Drug Policy in the Czech Republic

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ABSTRACT

Background: The legal background of the current pharmaceutical pricing and reimbursement (P&R) setting in the Czech Republic is based on Act 48/1997. Since 2008, the P&R process has been coordinated by the State Institute for Drug Control, which is the main stakeholder in the decision-making process; marketing authorization holders and insurance funds (IFs) also participate. Objectives: To present a general overview of the current Czech health care system and its P&R principles. Methods: The study used publicly available sources concerning health care, mainly acts related to public health care (amending some related laws) [3], public notices related to P&R setting [4,5], as well as statistical data [6,7]. Results: Regulation covers P&R. The official price represents the highest exactory price, which cannot be exceeded. It is calculated as the mean of the three lowest prices in the European Union reference basket. Reimbursement is based on the lowest price per daily dose across the whole European Union. For reimbursement, products can be clustered into jumbo groups (mutually interchangeable), stated by law. In each group, reimbursement is set at the lowest price of any substance within the group. For highly innovative drugs a temporary reimbursement can be granted for a period of 3 years. During the administrative proceeding, efficacy, safety, cost-effectiveness, and budget impact are assessed. The cost-effectiveness principles are aligned with the guidelines of the National Institute for Health and Clinical Care Excellence, preferring cost-utility analyses. The willingness-to-pay threshold has been implicitly set at 3 times the gross domestic product per capita. Products exceeding this threshold are subject to further risk-sharing negotiations. Budget impact is becoming increasingly important mainly for IFs. The IFs have recently introduced their own methodology, which allows only products with a budget impact in the range of CZK16 to CZK48 million (CZK = Czech koruna; ~€600,000 to €1.8 million) to enter the system. Products exceeding this budget impact have to negotiate risk-sharing schemes, mainly further discounts and/or budget caps. Conclusions: The Czech pricing and reimbursement system is rather complex, taking into account clinical evidence, cost-effectiveness and budget impact. The strict regulations are a result of financial scarcity. Keywords: Czech Republic, health technology assessment, pharmaceuticals, pricing and reimbursement.

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Introduction

The Czech Republic is located in Central Europe, with an area of 78,865 km² and 10,579,067 inhabitants (as in March 2017) [1]. It has been a member of the European Union (EU) since May 2004.

The aim of this article was to present a general overview of the Czech health care system and its pricing and reimbursement (P&R) principles. The article reflects the current situation (year 2017) of the Czech health care system.

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Methods

The study used publicly available sources concerning health care, mainly Act 20/1966 Coll. on public health care (amending some related laws) [2], Act 48/1997 Coll. on public health care insurance (amending some related laws) [3], public notices related to P&R setting [4,5], as well as statistical data [6,7].

Results

In this section, we provide a description of the present Czech health care system, focusing on P&R.

Health Care System

The legal background for health care in the Czech Republic is based on Act 20/1966 [2], which calls for mandatory insurance for all Czech citizens. Basic principles are solidarity (between the healthy and the sick and between the economically active and inactive) and equal availability of health care. This means that every employed citizen pays a premium, a percentage of income, regardless of whether health care is currently consumed or will be received in the future. For children, the retired, and the unemployed, the state pays a monthly fixed amount to insurance funds (IFs).
The health care in the Czech Republic is provided by a structured network, including outpatient care (primary care physicians and specialists), institutional care, emergency rescue service, and long-term care. Centers of excellence have been established within hospitals to guarantee efficiency in providing highly specialized care including prescription and application of costly pharmaceuticals.

Every citizen is registered with a general practitioner and can even visit a specialist without referral. This is often misused and the number of annual consultations in the country (11.1 consultations) exceeds the average of the member countries of the Organisation for Economic Co-operation and Development (6.8 consultations) [6].

The total public health care expenditure reached CZK269,157 million (CZK = Czech koruna; about £9,000 million) in 2015, which represents 6.5% of the gross domestic product (GDP) [7]. Pharmaceuticals account for about 20% of the total health care expenditure, with a declining trend over the past years [7]. Private expenditures are only about 15% of the total health care expenditure [7].

The largest IF (the General Insurance Fund) covers approximately 60% of the insured. The other six smaller IFs cover the remaining 40%. No commercial private insurance is available, and so IFs compete mainly in nonreimbursable services (such as rehabilitation, sport activities, and vaccination).

In general, the Czech health care system has developed significantly over the past decades, offering modern interventions (pharmacological and nonpharmacological). The proportion of patients’ co-payment is low, mainly in reimbursable medications, because manufacturers adopt pricing to limit co-payment (exact data not available).

P&R Principles
Since the early 1990s, the Czech Republic performed an assessment of new drugs for which reimbursement had been requested. This assessment was done by a categorization committee, representing IFs and medical societies. The committee was liable to the Czech Ministry of Health (MoH). This approach was not considered to be sufficiently structured and fully transparent (mainly because of the absence of appeal) and was therefore changed in 2008.

The legal background of the current P&R setting is based on Act 48/1997 Coll. on public health insurance [3]. The State Institute for Drug Control (SUKL) coordinates and leads the process; the marketing authorization holders (MAHs) and the IFs are the participants. Each submission is run as an administrative proceeding with clearly stated timelines and an opportunity to appeal to the MoH.

Drugs in the Czech Republic are regulated by price only if their reimbursement has been requested. All nonprescription drugs, with a few exceptions, are not covered by public sources.

The Czech Republic regulates the prices of pharmaceuticals and sets reimbursement levels. Both are based on external and/or internal reference pricing. The difference between the public price and the reimbursement represents co-payment.

In the administrative proceeding, the applicant (usually the MAH) presents the required documentation, which consists of a clinical dossier (describing efficacy and safety) and also an economic dossier (cost-effectiveness and budget impact analyses) for new drugs or indications not yet available or reimbursed on the Czech market. The whole process for P&R setting takes about 165 days; this period, however, is often exceeded. During the assessment, the SUKL issues an assessment report, which can be commented on by the MAHs or the IFs, followed by a subsequent assessment report (if comments are considered as relevant) or the final decision. During the 20-day period after issuing the decision, any of the proceeding participants (i.e., the MAHs or the IFs) can appeal to the MoH. If this is not the case, the decision becomes legally valid. During the process, the SUKL quite often consults medical societies to get their opinion on the drug and treatment pathways. Because economic models must not necessarily be presented to the SUKL, a detailed description of the model, underlying clinical data, and/or indirect comparisons and extrapolations are required. The SUKL often issues a set of additional questions, which have to be cleared within 10 days, to the applicant. Because of the strict and short timelines, applicants often ask for a clock-stop, which can be granted up to 3 months. P&R setting is regularly revised every 3 to 5 years.

Figure 1 shows a simplified scheme for outpatient products. Hospital products require only a price regulation. Reimbursement level is negotiated with IFs case by case.

Price Regulation
The price, strength, and pack size of each product are set according to the external reference pricing system [3]. For each product (brand), international prices are looked up from public databases. The price (called the maximum exfactory price) is set as an average of the lowest three from the EU reference basket. The reference basket covers all EU countries except Germany, Austria, Estonia, Romania, Bulgaria, Cyprus, Malta, and Luxembourg. The conversion from the local currency to Czech koruna is described in detail in the act. The exchange rate used is the mean rate during the previous quarter. The maximum price represents the highest exfactory price at which the product can be sold to distributors. Nevertheless, the manufacturer can decide to sell at a price lower than this maximum price and this is frequently done to limit co-payment.

To the manufacturer’s selling price, digressive margins (common for distributors and pharmacies) and value-added tax (10%) are added to obtain the public price.

Reimbursement Regulation
Reimbursement setting depends on the type of product/substance, which can be

1. included in jumbo groups (defined by legislation);
2. not included in jumbo groups;
3. highly innovative.

Products included in jumbo groups
Jumbo groups are defined in Public Notice No. 384/2007 [4]. Substances in a jumbo group are mutually interchangeable; for example, all statins are considered as interchangeable and therefore clustered. For all clustered substances and products available

![Fig. 1 – Simplified structure of the P&R process for outpatient drugs in the Czech Republic. HTA, health technology assessment; P&R, pricing and reimbursement; RWE, real-world evidence.](image-url)
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