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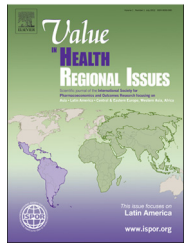

# The Drug Policy in Central European Countries—Slovakia

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ABSTRACT

Slovak law sets clear rules and timelines in the process of approving the price and reimbursement of drugs. During the last decade, the Ministry of Health adopted several cost-containment measures in the price and reimbursement policy. The most effective measures were the implementation of the external referencing of drug prices in 2008 and the reimbursement law in 2011. The new act introduced several regulations such as making stricter rules for the referencing of prices, setting cost per quality-adjusted life-year threshold, and defining new rules for the setting of reimbursements. On one side, implementation of these measures helped to achieve visible cost savings, but, on the other side, cost-containment policies have had some unintended consequences. In recent years, Slovakia has been facing a decreased availability of drugs because of parallel exports. As a result of the government's effort, Slovakia is the only country in the European Union that implemented a legal ban on the re-export of medicines. During the decade before 2011, many innovative drugs were included in the reimbursement system. Because of stricter legal conditions introduced in 2011, there has been a gradual shift in reimbursing innovative drugs from the standard reimbursement system to reimbursement by way of exceptions of health insurance companies. Recently, there has been an ongoing discussion on possible changes to the reimbursement law.

***Keywords:*** drug policy, health care, HTA, price and reimbursement, Slovakia.



## Introduction

Since 1990, after political and social changes that resulted in a total transformation from a centrally planned economy to a market economy, Slovakia has witnessed a huge reform of the health care sector and many changes in the pricing and reimbursement system. To find measures to cut drug costs, each new government tried to introduce new rules and as a result there are various restrictions set in the system. In 2003, the so-called fixed patient co-payment was introduced to prevent the prescribing of expensive drugs. In 2004, a digressive margin system for pharmaceuticals and dietary foods was first set in Slovakia. Initially, the margins were set as a fixed percentage from the pharmaceutical price (11% for the distributor and 21% for the pharmacy). In 2004, a lower margin (10%) was established (4% for the distributor and 6% for the pharmacy) for high-priced pharmaceuticals that put pressure on the budget. Since 2008, a more elaborate digressive margin system has been in place, which sets margins separately for distributors and pharmacies on the basis of the exfactory price. Value-added tax (VAT) on pharmaceuticals has changed several times since 1999. Until 1999 it was 6%, after which it rose to 10% in the period 2000 to 2002. In 2003, VAT was increased to 14%, and a flat rate of 19% VAT was introduced in 2004. In 2007, the new government reduced the VAT on pharmaceuticals to 10%. In 2007 and 2008, there were two obligatory flat price decreases for all drugs included in the reimbursement list (RL): 6.6% in 2007 and 7.4% in 2008. With the 2008 financial crisis, cost containment became the main focus of Slovak health reforms. In 2008, external reference pricing was implemented as an average price among six of the cheapest countries in the European Union (EU). In the first year, referencing saved more than €165 million in expenses [1]. During the years 2009 to 2011, the government introduced several changes to the system, including tightening up the referencing system by setting price ceilings of no higher than the average of the three lowest in the EU, introducing a cap on pharmaceutical spending for seniors and selected socially vulnerable groups, mandatory generic prescriptions, and setting of health technology assessment (HTA) principles.

In December 2011, the new reimbursement law introduced other new changes in the pricing and reimbursement system, including cost per quality-adjusted life-year (QALY) threshold and defining new rules for the setting of reimbursements. At the same time the new drug law came into force that introduced several measures such as generic prescription, changes to registration and pharmacovigilance procedures, changes to the management of non-interventional clinical studies, established obligatory reporting of pharmaceutical companies, and rules for visiting doctors.

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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Implementation of cost-containment measures helped to achieve visible cost savings. The first slowdown in the growth of drugs expenditure was notable in 2009 because of the introduction of price referencing, and then in 2012 after the new reimbursement law came into force. Since 2013, there has been a slight increase in drugs expenditure, caused predominantly by the introduction and wider usage of new costly drugs. According to the National Health Information Center data, expenditure on drugs covered fully or partially by health insurance companies (HICs) was €1273.40 million in 2015 and accounted for almost 30% of the public expenditure on health [2].

Cost-containment policies targeting price reductions have had some unintended consequences. In recent years, Slovakia has been facing a decreased availability of drugs because of parallel export. Slovakia, as the only country in the EU, started banning the re-export of medicines. From January 1, 2017, the law set out a series of measures primarily aimed at preventing the export of drugs. Thus, the shortage of products because of parallel export decreased significantly; nevertheless, it is still too early to evaluate the impact of the legislative update in a real-life setting. In 2016, Slovakia took over the presidency of the Council of the European Union and intended to build on the health care agenda on the work done by the Netherlands' presidency. The main topics were the availability of medicinal products in the context of high prices of innovative medicines, cuts in production, and parallel exports of medicinal products [3].

During the decade before 2011, many innovative drugs were included in the reimbursement system. The new reimbursement law introduced several barriers for the inclusion of innovative drugs in the reimbursement system, including cost per QALY threshold in the law. Furthermore, applicable legislation limits certain mechanisms (e.g., paybacks and risk-sharing and cost-sharing schemes) that are used in some countries to facilitate innovation and might result in decreasing drug costs [4]. As a result, there has been a gradual shift in reimbursing innovative drugs from the standard reimbursement system to reimbursement by way of HIC exceptions and limited availability of new drugs for patients. Recently, there has been an ongoing key stakeholders' discussion on changes to the reimbursement law that should come into force from 2018.

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## The Health Care System in General

The health care system in Slovakia is based on universal coverage, compulsory health insurance, a basic benefits package, and a competitive insurance model with selective contracting of health care providers and flexible pricing of health services. The Slovak Constitution guarantees all citizens universal free access to a broad basic package of health care covered by public health insurance. All residents must have health insurance and are obliged to pay contributions to the public health insurance under the administration of HICs. The state pays insurance for some citizens (children, students, mothers on maternity leave, the unemployed, sickness benefit recipients, pensioners, etc.). Three HICs are operating on the market: one state-owned (General Health Insurance Company Všeobecná zdravotná poist'ovňa [VsZP]) and two privately owned (Dovera and Union). The role of an HIC is to provide its policyholders affordable health care in accordance with relevant legislation. The health care system has undergone several reforms in the last few decades. Many of these reforms were reversed as soon as a new government took power [1]. Health care expenditure as a share of gross domestic product (GDP) is relatively low in Slovakia. During the last 15 years, total health expenditure has grown, reaching a peak of 8% of the GDP in 2009. In 2015, total health expenditure in Slovakia was 7.0% of the GDP, which was significantly lower than the EU average of 9.9%. Private out-of-pocket sources accounted for 18% of total health expenditure, higher than the EU average of 15% [5]. Because the key health status indicators are lagging behind neighboring countries and overall EU averages, the main goal of the government is to improve the efficiency and accountability of the system. There are two major challenges: first, to harmonize the different legislations and processes left by various unfinished reform periods, and second, to start proper monitoring of the population's health and develop health policies on the basis of actual population needs [1].

## The Role of Health Authorities in the Drug Policy

### *The Ministry of Health of the Slovak Republic*

The Ministry of Health (MoH) is a central administrative body and its responsibilities include drafting health policies and legislations, regulating health care provision, managing national health programs, participating in the management of health education, managing national health registers, determining the scope of the basic benefits package, defining health indicators, and setting minimum quality criteria, and it is competent in price and reimbursement regulation. Furthermore, the state is the owner of university hospitals, faculty hospitals, specialized national centers, sanatoria, and the largest HIC. The MoH coordinates the activities of advisory bodies in the field of price and reimbursement of medicinal products, medical devices, and dietetic foods; categorization committees; categorization councils; and expert working groups [1,6].

### *State Institute for Drug Control*

The State Institute for Drug Control (SIDC) is responsible for surveillance of medicinal products and medical devices. The SIDC issues approvals on clinical trials, grants marketing authorizations, assesses pharmacies, and maintains a pharmacopoeia. The SIDC can also impose sanctions. In the area of patient safety, it assesses reports on adverse drug effects (pharmacovigilance) and medical device failures. It withdraws or suspends medicinal products or medical devices from (entering) the market. The SIDC also supervises the regulation of re-exports. The SIDC is, however, not involved in reimbursement decisions concerning pharmaceuticals or medical devices [1,6].

## Decision-Making Process

The law sets clear rules, timelines, and competencies for individual subjects in the process of approving the price and reimbursement of drugs [6]. In 2014, a study was published that assessed the decision-making processes on drug reimbursement in member countries of the Organisation for Economic Co-operation and Development [7]. The authors assessed the decision-making process on the basis of three indicators: transparency of processes, inclusion of clinical and cost-effectiveness evidence, and the appeal process. Only five member countries satisfied all these indicators, Slovakia included [7]. The mentioned analysis, however, did not assess actual transparency and objectivity in evaluation and decision making; it evaluated processes, but not the content and real competencies.

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