



Study on enhanced cross-country coordination in the area of pharmaceutical product pricing

Final report

Executive Summary

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Executive Summary

European patients and citizens need access to safe, effective and affordable medicines while the health care system should be financially sustainable, and innovation should be encouraged. This is perhaps the key challenge for the national competent authorities and public payers as pharmaceutical pricing and reimbursement remains the competence of EU Member States. In the light of increasing financial pressure while further new high-priced medicines are expected to come to the market, new approaches to achieve the above-mentioned objectives might be required. Without disregarding the subsidiarity principle, possible benefits of cooperative approaches should be studied and discussed.

In this context, a consortium of Gesundheit Österreich Forschungs- und Planungs GmbH, SOGETI Luxembourg S.A. and the University for Health Sciences, Medical Informatics and Technology was commissioned by the European Commission (DG SANTÉ / Chafea) to explore the pharmaceutical pricing policies of external price referencing (EPR) and differential pricing (DP) with regard to their ability to achieve two of the three above-mentioned policy objectives: to improve patients' access to medicines and to generate savings for public payers.

In particular, this 'study on enhanced cross-country coordination in the area of pharmaceutical product pricing' aimed to survey existing EPR schemes in European countries and to develop possible improvements to the current EPR practice, as well as to analyse how DP schemes could possibly be designed for European countries, including addressing identified constraints to DP in Europe. Furthermore, it should be explored how EU-level coordination mechanisms could support the improvement of EPR systems and the establishment of a DP scheme.

To achieve these research objectives, the authors relied upon a range of methods including a literature review, a survey of competent authorities for pharmaceutical pricing, interviews with procurement experts, price simulations, a legal analysis, research of cooperation models and SWOT (strengths, weaknesses, opportunities, and threats) analyses. Extensive reviews involving the services of the EC, stakeholders and academics ('peers') were performed to ensure the high quality of the report.

External price referencing for medicines – Use and impact

External price referencing (EPR), also known under different names such as external reference pricing or international price comparison / benchmarking, is defined as the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of a medicine in a given country.

EPR is the most commonly applied pricing policy in European countries. As of 2015, apart from Germany, Sweden and the UK, all other EU Member States, as well as Iceland, Norway, Switzerland and Turkey, set the prices of (some of) their medicines based on price comparisons with other countries. In Germany, though the law provides for prices in other countries to be considered as an additional piece of information in pricing of new medicines, it is claimed that EPR is not applied in the follow-up procedure. In Denmark, EPR is only applied as a supportive pricing policy in the hospital sector. According to a survey undertaken in April/May 2015, 20 of the 29 countries that apply EPR use this policy as sole or main pricing policy. Typically, EPR is limited to specific medicines, such as originator, prescription-only or new medicines. The number of reference countries included in the basket varies between one country (Luxembourg) and 30 countries (Hungary and Poland). Countries most frequently referenced to are France, Belgium, Denmark and Spain followed by Italy, the UK and by, to a lesser extent, Austria, Germany and Slovakia. Major criteria defining the composition of country baskets are geographic neighbourhood or a comparable economic situation in the reference countries.

The methodological specifications of how an EPR scheme is designed differ between the mentioned countries. For instance, 21 countries do the comparisons of medicine prices at the level of ex-factory prices, and eight countries at pharmacy purchasing price (wholesale price) level. The EPR applying countries refer to the officially published list prices, thus taking neither statutory nor negotiated discounts into account. Germany, though not applying EPR, specified in its law that discounted prices are to be reported by the manufacturers. The most commonly applied method to calculate a reference price is an average, or some kind of modified average, of the prices in the reference countries. The price data required for EPR are provided by the marketing authorisation holder in 23 countries, and 26 countries validate the price information provided. Though price monitoring is provided for in the legislation of 25 countries, it is actually done on a regular basis solely in 17 countries. These regular intervals vary between countries and range from three months to five years.

A literature review conducted as part of the study suggests that EPR has proven to be effective in generating, sometimes substantial, savings for public payers. The extent of savings has considerably depended on the methodology applied. There are lost opportunities due to discounts, rebates and similar arrangements in the reference countries that are not considered in EPR. As illustrated by simulations done by the authors of this study, it may be possible to achieve major impacts on price reductions by referencing to discounted prices and by performing regular EPR reviews. With regards to patient access, EPR is likely to have a negative impact since it incentivises the pharmaceutical industry to first launch in higher-priced countries and delay, and refrain from entering the market in lower-priced countries, and may also inhibit them from offering medicines at lower prices in lower-priced countries.

External price referencing – Options for improvement and cooperation mechanisms

EPR is a pricing policy that considers the prices in other countries, but it is not a cooperation tool per se. However, both changes in the methodology undertaken unilaterally by countries as well as cooperative approaches between Member States can help improve the performance of EPR which is a resource- and time-consuming activity, and thus possibly positively impact the outlined policy objectives. The report discusses four options for improvement: 1) a central price database, 2) the consideration of discounts, 3) regular price monitoring, and 4) the coordination of EPR formulae.

A major tool to facilitate price comparisons could be a European medicine price database, such as the existing Euripid database of competent authorities of EU Member States and a few further European countries. According to its users, Euripid has proven to be extremely supportive for competent authorities when they carry out technical work related to EPR (price surveys, validation and comparisons). Thus, the authors consider a centralised price database as a promising cooperation mechanism that should be continued and possibly extended in future. It would be highly recommended to have a centralised database that covers all EU Member States. However, some countries may not be able to join a European price database (e.g. no possibility to share the price data of the own country due to a lack of ownership) which would limit the effectiveness of the database. A current limitation to a European price database is the provision of undiscounted list price data only. The inclusion of discounted prices could significantly improve the relevance and quality of such a database. If the inclusion of discounted prices is not possible, it is recommended to consider alternative approaches, such as at least an indication in the price database of whether, or not, discounts have been granted to that product.

As the analysis has shown, EPR could provide lower prices if the price comparisons were done at the level of real prices paid by payers (discounted prices) instead of list prices. As a unilateral measure, EPR applying countries could take into account, as a minimum, statutory manufacturer discounts in the reference countries (e.g. Germany) that are officially published. However, this would only cover parts, possibly small ones, of the

discounts granted. Higher savings might be generated if prices actually paid by public payers are referenced to, i.e. considering also confidential discounts, rebates, and similar financial arrangements in the other countries. One option to receive this information is a sharing of these data among Member States.

Another option to improve EPR would be regular price reviews with subsequent price revisions whose impact on reducing prices has been evidenced by simulations. However, industry could also benefit from regular price revisions if price increases (e.g. due to exchange rate fluctuations) were also considered. There is room for improvement since several Member States do not seem to perform regular (i.e. bi-annually, annually or at other defined time intervals) price re-evaluations even if provided for in the legislation.

Finally, another consideration could be the adaptation of the EPR formulae. For instance, countries could adjust prices by reference countries' purchasing power parities, rather than merely by nominal exchange rates, when performing EPR. This is a step that could be taken unilaterally by any EPR applying country. If several countries consider such changes, an exchange of information and best practice on criteria and methods for adjustment, which would support capacity building is recommended. A multi-national agreement on adjusting formulae in a particular method would be similar to the implementation of differential pricing in Europe (see below).

The four options presented can support policy-makers to improve the efficiency of performing price comparisons under EPR, and can help generating further savings for public payers. However, apart from the fourth option which contains traits of differential pricing, the other three options are not necessarily expected to impact the differentiation of prices between countries along the lines of ability-to-pay and thus improve access to medicines. The four options presented are not mutually exclusive, and it is recommended to consider a combination of these options.

Differential pricing for medicines – Use and impact

Overall, differential pricing (DP) describes the strategy of having different prices for the same product charged to different customers. This study regards differential pricing which is understood as an international, governmental policy defining the prices of medicines according to the ability-to-pay, and/or the economic situation of the countries under DP. There is a difference to 'price discrimination' ('market discrimination', 'Ramsey pricing') that describes a business strategy of economic actors to segment the market according to the observed demand-elasticity of consumers and that is not the focus of this study.

Experience with DP exists with medicines for specific indications (particularly HIV/AIDS, tuberculosis, malaria, vaccines) that were procured under DP by international agencies and programmes (UNICEF, PAHO, GAVI, Global Fund, UNITAID) for low- and middle-income countries, including least-developed countries. There is no experience with DP, as defined above, applied for high-income countries, such as European countries.

The applied DP schemes aimed to ensure access to medicines that would otherwise have been unaffordable for these countries. Though the results are mixed, it was found that in some cases DP might have resulted in an improved access to medicines for low-income countries. In addition, there was some evidence that DP helped to reduce prices and thus made medicines more affordable. However, the entry of generic medicines into the market was seen to be more effective in driving prices down than DP.

It has been argued that DP may benefit manufacturers as well since they gain additional markets, and low profit margins in these markets might be out-weighted by increased unit sales.

Under specific conditions DP might serve as a, however second-best, policy option to ensure short-term access to medicines, particularly new on-patent medicines. It should be supported by other policy options including generic competition, joint procurement,

voluntary licensing and compulsory licensing. A global legal framework for DP has been suggested by researchers advocating for access to medicines globally.

Differential pricing – Proposal for an EU coordination mechanism

The report discusses a possible outline of a DP scheme for medicines in Europe as requested by the project tender specifications. This possible DP framework is described for analytical purposes, to illustrate what DP could mean in practice and to be able to assess its feasibility; but it should be noted that the authors do not necessarily recommend that a DP scheme should be implemented in Europe.

Such a scheme would require the agreement on principles and mechanisms of the countries included (in case of a collaborative approach for the EU, these were all 28 Member States) which is a challenge and might not be politically feasible in the short term. Mechanisms to be agreed upon would involve a maximum or minimum entry price, one of the biggest challenges by itself, and the size of the mark-ups or mark-downs. When designing such mechanisms, economic indicators, such as the gross domestic product or the purchasing power parities, should be taken into consideration. Some would argue that a DP scheme should be designed in a way that prevents higher prices in the higher-income countries compared to a situation without DP; others that these higher price levels might be justified.

In any case, if the DP approach is chosen, it is recommended to start with a pilot project for one, or a few products, defined according to some eligibility criteria (candidate medicines could include orphan medicinal products, or other high-priced medicines, for instance). EU Member States are advised to accompany any DP pilots, and later possibly regular DP schemes, by evaluations, with the possibility to feed-in lessons learned in future mechanisms. The pilots could be launched in cooperation with pharmaceutical companies interested in marketing their product in the European Union under a DP scheme. Trust and better planning between the two parties could be ensured if both supply and purchase guarantees would be integrated into contracts for medicines procured under DP. Notwithstanding the subsidiarity principle, operationally, the DP schemes would benefit from a central coordinating structure.

A key constraint that limits any differential pricing in Europe is parallel trade. Parallel trade occurs, if a genuine product originally sold under the patent protection is traded in another country without control or permission from the original patent holder. This leads to the re-importation of medicines from lower-priced to higher-priced countries and thus contradicts the principles of DP in which prices vary according to economic parameters. From a legal perspective, medicines as such are no exception to the free mobility of goods in the internal market. Thus, though parallel trade should not be interfered with in order to not distort competition within the Union, export bans and notification/authorisation procedures related of exports of medicines might be justified if considered suitable, proportionate and necessary for achieving health and life protection goals. However, no legally binding Commission decision or European Court of Justice rule has yet been issued on this matter, although the effects of parallel trade on health and safe access to medicines remain a matter of strong controversy.

Policy options for the future

The exact impacts of a possible DP scheme within the European market are still unclear. It is evident, however, that the implementation of a DP scheme would be extremely challenging and would require enormous political will to address legal constraints and achieve agreements between Member States on principles and mechanisms. However, the challenge of ensuring patient access to new, possibly innovative medicines has become an urgent need in the light of new high-priced medicines. Thus, while the implementation of a DP appears to be unfeasible in the EU in the short run, EU Member States could consider using DP traits in EPR schemes. In the short term, EU Member States could improve their EPR systems, particularly by doing regular price revisions and considering (statutory)

discounts, but these measures primarily help generate savings, and do not necessarily improve access to medicines. Some of the latter measures can be taken unilaterally by EU Member States, and cooperation would mainly regard the exchange of good practise on the methodology to be employed.

Moreover, EU Member States could consider exploring other new pharmaceutical (pricing) policies such as joint procurement initiatives which were not within the scope of this study. It is recommended using fora, such as the stakeholder review meeting of this project, to openly discuss strategies among stakeholders on how to deal with new high-cost medicines.

