Health Policy 120 (2016) 867–874

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Factors influencing the difference between forecasted and actual drug sales volumes under the price–volume agreement in South Korea

Sun-Young Park[a], Euna Han[b], Jini Kim[c], Eui-Kyung Lee[a,*]

[a] School of Pharmacy, Sungkyunkwan University, Suwon, South Korea
[b] College of Pharmacy, Yonsei Institute of Pharmaceutical Sciences, Yonsei University, Incheon, South Korea
[c] Department of Benefits Management, National Health Insurance Service (NHIS), Wonju, South Korea

ARTICLE INFO

Article history:
Received 30 September 2015
Received in revised form 4 June 2016
Accepted 7 June 2016

Keywords:
Price–volume agreement
PVA
Forecasted volume
Pharmaceutical expenditure

ABSTRACT

This study analyzed factors contributing to increases in the actual sales volumes relative to forecasted volumes of drugs under price–volume agreement (PVA) policy in South Korea.

Sales volumes of newly listed drugs on the national formulary are monitored under PVA policy. When actual sales volume exceeds the pre-agreed forecasted volume by 30% or more, the drug is subject to price-reduction. Logistic regression assessed the factors related to whether drugs were the PVA price-reduction drugs. A generalized linear model with gamma distribution and log-link assessed the factors influencing the increase in actual volumes compared to forecasted volume in the PVA price-reduction drugs.

Of 186 PVA monitored drugs, 34.9% were price-reduction drugs. Drugs marketed by pharmaceutical companies with previous-occupation in the therapeutic markets were more likely to be PVA price-reduction drugs than drugs marketed by firms with no previous-occupation. Drugs of multinational pharmaceutical companies were more likely to be PVA price-reduction drugs than those of domestic companies. Having more alternative existing drugs was significantly associated with higher odds of being PVA price-reduction drugs. Among the PVA price-reduction drugs, the increasing rate of actual volume compared to forecasted volume was significantly higher in drugs with clinical usefulness.

By focusing the negotiation efforts on those target drugs, PVA policy can be administered more efficiently with the improved predictability of the drug sales volumes.

1. Introduction

Pharmaceutical expenditures have been steadily rising in many of the Organization for Economic Cooperation and Development (OECD) countries [1]. Pharmaceutical spending in South Korea increased by about 13.2% annually between 2001 and 2010 [2]. Furthermore, drug expenditures account for a large proportion of total health expenditures. In 2010, South Korean pharmaceutical expenditures comprised 21.6% of its total health expenditures, which was much higher than the average of the OECD countries (16.4%) [3]. The increase in pharmaceutical expenditures has become a financial crisis in South Korea's healthcare system. As a result, South Korea has implemented a variety of policy measures to control pharmaceutical expenditures.

* Corresponding author at: School of Pharmacy, Sungkyunkwan University, 2066 Seobu-ro, Jangan-gu, Suwon, Gyeonggi-do 440-746, South Korea. Tel.: +82 31 290 7786; fax: +82 31 299 4379.
E-mail addresses: sunyoung.pr@gmail.com (S.-Y. Park), eunahan@yonsei.ac.kr (E. Han), jinikim@nhis.or.kr (J. Kim), ekyung@skku.edu (E.-K. Lee).

http://dx.doi.org/10.1016/j.healthpol.2016.06.004
0168-8510/

Most of South Korea's pharmaceutical regulations have mainly focused on price controls [4]. However, price controls in the absence of volume controls might not sufficiently control the growth of total pharmaceutical spending because it could increase the overall volume of drugs or the use of relatively more expensive drugs. Hence, volume (i.e., the quantity of drugs consumed) control is an important consideration as a policy measure to regulate pharmaceutical expenditures [5,6]. Many studies have reported that the major factor contributing to increased pharmaceutical expenditures is the increase in the volume of drugs being used [7–10]. For example, an examination of the factors contributing to fluctuations in the pharmaceutical expenditures of South Korea's National Health Insurance (NHI) between 2005 and 2009 found that the price factor decreased total pharmaceutical expenditures by an average of about 1.7% compared to the previous year, whereas the volume factor significantly increased total pharmaceutical expenditures by an average of about 14.3% [11]. Therefore, volume control is necessary for better control of pharmaceutical spending.

A price–volume agreement (PVA) is an agreement to share risks between the public payer and the drug manufacturer based on a pre-arranged relationship between price and volume. Drug manufacturers that exceed pre-agreed sales volumes (i.e., sales volume thresholds) are forced to reduce drug prices or pay back a certain amount of their revenue to the payer [6]. PVA has been implemented to stabilize healthcare expenditures in many countries, such as the United Kingdom, Australia, New Zealand, Italy, France, Spain, and Canada [12,13].

In 2007, the South Korean government introduced the PVA as part of the Drug Expenditure Rationalization Plan to control pharmaceutical expenditures and stabilize the financing of the NHI. Under South Korea's PVA policy, a drug's listing price is negotiated between the public payer (i.e., National Health Insurance Service; NHIS) and the manufacturer based on the forecasted sales volume to consider the budgetary impact. Since then, the sales volumes of negotiated drugs have been monitored annually. If actual sales volume is equal to or exceeds 30% of the pre-agreed forecasted volume, the drug is subject to price-reduction. However, the amount of the price-cut is limited to a maximum of 10% based on a formula that determines the price-cut. According to Kim and Choi (2011), the increased rate of actual sales volume compared to the forecasted volume was approximately 68–487%, whereas the adjustment rate of the price was only −4.1% to −8.3% [1]. As a result, if the actual volume were much greater than was expected at the time of negotiating the drug price, the NHIS would face considerable financial risk. Therefore, it is crucial to accurately estimate the forecasted sales volume when the drug price is negotiated.

Despite the importance of accurately forecasting the drug-use volume, relevant studies of this process are scarce. Moreover, despite the large gap between forecasted and actual volumes, estimation methods used to forecast sales volume have not been properly established. As a result, the accuracy of forecasted volumes has been controversial in South Korea [14,15]. To accurately estimate the drug sales volumes, it is necessary to identify the characteristics of drugs with a high risk of exceeding the forecasted volumes [1]. Therefore, the purpose of this study is to identify the factors that lead to increases in actual sales volumes relative to the forecasted volumes of sales.

2. Materials and methods

2.1. Study design and data

A retrospective analysis was performed using data derived from the NHI claims database. In South Korea, the NHI provides health insurance coverage to about 96.8% of the population, and 81.9% of the drugs available in the South Korean market are dispensed under the NHI's pharmaceutical benefit scheme [3]. Thus, data extracted from the NHI claims database represent national patterns of current drug use in South Korea.

Monthly aggregated data were extracted for each of the individual drugs, including information on sales volumes and expenditures, from January 1, 2003, to December 31, 2012. The claims data file was merged with the medication information file to identify detailed characteristics of each listed drug. The Anatomical Therapeutic Chemical (ATC) Classification system was used to confirm the drugs' therapeutic classes.

2.2. Variables

2.2.1. Outcome variables

This study analyzed two outcomes to identify the factors influencing the difference between forecasted and actual drug sales volumes under the PVA policy. The first outcome variable was a dichotomous indicator of whether a drug was the PVA price-reduction drug. If the actual sales volume of a drug exceeds the pre-agreed forecasted sales volume by 30% or more, the drug is subject to the PVA and the listed price is reduced (hereinafter referred to as "PVA price-reduction drug"). The second outcome variable was the increasing rate of actual sales volume compared to the forecasted sales volume in the PVA price-reduction drugs. The forecasted sales volume was determined through price negotiation between the NHIS and the pharmaceutical companies. The actual sales volume was calculated based on the quantity of drugs consumed during the monitoring period used to select the PVA price-reduction drugs.

2.2.2. Explanatory variables

The sales volume of a newly listed drug on the national formulary could be influenced by the drug's characteristics such as its clinical superiority over existing drugs, the characteristics of the pharmaceutical company including its marketing activities, and the characteristics of the pharmaceutical market such as market expansion [1,14–16]. Therefore, this study focused on measures of the characteristics of drugs, pharmaceutical companies, and the pharmaceutical market.

Measures of the drugs' characteristics: The measures for the basic characteristics of the drugs under analysis were as follows: (1) type of drug monitored under the PVA policy, (2) status as an essential or nonessential drug, (3)