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Health technology assessment in reimbursement policy of the Slovak Republic

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Abstract

Evidence suggests that availability of medicines on the Slovak market is both comprehensive and prompt. The low co-payment rate of reimbursed products results in easy access to highly priced patented products. There is always at least one treatment available in determined therapeutic classes with no co-payment. Evidence suggests that Slovak pharmaceutical expenditures do not result in the most cost effective outcomes. The use of HTA in the decision-making process is vague.

Key words: HTA, decision-making process, reimbursement, Slovak Republic

According to OECD Health Data (2010), spending on pharmaceuticals in Slovakia (US$ 489 per capita in PPP) is at the same level as the OECD (US$ 490) and much higher than in Hungary (US$ 454), the Czech Republic (US$ 363) or Poland (US$ 274). Combined with the lower economic performance of Slovakia (US$ 22 193 per capita in PPP) compared to the OECD average (US$ 33 271) this means that pharmaceutical expenditure in Slovakia is 2.2% of GDP compared to 1.5% GDP in the OECD, or 28% of total health care spending versus 16% in the OECD. The Slovak Ministry of Health is responsible for determining which pharmaceuticals are reimbursed and at what share of the retail price reimbursement will be made. In the decision-making, the Ministry is assisted by an advisory body called the Categorisation Committee. The recommendation of the Categorisation Committee can be overruled by the Minister of Health. Decisions regarding the reimbursement level are made once the maximum retail price has been established. A single application is filed for both pricing and reimbursement. Applicants must submit the basic drug information (name, manufacturer, authorisation holder, pharmaceutical form, pack size and strength), evidence on effectiveness, the standard therapeutic dose (STD) and the number of the standard therapeutic doses (STDs)/pack. Applicants also present the desired reimbursement rate, the proposed indication and any prescribing restrictions.

The Categorisation Committee considers several factors when selecting the reimbursement category, which defines the rate of reimbursement: the efficacy, the morbidity and mortality reduction, the indications and contraindications, the incidence of side effects, treatment doses for the given indication, the frequency of administration, the interaction profile, the level of patient acceptance and the relative improvement of the drug compared with current standard treatment options. For those products designated as eligible for partial reimbursement, the decision on reimbursement level is based on three main considerations: the therapeutic benefit of the drug, its retail end price, and the reimbursed prices of other products within its reference category. The reasoning underlying particular reimbursement decisions is disclosed.

The positive list can include drugs, which are reimbursed with restrictions, e.g. they can be prescribed by certain specialists only, or in narrower indications than specified by the summary of product characteristics (the description of the product's properties and conditions of use, such as pharmaceutical form and strength, authorised applications, adverse reactions, etc.) or, in the case of certain oncology products, only in certain hospitals as well.

Price changes for a particular drug may influence the reimbursement of other pharmaceuticals in the same 5-digit or 4-digit ATC group. Internal reference pricing provides the basis for determining the actual reimbursement amount paid for drugs that have equivalents on the Slovak market. Reference pricing is generally applied to drugs with the same active ingredient (5-digit ATC). The actual reim-

bursement amount cannot be higher than that of the cheapest drug in the same 5-digit ATC category. For some therapeutic groups, internal reference pricing is extended to pharmaceuticals with the same molecular structure (4-digit ATC): the actual reimbursement of products with different active ingredients is linked to the cheapest alternative in that 4-digit ATC category. The price per STD of the cheapest available drug in the ATC group is the selected reference for reimbursement. The co-payment for other drugs in the reference group with a higher price per STD is the difference between the actual retail price and the price of the reference product after adjustment for the STD per pack size.

The prices of pharmaceuticals covered by health insurance companies are regulated, both in the ambulatory and inpatient sectors. After obtaining an authorization to enter the market, the ex-factory price of the pharmaceutical is determined by the Ministry of Health through external reference pricing. The ex-factory price may not exceed the second lowest prices of the same pharmaceutical sold across the EU. If the price of a drug for the Slovak market exceeds this level it can be rejected from the reimbursement list.

The prices of OTC pharmaceuticals and prescription pharmaceuticals not covered by health insurance have been deregulated. Since 2008, there is degressive system in place, which sets margins separately for distributors and pharmacies based on the ex-factory price (Szalay et al. 2011). The Categorisation Committee consists of 11 members. Ten of the eleven have permanent positions and one is a temporay expert, rotating according to the topic of disscusion. Five of the committee members are representatives of health insurance funds, 3 members are representatives of the Slovak Ministry of Health and the rest are representatives of the Slovakian Medical associations. The Categorisation Committee is assisted by 3 different boards: the medical, the economic and pharmacoeconomic board. The medical board is one of 22 medical expert groups organized by therapeutic areas. The economic board deals with drug pricing.

The submission for reimbursement from the side of pharmaceutical companies has to include pharmacoeconomic analysis for all new molucules, new indications or galenic forms of drugs. The board for pharmacoeconomics analyses dossiers related to economic studies submitted for categorisation process of drugs. There is no doubt that economic evaluations of drugs should aid the decision-making process in terms of enhancing the information on which decisions are based, allows decision-makers to make informed choices based on evidence, and contributes to an efficient resource allocation. The first Slovak guideline for pharmacoeconomic analysis was revealed on the website of the Ministry of Health of the Slovak Republic on the 26th of September in 2008. These methodological guidelines, provide guidance to manufacturers, sponsors and healthcare providers preparing health economic evaluation to support submissions to secure reimbursement for goods and services provided from public funds under the control of the health insurance funds and the Slovak Ministry of Health. They aim to stimulate the provision of standardised, reliable and good quality information for the Categorisation Committee. The ultimate objective of the guidelines is to facilitate the cost-effective use of scarce healthcare resources. In line with recommendations from the Ministry of Health, the pharmaceutical is assessed using cost-minimization, cost–effectiveness, and cost–utility analysis. The general principle is that the analysis should adopt the perspective of the audience targeted by the authors of studies. For the reimbursement process from public funds it has to be the perspective of health insurance companies. In the case of studies with a time horizon longer than 1 year the principles of time preference and the opportunity costs of investments should be taken into account through discounting. In the base case both future health gains and costs should be discounted at 5%. When the more effective therapy has higher costs than the alternative intervention, the incremental cost-effectiveness ratio must be calculated. In these cases the Categorisation Committee considers whether the unit of additional health improvement is 'worth' its additional cost. The recommended threshold of a cost-effective new technology was set in the Slovak republic € 18 000 - € 26 500/ per a quality-adjusted life year (QALY). Pharmaceuticals with lower costs per QALY than € 18 000 are considered cost-effective. In contrast, pharmaceuticals that exceed € 26 500 per QALY are considered non-cost-effective. Interventions with cost-effectiveness ratios between the lower and upper limit are subject to further consideration. Our decision-making approaches suggest that no single threshold value should apply to all interventions but cost per QALY results should be judged together with overall budgetary

impact of a treatment in question. However, there is significant room for improvement because the use of relevant HTA in the decision-making process is inaccurate within the Slovak Republic.

Evidence suggests that Slovak pharmaceutical expenditures do not result in the most cost-effective outcomes. According to study of Kaló at al. (2008), several potentially not cost-effective pharmaceuticals have been reimbursed in Slovakia. It is especially true if we consider that strategic pricing of the innovative products are not based on small markets with low purchasing power (like Slovakia). The price level of new drugs is adjusted to wealthier countries with greater willingness to pay for a quality adjusted life year gain. It can be concluded that economic evaluations of drugs and medical devices are mandatory in the Slovak Republic but the quality of evaluations and critical appraisals are rather poor. In addition to the available Slovak health economic evaluation guidelines a detailed checklist for appraisal processes have to be prepared. Approved changes in the legislation within the Slovak republic from 2011 emphasize the role of HTA for the reimbursement policy.

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