Reducing Public Spending at Private Expense? Out-of-pocket Pharmaceutical Expenditure in Bulgaria after the 1998 Healthcare Reform

By Adelina Gotseva

Submitted to

Central European University

Department of Economics

In partial fulfillment of the requirements for the degree of Master of Arts in Economic Policy in Global Markets

Supervisor: Prof. Péter Mihályi

Budapest

2015

Abstract

Bulgaria ranks among the countries in Europe with the lowest public expenditure on pharmaceuticals. In contrast, private expenditure usually expressed as out-of-pocket (OOP) payments represents a significant cost burden for some patient groups. Hence, foregone pharmaceutical consumption has often resulted in reduced health and economic benefits for patients themselves and society as a whole. Using three pharmaceutical consumption datasets from the World Health Organization for the period 2000-2006, IMS Health for 2009, and the European Commission for 2010, this thesis focuses on the post-2000 period to investigate the trends in private pharmaceutical expenditure in Bulgaria and to compare them to those in other European countries. It finds that over the period 2000 – 2010 following the 1998 Bulgarian healthcare reform which introduced social health insurance and out-patient pharmaceutical co-payment, Bulgaria has had one of the highest private out-patient pharmaceutical expenditure levels in Europe, and Bulgarian households have been paying an ever-increasing share of total pharmaceutical expenditure relative to income. Although OOP spending largely resulting from the patient co-payment mechanism is commonly recognized as beneficial to the public pharmaceutical budget, and it also decreases the demand-side moral hazard posed by patients, OOP expenditure on pharmaceuticals in Bulgaria is unsustainable in view of future fiscal and demographic challenges. The paper also investigates the factors that have potentially contributed to the high OOP spending, and provides policy alternatives to strengthening the financial protection of the Bulgarian health system.

Key words: health expenditure, pharmaceuticals, out-of-pocket expenditure, private spending, public spending, reimbursement policies, reference pricing

Acknowledgements

I would like to thank my supervisor Péter Mihályi, Professor in Health Policy at the Central European University (2015), for his advice and guidance during the thesis writing process. I would also like to thank Frederik Verelst, MSc Economics student at the Katholieke Universiteit Leuven (2015) and Krisztina Perlaky-Tóth, MA Economic Policy student at the Central European University (2015) for their valuable thoughts and remarks.

Table of Contents

List of Figures

List of Tables

List of abbreviations

DDD	Defined Daily Dose
HE	Health Expenditure
MAH	Marketing Authorization Holder (pharmaceutical companies)
MoH	Ministry of Health
NCE	New Chemical Entity
NHIF	National Health Insurance Fund (Bulgaria)
OECD	Organization for Economic Cooperation and Development
OLS	Ordinary Least Squares (regression)
OOP	Out-of-pocket (expenditure)
OTC	Over-the-counter (medicines)
PbHE	Public Health Expenditure
PDL	Positive Drug List
POM	Prescription-only medicines
PPP	Purchasing Power Parity
PPS	Purchasing Power Standard (as measured by Eurostat, equivalent to PPP)
PvHE	Private Health Expenditure
Rx	Prescription (medicines)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VHIC	Voluntary Health Insurance Companies

Chapter 1: Introduction

General Background

Private out-patient pharmaceutical expenditure[1] in Bulgaria is not a post-1989 phenomenon. Unlike the provision of health services during the communist period which was financed entirely publicly, the access to out-patient pharmaceuticals has never been free of charge. As it happened in many other socialist countries, people bought out-patient medicines from the pharmacy network of the monopolistic State Pharmaceutical Company (Nikolova 2011). The retail price paid by the patients was heavily subsidized, but it was still a burden to many of them. During the early transition period in the 1990s, ambulatory care patients had to fully finance all their pharmaceutical needs, except children and some limited categories of patients (Koulaksazov 2003). However, during the 1990s medicines became much less affordable due to price liberalization, the plunge of the uncompetitive supply of domestically produced pharmaceuticals, and the influx of expensive imports. Due to the rise in pharmaceutical prices, public pharmaceutical expenditure as a share of government health expenditure nearly doubled from 12.3% in 1990 to 23.8% in 1998, only to fall back to 14.4% in 2000 after the price stabilization program in Bulgaria (Koulaksazov 2003). In the late 1990s the largest share of private health payments was spent on pharmaceuticals (Koulaksazov 2003). Social health insurance in out-patient care was only launched in July 2000 with the introduction of the 1998 Bulgarian Health Insurance Act establishing the National Health Insurance Fund (Datzova 2003). The Health Insurance Act of 1998 reformed the Bulgarian health system into one with compulsory and voluntary health insurance where the participating agents were: the insured individuals (patients), health care providers and third-party payers represented by the National

[1] Out-patient = ambulatory = therapy administered outside of hospitals.

Health Insurance Fund (NHIF)[2] and its regional representations (RHIFs), and Voluntary Health Insurance Companies (VHICs).

Currently, Bulgaria's *total* health expenditure seems to be in line with its income level, standing at about 7% of GDP ever since the early 2000s (The World Bank 2013). Although relatively low by EU standards, these figures are very similar to the ones in most of the new EU member states. However, as a share of total government expenditure, *public* health expenditure in Bulgaria lags behind most of the new EU members; in 2010 for instance it stood at less than 10% (The World Bank 2013). Additionally, with out-patient pharmaceutical expenditure of about 2.4% of GDP in 2010, Bulgaria is second only to Hungary in the EU (Figure 1). Thus, pharmaceuticals bought from pharmacy and drug store networks represent a significant share of national expenditure.

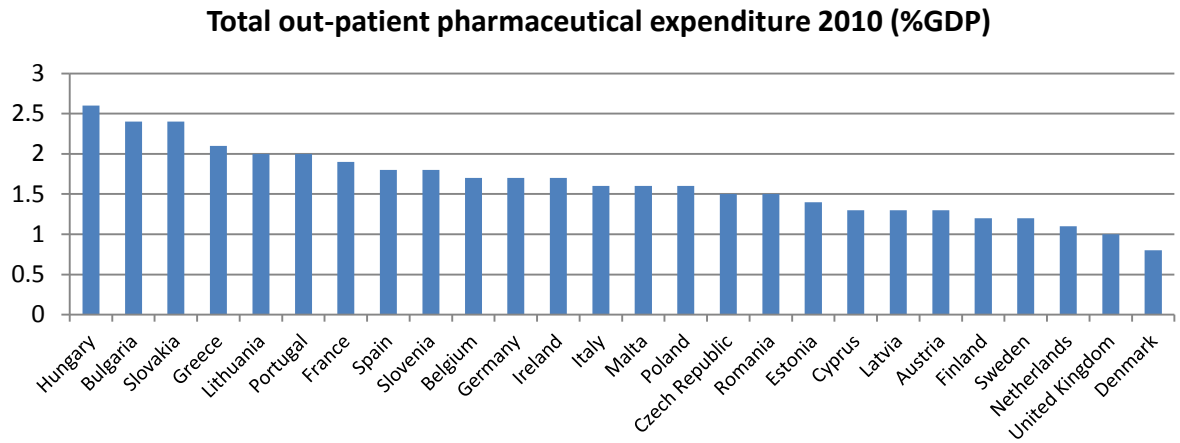


Figure 1. Total out-patient pharmaceutical expenditure 2010 (% GDP)

Source: EU Commission (Carone 2012). *Author's own presentation.*

A breakdown of health expenditures in 2011 indicates that retail purchases and medical goods in Bulgaria represent the second largest expenditure category after hospital expenditure (Figure 2). Bulgaria is also second among the Central and East European countries (CEE) according to the share that medical goods take up in total health expenditure. Thus, given the relatively low

[2] The NHIF is the sole payer that administers the social health insurance system in Bulgaria

public health expenditure, an educated guess leads to the assumption that out-patient pharmaceutical expenditure should be financed mostly with private rather than with public money. Indeed, in order to compensate for the low public share in health financing, out-of-pocket payments in Bulgaria take up a significantly larger part compared to the EU average (The World Bank 2013).

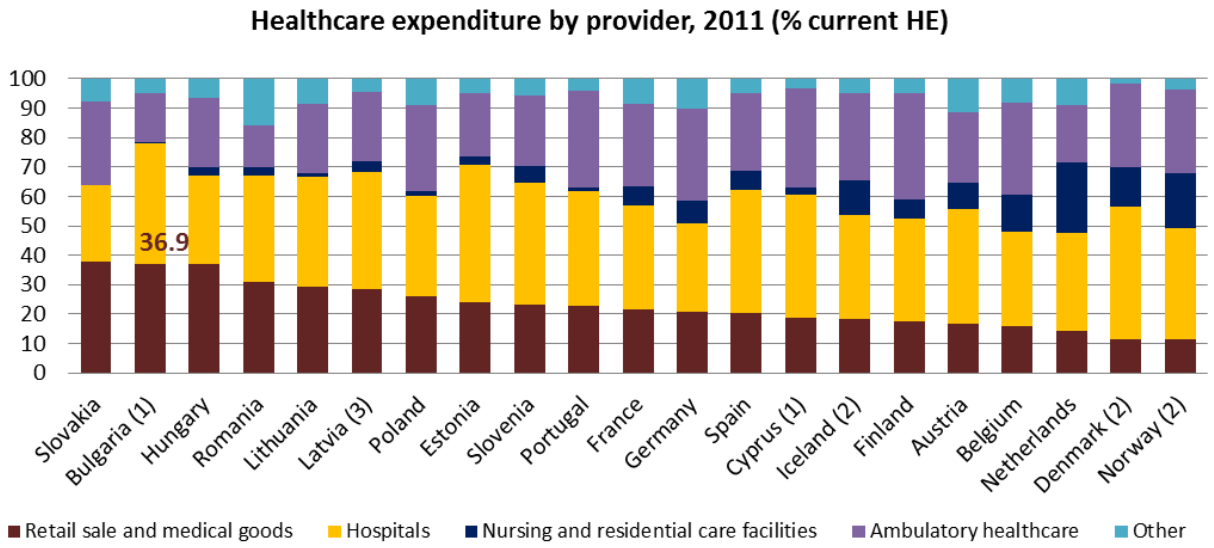


Figure 2. Healthcare expenditure by provider in 2011 (% of current health expenditure)

(1) 2008. (2) 2010. (3) 2009. Source: (Eurostat). *Author's own presentation.*

Today, the Bulgarian pharmaceutical sector is regulated and it follows much more market-oriented mechanisms in line with EU pharmaceutical legislation: the price of prescription medicines and the pharmaceutical reimbursement and disbursement rules are subject to national regulation. Similarly to most EU member states, the out-patient pharmaceutical financing system in Bulgaria is based on a mix of public and private payments, with patient co-payments reaching sometimes up to 75% of the regulated ex-factory (i.e. manufacturer's) price of prescription medicines. The price of over-the-counter (OTC) drugs, i.e. those that do not require a prescription, is not subject to price regulation and is only registered by

pharmaceutical companies with the National Council on Prices and Reimbursement of Medicinal Products.

By presenting a macro view of private pharmaceutical expenditure in the decade following the introduction of social health insurance, this thesis investigates the effectiveness of the post-2000 pharmaceuticals regulation in Bulgaria with respect to improving the access to, and affordability of, medicines and the financial protection provided by the health system in the later Transition period.

Key concepts

Out-patient pharmaceutical expenditure is defined as the spending on medical products during out-patient care, i.e. in a facility such as a doctor's private office, medical or ambulatory care center, where the patient goes for a consultation or treatment but is not admitted for hospitalization and overnight stay. Unlike during in-patient care where treatment occurs within a hospital environment and where expenditure on pharmaceuticals is 100% covered with public funds *via* public hospital budgets (Andre 2010), out-patient pharmaceutical expenditure in Bulgaria is only partially covered with public funds, just like in most EU member countries. Still, in-patients with chronic diseases for which they receive full or partial out-patient pharmaceutical treatment covered by the National Health Insurance Fund (NHIF) are supposed to carry their prescribed medication when hospitalized (Andre 2010). Patient **co-payment** is required in a number of out-patient pharmaceutical categories. It is based on conventional optimal insurance theory which suggests that co-payment, including the one in health insurance, increases social welfare by reducing moral hazard; thus, out-of-pocket payments are seen as beneficial not only to the third-party payer handling reimbursement but there is also an indirect demand-side effect that reduces moral hazard posed by patients (Nyman 2004).

For clarification purposes, this thesis classifies the major out-patient pharmaceutical categories in three groups as follows (Figure 3):

- critical,
- middle-range,
- and over-the-counter medicines (OTC).

The first group encompasses medicines of high societal importance such as life-saving medication, including but not limited to mandatory vaccinations, pharmaceuticals for the treatment of infectious diseases, diabetes, HIV/AIDS, etc. This group of medicines is financed entirely with public money in most of the EU countries including Bulgaria. On the contrary, medicines falling in the OTC group are paid entirely by the patient with no contribution from Bulgarian public funds. This group includes medication accessible without an official prescription from a physician. Lastly, the middle-range group includes medicines either fully, partially, or not at all financed with public money (at levels of 0%, 25%, 50%, 75%, or 100%) essential for the treatment of various chronic conditions, such as hypertension, etc.

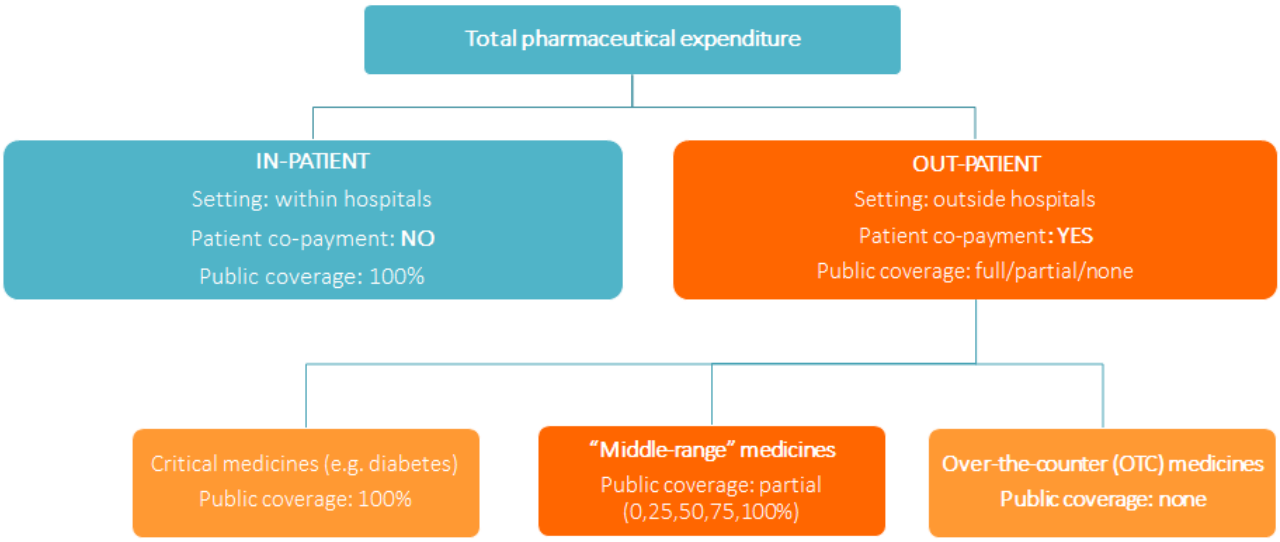


Figure 3. Structure of pharmaceutical categories

Source: Author

This thesis focuses particularly on out-patient pharmaceutical expenditure as opposed to total pharmaceutical expenditure for a few key reasons. First, the in-patient sector is largely irrelevant for the purposes of assessing the private financial burden of *pharmaceutical* expenditure due to its full public coverage and no patient co-payment requirements.

Second, out-patient treatment is crucial for capping total public health expenditure in the long run. That is, inadequate out-patient treatment poses potential threats to overall public health expenditure as patients deprived of appropriate out-patient care are exposed to higher risk of complications, and are later likely to undergo hospitalization much costlier to the public health budget compared to out-patient treatment. In fact, in-patient expenditure in Bulgaria, i.e. the costs associated with treatment in public hospitals and medical facilities, is the highest in Europe as a share of total health expenditure (Appendix III). This phenomenon can as well be due to other factors but inefficient out-patient treatment is also likely to have contributed to the problem of rising hospital admissions and in-patient costs, especially for chronic conditions. In addition to efficient out-patient treatment, prevention and screening, and early detection (e.g. breast-cancer screening) are other measures to decrease expensive hospitalization cost; however, this thesis does not discuss any additional measures other than out-patient pharmaceutical treatment.

Third, critical and middle-range medicines are both of high societal importance. More precisely, unlike critical medicines which are publicly covered in full, middle-range medicines are not and are therefore the pharmaceutical group of biggest interest for this thesis. Middle-range medicines treating predominantly chronic conditions help to improve personal productivity and increase quality of life. Hence, patient inability to access essential medication impacts negatively the patient's individual utility as well as overall level of economic activity due to lost work hours, both of the sick and the relatives providing care for them. Thus, excessive private co-payments and the often resulting inability to afford out-patient medication

are a burden for the individual patient as well as for the broader society in the longer run. These important phenomena often remain outside the scope of pricing and reimbursement decision-making frameworks.

Objectives and structure

This thesis represents a study of the structure, level and drivers of Bulgarian out-patient pharmaceutical expenditure in the late transition period following the 1998 healthcare reform. The analysis focuses on the post-2000 period and juxtaposes the Bulgarian situation with the ones in other European countries. Due to substantial data limitations on health performance indicators for reasons such as the fact that Bulgaria is not a member country of the Organization for Economic Cooperation and Development (OECD), and is one of the newcomers to the EU (joined 2007), thus is often excluded from international comparison statistical sources, this thesis presents a snapshot study based on three different datasets from different time periods and sources. Before all, the thesis aims to exclude misleading conclusions due to potential data measurement errors. It does so by performing analysis namely on three different datasets: from the World Health Organization, the European Commission and consulting company IMS Health (See Chapter 4). The thesis argues that Bulgaria is an extreme case according to its share of private out-patient pharmaceutical expenditure which the author finds to be abnormally high. Additionally, the author finds that Bulgaria is an extreme case with regards to the private expenditure particularly on out-patient *prescription* medicines. These findings pose questions on the effectiveness of the national health policy in the last decade, namely, in the period following the 1998 healthcare reform, which this thesis attempts to answer. The differentiation between the two findings is important because the second the one concerning *prescription* medicines points to the fact that patient access particularly to essential medication might be impaired. This is especially significant as it might have

repercussions on individual health as well as on economic activity and the general sustainability of the health system.

The thesis looks into **six potential explanations** as to why the private share in out-patient pharmaceutical expenditure might be abnormally high. It groups these explanations into two segments with respect to their source of origin: demand and supply side factors.

- **On the demand side**, possible explanations the thesis looks into are: a potentially high level of prescription pharmaceuticals consumption in Bulgaria due to overprescribing and lack of control measures; high OTC consumption; low, and cheaper, generic medicines utilization; and high, and expensive, innovative medicines utilization.[3]
- **On the supply side**, the thesis considers two important factors: low level of public reimbursement for prescription medicines driven by the external reference pricing mechanism (ERP); and the high value added tax (VAT) included in the final retail price of pharmaceuticals which patients pay with private resources.

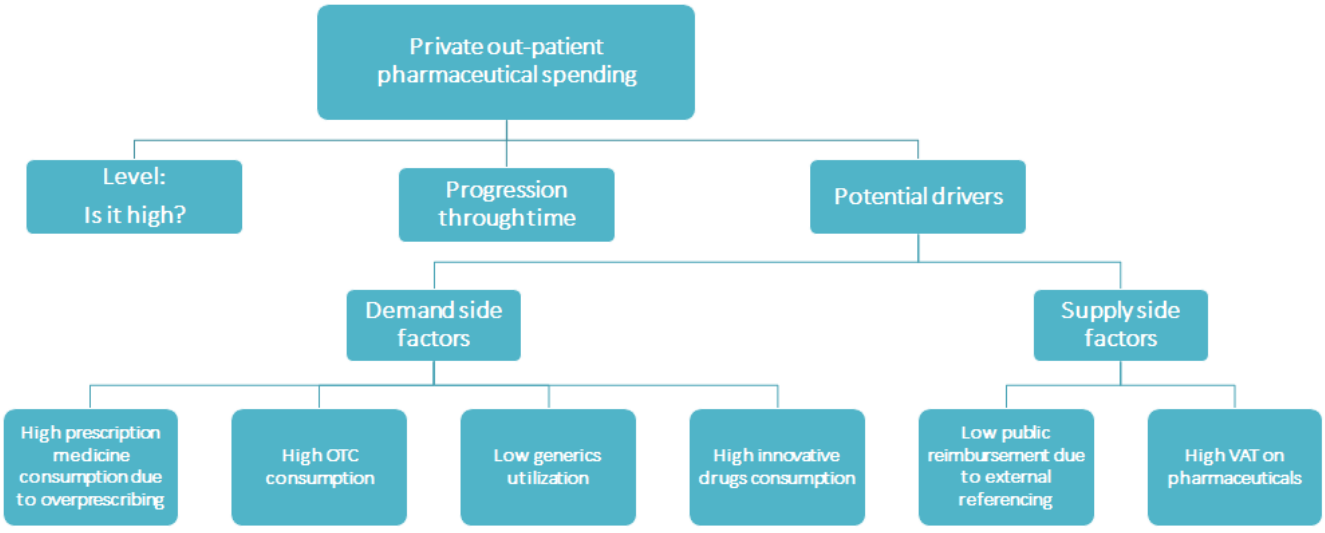


Figure 4. Thesis structure

Source: Author

[3] A factor that the thesis does not capture is the overall population health status and its effect on pharmaceutical demand.

In short, the thesis is organized in a way that aims to **answer three main questions**: first, whether out-patient pharmaceuticals are affordable given Bulgaria's income level; second, whether there have been any changes in affordability; and third, what are the factors potentially responsible for the changes in affordability, or the lack of such (Figure 4). So far, there are no comprehensive studies on the affordability of out-patient medicines in Bulgaria answering all the three questions above, and this thesis aims to fill this gap in literature.

Chapter 2: Review of Literature on Pharmaceutical Spending in Bulgaria

The following section is divided into two sub-sections: the first presents a review of international publications related to private health expenditure, and the second one a review of domestic key opinion leaders' positions regarding healthcare expenditure in Bulgaria. The two sub-sections are each divided into to two topics: private health expenditure and private expenditure particularly on *pharmaceutical* products.

Review of International Sources

Health expenditure

In a 2013 policy note on the Bulgarian health sector, the World Bank points out that although total health expenditure in Bulgaria is not considerably different than that of countries with similar income level, the financial protection that the Bulgarian health system provides is "incomplete" (The World Bank 2013, pg. 4). A major driver behind this phenomenon is the excessive out-of-pocket spending that has as well grown over time (The World Bank 2013). The Bank presents a survey on out-of-pocket expenditure in Bulgaria in 2007 according to which 'catastrophic' out-of-pocket health expenditure occurred in about 20% of Bulgarian households compared to only 7% of households in EU-15[4]. Data from the World Health Organization also points to similar observations, namely that Bulgaria in fact stands much closer to the former Soviet republics (now part of the Commonwealth of Independent States – CIS) than to CEE countries based on the level of total private households' out-of-pocket expenditures on health (Appendix V). The 2012 European Observatory on Health Systems and Policy review of the Bulgarian health system also puts the Bulgarian public health expenditure

[4] "Catastrophic" defined as comprising more than 10% of total household spending (The World Bank 2013)

share closest to the ones in the CIS countries, far below the shares in EU12[5] (73%), EU15[6] (77.5%), and EU27 (76.6%) (Dimova 2012). The review emphasizes that the share of public expenditure on health has been steadily decreasing during the transition period from virtually 100% in the early 1990s to about 58% in 2008 indicating the growing shortage of public health resources. Based on a 2010-2011 nationally representative survey analysis, Atanasova et al. (2012) also argue that the high levels of health-related out-of-pocket payments in Bulgaria, both formal and informal, pose a considerable burden and undermine access to adequate health services, especially pronounced among the poorer Bulgarian households.

Pharmaceutical expenditure

A 2012 report from the European Commission presents a pharmaceutical price index across the European Union based on 2005 data (Carone 2012). Although the study does not particularly focus on the case of Bulgaria, it indicates that although its pharmaceutical price index seems in line with the rest of the EU, it shows a significant upward deviation from the general EU trend when adjusted for income per capita (Appendix VI). That is, unlike in most EU member states where medicines are more or less affordable as shown by the Commission's index, in Bulgaria this is not the case. Another country showing a similar concern is Romania although its deviation is smaller. Also, it is worth noting that back in 2005 Romania had similar income levels but had a notably lower pharmaceutical price index compared to Bulgaria. Although not explicitly focusing on Bulgaria, the Commission's report touches upon the need for further analysis on why this might be the case in the country.

To put pharmaceutical expenditure into a broader context, a World Health Organization report from 2011 titled "The World Medicines Situation" shows that private out-of-pocket

[5] Belgium (BE), Denmark (DK), France (FR), Germany (DE), Greece (EL), Ireland (IE), Italy (IT), Luxembourg (LU), Netherlands (NL), Portugal (PT), Spain (ES) and United Kingdom (UK)

[6] EU-12 + Austria (AT), Finland (FI) and Sweden (SE)

expenditure is the main source of pharmaceutical financing in all countries except the high-income ones (Lu 2011). Also, since 1996, the private total pharmaceutical expenditure share is shown to have grown or remained relatively unchanged in all but high-income countries where it has in fact fallen (Appendix VII). In 2006, it reached 61.2%, 66.5% and 76.9% in upper middle-, lower middle- and low-income countries respectively in per-capita terms (Lu 2011). The WHO dataset used in both the WHO report as well as this thesis, shows that in 2006 the private pharmaceutical expenditure share in Bulgaria, which at the time was already an upper-middle income country, was strikingly 74.4%. That is, the private share in Bulgaria was closer to the share typically found in low-income countries. A report of the European Federation of Pharmaceutical Industries and Associations (EFPIA) points to a similar observation from a later period, namely that in 2011 public spending particularly for ambulatory-care medicines in Bulgaria is among the lowest in per-capita terms not only by EU standards but also across the CEEs (Appendix IV). On the one hand, the case of Bulgaria confirms the general trend that poorer countries have lower public financing share for pharmaceuticals compared to richer ones but it also represents a notable outlier when compared to countries with lower incomes.

The 2012 European Observatory on Health Systems and Policy review of the Bulgarian health system provides a likely explanation as to why Bulgarian patients' private contribution for pharmaceuticals is excessive (Dimova 2012). It points out that since 2002 prices of pharmaceuticals in Bulgaria have been decreasing but still remain high relative to the income level in the country. The report asserts that private co-payments for medicines only partially covered by NHIF are considerably high. As a result patients often cannot afford and therefore forego their prescribed pharmaceutical therapies. More precisely, a 2007 survey of Bulgarian patients shows that 23% of those interviewed could not afford to buy any prescribed medication, while 56% had to forego at least some of the prescribed medicines for their treatment,despite partial reimbursement by the National Health Insurance Fund (Dimova 2007).

Despite the rising private share in pharmaceutical financing, pharmaceutical sales and consumption in Bulgaria have shown an increasing tendency, both in value and volume (Andre 2010). Over the period 2005-2009 there has been a 71% increase in total pharmaceutical sales, and a 29% increase in consumption measured in DDD[7], with out-patient consumption rate of growth higher than the one in the hospital sector (Andre 2010). Some possible reasons for the increasing consumption include: firstly, the increased budget of the NHIF for pharmaceuticals over the period allowed for an increased number of medicines eligible for full or partial reimbursement; secondly, the increasing morbidity of the aging population required more and longer treatment; thirdly, the increasing awareness of the benefits from social health insurance, first introduced with the 1998 health reform, increased its level of utilization including utilization of pharmaceuticals (Andre 2010). Dimova et al. confirm that hospital consumption of pharmaceuticals was lower than out-patient consumption: for example, out of the total pharmaceutical market in Bulgaria in 2009, hospital consumption represented about 18%, publicly reimbursed ambulatory care medicines had about the same share, and the remaining 64% were private purchases (Dimova 2012). All of these facts and figures indicate an increased pharmaceutical consumption and an increased private pharmaceutical expenditure during the 2000s.

Review of Domestic Sources

Health expenditure

Unlike international sources which mostly report comparative statistics, domestic key opinion leaders are openly critical of the Bulgarian healthcare policies in the last decade. A key reason for the growing poverty in Bulgaria is the co-payment for medical services with private resources, according to a World Bank report in progress presented to the Bulgarian government

[7] DDD is used as a unit for measuring a prescribed amount of a pharmaceutical. DDD = defined daily dose.

in March 2015 (Nikolova 2015). According to Dessislava Nikolova from Capital Daily commenting on the World Bank's report, Bulgarian taxpayers make regular contributions to the health system but in addition to that they pay an equal amount out-of-pocket for treatment and pharmaceuticals, thus making up the biggest financing player in the system as opposed to the social health fund (NHIF). Based on the report's findings, she asserts that the health system does not fulfill its key function of protecting individuals from substantial and unforeseen health payments. According to the World Bank's criteria for adequate financial protection, out-of-pocket payments should not surpass 15-20% of total health expenditure, while in Bulgaria they are about triple this amount, 47%. The Bulgarian Chamber of Commerce projects further increases to 48-49% as well as health risks increasingly faced by the private individual, unlike the tendency in Europe where the risks and financial burden fall on social as opposed to private actors (Dimitrov 2014). On average, the World Bank estimates that each year about 4% of the population in Bulgaria falls into poverty due to unforeseen health co-payments (Nikolova 2015).

Further, the Economic Research Institute of the Bulgarian Academy of Sciences estimates that in 2000 private healthcare expenses represented about 3.6% of household income, in 2011 they had already grown to 5.6%, clearly indicating an upward trend (Beleva 2013). The Bulgarian Chamber of Commerce estimates a larger increase over the period 2007-2011 (from 5.5% in 2007 and 6.7% in 2011) and shows that private health expenditure in Bulgaria had had a much steeper rate of increase compared to other consumption categories such as food and beverages, or alcohol and tobacco (Dimitrov 2014). In view of the low incomes of the population, these figures pose notable problems related to access to health services.

Pharmaceutical expenditure

One of the main sources of private health payments are pharmaceuticals, which represent about three quarters of all private health payments, according to Nikolova and based on the World Bank's report (Nikolova 2015). In addition to the lack of clear pharmaceutical pricing and access strategy, the Bulgarian government has not made efforts to foster competition between generic drugs to bring down expenditures on medicines, and has not made progress in evaluating the economic effectiveness of the introduction of expensive innovative medicines included in the Positive List, the report says (Nikolova 2015). Another criticism of Bulgarian pharmaceutical policies is presented by the Economic Research Institute of the Bulgarian Academy of Sciences which ascertains that Bulgaria is the only country in the EU where patients pay on average more than half of the final pharmaceutical price (Beleva 2013). The Institute attributes this phenomenon to a big extent to the high value added tax in Bulgaria of 20% which applies to pharmaceutical products in its full amount, and is thus among the highest in Europe. Also, the Institute claims that in 2012 after evaluations of the pharmaceutical price regulation mechanisms, mainly the eternal referencing system, the Institute discovered that it had not achieved its desired effect but had instead led to an increase in pharmaceutical prices (Beleva 2013). The Institute also emphasizes that the lack of a clear pharmaceutical pricing strategy is evident in the increasing self-medication levels mostly due to the following factors: inappropriate prescribing by general practitioners (GPs) and specialists, their lack of consideration for patients' financial capabilities, the prescribing of expensive original medicines due to the strong marketing pressure from pharmaceutical manufacturers, and last but not least the constantly changing NHIF reimbursement shares and the changing patient co-payment levels (Beleva 2013). Due to the above-mentioned reasons, self-medication has been on the rise because of patients' efforts to save time and money from GP consultations and inappropriate prescribing. As policy recommendations the Institute suggests changes in the behavior of patients, medical facilities, and pharmacy outlets. Such changes include the establishment of a clear generic prescribing strategy, as well as the setting up of clear criteria

for the control of prescription medical therapy and responsibility for inappropriate prescribing, both missing today. The Institute concludes that the proclaimed solidary health insurance model is only "wishful thinking" while the government has gradually stepped away from its responsibly of insuring the good health of citizens and has effectively transferred the health financing risks to private individuals (Beleva 2013).

Summary

Although there exist a number studies on the level of private health expenditures in Bulgaria, including formal and informal ones, there are fewer studies focusing particularly on private pharmaceutical expenditure and affordability of medicines. Many studies emphasize the fact that Bulgaria is among the EU counties paying the least amount for prescription pharmaceuticals per-capita in monetary terms (Trifonov, *Analysis*, 2013). However, even fewer studies related these expenditures to national incomes to evaluate affordability of medication. Also, there are no comprehensive studies analyzing the trends in private pharmaceutical expenditures in Bulgaria and the drivers behind them. By far, there are no comprehensive studies answering all the three questions whether out-patient pharmaceuticals are affordable given Bulgaria's income level, whether there have been any changes in affordability, and what are the factors responsible for the changes in affordability in Bulgaria. This thesis attempt at providing an answer to all three of them.

Chapter 3: Institutional Environment

In order for the reader to understand better the pricing and reimbursement process in Bulgaria as well as the patient co-payment mechanism to a large extent related to the high private share in out-patient pharmaceutical expenditure, a review of the current Bulgarian institutional environment is presented below. Public health expenditure in Bulgaria consists of government spending (the central government budget, the Ministry of Health and the ministries managing parallel health systems such as the Ministry of Internal Affairs, Ministry of Defense, etc.) municipalities (operating municipal hospitals with allocated budgets) and the National Health Insurance Fund (NHIF). The NHIF is the sole institution responsible for social health insurance in Bulgaria, the largest purchaser of health services as well as the single payer responsible for the reimbursement of out-patient pharmaceuticals subject to the 1998 Bulgarian Health Insurance Act. The Bulgarian compulsory social insurance system administered by the NHIF guarantees a basic package of in- and out-patient health services for the insured which includes: primary and specialized out-patient medical and dental care; hospital treatment and diagnostics; laboratory services; and highly specialized medical services (Dimova 2012). The NHIF is only responsible for reimbursing medicines within the scope of the Health Insurance Act, and it does not reimburse medicines for HIV/AIDS or highly infectious diseases, vaccines, emergency, mental, and social care services etc. which are 100% funded by the Ministry of Health or municipalities (Koulaksazov 2003) (Appendix I).

Reimbursement in the out-patient sector

Patient co-payment for prescription medicines, i.e. the remaining share after reimbursement by the NHIF, serves as a major demand-side cost containment measure for out-patient pharmaceutical expenditures. The pharmaceutical products subject to reimbursement from the

NHIF are medicines prescribed by a General Practitioner (GP) or a specialist. These prescription pharmaceuticals are listed in Annex 1 of the Positive Drug List (PDL)[8] which contains a list of the maximum prices subject to regulation by the National Council on Prices and Reimbursement of Medicinal Products and the respective reimbursement levels by the NHIF (NATIONAL COUNCIL). The Council regulates the prices of prescription medicines, both reimbursable and non-reimbursable, while OTC products are priced freely and their price is only registered by the pharmaceutical manufacturers with the Council. Annex I of the PDL is updated every six months and the new maximum prices and reimbursement levels are registered according to specific price regulation mechanisms. The Council keeps and updates the publicly-accessible registries of:

- The pharmaceuticals included in the Positive Drug List;
- the prices of pharmaceutical products included on the Positive Drug List and paid with public funds (including the pharmaceuticals in Annex I paid by NHIF);
- the maximum prices of the pharmaceutical products subject to prescription, which are not included in the Positive Drug List;
- the maximum sale prices of pharmaceutical products not subject to prescription (OTC) (NATIONAL COUNCIL).

Price Referencing

One of the most common forms of indirect price control in Europe is the external reference price system (ERP), which is also the central prescription pharmaceuticals price regulation mechanism in Bulgaria. ERP is used to regulate prescription medicines prices through international comparisons. It is of indirect nature as it only sets a reference price and does not

[8] The PDL contains the pharmacetucal products' their trade names grouped together by pharmacological group (or anatomical therapeutic chemical classification, ATC), their international non-proprietary names (INN), defined daily dosage (DDD), regulated price, reference value per DDD, price calculated on the basis of this reference value, and their respective level of reimbursement.

directly determine the manufacturer's price in a given country. The reference price effectively sets a maximum level of NHIF expenditures for a group of pharmaceutical products with similar active ingredients and therapeutic effect. However, if the market price is higher than the reference price, the consumer pays the remaining amount. In Bulgaria, the reference price of pharmaceuticals included in Annex I of the Positive Drug List is calculated based on a system of international price comparisons with a basket of 10 key countries: Romania, France, Latvia, Greece, Slovakia, Lithuania, Portugal, Italy, Slovenia, or Spain. The reference price is the ex-factory (i.e. manufacturer's) price equivalent to the price reimbursed by the social insurance fund of the country with the lowest price in the above-mentioned basket. If there is no available price information in the basket of 10 key countries, the reference price is determined in the same way by taking the lowest price reimbursed by the respective social insurance fund in an additional basket of seven more countries: Belgium, Czech Republic, Poland, Hungary, Denmark, Finland, or Estonia. [9]

The two majors objectives of ERP are firstly, to cap public pharmaceutical expenditures, and secondly, to boost price competition by increasing the price elasticity of demand (Madjarova 2007). This cost-sharing mechanism in the out-patient pharmaceutical sector is seen as a means of restricting excessive demand for pharmaceuticals in addition to being a supplementary source of revenue for healthcare payers (governments, social healthcare funds, etc.). Although ERP is popular and widely-accepted regulatory tool, its impact on cost containment is not confirmed with certainty because ERP-generated price falls are not automatically transformed into final price reductions for reasons such that pharmaceutical prices are not regularly reviewed, etc. (Carone 2012).

[9] Ordinance of Regulation and Registration of Prices of Medicinal Products, as of April 2013. (НАРЕДБА за условията, правилата и реда за регулиране и регистриране на цените на лекарствените продукти. Април 2013г.)

After the reference price is determined via ERP, in order for medicines to be reimbursed, they need to be formally included in the Positive Drug List (PDL) first introduced in 2003 (Andre 2007). For medicines to be included in the PDL, they need to have been selected for reimbursement through public health funds (equivalent to NHIF in Bulgaria) in at least 5 of the 17 countries from among the two baskets.[10] In sum, while ERP sets the maximum price per standardised unit (DDD) of equivalent medicinal products, the internal referencing mechanism defines their respective reimbursment level.[11] Hence, the amount of out-patient pharmaceutical expenditure depends both on the external and internal referencing mechanisms because the former sets the maximum regulated price for prescription medicines while the latter determines how much the private patient co-payment amount would effectively be.

[10] Ordianance of Regulation and Registration of Prices of Medicinal Products, as of April 2013. (НАРЕДБА за условията, правилата и реда за регулиране и регистриране на цените на лекарствените продукти. Април 2013г.)

[11] The international non-proprietary name (INN) of the medicine is used in the process.

Chapter 4: Methods

Data

This thesis is based on three datasets from three different sources and time periods containing pharmaceutical expenditure data across three groups of European countries (Table 1).

Dependent variables

The first dataset encompasses the period 1995-2006. It was compiled and used for the World Medicines Situation Report published in 2011 by the World Health Organization (Lu 2011) and can be found as an annex under the Medicine Expenditures Chapter. It contains pharmaceutical expenditure data divided into private and public and presented both as shares of total (%) as well as in monetary values both in current and in PPP dollars (purchasing power parity).

The dataset does not differentiate between in- and out-patient pharmaceutical consumption. Nevertheless, since pharmaceuticals used in hospitals in Bulgaria are paid though the National Health Insurance Fund or the state budget, in-patient pharmaceuticals are fully included in the cost of treatment and are free of charge for the patient (Andre 2007). Therefore, the private pharmaceutical expenditure variable included in the WHO dataset represents entirely *out-patient* pharmaceutical private payments. While the monetary variable correctly represents out-patient pharmaceutical private expenditure, the share variable (%) is an underestimate for the purposes of this thesis. This is due to the fact that the total pharmaceutical expenditure denominator includes both in-patient public and out-patient public and private expenditure. Nevertheless, it will be used as a proxy for measuring private out-patient pharmaceutical expenditure and its progress over time.

The thesis focuses on data from the post- 2000 period for two major reasons. Firstly, the early post-communist transition period is associated with significant monetary and structural

fluctuations in post-socialist economies. Therefore, quantitative data on pharmaceutical expenditure is likely to be less precise than data from the later transition period when major healthcare reforms had already taken place in post-socialist countries including Bulgaria. The 1998 healthcare reform in Bulgaria created the National Health Insurance Fund responsible for administering social health insurance in out-patient care. As a result, health insurance financing began operations only in July 2000 when the reform was effectively launched (Datzova 2003). Hence, in the analysis that follow, the author takes into account only the data for the 2000-2006 period from the WHO dataset.

The second dataset contains data for 2010 only. It is part of a European Commission Directorate General for Economic and Financial Affairs report (Carone 2012) on pharmaceutical expenditures in the EU and contains data particularly for out-patient pharmaceutical consumption divided into private and public variables and presented both as shares of total pharmaceutical out-patient expenditure (%) as well as in monetary values in PPS Euros (Purchasing power standard) .

The third dataset presents data for 2009 only. It is derived from a report by IMS Health, a global pharmaceutical data management and consulting company, and encompasses data particularly for prescription (Rx) pharmaceutical expenditure in the out-patient sector (Trifonov, *Public*, 2013). It contains Rx pharmaceutical expenditure data divided into private and public variables and presented as shares of total (%) Rx out-patient expenditure.

A summary of the three key datasets used in this thesis and containing data for the dependent variable in the regression analyses that follow is presented in the table below:

DATASETS	(1) WHO	(2) EU	(3) IMS
Key variables	Public & Private shares (%) in pharmaceutical expenditure	Public & Private shares (%) in total **out-patient** pharmaceutical expenditure	Public & Private shares (%) in **out-patient prescription** pharmaceutical expenditure
Period	1995-2006	2010	2009
Source	World Health Organization (WHO)	EU Commission (ECFIN)	IMS Health
Number of countries	30	26	22

Table 1. Thesis datasets

Source: Author

Since the datasets use different definitions of private pharmaceutical expenditure and are compiled by different institutions that apply different methodologies, it is not possible to combine them into a single dataset. Hence, the thesis looks separately at all three datasets in order to firstly, dismiss any potential claims for measurement errors particularly for the case of Bulgaria, and secondly, to show progression of private pharmaceutical expenditure through time and across countries.

Independent variables

Data for GDP per capita both in current dollar terms as well as in PPP dollars are derived from the World Bank Database.

Other three variables that are used together with the 2010 dataset as independent variables are: value added tax on prescription medicines (%), generic pharmaceuticals share of total (%), and number of physicians per 1000 population – all showing data for 2010. Data for the first variable, *VAT* rate measured in percentages is derived from a 2010 EFPIA report (EFPIA 2010). Data for the second variable, an estimate of the share accounted for by *generics* in pharmaceutical market sales value at ex-factory prices, is derived from a 2012 EPFIA report (EFPIA 2012). And lastly, data for the number of *physicians per 1000* comes from the World Bank database.

Analytical Techniques

The empirical analysis presented in this thesis is based on the three key datasets described in the Data section above, and it aims at identifying Bulgaria as a potential outlier with regards to private pharmaceutical spending. It follows the initially defined structure presented in the Introduction Chapter and aims to answer the three main questions presented there:

1. Are out-patient pharmaceuticals affordable given Bulgaria's income level and compared to other European countries?
2. Have there been any changes in affordability?
3. What are the factors potentially contributing to these changes in affordability, or the lack of such?

1. Are out-patient pharmaceuticals affordable given Bulgaria's income level and compared to other European countries?

To provide an answer to the first question, the thesis uses per-capita GDP as the independent variable in order to map Bulgaria's private pharmaceutical expenditure share relative to per-capita income and compared to other European countries by running three cross-sectional OLS regression models of the following basic specification:

$$PvPE_i = \alpha + \beta * GDPpc_i + u_i \quad (1)$$

where *PvPE* represents private pharmaceutical expenditure share of total in percentage terms, *GDPpc* indicates per-capita GDP in dollar terms, α is a constant term, β is the regression coefficient on the independent variable, *u* is a random error term, and *i* is an index indicating a given country in the dataset. This regression is performed on the two most recent datasets: the EC dataset for year 2010 and the IMS dataset for 2009.

Before all, the analysis described above checks the consistency of the data on the dependent variable, namely whether the data on the public-private mix of pharmaceutical out-patient expenditure used in this thesis is trustworthy, thus eliminating potentially erroneous conclusions that Bulgaria is indeed an outlier with regards to private pharmaceutical spending but due to bad data and measurement errors. It does so by using the EC and IMS datasets to compare and eventually point to the same phenomenon, namely, that Bulgarian private share in pharmaceutical expenditure is the highest in Europe adjusted for income, for both prescription and total pharmaceutical markets, regardless of the method of data collection used by the two data sources. The analysis is also reaffirmed in the second part of the Analytical Techniques section which uses the remaining dataset, namely the WHO dataset.

On the independent variable side, the thesis takes into account the potential differences caused by using current GDP per capita and GDP per capita in PPP terms by running two regression models using each. Also, dummy variables for Bulgaria and for post-socialist countries as included in the regressions to check whether the post-socialist group of countries is any different than the overall dataset, and whether Bulgaria in particular is exceptionally different:

$$PvPE_i = \alpha + \beta_1 * GDPpc_i + \beta_2 * Bulgaria + u_i \quad (2)$$

$$PvPE_i = \alpha + \beta_1 * GDPpc_i + \beta_2 * Post\_Socialist + u_i \quad (3)$$

2. Have there been any changes in affordability?

To answer this question, the thesis uses the WHO dataset for the period 2000-2006 as well as the EC dataset for year 2010 to track the evolution of private pharmaceutical expenditure share over the last decade by running a total of seven cross-sectional OLS regression models for each year of the same basic specification shown above (1).

Also, a pooled OLS regression of the same specification is ran in the WHO dataset for 2000-2006:

$$PvPE_{it} = \alpha + \beta*GDPpc_{it} + u_{it} \quad (1)$$

where *t* represents year (2000 to 2006). Also, dummies for Bulgaria and for post-socialist countries are added to the model above, each in a separate model:

$$PvPE_{it} = \alpha + \beta_1*GDPpc_{it} + \beta_2*Bulgaria + u_{it} \quad (2)$$

$$PvPE_{it} = \alpha + \beta_1*GDPpc_{it} + \beta_2*Post\_Socialist + u_{it} \quad (3)$$

3. What are the factors potentially contributing to the changes in affordability, or the lack of such?

The factors potentially related to the level of private pharmaceutical expenditure that this thesis looks into are: generic pharmaceuticals utilization approximated by the share of generics in total pharmaceutical market; pharmaceutical taxation approximated by V.A.T. rate on original drugs; the overall level of drug prescribing approximated by the number of physicians per 1000 people; the level of OTC utilization; the utilization of innovative therapies; and the pharmaceutical pricing system.

For the latter three factors, this thesis does not provide empirical quantitative analysis due to lack of data. It discusses them in a qualitative manner in the Discussion Chapter. For the former three factors, this thesis uses quantitative data and applies the following regression models on the EC dataset for year 2010:

$$PvPE = \alpha + \beta*generic_i + u_i \quad (4)$$

where *generic* stands for the share of generic pharmaceuticals sales in total pharmaceutical market sales value expressed in percentage terms,

$$PvPE = \alpha + \beta * VAT_i + u_i \quad (5)$$

where *VAT* stands for the V.A.T. rate on prescription medicines (Rx) expressed in percentage terms; and

$$PvPE_i = \alpha + \beta * physicians_i + u_i \quad (6)$$

where *physicians* stands for the number of physicians per 1000 population in 2010.

After identifying whether there is a meaningful relationship between the dependent and the independent variables in the three regressions above, this thesis aims at placing Bulgaria relative to other European countries with respect to the relationship between private pharmaceutical spending and generic utilization, pharmaceutical taxation, and prescription practices approximated by the three independent variables above.

Chapter 5: Results

1. Are out-patient pharmaceuticals affordable given Bulgaria's income level and compared to other European countries?

The performed OLS regressions show that GDP per capita both in current $ and in PPP $ is correlated with Private pharmaceutical expenditure (significant at 1%; R^2 =0.23 and 0.33, respectively) (Table 2). That is, the negative relationship indicates that, on average, in countries where GDP per capita is higher by $10,000 (PPP), private pharmaceutical expenditure share is about 11 percentage points lower. Intuitively, in poorer countries like the post-socialist countries, private expenditure shares are expected to be relatively high. And indeed they are, as seen on the graph below. However, the post-socialist dummy turns out to be insignificant, that is, together as a group, these countries are not exceptionally different than the general pattern. Conversely, the significant positive sign of the Bulgaria dummy variable indicates that Bulgarian private pharmaceutical expenditure is further away than predicted by its income level.

Dependent variable: Private pharmaceutical expenditure (%total)	**(1) (a)**	**(1) (b)**	**(2) (a)**	**(2) (b)**	**(3) (a)**
Constant	57.76***	74.93***	53.02***	67.82***	74.51***
	(6.52)	(8.66)	(5.73)	(7.17)	(21.80)
GDP p.c. ($ current)	-0.00054***		-0.00042**		
	(0.00018)		(0.00016)		
GDP p.c. ($ PPP)		-0.001115***		-0.00091***	-0.001104*
		(0.00027)		(0.00023)	(0.00054)
BG dummy			31.78***	27.32***	
			(4.83)	(4.26)	
Post-soc dummy					0.2401
					(10.89)
R^2	0.23	0.33	0.35	0.41	0.33
N	26	26	26	26	26

Table 2. Out-patient pharmaceutical expenditure, 2010 (EU dataset), OLS (Robust S.E.)

The regression plot below (Figure 5) displays the distance between Bulgaria and the fitted line. Also, it gives a clear indication that Bulgaria (along with Cyprus) is the observation with the

biggest positive deviation from the predicted line.[12] That is, in Bulgaria there are country-specific characteristics, other than simply income, that significantly influence private pharmaceutical expenditure. To sum up, the problem of high private payments for pharmaceuticals in Bulgaria is not simply due to the fact that it is poor, nor because it is a post-socialist country; nevertheless, such a problem clearly exist.

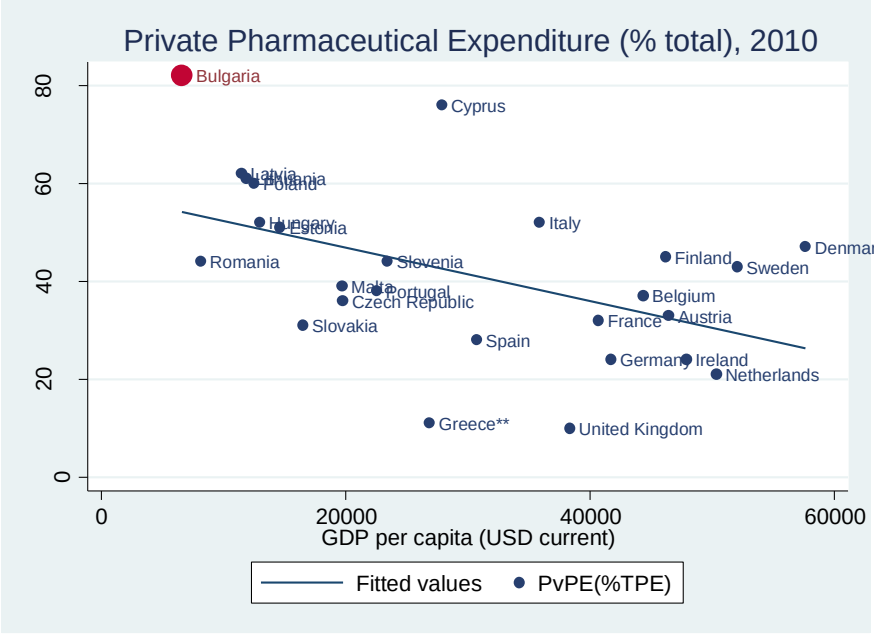


Figure 5. Private pharmaceutical expenditure vs. GDP per capita, 2010 (EC dataset)

Similarly to the results above showing the correlation between total private out-patient pharmaceutical expenditure with income per capita, GDP per capita is as well associated with private prescription pharmaceutical expenditure, showing an even stronger relationship (significant at 1%; $R^2 = 0.44$) (Table 3). The negative relationship indicates that, on average, in countries where GDP per capita is higher by $10,000 (PPP), private pharmaceutical expenditure share is about 9 percentage points lower. Here, the dependent variable is different in a way that it encompasses the consumption of prescription medicines (Rx) only as opposed to all out-patient medicines. Once again, Bulgaria is the country with the highest positive

[12] This thesis will not discuss the case of Cyprus or compare it to Bulgaria due to the significant differences in the structure and organization of the two healthcare systems. For example, in Cyprus there is no social insurance fund like the NHIF in Bulgaria.

deviation from the line of best fit. That is, given its income level, private pharmaceutical expenditure is excessive.

Dependent variable: Private prescription pharmaceutical expenditure (%total)	**(1) (c)**	**(2) (c)**	**(3) (b)**
Constant	49.67***	41.70***	33.09**
	(8.35)	(8.60)	(15.05)
GDP p.c. ($ PPP)	-0.00092***	-0.00072***	-0.00053
	(0.00023)	(0.00024)	(0.00038)
BG dummy		24.72*	
		(11.86)	
Post-soc dummy			11.65
			(8.87)
R^2	0.44	0.55	0.49
N	21	21	21

Table 3. Out-patient prescription (Rx) pharmaceutical expenditure, 2009 (IMS dataset), OLS (Robust S.E.)

This finding is also presented on regression plot below (Figure 6). In sum, prescription medicines which are an integral part of patients' successful therapy are subject to a private co-payment much higher than the reasonable limit suggested by income level and purchasing power in the given dataset and year.

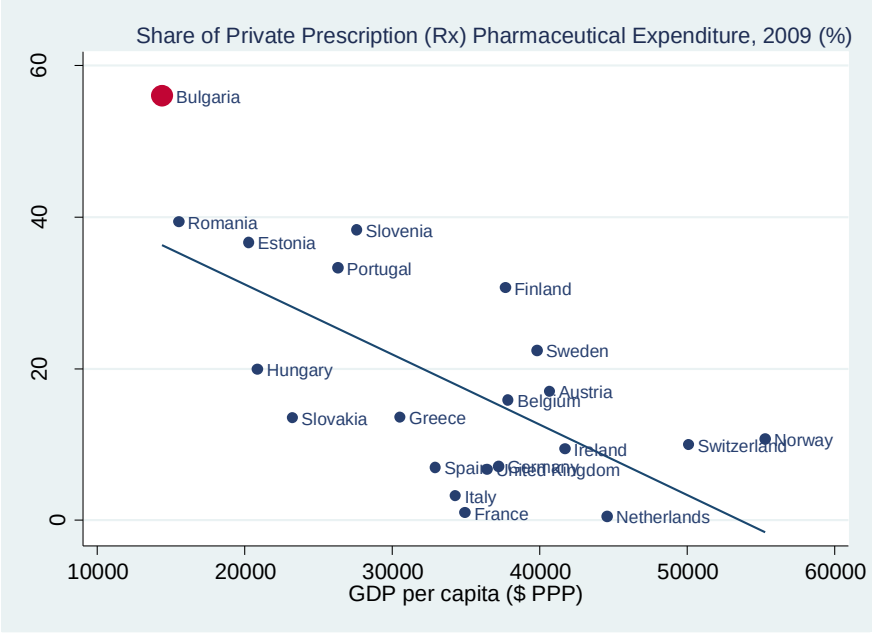


Figure 6. Private prescription (Rx) pharmaceutical expenditure vs. GDP per capita, 2009

2. Have there been any changes in affordability?

Dependent variable: Private pharmaceutical expenditure (%total)	2000	2001	2002	2003	2004	2005	2006
Constant	42.73***	48.34 ***	49.06***	59.00***	60.95***	56.54***	57.63***
	(8.99)	(9.07)	(7.54)	(7.78)	(8.03)	(7.92)	(8.27)
GDP p.c. ($ PPP)	-3.94e-06	-0.000277	-0.00036	-0.0007**	-0.00079**	-0.00062**	-0.00059**
	(0.00039)	(0.00038)	(0.00031)	(0.00031)	(0.0003)	(0.00028)	(0.00027)
R^2	0.00	0.02	0.05	0.18	0.20	0.15	0.15
n	30	30	30	30	30	30	30

Table 4. Private pharmaceutical expenditure, 2000 – 2006 (WHO dataset), OLS (Robust S.E.)

The individual OLS regression ran on data in each year after 2000 (inclusive) show similar correlation between GDP per capita (PPP) and private pharmaceutical expenditure starting from year 2003 on (inclusive) (Table 4). The pooled OLS regression confirms this correlation (significant at 1%; $R^2 = 0.08$). The dummy variable for Bulgaria turns out to be insignificant when separate OLS regressions are ran for each year.

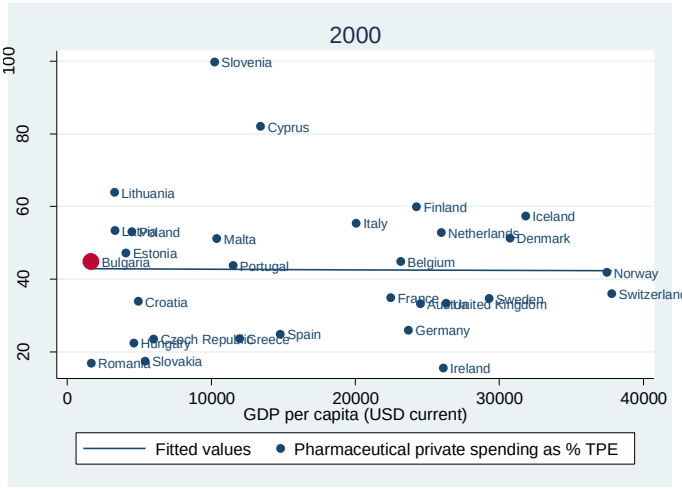
Dependent variable: Private pharmaceutical expenditure (%total)	(1) (d)	(2) (d)	(3) (c)
Constant	52.95***	50.04***	55.89***
	(3.00)	(3.14)	(6.08)
GDP p.c. ($ PPP)	-0.00048***	-0.00039***	-0.00057***
	(0.00011)	(0.00011)	(0.00019)
BG dummy		17.65***	
		(6.47)	
Post-soc dummy			-2.21
			(3.98)
R^2	0.08	0.11	0.08
n	210	210	210

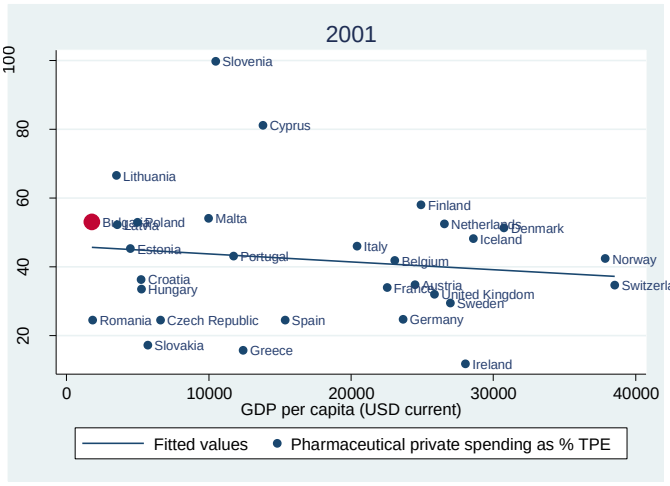
Table 5. Private pharmaceutical expenditure, 2000 – 2006 (WHO dataset), Pooled OLS (Robust S.E.)

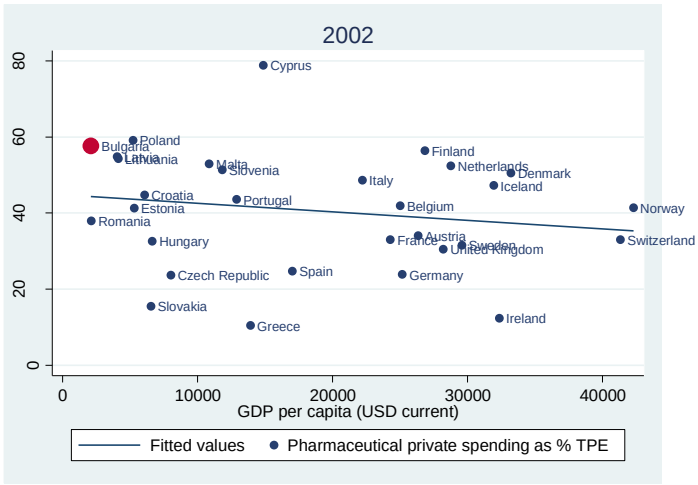
However, the dummy for Bulgaria is significant positive in the pooled OLS regression for the period 2000-2006 (Table 5). That is, over this period Bulgaria has had a significantly higher private pharmaceutical expenditure than explained by GDP per capita, precisely 17 percentage points higher than expected given income level. Although this analytical method does not

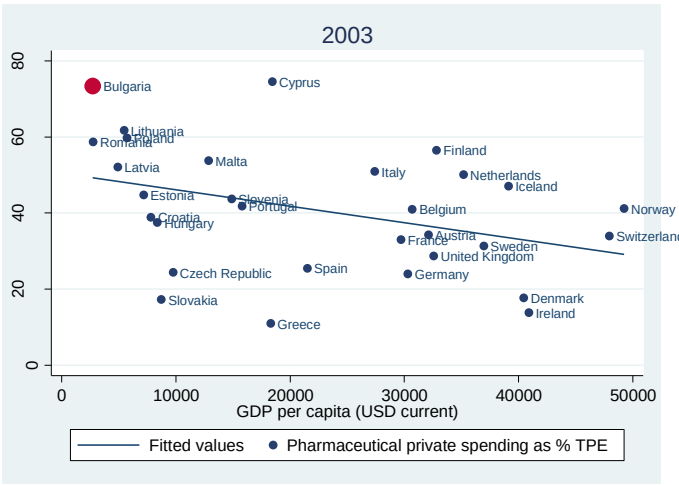
precisely show a progression of Bulgaria's relative private pharmaceutical spending, it does indicate an existing problem worth being examined further.

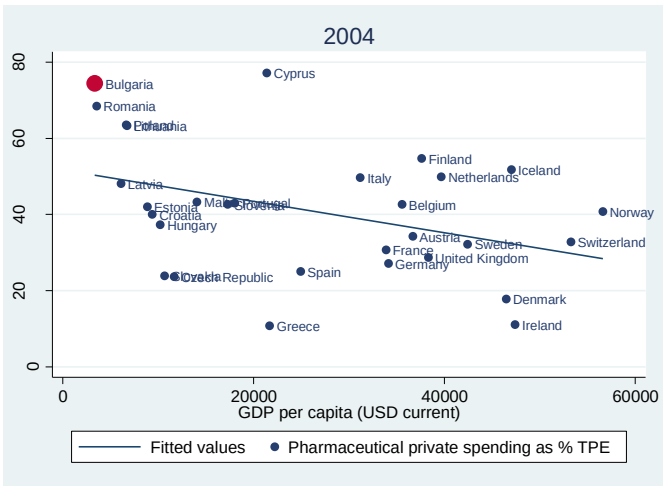
The series of regression plots (Figure 7) with private pharmaceutical expenditure share regressed on GDP per capita (based on the regressions form Table 4) visually indicates an increasing gap between the line of best fit and the case of Bulgaria over the period 2000-2010 (the last plot represents Table 3). On the regression plots, the line of best fit indicates the predicted level of private pharmaceutical expenditure given GDP per capita. In other words, Bulgarian private contribution to pharmaceutical cost has increased continuously along with the burden on individual patients since the observation of Bulgaria is going further away from the line in an upward direction. Interestingly, the 2003 jump in the share of private pharmaceutical expenditure in the public/private mix coincides with the introduction of a Positive Drug List in the same year (see Chapter 3). The trend of growing private expenditure, and presumably decreased affordability in view of GDP per capita, is also displayed on Figure 8 showing the changes in the share of private pharmaceutical expenditure versus the changes in GDP per capita ($PPP) over the period 1995-2006. It is notable that Bulgaria has had the smallest income increase but the second largest private pharmaceutical expenditure share jump.

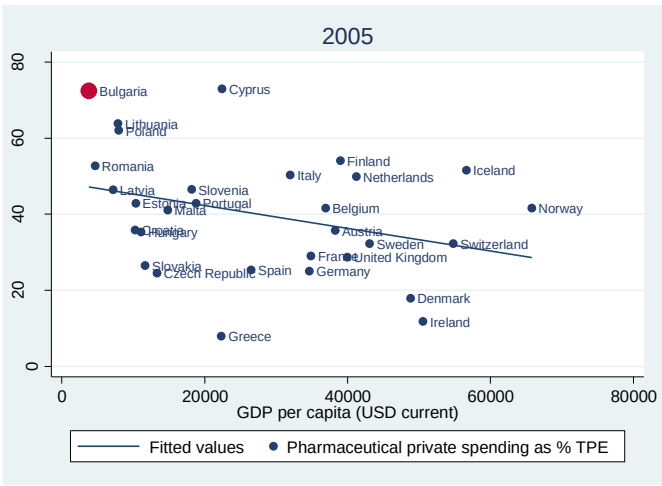


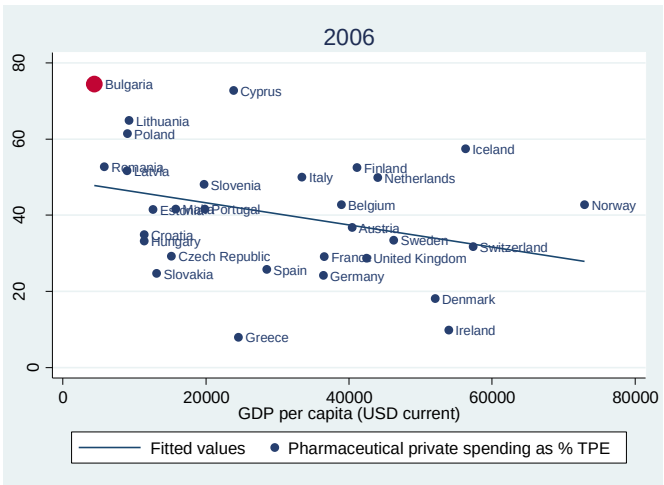












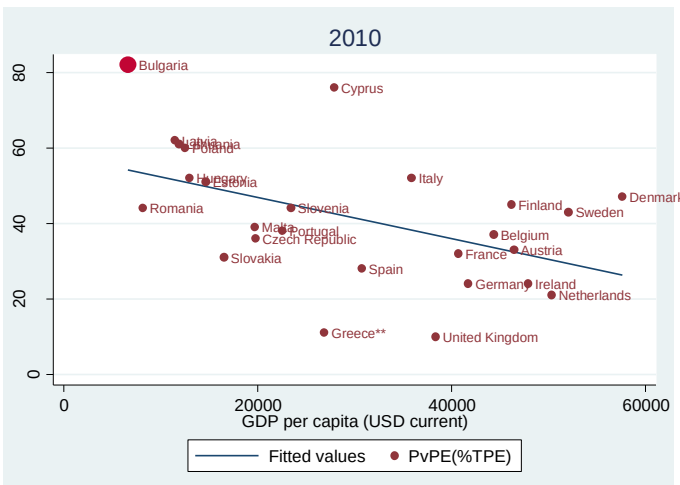


Figure 7. Private pharmaceutical expenditure vs. GDP per capita, 2000 – 2006 (WHO dataset). 2010 (EC dataset)

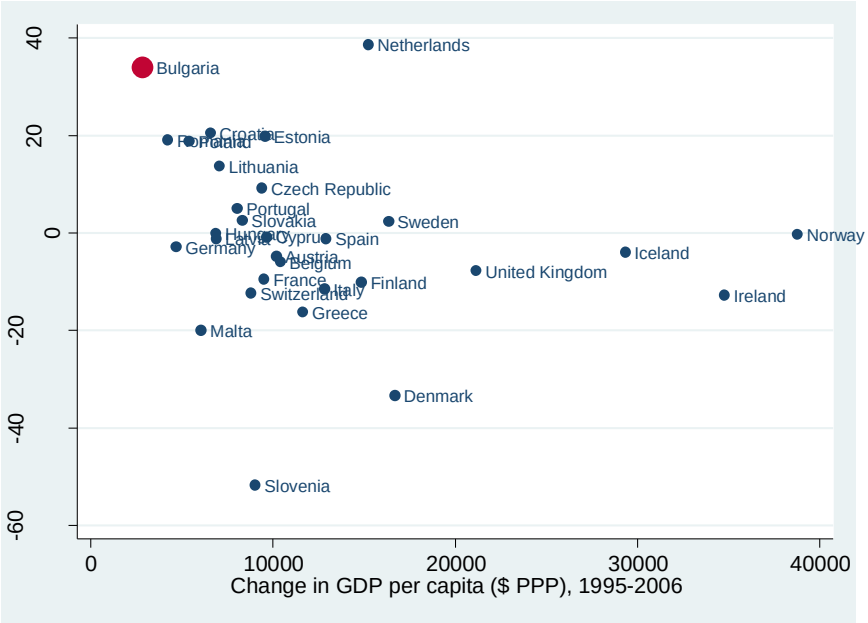


Figure 8. Private pharmaceutical expenditure change vs. GDP per capita change, 1995 – 2006 (WHO dataset)

3. What are the factors potentially contributing to the changes in affordability, or the lack of such?

Prescription practices

Prescription practices approximated by the variable *physicians per 1000* turn out not to follow a particular trend when used as an independent variable in the cross-sectional OLS model where private pharmaceutical expenditure share is the deepened variable (Appendix VIII). That is, the number of doctors across European countries is not correlated with their respective level of private pharmaceutical expenditures. Therefore, the author does not have evidence to conclude that Bulgaria is in any way an outliner with respect to its number of physicians per capita. Therefore, it remains inconclusive from the current analysis whether prescribing

practices have any relationship with the high private pharmaceutical spending in Bulgaria, or at least if prescribing practices are measured with the *physicians per 1000* variable.

Pharmaceutical Taxation

There is no significant relationship between private pharmaceutical expenditure share in GDP per capita and value added tax (V.A.T.) on prescription pharmaceuticals, nor between private pharmaceutical expenditure share in total pharmaceutical expenditure and V.A.T. (Table 6). This could be attributed to the fact that the dataset has a limited number of observations, or to a lack of such a relationship. Nevertheless, Bulgaria is an obvious outlier with regards to the size of its pharmaceutical sales tax. Notably, almost all of the countries in the dataset have a V.A.T. on prescription medicines lower than or equal to 10%. And it is only Bulgaria, Germany and Denmark with significantly higher pharmaceutical V.A.T. rate (Figure 9).

Dependent variable: Private pharmaceutical expenditure (%total)	**(5) (a)**	**(5) (b)**
Constant	32.32***	35.04***
	(5.48)	(5.24)
V.A.T. rate	0.97	0.45
	(0.66)	(0.50)
BG dummy		37.95***
		(6.65)
R^2	0.12	0.29
n	24	24

Table 6. Private pharmaceutical expenditure vs. Rx VAT, 2010 (EC dataset)

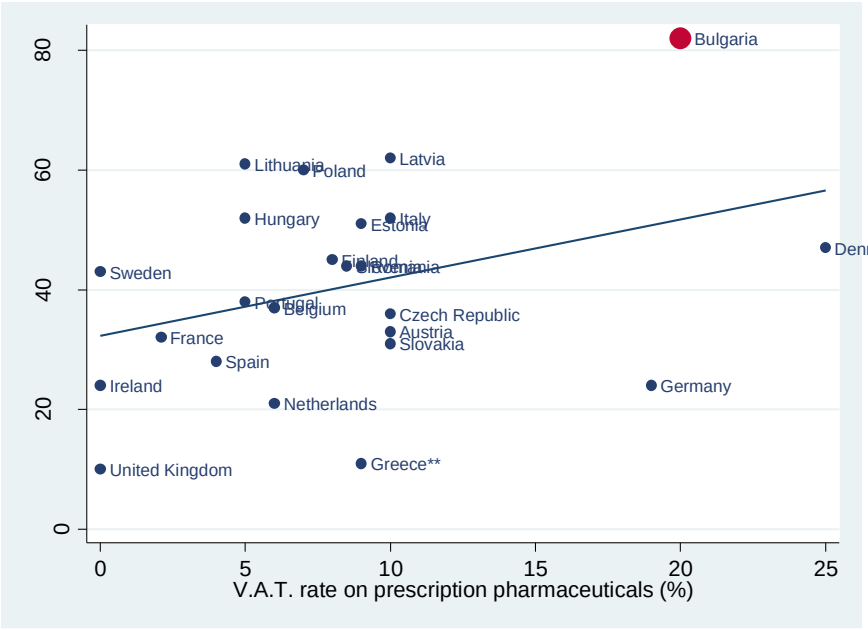


Figure 9. Private pharmaceutical expenditure vs. Rx VAT, 2010

Generics Utilization

In the regression plot which shows private pharmaceutical expenditure share regressed on generic pharmaceuticals share in total pharmaceutical market sales value, it is evident that Bulgaria's private pharmaceutical expenditure share is the highest from among all the European countries in the dataset. Bulgarian patients seem to be paying a lot for pharmaceuticals relative to the level of generic medicines utilization. A country of very similar income level to Bulgaria, namely Romania, can be found on the line of best fit unlike Bulgaria which lies much above it and represents the second biggest positive outlier in the dataset after Cyprus.

Dependent variable: Private pharmaceutical expenditure (%total)	**(4) (a)**	**(4) (b)**
Constant	21.55***	23.50***
	(5.97)	(5.66)
Generics share	0.77***	0.653***
	(0.23)	(0.19)
BG dummy		30.70***
		(4.84)
R^2	0.31	0.42
n	24	24

Table 7. Private pharmaceutical expenditure vs. Generics share, 2010 (EC dataset)

In other words, for the private pharmaceutical expenditure share found in Bulgaria, the level of generic medicines utilization in the country is too low. To contrast, other post-socialist countries like Lithuania, Slovakia and Poland which have smaller pharmaceutical expenditure shares use much more generics (Figure 10). This begs the question whether it is the generic utilization in Bulgaria that is indeed too low or whether there are any other reasons behind the high private contribution for medicines such as an inefficient pharmaceutical price regulation mechanism?

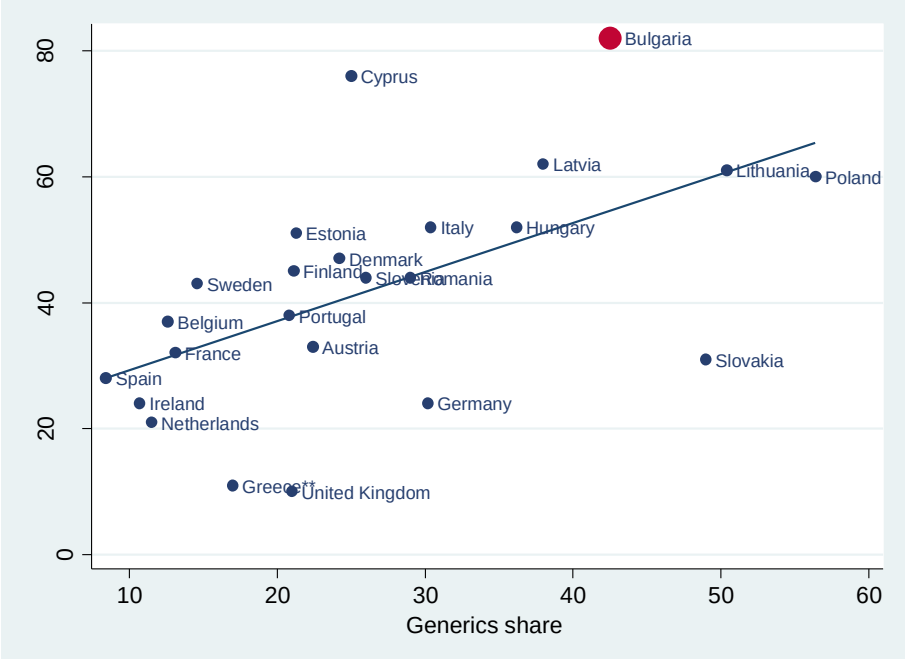


Figure 10. Private pharmaceutical expenditure vs. Generics share, 2010

Chapter 6: Discussion of Results & Limitations, Challenges & Recommendations

Discussion of Results

Prescription practices

Although this thesis uses the number of *physicians per 1000 population* as a proxy for prescription practices, there exist other ways of assessing it. One such way is using the number of prescriptions issued per capita as opposed to simply the number of physicians per capita. However, the author of this thesis did not have access to such comprehensive data for all countries in the dataset, neither for the full period of time investigated in this thesis. The only indication of the number of prescription available is presented in Figure 11 which indicates an increasing number and value (BGN) of total prescriptions issued over the period 2005-2009. Given the fact that the Bulgarian population decreased over the same period, it follows that prescriptions per capita also increased both in number and in value terms. This in turn might be interpreted as an indication of relaxed prescription regulation or lacking whatsoever, and patients being prescribed more as well as more expensive pharmaceuticals for outpatient treatment. Still, a prescription might contain up to three pharmaceutical items, and the data presented on the graph below shows no indication of this fact. Nevertheless, the existing information indicates that prescription practices in Bulgaria need to be further investigated but certainly cannot be overlooked as a potential factor contributing to the rising private pharmaceutical expenditures over the last decade.

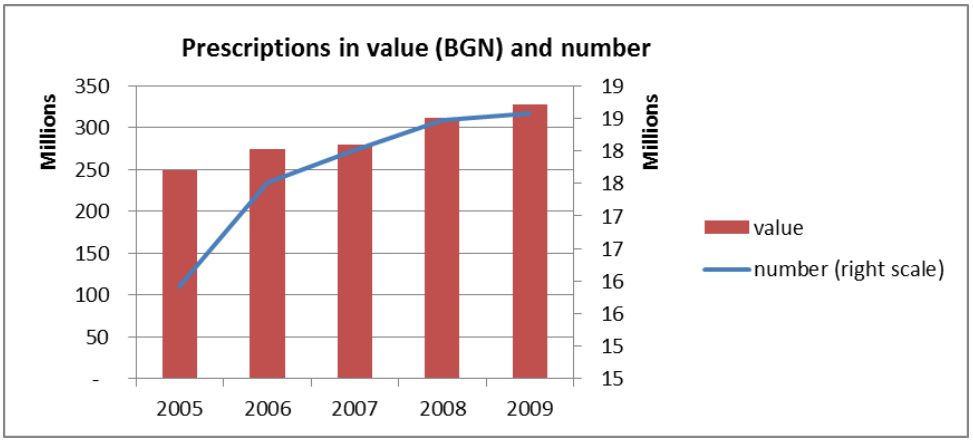


Figure 11. Prescriptions growth (BGN), 2005 – 2009

Source: (Andre 2010). *Author's own presentation.*

OTC Consumption

This thesis does not examine OTC Consumption through the use of regression models due to the unavailability of such data. Instead, it presents information from consulting company IMS Health for 2010 (Figure 12) (Tisman 2010) which clearly emphasizes the recent OTC market growth and future growth potential in Central and Eastern Europe. Despite the global financial crisis of 2007-2008, sales of OTC drugs have continued to rise due to recent innovation, increased access via expanded distribution channels, and larger promotion of self-medication. Consistently outperforming the overall pharmaceutical market, today the OTC market is a key source of growth for pharmaceutical companies. Developing regions in particular play a far greater role in the OTC market compared to their role in the larger pharmaceutical market, and their share is projected to increase as they further outgrow the developed markets (Tisman 2010).

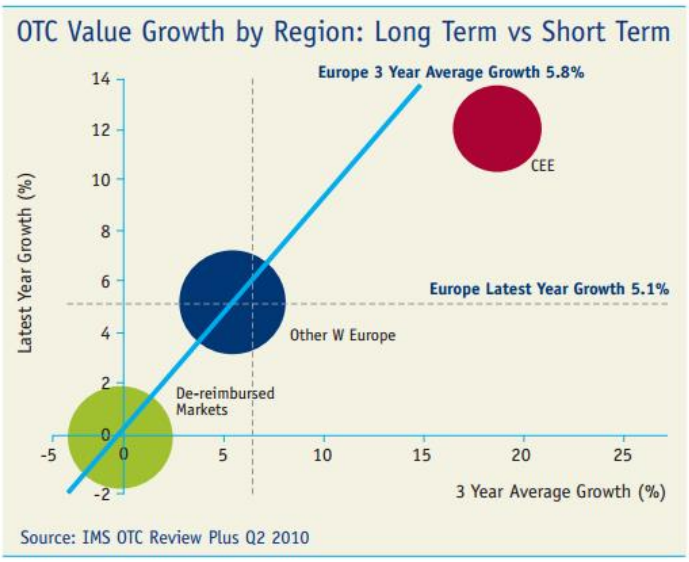


Figure 12. OTC value growth by region

Source: IMS Health (Tisman 2010)

According to IMS Health, by far the strongest driver of growth is the CEE region, led by Russia and Poland, and fuelled by the recent rise in disposable income, increased market penetration by foreign pharmaceutical manufacturers, as well as the fast expansion of pharmaceutical sales channels, such as pharmacy chains and drug stores (Tisman 2010). In addition, switching the status of a drug from Rx to OTC has also been an important driver of recent growth in the sector. According to IMS Health, the OTC market in Bulgaria is expected to grow at an annual rate of 10%, i.e. at the rate of Poland's and only second to the rate of the Russian OTC market (Figure 13) (Tisman 2010). It is important to point out here that in Bulgaria OTC drugs are not subject to reimbursement by the NHIF. Also, the number of medicines switching from Rx to OTC is projected to continue both in Bulgaria and worldwide, especially for medicines treating chronic conditions (Danchev 2011). This is good for public spending but equally bad for private pharmaceutical spending. Hence, in view of the recent growth and the projected growth in the OTC market in Bulgaria, we cannot disregard OTC consumption as a potential factor contributing to the rising private pharmaceutical expenditures in the country in the past decade.

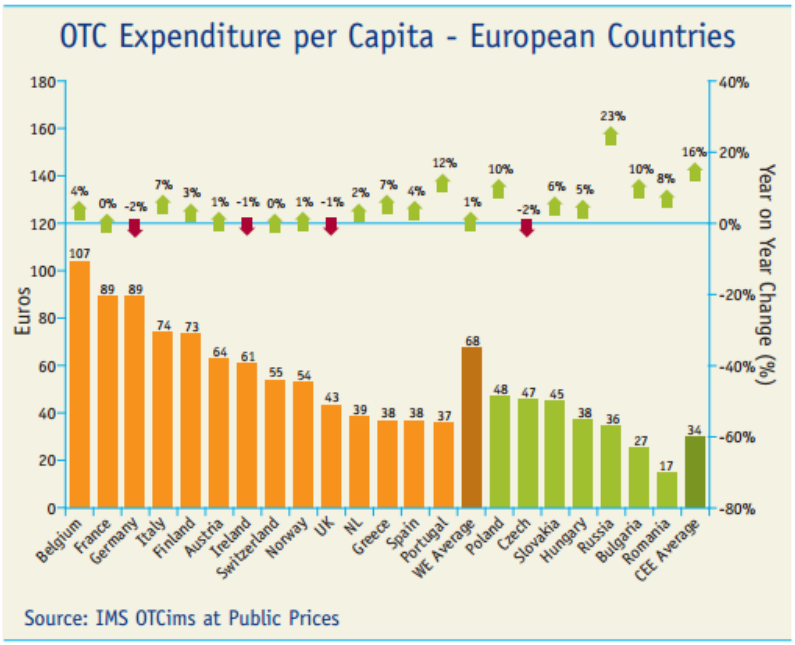


Figure 13. OTC Expenditure per capita – Europe

Source: IMS Health (Tisman 2010)

Generic Substitution

Although generic medicines are included in the Positive Drug List, there is no formal generic substitution policy in Bulgaria. Generic prescribing is only indicative although generic pharmaceuticals are proven to have the same therapeutic effect as original drugs and are allowed to enter the market once the patent of the original drug has officially expired. That is, physicians are allowed but are not formally required to prescribe in international non-proprietary names (INN), which is in a way a universal therapy that only prescribes the substance and dose but not the brand of the medicine. Also, pharmacists are not allowed to substitute generic drugs for branded medicines unless explicitly indicated by the physician on the prescription (The World Bank 2013). In fact, this is hinted by the data presented on the Figure 14 below which shows that the generic consumption trend in Bulgaria has been opposite to expectations, namely that the share of generic pharmaceuticals in the poorest country in the

EU has been falling both in value and in volume during the last few years, yielding room for expensive original drugs (Trifonov, *Analysis*, 2013).

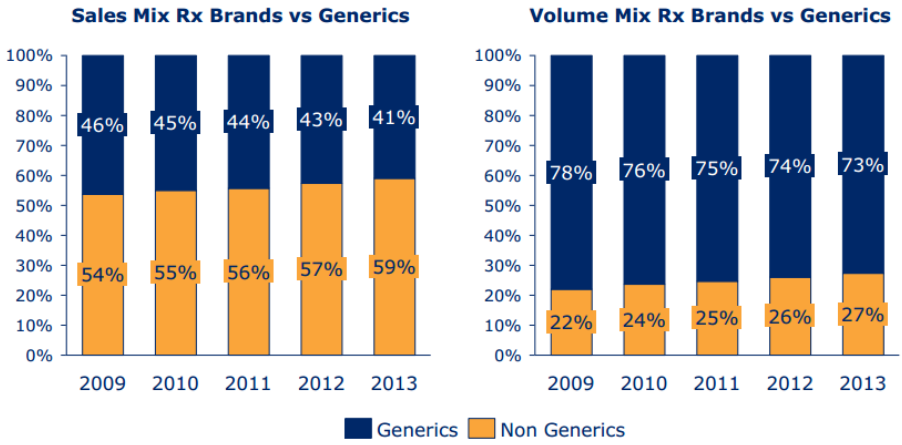


Figure 14. Generics decline in Bulgaria

Source: IMS Health (Trifonov, *Analysis*, 2013).

The purpose of using generic drugs as substitutes for original ones is to increase the number of patients with access to pharmaceutical therapies and to reduce both private and public costs. Simple logic says that as a result of the cost savings generated through the use of generic substitutes, additional resources can be freed for subsidizing new therapies which do not have a generic alternative, thus increasing overall access to, and quality of, treatment. If generics however get withdrawn from a given national market and there is no generic left available on the market, they need to get replaced with more expensive original drugs, thus increasing both public and private expenditures, i.e. both NHIF reimbursement costs and private co-payments.

Withdrawal of generic drugs from a given market occurs for several reasons. More recently in Bulgaria it has occurred as a result of imposed mandatory rebates on all drugs purchased and reimbursed by the NHIF (Nikolova 2014). These mandatory rebates came about as a policy initiative to reduce the increasing NHIF costs on pharmaceuticals to free up resources for hospital and ambulatory care (Nikolova 2014). Also, unlike in bigger pharmaceutical markets where discounts and rebates are negotiated based on large volumes, in the relatively small

Bulgarian market this is not the case. Thus, pharmaceutical companies get discouraged by the low attainable price for their drugs in addition to the small expected sales volume, and choose to withdraw. These mandatory discounts are efficient only in the case of expensive innovative therapies lacking the option for cheaper generic substitution. Discounts are not universally efficient for all drugs and are particularly inefficient in the case of generic pharmaceuticals. In the case of generics, this imposition of mandatory rebates has led to the withdrawal of many of them and according to experts will continue to induce further withdrawals (Marinova, 100 Cheap Medicines Withdrawn from Market during the Past 18 Months (100 евтини лекарства са изтеглени от пазара за последните 18 месеца) 2015). A smart solution to achieving effective mandatory rebates application could be their application only to original medicines which do not have generic substitutes and thus face no competition. These are usually the medicines in the Positive List with the highest prices and consuming the biggest NHIF resource (Marinova 2014).

Generic medicines in Bulgaria have strong presence in the treatment of socially significant diseases for many of which the NHIF reimbursement rate is only 25%, the rest financed by private patient co-payment, thus blocking patient access to essential therapy (Bulgarian National Audit Office 2012). What is more, many socially significant and chronic diseases could be just as dangerous as other health conditions requiring expensive treatment, and the NHIF should not discriminate against patients from the former group (Marinova 2014). On the contrary, basic essential treatment should be guaranteed for both patient groups. If more generic medicines get included in the Positive Drug List, NHIF reimbursement levels would rise and thus increase access to therapy for both groups.

Reimbursement and ERP

The withdrawal tendency of pharmaceuticals from the Bulgarian market has been observed ever since the moment of the introduction of the External Reference Pricing mechanism which obliges pharmaceutical companies in Bulgaria to register the lowest price observed in the basket of countries to which Bulgaria references. ERP applies equally to original as well as to generic medicines. Sometimes, however, pharmaceutical companies prefer not to enter small markets such as the Bulgarian one. Although ERP is generally accepted as an efficient pharmaceutical pricing tool, its effects are not so clear-cut in Bulgaria. In fact, the Bulgarian policy initiative to decrease pharmaceutical prices by taking the lowest of all has effectively has led to the opposite result, namely the withdrawal of and inability to use cheaper substitutes (Marinova, A. Valev: The Drastic Regulatory Decrease of the Price of Medicines is an Erroneous Policy Measure (А. Вълев: Драстично сваляне на цените на лекарствата е погрешна политика) 2015). Other problems with ERP include the so-called *ghost drugs* (PMR 2013). These are products which get registered and formally enter the national pharmaceutical market bringing down the prices of analogous drugs, but are actually not available on the market due to withdrawal, export, or other factors (PMR 2013).

Over the period 2003–2007 expenditure of NHIF on pharmaceuticals has remained relatively constant at around 130 million euro per year. However, household expenditure on pharmaceuticals outside the ones reimbursed by the NHIF has increased substantially from about 370 million euro in 2003 to 600 million euro in 2007 (Atanasova E. 2011). With NHIF expenditure remaining relatively constant, it follows that NHIF reimbursed about one-fourth of total pharmaceutical consumption in 2003 which fell to about 18% in 2007 (Atanasova E. 2011). Over this period, NHIF-funded pharmaceutical purchases have decreased for various reasons among which the exclusion of some commonly used medicines from the Positive List such as ones for chronic conditions (e.g. cardio-vascular diseases), as well as due to preferred

suppliers by the NHIF (Atanasova E. 2011). Consequently, as a result of the application of ERP, nearly half of the medicines subject to reimbursement are financed at 25% by the NHIF, and their total reimbursed value is relatively low, which makes the resource utilization ineffective (Bulgarian National Audit Office 2012). In order to increase efficiency of public pharmaceutical spending, policy makers need to reconsider the application of ERP on generic pharmaceuticals. This is because competition on the internal domestic market between pharmaceutical companies alone is able to achieve lower prices for generics and at the same time boost competitiveness.

Innovative Therapies

The introduction of innovative therapies treating existing health conditions more effectively but at a higher cost is another factor potentially responsible for the high private spending in Bulgaria. However, the unavailability of such data does not allow any empirical analysis to be included in the current thesis. Nevertheless, a figure placed in a 2014 IMS Health report throws some light onto the topic as well as on the relative place of Bulgaria with regards to the penetration of innovative therapies (Figure 15). The figure shows a set of European country innovation profiles according to number of new chemical entities (NCE) launched and NCEs market share in total Rx market over the period 2008-2012. Not surprisingly, Bulgaria falls in the group of Eastern European countries which have the lowest number of NCE launches market. Bulgaria in particular has the lowest market share of NCEs in total Rx market. Although this evidence is not enough to conclude that innovative therapies are not a contributor to high private pharmaceutical costs in Bulgaria, this evidence indicates that this factor is certainly not a major one, if at all.

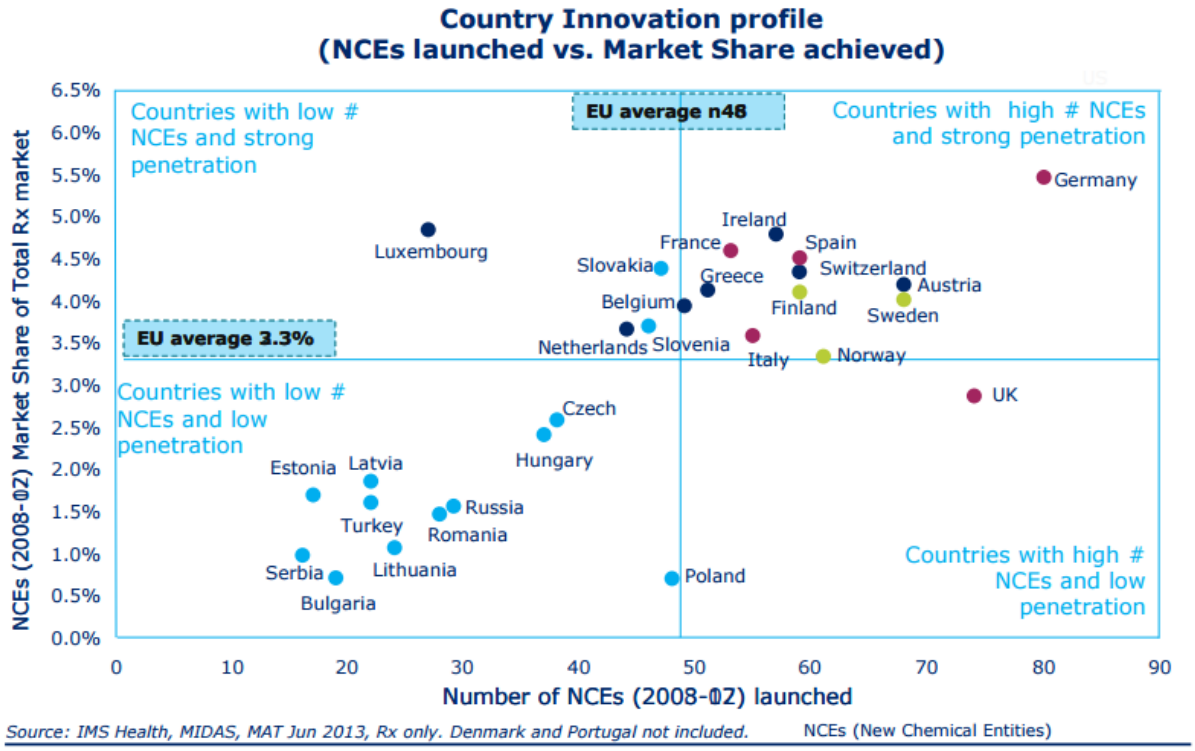


Figure 15. Innovative therapies: country innovation profiles

Source: IMS Health (Pilkiewicz 2014)

Pharmaceutical Taxation (VAT)

In January 2002 the government introduced a universal Value Added Tax which led to the increase in the prices of all drugs as well as to the co-payment charge. This naturally hit hard vulnerable groups such as pensioners (about 2.5million), the unemployed (nearly 17 % of the population) and people who live below the poverty line (Datzova 2003). The 20 % VAT on drugs brought about the purchasing power for drugs being diminished by 17 % (Datzova 2003). Currently, VAT in Bulgaria is the second most important component determining the final pharmaceutical price after manufacturer's price (Figure 16). Unlike changes in pharmaceutical profit regulation policies which significantly decreased retail and wholesale margins in 2011 in an effort to contain rising prices of medicines, [13] pharmaceutical VAT policies were left

[13] Ordinance of Regulation and Registration of Prices of Medicinal Products, as of Nov. 2011. (НАРЕДБА за условията, правилата и реда за регулиране и регистриране на цените на лекарствените продукти. Ное.

untouched despite ongoing public discourse. Indeed, there exist economic arguments against the differentiation of VAT across different sectors of the economy. However, in the case of Bulgaria they do not seem to hold any longer because the decrease of VAT for tourism has already set a precedent. Tourism, where VAT is set at 9% and is more than twice lower than the standard 20%, is the only sector in which VAT differs from the standard (Slavova 2014). That is, based on strategic sector arguments, the government has already shown preferential treatment for a particular economic sector with regards to relaxed taxation polices. Such actions, however, discriminate against other sectors and beg the question whether health or tourism is the more strategic sector?

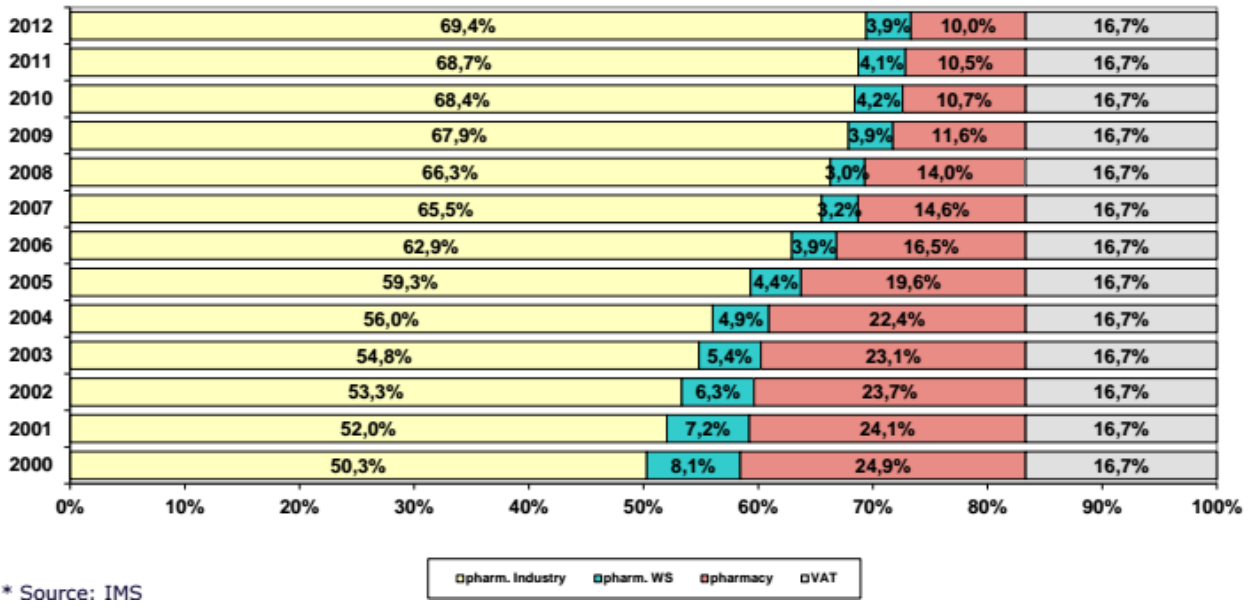


Figure 16. Share of drug expenditures – Value Added Process, 2000 – 2012

Source: IMS Health (Trifonov, *Public*, 2013)

2011г.) ; Ordinance of Regulation and Registration of Prices of Medicinal Products, as of Dec. 2007. (НАРЕДБА за условията, правилата и реда за регулиране и регистриране на цените на лекарствените продукти. Дек. 2007г.)

Challenges

Demographic challenges

"Bulgaria is heading for the steepest drop in the working-age population of any country, and it will impose a heavy burden on the economy" (The World Bank 2013). Its decline is likely to stifle growth because the proportion of working population is a key determining factor for a country's GDP and standard of living. In addition, aging will positively affect the demand for public services, such as demand for health services which tends to increase with age. According to the United Nations, Bulgaria's labor supply is projected to decline by as much as 40% and the share of elderly in the total population (old-age dependency ratio) is expected to double till the middle of the century (The World Bank 2013). Precisely, by 2050 only one in every two Bulgarian citizens will be of working age, and one in every three is expected to be older than 65 (The World Bank 2013). These projections put increasing pressure on the public health system and require firm actions aiming at increasing the efficiency of health provision, including the design and implementation of more effective pharmaceutical policies. According to the Word Bank, in Bulgaria the "financial protection provided by the National Health Insurance Fund has significant gaps and out-of-pocket (OOP) expenditures are large" (The World Bank 2013, pg. 47). There is an urge for targeted actions.

Fiscal challenges

In addition to the demographic challenge, the strict government budget restrictions and deficit limits set by the Stability and Growth Pact applicable to all EU member states put further pressure on healthcare spending. Along with expenditure concerns however, the question of ensuring inflows into the health system is another pressing issue. Currently, there are about 1.2 million uninsured people out of a population of 7.2 million (Dimitrov 2014) many of whom make use of public health services through calling on emergency services which are provided

free of charge for all citizens. This problem destabilizes the equity in financing healthcare and further disincentivizes those who do pay for social health insurance. In addition to the concern of the high number of uninsured, there is another issue stemming from the way the government contributes to the health system when insuring government employees, pensioners, children, students and vulnerable groups. That is, when paying the respective health insurance contribution for these population groups, the state pays only a fraction of it, while employers and employees in private firms as well as the self-employed are obliged to pay the full amount of their required social health insurance contribution based on their respective income level (Marinova 2014). What is more, the population groups for which the government pays are the ones consuming the highest amount of resources, especially children and the elderly. This partially explains the underfinancing and the recurring deficits in the NHIF. In an attempt to close health budget gap, in 2008 the health insurance contribution was raised from 6% to 8% of earnings but this policy did not bring about any significant effects in the financing of the health system (Beleva 2013). The problem of keeping the number of the ensured population constant remains.

Policy Recommendations

Based on the findings, analysis, discussion and encountered limitations presented in this thesis, the author established the need for further research relying on more detailed and precise data aiming to analyze the current private out-patient pharmaceutical burden in Bulgaria as well as its past developments. Also, based on the findings in this research, the author would like to emphasize a few key areas that need improvement and suggest potential policy measures of how these can be handled.

Firstly, with regards to generic pharmaceuticals availability and utilization, it is worth considering the inclusion of more generic pharmaceuticals in the Positive Drug List with an

aim to reduce public costs and free up resources for more expensive therapies. Also, the exemption of generics from the external reference pricing mechanism (ERP) would bring down their withdrawal rate, thus ensuring availability. It would also stimulate competition between generic products and ensure affordability. Generic prescribing should be encouraged in a targeted way, so that on the one hand, patients get informed about cheaper generic alternatives and on the other, pharmacists are formally allowed to substitute more expensive branded drugs with cheaper generic substitutes where appropriate. Also, this should be accompanies by clear line of accountability measures.

With regards to prescribing measures, in addition to generic prescribing, a clear way of tracking and assessing prescription by specialists and GPs should be established for the purpose of better monitoring and control of both patient safety as well as public resource expenditure. Such a measure would reduce the room for overprescribing which is likely to exists in an unmonitored environment with strong marketing pressure coming from pharmaceutical companies. Also, such a measure should aim at achieving full electronic monitoring of pharmaceutical prescribing. In addition, such a monitoring system would allow for future analyses the capability for which does not exist today. Patient and prescription statistics would help future public resource spending optimization.

Pharmaceutical taxation is another area that needs attention although this thesis does not achieve significant quantification of the burden of the pharmaceutical sales tax (VAT). Nevertheless, it is a notable fact that Bulgaria has the second highest pharmaceutical VAT in Europe and it applies to all pharmaceutical categories including life-saving prescription drugs. A differentiated VAT for pharmaceuticals, particularly for prescription drugs many of which are reimbursed by the NHIF, would achieve additional savings, both for public and private. Pharmaceutical taxes reduce utilization especially of vulnerable groups, thus reducing adherence to prescribed therapy, worsening preventive and chronic treatment outcomes, and

putting additional cost pressure on the health system. For achieving an optimal tax modification, the implementation of lower VAT on prescription medicines could be combined with increased taxation on unhealthy products and behavior.

Limitations

This thesis is not without limitations. These are mostly related to the lack of quantitative data on pharmaceutical prescribing practices, OTC consumption as well as the volume and value of innovative therapies in Bulgaria. Also, the lack of consistent data on private pharmaceutical spending encompassing a longer and uninterrupted period of time makes a substantial time series analysis impossible. The different measurement methods and time periods of pharmaceutical expenditure applied by the three major sources used in the thesis, namely the World Health Organization, the European Commission, and IMS Health, also makes the analysis difficult as the different data cannot be combined together into a single dataset. Additionally, the availability of aggregate data on private pharmaceutical expenditure as opposed to household-level data does not help for a more comprehensive analysis of pharmaceutical expenditure burden across different household quartiles and most affected groups. Also, the fact that Bulgaria is not an OECD country and is a late EU entrant, poses additional data availability problems. For example, data on generic pharmaceutical utilization in Bulgaria is not available in the OECD database, and it was collected manually from European Federation of Pharmaceutical Industries and Associations (EFPIA) reports. Regarding the analysis of potential drivers of the high private pharmaceutical expenditure in Bulgaria, health status and increasing morbidity of certain diseases such as diabetes is omitted in this thesis due to inability to find reasonable proxy data.

Chapter 7: Summary, Major Findings & Conclusions

This thesis presents a macro view of the public/private mix of out-patient pharmaceutical spending in Bulgaria and its evolution during the 2000-2010 period.[14] It aims to assess the financial burden on patients in the period following the introduction of the social health insurance system in 1998 by tracing Bulgaria's relative position with respect to other European countries throughout this period, and by using purchasing power as a normalizing factor. The findings in this thesis confirm the general trend that poorer countries have higher private expenditure shares in total pharmaceutical spending as opposed to richer countries where public spending often dominates the public/private mix. However, starting from 2003 Bulgaria has continually and significantly exceeded the observed average value of private pharmaceutical spending share of about 60% typical for upper-middle income countries as estimated by the WHO (Appendix VII), reaching levels much more typical for low income countries. Also, this thesis finds that starting from 2003 Bulgaria has been continuously found above the line predicted by purchasing power in the European country datasets used. That is, there are factors that drive Bulgarian private pharmaceutical spending higher than predicted by income level.

Although private pharmaceutical spending should not be seen as a negative phenomenon per se because it results from the widely-applied patient co-payment mechanism aimed to decrease demand-side moral hazard. In addition, patient co-payment also reduces supply-side moral hazard since high co-payments act as a credible threat in pricing negotiations between third-party payers (e.g. NHIF) and pharmaceutical suppliers. That is, if the payer decides to

[14] This thesis does not look at the period 2010-2015 due to unavailability of data. However, the author has reasonable reasons to assume that the figures for private out-patient pharmaceutical expenditure have not changed for the better due to the lack of major healthcare or pharmaceutical reforms being undertaken in Bulgaria.

reimburse at a low level or not to reimburse at all, prices of drugs are set according to patients' willingness to pay.

Continuously excessive OOP levels, however, do raise certain questions. Such questions relate to the potential factors that might be contributing to these high levels, as well as to the general health status of the population foregoing medicines consumption due to unaffordability. Foregone out-patient pharmaceutical consumption, in turn, is associated with rising in-patient costs in the future because untreated existing conditions pose higher risk of future complications, eventually putting more pressure on the public health budget. This is why, cross-effects of out-patient medicines intake and probability of subsequent hospitalization should be incorporated into future pharmaceutical pricing and reimbursement decisions. For Bulgaria this issue should be of particularly high priority due to the increasingly expensive public hospital sector, as well as the pressing demographic and fiscal challenges.

The large and unsustainable OOP spending on pharmaceuticals in Bulgaria has led to exclusions from the universal health insurance system and increased inequity, and has caused numerous inefficiencies. These are evident in the rising number of uninsured population. Given the projected fiscal and demographic challenges, prevention and early detection should be included as a specific policy to contain future public spending and free up resources for innovative therapies. In addition, further savings due to generic use could also be used to increase number of patients treated or decrease the patient co-payment rate in pharmaceutical expenditure. In addition to generic prescribing policies, a clear way of tracking and assessing pharmaceutical prescription should be introduced to better monitor both patient safety as well as public resource expenditure, and thus reduce the room for overprescribing. Such a monitoring system would allow for healthcare trends analyses and help future public resource spending optimization. The system of reference pricing (ERP) should be reassessed as well as its potential effects on driving up OOP payments for pharmaceuticals due to reasons such that

reference countries have quite different internal pharmaceutical regulations and health systems which makes them rather imperfect references. In a way "importing" the prices of other countries through ERP entails adopting their respective health priorities over these of the population of the "importing" country. Lastly, the undifferentiated and rather high VAT rate for prescription pharmaceuticals in Bulgaria of 20%, the third highest in Europe after Denmark and Germany, is another legislative issue which needs particular attention. The prescription pharmaceuticals VAT should be reexamined especially in view of the fact that the Bulgarian tourism sector has already been granted a lower VAT rate, thus seriously questioning national health priorities.

To sum up, the existing legislation (ERP taking the lowest price, high and undifferentiated Rx VAT) or the lack of such (no policy on generic substitution, no monitoring of prescribing practices) remain at the center of the unsustainable OOP spending on pharmaceuticals in Bulgaria.

References

Andre, G. and I.Semerdjiev. *Pharmaceutical Pricing and Reimbursement Information: Bulgaria Pharma Profile.* European Commission - Health and Consumer Protection Directorate-General, and Austrian Ministry of Health, Family and Youth, 2007.

Andre, G. and I.Semerdjiev. *PHIS Pharma Profile: Bulgaria.* Pharmaceutical Health Information System, 2010.

Atanasova E., M. Pavlova, R.Velickovski, B.Nikov, E.Moutafova, W. Groot. "What have 10 years of health insurance reforms brought about in Bulgaria? Re-appraising the Health Insurance Act of 1998." *Health Policy*, no. 102 (2011): 263– 269.

Atanasova, E. et al. "Out-of-pocket payments for health care services in Bulgaria: financial burden and barrier to access." *European Journal of Public Health* (Oxford University Press), December 2012.

Beleva, I. et al. *Economic Development and Politics in Bulgaria: Assessment and Expectations. Healthcare Policies: Economic Analysis and Assessment. (Икономическо развитие и политики в България: оценки и очаквания.Политики в здравеопазването - икономически анализ и оценки).* Annual Report 2013, Economic Research Insitute of the Bulgarian Academy of Sciences., Bulgarian Academy of Sciences , Sofia: Gorex Press, 2013.

Bulgarian National Audit Office. *Audit Report No. 112 (Одитен доклад No. 112 за извършен одит на изпълнението на регулирането на цените на лекарствените продукти, включени в Позитивния лекарствен списък и заплащани с публични средства).* Sofia: Bulgarian National Audit Office, 2012.

Carone, G., Schwierz, C., Xavier, A. *Cost-containment policies in public pharmaceutical spending in the EU.* European Economy. Economic Papers 461., Directorate-General for Economic and Financial Affairs., Brussels: European Commission, 2012.

Danchev, N. et al. "OTC Medicines: Bulgarian and International Experience (OTC лекарствени продукти: български и световен опит)." Наука Фармакология 1/2011, Department of Pharmacy, Medican University of Sofia, Sofia, 2011.

Datzova, B. *Health Care Reform and Inequality of Access to Health Care in Bulgaria.* United Nations Institute for Social Development (UNRISD)., 2003.

Dimitrov, G. *Healthcare 2014: Status, Problems, Solutions, Challenges (Здравеопазване 2014: състояние, проблеми, решения, предизвикателства).* Sofia: Bulgarian Industrial Association, 2014.

—. *The Health System: More Expensive and Less Efficient (Здравната система - все по-скъпа, но все по-неефективна).* Bulgarian Industrial Association. April 22, 2014. http://www.bia-bg.com/analysis/381/%D0%97%D0%B4%D1%80%D0%B0%D0%B2%D0%BD%D0%B0%D1%82%D0%B0_%D1%81%D0%B8%D1%81%D1%82%D0%B5%D0%BC%D0%B0_%D0%B2%D1%81%D0%B5_%D0%BF%D0%BE_%D1%81%D0%BA%D1%8A%D0%BF%D0%B0_%D0%BD%D0%BE_%D0%B2%D1%81%D0%B5_%D0%BF%D0%BE_%D0%BD%D0%B5%D (accessed May 18, 2015).

Dimova, A. et al. *Bulgaria: Health system review.* Health Systems in Transition, European Observatory on Health Systems and Policy, 2012, 14(3).

—. "The Health-Care Reform in Bulgaria: Analysis." 2007.

EFPIA. *The Pharmaceutical Industry in Figures: 2010.* European Federation of Pharmaceutical Industries and Associations , 2010.

EFPIA. *The Pharmaceutical Industry in Figures: 2012.* European Federation of Pharmaceutical Industries and Associations, 2012.

EFPIA. *The Pharmaceutical Industry in Figures: 2013.* European Federation of Pharmacetucal Industries and Associations (EFPIA)., 2013.

Eurostat. *Healthcare Statistics.* n.d. http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_statistics (accessed May 18, 2015).

Koulaksazov, S. et al. *Health care systems in transition: Bulgaria*. Copenhagen: European Observatory on Health Care Systems., 2003.

Lu, Y. et al. *THE WORLD MEDICINES SITUATION 2011: MEDICINE EXPENDITURES.* WHO Press, Geneva: World Health Organization, 2011.

Madjarova, M. "Impact of the Reference Price System on the Pharmaceutical Market." *Economic Alternatives* (University of National and World Economy (Bulgaria)), no. 2 (2007).

Marinova, E. *100 Cheap Medicines Withdrown from Market during the Past 18 Months (100 евтини лекарства са изтеглени от пазара за последните 18 месеца).* Invostor.BG. January 5, 2015. http://www.investor.bg/ikonomika-i-politika/332/a/100-evtini-lekarstva-sa-iztegleni-ot-pazara-za-poslednite-18-meseca-186635/ (accessed May 18, 2015).

—. *A. Valev: The Drastic Regulatory Decrease of the Price of Medicines is an Erroneous Policy Measure (А. Вълев: Драстично сваляне на цените на лекарствата е погрешна политика).* January 6, 2015. http://www.investor.bg/bulgaria-on-air/462/a/a-vylev-drastichno-svaliane-na-cenite-na-lekarstvata-e-pogreshna-politika-186747/ (accessed May 18, 2015).

—. *Nikolay Hadzhidontchev: The Withdrawal of Drugs from the Market Will Continue (Николай Хаджидончев: Изтеглянето на лекарства от пазара ще продължава).* April 25, 2014. http://www.investor.bg/imenata-na-biznesa/107/a/nikolai-hadjidonchev-izteglianeto-na-lekarstva-ot-pazara-shte-prodyljava-171068/?page=3 (accessed May 18, 2015).

NATIONAL COUNCIL ON PRICES AND REIMBURSEMENT OF MEDICINAL PRODUCTS. n.d. http://www.ncpr.bg/en/ncprmp/about-council (accessed May 18, 2015).

Nikolova, D. *Poor because of Poor Health (Бедни заради здравето).* Capital Daily. March 13, 2015. http://www.capital.bg/politika_i_ikonomika/bulgaria/2015/03/13/2491195_bedni_zaradi_zdraveto/ (accessed Маъ 18, 2015).

—. *Production of More than 30 Medicines Ceased due to Low Price (Над 30 медикамента излизат от производство заради твърде ниска цена).* Capital Daily. May 11, 2014. http://www.capital.bg/politika_i_ikonomika/bulgaria/2014/05/11/2297200_nad_30_medikamenta_izlizat_ot_proizvodstvo_zaradi/ (accessed May 18, 2015).

—. *Recipe for Communism. (Рецепта за комунизъм). Capital Daily.* May 11, 2011. http://www.capital.bg/politika_i_ikonomika/bulgaria/2011/05/20/1093027_recepta_za_komunizum/ (accessed May 18, 2015).

Nyman, John. "Is 'Moral Hazard' Inefficient? The Policy Implications Of A New Theory." *Health Affairs* (Health Affairs) 23, no. 5 (September 2004): 194-199.

Petrova, Guenka. *The Socio-Economic Impact of Health Care Cost-Containment Measures During Economic Crisis in Bulgaria.* Medical University Sofia, 2012.

Pilkiewicz, Michał. *What the structure of the market will be: EU vs. CEE. Presentation at conference „UKRAINIAN PHARMACEUTICAL MARKET – 2014".* IMS Health, 2014.

PMR. *Romanian and Bulgarian pharma markets expected to witness most substantial increases in generic and innovative markets between 2013 and 2015.* PMR, 2013.

Slavova, Zornitsa. *Differentiated VAT in Tourism Creates Pressures Once Again (Диференцираното ДДС за туризма отново създава напрежение).* July 18, 2014. http://ime.bg/bg/articles/diferenciranoto-dds-za-turizma-otnovo-syzdava-naprejenie-2/#ixzz3a6OPdZ5w (accessed May 18, 2015).

The World Bank. *Bulgaria - Health sector diagnosis policy note.* Washington, DC: The World Bank, 2013.

The World Bank. *Bulgaria - Health sector diagnosis policy note.* Washington, DC: The World Bank, 2013.

The World Bank. *Mitigating the Economic Impact of an Aging Population: Options for Bulgaria.* Poverty Reduction and Economic Management Unit: Europe and Central Asia Region, The World Bank, 2013.

—. *World Bank Data.* n.d. http://data.worldbank.org/indicator.

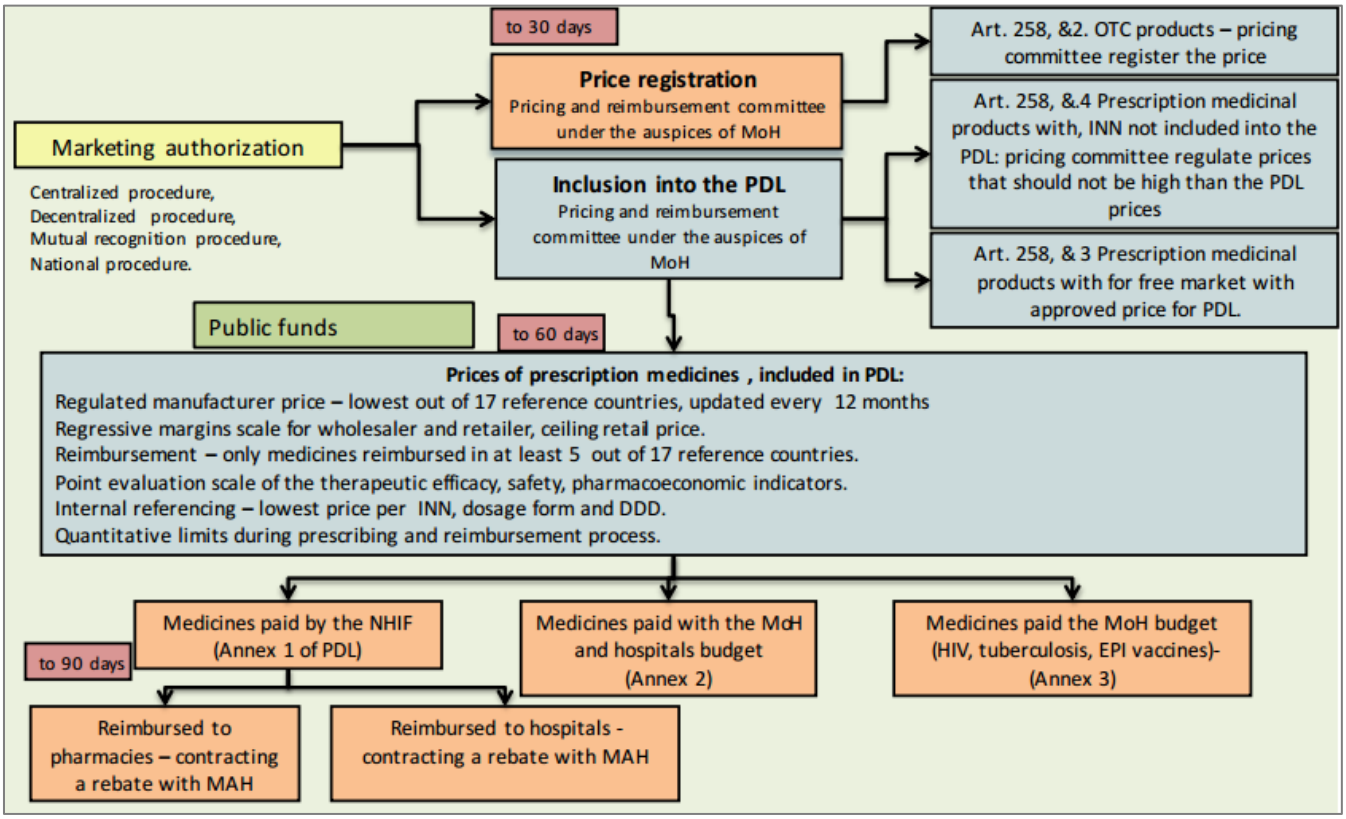
Tisman, Andy. *The Rising Tide of OTC in Europe: Trends, Challenges and New Potential in a Rapidly Evolving Market.* IMS Health, 2010.

Trifonov, Kountcho. *Analysis of the Bulgarian Generic Drugs Market (Анализ на пазара на генеричните лекарства в България).* IMS Health - Bulgaria . November 14, 2013. http://static.framar.bg/filestore/Kuncho_Trifonov.pdf (accessed May 18, 2015).

Trifonov, Kountcho. *Public Pharmaceutical Expenditure Dynamics: Comparison with EU (Динамика на публичните разходи за лекарства. Сравнение със страни от ЕС. Стойности и цени.).* IMS Health, 2013.

Appendices

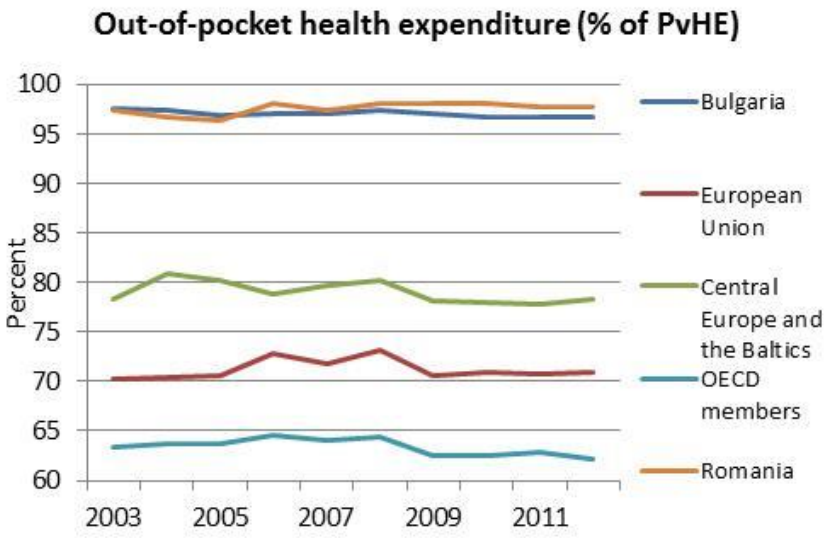
Appendix I



Appendix 1. Regulatory framework of the medicines access to the market in Bulgaria

Source: (Petrova 2012)

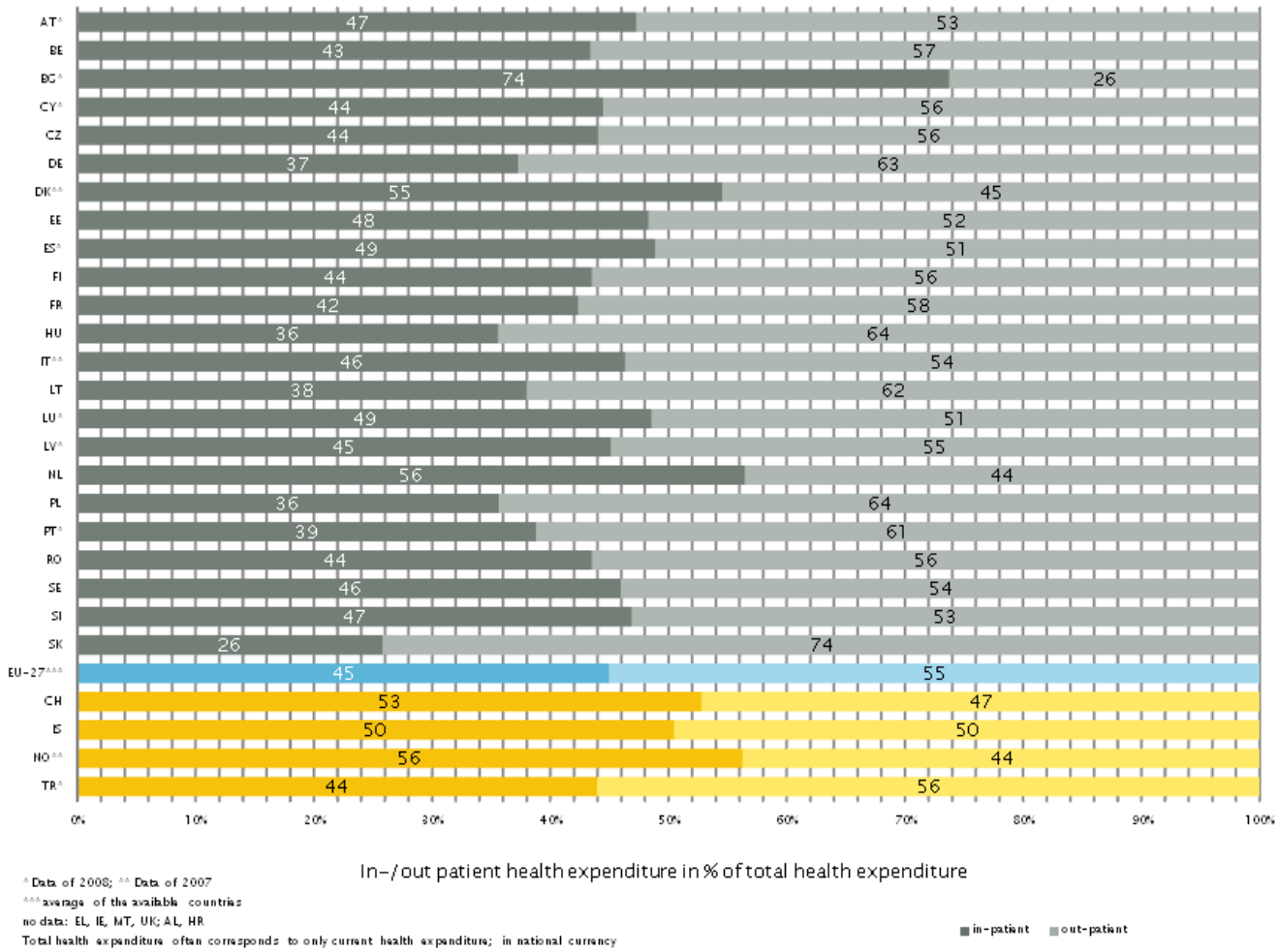
Appendix II



Appendix 2. OOP health expenditure as % of Private Health Expenditure, 2003-2011

Source: The World Bank Database

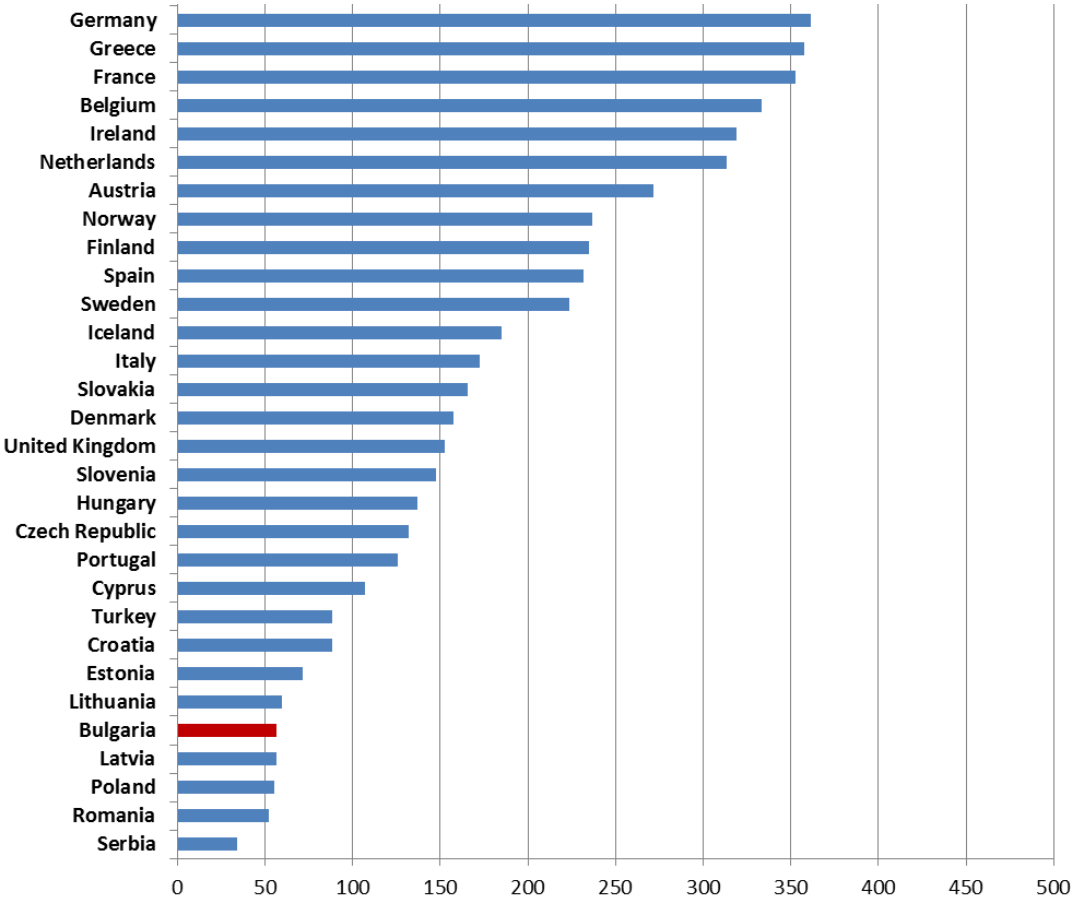
Appendix III



Appendix 3. In-patient/out-patient Health Expenditure in % of total Health Expenditure

Source: Pharmaceutical Health Information System (PHIS). https://phis.goeg.at/index.aspx?_nav0031

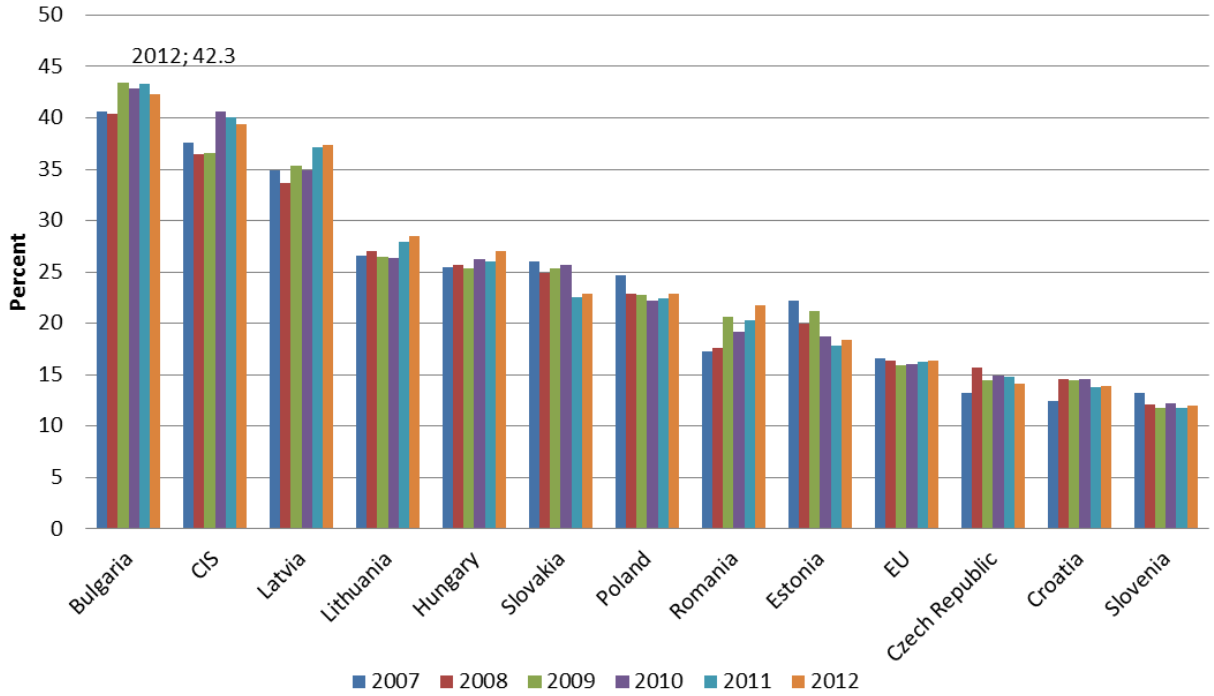
Appendix IV



Appendix 4. Payment for pharmaceuticals per capita by compulsory health insurance systems and national health services in 2011 for ambulatory care only (euro)

Source: EFPIA (http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf), population data from Eurostat. Author's own presentation

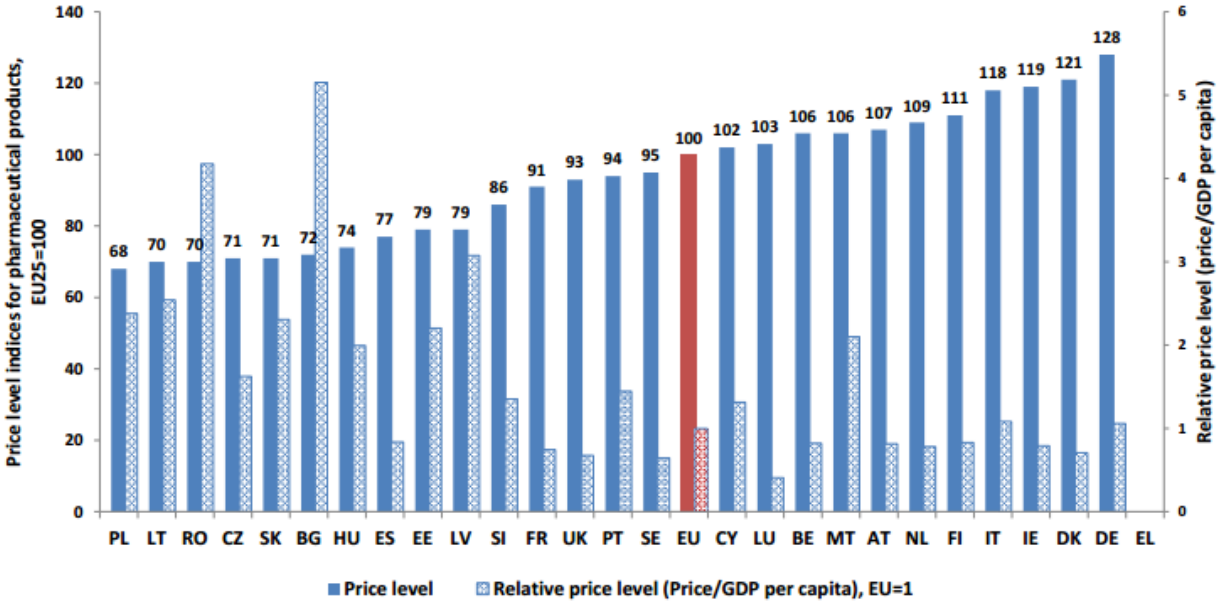
Appendix V



Appendix 5. Private Households' OOP Spending as % of Total Health Expenditure

Source: European health for all database (HFA-DB), World Health Organization Regional Office for Europe.
http://data.euro.who.int/hfadb/tables/tableA.php?id=tbla_279912001422367311&ind=6860
Author's own presentation.

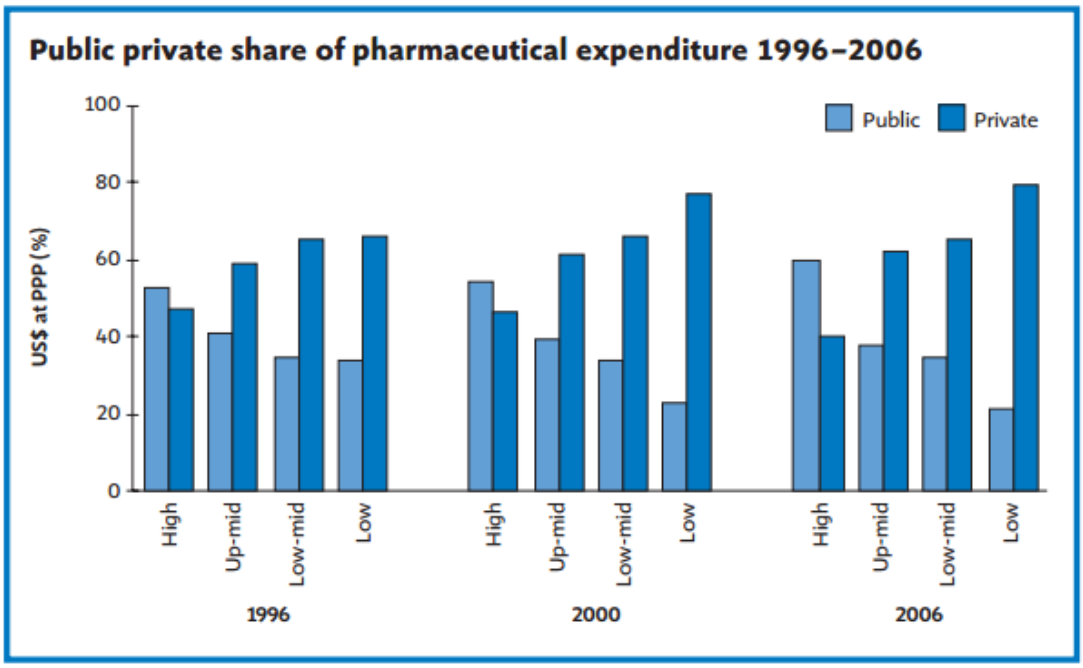
Appendix VI



Appendix 6. Price level index for pharmaceutical products in 2005, EU25=100

Source: (Carone 2012)

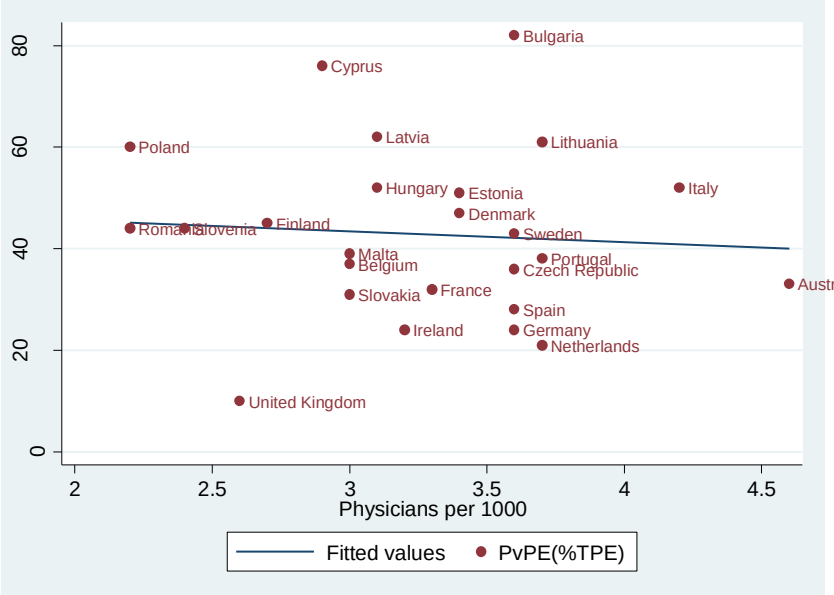
Appendix VII



Appendix 7. Public vs. Private share of pharmaceutical expenditure according to income group

Source: (Lu 2011)

Appendix VIII



Appendix 8. Private pharmaceutical expenditure share of total vs. Physicians per 1000