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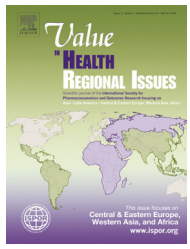

Highly Innovative Drug Program in the Czech Republic: Description and Pharmacoeconomic Results—Cost-Effectiveness and Budget Impact Analyses

Eva Ornstova, MPharm, Monika Sebestianova, MSc, Tomas Mlcoch, MSc, Klara Lamblova, MSc, Tomas Dolezal, MD, PhD*

Value Outcomes, Prague, Czech Republic

ABSTRACT

Background: Highly innovative drugs (HIDs) can be granted 2 to 3 years of temporary reimbursement (TR) to provide timely patient access and to collect real-world evidence through registries in the Czech Republic. A TR applicant does not need to comply with cost-effectiveness (CE) requirements and the willingness-to-pay threshold. It is only when mandatory transition to permanent reimbursement (PR) status occurs does the drug need to comply with CE and willingness-to-pay requirements. **Objectives:** To describe and evaluate the HID program in the Czech Republic by analyzing the pharmacoeconomic results when a drug starts with TR status and transitions to PR status. **Methods:** The study was a retrospective analysis of reimbursement decisions of HIDs. All drugs approved for TR (valid from January 2008 to January 2018) were identified. A description of the HIDs and their pharmacoeconomic results were analyzed. **Results:** Fifty TR drugs were identified. Most (68%) were oncology drugs and 44% were orphan drugs. After the expiration of their TR status, 83% were successfully transitioned to PR status. Cost-utility analysis was used to support CE results in 42% of the TR drugs. The mean incremental cost-effectiveness ratio (cost/quality-adjusted life-year) of drugs that entered TR status was €97,868. When the time came for transition to PR status, the mean incremental cost-effectiveness ratio was €34,086 (lower by 65%). Net budget impact increased by 3% and decreased by 25% in the first and fifth years, respectively, after applying for PR. **Conclusions:** This analysis provides better insight into the HID program for costly innovative drugs over a 10-year follow-up. A successful transition to PR status was observed for most of the HIDs (83%).

Keywords: budget impact, cost-effectiveness, Czech Republic, highly innovative drug program, orphan, pharmacoeconomics, pricing and reimbursement.

Introduction

There are various drug reimbursement systems used across Europe and around the world. Most of them grant direct permanent reimbursement (PR) on the basis of health technology assessments [1], whereas some also allow temporary (or conditional) reimbursement (TR) as part of innovative schemes for quick access to new and expensive medicines. These schemes try to give patients early access to highly innovative drugs (HIDs) under certain circumstances and, at the same time, take steps to protect health insurance budgets [2–6].

The Czech Republic uses this two-tier system. It has two reimbursement options for pharmaceuticals: 1) PR and 2) a 2- to 3-year TR period. The second option is available if a drug addresses a very serious disease or fulfills certain conditions for high innovativeness (i.e., markedly higher efficacy, greater safety, or no existing alternative treatment; see the "Methods" section for further details) [7–9].

The general reimbursement system of pharmaceuticals in the Czech Republic is characterized by value-based reimbursement where clinical efficacy and/or effectiveness, cost-effectiveness (CE), and budget impact (BI) are taken into consideration during reimbursement decisions. The explicit CE threshold (currently CZK 1.2 million [CZK = Czech koruna] per quality-adjusted life-year [QALY] [~€47,000] [10]) cannot be exceeded and still receive PR. Nevertheless, as mentioned, exceptions can be made for pharmaceuticals demonstrating high innovativeness. All HIDs with unacceptable incrLemental cost-effectiveness ratios (ICERs) can be given conditional TR status [4,7–11]. The quality of submitted pharmacoeconomic analyses is evaluated for informative purposes only.

The aim of this study was to describe the highly innovative drug program (HIDP) in the Czech Republic and explore results from CE and BI analyses of drugs accepted in the HIDP over the past 10 years (from January 2008 to January 2018). We then compared the CE and BI results of the HIDs between the time they entered TR and when they received PR status. We also described what types of drugs met the criteria for high innovativeness and specifically which criteria were fulfilled to justify an HID status.

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

* *Address correspondence to:* Tomas Mlcoch, Value Outcomes, Vaclavska 316/12, Prague CZ 12000, Czech Republic.
E-mail: tomas.mlcoch@valueoutcomes.cz.

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Methods

Description of HIDP

The State Institute for Drug Control (SUKL) is the regulatory authority with respect to the pricing and reimbursement of medicinal products in the Czech Republic. A general description of the Czech drug policy system was presented in a previous study [7].

The legal framework for the HIDP in the Czech Republic is based on Law 48/1997 Coll. on public health insurance (amending related laws), Section 39d, and the specific provisions of Decree No. 376/2011 (i.e., criteria for granting HID [henceforth, HID criteria], commitment, or reimbursement calculation methods) [8,9]. Interestingly, reimbursement from public health insurance is based on the lowest price per pack across all European countries compared with non-HIDs for which the lowest price per daily dose is referenced; this allows so-called flat pricing for HIDs (i.e., every pack is referenced separately).

Besides being used for a very severe disease, a drug has to fulfill at least one of the following HID criteria (Section 40 of Decree No. 376/2011 and following Section 27 of Decree No. 376/2011 [9]):

1 Significantly higher efficacy or safety compared with alternative therapies (named as "Other alternative therapy and better efficacy or safety" in Fig. 1):

- fewer serious adverse events, by at least 40% ("Adverse events reduction");
- fewer dropouts (discontinuations) due to adverse events, by at least 40%;
- fewer drug interactions, by at least 40%;
- a significant reduction in mortality and extension of the median survival by more than 2 years, or in cases when

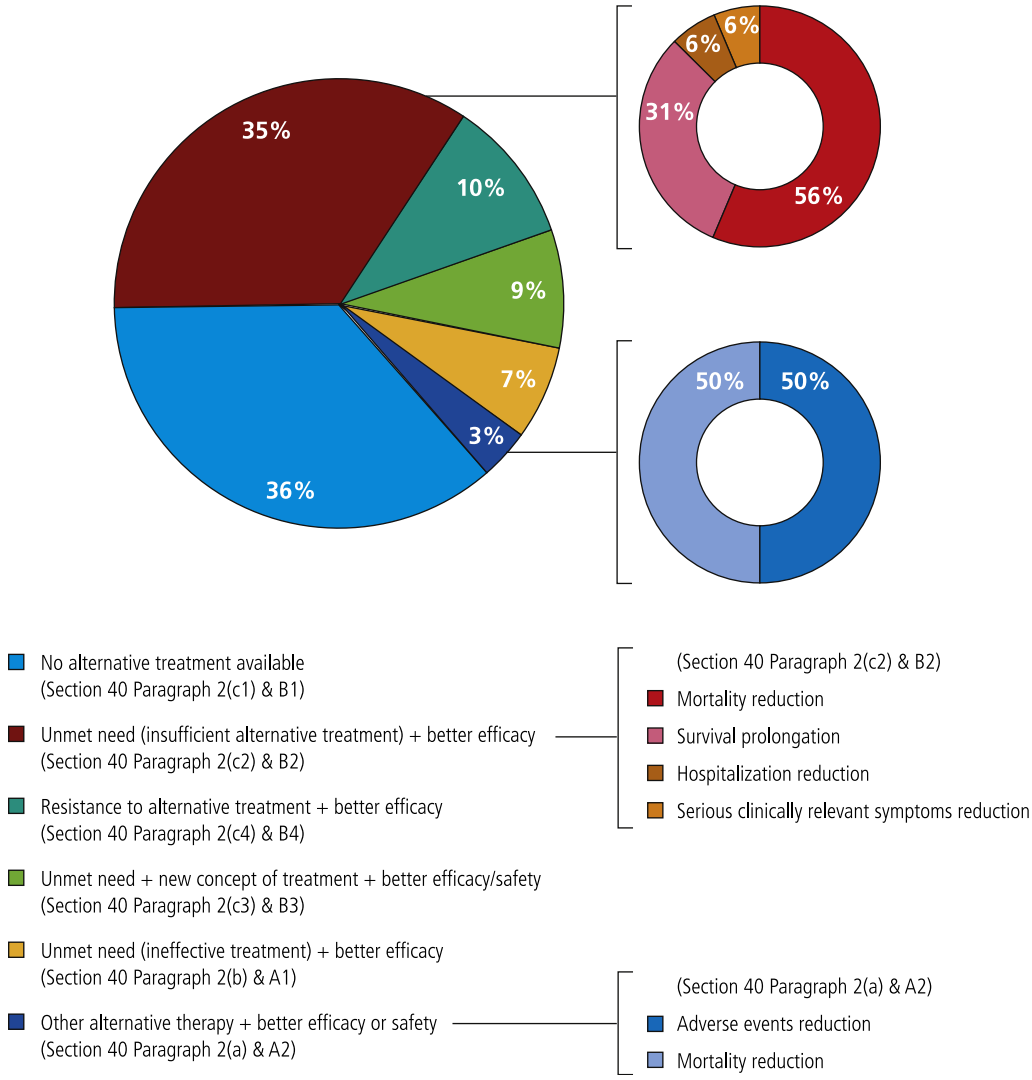

Fig. 1 – Classification of HID criteria on the basis of SUKL decisions (n = 58). HID, highly innovative drug; SUKL, State Institute for Drug Control.