REIMBURSEMENT AND PUBLIC EXPENDITURE ON MEDICINAL PRODUCTS IN THE REPUBLIC OF BULGARIA

R. Stoyanova[1], N. Atanasov[1], G. Petrova[1]

[1]Faculty of Public Health, Medical University Plovdiv, Bulgaria

Abstract. The objective of this study was to analyse the reimbursement of the cost of medicinal products by the National Health Insurance Fund (NHIF) and the public expenditure on such products over the period 2007-2012. The method used was based on analyses of legal framework and historic records from the NHIF and the National Statistics Institute. It was established that the number of medicinal products on the positive reimbursement list had increased significantly over the analysed period by 211.75%. The annual average rate of increase of public expenditure on medicinal products designed for treatment at home is 12.59%. Nevertheless, the share of public sources in the total health expenditure has decreased from 61.0% in 2003 to 56.3% in 2011. The slower rate of increase of the public expenditure on health care compared to private funds limits the possibility of achieving one of the major objectives of reimbursement, namely improving the access to health care. Bulgaria's health policy should aim at extending the public funding sources by introducing additional health contributions or health insurances.

Key Words: reimbursement, medicinal products, public expenditure.

Introduction

The first separate list of reimbursed medicinal products in Bulgaria was made in 2001 by the NHIF. It included 304 international generic medicinal products paid for entirely or partially using public funds.

In accordance with the amendments to the Law on medicinal products in human medicine of 2008 and with Regulation No 10 issued by the minister for health, as of January 30, 2009 the responsibility for including new drugs and amending the existing Positive Drugs List (PDL) was transferred to a dedicated committee within the Council of Ministers. That committee identifies the medicinal products and sets forth the prices and margins that are to be paid for by the NHIF.

From December 21, 2012 to the Minister of Health was established a National Council on prices and reimbursement of medicinal products which is responsible for the maintenance and changes in the positive list of medicines and the prices of the drugs in the list [1].

The main requirement for the positive drugs list is to include medicinal products that meet the following criteria [2]:

- Efficacy and therapeutic efficiency: the therapeutic benefits of the medicinal product such as life extension level, improving the quality of life, mitigating the complications from the primary disease, and so on, are evaluated. There should not be any alternative medication of that specific disease;
- Safety of medicinal products: evaluation of the frequency and severity of adverse reactions, and the need for implementation of additional preventive or therapeutic measures to prevent adverse events;
- Pharmaceutical and economic efficacy: assessment of the direct and indirect benefit and cost, the social and economic impact of the given disease, and economic assessment of possible additional therapeutic benefits

The primary objectives of reimbursement policies are to reduce the prices of medicinal products through stimulation of price competition and reducing the rate of growth of public expenditure on medicinal products.

The objective of this study was to analyse the reimbursement of the cost of medicinal products by the NHIF and the public expenditure on such products over the period 2007-2012.

Materials and methods

The methods used were based on analysis of legal framework and analysis of historic records from the NHIF and the National Statistics Institute.

In view of attaining the objective were analysed official data from:

- indices relating to the drugs policy for patients with chronic diseases in Bulgaria from the NHIF;
- consolidated financial reports on funds paid by the NHIF for medicinal products and medicinal devices over the period 2007-2012;
- report on 10 most costly drugs diseases for the period 2007-2012 by the NHIF;
- information from the NSI about the Health Accounts system

All data were processed using the SPSS 17.0 program and MS Excel for Windows. Comparative, graphical analyses and indices for linked database for defining trends in development of dynamic rows were used. The results are shown as numbers, percentage and mean values, and presented in the form of tables and figures. To explain the strength of relation between observed variables correlation coefficient of Pearson (R) was applied, and for this a level of significance of 5% probability ($P < 0.05$) was adopted.

Results

After its creation in 2001, the first reimbursement list of drugs containing only 304 international generic drugs, it grew up to a total 1079 drugs, foods and medicinal devices for more than 130 diseases by the end of 2008. This means that 775 new products have been included or a growth rate of 255% within eight years.

After the amendment of the Law on medicinal products in human medicine and the assignment of the positive drugs list to a dedicated committee at the Council of Ministers the number of drugs included on that list continued growing but not as quickly as before 2008. The relevant data are shown in Table 1.

The number of diseases, for which medicinal products, devices or diet foods fully or partially reimbursed by the NHIF are accounted for, increases at a slower speed. Nevertheless, there is a clear positive correlation between the number of drugs on the positive list and the number of diseases for which medicinal products are reimbursed ($R = 0.893$; $P = 0.017$).

The list of diseases for which the NHIF reimburses fully or partially the cost of medicinal products, devices or medical diet foods for home treatment is approved by decision of the minister for health made on the basis of [3]:

√ a positive opinion of the national consultant in the relevant medical specialty;

√ a positive opinion of the NHIF about the financial possibility to include that disease on the list with included analysis of the impact on the budget;

√ opinions of the relevant special directorates of the Ministry of Health concerning the registration status of the medicinal products for home treatment proposed by the national consultant and the expected mean cost of the treatment of one patient for one year;

Despite the heavy procedure for inclusion of new diseases, and thus of new drugs on the PDL, over the period 2007-2012 the number of drugs included on that list of medicinal products has increased by

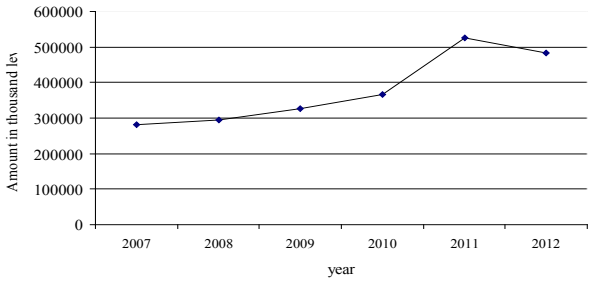
Table 1. *Mean recovery (n = 3) of selected flavonoids obtained by SPE using sorbents C18 and CN, and different eluents*

Indicators	***Year***					
	2007	***2008***	***2009***	***2010***	***2011***	***2012***
Number of drugs on the positive drug list	766	1079	1254	1198	1457	1622
Rate of increase of the number of drugs on the positive drug list on a chain basis (%)	-	40,86	16,22	-4,47	21,62	11,32
Number of diseases for which medicinal products, devices or foods fully or partially reimbursed by the NHIF are included	128	133	134	133	149	146
Rate of increase of the number of diseases for which medicinal products, devices or foods fully or partially reimbursed by the NHIF are included on a chain basis (%)	-	3,91	0,75	-0,75	12,03	-2,01

** According to information from the NHIF*

50.3% resulting in a significant increase of the public expenditure on medicinal products (R=0.864; P= 0.026) (see Fig. 1). Furthermore, there is also a very clear positive correlation between the drugs on the positive list and the funds spent on drugs for such diseases (R = 0.971; P = 0.001).

The annual average rate of increase of the funds spent on drugs for home treatment for the concerned period was 12.59%. It is higher than the average rate of increase of the total sum of health insurance payments made by the monopoly holder NHIF, which is 11.49%.



* According to information from the NHIF

Figure 1. *Public expenditure on medicinal products for home treatment (BGN thousands) according to report*

It is interesting to see the structure of health expenses according to the criterion public vs. private sources of funding in Bulgaria. It is quite different from the one in other countries with higher standard of living. In Bulgaria, the share of public sources in the total health expenditure has decreased from 61.0% in 2003 to 56.3% in 2011, which could be interpreted as a restriction of the access to different medical services and medicinal products for patients.

The evolution of the proportion of public sources in the total health expenditure in Bulgaria is shown on Fig. 2.

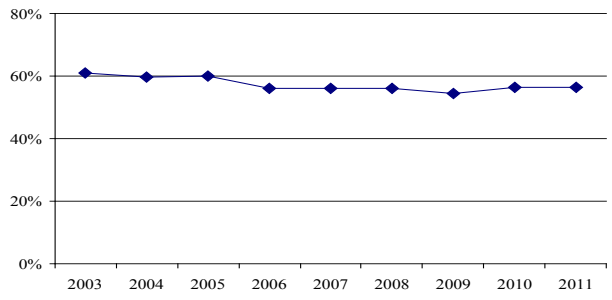
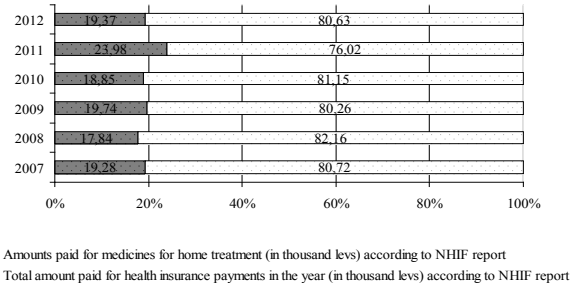


Figure 2. *Proportion of public funds in the total health expenditure (calculations made by the authors on the basis of information from the NSI (www.nsi.bg)*

In the same, there is trend towards increase of the relative weight of public expenditure on medicinal products in the structure of public health insurance payments made by the NHIF (see Fig. 3).



* According to information from the NHIF

Figure 3. *Proportion of the expenditure on drugs for home treatment from the total health insurance payments made by the NHIF*

A major part of the expenditure on medicinal products goes to reimbursed drugs for a relatively small number of diseases. According to information from the NHIF, the list of these primary diseases is more or less stable and the cost of drugs to them occupies an almost unchanging proportion of the total drugs expenditure. In this regard, it should be noted that 65.23 % in average of the total expenditure on medicinal products goes for only the ten diseases. The data are shown in Table 2.

This in turn could result in reducing the financial support for other groups of patients thus restricting their access to drugs, and raise questions relating to the fair repartition of public funds. Therefore, a responsible health policy and strict control on the prescription and allowance of drugs reimbursed by the NHIF are required.

The regulatory thresholds for reimbursement of drugs on the PDL in Bulgaria are: 100% for drugs administered to patients at hospitals; 100% upon decision of the minister for health; 100% for drugs for some rare diseases, AIDS, and prevention and treatment of infectious diseases; up to 100% for medicinal products for chronic diseases that may lead to severe disturbance to the quality of life or disability, and require long-term treatment; up to 75% for medicinal products for chronic diseases with high levels of prevalence; up to 50% for medicinal products designed for diseases different from the above listed [2].

This part of the legislation that governs the reimbursement of medicinal products in Bulgaria is quite ambiguous and uneven and could lead in turn to unjustified public expenditure on certain groups of drugs.

Table 2. *Ten most costly drugs diseases for the period 2007-2012*

ICD code	*Designation*	*Annual average* ***reimbursed amount for medicinal products*** *for the period 2007-2012 by ICD code (BGN thousands)*
I11	Hypertensive heart disease	42 932
F20.0	Paranoid schizophrenia	37 135
E11	Non-insulin-dependent diabetes mellitus	33 211
E10.4	Diabetes mellitus with neurological complications	29 152
J44.8	Other specified chronic obstructive pulmonary disease	22 423
G35	Multiple sclerosis	19 519
I20	Angina pectoris	19 259
J45.0	Predominantly allergic asthma	16 667
G40.6	Grand mal seizures, unspecified (with or without petit mal seizures)	15 817
B18	Chronic viral hepatitis	11 536
	Total sum for the 10 most costly drugs diseases (BGN thousands)	**247 651**
	Annual average expenditure on medicinal products for the period 2007-2012 (BGN thousands)	**379 633**
	Proportion of 10 most costly drugs diseases from the annual average expenditure on drugs (%)	**65,23**

* According to information from the NHIF and own calculations

Discussion

Issues relating to the significantly increased use of medicinal products reimbursed by the state or other public funds and access to specific drugs for given groups of diseases are also observed in other countries[4].

In most European countries, 60% in average of the expenditure on medicinal products come from public funds, like in Bulgaria [5]. However, there is a wide variation in public spending on pharmaceuticals ranging from less than 40% in Italy or Poland to more than 80% in Ireland or the Netherlands [4]. The personal expenses on drugs of consumers also vary in a wide range between 60% in Denmark to almost 0% in the Netherlands [6]. The remaining percentage is covered from insurances or voluntary health funds. Such a practice is underdeveloped or almost absent in Bulgaria.

The cost of medicinal products forms the third largest component of the health care budged in EU Member States and it keeps growing as a percentage of the GDP. In the same time, there are significant differences between the spending on drugs per capita among the individual countries [6, 7]. Member States where the growth of expenditure on drugs per capita is the greatest are Greece, Ireland and France and therefore the public funds allocated for reimbursement of the price of medicinal products in these countries. For example, the public expenditure on drugs in Ireland has increased by 350% [8] over the period 2000-2009, whereas in Greece it has increased by 400% over a period of 12 years (1995-2007) [9].

This requires the implementation of specific policies in those countries relating to reduction of the public expenditure on medicinal products through adoption of specific rules for inclusion of drugs on a specific positive list, reference pricing and assuming responsibilities for the drug policy in place[10].

In most countries circumscription of the expenditure on drugs is achieved by applying efficient measures aiming at refraining expenditure on the part of supply through inclusion of drugs on a positive or a negative list, reference pricing, control on the profit of wholesalers and retailers, individual or global budgets for general practitioners, aggravated procedures for approval of the prices of drugs and

their reimbursement, incentives for prescription of generic products, etc. [4, 6, 8, 11, 12, 13, 14]. Some of these measures hamper the access to drugs for patients but they are recognised as positive measures to hold back expenditure.

Policies implemented to regulate the demand mainly involve introducing partial payment by patients but in many countries this could restrict additionally the access to some drugs for patients [4, 6, 15, 16].

Most of the measures used to regulate both supply and demand of medicinal products are successfully applied in Bulgaria as well but the results still show that the public expenditure on reimbursement of medicinal products is growing.

Analysing the measures for control on the prices of medicinal products many researchers come to the conclusion that these policies can not guarantee a decrease of expenditure unless they are paired with control on the volumes of drugs prescribed [17].

The circumscription of public expenditure on medicinal products without restricting the access to drugs for patients is a topic that is widely discussed in many countries and the issue will most probably intensify with the ageing of the population.

Conclusions

Along with the primary objectives of the reimbursement policy such as keeping the prices of pharmaceutical products relatively low and decreasing the rate of growth of the public expenditure on drugs there is another objective that is not less important, which is improving the access to the drugs and medical products market for patients suffering from specific groups of diseases. The practice for reimbursement of medicinal products of each country has its specific characteristics. It takes into account the financial strength of their respective public funds.

The results of this study have shown a significant growth of public funds allocated for drugs and medical products over the analysed period. Nevertheless, the proportion of private expenditure on health services in Bulgaria remains high compared to countries with higher standard of living. At equal other conditions this process will most probably have a negative effect on the access to medicinal products.

Furthermore, the question of the efficacy and efficiency of the Bulgarian legislation remains controversial because the regulations create conditions for continuous changes to the levels of reimbursement compared to the reference values for a large group of medicinal products.

To overcome or solve the above mentioned issues, the Bulgarian health policy should aim towards expanding the public sources of funding in order to improve the access to medicinal products through additional health contributions or health insurances. On the other hand, the regulations should provide a more stable, predictable and competitive environment, both for patients and for manufacturers of and traders in medicinal products.

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✉ **Corresponding author**
Rumyana Gencheva Stoyanova
Medical University-Plovdiv, Faculty of Public Health,
Department of Health management, Health economics and Primary Health
15 A "Vasil Aprilov" Blvd, 4002 Plovdiv, Bulgaria
Tel: +359 32 602 042
e-mail: rumi_stoqnova@abv.bg