The dependency of public expenditure on the number of reimbursed medical products – A decade of experience in Bulgaria

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Abstract

This study analyzes the differential growth of the relative changes of the quantity of the medical products in the reimbursement list and the respective relative changes of public expenditure in Bulgaria for a decade of experience (2004-2013). For this purpose, we used the reimbursement lists for the respective years and the accounts on the cash execution of the budget of the National Health Insurance Fund in Bulgaria.
After 2008, a double digit growth was registered in the number of reimbursed medicines annually, and the dynamics and the public expenditure for these medicines were similar. We propose additional conditions for including medical products in the positive and reimbursement lists, in order to optimize the control both of the public, as well as the personal expenses for the price of the medical therapies in Bulgaria.

Keywords: control, medical products, public expenditure, reimbursement lists.

Introduction

All European Union (EU) states have reimbursement lists which determine which medicines should be reimbursement (positive lists) and which medicines are excluded from the reimbursement system (negative lists) (1). The criteria based on which medicines should be included in the positive list are therapeutic and economic and analyze the achieved benefit for the patient per unit of cost in comparison to an alternative product (2). The impact of the reimbursement lists on the limitation of expenditure can be implemented through several mechanisms. First, the decrease of the number of medical products in the positive lists as a rule decreases public expenditure.

The following question arises though: what are the objective criteria for cutting down the positive lists? In a number of EU states such as Germany and France, innovative medical products are included in the reimbursement lists only in the cases when they have superior pharmaco-economic indicators as compared to the existing therapeutic alternatives. Moreover, these indicators are periodically revised and the pharmaco-economical ineffective medical products are removed from the lists (3).

When dealing with generic medical products it has become increasingly mandatory that these products should be in the reimbursement lists only when their prices correspond to the reference costs for the respective international non-proprietary names (4). Secondly, it should be considered that the exclusion of medical products from the reimbursement system could have uncertain consequences on cutting the expenditure, if it is not correctly planned. When an excluded medicine has substitutes in the positive list, expenses could increase, if the substitutes are more expensive (5). A similar result was found in Spain, when the average price of the prescribed reimbursed medicines increased after the exclusion of some previously publicly reimbursed medicines (6).

We can therefore conclude that, in order for the positive lists to be effective, they have to be updated systematically and periodically as the newly registered medical products could cause the removal and/or recalculation of the prices of the existing medical alternatives (7).

The application of the reimbursement lists in Bulgaria, based on internal and external reference pricing, has a ten-year history, which permits us to assess a possible relation between the number of the reimbursed medical products and their related public expenditure. More specifically, the objective of this study was to analyze the differential growth of the relative changes in the quantity of the medical products in the reimbursement list and the respective relative change in the public expenditure in Bulgaria within a decade (2004-2013).

Methods

In order to address the study objective, we used data from the reimbursement lists for the respective years and the accounts for cash execution of the budget of the National Health Insurance Fund (NHIF) in Bulgaria.

In order to calculate the relative change in the costs, we used the following formula:

$$\Delta q_i = \frac{q_i - q_{i-1}}{q_{i-1}} \text{ x } 100 \text{ ;} \qquad \Delta v_j = \frac{v_j - v_{j-1}}{v_{j-1}} \text{ x } 100$$

Where:

Δq – differential growth and the relative change in the quantity of the reimbursed medicinal products;

$q_{i\,(i-1)}$ – quantity per year i (i – 1);

Δv – differential growth of the relative change of the public expenditure;

$v_{j\,(j-1)}$ – public expenditure per year j (j – 1).

Results and Discussion

The number of the included medical products in the NHIF reimbursement list for the period of ten years (2004-2013) is presented in Table 1. The study did not analyze a possible correlation depending on the changes in the relevant regulations during the considered period and the quantity of the reimbursed medical products.

Up to 2008, the reimbursement of medical products was based on internal reference pricing, negotiation of the prices between the NHIF and the manufacturers, as well as on programs for controlled patient access to some expensive medical products. After 2008, a Positive Drug List was introduced based on internal and external reference pricing.

Table 1. Number of reimbursed medical products for the period 2004-2013 and the relative annual changes in Bulgaria

Year	Quantity of the reimbursed medicines (number)	Relative change (%)
2004	846	–
2005	857	+ 1.30
2006	837	– 2.33
2007	882	+ 5.38
2008	1031	+ 16.89
2009	1165	+ 13.00
2010	1308	+ 12.27
2011	1580	+ 20.80
2012	1752	+ 10.89
2013	1980	+ 13.01

Source: NHIF Reimbursement Lists, 2004-2013.

Double digit growth of the reimbursed medical products was registered every year after 2008, when the Positive Drug List was brought under regulation. Similar to this was also the public expenditure trend (Table 2). A clear correlation was evident between the number of the reimbursed medical products and public expenditure. The The analysis of the average annual public expenses for a single medical product shows changes within a narrow range between 269 thousand BGN and 322 thousand BGN. This fact confirms that the most important factor for the increase of public expenditure consists of the changes in the model for prescribing medical products and the increase of the use of combined therapies, including more than four medical products for the major diseases such as hypertension, diabetes, heart failure, ischemic heart disease, and the like (9).

increase in the number of medical products increased the public expenditure for their reimbursement. The possible factors for this direct positive correlation include the increase of therapeutic doses, the quantitative increase of the combined drug therapies, as well as the higher prices of the newly included drugs in the reimbursement lists (8).

The differential growth of the relative change of the number of the medical products and the public expenditure are shown in Figure 1.

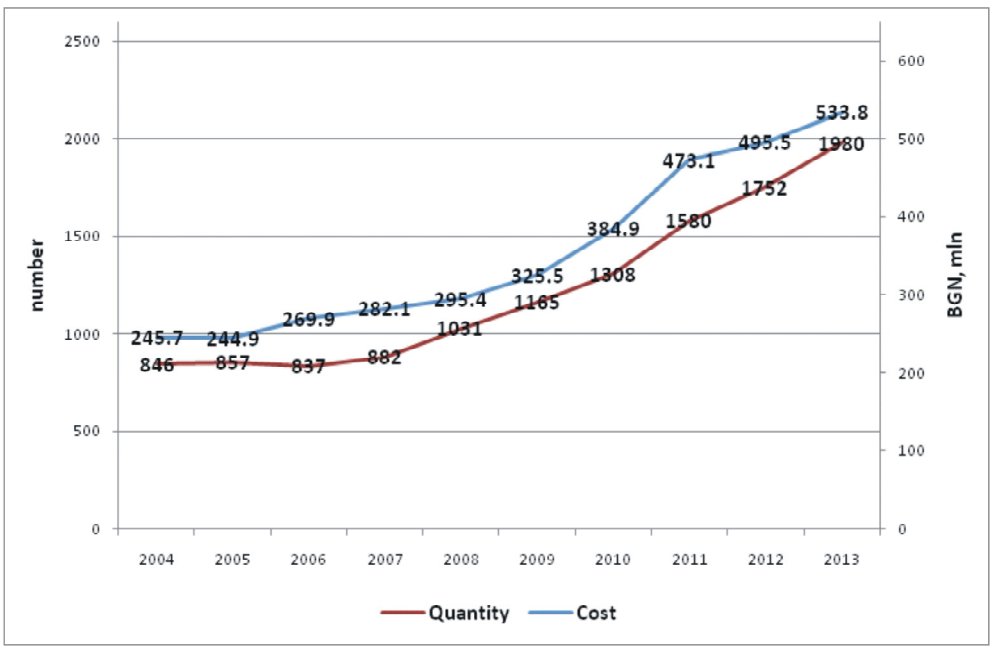
The differential growth curves illustrate the correlation between the number of the reimbursed medical products and the respective increase in the public expenditure.

Table 2. Public expenditure on medical products for the period 2004-2013 and the relative annual changes in Bulgaria

Year	Public expenditure (BGN)	Relative change (%)
2004	245,700,000	–
2005	244,900,000	– 0.32
2006	269,979,500	+ 10.24
2007	282,065,400	+ 4.48
2008	295,481,000	+ 4.76
2009	325,598,000	+ 10.19
2010	384,935,800	+ 18.23
2011	473,163,088	+ 22.92
2012	495,525,000	+ 4.73
2013	533,881,656	+ 7.74

Source: Accounts on the cash execution of the budget of the NHIF, 2004-2013.

Figure 1. Differential growth of the relative change of the quantity of the reimbursed medicines and public expenditure in Bulgaria



The current problems of the Bulgarian reimbursement system, connected with the therapeutic and economic effectiveness of the medical therapies, apparently have to seek their solution in a compromise between the number of reimbursed medical products, the patient accessibility to reimbursed therapies and the possibility for doctors, who make therapeutic decisions, to choose medical products (10). In order to reach a compromise for an effective solution, there should be an integrated

approach to drug policy, depending on the effectiveness and the price of each medical therapy on the reimbursement level, a decrease in the additional payments by patients for pharmaco-economic effective therapies and a regular analysis of the products in the reimbursement lists with the purpose of removing the least adequate and/or the comparatively expensive drugs in relation to their therapeutic advantages (11).

Conclusion

Public expenditure is proportionally dependent on the number of reimbursed medical products. The inevitable conclusion is that the application of a Positive Drug List, based on external reference pricing at the trademark level and internal reference reimbursement on the level of international non-proprietary names of the medical products, combined with the inclusion of new products without additional pricing conditions every month, does not lead to the desired control of the number of reimbursed medicines and public expenditure.

There is a need for specific reforms, connected with additional conditions for including medicines in the positive and reimbursement lists:

- For innovative medical products, which do not have generic analogies, it is necessary to bring under regulations a requirement for pharmaco-economic evaluation, which would indicate objective and undeniable benefits in comparison to the existing reimbursed therapeutic alternatives (12).
- For generic medical products it is necessary to introduce a requirement for a maximum price which should not exceed the existing reference price of the respective international non-proprietary name (13).

The introduction of the proposed requirements would improve the therapeutic and economic effectiveness of the medical therapies in Bulgaria, where the correct management of the reimbursed lists supplies the necessary control mechanisms both of the reimbursed cost (the public expenditure), as well as the participation of the patient (the personal costs) in the price of medical therapies. The last is of a particular importance for patients' accessibility to medical therapies in Bulgaria.

Conflicts of interest: None declared.

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