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Drug Policy in Central Eastern Europe—Hungary

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ABSTRACT

We present a brief overview of the health care system in Hungary, focusing particularly on the pricing and reimbursement procedures of medicines. The National Institute of Health Insurance Fund Management is responsible for the administration of the health insurance system and public reimbursement of health technologies. There are two major types of reimbursement techniques in the outpatient care: the normative reimbursement is applied to all physicians and may be used for all indications listed in the Summary of Product Characteristics, and the indication-linked reimbursement is applied only to specialists who are authorized to prescribe the drug. Pharmaceuticals used in the inpatient care are fully reimbursed and are financed through diagnosis-related groups. Several cost-containment measures such as external price referencing and internal price referencing

with blind bidding are applied. Proposing managed entry agreements is a mandatory condition for reimbursing innovative pharmaceuticals. Compared with other countries in the region, the implementation of health technology assessment has a relatively long history in Hungary. The health technology assessment body critically evaluates reimbursement submissions of pharmaceuticals, simple medical devices, and complex medical devices such as hospital technologies. **Keywords:** Central Eastern Europe, cost-containment, health technology assessment, Hungary, pharmaceutical policy, reimbursement system.

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Introduction

This article is part of a project conducted by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Central Eastern European (CEE) Publication Network working group aiming to give an overview on the Hungarian pharmaceutical pricing and reimbursement system. Hungary is a CEE country with a slowly declining population, currently estimated at about 9.8 million. Like many countries in the European Union (EU), Hungary is facing the problem of an aging population. Life expectancy at birth for the total population was 75.7 years in 2013, which was 4.7 years lower than the average among the European members of the Organisation for Economic Co-operation and Development (OECD) and was also lower than that for the other three Visegrad Group countries (i.e., the Czech Republic, Poland, and Slovakia) [1,2]. Similarly, figures of life expectancy at the age of 65 years and healthy life expectancy are unfavorable, even compared with countries with similar economic status. Disease-specific indicators, such as standardized death ratio in cancer and cardiovascular diseases, are especially poor [3].

On the basis of OECD data from 2014, the total health expenditure in Hungary was 7.2% of the gross domestic product (GDP) (less

than the average in the European OECD countries, which is 9%). In 2014, per-capita spending on health was €756 (based on local currency exchange rate), which was lower compared with the average of European OECD countries (€3114). Per-capita health expenditure expressed in purchasing power parity was US \$1797; the average of the European OECD countries was US \$3782. Pharmaceutical spending was 30.2% of the total health expenditure, which was 2.1% of the GDP (Table 1). These indicators, however, should be handled with care in international comparisons because of methodological questions (e.g., different types of pharmaceuticals in the basket, consideration of payback of pharmaceutical companies, drugs financed in inpatient care via diagnosis-related groups, ratio of public vs. private pharmaceutical expenditures, and cluster analysis of countries with similar economic status [4,5]). Because of lower salaries in the health care sector, costs of health services are lower in CEE than in Western European (WE) countries, whereas prices of innovative drugs are not significantly different between CEE and WE because of international price referencing and the fear of pharmaceutical parallel trade. Hungary therefore, like other CEE countries, tends to spend a higher percentage of its health care expenditure on pharmaceuticals compared with high-income WE countries [6].

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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Table 1 – Health care and pharmaceutical expenditures in Hungary compared with European OECD countries and Visegrad Group countries.

Health care spending 2014	Hungary	Visegrad Group* average without Hungary	OECD Europe† average
Health expenditure as a share of GDP (%)	7.2	7.0	9.0
Public health expenditure as a share of GDP (%)	4.8	5.5	6.8
Per-capita expenditure on health (€)‡	756	930	3114
Per-capita expenditure on health (US \$ PPP)§	1797	1994	3782
Pharmaceutical spending (% of total health expenditure)	30.2	21.7	15.2
Pharmaceutical spending (% of GDP)	2.1	1.5	1.4

EU, European Union; GDP, gross domestic product; OECD, Organisation for Economic Co-operation and Development; PPP, purchasing power parity.

* The Visegrad Group consists of the Czech Republic, Hungary, Poland, and Slovakia.

† OECD Europe comprises all European members of the OECD (not necessarily EU members). In 2012, these were Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.

‡ Calculated on current exchange rate in 2014 by the Central Bank of Hungary.

§ PPP expressed in US dollars, an internationally comparable scale reflecting the relative domestic purchasing power of currencies.

The Hungarian government has almost exclusive power in formulating strategic direction of the health care system and it is responsible for issuing and enforcing related regulations [7]. A single-payer system was established when the National Health Insurance Fund, the organization responsible for financing health care, was established in 1993, 3 years after the political transition [8]. The Hungarian health care system is financed through both taxes and compulsory, non-risk-related health care contributions by eligible individuals. It can therefore be described as a mandatory public health insurance system [7]. Health services are granted to all Hungarian citizens with only a few exceptions. In addition to the highly centralized public health care system, private health insurance and privately owned hospitals remain to have only a marginal role in Hungary, whereas informal payments represent a significant factor to operate the entire health care system [9].

Stakeholders of Decision Making on Health Technologies

The following key stakeholders are involved in the decision-making process in case of health technologies [10]:

The National Institute of Pharmacy and Nutrition issues marketing authorizations through the same process that has been standardized across the EU. Only health technologies that have received marketing authorization can apply for public reimbursement.

The Hungarian HTA Department was established in 2004. The department is currently part of the National Institute of Pharmacy and Nutrition. Like other EU member states, the aim of establishing an independent health technology assessment (HTA) body in Hungary was to support decision makers in the rational and efficient use of scarce resources, by providing critical appraisals of different health technologies [11]. The HTA Department critically evaluates reimbursement submissions of pharmaceuticals (since 2004), simple medical devices such as therapeutic appliances (e.g., walking stick and hearing aids) (since 2007), and complex medical devices such as hospital technologies (since 2010). The department participates in international projects such as the European Network for Health Technology Assessment, consults with decision makers regarding financial protocols/guidelines, and provides an expert opinion on various issues related to health economics.

Until December 2016, the National Health Insurance Fund (NHIF) was responsible for the administration of the health insurance system and public reimbursement of health technologies. The NHIF collected, processed, and analyzed statistical data on the health insurance system for internal purposes. As a result of recent legal and organizational changes, the NHIF was reorganized to National Institute of Health Insurance Fund Management (NIHIFM) with highly similar responsibilities. In the NIHIFM, the Department of Reimbursement is responsible for coordinating the pricing and reimbursement decision-making process. Health technologies are reimbursed from different dedicated budgets (e.g., primary care, outpatient care, and acute and chronic inpatient care) [12], which are allocated by the NIHIFM from the annual health care budget set by the Ministry for National Economy.

The State Secretary of Health (SSH) together with the Ministry for National Economy have a major influence on the system for financing health technologies through developing, improving, and revising the laws and decrees, in cooperation with the NIHIFM.

There is an independent professional college in Hungary with around 60 branches that support the decision making of the SSH. Professional councils are involved in the development of therapeutic and methodological guidelines and they also participate as a part of the committees and bodies involved in the process of reimbursing health technologies.

The Technology Assessment Committee (TAC) is responsible for preparing recommendations on the reimbursement applications submitted by manufacturers. All relevant stakeholders involved in the HTA process have the opportunity to participate in TAC (i.e., representatives of the NIHIFM, medical professional colleges, Ministry for National Economy, SSH, and the HTA Department) [10].

The National Pharmaceutical Therapeutic Committee is responsible for the development and management of the essential medicines list as well as for coordinating the purchasing procedures and the use of pharmaceuticals that are financed through hospital budgets. The committee produces background analyses to support appropriate therapeutic practice.

Pricing and Reimbursement of Medicines

Procedures for Including Pharmaceuticals in the Positive List

The NIHIFM determines the list of medicinal products that are publicly reimbursed in Hungary. In addition, the NIHIFM may

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