8.3 Pricing and reimbursement

See Background Paper 8.3 (BP8_3Pricing.pdf)

Many European countries share the health policy objectives of sustainability, equity and quality of care, but the way in which these are handled can differ substantially between countries. Pricing and reimbursement policies used in the EU include: external price referencing (international price benchmarking); internal reference pricing; decision making based on Health Technology Assessment (HTA) and economic evaluations; value-based pricing; caps and co-payments; taxes; price-volume agreements; fixed margins in distribution channels; and tendering. The impact of these policies on the price of medicines, the availability of and access to medicines, and pharmaceutical expenditure vary. In some cases, these policies can have adverse effects, such as creating shortages or inappropriate incentives. In other cases, more efficient allocation of resources can create “headroom for innovation” by allowing budget savings elsewhere to be invested in innovative medicines that address medical needs. Although an individual European country’s pricing and reimbursement policies may not have a major influence on the global pharmaceutical industry, the combined European pharmaceutical market ranks second only to that of the United States. Therefore, the joint or shared policies of European countries help shape the global landscape for pharmaceutical R&D. However, it is important to note that the balance is shifting rapidly. Between 2011 and 2016 the combined market of Brazil, China, India and Russia will, for the first time, overtake the traditional EU5 markets (France, Germany, Italy, Spain and the United Kingdom).

In most OECD countries, the government has the main role in decision-making regarding the pricing and reimbursement of medicines. Within the EU, pricing and reimbursement decisions are prerogatives of the Member States. However, rules and regulations at the EU level (mainly regarding transparency and the free movement of goods) also influence pricing and reimbursement policies at the Member State level. In general, three key strategies are open to governments to control costs and reward innovation for marketed medicines: managing price; determining which products will be reimbursed; and managing volumes (as determined by prescribing and dispensing). Policies of the EU and Member States have to address a number of interacting and sometimes conflicting elements that are inherent in the health care system. These include:

**Incentives for innovation - controlling costs**

Pharmaceutical companies are provided with a period of market exclusivity (mostly due to patent protection) whereby R&D investments can be recouped and additional profit made, which in turn can be reinvested in the development of future medicines. Coverage and reimbursement policies are critical factors in the reward of innovation. At the same time, increases in health care expenditures often exceed economic growth in the EU and need to be managed to avoid becoming unsustainable. What constitutes
a fair ‘premium price’ for a new medicine, therefore, is a crucial element in any pricing policy that seeks to reward innovation.

**Role of the EU - role of Member States**

The EU Transparency Directive, for which the European Commission proposed a revision in 2012, provides a common procedural framework for pricing and reimbursement decisions, notably with regard to the time-frame for decision-making and how decisions should be communicated. The Transparency Directive explicitly states that the decision-making process itself is and shall remain a responsibility of the Member States. At the same time, a number of European countries cooperate through networks such as the EU-supported EUnetHTA and increasingly exchange knowledge and information regarding the assessment of data that can inform reimbursement decision-making. For example, EUnetHTA is currently exploring a common ‘Core Model’ for the assessment of new medicines seeking reimbursement in EU Member States.

**Medicinal products – health care services**

The way in which medicinal products are priced and reimbursed can influence the use of medicines and the uptake of innovations. Furthermore, in many cases the incomes of health care providers (in particular pharmacists) are linked to discounts, rebates and dispensing fees. This can have a positive impact, by creating the right incentives for rational use of medicines, but it can also have adverse effects by creating a stimulus for inappropriate use of medicines, or create a threat to the economic sustainability of health care providers (e.g. if incomes are linked to certain margins on products, and these margins are excessively reduced).

**Influence of policies on other Member States**

Policies in one Member State can influence those in another. For example, pricing policies in one country can have an impact on parallel trade or external price referencing (see Background Paper 8.3).

**Current trends**

The 2004 Priority Medicines Report highlighted differential pricing as a key policy for the future and also put a strong emphasis on pharmacoeconomics as a tool to value new medicines. Since then, more European countries have incorporated HTA and economic evaluations in their reimbursement – and sometimes pricing-policies.6

However, in most of Europe external price referencing remains the predominant pricing policy, being used by 24 out of 27 Member States (although the exact implementation and the basket of reference countries varies). An alternative to external price referencing is value-based pricing, in which the price of a new medicine is determined by the (added) value it generates, using cost-effectiveness as the main
criterion to determine the price. At present, this pricing policy is only used in Sweden according to the narrow definition of value-based pricing used in the corresponding background paper to this chapter, though other countries do include cost-effectiveness in the price negotiation process. The United Kingdom is planning to implement value-based pricing in 2014, and many countries have already implemented ‘value-based’ elements in their decision-making.

In recent years, European countries have implemented a number of measures to capture the potential value, in terms of cost savings, created by patent expiration leading to the subsequent market entry of generic medicines stimulating their appropriate use. Yet, in many European countries opportunities still exist to either speed up generic entry, increase generic consumption and/or lower the prices of generic medicines, as substantial differences remain in generic entry, uptake and prices, compared, for example, with the United States. Savings could create “headroom for innovation” and partly be used to facilitate uptake of, or rewards for, innovative medicines. But explicitly linking generic uptake to rewards for innovation in policy practice can be challenging.

Another important development since the publication of the 2004 Report is the increasing role played by networks such as EUnetHTA, Competent Authorities on Pricing and Reimbursement (CAPR) and Pharmaceutical Pricing and Reimbursement Information (PPRI) in informing and collaborating in the discussions between Member States about methods used for pricing and reimbursement decision-making and exchanging information. In addition, little information is available about various aspects of health care systems, such as prices in hospitals; these areas are still a “black box” from a research perspective. Furthermore, discounts and rebates of medicine prices are widespread and are often held to be confidential. As a result, the list prices of medicines in most EU countries do not reflect the actual prices. Although confidential discounts and rebates hinder the potential for savings through external price referencing, they are the only tool through which lower-income countries can negotiate lower actual prices. Due to the existence of parallel trade within Europe and the widespread use of external price referencing, there is limited incentive for companies to offer lower prices to lower-income countries when this would subsequently decrease prices (through external price referencing) or lost sales (through parallel trade) in other European markets. Companies frequently offer confidential discounts or rebates to get around this issue.

In order to align the health policy objectives of sustainability, equity, and quality of care with the continued reward for pharmaceutical innovation, countries have tended to move towards pricing and reimbursement practices that are adapted to three distinct categories of medicines:

- Patent-protected medicines, primarily those with high volumes: value-based pricing, possibly with (confidential) discounts and rebates for differential pricing and/or with price-volume agreements;
- Low-volume medicines (including patented and off patent medicines and medicines for rare diseases as well as stratified disease medicines): price-volume
agreements that reward innovation, possibly with (confidential) discounts and rebates for differential pricing;

- Generics: competition (including tenders) with price transparency. When tenders are used, sustaining a competitive market with multiple players should be a focus. However, this principle may not be applicable for all generics (e.g. biosimilars).

**Research priorities**

The research priorities identified include studies that focus on the broader environment of pricing and reimbursement policies and the specific ‘tools’ that are used. In addition, in order to conduct these studies there is a critical need for cross-country learning, co-development of methodology and exchange of information and experiences. To achieve these objectives, it is essential to build an appropriate research infrastructure, including a research network.

Priority research is recommended in the following areas:

**Policy environment:**

- The meaning of innovation for pricing and reimbursement authorities: what do the various stakeholders perceive as innovation? A particular topic for research is how this relates to (cross-country) willingness to pay to reward innovation.
- The impact of the current financial crisis in Europe on issues such as access and availability; consumption volumes (particularly generics use) and the price of medicines; tax levels; co-payments; and coverage decisions.
- The effects of newly implemented pricing and reimbursement policies and regulations (such as an updated Transparency Directive) and, in particular, the effects that they have on time to market entry for medicines and on innovation.
- Issues surrounding delays to entry should also be seen in the light of potential market entry strategies by pharmaceutical companies due to external price referencing. The interaction between price referencing policies and marketing strategies of companies (and impact on patient access) should be studied.
- The extent to which pricing and availability issues are related at the global level. In particular, information is needed about the differences between public and private sector channels and the different price components. Creating high quality longitudinal datasets in this area could help to study trends and the impact of policy.

**Methods and tools:**

- The effects of external price referencing (EPR) and the effects of parallel trade. Although EPR is still a widely used method, little is known about the potential adverse effects of these policies in Europe and at the global level (such as how it relates to equity, access and possibilities for differential pricing in Europe). Some studies indicate, for example, that EPR may have negative effects for ‘low price’ countries. The results of any ongoing study should be taken into account.
8. New approaches to promoting innovation

- Value-based pricing: evaluate experiences, compare methods, share experiences, assess resource requirements and how societal values can be included. Further studies should focus on how experiments in value-based pricing interact with other aspects of pricing practices (such as parallel trade or external reference pricing).
- Differential pricing mechanisms and policies. At present, the pricing of medicines at a ‘formal’ level (official list prices) does not reflect differential pricing achieved through rebates and discounts. Case studies may be needed to further elucidate the actual end user prices between and within countries.
- The impact of policies including generic entry and managed entry practices. At present, experiments are taking place with various generic policies such as tendering and price-volume agreements. In many instances, these policies have been successful in driving down prices. However, these policies can also have adverse effects on availability as well as on pharmacies and dispensers (for example, shortages are threatening the economic viability of pharmacies).
- Pricing and reimbursement policies in areas with small volumes, such as orphan diseases and stratified medicines (see Background Paper 7.4). Although tools such as value-based pricing could also be used in this field, the special conditions on the market (high medical needs, small volumes) require specific policies and tools. As orphan and stratified medicines will become more prominent in coming years, further research in this area (e.g. on experiences and best practices) will be needed.
- How patients can best be involved in pricing and reimbursement decision-making (see Chapter 8.5 and the related Background Paper for additional research priorities). Where patients are already involved the impact needs to be assessed (e.g. in Malta and the United Kingdom).

Research network:

For the above recommendations to be successful, it is critical to build and support a research infrastructure that is able to create a research network that links all stakeholders and existing networks such as EUnetHTA, CAPR and PPRI with international organizations such as Health Action International (HAI), the WHO and the World Bank (especially for networks between the EU and low- and middle-income countries). Existing networks such as EUnetHTA and the PPRI network could also provide a basis for future networks (e.g. by adding a more explicit academic component), and make important contributions to the development of methodology, such as generalizability and transferability of economic evaluations. Whole such networks may appear costly. They build on the strengths of the European Union to share and develop knowledge.

In conclusion, one of the major challenges in government policies relating to medicines is how to align the need to control health care expenditures, with creating incentives for innovation that addresses public health needs. In recent years, there have been a large number of developments in this area. For the coming years, this will require efforts to carefully weigh and evaluate the different tools that are available, refine methodologies and assess the impact on medicine use and innovation. This will require
significant investments and the involvement of all stakeholders. Sometimes this will lead to the discovery of uncomfortable truths and a need to accommodate strongly divergent points of view. However, the development and implementation of policies that can make an innovative and sustainable pharmaceutical market a reality will bring substantial benefits for patients, governments, companies and payers.

References


9 Charles River Associates. The implications of international reference pricing and parallel trade on social welfare and patient access, CRA, September 2012.