

## **MARKETING STRATEGIES FOR RETAINING THE MARKET SHARE OF PHARMACEUTICAL PRODUCTS AFTER THE PATENT PROTECTION**

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### **SUMMARY**

After a patent expires, pharmaceutical companies face the risk of losing market shares. Reclassifying a brand drug that is “prescription only” as OTC (over-the-counter) drug is a company strategy for retention of revenue and profit that come from the sales of this product. The tendency for reclassification of medical products as OTC drugs corresponds both to the already prevailing model of patient-centered care in the health systems and to the greater autonomy of the individual patient in health care. The decision to switch from Rx to OTC is a real challenge.

**KEYWORDS:-** patent expires, reclassification, pharmaceutical companies face.

### **INTRODUCTION**

According to Art.171 <sup>[1]</sup> of the Law on the medicinal products in human medicine, the medicinal products dispensed on the Bulgarian market shall be classified as medicinal products dispensed with medical prescription and medicinal products dispensed without medical prescription (over-the-counter drugs). <sup>[9]</sup>

In most countries, access to and supply of medicinal products are governed by a regulatory framework which is based on the risk-benefit assessment of a particular drug. In the United Kingdom, for instance, there are three categories of medicines: POM (prescription only medicines) – drugs available to patients only when prescribed by a medical practitioner, P (pharmacy supervised sale) – drugs sold only under the supervision of a pharmacist, and GSL

(general sales list) – drugs available even outside pharmacies. <sup>[1]</sup> These three categories are in dynamic equilibrium and jointly shape the pharmaceutical market. When a new medicinal product is licensed for use in the UK for the first time, in accordance with the evidence of its safety and efficacy provided in the preclinical period, it is classified as POM. Two years later, this medicine can be reclassified as P, unless there are specific circumstances to retain its POM status, which is the more normal practice. The reclassification of a medicine goes through a stringent and precise process of evidence submission and consultations with the MHRA (Medicines and Health care products Regulatory Agency).

In Europe, there are also clear requirements about the criteria defining when a medicine retains its POM status (Directive 92/26/EEC). There are various options for reclassification across European countries, regardless of the initiatives for achieving harmonization of pharmaceutical regulations within a common framework. When the patent expires, generic products enter the market almost immediately, causing drastic decline in market share and sales slump. The switch from Rx status to OTC status can be a good strategy for sales retention long after patent expiration. Switches are motivated mainly by three factors: pharmaceutical firms' desire to extend the viability of brand names; attempts by healthcare funders to contain costs; and the self-care movement. Making drugs available over the counter affects a large number of stakeholders, including patients, pharmaceutical firms, physicians, pharmacists, drug regulatory agencies, and private and public health funding organizations. <sup>[3]</sup>

Over the counter licensing is linked to direct to consumer advertising. <sup>[2]</sup> This gives much more marketing possibilities for drug promotion, as switch to over the counter can become indirect advertising directly to consumers. <sup>[4]</sup> A successful Rx-to-OTC switch depends on several factors including the intensity and timing of the OTC marketing campaign of the drug itself. <sup>[5]</sup>

In practice however, it is unusual for companies to switch the drug status as long as the patent is still valid. The decision for drug reclassification is dependent on healthcare policies across countries and, in particular, on attitudes of medical professionals, evolution of scientific knowledge, national reimbursement and pricing policies, brand rules and regulations. Drug deregulation reduces public expenditures, because when a number of drugs switch from prescription-only to OTC status, they attract new consumers who already do not need a prescription from a medical practitioner. Since 2007, there have been common European

standards guiding the reclassification to OTC status. There is also a draft guide developed by the European Medicines Agency (EMA) on the packaging of OTC drugs, which includes guidelines on pictorial symbols, web link, etc. supposed to help patients sort through the information. The UK has the most “liberal” regime for switching to OTC status. Italy and Hungary are also in the process of approving the sale of OTC drugs outside pharmacies.<sup>[6]</sup> The aim of the European regulatory bodies is to introduce a centralized unified European guidance on OTC drug status by 2015. (10) The number of medicines that have their status switched to OTC will continue to grow worldwide, particularly the number of drugs for treatment of chronic conditions. On a global scale, the most well-established procedures for switching to OTC status are in the US, the UK, Germany, Spain and Mexico.<sup>[8]</sup>

**Objectives:** To examine the impact of drug reclassification on the sales volume across pharmacies in the city of Varna.

**Methodology:** We surveyed four allergy products after their switch to OTC status and examined the impact on their sales volumes. We used data provided by a retail pharmacy chain of five pharmacies located in the city of Varna.

## FINDINGS AND DISCUSSION

For the purpose of this research, we decided to trace the changes in sales volumes of four different medical products: Allergosan tb. (Chloropyramine hydrochloride) 25 mg / 25 Tablets; Lorano tb. (Loratadine) 10 mg / 7 Tablets; Zyrtec tb. (Cetirizine dihydrochloride) 10 mg / 10 Tablets and Claritine tb. (Loratadine) 10 mg / 10 Tablets.

We selected these antihistamines for a couple of reasons. Allergosan is a typical antiallergic agent manufactured by a Bulgarian company - Sopharma AD, it is familiar to patients across a wide age range, and its price is low (BGN 3.06). Zyrtec tb. is a brand name drug manufactured by UCB Pharma GmbH, Germany. In comparison with Allergosan, it is a more recent product with less side effects, its dosing is more convenient, but its price is considerably higher (BGN 13.53). Lorano tb. and Claritine tb. are drugs with different brand names but with the same INN (both products have the same original molecule - loratadine). Lorano tb. and Claritine tb. are non-sedating antihistamines with relatively lower prices as compared to Zyrtec. Lorano tb. is manufactured by Salutas Pharma GmbH Otto-von-Guericke-ALLEE 1 and its price is BGN 11.60. Claritine tb. is manufactured by Schering-Plough and its price is BGN 11.60.

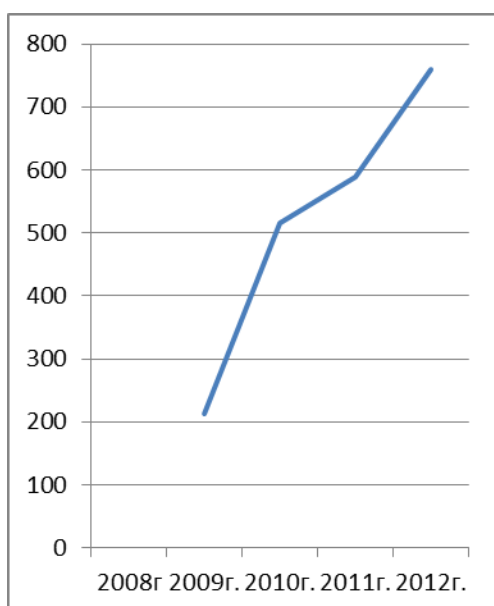
Table 1 displays unit sales data by year (the data corresponding to the year of reclassification are in bold).

**Table 1. Unit sales before and after deregulation.**

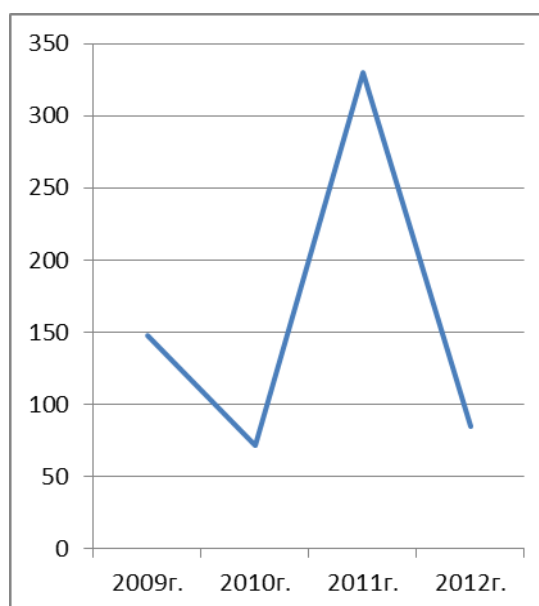
	<b>Zyrtec</b>	<b>Allergosan</b>	<b>Lorano</b>	<b>Claritine</b>
2008	332	439	Not available	430
2009	<b>480</b>	<b>652</b>	276	<b>627</b>
2010	404	955	<b>389</b>	515
2011	662	1028	344	478
2012	417	1198	397	536

Data show that the sales of all surveyed products increased after the Rx-to-OTC switch. Especially distinct is the sales trend of Allergosan tb. - the sales in 2012 increased 2.73-fold in comparison to the sales in 2008 (the year preceding the status switch). The sales after the switch to OTC status of the other surveyed drugs increased as well – a 1.26-fold increase for Zyrtec tb, a 1.44-fold increase for Lorano tb, and a 1.25-increase for Claritine tb. The sales of Allergosan for the period 2008-2012 surged at an average annual sales growth rate of 213.16 percent. Though Claritin tb. saw a downward sales trend from 2009 until 2011, its average annual sales growth rate from 2008 through 2012 was 124.72 percent. For the same period, Zyrtec tb. faced an unstable growth and an average annual sales growth rate of 14.88 percent. For the period 2009-2012, Lorano tb. experienced an unstable growth and its average annual sales growth rate was 135.78 percent.

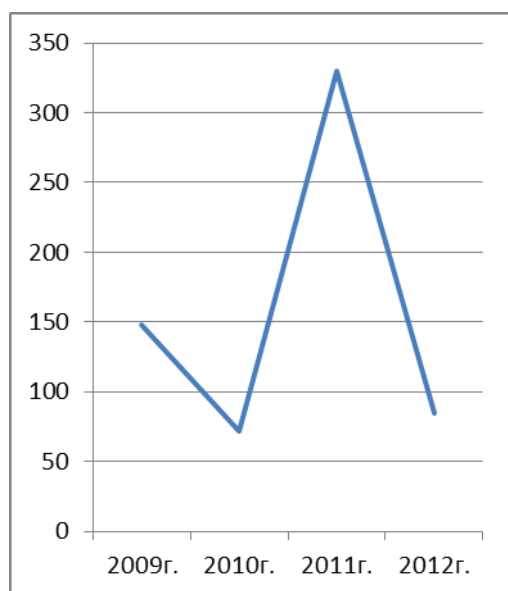
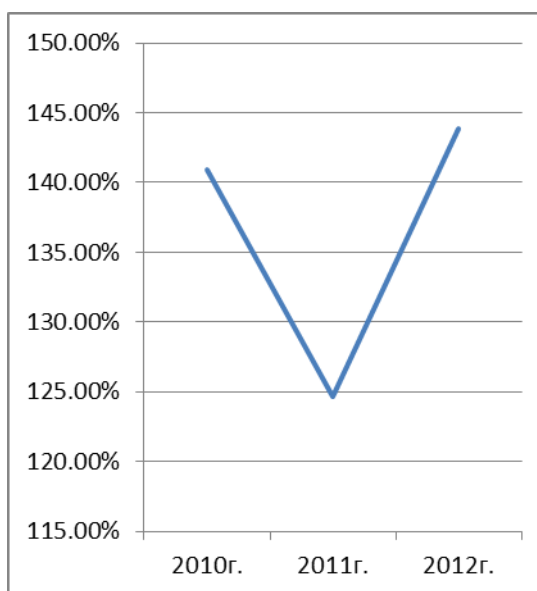
The graphs below display the sales trends of each separate product.



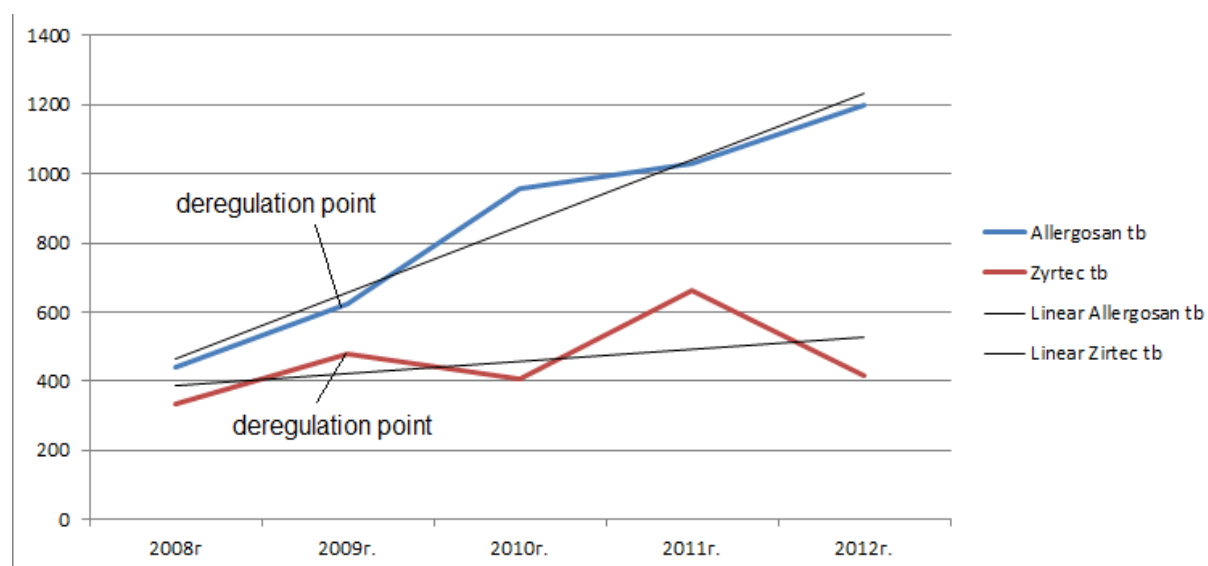
**Fig.1 Allergosan tb.**



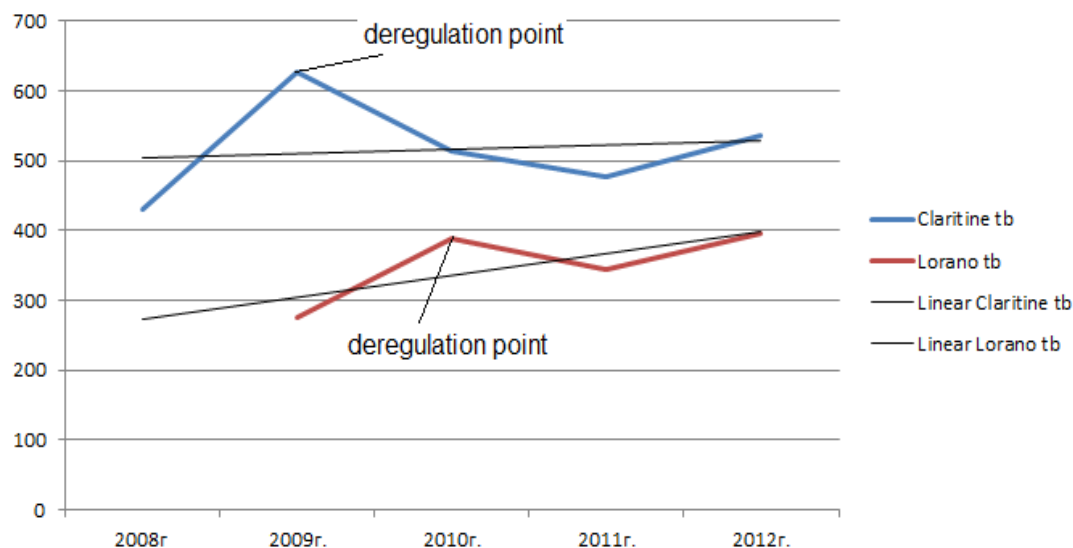
**Fig.2 Zyrtec tb.**

**Fig.3. Claritine tb.****Fig.4. Lorano tb.**

The model of annual sales trends was developed with regression analysis techniques. As we can see, the annual sales of Allergosan continued an upward trend throughout the entire period, whereas Zyrtec tb. faced an unstable sales growth. As a result of deregulation, both Allergosan and Zyrtec faced an increase in sales in the first year of Rx-to-OTC switch. And while this uptrend continued throughout the entire period for Allergosan, Zyrtec faced an increase in sales and sales fluctuations alike. It seems reasonable that the economic crisis and the considerably higher price of Zyrtec have influenced consumers in their decision to choose Allergosan rather than Zyrtec.

**Fig.5 Sales volume in pharmacies before and after deregulation.**

As a result of deregulation, both Lorano sales and Claritine sales rose in the first year after the Rx-to-OTC switch. In the years following the peak in 2009, both products experienced a sales decline. Still, the levels of sales remained higher than 2008 (the last year the medicines were dispensed on prescription). Throughout the entire period, both products faced a gradual increase in sales, more pronounced for Lorano tb. The similar trends of both medicines indicate the impact of market factors over the sales.



**Fig.6 Sales volume in the pharmacies before and after deregulation.**

## CONCLUSIONS

Intensifying competitive pressure in the health care market and patients' discontent with the long waiting times for prescriptions create favourable conditions for a future broadening of pharmacists' authority to include pharmaceutical care activities. The trend to deregulation from POM status and the fact that OTC drugs are available only in pharmacies should be considered by the pharmacy profession as an opportunity for extending the range of effective patient counselling and a way of maintaining market positions. The Rx-to-OTC switch enhances the sales volume and has a positive impact on retailers.

The tendency of Rx-to-OTC switch is inextricably linked to another tendency – the transfer of drug related costs from the government to the individual consumer. As far as low-priced OTC drugs are concerned, this is not a major issue. However, some of the newly deregulated drugs are quite expensive, which additionally restricts patient access and increases health inequalities. There is a trend toward broadening the range of medicines with OTC status. The

OTC market is becoming more competitive and profitable. The Rx-to-OTC switch is one of the strategies for retention of revenue and profit resulting from product sales. <sup>[7]</sup>

According to FDA, pharmacists have not only more professional opportunities but also more responsibilities within this new drug paradigm. <sup>[11]</sup>

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