

International reference pricing in the Slovak Republic

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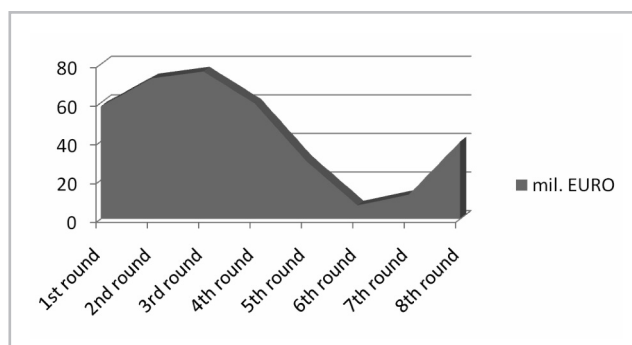
The main factors leading to price differences among countries include national income per capita, national regulatory policies for pricing, value assessment of pharmaceuticals, approaches to regulating wholesale and taxation of pharmaceuticals. The Slovak Republic uses a range of mechanisms to regulate pharmaceutical prices and reimbursement rates. In the past, the Slovak Republic was considered as a country with relevant potentials for parallel import of drugs. In the present time, the ex-factory price is fixed at the second lowest price in the EU and the situation was changed. Significant positive effects within the Slovak health care budget can be seen due to the international reference pricing between 2007 and 2012. We have not seen significant consequences for patient access to medicines in terms of both availability and affordability due to international reference pricing until now.

It is well known that there are significant price differences among EU Member States. Studies show, that for a basket of 150 medicines, the national averages differ by up to 25%. For individual pharmaceuticals sold across the EU, price differences are even higher. For patent-protected individual pharmaceuticals, differences as high as 4:1 have been observed between the highest and lowest prices. Price differences appear even greater for pharmaceuticals whose patents have expired, as generic versions increase market competition. For these medicines, differences as high as 16:1 have been observed among EU Member States for individual generic pharmaceuticals [1].

Different countries using international reference pricing create a basket of other countries whose prices they wish to use as benchmarks to set national pharmaceutical prices. The lowest price, or an average of the lowest prices in the basket, is defined as the reference price. International reference pricing is used as a means to set a maximum price for a pharmaceutical product. International reference pricing can help cost-containment by reducing prices. However there are concerns arising from the fact that it is an arbitrary measure targeting prices that ignores other aspects of the market, the particular health priorities in each country and creates uncertainty for particular segments of the pharmaceutical industry, especially due to the impact of exchange rate fluctuations on reference prices.

International reference pricing significantly contributes to lower pharmaceutical prices within the Slovak Republic. The following changes in methods for international reference pricing in the Slovak Republic could be seen.

- The ex-factory price may not exceed the average of the three lowest prices of the same pharmaceutical sold across the EU plus 10%.
- The ex-factory price may not exceed the average of the six lowest prices of the same pharmaceutical sold across the EU.
- The ex-factory price fixed at the second lowest price in the EU.



Graph 1
Savings based on international reference pricing within the Slovak pharmaceutical market between 2007 and 2012.

In the graph 1, savings based on international reference pricing using different methods within the Slovak pharmaceutical market can be seen. The first round of international reference pricing was in 2007 and the 8th in 2012. Currently, we can see significant positive effects within the Slovak health care budget due to the international reference pricing in the Slovak Republic. We have not seen significant consequences for patient access to medicines in terms of both availability and affordability due to international reference pricing until now.

We are aware, that among the unintended consequences of international reference pricing is the reality that manufacturers are likely not to launch a product in a certain country if that country's price influences third countries, or it is likely to be too low and, therefore, encourages parallel exports. "Parallel trade" practices have developed to take advantage of the differences in prices among countries. The EU single market allows distributors and other market actors to purchase pharmaceuticals in EU Member States with lower prices and re-sell them where prices are higher. The market share of parallel-traded pharmaceutical products in the main importing Member States stands between 1.7% in Finland and 16.5% in Denmark. This practice, which has been reviewed and upheld by the European Court of Justice, has been cited as a mechanism that can reduce prices in the sales markets [1]. There is intense debate about

the extent to which parallel trade can reduce or eliminate price differences between countries. Evidence suggests that a large share of the surplus generated by parallel trade is captured by intermediaries, and does not accrue to patients or health systems. Parallel trade does not appear to be significantly reducing pharmaceutical prices in those countries where they are high. In the past, the Slovak Republic was considered as a country with relevant potentials for parallel import of drugs. 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. (OECD Health Data 2010)

In the present time, the ex-factory price is fixed at the second lowest price in the EU and the situation concerning to parallel import to Slovakia was changed.

The important price differences across countries can be explained by a number of factors. One broad factor is national income per capita. Prices of in-patent pharmaceuticals seem to be proportionally higher in countries with higher levels of per-capita income. In addition, higher-income countries appear to spend more on pharmaceuticals.

A second key factor relates to particular national regulatory approaches. Countries use a variety of tools, both on the supply side (for determining both prices as well as the share of prices that are reimbursed) and on the demand side. On the supply side, health care systems usually negotiate prices with manufacturers based on a range of methods and criteria, and this is a factor in the price differences for pharmaceuticals, both those covered by patent and those for which the patents have expired. There is no doubt that reimbursement decisions also affect price.

Countries use a range of mechanisms to regulate pharmaceutical prices and reimbursement rates. External price referencing can be either applied at the launch of new medicines, where it usually follows an average price rule, or on an ongoing basis, where the use of a lowest price rule can result in price reductions over time. Health Technology Assessment (HTA) is increasingly used to appraise new pharmaceuticals in relation to comparable existing ones. As different countries have different ways of accepting evidence and interpreting it, variations exist in the application of HTA appraisals, and these can result in diverging coverage

decisions for the same pharmaceutical across different countries. Evidence suggests that availability of medicines on the Slovakian market is both comprehensive and prompt. The Slovakian coverage scheme promotes access to medicines. However, it can be seen that Slovak pharmaceutical expenditures do not result in the most cost effective outcomes [3].

The main regulatory approaches for pharmaceuticals no longer protected by patents and subject to competition from “generics” include internal reference pricing, tendering for out-patient medicines and price capping linking generic prices to those of originator prices. These policies can allow health systems to achieve some savings on their pharmaceutical budgets through the purchase of lower-priced generic medicines. Another important factor is the level of VAT rates, which vary across countries and have risen in recent years in some of them. Differences in distribution systems and their regulation account for a share of the differences in the cost of medicines across countries.

It is clear that a problem is seen where a low price in one national market for a new product can lead manufacturers to refrain from launching the product in other markets, since the low price might jeopardise their pricing prospects elsewhere due to the wide application of external price referencing. The availability of some generic medicines may be related to the size of geographical or product markets. In small national markets, the expected return from the sales of generic medicines may not exceed the entry cost. The same may hold for small product markets. In such cases, generics are not available for one or more medicines. The result is often more expensive choices for patients and health systems. One important concern is that parallel trade might potentially lead to shortages in exporting countries.

On the other hand, richer countries appear to spend more on pharmaceuticals. This may be due to either higher average pharmaceutical prices or higher per capita consumption in volume terms. Manufacturers in turn, have greater incentives to launch and market products in countries with high reimbursement levels and comprehensive coverage, as it is more likely that there will be sufficient demand to ensure their profitability. Higher-income countries are thus better placed to ensure access to new and expensive pharmaceuticals. Conversely, smaller countries, especially those with lower per capita GDP may be unable to afford widespread coverage or high reimbursement levels, and will therefore have a smaller market width to attract manufacturers. It is well known, that access to certain categories of pharmaceuticals tends to be negatively correlated with market size and per capita GDP [1].

LITERATURE

[1] Panos Kanavos at al. Differences in costs of and Access to pharmaceutical products in the EU.

[<http://www.europarl.europa.eu/document/activities/cont/201201/20120130ATT36575/20120130ATT36575EN.pdf>, accessed 20th august 2012].

[2] Health Data 2010. Paris, Organisation for Economic Co-operation and Development [<http://www.oecd.org>, accessed 27 March 2011].

[3] Zoltán Kaló, Elizabeth Docteur and Pierre Moïse: Pharmaceutical pricing and reimbursement policies in Slovakia, OECD Health working paper, 2008.

RÉSUMÉ



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Folytatás az 55. oldalról

Mennyit tudunk a veséről és a vese betegségeiről?

A vese program kérdőívét 250-en töltötték ki. A tesztben részben a vese működésére vonatkozó ismeretekre, részben a vesebetegségekkel kapcsolatos statisztikai adatokra kérdeztünk rá.

Elképesztő, hogy akadnak olyanok is, – a válaszolók 10 százaléka – akik szerint egyetlen vesénk van. Ez azt is jelenti, hogy nem vagyunk tisztában testünk felépítésével, szerveink működésével, ami azért baj, mert így nem ismerhetjük fel időben a tüneteket, testünk jelzéseit sem.

Sajnos keveset tudunk arról is, hogy hány embert érint ma Magyarországon a vesebetegség. Sokan tippeltek mindössze 5-6 ezer emberre, a legtöbben viszont – 70 százalék – félmillióra. Tehát viszonylag kevesen tudták, hogy minden tízedik ember érintett.

A tesztet kitöltők nagy része – 60 százaléka – nem tudta, hogy a vesebetegség legfontosabb oka, nem az életkor előrehaladása – amire a legtöbben voksoltak – hanem a magas vérnyomás, a túlsúly, és a diabétesz.

Ez azért is figyelemre méltó, mert a Nemzeti Veseprogram mellett a Magyar Hypertónia Társaság és a Magyar Diabétesz Társaság is rendszeresen tart felvilágosító kampányokat a témáról. A megkérdezettek egy része azért tudta, hogy az említett népbetegségek vesebetegséghez vezethetnek. A kérdőív második oldala szubjektív információkra épített. Azt tudakolta például, hogy a válaszoló melyik három betegségről hallott a legtöbbet. A rák, a stroke, és az infarktus a legismertebb, a vese megbetegedései nem szerepelnek a válaszolók listáin. A vesebetegségekről szóló informálást egy 5-ös fokozatú skálán 2 és 3 közé teszik a legtöbben.

Abban, hogy a kommunikáció nem ér el jobb osztályzatot, jelentős szerep hárul a médiára, és arra a ma divatos helytelen megközelítésre, hogy csak a rémhír, a tragédia, a negatív szenzáció, és a politikai hír szerepel elsősorban a hírkategóriában. Ebből az is következik, hogy a Nemzeti Vese Programnak növelnie kell aktivitását. Csak így érheti el célját, hogy Magyarországon társadalmi összefogással minél többen ismerjék meg a prevenció lehetőségeit, a vese alap- és kísérőbetegségeit, kezelési módjait, a szövődmények elkerülésének lehetőségét, illetve, ha ez már nem megy: a vesepótló eljárásokat, beleértve a dialízist és a transzplantációt is.

Szerk.