EUCOPE

European Confederation of Pharmaceutical Entrepreneurs AISBL

EXPLANATORY MEMORANDUM

Pharmaceutical Prices: Why are there differences between Member States?

Summary

- Prices of pharmaceuticals differ across Member States due to factors which are beyond responsibilities of pharmaceutical companies (**different wholesale / pharmacy margins, different VAT rates, different pack sizes and distribution channels, exchange rate fluctuations, and most importantly, different price-settings by authorities, but also differences in national health and pharmaceutical policies and priorities**).

- **Price-setting is a competence of Member States** and reflects the different national healthcare policy priorities and purchasing power.

- Comparisons of pharmaceutical prices among Member States must be performed with great caution taking into account that prices are usually set by payers / governments. Member States compare their prices to other countries' prices and reference to other countries' prices (International Reference Pricing, IRP). **In an "ideal" scenario they reference only to countries which are economically comparable**.

- National reimbursement systems should appreciate the unique nature of biologic products, such as plasma protein therapeutics, and the related costs of manufacturing these safe, effective and life-saving therapies. Thus, the European IRP systems and models should appropriately reflect this in their applied methodologies.

- From the perspective of EUCOPE, it is important that the choice of the country basket for International Reference Pricing takes into account the differences between Member States, e.g. purchasing power / GDP per capita. Germany recently decided to include the Czech Republic, Slovakia and Greece in the country basket. The German price is again referenced by 19 other Member States[1].

- The number of countries applying an especially restrictive pricing policy due to **austerity measures** is increasing. **These countries should be excluded from country baskets** as those prices / rebates are set under exceptional circumstances, may be temporary and should not be exported to other countries.

- **Prices of medicinal products are already made public by Member States so that no regulation in this regard is needed in the context of the Transparency Directive.** The directive is aimed at guaranteeing transparent procedures and payer decisions for pharmaceutical companies.

- Innovation in pharmaceuticals have affected millions of people positively by being able to treat and prevent diseases. It has also affected the economy by creating a healtier workforce increasing overall efficiency and reducing costs for other often costly medical procedures. Facilitating innovation in pharmaceuticals is a way to make sure this trend continues. EUCOPE would thus like to underline: In order to make long-term R&D investments attractive for the benefit of patients and society and to preserve the competitiveness of the European pharmaceutical sector, especially of medium-sized companies, it is crucial

    - to allow for differential pricing

    - to restrict International Reference Pricing to economically comparable Member States and to exclude from IRP elements related to pharmaceutical regulation and policies, which are country-specific and likely to distort price comparisons

    - to exclude countries under austerity measures from International Reference Pricing.

[1] P. Kanavos et al for European Parliament, ENVI „Differences in costs of and access to pharmaceutical products in EU", 2011, p.80.

This paper aims to explain the reasons for price differences between Member States and their importance for patients' access to innovative treatment (I), the effects of International Reference Pricing (IRP) by Member States (II) and why the disclosure of prices and voluntary contractual agreements in IPR can have negative effects on the availability of pharmaceuticals (III).

I. PRICE DIFFERENCES BETWEEN MEMBER STATES: REASONS AND IMPORTANCE

The price of a particular medicine in an individual Member State is determined by a number of **nationally dependant variables**. Prices depend on various factors such as different wholesale / pharmacy margins, VAT rates, different pack sizes and distribution channels, exchange rate fluctuations, terms of payment and the national price-setting by payers / governments which render any direct comparison inappropriate. For this reason prices are not directly comparable among Member States.

In particular, it should be noted that pharmaceutical companies do not fully control the price of pharmaceuticals. **Prices are the result of complex evaluation/negotiation processes established by national rules**. It is essential that the decision-making process for setting the price is objective and transparent which underlines the importance of the Transparency Directive.

The factors for price differences among Member States are in particular addressed in a study commissioned by the European Parliament and conducted by the London School of Economics on 'Differences in Costs of and Access to Pharmaceutical Products in the EU'[2].

The study reveals that price differences between Member States remain largely due to the differences in national healthcare and societal/political priorities (even between countries with equivalent income level), pharmaceutical policies and market regulation. These are an area of national competence. Several studies identified a positive correlation between the income/capita and the pharmaceutical prices in general.

Importance of price differences for patient access to innovative therapies and R&D incentives

Allowing for price differences between countries enables an adaption of the price level according to each country's purchasing power and willingness to pay, without compromising patient access. This is particularly important for those countries which could not afford the product at the EU single price and countries under austerity measures. A single European price would not be beneficial for patients' access to pharmaceuticals. This has been well-documented by the literature. According to the state of the academic research, differential pricing can lead to an increase of pharmaceutical companies' output, contributing to a broader access in all countries while allowing companies to better recoup their initial investment. A good practical example of the successful implementation of differential pricing is the market for vaccines where most vaccines have a differential pricing structure with reasonable market prices in high-income countries, low prices in countries belonging to the Global Alliance for Vaccines and Immunisations (GAVI) and intermediate prices in middle-income countries[3]. Several studies also demonstrated that differential pricing has a positive impact on the incentives for pharmaceutical companies to develop new products and invest in R&D.

Danzon and Towse (2003)[4] stress that differential pricing allows to broaden access for patients to innovative products in a sustainable way while promoting innovation.

[2] P. Kanavos et al for European Parliament, ENVI „Differences in costs of and access to pharmaceutical products in EU", 2011, available at http://www.europarl.europa.eu/document/activities/cont/201201/20120130ATT36575/20120130ATT36575EN.pdf.
[3] See P. Yadav, "Differential Pricing for Pharmaceuticals, Review of current knowledge, new findings and ideas for action", A study conducted for the U.K. Department for International Development (DFID), August 2010, p.28.
[4] See P.M. Danzon and A Towse (2003), „Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents" *International Journal of Health Care Finance and Economics*, 3: 183-205, 2003.

For these reasons, differential pricing increases social welfare as a whole. Particularly, this is the case when differential pricing leads to the opening of new markets in countries where the ability to pay for the medicine is lower than the existing price[5].

Specific Challenges for Biotherapies

Biotherapies as e.g. plasma therapeutics are particularly challenged by the implications of international reference pricing because of spillover effects from national cost containment interventions (e.g. price cuts or mandatory rebates) as well as country specific economic settings (e.g. exchange rate changes or austerity measures).

Plasma therapeutics are different from traditional pharmaceuticals in many important ways. These medicinal therapies are extracted and purified from donated human plasma which contains only approximately 8% of proteins which can be used for plasma therapeutics. Thus, the starting material is of human origin and not a chemical compound. Manufacturing plasma therapeutics is a complex, highly sophisticated process that takes about seven to eight months from plasma donation to completion of the finished product. The basic costs associated with collecting, testing, storing and transporting this life-saving starting material are significant. With pharmaceutical chemical compounds, the cost of raw materials typically represents a proportionally smaller portion of the cost of the products.

Furthermore, plasma disorders are mostly severe, chronic and congenital rare diseases. Thus, plasma therapeutics treat small patient populations, while many pharmaceuticals treat millions of patients worldwide. This means that the related costs of therapies are spread over a much smaller base of patients which minimizes the budget impact.

National reimbursement systems should appreciate the unique nature of biologic products, such as plasma protein therapeutics, and the related costs of manufacturing these safe, effective and life-saving therapies. Thus, the European International Reference Pricing systems and models should appropriately reflect this in their applied methodologies.

II. DISTORTIONS CREATED BY INTERNATIONAL REFERENCE PRICING

Practices of International Reference Pricing among Member States

International or External Reference Pricing consists of pinning the price of a medicinal product in one country to the price of the same medicinal product in a basket of other countries (ESMT report, p. 34)[6]. While it is currently used in 24 out of the 27 Member States, the practices of IRP vary significantly across Member States.

In that regard, concerning the concrete implementation of International Reference Pricing schemes, the choice of the country basket is decisive. While Member States tend to select the benchmark countries based on specific criteria such as geographic or economic factors, political factors also play a role. Countries such as Greece, Hungary and Poland are often chosen for their relatively low pharmaceutical prices (ESMT White Paper, 2010, p. 34). The practice of International Reference Pricing has led to the effect that many countries, which are not necessarily facing financial problems, are referencing to countries under austerity measures. **An example is the "country basket" in Germany which includes countries like Greece that are under heavy pressure to reduce pharmaceutical expenditures and are thus applying a special pricing policy including severe price-cuts and rebates of exclusive and temporary nature[7].**

The choice of the country basket is also decisive in terms of **exchange rates**, as quite often countries included in the reference basket do not share the same currency. A recent simulation exercise in some countries that implement International Reference Pricing, e.g the Czech Republic, the Netherlands and Greece, demonstrated that the exchange

[5] See P. Yadav, "Differential Pricing for Pharmaceuticals, Review of current knowledge, new findings and ideas for action", A study conducted for the U.K. Department for International Development (DFID), August 2010.
[6] See H. Friederiszick, N. Tosini, F. de Véricourt, S. Wakeman, ESMT White Paper, „An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in the Pharmaceutical Industry, 2010, available at http://www.esmt.org/en/271562.
[7] In Germany, the price negotiations between payers and pharmaceutical companies take place on the basis in the following countries: Belgium, Denmark, Finland, France, Greece, UK, Ireland, Italy, the Netherlands, Austria, Portugal, Sweden, Slovakia, Spain and the Czech Republic.

rate volatility was likely to have a -26% impact on Czech prices and -6% in the Netherlands and Greece[8]. **Such decrease of prices is purely mechanical and is not driven by any health or economic rationale, while being an important distortion and a source of great uncertainty and revenue losses for manufacturers**.

Finally, the type of the price to be included for International Reference Pricing is also a decisive factor. Pharmaceutical markets have become more complex and diverse over the last 20 years, with the development of different tools and mechanisms that allow Member States to manage their pharmaceutical expenditures and adapt them according to their income and health priorities. The portfolio of tools and their implementation are defined by national pricing and reimbursement rules, and therefore differ from one country to the other.

Examples of mechanisms include (a) the use of payback, as a mechanism through which manufacturers previously agree to return money to public institutions in the form of annual lump-sums; (b) the general discount system, used in some countries where manufacturers have to return part of their sales, (c) different risk-sharing/price-volume agreements, where the cost of the medicines evolves in accordance with the use of the product in real-life (e.g; national/regional/local reimbursement criteria).

These tools lead to a greater complexity of pharmaceutical prices, and a limited comparability of prices from one country to the other, which will distort International Reference Pricing.

Implication of International Reference Pricing on prices, innovation incentives and launching

In that context, International Reference Pricing acts as a barrier to adapt prices to take into account a country's economic situation because IRP mechanically leads to a stronger price convergence. Some practices of cross-border reference pricing can also contribute to a heavy distortion of prices especially in times of financial crisis. This is especially the case in countries where the price is set based on the lowest price in the country basket rather than on the average price in the country basket.

While we understand the need to consolidate the (healthcare) budgets of countries under austerity measures, it is crucial to take into account the long-term effects of IRP. It is not an economically sound policy to import the Greek price, for example (under austerity measures), to Germany. Such a policy would contradict other efforts to increase innovation in the EU, e.g. by research funding, and thereby put future innovation in medical treatment and patient access at risk.

Some practices of International Reference Pricing may, because of their potential spill-over effects on other countries, decrease the global incentives to innovate. It may also, as a direct consequence, force companies to consider the impact of launching a product in one country on the revenues of the other country. Ultimately, when International Reference Pricing policies are extremely aggressive, such as when they base their price on the lowest price in the country basket, it directly impacts the profitability of launching a product. Such developments do not only impact the revenues of pharmaceutical companies but can act as a delay to patients' access to a much-needed innovative treatment. The ESMT White Paper (p.17) finds that fewer projects are developed in low-margin therapeutic areas.

In that regard, when designing pricing and reimbursement policies it is essential to balance the impact of lower prices with the costs associated with less innovation and with fewer products being launched (ESMT White Paper, 2010, p.17).

III. DISCLOSURE OF PRICES AND VOLUNTARY CONTRACTUAL AGREEMENTS NOT NEEDED

Further publication of prices and discounts is likely to magnify the existing distortion of pharmaceutical prices.

Extensive information regarding pharmaceutical prices is already available in the public domain today. Member States publish the prices of medicines that are reimbursed by their healthcare system in databases which are publicly available. In addition, the European Commission is financing a pilot project run by the National Health Insurance Fund

[8] Short- and Long-Term Effects of Value-Based Pricing vs. External Price Referencing, Panos Kanavos, Elena Nicod, Jaime Espin, Stacey van den Aardweg, http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/valuebased_pharmapricing_012010_en.pdf.

Administration of Hungary which aims at creating a central database of national prices. This Common European Drug Database (CEDD) is available at http://cedd.oep.hu/. From that perspective, no further regulation is needed concerning price disclosure as data for medicinal products is already available.

Seeking further price transparency, for instance by including elements of country specific regulation (temporary rebates, special discounts, commercial arrangements or other mechanisms introduced for cost-containment purposes) would magnify existing price distortions and have anti-competitive effects.

The resulting downward pressure on pharmaceutical prices across Europe, when countries are using as a reference lower-income countries with the lowest prices, ultimately undermines manufacturers' incentives and ability to market their product in these countries at a lower price. In the absence of confidential commercial arrangements there would be little scope to lower prices in these markets without jeopardizing the broader EU price.

In addition to its potential impact on access, further price transparency can also result in undesirable consequences by reducing the amount of funding available for research and development and the number of new pharmaceuticals available. R&D activities of pharmaceuticals require a significant and risky investment, while potentially benefiting to all consumers, regardless of their income or their country of origin, provided they have access. To recoup their initial investment and apply it in further investment, manufacturers need a certain price level for their products. Negative consequences of pricing and reimbursement measures will be observed in the future with a decreasing number of launches of new products or products being launched at a later stage in their life-cycle.

Payers might benefit from such policies in the short run, because it would reduce the amount they have to pay. However, the medium and long term impact could severely damage access and healthcare innovation.

Also in the U.S. voluntary agreements are not disclosed. The **U.S. antitrust authority Federal Trade Commission** (FTC) and also the **Congressional Budget Office** (CBO) found that proposed laws **requiring disclosure of negotiated pharmaceutical rebates might have anti-competitive effects on pharmaceutical markets**, and that such rules should not be enacted.

In case of any comments or questions please do not hesitate to contact us.

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