THE OVER-THE-COUNTER PHARMACEUTICAL MARKET. A PHARMACOECONOMIC ANALYSIS

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ABSTRACT

The resource analysis in health care is of particular importance since resources are of fundamental importance to both market and non-market economic activities. The economic analysis in health care is an accurate reflection of the system, that is, it is an economic analysis of the supply, encompassing the provision, allocation and usage of resources. The pharmacoeconomic analysis is the application of the methods of economic analysis for the assessment of alternative drug therapies and their social cost and consequences with respect to the highly fragmented and specific pharmaceutical market. For the purposes of this article, we consider suitable the application of the cost-minimization analysis of two OTC antihistamine drugs for allergic rhinitis and their corresponding generic substitutes. Allergic rhinitis is a global health problem and a serious socioeconomic burden, and it is a risk factor for the development of asthma. According to a Eurostat survey, untreated allergies result in 10% reduced performance at work; 60 days with symptoms generate an annual loss of 34 work hours per worker, which is estimated approximately at 1000 € productivity loss.

KEYWORDS: allergic rhinitis, cost-minimization, generic OTC antihistamines, pharmaceutical policy.
INTRODUCTION
The economic analysis of medical technologies and, in particular, of drug therapies, involves the comparison of two or more alternatives in terms of costs and health outcomes. The cost-minimization analysis as one of the available methods is considered suitable for the purpose of this article. A survey of the Health Care Cost Institute (HCCI) shows that there is an upward trend in both public and private health care expenditures in the developed countries.\textsuperscript{[9]}

The increasing private expenditures, e.g. various types of health insurance plans and the out-of-pocket payments, can be easily explained with patients’ desire to maintain and improve their health and well-being. Data provided by the World Bank for the period 2009-2013 show that the increase of private expenditures is greater in the developing countries.\textsuperscript{[10]}

According to Eurostat figures, Bulgaria is the poorest country in the European Union.\textsuperscript{[8, 13]} As result of the increasing share of private health care expenditures in Bulgaria, certain social groups are at risk of facing seriously restricted access to health care services. With its public pharmaceutical expenditures per capita, Bulgaria ranks in the penultimate position among EU countries, being followed only by Serbia. Furthermore, the cost of the medication therapy per day in Bulgaria remains the lowest within the EU. The medication expenditures in the country are as low as 0.9\% of the GDP, surpassing only the counterpart expenditures in Poland - 0.6\% of the GDP. In comparison with the European countries, the distributor markup in Bulgaria is the lowest; still, Bulgarians’ out-of-pocket payments on medications are the highest.

The national health funds in the EU countries generate annually € 20 million generic drug savings. Physicians and pharmacists should gain deeper understanding of the generic substitution benefits for private and public funds alike, as well as for patients who can have access to health care at an affordable cost. In an environment of constant financial austerity, the Bulgarian Generic Pharmaceutical Association (BGPA) actively tries to foster public understanding of the significance of generic substitution for both public and private funds, and for maintaining a transparent and efficient drug policy that benefits the society as a whole.

The resource analysis in health care is of particular importance since resources are of fundamental importance to both market and non-market economic activities. The economic analysis in health care is an accurate reflection of the system, i.e. it is an economic analysis of the supply, encompassing the provision, allocation and usage of resources.\textsuperscript{[3]} A
pharmacoeconomic analysis is the application of the methods of economic analysis for the assessment of alternative drug therapies and their social cost and consequences with respect to the highly fragmented and specific pharmaceutical market. The economic analysis of medical technologies and, in particular, of drug therapies involves the comparison of two or more alternatives in terms of treatment costs and health outcomes. The cost-minimization analysis (CMA) as one of the available methods is considered suitable for the purpose of this article. From a practical perspective, the application and the benefits of the CMA are narrowed down to the evaluation of new medical interventions and, in particular, of new medicinal products. CMA is used for the comparison of “me too” products which, though with slightly different molecules, produce similar clinical results that can be considered essentially equivalent for measurable clinical goals. The comparison aims at determining the least costly alternative and driving down the treatment cost.

RESULTS AND DISCUSSION

The practical example we explore in this article is the sales patterns of two pharmaceuticals - Lorano tablets and Claritin tablets. These two non-sedating OTC antihistamines have different trade names but identical INN, that is, the same molecule of the active ingredient Loratadine is present in both products. Antihistamines are medicines that work by blocking the H1 receptors, thus reducing or stopping the production of histamine and relieving the symptoms of the allergic reaction. They are administered for the treatment of allergic diseases and allergic rhinitis. They are administered once a day and combine antihistamine properties and clinical effectiveness with additional anti-inflammatory effects and cardiovascular and central nervous system safety. Given today’s fast-paced modern lifestyle, their easy route of administration provides convenience and does not affect patients’ daily routines, thus improving patients’ quality of life and work performance. The economic burden of allergic rhinitis is often underestimated because it does not incur direct costs. However, the indirect costs of allergic rhinitis resulting from patients’ impaired quality of life are substantial. Bernard N. Halpern, a French research biologist and physician, introduced antihistamines for the therapy for allergic diseases in 1942. This triggered a new and rapidly developing branch of the pharmaceutical industry.

Lorano tablets is manufactured by Salutas Pharma GmbH Otto-von-Guericke-ALLee 1 and its price is BGN 11.60. Claritin tablets is manufactured by Schering-Plough and its price is BGN 11.60. Although with different brand names, both medicines have the same INN, that is,
both products have the same original molecule (loratadine) and are OTC antihistamine drugs for the treatment of allergic rhinitis. We traced the sales of Claritin tablets in 5 community pharmacies in the city of Varna for the period 2008-2012.

Table 1: Absolute growth and growth rate of Claritin tablets.

<table>
<thead>
<tr>
<th>total packs sold</th>
<th>absolute growth</th>
<th>growth rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>430</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>627</td>
<td>197</td>
</tr>
<tr>
<td>2010</td>
<td>515</td>
<td>85</td>
</tr>
<tr>
<td>2011</td>
<td>478</td>
<td>48</td>
</tr>
<tr>
<td>2012</td>
<td>536</td>
<td>106</td>
</tr>
</tbody>
</table>

Within the period 2008-2011, Claritin tablets saw a downward trend in its annual growth rate but its average annual sales growth rate for the period was 124.72 percent.

The sales volume in 2012 increased and equaled the sales volume in 2010. The survey of the consumption patterns of Lorano tablets was performed using sales data provided by the same five community pharmacies in Varna for the period 2009-2012. Table 2 displays the data summary.

Table 2: Absolute growth and growth rate of Lorano tablets

<table>
<thead>
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<th>total packs sold</th>
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<tbody>
<tr>
<td>2009</td>
<td>276</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>389</td>
<td>113</td>
</tr>
<tr>
<td>2011</td>
<td>344</td>
<td>68</td>
</tr>
<tr>
<td>2012</td>
<td>397</td>
<td>121</td>
</tr>
</tbody>
</table>

Within the survey period, there was an unstable upward trend in the annual sales of Lorano tablets with an average annual sales growth of 143,84%. 2009 was the year when Lorano tablets was registered and authorised for marketing in Bulgaria.

Table 3: Sales of Lorano tablets and Claritin tablets 2008 – 2012.

<table>
<thead>
<tr>
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</tr>
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</table>

Throughout the entire period, both OTC products faced an increase in sales. The upward trend was more pronounced for Lorano tablets with an average annual sales growth of
143.84%. The average annual sales growth of *Claritin tablets* was 124.65% despite its longer presence (as compared to *Lorano tablets*) in the Bulgarian pharmaceutical market, first as a prescription drug and later as an OTC drug.

The monthly sales are characterized by a pronounced peak in July, with the exception of those in 2011 when the highest volume of sales was reported in September.

![Figure 1: Monthly sales of Lorano tablets](image)

The projected annual sales were calculated with the statistical method of the moving average. Figure 2 summarizes the results.

![Figure 2: An annual sales projection of Lorano tablets](image)
Figure 3: A monthly sales projection of Claritin tablets

The projection of annual sales was calculated using the statistical method of the moving average. The results are displayed in Figure 4.

Figure 4: An annual sales projection of Claritin tablets

As a result of deregulation, both Lorano and Claritin sales rose in the first year after the Rx-to-OTC switch as compared to the preceding period. In the years following the peak in 2009, both products experienced a decline in sales. Still, the sales level remained higher than the corresponding level in 2008 (the last year the medicines were dispensed on prescription). Both drugs faced a gradual upward trend in sales volume, more pronounced for Lorano tablets. The sales pattern similarity of both products indicates the influence of market factors over the sales. The faster growth of Lorano tablets is most likely due to its significantly lower price as compared to the price of Claritin tablets.
The possibility to manage the treatment cost is considered most valuable by the prototypical consumer. When calculating the treatment cost, patients add up not only the direct out-of-pocket payment in the pharmacy, but also all the direct and indirect treatment costs such as the outpatient fee, the wait time for doctors’ appointments, and the cost of absenteeism.\(^5\) As both drugs have OTC status and can be purchased without a prescription, the role of the pharmacist in patient counseling and drug dispensing is of paramount importance. Pharmacists are expected to provide patients with good quality treatment alternatives that guarantee the expected treatment outcome. This is an integral part of the new professional responsibilities of the community pharmacist.\(^6\)

Patients should be properly informed about the characteristics of the generic drugs. Both patients and health care professionals shall be properly educated on the benefits of generic drug treatment. Lucrative profits from OTC drugs sales might induce pharmacists to deviate from the code of professional ethics. On the one hand, OTC sales profits might compromise patient counseling on drug abuse; on the other hand, pharmacists are health care professionals and they are expected to promote patients’ well-being and prevent patients from drug misuse and corresponding adverse effects. Fair remuneration would give pharmacists the motivational incentive to play a more active role in patient counseling.\(^2\)

Generic sales generate significant savings to health care budgets and contribute to better patient access to quality drug treatment. The competitive pharmaceutical market is the most effective method for managing optimal allocation of resources and generating cost savings that benefit both the society as a whole and the individual consumers. Effective and appropriate measures shall be adopted both to raise public and patient awareness of the benefits of generic pharmaceuticals and to promote generic prescribing and dispensing among physicians and pharmacists.\(^11\)

**CONCLUSION**

Failing to exploit the potential of generic pharmaceuticals engenders not only forgone potential savings and higher levels of public and private drug expenditures, but also poor disease treatment and even treatment refusal. The pharmacist’s role in patient counseling is fundamental. It encompasses educating patients on self-medication, providing comprehensive and accurate information on alternative drug therapies and treatment regimens, and improving patients’ understanding of the characteristics of alternative medicines and the corresponding treatment outcomes.
REFERENCES


