

Position Paper

External Reference Pricing for Generic and Biosimilar Medicines

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Summary

External Reference Pricing (ERP) is not a suitable price control mechanism for ensuring an appropriate and competitive price environment for generic and biosimilar medicines.

While the primary objective of ERP is to keep medicines affordable and accessible to all patients, applying this policy to generic and biosimilar medicines does not seem effective and results in a significantly negative impact which does not reflect the objective.

Generic and biosimilar medicines operate in a highly competitive market environment. Medicines for Europe considers that policies other than ERP are more appropriate to stimulate competition in the off-patent market. Competitive and dynamic pricing, combined with policies to incentivize the use of generic and biosimilar medicines (demand-side policies), would be a more sustainable pricing model benefiting patient access to affordable, high-quality and essential medicines.

This was acknowledged by the World Health Organization (WHO), who stated that “in case of off-patent medicines there are other price control mechanisms, [...] which might be more appropriate to ERP in terms of the level of the technical capacities and information required to apply them”.

1. Background

External reference pricing (ERP), also known as international reference pricing (IRP), is a direct price control mechanism, whereby a government considers the price of a medicine in other countries to inform or establish the price in its own country. ERP is used to ensure that a country does not pay more for medicines than other countries in the reference basket¹.

WHO Definition:

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 the product in a given country

ERP may be used formally or informally to set ex-factory and retail prices; at launch and/or during the product life cycle on a regular basis; as the primary criterion for price setting, price revision and/or as the sole or as one of the many inputs used to inform the pricing decision.

There is a great variation in methods used to compute the reference price which could relate to the lowest, average or a weighted average price of selected countries. The scope and frequency of referencing varies between countries as well as the basket of reference countries.

¹ This is a very controversial practice as it goes beyond the principle of solidarity and ability and willingness to pay for medicines between Member States, especially if you see how countries have constructed their reference baskets

ERP is relatively easy in comparison to other more rigorous approach to price setting and therefore a widely-used element of price regulation of originator prescription medicines in the vast majority of EU countries in one or other form, except Sweden and UK.

Several EU countries also apply ERP to set the price of generic and biosimilar prescription medicines, directly or indirectly. Table 1 provides an overview of the application of ERP on generic and biosimilar medicines.

Table 1: overview of application of ERP on generic & biosimilar medicines

	Country
ERP as main criteria to set price level of generic medicines	BU, RO, SK
ERP with indirect immediate impact on price level of generic medicines	HR, CZ, EE, IE, LT, LV, NL, PO, SL, PT

2. Generic medicines already operate in a highly competitive market environment

The off-patent pharmaceutical market has totally different dynamics compared to the patented pharmaceutical market. Generic and biosimilar medicines already operate in a highly competitive market environment and governments have a wide range of policies at their disposal to control their prices:

- **Price linkage:** the maximum price of the generic medicine is linked to the price of the reference product, typically as a percentage.
- **Internal reference pricing:** this policy typically means determining the maximum price for generic medicines and the maximum reimbursement rate for each medicine for a group of identical medicines (ATC 5 level) or therapeutically equivalent products (ATC 4 or 3 level)².
- **Retail tendering:** the acquisition of pharmaceuticals based on a competitive bidding process where the contract is granted to the pharmaceutical supplier who offered the best bid following strict criteria, usually based on the lowest price³.
- **Discounts and rebates:** policy imposed on manufacturers so that they have to return a part of their revenue to the authorities. The rebate does not have to be linked to a specified target budget and it is often seen as an alternative to decreasing list-prices, which can have implications in ERP applying countries⁴.
- **Payback:** policy which requires manufacturers to pay back a share of their revenue to the authorities, if a pre-specified budget ceiling for public pharmaceutical expenditure is exceeded.

Each country usually applies a different mix of these policies which has resulted in competitive and cost-effective prices of generic and biosimilar medicine taking the local market dynamics into account (e.g. International Non-proprietary Name (INN) market vs. branded market).

Apart from the price control mechanisms, the price of generic and biosimilar medicines is also highly dependent on the market share of the generic medicines. The economic model of generic medicines pricing is like any other normal economic model related to the demand. It has been demonstrated that countries with high market shares

² Carone et al. (2012) Cost-containment policies in public pharmaceutical spending in the EU.

³ Leopold et al. (2008) Tendering of pharmaceuticals in EU Member States and EEA Countries.

⁴ Carone et al. (2012) Cost-containment policies in public pharmaceutical spending in the EU.

of generic medicines have seen substantially larger price decreases compared to countries with low market shares.⁵

In conclusion, we do not consider ERP as an appropriate price control mechanism for ensuring an appropriate and competitive price environment in the off-patent market. Governments must acknowledge the different market dynamics of the generic and biosimilar medicines markets across Europe and importing prices from other EU countries might distort the competitive nature of these markets.

3. Expected impact of applying ERP to generic and biosimilar medicines

Artificially low prices

Referencing prices of generic and biosimilar medicines to countries with different market structures, conditions, regulations and dynamics might result in artificially low prices. In some cases, the prices of generic and biosimilar medicines might even reach a level below which it is commercially sustainable for the pharmaceutical manufacturers. This can be detrimental to the entire generic and biosimilar medicines industry as well as for the quality of healthcare, as these artificially low prices might endanger the security and continuity of supply.

Also in countries where ERP is not directly applied on generic and biosimilar medicines, the impact can be significant. In some countries, the price of the generic medicine is linked to the price of the originator ('reference') product. If the price of this originator product is revised on a regular basis and alignment of generic prices is required, this will have a detrimental impact on the price level of generic medicines. In this case, price levels of generic medicines are subject to double price regulation (e.g. Portugal).

Example: Bulgaria

In December 2012, the prices of the generic olanzapine in Bulgaria dropped by up to 98% due to the application of ERP referencing to Denmark. This made the marketing of the product in Bulgaria non-profitable and, above all, limited patient access to this essential medicine.

Hampered patient access

The scientific evidence has shown that ERP leads to delayed, or even no launch of medicinal products in certain national markets⁶. For generic and biosimilar medicines, an immediate launch after expiry of exclusivity rights might enable efficiencies for governments but also increase access for patients. This is of particular importance for the CEE region, where the introduction of generic and biosimilar medicines has significantly increased patient access. Any delayed launch of generic and biosimilar medicines as a consequence of the application of ERP might seriously affect the wellbeing of patients.

In addition, the artificially low prices resulting from the application of ERP might lead to hampered patient access. Besides the reduced market attractiveness, which may influence pharmaceutical companies' decision to launch a medicine, the prices of generic and biosimilar medicines might also reach a level below what is commercially sustainable for the manufacturers, potentially leading to market withdrawals. In both scenarios, the consequences for patients are severe as they cannot get access to their essential medicines.

⁵ Dylst et al. (2011) Does the market share of generic medicines influence the price level? A European analysis.

⁶ European Commission (2015) Study on enhanced cross-country coordination in the area of pharmaceutical product pricing

Example: Romania

In Romania, the prices of generic medicines are determined by ERP (lowest price of 12 EU countries) or price linkage (-35%), whatever policy provides the lowest price. In combination with a significant clawback on the sales of generic medicines, the Romanian market has witnessed the withdrawal of more than 2000 stock keeping units (SKUs) over the last years. Although ERP is not the only contributing factor, the Romanian government acknowledged the problem and changed the application of ERP for 56 essential medicines (average of 3 lowest prices) to ensure that patients can have continued access.

Impact on investment for Research & Development

The dynamic erosion of generic and biosimilar medicines prices through the application of ERP will have a serious impact on their ability to improve current pharmacotherapy by addressing patients, physicians and pharmacists' needs. The generic and biosimilar medicines industry is committed to investing in Research & Development (R&D) to the benefit of stakeholders (up to 17%) but this commitment is seriously endangered if ERP is leading to price levels which are jeopardizing the long-term sustainability of this industry and the welfare of future generations.

4. Challenges of the ERP system

Generic and biosimilar medicines fulfil the needs of many patients and physicians while still giving budgetary certainty and reliability to budget holders. Comparing prices between European countries is extremely complicated due to a variety of reasons. ERP also limits the flexibility of pricing according to local market conditions and contradicts the principle endorsed by the High Level Pharmaceutical Forum of the European Commission which outlined that the impact of national price controls should be limited to the territory of the country concerned⁷.

Different price structures

Pricing and reimbursement systems for generic and biosimilar medicines vary considerably within Europe, making it very difficult to compare prices between countries. There are significant differences between countries concerning the distribution and dispensing cost and the taxation of pharmaceutical products (e.g. value-added tax (VAT), rebates, payback taxes). Also, the publicly available prices can be set at the producer (ex-manufacturer), wholesaler or pharmacy level⁸.

Example: Germany

In Germany, the combination of rebate contracts and internal reference pricing for generic medicines in the retail market has resulted in prices which are amongst the lowest in Europe. However, what most people tend to forget is that these prices do not include the pharmacist remuneration: a German pharmacist receives a dispensing fee from the competent authorities of €8.35 for each medicine⁹. In other countries, the remuneration of pharmacists is included in the pharmacy retail price, which automatically results in higher prices compared to German prices.

Reliability of price information

The frequency and process of reviewing prices can differ considerably between countries, questioning the reliability and accuracy of the price information provided by the authorities.

⁷ High Level Pharmaceutical Forum 2005-2008 – Final report.

⁸ Kanavos et al. (2011) Differences in costs of and access to pharmaceutical products in the EU.

⁹ ABDA (2017) German pharmacies: figures, data and facts 2016.

Different market structures

The use of generic and biosimilar medicines varies between European countries. This is the result of differences in culture and mind-set but most importantly the approach by governments to incentivise the use of generic and biosimilar medicines (mix of demand-side policies). Referencing the price of a country with a mature generic or biosimilar medicines market cannot give an appropriate reference for price setting in a country with no or few measures to stimulate the use of generic and biosimilar medicines.

Demographic & economic differences

The demographic and epidemiologic structure of populations can vary between European countries, leading to relevant differences in the overall patient population and burden of disease. Combined with the different economic situation (GDP) and industrial objectives, countries may have a different willingness to pay, complicating the comparison across countries.

Differences in sales units

Pharmaceutical companies may market different pack sizes, dosages or formulations in different countries due to local preferences or local reimbursement systems. This may complicate the comparison across countries.

Different currency exchanges

The choice of reference countries and the computation of prices in the destination country have an obvious and decisive impact on the prices to be defined. Nonetheless, there are no guidelines and scientific rationale on this issue and it is based on rather arbitrary decisions as well as the frequency of pricing.

5. Conclusion

External reference pricing is a relatively easy to use mechanism practiced by governments throughout Europe to control prices of (mostly patented) medicines. Its primary objective is to keep medicines affordable and accessible to all patients.

Generic and biosimilar medicines already operate in a highly competitive market environment. Medicines for Europe considers that policies other than ERP are more suitable to stimulate competition in the off-patent market. As such, ERP is not an appropriate price control mechanism for ensuring an appropriate and competitive price environment for generic and biosimilar medicines. **Competitive and dynamic pricing, combined with policies to incentivize the use of generic and biosimilar medicines (i.e. demand-side policies), would be a more sustainable pricing model benefiting patient access to affordable, high-quality and essential medicines.**

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.