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RESEARCH ARTICLE

FACTORS INFLUENCING THE USE OF MEDICATIONS IN THE TREATMENT OF ASTHMA IN CHILDREN

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ABSTRACT

Based on the established growth in the consumption of medications for the outpatient treatment of asthma in children, we set ourselves the objective to identify the factors that influence the use of medications.

The research was conducted in the territory of the city of Varna. We used the results from the analysis conducted with reference to the medications prescribed to asthmatic children aged 6–12 and 13–16, for the period 2008–2013. The research of dependencies has been conducted through regression analysis.

In result of the conducted analyses we established that the main factors influencing the use of anti-asthmatic medications with children are: patient's age, use of generic drug products and level of reimbursement.

The introduction of generic products on the market and the improved access to medications because of the reduced weight on the health-insurance funds, provide opportunities for the conducting of efficient prevention and treatment of the disease.

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INTRODUCTION

In the recent couple of decades and especially in the recent years, the asthmatic morbidity has been growing on a global scale. According to the World Health Organization, the number of asthmatic people is 300 million worldwide and the number of asthmatic children has been growing. (WHO)

The main goal of the Global Initiative for Asthma (GINA) is to develop a universal approach for the achievement of a long-term control and improvement of the treatment and prevention of bronchial asthma. (GINA,2012). Asthma is a variable disease and two main groups of medications are used for the treatment of asthma: drugs for control of the disease and drugs for relief of the acute stage. (Global Strategy for Asthma Management and Prevention, GINA,2012). According to GINA, the short acting agonist (SABA) has to be used only when needed while in order to put the disease under control, a control medication should be included (ICS, LTRA or a combined medical product - LTRA/ICS).

According to the guidelines for modern anti-asthmatic treatment in the last 15 years, changes have been observed in the use of the two main groups of medications applied for

asthma treatment, in favour of the control medications (Brian *et al.*, 2012, Davidsen JR, 2012, Janson C.*et al.*, 2005, Miller and Sarpong, 2011, Phillips C, McDonald T., 2008). The trend in the use of controllers and bronchodilators and their ratio is a reliable indicator for the quality of the treatment and predetermines the therapeutic result. (Shelley *et al.*, 2000).

Objective: The objective of this research is to study the factors influencing the use of medications in the treatment of asthma in children.

MATERIALS AND METHODS

The research was conducted in the territory of the city of Varna. We used the results from the analysis conducted on the medications prescribed to asthmatic children between 6–12 years old and 13–16 years old that have been fully or partially paid by the National Health Insurance Institute for the period 2008 – 2013.

The data for the use of medications have been collected from the representative sample referring to 37 pharmacies in the city of Varna that have contracts with the National Social Insurance Institute. The pharmacies have been chosen by the random

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principle and are situated mostly in regions populated by young residents, the total aggregate being 148 pharmacies at 2013. We researched the medications intended for the treatment of obstructive diseases of the respiratory system (ATC – R03) prescribed for the treatment of “Asthma with predominant allergic component” (International Classification of Diseases code – J.45.0) and “Non-allergic asthma” (International Classification of Diseases code – J.45.1).

With the help of statistical methods (regressive analyses, research of dynamic changes and graphic analyses) we established the dependencies between the use of anti-asthmatic medications and the patients' age, the level of reimbursement and the use of generic equivalents.

RESULTS AND DISCUSSION

The conducted analysis concerning the use of anti-asthmatic medications in children established a growth in the overall use of medications for the period 2008 – 2013. The trend of continuous growth is observed in both age groups of children; with the children aged 6-12 the growth is 311.22% in the end of the period while with children aged 13–16 the growth is 444.68% compared to the values of 2008.

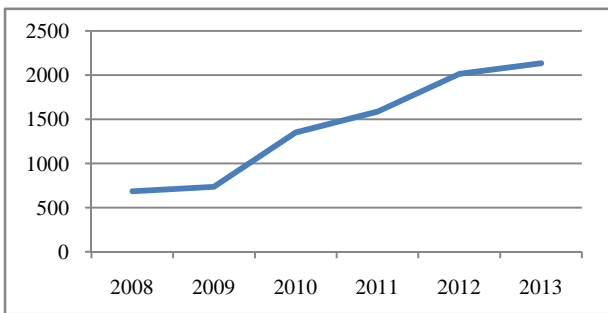


Figure 1 Assessment of the use of anti-asthmatic medications in packs for the period 2008 – 2013, children aged 6 – 12.

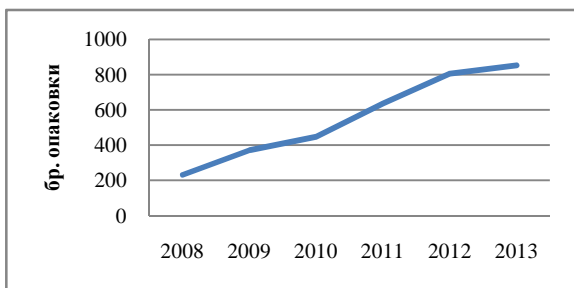


Figure 2 Assessment of the use of anti-asthmatic medications in packs for the period 2008 – 2013, children aged 13 – 16.

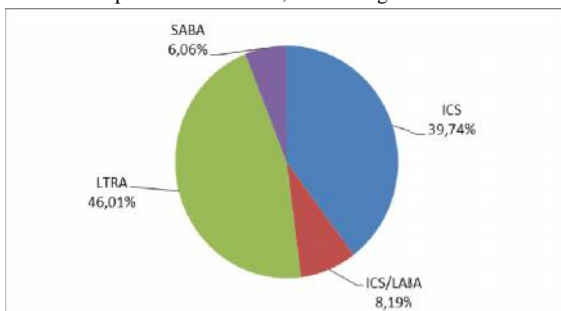


Figure 3 Percentage distribution of drug groups used for the treatment of paediatric patients with asthma, 6-12 years old (number of packs)

We establish that, in compliance with the GINA recommendations and the therapeutic manuals, the physicians rely on well-established control medications such as Inhaled Corticosteroids (ICS), Leukotriene receptor antagonists (LTRA), combined preparations containing inhaled corticosteroids and beta agonists with long action (ICS/LABA), as well as the short action -2 agonists (SABA) used for the symptomatic treatment of asthma attacks.

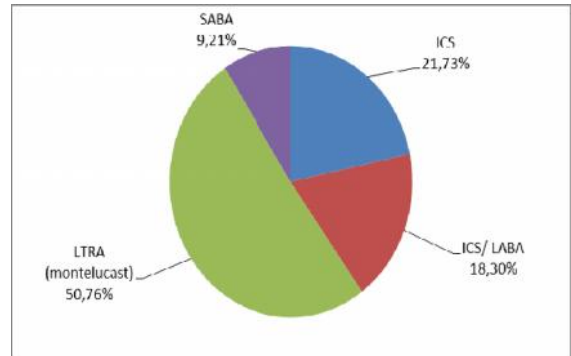


Figure 4 Percentage distribution of drug groups used for the treatment of paediatric patients with asthma, 13-16 years old (number of packs)

In both age groups, Leukotriene antagonists (montelukast) have the highest share in the overall use; they account for 46.01% in the children aged 6 – 12, while in the children aged 13 – 16 they account for 50, 76%.

According to the GINA manuals, the antagonists of the Leukotriene receptor can be used as an alternative monotherapy in certain patients with mild persistent asthma or as an additional preparation to the corticosteroid treatment of moderate to severe persistent asthma in children. Montelukast is of wide application and proven therapeutic effect in asthmatic children with accompanying AR. (GINA, 2012)

Another factor that stimulates the use of Montelukast, apart from its action profile, is the conducting of generic medicinal policy.

Under “Generic medicinal policy” we understand a system of measures that support the manufacturing and distribution of medications of expired patent protection, also known as generic medications.

The term “generic drugs” is used to indicate medications that have the same qualitative and quantitative composition intended to be introduced into the organism via the same route, which are being distributed under their international non-proprietary name (INN) and have been proven to be bioequivalent to the original pharmaceutical product. The generic drugs are “therapeutically equivalent,” which presupposes that they give equivalent therapeutic results (Bulletin of WHO)

The manufacturing of generic drugs is possible upon the lapse of the 20-year patent period for the active chemical substance.

The expiration in 2009 of the patent that covered the original drug containing Montelukast, led to the entry of generic equivalents on the market. A considerable growth in the use of Montelukast-containing generic products has been noted.

In the period after 2009, the use of generic products containing Montelukast 5 mg has been 3.19 times higher compared to the original LTRA, while for Montelukast 10 mg the reported growth has been approximately 3.35 times compared to the original product.

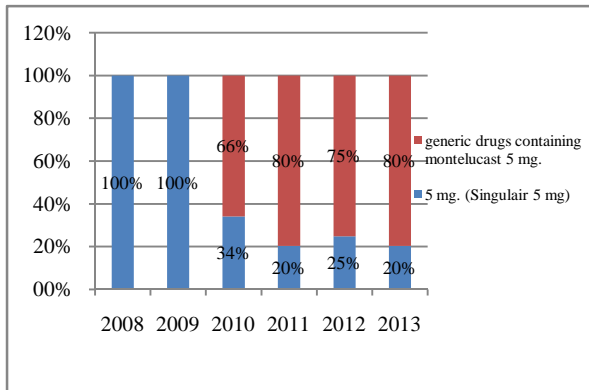


Fig. 5 Ratio of the used packs of original and generic products containing Montelukast 5 mg within the period 2008 – 2013.

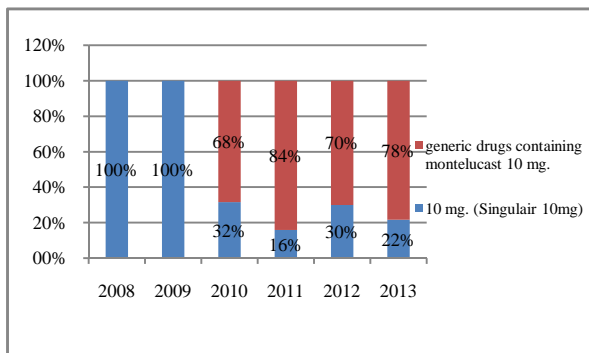


Fig. 6 Ratio of the used packs of original and generic products containing Montelukast 10 mg within the period 2008 – 2013.

It is impossible to have an adequate drug policy if it is not generics-based. (www.hospital.bg) The purpose of the generic industry is to provide for the treatment of the largest number of patients at the lowest cost, thus freeing resources for new therapies that have no alternatives. The accessibility of treatment with generic drugs finds expression in their price, which is by 20% to 90% lower compared to the price of the original drugs. (IMS Health; Puig-Junoy J, 2010) According to IMS, there exist all reasons for the increased use of generic drugs worldwide, since they are the most cost-effective for both patients and public healthcare funds; this statement has been made based on the indices of quality, efficacy, safety and accessibility. (IMS Institute for Healthcare Informatics, 2013)

A research of the European Generic Association shows that on European scale the generic drugs save annually 35 milliards Euro and their full saving potential has not yet been reached. (www.egagenerics.com, EGA)

For low-income countries like Bulgaria, the encouraged use of generic products is of significant importance for the patients' improved accessibility to treatment.

The lower value of additional payments contributed by the patient to the reimbursement system and the reduced financial pressure for the health-insurance funds stimulate the prescription of generic drugs.

Fig. 7 and Fig. 8 represent the trends in the changing of drug use and the level of drug reimbursement.

Growth has been established in both the use of anti-asthmatic drugs and reimbursed percentage with the two age groups of children.

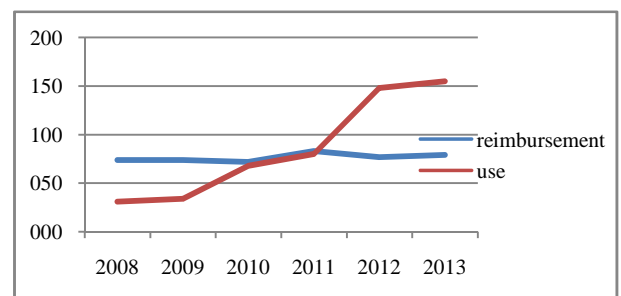


Fig. 7 Trends in the changes of drug use and the level of drug reimbursement, children 6 – 12 years old.

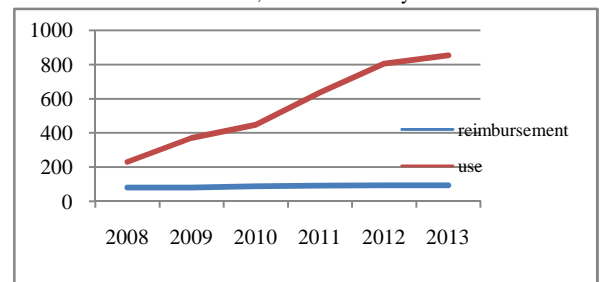


Fig. 8 Trends in the changes of drug use and the level of drug reimbursement, children 13 – 16 years old.

The results from the regressive analysis and the relationship between the use of drugs and the level of reimbursement show statistically significant dependencies (p 0, 05) between the variables in both age groups of children.

Table 1 Results from the regressive analysis of the dependency “level of reimbursement – use of drugs”

Type of test	Coefficients	Age: 6 – 12 years old	Age: 13 – 16 years old
Regressive analysis between the level of reimbursement and the use of drugs	Correlation coefficient	0,91	0,89
	Determination coefficient	0,83	0,78
	P-value of the free member	0,049	0,07
	P-value for the coefficient in front of x	0,032	0,046

Table 2 Results from the regressive analysis of the relationship between the patients' age and the use of drugs.

Type of test	Coefficients	Age: 6 – 12 years old	Age: 13 – 16 years old
Regressive analysis between the age and number of taken medications	Correlation coefficient		0,34
	Determination coefficient		0,12
	P-value of the free member		0
	P-value for the coefficient in front of x		3,2.10 ⁻²⁸³

A very strong dependency has been established with the children's group of 6 – 10 years old with correlative coefficient $R=0,91$; the dependency with the children's group of 13 – 16 years old is strong at $R=0,89$; the determination coefficients are, respectively, $R^2=0,83$ and $R^2=0,78$ for the two groups. We can sum up that 83% of the changes in the use of drugs in the children's group of 6 – 12 years old and 78% in the children's group of 13 – 16 years old are due to the reimbursement-level factor.

The established dependency is in direct ratio – the use of anti-asthmatic drugs expressed as number of packs grows with the increase of the reimbursement percentage. The results from the conducted regressive analysis are presented in Table 1. We researched the patients' age as a factor that influences the use of drugs.

The results from the analysis of the dependency between the age of the children and the number of used packs of drugs are presented in Table 2.

A moderate ($R=0,34$) statistically significant reverse-ratio dependency ($p=0,05$) has been established between the variables age and number of prescribed medications – i.e. the number of taken medications decreases with the increasing of age. The value of determination coefficient is $R^2=0,12$, which shows that 12% of the changes in the number of used medications are accounted for by the age factor.

With the younger children, an expressed frequency of respiratory and viral infections, sinusitis, otitis and others is observed; they run synergically with the asthma and unlock severer exacerbations. The allergic and infectious factors that provoke the asthma attacks are in varying ratios and often compete with each other in one and the same child. Certain viruses can increase the bronchial reactivity for periods of time of varying length. Because they damage the epithelium, the viral infections occurring during allergenic explosion can increase the allergenic sensitivity. In 60 – 80% of the cases, the asthmatic exacerbations in children are result from respiratory viral infections – rhinoviruses. (Lemanske et al., 2005).

According to reference data, with the beginning of puberty i.e. after the age of 12, children's asthma gradually fades away and in certain cases the recovery is complete, which circumstance determines the decreasing use of anti-asthmatic medications with the growing in age. (National consensus for diagnosing, prevention and treatment of bronchial asthma in children, 2003)

CONCLUSION

The conducted analyses established that the factors which influence the increasing use of anti-asthmatic drugs in outpatient children are the patients' age, the entry of generic equivalents on the market and the increased reimbursement level of the medications resulting from such entry. The generic drug policy that is being conducted is intended to improve the access to asthma-control drugs and conforms to the requirements of the international therapeutic guidelines, and is

a prerequisite for the quality of the conducted treatment and achievement of optimal therapeutic results.

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