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Cost Evaluation of Inhaler Therapies Used in Respiratory Diseases: 1998–2015 Period in Turkey

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ABSTRACT

Background: With the rise in life expectancy, the burden of chronic diseases, including obstructive pulmonary diseases, has increased throughout the world. **Objectives:** To evaluate the sales trends of inhaler pharmaceuticals. **Methods:** The changes in box sales and sales amounts (in Turkish lira) of inhaler pharmaceuticals during the period 1998 to 2015 were examined and sales were projected for the next 3 years. Pharmaceutical groups were classified according to form and pharmacological groups. **Results:** The sales of inhaler pharmaceuticals have increased rapidly since 2008. The fastest increase in consumption has occurred in short-acting β_2 agonist preparations and nebulizer pharmaceuticals. Inhaled corticosteroid and long-acting β_2

agonist combination sales have been the highest since 2002, when these products entered the Turkish market. **Conclusions:** The inhaler pharmaceutical market has grown over the years, and this growth will continue in the future. The increased use of short-acting preparations, which should be used as symptom relievers, indicates that treatment management continues to be inadequate.

Keywords: inhaler pharmaceuticals, obstructive pulmonary diseases, pharmaceutical economics.

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Introduction

Life expectancy at birth in Turkey increased from 71 years in 2000 to 77.1 years in 2015 [1]. Because increasing life spans represent a global trend, the disease burden of many countries has shifted from acute to chronic diseases. For this reason, chronic diseases, such as hypertension, diabetes, coronary heart diseases, chronic obstructive pulmonary disease (COPD), and asthma, have become a significant economic burden [2].

COPD is one of the major causes of morbidity and mortality worldwide [3]. According to the World Health Organization (WHO), COPD, which causes more than 3 million deaths per year and 5% of all deaths [4], is the fourth most common cause of death in the world and the third most common cause of death in Turkey. In a study conducted by the Ministry of Health using the Global Burden of Disease study method, COPD was found to be the eighth leading cause of disease burden [5].

Pharmaceuticals used in the treatment of COPD are divided into the following four groups: bronchodilators (i.e., β_2 agonists, anticholinergics, and methylxanthines), systemic and inhaled corticosteroids, phosphodiesterase-4 inhibitors, and others (e.g., mucolytics, antitussives, immunoregulators, and vasodilators). It has been observed that when different bronchodilator pharmaceuticals are used together, the effect mechanisms can provide more bronchodilation without increasing side effects. There are also groups of patients for whom regular treatment with intractable corticosteroids with a long-acting bronchodilator is recommended. Some global findings indicate that in most cases of stable COPD treatment, current clinical guidelines are not followed, leading to cases of overtreatment as well as incomplete cure [6,7].

Asthma is thought to affect about 300 million of the world's population. Prevalence rates range from 1% to 18%, varying among different regions of the world. On the basis of age group, the prevalence rates are 2% to 15% in children and 2% to 5% in

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adults. Despite all the developments in diagnosis and treatment, it is estimated that approximately 250,000 people die annually from asthma worldwide [8,9], and the disease is a major cause of school absences and workforce loss worldwide. Therefore, along with treatment and hospital costs, early death and workforce losses due to asthma should be considered when calculating the costs associated with the disease [9,10]. It is important to note that, similar to COPD, emergency admission and hospital admission have greatly increased costs associated with asthma [9].

The aim of treatment in asthma is to control inflammation of the airways. When a patient's current condition is controlled, future risks of asthma attacks will be prevented. If anti-inflammatory treatment is discontinued, recurrences of the problem result. In asthma treatment, two groups of pharmaceuticals are used: controller medications and rescue medications. Controller medications are daily and long-term medications used to keep asthma under control and to prevent future risks. Rescue medications are used to provide comfort as needed [8,9].

The desire to increase life expectancies in Turkey and throughout the world, combined with the need to reduce the growing burden of chronic illness, has increased the amount of research conducted in these areas. This study aimed to evaluate the sales trends of the pharmaceuticals in the Anatomical Therapeutic Chemical (ATC) Classification System R03 inhaler group (pharmaceuticals used in obstructive respiratory disease) and to examine the groups of active agents that constitute these pharmaceuticals in terms of value-based sales (in Turkish lira [TL]) and box sales. Our study is a retrospective study of the sales trends and factors that influenced these pharmaceuticals.

Methods

This article is based on the health technology assessment report of the same name (Evaluation of the Costs of Inhaler Therapy Used in the Treatment of Respiratory Diseases in Turkey: 1998–2015), prepared by the Turkish Medicines and Medical Devices Agency (TMMDA).

Sales values of inhaler pharmaceuticals in the ATC R03 group (obstructive respiratory disease drugs) during years 1998 to 2015 were examined, and the Pharmaceutical Price List published regularly by the TMMDA was used as the basic database of the pharmaceuticals evaluated in this study. The medicines selected were those listed in the R group (respiratory system) at the ATC I level included in this list. The Health Code Coding Reference Server 3 list published by the TMMDA was used to determine the pharmaceuticals' market availability on the basis of their active or passive status. The Pharmaceutical Price List and the Health Code Coding Reference Server 3 list dated December 29, 2015, were used. Since 1998, sales data on the basis of value (in TL) and box number have been obtained from the Information Medical Statistics-Health-Turkey (IMS-Health Retail; Turkey Pharmaceutical National plus Molecule Data view) database. The total number of boxes and sales values in these groups were calculated using Microsoft Excel 2010, and the lines were created via this software. Box and sales values of the inhaler pharmaceuticals in the R03 group were obtained monthly during years 1998 to 2015 from the IMS-Health database. A statistical analysis of the data was performed with IBM SPSS version 20.0 (IBM Corp., Armonk, NY). Inhaler pharmaceuticals included in the Pharmaceutical Price List dated December 29, 2015, were classified according to their descriptive characteristics and ATC groups. The sales trends of inhaler medicines in the R03 group that were licensed at any time before the end of 2015 were examined in detail. Pharmaceuticals in the R03 group were categorized into the following subgroups: metered-dose inhalers (MDIs), nebulizer solutions, and dry-powder inhalers

(DPIs). In addition, inhaler medications were also subgrouped according to their pharmacological activity as follows: inhaled corticosteroid (ICS), combination of ICS and long-acting β_2 agonist (ICS + LABA), LABA, long-acting antimuscarinic agonist (LAMA), short-acting β_2 agonist (SABA), combination of SABA and short-acting antimuscarinic agonist (SABA + SAMA), SAMA, and others. The inhaler products external to the R03 group were not included in the study. Pharmaceuticals investigated in the study were also subgrouped according to whether they were manufactured or imported.

Assuming that the market has not changed, estimated box sales values and pharmaceutical market expenditures during 2016 to 2018 were calculated using the sales values of 2010 to 2015, for which we have the actual data. The Health Transformation Program was initiated in 2003, and the Social Security Reform was implemented in 2006. For this reason, sales figures for the year 2010 and after were used in forecasts, in which the conversion effects are fully occupied (health services and increased access to leisure). In the forecasts, models were developed with time series methods, such as the autoregressive integrated moving average, seasonal autoregressive integrated moving average, and exponential smoothing methods. The model most appropriate for use in this study was determined by testing with mean absolute error, the mean absolute percentage error, and the root mean square error.

Data in our study consist of retail sales. Hospital data were excluded in our study. The Social Security Institution covers 97% of the population and so this majority gives us a chance to understand these trends in almost all populations from each care level.

Results

General Characteristics of Inhaler Pharmaceuticals Used in Obstructive Respiratory Disease

There are a total of 457 active pharmaceuticals in the respiratory system group (ATC-1 R) on the agency's Pharmaceutical Price List dated December 29, 2015. There are 161 active pharmaceuticals listed in the R03 (drugs used in obstructive respiratory disease) group, of which 103 are inhaled.

The number of inhaler pharmaceuticals in the R03 group has shown a rapid increase since 2009 in terms of both product and brand, whereas the number of molecules has not changed considerably. From 1998 to 2015, the number of inhaler pharmaceuticals in the R03 group increased from 45 to 103 (Fig. 1).

Sales Trends of Inhaler Pharmaceuticals Used in Obstructive Respiratory Disease

The total annual sales volume of inhaler pharmaceuticals according to number of boxes and sales amounts (in TL). In the R03 group, 2.6 million boxes of inhaler medicines were sold in 1998, whereas sales in 2015 reached 40 million boxes. Over the years, the share of inhaler sales in total pharmaceutical sales has increased on a box basis. The share, which was 0.4% in 1998, increased to 1.45% in 2010 and to 2.10% in 2015. Similarly, the total amount of sales of these medicines was 6.6 million TL in 2010 and reached 625 million TL in 2015. The highest annual amount, of the years examined in the survey, was realized in 2010, which was 645 million TL. The share of inhaler pharmaceuticals investigated in the study was 1.3% in 1998 and 3.5% to 4.5% in 2006 (both in TL).

The rates of inhaler pharmaceuticals used in the treatment of obstructive respiratory diseases according to their manufacturing and import status are shown in Figure 2A,B. A review of

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