Drug Policy in 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].

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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].

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.

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

<table>
<thead>
<tr>
<th>Health care spending 2014</th>
<th>Hungary</th>
<th>Visegrad Group average without Hungary</th>
<th>OECD Europe(^{1}) average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health expenditure as a share of GDP (%)</td>
<td>7.2</td>
<td>7.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Public health expenditure as a share of GDP (%)</td>
<td>4.8</td>
<td>5.5</td>
<td>6.8</td>
</tr>
<tr>
<td>Per-capita expenditure on health ((^{6}))</td>
<td>756</td>
<td>930</td>
<td>3114</td>
</tr>
<tr>
<td>Per-capita expenditure on health (US $ PPP(^{6}))</td>
<td>1797</td>
<td>1994</td>
<td>3782</td>
</tr>
<tr>
<td>Pharmaceutical spending (% of total health expenditure)</td>
<td>30.2</td>
<td>21.7</td>
<td>15.2</td>
</tr>
<tr>
<td>Pharmaceutical spending (% of GDP)</td>
<td>2.1</td>
<td>1.5</td>
<td>1.4</td>
</tr>
</tbody>
</table>

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

\(^{1}\) 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.

\(^{2}\) PPP expressed in US dollars, an internationally comparable scale reflecting the relative domestic purchasing power of currencies.

### 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.

### 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
Decision-Making Criteria

Several clinical and economic criteria are discussed during the TAC meetings. Accordingly, pursuant to the New Medicines Act [18], a pharmaceutical product may be included into the reimbursement list only at the request of the marketing authorization holder or its representative only if:

1. the competent authority has verified its safety and efficacy and authorized its marketing rights;
2. it is available in an economic and reasonable manner for the purposes of therapeutic use;
3. the cost-effectiveness of its use is proven;
4. the necessary health insurance funding is available (i.e., budget impact);
5. the marketing authorization holder or its representative distributes the product with reimbursement and keeps the product in stock [14].

Reimbursement Categories of New Pharmaceuticals

The Hungarian reimbursement system for pharmaceuticals is very complex and applies several reimbursement techniques. The reimbursement levels are established according to the specifications of the therapies; the more chronic and severe the disease, the higher is the reimbursement level. There are two major types of reimbursement techniques in the outpatient care: the normative reimbursement and the indication-linked reimbursement (Table 2) [12].

Normative reimbursement applies to all physicians with general prescription rights and may be used for all indications listed in the Summary of Product Characteristics. This technique is associated with reimbursement levels of 25%, 55%, and 80%, resulting in levels of patient’s co-payment of 75%, 45%, and 20%, respectively.

Indication-linked reimbursement restricts reimbursement to only certain professionals who can prescribe the drug. The reimbursement is granted only in a subset of authorized indications and is granted if the conditions defined by the payer are met. The levels of reimbursement are 50%, 70%, 90%, and 100%, resulting in levels of patient’s co-payment of 50%, 30%, 10%, and 0%, respectively.

For each unit, there is a fixed prescription fee of ft300 (ft = Hungarian forint; €1 = -ft315 [2016]) for drugs with 0% co-payment. Pharmaceuticals used in the inpatient care have 100% reimbursement and are financed through the implemented hospital financing system (i.e., diagnosis-related groups) [10]. Patient’s co-payment may also vary according to the applied internal reference pricing system for off-patent products (for generics and biosimilars, see detailed descriptions later).

There is no separate reimbursement technique for orphan drugs in Hungary. Patients can, however, receive these pharmaceuticals individually or through the itemized reimbursement system purchased via central tendering. Individual reimbursement is also available under the principles of equity in case of pharmaceuticals that are not on the regular reimbursement list (named patient program) [19].
Pricing and Reimbursement of Generic Drugs

In Hungary, internal price referencing is applied for generic (multisource) drugs. This means that drugs with the same active compound (international nonproprietary name [INN]) or same therapeutic effect (e.g., me-too products such as different proton pump inhibitors—pantoprazole, omeprazole, etc.) are considered to be equivalent from a reimbursement perspective. In such a group, the lowest priced product is the reference drug, which is reimbursed at a predefined percentage (see reimbursement categories earlier). Products with minor price differences compared with the reference product have the same amount of reimbursement but an increased co-payment (i.e., resulting lower percentage of reimbursement). Products with significant price differences over the reference drug are delisted from the reimbursement list.

Until 2011, the generic drug with the lowest price became the reference product and a new reference product was announced every 3 months. Before 2011, the entrance of new generic drugs was the main driver of generic price erosion with a predefined mandatory reduction for new entrants of 40%, 20%, 10%, 5%, 5%, and 5% for the first, second, third, and so on generic product. For the seventh generic product on the market, it was enough to offer an initial price reduction of Ft1.

From 2011, a new blind bidding procedure for the generic reference pricing scheme has been introduced to further facilitate price erosion. In every 6 months, generic manufacturers may submit their price reduction proposals via an online application system operated by the NIHIFM for their drugs, but without knowing the proposals submitted by their competitors. After the closure of the bidding process, the lowest price drug becomes the reference product. Products with less than 15% price differential compared with the reference product have equal amount of reimbursement, which translates to a relatively higher percentage of co-payment because of higher total price. Products with more than 15% price differential compared with the reference product can have only 85% reimbursement of the price of the reference product. The blind bidding procedure has been proven to be a very efficient tool to

Table 2 – Reimbursement techniques in the outpatient care.

<table>
<thead>
<tr>
<th>Name of reimbursement technique</th>
<th>% of reimbursement</th>
<th>% of co-payment</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normative reimbursement</td>
<td>25</td>
<td>75</td>
<td>Acute antibiotics, analgesics</td>
</tr>
<tr>
<td></td>
<td>55</td>
<td>45</td>
<td>β-Blockers, proton pump inhibitors</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>20</td>
<td>Statins, ACE inhibitors</td>
</tr>
<tr>
<td>Indication-linked reimbursement</td>
<td>50</td>
<td>50</td>
<td>Acarbose, trimetazidine</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>30</td>
<td>Clopidogrel, bisphosphonate</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>10</td>
<td>Levetiracetam, ivabradine</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>0</td>
<td>Analogue insulin, erythropoietin</td>
</tr>
</tbody>
</table>

ACE, angiotensin-converting enzyme.
facilitate price erosion of generic medicines resulting in regularly changing generic reference products.

Physicians are obligated to offer the cheapest alternative generic product from an interchangeability list. Patients need to be informed on generic substitution the first time they start using their medication. Also, preferred reference products need to be kept in stock by pharmacies.

Prescribing generics as an INN is not mandatory for physicians. Nevertheless, INN prescription was introduced for statins in 2012 as a pilot program. Unfortunately, no results of this policy have been published yet.

Pricing and Reimbursement of Biosimilar Drugs

For follow-on biologics (biosimilars), the first biosimilar entering the market needs to offer a price reduction of 30%, the second an additional 10%, and the third a further 10% as well. For erythropoietins and granulocyte colony-stimulating factors, a so-called bio bidding system was introduced in 2012 [20]. Bio bids are organized annually; in each group of biologics the ones with the lowest price are "preferred" drugs. Because these products have 100% reimbursement, there is only a prescription fee of Ft300 (€1) as co-payment. Drugs with a price of maximum 10% higher than the reference product (i.e., the cheapest) can still be preferred drugs. Drugs with a price between 10% and 50% higher than that of reference products are required to compensate the payer for the increased price with payback and are associated with a co-payment between Ft1500 (€5–€11). Increased co-payment is therefore a disincentive for patients to use these products. Products with more than 50% higher price than the reference product are delisted from reimbursement (i.e., positive list) 4 months after the bio bidding. Until that time, they have a co-payment of ft3500 (€11). This allows some time for the patients and the physicians to switch to a preferred product if necessary. In addition, physicians are required to prescribe preferred biologics in a minimum of 10% of their overall biologic prescription in year 0, 40% in year 1, and 70% from year 2. Other biologics, such as monoclonal antibodies, are purchased through a central tendering system because of their higher complexity and longer use of treatment. The key criterion to win the 2-year tender is the price.

Reimbursement of Nonpharmaceutical Technologies

The reimbursement decision-making process for medical devices and technologies is similar to the one described for pharmaceuticals except that in 2010 multicriteria decision analysis was introduced by the NIHIFM for these devices and technologies [21]. The reimbursement process is even more simplified in the case of simple medical devices such as therapeutic appliances, with no TAC meeting taking place.

Revision of Reimbursement Decisions

According to the regulation, the NIHIFM shall routinely review the scope of subsidized health technologies. This should be conducted if any doubt arises in terms of cost-effectiveness with respect to products already approved for reimbursement. In addition, revision is required if the product imposes an unreasonable burden on the budget of the NIHIFM compared with the advantage it offers in terms of therapeutic efficacy. Furthermore, reimbursement should be revised for the products that are subject to be included in a financing protocol/guideline, or for the products for which the related financial protocol/guideline is under revision after 3 years of development [14]. Nevertheless, in practice, reimbursement decisions are revised only ad hoc.

Additional Cost-Containment Measures

Several additional cost-containment measures besides those introduced earlier are applied in Hungary, which may affect all stakeholders, including manufacturers, wholesalers, pharmacists, physicians, and patients.

1. In 2013, itemized reimbursed technique (special case-by-case reimbursement technique) was established. It is applied for high-price innovative products generally used in inpatient care. They usually require additional budget and/or legislative adjustments and are purchased via central tendering (government procurement) system. This means that for these products quotas are defined at the institutional level, resulting in assigned volume for annual consumption for each hospital. A special committee (Itemized Reimbursement Committee) similar to TAC was also established to evaluate pharmaceuticals applying for such reimbursement.

2. There is an obligatory contribution for manufacturers after their reimbursed products are sold in pharmacies, amounting to 20% of the reimbursement amount calculated on exactory price level and an additional 10% tax for innovative drugs with a history of at least 6 years of reimbursement and without reimbursed generic alternatives in Hungary [22].

3. Wholesalers need to pay back a certain percentage of their wholesale margin.

4. Marketing activities of manufacturers are strictly regulated (e.g., there is a registration fee for sales representatives).

5. Wholesale and pharmacy margins are regressive, capped, and regulated in a ministerial decree [23].

6. General practitioners receive feedback of their prescribing practice from the NIHIFM on the basis of multiple indicators. Their prescription practice is guided with target levels and financing protocols. Quality standards for general practitioners are used to improve their prescription practice. If they meet multiple criteria of rationale prescribing defined in disease areas such as dyslipidemia, antibiotics, and hypertension, additional funds are available for them. Physicians are not assigned to pharmaceutical budgets.

HTA Implementation

In Hungary, compared with other CEE countries, HTA implementation and the related capacity building has a relatively long history [11,12]. The Hungarian Health Economics Association was established in 2003 [8] and became the ISPOR Hungary chapter in 2007. The association organizes monthly meetings dedicated to various topics on health economics, health policy, and outcomes research and organizes a 2-day annual conference providing a platform for scientific discussions and networking for multiple stakeholders from the academia, industry, government, and health care professionals [11]. The association also publishes methodological articles in the field of health economics, most notably the Hungarian Pharmacoeconomic Guideline that was first published in 2003 [24] and was revised in 2013 [25] and 2016. The guideline gives an in-depth description of the requirements of conducting a proper HTA analysis in Hungary. It also sets an explicit cost-effectiveness threshold at 2 to 3 times the annual GDP per capita. Furthermore, it highlights that HTA analyses should be adapted to the Hungarian settings and should follow the Hungarian Pharmacoeconomic Guideline as much as possible [26]. A detailed methodological checklist of 91 questions is also available for the critical appraisal of HTA analyses that covers a wide range of potential methodological issues from 11 main topics including comparator selection, efficacy, effectiveness, costs, sensitivity analysis, and interpretation of the results. The
Data Collection and Real-World Data Use

The NIHIFM manages, operates, and develops the information database (payers’ database) to perform its health insurance functions. Hence, real-world data are collected and used to inform the government to define the annual health insurance fund included in the central government budget. Real-world data are also used for internal purposes to allocate financial resources of the annual health care budget and to monitor health care spending. In addition, the NIHIFM collects statistical data and publishes information on the consumption of medicines or simple medical devices and list prices of registered drugs.

For research purposes, more detailed data (i.e., anonymized personal level data) may be available on request. Quality of the data is ensured internally only by the NIHIFM. For nonprofit organizations (e.g., universities and governmental bodies), the data provision is generally free of charge. For profit-oriented organizations, the service fees of NIHIFM for data provision are defined depending on the required effort to provide the data (i.e., working hours of the NIHIFM IT Department) and on the requested quantity and type of data (e.g., need for linking different databases). Nevertheless, access to data is sometimes not fully transparent.

It is well recognized that real-world data analyses may contribute to continuous improvement in pharmaceutical policy decisions in CEE countries [22]. Several such cases can be identified in Hungary. For instance, the full reimbursement of analogue insulin after 1 year is granted only if the glycated hemoglobin level decreases below a predefined level, which is regularly monitored and reviewed by the national payer. In case of high-priced medicines on the itemized reimbursement list, the central tendering process is also based on real-world data (i.e., consumption of previous years). Because risk-sharing agreements such as price-volume agreements are mandatory in case of all new active ingredients, the NIHIFM collects, monitors, and evaluates real-world data for this purpose as well. The Hungarian National Cancer Registry was established in 2000, and efforts to link the registry with the NIHIFM database were made to improve the monitoring of services provided to patients with cancer (e.g., population-based cancer screening). There is, however, no publicly available information on the success of such a linking process. Similar processes can be identified in case of the National Myocardial Infarction Register.

Conclusions

Hungary is a lower income EU member state with a mandatory health insurance system financed through both taxes and compulsory health care contributions. Compared with other CEE countries, HTA has a relatively long history in Hungary. Clinical and economic (cost-effectiveness and budget impact) inclusion criteria are key factors in pharmaceuticals’ reimbursement decision-making process. For patented and off-patent medicines to be included in the positive drug list, the external price referencing system and the internal price referencing system are applied, respectively. Public reimbursement of medicines has a well-established and complex system in Hungary with various implemented cost-containment measures.

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REFERENCES


