

# Rewarding innovation? An assessment of the factors that affect price and reimbursement status in Europe

Received (in revised form): 13th December 2009

## Adam Hutchings

is a health economist with experience of negotiating pricing and market access for medical products across many geographies. As a partner in Global Market Access Solutions, he provides consultancy services to pharmaceutical and medical device manufacturers to aid them in maximising the value of their portfolios.

**ABSTRACT** In countries with social health-care systems, pricing and market access barriers represent perhaps the biggest challenge to pharmaceutical and medical device companies trying to commercialise new products. It is important for both health system managers and manufacturers to be clear about which product attributes these complex 'reward frameworks' are trying to incentivise. This transparency will allow pricing and market access systems to be closer aligned with broader health policy goals, and give manufacturers clear guidance on the types of products society wishes them to deliver. This article seeks to deconstruct the pricing and market access frameworks for five European countries and identify the product attributes and manufacturer behaviours that are implicitly being rewarded.

*Journal of Medical Marketing* (2010) 10, 83–90. doi:10.1057/jmm.2009.49

**Keywords:** market access; health economics; Europe; pharmaceuticals; medical devices

## BACKGROUND

The pharmaceutical and medical device industry is perhaps the most tightly regulated marketplace in the world. In countries with social health-care models this oversight increasingly extends beyond licensing and into the pricing and reimbursement of products.

This interference may be legitimate. Economists recognise that health-care insurance markets have inherent weaknesses and may deliver sub-optimal results for society as a whole. While the validity of this argument is currently being debated loudly in the United States, in most other

developed countries a consensus has long since been reached.

When surveying the health-care systems of Europe, Canada, Australia, much of South America and growing swathes of Asia, governments can be seen to be underwriting health-care provision, either through mandatory health insurance, direct taxation, public procurement or public provision. Consequently, in many major international medical markets the government is both the ultimate purchaser of health-care products and the arbiter of the markets in which they are traded.

### Correspondence:

Adam Hutchings  
Global Market Access  
Solutions LLP, 122A Acton  
Lane, London W4 5HH, UK  
E-mail: adam@mmasoln.com

Given finite budgets and acute political sensitivity towards access to medicines, governments use their monopsony power to negotiate as many new products for as little as possible. To achieve this they have created complex rules, assessment mechanisms and negotiation processes. Increasingly, the outcome from these negotiations determines the commercial success of pharmaceutical and medical device manufacturers.

Although rarely positioned as such, these processes and negotiations form a 'reward framework' that establishes the return (in the form of reimbursed price) that manufacturers receive for their medical products. Through rules and precedents, governments send signals to manufacturers about the product attributes and manufacturer behaviours that they are trying to encourage, and the disease areas that they are prioritising.

The policy objectives underpinning these reward frameworks are not always explicit. This analysis seeks to deconstruct the reward frameworks of five European health-care systems and identify common factors that influence the return awarded to manufacturers for new products.

The nomenclature in this area is often confusing. For this article, 'pricing and market access (P&MA) system' and 'reward framework' will be used interchangeably as collective terms for all the cost barriers that lie between product registration and patient use. The phrase 'effective price' and 'manufacturer reward/return' will also be used synonymously to depict the real, reimbursed price that a manufacturer obtains for their product.

## METHODS

The five countries included in this assessment were Germany, France, Italy, Spain and the United Kingdom.

A comprehensive yet informal review of the literature describing the P&MA

systems within these countries was conducted. The following sources were appraised:

- Peer reviewed articles.
- Information provided by the local P&MA agencies in each country, including conference presentations by representatives of these organisations.
- Industry P&MA reports.
- Reviews by international institutions, including the ÖBIG/European Commission Member State pharmaceutical survey.
- Product case studies reported in the medical press.

The review sought to answer the following questions:

- What is the reward framework (P&MA system) within each country?
- What factors are most important in determining the effective price of a new product?
- What is the nature of the relationship between each factor and the size of the reward?

Based upon the findings from this review, a list was compiled of factors that influence the size of the reward for manufacturers. The relative importance of each factor was appraised subjectively by the author based upon examples from the literature and personal experience.

## RESULTS

Table 1 lists the factors that were found to influence the effective price that manufacturers receive for new products in the five European countries appraised. The terms used to describe these factors have been defined in a way that minimises duplication of concept, and so they may differ slightly from commonly used phraseology. Examples of other terms used to describe these factors have been

**Table 1:** A description of the main factors influencing manufacturers' returns within European pharmaceutical reward frameworks

Factor	Description	Synonyms/metrics
Clinical benefit	<p>The ultimate consequences for the patient from an intervention, incorporating both efficacy and side effects. Benefit can come from reduced mortality, morbidity or improved quality of life. It can be quantified either quantitatively or qualitatively. It is invariably assessed relative to another intervention. Clinical benefit can potentially be deemed to be negative.</p> <p>Clinical benefit can be divided into two separate components:</p> <ul style="list-style-type: none"> <li>• Size of clinical benefit</li> <li>• Uncertainty of clinical benefit.</li> </ul>	Medical benefit; health outcomes; patient benefit; ASMR; QALY; innovation
Other user benefits	<p>Other benefits of the product (beyond clinical benefit) that are accrued by the end users (patients, doctors, nurses). Examples might be combination drugs that reduce the number of pills a patient has to take, or packaging improvements that reduce the risk of needle-stick injuries.</p>	Convenience; compliance; safety
Health economic benefit	<p>Cost offsets elsewhere in the health-care system as a result of using the new product.</p>	Cost offsets; downstream cost savings; reduced resource utilisation
Social economic benefit	<p>Economic benefits to wider society (beyond the health-care system) as a consequence of the new product being developed. In particular, benefits from a healthier populace, such as improved productivity.</p>	Productivity; social gain
Manufacturer investment in local country	<p>Summation of the economic value being accrued to the country as a consequence of the manufacturer's inward investment in production plants, research facilities and marketing operations. These economic benefits can include tax receipts, employment/wages and research grants.</p>	Inward investment; tax receipts; employee count; number of plants/facilities; headquarters in local country
Investment in R&D of product	<p>The total cost of the manufacturer's investment to bring a new product to market. Some countries use this as a quantitative way of assessing the research effort.</p>	Total R&D investment; number of patients in clinical trial programme; number of publications relating to R&D of product
Cost of goods/profit margin	<p>The manufacturing cost to produce the product (and the implied profit margin given the proposed price).</p>	Profit margin; mark up
Technological advancement	<p>The extent to which a new product uses a novel process, mechanism or technology. This does not necessarily have to provide a clinical benefit (for example, inhaled insulin represented a technological advancement, but was widely considered not to provide a clinical benefit).</p>	New mechanism of action; new scientific method (biotechnology; stem-cell research)
Patent/marketing exclusivity	<p>Whether a product is early to market and with patent/marketing exclusivity, or whether it is a late-entrant to a market with other (possibly generic) products already in the same class. This factor influences the effective price through the many reference-pricing schemes in place in European markets.</p>	Newness/speed to market/intellectual property; patent exclusivity; marketing exclusivity; lack of generic comparators
Comparator product price	<p>The price of the product that is currently considered most appropriate for the indication that the new product is licenced for – that is the comparator product within the P&amp;MA assessment.</p>	Incremental cost

**Table 1: continued**

Factor	Description	Synonyms/metrics
Budget impact	The cost to the country's health-care system of providing the new product in their market. Some countries consider the net cost, others the gross cost.	Net cost; sales forecast
Equity	The nature of the patient population who obtain the benefit from a new product. For example, young versus old, rich versus poor.	Fair innings; triage
Rarity of disease	The prevalence of the disease for which the product is indicated. Low prevalence (rarity) is sometimes considered a factor affecting the price of a product irrespective of the often-concomitant burden/unmet need.	Prevalence; incidence; orphan disease/drug
Unmet need Severity/burden of disease	The lack of effective alternative treatments currently available for the disease in question. The size of the impact that a disease has on a patient's length and quality of life.	Orphan disease Life expectancy; disability; morbidity; prognosis

included alongside the descriptions of the metrics used to quantify them.

A full discussion of the relative importance of all of the factors in Table 1 is impossible within the constraints of this article. Below, the most important factors are summarised and the perceived difference in importance of factors between countries is discussed.

## CLINICAL BENEFIT

The additional clinical benefit associated with a product can be broken into two parts: the magnitude of the benefit and the uncertainty of this being achieved in reality. (The latter is closely linked to the size of the evidence base supporting the product.)

Perhaps unsurprisingly, clinical benefit – as measured by improvements in patient health outcomes – is the single most important factor affecting the size of the reward a company receives for a new product in Europe. However, the importance of this factor varies considerably between countries.

In Germany, the therapeutic benefit of a new product is the single most important factor in determining the effective price of a new product.<sup>1</sup> This is the variable that decides the reimbursement decisions of both ambulatory and hospital product assessment agencies, including the Federal Joint Committee (G-BA), the Institute for Quality and Efficiency in Health-care (IQWiG), the Institute for Sickfund Payments (InEK) and the Drug Commission. It is especially important because there is no linear relationship between the size of the clinical benefit and the size of the price premium. The principle arbiters of the reimbursement and internal reference pricing systems – the G-BA and IQWiG – have in the past made yes/no decisions on reimbursement based solely on the perceived magnitude of the clinical benefit, rather than on the benefit relative to the additional cost

over a comparator product. Therefore a product that is deemed to offer 'clinically significant' therapeutic benefit can potentially command a very large price premium, whereas one that fails that test may not be reimbursed at all.

Similarly, the size of the clinical benefit is probably the single most important factor affecting manufacturer returns in the United Kingdom. The incremental cost effectiveness ratio (ICER) framework used by the National Institute of Health and Clinical Excellence (NICE) attempts to exactly quantify the additional clinical benefit of the product in quality adjusted life years (QALYs) gained. This benefit is directly and proportionately linked to the additional price a manufacturer can charge.<sup>2</sup>

The NICE methodology also places significant weight on the uncertainty around the clinical benefit.<sup>2</sup> Companies are required to conduct probabilistic sensitivity analysis around the ICER of their product, and it is the likelihood of that ICER falling within the appropriate threshold – rather than the base case estimate – that is of most importance in determining NICE's decision. This factor is obviously influenced considerably by the availability of data, as the probability distribution around the ICER is a function of the uncertainty around key clinical parameters that are themselves dependent upon clinical trial sample sizes. Hence the size of the evidence package is very important in the United Kingdom.

In Italy and Spain the relative importance of clinical benefit is lower than in Germany and the United Kingdom. For both countries this reflects the limited opportunity for price premiums regardless of the clinical benefit, given the stringent focus on cost containment in these markets. For example, in Spain the maximum potential price of a new product is effectively capped by constraints on profit margins (see below) that apply

regardless of the size of the clinical benefit.

## COMPARATOR PRODUCT PRICE

One factor that is very important in determining the effective price – yet is unrelated to either the product profile or the manufacturer's behaviour – is the price of the comparator product. This is important in all five European countries included in this review.

In France, the price negotiation between the manufacturer and the Economic Committee on Health Products (CEPS) is a relative discussion, with price premiums considered over and above the assumed baseline of price parity with the comparator product.<sup>3</sup> Thus the price of the comparator is an important variable in determining the price of the new product. This relationship can be especially contentious if the comparator product is generic or not even licensed for the disease in which the new product is indicated. The CEPS makes no explicit rule on whether they do or do not consider off-label products to be appropriate comparators for pricing purposes.

This comparator effect is modulated to some extent by the external reference pricing rules that the CEPS also consider in their negotiations. For products with an Evaluation of Therapeutic Benefit (ASMR) rating of III or better, the rules suggest that the French price cannot be below the lowest of the list prices in Germany, the United Kingdom, Italy and Spain. Thus for innovative products a premium is still possible even if the comparator price is very low.<sup>4</sup>

Given that the NICE methodology is inherently relative, the price of the comparator product is also a very important factor in determining the effective price of a new product in the United Kingdom. This is particularly true as the United Kingdom does not use any

external reference pricing schemes to modulate the effect of a low priced comparator.<sup>4</sup> Therefore in the United Kingdom the availability of a cheap generic comparator can significantly curtail the effective price of a new product.

The cost of the comparator product is probably least important in Germany, where in the past there has been a dichotomy between the assessment of additional benefit and the assessment of the additional price.<sup>5</sup> Effectively, this has meant that if benefit has been established, the product can be reimbursed regardless of the incremental price over existing products.

### **UNMET NEED AND DISEASE SEVERITY**

Although these two factors are not synonymous, there is overlap between the concepts. Both are important in influencing the outcome of price negotiations in all markets, but are perhaps most important in France, where the disease burden is recognised explicitly through the level at which the product is reimbursed – the Medical Benefit (SMR). The SMR is based on five criteria, including two pertinent to this factor: ‘the seriousness of the disease being treated’ and ‘whether the drug cures the disease, prevents it or ameliorates the disease’s symptoms’.<sup>4</sup> A similar algorithm used to define ‘innovation’ within the Italian P&MA system also places emphasis on these two factors.<sup>6</sup>

Unmet need and severity of disease matter much less in the United Kingdom than in other European countries, largely owing to the strictures of the NICE methodology. While the appraisal committee ostensibly have the latitude to factor these considerations into account, it is suspected that they do not impact significantly. The exception to this is the End of Life guidance that was recently introduced into the NICE process to

allow for greater flexibility in the willingness-to-pay threshold for therapies that prolong life in certain situations.<sup>7</sup>

### **BUDGET IMPACT**

The budget impact of a new product is a factor that health policymakers rarely ever acknowledge as influencing P&MA decisions, but is nevertheless very important in determining the effective price a product receives. Budget impact is particularly important in Spain, Italy and France. In these countries, manufacturers are obliged to provide sales forecasts at the time of price negotiations, with the widely held perception that the larger the sales estimates the lower the acceptable price premium.<sup>4</sup>

In Spain and France, sales volumes are explicitly linked to price through price-volume agreements negotiated pre-launch. Manufacturers who exceed their forecast sales can expect to have their price cut accordingly.<sup>3,8</sup>

In the United Kingdom and Germany there is no mechanism by which forecast sales influence price, given the ‘free-pricing’ nature of these markets. Similarly, while NICE requires manufacturers to provide estimates of budget impact, this information is supposedly only considered for the purposes of health service planning.

### **COMPANY INVESTMENT IN LOCAL MARKET**

In some European markets the extent to which a manufacturer invests in the local country impacts the effective price they receive for their products. As with budget impact, few payers emphasise the importance of this factor in P&MA processes, but it is believed to have direct relevance to price negotiations in France, Italy and Spain.

The Italian Ministry of Health, at least, is open about this. Inward investment is considered by the Italian Drug Agency (AIFA) when making pricing decisions. Indeed, the Law 222/2007 introduced

in 2007 placed special emphasis on the need for pharmaceutical companies to invest in pharmaceutical R&D in Italy.<sup>6</sup> The law makes specific reference to the quantity of clinical research conducted by companies in Italy and the number of manufacturing sites they own in the country.

In Germany and the United Kingdom manufacturers with large local operations undoubtedly enjoy greater influence at a political level than smaller companies, but this strength is unlikely to benefit those manufacturers in individual P&MA negotiations.

### **COST OF GOODS/PROFIT MARGINS**

In four of the five markets included in this analysis, the relationship between the price sought by the manufacturer and the cost of manufacturing the product (cost of goods) is not a critical factor. Even in the United Kingdom, where the Pharmaceutical Price Regulation Scheme ostensibly limits manufacturer profits to a margin of no more than 21 per cent return on capital, the reality is that this is not a major curb on manufacturer profitability.<sup>9</sup>

However, in Spain this factor is highly influential in determining the effective price a manufacturer receives. Although the Spanish authorities consider a product's therapeutic value, the pricing decision (separate from the reimbursement decision) is effectively a 'cost-plus' negotiation, with the Ministry of Health looking to explicitly sanction a certain profit margin for the company. This margin rarely exceeds 18 per cent of total cost.<sup>8</sup> To mitigate the risk of companies submitting inflated cost estimates or subsidising inefficient production, the authorities also benchmark the product's price against other equivalent products already on the market in Spain and the same product in other countries.

### **HEALTH ECONOMIC BENEFIT**

Within this analysis, health economic benefits – as defined by the cost offsets produced as a result of using the new product – is not terribly important in determining the manufacturer's reward. This may seem odd, given NICE's well publicised use of cost effectiveness. However, the outcome of the NICE process is influenced mostly by the clinical benefit and the price of the product. Cost offsets can legitimately impact a NICE economic evaluation and provide scope for higher prices, but demonstrating these savings to the evidence standards required is very difficult.

Of the five markets, this benefit is most important in Germany. This reflects the importance of demonstrating cost offsets when seeking reimbursement for new secondary care products. The InEK considers economic variables when determining whether products should be eligible for additional top-up payments within the diagnosis-related group (DRG) system.<sup>1</sup> The Institute's approach is pragmatic and less rigid than that of IQWiG or NICE, and focuses on the economic impact on the hospital, rather than on the broader health-care system.<sup>8</sup> The New Investigation and Working Method (NUB) payment – a supplement to an existing DRG fee – will not be granted if there is insufficient medical or economic evidence, or if the new technology does not lead to a specific increase of costs.<sup>10</sup>

### **CONCLUSION**

Although this review represents only an informal and subjective assessment of the P&MA systems of these five European countries, the list of factors that are described in Table 1 is likely to be reasonably comprehensive. Undoubtedly, this work requires validation by local experts and, ideally, empirical testing. Regardless, it is important that these

factors (and their relative importance) are understood, for two reasons.

First, it is critical that manufacturers understand what attributes to consider when making strategic decisions concerning research and development and capital investment. Timelines for product development are long, and thus governments have a responsibility to be clear and consistent in identifying what product attributes they are prepared to reward.

Second, it is necessary to understand the attributes that P&MA systems are incentivising in order to assess whether they are aligned with the government's broader health policy objectives (and, indeed, with the values of society).

Based upon this limited assessment, it appears that the existing reward frameworks within Europe have mostly reached their current structure through an organic process of incremental adjustment. As such, it is questionable whether these systems are achieving either the health policy or industrial policy goals that governments are trying to reach.

## REFERENCES

- 1 Hess, R. (2009) Restrictions and changes to the German reimbursement policy. Presented at the 4th Annual Pharma Pricing Strategies Meeting; 16 January 2009, Amsterdam.
- 2 National Institute of Health and Clinical Excellence (NICE). (2008) Guide to the methods of technology appraisal, <http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf>, accessed 1 September 2009.
- 3 Meyer, F. (2009) Assessment of pharmaceuticals in France. What's new? Presented at the Pharma Pricing and Market Access Outlook Europe 2009 Meeting; 30 April 2009, London.
- 4 Espin, J. and Rovira, J. (2007) *Analysis of Differences and Commonalities in Pricing and Reimbursement Systems in Europe*. Brussels, Belgium: European Commission Directorate General Enterprise and Industry.
- 5 Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). (2008) General methods, [http://www.iqwig.de/download/IQWiG\\_General\\_methods\\_V-3-0.pdf](http://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf), accessed 1 September 2009.
- 6 Garratini, S. (2009) Italy. Latest changes in reimbursement and pricing policy. Presented at the Pharma Pricing and Market Access Outlook Europe 2009 Meeting; 30 April 2009, London.
- 7 National Institute of Health and Clinical Excellence (NICE). (2009) Appraising life-extending, end of life treatments, <http://www.nice.org.uk/media/E4A/79/SupplementaryAdviceTACEoL.pdf>, accessed 1 September 2009.
- 8 Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG). (2006) *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*. Brussels, Belgium: European Commission Directorate General Competition.
- 9 United Kingdom Department of Health. (2008) The Pharmaceutical Price Regulation Scheme 2009, [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098498.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf), accessed 1 September 2009.
- 10 Briswalter, S. and Welte, R. (2007) Reimbursement of new health technologies in a DRG-system. iHEA 2007 6th World Congress: Explorations in Health Economics Paper. <http://ssrn.com/abstract=992773>, accessed 1 September 2009.