaccination calendar of the Republic of Bulgaria, as well as in emergency epidemic situations.

Local producers classify themselves as generics manufacturers. Till 2005 the BDA was publishing data in volume and value about the medicines sold by the local and foreign manufacturers, but at present official data is not published any longer.

Several associations of manufacturers are established in the country. Each of them is very active concerning the regulatory environment in the sector.

The Bulgarian Generic Pharmaceutical Association (until September 2008, “Association of Bulgarian Pharmaceutical Manufacturers”) was founded in July 2001. At the time of writing this report it has 19 members. Additional information is available on <http://www.bgpharma.bg/en> (as of October 2010).

In Bulgaria an Association of Research-based Pharmaceutical Manufacturers (ARPharM) is registered as well. Twenty-three (23) foreign manufacturers are members. <http://www.arpharm.org/en> as of September 2010.

There is a third association of manufacturers – **The American Pharmaceutical Manufacturers’ Association (AmPharMA)** which has been established in 2008 and currently unites 9 US research-based pharmaceutical companies, represented in Bulgaria (<http://www.ampharma.org/en> as of September 2010).

Another recently established association is the Bulgarian Association of Pharmaceutical Technologies, which was established in April 2010. Currently it has 12 members. More information is available on http://bapht.org/about_en.html (as of October 2010).

2.4.2 Wholesalers

The wholesalers' activities are regulated by Chapter N9 of the Law on Pharmaceutical Products in Human Medicine and Regulation No 39 of 13.09.2007 on the principles and requirements for Good Distribution Practice (OJ 77, 2007).

As per article 195 wholesales could be carried out only by physical and legal persons who possess an authorisation for this activity issued by the regulatory authority of the respective Member State. If the wholesaler has warehouse premises in the territory of the Republic of Bulgaria, he is entitled to perform wholesale trade of medicines only after receiving an authorization, issued by the BDA. The importers of medicinal products may perform wholesale trade only with products for which authorisation for import has been granted.

Authorisation is granted for an indefinite period by the Bulgarian Drug Agency (BDA). The procedure of authorisation takes three months. For the wholesalers, who has license issued by a regulatory body of a member state, the Executive Director of the BDA shall issue a certificate for registration within 15 days of submission of the documentation.

The wholesalers have to provide adequate infrastructure - premises, equipment, vehicles, etc. at their disposal to ensure proper storage and distribution of the medicinal products in compliance with the requirements of Good Distribution Practice, qualified personnel and a responsible qualified pharmacist with at least two years of relevant professional experience. The BDA is responsible for maintaining a register of the issued authorisations for wholesale trade.

Data from IMS Bulgaria shows that in 2009 the 80% of the sales on wholesale market level is made by 5 wholesalers. Each of the top two wholesalers has around 21 % and the fifth one has 2.3% of the market.

In Bulgaria there is still no experience with parallel imports. One possible reason might be the fact that although the principal regulations are synchronised with the European legislation, there are purely national administrative obstacles for wholesalers to place the parallel imported medicines on the reimbursement market.

Data on the number of employed people in the wholesale sector are not officially available in Bulgaria. When an application for a licence is submitted, the candidate only gives information about the qualified pharmacist, who is responsible for the overall activities of the wholesaler and the person who is responsible for the narcotic and precursor medicines.

Partial data about the employees, the logistics processes, availability of stock, daily deliveries, etc., might be obtained though the web sites of some of the wholesalers, as shown in section 6.3. Web links.

According to article 209a of the Law on Pharmaceuticals in Human Medicine a wholesaler may deliver medicines to other wholesales, pharmacies, incl. hospital pharmacies and drugstores, the Ministry of Defense and the Ministry of Internal Affairs for their own needs except for the medical facilities belonging to these Ministries, the State Agency for "Reserves

and War-time Reserves”, physicians and dentists in the areas where there is no pharmacy as well as the Ministry of Health with:

- vaccines, toxins and serums which are necessary for the Immunisation Calendar of the Republic of Bulgaria and for exceptional epidemic situations;
- medicinal products intended for the treatment of diseases which are reimbursed directly through the budget of MoH under the terms of the Law for Health and for national programmes in the field of health care.

There are two registered wholesale associations: the Association of the Wholesalers of Medicines and the Professional Chamber of Wholesalers. None of these associations is a member of the committees functioning in the pharmaceutical sector and they are rarely officially involved in policy-making or decision-making processes; their influence is more through their media performance. They do not have web sites.

Table 2.11: Bulgaria – Key data on pharmaceutical wholesale 2000, 2005–2010

Wholesalers	2000	2005	2006	2007	2008	2009	2010
Total number of wholesale companies	n.a.	349	n.a.	n.a.	n.a.	145	n.a.
Total number of importers	n.a.						
Total number of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	196	n.a.

Data as of 1 January

n.a. = not available

Source: BDA report 2005 and

http://www.bda.bg/images/stories/documents/registers/register_LP.pdf from 20.08.2010

The decreased number of wholesalers is due to regulatory changes and the process of acquisitions and mergers in the sector.

2.4.3 Retailers

The legislation in Bulgaria allows medicines to be sold at retail level only by pharmacies and drugstores. Exceptionally doctors and dentists may sell medicines only in places/regions without a pharmacy.

A pharmacy by definition is a health facility where the following activities are performed: storage, preparation, packaging, control, consultation, dispensing of POM or OTC medicinal products, as well as medical devices, diet foods for special medical purposes and foods for breast-fed children and transitional foods, food supplements, cosmetic and hygienic products.

2.4.3.1 Community pharmacies

Chapter ten of the Law on Pharmaceutical Products in Human Medicine provides detailed information about the requirements, procedures and obligations of the pharmacies. Art. 222 states that the right to carry out retail trade can be granted to a physical or legal person who is registered as a trader in accordance with the Bulgarian legislation or in accordance with the legislation of a Member State if he has concluded a labor contract or a contract for management of the pharmacy with a qualified pharmacist or, in the cases laid down in the law, with a pharmacist assistant. Such person is authorised to open up to 4 pharmacies on the territory of Bulgaria. The qualified pharmacist or a pharmacist assistant may be the manager of only one pharmacy and must work within the pharmacy. This person cannot be employed on a labor contract or participate in another company involved in the manufacture, import, wholesale or retail sale of medicines, neither can work in other companies of related persons in accordance with the Trade Law.

In an area, where no other pharmacy is available, the right to open a pharmacy might be granted to a person who has concluded a labor contract or a contract for management of the pharmacy with a pharmacist assistant or a qualified pharmacist even with experience less than a year.

To motivate opening of pharmacies in locations with less than 10 000 inhabitants a separate specific form and 5 times reduced fees are introduced.

To open a pharmacy which dispenses and sells medicines containing narcotic substances, the provisions under the Narcotic Substances and Precursors Control Act must also be followed, e.g. a second licence should be obtained.

The municipalities and the medical establishments for hospital care can register a pharmacy fulfilling their own needs under same procedure as the other pharmacies. The pharmacist is the licence holder for these types of pharmacies and he cannot open a private pharmacy.

The consultative body to the Minister of Health on pharmacy issues is the Supreme Pharmaceutical Council. It is to be comprised of an equal number of representatives of the Ministry of Health, the Bulgarian Drug Agency, the Pharmaceutical Faculties of the Medical Universities, the Bulgarian Pharmaceutical Union and a representative of the National Health Insurance Fund (NHIF).

The Supreme Pharmaceutical Council makes a motivated proposal to the Minister of Health. The whole procedure should last one month of receiving valid documentation. The Minister of Health issues an authorisation for opening a pharmacy or makes a motivated refusal.

At the time of writing, there is a small number of pharmacies which belong to the municipalities or to hospitals (the hospitals may be classified as municipal or state, mixed or private).

In September 2006 the first law for Bulgarian pharmacists in the recent history of the country was introduced – the Law on the Professional Association of Pharmacists (PAP) (OJ 75, 2006). According to this Law, the professional organisation of the Masters of Pharmacy is the

Bulgarian Pharmaceutical Union (BPU) and the membership is obligatory. The BPU operates through its national and regional structures. http://www.bphu.bg/about_us.php?id_page=26

The Law defines the structure, organisation and activity of the BPU, as well as the conditions under which the pharmacist can practise her/his profession and the responsibility of maintaining the Professional Ethical Code and Good Pharmaceutical Practice. Professional organization is built on national and regional level. At national level the Congress of the Bulgarian Pharmaceutical Union, its management and supervisory bodies and the Committee on Professional Ethics exist. The law defines as well the responsibility of the its' members for breach of the professional ethics and the Good Pharmaceutical Practice. As per article 3 of the Law on PAP, practising pharmacists are members of the Bulgarian Pharmaceutical Union (BPU). Those pharmacists, who are not practising their profession, are voluntary members of the Union.

Some of the main functions of the BPU are to represent its members and defend their professional rights and interests; to prepare and adopt a Code of Professional Ethics of the Master of Pharmacy and supervise its observance; to adopt rules of good pharmaceutical practice, offering them for approval by the Minister of Health and exercise control over their observance; to establish and maintain national and regional registers of its members; to organize, coordinate, conduct and record continuing education of pharmacists; to participate with its representatives in the Supreme Medical Council and the Supreme Board of Pharmacy to the Minister of Health; to participate in drafting and give opinions on draft regulations in the field of pharmacy; to issue opinion for opening a pharmacy according LPPHM; cooperate with other organizations and institutions in the country and abroad, etc. In 2010 after long process of coordination with MoH, the Code of ethics came into force.

A pharmacist may practise her/his profession in Bulgaria if s/he responds to the conditions of Chapter 7 of the Health Act and is registered in the regional structure of the Bulgarian Pharmaceutical Union (BPU) according to the territory in which s/he works.

Since the time of its' establishment, the BPU gains experience with the regulatory issues in the pharmaceutical sector. What seems doubtful is the contradiction between the task to defend the professional interest of all its members from one side and the officially stated ideas for reforming the pharmaceutical sector. The different points of view of some of the members of BPU led to the establishment of the Association of Owners of pharmacies (ASA) in July 2007, which include owners of pharmacies throughout the country- <http://www.asa-pharmacy.com/?cid=23> and in 2010 to the establishment of the association "National chamber of pharmacy" - <http://www.nphc-bg.eu/>.

Not all of the registered pharmacies can work with the National Health Insurance Fund. They need to meet NHIF's requirements in terms of record-keeping software and monthly reporting, and they are inspected by the National Health Insurance Fund and the Bulgarian Drug Agency. The contracts between Pharmacies and NHIF are renewed annually.

It is forbidden to sell POM by internet. At the time of writing this report a campaign against the internet sale of medicines takes place on the website of the BPU.

Table 2.12: Bulgaria – Retailers of medicines 2000, 2005–2010

Retailers	2000	2005	2006	2007	2008	2009	2010
No. of community pharmacies	2,275	3,843	4,299	n.a.	n.a.	n.a.	4,012
– Thereof: No. of private pharmacies	1,937	3,611	4,056	n.a.	n.a.	n.a.	3,949
– Thereof: No. of public pharmacies ¹	338	232	243	n.a.	n.a.	n.a.	63
– No. of hospital pharmacies for out-patients ²	n.appl.						
– No. of dispensing doctors ³	n.a.						
Total no. of POM dispensaries	2,275	3,843	4,299	n.a.	n.a.	n.a.	4,012
No. of internet pharmacies	n.appl.						
No. of OTC disp., like drugstores *	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	882

Disp. = dispensaries, n.a. = not available, n.appl. = not applicable, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (PHIS Glossary).

Data as of 1 January

¹ Public pharmacies are the municipal pharmacies, which constantly reduce in number due to the market development of the sector.

² in Bulgaria the hospital pharmacies are for in-patients only –art.226 LPPHM, so they are not included in these figures.

³ self-dispensing (SD-) doctors are allowed to prescribe medicines if there is no pharmacy in the settlement

⁴ Internet pharmacies are not allowed in Bulgaria

Source: IHHI compilation, based on the MoH web site, section Register of pharmacies for 2003, 2004, 2006, for 2010

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=387&categoryid=1104>

20.08.2010. Figures might be not completely precise, but are giving orientation about the development of the in the number of pharmacies and

* Register of drugstores within the BDA web site:

<http://95.87.254.60:8888/DrugStoreApp/faces/webSearchForm.jspx> 30.09.2010

2.4.3.2 Dispensing doctors

Article 209a (2) from the LPPHM gives the right to physicians and dentists in the towns and villages where there is no pharmacy to be supplied with medicines by the wholesalers and art. 232 from the same law give them the right to sell medicines to patients. A specific regulation on this issue should be published, but is yet not available at the time of writing. Previous regulation - Regulation N6 on terms and conditions under which doctors and “feldshers” (medical assistant), dentists and nurses may store and sell medicines (OJ 11, 2001) is still not cancelled and provides the possibility for a doctor or “feldsher”, dentist or nurse to sell medicines, where there is no pharmacy in the community. Such cases should be registered with the regional health centre (RHC). The permission is valid until the opening of a pharma-

cy within the community. There are precise conditions that should be followed, e.g. selling medicines at a price not higher than the registered ceiling price, and dispensing medicines only to their patients. "Feldshers" are not allowed to store and dispense medicines from certain pharmacological groups, such as antiarrhythmics, neuroleptics, narcotic drugs, etc.

2.4.3.3 Hospital pharmacies

As per article 222 of the LPPHM, the medical facilities for in-patient care and the dispensaries may open pharmacies for satisfying their own needs. However the number of hospital pharmacies is smaller than the number of hospitals. For example, in 2007 there are 292 hospitals in the country with only 157 pharmacies. As it is prohibited for them 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 pharmacy⁴. The hospital pharmacies are also licensed like out-patient pharmacies as per chapter 10 of the LPPHM, by the Minister of Health after the application from the head of the hospital.

According article 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 article 75 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. 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 extempore.

⁴ 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

2.4.3.4 Other POM dispensaries

There are no other POM dispensaries.

2.4.3.5 Other retailers

Since 2000 drugstores have opened in Bulgaria in which OTC products, medical devices, health-related products, food supplements, special purpose foods, cosmetic products disinfectants and general biocides and pest control products are sold. Regulation N29 on the terms and conditions for opening drugstores (OJ 109/2008) defines how these drugstores function and who can work in them. They have to be registered with the Bulgarian Drug Agency (BDA). All individuals and corporate bodies shall have the right to open a pharmacy. The manager of the drugstore might be a person with pharmaceutical or medical education, including a person having graduated from a medical college.

Under art. 240 of the LPPHM, within 30 days from receipt of the documents, the Director of the Bulgarian Drug Agency shall issue a certificate for registration of the drugstore or make a motivated refusal. The BDA is maintaining a register of the issued licenses, available on its' web site - see section 6.3 - Web links.

2.4.4 Promotion

The promotion of medicines is regulated in the LPPHM – chapter eleven and the relative Regulation 13 on the terms and conditions for approval of the advertisement of the medicines (OJ 59/2000). At the time of writing the report a new Regulation on the requirements for the advertisement was available for public discussion, but it is not published in the OJ. These acts are fully transposing the European requirements, set in Directive 2001/83/. The leading role in the implementation is within the responsibilities of the BDA. Any form of information, presentation, promotion or inducement designed to promote the prescription, sale or consumption of medicines is considered as advertising of medicinal products and includes in particular:

- advertising of medicinal products to the general public;
- advertising of medicinal products to medical professionals;
- visits by medical sales representatives to medical professionals;
- the supply of samples;
- sponsorship of promotional meetings and scientific congresses attended by medical professionals and in particular payment of their travelling and accommodation expenses in connection therewith in the country where the activity is held.

Article 247 gives the right OTC products to be directly advertised to the general public. Advertising of POM in Internet is prohibited. Exceptions of advertising (incl. in the internet) of some POMs is made for some vaccination campaigns after prior approval of the competent authority.

No specific measures are implemented in order to restrict or control promotional spending of manufacturers. Any kind of promotion as defined in the art.2 (1) of Regulation N13/2000 is subject of preliminary authorisation by BDA. The procedure lasts one month. The proposal is made by the special interdisciplinary committee, set as advising body to the Director of BDA. The medical sales representatives have to be adequately trained by the marketing authorisation holder. During each visit, the medical sales representatives shall have the summary of the product characteristics of each medicinal product together with details of the price and conditions for payment available. No gifts, pecuniary advantages or benefits in kind may be offered by the medical sales representatives to the medical specialists. The manufacturers or the wholesalers are allowed to give no more than two samples of the same product in the smallest possible pack to the medical specialist within a year.

Additionally Article 246 paragraph 2, states that the advertising of a medicinal product shall encourage its rational use by presenting the therapeutic indications of the medicinal product objectively and without exaggerating the effects of its treatment, prevention or diagnosis.

2.5 Funding

2.5.1 Pharmaceutical expenditure

The structure of the pharmaceutical expenditures is an important indicator for the development of the pharmaceutical sector in a country. The attempts to obtain the data from official national sources were not very successful.

Table 2.13: Bulgaria – Total pharmaceutical expenditure 2000, 2005–2009

Pharmaceutical expenditure in Mio.	2000	2005	2006	2007	2008	2009
TPE in NCU = Mio. BGN'	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof public ²	n.a.	574.94	567.98	616.07	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PE in the out-patient sector ¹	n.a.	1,110.32	1,287.60	1,379.93	1,616.25	n.a.
– thereof public	n.a.	244.94	269.98	282.07	295.48	n.a.
– thereof private	n.a.	865.39	1,017.62	1,097.86	1,320.77	n.a.
PE in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof public	n.a.	330	298	334	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure

¹ Tot. exp. on pharmaceuticals & other medic. non-durables dispensed to out-patients

² calculated by adding in- and out-patient data of different sources

Data as of 31 December

Source: out-patient data: Eurostat Public Health Database 2011 (last update of data: 01 February 2011); in-patient data: National Center of Health Informatics (used in PHIS Hospital Pharma Report Bulgaria, 2009)

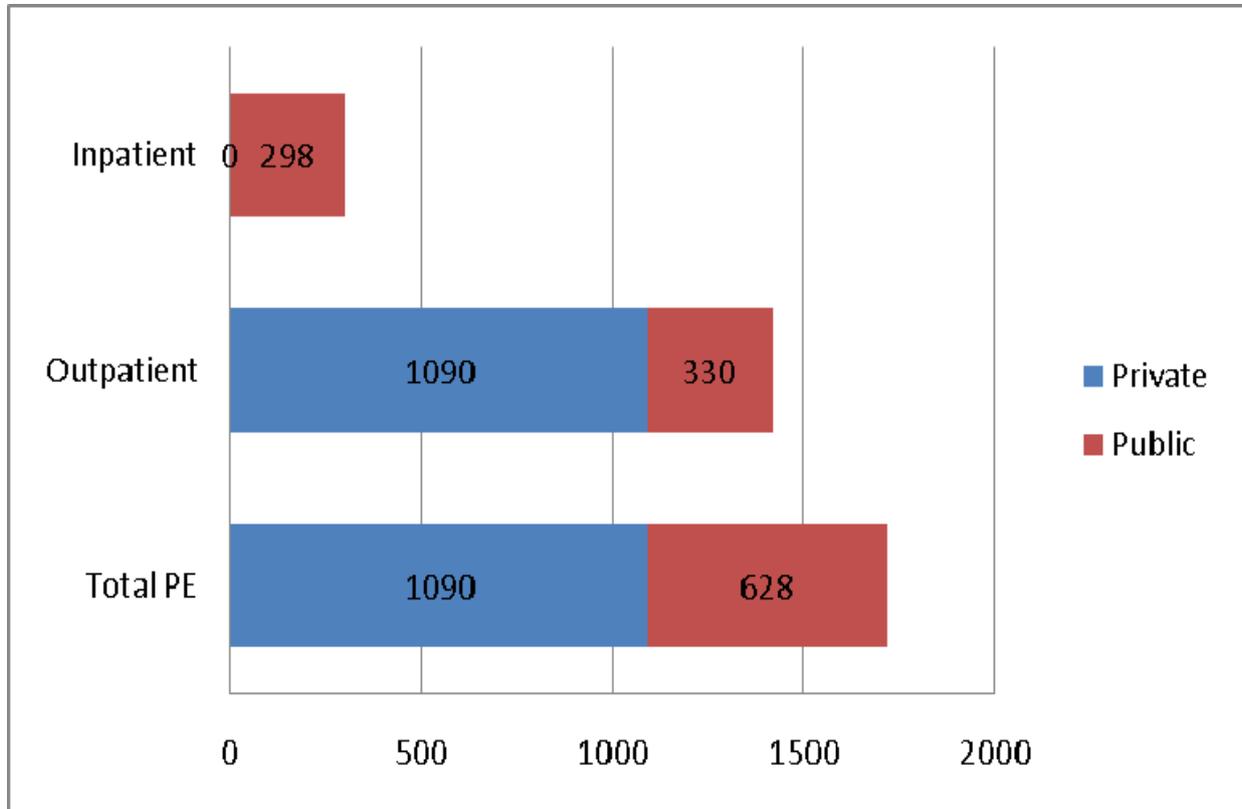
2.5.2 Sources of funds

The main funding sources for public pharmaceutical expenditure in the country are social health insurance contributions via the National Health Insurance Fund and the state budget via the Ministry of Health and the Municipalities, incl. the contributions to pharmaceutical funding for a very limited group of medicines for war veterans and victims and military disabled persons.

Private pharmaceutical expenses are made up of expenses for out-of-pocket payments for the reimbursed medicines; expenses for non-reimbursed prescription medicines; self-medication expenses paid to Voluntary Health Insurance Funds and informal payments.

The current relation of in-patient to out-patient as well as private to public pharmaceutical expenditure is shown in Figure 2.2. Data for 2009 is provided by IMS Bulgaria. The reason why in the in-patient sector no private pharmaceutical expenditures exist, is connected with the shift of these expenditures to the out-patient sector due to fact that hospital pharmacies are not allowed to sell medicines and the patients, when needed, purchase them from the out-patient sector.

Figure 2.2: Bulgaria – Share of public and private pharmaceutical expenditure in the in-patient and out-patient sector, 2009



PE = pharmaceutical expenditure, in Mio BGN.

Source: IMS Bulgaria

3 Pricing, reimbursement and volume control in the out-patient sector

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

Two of the main legal documents that have established the statutory pricing system in the country are the LPPHM 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 medicines (Pricing Regulation). Two committees are involved in the process: the Pricing Committee (PC) and the Transparency Committee (TC).

The Council of Ministers, based on a proposal by the Minister of Health, is establishing a PC at the Ministry of Health, which consists of representatives of the Ministry of Health, the Ministry of Finance, the Ministry of Economy and Energy, the National Health Insurance Fund and the Bulgarian Drug Agency. Their mandate is 4 years and half of the members are changed each 2 years. This Committee deals with all medicines, whether publicly financed or not, and whether prescription-only medicine(s) or over-the-counter products and whether in out-patient care or in hospitals. It approves the ceiling prices for all products, within which pharmacy retail prices (PRP) are subject to competition and negotiation. It is supposed to have meetings at least once per month.

The Pricing Regulation defines the terms for regulation of the prices of medicines, included in the positive list and paid with public funds, regulates the ceiling prices of the POM medicines not included in the positive list and the registration of the prices of OTC medicines. When a medicine will apply later for inclusion in the Positive List, both applications – for price and for reimbursement price - can be filed at the same time. The reimbursement price will be effective from the moment of inclusion of the medicine in the positive list.

The price, at which a medicine can be sold, is the price approved by the PC. 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 medicine in excess of this price.

Approved prices are publicly available on the website of the MoH under the section registers at: <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=383>

For POM the price is determined at manufacturer level based on the methodology of external price referencing, and at wholesale and pharmacy levels statutory maximum mark-ups are applied. The remuneration of the wholesalers and pharmacies is based on regressive mark-ups. The regulation approves the price for POM at each level – at manufacturer, at wholesale and retail sale level with all elements, e.g. from the ex-factory price, the mark-up for each level and value-added tax (VAT) at each level.

The pricing procedure is the second step towards market access for the medicine. In an ideal scenario the procedure for prescription-only medicine(s) (POM) lasts 45 days.

After the pricing decision, medicines seeking to be included in the reimbursement lists are subject to the next stage in the process which is the application to the Positive Drug List (PDL). Medicines not seeking reimbursement are ready to be sold on the free market – see Figure 2.1, Chapter 2.

According to article 265 of LPPHM, the Council of Ministers establishes a Transparency Committee (TC) for the approval, adoption and control of the reimbursement lists. The members of the TC are appointed by the Council of Ministers. It includes representatives of the Ministry of Health, the Bulgarian Drug Agency, the National Health Insurance Fund, Bulgarian Medical Union, the Bulgarian Dental Association and the Bulgarian Pharmaceutical Union, representatives of the Patient organisations and representatives of the industry.

3.1.2 Pricing policies

There is statutory pricing for prescription-only medicine(s). At manufacturer level, the price is determined based on the methodology of external price referencing, and at wholesale and pharmacy level statutory maximum mark-ups are applied.

The procedure for over-the-counter (OTC) products is simplified and there is no reference pricing. The manufacturer has to announce the price at manufacturer level as well as the final pharmacy retail price (PRP).

However, the pricing of over-the-counter (OTC) products is not simply a matter of notification, as the prices enter into force after a certain procedure. Its duration is 30 days. The final pharmacy retail price (PRP) affirmed by the PC, enter in the official register of the over-the-counter (OTC) medicines, available on the web site of the MoH.

Therefore, the pricing procedure for over-the-counter (OTC) products can be defined as a statutory pricing system.

Table 3.1: Bulgaria – Ways of pricing of medicines at manufacturer level, 2010

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine	
	POM	OTC	Reimbursable	Non-reimbursable	Generics	Parallel traded
Free pricing	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.
Statutory pricing	yes	Yes - OTC products (simplified procedure) – notification of manufacturer price by manufacturer	yes	yes	yes	Not appl.
Price negotiations	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.
Tendering	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.	Not appl.

POM = prescription-only medicine, OTC = over-the-counter medicines, appl. = applicable

Source: LPPHM

3.1.2.1 Statutory pricing

In the out-patient sector the determination of the price is made by the state and is based on the statutory pricing regardless of the type of medicines - POM, OTC, reimbursable, not reimbursable, generic or others. At manufacturer level, the prices of POM are determined based on the methodology of external price referencing, and at wholesale and pharmacy level statutory maximum mark-ups are applied.

The difference for over-the-counter products is that it is not required to compare with reference prices. The manufacturer has to announce the price at manufacturer level as well as the final pharmacy retail price.

3.1.2.2 Negotiations

Not applicable

3.1.2.3 Free pricing

There is no free pricing for medicines in Bulgaria. Even the simplified price notification procedure for over-the-counter (OTC) products is to be classified as statutory pricing.

3.1.2.4 Tendering

Tendering is not applicable for the pricing in the out-patient sector.

3.1.3 Pricing procedures

The pricing procedure for POM in use at the time of writing this report is external price referencing and it has been applied in Bulgaria since the year 2000. At present it is enforced by the LPPHM 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 medicines (Pricing Regulation).

Table 3.2: Bulgaria – Pricing procedures, 2010

Pricing procedure	In use: yes / no	Price type ¹	Scope
External price referencing	Yes	Manufacturer price	For all POM
Internal price referencing	No	Not appl.	Not appl.
Cost-plus pricing	No	Not appl.	Not appl.
Indirect profit control	No	Not appl.	Not appl.

¹ Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

Source: LPPHM

3.1.3.1 External price referencing

The price of the medicine is the final consumer price, fixed in accordance with the price proposed by the manufacturer, which should not be higher than the reference price. The reference price, is the lowest manufacturer price in BGN in Romania, Greece, Estonia, the Czech Republic, Lithuania, Hungary, Portugal and Spain. In the cases, when there is no registered price of manufacturer in these countries, additional five countries are used as a reference – Poland, France, Belgium, Latvia, Slovakia.

A mark-up, for the wholesale and for pharmacy level is then added according to the price category of the medicine. Either manufacturers or their authorised representatives may register and change the prices of their registered products once a year. In the event that they would like to reduce the price then the time limitation is not valid. In the cases, in which the MAH wish to increase the price, this should be done within the statistic percent of the officially registered inflation for the period of the last change or registration of the price.

The prices declared by the manufacturers in the reference countries are proven with official documents by the market authorisation holder. There is procedure, which allows MoH to reduce the price in certain cases, when the reference price in some countries has been changed and the MAH fail to fulfill its' obligation for declaring that to the MoH. The producers, wholesalers and pharmacies are not allowed to sell the medicine at a price exceeding the reported one.

Article 14 (8) of the "Pricing Regulation" grants the PC the right to approve a price higher than the reference price, with the necessary motivation.

The declared reference prices are checked up by a special analytical department within 20 days of the receiving the application. The analytical department is created especially to support the activity of the PC. The MAH might submit a declaration for eventual change of the prices in the referent countries in a 6 months period after approving the price. In case that such a declaration is not submitted, the PC can change the price according to the observed changes.

3.1.3.2 Internal price referencing

Not applicable in the country.

3.1.3.3 Cost-plus pricing

Cost-plus pricing is not applied in Bulgaria.

3.1.3.4 (Indirect) profit control

Indirect profit control is not applied in Bulgaria.

3.1.4 Discounts / rebates

There are no mandatory discounts in the country. Within the approved ceiling price of the medicines, commercial discounts or also discounts in kind are possible as a result of a certain marketing approach from the side of the manufacturers or wholesalers. These are mainly possible at the public procurement procedure in the MoH or public hospitals or at the retails level on the free market. No specific rules are applied.

3.1.5 Mark-ups and taxes

Table 3.3: Bulgaria – Regulation of wholesale and pharmacy mark-ups, 2010

	Wholesale mark-up			Pharmacy mark-up		
	Regulation	Content	Scope	Regulation	Content	Scope
Your country	Yes	<i>Regressive mark-ups</i>	POM	Yes	<i>Regressive mark-ups</i>	POM

Source: LPPHM

3.1.5.1 Wholesale remuneration

The remuneration of wholesalers is based on regressive mark-up schemes, valid only for POMs (cf. Table 3.4), set out in the Council of Ministers Decree N295/2007 (OJ104/2007) for adopting a regulation on the terms and conditions for regulating and registration of the prices of medicines (“Pricing Regulation”). The relation of the wholesalers with the manufacturer is on a contractual basis and also depends on whether the wholesaler is the exclusive importer of the medicine and on the volume of the sales. Other conditions, i.e. payment terms, expiry

dates, etc. also influence the extent of the remuneration. There is no published information about average mark-ups.

Table 3.4: Bulgaria – Wholesale mark-up scheme, 2010

Ex-factory price in €	Maximum mark-up in % of ex-factory price
BGN 0.01 / €0.005 – BGN 10.00 / €5.11	9%
BGN 10.01 / €5.11 – BGN 30.00 / €15.34	8%
> BGN 30.01 / €15.35	6% (up to 15 BGN)

Source: Council of Ministers Decree N295/2007 (OJ104/2007) for adopting a regulation on the terms and conditions for regulating and registration of the prices of medicines.

3.1.5.2 Pharmacy remuneration

The situation with the pharmacy mark-ups is similar to that of the wholesalers. They are regulated by the same decree. The difference is that the pharmacies do not make contracts with wholesalers, but rather work with the one that offers the best conditions at the time of purchase. For the medicines, 100% reimbursed by the NHIF, pharmacies are not calculating mark-up over the price of the wholesaler. For these particular medicines they receive a flat fee of 1 BGN from the NHIF.

Table 3.5 shows the regressive mark-ups.

There are no statutory mark-ups for over-the-counter (OTC) products. It is not possible to identify the average mark-up for over-the-counter (OTC) products. One hypothesis is that a lot of them have similar mark-up as the prescription-only medicine(s) (POM), because in the past, when the “Pricing Regulation” was amended, the registered prices of the OTC products at that time were automatically transferred to the over-the-counter (OTC) products register.

As explained earlier, the mechanism of registering the ceiling prices encouraged competition, but it has also led to the phenomena of “pharmaceutical tourism”, which means that some people are checking the prices in several pharmacies and then going back to the one which sells cheaper. This is valid for both prescription-only medicine(s) (POM) and over-the-counter (OTC) medicines.

Table 3.5: Bulgaria – Pharmacy mark-up scheme, 2010

Pharmacy purchasing price in €	Maximum mark-up in % of pharmacy purchasing price
BGN 0.01 / €0.005 – BGN 10.00 / €5.11	22%
BGN 10.01 / €5.11 – BGN 30.00 / €15.34	20%
> BGN 30.01 / €15.35	18% (up to 30 BGN)

Source: Council of Ministers Decree N295/2007 (OJ104/2007) for adopting a regulation on the terms and conditions for regulating and registration of the prices of medicines.

3.1.5.3 Remuneration of other dispensaries

Not applicable.

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

Standard value-added tax (VAT) in Bulgaria is 20%. There is no exclusion or lower value-added tax for medicines. Periodically there are public discussions on the level of value-added tax, but changes are not envisaged at present.

3.2 Reimbursement in the out-patient sector

3.2.1 Organisation

Several legislative acts are structuring the reimbursement system in the country in 2010. The Health Insurance Act (OJ 70/1998, last amended OJ 62/2010) is an act, which frames the overall structure and functioning of the national health insurance system. It regulates the signing of the National Framework Agreement (NFA) between National Health Insurance Fund (NHIF) and the professional associations of health care providers – doctors and dentists. The NFA provides for the parameters and procedures related to the functioning of the health insurance system as a whole. It defines the order, content and the payment of the health care activities and services to be provided to the insured population. Aside from the Health Insurance Act, the regulative framework of the reimbursement system is determined by several other main laws – the Health Act (OJ 70, 2004), the LPPHM (OJ 31/2007), and the War Veterans Act (OJ 152, 1998), Military disabled and war victims Act (OJ27/2005) as well as the regulations related to their application.

Regulation N38/2004 is defining the list of diseases, for which medicines for out-patient treatment are paid fully or partially by the NHIF. To be covered by the existing mechanisms for reimbursement, the medicines should be included in the Positive Drug list. The regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee

are adopted by the Council of Ministers Decree N311/2007. The reimbursable medicines for out-patient sector are in the Annex 1 of the four annexes of the Positive Drug List.

A Positive Drug List Committee (PDLC) is established at the Council of Ministers after a proposal of the Minister of Health. The decisions of the PC and the PDLC might be appealed in front of the Transparency Committee, set up by the Council of Ministers. The composition of the Transparency Committee is also proposed by the Minister of Health. This Committee includes representatives of the Ministry of Health, the Bulgarian Drug Agency, the National Health Insurance Fund, the Bulgarian Medical Association, the Bulgarian Union of Dentists, the Bulgarian Pharmaceutical Union and the organizations of the patients and the pharmaceutical industry. The Council of Ministers determines the rules functioning of the Transparency Committee. The decisions of the Transparency Committee have to be taken by the majority of two thirds of its members. Its' decisions are subject to appeal under the Code of Administrative Proceedings and the appeal shall not suspend these decisions.

Two limited but relatively well socially oriented lists of medicines for reimbursement by municipal budgets were established in fulfilment of the provisions of two regulations. In the first regulation N 1 from 2007 of the MoH and MoD for the military victims and military disabled persons it is stated that for persons with 50% and more disability 75% of the expenses of medicines on these lists are covered by the municipal budgets, 25% by the veterans. For persons with less than 50% disability the proportion is 50% covered by the municipality and 50% covered by the person. If the prescribed medicines are included in the reimbursement list of NHIF, then the respective % covered by the municipality is going to cover the respective % from the co-payment of the patient. The second is Regulation N 17 from 2000, according to which the war veterans might receive medicines covered 100% by the municipality.

3.2.2 Reimbursement schemes

The general reimbursement scheme is obligatory for all population in the country and is performed by the NHIF. This includes: all Bulgarian citizens who are not citizens of any other country; Bulgarian citizens who are citizens of another country and live permanently in the territory of the Republic of Bulgaria; foreign citizens or persons without citizenship who have permits for long-term residence in the Republic of Bulgaria, unless otherwise provided for by an international agreement to which the Republic of Bulgaria is a party; persons with the status of refugees or with granted right of refugee.

As mentioned before the social health insurance system was firstly introduced with the Health Insurance Act from 1998 and applied in practice since 2000 when the NHIF start to operate.

The privileges for the war veterans, military victims and military disabled persons can be considered as a kind of additional individual reimbursement, see section 3.2.1. – Organisation.

The very limited reimbursement scheme so far provided by some Voluntary Health Insurance funds, which include some coverage of out-patient medicines in their insurance packages, should also be mentioned here.

3.2.2.1 Eligibility schemes

In Regulation No. 10/2009 (OJ 24/2009) on the conditions and procedures for reimbursement of the medicinal products referred to in point 1 of Article 262(4) of the Law for Medicinal Products in Human Medicine, medical devices and diet foods for special medical purposes the following eligibility schemes to grant reimbursement in the out-patient sector are presented: NHIF reimburses the products which:

- Are intended for treatment of the diseases specified in the Regulation N38/2004 determining the list of diseases, for which medicines for out-patient treatment are paid fully or partially by the NHIF;
- Are prescribed and received in compliance with the provisions of the Health Insurance Act, the LPPHM and all additional regulations specified therein;
- Are dispensed on the territory of this country to persons with permanent health insurance rights.

The reimbursement will be done within the amount of money allocated by law for the respective year to the NHIF Budget.

3.2.2.2 Reimbursement lists

For the first time in 2003, a Positive Drug List (PDL) was introduced in Bulgaria. Currently, the Council of Ministers Decree N311/2007 adopts the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List as well as the conditions for the functioning of the Positive drug list Committee.

Article 262 of LPPHM states that the Positive Drug List includes POMs, which cover the health needs of the population and are reimbursed by the budget of the NHIF, the state budget out of the scope of obligatory health insurance and by the budgets of the in-patient public medical facilities.

The Positive Drug List is a list of medicinal products showing their trade name, drawn by pharmacological groups with the relevant international non-proprietary names, defined daily dosage, defined prices by the PC, reference value for a defined daily dosage, price calculated on the basis of the reference value and level of reimbursement. At present, the Positive Drug List consists of 4 Annexes. It is available on the MoH's web site on: <http://www.mh.government.bg/Articles.aspx?lang=bq-BG&pageid=384>

The medicines in the Positive Drug list are included on the basis of evidence for efficacy, therapeutic efficiency, safety and analysis of the pharmacoeconomic indicators. The procedure for inclusion of medicinal products in the Positive Drug List is 90 days from the submission of valid documentation and 60 days for a change in the conditions for medicines already included in the PDL.

Evaluation of the reimbursement list by NHIF is taken from purely financial and administrative point of view and mostly affects the level of reimbursement of the medicines.

The decision for the inclusion/exclusion or change of the medicines in the PDL is made by a Positive Drug List Committee, which is established at the Council of Ministers after a proposal of the Minister of Health. The mandate of the members of the Positive Drug List Committee is 4 years. Every year half of the members of the Committee are replaced. The Positive Drug List Committee consists of 11 members and includes three representatives of the MoH, one of the Ministry of Labor and Social Policy, two of the NHIF, two of the Bulgarian Drug Agency, one of the MoF, one the Bulgarian Medical Association and one of the Bulgarian Dental Association. Members of the Bulgarian Pharmaceutical Union are not members of the committee.

The appointed members of the Committee are medical professionals, lawyers and economists with scientific achievements or practical experience in the field of medicines and the respective areas of their application.

3.2.2.3 Reimbursement categories and reimbursement rates

Reimbursement categories and rates are determined by the PDLC and are set according to the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee. Currently there are 3 reimbursement categories in the out-patient sector, based on INN and pharmaceutical form of the medicines, included in the PDL. These are:

- medicines for the treatment of chronic diseases, which lead to severe disturbance of the quality of life or disability and requiring prolonged treatment – reimbursement up to 100 percent;
- medicines for chronic diseases occurring with high prevalence of disease – reimbursement up to 75 percent;
- medicines for diseases other than those under the previous points - reimbursement up to 50 percent.

The level of payment of the products with the same INN and the same pharmaceutical form is determined in article 19 of Positive Drug List regulation according to the following: evaluation of the criteria for efficacy and therapeutic effectiveness, safety and pharmaco-economic data; therapeutic indications, included in the SPC; the social significance of the disease in Bulgaria, for which treatment the product is used; duration of treatment and outcome of it; therapeutic algorithm in accordance with established medical standards in Bulgaria and in the absence thereof - standards of treatment and good medical practice in the European Union; number of patients, determining the proportion of disease for which medicinal product is intended, according to data from the previous year and changing trends of morbidity; funds spent for the medicine for the number of patients in the previous year; budget, provided for the medicine for certain the period.

The level of payment determined in the upper mentioned categories is multiplied with the value of the pack, defined based on the referent value, finally resulting in the value, which is paid by NHIF.

The PDLC can change the level of payment of the products from the PDL six times per year, according to the frames of the budget.

3.2.3 Reference price system

A reference price system is applied for all the medicines included in the Positive List. A detailed explanation is given medicines fully or partially reimbursed by the National Health Insurance Fund. As parallel traded medicines are not part of the reimbursement system, they are not included in the reference group. Generally, the reference price is made at ATC 5 level. The methodology is described in details in the Positive Drug List Regulation.

For the determination of the payment value for the medicines included in the PDL a reference price is calculated for the DDD of the INN and pharmaceutical form. It is calculated as follows: Medicines containing the same INN are grouped by pharmaceutical form. Then the value of the DDD is calculated for the various drugs with the same INN and pharmaceutical form and the lowest price is determined. This lowest price is the reference price for all medicines with the same INN and form. The reference price for DDD for medicines containing more than one INN is formed on the basis of the lowest levels of DDD for the each separate INN of a drug with a single active ingredient, calculated as already explained in the previous paragraph.

As exception, the reference price can be determined at ATC 4 level, when the included therein medicinal products by INN and form have demonstrated similar efficacy and safety for treatment of a disease with similar clinical course and severity according to the SPC. In this case, the reference price is determined as follows: for each INN with the same form within the subgroup of ATC a value of DDD is assigned as explained. The lowest value of determined reference price for the DDD is taken as the reference price of the chemical subgroup. To determine the value for medicines included in the PDL, for which no DDD is defined, reference price is calculated for therapeutic course by INN and form, using the recommended daily dose stated in the SPC of the product. The value for a pack of the product, calculated on the basis the reference price is obtained by multiplying the reference price with the number of DDD / recommended daily doses contained in the medicinal product. The reference price for a medicine, which is covered by 100 % is determined on the basis of the price for a wholesaler as laid down in the Pricing regulation. The reference price for medicines, which is covered by less than 100 %, is calculated on the basis of the pharmacy price.

When the physician prescribes a medicine with a higher price than the reference price, the difference has to be covered by the patient.

3.2.4 Private pharmaceutical expenses

In Bulgaria there is no developed system for monitoring, evaluation and analysis of private pharmaceutical expenses. According to some expert evaluations (Salchev 2004, Health XXI) these make up a significant part of the country's personal health care expenditure and for 2003 were estimated at approximately BGN 200 Mio. There are no specific mechanisms in place to protect vulnerable groups of people. However, for certain diseases patients are exempted from payment, i.e. oncological conditions, diabetes type 1, transplantation, AIDS, etc. An example of low co-payment can be seen in the military disabled people co-payment level, which is 25% as per Regulation N1/2007.

3.2.4.1 Direct payments

For all POM medicines, which are not included in the Positive List, as well as for the OTC medicines patients have to pay the full price.

3.2.4.2 Out-of-pocket payments

Out-of-pocket payments (OPPs) take the form of percentage co-payments.

Data is not available.

3.2.4.2.1 Fixed co-payments

There are no fixed co-payments in place.

3.2.4.2.2 Percentage co-payments

There are percentage co-payments which vary for each medicine. Besides the category of fully reimbursed medicines, for the others which are partially reimbursed, the patients actually make the co-payment. There some medicines, which are reimbursed only 10% and in these cases the co-payment might reach 90%.

3.2.4.2.3 Deductibles

There are no deductibles in place at the time of writing this profile.

3.2.4.3 Mechanism for vulnerable groups

There are no mechanisms for vulnerable groups in place.

3.3 Volume control in the out-patient sector

3.3.1 Pharmaceutical budgets

There are no pharmaceutical budgets in place.

3.3.2 Generic policies

For many years the creation and implementation of overall generic policy is discussed among the interested parties, but no practical legislative steps have been taken so far.

3.3.2.1 Generic substitution

In 2010, still generic substitution is not allowed in Bulgaria.

3.3.2.2 INN prescribing

Regulation № 4/2009 on the terms and conditions for prescribing and dispensing of medicinal products OJ (21/2009), article 8 gives the possibility to the physicians to prescribe under INN together with the right to prescribe by brand names. INN is not mandatory and thus very rare.

3.3.2.3 Other generic promotion policies

There are no generic promotion policies implemented in the country.

3.3.3 Claw-backs / Pay back

Not applicable

3.3.4 Monitoring

3.3.4.1 Prescription monitoring

There are no official prescription guidelines. Regulation № 4/2009 on the terms and conditions for prescribing and dispensing of medicines sets out some purely administrative criteria such as maximum quantities prescribed for acute or chronic diseases, maximum number of medicines prescribed for one disease, etc. The NHIF is able to monitor the prescriptions, which are made by the physicians, who are working with NHIF. As a result, there is a regular clinical audit of the doctors, but it is still carried out with the focus on the administrative criteria mentioned above.

Doctors' access to information depends on their own sources, but is mainly obtained through pharmaceutical company representatives and events, i.e. conferences, training, symposia, etc.

3.3.4.2 Price monitoring

There is no price monitoring in the country.

3.3.4.3 Pharmaceutical expenditure monitoring

The National Health Insurance Fund (NHIF) is involved in monitoring the pharmaceutical expenditures on behalf of the NHIF. The monitoring is possible per region, per patient or per diagnosis. Data of the monitoring activity is not publicly available.

3.3.4.4 Consumption monitoring

The situation with the consumption monitoring is more or less the same as the expenditure monitoring. The NHIF monitors the consumption concerning the medicines, for which it is fully or partially paying.

3.3.5 Assessment and evaluation

3.3.5.1 Decision-making tools

Health economics analysis and particularly pharmacoeconomic analysis do not have a long history in Bulgaria. The one legal provision in this field is in the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee. This provision is very general and it simply states that pharmacoeconomic analysis is taken into consideration when medicines are evaluated for inclusion in the Positive Drug List.

3.3.5.2 Evaluation of measures

Evaluation measures are not applied in the country.

3.3.5.3 Reports and results

Not applicable for the country.

3.4 Overview on policy measures in the out-patient sector

Table 3.6: Bulgaria – Policy measures in the out-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing policies (e.g. new policies or methodology and changes, external price referencing; price freezes / cuts, (obligatory) discounts)	Changes in the basket of reference countries – Russia, Slovakia, Poland and Austria are taken out and replaced by Estonia, Greece, and Lithuania.	2007
Changes in the regulation of the mark-ups	Decreasing of the mark-ups for both- wholesalers and pharmacies. Changes of the price levels, on which the mark-ups are based.	2007
Changes concerning the VAT rates on medicines	No	
Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)	Constantly increasing of the number of reimbursed medicines. New regulation for the Positive Drug list. NHIF is no longer negotiating the prices of the reimbursed medicines by itself. The medicines, covered by MoH and Public hospitals become a part of the PDL.	2007
Changes regarding a reference price system (e.g. introduction, methodology changes conc. clustering and/or the reference price)	Changes in the methodology for determining the maximum value up to which MoH is paying for the medicines, provided by the state budget.	2008
Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)	Increase of percentage co-payments for some medicines, treating Parkinson, osteoporosis, Glaucoma, etc. Changes in the reimbursement level of the medicines in the PDL are possible 6 times per year.	2010
Changes in the generics policies (e.g. introduction of INN prescribing, generics substitution)	no	
Changes concerning monitoring of medicines (e.g. new monitoring tools)	no	
Changes concerning evaluations and assessments (e.g. price review, reimbursement reviews)	no	

conc. = concerning, OPP = out-of pocket payment, VAT = value added tax

Source: author's compilation

4 Pricing, reimbursement and volume control in the in-patient sector

4.1 Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

Pricing in the in-patient sector is organised in the same way and is regulated by the same legislation acts like the pricing in the out-patient sector, see section 3.1.1 – Organisation of pricing. It is by nature statutory pricing and is determined by the state according the LPPHM.

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

The PC deals with all medicines, whether publicly financed or not, whether prescription or over-the-counter (OTC) and whether in out-patient care or in hospitals. The regulation approves the price at the different levels – at manufacturers, at wholesale and retail sale level for POM and the mark-up for each level and value-added tax (VAT) at each level.

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

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 not more than the registered inflation. In the opposite way the price can be decreased at any time.

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

4.1.1.2 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 due to the commercial approach of the suppliers in each separate case. The State Financial Control Agency is the body to monitor this type of activities of state and municipal hospitals and the MoH for the state hospitals.

Legally the Access to Information Act gives a possibility for everyone interested 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% for all types of medicines, incl. the hospital ones. The hospital pharmacy has no right to add its own mark-ups to medicines. 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 medicines 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 medicines. So far, there are no officially announced ways of cooperation for neither public nor private hospitals concerning exchange of information or organising common negotiations or tenders.

4.1.2 Purchasing policies

The hospitals are supplied with medicines through licensed wholesalers after procurement for public hospitals or negotiation or tendering for private hospitals. There is no specific institution involved with the decision of the purchasing process. In each hospital a commission is appointed by the manager of the hospital for purchasing of medicines.

4.1.2.1 Tendering

Tendering is a policy, which some private hospitals are using for provision of the medicines. The process is strictly individual and confidential. Usually the hospitals are doing it annually. As private structures, they are not obliged to follow the Public procurement act. The practice is to invite suppliers to present their offers and then the one whose offer is fitting best the needs of the hospital is chosen. Besides the price, also delivery terms, discounts, payment terms, etc. are taken into consideration. Tendering might be combined with negotiations as well.

4.1.2.2 Negotiations

Negotiations are more often used as a procedure in the private hospitals. Negotiations are usually held after a process of preselection of suppliers according to defined criteria by the hospital. Each hospital organises the negotiation process itself. Some hospitals are doing it annually; some are doing it 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 medicine as well as other conditions (delivery terms, discounts, payment terms, etc.). Usually the price of the medicinal product is the most important criteria, but sometimes payment terms are also of great importance. Hospitals might be in contact with manufactures 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 a

limited number of products. Private hospitals do not share the results of the negotiations in public.

4.1.3 Organisation of procurement

Public procurement is the obligatory procedure for providing medicines paid from funds from the state or public budget. This applies for procurement procedures for medicines for the Ministry of Health and for public hospitals.

Legally procurement 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 relevance of the application of the Public Procurement Act to the process of purchasing medicines in the in-patient sector is often publicly discussed. Some of the concerns are about purely administrative issues, i.e. the possibility to block the procedure in the case of appeals; others are about the principle of the lowest price and most economic proposal, which is not always easily achieved in terms of medicines.

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 has to organise the procurement annually. As long as prices are not exceeding the price defined in the pricing regulation, they can be different from the determined. 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. It is available on: http://rop3-app1.aop.bg:7778/portal/page?_pageid=173,1&_dad=portal&_schema=PORTAL

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 medicines. It is possible for more than one wholesaler to obtain a contract, but each wholesaler supplies different groups of medicines or medical consumables, which means that for one medicine only one contract with wholesalers can be signed. The decision is taken by the director of the hospital, usually based on the decision of the evaluation committee.

The procurement made by the MoH for a list of medicines, which are included in a Regulation N34 besides the Positive Drug List, might also be considered as centralised procurement.

“Centralised deliveries” of medicines, provided by funds from the Ministry of Health’s republican/state budget existed since the end of 1997 according to Regulation N12 of the Ministry of Health. Then Regulation N23 on the Order of Prescription and Receiving of Expensive Medicines, Paid by the Republican Budget entered into force in October 2000, and was then replaced by Regulation N36 and more recently by Regulation N34, based on article 82 (1), point 7 of the Health Law. In 2005, the Ministry of Health introduced a maximum value of International Non-proprietary Name(s) (INN) of a pharmaceutical form, for the public procurement of fully reimbursed medicines. This value should not be exceeded and is included in the specification of the procurement. The maximum value is the lowest value from the tender of the previous year and the average price of the International Non-proprietary Name (INN) of the three lowest prices covered by the social security funds in the reference countries.

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

The value of the medicines, used in hospitals is part of the clinical pathway. Thus medicines for the in-patients should be fully covered by the hospital budget. Patients with chronic diseases, for which they receive medicines for out-patient care from the NHIF, are supposed to carry the already prescribed medicines when hospitalised with them.

Some medicines, for treating specific diseases – oncologic, HIV, after transplantation of organs, haemophilia, etc. – are paid from the state budget through the MoH – see section 4.1.3 –organisation of procurement. 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.

The criteria for funding of medicines in the hospital sector are the same as the others and are stated in the Positive drug list regulation – see section 3.2.2.2.

Bulgaria established the first positive list for medicines in 2003. At that time it was only for medicines for the out-patient sector. The present reimbursement system has undergone different developments and the hospital medicines now are part of the Positive List. For the year 2010, they are within annexes – N2; N3 and N4:

- 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.

In 2009 PDL Annex 2 – medicines for in-patient care – has 1,671 positions by brand name, including different pharmaceutical forms, dosages and pack size. They correspond to 513 INN. The level of reimbursement of the medicines, included in the Annex 2, 3, 4 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 (within the global budgets). 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) are paying the cost of their treatment, including medicines. The Bulgarian PDL 2010 is published on the website of MoH⁵.

4.2.2 Hospital pharmaceutical formularies

As per art. 37 of Regulation 28 (OJ 109/ 2008) the Pharmaceutical and Therapeutic Committee (PTC) (see section 4.2.3) annually creates the hospital pharmaceutical formulary (HPF) in public hospitals, 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 range of medicines included in 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 HPF. HPFs are available internally in the hospital and in most cases are mandatory for physicians in hospitals. Of course in exceptional cases, medically argued, physicians can prescribe out of the HPF.

4.2.3 Pharmaceutical and Therapeutic Committees

As per article 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). These are internal for the hospital structure. Usually the pharmaceutical and therapeutic committee (PTC) comprises the heads of the different departments of the hospital, the economic director, and the chief pharmacist. This committee has different tasks and responsibilities from the medical council. 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 on the HPF.

According article 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 article 75 Health Establishments Act, the medical Council is a consultative body to 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 (BMU), dental union, the Bulgarian association for the professionals of health care and the chief nurse of the hospital. The mentioned units of the BMU and dental union are local for the hospital units. Other committees for the support of the management might be created as well. The head of hospital pharmacist is a member of the pharmaceutical and therapeutic committee (PTC) as well. The

⁵ <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=384&categoryid=1355>

head of the hospital pharmacy is the leading specialist in developing practical prescription lists, based on the quality, safety and efficacy as well as pharmacoeconomic evaluation of medicines. He/she participates in all activities connected with negotiations, supply and delivery of the necessary medicines; makes propositions for the project of the budget, concerning medicines; creates standard operating 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.

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 are now producing medicines ex-tempore.

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

Since many years the Monitoring and Evaluation are weak points in the Bulgarian pharmaceutical sector. There is no institution on central or regional level in the sector, which is obliged to collect and analyse data. The National Health Insurance Fund has the capacity to evaluate the consumption of the medicines that are in the reimbursement list, and it is doing so but only for the out-patient sector. Each hospital is doing monitoring of its own consumption of medicines for management purposes. Traceability of medicines theoretically is possible, because the wholesalers are obliged to keep track of their sales, but in practice there is no aggregated data available - neither for individual hospitals nor generally for the in-patient sector.

4.3.1.1 Price monitoring

On national level, price monitoring is still not a routine process. Occasionally the MoH is monitoring prices of public hospitals under its supervision, obtained after the public procurement, but data is not publicly available.

4.3.1.2 Consumption monitoring

So far the evaluation of consumption in Bulgarian hospitals has not been regularly monitored. In Bulgaria official information and data on consumption (utilisation) of medicines in hospitals is not available at a national level. Practical information is available from the BDA, who collects this data from wholesalers. Each hospital monitors its consumption, but this information is not shared publicly and it is uncertain whether this information will ever be used in connection with pharmaceutical policy decisions.

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

There is lack of complete, actual and reliable statistic data about medicines in hospitals on regional and on national level, which might be used for analytical and decision making purpose. This represents an important obstacle for decision making.

4.3.2.2 Evaluation of measures

Health-economic analysis and particularly pharmacoeconomic analysis do not have a long history in the country. The only legal provision can be found 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 pharmacoeconomic analysis is considered for the inclusion of medicines in the positive list of medicines. There is no established structure for performing pharmacoeconomic analyses in the country or official guidelines.

4.3.2.3 Reports and results

There is no legislative obligation or structure that performs Health Technology Assessments.

4.4 Overview of policy measures in the in-patient sector

Table 4.1: Bulgaria – Policy measures in the in-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing framework (e.g. change pricing regulation with relevance for the in-patient sector, change in hospital specific mark-up / VAT which is relevant for the in-patient sector)	Changes are the same as in out-patient sector - changes in the basket of reference countries – Russia, Slovakia, Poland and Austria are taken out and replaced by Estonia, Greece, and Lithuania.	2007
Changes in procurement (e.g. establishment of new procurement agency, change in relevance of tendering vs. negotiations etc.)	no	
Changes regarding the reimbursement lists (e.g. concerning a national hospital list, the HPF, ...)	Constantly increasing of the number of reimbursed medicines. New regulation for the Positive Drug list. The medicines, covered by MoH and Public hospitals become a part of the PDL.	2007
Changes in funding (e.g. specific budgets for specific medicines, concerning OPP in the in-patient sector)	no	
Changes concerning evaluations and assessments	no	

HPF = hospital pharmaceutical formulary, OPP = out-of pocket payment, VAT = value added tax

Source: author's compilation

5 Interface management and developments

5.1 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 improved much.

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.

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

5.2 Developments in the out-patient and the in-patient sectors

Table 5.1: Bulgaria – Measures in the pharmaceutical system, 2010

Measures	Under discussion
General health reforms (e.g. changes in responsibilities and institutions)	Establishing of a Mega Agency under Council of Ministers for Drug regulation, pricing and reimbursement; cancellation of the Transparency committee;
Pricing policies in general	Changes in the mechanism of determining the reference price for the medicines, which has no registered price in the reference countries
Mark-ups	no
Taxes	no
Reimbursement policies	Changes in the PDL. Some medicines are transferred to NHIF from the MoH. Facilitating the inclusion of generics in the PDL. NHIF would be able to negotiate discounts with the suppliers for the pharmacies.
Out-of pocket payments	no
Generic policies	no
Reforms targeted at the in-patient sector	Hospitals will supply certain medicines that were supplied so far by MoH by themselves.
Evaluation & assessment	no

Source: drafts of legislation, published for discussion on MoH web site.

For a relatively young and still reforming health care system like the Bulgarian, there is still a lot to be done in both healthcare and especially in the pharmaceutical sectors. Some of the points, regularly entering in the public attention and still looking for its decision are connected with:

- Introducing legal requirements for monitoring of pharmaceutical consumption, prices, expenditures on national and regional level for both out- and in-patient sector.
- 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;
- Creating a system for monitoring of pharmaceutical consumption and a system for qualitative and quantitative measurement of the consumption
- Promotion of rational use of medicines and improving the knowledge of the health professionals;
- A system for professional development of personnel in the pharmaco-economic field
- More comprehensive disclosure of information in websites, annual reports, public forums concerning public procurement and other statistic information;

To improve the overall organisation and management of the pharmaceutical sector, numerous changes in the structural, pricing and reimbursement aspects are planned from the side of MoH and available on <http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=393¤tPage=2&categoryid=3381>

6 Bibliography

6.1 Literature

Eurostat (2011). Public health database. Expenditure of providers of health care by financing agents in health care, in millions.

In online: <http://epp.eurostat.ec.europa.eu/>

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

In online: <http://www.nhif.bg/bg/default.phtml?w=1280&h=770>

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

PPRI (2007): Pharmaceutical Pricing and Reimbursement Information. PPRI Pharma Profile Bulgaria 2007.

In online: <http://ppri.goeg.at/>

Petrova, G. (2004): Model of the reform of the pharmaceutical sector in the Balkan region - analysis of the application of the theoretical concepts. Doctor of Science Dissertation, Medical University in Sofia

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.

Letter provided by MoH dated 23 June 2010, not published

Letter provided by NHIF dated May 2010, not published.

6.2 Legislation as per August 2010

1. Law on Pharmaceutical Products in Human Medicine – OJ 31/2007 last amended OJ 59/2010
2. Control of Narcotics and Precursors Act - OJ 30/1999 last amended OJ31/2010
3. The Health Act – OJ 70/2004 last amended OJ 62/2010

4. The Health Establishments Act - OJ 62/1999 last amended OJ 38/2010
5. The Health Insurance Act - OJ 70/1998 last amended OJ 62/2010
6. War Veterans Act - OJ 152/1998 last amended OJ 57/2007
7. Military disabled and war victims Act - OJ27/2005 last amended OJ 16/2010
8. **Regulation N38/2004** is defining the list of diseases, for which medicines for out-patient treatment are paid fully or partially by the NHIF OJ 106/2004 last amended OJOJ 60/2006
9. **Regulation N3** for the criteria for classification of the pharmaceutical products and the requirements to the documentation for changes in the classification – OJ 28/2008
10. **Regulation N15** on conditions for authorization of the manufacture/ import and the principles and requirements of Good manufacturing practice for all types of medicines, incl. those for clinical trials and active ingredients - OJ 38/2009
11. **Regulation N 38** for the data requirements on packaging and leaflets of the pharmaceuticals - OJ.77/2007
12. **Regulation No 39** on the principles and requirements of Good Distribution Practice. OJ No. 77/2007. last amended OJ 16/.2010
13. **Regulation N28** on the structure, terms and conditions of work of the pharmacies and the nomenclature of the medicinal products – OJ 109/2008 last amended OJ 67/2010
14. **Regulation N29** on the terms and conditions for opening a drugstores (OJ 109/2008)
15. **Regulation № 4** on the terms and conditions for prescribing and dispensing of medicinal products OJ 21/2009 last amended OJ 91/2009
16. **Regulation N 34** for the terms and conditions for payment from the state budget in the treatment of diseases of the Bulgarian citizens, outside the scope of mandatory health insurance OJ 95/2005 last amended OJ63/2010
17. **Council of Ministers Decree N295/2007** for adopting a regulation on the terms and conditions for regulating and registration of the prices of pharmaceuticals OJ 104/2007
18. **Regulation N 1** for the military victims and military disabled persons OJ 9/2007
19. **Regulation N17** for the terms and conditions for prescribing and dispensing medicines to the War veterans OJ 80/2000 last amended Oj 30/2009
20. **Council of Ministers Decree N311/2007** adopts the Regulation for the terms and conditions for the inclusion, changes or exclusion of the medicines in the Positive Drug List and the conditions for the functioning of the Positive drug list Committee OJ-110/2007 last amended OJ 28/2010

21. **Regulation No. 10/2009** on the conditions and procedures for reimbursement of the medicinal products referred to in point 1 of Article 262(4) of the Law for Medicinal Products in Human Medicine, medical devices and diet foods for special medical purposes – OJ 24/2009 last amended OJ 9/2010.

6.3 Web links

<http://www.bda.bg> – Bulgarian Drug Agency

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=387&categoryid=1104> – MoH, Register of pharmacies

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=383> – MoH price register

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=384> – MoH register for Positive Drug List

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=393¤tPage=2&categoryid=3381> - MoH section for proposals for amendments in the healthcare legislation

<http://95.87.254.60:8888/DrugStoreApp/faces/webSearchForm.jspx> - BDA register of drug-stores

<http://www.bgpharma.bg/en> - The Bulgarian Generic Pharmaceutical Association

<http://www.arpharm.org/en> - Association of Research-based Pharmaceutical Manufacturers

<http://www.ampharma.org/en> - The American Pharmaceutical Manufacturers' Association

http://bapht.org/about_en.html - Bulgarian Association of Pharmaceutical Technologies

<http://www.bphu.bg> - Bulgarian Pharmaceutical Union

<http://www.asa-pharmacy.com/?cid=23> - Association of Owners of pharmacies

<http://www.nphc-bg.eu/> - National chamber of pharmacy

<http://www.libra-ag.com> – Libra AG

http://www.sopharmatrading.bg/s_27_19_BG.html - Sopharma trading

<http://www.stingpharma.com> – Sting Ltd

<http://www.farkol.bg/> - Farcol