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Differences in external price referencing in Europe—A descriptive overview

Christine Leopold [a,b,*], Sabine Vogler [a], A.K. Mantel-Teeuwisse [b], Kees de Joncheere [c], H.G.M. Leufkens [b], Richard Laing [d]

[a] Department of Health Economics, Gesundheit Österreich GmbH/Austrian Health Institute, Vienna, Austria
[b] Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht, The Netherlands
[c] Regional Office for Europe, World Health Organization, Copenhagen, Denmark
[d] Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland

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ABSTRACT

Objective: This study aimed to provide an up-to-date description as well as comparative analysis of the national characteristics of pharmaceutical external price referencing (EPR) in Europe.
Methods: Review of the country-specific PPRI (Pharmaceutical Pricing and Reimbursement Information) Pharma Profiles written by representatives of the PPRI Network. The Profiles were analysed according to predefined criteria.
Results: Of 28 analysed European countries 24 applied EPR in 2010. The majority of countries have statutory rules to implement EPR. Most countries had less than 10 countries in their reference baskets. Higher income countries tend to include higher income countries in their basket, whereas lower income countries refer to lower income countries. Taking the average price of all countries in the basket as the basis to calculate the national price was the most common strategy ($n = 8$). The methodology of EPR has changed in most European countries over the past 10 years ($n = 19$).
Conclusions: EPR is a widely used pricing policy in Europe and is still actively used as well as adjusted by national authorities. However, we still see room for improvement by implementing more detailed legislations in terms of the revision of prices and by identifying alternative countries in case a product is not on the market. We also see the need for formal information sharing (e.g. congresses dedicated to pricing strategies and systems) with other public pricing authorities to learn about the different EPR methodologies as well as the national experiences. These congresses might also give room to better understand national pricing methods including discussions on possible limitations of these pricing methods.

1. Introduction

All European countries have different national pharmaceutical systems due to historic, political, legal and economic developments but also due to the ways in which the health care system is funded [1]. These countries all face the same challenge of guaranteeing their populations affordable access to medicines within their limited public resources.

National governments take different interests into consideration when shaping a national pharmaceutical policy. Notably, payers are under pressure from citizens and other stakeholders to promote public health and to ensure prompt access to affordable medical treatment. At the same time there is also pressure for some countries to

* Corresponding author at: Gesundheit Österreich/Austrian Health Institute, Stubenring 6, 1010 Vienna, Austria. Tel.: +43 1 515 61 149.
E-mail address: Christine.leopold@goeg.at (C. Leopold).

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serve the objectives of a national industry policy, by offering relatively high ex-factory prices or other concessions intended to incentivise or reward the domestic pharmaceutical industry [2–4].

Another relevant aspect to consider is that market dynamics in the pharmaceutical markets differ from other markets for consumer products. Market demand for medicines is characterised by low price sensitivity (as reimbursable medicines are paid to a large extent by Third-Party Payers) and a relatively high level of asymmetric information between patient and prescriber (as prescribers decide which medicine the patient should take). In addition supply is characterised by a market with imperfect competition (pharmaceutical companies and distributors have a significant amount of market power). This situation requires that the state intervenes either to promote competition or to implement regulations to prevent exploitation of sick patients who may be willing to pay excessive amounts for an unreasonable hope of cure [5–8].

In the early 90s, most governments in Europe decided to implement a mix of different pharmaceutical policies which aimed at containing public spending while stimulating research and development (R&D) and industrial development. These policies focused on either controlling medicine prices and/or on containing the prescribed volume of medicines or both. Until today, there is still no agreement as to which policies or interventions are perceived as successful. However, time has shown that it is crucial to regularly adjust these policies and to have a fair mix of pricing and volume-control polices [9]. Otherwise it would lead to a so called "pendulum effect", meaning that the desired cost-saving effects would diminish as market players adjust [10].

Pharmaceutical price regulations can occur at various points along the distribution chain, from manufacturer to wholesaler to pharmacists and patient. Regulations of the ex-factory price may be direct or indirect. Measures for direct price setting include negotiations, statutory pricing – either through external price referencing or internal price comparisons – and price cuts/freezes. External price referencing refers to prices of other countries whereas internal price referencing (or also referred to as national reference pricing) is a method to compare prices of medicines in a country with the price of identical pharmaceutical or similar product level or even with therapeutic equivalent treatment (not necessarily a medicine) in a country. Other measures have taken a more indirect approach to regulating medicine prices by regulating profits or calculating "cost-effective" prices using pharmaco-economic analysis [11].

Most research studies in the field of pharmaceutical policy analysis describe different pricing as well as volume regulations and analyse their impact on pharmaceutical expenditure (e.g. Mrazek [12] aimed in her study to review pharmaceutical pricing policies in Europe to understand the impact of regulations on pharmaceutical expenditures and evidence of actual outcomes).

Only a few studies have described the detailed characteristics of one particularly widely used pricing policy, namely external price referencing (EPR also referred to as international price benchmark/comparison). EPR is defined by the European Pharmaceutical Pricing and Reimbursement Information (PPRI) glossary 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 the product in a given country" [8]. EPR is however a policy that is applied by countries worldwide and often European countries are taken as reference countries. Examples of countries which use European country prices as reference prices are Jordan[1], Brazil[2] and South Africa[3] [9]. As a consequence price changes in one country influence prices in other countries worldwide. Stargardt and Schreyögg showed in their study that a marginal price change in Germany led to price changes in countries that have Germany in the country basket [13].

In order to analyse and understand pricing policy trends in Europe, attention needs to be given to the different characteristics of each single pricing policy. This needs to be done as many countries use a combination of methods. The objective of this study was to examine the differences and commonalities of EPR in all 27 European Union (EU) Member States plus Norway by describing and analysing the different methodologies taking into account the geographic distribution of EPR, the reference countries, the price calculation methodology and any changes in the EPR methodology over time. In this study only the out-patient sector is analysed and no comparison of impact on prices has been attempted. This study will provide policy makers and scientists in the field of pharmaceutical policy an up-to-date picture on the pricing policy tool EPR in Europe and will discuss whether this tool is still appropriate for all countries and in which ways (Fig. 1).

2. Materials and methods

The main source of data was information published by the PPRI network. The PPRI network started as an EU-funded project from 2005 until 2007 and continues as a sustainable network for public authorities in pricing and reimbursement in Europe. Within the scope of the PPRI network country-specific reports, PPRI Pharma Profiles, on national pricing and reimbursement systems of the European Member States as well as associated countries were published. This approach of collecting information is unique as the PPRI Pharma Profiles were written by representatives of public authorities, such as Ministries of Health or Third Party Payers, who are responsible for pricing and reimbursement[4].

As the PPRI Pharma Profiles referred to the years 2007 and 2008, further research was required to obtain the most recent information available. This was done through

[1] Jordan refers to among other countries United Kingdom, France, Spain, Italy, Belgium, Greece and the Netherlands.

[2] Brazil refers to among other countries Portugal, Spain, France, Italy, and Greece.

[3] South Africa refers to among other countries Spain; and Lebanon refers to among other countries France, United Kingdom, Belgium, Italy, Spain and Portugal.

[4] Pharmaceutical Pricing and Reimbursement Information. Available online at: http://ppri.goeg.at (last accessed 25.02.11).