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ORIGINAL RESEARCH

Public expenditure and drug policies in Bulgaria in 2014

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Abstract

Aim: The objective of this study was to provide an analysis of the factors which have a significant impact on the growth of public expenditure on medical products in Bulgaria.
Methods: This research work consists of a critical analysis of the data reported by the National Health Insurance Fund in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for 2014.
Results: The results from the current analysis indicate that the growth of public expenditure is directly proportional to the number of reimbursed medical products and that the pattern of prescriptions including the innovative medical products mainly for the treatment of oncological and rare diseases has a significant impact on it.
Conclusion: The reasons for the increase of public expenditure in Bulgaria include the non-transparent decisions in pricing and reimbursement of the products, the lack of guidelines for presenting pharmacological evidence and the lack of legislatively-defined drug policies for the management and control of the patterns of medical prescriptions.

Key words: Bulgaria, drug policies, reimbursement, public expenditure.

Conflicts of interest: None.

Introduction

Healthcare in the European Union (EU) countries including Bulgaria is funded by the healthcare systems and/or through general taxation. The main objective of the healthcare systems is the protection of public health, based on the principles of solidarity and universal access. The drug policy in every country is part of the healthcare policy and adopts the same objectives and principles (1). The expenses on medical products are an important component of the healthcare budgets of all the EU member states. There is an increasing necessity to limit the escalating expenses on healthcare including those on medical products, as well as the effective spending of the financial resources (2).

The good European practice on drug policy implies the determining of Positive Drug Lists (PDL) provided by the healthcare system, and the regulation of the drug prices in a certain order.

The main focus of the approaches to drug policies includes the rational use of medical products, which contributes to the control of public expenditure (3). Considering the fiscal impact of the economical and financial crisis, as well as the expected healthcare expenses for the aging population, these policies are of an increasing interest to the institutions which pay for the public expenses in healthcare (4).

The contemporary views of the European healthcare policies are that through the correct regulation of the pharmaceutical markets economies can be achieved, without having an impact on the provision of care (5).

The drug policy in Bulgaria is legally established by the Ministry of Health and practically applied by the National Council on Prices and Reimbursement of Medical Products (NCPRMP). This is the authority which regulates the prices and makes decisions regarding the reimbursement of the medical products with public funds. The control on prices is based on external and internal reference pricing and regressive margins for distributors and pharmacies. The reimbursing decisions are formally based on pharmaco-economic valuations, but the experts' reports are not available to the public and the objectivity of these decisions cannot be established.

In this context, the aim of this study was to analyze the public fund expenses on medical products in Bulgaria in 2014 in order to determine the impact of the legislative approaches to drug policies and their possible impact on public health.

Methods

This article is a critical analysis of data from the report of the National Health Insurance Fund (NHIF) in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for 2014 (6). A commentary is provided concerning the existing prescribing patterns, national policies for the inclusion of medical products in PDL and their impact on the increasing public expenses. A detailed analysis of the expenses by disease groups and the pattern for the prescription of medicines is also provided.

All graphs and tables included in this article are created on the basis of the data derived from the report of the NHIF in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for the year 2014 (6).

The difference of costs and amount of reimbursed products in the PDL for the period under investigation is presented as a percentage and is calculated with a mathematical method based on the determination of proportionality coefficients.

When trying to predict the future value, one follows the following basic idea:

future value = present value + change

From this idea, we obtain a differential, or a difference equation by noting that:

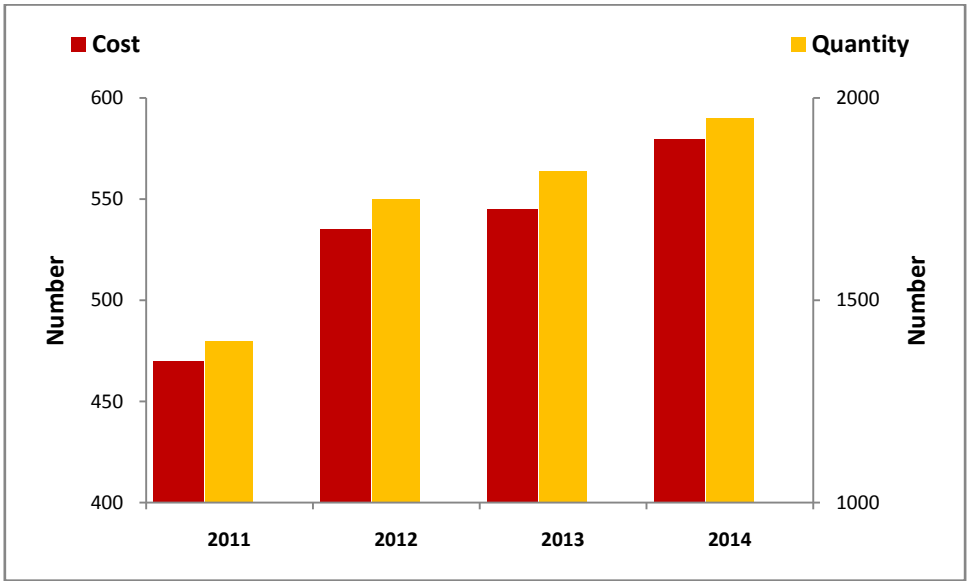
change = future value – present value

The growth of public expenses is influenced by a number of factors discussed in the report of the NHIF in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for 2014 (6).
All prices are given in BGN with current exchange rates of: 1.95583 BGN = 1 EUR.

Results

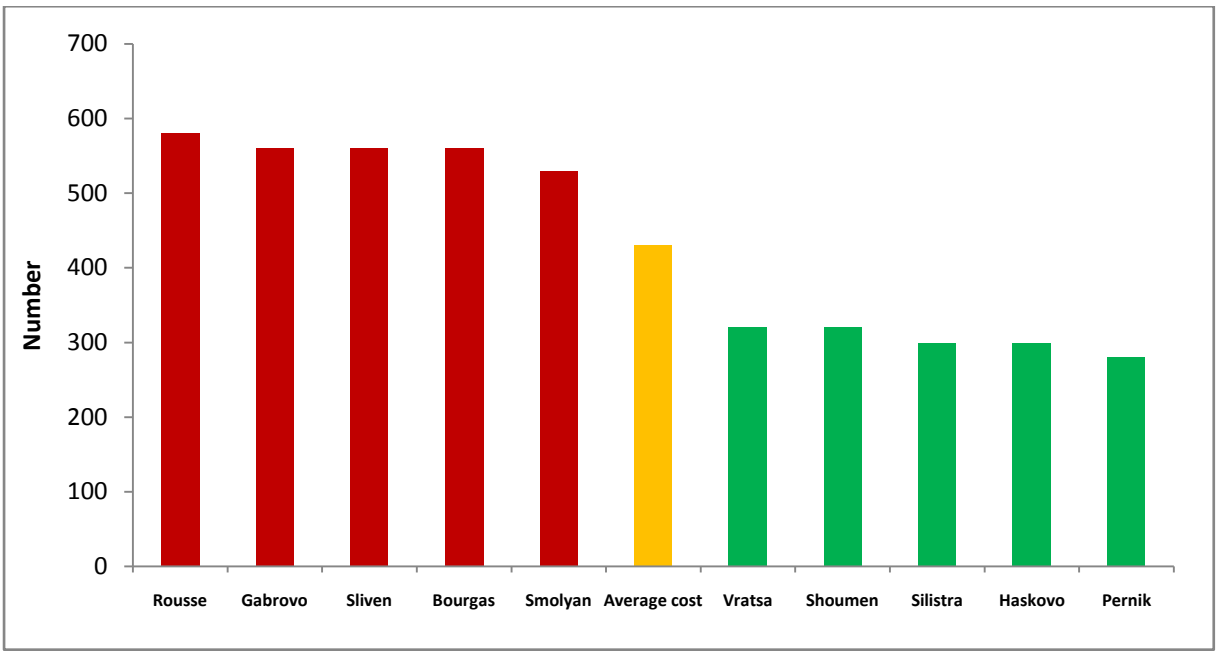
The review of the development of the PDL in Bulgaria in the past three years (2011-2014) from the viewpoint of quantitative indicators shows a big volume (1997 medical products) and a list with frequent changes (every 15 days).
In 2011, the PDL included 1382 medical products, in 2012 it included 1673 products, and in 2014 there were 1997 products. During this three-year period, the number of reimbursed medical products increased by 45%.
The proportion of public expenditure and the number of reimbursed medical products is presented in Figure 1. The established relationship is directly proportional, whereas the cost of public expenses increased by 25%.

Figure 1. Reimbursed medicines for home treatment and the cost of public expenses (both in BGN) in Bulgaria; data for 2014 consists of estimates *(Source: NHIF Report for June 2014)*



The other factor which has a marked impact on public expenditure is the pattern of prescription of the medical products. The presented results (Figure 2) of the average cost of public expenditure for the treatment of non-insulin diabetes in 2013 are indicative – the cost of the expense differs doubly in the various regions, considering that the list of the medical products, their prices and the reimbursed amounts are the same for all the regions of Bulgaria. The different cost of public expenses in the various regions of Bulgaria directly depends on the level of prescribing of DPP-4 inhibitors and GLP-1 receptor antagonists. These are the two groups of innovative medical products for the oral therapy of diabetes, which are rather recommended as a second and a third line of treatment, due to unclear data for the long-term cost effectiveness and doubts about the safety profile (7).

Figure 2. Average cost per patient (in BGN) for the treatment of non-insulin dependent diabetes in Bulgaria in 2013 *(Source: NHIF Report for June 2014)*



The analysis of public expenses by groups of diseases outlines the clear tendencies for an abrupt increase in the expenses for the treatment of rare diseases and oncological diseases.
The expenses for the treatment of rare diseases increased by 36% in 2013 compared to 2012 and reached 59 million BGN, which constitutes 10.7% of all public expenses for medical products (Table 1). This points to a pronounced imbalance of solidarity in the insurance system, because these public costs are absorbed by only 0.15% of the insured individuals. At the same time, public expenses for socially significant diseases such as the cardiovascular disease, diseases of the neural system and diseases of other systems are decreasing (6). These results are an expression of the flaws in the drug policy, part of which are the application of internal reference pricing without a system for the control of medical prescriptions (8), the lack of transparency in the decisions on pricing and reimbursement, based on an expert evaluation of pharmaco-economical evidence, the lack of a defined limit of public expenses for one gained Quality-Adjusted Life Year (QALY), and the like (9).

Table 1. Expenses for the treatment of rare diseases in 2013
(Source: NHIF Report for June 2014)

Disease	Public expense	Average annual cost per patient in BGN	Number of patients
Haemophilus	20 009 544	5290	3783
Beta-thalassemia	8 323 230	3692	2254
Gaucher disease	8 196 183	32 795	250
Blonhopulmonal Dysplasia	4 245 087	2828	1501
Mukopolizaharoidosis	3 294 574	68 637	48
Hereditary amyloidosis with neuropathy	1 625 885	27 098	60
Pompe disease	477 953	47 795	10

The analysis of the expenses on the medical therapy for oncological diseases, paid outside the cost of clinical pathways emphasizes several main facts:

- The expanding of the indications for innovative medicines, mainly for monoclonal antibodies and tyrosine kinase inhibitors. However, there is no data on the evaluation of the efficacy, benefits and costs of the new indications.
- The addition of monoclonal antibodies to the target therapies, which increases the cost of the therapy more than 30 times, while the benefits, expressed as final health outcomes, are minimal. The willingness of society to pay such a high price for the gain of a QALY remains uncertain.
- The inclusion of new international non-proprietary names in the PDL without a clear evaluation of their differential cost-effectiveness as compared to the existing therapies.

As a result of all these factors, the public expenditure on oncological medical products significantly exceeded the settled budgets for the past years, as indicated in Table 2.

Table 2. Expenses of the medical therapy for oncological diseases, paid outside the costs of clinical pathways *(Source: Report on the implementation of the budget of NHIF, 2013-2014)*

YEAR	YEAR	
	2013	**2014**
Budget in BGN	90 000 000	145 000 000
Public expenditure in BGN	172 443 480	203 472 732*
Relative share of the overspending (%)	91,60	40,30

* Data for 2014 consists of estimates.

Discussion

Several main factors have been identified which have an impact on the annually increasing public expenses on medical products in Bulgaria:

- *Non-transparent decisions for the inclusion of medical products in the PDL with unclear cost-effectiveness compared to the existing drug alternatives.* There is no data on the recommendations of NCPRMP for the pharmaceutical industry and set out denials for reimbursement justified by the lack of sufficient evidence of effectiveness and/or high prices. The practice in the economically developed countries is different. For example, the Committee for the Evaluation of Medicinal Products in Canada refused to reimburse Pemetrexed for the treatment of malignant pleural mesothelioma, because the product does not provide added value for the price difference compared to the existing alternatives (10).

  Another Canadian solution sets to reimburse Sunitinib for the treatment of metastatic renal cell carcinoma only after negotiating the price because of poor cost-effectiveness, despite the improved efficacy over the existing therapeutic alternatives.

  Many similar negative decisions regarding the reimbursement of medical products for a specific diagnosis can be found in the scientific literature. Their aim is both to facilitate the access of patients to therapies which give them additional therapeutic value and use, as well as to protect patients from health risks connected to severe adverse drug reactions (11,12).

- *The lack of legally defined public expenditure related to one gained QALY.* This is a widely used instrument for limiting public expenditure and for the control of the innovative medical therapies (13).
- *Lack of legal control on the patterns of prescribing medicines.* The EU states have a number of measures in working order for improving the patterns of prescribing medicines. Most often they entail the monitoring of the prescriptions, recommendations and guidelines of advisory/obligatory nature regarding the prescriptions, including the requirements to prescribe an international non-proprietary name, a maximum limit on the prescribed medicines, prescription quotas, financial incentives, as well as educational and informational approaches (14-16).

The aim of all enumerated policies is to promote the rational use of medical products for the benefit of public health. The combinations of diverse measures, as electronic monitoring in prescription and in guidelines, connected with electronic systems which support the process of decision-making and give feedback to the physician, are an effective way to improve the patterns in prescribing medicines (17). In addition, educational and informational instruments should be activated.

The prescription of international non-proprietary names and prescription quotas, if possible in combination with target budgets and financial incentives, seem to be effective tools for the purpose of regulating public expenditure.

Conclusion

The effectiveness of public expenditure in Bulgaria will improve when it becomes the main objective in medical policy, i.e., when medical therapies are evaluated in a real and transparent way as a ratio of expenses and use as compared to the existing alternatives. It is necessary that the first steps are aimed at developing a control system of the prescription and evaluation of medicines' pharmaco-economical evidence, as well as determining public expenditure of the medical therapy at the level of one gained QALY.

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