

ability to maintain a broad technological base which would otherwise provide a form of insurance against inevitable research dead-ends. Within the context of VBP this occurs not only within but also potentially across companies as they will have an incentive to compete for areas of highest health gain.

Conclusion

The design of optimal regulation is not straightforward. The current discussion of how to regulate pharmaceutical prices in the UK highlights this. The existing UK regulatory environment has been voluntary and has allowed high rates of return as an incentive to motivate R&D. The proposed system emphasises that the presumed high prices consistent with these returns have eroded consumer surplus. Such a debate brings a clear perspective to the tensions associated with the pursuit of static and dynamic efficiency concerns. With either regulation there is a trade-off; with the PPRS the trade-off is that static efficiency concerns are relaxed to allow the pursuit of dynamic efficiency through the provision of incentives for R&D investments and, hopefully, a quick rate of market launch of beneficial products. Under the proposed VBM the trade-off would be to tighten static efficiency concerns against the cost of potentially reduced incentives for R&D. The actual judgement regarding which is, of course, an empirical one.

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Pharmaceutical pricing in France: a critique

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Summary: In France, pharmaceutical pricing relies on an ex ante evaluation of the medical value of drugs. Prices are negotiated on the basis of an industry-wide contract between drug manufacturers and the Health Products Pricing Committee (Comité Economique des Produits de Santé). Together the Committee and the drug companies sign a number of contractual agreements, which give the national health system a variety of flexible means to monitor prices and drug use, also ensuring that public resources are properly allocated. Some drugs have different levels of therapeutic value, depending on who takes them. These products in particular need close monitoring. Rebate policies are one of the tools available to control such spending. The economic efficiency of such rebates should not be overestimated; in practice they do not significantly decrease spending.

Keywords: Pharmaceutical Policy, Reimbursement, Rebates, Evaluation, Added Therapeutic Value

A few words on pricing and reimbursement

Pricing and reimbursement decisions in France are taken on a step by step basis. Firstly there is the market authorisation of a drug at a national or European level. The product is then evaluated by an independent scientific committee, prior to price negotiations. This Transparency Committee, named after the European Transparency Directive, assesses the therapeutic value, or clinical benefits of a drug, and proceeds to compare it with existing therapies. Drugs are evaluated against two sets of complex criteria: their therapeutic value (*service médical rendu*) and added therapeutic value (*amélioration du service médical rendu*).

Therapeutic value takes into account the severity of the illness and the efficacy of

the drug. Although a drug's therapeutic value does not impact on pricing, it helps determine its reimbursement rate. The added therapeutic value of a drug is a relative notion, as it is measured through a comparison with the clinical benefits of existing drugs or therapies. Thus, it represents the 'added health gain' or the 'relative effectiveness' of a drug, compared to its alternatives. The main problem in assessing this added therapeutic value is the time it takes, as well as the lack of proper clinical trials against alternative products on the market.

Nonetheless, such evaluations are necessary and need to take place prior to any decision on reimbursement. They should also fit within the timeframe (normally ninety days) to reach a decision on reimbursement set out in the 1989 Transparency Directive (Directive 89/105/EEC). The duration of such evaluations have in fact decreased in recent years and now meet this requirement, while fast track procedures were also introduced to help assess those drugs of great significance.

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There are five levels of added therapeutic value (ATV) that may be assigned to a drug after comparison assessing the degree of improvement against existing therapies:

- I – major improvement;
- II – significant improvement;
- III – moderate improvement;
- IV – minor improvement; and
- V – no improvement.

ATV is the most influential factor in drug pricing. It is re-evaluated every five years or earlier, if the committee chooses. In most cases, a re-evaluation includes additional assessment of the drug's therapeutic value under real life conditions.

It should also be noted that evaluation and price negotiation is carried out before any reimbursement schemes are devised. In most cases this is before the drug is launched in the market. There are also specific procedures that allow a drug to be put on a temporary reimbursement list in the case of interventions for life threatening diseases. These procedures are however used prudently, reflecting the fact that once an individual is placed on a course of therapy it then becomes very difficult to interrupt such treatment. Thus without care these procedures might provide pharmaceutical companies with considerable leverage in subsequent negotiations on the longer term use of a drug.

General agreements and rules

Following the determination of added therapeutic value, the Health Product Pricing Committee negotiates with the drug manufacturer. The Committee follows a number of guidelines defined either by law or by general agreement with the pharmaceutical industry. All negotiations are contractual and may include provisions regarding volume limitations, rebates and price re-evaluations.

There are, however, two main rules: (1) ATV level V drugs can only be added to the reimbursement list if they allow savings for the social security system; and (2) prices of drugs which offer considerable improvement over existing therapies (levels I to III) must remain stable for the subsequent five years, and in line with other major European markets.

The agreement between the pharmaceutical industry and the Pricing Committee also includes a general payback procedure. Every year, parliament votes to approve a prospective budget for the public health insurance system, defining target increase-

rates (so called "k-rates") for each category of expenditure. When the increase in pharmaceutical expenditure exceeds the respective k-rate, the manufacturer must contribute via a rebate scheme.

Rebates are calculated for each company on the basis of how innovative their products are, i.e. their ATV levels and their share of the increase in expenditure (orphan drugs are exempt). Rates are subdivided by category and homogenous groups of products within each category, for example, statins. The pharmaceutical industry contribution can represent a large part of the excess, often 40% or more. 65% of rebate payments are proportional to turnover and 35% to growth.

The rationale for rebates

In recent years, the pharmaceutical industry has undergone great change. Manufacturers now tend to develop more complex products, targeted at very specific sub-groups of the population, or sometimes even sub-groups of a specific disease. Now that the most simple of ailments can be cured by drugs that are becoming ever cheaper (for example, generic drugs), companies need to find new, often biotech-oriented solutions, in order to address more complex medical conditions.

One consequence is that the characteristics of the target populations of many important drugs are becoming ever more similar to those for orphan drugs. The sheer cost of many of these drugs makes it crucial for the public health authorities to ensure that they are prescribed only to those who can benefit from their use. Physicians, of course, play a crucial role when it comes to ensuring that these new drugs are prescribed correctly. France has devised a number of schemes to encourage appropriate prescribing practices. Yet drug manufacturers also play a large part in how their products will be used. That is why the agreements they conclude with the Pricing Committee can include provisions on the volume of prescriptions, dosages and advertising campaigns. Companies are also held accountable for the correct use of their products.

Interestingly, French physicians tend to be heavier prescribers of drugs than most of their European counterparts. France's pharmaceutical history and culture, as well as the comparatively low price of many widely used drugs (i.e. aspirin and paracetamol), have led to a situation where 90% of doctor-patient appointments end with a prescription. It is critical therefore that all

products are used by their intended targeted populations.

Take a product that was recently included in the reimbursement list. It provides a very high level of improvement for a small population (population A). Its market authorisation is also valid for a much larger population (population B), even though it does not provide them with any health gain, compared to existing, very cheap therapies. It would obviously have been wrong to ban access to this product for population B. But why should the health care system pay a premium on a product that does not give most people any added medical value?

There are two options. One can either devise a reimbursement scheme for everyone, defining a 'median price' between the innovative part and the ordinary part of a product, or one could limit drastically the use of this product beyond the small target population. Nevertheless, both options call for scrupulous monitoring. Depending on market share and prices, rebate rates can be adjusted according to the terms of contracts. Furthermore, rebates are expected when a manufacturer's advertising campaign is not in line with a product's characteristics.

The rebate scheme for drugs has recently grown more complex. Increased access to hospital drugs has been granted through the creation of an 'additional list'. It registers expensive and innovative hospital drugs that may be reimbursed by hospitals, on top of diagnostic-related group payments. The reason for this scheme is that it is necessary to provide general access to expensive drugs. Yet such drugs may be used for very different purposes from one hospital to the other, depending on the nature of patients being treated. For example, a world-renowned cancer specialist may need to resort to more expensive drugs for complex cases, compared with an oncologist in a less specialised hospital. If both hospitals receive the same level of funding the more difficult cases will not necessarily get what they need. And if both hospitals are given the same access to expensive drugs, they will not have incentives to control their costs.

To go back to the earlier example, if a given drug is more expensive than its competitor in the B market, so much so that its competitor does not feature in the additional list, hospitals would have an

incentive to use the drug in both A and B markets, since they do not need to pay for it. Resources, in such a case, are not efficiently allocated. The solution is to restrict access to the additional list as much as possible, and monitor the use of the product.

Let us complicate things a bit further and consider that one such drug shares the A market with another expensive drug. If both drugs are authorised for the whole target population, they will spill into the B market without their manufacturers having to face any rebates. This is the reason why it was recently made possible to limit use to a given volume of products.

Conclusion

These examples demonstrate that rebate schemes are necessary to limit price increases in France and to monitor drug use. However, their impact should not be overestimated. Prices are essential in any regulated market to send the right message. Many factors in the system may lead to spontaneous price adjustments without the need to resort to rebates.

All in all, rebates in France do not account for more than 1% or 2 % of the total expenditure on pharmaceutical products in any given year. This is somewhere in the range of €500 million per annum, a sum which seems considerable in its own right. But it is still small, compared with the €25 billion that France spends on drugs every year. Such a modest share in the total health care budget means that one cannot accuse rebate schemes of distorting prices. Yet rebates still represent a crucial tool to control the use of very specific products. In some cases, the fact that they potentially may be used is more important than their actual use. They allow the public health care system to monitor marketing, advertising and use.

In conclusion, rebates do play a part in the correct allocation of health-insurance resources. The general rebate also helps to devise a more accurate estimate of annual pharmaceutical expenditures. An emphasis should be placed on the importance of the ex ante evaluation of any drug: it provides the health care system with a large number of tactics to control drug spending. Moreover, it also facilitates access to very innovative drugs by those patients in most need.

Can Europe afford innovation?

Thomas B Cueni

Summary: Finding a balance between reward for innovation, improved patient access to innovative medicines and controlling budgets remains a challenge for decision-makers, patients and industry in Europe. The industry has a clear preference for market-based pricing, yet, the predominance of administered pricing in most European countries, given, alternatives need to be explored. Today, Europe sees health care innovation too much as a cost rather than an asset. There is a need for constructive dialogue on what constitutes the value of new medicines and how added therapeutic value should be rewarded.

Keywords: Innovation, Value Based Pricing, Pricing, Reimbursement, Added Therapeutic Value

Pricing – an unpredictable lottery?

Finding a consensus among different stakeholders on what constitutes ‘value of innovation’ is almost like squaring a circle. From an industry perspective, it appears that payers are primarily interested in controlling costs, are unwilling to grant premiums for innovative new medicines and are delaying patient access to therapeutic advances. From a payer perspective, it may look as if pharmaceutical companies expect to recoup their investments into research and development (R&D), irrespective of added therapeutic value, want to meet or better exceed shareholder expectations for hefty profits, and are not concerned about escalating health care costs.

The truth may be somewhere in the middle and the problem for companies is less the requirement to justify higher prices with added value than the lack of predictability and erratic changes in national pricing and reimbursement systems. This is reflected in the World Health Organization’s report on Priority Medicines for Europe and the World: “at present, reimbursed prices are determined

by each country, often in a black box fashion where country reimbursement authorities set prices to ensure access and control costs. This results in an unpredictable lottery for companies who have brought a product to market through a series of regulatory hurdles and still do not know what the final reimbursed price will be.”¹ Now, the question of what constitutes a “just price” has been debated since Saint Augustine but it is interesting to note a statement from Vice-President Verheugen, Commissioner in charge of DG Enterprise, who said, “to begin with, the pricing for innovative products in Europe...needs to be improved.”²

Innovation – driver of economic growth

The underlying problem is that the European health care debate focuses too much on regarding innovation as a cost factor. Medical progress is seen as burden rather than an asset, and the concern is often about the high cost of new medicines rather than about the burden of disease. Such an approach is short sighted. In modern economies, innovation, i.e. technological progress, is the most important driver of competitiveness and economic growth. The effect of R&D activities on economic growth and productivity gains has been proven by numerous empirical studies. The main difference between the success story of market economies and all other economic systems “is free-market pressures that force firms into a continuing process of innovation, because it becomes a matter of life and death for many of

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