Impact of the Reference Price System on the Pharmaceutical Market

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Summary: The Bulgarian pharmaceutical market has been expanding rapidly and substantially increased its size in the transitional period. At the same time, the expenditures for drugs have significantly raised, given the relatively constant level of the total health expenditures. As a result various restrictive measures have been introduced for reduction of pharmaceutical expenditures. In the article we examine the system of reference prices implemented in Bulgaria. The objective of this paper is to present the essence of that approach, its advantages and flaws and its applicability by using an econometrical model for evaluation of the effects of introducing such system. We demonstrate that it is possible to decrease the drug prices and to limit the public expenditures for pharmaceuticals simultaneously, but only if the reference price is set in a certain interval.

Key words: pharmaceutical market, reference prices, Bulgaria.

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1. Introduction

The problems of the pharmaceutical market are among the most widely discussed issues in the EU and Bulgaria in the period after 1989 ([6], [13], [17], [19]). A number of studies about the different aspects of the market have been made, targeted primarily at the methods for pricing and reimbursing of pharmaceutical products by the public funds. At the same time, there are only a few studies analyzing the impact of these methods on the various participants in the pharmaceutical market.

The objective of the article is to present the essence of the reference price system implemented in Bulgaria. On the basis of an econometrical model we analyze and evaluate the effects of such system on the Bulgarian pharmaceutical market.

Despite some restrictions of the analysis, the presented model enables us to prove that both main objectives of a reference price system could be achieved simultaneously under certain conditions.

2. The Bulgarian pharmaceutical market

The pharmaceutical market in Bulgaria has been expanding substantially in the period after the year 1989, as a result of some more general and specific *reasons*. We could summarize them briefly in the following aspects:

- the establishment of a market-based economy and the transformation of all sub-sectors of the economy, including the healthcare system (an integrated part of which is the pharmaceutical market);

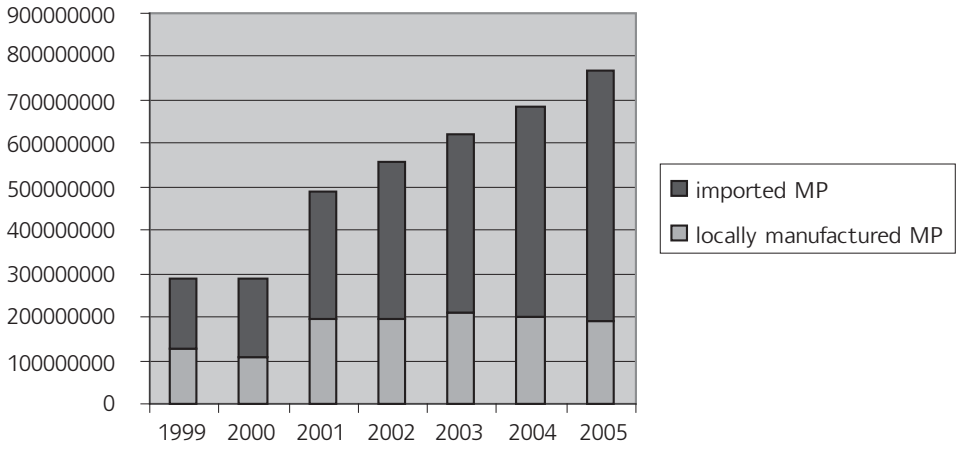

Figure 1. Volume of the Bulgarian pharmaceutical market, 1999 - 2005

• the process of the EU accession requiring restruction and harmonization of the basic market sectors (more precisely, with respect to the pharmaceutical market the European integration process implies significant changes in the fundamental regulatory framework in compliance with the Community legislation[1]);
• health and demographic dynamics (the aging of the population, the increased life expectancy, the deterioration of the health indicators);
• the development of statutory health insurance system in Bulgaria and the existence of substantial reimbursement market for drugs;
• the introduction of new pharmaceuticals and the patent expiry of drugs already sold on the market;
• the development of biotech and generic products;
• the growing influence of the regulatory authorities in order to restrict the pharmaceutical expenditures.

As a result **the pharmaceutical market in Bulgaria substantially increased its size** both in absolute and relative terms in the transitional period. The volume of the market reached almost 770 million leva in 2005 (according to BDA)[2], and over 1.3 billion leva (according to IMS Health). Compared to 2000 the volume of the pharmaceutical market has doubled its size, while the average annual growth rate had been relatively constant at 10-14 %.[3]

Meanwhile, this sector of the healthcare system requires substantial financial resources – **the expenditures for pharmaceuticals have been growing significantly in Bulgaria** in absolute terms and as a proportion of the total health expenditures (up to approx. 30 per cent), with a relatively constant rate of the total healthcare costs (4-4.5 % of the GDP)[4]. On the other hand, the public expenditures for drugs present between 60 and 70 % of total pharmaceutical

[1] For a comprehensive analysis on the adaptation of the Bulgarian pharmaceutical legislation in compliance with the EU legislative framework, see Madjarova M., Market transformation of the pharmaceutical market, in [1].
[2] The BDA data is calculated on the basis of CIP prices for imported drugs and ex-works prices for locally manufactured pharmaceuticals, while the IMS Health data reflects ex-manufacturer prices.
[3] More detailed data and specific analysis of the different aspects of Bulgarian drug markets, see Madjarova M., Market transformation of the pharmaceutical market, in [1].
[4] In comparison, healthcare expenditures in the EU are between 7.4 per cent in Finland up to 11.1 per cent in Germany (the EU-25 average level is 9 per cent of GDP) and the pharmaceutical expenditures present approx. 16 per cent of total healthcare expenditures for EU-25 average (OECD Health Data 2005).

expenditures over the period 2000 – 2003, which is higher than the average level for the EU Member States (50-55 %).

This unfavorable situation necessitates the *enforcement of various measures for restriction of drug expenditures* in Bulgaria. These measures are integrated part of the general measures regulating the pharmaceutical market, described briefly in the subsequent section.

3. Pharmaceutical market regulation

The pharmaceutical market is **one of the most regulated sectors** in the healthcare system, considering market failure in both supply and demand, on the one hand, and balancing the different contrasting objectives of the patients, the industry and the third party payer, on the other. Although the regulation of pharmaceutical market[5] is implemented in different ways depending on the health systems type in a particular country, we could summarize that all countries enforce a *wide range of measures*[6] in an attempt to cost containment the expenditure for pharmaceuticals, both on the demand and the supply side. These measures include various forms of direct and in most cases, indirect economic regulation of pharmaceutical market, as well as some kind of administrative measures[7].

Regulation of the demand for pharmaceuticals

The main objective of **measures regulating the demand side** is to influence the behavior of the patients, the insurers and the third party payers. In practice, it is attained throug *three basic mechanism:* cost-sharing systems in which the expense is shared between the patient and the third party payers (most commonly co-insurance based on a fixed percentage of the total cost of given medicinal product is being applied); systems for reimbursement of expenses targeted at public health expenditures containment (predominantly positive, negative and selective lists with medicinal products are defined); to promote prescription and consumption of generic products through different specific measures.

Regulation of the supply for pharmaceuticals

The supply side measures are preferred to those used for restriction of drug demand. These are based on direct or indirect regulation of pharmaceutical prices. A range of various practical approaches are applied for defining the price: negotiated prices, price caps, cost-plus formula, cross-country comparison, etc.

In the case of **direct price control** a maximum level of the price for a pharmaceutical product in a given country is determined by using different methods. Most of the EU Member States apply direct price control for proprietary medicinal products, most commonly by fixing the prices of drugs in a given country on the basis of *price comparisons*.

Indirect price control measures include profit regulation (a limit over the companies' returns) and implementation of a reference price system (reimbursement limits). The main objective is to restrict the possibilities of the pharmaceutical firms to gain excessive profits on public expense

[5] Drug regulation could be defined as a system of rules and activities in the pharmaceutical sector in order to provide qualitative, efficacious and safe medicinal products. Regulation represents any direct or indirect influence of the State on the demand, supply and prices of drugs through specific administrative and economic requirements, standards and restrictions.

[6] Some studies provide overview and discussion about the various regulatory mechanisms applied in the pharmaceutical industry - [4], [11], [17], [19].

[7] It is worth mentioning that the various measures implemented in practice for regulation of pharmaceutical markets possess both advantages and disadvantages, which implies them to be enforced jointly.

and to provide incentives for innovation. One of the most commonly used forms of indirect price control is the *reference price system,* which we will review consequently.

4. Reference prices

4.1. The scope of the problem

A **reference price system**[8] includes setting a maximum level of expenditures (the co-called reference price) for a group of similar pharmaceuticals (with similar active ingredients and similar therapeutic effects), which the health insurance funds are willing to reimburse. As firms are free to set their price, if the market price is higher than the reference price the customer pays the difference[9].

The main objectives of such regulatory mechanism are two-fold: first, to stimulate price competition by increasing the price elasticity of demand[10] and second, to reduce public expenditures for pharmaceuticals (or at least to restrict their growth). As a result of implementing a reference price system two positive effects are being achieved: the prices of drugs paid by the customers are lower and premises for reducing the profits of pharmaceutical producers are found.

As reference price systems are intended to control the reimbursement, not the manufacturer's prices, the approach is usually considered as less restrictive than direct price control measures.

The reference price system is most widely used in the EU, since it is considered to be an effective tool at eliminating price gaps between therapeutically similar products and improving market transparency (Mossialos et al., p. 11). In practice, if there is no additional intervention, the market prices for drugs convergence to the reference level, due to the competition among the drugs in the reference clusters and the patients' awareness of the co-payment associated with the difference between the two prices, as well as the existing incentives for pharmaceutical companies to lower their prices in order to maintain their market shares.

Nevertheless, **the effects on the restriction of the total pharmaceutical expenditures could not be clearly defined.** It is necessary to consider that the pure price effect (the decrease in the drugs expenditure when implementing a reference price system) is nullified by the indirect price effect (the increase in prices and the volume of the drugs, excluded from the system).

On the other hand, the system of reference prices is coupled with initiatives stimulating the rational demand for drugs and generic substitution and it could be difficult to distinguish the two effects.

Despite the existing disadvantages, the reference price system is widely applied mechanism for controlling the pharmaceutical market in many countries, where the system is enforced in various ways. Table 1 presents

[8] Quite often the system is designated as reference pricing, but we consider that the term reference prices is more correct having in mind that the mechanism is related to the regulation of the reimbursement level in a given country and it is not intended to restrict the pharmaceutical companies to set their prices freely (although this result could be achieved when implementing a reference price system).

[9] On the other hand, if the price set by the pharmaceutical firm is below the reference price, the saving could be shared between the third party payer and the dispensing pharmacy.

[10] The pharmaceutical markets are characterized by inelastic price demand, mainly due to significant health insurance. The individuals pay only a certain proportion of their drug treatment and the prices have a limited effect not only on the choice whether to purchase certain pharmaceutical or not, but also concerning the choice between alternative drug therapies.

the different mechanisms to determine the reference price, usually based on a pharmaceutical with a relatively low price (the minimum or average price) in the reference group.

4.2. Reference prices in Bulgaria

In Bulgaria the new reference price system was introduced in March 2004. A given pharmaceutical could be subject to reimbursement from the National Health Insurance Fund (NHIF), only if it meets the following criteria:

- To be included in the Positive drugs list
- To be indicated as medicinal product for treatment of diseases, included in the NHIF list (in accordance with Regulation 38)
- To be indicated for outpatient treatment
- To be included in a drug list, covered by a public health insurance fund in at least three of the following countries: The Czech Republic, Greece, Slovenia, Poland, Hungary, Latvia, Romania, and Slovakia, by its International non- proprietary name (INN).

The NHIF reimbursement methods are based upon defining a reference value per unit of chemical substance. The process of defining the reimbursement level undergoes *three stages*:

1) Determining the category of the pharmaceutical, according to the disease, for the treatment of which it is intended – there are three basic categories of products:

Category I – pharmaceuticals for treatment of diseases with low morbidity rate, but leading to severe deteriorations in the health status and disability, dispensed through programs

Category II – pharmaceuticals for treatment of diseases with significant public importance (with high level of prevalence and requiring long and continuous treatment)

Category III – pharmaceuticals not included in the previous two categories.

2) Setting the reference value – the drugs are grouped in accordance with INN and dosage form with identical route of administration. A maximum level (as a percentage) is being

Table 1. Methods for defining the reference price in selected European countries

Country	Year introduced	Definition of reference price
Germany	1989 (revised in 1996 and 2004)	Statistically derived median price for drugs containing the same active substance and having comparable efficacy
Netherlands	1991	Average price of drugs with similar pharmacotherapeutic effects
Denmark	1996	Lowest priced generic equivalent available on the market
Spain	2000	Arithmetic mean of the three lowest cost-per-treatment-day grouped by formulation and calculated by DDD
Belgium	2001	Equal to a price that is 26 per cent lower than the price of the original brand for generic equivalent products
Italy	2001	Lowest priced generic equivalent available on the market
Portugal	2003	Lowest priced generic equivalent available on the market

Source: European Observatory on health systems and policies, 2004.

determined for all pharmaceuticals in a given reference cluster- for the first two categories up to 100 %, and for Category III – up to 75 %. The lowest value for a unit of chemical substance for dosage forms with identical route of administration is calculated, based on the candidates' price proposals.

When defining the reference value the NHIF consider the lower value of the following two: 1) the value of a unit of chemical substance as per INN and dosage form, negotiated in a previous agreement and 2) the arithmetic mean of a unit of chemical substance of a pharmaceutical product, included in the reimbursement list applied in at least one of the specified countries or locally produced. The estimated lowest value is multiplied by the relevant reimbursement rate (but not lower than 25 %), thus obtaining the reference price for all products in a reference group.

3) Defying the reimbursement level for a particular product – the reference value is multiplied by the units of chemical substance in each pharmaceutical product and the NHIF level of payment is set. The obtained value reimbursable by the NHIF could not exceed the maximum value for a unit of chemical substance per INN and dosage form. The difference between the market price and the reference price is paid by the patient (co-payment).

The NHIF has the legal right to revise the rate and the value of payment for negotiated pharmaceuticals once a year.

4.3. Evaluation of the reference price system

There is a number of studies attempting **to evaluate the effects of implementing a reference price system** in different countries, especially in Europe. For example, Pavcnik [18] provides empirical evidences that the introduction of reference prices in Germany stimulates the reduction of the pharmaceutical prices and analyzes the changes in patient out-of-pocket expenses.

Aronson et al. [8] obtain similar results using data from Sweden, by assessing how the market shares for the branded drugs are influenced by the generic competition and the reference price system, in particular. Brekke et al. [9] draw identical conclusions, comparing the reference price system and the system of pharmaceutical price caps, based on the Norwegian experience.

Danzon and Ketcham [12] analyze the effects of reference prices on the access to drugs and the levels of profitability of the pharmaceutical companies, juxtaposing the systems in Germany, the Netherlands and New Zealand.

It is necessary to underline that the essential part of the studies are *mainly descriptive* [López – Casasnovas and Puig – Junoy, 14] and provide empirical evidences, while there are only a **few theoretical models** for analyzing and assessing these problems. Zweifel and Crivelli [20] analyze the market reactions of the pharmaceutical companies and the price changes in response to the implementation of a reference price system, using a Bertrand duopoly model. They ground their analysis in the context of implementing the system in Germany in 1989 and demonstrate that the reference price system leads to immediate reduction in prices of the branded goods, but does not affect the generic alternatives.

Danzon and Liu [11] apply a monopolistic competition model with imperfect physician-patient agency to predict how the pharmaceutical firms respond through the price to a reference price system. They determine that in a case of kinked demand curve, the prices tend to convergence to the reference price, i.e. the price of the more expensive drug is reduced and the price of the cheaper product is increased, thus implying that the effects of reference prices on

the net price and the reduction of the costs are intangible. Furthermore, they argue that it would never be optimal to determine a pharmaceutical price at lower level than the reference price. It is necessary to underline that the result relies on the assumption that the reference price is set above the lowest price in the reference cluster, while the co-payment related to purchase the generic alternative (with a price below the reference level) is zero and that the demand is perfectly inelastic below the reference price.

Brekke et al. [10] apply somewhat different approach based on a model of horizontal and vertical differentiation between pharmaceuticals to analyze and compare the systems of therapeutic reference pricing and generic reference pricing with the situation before implementing it (no reference pricing). Furthermore this model enables researchers to analyze the market entry of new products and to evaluate the health risk for patients – important details, not included in the above mentioned studies.

Mestre-Ferrándiz [15, 16] develop a model of duopoly pharmaceutical market (on the supply side), which differs from the analysis of Danzon and Liu (1997) in the assumption of perfect agency between the patient and the doctor, on the one hand, and that the co-payment for the patient will not always be zero, if the consumer choose to purchase a generic drug, since the former is based on the Spanish reference price system, where there is always some (fixed) co-payment, regardless which product – branded or generic – is being consumed, on the other hand.

In the subsequent section we briefly present the Mestre-Ferrándiz model (2001, 2003), since that theoretical concept is the most appropriate instrument **to evaluate the effects of implementing a reference price system in Bulgaria.**

We consider a pharmaceutical market of prescribed drugs with the following characteristics. There are two pharmaceutical companies on the market, each producing one good only – an original branded drug (denoted as B) and its generic alternative (G), which are horizontally differentiated (i.e. it is possible for both goods not to be perfect substitutes and there is a certain degree of differentiation $\alpha \in [0,1)$). These products are available on the market at prices p_B and p_G, respectively, and q_i stands for the quantity of the good i, $i = B, G$.

The consumers are (partly) insured, thus meeting a co-payment $\beta \in [0,1)$[11]. Comparing the scenarios before and after the introduction of a reference price system, we obtain that:

- before implementing reference prices

$$\hat{p}_i = \beta p_i,\ i = B,G\ , \qquad (1)$$

- with reference prices

$$\hat{p}_i = \begin{cases} \beta p_i & \text{if } p_i \le p_r, \\ \beta p_r + (p_i - p_r) & \text{if } p_i > p_r, \end{cases} \qquad (2)$$

where p_r is the reference price[12], and $\hat{p}_i$ is the net price paid by the consumer for good i (the price is of the following kind $\hat{p}_i = a_i - bq_i - b\alpha q_j\ ;\ i = B,G,\ i \neq j$).

The equation (2) shows that if the customer chooses to purchase a drug priced near the reference level (the generic product), he/she would have to pay the co-payment only, otherwise if (s) he decides to purchase a drug within the

[11] In contrast to the Mestre-Ferrándiz model we assume the possibility the co-payment to be zero, since this is the case in Bulgaria for given reimbursable by NHIF pharmaceuticals.
[12] It is preliminary defined by the regulatory authorities and the present model considers it as exogenously given.

reference group, the price of which is higher than the reference price (the branded pharmaceutical) the patient would have to pay the difference with the full price.

In order to determine the optimal pricing strategies for the pharmaceutical companies, we should identify the Nash Equilibrium, where both firms are functioning, competing à la Bertrand and choose prices simultaneously. The demand functions faced by the producers are, respectively:

$$q_{Bi} = \frac{(a_B - \alpha a_G)}{b(1 - \alpha^2)} - \frac{1}{b(1 - \alpha^2)} \hat{p}B_i + \frac{\alpha}{b(1 - \alpha^2)} \hat{p}G_i , \quad (3)$$

$$q_{Gi} = \frac{(a_G - \alpha a_B)}{b(1 - \alpha^2)} - \frac{1}{b(1 - \alpha^2)} \hat{p}G_i + \frac{\alpha}{b(1 - \alpha^2)} \hat{p}B_i , \quad (4)$$

where $i = \beta, r$ refers to the situation of co-payment and the reference price system, respectively.

Equations (3) and (4) demonstrate that the net price paid by the consumer in a reference price system now comprises of two elements: a certain proportion of the reference price (β) and the difference between the actual price defined by the producer and the reference price. Because of the specifics of the pharmaceutical market, it is necessary to restrict the parameters by using the following three assumptions:

1) The size of the market for the branded pharmaceutical is larger and the demand for both products is positive, i.e. $a_B \geq a_G > 0$

2) $ai \geq ci$, $i = B, G$, i.e. there are non-negative profits for all the non-negative prices (where c_i denotes the marginal costs for $i = B, G$)

3) The marginal cost of production for the branded good producer is not less than the marginal cost for the generic producer, i.e. $c_B \geq c_G$.

On the basis of these assumptions and the demand functions, pointed in equations (3) and (4), the profit functions for both companies could be obtained:

$$\pi_{ij} = (p_{ij} - c_i)\, q_{ij} , \quad (5)$$

where $i = B, G$ and $j = \beta, r$.

In the case of the **co-payment system** we could derive the following profit functions for each of the firms by substituting (1), (3) and (4) into (5):

$$\pi_{i\beta} = (p_{i\beta} - c_i)\left(\frac{(a_i - \alpha a_i)}{b(1 - \alpha^2)} - \frac{1}{b(1 - \alpha^2)} \alpha p_{ia} + \frac{\alpha}{b(1 - \alpha^2)} \alpha p_{ja}\right) \quad (6)$$

By differentiating (6) and with some additional arithmetic transformations the following equilibrium prices[13] which maximize $\pi_{i\beta}$ for both producers are de rived:

$$p^*_{i\beta} = \frac{(2 - \alpha^2)a_i - \alpha a_j + \beta(2c_i + \alpha c_j)}{\beta(4 - \alpha^2)} , \quad (7)$$

where $i, j = B, G$, $i \neq j$.

Consequently, an increase in the co-payment β will increase the price demand elasticity and will decrease the equilibrium price for the branded drug, while in the case of its generic alternative the change in the price will depend on the relative mag nitude of the market sizes. I.e. if the above assumptions are fulfilled, then $p^*_{B,\beta} \geq p^*_{G,\beta}$[14].

[13] The procedure to obtain the equilibrium prices is beyond the scope of our research and we only submit the final equations.
[14] The proof of this inequality is established by calculating the difference between equilibrium prices for each of the pharmaceuticals in the case of the co-payment system and a conclusion that under the given conditions of the model the dividend and the quotient are always non-negative is drawn.

The next step is to determine the relevant equilibrium quantities in the co-payment system:

$$q^*_{i\beta} = \frac{(2 - \alpha^2)(a_i - \beta c_i) - \alpha(a_j - \beta c_j)}{b(4 - \alpha^2)(1 - \alpha^2)}, \qquad (8)$$

where i, j = B, G, i ≠ j.

After differentiating (8) and some arithmetic transformations we obtain that

$$\frac{(2 - \alpha^2)}{\alpha} > \frac{C_B}{C_G} \geq 1 .$$

Hence, with the increase of the co-payment β the demanded quantity for the branded drug decreases, while for the generic product this relation depends on the relative size of the marginal costs. If c_B is not significantly higher than c_G, there is still a negative relationship between the co-payment level and the quantity demanded of the generic good. Otherwise, this relationship is positive since if c_B is very high the difference between the equilibrium prices of the brand-name and the generic good is significant and the increase of β forces the customers to shift from the original to the generic pharmaceutical.

In the case of **a reference price system** we construct the profit functions for each of the firms, as well as the associated equilibrium prices and quantities. Appling a similar approach we obtain the subsequent results:

$$\pi_{Br} = (p_{Br} - c_B)\left(\frac{(a_B - \alpha a_G)}{b(1 - \alpha^2)} - \frac{1}{b(1 - \alpha^2)}(\beta p_r + p_{Br} - p_r) + \right.$$

$$\left. + \frac{\alpha}{b(1 - \alpha^2)}\beta p_{Gr}\right),$$

$$\pi_{Gr} = (p_{Gr} - c_B)\left(\frac{(a_G - \alpha a_G)}{b(1 - \alpha^2)} - \frac{1}{b(1 - \alpha^2)}\beta p_{Gr} + \right.$$

$$\left. + \frac{\alpha}{b(1 - \alpha^2)}(\beta p_r + p_{Br} - p_r)\right),$$

$$p^*_{Br} = \frac{(2 - \alpha^2)a_B - \alpha a_G + 2c_B + \alpha\beta c_G + (1 - \beta)(2 - \alpha^2)p_r}{4 - \alpha^2}$$

$$p^*_{Gr} = \frac{(2 - \alpha^2)a_G - \alpha a_B + \alpha c_B + 2\beta c_G - \alpha(1 - \beta)p_r}{\beta(4 - \alpha^2)}$$

$$q^*_{Br} = \frac{(2 - \alpha^2)(a_B - c_B) - \alpha(a_G - \beta c_G) + (1 - \beta)(2 - \alpha^2)p_r}{b(4 - \alpha^2)(1 - \alpha^2)}$$

$$q^*_{Gr} = \frac{(2 - \alpha^2)(a_G - \beta c_G) - \alpha(a_B - c_B) - \alpha(1 - \beta)p_r}{b(4 - \alpha^2)(1 - \alpha^2)} .$$

As a result of these equations several conclusions could be drawn. Firstly, if the *reference price p_r, is changed, the two manufacturers respond in a different way*. With the increase of p_r the optimal response for the branded drug producer is to increase its price, while the generic producer should decrease the price when the reference price is increased, ceteris paribus.

Secondly, *the effect of changing the co-payment β depends on the reference level*. For the branded pharmaceutical producer the increase in the co-payment (with a relatively high p_r) is associated with the increase in one of the price elements – βp_r[15]. In order to maintain sufficient level of demand this company should reduce its price, so that the second element that the consumer has to pay – $(p^*_{Br} - p_r)$ would not be sufficiently high. The producer of the generic alternative, on his behalf, reduces the price when β is increased (with low values of p_r), in order to keep attracting customers. As a result the net price paid by the customer of the generic is not too high.

[15] See equation (2).

Thirdly, the change of p_r *also exerts influence on demanded quantities*. With other things being equal, an increase in the reference price induces an increase in the quantity demanded for the branded drug, while the demanded quantity for the generic is decreased, respectively.

In order to determine the effect with the implementation of a reference price system, we should compare the equilibrium prices for both goods under the different reimbursement systems. When the reference price is set at a relatively high level, the price for the original branded pharmaceutical under reference price system is higher than the price under the co-payment system, i.e. $p^*_{B,r} \geq p^*_{B,\beta}$ [16], and vise versa. Consequently, in the former case the brand-name drug producer would have incentives to reduce its price, if the reference price is not too high. On the other hand, if the reference price is defined at a relatively high level, that producer will increase the price up to a level which is higher than the price under the co-payment system.

By analogy, it could be proved that, if the reference price is set higher than the marginal cost for the producer of the branded pharmaceutical the price for the generic is higher under the co-payment situation (if $p_r \geq c_B$, then $p^*_{G\beta} \geq p^*_{Gr}$), and vice versa[17].

Due to the opposing effect that the reference price has on the behaviour of the pharmaceutical firms, *it is necessary to determine that point or interval in which both prices will be reduced simultaneously* under a reference price system (in comparison with the situation before implementing it). In addition, we should assess how the equilibrium quantities change under both scenarios and to analyze whether and how the profits of the producers change in the specified interval.

In order to determine that specific point it is necessary to solve the following system of inequalities:

$$\begin{vmatrix} p^*_{B\beta} > p^*_{Br} \\ p^*_{G\beta} > p^*_{Gr} \end{vmatrix} \leftrightarrow \begin{vmatrix} p^*_{B\beta} - p^*_{Br} > 0 \\ p^*_{G\beta} - p^*_{Gr} > 0 \end{vmatrix}.$$

After some arithmetic transformations we obtain that

$$\begin{vmatrix} \frac{(1-\beta)[(2-\alpha^2)a_B - \alpha a_G + \alpha\beta c_G - \beta(2-\alpha^2)p_r}{\beta(4-\alpha^2)} > 0 \\ \frac{\alpha(1-\beta)(p_r - c_B)}{\beta(4-\alpha^2)} > 0 \end{vmatrix}.$$

Considering the restrictions introduced for α and β the following system is derived:

$$\begin{vmatrix} \frac{(2-\alpha^2)a_B - \alpha a_G + \alpha\beta c_G}{\beta(2-\alpha^2)} > p_r \\ p_r > c_B \end{vmatrix}$$

Hence, **the prices for both products will be reduced simultaneously when introducing a reference price system (in comparison with the co-payment system), only if** $C_B < p_r < d$, where

$$d = \frac{(2-\alpha^2)a_B - \alpha a_G + \alpha\beta c_G}{\beta(2-\alpha^2)}.$$

We could prove that in the interval (C_B, d) the demand for the more expensive (brand-name) drug is higher, while the quantity demanded for the generic is reduced, compared to the co-payment scenario[18].

16 This proposition is proved by obtaining the difference between the equilibrium price for the branded pharmaceutical under the reference price system and its equilibrium price under the co-payment system.
17 The proof is similar to the previous - the difference between the equilibrium prices for the generic good under the co-payment and under the reference price system is non-negative, when $(p_r - c_B) \geq 0$, and vice versa.
18 The proof is similar: the differences between the equilibrium quantities for each of the products under both systems are obtained.

Identically, we obtain that in the interval $p_r \in (c_B; d)$, the consumer should pay a lower net price for both products under a reference price system.

Considering the relations between the equilibrium prices and the quantities of the pharmaceuticals under both reimbursement systems a number of conclusions could be drawn about *the change in the equilibrium profits for both firms* when implementing a reference price system. The price for the branded product is reduced, but the demanded quantity is increased in the interval $p_r \in (c_B; d)$. Therefore we could summarize that the effect of the increased demand will be as stronger than the effect of the reduced price, as higher the reference price. I.e. the profit for the branded drug producer is higher under reference price system (compared with the other system) only if the reference price is set at a relatively high level.

With respect to the generic producer it is evident that the profit is reduced when implementing a reference price system, since in the interval $p_r \in (c_B; d)$ the price and the quantity demanded for the generic alternative are reduced simultaneously.

Table 2 summarize the results obtained by evaluating the changes in the equilibrium prices and quantities for both pharmaceuticals, as well as the change of the net prices, paid by the consumers and the profits for both producers after the introduction of a reference price system.

In conclusion we could summarize that one of the objectives of implementing a reference price system – that is to stimulate the price competition, resulting in decreased prices for pharmaceuticals- could be achieved if the reference price is set within the bounds of the marginal cost for the brand-name good producer and a given critical point $p_r \in (c_B, d)$. With respect to the other basic objective – to reduce the public expenditures for drugs through the implementation of a reference price system, some conclusions could also be

Table 2. Equilibrium prices, quantities, net prices and profits

	$p_r < c_B$	$p_r = c_B$	$p_r \in (c_B, d)$	$p_r = d$	$p_r > d$
$p^*_{B,\beta} - p^*_{B,r}$	+	+	+	0	-
$p^*_{G,\beta} - p^*_{G,r}$	-	0	+	+	+
$q^*_{B,\beta} - q^*_{B,r}$	+	0	-	-	-
$q^*_{G,\beta} - q^*_{G,r}$	-	0	+	+	+
$\hat{p}_{B,\beta} - \hat{p}_{B,r}$	-	0	+	+	+
$\hat{p}_{G,\beta} - \hat{p}_{G,r}$	-	0	+	+	+
$\pi^*_{B,\beta} - \pi^*_{B,r}$	+	+	+ / -	-	-
$\pi^*_{G,\beta} - \pi^*_{G,r}$	-	0	+	+	+

Table 3. Comparison between total expenditures for health authorities under each of the reimbursement systems

	$p_r < c_B$	$p_r = c_B$	$p_r \in (c_B, d)$	$p_r = d$	$p_r > d$
$TC^{govt}_{G\beta} - TC^{govt}_{Gr}$	-	0	+	+	+
$TC^{govt}_{B\beta} - TC^{govt}_{Br}$	+	+	+ / -	-	-

drawn on the basis of the considered model. The results are summarized in Table 3.

In the first case, we compare the total costs for health authorities for purchasing the branded pharmaceutical under the co-payment and the reference price system – $TC^{govt}_{B\beta} = (1-\beta)(p^*_{B\beta}q^*_{B\beta})$ in the former case and $TC^{govt}_{Br} = (1-\beta)(p_rq^*_{Br})$ in the latter. Respectively, for the generic drug $TC^{govt}_{G\beta} = (1-\beta)(p^*_{G\beta}q^*_{G\beta})$ under the co-payment system and the proportion remains unchanged once the reference price system is implemented, but is denoted as TC^{govt}_{Gr}.

Given the illustrated relations in Table 3, within the interval where the prices for both pharmaceuticals are reduced the total costs for purchasing the generic product are also reduced with the introduction of the reference price system. With respect to the branded drug the result is ambiguous and depends on the value of the reference price[19]. With other things equal, the higher the p_r, the greater the probability total costs for B to be higher under the reference price system, and vice versa.

Hence, when implementing a reference price system the health authorities should consider the **different implications, which the system exercises on the patients, the companies and the third party payers.** In the determined interval $p_r \in (c_B, d)$ a reduction in the prices for both pharmaceuticals is achieved, as a result of which the customers meet lower net prices for both products. On the other hand, the total demand would be higher with a reference price system, despite the relative decrease in the equilibrium quantity for the generic. At the same time, (with a certain level of the reference price) it is possible for the total costs of the health authorities in financing the purchase of pharmaceuticals to be lower. Last but not least, in the specified interval the equilibrium profits for both pharmaceutical firms could also be diminished.

5. Conclusions

On the basis of the presented model for evaluation of the impact of introducing a reference price system on key market players, it was proved that **it is possible to achieve both objectives of that reimbursement system** – to reduce the pharmaceutical prices by stimulating the price competition and to restrict/to decrease the growth rate of the public expenditure for drugs. We should underline, that the conclusions obtained in the analysis crucially depend on the construction of the theoretical model. We consider a duopoly market with only two companies, producing one product respectively. Furthermore, the value of the reference price is assumed to be exogenous to the model, but with the existing system in Bulgaria the producers themselves have the possibility to influence the determination of the maximum reimbursement level, if they are able to offer the lowest price for a unit of chemical substance.

At the same time, the model is static and does not permit to analyze the response of pharmaceutical firms in a long-term period, and more precisely how the reference price system affects the producers' decision for innovation and its marketing strategies, given that in a short-term period the profits of the firms are reduced when a reference price system is introduced. It is important to underline that this aspect of the problem does not have significant importance for the analysis, taken into account that the Bulgarian pharmaceutical

[19] This is due to the fact that the reference price system impacts the equilibrium prices and quantities for each of the pharmaceuticals differently.

industry is mainly generic and does not spend substantial resources for R&D.

Despite that, an analysis of the impact of the reference price system on R&D in a long run could be a natural continuation of the Mestre-Ferrándiz model (2001, 2003).

On the other hand, it could be extended by introducing an additional product with some degree of vertical differentiation with the branded pharmaceutical already on the market. That modification of the reviewed model would provide a possibility to analyze what are the effects of implementing a therapeutic and generic reference pricing simultaneously (in an analogy to the model of Brekke et al., 2005). One could be interested in evaluating the two scenarios, if the producer of the branded pharmaceutical with expired patent protection, introduces its own generic alternative, considering that was the global trend in the recent years, due to the great number of patents expired in the 2004 – 2006 period.

Most significant theoretical contribution would probably provide a model of reference prices, which corresponds most to the real situation in the pharmaceutical market – there are a large number of producers on the market each supplying various products simultaneously (branded and generic drugs; produced by one or several companies; pharmaceuticals which the customers recognize as possessing different quality[20]) and making price decisions not only in a short run, but also in a long- term period. In practice, the development of such model might be problematic, due to the complex relations among the individual participants on the pharmaceutical market, their (often conflicting) objectives and behaviour on the market.

Despite the existing restrictions to develop an integrated theoretical conception for analysis and evaluation of the results obtained when implementing a reference price system, we could summarize that **the reimbursement system proved to be an appropriate mechanism for controlling the public expenditures for pharmaceuticals and to intensify the price competition on the market**. Hence, the reference price systems are preferred instrument to other various measures regulating the pharmaceutical market, both from the third party payers and customers' point of view. For this reason the system has been widely implemented (with various modifications) in the EU Member States, including our country.

The reference price system in Bulgaria has been introduced relatively recently and the time horizon is not sufficiently prolonged to draw some general conclusions for the efficiency of the mechanism. Despite that, we could underline that there has been a positive trend for cost containment of the NHIF pharmaceutical expenditures since 2004 and no additional overspend of the health insurance fund's budget for drugs is permissible under present conditions. In Bulgaria like most other countries several mechanisms regulating the pharmaceutical market have been enforced both on the demand and the supply side and it is difficult to define and evaluate the "clear" effect of implementing the reference price system. In addition, a specific for our country empirical analysis is required to verify the accuracy of the drawn up dependencies between the reference price level and the equilibrium quantities, prices and profits in the Mestre-Ferrándiz model (2001, 2003).

[20] So the companies could compete à la Cournot, not solely on the price.

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