

SHORT REPORT

Control of public expenditure on drug products in Bulgaria – Policies and outcomes

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Abstract

Aim: The aim of this study was to assess the economic performance of the application of the policy for negotiating discounts on drug products and agreements on the controlled access of patients in Bulgaria.

Methods: The methodology involves comparison of the amounts of public spending on medicines in two periods – during the course of the analyzed drug policies (January 2007 – June 2009), and the period in which negotiations on the price of medicines and programs for the controlled access of the patients was discontinued (July 2009 – December 2012).

Results: In Bulgaria, the government did not apply methods for controlling public expenditure on medicines bargaining price concessions from manufacturers and implementing agreements on controlled access of patients after June 2009. This led to an annual increase in the expenditures on drug products for home treatment (on average, 17% for the period 2009-2012).

Conclusion: This trend in Bulgaria will continue in the future since expenditure control only through price control by means of a reference system and the positive list of medicines is ineffective. There is a need for implementation of combined drug policies in Bulgaria in the form of negotiations on rebates with manufacturers and agreements on controlled access of patients and reference pricing.

Keywords: Bulgaria, drugs, negotiation, National Health Insurance Fund, prices.

Conflict of interest: none.

Introduction

The contemporary approaches to drug policy in a number of European Union (EU) countries include negotiating discounts and rebates between the health insurance funds and the pharmaceutical manufacturers, as well as agreements for risk sharing in order to reduce the impact of the new patented medicines on the public budget.

Negotiating some form of discount between the manufacturers and the funds has different forms and ways of administration in different countries and, in some cases, pharmacies give up part of their statutory surcharges (e.g. the Netherlands) (1). In other cases, they impose administrative requirements for discounts on the pharmaceutical manufacturers (Germany, Spain, Portugal) (2), whereas in further cases manufacturers recover part of the cost of the reimbursed medicines when the previously agreed annual limits are exceeded (France) (3).

Such policies of paying back are becoming more and more popular and are currently being applied in at least ten EU countries.

Until June 2009, the National Health Insurance Fund (NHIF) in Bulgaria negotiated discounts with manufacturers on the prices of patented medicines and administratively determined the conditions of pharmacies for their dispensing. For these products, pharmacists were not allowed to charge the statutory determined retail surcharge and received a minimum fixed fee for the dispensing of medicines. Subsequently, in June 2009, with the adoption of a Positive Drug List (PDL), the possibility of NHIF to negotiate prices and discounts on medicines were legally discontinued.

The agreements for sharing the financial risk and the controlled access of patients to treatment with proprietary medicinal products are also a tool for the management and control of public spending. The need for such agreements highlights the rapidly growing share of drug costs for the treatment of certain diseases such as cancer, viral infections, neurological diseases, or diabetes and the increasing concern of the governments about the relatively high level of health consumption of new drugs compared to the standard therapeutic alternatives.

In the EU countries, there exist several different schemes for financial risk sharing:

- Agreements of the type “price-quantity”. These are purely financial schemes that lead to recovery when there is an excess in the previously agreed schemes by the producers’ sales.
- Agreements of the type “controlled access for the patients”. They are based on an approach that the medicines are provided free-of-charge or at a lower price by the manufacturer for a limited period in order to facilitate financing (4).
- Agreements based on the results. They are based on the recovery of the costs, if a previously agreed upon level of therapeutic results is not reached, e.g. the desired improvement of health.

Ultimately, no matter what the specific approach will be, the agreements for risk sharing reduce the risk of overspending the budget of the public health insurance fund. They are particularly useful for restricting the use of drugs by those segments of the population which generate the least benefits (5).

In the Bulgarian health system, agreements for the controlled access of patients were applied until June 2009 in the form of health programs for expensive treatment of socially significant diseases such as diabetes, chronic renal failure, hepatitis, multiple sclerosis, schizophrenia, bipolar disorder, or Parkinson’s disease. Access to these health programs was granted for patients who met specific criteria for the disease and diagnostic indicators, confirmed by special medical commissions. These health programs for the controlled access of patients have been discontinued since June 2009 and the access was extended to all patients with these diagnoses.

As a modern political tool that limits the impact on public spending, especially for innovative

drugs of uncertain benefit, the agreements for sharing the financial risk are an interesting and promising approach. At present, however, there is no systematic evaluation of their application and results achieved in Bulgaria.

In this context, the aim of the current study was to assess the economic results of the implementation of the policies for negotiating discounts and medical products and the agreements on the controlled access of patients in Bulgaria. The study questions included a comparative analysis of the cost of the expenses for drug products throughout two periods, in which different practices for their regulation were employed – in the first period there were employed policies of negotiating the prices, internal reference pricing and programs for regulated access to patients, while in the next period only policies for external and internal reference pricing were used. The tested hypothesis was that the complex policy of reference pricing, negotiating prices and programs for a controlled access contribute to the success of a more effective regulation of the drug products costs, in comparison to the separate employment of policies for external and internal reference pricing.

Methods

The methodology consisted of comparing the value of public spending on medicines in two periods – during the course of the analyzed drug policies (January 2007 – June 2009) (6) and the period when negotiating the price of medicines and the programs for the controlled access of patients was discontinued (July 2009 – December 2012) (7).

The official data for the expenses of NHIF for reimbursing the medicinal products were used for the current analysis. We compared the quantities and the value of the medicinal products, which have been completely reimbursed and were used for the treatment of multiple sclerosis, hepatitis, schizophrenia and diabetes. These expenses constitute 25% of the costs for the completely reimbursed medicinal products. At the beginning of the period under consideration (2007), medicines had patent protection and there were no registered generic products in the market. Up to 2009, public expenses of these medicinal products were controlled through a complex of measures which included agreements for sharing the financial risk and policies of price discounts.

Results

The public expenditure on NHIF medicines for the period of 2007-2012 are presented in Figure 1. The costs up to June 2009 are presented in two parts – partially reimbursed medicines and completely free medicines, which are controlled by negotiating discounts, an administrative reduction of the surplus charge of pharmacies and programs to control patient access to the expensive treatment of certain socially significant diseases. After June 2009, all the NHIF approaches employed to control costs were terminated, and the cost of public funds for medicines were operated only by the PDL, based on external and internal reference pricing.

The data analysis shows that during the period 2007-2009 (when discount policies and agreements on the controlled access were applied), the cost of medicines for three years increased from 282 million BGN to 325 million BGN, i.e. an increase of 15%. For a similar period (2010-2012), when the public spending was controlled only by external and internal reference pricing, the cost of medicines increased from 366 million BGN to 524 million BGN (up to 43%). Therefore, it is reasonable to conclude that the long-term results of drug policies on discounts and programs for the controlled access of patients are more effective in terms of public spending, than the independent application of a reference price system within the PDL.

Figure 1. Public expenditure on NHIF medicines for the period 2007-2012
(Source: Statement of the cash execution of the NHIF budget)

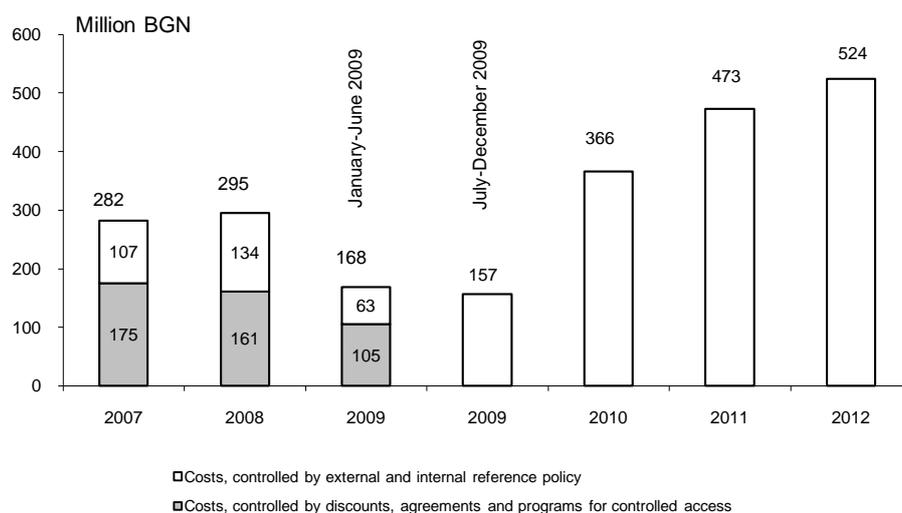


Table 1 displays the quantitative analysis of the most commonly used medicines for the treatment of multiple sclerosis, hepatitis, schizophrenia and diabetes, which in 2008 were dispensed under the programs for controlled access that were discontinued after June 2009. After the termination of the agreements for controlled access, the reimbursed amounts of the NHIF drug products increased between 14% (Insulin human) and 157% (Peginterferon) by 2012 compared to 2008.

Table 1. The amount of annual sales during the period 2008-2012
(Source: IMS Health, 2008-2012)

Medicine	2008 (number)	2009 (number)	2010 (number)	2011 (number)	2012 (number)
Interferon β	12,277	15,863	19,364	21,175	25,741
Peginterferon	14,087	18,285	35,435	34,731	36,244
Olanzapine	62,650	70,145	64,002	71,958	105,744
Aripiprazole	24,224	26,799	35,265	39,147	41,429
Insulin human	4,527,237	4,783,584	4, 854, 414	5,082,538	5,166,258

Table 2 displays an analysis of the values that were reimbursed by the NHIF for the same products. Public spending on the examined medicinal products increased between 16% (Insulin human) and 118% (Peginterferon) by 2012. An exception is the reimbursed expense for Olanzapine. The main reason is the expiry of the patent protection and the registration of generic medicines.

Table 2. The value of annual sales during the period of 2008-2012
(Source: IMS Health, 2008-2012)

Medicine	2008, BGN	2009, BGN	2010, BGN	2011, BGN	2012, BGN
Interferon β	9,717,166	12,585,278	16,392,076	16,207,345	18,495,318
Peginterferon	5,571,752	6,563,072	12,485,396	12,293,382	12,166,795
Olanzapine	11,871,082	11,319,137	9,592,246	8,795,552	7,686,233
Aripiprazole	5,178,861	4,883,137	5,713,810	6,376,297	6,711,932
Insulin human	44,209,976	45,246,122	44,617,054	49,667,806	51,433,736

Discussion

The increased public spending after 2009 once again demonstrates that the combination of various drug policies like negotiating discounts with manufacturers, agreements for the controlled access of patients and reference pricing are much more effective for the management and control of costs, than the administration of external and internal reference pricing by a PDL. The complex approach is the only possibility for price control of the innovative medicinal products (Interferon, Peginterferon, Insulin, Aripiprazole), where there are no generic alternatives and the internal reference pricing approach cannot be applied. Moreover, the pharmaceutical companies have control over the external reference pricing to a large degree and prefer to register their innovative products first at the high price markets in the EU (8). In these situations, the small pharmaceutical markets, such as the Bulgarian market, are threatened by a delayed access to the contemporary drug therapies. There is a high probability that analogical cases would occur in all countries in Southeast Europe and it is recommended that complex drug policies are applied for the management of the public costs on medicinal products.

The general rationale of the integrated approach to the drug policy is to accelerate the patient access towards innovative medicines, while ensuring that the financial risks are shared on the basis of estimated or actual cost-effectiveness and the impact of the consumption of medicines on the public budget.

The decrease in the cost of the product Olanzapine by 35% in 2012 compared to 2008, confirms the effectiveness of the approach for generic substitution, which regulates public spending without compromising the therapeutic goals. By 2015, according to the data from IMS Health, over 60% of the patent-protected drugs as of 2012 will be available as generics (9,10). The expiration of patent protection will make a large segment of the market available for generic medicines, and this will create a huge potential for saving financial resources. In addition, generics are just as good for health as original drugs are (11).

Conclusion

After June 2009, the government of Bulgaria did not apply methods to control the public expenditure of drug products, such as negotiating price discounts from manufacturers and the implementation of agreements for the controlled access to patients. This led to an annual increase in the expenditure of NHIF for medicines for home treatment by an average of 17% for the period 2009-2012. This trend will continue in the future because the cost control only through price controls by the reference system and the PDL is ineffective. It is necessary to implement a combination of policies on medicines, like negotiating discounts with the manufacturers, agreements for the controlled access of patients and reference pricing (12,13). The contemporary drug policies presume that there is an increase in the role of pharmacoeconomic evaluation when making decisions for the reimbursement of the medicinal products and the management of public expenses (14). The countries of Southeast Europe are still beginners in this process, but the fast creation of academic structures for economic evaluation of the medicinal therapies, which help the decision making committees on reimbursement, will improve the future efficacy of the complex drug policies for control of public expenses on medicinal products (15).

References

1. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability and affordability in 36 developing and middle-income countries. *Lancet* 2009;373:240-9.

2. Adamski J, Godman B, Ofierska-Sujkowska G, Osińska B, Herholz H, Wendykowska K, et al. Risk sharing arrangement for pharmaceuticals: potential considerations and recommendations for European payers. *BMC Health Serv Res* 2010;10:153. DOI: 10.1186/1472-6963-10-153.
3. Espin J, Rovira J, Garcia L. Experiences and impact of european risk-sharing schemes focusing on oncology medicines. European Commission, 2011. http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/risksharing_oncology_012_011_en.pdf (accessed: August 10, 2014).
4. Espin J, Rovira J. Analysis of differences and commonalities in pricing and reimbursement systems in Europe. European Commission, 2007.
5. Aaserud M, Dahlgren AT, Kösters JP, Oxman AD, Ramsay C, Sturm H. Pharmaceutical policies: effects of reference pricing, other pricing and purchasing policies. *Cochrane Database Syst Rev* 2006;2:CD005979.
6. National Health Insurance Fund, Bulgaria. Statements of the cash execution of the budget of NHIF for the period of 2008-2012. Bulgaria, 2013.
7. Statistical Bureau of Bulgaria. IMS Health, 2008-2012. Bulgaria, 2013.
8. Gandjour A. Reference pricing and price negotiations for innovative new drugs: Viable policies in the long term? *Pharmacoeconomics* 2013;31:11-4.
9. Frayman J, Van Hal G, De Loof H. Potential impact of policy regulation and generic competition on sales of cholesterol lowering medication, antidepressants and acid blocking agents in Belgium. Scientific conference, Vienna, September 2011.
10. Dylst P, Simeons S. Generic medicine pricing policies in Europe: current status and impact. *Pharmaceuticals* 2010;3:471-81.
11. Holloway K, Dijk E. Rational use of medicines. Geneva: WHO, 2011.
12. Dylst P, Vulto A, Simoens S. Tendering for outpatient prescription pharmaceuticals: what can be learned from current practices in Europe? *Health Policy* 2011;101:146-52.
13. Dylst P, Simoens S. Does the market share of generic medicines influence the price level? A European analysis. *Pharmacoeconomics* 2011;29:875-82.
14. Bae S, Lee S, Bae E, Jang S. Korean Guidelines for Pharmacoeconomic Evaluation. Consensus and Compromise, *Pharmacoeconomics* 2013;31:257-67.
15. Grigorov E, Vaseva V, Getov I. Applied pharmacoeconomics – methodology, structuring and conducting of pharmacoeconomical studies. *Journal of International Scientific Publications: Economy & Business* 2013;7:540-51.