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# Pharmaceutical pricing

The use of external reference pricing

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# Summary

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External reference pricing, or international price comparison, is a commonly employed instrument to control prices of pharmaceuticals that are protected by intellectual property rights and benefit from a legal monopoly (in-patent drugs). The UK is among those countries that are most widely referenced by other countries in relation to pharmaceutical prices. Therefore, although the UK pharmaceutical market accounts for just over 3 percent of global sales, pharmaceutical prices in the UK likely impact on prices in countries that reference their prices to the UK. As negotiations are under way in the UK that seek to define new arrangements for the pricing of branded (new) medicines from 2014, there is a need to better understand approaches to pharmaceutical pricing in a select set of high-income countries and, where applicable, the role of external reference pricing as a means to determining pharmaceutical prices.

This report seeks to contribute to this understanding by reviewing approaches to pharmaceutical pricing in six high-income countries: Canada, France, Germany, Italy, the Netherlands and Spain. Data collection involved a review of the published and grey literature, complemented by information provided by key informants in the selected countries.

## **Pricing strategies for patented drugs vary among countries**

All countries reviewed use a range of policies, typically involving elements of statutory pricing, external reference pricing, and negotiations and price-volume agreements although the relative weight placed on each varies. Only Germany permits principally free pricing of in-patent drugs by manufacturers and price regulation mainly relates to the way in which medicines are reimbursed. Several countries employ negotiations between government and the pharmaceutical industry to determine the price of new medicinal products considered of high therapeutic value, which may be informed by external reference pricing (France, Italy, Spain) while the Netherlands uses government-set maximum wholesale prices for all outpatient prescription-only medicines. Generics are typically subject to internal reference pricing (Italy, Spain), or price capping (France). Prices of non-prescription drugs are typically not regulated.

## **Pricing strategies in place in different countries are informed by the value that is attached to a given pharmaceutical product**

Most countries use the notion of 'innovation' as a key determinant although the interpretation of what constitutes innovation varies. The degree to which a drug improves health outcomes is considered a core criterion in all countries, whereas cost (effectiveness)

or budget impact is taken into account by a smaller number of countries only (Italy, Netherlands, Spain).

Responsibility for determining value varies across countries, typically involving an organisation or agency independent of (while accountable to) government. In Spain the agency responsible for determining the value of pharmaceutical products is located within the Ministry of Health although the ultimate decision on the price of given (new) medicinal product is taken by an interdepartmental committee. In the Netherlands, although valuation is undertaken by the Pharmaceutical Care Committee outside government, the Ministry of Health takes the ultimate decision on pricing. Canada has set up a special agency, the Patented Medicine Prices Review Board (PMPRB), which is responsible for evaluating and regulating ex-factory prices for patented drugs.

### **Most countries reviewed use some form of external reference pricing to inform decisions on prices of new (innovative) pharmaceutical products**

The relative role of external reference pricing vis-à-vis other pricing strategies varies among countries and so do the actual methods used. Thus, countries differ with regard to the number and composition of countries considered for referencing, ranging from four countries in France and the Netherlands, seven countries in Canada to over twenty countries in Spain. Reference prices are typically applied at market entry and followed up with later revisions. The actual approach to calculating the reference price varies among countries and details of algorithms used often remain unclear.

Experts confirmed that external reference pricing typically forms only one of many aspects to pricing and that the relative weight of approaches used is highly dynamic. For example, in the Netherlands reference pricing presents an important mechanism as it applies to all prescription-only drugs but as generic options become available its role is becoming less important. In France and Spain, external reference pricing was perceived as important in that it forms the basis for price negotiations for new, innovative medicines. It was also noted that the prices used from other countries may not be reliable because of a lack of transparency on pricing mechanisms related to rebates and insurance payments.

Among the countries reviewed, Italy abolished external reference pricing in 2001 because of a perceived lack of evidence of effectiveness in controlling costs. Likewise, Germany does not strictly use a formal system of external reference pricing although since 2011, all newly licenced medicines are subject to a ('early') benefit assessment, which forms the basis for determining the price of the new product.

### **The variation in the role of external reference pricing as one of many pricing mechanisms makes the assessment of the potential impact of a price change in one country on the price in another country difficult**

Our review echoes evidence presented elsewhere about the high variability of external reference pricing across different settings and of the relative importance of this approach in comparison with other pricing strategies.

There is also considerable variation in the terminology and practices used, and understanding the complexities of countries included in reference baskets for external pricing requires considerable semantic clarification. Furthermore, there is considerable overlap between countries that cross-reference, and it remains challenging to estimate the direct, immediate impact on external reference baskets.

Overall, our review suggests that an impact is likely to be minimal or indirect, largely because of the diverse ways in which reference pricing is implemented in the countries examined. The position of this report is to confirm that these are relevant countries, particularly for the United Kingdom, but that understanding the specific influences on drug prices in the scope of external references is unclear.