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Drug Policy in Bulgaria

Antoniya Dimova, PhD[1], *Maria Rohova, PhD*[1], *Elka Atanasova, PhD*[1], *Paweł Kawalec, MD, PhD*[2,*], *Katarzyna Czok, MSc*[3]

[1]*Department of Health Economics and Management, Varna University of Medicine, Varna, Bulgaria;* [2]*Faculty of Health Sciences, Institute of Public Health, Jagiellonian University Medical College, Krakow, Poland;* [3]*The Polish Social Insurance Institution*

ABSTRACT

Bulgaria has a mixed public-private health care financing system. Health care is financed mainly from compulsory health insurance contributions and out-of-pocket payments. Out-of-pocket payments constitute a large share of the total health care expenditure (44.14% in 2014). The share of drugs expenditure for outpatient treatment was 42.3% of the total health care expenditure in 2014, covered mainly by private payments (78.6% of the total pharmaceutical expenditure). The drug policy is run by the Ministry of Health (MoH), the National Council on Prices and Reimbursement of Medicinal Products, and the Health Technology Assessment Commission. The MoH defines diseases for which the National Health Insurance Fund (NHIF) pays for medicines. The National Council on Prices and Reimbursement of Medicinal Products maintains a positive drug list (PDL) and sets drug prices. Health technology assessment was introduced in 2015 for medicinal products belonging to a new international nonproprietary name group. The PDL defines prescription medicines that are paid for by the NHIF, the MoH, and the health care establishments; exact patient co-payments and reimbursement levels; as well as the ceiling prices for drugs not covered by the NHIF, including over-the-counter medicines. The reimbursement level can be 100%, 75%, or up to 50%. The PDL is revised monthly in all cases except for price increase. Physicians are not assigned with pharmaceutical budgets, there is a brand prescribing practice, and the substitution of prescribed medicines by pharmacists is prohibited. Policies toward cost containment and effectiveness increase include introduction of a reference pricing system, obligation to the NHIF to conduct mandatory centralized bargaining of discounts for medicinal products included in the PDL, public tendering for medicines for hospital treatment, reduction of markup margins of wholesalers and retailers, patient co-payment, and the introduction of health technology assessment. Although most of the policies have been introduced since 2011, there is still weak evidence for improvement regarding cost containment and effectiveness.

Keywords: Bulgaria, health care system, pharmaceutical sector, pricing, reimbursement.

Introduction

Bulgaria is a parliamentary representative democratic republic with a multiparty system and free elections. The population of Bulgaria was 7.128 million in 2016 [1]. The demographic development in Bulgaria is characterized by a population decline, low crude birth and fertility rates, high mortality rate, and aging population. The country has a mixed public-private health care financing system with 54.57% public expenditure in total health care spending [2]. The health care is financed from compulsory health insurance contributions, taxes, out-of-pocket (OOP) payments, voluntary health insurance premiums, corporate payments, donations, and external funding [3]. The total health care expenditure was 8.4% of the gross domestic product for $1398.88 purchasing power parity per capita in 2014 [2]. Bulgaria has a relatively high percentage of OOP health expenditure (44.19% in 2014) [2]. Growth in private health care spending has outstripped public spending over the last 20 years [3–5]. The increase in pharmaceutical spending has made the biggest contribution to this trend. The total pharmaceutical expenditure for outpatient treatment was 42.37% of the total health care spending in 2014, 78.6% of which was OOP expenditure [6]. Although the Bulgarian pharmaceutical market is one of the smallest in the European Union (EU), it has had stable and strong growth over the last few years [5,7]. There are no studies particularly focused on the causes of the high share of drugs spending in Bulgaria. Nevertheless, there is significant syllogistic evidence that a complex of causes leads to this high share of spending, such as high drug prices compared with other EU countries, prescribing practices and overutilization, promotion of more expensive medicines, 20% value-added tax for drugs, and parallel trade [5,8].

Together with the high share of pharmaceutical expenditure in the total health care spending and the significant share of OOP

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

* *Address correspondence to:* Paweł Kawalec, Faculty of Health Sciences, Institute of Public Health, Jagiellonian University Medical College, Grzegorzecka 20, Krakow 31-232, Poland.

E-mail: ppkawa@poczta.onet.pl

2212-1099$36.00 – see front matter

http://dx.doi.org/10.1016/j.vhri.2017.08.001

payments, access to medicines and quality of treatment are the other concerns that have been addressed by various health policy initiatives more intensively in the last few years. These policy initiatives aimed at pharmaceutical cost containment, public spending effectiveness increase, and improvement in access to medicines. Some of the developments in the field of drug policy have been initiated by experts and pharmaceutical sector representatives within the frame of the Partnership for Health, a consultative body to the Council of Ministers that has been engaging various stakeholders to shape and improve health policies in Bulgaria since 2015 [9,10].

The aim of this article was to present an overview of the recent drug policy initiatives in the context of the general health care system development in Bulgaria, focusing on the national pharmaceutical pricing and reimbursement policy analysis.

The article was prepared as part of a project conducted by the working group under the International Society for Pharmacoeconomics and Outcomes Research, Central and Eastern Europe Network.

Health Care System Context

The Ministry of Health (MoH) in Bulgaria is responsible for the national health policy and the overall organization and functioning of the health care system as well as cooperation with all ministries relevant to public health [3]. The health care system is based on an insurance model consisting of compulsory social health insurance (SHI) and voluntary health insurance (VHI). The National Health Insurance Fund (NHIF) is a single payer that administers the SHI system, whereas the VHI covers less than 3% of the Bulgarian population [11]. VHI plays predominantly a supplementary role, giving people direct and faster access to specialist visits and inpatient care and free access to services not covered by the SHI. VHI is provided by commercial joint stock companies who possess license for insurance against sickness and/or incident.

Health care providers are autonomous self-governing organizations. The private sector encompasses all primary medical and dental care facilities and the pharmaceutical sector, most of the specialized outpatient care, and some hospitals. Relations between the NHIF and health care providers are based on the contract model. Although the insurance system covers diagnostic, therapeutic, and rehabilitation services as well as medications for insured individuals, the MoH is responsible for providing and funding public health services, emergency care, transplantations, transfusion hematology, tuberculosis treatment, and inpatient mental health care. The MoH is also responsible for planning and ensuring human resources for the health care system, for developments in medical science, and for collecting and maintaining data on the health status of the population and national health accounts [3].

Pricing and Reimbursement Process

The pharmaceutical sector in Bulgaria is regulated by the 2007 Law on Medicinal Products in Human Medicine, which is harmonized with the EU legislation in the fields of manufacturing, import, and wholesale and retail of drugs; import of medicinal products registered in EU member states; parallel trade of pharmaceuticals; as well as the governance of the pharmaceutical sector, a positive drug list (PDL), and pharmaceutical prices [12].

Medicine prices and reimbursement decisions in Bulgaria (Fig. 1) are further regulated by several legal acts:

1. An ordinance of the Minister of Health sets criteria for defining diseases for which the NHIF pays for drugs [13].
2. Drugs are included in the PDL on the basis of criteria defined by the Law on Medicinal Products in Human Medicine [14] and the health technology assessment (HTA) ordinance [15].
3. Terms and conditions for drug reimbursement by the NHIF are the subject of a special ordinance by the Minister of Health [16].
4. An ordinance on the regulation and registration of pharmaceutical prices, conditions, rules, and criteria for inclusion, changes, and/or exclusion of PDL drugs, and the Prices and Reimbursement Commission terms and conditions issued by the Council of Ministers [17].

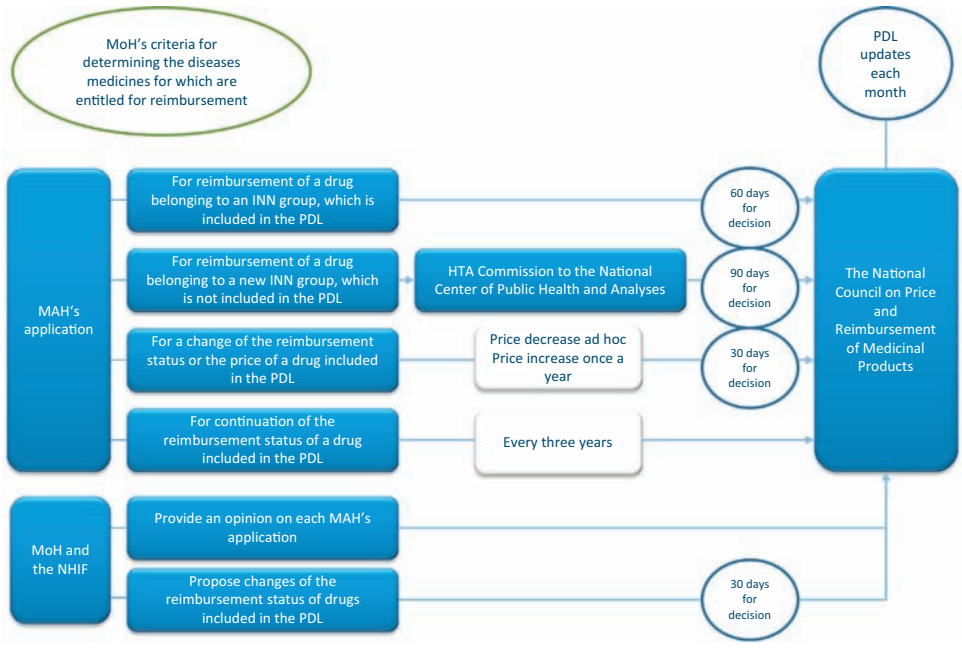

Fig. 1 – Flowchart of the reimbursement decision-making process. HTA, health technology assessment; INN, international nonproprietary name; MAH, marketing authorization holder; MoH, Ministry of Health; NHIF, National Health Insurance Fund; PDL, positive drug list.