

Reimbursement of pharmaceuticals in the Czech Republic, Slovakia and Hungary – the update on reference pricing and risk sharing

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Abstract

There is a limited amount of published evidence, available to the international audience, on experiences from implementation of various initiatives within the field of pharmaceutical policies of the Czech Republic, Slovakia and Hungary. The reference pricing, both internal and external, has been introduced in the nineties of the 20th century in all countries of the Visegrad Group, however each country has developed its own local version. Hungary has the strongest experience related to the pharmaceutical risk sharing. Due to the economic crisis, the Hungarian health care system is under extremely strong pressure to keep pharmaceutical expenditures on a low level, which could possibly conflict with the appropriate provision of drugs. There is a well justified need for a more intensive exchange of experiences related to pharmaceutical pricing and reimbursement among the Visegrad Group countries - especially today, in the era of the global financial austerities.

Article contains current information on pharmaceutical reference pricing and risk sharing in Czech Republic, Slovakia and Hungary.

Key words: pharmaceutical policy, pharmaceutical pricing and reimbursement, reference pricing, risk sharing, Czech Republic, Slovakia, Hungary

Introduction

On 15th of February 1991, during a high-level meeting in Visegrad, Hungary, the Presidents of Poland (Lech Walesa) and the Czechoslovak Republic (Vaclav Havel) together with the Hungarian Prime Minister (Jozsef Antall) created a network of cooperation between their three neighboring countries. It was named the Visegrad Group and later, after the division of Czechoslovakia in 1994, the Visegrad Four or just simply V4. The idea of cooperation among countries of Central Europe (CE) could be closely linked to expectations, which had three other leaders, the Kings of Poland, Bohemia and Hungary, far back in time,

in 1335. Those kings met exactly in the same place near today's Budapest in order to intensify cooperation and friendship between their states [1].

In June 2012 the Hungarian Journal for Healthcare Managers (IME) together with the Hungarian Health Economics Association (META) organized a big conference in Budapest on a vast array of current problems of health economics. Its title was quite self-explanatory: "Health economics, growing importance in scarcity". Large number of participants came mostly from Hungary and they included academics, professionals from fields of medicine, pharmacy, HTA and pharmaceutical policy, and industry representatives. From about 40 presentations and numerous posters, five lectures were clustered into one international session: "International reference pricing and individual price agreements in drug pricing". During that session the speakers analyzed problems of pharmaceutical policies in Hungary, the Czech Republic, Slovakia and Poland [2, 3, 4, 5]. The synthetic approach was also taken and all speakers, as well as the Hungarian audience, concluded that there are so many features and problems of the national health care systems, which are common to all four countries, that it would be unwise not to draw from the neighbor's experiences and to ignore lessons learned just behind the border.

There is much more evidence on pharmaceutical pricing and policy problems, published in English (being truly the "lingua Latina" of today's scientific world) and coming from countries, like the USA, the UK or even Australia - than evidence coming from countries of CE. Local environment, political culture, level of economic development and many other features and experiences of the CE

countries are often very different from those countries, which have been more extensively described in the scientific literature. It is also much easier to find the published evidence related to several far-away countries (in terms of either geography or important contexts influencing applicability of research conclusions), than to any country of the V4 Group. A “quick and dirty” test seems to be proving it. Exercise of typing into the Embase (date of testing: 29.08.2012) the search words “pharmaceutical“, “reimbursement”, combined by operator AND, and then adding alternatively the name of a given country, gives the following results: 348 records for the USA, 266 for the UK, 147 for Australia, 32 for the Czech Republic, 14 for Slovakia, 29 for Hungary and 28 for Poland. Many records relevant for the CE countries are available only in abstract forms, in the English language. Their full text versions turn out to be difficult to obtain and written in national languages. It seems that the old idea of cooperation among the CE countries, the same which gave rise to establishing the V4 Group more than 20 years ago, still waits for a more complete implementation, as it comes to the exchange of scientific knowledge and sharing evidence on health care policy developments. This paper presents some of the current problems of pharmaceutical pricing and reimbursement policy in CE and it utilizes lessons learned from the Budapest meeting of health economists.

The Czech Republic

Development of the current pharmaceutical pricing and reimbursement system in Czechia has been marked by four milestones [3]:

1. introduction of therapeutic groups in 1994,
2. generic substitution in 2007,
3. application of international reference pricing, using the EU lowest price as reference and introduction of provisional reimbursement in 2008,
4. introduction of electronic auctions and tight price regulations in 2012.

The Czech Republic regulates ex-factory prices of reimbursed pharmaceuticals and strives to achieve the lowest EU prices. For calculating the maximum price, the average price of the three lowest prices of a product in a basket of selected EU countries is being used. Since 2008, within framework of external (international) referencing, the lowest price of all drugs from therapeutic group,

from the entire EU, has been used as a reference price for basic reimbursement. These processes in the Czech pharmaceutical pricing and reimbursement policy have been named “the double regulation”. The internal and external referencing have been interrelated in the Czech Republic. Therapeutic groups (clusters) have been applied since 1994. There are more than 300 of them now and they differ in level of heterogeneity – from very low (e.g. ACE inhibitors) through intermediate (e.g. atypical antipsychotics) to very high (e.g. biological drugs like etanercept, infliximab, adalimumab, abatacept). The WHO system of ATC (Anatomical Therapeutic Chemical) classification of pharmaceuticals has been used in defining reference groups. There is a tendency to keep prices of drugs within therapeutic groups on a rather homogenous level, according to the rule that a surcharge rewarding superior, evidence-based benefits, in comparison to other drugs in the same group, should not exceed 30% above the basic reimbursement level within a group. About 60% of prescribed pharmaceuticals (measured by a number of packs sold) do not require co-payment higher than a small user fee introduced in 2008; slightly above EUR 1,00 [3, 6].

Besides the external and internal referencing, the application of HTA is considered one of the main pillars of the current drug reimbursement system in the Czech Republic. However, no specialized national HTA agency has been created so far. Instead, the State Institute of Drug Control serves as a hybrid institution responsible for simplified HTA application. The Ministry of Health is planning to implement new, more advanced HTA procedures in 2013, separating assessment from appraisal of health technologies. Risk sharing, which has been increasingly popular in many countries, over a span of recent years, has not been introduced yet into the Czech pharmaceutical reimbursement system [3].

Slovakia

The international reference pricing in Slovakia has been evolving. According to regulations of 2004 the ex-factory price could not exceed 110% of the average of the three lowest prices of the same drug sold across the EU. In practice, implementation of this rule was hampered by a poor access to relevant information and a weak political will. There was a noticeable impact of a relative

strength of the Slovak local currency (Slovakia entered the Euro zone on 01.01.2009), especially in 2005. Many drugs on the Slovak market between 2005 and 2007 had exceptionally high prices, as compared to countries of the EU. The pricing regulations were changed in 2008 and since then the price could not exceed the average of the six lowest prices of the same drug within the EU. Starting from 2012 the second lowest price within the EU has been used in order to set prices of drugs entering the Slovak market. The above regulations and recent changes have not influenced drug deliveries for the Slovak pharmaceutical market in a dramatic way. The impact of external reference pricing on the health care budget within last five years has been assessed positively [4].

The definition of reference group is narrow in Slovakia and it relates to drugs which contain the same active substance and are administered uniformly. Only in certain cases the health authorities (role of the Reimbursement Committee) may decide to create a separate reference group for pharmaceuticals having a different way of administration and a different amount of active substance per dose. The reimbursement from public sources is set as the maximum price for a standard daily dose in the reference group. Generic substitution has been in place since 2005, although in case of some active substances it has been prohibited, according to the list issued by the Minister of Health [7].

Application of HTA in pharmaceutical reimbursement decision-making is considered rather vague in Slovakia, although there have been on-going legislative changes, starting 2011, which should result in a stronger impact of HTA on the pharmaceutical reimbursement policy [8].

Hungary

Hungary regulates prices of reimbursed pharmaceuticals and setting them is being achieved through negotiations. Both external and internal referencing have been applied and the HTA has been used for new substances. The generic reference pricing was introduced in 1999 and in 2003 it was supplemented by the therapeutic referencing. Decisions on inclusion into drug groups were based on the ATC classification and the Defined Daily Doses of active ingredients [9]. The price of a new preparation cannot exceed the price from a group of selected countries. Starting 2007 the Hungarian government has been

increasingly putting emphasis on fostering competition and refining the internal reference pricing. Introduction of more rigorous rules for excluding the most expensive products from competitive substance groups was a part of this new policy. Other pro-competitive measures have embraced liberalizing rules of ownership of pharmacies, increasing accountability of physicians in their prescribing behavior and more extensive use of information technologies in monitoring of the drug market [10].

The claw-back system is also in use and risk sharing, in the form of individual price-volume agreements on selected drugs, has been used since 2003. The partial repayments made by manufacturers are based on an agreed limit of a yearly volume of sales and the share of repayment changes progressively, depending on the level of overspending [10]. Outcome-based reimbursement schemes as a form of risk-sharing have become a part of a broader response to intrinsic problems of the Hungarian economy and the global crisis. As representatives of the National Health Insurance Fund Administration (in Hungarian: OEP) were reporting in 2009, the most important challenges related to design and implementation of those schemes were related to appropriate measurement of treatment outcomes, as well as both direct and indirect costs. Obtaining those data was necessary for calculation of expected payback and three main difficulties were identified with regard to this [11]:

1. low reliability of epidemiological data and general health outcome indicators,
2. frequent practices of subjecting the financing (DRG) data, through which indirect costs could be assessed, to profit-maximizing style of coding,
3. necessity to keep the administrative costs of these schemes on a reasonably low level.

The news from Hungary in the middle of summer of 2012 were rather disturbing. The OEP reported to be running out of funds in its pharmaceutical budget, since 80% of it were spent by the beginning of August. The injection of the substantial sum of USD 316, 39 million into the healthcare system's financial bloodstream has been reported to be necessary. This would prevent a financial crash of the system but the OEP reserves have been reported to be only USD 185, 31 million. This situation has been posing a threat of drug shortages and hampering patient access to medicines [12].

The problems of keeping spending within limits of the drug budget coincide with efforts of the state authorities to combat the economic crisis, which started with a sharp slow-down of the economy in 2007 and was quickly followed by the deep recession. Pharmaceutical spending was reduced in order to diminish the country's budget deficit. The current problems on the drug market can be at least partially explained by preceding cuts, written into the so-called Szell Kalman Plan, according to which Hungary can retain EU subsidies. Besides pharmaceutical budget cuts, other measures undertaken from 2011 onwards have already been included [13]:

- increasing (from 12 to 20%) the mandatory levy which pharmaceutical companies have to pay on sales of reimbursed drugs,
- doubling of the registration fee for pharmaceutical representatives,
- introduction of blind tenders for reimbursed drugs,
- monitoring and assessment of drug effectiveness (introduction of a system based on registers),
- imposing prescribing by international non-proprietary name for some drugs.
- planning to introduce electronic prescriptions in 2013.

Conclusions

The pharmaceutical reference pricing has different forms but a well-grounded position within health care systems of the Czech Republic, Slovakia, Hungary and Poland. The risk-sharing between payers and pharmaceutical industry still remains a novel tool in the Visegrad Group countries. Geographical proximity, common history and many features of health care systems, which are shared by all V4 countries, call for a more intense exchange of experiences related to pharmaceutical pricing and reimbursement - especially today, in the era of the global financial austerities.

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Acknowledgements

The author would like to express his gratitude to Dr Zoltan Kalo, the Chair of International Session at the conference of Hungarian health economists "Health economics, growing importance in scarcity", which took place in Budapest on the 20th and 21st of June 2012, for inviting and hosting him during that scientific event.