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Pharmaceutical Pricing and Reimbursement Information

BULGARIA

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Pharma Profile

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Executive Summary

BACKGROUND

With the health reform that started in 1999, most of the good structural and functional solutions for health care systems of the social insurance type were applied in Bulgaria, combined with some elements of a National Health Service. The model is defined as having a “public–private mix” of health care. The reform of treatment health care started with the adoption by the National Assembly of five new laws concerning the health system by the year 2000 (Law on Health and Safety at Work, 1997; Health Insurance Act, 1998; Law on Professional Organisations of Medical Doctors and Dentists, 1998; Health Establishments Act, 1999; Law on Pharmaceuticals and Pharmacies in Human Medicine, 2000) and another law concerning mainly public health care in 2004 (Health Act, 2004).

The funding of health care for insured citizens (health insurance in Bulgaria is mandatory) is provided by the National Health Insurance Fund (NHIF). In addition to the insurance contribution, the (obligatorily) insured individuals pay a customer fee for all visits to a primary care doctor or to 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. The range of income for which the 6% obligatory health insurance contribution is applied varies from 2 to 10 times the minimum insured income. At the time of writing, the employer pays 65% of the contribution and the employee pays 35%; in future (expected for 2010) these percentages will be equal.

Public health care expenditure in 2005 increased to BGN 229 / € 115 per capita, which is almost twice the expenditure in 2000. As a percentage of gross domestic product (GDP), public health care expenditure in the last five years has been steadily positioned within the range of 4-4.3% on average.

The health care system is managed by the Ministry of Health (MoH), which has 28 local units – regional health centres (RHC). The National Health Insurance Fund (NHIF) is a relatively independent institution with its own budget, approved on an annual basis by the National Assembly. The health establishments for out-patient and in-patient care have the legal status of limited liability or joint-stock companies.

Individual contracts are signed between the health establishments and Regional Health Insurance Funds (RHIF), as well as with the 12 voluntary health insurance (VHI) companies existing in the country.

The territorial distribution and coverage of the country by the health establishment network and the planning for its development are regulated by the elaboration of National and Regional Health Maps that are updated on 5-year basis. Such maps contain the various types of health establishment in the separate territorial units (regions and municipalities). The health establishments carry out agreements with the Regional Health Insurance Funds, providing health care for the relevant population.

The social health insurance (SHI) does not provide for any exceptions from the obligatory insurance system.

General practitioners (GPs) are paid on a capitation basis, with subsequent payments for certain activities. They are the gatekeepers for access to specialist care. Out-patient specialists are paid in the form of a flat rate per visit. Highly specialised diagnosis services are paid in the form of a fee-for-service system.

Registered as corporations, hospitals receive funding at prices determined administratively by the National Health Insurance Fund (NHIF). Once a year the National Health Insurance Fund (NHIF) and the doctors' branch organisations negotiate the specific prices, which are then included in the National Framework Contract. In the case of over-spending of the National Health Insurance Fund (NHIF) budget, the prices may be reconsidered on 6-month basis. Every insured patient pays for hospital treatment, along with a fee of 2% of the minimum salary, for not more than 10 days throughout any one year. A small number of institutional hospitals are funded by the State.

PHARMACEUTICAL SYSTEM

The first in a series of new legislation was the Law on Pharmaceuticals and Pharmacies 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.

Parallel to the Law on Pharmaceuticals and Pharmacies in the Human Medicine, the sector is also regulated by 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.

Despite several attempts to do so on the part of the Ministry of Health (MoH), in the country still has not officially adopted a National Drug Policy Paper. The selection of pharmaceuticals for reimbursement is made according to the criteria set out in the Regulation on the terms and conditions for inclusion of pharmaceuticals in the Positive Drug List (PDL) (Council Decree N304, OJ 2003).

According to Art. 10 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, the policy in the pharmaceutical sector in Bulgaria is executed by the Ministry of Health (MoH), together with the Bulgarian Drug Agency (BDA).

The Ministry of Health (MoH) is in charge of the overall pharmaceutical policy planning, as the executing and controlling authority. The Ministry issues licences for wholesale and retail pharmacies and providing some pharmaceuticals for treating of specific diseases, obligatory vaccinations and some health programmes, such as tuberculosis, AIDS, etc.

The market authorisation of a pharmaceutical is issued by the Director of the Bulgarian Drug Agency (BDA). After receiving market authorisation, a ceiling price is registered by the Pricing Committee (PC).

The Council of Ministers defines by regulation the criteria, rules and procedure for including pharmaceuticals in the country's Positive Drug List (PDL). The Positive Drug List (PDL) is defined annually by the Committee for the Positive Drug List (PDL).

When the first Law on Pharmaceuticals and Pharmacies in Human Medicine was adopted in 1995, Bulgarian manufacturers with existing manufacturing licences were granted a grace period, until the beginning of the year 2000, to align their practices with the requirements of the Law, and after that it was extended twice (running until 18 April 2003).

Local producers classify themselves as generics manufacturers. In recent years a strong tendency towards mergers and acquisitions between local producers and foreign investors has become evident.

According to Art. 54 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, only licensed wholesalers may perform wholesale activities. The authorisation is issued for an indefinite period by the Minister of Health after a proposal on the part of the Bulgarian Drug Agency (BDA). In 2005 there are registered 349 wholesalers in Bulgaria.

The retail sale of pharmaceuticals is only allowed in pharmacies licensed by the Minister of Health. The activities in the pharmacy are to be carried out by a Chief Pharmacist (with a Master of Pharmacy Degree) with at least one year of working experience. In 2006 there were 4,453 pharmacies in the country, of which 4,034 were private.

Regulation N6 on terms and conditions under which doctors and feldshers (medical assistant), dentists and nurses may store and sell pharmaceuticals (OJ 11, 2001) provides for the possibility for a doctor or feldsher, dentist or nurse to sell pharmaceuticals, only where there is no pharmacy in the community.

Bulgaria still does not have official statistics to support certain information concerning pharmaceutical expenditure (PE), e.g. the size of the total pharmaceutical market, especially the free market. Partial estimated data are available, and the data indicated as total pharmaceutical expenditure (TPE) (BNG 443 Mio. / € 223) for 2005 are, in fact, the expenditure of the Ministry of Health (MoH), the National Health Insurance Fund (NHIF), municipalities and hospitals, which are actually the public expenditure.

In the years 2001 and 2002 in particular, there was an increase in expenditure from the national budget. This was connected with the introduction of the National Health Insurance Fund (NHIF) reimbursement system, which started in mid-2000 and was gradually developed throughout 2001. In 2002 value-added tax (VAT) was introduced for pharmaceuticals and this also affected the prices and the budgets for pharmaceuticals.

PRICING

Two of the main legal documents that have established the statutory pricing system in the country are the Law on Pharmaceuticals and Pharmacies in Human Medicine, and the Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria (called hereafter the "Regulation"). Two committees are involved in the process: the Commission for the Prices of Pharmaceuticals and the Transparency Committee (TC).

The State regulates the prices of prescription-only medicine(s) (POM) and registers the prices of over-the-counter (OTC) pharmaceuticals.

The ceiling price is the price approved by the Pricing Committee (PC) and by the Minister of Health (MoH). The Pricing Committee (PC) deals with all pharmaceuticals, whether publicly financed or not, and whether prescription or over-the-counter (OTC). The producers, wholesalers and pharmacies are not allowed to sell the pharmaceutical in excess of this price. The act approving the ceiling price at the different levels – at manufacturers, at wholesale and retail sale level for prescription-only medicine(s) and elements – mark up for each level and value-added tax (VAT) at each level is published in the Official Journal

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

The remuneration of the wholesalers and pharmacies is based on regressive mark ups, set out in the Council of Ministers Decree N257/2004 (OJ 87, 2004, last amended August 2006) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria ("Regulation").

Standard value-added tax (VAT) in Bulgaria is 20%. There is no exclusion or lower value-added tax (VAT) for pharmaceuticals.

REIMBURSEMENT

One source of reimbursement is the republican budget, through the Ministry of Health (MoH), covering 100% of the pharmaceutical expenditure (PE) related to the provision of treatment of 12 groups of diseases and conditions (Regulation N36) including treatment of patients after transplantation of organs and tissues, cancer patients, AIDS patients, patients undergoing haemodialysis, etc., as well as the expenses for the provision of pharmaceuticals, covered by national programmes, the country's vaccination schedule, etc.

Another aspect is the existing list of pharmaceuticals available in the hospital pharmacies and in the health establishments for hospital care, according to Appendix 10 of Regulation N8 of June 23 2000 on the set-up, order and organisation of the operation of pharmacies and the product range of pharmaceuticals. This list is organised by International Non-proprietary Name(s) (INN) and gives the minimum nomenclature that should be available in the hospital pharmacy. The type of hospital – district or municipal – is also taken into consideration.

There is a limited but relatively well socially oriented list of pharmaceuticals for reimbursement, which has been established in fulfilment of the provisions of the War Veterans Act. Within this list, 75% of the expenses are covered by the municipal budgets, 25% by the veterans.

There is no doubt that the adoption of the Health Insurance Act in 1998 (OJ 70,1998, last amended OJ 59, 2006) and the establishment of the National Health Insurance Fund (NHIF) are key elements of the reimbursement system in medical and economic terms. This is the legal basis for changing the Bulgarian health care system and for the introduction of both compulsory and voluntary health insurance (VHI) in the country.

So far there is no link between the pricing of the pharmaceuticals and the reimbursement procedure, except the fact that without a registered ceiling price, a pharmaceutical can not enter onto the market and cannot be included in any reimbursement lists.

In 2003, for the first time in Bulgaria a Positive Drug List (PDL) was introduced (an updated list for 2007 is available on <https://www.zdrave.net>). In 2006, the List included 574 substances (2,473 trade names (International Non-proprietary Name (INN)) and consists of two parts – Part A and Part B.

According to Art. 2 of Council Decree N81 (OJ 34, 2003, last amended OJ 64 of 2006) on the regulation of the criteria and terms for inclusion of pharmaceuticals in the Positive Drug List (PDL), in Part A the pharmaceuticals are arranged according to the health needs of the population, presented by International Non-proprietary Name (INN) with their approved concentrations and pharmaceutical forms.

In Part B, pharmaceuticals are listed which were candidates to be included in the Positive Drug List (PDL) and which meet the requirements in Part A. The products in Part B are arranged according to the proof of their quality, efficacy and safety and the analysis of their pharmacoeconomic indices. The sequence into which the pharmaceuticals of the relevant International Non-proprietary Name (INN) are arranged carries information as to what extent a certain pharmaceutical is recommendable for reimbursement.

The criteria and conditions for including pharmaceuticals in the Positive Drug List (PDL) are specified by Section II of the Regulation on the criteria, conditions and rules for including pharmaceuticals in the Positive Drug List (PDL) of the Republic of Bulgaria. The Positive Drug List (PDL) is updated annually and published in the Official Journal.

The pharmaceuticals in the National Health Insurance Fund (NHIF) list are grouped into three reimbursement categories as per Council Decree N211 (OJ 73) (Regulation on the terms and conditions for negotiating the pharmaceuticals, medical devices and dietary medical foods which are paid fully or partially by the National Health Insurance Fund (NHIF)). The maximum reimbursement level of each International Non-proprietary Name (INN) is defined as a percentage, according to the reimbursement categories.

- **Category I, with a reimbursement rate of up to 100%** – these are pharmaceuticals for out-patient treatment of low morbidity and mortality, but leading to significant deterioration of the health status and disability of the patients. The pharmaceuticals are prescribed according to Art. 78, paragraph 2 of the Health Insurance Act.
- **Category II, with a reimbursement rate of up to 100%** – these are pharmaceuticals for out-patient treatment of common diseases, which require long and continuous treatment, including cardiovascular, mental, neurological, broncho-obstructive and metabolic diseases.
- **Category III, with a reimbursement rate of up to 75%** – these are pharmaceuticals for out-patient treatment of the remaining diseases included in the regulations, according to Art. 45, paragraph 3 of the Health Insurance Act.

Bulgaria has a reference price system. The reference price is an element of the reimbursement price. It is the lowest price for a unit active ingredient for the same pharmaceutical form, calculated according to the annual applications of the producers. The value that the National Health Insurance Fund (NHIF) pays for each trade name is then calculated by multiplying the quantity of the active ingredient within it.

In 2005, the Ministry of Health (MoH) introduced a maximum value of International Non-proprietary Name(s) (INN) for a pharmaceutical form, for the public procurement of fully reimbursed pharmaceuticals. This value should not be exceeded and is included in the specification for the tender. The maximum value is the lower 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.

The co-payment rate depends on the reimbursement group. It is not fixed and varies for each pharmaceutical.

- **Group IA** contains pharmaceuticals from Category I, with a co-payment rate of 0%
- **Group IB** contains pharmaceuticals from Category I, with 0% co-payment
- **Group IC** contains pharmaceuticals from Category I, with up to 95% co-payment
- **Group II** contains pharmaceuticals from Category II and III, with up to 100% co-payment.

The co-payment rates are product-specific, and do not differ depending on patient groups. In addition, this grouping carries information about the administrative procedure of prescribing and dispensing the pharmaceuticals.

Pharmaceuticals in hospitals in Bulgaria are paid for through the state budget or through the National Health Insurance Fund (NHIF) as part of the medical activities carried out through Clinical Pathways. The pharmaceuticals are included in the cost of the treatment and theoretically the patient is not supposed to pay for them in the hospital.

RATIONAL USE OF PHARMACEUTICALS

There are no official prescription guidelines. 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.

The Law on Pharmaceuticals and Pharmacies in Human Medicine and Regulation N13 (OJ 59, 2000) define the process for the approval of medical advertisements as well as the sanctions to be imposed for non-observance of the advertisement rules. The activities carried out by the medical representatives of pharmaceutical manufacturers and the conditions under which samples of registered pharmaceuticals may be provided are also regulated.

At the time of writing there have been no measures implemented to control the prescribing and use of pharmaceuticals.

Health economics analysis and particularly pharmacoeconomic analysis have no long history in Bulgaria. The one legal provision in this field is in the regulation on the terms and conditions for including pharmaceuticals in the Positive Drug List (PDL), from 2003. This provision is very general and it simply mentions that pharmacoeconomic analysis is taken into consideration when ranking the pharmaceuticals in Part B of the Positive Drug List (PDL).

Generics are so far not mentioned in Bulgarian legislation. The introduction of generic substitution, prescription and promotion is regularly discussed in the professional societies and the Association of Bulgarian Pharmaceutical Manufacturers (ABPM) is actively participating, but no

practical legislative steps have been taken. Such action is not foreseen in the National Health Care Strategy 2007-2012.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

A newly amended Law on Pharmaceuticals and Pharmacies in Human Medicine (which in practice will be a new law) is expected to be voted by the Parliament at the end of the year 2006 (or the beginning of 2007). This will be the basis for the changes in the system over the short and medium term.

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List of abbreviations

ABP	Association of Bulgarian Pharmacists
ABPM	Association of Bulgarian Pharmaceutical Manufacturers
ARPharM	Association of Research-based Pharmaceutical Manufacturers
ATC	Anatomic Therapeutic Chemical classification
AWM	Association of the Wholesalers of Medicines
BAPID	Bulgarian Association for Persons with Intellectual Disabilities
BDA	Bulgarian Drug Agency
BDU	Bulgarian Dentists Union
BGN	Bulgarian lev
BMU	Bulgarian Medical Union
BPU	Bulgarian Pharmaceutical Union
BSP	Bulgarian Socialist Party
DG SANCO	Health and Consumer Protection Directorate General
EC	European Commission
EU	European Union
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HIA	Health Insurance Act
INN	International Non-Proprietary Name(s)
Mio.	Million
MoE	Ministry of Economy and Energy
MoF	Ministry of Finance

MoH	Ministry of Health
MRF	Movement of Rights and Freedom
NCU	National Currency Unit
NHIF	National Health Insurance Fund
NMSS	National Movement Simeon the Second – the party of the former monarch
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PAP	Professional Association of Pharmacists
PC	Pricing Committee
PCT	Patent Co-operation Treaty
PCW	Professional Chamber of Wholesalers
PDL	Positive Drug List
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
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
SPC	Supplementary Protection Certificate

TC	Transparency Committee
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UDF	Union of Democratic Forces
VAT	Value Added Tax
VHI	Voluntary Health Insurance
VHIF	Voluntary Health Insurance Fund(s)
WHO	World Health Organization

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

Population

Bulgaria's population at the beginning of the 21st century is showing a declining trend and as of 31 December 2001, when the latest official census was carried out, there were 7,932,984 permanent residents of the country. Compared to the previous census, carried out in 1992, the population has decreased by 544,333 people. This trend is expected to continue with the population reaching as low as 7,362,300 in 2010.

Population density and distribution by age

Bulgaria's territory is 111,000 km². The population density per km² has decreased from 75.5 in 1995 to 69.5 in 2005, which is an effect of the declining trend of the number of permanent residents in the country. Non-arable land accounts for more than half of the country's territory at 61,200 km² (55.2%), of which 31.7% is forests and forest shelterbelts. The location of the population over the country's territory depends directly on the availability of arable land. Districts in northern Bulgaria are better supplied with arable land; the most are found in the north-east region and the least in the south-west. This territorial disproportion is mainly due to the lay of the land. The built-up areas in towns and villages, along with other urbanised areas, cover 3,900 km² (or 5%) of the national territory. According to this indicator, Bulgaria is among the moderately urbanised European countries. The number of towns and villages is highest in the north-central and north-east regions. The areas of so-called "managed land" reach some 55.8% of the country's territory of common land, and pastures¹ are added to the arable land. The managed land per person of the population is 7.8 decares and thus Bulgaria is among the European countries with highest share of managed land, relative to other European countries². The total territory appropriate for agriculture is determined at 65,200 km² (or 58.7%) of the country.

Bulgaria's population is ageing as a result of the unfavourable trends in the development of demographic processes since the mid-1970s. In 2001 the share of the population below 15 years of age had dropped to 15.2% of the total population and the share of people above 64 had risen to 17.4%. The active population as an absolute number had dropped in 2001 to 5,382,804, but its relative share had increased to 67.4%. The expectation is that the largest decrease by 2010 will be that of the population below active age, whose relative share will drop to 13.5% of the population (1.7% less than its share in 2001). The active population is expected to decrease by 2010 to 9.2%, and its relative share by 1.4 percentage points – down to 66%. The number of people of active age is expected to increase by 10.9% and their share of the population by 3.3 percentage points to reach 20.7%.

¹ With a total area of 12,200 km², 63.3% of which are in the southern Bulgarian districts.

² The indicators are, e.g. Greece 8.5 decares per person; Spain 7.6 decares; Romania 6.5 decares; Hungary 5.9 decares; Austria 4.4 decares.

Changes in the age structure of the population concern both towns and villages. As of 2001 every fourth person living in a village was over 65 years old. In the towns the share of people over 65 is almost twice as low, at 13.4%. These changes are a result of the trends in the development of internal migration during the past few years, the specific feature of which is the return of elderly people from towns to villages. The migration process, however, concerns mainly the active population and is mostly oriented from the Bulgaria to foreign countries and to a much lesser extent from villages to towns.

Average life expectancy

The demographic and health features of the population have an integrative effect on one of the most synthetic indicators of population's health, which is the average life expectancy. This indicator for Bulgaria has shown a descending trend in the period from 1980 to 1995, to reach its lowest levels in the period 1995-1996, namely 70.50 years in total (67.10 for men and 74.30 for women). After that period the negative trend was broken and the average life expectancy started increasing again to reach a total of 72.60 years in 2005 (69.00 for men and 76.30 for women). This is one item that indicates the health care reform in Bulgaria was necessary and that its implementation had a positive effect on the main health indicators of the nation. The average life expectancy increase during 1995-2005 (Table 1.1) from 70.50 to 72.60 years; the decrease in the birth rate; the emigration flows; the reduced number of active population; and the increased number of population of active age have caused significant changes in the age structure of the Bulgarian population, which may be defined as demographic ageing, i.e. an increased absolute number and relative share of elderly people. Since the elderly often suffer from more than one chronic illness (for Bulgaria on average 3.2 per person above 64 years of age), demographic ageing significantly changes the structure of the health needs of the population and creates specific and high requirements for the satisfaction of these needs. This makes it necessary to develop a national strategy dealing with the problems related to the ageing population.

Morbidity and mortality

The registered morbidity at health establishments since the mid-1990s has been relatively stable. Analysis of classes of diseases shows that the predominant conditions are those of the respiratory system (40%), followed by those of the nervous system and the sensory organs (12%); diseases of the blood circulation organs; traumas and poisoning; diseases of the urinogenital system, the skin and subcutaneous tissue; and diseases of the digestive system. These classes of diseases form over 86% of the total morbidity in Bulgaria. The nosological structure of disabling diseases, depending on the level of disability, is quite specific. People with more than 90% loss of ability to work have, as primary diseases, those of the blood circulation organs, followed by neoplasms, diseases of the nervous system and sensory organs, diseases of the bone and muscular system and cellular tissue, etc. People with lost ability to work of between 71% and 90% also have, as primary diseases, those of the blood circulation organs, followed by diseases of the bone and muscular system and cellular tissue, neoplasms, diseases of the endocrine glands, nutrition-related conditions, metabolism and immunity disorders, diseases of the nervous system and sensory organs, etc., while people with lost ability to work of 50-70% have, as primary diseases, those of blood circulation organs, followed by diseases of bone and mus-

cular system and cellular tissue, diseases of the nervous system and sensory organs, diseases of the endocrine glands, nutrition-related conditions, metabolism and immunity disorders, etc.

The causes of mortality have retained a relatively stable structure for more than a decade. Since the mid-1990s approximately two thirds of deaths are caused by diseases of the blood circulation organs (more than 66%). Ranking second are neoplasms (13%), followed by diseases of the respiratory system (approximately 4%) and traumas and poisoning (also approximately 4%). Nearly 88% of deaths in Bulgaria are a result of the above four groups of diseases. During the past several years, due to the upward trend in and increased frequency of deaths, more and more attention is paid to the traumas caused by traffic accidents. Deaths and suicides have increased since the mid 1980s, with the trend increasing particularly strongly after 1990. The effect of suicides on the mortality rate is not particularly significant, however.

Total mortality by cause of death (disease category) in Bulgaria since the mid-1990s is about 14 per 1,000 people, and mortality for deceased men is on average 12% more than that for deceased women. The main causes of death are diseases of the blood circulation organs. The death rate for diseases of the blood circulation organs is about 970 per 100,000 people, with a higher intensity for men (1,004 per 100,000 men and 940 per 100,000 women). Among the deceased men approximately 1.4% are 39 years or younger, 14% are in the 40-59 years bracket, 19% are 60-69 years old and approximately 64% are over 70 years old. Among the deceased women the age distribution is as follows: about 0.7% are 39 years or younger, 5% are between 40 and 59 years, 12% are 60-69 years and about 81% are over 70 years old. Among the deaths caused by diseases of blood circulation organs the most frequent are those caused by cerebrovascular disease and ischemic heart disease, with mortality rates respectively of 277 and 262 per 100,000 people.

The second most common cause of death is neoplasms, with male mortality again exceeding that of women (240 men per 100,000 versus 163 women per 100 000). More than a third of men dying from malicious neoplasms have them located in the digestive organs and peritoneum (approximately 37%), and 31% are located in the respiratory system. For women, the highest relative share of deaths is caused by malicious neoplasms localised in the breasts (approximately 17%) and the uterus, cervix and ovaries (16%). The remaining causes of death are structured as follows: conditions of the respiratory system, traumas and poisoning, diseases of the digestive system (approximately 2.5%), and others.

Table 1.1: Bulgaria - Demographic indicators 1995, 2000-2005

Indicator	1995	2000	2001	2002	2003	2004	2005
Total population	8,384.7	8,149.4	7,891.1	7,845.9	7,801.2	7,761.0	7,718.7
Population density per km ²	75.5	73.4	71.1	70.6	70.3	69.9	69.5
Population aged 0-14 (as a % of total)	17.66	15.54	15.12	14.75	14.17	13.82	13.56
Population aged 15-64 (as a % of total)	66.08	68.12	68.40	68.61	68.72	69.02	69.22
Population aged > 64 (as a % of total)	16.26	16.34	16.84	17.02	17.11	17.14	17.22
Life expectancy at birth, total	70.50	71.70	71.80	71.87	72.07	72.40	72.60
Life expectancy at birth, females	74.30	75.34	75.20	75.37	75.59	76.20	76.30
Life expectancy at birth, males	67.10	68.15	68.50	68.54	68.68	69.10	69.00

Source: National Statistical Institutes

1.2 Economic background

By the end of the 1980s, the Bulgarian economy, similar to the economies of the other former socialist countries, was working in an environment of dominating state ownership and centralised planning. Being a small and open economy, the large portion of Bulgaria's gross domestic product (GDP) was being formed within COMECON. After the disintegration of COMECON in 1989, export revenue dropped suddenly and in March 1990 Bulgaria announced a moratorium of its foreign debt payments. After 1990 Bulgaria lacked political consensus regarding economic policy priorities and the transition towards a market economy was implemented inconsistently. This resulted in a decline in gross domestic product (GDP) of 24% for the period 1990-1997 and a nearly 20-fold increase of consumer prices. The monetisation of fiscal and quasi-fiscal deficits in the economy was the main factor behind the high inflation.

Having won the majority during the parliamentary elections in December 1994, the socialist party declared the start of a radical economic reform. The solid majority supporting the Government and the high interest margin attracted some short-term foreign capital, which kept the exchange rate stable and helped the relatively low inflation in 1995. The Central Bank did not regulate the rate of increase of foreign assets and the money supply grew faster than inflation and real growth. In 1996 the Central Bank continued printing money to refinance commercial banks because of the bad debts they had accumulated. The growth of the money base and the soft budget restrictions for non-financial enterprises caused devaluation of the national currency unit (NCU (BGN)) and a decrease of the interest margin. This caused a drain of foreign capital during the second half of the year. In its attempts to stop the capital drain the Central Bank raised the basic interest rate to 300% per annum. In 1996 the average interest of government securities reached 262.8% and the interest expense was 63.5% of the total state budget expen-

diture. By the end of 1996 the budget was unable to cover the government debt and monetised all payments. The money supply almost doubled and continued growing at the beginning of 1997 as well. This led to an almost six-fold rise in the price of the US\$ during the period from the end of 1996 to mid-February 1997, and monthly inflation was at hyperinflationary levels³. After a short time the financial and economic crisis grew into political crisis. The Government resigned and in February 1997 the Parliament dissolved itself after setting a date for extraordinary parliamentary elections. The right-wing coalition, which won the elections (Union of Democratic Forces (UDF)), set up a new government, which introduced a Currency Board on 1 July 1997. After the introduction of the Currency Board, the discontinued monetisation of economic deficits led to decline in inflation and became a prerequisite for the reviving of economic activity. The accumulated gross domestic product (GDP) growth for the period 1998-2001 was 16.7%. Inflation dropped significantly and gradually approximated industrial countries' levels. The ratio of state debt expressed in gross domestic product (GDP) dropped to 56% at the end of 2002. For several consecutive years Bulgaria witnessed economic growth and since 2000 this has always exceeded the 4% level. The gross domestic product (GDP) for 2003 amounted to BGN 34.5 billion, which is a real growth of 4.5% compared to the previous year. This gross domestic product (GDP) reached its 1991 level in 2003, in terms of permanent prices, and at the time of writing it is only 12% below its level in 1989. In 2004 and 2005 the gross domestic product (GDP) growth permanently exceeded the 5% level (5.7% for 2004 and 5.5% for 2005: cf. Table 1.2), which gives grounds to claims that during the past few years, thanks to the recent macroeconomic stability, Bulgaria has entered a period of sustainable and relatively high economic growth. Looking at state expenditure as a percentage of gross domestic product (GDP) it is clear that over recent years there has been a trend of permanent decline, below 40% (39.7% in 2004 and 2005).

At the time of writing, the starting position for achieving the standards of other European Union (EU) Member States' looks good: Bulgaria has a low budget deficit and low inflation, a well-capitalised Currency Board and reduced ratio of debt/gross domestic product (GDP). The increase of the credit rating of the country's foreign state debt from B2 to B1 level by Moody's (credit agency) at the sign of Bulgaria's stable prospects at the beginning of 2002 and later by the rest of the leading international credit rating agencies, showed the regained trust of investors in the potential of the Bulgarian economy to repay its foreign debt in the long-term perspective. A major step forward was also taken in terms of the country's European Union (EU) accession negotiations, and on 25 April 2005 Bulgaria and Romania signed the accession agreement with the agreed date for accession to the European Union (EU) set as 1 January 2007.

In the period 2005-2007 Bulgaria has retained its positive economic development. The expected gross domestic product (GDP) growth for the period is more than 5.5% per annum. The forecasts are that the annual growth of investments for the period will be more than 9%. This outstripping of investment growth compared to gross domestic product (GDP) growth will lead to an increased share of gross domestic product (GDP) and by the end of 2007 it is expected to reach nearly 23%. The biggest contribution to the gross domestic product (GDP) growth, with about 4-4.5%, is to be attributed to end consumption, which has had a relatively sustainable growth rate

³ The monthly increase of the consumer price index for January 1997 was 48.9%, and for February it was 242.4%.

of approximately 4.5% per annum for the period. This growth is achieved mainly through the real increase of the total income within the economy.

Table 1.2: Bulgaria - Macroeconomic indicators 1995, 2000-2005

Variable (in national currency unit (NCU) or %)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU	880.322	26 753	29 709	32 335	34 547	38 275	41 948
GDP per capita in NCU	105.00	3 282	3 754	4 109	4 428	4 919	5 435
GDP per capita in PPPa	n.a.	25.53	24.65	24.75	n.a.	n.a.	n.a.
Growth rate from 1995 to 2000	3 040	-	-	-	-	-	-
Growth rate from 1995 to 2005	-	5.4	4.1	4.9	4.5	5.7	5.5
GGE	337.9	11 368	12 017	12 732	14 068	15 198	16 657
GGE as a % of GDP	38.40	42.49	40.4	39.4	40.7	39.7	39.7
Exchange rate (NCU per €), annual rate	-	1.95583	1.95583	1.95583	1.95583	1.95583	1.95583

NCU = national currency unit (BGN), GGE = general government expenditure, GDP = gross domestic product, PPPa = purchasing power parity

Sources: Ministry of Finance, Bulgarian National Bank

1.3 Political context

Bulgaria is a Parliamentary Republic with central (legislative, executive, president) and local governments. It is divided into 28 administrative districts, managed by District Governors appointed by the Government. Local governments are represented in 264 municipalities, each managed by a Mayor and a Municipal Council. At national level, the legislative body is the National Assembly and the Municipal Councils make decisions at local levels with the District Governors controlling their conformity with the law. The fiscal policy is to a large extent centralised, although there have been intensive debates over the last few years regarding fiscal decentralisation. In 2005, after the last parliamentary elections, a coalition government was formed between: the Bulgarian Socialist Party (BSP); the National Movement Simeon the Second (NMSS) (the party of the former monarch); and the Movement of Rights and Freedom (MRF) (the party of the Turkish ethnic minority), with an 8-5-3 distribution, respectively, for both the number of Ministers and the distribution of all senior managerial positions in the state and regional governments.

1.4 Health care system

The main goal of the health policy and health reform in Bulgaria is to improve the population's health and the condition of the health care system. This includes the following main priorities:

- reducing child mortality and improving maternal health care;
- limiting the morbidity, mortality and disability caused by socially significant diseases through the development and introduction of health programmes;
- maintaining efficient anti-epidemic control levels;
- limiting health risks and ensuring workplace safety, and limiting environmental health risks;
- reducing the health risk factors for the health of the elderly and people in disadvantaged or unequal positions;
- improving the mental health of the population;
- creating conditions for and promoting healthy lifestyles, health promotion and disease prevention;
- improving and continuously developing the health system and its efficient functioning.

1.4.1 Organisation

With the health reform that started in 1999, most of the good structural and functional solutions for health care systems of the social insurance type were applied in Bulgaria, combined with some elements of a National Health Service. This is a new model, becoming increasingly more popular within the practices of the different states, defined as a “public–private mix”. Thus, Bulgarian health care incorporates to varying extents and on varying scales the state, social insurance (public and corporate) and private sectors, where each of them has its own scope, rights and obligations. The most specific features of the public–private model are that all health activities with divisible effect are within the sphere of private service production and that it is mostly publicly financed with a small share of private co-financing. This classic market segment excludes only those health services for which the consumer is unable to make independent decisions, e.g. emergency medical care, hospital psychiatric care and similar. At the same time, health activities with indivisible effect, such as state health control, programmes for the control of socially significant diseases, mandatory treatment, anti-epidemic measures, etc., remain within the scope of the public financing, and are mostly publicly rather than privately funded.

The reforms in the field of treatment health care are radical and rather significant. They lead to regulation and protection of: citizens’ rights with regard to the health system; patients’ rights with regard to medical care provided by health establishments; and rights of health professionals providing medical aid and health care. The reform of treatment health care started with the adoption by the National Assembly of five new laws concerning the health system by the year 2000 and another law concerning mainly public health care in 2004.

- Law on Health and Safety at Work, 1997
- Health Insurance Act, 1998
- Law on Professional Organisations of Medical Doctors and Dentists, 1998
- Health Establishments Act, 1999
- Law on Pharmaceuticals and Pharmacies in Human Medicine, 2000

- Health Act, 2004

These laws regulate the structure, activities, organisation and management of the medical, dental and pharmaceutical fields and their financing.

Another specific feature of the changes in the health care system is the regulation of the contractual rule with regard to the relations between the health establishments and the financing body (the National Health Insurance Fund (NHIF)). All Bulgarian citizens are mandatorily insured for a certain package of health care services, paid for by the National Health Insurance Fund (NHIF). The health establishments provide health care by the virtue of a contract between them and the National Health Insurance Fund (NHIF) units – the Regional Health Insurance Funds (RHIF). The Regional Health Insurance Funds (RHIF) pay the health establishments for health care they have provided to insured people via a predetermined process. The main obligations of the contracting parties, along with the prices, payment methods and procedures are determined in the National Framework Contract, which is signed between the National Health Insurance Fund (NHIF) and representatives of the Professional Organisations of Medical Doctors and Dentists. The individual contracts are signed between the health establishments and the Regional Health Insurance Funds (RHIF), as well as with the 12 voluntary health insurance (VHI) companies existing in the country.

The third main feature of the system is the right of the consumer to choose health care providers, which has been in effect since 2000. They have the right to choose their personal medical doctor and dentist for primary care, health establishment for specialised out-patient care and, since 1 January 2004, also for in-patient care. Thus, the administrative obligation have finally been eliminated, which were previously significantly limiting the rights of the citizens to choose their health care specialists or establishments. The legally established managerial, legal and economic independence of legal subjects in health care – health establishments and financing bodies, together with the newly introduced contractual relations and the right of free choice of the consumer – are the main prerequisites for the establishment of a health care services market and competition between the health establishments.

The health care system is managed by the Ministry of Health (MoH), which has 28 local units – regional health centres (RHC). The National Health Insurance Fund (NHIF) is a relatively independent institution with its own budget, approved on an annual basis by the National Assembly. The health establishments for out-patient and in-patient care have the legal status of limited liability or joint-stock companies.

1.4.2 Funding

The funding of health care for insured citizens (health insurance in Bulgaria is mandatory) is provided by the National Health Insurance Fund. When a person is also insured by a voluntary health insurance (VHI) company, depending on the insurance contract, the expenses for her/his treatment are also covered by the relevant insurance company. If the person goes to a health establishment of her/his will (without referral from the general practitioner (GP) or a specialist) s/he alone pays the treatment expenses. In addition to the insurance contribution, the obligatorily insured individuals pay a customer fee for each visit to a primary care doctor or a dentist at the rate of 1% of the minimum salary and at the rate of 2% of the minimum salary for each day

of hospital treatment (but not more than 10 days a year). Some categories of patient are relieved of having to pay customer fees.

The social health insurance (SHI) in the Republic of Bulgaria, administered by the National Health Insurance Fund (NHIF), does not provide for any exception from the obligatory insurance system. The categories of insured people are listed here.

- 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 people 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 refugee status or with the right of refuge.

The range of income for which the 6% obligatory health insurance contribution is applied varies from 2 to 10 times the minimum insured income. At present the employer pays 65% of the contribution and the employee pays 35%; in future these percentages will be equal. There are certain sanction mechanisms for people who have not paid more than three health insurance contributions: they lose their right to insurance and have to pay for any medical care themselves and at market prices. When the health insurance contributions are paid the right to insurance is reinstated. The non-payment of insurance contributions due to the fault of the employer does not deprive a person from the right to insurance and the amounts that may be paid for medical care by people in such circumstances are subject to refund. There are no differences in insurance and access to medical care based on gender, religious, ethnic, racial or any other factors. However, in practice certain groups of the population fail to take full advantage of the benefits guaranteed by the social health insurance (SHI) system as a result of educational, cultural or other factors.

The State, represented by the Ministry of Health (MoH) and the municipalities, through the consolidated state budget, ensures tax funding for the public health care institutions that are publicly owned, including:

- regional inspectorates for public health control;
- emergency care centres;
- transfusion haematology centres;
- health establishments for hospital psychiatric care;
- medical and social care homes for medical supervision and some specific childcare-related circumstances;
- health establishments at the Council of Ministers and institutional health establishments.

The labour pharmaceutical centres are funded by the relevant enterprises and the school medical offices are funded by the relevant municipal councils.

The public health care expenditure in 2005 rose to BGN 229 per capita, which is almost twice as high as the expenditure in the year 2000. As a percentage of gross domestic product (GDP), public health care expenditure in the last five years has been steadily positioned within the range of 4-4.3% on average. According to the expert evaluations of the World Health Organization (WHO) (Sekhri 2003), for the same period the private health care funding gradually rose to meet the public funding. The majority of the private funding is provided unlawfully and to the detriment of good practice.

Table 1.3: Bulgaria - Health expenditure (HE) 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE in BGN	318,42	1,087	1,196	1,493	1,698	1,769	1,773
THE as a % of GDP	3.66	4.0	4.0	4.4	4.9	4.6	4.2
THE per capita in BGN	37.90	129.70	151.56	190.31	217.66	227.93	229.72
Public HE as a % of THE	> 90	> 80	> 80	> 70	> 60	> 60	> 55
Private HE as a % of THE	≈ 10	≈ 20	≈ 20	≈ 30	≈ 40	≈ 40	≈ 45

HE = health expenditure, THE = total health expenditure, GDP = gross domestic product

Source: Ministry of Finance, Private Health Insurance, International and European Experiences, Health XXI Sofia 2005

1.4.3 Access to health care

1.4.3.1 Out-patient care

The territorial distribution and coverage of the country by the health establishment network and the planning for its development are regulated by the elaboration of National and Regional Health Maps that are updated on 5-year basis. Such maps contain the various types of health establishment in the separate territorial units (regions and municipalities). The health establishments carry out agreements with the Regional Health Insurance Funds, providing health care for the relevant population. The equality of public (state and municipal) and private health establishments is prescribed by law.

A major feature of the health care reform is the radically changed legal status and complete juridical, financial and economic independence of the health establishments.

- Individual practices for primary and specialised medical and dental care can be registered and are owned by the relevant doctors and dentists.
- Group practices for primary and specialised medical and dental care are established as trade companies or cooperatives, along with: medical, dental and medicodental centres; centres for diagnosis and consultation; independent laboratories for medical diagnosis; medical equipment and hospices; and, if necessary, such health establishments may be established as limited liability companies or joint-stock companies, whether by the State and municipalities alone, or jointly with other actors.

- In-patient health establishments, homes for medical and social care and dispensaries are established by the State and the municipalities, by legal entities and natural persons such as trade companies or cooperatives.
- The following entities remain state owned and state governed: emergency care centres, transfusion haematology centres, health establishments for hospital psychiatric care, health establishments for medical supervision and the specific care of children, as well as health establishments at some ministries (i.e. of defence, interior, transport, justice).

The population's access to the infrastructure of health care provided by doctors and dentists is very good. This access is regulated by the State and is not dependent on the financial or property status of any person. Medical services are free of charge for the patient at the point of delivery, and the costs are covered by the National Health Insurance Fund (NHIF) or by the state budget. The National Health Map defines the standards of territorial coverage by health establishments and the number of specialists required given the population demand for health care. At present in Bulgaria there are no statutory or actual lists of waiting patients, with some minor exceptions relating to heart surgery, valve prosthetics, transplantations, and joint prosthetics.

The selection of a health care provider is regulated by a regulation of the Ministry of Health (MoH). In primary medical care the selection of a general practitioner (GP) is absolutely free and each person is allowed to change her/his general practitioner (GP) once every six months. The selected dentist may be changed every day. The patient and her/his general practitioner (GP) (family doctor) select an out-patient specialist or a health establishment. Until 2003 a hospital could be selected only within the region of residence. Since 1 January 2004, patients and general practitioners (GPs) are allowed to freely select a hospital for the relevant (free-of-charge) in-patient treatment anywhere in the country, without any exception. However, the free choice of a specific treatment doctor or team in the desired hospital is considered a personal choice and health care based on personal choice is paid by the patient at the market-based prices of the relevant health establishment.

General practitioners (GPs) are paid on a capitation basis, with subsequent payments for certain activities. They are the gatekeepers for access to specialist care. Out-patient specialists are paid in the form of a flat rate per visit. Highly specialised diagnosis services are paid in the form of a fee-for-service system.

Table 1.4: Bulgaria - Out-patient care 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total no. of doctors ¹	29,069	27,526	27,186	27,688	28,128	27,423	28,197
No. of doctors ¹ per 1,000 inhabitants	3.46	3.38	3.42	3.44	3.61	3.53	3.65
Total no. of out-patient doctors	15,333	11,648	11,153	11,287	11,342	12,370	14,352
<i>of which GPs</i>	9,852	4,870	5,022	5,143	5,528	5,897	5,262
<i>of which dentists</i>	5,481	6,778	6,482	6,144	6,475	6,491	6,493
No. of out-patient doctors per 1,000 inhabitants	0.54	0.69	0.65	0.69	0.70	0.62	0.53
No. of out-patient clinic departments ("ambulatories")	3,742	1,003	1,190	1,423	1,455	1,489	1,554

¹ Retired and non-practising doctors are excluded

² General practitioners (GPs) plus paediatricians and interns (before the health reform in 1999)

Source: National Health Information Centre

1.4.3.2 In-patient care

The health establishments for in-patient care are multi-profiled and specialised hospitals, which may be for: active treatment; follow-up and extensive treatment; rehabilitation; follow-up treatment, extensive treatment and rehabilitation, etc. In terms of service categories and relevant accreditation, the hospitals can be categorised as: district, regional, inter-regional, university and national. In 2003 there were 251 hospitals in the country with 46,929 beds. There were 137 multi-profile hospitals for active treatment, with 33,237 beds. These hospitals constituted 55% of all hospitals, with 71% of all beds. The distribution of the beds among these hospitals varied greatly, with the average number of beds at 244. There were 109 specialised hospitals, with 13,307 beds. Among these, the number of specialised hospitals for active treatment accounted for the most beds (51 hospitals with 4,494 beds). Psychiatric hospitals are also specialised hospitals – there were 11 of these, with 2,780 beds. There were 49 dispensaries throughout the country with 4,101 beds. In Bulgaria, a dispensary is a health care establishment which manages a register of certain chronic diseases. Its main scope of activity is active research, active monitoring and active treatment of a specific nomenclature of diseases. There are dispensaries both with and without beds. According to the Health Establishments Act, they fall into the category of "other treatment and health establishments", but for the purposes of registration they define their major objective as hospital care.

There were 13,161 doctors employed by hospitals and dispensaries in 2003. The largest share of these was the internal disease specialists, making up 22.3% of the total. Among the in-patient doctors, 83.1% were specialists. The other treatment and health establishments include emergency care centres, homes for medical and social care of children, hospices and the Regional Inspection(s) for Protection and Control of the Public Health (RIPCPH), etc. The number of such establishments is relatively stable, whereas there was some increase in the number of hos-

pices. In 2001 there were 32 hospices without beds, in 2002 there were 43 such hospices. The number of establishments and beds in homes for medical and social care of children (until 2000 known as Mother and Child Homes) has not changed considerably and in 2003 there were 32 such establishments, with 4,037 beds (683 beds fewer than in 2001). The usage of beds in the homes for medical and social care of children is an indicator showing the average occupation in days of one bed throughout the year and is calculated as the ratio of the total bed days spent by all children during the year and the average number of beds. In 2002 the usage was 289 days and was higher (by 31 days) than the usage in 2001. There were 3,139 children living in medical and social care homes in 2003 and 39% of these were one year old or younger. In 2002, 1,458 children from medical and social care homes were adopted. Medical care and services for children living in homes for medical and social care are provided by more than 3,000 employed personnel, of which 165 are doctors. The health care reform also imposed considerable changes in sanatorium and spa establishments. Only two sanatoria exist now, with 410 beds. The others were transformed into other types of health establishments in compliance with the Health Establishments Act.

By the end of 2002 the health care system in the country had 56,027 beds in all types of establishments, of which 45,711 were hospital beds. There were 71 beds in all establishments and 60 beds in hospitals per 10,000 inhabitants. For comparison, since 1995 the number of beds per 1,000 inhabitants had decreased by 4.6 beds, and since 2000 by 0.6 beds. As part of a structural reform, the beds have been closed.

All hospitals for active treatment, follow-up treatment and rehabilitation, as well as hospices, were transformed in 2000 into limited liability companies or joint-stock companies, owned either by the State or by the municipalities. At present the hospitals are not privatised. Payment for in-patient care is made on the basis of an agreement with the National Health Insurance Fund (NHIF) by groups of diseases, defined as Clinical Pathways. Each hospital is entitled to sign a funding agreement with the 12 voluntary health insurance (VHI) companies existing in Bulgaria. Doctors are employed by the hospitals and their salaries are formed as 40% of hospital revenue, implying that the doctor's salaries vary each month. Although registered as corporations, hospitals receive funding at prices determined administratively by the National Health Insurance Fund (NHIF). Once a year the National Health Insurance Fund (NHIF) and the doctors' branch organisations negotiate the specific prices, which are then included in the National Framework Contract. In the case of over-spending of the National Health Insurance Fund (NHIF) budget, the prices may be reconsidered on 6-month basis. Every insured patient pays for hospital treatment, along with a fee of 2% of the minimum salary, for not more than 10 days throughout any one year. The insufficient funding of in-patient care has resulted in a highly developed black market. A small number of institutional hospitals are funded by the State, but the municipalities are not involved in the hospital funding.

Table 1.5: Bulgaria - In-patient care 1995, 2000-2005

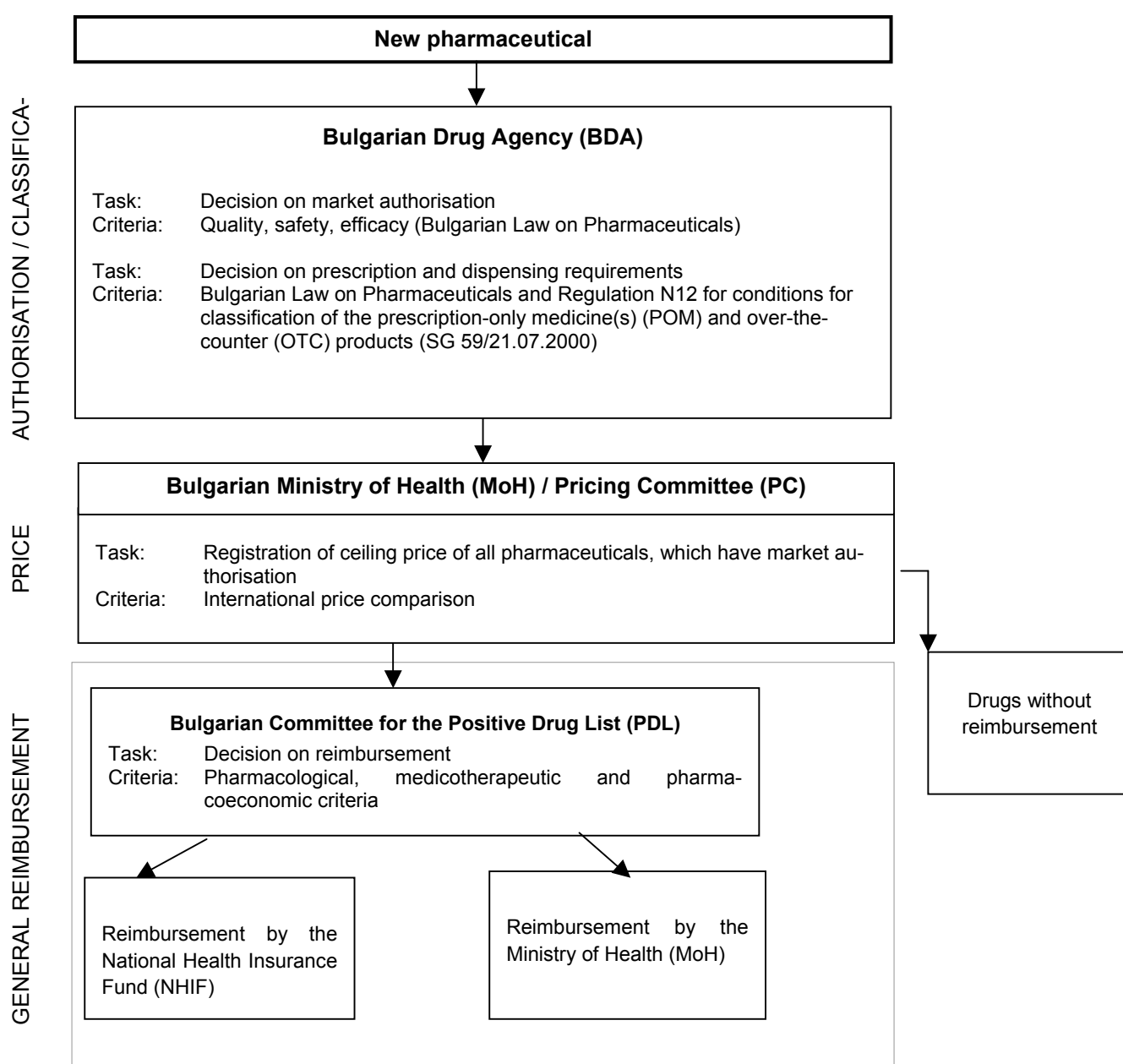
Variable	1995	2000	2001	2002	2003	2004	2005
No. of in-patient doctors	N.a.	N.a.	N.a.	N.a.	13,161	N.a.	N.a.
No. of in-patient doctors per 1,000 inhabitants	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
No. of hospitals	289	253	244	248	249	257	262
No. of acute care beds	87,148	53,993	52,712	45,711	45,070	43,597	45,537
<i>of which private sector</i>	139	306	414	475	528	819	1,565
Acute care beds per 1,000 inhabitants	10.6	6.6	6.5	6.0	5.8	5.6	5.9
Average length of stay in hospital	13.7	11.5	10.0	9.2	8.5	8.2	7.9

Source: National Health Information Centre

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Bulgaria - Flowchart of the pharmaceutical system



Source: Law on Pharmaceuticals and Pharmacies in Human Medicine OJ 36, 2000

2.1.1 Regulatory framework

This section includes a description of the legal framework of the pharmaceutical policy, the principal authorities and important players within this framework and their roles.

2.1.1.1 Policy and legislation

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 legislation was the Law on Pharmaceuticals and Pharmacies 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 specific pharmaceutical legislation has been implemented in Bulgaria. It defines the process of market authorisation, classification, clinical trials, manufacturing, registration of ceiling prices, the process of granting a reimbursement statute, wholesale and retail sales, importing, exporting, prescribing, dispensing and advertising of pharmaceuticals, as well as what standards are required in terms of quality, efficacy and safety of the pharmaceuticals. Via an order by the Minister of Health, the European Pharmacopoeia came into act.

The Law on Pharmaceuticals and Pharmacies in Human Medicine of 1995 had been amended more than 20 times throughout the years. At present a new radical amendment has been put before the Parliament, waiting to be voted on before the end of 2006. This latest version is intended to adopt fully relevant European Union (EU) legislation in the field and to facilitate the European Union membership of the country from January 2007.

Parallel to the Law on Pharmaceuticals and Pharmacies in the Human Medicine, the sector is also regulated by 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 Pharmaceuticals and Pharmacies in Human Medicine and the Control of Narcotics and Precursors Act, consists of over 50 regulations and other bylaw acts. There are around 50 bylaw acts (regulations, orders, tariffs, etc.) for both the laws (35 concerning the Law on Pharmaceuticals and Pharmacies in Human Medicine and 13 concerning the Control of Narcotics and Precursors Act).

Despite several attempts to do so on the part of the Ministry of Health (MoH), in the country still has not officially adopted a National Drug Policy Paper. The selection of pharmaceuticals for reimbursement is made according to the criteria set out in the Regulation on the terms and conditions for inclusion of pharmaceuticals in the Positive Drug List (PDL) (Council Decree N304, OJ 2003).

2.1.1.2 Authorities

According to Art. 10 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, the policy in the pharmaceutical sector in Bulgaria is executed by the Ministry of Health (MoH), together with the Bulgarian Drug Agency (BDA).

The Ministry of Health (MoH) is in charge of the overall pharmaceutical policy planning, as the executing and controlling authority. The Ministry issues licences for wholesale and retail pharmacies and providing some pharmaceuticals for treating of specific diseases, obligatory vaccinations and some health programmes, such as tuberculosis, AIDS, etc.

The market authorisation of a pharmaceutical is issued by the Director of the Bulgarian Drug Agency (BDA). The duration of the procedure is seven months and is carried out in compliance with European requirements.

Market authorisation is granted after assessing the quality and safety of the pharmaceutical (three months), followed by the approval of a specialised commission for the assessment of therapeutic efficacy compared to the safety of the pharmaceutical (three months). The classification of the pharmaceutical, e.g. prescription-only medicine(s) (POM), over-the-counter (OTC), etc., is decided during the assessment, is part of the market authorisation and is set according to Regulation N12 (OJ 59, 2000) on the terms and conditions for the classification of prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals. The last month of the procedure is set aside for the Director of the Bulgarian Drug Agency (BDA) to grant the market authorisation or to make a motivated refusal.

After receiving market authorisation, a pharmaceutical has to apply to the Pricing Committee (PC) for a ceiling price (cf. 3. Pricing, for the criteria and rules for receiving a ceiling price). According to Art. 85 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, the Pricing Committee (PC) is formed by the Council of Ministers, but is subordinate to the Minister of Health. The Pricing Committee (PC) includes representatives from the Ministry of Health (MoH), the Ministry of Finance (MoF), the Ministry of Economy and Energy (MoE), the Bulgarian Drug Agency (BDA), and the National Health Insurance Fund (NHIF).

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

According to Art. 10, paragraph 2 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, the Council of Ministers defines by regulation the criteria, rules and procedure for including the pharmaceuticals in the Positive Drug List (PDL). The Positive Drug List (PDL) is defined annually by the Committee for the Positive Drug List (PDL), which is formed with the proposition of the Minister of Health and is subordinate to the Council of Ministers.

The inclusion of a pharmaceutical in the Positive Drug List (PDL) gives the right for the pharmaceutical to be reimbursed by the National Health Insurance Fund (NHIF) or Ministry of Health (MoH).

The next step in the process is as follows: the National Health Insurance Fund (NHIF) and the Ministry of Health (MoH) choose which molecules to include in their reimbursement lists (cf. 4.1), following Regulation N34 (defining the terms of payment from the state budget for the treatment of the Bulgarian citizens for diseases out of the compulsory health insurance (OJ 95, 2005)), and Regulation N38 (defining the list of diseases for which out-patient treatment, pharmaceuticals and medical supplies the National Health Insurance Fund (NHIF) pays for in full or partially (OJ 106, 2004)).

The final completion of the reimbursement lists with the pharmaceuticals and their reimbursed prices is the result of a public procurement procedure for the Ministry of Health (MoH) list, and of a negotiation procedure for the National Health Insurance Fund (NHIF) list.

According to Art. 45, paragraph 4 of the Health Insurance Act, the National Health Insurance Fund (NHIF) procedure for purchasing the pharmaceuticals from its reimbursement list is exempted by the provisions of the Public Procurement Act and is achieved according to a regulation from the Council of Ministers (cf. 4.1). The described process is carried out annually, so the pharmaceuticals and their prices differ each year.

A Transparency Committee (TC), subordinate to the Council of Ministers, is involved in the described process. According to Art. 85b, paragraph 3 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, its functions are to supervise the creation of the reimbursement pharmaceutical lists and to monitor the method of defining the ceiling prices.

Membership of the Transparency Committee (TC) is defined by the Council of Ministers and includes representatives from the Ministry of Health (MoH), the Bulgarian Drug Agency (BDA), the National Health Insurance Fund (NHIF), the Bulgarian Medical Union (BMU), the Bulgarian Dentists Union (BDU) and the Bulgarian Pharmaceutical Union (BPU).

Table 2.1: Bulgaria - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English (Abbreviation)	Description	Responsibility
Министерство на здравеопазването (МЗ)	Ministry of Health* (MoH)	Executive administrative body	Overall health, including pharmaceutical policy planning, as the executing and controlling authority. Issuing licences for retail pharmacies and providing some pharmaceuticals for specific diseases.
Изпълнителна агенция по лекарствата (ИАЛ)	Bulgarian Drug Agency (BDA)	Regulatory body for pharmaceuticals – subordinate to the MoH	In charge of market authorisation, classification, advertising and promotion of pharmaceuticals, vigilance, producers licensing, clinical trials, proposing to the Minister the wholesalers to be licensed, import permissions, registering pharmacies and the control of all above-mentioned activities.
Комисия по прозрачност	Transparency Committee (TC)	Subordinate to the Council of Ministers	Supervising the creation of the reimbursement pharmaceutical lists and control of the methods for defining the ceiling prices.
Комисия по цени на ЛП	Pricing Committee (PC)	Created by the Council of Ministers – subordinate to the MoH	Registering ceiling prices of pharmaceuticals.
Комисия по позитивен списък	Committee for the Positive Drug List (PDL)	Subordinate to the Council of Ministers	In charge of the reimbursement decision.
Висш съвет по фармация (ВСФ)	Supreme Pharmaceutical Council	Subordinate to the MoH	Make proposals to the Minister of Health on the opening and closing of pharmacies and on cancellations of current pharmacy permits.
Национална здравноосигурителна каса (НЗОК)	National Health Insurance Fund (NHIF)	Third-party payer – the sole compulsory insurance body	In charge of creating its reimbursement list and setting the reference prices of the pharmaceuticals reimbursed by the NHIF.
Български лекарски съюз (БЛС)	Bulgarian Medical Union (BMU)	Professional association of physicians	Participating in the negotiation of the prices of the pharmaceuticals reimbursed by the NHIF.
Съюз на стоматолозите в България (ССБ)	Bulgarian Dentists Union (BDU)	Professional association of Bulgarian dentists	Participating in the negotiation of the prices of the pharmaceuticals reimbursed by the NHIF.

* 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)

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

Source: Law on Pharmaceuticals and Pharmacies in Human Medicine, Health Insurance Act (OJ 70, 1998)

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

In Table 2.2 the total number of authorised pharmaceuticals is shown, along with those reimbursed by the National Health Insurance Fund (NHIF), including different pharmaceutical forms, different pack sizes and different dosages. A certain number of pharmaceuticals, which are fully paid for and procured by Ministry of Health (MoH), are not included in the table.

Table 2.2: Bulgaria - Number of pharmaceuticals 1995, 2000-2006¹

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	n.a.	7,497	6,042	3,964	4,278	4,399	5,830 ²	n.a.
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM	n.a.	n.a.	n.a.	n.a.	n/av	n.a.	n.a.	n.a.
Reimbursable ³	n.a.	749	1,053	1,368	1,423	1,337	857	925
Generics	n.a.	n.a.	n.a.	n.a.	925	n.a.	n.a.	n.a.
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicine(s) (POM)

¹ as of 1 January, counted including different pharmaceutical forms, different pack sizes, and different dosages

² The number of authorised pharmaceuticals for 2005 is an estimation from the number authorised in 2004 plus the newly authorised products for 2005, as per the Bulgarian Drug Agency (BDA) report.

³ Reimbursement by the National Health Insurance Fund (NHIF) initiated from the second half of 2000. Before that the reimbursement for out-patient treatment was regulated by other financial mechanisms and according to Regulation N2 (OJ 24, 1993) until 1997, and N12.

Sources: Bulgarian Drug Agency reports, National Health Insurance Fund

Market availability of pharmaceuticals in Bulgaria is quite good. There are no registered significant shortages of pharmaceuticals. The implementation of some regulatory changes concerning market authorisation of the pharmaceuticals led to a significant decrease in the number of the authorised pharmaceuticals in 2002. Since then there has been a steady increase in newly registered pharmaceuticals.

In the event that a producer of certain pharmaceutical neglected to provide it to the Bulgarian market and a physician wants to prescribe this particular pharmaceutical, there is a procedure to buy it from abroad and to use it in the country without market authorisation. The procedure to obtain it is defined in Ministry of Health (MoH) Regulation N2 on the terms and conditions for treatment of pharmaceuticals without market authorisation (OJ 6, 2001). In principle, these should be pharmaceuticals which have market authorisation in other countries and are for the treatment of rare diseases or conditions, when the treatment pharmaceuticals available in Bulgaria have not yielded any therapeutic result.

The classification of the pharmaceuticals is decided during the process of market authorisation by the Bulgarian Drug Agency (BDA). The classification is carried out according to Regulation N12 (OJ 59, 2000) and follows European Commission (EC) criteria.

At pharmacy retail level, as soon as a pharmacy has the necessary licence, e.g. for narcotic or psychotropic pharmaceuticals, there are no restrictions on whether they sell prescription-only medicine(s) (POM) for out-patient or for in-patient use. This is defined by the marketing strategy of each pharmacy.

At the moment there is not a clear policy on the switch between prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals. There are few pharmaceuticals that change their classification, but from the authors' point of view this can be perceived as motivated mostly by the possibility to boost public advertisement.

2.1.2.2 Market data

Table 2.3: Bulgaria - Market data 1995, 2000-2005

Pharmaceutical industry in Mio. NCU / €	1995	2000	2001	2002	2003	2004	2005
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level in Mio. NCU (finished products)	n.a.	165	232	155	163	152	157
Sales at ex-factory price level in Mio. €	n.a.	84	119	79	83	78	80
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at PRP level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<i>Exports and imports</i>							
Total pharmaceutical exports	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical imports in BGN	n.a.	185	289	359	410	484	577

NCU = national currency unit (BGN), PRP = pharmacy retail price, n.a. = not available

Source: BDA

In Bulgaria there are no available official statistics or data about sales at wholesale and retail sale price levels. Approximate calculations can be made considering the sales at ex-factory price level and adding average mark ups for the next two levels. However, this kind of calculations is really very general, because in practice there are four different mark ups according to the ex-factory price (cf. 3).

Art. 3, paragraph 12 of the regulation on the terms and conditions for wholesale delivery of pharmaceuticals (OJ 94, 2000) requires the wholesalers to give information to the Ministry of Health (MoH) annually (up to 30 January each year) regarding their sales to pharmacies and hospitals in terms of volume and price. However, at the time of writing such data is not publicly available.

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

Pharmaceutical consumption is monitored by the Bulgarian Drug Agency (BDA). Data are available on consumption in volume and in value for the period 2000-2005 at http://www.bda.bg/web_engl/main.htm (under market analysis).

Table 2.4: Consumption of pharmaceuticals in Bulgaria by value and volume 2000-2005

Year	Imported pharmaceuticals	Locally produced pharmaceuticals	Total by value in BGN
2000	185,224,658	105,313,472	290,538,130
2001	289,861,697	197,221,137	487,082,834
2002	359,661,386	196,415,953	556,077,339
2003	410,920,392	211,213,684	622,134,076
2004	484,638,822	200,386,700	685,025,522
2005	577,063,349	190,910,392	767,973,741

Year	Imported pharmaceuticals	Locally produced pharmaceuticals	Total by no. of packs
2000	31,538,127	133,733,785	165,271,912
2001	38,815,861	193,195,158	232,011,019
2002	41,089,372	114,344,794	155,434,166
2003	45,133,674	118,232,058	163,365,732
2004	53,743,511	99,072,950	152,816,461
2005	65,245,245	92,121,860	157,367,105

Source: BDA

Table 2.5: Bulgaria - Top 10 best-selling pharmaceuticals, by International Nonproprietary Name (INN), in percentage (volume) 2005

Position	Pharmaceutical, by active ingredient
1	Acetylsalicylic acid
2	Enalapril
3	Metoprolol
4	Ascorbic acid
5	Sodium chloride
6	Sodium hydrogen carbonate
7	Paracetamol
8	Nifedipine

Position	Pharmaceutical, by active ingredient
9	Diclofenac
10	Amoxicillin

Source: BDA report for 2005 activities

2.1.2.3 Patents and data protection

The protection of intellectual property is a subject regulated in the Patents Act, which has been in force since 1 June 1993. It was harmonised to a great extent with international norms, particularly with the European Patent Convention and the Patent Cooperation Treaty (PCT). It supersedes the Inventions and Rationalisations Act of 1969 and the Inventions, Rationalisations and Discoveries Act of 1961, as far as discoveries are concerned. It was recently amended and the title was also changed to the Patents and Useful Models Act.

By definition, the Patents and Useful models Act provides for the establishment, protection and use of patentable inventions and useful models. According to Art. 16, legal protection of the invention shall be provided by a patent, certifying the availability of a patentable invention, the priority, authorship and the exclusive right of the patent holder over the invention. According to this, the patent shall also be valid for 20 years, providing 20-year protection, which shall start on the date of application submission.

The Supplementary Protection Certificate (SPC) has not been introduced into Bulgarian legislation at the time of writing, but EC Regulation 1768/92 is to enter into force from the date of the accession of the country to the European Union (EU).

Some provisions within Art. 32, paragraph 3 on compulsory licensing in the public interest are included in the Patents and Useful Models Act, due to enter into force in November 2006.

According to the Law on Pharmaceuticals and Pharmacies in Human Medicine, Art. 18, paragraph 6, when there is already an effective patent in the territory of the country for the pharmaceutical or for the method of its production, for which a market authorisation is requested, the manufacturer or the person authorised by her/him shall be obliged to inform in writing the Bulgarian Drug Agency (BDA).

Since the amendments and supplements to the Law on Pharmaceuticals and Pharmacies in Human Medicine of December 2002, provisions for data exclusivity have been introduced: six years for pharmaceuticals and ten years for biotechnological products. The recently adopted European Union (EU) legislation providing data protection for an 8+2+1-year period is expected to be introduced in the country by the project of the Law on Pharmaceuticals and Pharmacies in Human Medicine.

Parallel to this, Art. 18, paragraph 6 grants the possibility to carry out clinical trials of non-original products up to two years before the original product patent expires. This is the so called Rosh-Bolar provision. According to the recent amendments and supplements of the Law on Pharmaceuticals and Pharmacies in Human Medicine, the availability of an effective patent, up

to two years before the expiration of the patent protection, shall not be an obstacle for carrying out clinical trials and considering the application for market authorisation.

2.1.3 Market players

2.1.3.1 Industry

Table 2.6: Bulgaria - Key data on the pharmaceutical industry 1995-2005¹

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	84	46	49	58	63	73	76
- research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generic producers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of people employed	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

¹ as of 1 January

Source: BDA

In Bulgaria manufacturing is regulated by Chapter 2 of the Law on Pharmaceuticals and Pharmacies in Human Medicine and Regulation N12 on Good Manufacturing Practice (OJ 47, 2001).

When the first Law on Pharmaceuticals and Pharmacies in Human Medicine was adopted in 1995, Bulgarian manufacturers with existing manufacturing licences were granted a grace period, until the beginning of the year 2000, to align their practices with the requirements of the Law, and after that it was extended twice (running until 18 April 2003).

According to the Law on Pharmaceuticals and Pharmacies in Human Medicine, manufacturing authorisation shall be provided by the Director of the Bulgarian Drug Agency (BDA) after spot-check is performed to establish compliance with the actual manufacturing conditions, control and storage of the pharmaceuticals with the presented documentation and the requirements of Good Manufacturing Practice regulations. The procedure is of three months duration.

According to Art. 54, paragraph 2, Bulgarian manufacturers may carry out wholesale practices only with pharmaceuticals manufactured by them, under a manufacturing licence.

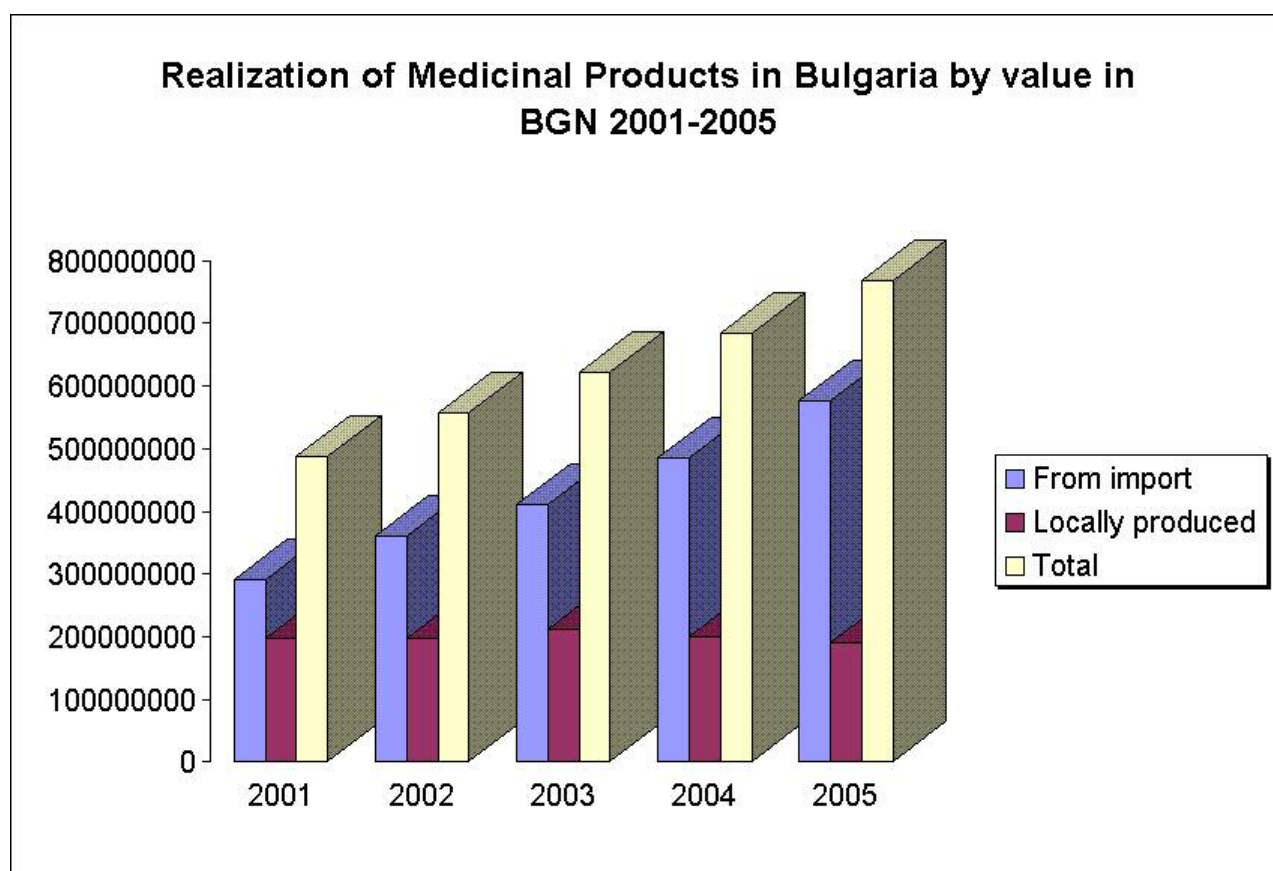
Manufacturers may only supply the following, with pharmaceuticals that they have produced themselves:

1. wholesale pharmaceuticals traders;
2. other manufacturers, only if necessary for the production activities;
3. the Ministry of Defence, the Ministry of the Interior and the other military departments – for their own needs, except their affiliated medical treatment facilities;

4. the 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. The relevance of local producers is comparatively low versus international manufacturers in terms of “drug realisation”, which is the term used by the Bulgarian Drug Agency (BDA) for turnover.

Table 2.7: Turnover of pharmaceuticals in BGN 2001-2005



Source: <http://www.bda.bg> , dated September 2006

In recent years a strong tendency towards mergers and acquisitions between local producers and foreign investors has become evident.

Until recently, the Bulgarian producers and foreign manufacturers were selling their products through different wholesalers. What is seen on the market today is due to the fact that most of the producers have licensed and developed separate entities for wholesale distribution. This was carried out either by acquiring existing wholesale companies or by creating completely new juridical entities.

The Association of Bulgarian Pharmaceutical Manufacturers (ABPM) was founded in July 2001. At the time of writing it has 17 members⁴.

In Bulgaria an Association of Research-based Pharmaceutical Manufacturers (ARPharM) is registered as well. Twenty-three (23) foreign manufacturers are members⁵.

There is a third association of manufacturers – those from central and eastern Europe, registered in 2002, with seven members. Its activities are not well known so far. Recently, the association has had a change in management board and future action is therefore foreseen.

2.1.3.2 Wholesalers

The wholesalers' activities are regulated by Chapter N6 of the Law on Pharmaceuticals and Pharmacies in Human Medicine and Regulation of the Ministry of Health (MoH) on the terms and conditions for wholesale delivery of pharmaceuticals (OJ 94, 2000).

According to Art. 54 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, only licensed wholesalers may perform wholesale activities. Authorisation is granted for an indefinite period by the Minister of Health after a proposal on the part of the Bulgarian Drug Agency (BDA). The procedure is of three months duration. Pharmacists with a Master's Degree and assistant pharmacists are employed in pharmaceutical wholesale. This qualification is not needed in the wholesale business with medical devices.

Until the end of 2002 there were two types of wholesale licence – full and partial. Wholesalers dealing only with specific nomenclature or only with medical devices mostly obtained a partial licence. After the recent amendments to the Law on Pharmaceuticals and Pharmacies in Human Medicine at the end of 2002, the so-called partial authorisation was invalidated.

Data about 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 Chief Pharmacist, who is responsible for the overall activities of the wholesaler and is the person who is responsible for the narcotic and precursor pharmaceuticals. According to the requirements the Chief Pharmacists must have a Master's Degree in pharmacy and at least two years of relevant working experience.

Partial data about the employees, the logistics processes, availability of stock, daily deliveries, etc., might be obtained through the web sites of some of the wholesalers. Some examples of wholesalers are listed here.

- **Libra Ag** has five warehouses in the country with a total area of 600 m²; 3,000 clients serviced on a daily basis, partially delivered goods several times a day; duty-free warehouse area in Sofia; 350 employees, of which 110 are employed in the sales department; 150 vehicles in the car park; range of 8,500 products. <http://www.libra-ag.com>, 22 September 2006).

⁴ <http://www.abphm.bg>

⁵ <http://www.arpharm.org>

- **Commercial League** employs 447 people on labour contracts from the following occupations: 46 Masters of Pharmacy, 40 assistant pharmacists, 12 doctors, 10 jurists, 20 engineers and technical specialists, 30 economists, 139 drivers, 80 operators, 27 specialists from other professions. (Forty-three (43) other specialists work part-time in the company.)
<http://www.comleague.com>
- **STING Ltd** has over 4,800 pharmaceutical units registered in Bulgaria; 4,970 m² of storage area; warehouse type A; 530 highly qualified and motivated employees; over 160 auto-park transport units; a regional structure including four warehouses in Plovdiv, Varna, Razgrad and Bourgas; 4,500 documents issued and over 64,000 articles; over 2,200 clients throughout the country serviced on a daily basis; approximately 2,700 deliveries per day to any location countrywide. <http://www.stingpharma.com>, 22 September 2006.

As mentioned in 2.1.3.1, the recent trend involves progress in the process of vertical integration in the pharmaceutical sector. As a result, few of the leading wholesalers are now owned by local producers. Others were bought by foreign investors, e.g. Phoenix group.

According to Art. 61 (2) of the Law on Pharmaceuticals and Pharmacies in Human Medicine a wholesaler may sell pharmaceuticals to another wholesaler, to retail pharmacies, and to pharmacies and hospitals for their own needs.

At the time of writing there are two registered wholesale associations. One is called the Association of the Wholesalers of Medicines (AWM) and the other is called the Professional Chamber of Wholesalers (PCW). Neither association 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. Neither has a web site.

Table 2.8: Bulgaria - Key data on pharmaceutical wholesale 1995-2005¹

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	230	346	383	344	322	289	349
Total no. of outlets	250	488	557	437	n.a.	n.a.	n.a.

¹ as of 1 January

Source: BDA

Over the last few years a negative trend that has been observed is the tendency towards a "lack of liquidity" where the Bulgarian wholesalers are concerned. Owing to problematic payments (having been postponed over a long period) on the part of the hospitals, considerable debts to the wholesalers and the pharmaceutical producers have been accumulated.

In 2005, delays in the payments meant that two of the leading wholesalers had to enter bankruptcy proceedings.

This experience then resulted in tougher requirements on the part of the Banks and the pharmaceutical companies, leading them to reconsider their policy towards the wholesalers, including terms of payment, discounts, etc., in order to minimise the risk of financial loss.

2.1.3.3 Pharmaceutical outlets / retailers

2.1.3.3.1 Pharmacies

Chapter seven of the Law on Pharmaceuticals and Pharmacies in Human Medicine provided detailed information about the procedures and operating methods of the pharmacies. The retail sale of pharmaceuticals is only allowed in pharmacies licensed by the Minister of Health. The activities of the pharmacy are to be carried out by a Master of Pharmacy. The ownership of the pharmacy is not dealt with in the Law on Pharmaceuticals and Pharmacies in Human Medicine. The Chief Pharmacist is the licence holder and should be a Master of Pharmacy. In order to receive a licence for a pharmacy, the pharmacist has to have least one year's experience in the speciality. The Chief Pharmacist is not allowed to participate in other commercial entities, i.e. producers or wholesalers, as well as to work under another labour contract. A Master of Pharmacy with less than one year of practical service shall be eligible for becoming a Chief Pharmacist in a settlement where there is no other pharmacy. To open a pharmacy to dispense and sell pharmaceuticals 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.

Art. 66 (2) of the Law on Pharmaceuticals and Pharmacies in Human Medicine allows an assistant pharmacist to dispense over-the-counter (OTC) pharmaceuticals and to perform the activities connected with the preparation and the packaging of the pharmaceutical, under the supervision of a Master of Pharmacy.

An assistant pharmacist can open a pharmacy or be a Chief Pharmacist located in a settlement with a population of fewer than 5,000 residents, if within that settlement territory there is no other pharmacy and until a candidate for the position with a pharmacy Master's Degree appears. The Minister of Health shall approve the list of pharmaceuticals that are to be allowed for sale in such pharmacies.

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 can not 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 (MoH), the Bulgarian Drug Agency (BDA), the Pharmaceutical Faculty of the Medical University of Sofia, the Professional Association of Pharmacists and a representative of the National Health Insurance Fund (NHIF).

Table 2.9: Bulgaria - Retailers of pharmaceuticals 1995, 2000-2006¹

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies	n.a.	2,338	3,116	3,735	4,395	4,441	4,001	4,453
No. of private pharmacies	n.a.	1,937	2,648	3,211	3,827	3,883	3,611	4,034
No. of public pharmacies	n.a.	338	375	393	410	396	232	243
No. of hospital pharmacies ²	n.a.	63	93	131	158	162	158	176
No. of other POM dispensaries ³	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total no. of POM dispensaries ¹	n.a.	2,338	3,116	3,735	4,395	4,441	4,001	4,453
No. of internet pharmacies ⁴	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries, such as pharmacies	n.app.	n.a.	195	360	330	n.a.	n.a.	n.a.

OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s) (POM);

¹ as of 1 January

² in Bulgaria the hospital pharmacies are for in-patients only. Art. 70 (2) of the Law on Pharmaceuticals and Pharmacies in Human Medicine prohibits hospital pharmacies to sell pharmaceuticals

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

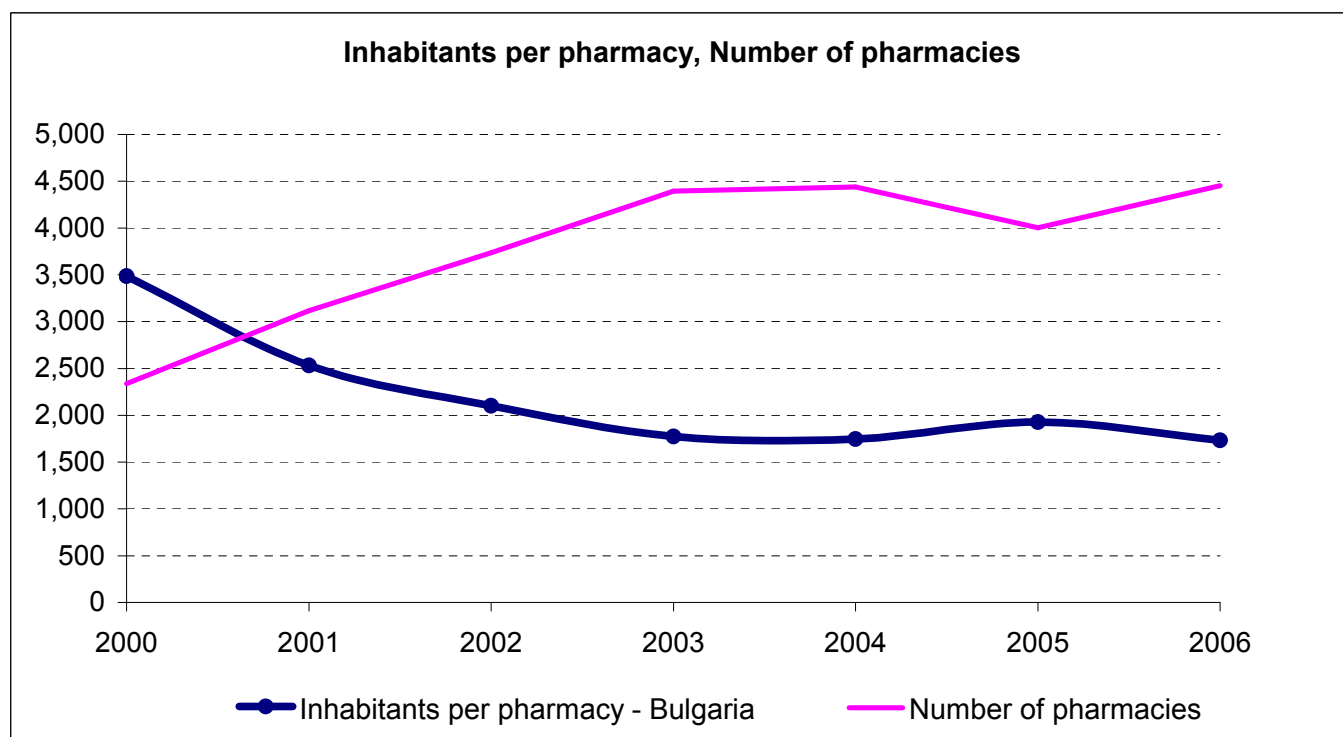
⁴ registering Internet pharmacies is not allowed in Bulgaria

Source: Ministry of Health web site 2003, 2004, 2006

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

Art. 78 of the Law on Pharmaceuticals and Pharmacies in Human Medicine allows, as an exception, doctors and feldshers to sell pharmaceuticals only in places where there is no pharmacy already registered.

Figure 2.2: Bulgaria - Number of retail pharmacies and number of inhabitants per retail pharmacy 2000-2006



There is registered trend of uneven territorial distribution of pharmacies in general and the number of pharmacies in the urban areas of Sofia, Plovdiv, Varna, Burgas regions is higher than the pharmacies in the rural Silistra, Kardjali and Razgrad regions, where an average of 2,400-3,000 patients are serviced by each pharmacy.

There is also an uneven distribution trend, observed by the territorial distribution situation in 2005 of the pharmacies that have contracts with the National Health Insurance Fund (NHIF) for dispensing partially or fully reimbursed pharmaceuticals. In terms of all licensed pharmacies in the region, the highest number of pharmacies contracting with the National Health Insurance Fund (NHIF) are in Shumen, Lovech and Varna and are servicing approximately 3,000-3,500 inhabitants. In the cities with the smallest number of National Health Insurance Fund (NHIF) pharmacies (Montana, Haskovo, and Veliko Tarnovo) between 4,600 and 5,200 citizens are served per pharmacy.

Until recently, two pharmacists' associations existed in Bulgaria: the Bulgarian Pharmaceutical Union (BPU), as a branch organisation, uniting pharmacists with higher education, irrespective of their practising as scientists, wholesalers or distributors, whether they work within or own pharmacies, represent educational facilities or work in the social administration sphere. Their web site is <http://www.pharma-union-bulgaria.com>. The other organisation was the Association of the Bulgarian pharmacists (ABP), for which no web site is available.

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 pharmacists are only to have one professional association to represent them. It will operate through its regional structures.

The Law defines the structure, organisation and activity of the Professional Association of Pharmacists, 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.

As per Art. 3 of the Law on the Professional Association of Pharmacists, practising pharmacists are members of the Bulgarian Pharmaceutical Union (BPU). Those pharmacists, who are not practising their profession, are voluntary members of the Union.

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

Not all of the registered pharmacies can work with the National Health Insurance Fund (NHIF). They need to meet National Health Insurance Fund (NHIF) requirements in terms of record-keeping software and monthly reporting, and they are inspected by the National Health Insurance Fund (NHIF) and the Bulgarian Drug Agency (BDA). A pharmacy must be licensed and ready to operate in time to apply for a National Health Insurance Fund (NHIF) contract within 30 days of the ratification of National Framework Contract with the National Health Insurance Fund (NHIF), or otherwise wait until the next year. Pharmacies apply annually to contract with the National Health Insurance Fund (NHIF) to supply reimbursable pharmaceuticals.

The Law on Pharmaceuticals and Pharmacies in Human Medicine (Art. 67 and Art. 72) prohibits pharmacy ownership by manufacturing and wholesale companies, and permits pharmacists each to open only a single pharmacy. These provisions, created by recent amendments, forced chain enterprises to restructure so as not to infringe the restrictions. Some have transformed their store chains into freestanding franchises that obtain credit and training from wholesalers. The amendments are an example of the frequent legislative changes that make it difficult for firms in the pharmaceutical sector to plan ahead (borne out by an IRIS study on governance of the pharmaceutical system in Bulgaria).

2.1.3.3.2 Other pharmacy outlets

Since 2000, pharmacies have opened in Bulgaria in which non-pharmaceutical goods that are important for the population health are sold, along with over-the-counter (OTC) pharmaceuticals as per a list specified by the Minister of Health. Pharmacies have to be registered with the Bulgarian Drug Agency (BDA). All individuals and corporate bodies shall have the right to open a pharmacy. The Chief Pharmacist can be a person with pharmaceutical or medical education, including a person having graduated from a medical college.

Under Art. 81d, paragraph 2 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, within 30 days from receipt of the documents the Director of the Bulgarian Drug Agency (BDA) shall issue a certificate for registration of the pharmacy or make a motivated refusal.

2.1.3.3.3 Internet pharmacies

In Bulgaria, sales of pharmaceuticals via the Internet are not allowed by law.

2.1.3.3.4 Dispensing doctors

Regulation N6 on terms and conditions under which doctors and feldshers (medical assistant), dentists and nurses may store and sell pharmaceuticals (OJ 11, 2001) provides for the possibility for a doctor or feldsher, dentist or nurse to sell pharmaceuticals, only 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 pharmacy within the community. There are precise conditions that should be followed, e.g. selling pharmaceuticals at a price not higher than the registered ceiling price, and dispensing pharmaceuticals only to their patients. Feldshers are not allowed to store and dispense pharmaceuticals from certain pharmacological groups, such as antiarrhythmics, neuroleptics, narcotic drugs, etc.

2.1.3.4 Hospitals

As per Art. 68 of the Law on Pharmaceuticals and Pharmacies in Human Medicine, medical establishments for in-patient care and dispensaries for oncologic or mental diseases may open pharmacies to dispense pharmaceuticals in the fulfilment of their own needs. According to the Ministry of Health (MoH) register, as of January 2006 there were 176 licensed hospital pharmacies in the country. As it is prohibited to sell pharmaceuticals, the hospital pharmacies cover only the needs of the hospital itself. Regulation N4 on the terms and conditions for prescribing and dispensing pharmaceuticals (OJ 10, 2001) states that when a hospital has no pharmacy, then the needs of the hospital are to be covered by the closest pharmacy of another hospital.

Each hospital in Bulgaria has the choice and the right to create its own pharmaceutical policy, and, respectively, its own list of preferred pharmaceuticals. In the previous regulation that was cancelled in 2003, there was a minimum nomenclature that it was obligatory to have available in the hospital.

At the time of writing the hospitals are creating internal pharmaceutical committees to define which pharmaceuticals are to be used in the hospital and to be purchased through public procurement procedure. The heads of the clinics, the economic director, and the Chief Pharmacist participate in these committees. The content and scope of the hospital pharmaceutical list will depend on the budget of the hospital.

2.1.3.5 Doctors

The Bulgarian Medical Union was created in 1901. It is the second oldest medical association in Europe after the British Medical Association. From the very beginning the Association played a major role in health care development and policy, as there was no Ministry of Health (MoH) at

that time. It was the licensing body for medical practice and it defined payment criteria. Membership was obligatory.

In 1947, during the communist regime, the Bulgarian Medical Union ceased to exist. At the end of that period, in 1990, the Association was restored. The Bulgarian Medical Union is the legal representative of all Bulgarian physicians and it defends the professional and financial issues of medical specialists. It organises continuous medical education and maintains a register of its members. The Association is comprised of 28 regional colleges, with a total of 34,000 members. Its web site is <http://www.blsbg.com> (22 September 2006).

Since 2004, according to Art. 45, paragraph 5 of Law on Pharmaceuticals and Pharmacies in Human Medicine, the Bulgarian Medical Union and the Bulgarian Dentists Association are involved, together with the National Health Insurance Fund (NHIF), in negotiations with the market authorisation holders over the prices of the pharmaceuticals to be included in the Positive Drug List (PDL) and subject to full or partial reimbursement by the National Health Insurance Fund (NHIF).

Representatives of the same two professional associations are members of the Transparency Committee (TC).

At the time of writing the Bulgarian Medical Union is not involved in prescribing policy.

2.1.3.6 Patients

The mechanism of registering ceiling prices is allowing a heavy competition in the prices of the pharmaceuticals within the ceiling price. It is therefore not unusual for patients to engage in so-called “pharmaceutical tourism”, hoping to find the best price pharmaceutical. This can be the case for either prescription-only medicine(s) (POM) or over-the-counter (OTC) pharmaceuticals, as a possible price difference may arise for all pharmaceuticals.

No system exists to inform the patient of the price of the pharmaceuticals. The ceiling prices are published in the Official Journal, but (a) not many patients read it and (b) the pharmacy can sell the pharmaceutical at a different price to the ceiling price (usually lower). The patient organisations so far are mostly organisations organised according to a particular disease, e.g. oncologic, epilepsy, multiple sclerosis, etc., and their fields of activity differ. Usually, patients are attracted by the discounts that the pharmacies offer, which are also well advertised (displayed clearly) in the windows of the pharmacy. In principle, the general practitioner (GP) prescribing the pharmaceutical is supposed to inform the patient of all aspects of the treatment, including the price of the pharmaceutical, but there is no evidence of such practices being carried out.

One representative of each patient association is granted the right to participate in the Assembly of Representatives of the National Health Insurance Fund (NHIF). Until recently this right was not exercised, because there was no single patient association that was nationally recognised.

Some of the most popular patient associations are listed here.

- The **Bulgarian Association for the protection of the patients**⁶ was established in 2002. The aim is improving the health system in Bulgaria through exchange of information, knowledge and experience with the patients all over the country.
- The **Association of Bulgarians suffering from asthma**⁷ was established in 2002. This is a national society of patients suffering from bronchial asthma and other pulmonary diseases. The association organises a number of initiatives for patient assistance, including individual consultations; standing up for health care rights according to European and world standards; assuring access to effective modern forms of diagnosis, treatment and prevention; and providing up-to-date health and pharmaceutical information.
- The **Association of patients with oncology diseases** is an international oncology consultancy centre⁸. The aim of the centre is to create another possibility for implementing state-of-the-art standards in diagnostics and treatment of oncological patients from the Balkans and Middle East countries. By creating such a centre in Sofia, the major expenses incurred and difficulties experienced by patients when consulted abroad will be relieved.
- The **Bulgarian Cancer Association** is a national society of women with oncological diseases⁹. The Bulgarian Cancer Association is a nationwide, community-based voluntary health organisation. With its headquarters in Varna, the Bulgarian Cancer Association has over 30 local offices across Bulgaria. The Association is dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through services, education and advocacy.
- The **Autism Association**¹⁰ was established in May 2003 by a group of parents of autistic children and adolescents. It is legally registered and has official status in Bulgaria. The main objectives of the Association are to stand up for the social and civil rights of children and adolescents with special needs (pervasive developmental disorders and autistic spectrum disorders) and their families; to help them to overcome their social isolation and to join successfully the community; as well as to raise public awareness of their problems.
- The **Association of the parents of children with injured eyesight**¹¹ is an association that assists development and integration of children with eyesight disorders.
- The **Association of parents of children with injured hearing**¹² aims to protect and defend the interests of children with injured hearing and their families; to represent and protect the rights and interests of children with injured hearing and their families in the public and municipal institutions and in the community as a whole; and to work towards better social and personal integration of children with injured hearing.

⁶ <http://www.patient.bg>

⁷ <http://www.asthma-bg.com/about.html>

⁸ <http://www.oncology-bg.net>

⁹ <http://www.bulgariancancerassociation.org>

¹⁰ <http://www.autism-bg.hit.bg/>

¹¹ <http://www.ardnz.hit.bg>

¹² <http://www.ardusbg.com>

- The **Bulgarian Diabetes Association** is a legal entity whose activities of the association have public benefit.
- The **Bulgarian Association for Persons with Intellectual Disabilities**¹³ (BAPID) is an association of intellectually disabled people, their families and their friends. The Association was established in 1993 and in 1996 the Council of Ministers acknowledged its national representation. The Bulgarian Association for Persons with Intellectual Disabilities (BAPID) is registered in the Central Registry for Public Benefit Organisations. The mission of the Bulgarian Association for Persons with Intellectual Disabilities (BAPID) is to defend human rights, including achieving non-discrimination and dignity in life for people with intellectual disabilities, delivered by means of secure access to quality services, including developmental training and employment opportunities.
- The **National Hepasist Society**¹⁴ is a nongovernmental patient organisation. It has been established to support patients affected by hepatitis and to protect their interests.
- The **Children's Heart Association**¹⁵ was established in 1990. It unites people with the problems of children and young people suffering from cardiac disease, including parents, paediatric cardiologists, psychologists, lawyers and others who might be interested in such children's problems and would be willing to volunteer her/his help. The association was created to meet the needs of a considerable number of Bulgarian children and their families.
- The **Bulgarian "Children with cerebral paralysis" Society** is a society for supporting the deserving lives of Bulgarian Parkinson's disease patient. In addition, there is a society of parents of children with phenylketonuria and other metabolic disorders.
- The **"Multiple sclerosis community" Foundation**¹⁶ interacts with country and community institutions in order to influence national health and pharmaceutical policy and to facilitate access to health services and pharmaceuticals. The foundation has good relations with all national centres for diagnosis and treatment of multiple sclerosis.
- Foundation of patients with chronic renal failure and patients on haemodialysis.
- Foundation of parents of children with epilepsy.

¹³ <http://bapid.com>

¹⁴ <http://www.hepasist.com/>

¹⁵ <http://www.lex.bg/members>

¹⁶ <http://www.msobshtestvo.org/index.php?page=32>

2.2 Funding

2.2.1 Pharmaceutical expenditure

Table 2.10: Bulgaria - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in NCU	5,531,972,000	249,000,000	348,000,000	484,000,000	436,000,000	468,570,000	443,200,000
TPE as a % of THE	17.37	22.91	29.10	32.42	25.68	26.49	25.00
TPE per capita in NCU	659.77	30.55	44.10	61.69	55.89	62.69	57.42
Public PE as a % of THE ¹	17.37	22.91	29.10	32.42 ²	25.68 ²	26.49 ²	25.00 ²
Private PE as a % of THE (estimate)	n.a.	0.90	0.66	n.a.	n.a.	n.a.	n.a.

NCU = national currency unit (BGN), GDP = gross domestic product, TPE = total pharmaceutical expenditure, PE = pharmaceutical expenditure, THE = total health expenditure

¹ Public PE as a % of THE is de facto equal to TPE as a % of THE

² The values for municipalities and hospitals for 2002, 2003 and 2004, 2005 are estimated figures based on historic data

Source: IHHII

2.2.2 Sources of funds

The main funding sources for public pharmaceutical expenditure (PE) in the country are social health insurance (SHI) contributions via the National Health Insurance Fund (NHIF) and the state budget via the Ministry of Health (MoH) and the Municipalities. An additional, smaller contribution to pharmaceutical funding is made by the Ministry of Defence for a very limited group of pharmaceuticals for war veterans.

Since 2002, with the start of the functioning National Health Insurance Fund (NHIF), the percentage of public pharmaceutical expenditure (PE) is gradually growing. While this tendency is a reality, the lack of data about hospitals' and municipalities' spending in recent years means that the percentages will be smaller than they appear.

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

2.3 Evaluation

Unfortunately, so far the evaluation of pharmaceutical policy in Bulgaria has not been provided for in the law. The Bulgarian Drug Agency (BDA) is analysing consumption to a certain extent, broken down by groups of pharmaceuticals, but this is still not a routine process and it is uncertain whether this information is ever used in connection with pharmaceutical policy decisions.

The National Health Insurance Fund (NHIF) has the capacity to evaluate of the consumption of the pharmaceuticals that are in the reimbursement list, and it is doing so. This evaluation mostly concerns the financial expenditure and is used when decisions are made on the inclusion/exclusion of pharmaceuticals in the reimbursement list and on the level of reimbursement of pharmaceuticals.

3 Pricing

This chapter gives an overview of the pricing system by describing the process and the regulation of pharmaceutical pricing.

3.1 Organisation

Apart from the Law on Pharmaceuticals and Pharmacies in Human Medicine, the Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a “Regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale” (in the following only called “Regulation”) defines the methods of pricing in Bulgaria.

Art. 85 of the Law on Pharmaceuticals and Pharmacies in Human Medicine stipulates that the State regulates the prices of prescription-only medicine(s) (POM) and registers the prices of over-the-counter (OTC) pharmaceuticals. Price regulation is carried out through the mechanism of registering ceiling prices.

The price is the final consumer price, fixed in accordance with the price proposed by the manufacturer, which should not be higher than the reference price, which is the lowest manufacturer price in BGN in Romania, Russia, the Czech Republic, Slovakia, Hungary, Poland, Portugal, Spain and Austria. A mark up for the wholesale and for pharmacy level is then added according to the price category of the pharmaceutical. 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. The prices declared by the manufacturers in the reference countries are proven with official documents from the market authorisation holder or the producer in the respective country. The official (ceiling) price is approved by the Pricing Committee (PC) and the Ministry of Health (MoH) prices. The producers, wholesalers and pharmacies are not allowed to sell the pharmaceutical at a price exceeding this one. The act approving the ceiling price (at manufacturers', at wholesale and retail sale level for prescription-only medicine(s) (POM)) is published in the Official Journal.

As for over-the-counter (OTC) products, the authorised person declares to the Pricing Committee (PC) the manufacturer's price and the final consumer price. Only the final pharmacy retail price (PRP) is fixed in the Order approving the price.

The pricing procedure is the second step towards market access for the pharmaceutical. In an ideal scenario the procedure for prescription-only medicine(s) (POM) lasts 55 days, plus one month for publication of the Minister of Health's Order in the Official Journal. The Order is valid from the date of publication in the Official Journal.

Art. 11 of the “Regulation” grants the Minister of Health the right to approve a price higher than the reference price, with the necessary motivation.

After this, pharmaceuticals seeking to be included in the reimbursement lists are subject to the next stage of the procedure – application to the Positive Drug List (PDL). Pharmaceuticals not seeking such reimbursement are ready to be sold on the free market.

The Council of Ministers, based on a proposal by the Minister of Health, is establishing at the Ministry of Health (MoH) a Commission for the Prices of Pharmaceuticals which consists of representatives of the Ministry of Health (MoH), the Ministry of Finance (MoF), the Ministry of Economy and Energy (MoE), the National Health Insurance Fund (NHIF) and the Bulgarian Drug Agency (BDA). This Commission deals with all pharmaceuticals, whether publicly financed or not, and whether prescription-only medicine(s) (POM) or over-the-counter (OTC) products. These controls set ceiling prices for all products, within which pharmacy retail prices (PRP) are subject to competition and negotiation.

Prices of over-the-counter (OTC) pharmaceuticals have been partially liberalised. This means they follow a simplified regulatory process, consisting of the producer's notification of her/his proposed price to the Commission for the Prices of Pharmaceuticals, which is required to "register" a ceiling price for the pharmaceutical within 45 days and to enter it in the official register of the over-the-counter (OTC) pharmaceuticals.

According to Art. 85b, the Council of Ministers establishes a Transparency Committee (TC) for the approval, adoption and control of the reimbursement lists. The members of the Transparency Committee (TC) are appointed by the Council of Ministers. It includes representatives of the Ministry of Health (MoH), the Bulgarian Drug Agency (BDA), the National Health Insurance Fund (NHIF), Bulgarian Medical Union, the Bulgarian Dental Association and the Professional Association of Pharmacists.

Directive 89/105/EEC of the European Union (EU) lays down unified rules relating to the transparency of measures regulating the pricing and reimbursement of pharmaceuticals in European Member States. In accordance with this regulation, national measures and actions in this area should be based on objective and verifiable criteria and for all individual decisions reasons should be given.

The procedure periods in Bulgaria for access of pharmaceuticals to the market do not currently correspond to the periods set out in the Transparency Directive and this is one of the areas in which the pharmaceutical legislation in Bulgaria should improve.

3.2 Pricing policies

There is statutory pricing for prescription-only medicine(s) (POM). 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 similar to that for prescription-only medicine(s) (POM), but it 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 notification, as the prices enter into existence after a certain procedure. Therefore, the pricing procedure for over-the-counter (OTC) products can be defined as a statutory pricing system.

In addition, there is the instrument of negotiations, but these are only applicable for pharmaceuticals reimbursed by National Health Insurance Fund (NHIF) pharmaceuticals. Negotiation can take place within the scope of the registered ceiling price. Others, i.e. the Ministry of Health (MoH) and hospitals, use the public procurement procedure.

Table 3.1: Bulgaria - Ways of pricing pharmaceuticals

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	Not applicable		Not applicable
Statutory pricing	POM OTC products (simplified procedure) – notification of manufacturer price by manufacturer	POM, regulated via a regressive mark-up scheme No mark ups for OTC products	POM, regulated via a regressive mark-up scheme No mark ups for OTC products – notification of PRP by manufacturer
Price negotiations	Reimbursable pharmaceuticals by NHIF	Not applicable	Not applicable
Discounts / rebates	to the NHIF	to the NHIF	8% in 2005 and 2006 to the NHIF
Public procurement	Relevant for products paid for by the state budget through the MoH and in hospitals		
Institution in charge of pricing	➤ MoH through the PC		
Legal basis	➤ Law on Pharmaceuticals and Pharmacies in Human Medicine ➤ Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria		

NHIF = National Health Insurance Fund, POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals), PC = Pricing Committee, MoH = Ministry of Health, PRP = pharmacy retail price

Source: IHHI

The current pricing system has existed since 2000, but has undergone some amendments. The procedure for statutory pricing of over-the-counter (OTC) products was simplified in 2003. Before that time over-the-counter (OTC) products were treated as equal to prescription-only medicine(s) (POM). Another difference concerns the reference pricing countries. The previous version of the regulation stipulated that the proposed manufacturer price should not be higher than the lowest price in the countries that were members of the Council of Europe (cf. 3.1).

3.2.1 Statutory pricing

Two of the main legal documents that have established the statutory pricing system in the country are the Law on Pharmaceuticals and Pharmacies in Human Medicine, and the Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and condi-

tions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria (called the “Regulation”). Two committees are involved in the process: the Commission for the Prices of Pharmaceuticals and the Transparency Committee (TC).

The State regulates the prices of prescription-only medicine(s) (POM) and registers the prices of over-the-counter (OTC) pharmaceuticals.

The pricing procedure is the second step towards market access for the pharmaceutical. In an ideal scenario the procedure for prescription-only medicine(s) (POM) lasts 55 days, plus one month for publication of the Minister of Health’s Order in the Official Journal. The Order is valid from the date of publication in the Official Journal.

Art. 11 of the “Regulation” grants the Minister the right to approve a price higher than the reference price, with the necessary motivation.

Prices of over-the-counter (OTC) pharmaceuticals have been partially liberalised. This means they follow a simplified regulatory process, consisting of the producer’s notification of her/his proposed price to the Commission for the Prices of Pharmaceuticals, which is required to “register” a ceiling price for the pharmaceutical within 45 days, plus the time taken to enter it in the official register of the over-the-counter (OTC) pharmaceuticals.

3.2.2 Negotiations

The instrument for price negotiations is only for the pharmaceuticals reimbursed by the National Health Insurance Fund (NHIF). Such negotiation can take place within the scope of the registered ceiling price. It was introduced via an amendment to the Health Insurance Act in 2002 and defined in detail in the Decree of the Council of Ministers. The aim of the regulation is to improve efficiency of budget spending, guaranteeing:

- the right of insured people to receive pharmaceuticals for out-patient treatment;
- transparency of the procedure and the negotiation criteria;
- free and fair competition;
- conditions for effective control over the expenditure of the National Health Insurance Fund (NHIF).

3.2.3 Free pricing

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

3.2.4 Public procurement / tendering

The public procurement process is an obligatory procedure for providing pharmaceuticals paid with funds from the state budget. Legally it is defined by the Public Procurement Act (last amended OJ 37.2006). Within its scope are the procurement procedures for pharmaceuticals in the Ministry of Health (MoH) and in the hospitals.

The National Health Insurance Fund (NHIF) is exempted from the public procurement process due to Art. 45, paragraph 4 of the Health Insurance Act, which allows the Insurance Fund to negotiate its list of pharmaceuticals according to the Regulation on the terms and conditions for negotiating the pharmaceuticals, medical devices and dietary medical foods which are paid fully or partially by the National Health Insurance Fund (NHIF) (cf. 4.2). The reasons for this are the impossibility of defining exact quantities of the required pharmaceuticals and the concern over potentially limiting therapeutic choice.

The relevance of the application of the Public Procurement Act to the process for providing pharmaceuticals 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 pharmaceuticals.

3.3 Pricing procedures

The pricing procedure in use at the time of writing is external price referencing and it has been applied in Bulgaria since the year 2000. It is enforced by the Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria ("Regulation").

Table 3.2: Bulgaria - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing ¹	Scope ²
Internal price referencing	Yes. However, only used in NHIF reimbursement	Pharmacy retail level (PRP)	For pharmaceuticals reimbursed by NHIF
External price referencing	Yes	Manufacturer level	For POM
Cost-plus pricing	No		
Other, e.g. indirect profit control	No		

¹ Level of pricing = at what stage of the pricing process does the pricing take place (e.g. at the pharmacy retail price (PRP) level)?

² Scope = A pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for over-the-counter (OTC) pharmaceuticals there is free pricing

NHIF = National Health Insurance Fund, POM = prescription-only medicine(s), PRP = pharmacy retail price

Source: Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria

3.3.1 External price referencing

External price referencing is the only procedure used and it is applied only for prescription-only medicine(s) (POM) at the manufacturer price level. The countries that are taken as a reference

are Romania, the Russian Federation, the Czech Republic, Slovakia, Hungary, Poland, Portugal, Spain and Austria. There are no alternative countries. The applicant declares certain information and the prices, and s/he is obliged to provide all the necessary data. Such price comparison directly influences pharmaceutical prices because the Pricing Committee (PC) registers the lowest price from the selected countries. There is the possibility of exceptions, because Art. 11 from the „Regulation” gives the Minister of Health the right to approve a price higher than the reference price, with the necessary motivation.

3.3.2 Internal price referencing

As mentioned before, internal price referencing is only applied only at the reimbursement negotiations, carried out by the National Health Insurance Fund (NHIF) for fully or partially reimbursed pharmaceuticals (cf. 4.3).

3.3.3 Cost-plus pricing

Cost-plus pricing is not applicable in Bulgaria.

3.3.4 (Indirect) Profit control

Indirect profit control is not applicable in Bulgaria.

3.4 Exceptions

3.4.1 Hospitals-only

Publicly funded hospitals are subject to the Public Procurement Act. According to the Act, these hospitals have to organise their own procurement on a yearly basis. There is no experience in Bulgaria of using public procurement/purchasing agencies.

Hospitals should purchase their pharmaceuticals from wholesalers, thus the purchasing price should not be higher than that defined in the pricing regulation. In practice, the prices of procured pharmaceuticals differ from case to case. The State Financial Control Agency is the body to monitor this type of hospital activity and the Ministry of Health (MoH) monitors the state hospitals.

Legally, the Access to Information Act provides for the possibility of asking for information about prices, but often this information is difficult to obtain.

3.4.2 Generics

The system for the pricing of generics does not differ from the pricing methods and procedures explained thus far.

3.4.3 Over-the-counter pharmaceuticals

The system for the pricing of over-the-counter (OTC) pharmaceuticals differs from the pricing methods and procedures used for prescription-only medicine(s) (POM). This system is a simplified regulatory process, consisting of the producer's notification of the proposed price to the Commission for the Prices of Pharmaceuticals, which is required to register a ceiling price at retail level for the pharmaceutical within 45 days (cf. 3.2).

3.4.4 Parallel traded pharmaceuticals

Not applicable.

3.4.5 Other exceptions

Not applicable.

3.5 Margins and taxes

Table 3.3: Bulgaria - Regulation of wholesale and pharmacy mark ups 2006

	Wholesale mark up			Pharmacy mark up		
	Regulation (yes / no)	Content	Scope	Regulation (yes / no)	Content	Scope
Bulgaria	Yes	Regressive mark ups	POM	Yes	Regressive mark ups	POM

POM = prescription-only medicine(s)

Source: Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria

3.5.1 Wholesale remuneration

The remuneration of wholesalers is based on mark ups, set out in the Council of Ministers Decree N257/2004 (OJ 87, 2004, last amended August 2006) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of

pricing in Bulgaria (“Regulation”). Their relation with the manufacturer is on a contractual basis and also depends on whether the wholesaler is the exclusive importer of the pharmaceutical and on the volume of the sales. Other conditions, i.e. payment terms, expiry dates, etc. also influence the extent of the remuneration.

Regulation of the mark ups is defined as a regressive scheme, shown in Table 3.4, valid only for prescription-only medicine(s) (POM). In the third column, the range of pharmacy purchase prices are indicated in monetary terms.

Table 3.4: Bulgaria - Wholesale mark-up scheme 200

Ex-factory price in BGN / €	Maximum mark up as a % of ex-factory price	Wholesale price range in €
BGN 0.01 / € 0.005 – BGN 7.00 / € 3.58	10	€ 0.0055 – € 3.94
BGN 7.01 / € 3.59 – BGN 30.00 / € 15.34	9	€ 3.91 – € 16.72
> BGN 30.01 / € 15.35	7	Not more than BGN 15.00 / € 16.42

Source: Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria

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 most of them have similar mark up as the prescription-only medicine(s) (POM), because when the “Regulation” was amended, the registered prices were automatically transferred to the over-the-counter (OTC) products register.

3.5.2 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. Table 3.5 shows the regressive mark ups. As example, the relevant price ranges (pharmacy purchase price and pharmacy retail price) are indicated.

Table 3.5: Bulgaria - Pharmacy mark-up scheme 2006

Ex-factory price in BGN / €	Wholesale maximum mark up as a % of ex-factory price	Pharmacy mark-up coefficient as a % of pharmacy purchasing price (PPP)
BGN 0.01 / € 0.005 – BGN 7.00 / € 3.58	10% 0.0055 – 3.94 €	28% 0.0064 – 4.58 €
BGN 7.01 / € 3.59 – BGN 30.00 / € 15.34	9% 3.91 – 16.72 €	25% 4.49 – 19.17 €
> BGN 30.01 / € 15.35	7 % 32.11 € (Not more than +15.00 BGN)	20% 36.01 € (Not more than 30.00 BGN)

NCU = national currency unit (BGN), PPP = pharmacy purchasing price

Source: Council of Ministers Decree N257/2004 (OJ 87, 2004) for adopting a regulation on the terms and conditions of the pricing of pharmaceuticals at their retail sale, defining the method of pricing in Bulgaria

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 most of them have similar mark up as the prescription-only medicine(s) (POM), because when the “Regulation” was amended, the registered prices 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 is valid for both prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals.

3.5.3 Remuneration of other dispensaries

Not applicable.

3.5.4 Value-added tax

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

3.5.5 Other taxes

Not applicable.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

There are no legal requirements concerning pharmaceuticals discounts. They may be both in cash and in kind, and are negotiated between the manufacturer and the wholesaler within their contract. In the pharmacies the most popular type of discount is in kind. Both types of discount are voluntary, although in the regulation for the National Health Insurance Fund (NHIF) it states, e.g., that the suppliers of insulin should provide needles or injectable devices free of charge.

3.6.2 Margin cuts

Not applicable.

3.6.3 Price freezes / Price cuts

Not applicable.

3.6.4 Price reviews

Not applicable.

4 Reimbursement

4.1 Organisation

At the time of writing the reimbursement system in Bulgaria consists of four segments. One part is funded by the republican budget through the Ministry of Health (MoH); another consists of a minimum list of pharmaceutical products at the disposal of the hospital pharmacies within in-patient health care establishments; a third portion includes 75% coverage by the municipality budgets and 25% by the veterans as set out in the War Veterans Act; and undoubtedly the most considerable aspect of the reimbursement system, in terms of medical and economic considerations, was put into action with the passing of the Health Insurance Act in 1998 and the establishment of the National Health Insurance Fund (NHIF) in 1999.

Of the total number of market authorisation pharmaceutical products in the year 2002 (4,550), over 55% have been included in all types of reimbursement lists.

The existence of a system of such scope results in higher operating and maintenance costs, including distribution of the responsibility among the different structures, as well as the difficult (or impossible at this stage) collection, summarising and analysing of the information/data related to this sector.

4.2 Reimbursement schemes

One source of reimbursement is the republican budget, through the Ministry of Health (MoH), covering 100% of the pharmaceutical expenditure (PE) related to the provision of treatment of 12 groups of diseases and conditions (Regulation N36) including treatment of patients after transplantation of organs and tissues, cancer patients, AIDS patients, patients undergoing haemodialysis, etc., as well as the expenses for the provision of pharmaceuticals, covered by national programmes, the country's vaccination schedule, etc.

"Centralised deliveries" of pharmaceuticals, provided by funds from the Ministry of Health's (MoH) republican budget have existed since the end of 1997 according to Regulation N12 of the Ministry of Health (MoH). 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.

Another aspect is the existing list of pharmaceuticals available in the hospital pharmacies and in the health establishments for hospital care, according to Appendix 10 of Regulation N8 of June 23 2000 on the set-up, order and organisation of the operation of pharmacies and the product range of pharmaceuticals. This list is organised by International Non-proprietary Name(s) (INN) and gives the minimum nomenclature that should be available in the hospital pharmacy. The type of hospital – district or municipal – is also taken into consideration.

There is a limited but relatively well socially oriented list of pharmaceuticals for reimbursement, which has been established in fulfilment of the provisions of the War Veterans Act. Within this list, 75% of the expenses are covered by the municipal budgets, 25% by the veterans.

Since 2000, the model for the financing and reimbursement of pharmaceuticals in Bulgaria is in effect carried out according to four separate mechanisms (cf. 4.2).

There is no doubt that the adoption of the Health Insurance Act in 1998 (OJ 70, 1998, last amended OJ 59, 2006) and the establishment of the National Health Insurance Fund (NHIF) are key elements of the reimbursement system in medical and economic terms. This is the legal basis for changing the Bulgarian health care system and for the introduction of both compulsory and voluntary health insurance (VHI) in the country.

The compulsory health insurance is a system of social health protection for the population, which guarantees a package of health-related services, and is administered by the National Health Insurance Fund (NHIF) and carried out by its territorial divisions – the 28 Regional Health Insurance Funds (RHIF).

Voluntary health insurance (VHI) is supplementary and is implemented by joint-stock companies registered under the Commercial Law and licensed under the terms and procedures of the Health Insurance Act.

The Health Insurance Act also regulates the signing of the National Framework Contract between National Health Insurance Fund (NHIF) and the professional associations of health care providers – doctors and dentists. The National Framework Contract 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. The National Framework Contract is valid for one year, until the signing of the next one. The first National Framework Contract was signed on 27 April 2000.

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 Law on Pharmaceuticals and Pharmacies in Human Medicine (OJ 10/2000), and the War Veterans Act (OJ 152, 1998), as well as the regulations related to their application.

It is important to mention the significance of the National Framework Contract, signed each year between representatives of the National Health Insurance Fund (NHIF), the Bulgarian Medical Union, the Bulgarian Dentists Union (BDU) and the Minister of Health, as well as Regulation N38 of December 12, 2003 on specifying the list of diseases for which out-patient treatment the National Health Insurance Fund (NHIF) pays fully or partially (OJ 106, 2004, last amended OJ 70 of 2006). At the time of writing the criteria for selection of these diseases are not specified in the regulation. The National Health Insurance Fund (NHIF) reimbursement list of partially or fully paid pharmaceuticals is created on the basis of this list.

In 2004, with Council Decree N211 (OJ 73), a regulation was adopted on the terms and conditions for negotiating the pharmaceuticals, medical devices and dietary medical foods which are paid fully or partially by the National Health Insurance Fund (NHIF). It specifies the criteria and

conditions for negotiating the specific pharmaceuticals and the methodology for defining their level of payment as well as their prices.

According to Art. 45, paragraph 5 of the Health Insurance Act, the Bulgarian Medical Union (BMU) and the Bulgarian Dentists Union (BDU), but *not* the Bulgarian Pharmaceutical Union (BPU) are involved in the negotiation procedure for purchasing reimbursed pharmaceuticals.

The process of creating and negotiating the reimbursement list is organised and carried out by three commissions established by the Director of the National Health Insurance Fund (NHIF), listed here.

1. Commission on the preparation of the draft pharmaceutical list – specification by international non-patent names and forms and grouping in categories.
2. Commission on the preparation of draft documentation for participation in the negotiation procedure.
3. Commission on carrying out the negotiation end evaluation of the results according to Art. 14 of the Health Insurance Act.

4.2.1 Eligibility criteria

Since 2004, the criteria for inclusion of the pharmaceuticals in the reimbursement list of National Health Insurance Fund (NHIF) are defined in Art. 4 of the Regulation on the terms and conditions for negotiating the pharmaceuticals, medical devices and dietary medical foods which are paid fully or partially by National Health Insurance Fund (NHIF). They are listed here.

1. The pharmaceutical, the pharmaceutical(s) contained in it and the pharmaceutical form under which it is offered, should be included in Part A and Part B of the Positive Drug List (PDL), according to Art. 10, paragraph 2 of the Law on Pharmaceuticals and Pharmacies in Human Medicine.
2. There should be compliance between the indications for the pharmaceutical application, included in the market authorisation, and the diseases list, according to the Regulation as per Art. 45, paragraph 3 of the Health Insurance Act.
3. The pharmaceutical form and the quantity of the pharmaceutical substance should be intended for out-patient treatment.
4. The International Non-proprietary Name (INN) to which the pharmaceutical belongs should be included in the pharmaceutical list covered by the public social insurance fund of at least three of the following countries: Slovenia, Greece, the Czech Republic, Poland, Hungary, Latvia, Romania, Slovakia.

4.2.2 Reimbursement categories and reimbursement rates

The pharmaceuticals in the National Health Insurance Fund (NHIF) list are grouped into three reimbursement categories, as show in Table 4.1. The maximum reimbursement level for each

International Non-proprietary Name (INN) is defined as a percentage, according the reimbursement categories.

Table 4.1: Bulgaria - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate (%)	Characteristic of category
Category I	Up to 100	Pharmaceuticals for out-patient treatment of low morbidity and mortality, but leading to significant deterioration of the health status and disability of the patients. The pharmaceuticals are prescribed according to Art.78, paragraph 2 of the Health Insurance Act.
Category II	Up to 100	Pharmaceuticals for out-patient treatment of common diseases, which require long and continuous treatment, including cardiovascular, mental, neurological, broncho-obstructive and metabolic diseases.
Category III	Up to 75	Pharmaceuticals for out-patient treatment of the remaining diseases included in the regulations, according to Art. 45, paragraph 3 of the Health Insurance Act.

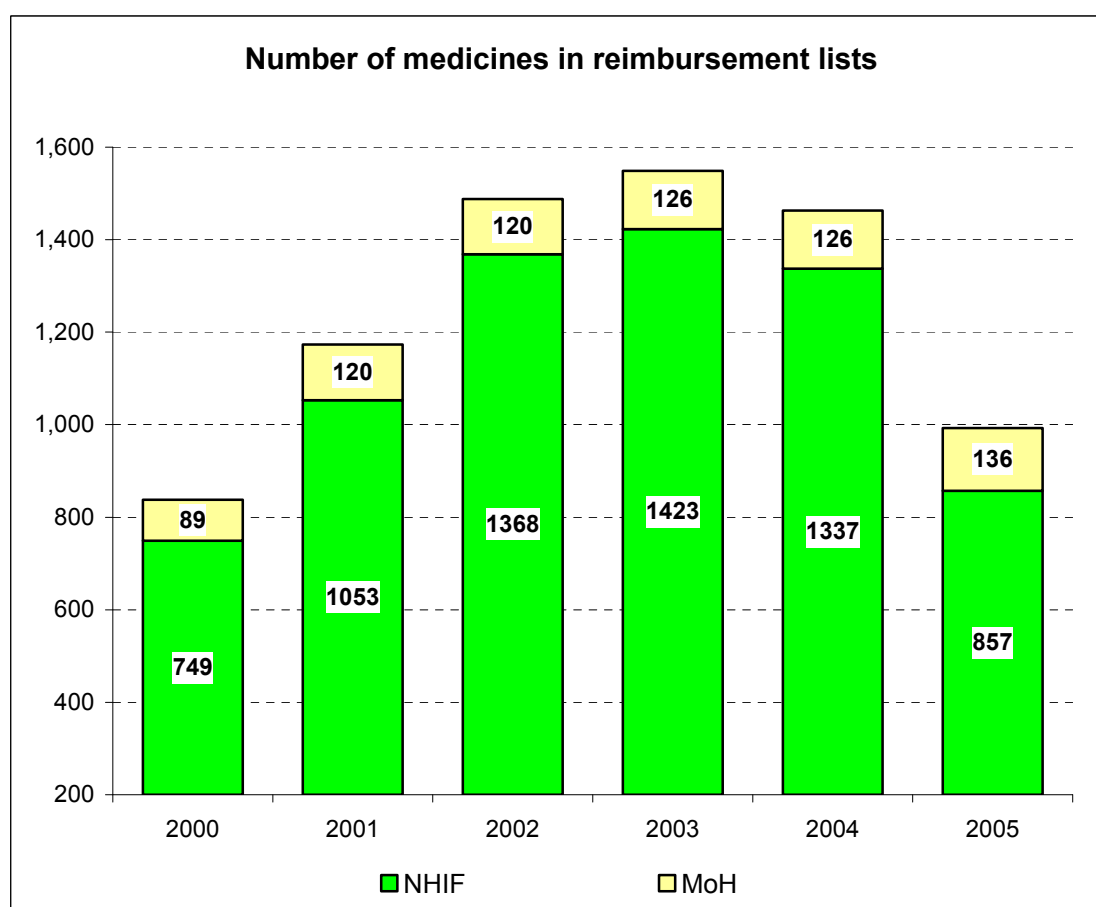
Source: Council Decree N211 (OJ 73) Regulation on the terms and conditions for negotiating of the pharmaceuticals, medical devices, dietary medical food which are paid fully or partially by National Health Insurance Fund (NHIF)

The maximum value that the National Health Insurance Fund (NHIF) pays for a unit active ingredient (International Non-proprietary Name (INN)) is defined as follows:

1. the lowest value for a unit active ingredient and pharmaceutical form from the previous year and the average value per unit active ingredient by International Non-proprietary Name (INN) covered by the public social insurance funds of the following countries: Slovenia, Greece, the Czech Republic, Poland, Hungary, Latvia, Romania and Slovakia;
2. the value from point 1 is multiplied by not less than 25% and not higher than the maximum level for each category, defined according to the social importance of the disease and if it is for first line treatment or symptomatic treatment, as well as considering the level from the previous year.

Figure 4.1 presents the development of the reimbursement lists of the Ministry of Health (MoH) and the National Health Insurance Fund (NHIF). The pharmaceuticals in the Ministry of Health (MoH) list are fully paid by the budget and their number is gradually increasing. The pharmaceuticals in the National Health Insurance Fund (NHIF) list are fully or partially covered and in significantly decreased in 2005 for financial reasons, connected with overspending of the National Health Insurance Fund (NHIF) budget.

Figure 4.1: Bulgaria - Development of pharmaceuticals in reimbursement lists* 2000-2005



* Pharmaceuticals included in the Ministry of Health (MoH) and National Health Insurance Fund (NHIF) lists

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

Source: MoH, 2002, Round table on National Drug Policy and NHIF

4.2.3 Reimbursement lists

In 2003, for the first time in Bulgaria a Positive Drug List (PDL) was introduced (an updated list for 2007 is available on <https://www.zdrave.net>). In 2006, the List included 574 substances (2,473 trade names (International Non-proprietary Name (INN))) and consists of two parts – Part A and Part B.

According to Art. 2 of Council Decree N81 (OJ 34, 2003, last amended OJ 64 of 2006) on the regulation of the criteria and terms for inclusion of pharmaceuticals in the Positive Drug List (PDL), in Part A the pharmaceuticals are arranged according to the health needs of the population, presented by International Non-proprietary Name (INN) with their approved concentrations and pharmaceutical forms.

In Part B, pharmaceuticals are listed which were candidates to be included in the Positive Drug List (PDL) and which meet the requirements in Part A. The products in Part B are arranged ac-

according to the proof of their quality, efficacy and safety and the analysis of their pharmaco-economic indices. The sequence into which the pharmaceuticals of the relevant International Non-proprietary Name (INN) are arranged carries information as to what extent a certain pharmaceutical is recommendable for reimbursement.

Table 4.2: Bulgaria - Positive Drug List (PDL) I, Part A

ATC code	INN	Quantity of active substance	Pharmaceutical form
1	2	3	4
A02BA04	Nizatidine	25 mg/ml - 4 ml	sol.inf.
A02BC01	Omeprazole	20 mg	caps. gastr.-res.
		20 mg	caps.
		10 mg	caps.
		40 mg/ml- 10 ml	powd.inf.

ATC = Anatomic Therapeutic Chemical (classification), INN = International Non-proprietary Name

Table 4.3: Bulgaria - Positive Drug List (PDL) II, Part B

ATC code	INN	Trade name	Active substance quantity	Pharmaceutical form	Holder of the market authorisation	Manufacturer(s)
1	2	3	4	5	6	7
A02BA04	Nizatidine	Axid	25 mg/ml - x 5 4 ml	sol.inf.	Eli Lilly Export S.A. Geneva, Switzerland 16, Chemindes coquelicots, P.O.Box 580, CH - 1214 Vernier, Geneva Switzerland	Eli Lilly Italia S.p.A., Via Gramsci, 733, Sesto Fiorentino (Firenze), Italy Alfa Wassermann SpA, Contrada S. Emidio Alanno Scalo Percara, Italy
A02BC01	Omeprazole	Bioprazol	20 mg x 28	caps.	Inbiotech OOD	Inbiotech OOD
A02BC01	Omeprazole	Ulcoprol	20 mg x 30	caps. gastr.-res.	Balkanpharma—Dupnitsa AD	Balkanpharma—Dupnitsa AD
A02BC01	Omeprazole	Bioprazol	20 mg x 14	caps.	Inbiotech OOD	Inbiotech OOD
A02BC01	Omeprazole	Sopral	20 mg x 28	caps.	Sopharma AD	Sopharma AD
A02BC01	Omeprazole	Probitor	20 mg x 7	caps. gastr.-res.	Biochemie GmbH, 10 Biochemiestrasse 6250 Kundl/Tyrol-Austria	Esteve Quimica S.A., Av. Mare de Deu de Montserrat 12, 08024 Barcelona Spain

PPRI - Pharma Profile
Bulgaria

ATC code	INN	Trade name	Active substance quantity	Pharmaceutical form	Holder of the market authorisation	Manufacturer(s)
1	2	3	4	5	6	7
A02BC01	Omeprazole	Probitor	20 mg x 28	caps. gastr.-res.	Biochemie GmbH, 10 Biochemiestrasse 6250 Kundl/Tyrol-Austria	Esteve Quimica S.A., Av. Mare de Deu de Montserrat 12, 08024 Barcelona Spain
A02BC01	Omeprazole	Probitor	20 mg x 14	caps. gastr.-res.	Biochemie GmbH, 10 Biochemiestrasse 6250 Kundl/Tyrol-Austria	Esteve Quimica S.A., Av. Mare de Deu de Montserrat 12, 08024 Barcelona Spain
A02BC01	Omeprazole	Omeprazol AL 20	20 mg x 30	caps. gastr.-res.	Aliud Pharma GmbH & Co.KG	Aliud Pharma GmbH & Co.KG
A02BC01	Omeprazole	Omeprazol AL 20	20 mg x 15	caps. gastr.-res.	Aliud Pharma GmbH & Co.KG	Aliud Pharma GmbH & Co.KG
A02BC01	Omeprazole	Helicid 20	20 mg x 14	caps.	Leciva a.s. - Czech republic	Leciva a.s. - Czech republic
A02BC01	Omeprazole	Helicid 10	10 mg x 28	caps.	Leciva a.s. - Czech republic	Leciva a.s. - Czech republic
A02BC01	Omeprazole	Helicid 20	20 mg x 28	caps.	Leciva a.s. - Czech republic	Leciva a.s. - Czech republic
A02BC01	Omeprazole	Helicid 10	10 mg x 14	caps.	Leciva a.s. - Czech republic	Leciva a.s. - Czech republic
A02BC01	Omeprazole	Losec	40 mg/ml-10 ml x 5	poud.inf.	AstraZeneca Ltd, Home Park, Kings Langley, Hertfordshire, WD4 8DH, UK	AstraZeneca AB, S - 151 85 Södertälje, Sweden; AstraZeneca GmbH, Otto-Hahn-Strasse, 68723 Plankstadt, Germany

ATC = Anatomic Therapeutic Chemical (classification), INN = International Non-proprietary Name

The criteria and conditions for including pharmaceuticals in the Positive Drug List (PDL) are specified by Section II of the Regulation on the criteria, conditions and rules for including pharmaceuticals in the Positive Drug List (PDL) of the Republic of Bulgaria.

In general, the regulation in force has several important weaknesses, listed here.

- No mechanism is provided for including in Part B a new authorised pharmaceutical, the International Non-proprietary Name (INN) of which is already in Part A.
- The separation of the list into two parts itself negates the concept of a Positive Drug List (PDL), i.e. a choice among pharmaceutical molecules and not trade names.
- In practice, the procedure for annually updating the lists puts the pharmaceuticals authorised after 31 May each year in the position of a minimum 17-month delay in access to the reimbursement market.

The Positive Drug List (PDL) is updated annually and published in the Official Journal.

4.3 Reference price system

Art. 3 of the Regulation on the terms and conditions for negotiating the pharmaceuticals, medical devices and dietary medical foods which are paid fully or partially by National Health Insurance Fund (NHIF) defines the methodology for calculating the payment levels of the annually reimbursed pharmaceuticals. For that purpose the reference price of a unit active ingredient of an International Non-proprietary Name (INN) is calculated, including the pharmaceutical form.

Art. 21 of the same Regulation states that pharmaceuticals are grouped at Anatomic Therapeutic Chemical classification ATC-5 level by pharmaceutical form. The value of a unit active ingredient for each pharmaceutical form is then calculated according to the prices proposed by the producers. The lowest value is chosen and this is the reference value for each pharmaceutical from the respective group for that year's reimbursement list.

For similar pharmaceuticals an average monthly therapeutic course of treatment is used.

For combinations, the reference value is set as per the lowest values of the components of the pharmaceutical. In the event that such values are not available the reference price is determined according to the level at which the National Health Insurance Fund (NHIF) covers that pharmaceutical group.

As soon as the reference value is defined, it is then multiplied by the quantity of the units of active ingredient in each particular pharmaceutical.

For the pharmaceuticals from Category I, the National Health Insurance Fund (NHIF) only reimburses the pharmaceutical which has the lowest price within Anatomic Therapeutic Chemical classification ATC-4 level.

For all insulin products the National Health Insurance Fund (NHIF) negotiates the price, the criteria for which should be as follows:

- the price should not be set higher than in the previous negotiations;
- prices of similar products, which have not been negotiated before, should not be higher than those that are already contracted;
- for those that are without equivalents, the price should not be higher than the lowest price in the pharmaceuticals covered by public health insurance funds in one of the countries listed above (cf. 4.2.1).

The reference price is an element of the reimbursement price. It is the lowest price for a unit active ingredient for the same pharmaceutical form, calculated according to the annual applications of the producers. The value that the National Health Insurance Fund (NHIF) pays for each trade name is then calculated by multiplying the quantity of the active ingredient within it.

In 2005, the Ministry of Health (MoH) introduced a maximum value of International Non-proprietary Name(s) (INN) for a pharmaceutical form, for the public procurement of fully reimbursed pharmaceuticals. This value should not be exceeded and is included in the specification for the tender. The maximum value is the lower 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.

4.4 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 veterans co-payment level, which is 25%.

4.4.1 Direct payments

Patients pay directly for all pharmaceuticals that are not included in the previously mentioned reimbursement lists.

4.4.2 Out-of-pocket payments

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

4.4.2.1 Fixed co-payments

Not applicable.

4.4.2.2 Percentage co-payments

There are percentage co-payments which vary for each pharmaceutical.

Besides the categories of fully reimbursed pharmaceuticals (Group IA and IB), Group IC contains some pharmaceuticals which are fully reimbursed, others which are partially reimbursed, and some which are only 10% reimbursed.

In Group II, some pharmaceuticals are fully reimbursed, some not at all, and some are reimbursed at a certain percentage. In addition, this group carries information about the administrative procedure of prescribing and dispensing the pharmaceuticals. The prescription and all documentation for pharmaceuticals from Group IA are approved by a commission in the central administration of the National Health Insurance Fund (NHIF); for Group IB these are approved

by a commission in the regional administration; and for Group II by all physicians contracting with the National Health Insurance Fund (NHIF).

The information on percentage co-payments is summed up in Table 4.2.

Table 4.4: Bulgaria - Reimbursement rates and patient co-payment rates 2006

Reimbursement groups	Co-payment rate in %	Reimbursement rate in %
Group IA (pharmaceuticals from Category I) E.g. Venofer, Oncotrone	0	100
Group IB (pharmaceuticals from Category I) E.g. Dostinex, Endoxan	0	100
Group IC (pharmaceuticals from Category I) E.g. Mixtard 20 NovoLet Tegretol 200 mg	Up to 90 0 52.04	Up to 100 100 47.96
Group II (pharmaceuticals from Category II and III) E.g. Diaprel MR Cefzil	Up to 100 68.53 75.98	Up to 100 31.47 24.02

4.4.2.3 Deductibles

Not applicable.

4.5 Reimbursement in the hospital sector

The pharmaceuticals in the hospitals in Bulgaria are paid through the state budget or through the National Health Insurance Fund (NHIF) as a part of the medical activities carried out. The pharmaceuticals are included in the cost of treatment and the patient is not supposed to pay for them when receiving treatment in hospital.

4.6 Reimbursement-related cost-containment measures

4.6.1 Major changes in reimbursement lists

The first National Health Insurance Fund (NHIF) reimbursement list started with 749 pharmaceuticals in 2000. In 2001 it was expanded to 1,053 pharmaceuticals. In 2002 the National Health Insurance Fund (NHIF) signed framework contracts for 1,368 products (433 of them fully and 935 partially reimbursed). In 2004 the list reached as many as 1,418 pharmaceuticals, in 2005 it contained 1,081 and in January 2006 it consisted of 1,082 pharmaceuticals (cf. Figure 4.1).

In 2003, the parties of the National Framework Contract agreed that a list negotiated according to the National Framework Contract for 2002 would remain, until the Positive Drug List (PDL) entered into force in compliance with Art. 10, paragraph 2 of the Human Medicines and Pharmacies Act. In 2003, the National Health Insurance Fund (NHIF) carried out three amendments to the list of reimbursement pharmaceuticals – in January, February and May. The purpose of the amendments was to limit the expenses for pharmaceuticals.

The amendments made were related to:

- decreasing the level of payment for certain pharmaceutical groups by the National Health Insurance Fund (NHIF);
- introducing restrictive mechanisms to decrease the prescription of high doses, or large numbers of pharmaceuticals, by limiting the prescribed items for one disease.

4.6.2 Introduction / review of reference price system

Not applicable.

4.6.3 Introduction of new / other out-of-pocket payments

Not applicable.

4.6.4 Claw-backs

Not applicable.

4.6.5 Reimbursement reviews

The reimbursement decisions are reviewed mostly in terms of expenditure. If the expenditure is running high in comparison with the allocated budget, then the reimbursement decisions are reviewed. The National Health Insurance Fund (NHIF) is involved in this type of review.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

Not applicable.

5.2 Prescription guidelines

There are no official prescription guidelines. Regulation N4 on the terms and conditions for prescribing and dispensing pharmaceuticals sets out some purely administrative criteria such as maximum quantities prescribed for acute or chronic diseases, maximum number of pharmaceuticals prescribed for one disease, etc. 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.

5.3 Information to patients / doctors

The Law on Pharmaceuticals and Pharmacies in Human Medicine and Regulation N13 (OJ 59, 2000) on the terms and conditions for approving the advertising of pharmaceuticals define the requirements for information to patients and doctors, more or less in compliance with the Directive 2001/83/EC. They set out the basic requirements regarding the contents of advertisement messages meant for the general public and professionals. Other areas of regulation include the activities carried out by the medical representatives of pharmaceutical manufacturers, the conditions under which samples of registered pharmaceuticals may be provided, and so on. The legislation defines the process for the approval of medical advertisements as well as the sanctions to be imposed for non-observance of the advertisement rules.

5.4 Pharmacoeconomics

Health economics analysis and particularly pharmacoeconomic analysis have no long history in the Bulgaria. The one legal provision in this field is in the regulation on the terms and conditions for including pharmaceuticals in the Positive Drug List (PDL), from 2003. This provision is very general and it simply mentions that pharmacoeconomic analysis is taken into consideration when ranking the pharmaceuticals in Part B of the Positive Drug List (PDL).

5.5 Generics

Generics are so far not mentioned in Bulgarian legislation. The introduction of generic substitution, prescription and promotion is regularly discussed in the professional societies and the Association of Bulgarian Pharmaceutical Manufacturers (ABPM) is actively participating, but no practical legislative steps have been taken. Such action is not foreseen in the National Health Care Strategy 2007-2012.

Table 5.1: Bulgaria - Development of the generics market in the out-patient sector 2000-2005

Generics market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

5.5.1 Generic substitution

Not applicable.

5.5.2 Generic prescription

Not applicable.

5.5.3 Generic promotion

Not applicable.

5.6 Consumption

Not applicable.

6 Current challenges and future developments

6.1 Current challenges

- Development of a National Drug Policy, including selection and approval of indicators relevant to the various National Drug Policy components; and checking the reliability and validity of the indicator-based information.
- Unifying the fragmented reimbursement system.
- Development of information links between the Ministry of Health (MoH), the Bulgarian Drug Agency (BDA) and the National Health Insurance Fund (NHIF); as well as development of their own information systems.
- More comprehensive disclosure of information in web sites, annual reports and public forums concerning public procurement and other statistical information.
- Establishing an independent body for the selection and procurement of pharmaceuticals in all sectors of the system.
- Promotion of rational use of pharmaceuticals.
- Creating a system for the professional development of personnel in the pharmacoeconomic field.
- Creating a system to monitor pharmaceutical consumption.

6.2 Future developments

A newly amended Law on Pharmaceuticals and Pharmacies in Human Medicine (which in practice will be a new law) is expected to be voted by the Parliament at the end of the year 2006 (or the beginning of 2007), which will be the basis for the changes in the system over the short and medium term.

The Ministry of Health (MoH) has presented its National Health Care Strategy 2007-2012 (<http://www.mh.government.bg>), in which Goal No. 5 describes the vision of the Ministry of Health (MoH) regarding the development of the pharmaceutical sector.

Strategic Goal 5: Transparent and fair pharmaceutical policy

Objectives are:

- raising patient awareness of pharmaceutical policy;
- guaranteeing quality and establishing strict control over prices and introducing a fair system of reimbursement of pharmaceuticals and medical articles;

- raising patient awareness of the correct use of pharmaceuticals and implementing rational pharmaceutical treatment.

The approaches intended to achieve the goals are:

- printing ceiling prices and the amount payable by the patient on the packaging of pharmaceuticals to defend the rights of patients;
- building a system to monitor health establishments' prescription of pharmaceuticals;
- creating incentives for payment of pharmaceuticals outside the reimbursement system, by Voluntary Health Insurance Funds (VHIF).

7 **Appendixes**

7.1 **References**

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7.3 Authors

Dr. Semerdjiev graduated from the Stomatological Faculty of the Medical Academy in Sofia in 1984. Subsequently he specialised in health management and management of social and health insurance in the United States, United Kingdom, Ireland, Iceland, Spain, France and Germany.

Dr. Semerdjiev has an MA in health management and is currently undertaking a Ph.D in Business Administration from the Prof. Assen Zlatarov University in Bulgaria.

His professional experience includes work at all levels of the health care system – starting as a doctor in a village health service through to being a director of a medical centre and later of a hospital in Sofia.

In his career he has been Deputy Minister of Health three times, in three governments; he is founder and first Director of the National Health Insurance Fund (NHIF); and was Minister of Health of the Republic of Bulgaria in 1999-2001 in the Government of the United Democratic Forces.

Dr. Semerdjiev is founder of the Bulgarian Medical Union in 1989 and was its Deputy Chairman for two mandates.

He is founder and Member of the Boards of the Private Health Care Establishments Association (1993-1997), the Medical Law Association (1994-1997) and the Health Managers Association in Bulgaria (2002). For two mandates he was Member of the Supreme Medical Council, and for one mandate he was its Chairman. Dr. Semerdjiev was also Chairman of the Supreme Pharmacy Council and of the National Council on Narcotic Substances, as well as being Member of the Governing Board of the National Insurance Institute (1993; 1997-1998) and of the Board and the Assembly of the Representatives of the National Health Insurance Fund (NHIF) (1999-2002).

Dr. Semerdjiev is author of many publications and books in the field of health policy, health reform, health care management and health insurance. He led the team that developed the National Health Strategy 2001-2010 and the Action Plan accompanying it.

At present he is Chairman of the International Healthcare and Health Insurance Institute.

Gergana Andre has a Master's Degree in Pharmacy from the Faculty of Pharmacy at the Medical University in Sofia and a Master's Degree in Health Management, as well as a postgraduate specialisation in "Economy and management of the wholesale and retail sale sectors".

Since 1995 she has been working in the pharmaceutical sector for the Bulgarian state administration and a number of nongovernmental organisations.

From 2000 to 2002 Mrs. Andre led the “Drug Policy” Department at the Ministry of Health (MoH) in Bulgaria, where she was responsible for harmonisation of the legislation specific to the pharmaceutical sector with European Union (EU) standards. In addition, she was Member of the specialised committee for approving clinical trials and Member of the specialised council for approving pharmaceutical advertisements.

At present Mrs. Andre is Head of the “Pharmaceutical Analysis and Drug Policy” Department of the International Healthcare and Health Insurance Institute where she works on the integration of information in the pharmaceutical sector, as well as organisation and participation in international projects in the pharmaceutical sector, including projects under the Phare Programmes, DG SANCO, participation in the Study of Governance in Bulgaria’s Pharmaceutical System by the IRIS Center, University of Maryland, etc.