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Bulgaria Health Sector Diagnosis Policy Note

Table of Contents

1.	Summary and key recommendations	4
2.	Introduction	7
3.	Overview of health system's characteristics and performance	8
	Health Status	8
	Coverage of services and access to the health system	11
	Perceptions about the health system	13
	Health Expenditure	14
4.	Main issues, latest developments, and way forward	16
	Rationalizing the hospital sector	16
	Strengthening outpatient care, with a focus on NCDs and in particular cardio-vascular dise	eases
		21
	Pharmaceutical policies	22
	Additional priorities for the mid-term	

Abbreviations and Acronyms

BGN Bulgarian Lev

CCPs Clinical Care Pathways
DRGs Diagnostic Related Groups
ECA Europe and Central Asia

EU European Union

EU-12 European Union of 12 member states: Belgium, Denmark, and France,

Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal,

Spain, and United Kingdom

EU-15 European Union of 15 member states: EU-12 plus Austria, Finland, and

Sweden

EU-25 European Union of 25 member states: EU-15 plus Czech Republic, Cyprus,

Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia

EU-27 European Union of 27 member states: plus Bulgaria and Romania

GDP Gross Domestic Product GNI Gross National Income

HFA Health For All

HiT Health Systems in Transition

LE Life Expectancy
LTC Long-term Care
MoH Ministry of Health

NCDs Non-communicable Diseases NHA National Health Accounts

NHIF National Health Insurance Fund

NICE National Institute for Health and Clinical Excellence, UK

NMS New Member States

OOP Out-of-Pocket Expenditure

PDL Positive Drug List

PHE Public Health Expenditure

QOF Quality and Outcomes Framework

SDR Standard Death Rate

USAID United States Agency for International Development

WHO World Health Organization

Bulgaria Health Sector Diagnosis Policy Note¹

1. Summary and key recommendations

The health system in Bulgaria has undergone significant transformations since the transition and it continues to evolve. This policy note² updates a similar document prepared in 2009. It highlights some positive developments, particularly in the area of public health, but continues to find gaps that recent reforms have been unable to reverse. In particular:

- Health status in Bulgaria is improving at a slower pace than in other EU countries, and the burden of non-communicable diseases is particularly high.
- Coverage of preventive services is low and Bulgarians are much more frequently hospitalized than other Europeans, a sign that the system may not be producing the right mix of services³.
- Bulgarians are among the least satisfied Europeans when it comes to their health system.
- Total health expenditure is comparable to that of countries with similar income, but the out-ofpocket share is disproportionately large and has grown over time, and the financial protection
 provided by the system is incomplete.

Whilst more public expenditure on health will be needed in the medium to long-term, any increases should be accompanied by improvements in efficiency and effectiveness in order to make the best use of resources and ensure the delivery of better health outcomes. This policy note thus primarily focuses on three areas where decisive and prompt action could rapidly bring results and improve the experience of Bulgarian citizens: hospitals, outpatient care, and drug policies. These issues are closely interlinked and tackling them is key to the modernization of service delivery in all European countries. Indeed, in order to face the challenges brought about by ageing and non-communicable diseases and to meet the population's needs and expectations, new models of health and social care need to emerge that enable patients to stay out of hospital. This is possible through technological change, but can only happen if the outpatient sector delivers more and patients can manage diseases and risk factors through access to appropriate services and medicines.

¹ This note was prepared by Agnès Couffinhal (Senior Economist, World Bank), with the support of Travis Lim, Consultant, Kate Mandeville (Health Specialist World Bank), and Petko Salchev (Consultant). The Note was peer reviewed internally and comments were received from Owen Smith (Senior Economist, World Bank), Marcelo Bortman (Senior Public Health Specialist, World Bank), Armin Fidler (Advisor, Policy and Strategy, HNP, World Bank) and Markus Repnik. Comments were also received from the Ministry of Health and the Ministry of Finance, following which the note was further amended and additional clarifications provided.

² A policy note is a rapid and selective assessment undertaken to inform the policy dialogue between the World Bank and a government. The Bulgarian HiT report 2012 provides a more comprehensive description. http://www.euro.who.int/en/who-we-are/partners/observatory/health-systems-in-transition-hit-series/countries-and-subregions/bulgaria-hit-2012

It must be noted from the onset that international comparisons are based on the last year for which data is available for all countries from a single source (Eurostat or the WHO Health for All database) which is typically 2010. Since then, numbers may have changed in Bulgaria which could, at least in theory, affect the country's ranking.

Rationalizing the hospital sector

Bulgaria faces enormous challenges in the rationalization and management of the hospital sector. Among New Member States, Bulgaria is now the country with the highest number of acute care beds per capita, and this number is still growing, one of many indicators that service delivery is overly hospital-based. The National Health Insurance Fund is under the obligation to contract with all new entrants in the hospital market which leads to an inefficient fragmentation of service delivery. An attempt was recently made at limiting the number of contracts by introducing minimum standards that hospitals had to meet in order to be allowed to provide specific services. This resulted in reducing the scope of services provided by some municipal hospitals but had practically no impact on the number of hospitals contracted or in operation. The incentives thus remain strong in the system to provide an everincreasing number of services in a hospital setting. Individual hospital caps on the volume of services were introduced in 2010, which put a stop to volume escalation. The implementation of payment by Diagnostic-Related Groups (DRG) continues to be delayed. Provided that they are implemented along with global budgets, their introduction would increase the transparency of hospital funding while maintaining costs under control. Quality assurance and monitoring systems require strengthening as information on quality of care could be usefully leveraged (i) to support rationalization efforts and (ii) to ensure that the economic incentives brought by tightening financial constraints do not unduly undermine quality.

Key recommendations:

- Implement a technically-driven hospital rationalization plan to consolidate service delivery;
- Support this implementation by genuinely selective contracting and, as relevant, strategically selected investments;
- Encourage consolidation and streamlining in areas of high density by merging facilities into autonomous and fully financially accountable networks;
- Introduce DRG-based payments together with expenditure caps to maintain strong incentives to limit volume escalation;
- Generate, collect, use and publicize information on quality to support the rationalization process;
- Strengthen quality assurance mechanisms.

Strengthening outpatient care, with a focus on non-communicable diseases

Outpatient care is underdeveloped in Bulgaria, receiving just 12% of current health expenditure in 2008 compared to 25-30% in the majority of EU-15 countries. Primary care is particularly well-placed to manage the burden of non-communicable diseases facing Bulgaria, however primary care professionals lack specific training and confidence in managing chronic diseases. Referral to specialist care is high: whilst about 80% of medical contacts should be able to be resolved in primary care, in Bulgaria this rate is around 70% or less. This is compounded by the current payment system based mainly on capitation without performance-related elements. Overall, the scope of outpatient care needs to increase dramatically as well as the accountability of providers for results. This effort should be complemented by additional cross-sectoral measures to tackle risk factors for non-communicable diseases, as was recently done for tobacco control.

Key recommendations:

- Strengthen the capacity of primary care health professionals to manage the prevailing burden of disease and play an active role in the coordination of their patients' care;
- Introduce elements of pay for performance with a focus on non-communicable diseases in order to increase the management of chronic diseases at the primary care level;
- Select and implement additional multi-sectoral measures to combat risk factors for noncommunicable diseases.

Pharmaceutical policies

Whilst government spending on pharmaceuticals is currently in line with other New Member States, pharmaceutical policies and regulations are frequent subjects of public controversy, undermining public confidence in the system. Out-of-pocket spending on pharmaceuticals in Bulgaria is very high, representing more than 70% of household expenditure on health. Contributing factors include a sub-optimal use of generic medicines, with no requirement for physicians to prescribe in nonproprietary names and no freedom for pharmacists to substitute generics for branded medicines. In addition, inappropriate prescribing is common and influenced by pharmaceutical marketing practices. Health Technology Assessment processes are not used to decide on the inclusion of drugs in the NHIF reimbursement list.

Key recommendations:

- undertake a complete and transparent audit of the current Positive Drugs list, a review of public purchasing methods and elaborate a strategy to improve the transparency of management practices in the sector;
- ensure this process is supported by reputable and indisputably independent experts in order to limit influence from interest groups;
- develop and implement policies to encourage and monitor the rational use of medicines (including generics).

Many technical experts in Bulgaria would agree with the above recommendations and in fact, some changes in this direction have already been attempted but not carried through to completion. Delivering better health outcomes for the citizens of Bulgaria will require strong and consistent strategic leadership at the system level. The process should start with an open discussion to establish a realistic vision and explicitly articulate system-level priorities. The subsequent choice and design of reforms should be undertaken in a way that contributes to achieving these priorities. A forthcoming report on Health Systems in Eastern Europe and Central Asia⁴ highlights that while there are no specific recipes to building better performing health systems, the use of information for decision making and strong leadership are crucial. As the report puts it: "Successful reform requires vision and leadership. It means taking on vested interests, whether in the medical establishment, political actors, or elsewhere in society, to usher in new reforms that will help achieve sectoral objectives."

⁴ World Bank. (forthcoming). Getting Better: Improving Health System Results in Eastern Europe and Central Asia. Human Development Unit, Europe and Central Asia Region.

2. Introduction

- 1. Fifty years ago, the countries of Europe and Central Asia (ECA) were faring quite well in matters of health but the picture today is very different⁵. Life expectancy in ECA was just five years less than in Western Europe, but ten years more than in Latin America and twenty years more than East Asia and the Middle East. In the period since, the life expectancy gap with the EU-15 has more than doubled, to eleven years, and the other middle-income regions have all overtaken ECA. The divergence in health indicators between Eastern and Western Europe has come despite converging income levels, reflecting the global experience that growth does not automatically lead to better health.
- 2. Health systems in Eastern Europe are not delivering enough results. In large part, the limited convergence in health outcomes is explained by slow progress on cardiovascular diseases, which are largely amenable to intervention. Further, few countries have significantly improved the financial protection provided by the health system and many people in ECA fall into poverty due to medical bills.
- 3. This long-term trend matters because health is valued highly by the population. People are willing to give up a lot in order to improve their odds of living long, healthy lives. As countries grow richer and basic needs are met, this becomes even more true. Survey evidence also indicates that the health sector is consistently ranked as the top priority for additional government spending in about three-quarters of the countries in ECA, including among men and women, old and young, rich and poor.
- 4. In many respects Bulgaria exemplifies the ECA story but demographic trends give an additional sense of urgency to the health agenda. Bulgaria's population is declining faster than any other country in the European Union. Future growth critically depends on (a) the ability to keep older workers in good health and to manage their cardiovascular and chronic diseases effectively and (b) ensuring that a maximum of young people enter the labor market and reach their full potential. This means in particular better care for the young and growing Roma population which has lower health outcomes and access to care than the rest of the population.
- 5. The Government of Bulgaria is cognizant of these challenges and set on tackling them. In order to pave the way for future reforms and in agreement with the Ministry of Health, the enclosed policy note was prepared in 2012 to update a 2009 document of similar nature⁶. To set the context, this policy note starts with a brief assessment of the Bulgarian health system's performance and puts it in perspective with its level of expenditure. The following section analyses key policy developments in the past three years and proposes options moving forward. The analysis deliberately focuses on 3 areas which, if prioritized, would have a chance of rapidly improving the experience of citizens and the performance of the health system: the hospital sector, outpatient care and pharmaceuticals. The note concludes by listing additional issues which will require concerted efforts in the long-term. The recently published Bulgaria HiT provides a wealth of additional background information on the Bulgarian health system's features and reforms⁷.

⁵ World Bank. (forthcoming). Getting Better: Improving Health System Results in Eastern Europe and Central Asia. Human Development Unit, Europe and Central Asia Region.

⁶ World Bank. Bulgaria: Improving quality and sustainability of the health system. Health Sector Reform Policy Note, September 2009, prepared by Owen Smith.

⁷ Dimova A, Rohova M, Moutafova E, Atanasova E, Koeva S, Panteli D, van Ginneken E. (2012) Bulgaria: Health system review. Health Systems in Transition, 2012, 14(3):1–186.

3. Overview of health system's characteristics and performance

- 6. The health system in Bulgaria is profoundly diverse with a mix of public and private, centralized and decentralized features among financiers and providers of health care. At the center of the public funding system lies the National Health Insurance Fund (NHIF), meant to cover all citizens, and through which the bulk (about 70%⁸) of public resources is channeled into the health system. Health services are delivered by a network of providers which operate in the public or in the private sector. Outpatient care is provided in single and group practices, and in medical, diagnostic, and dental centers, most of which are private. Hospitals operate as commercial companies and are predominantly owned by the central and local governments. Around 10 percent of the beds and a third of hospitals are private. Virtually all providers have a contract with the NHIF. General practitioners are primarily paid based on capitation and other outpatient services on a fee basis. Hospitals are paid for services on the basis of Clinical Care Pathways (CCPs) which are case-based payments. Private expenditure almost exclusively out-of-pocket represents more than 45% of the money spent on health in Bulgaria⁹.
- 7. The system has thus gone a long way from its centralized pre-transition status. Yet, this section, which examines various dimensions of the health system's performance, shows that much progress is needed to bring Bulgaria on par with comparable countries.

Health Status

Table 1. Health Status Indicators, Bulgaria and Comparator Countries (2009 or last available)

Countries	Life expectancy (LE) at birth, in years	Reduction of LE through death before 65*	Infant deaths per 1000 live births	Standard Death Rate (SDR) all causes, per 100000	SDR, diseases of the circulatory system, per 100000	SDR, malignant neoplasms, per 100000	SDR, chronic liver disease / cirrhosis, per 100000	Tuberculosis incidence per 100000
Austria	80.6	4.1	3.8	563	213	158	15	5.3
Bulgaria	73.4	6.9	8.6	995	611	172	18	35.4
Czech Republic	77.5	4.8	2.9	744	357	197	16	6.0
Greece	80.3	4.0	3.2	577	245	154	5	4.1
Romania	73.6	7.2	10.1	959	549	181	47	97.2
Slovakia	74.3	6.3	7.2	945	509	208	25	8.1
Slovenia	79.3	4.6	2.6	632	235	202	25	9.1
EU	79.6	4.6	4.3	622	234	173	14	13.5
New Member States	75.1	6.6	6	873	436	199	27	35.9

Source: HFA database (accessed Aug 2012). *Hypothetical increase in life expectancy if no one died before 65.

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⁸ Source: National Health Accounts 2010 (preliminary data from National Institute of Statistics)

⁹ WHO NHA database for 2010 (last year available).

- 8. Health outcomes have improved over time but Bulgaria has been falling behind most EU countries. Table 1, for instance, shows that the average life expectancy at birth for a Bulgarian is 73 years, compared to 80 in the EU27 and 75 among the New Member States (NMS). In fact, Bulgaria now lags behind most neighboring countries which joined the EU after 2004, when twenty years before it was performing relatively better (a pattern illustrated by Figure 1 which holds across many indicators¹⁰).
- 9. Bulgaria still has relatively high infant mortality rates, but the burden of non-communicable diseases is dominant. The burden of diseases of the circulatory system is particularly high in Bulgaria, more than 2.5 times the EU average (Table 1). Figure 1 displays the mortality rate for circulatory diseases for the population below 64 which was 143 per 100,000 in 2009, 46% higher than the average of NMS. In fact, heart attacks, heart failures, and strokes jointly comprise more than 65% of all reported causes of death (Figure 3.). Cancer is the next major cause of death in Bulgaria, with cancer death rates (172 per 100,000) similar to the EU-27 (173 per 100,000) and better than NMS on average (199 per 100,000).

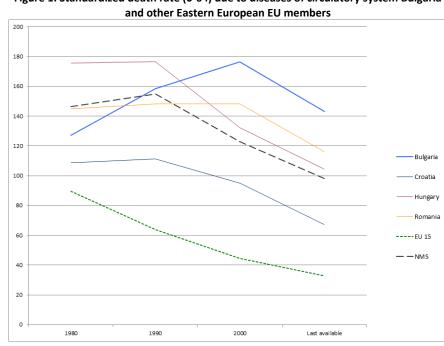


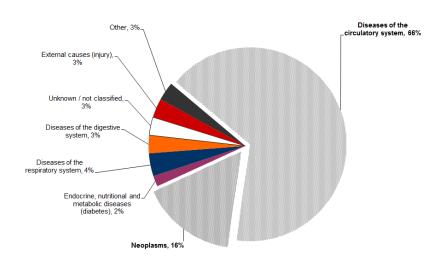
Figure 1. Standardized death rate (0-64) due to diseases of circulatory system Bulgaria

Source: World Health Organization, European Region - Health for All Database

 $^{^{}m 10}$ Including life expectancy, standardized mortality and infant mortality.

10. Smoking, a kev risk factors for the above described burden of cardiovascular diseases cancer, is widespread in Bulgaria, but recent steps have been taken strengthen tobacco control. Lifestyle factors such as smoking, poor diet psychosocial stress thought to explain much of the gap between chronic disease rates in NMS compared to the EU-15, although little research has been done into this trend. 11. Standardized death rates from smoking-related causes are higher in Bulgaria compared to the EU-1212,

Figure 3. Leading causes of death in Bulgaria 2009.



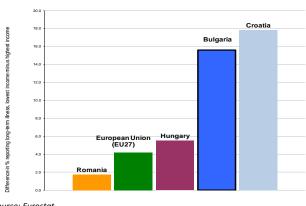
Source: Public Health Statistics 2010National Center of Health Informatics Bulgaria

due to the high prevalence of smoking, which at around 40% was the second highest in the EU in 2008¹³. Bulgaria also has the second highest number of people who smoke every day (31%). In 2010, tobacco tax rates were increased sharply, and bans on public smoking were instituted in 2012 to the support of the majority of the public, two commendable policy actions that have had proven public health impacts elsewhere. With respect to alcohol related mortality, Bulgaria, at 70 per 100,000 performs better than

most NMS (96 per 100,000 on average), but remains behind the EU-15 (53 per 100,000). Another encouraging sign is that obesity remains low in Bulgaria: results of the 2008/9 European Health Interview Survey show that between 8% and 25% of adults are obese across all European Member States and Bulgaria has the third lowest rate at around 11%.

11. There are considerable socio-economic inequalities in health outcomes in Bulgaria. Compared to the rest of the EU,

Figure 2. Inequality in reported long-term illness in Bulgaria and selected EU countries in 2010.



Source: Eurostat

disparities in health status between different income levels are high in Bulgaria. Together with Croatia,

¹¹ European Observatory on Health Systems and Policies. (2009). Health in the European Union – Trends and Analysis. P. 30.

¹² Dimova et al. (2012).

¹³ Eurobarometer. (2009). Flash EB Series #253: Survey on Tobacco

Bulgaria had among the largest gaps between the richest and poorest, both for long-term illness (Figure 2) and self-reported health status. These health inequalities also exist between geographic regions¹⁴, with worse outcomes in rural areas, and among the Roma ethnic minority¹⁵. For instance, while in some districts, infant mortality rates are comparable with the average EU level (e.g. Silistra – 3.5 per 1 000 live births; Sofia city – 4.2), other districts have considerably higher infant mortality rate than the 8.6 average for the country (Sliven – 20.5; Yambol – 19.4; Shumen – 16.2)¹⁶.

12. The high burden of chronic diseases in Bulgaria is exacerbated by the continued demographic transition, with a steadily growing proportion of the population aged over 65 years. The age dependency ratio of Bulgarians aged 65 and older versus working-age Bulgarians has also steadily risen to 25%, suggesting increased pressure on the health workforce. Moreover, elderly populations are more financially vulnerable and unable to afford care, requiring better linkages to formalized long-term care. Conversely, fertility rates among the Roma population remain high, but Roma children have disproportionately lower access to care, contributing to the health inequity situation.

Coverage of services and access to the health system

13. Data on the coverage and use of services suggest that the health system is not efficiently geared towards dealing with the burden of disease described above. First, as shown by Table 2, the coverage of most preventive services is much lower than in other EU countries, with the exception of Romania. To take the example of women's health, 10% of women aged 50-69 received mammography screenings in Bulgaria compared to 23% in Latvia and 37% in Hungary (3.5% in Romania). Only 18% of women aged 20-69 had a cervical smear test in Bulgaria, compared to about 35% in Eastern Europe and about 50% in Western Europe (4.4% in Romania). Death rates from cervical cancer remain high. Influenza vaccine coverage in Bulgaria provides another illustration of the limited focus on prevention. The World Health Organization recommends immunization for some categories of the population (the elderly) and although immunization is rarely mandatory, it is encouraged in most developed countries. Coverage in Bulgaria is less than 5%, compared to about 20% in Eastern Europe and more than 50% in Western Europe.

¹⁴ Eurostat. (2009), Health statistics – Atlas on mortality in the European Union. p. 34

¹⁵ Dimova et al. (2012).

¹⁶ Health Inequalities and Inequities in Bulgaria – Current Evidence. Rohova, Dimova, Mutafova, Atanasova, Koeva, and van Ginneken, draft manuscript 2012.

Table 2. Percentage reporting use of preventive services within the past 12 months, in Bulgaria and selected EU countries

	Breast exam (women 50-69) (%)	Colorectal cancer screening age 50-74 (%)	Cervical smear test (women 20-69) (%)	Cervix Cancer death rate* (per 100,000)	Influenza immunization (%)
Bulgaria	10.3	8.5	18	7.9	4.8
Czech Republic	39.8	14.1	46.3	4.9	19.4
Germany	44.7	36.6	58.3	2.5	56.2
France	50.3	13.6	48.7	1.9	66.7
Latvia	23.1	8.5	41.7	5.9	2.9
Hungary	37.4	2.9	35.4	5.7	30.3
Poland	29.4	1.7	35.8	7.1	12.9
Romania	3.5	0.7	4.4	13.4	18.1
Slovenia	25.6	3.3	38.5	3.7	22.3
Slovakia	31.9	9.6	33.1	6.3	24.4

Source: European health interview survey, most recent year available (circa 2008). *Eurostat, 2009 or 2010

14. Information about utilization of care confirms that the system is not addressing the burden of disease in an efficient way. Indeed, despite the fact that the number of physicians per capita is high in comparison with other countries, Bulgarians have relatively fewer contacts with primary care and specialist physicians than citizens in other EU countries, with the exception of Romania (Figure 4). In contrast, the number of hospital episodes per capita jumped sharply by 68% between 2000 and 2010 during a period where hospitalizations in other countries were decreasing or stabilizing (Table 3). In 2011, the rate of hospitalizations was so high that effectively one in four Bulgarians was hospitalized 17. For efficiency and quality reasons, most countries aspire to reducing hospitalizations by relying on a combination of prevention and outpatient treatment, particularly for chronic disease management. It would seem that Bulgaria is drifting in the opposite direction.

Table 3. Inpatient hospital discharges per 100 persons, Bulgaria and selected EU countries.

Countries	1990	2000	2005	2010
Bulgaria	19.0	15.4	21.0	25.9
Croatia	15.4	15.7	16.6	16.8
Hungary	21.8	23.6	25.0	20.8
Romania	20.1	22.4	24.6	24.9
EU 15	16.9	17.7	16.9	16.9
New Member States	16.8	19.0	20.8	21.0

Source: HFA database.

¹⁷Although multiple hospitalizations tend to be concentrated amongst a subset of sicker patients. Statistics from: National Center of Public Health and Analysis. Public Health Statistics, Annual, Bulgaria 2012. Editors Christian Griva, Krasimira Dikova. Sofia, 2012.

■ Saw a physician, past 4 weeks Saw a specialist, past 4 weeks - Physicians per 100,000 45% 400 Percentage of respondants who saw 41% 370 364 39% 40% 350 35% Physicians per 100,000 population doctor past 4 weeks 33% 35% 302 300 300 30% 27% 250 26% 226 23% 25% 22% 200 20% 17% 15% 150 15% 10% 100 10% 5% 50 5% 0% Bulgaria Hungary Romania Slovakia Germany Belgium

Figure 4. Proportion accessing a physician in the past 4 weeks, and number of physicians per capita in Bulgaria and selected EU countries.

Source: EUROstat and the European Health Interview Survey (2008).

Perceptions about the health system

15. Overall, a significant majority of Bulgarians express dissatisfaction with the health system. In 2009, only 28% rated the Bulgarian system as "good" or higher, the second-lowest rate in the EU¹⁸. There are several possible reasons for this low patient satisfaction. One is unmet need, which declined over time but remains higher than other EU countries: In 2008, almost a quarter of Bulgarian respondents reported an unmet need for medical consultation, with the most commonly cited reason being cost. In 2010, the rate of dissatisfaction had dropped to around 15%, however, the EU average was around 7%19. Corruption could also factor in the dissatisfaction: a 2009 survey found that 65% of Bulgarians believed corruption was widespread in the public health care sector - slightly higher than the EU12 average of 54%, but virtually the same as the corruption perceived in other public sector domains, such as building inspections, public contract tenders, licensing inspections and business permits (all 60-65%)²⁰. A recent international comparison, the Euro Health Consumer Index²¹, appears to confirm Bulgaria's poor user-focus: it scored 33rd out of 34 countries, a virtual tie for worst with Serbia.

¹⁸ European Commission. (2010). Report: Patient Safety and Quality of Health Care. Eurobarometer. 327(72.2), p.55 ¹⁹ Hungary 7.9%, Slovakia 5.5%, Romania 13.6% (Statistics of Income and Living Conditions survey, via EUROstat).

²⁰ European Commission. (2009). Attitudes of Europeans Toward Corruption – Full Report. *Eurobarometer*. 325(72.2): p. 30.

²¹ A compound measure of nearly 40 indicators which assess patient rights, health services and pharmaceuticals accessibility, and health outcomes. Source: Health Consumer Powerhouse. (2012). Eurohealth consumer index 2012.

Health Expenditure

16. Bulgaria's total expenditure on health, although low standards, appears broadly in line with its income level. Health expenditure in Bulgaria represents around 7% of GDP, a level which is comparable to that reached in many new member states (NMS). The fact that, in absolute terms, Bulgaria spends less on health than other EU countries is primarily explained by its lower income level. Indeed, Figure 5 which places Bulgaria among a sample of countries in the world²², highlights that its health expenditure is standard given its income level.

17. Compared with many countries in Europe, Bulgaria is investing relatively less of its public resources

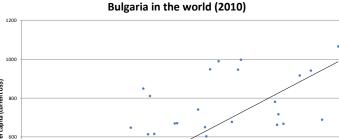
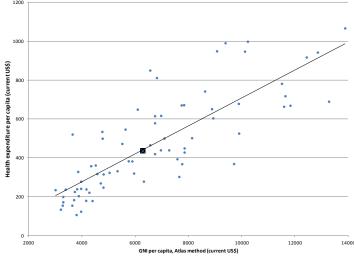


Figure 5. Total health expenditure and GNI per capita -



Source: World Development Indicators (WDI)

in health. Table 4 presents data on total and public health expenditure for a group of European countries in 2010²³. In 2010, public health represented 3.7% of GDP and less than 10% of total public expenditure across all sectors in Bulgaria. Both of these figures are rather low by European standards. Conversely, private expenditure - and more specifically out-of-pocket payments (OOP) incurred by households when they need care - represents a large (44%) share of total expenditure²⁴. Figure 6 compares this number with the 1997 level in Bulgaria and across Europe. It shows that richer countries tend to rely relatively less on out-of-pocket payments and that Bulgaria is an outlier among EU countries: its share of OOP is currently among the highest in the region and has increased substantially over time.

²² Figure 1 plots health expenditure for all countries with a GNI per capita between \$2,000 and \$14,000.

²³ Last year with comparable data available.

²⁴ Out of pocket expenditure is derived from various sources and pertains to goods and services purchased privately, formal public sector copayments and informal payments, although the latter tend to be under reported.

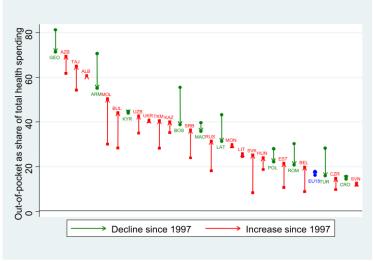
Table 4. Health Expenditure - Bulgaria and Comparator Countries (2010)

	Health Expenditure per Capita (\$)	Total health expenditure (% of GDP)	Public Health expenditure (%GDP)	PHE (%Government Expenditure)
Albania	240.8	6.5	2.6	8.4
Macedonia, FYR	316.9	7.1	4.5	12.9
Serbia	546.0	10.4	6.4	14.1
Belarus	319.6	5.6	4.4	9.9
Bulgaria	434.9	6.9	3.7	9.8
Romania	428.0	5.6	4.4	10.8
Lithuania	781.4	7.0	5.2	12.6
Latvia	717.6	6.7	4.1	9.2
Poland	917.1	7.5	5.4	11.9
Croatia	1066.7	7.8	6.6	17.7
Estonia	853.3	6.0	4.7	11.7

Source: WHO, Global Health Expenditure Database. Countries in the table are ranked by income per capita

18. As expected, high OOPs limit the financial protection provided by the system. In 2007²⁵, OOPs represented nearly 6% households spending in Bulgaria on average. If OOPs exceed 10% of household spending, they are deemed catastrophic. In Bulgaria, catastrophic spending occurred in 20% of households compared to only 7% of households in EU15 countries. OOPs also had a significant poverty impact in Bulgaria. Using a poverty line of \$5 day, OOPs were responsible for increasing poverty from 12 to 15.7%.

Figure 6. Changes in out-of-pocket payment share (1997-2010)



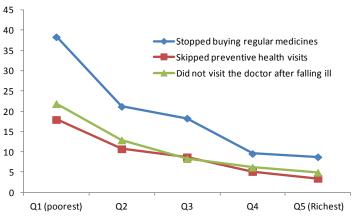
Source: WHO, Global Health Expenditure Database.

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 $^{^{\}rm 25}$ Last Living Standards Measurement Study available.

19. The financial protection provided by the system is quite low and the poor are particularly vulnerable. A 3-wave household survey conducted in 2010 and 2011 showed that many households curbed their investments in health in response to the crisis²⁶. In fact, 40% of the lowest income quintile households declared having suspended the purchase of regular medicines as a crisis coping mechanism (the average for all households was 19%). Other strategies included skipping preventive health visits, not seeking care when sick (around 10% of

Figure 7. Health response to the crisis by income group



Source: World Bank 2012.

households each) and cancelling health insurance (5%). Although these coping techniques may not all have an impact on health in the long run, the data highlights that the financial protection provided by the system is limited.

4. Main issues, latest developments, and way forward

20. Taken together, the data demonstrate increasing gaps in the Bulgarian health system which legislation and new regulations over the past five or six years have been unable to reverse²⁷. A number of attempts at reforms have not been followed through to completion, compounded by multiple changes in leadership with four ministers and three directors of the NHIF appointed in less than 3 years. The following sub-sections summarize recent changes, as well as currently envisaged plans, and suggest possible options for the government's consideration in the short to mid-term. Three areas are highlighted where decisive and prompt action could rapidly bring results and improve the experience of Bulgarian citizens. For each of these areas, key recommendations are summarized at the end. The section concludes with further priorities for consideration in the mid-term.

Rationalizing the hospital sector

21. Bulgaria still faces enormous challenges in the rationalization and management of the hospital sector. Despite large cuts in the hospital infrastructure in the 1990s, New Member States still have a relatively high stock of hospitals and beds. Figure 8 shows the trend of beds per 100,000 since 2000, with the United Kingdom at the bottom for reference. The NMS and the EU15 are all positioned above it. Among NMS, Bulgaria is now the country with the highest number of beds per capita and also

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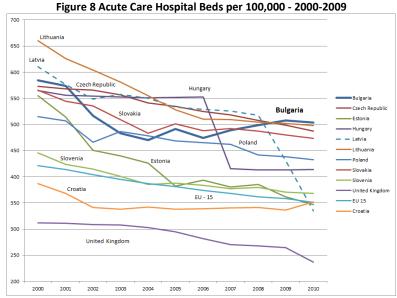
²⁶ World Bank (2012). Bulgaria: Household Welfare during the 2010 Recession and Recovery

²⁷ Neykov, Salchev 2012. ASISP Annual Report, Bulgaria.

appears to be defying the downward trend²⁸. Many of the new entrants in the market are specialized institutions that have opted for a narrow focus on the most lucrative services. Existing hospitals also seek to open new wards in order to be contracted by the National Health insurance Fund (NHIF) for

delivery of additional clinical care pathways (CCPs).

22. The multiplication of hospitals and beds reinforces some more deeply-rooted problems. First, as mentioned earlier, hospitals are primarily funded on a case-basis, which provides strong incentives to multiply hospitalizations. significant proportion of cases could be treated on an outpatient or day-case basis²⁹. Further, in 2008, 40% of patients were admitted more than once in a year³⁰ which indicates ineffective clinical management and poor quality of care, а reinforced by the fact that many departments have too low a



Source: Health for All Database 2011

volume to maintain a high quality of service. In addition to quality concerns, this suggests that resources are wasted in a system where many patients should be treated in less resource-intensive settings. Overall, the resulting fragmented system is not financially sustainable and, at the level of individual public facilities, the accumulation of arrears and debts has become a recurring issue³¹. Last, the resulting system is characterized by the duplication and overlap of services, and competition between facilities hinders the coordination of care and investments.

23. Recent measures have sought to limit the sector's growth, including an attempt to introduce some elements of selective contracting. Until recently, the NHIF was legally obliged to contract with all new providers (and all existing providers for accredited services), with minimal delay, which further encouraged new entrants seeking this assured revenue flow. In early 2011, a new National Health Map was approved which puts a lower and upper limit to the number of establishments the NHIF can contract in a region. The law also stipulates that all hospitals with a majority ownership by the state must be contracted. In other words, only municipal and private hospitals can be excluded from contracting. In contrast, the plan did not appear to provide leverage to the NHIF to select amongst other state providers. In any case, the plan met with some resistance and to date has not been implemented. In a separate effort, municipalities were invited to apply for funding to transform hospitals into medical

²⁸ For the sake of brevity, the number of beds is used to highlight the predominance of the hospital sector but the fragmentation of service delivery across a large number of hospitals, their geographic distribution and the mix of service hospital deliver are also of concern.

²⁹ Dimova et al (2012) op. cit. The World Bank is also currently undertaking a study which aims to highlight the extent to which practices in Bulgaria deviate from those of other countries in this respect.

³⁰ Dimova et al (2012). In many cases the initial admission is made chiefly in order to submit a medical claim (with CCPs requiring a minimum length of stay for payment) rather than provide any meaningful treatment services prior to referral.

³¹ Data on hospital debts and arrears is not readily available.

centers, but all declined. <u>The implementation of the rationalization strategy should be pursued and incorporate a stronger selective contracting component.</u>

24. Bolder measures will be required to avoid the duplication of services within the public sector, to create incentives for increased coordination and consolidation between establishments. In areas of high density, the integration of public hospitals into competing networks should considered. These networks, comprising hospitals of different levels, should be fully accountable for their financial results and not be allowed to incur deficits or accumulate debts. Each network would have one contract with the NHIF and would therefore have strong incentives rationalize service delivery internally³². In areas of lower density, consolidation and coordination will require more active interventions. In this context, the opportunity of accessing EU structural funds for the health sector in the next European financial perspective could be seen as a

Box1. Rationalising hospitals in Estonia

Hospital master plans have been applied in many countries and can identify an optimal mix of facilities to guide the rationalization process. With the aid of a hospital masterplan, Estonia succeeded in reducing the total number of acute care facilities from over 100 to less than 40 between 1992 and 2002, substantially reducing duplication of services and costs. The enforcement of the master plan was obtained through a combination of mergers and hospital autonomy which helped insulate consolidation decisions from politics and strengthened the role of technocratic expertise and hospital management. Financial incentives were also used, in particular the linkage of investment finance and service purchasing to compliance with the hospital masterplan.

Source: Hawkins, L (2010). "Optimization of Hospital Capacity: Lessons from the Estonian Experience". World Bank draft. Haazen, D.S. and A.S. Haer (2010). "Financing capital costs and reducing the fixed costs of health systems". In Implementing Health Financing Reform: Lessons from Countries in Transition. Ed. Kutzin, J, C. Cashin, and M. Jakab. WHO Euro Observatory: Copenhagen.

strategic opportunity to leverage support for what are likely to be difficult reforms.

25. The consolidation of hospital services should be undertaken in conjunction with the development and implementation of a cross-sectoral long-term care strategy (LTC). Bulgaria's population is aging rapidly. At present, many acute care hospitals are burdened with long-term care patients, who could receive higher quality services at a lower cost in better adapted settings. Evidently, the need for LTC will continue to rise. A strategy incorporating health should be articulated around the existing LTC policy goals of the Ministry of Labor and Social Policy. A recent World Bank Report³³ recommends converting municipal hospitals into social centers that provide a whole range of home-based and community-based social and medical services. These services include community nurses, mobile medical services, outpatient services, physical therapy, day-care services, and to some extent, respite care and hospice services (both institutional and home-based). In the medium and long-term, it will be necessary to develop a model for multidisciplinary teams (consisting of doctors, nurses, therapists and social workers) that can assess patients' need for LTC services in a comprehensive way. Finally, in order to overcome fragmentation of financing and cost-shifting behavior, it will be necessary to consolidate the financing of LTC services across the social and health ministries as well as municipalities. A promising development is the recent launching (2012) of a Swiss-Bulgarian cooperation project involving the Ministries of Labor and Social Policy and Health to develop home care services in Bulgaria.

³² Closings and mergers of departments or hospitals can be expected to meet a significant amount of resistance and may turn into political problems. Reorganizations within a network of facilities, as long as the network is a sufficiently accountable and autonomous financial entity, belong more squarely to the sphere of managerial decisions. This lever was judiciously used in Estonia (see Box).

³³ This paragraphs draws on Long Term Care Policies for Older Populations in New EU Member States and Croatia: Challenges and Opportunities, World Bank 2010 which includes a case study of LTC in Bulgaria

- 26. Many measures, already implemented or currently envisaged, attempt to better leverage financing tools to improve hospital efficiency and curb expenditure. An example of such positive steps was the introduction in 2010 of 12 new clinical pathways for day surgery. More importantly, hospitals have been financed on the basis of CCPs and until 2008 and this financing was open-ended, which undoubtedly contributed to the inflation of the number of cases. In addition, CCPs are known to be prone to manipulation and "upcoding" and to reflect costs inadequately (under and overpricing). Furthermore, they describe a standard menu of services that are expected to be provided and do not constitute an incentive to be more efficient in contrast to case-based payments. Indeed, if hospitals do not provide *all* the services listed or for instance reduce the length of stay for a given pathway, they can be denied a payment by the NHIF. Over the last two years, some of the CCP prices have been adjusted in an attempt to eliminate some distortions, but more systematic examination of unnecessary care and poor coding practices is recommended.
- 27. The implementation of Diagnostic-Related Group (DRG) payments is set to resume. DRGs are standardized classifications of patients which use hospital data to match diagnoses to appropriate clinical services, and payments to hospitals for those services. In theory, DRGs generate incentives to deliver services efficiently, reduce unnecessary procedures and improve the transparency of hospital financing. Unlike CCPs, DRGs also account for the severity of the disease and any concurrent diseases³⁴. A plan to introduce DRGs has been under consideration for many years, but efforts to implement them have not been sustained. In late 2011, the council of ministers approved a plan to resume implementation. However, many technical issues remain to be addressed, including improving data quality (efforts to harmonize accounting reporting have already been undertaken) and deciding on the responsibilities for data collection, utilization and sharing. If successfully implemented, DRGs could help improve the allocation of funding across the sector and are likely to be less prone to manipulation than CCPs. They could also create an incentive for individual hospitals to be more efficient. DRGs per se will not solve the overcapacity issue and international evidence suggests that they do not constitute an incentive for hospitals to reduce the number of patients hospitalized. Yet, DRGs based on good medical and costing data would constitute a significant improvement over CCPs and their implementation should be accelerated. DRGs must however be used in combination with global budgets for hospital to limit volume escalation.
- 28. Volume caps have been instrumental in containing hospital costs since 2008. In 2008 and 2009, volume caps were introduced for hospitals, with an immediate impact. Hospitalizations, which had increased by more than 20% in 2008 and 2009, stabilized in 2010 and 2011³⁵. Stricter controls on multiple admissions may have also helped. These limits greatly increase the financial pressure on (public) hospitals which, in the absence of significant internal and system-level restructuring levels, may run deficits and accumulate ever increasing amounts of arrears. Looking forward, the Ministry of Finance intends to increase controls on the deficits, arrears, and debt of public establishments in order to meet the Financial Stability Pact criteria³⁶. This will further increase the pressure on all the public facilities to rationalize services, particularly in the areas where competition is strong.
- 29. In 2012, the authorities were debating whether to change the way volume caps are used. Since their introduction, individual caps on hospital budgets have been heavily criticized by providers. In June

³⁴ European Observatory of Health Systems and Policies. (2011). Diagnosis-related Groups in Europe. (2011). p. xxvi.

³⁵ National Center of Public Health and Analysis data

The Financial Stability Pact was elaborated by the Ministry of Finance in early 2011 in order to improve the fiscal framework and financial management in the public sector by (in particular) introducing of fiscal rules on public expenditure levels and thresholds for consolidated public deficits.

2012, authorities in the health sector were debating whether to introduce regional volume caps to replace individual ones. The monitoring of volumes in each hospital (which report their activity daily to the NHIF) and heavily strengthened controls were expected to enable the NHIF to troubleshoot and take corrective measures required to ensure the planned regional volume was not exceeded. Case-based payments generate powerful incentives to increase the number of cases, which can threaten the total health budget, given the current context of pressure on providers and public facilities to make ends meet and balance their budgets. If individual caps were removed, the new system would need to be carefully designed to counterbalance these incentives. Its impact should be closely and transparently monitored, and the measure promptly re-considered or adjusted if it leads to cost-escalation.

30. Quality assurance and monitoring should be strengthened. As mentioned before, quality of care is an area of concern in Bulgaria and a series of adverse events generated a lot of media attention in the past year. In 2009, some of the minimal standards for the provision of care were increased. This led to the closure of a few municipal hospitals and departments that were unable to meet these new standards and thus could not contract with the NHIF for corresponding CCPs. Another control mechanism was set-up in 2010: a Medical Audit Agency which mostly focuses on

Box 2. Jointly pursuing rationalization and quality improvement in the Czech Republic

In 2008, the Ministry of Health in the Czech Republic launched a program to improve the quality of highly specialized care such as oncology or trauma. High-performing facilities in these areas could apply to become Specialized Care Centers and receive special contractual conditions with the health insurance funds. The aims of the program were to ensure specialized care was only carried out in facilities with high quality standards and to concentrate demand and the use of expensive technology.

Source: Bryndová L, Pavlokavá K, Roubal T, Rokosová M, Gaskins M and van Ginneken E. Czech Republic: Health system review. Health Systems in Transition. 2009;11(1):1-122

investigating patients' complaints (the Health Insurance Fund also undertakes audits). However, such measures are more characteristic of a command-and-control governance style and have been shown to be not as effective in the long term as continuous quality improvement processes supported by centrally-supported remediation plans with clear interim targets. In 2010, the accreditation of providers, became no longer mandatory, except for teaching hospitals. There are no clinical guidelines in Bulgaria. Overall, quality assurance processes are fragmented, too control-oriented and rather weak. Quality assurance, based on medical audits and accreditation processes, should be strengthened. Furthermore, information about care quality should be used to drive the restructuring of hospitals and selective contracting. A preliminary requirement would be that standardized information about quality is systematically collected and used for feedback in the quality improvement cycle.

31. Overall but somewhat implicitly, Bulgaria appears to have chosen a market-based approach to hospital sector consolidation rather than a more politically difficult service-planning driven process. Yet, the effectiveness of this market-based approach is currently limited by three policy barriers. First, additional resources are regularly and somewhat indiscriminately availed to the sector; second, public hospitals are able to accumulate arrears; and third, the NHIF is compelled to contract with every provider. In order to meet macro-economic requirements of the financial stability pact, additional pressure will be put on public hospitals to cover their costs in 2012, but it may not be sufficient. The experience of other countries suggests that the consolidation of the hospital sector would require coordinated efforts in terms of planning, financing, and purchasing of services based on quality criteria.

Key recommendations for the hospital sector:

✓ Implement a technically-driven hospital rationalization plan;

- ✓ Support this implementation by genuinely selective contracting and, as relevant, strategically selected investments;
- ✓ Encourage consolidation and streamlining in areas of high density by merging facilities into autonomous and fully financially accountable networks;
- ✓ Introduce DRG-based payments and maintain strong incentives to limit volume escalation;
- ✓ Generate, collect, use and publicize information on quality to support the rationalization process.
- ✓ Strengthen quality assurance mechanisms.

Strengthening outpatient care, with a focus on NCDs and in particular cardiovascular diseases

- 32. In order to better address Bulgaria's burden of disease, primary and outpatient care will need to be strengthened. The ambulatory sector has received little attention and investment in the past ten years. Outpatient curative care, which represented only 14% of current health expenditure in 2003, decreased to 12% in 2008 (it represents between 25 and 30% in the majority of EU-15 countries).
- 33. In addition to underfunding, the primary care sector suffers from a number of weaknesses. The payment method of primary care doctors mainly by capitation does not provide adequate incentives for improved service provision, and referral rates to specialized out-patient and hospital care are high. A primary care sector should be able resolve at least 80% of the cases of demand for medical care, but in Bulgaria this rate has been estimated at about 70% or less. Furthermore, only 5% of primary care doctors were originally trained as general practitioners, and a requirement to complete a specific training program has been repeatedly postponed (the target date is now 2015). As seen earlier, population behavior reflects low levels of trust in family doctors, including low uptake of preventive exams and frequent bypassing of primary care in favor of direct contact with specialists. Lastly, the number of primary care providers is relatively low and their distribution is unequal across the country.
- 34. Strengthening primary health care could improve the overall health status of the population and help achieve greater system-wide efficiency. The disease burden in Bulgaria is dominated by cardiovascular diseases, and primary care can play a central role in diagnosing and managing risk factors such as cholesterol and high blood pressure. The same is true for the early detection of cancers.
- 35. A number of steps could be taken to give a more prominent role to primary care. The introduction of stronger pay-forperformance measures at the primary care level should be considered a key priority. Performance indicators could be geared towards the prevention and management of NCDs and in particular the control of risk factors and secondary prevention for **Preliminary** cardio-vascular diseases. discussions were undertaken with professional associations on this issue but the idea was shelved, in view of the initial reaction of providers, the tightening budget situation, and the need to fund hospitals.

Box 3. Primary care performance payments associated with reduced hospital costs in the UK

In 2004, the UK government introduced a Quality and Outcomes Framework (QOF) for primary care centers in order to improve the prevention and management of chronic diseases. Financial rewards were provided to primary health centers that achieved certain QOF indicators. From 2004 to 2008, improved stroke prevention in primary care may have reduced secondary care costs by some GBP165 million. The associated incentive payments were small compared to the resulting hospital cost savings.

Source: Martin S, Smith PC, Dusheiko M et al. Do quality improvements in primary care reduce secondary care costs? The Health Foundation, London: 2012

On a more positive note, incentives to encourage the development of group practices, key to providing care continuously in remote areas, have been recently introduced.

- 36. Devising effective ways to increase the capacity of primary care providers. The previously mentioned primary care training is unattractive for physicians who need to leave their practice for a few months to complete it. A more effective and attractive continuous medical education curriculum should be developed in light of the current burden of disease, and the Ministry is taking steps in that direction. Additional regulatory standards must also be removed in order to expand the list of conditions that can be managed fully in primary care. For example, in the past patients with uncomplicated hypertension and/or diabetes were required to undertake a minimum number of annual visits to hospital-based specialists. Measures to promote outpatient care could include: (i) the establishment of care management plans for chronic care conditions which are significant contributors to costs and morbidity and mortality in the country, (ii) a systematic review of the regulations which mandate referrals or prohibit the delivery of uncomplicated diagnostic and treatment services at lower levels of care; (iii) the development of high-frequency, low-cost diagnostic and treatment centers. To sum up, a concerted effort should be made to invest in the capacity of outpatient providers in order to address the prevailing burden of disease and their performance should be measured and rewarded. The necessary resources should be availed to support these efforts.
- 37. The development of a new health information management system has been proposed to monitor referral and prescription patterns by individual physicians, and take corrective action when necessary. This would be very useful, but ultimately a re-allocation of budget resources from hospital to primary care will be a crucial complement to these measures.
- 38. Efforts to improve primary care could be reinforced by simultaneously strengthening population-based health interventions. Multi-sectoral measures to combat risk factors for non-communicable diseases (NCDs) have made very significant contributions to improved health outcomes in advanced economies. In June 2012, Bulgaria instated a ban on smoking in indoor public places and certain outdoor public places, which is clearly a step in the right direction. The Ministry will launch in 2013 a National Program for Cancer Screening and it is finalizing a plan to reinforce the prevention of NCDs. It would be important to ensure that it is evidence-based, adequately funded and that the results are monitored.

Key recommendations for outpatient care:

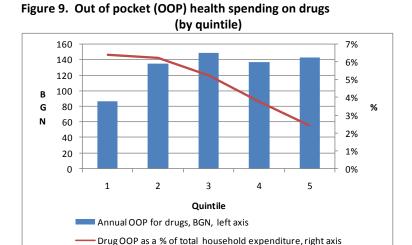
- ✓ Strengthen the capacity of primary care health professionals to manage the prevailing burden of disease and play an active role in the coordination of their patients' care;
- ✓ Introduce elements of pay for performance with a focus on non-communicable diseases in order to increase the management of chronic diseases at the primary care level;
- ✓ Select, based on evidence, and implement additional multi-sectoral measures to combat risk factors for non-communicable diseases.

Pharmaceutical policies

39. **Pharmaceuticals represent 35% of current expenditure on health** in Bulgaria (Eurostat 2008), which is a high proportion in comparison with the EU average of around 25%, but comparable to the level in many NMS. Data on the market size shows an increase of sales of more than 10 percent per year, a growth which seemingly was not slowed by the financial crisis³⁷.

³⁷ most recent year available is 2010

40. Out-of-pocket expenditure on pharmaceuticals is very high. Of the total market expenditure, less than 40% is government spending. Out-ofpocket expenditure on drugs is thus very high in Bulgaria and in fact represents more than 70% of household expenditure on health. **Figure** 9 shows that expenditure represent a particularly heavy burden for the poor. The fact that the value of consumption in the poorest households is significantly lower (BGN 80) than that of other households (around BGN 140), suggests that the poor are probably foregoing some purchases of medicines. Surveys of Bulgarian



Source: Staff estimates based on Multi-Topic Household Survey (LSMS), 2007

patients in fact show that 23% lacked financial means to purchase any prescribed medications, while 56% could not afford at least some of the prescribed drugs necessary for their treatment, even under existing co-payment rules³⁸.

- 41. **Bulgaria's framework for pharmaceutical regulation is comprehensive but still evolving**. The Law on Pharmaceutical Products in Human Medicine, drafted in 2007 to align Bulgarian policies with European standards, enshrines multiple core government regulations for pharmaceuticals including sale, production, import, purchasing, and contracting. The law established a framework which, at least formally, puts in place the authorities and structures required to regulate the pharmaceutical sector. Yet this has undergone multiple amendments over the past several years and is still evolving³⁹. Most recently, the pricing commission and the commission which sets the drug reimbursement rates were merged in an attempt to simplify processes and a decision was taken to increase the frequency of revisions of the essential drugs list prices.
- 42. The pharmaceutical sector and policies are frequent subjects of public controversy⁴⁰. For instance, in 2012, independent investigations revealed that the external reference price control mechanism was not having the intended effect because a local manufacturer was charging higher prices in Bulgaria than neighboring countries. Another controversy arose from the gradual transfer of the responsibility for purchasing certain expensive medicines from the MoH to hospitals. Until 2010, the MoH procured some expensive drugs centrally (e.g. cancer and hemodialysis). The process was deemed unsatisfactory for a number of reasons including delays in the procurement and distribution and volume caps which led to shortages at the hospital level. There were a considerable number of appeals to the MoH against the outcome of the procurement process. The decision was taken to include the cost of these drugs in the clinical care pathways and to allow hospitals to purchase them alongside their routine drug procurement. The transition process was disorganized and some hospitals were reported to have paid a higher price that the Ministry was able to obtain previously.

⁴⁰ Talha Khan Burki. (2012). Unrest in Bulgarian health services. *The Lancet, February 2012* News section.

³⁸ Dimova A, Popov M, Rohova M (2007). The health-care reform in Bulgaria: analysis. Sofia, Open Society Institute.

³⁹ PHIS pharma profile, Bulgaria 2010.

- 43. **Drug procurement procedures were changed in 2012.** In an attempt to address the issue, the NHIF has been allowed to undertake centralized negotiations with pharmaceutical providers, first for the medicines which were the subject of the controversy (hospital purchased) and later potentially all products on the essential drugs list. These price negotiations follow the usual public procurement procedures (with an open and then a closed phase), and the final price obtained by the NHIF must be lower than the one previously obtained by the Ministry or the one in the price list. Negotiations of this kind sometimes take place for highly expensive innovative drugs but do not generally occur on such a large scale. This additional layer could potentially raise concerns about transparency and the overall effectiveness of the pricing policy⁴¹. A comprehensive review of the public purchasing of drugs should be undertaken. In order to strengthen cost control, consideration should be given to competitive tendering within high-volume drug clusters and the introduction of a claw-back tax⁴².
- 44. The implementation, rather than the content, of policies has been the subject of considerable criticism and debate. Discussions undertaken in preparation for this note with a range of stakeholders suggest that the content of many existing policies are consistent with good practice standards. At the same time, however, their implementation has been less than ideal. For example, the criteria for membership of the Positive Drug List (PDL) and pricing commissions have not been publicly articulated and the turnover of membership is reported to be high. Moreover, the decision-making process is not transparent and the minutes of the deliberations are not made public. Founded or not, trust is low and is likely to remain so unless transparency increases greatly. A complete and transparent audit

Box 4. Increasing Value for Money spent on drugs in Romania

Romania's pharmaceutical policies have been described as complex and decisions about inclusion on the reimbursement lists as non-transparent, inconsistent, and only weakly evidence-based. Other issues include cost escalation and limited coverage. In order to increase value for money, Romania completed with the support of the UK's National Institute for Health and Clinical Excellence (NICE) an analysis of its management practices and a review of the reimbursement list focusing on the top 50 drugs the health insurance fund was paying for. Subsequently, a new legal framework for Health Technology Assessment was put in place and an interim de facto HTA is being conducted for drugs previously approved but not yet included in the list of reimbursed drugs. In addition, three drugs were excluded off the lists and the indication for two drugs were restricted.

Source: World Bank (2011. Romania Functional Review Health Sector and personal

of the current Positive Drugs list, undertaken in collaboration with reputed independent experts, would help ensure the system is getting the best value for money and greatly strengthen public confidence in the legitimacy of these processes. The audit should also recommend methods to durably improve the transparency of decision-making.

45. In addition, consideration should be given to the medium-term pharmaceutical reform agenda. Several challenges stand out. First, inappropriate prescribing patterns are common (i.e., too many and/or too expensive drugs are prescribed compared to a more evidence-based approach), in part due to marketing programs pursued by the industry. Closer monitoring of prescription patterns (including

put in place.

changes had created a lot of confusion and that a transparent system to continuously monitor prices needed to be

⁴¹ A Parliamentary commission was set up to investigate the reasons behind the increase in prices of certain groups of medicines and published a report in October 2012 (http://www.parliament.bg/bg/parliamentarycommittees/members/1460/reports/ID/3789). In the case of hospitals it found that, by and large, they were able to pay less than the reference price but that the recent

⁴² A clawback tax is essentially an agreement by which manufacturers and the government agree to on a volume of sales and share the cost if the threshold is exceeded.

performance incentives) would undoubtedly yield some returns. However, a key challenge to this effort will be that many drugs are obtained without prescription, because NHIF reimbursement rates are low and patients prefer to avoid the cost and time burden of consulting a physician first. Self-medication is common, and efforts to increase controls on pharmacies have not had a lasting impact. In summary, a comprehensive framework to promote the rational use of medicines and alter the behavior of patients, health care providers, and pharmacies should be developed and implemented.

- 46. Second, the generic policy should be significantly strengthened through the introduction of international best practices. The generics market in Bulgaria is quite strong and represents more than half of the market, yet there is no specific generic policy. Physicians are not required to prescribe in international nonproprietary name and pharmacists do not have the right to substitute. Third, the pricing approach that underlies the positive drug list encourages manufacturers to compete through alternative means (such as offering free drugs to retailers in order to squeeze out alternative brands), which ultimately reduces competition.
- 47. A much-needed law to regulate medical equipment and devices has been adopted. The current legal framework for medical devices is defined under the Act on the Integration of Persons with Disabilities of 2007, mainly intended for improving the quality of life for persons with disabilities. There is a need for articulated policies on the prescription, procurement, subsidy, maintenance and use of medical and pharmaceutical devices used in advanced procedures at hospitals, such as pacemakers, drug-eluting stents, and artificial hips. Starting in 2013, the NHIF will undertake some price negotiations.

Key recommendations on pharmaceuticals

- ✓ undertake a complete and transparent audit of the current Positive Drugs list, a review of purchasing methods and elaborate a strategy to improve the transparency of management practices in the sector;
- ✓ develop and implement policies to encourage and monitor the rational use of medicines (including generics);
- ✓ seek the support of internationally reputed independent experts in order to build local capacity
 and limit influence from interest groups;
- ✓ Finalize and implement the regulation of medical devices/equipment.

Additional priorities for the mid-term

- 48. The previous section primarily focuses on specific measures which, if decisively and effectively implemented, could improve the performance of the system. Yet the sustainability of these improvements will require addressing many additional issues. To conclude, three key challenges are briefly discussed.
- 49. **Improving financial protection**. Providing financial protection to all so that no one falls into poverty due to health care costs is a core objective of the health system. The note previously highlighted gaps in the financial protection provided by the NHIF with a significant share of the population (between 10 20%) not insured⁴³. A 2008 survey showed that the vast majority are of very low socio-economic background and belong to ethnic minorities⁴⁴. They lack access to outpatient care and typically enter the health system though emergency departments. It is important to note that both large out-of-pocket expenditure on drugs which are more problematic for the poor and exclusions

⁴³ No official data is available.

⁴⁴ Health-uninsured individuals and health insurance in Bulgaria, Open Society Institute of Sofia 2009

from the regular insurance system – are potential sources of inefficiency in the system. Indeed, patients who forego care or do not manage their existing conditions are at higher risk of complications and ultimately end up costing more to the public system. In other words, in addition to being equitable, improving financial protection is efficient.

- 50. **Devising a human resources policy for health**. Although the number of physicians per capita is high, the profession's specialty mix is not adapted to the population's needs. The number of nurses per capita is by far the lowest in the region (9 per thousand population in EU15, 6 in New Member States and 4 in Bulgaria). Many of them have emigrated. In 2011, more physicians than nurses completed their education. In both professions, the currently active population is aging rapidly. The Open Society Institute is in the process of completing a comprehensive study (undertaken under the initiative of the Presidency) on human resources in health. It should serve as a platform for debate and a basis for action. Solutions will require interventions on various fronts, including planning for human resources, adapting training, and addressing financial and other constraints to retaining qualified staff in Bulgaria or to ensuring they work in right setting and are adequately accountable for their performance.
- 51. Building information systems and capacity for transparent monitoring and evaluation policies. Much of the information essential for decision-making is not collected, analyzed, or shared between public authorities or with the public. In a context of high dissatisfaction with health services, where the performance of the system is being questioned and where difficult choices will have to be made, it would be important to strengthen the capacity, incentives and requirements to share data among institutions and to make it broadly available to researchers and the wider public. In order to kick-start this effort, an independent unit could be created in which competitively selected staff would be mandated to analyze data, reach out to international research institutions, bring in best practices, and generally provide evidence on policies in the sector.
- 52. Various parts of the Government express considerable interest in developing e-health, and all forms of linked electronic records. However, large investments in IT infrastructure often fail to improve operational efficiency-related decision making in any systematic way. Large scale investments should only be envisaged when there is sufficient evidence that the existing information is being used for performance analysis and decision making in a way which is commensurate to its potential.
- 53. To conclude, progress on the various issues highlighted in this document require strong and consistent strategic leadership at the system level. Transparent debates which articulate clear priorities are likely to improve trust in the health system over time. The initiative led by the Presidency to hold consultations to elaborate the Bulgaria 2020 strategy represent an encouraging first step in this direction. The subsequent choice and design of reforms should be undertaken in a way that contributes to achieving a clear set of priorities underpinned by an explicit vision. The forthcoming report on Health Systems in ECA highlights that while there are no specific recipes to building better performing health systems, the use of information for decision making and strong leadership are crucial. As the report puts it: "Successful reform requires vision and leadership. It means taking on vested interests, whether in the medical establishment, political actors, or elsewhere in society, to usher in new reforms that will help achieve sectoral objectives."