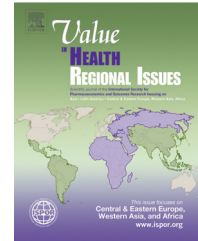




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Impact of Health Policy Changes on Trends in the Pharmaceutical Market in Turkey

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ABSTRACT

Background: The implementation phase of the Turkish Health Transformation Program (HTP) began in 2003, with the aim of organizing, financing, and delivering health care services effectively, efficiently, and equally. The HTP impacted all clinical and economic outcomes of health, including pharmaceutical sales, by improving access to health services. **Objectives:** To understand the impact of five selected major policy changes that made an impact on supply, demand, or price in the pharmaceutical market between 1998 and 2012. **Methods:** Monthly sales data (in units and value in US \$) of a total of 180 pharmaceuticals covering the period between 1998 and 2012 were used for statistical analysis. Five major policies that could affect health expenditures and the demand and supply of pharmaceuticals were selected and led by the Ministry of Health. A P value of less than 0.05 was considered as the cutoff value for statistical significance.

Results: There was a growing trend in pharmaceuticals value and units in years, possibly as a result of the HTP implementation. Supply- and demand-related policies had a negative impact on the trends for value, whereas the pricing policy had a positive impact. **Conclusions:** It could be said that the HTP had an impact on units for improved access to health care services. Although this access increased the consumption of pharmaceuticals in units, the policies implemented were successful in controlling pharmaceutical expenditures.

Keywords: health policy, Health Transformation Program, pharmaceutical market.

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Introduction

The implementation phase of the Turkish Health Transformation Program (HTP) began in 2003, with the aim of organizing, financing, and delivering health care services effectively, efficiently, and equally. The main focus of this program was to provide an “accessible, high-quality and sustainable healthcare service for all” [1].

The primary objectives of the HTP were the creation of a single-payer system; improved patient choice with regard to where to receive treatment; increased health insurance coverage for the poorest people; decreased infant, child, and maternal mortality rates; and increased patient satisfaction with health care services [1].

Some of the major implementations carried out by pharmaceutical companies during the reform were establishing the reimbursement commission for pharmaceuticals, beginning the family physician system in some cities, and starting reference pricing for pharmaceuticals in 2004; putting a maximum reimbursement limit on one molecule, which was correlated

with the lowest price, and establishing a positive list for pharmaceuticals in 2006; beginning to provide all medical devices and pharmaceuticals for inpatients in hospitals by 2007; introducing the statutory economic analysis for pharmaceuticals for reimbursement applications in 2009; and introducing a global budget for pharmaceuticals in 2010. A list of these major implementations is presented in Table 1 [1,2].

Access to health care has improved in accordance with these implementations, and this improved access has led to an increase in consumption of pharmaceuticals, the result of which has been a rise in total pharmaceutical sales, from US \$2.5 billion in 2002 to US \$8.0 billion in 2012. Over the same period, total public health expenditure increased from US \$5 billion to US \$23 billion, the Social Security Institution (SGK) health expenditure increased by US \$4 billion to US \$22 billion, and the consumption of medicines increased from 1.7 billion units to 700 million units. In addition, the average cost per prescription decreased from US \$25 in 2009 to US \$20 in 2012 [3].

The consumption of units of medicines increased by 5 times the public expenditure on pharmaceuticals [2]. Compared with

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Table 1 – Implementation year and description of selected policies.

Policy	Impact	Implementation year	Description
International reference pricing of pharmaceuticals	Price	February 2004	Selecting the lowest price from France, Italy, Spain, Portugal, and Greece, plus country of manufacture and export
Good manufacturing practice	Supply	February 2010	Production-level inspection of all pharmaceuticals, both originals and generics, for certification
Compulsory medical service for physicians	Demand	June 2005	All physicians are obliged to work for the Ministry of Health for 1.5–2 y in designated areas of the country
Family physician system	Demand	September 2008	System launched in some cities in 2004 and expanded to the entire country in 2010, with the aim of providing primary health care services
Mandatory reimbursement dossier submission	Supply	June 2008	Cost-effectiveness and budget impact analysis mandatory for reimbursement applications

BRIC (Brazil, Russia, Indonesia, and China) countries, the proportion of public health expenditure out of the total health expenditure (an average of 52.9%) is fairly high in Turkey, at 75.2% [4]. In the HTP report, according to the Ministry of Health, if the pricing mechanism for pharmaceuticals had not changed during the HTP implementation, public expenditure on pharmaceuticals would have risen to US \$24 billion after previously increasing to US \$8 billion [2]. The WHO Global Health Expenditure Atlas of the World Health Organization (WHO) in 2014 [5] reported that the total government expenditure was in the median range (36%), the share of government spending allocated to health was high (13%), and the government expenditure on health as a percentage of gross domestic product (GDP) was also high (5%) compared with those reported for upper-middle European Union countries. As a result of improved patient access to health services, satisfaction with health care services increased from 39% in 2002 to 76% in 2011, and became even higher than the European Union average, which was stable at 62% during this period [6].

The HTP changed the entire health care system. Following the implementations made, state and university hospitals became the major service providers and the SGK became the main purchaser. Social insurance contribution rates and premium levels are determined by the central government. The HTP affected all clinical and economic outcomes of health, including pharmaceutical sales, by improving access to health services. Nevertheless, despite this improvement and improved health coverage, additional policies for controlling this increasing trend toward pharmaceutical consumption, such as reference pricing, establishing a reimbursement commission, establishing a family physician system, a maximum payment limit for each molecule correlated with the lowest price, a positive list for reimbursement, auditing for good manufacturing practice, a limitation on pricing of generic molecules, a mandatory reimbursement dossier submission for new molecules, a global budget limitation for pharmaceuticals, establishment of health technology departments, market access agreements, and so forth, have been implemented by the government. The aim of this study was to understand the impact of five selected major policy changes that made an impact on supply, demand, or price of the total pharmaceutical market between 1998 and 2012.

Methods

Monthly sales data (in units as well as value in US \$) for a total of 180 pharmaceuticals covering the period between 1998 and 2012 were used for statistical analysis. Led by the Ministry of Health,

the following five major policies that could affect health expenditures, demand, or supply of pharmaceuticals were selected: international reference pricing of pharmaceuticals (impact on price); mandatory reimbursement dossier submission for new molecules, new indications, and line extensions with medical and economic evaluations (impact on supply); auditing for good manufacturing practice (impact on supply); a family physician system (impact on demand); and compulsory medical service for physicians (impact on demand) (presented in Table 1).

We used an interrupted time series analysis to estimate changes in levels and trends cost and unit sales for all pharmaceutical products after the implementation of the five selected policies of the HTP. This method controls for baseline level and trend when estimating expected changes in cost/unit sales because of the intervention. In addition, the analysis was conducted for total imported pharmaceutical sales and total locally manufactured pharmaceutical sales. We also compared the slopes using a specific t test methodology [7]. A P value of less than 0.05 was considered as the cutoff value for statistical significance when the t value was $-1.96/+1.96$. The IBM (United States) SPSS version 20 software for Windows was used to carry out the statistical analysis.

Results

There was a growing trend in pharmaceuticals value and units in the years, possibly as a result of the HTP implementation. Supply- and demand-related policies had a negative impact on the trends for value, whereas pricing policy had a positive impact (Table 2).

Reference pricing policy had a positive impact on value and units for both locally manufactured and imported pharmaceuticals. Only the positive impact on units was statistically significant ($t = -1380$ and $P > 0.05$ for value, $t = 2470$ and $P < 0.05$ for units).

Submission of the reimbursement dossier policy, which had an impact on supply, had a negative impact on value for both locally manufactured and imported pharmaceuticals and on units for locally manufactured pharmaceuticals, but a positive impact on units for imported pharmaceuticals. The policy, however, had no statistically significant impact on consumption ($t = 1580$ and $P > 0.05$ for value, $t = -1820$ and $P > 0.05$ for units). The same results were observed for the good manufacturing practice process, which had an impact on supply ($t = 1150$ and $P > 0.05$ for value, $t = -610$ and $P > 0.05$ for units), and the family physician system, which had an impact on demand ($t = 1540$ and

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