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POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection

**DIFFERENCES IN COSTS
OF AND ACCESS TO
PHARMACEUTICAL
PRODUCTS IN THE EU**

ENVI





DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

DIFFERENCES IN COSTS OF AND ACCESS TO PHARMACEUTICAL PRODUCTS IN THE EU

STUDY

Abstract

This report reviews the differences in the prices of pharmaceuticals among Member States. It presents an overview of the prices for pharmaceuticals protected by patents as well as those for off-patent pharmaceuticals subject to competition from lower-priced “generic” versions. The report reviews the approaches that Member States have used to regulate the pharmaceutical market on both the supply and demand sides, and assesses evidence regarding the impact of these different approaches on pharmaceutical prices, cost-containment, industry innovation. The report also considers the implications for patient access to pharmaceuticals. The report considers policy options to strengthen coordination among Member States and exchange best practice.

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EXECUTIVE SUMMARY

This report has been prepared at the request of the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament. It aims to contribute to a better understanding of why pharmaceutical prices and public pharmaceutical expenditures vary across Member States.

While Member States have the primary role in providing health care for EU citizens, the 2009 Lisbon Treaty has given the European Union a greater role in the area of public health, including in the exchange of best practice regarding Member State activities.

Pharmaceutical prices are a key issue for health care, as medicines represent the third most important cost component in Member States' health care budgets. These costs are substantial and are rising faster than Member States' GDP, mainly due to an ageing population and the increasing cost of developing new pharmaceutical technologies.

At the same time, the regulation of pharmaceutical prices will affect an industrial sector that is a major component of Europe's economy in terms of employment, manufacturing, and research and development (R&D).

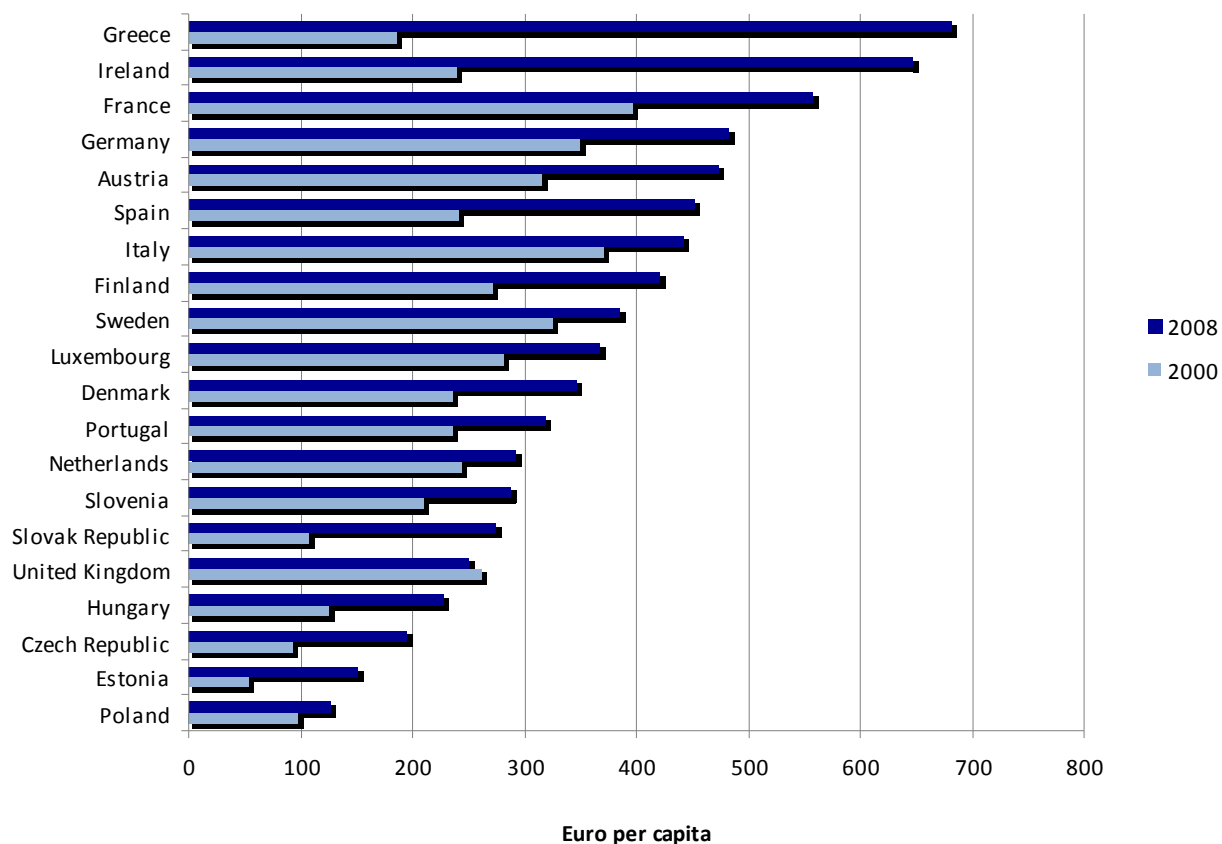
This report reviews the differences among Member States in terms of several key areas:

- Expenditure on pharmaceuticals that are reimbursed by health systems
- Prices of pharmaceuticals
- Pharmaceutical production and research

The report then studies possible reasons for the differences in pharmaceutical prices. It discusses the complexity of interactions among different regulatory measures used by Member States and their impact on pricing, cost-containment, innovation and access to pharmaceuticals.

Differences in pharmaceutical prices and expenditures across Member States

Member State spending per capita on pharmaceuticals varies significantly (see Figure 1 below). This appears to be due to a range of factors: the amount of pharmaceuticals that are consumed; the mix of pharmaceutical products (brands versus generics); and their prices; as well as the share of the price that is reimbursed by national health systems.

Figure 1: Total Pharmaceutical expenditure per capita (Euros), 2008 compared to 2000

Source: OECD Health Data 2010 - Version: June 2010

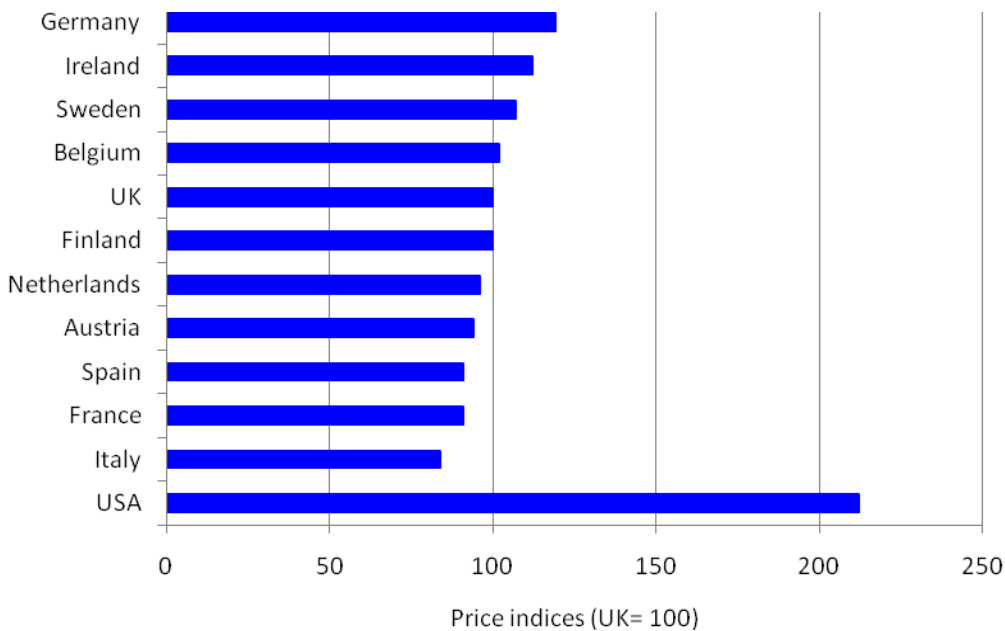
Note: 2009 data for Greece (from local health insurance sources); 2006 data for Portugal; instead of 2000 data for the Netherlands and Poland, 2002 data are used. The reduction in the UK is attributable to the sterling depreciation against the Euro.

The prices of the pharmaceuticals themselves also vary across Member States. A recent review of the prices for 150 pharmaceuticals shows that the average price for this "basket" among 11 Member States found a 25% difference between the lowest and highest Member States (UK Department of Health, 2009), as shown in Figure 2, below. (Prices in the USA are significantly higher than any of the 11 Member States.)

Price variation for an individual pharmaceutical product can be even greater. A key distinction is between pharmaceuticals that are covered by patents and related forms of intellectual property rights (including market exclusivity periods and supplementary protection certificates) and pharmaceuticals that are not: in the former, the manufacturers hold a monopoly. For pharmaceuticals covered by patents, variations in price among Member States of up to four to one for a single product have been observed (Kanavos and Costa-Font, 2005).

For price variation assessment purposes, "orphan" medicines, i.e. those for rare diseases, can be assimilated to patent-protected medicines.

Figure 2: Price comparisons among EU Member States (and with the US) for a basket of 150 pharmaceutical products; 2008 price index with UK=100



UK Department of Health, 2009

For pharmaceuticals no longer covered by patents, “generic” versions can compete with those produced by the original manufacturer. Generic versions can cost much less, typically one-quarter of the price of the original, “branded” pharmaceutical. In this market, the variation in price can be even greater: the difference between the highest and lowest prices for one generic medicine for hypertension was found to be 16-fold (Kanavos and Casson, 2011 forthcoming). This is important, as a large share of the medicines consumed across the EU-27 is no longer covered by patents. However, the share of generic pharmaceuticals purchased also varies across Member States: it is over 50% of the total volume of pharmaceuticals consumed in the UK, Germany, Denmark and Sweden, but lower in most other Member States.

Pharmaceutical production and research

The level of pharmaceutical prices (and the methods for price regulation) will affect the pharmaceutical sector, which directly employs 633,100 people across Europe and spends in excess of €26 billion annually on research and development (R&D). Production takes place in several Member States, but the bulk of manufacturing is accounted for by only a few: France, Germany, Ireland, Italy, Spain and the UK. The location of manufacturing can be explained in part by the size of domestic markets; another important factor has been the business environment.

Research and development is a critical component of the pharmaceutical sector, and the EU is the world leader in terms of pharmaceutical R&D spending, slightly ahead of the United States.

Basic and discovery research is concentrated in several Member States: on a per capita basis, Denmark and Belgium are leaders, followed by Sweden, the UK, France and Germany. Developmental R&D (including clinical trials) is carried out across the EU. Member State policies regarding the pricing and reimbursement of new pharmaceuticals clearly have an impact on the industry and its incentives for devoting resources to innovation.

Key factors influencing the differences in pharmaceutical prices

The important price differences across Member States can be explained by a number of factors.

One broad factor is national income per capita: in general, prices of in-patent pharmaceuticals seem to be proportionally higher in Member States with higher levels of per-capita income. In addition, higher-income Member States appear to spend more on pharmaceuticals.

A second key factor relates to Member State national (and, sometimes, regional) regulatory approaches. Member States use a variety of tools, both on the supply side (for determining both prices as well as the share of prices that are reimbursed) and on the demand side. The latter can include policies to encourage physicians to prescribe and pharmacists to dispense lower-priced generic pharmaceuticals, as well as requirements that patients pay a share of pharmaceutical costs.

On the supply side, Member State health systems usually negotiate prices with manufacturers based on a range of methods and criteria, and this is a factor in the price differences for pharmaceuticals, both those covered by patent and those for which the patents have expired.

A widely used tool (by 24 out of the 27 EU Member States) for determining prices is external price referencing. Under this mechanism, a Member State sets a pharmaceutical's price based on a comparison with prices in other Member States. This approach can lead to lower pharmaceutical prices, in particular when a Member State makes decisions based on the lowest comparison prices rather than an average. There are concerns, however, that it ignores other aspects, such as health priorities for each country, and moreover that it can create uncertainty for innovative sectors of the industry.

Tendering for off-patent pharmaceuticals in primary care (i.e. outpatient care) has been used in a few Member States, including the Netherlands and Germany, where it has led to a significant reduction in prices. Some Member States have also used price caps for generic pharmaceuticals, but a review suggests that price levels are lower in Member States that do not use this approach (Puig-Junoy 2010). Internal reference pricing is also used extensively to promote generic use and, through that, achieve savings for health systems.

Reimbursement decisions also affect price. Member States can establish a formulary that lists pharmaceuticals that are reimbursed by health care insurance (or a negative formulary, for those that are not reimbursed). A key method for reimbursement decisions in the context of in-patent pharmaceuticals is Health Technology Assessment (HTA): it is increasingly used to appraise the additional clinical benefit of new pharmaceuticals against existing ones, in relationship to their respective costs.

Its results are used primarily to make reimbursement decisions. However, as Member States have different ways of accepting evidence and interpreting it, variations exist in the application of HTA appraisals and these can result in different prices as well as diverging coverage decisions for the same pharmaceutical across different Member States.

The level of value added tax (VAT) will also affect prices: the rate for pharmaceuticals varies across Member States from zero (e.g. UK and Sweden) to 25% in Denmark. Some Member States such as Greece have recently raised VAT rates for pharmaceuticals.

Another factor influencing pharmaceutical prices is the margin taken by wholesalers and retailers: this too differs greatly across Member States. Government policies can influence these margins, can set requirements for the number of pharmacies and can encourage or limit the consolidation of companies in the wholesale and retail markets. In those Member States where allowed, some manufacturers have put in place direct sales to pharmacies, or chosen to work with a restricted number of wholesalers, methods that can indirectly reduce the overall cost of distribution.

The EU single market allows distributors and other market actors to purchase pharmaceuticals in Member States with lower prices and re-sell them where prices are higher. The market share of parallel-traded pharmaceutical products in the main importing Member States stands between 1.7% in Finland and 16.5% in Denmark (EFPIA, 2010). This practice, which has been reviewed and upheld by the European Court of Justice, has been cited as a mechanism that can reduce prices in the sales markets. Overall, however, it appears that the final sale prices of pharmaceuticals have not been significantly reduced by parallel trade. In other words, most of the difference in price accrues to the intermediaries (Kanavos and Costa Font, 2005; Kanavos and Vandoros, 2010). Manufacturers have turned to direct sales methods as a response to parallel trade.

Access to medicines

The different Member State approaches regarding pharmaceutical prices and reimbursement have consequences also for patient access to medicines in terms of both availability and affordability. HTA appraisals for new pharmaceuticals covered by patent may be different in one Member State from those in another. As a result, the access that patients have to such medicines varies across the EU. In particular, access to certain categories of in-patent pharmaceuticals tends to be negatively correlated with market size and per capita GDP.

In some cases a low price for a new product in one national market can lead manufacturers to refrain from launching the product in other markets, since the low price might jeopardise their pricing prospects elsewhere due to the wide application of external price referencing.

A different problem is seen regarding generic medicines: here, manufacturers of generics may decide not to enter smaller markets. As a result, health systems and patients in these markets may not have access to these lower priced alternatives. Small markets face similar problems for new orphan medicines.

Parallel trade has also raised concerns regarding access to pharmaceuticals, as it has been associated with shortages in exporting Member States (Kanavos and Costa-Font, 2005, Gainsbury, 2009; Taylor, 2010).

Policy options

The Lisbon Treaty has established a more important albeit limited role for the EU in health care policy. The EU can organise and further the exchange of best practice and carry out monitoring and evaluation of Member State health care systems.

One option could be to strengthen the sharing of information and policy experience among Member States on mechanisms used to purchase pharmaceutical products. This could be done by building on existing initiatives such as the network of Competent Authorities on Pricing and Reimbursement. An exchange of information could be used to identify good practices at the Member State level. Approaches to Health Technology Assessment (HTA) could be a key topic of further discussion, given that a growing number of Member States use this approach, but their results in terms of reimbursement decisions often vary. Clinical cost-effectiveness is one of the factors considered in HTA analysis. Here, EU institutions could foster stakeholder discussions to help define the value of innovation for patients, health systems and the EU pharmaceutical industry and its role in the European economy.

Deeper coordination among Member States in the field of biomedical innovation could avoid duplication in research efforts by national competent bodies. Setting research priorities in accordance with unmet medical needs at EU level would likewise be desirable.

EU policies can also encourage greater and earlier use of generic medicines, which could lead to significant price reductions in a number of markets.

Parallel trade also deserves further study and exchange of information at EU level.

Other options for attention include the problem of small markets, which face lower competition from generic pharmaceuticals and thus higher prices, as well as the problems related to the lack of availability of certain products in individual Member States. The EU could seek to identify mechanisms to address these issues.

GENERAL INFORMATION

Across the EU, health care is publicly financed and provided by health insurance systems based on solidarity and universal access.

While Member States have the primary role in providing health care for EU citizens, the 2009 Lisbon Treaty has nonetheless given the European Union a greater role in the area of public health. The Treaty on the Functioning of the European Union (TFEU) states that EU action "...shall complement national policies..." (Article 168(1)). Among the roles at EU level, the European Commission may:

"...take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation..." (Article 168(2)).

The TFEU also affirms the primary responsibility of Member States in the provision of health care, as stated in its Article 168(7):

"Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them..."

Member State governments face substantial and rising costs for the provision of health care (average costs are rising at a faster rate than GDP), mainly due to Europe's ageing population and the increasing cost of new medical technologies. Pharmaceutical costs are the third most important component in EU Member States' health care budgets.

At the same time, health is a high priority for Europe's citizens.¹ In addition, the pharmaceutical industry is a major component of Europe's economy in terms of employment, manufacturing, and research and development.

Member State governments take a strong role in regulating national pharmaceutical markets and thus in influencing prices.

They do so because the pharmaceutical market is different from that in other sectors of the economy. First, patients with the same disease may respond differently to a given treatment. Second, in a normal market, consumers in principle weigh costs and benefits of alternatives and make an informed decision. In the pharmaceutical market, patients have insufficient information on their health needs and largely rely on physicians to make the treatment decision on their behalf. A further element is that patients do not usually pay directly for their health care, including most pharmaceuticals, which are covered by national health systems.

¹ Despite rising concerns about the economic situation, health and healthcare remained in the top five concerns of EU citizens in 2009 Eurobarometers (e.g. No. 71 Spring 2009, No. 72 Autumn 2009). See for example: http://ec.europa.eu/public_opinion/archives/eb/eb72/eb72_en.htm.

On the supply side, the costs to develop a new product are difficult to assess as they result from years of multidisciplinary research involving multiple projects. Manufacturers that develop new pharmaceuticals are protected for a fixed period by patents, whereby their product is granted market exclusivity for a defined period of time.

Governments have introduced regulatory measures aiming at containing pharmaceutical costs by targeting price, volume, or both. These regulatory measures target either the demand side (i.e. physicians, pharmacists or patients), or the supply side (i.e. prices and market exclusivity of pharmaceuticals). Once patents expire, regulatory measures encouraging the market entry and uptake of lower-priced “generic” versions of pharmaceuticals can promote more efficient use of healthcare resources. Such cost-containment measures are aimed at cutting down inefficient expenditure while enabling access to other efficient, often more expensive, treatments.

The report is divided into three sections. The first section reviews differences in expenditure on health care and on medicines, as well as differences in the price of medicines that are reimbursed by health care systems. It also outlines the main features of the pharmaceutical sector in Europe. The second section analyses the effects of regulatory measures on pharmaceutical pricing and on access to pharmaceuticals.

The last section presents key findings and formulates policy options.

To download the full report, click here [Differences in costs of and access to pharmaceutical products in the EU.pdf](#) (1.21 MB)