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.”

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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them...It seems indisputable that innovation accounts for much of this enviable growth record,” is how William J Baumol, the eminent US economist, put it.3

We live longer and in better health

The crux of today’s health care debate is that pharmaceutical innovation focuses on the needs of the patients whereas the health policy debate is dominated by numbers and cost containment. Today, we can expect to live thirty years longer than one hundred years ago. Huge reductions in mortality (for example, in HIV/AIDS, many cancers or cardiovascular diseases) and a significant progress in the quality of life are the results of some big and many small steps in biomedical research. Contrary to common belief, higher life expectancy does not inevitably lead to degenerative disease and ever longer stays in nursing homes because we cannot only expect to live longer but we get older in better health. Higher blood pressure and cardiovascular disease can be controlled with antihypertensive drugs and cholesterol-lowering drugs, knee or hip replacements keep us from wheelchairs, and some cancers can be controlled or even cured thanks to newer targeted medicines. Yet, there remain huge challenges in areas such as Alzheimer’s disease, multiple sclerosis, many cancers or orphan diseases.

Cost containment, however, dominates the debate in a majority of countries. Reference pricing, budget ceilings, tough generics policies and price cuts are the most widely used cost containment measures. Often, new policy measures are initiated before the success or failures of their predecessors are evaluated. Indeed, Jaime Espin and Joan Rovira recently concluded that it was difficult to assess the effectiveness of many of these policies since the (positive) impact on budgets has to be weighed against the (negative) impact on patient access to innovative treatments.4

Nonetheless, it would be unfair to state that the picture is all bleak. Many governments are trying to square the circle between rewarding innovation and improving patient access while maintaining budget control. In a number of European countries such as Ireland, France and the UK, framework agreements between the government and industry have been signed, and the EU Commission’s agenda has generally been driven by an attempt to find a good balance between health policy and industrial policy objectives. Although some people from industry are impatient with the slow process of implementation of the recommendations of the G10 Medicines High Level Group5 or the Pharmaceutical Forum, legislative measures such as the Supplementary Protection Certificate (SPC) restoring lost patent term, the setting up of an efficient European market approval system with the European Medicines Agency (EMEA), improved regulations for data exclusivity, incentives for research into orphan diseases, better incentives for research into paediatric medicines as well as the most recent Innovative Medicines Initiative (IMI) all aim to make Europe more innovation-friendly for patients and industry alike. However, the predominance of Member States’ more serious concerns about health care budgets has limited the positive impact of some of these EU-driven industrial policy initiatives, which explains why the EU was unable to regain relative attractiveness for pharmaceutical R&D investments over the past decade.

No progress on pricing and reimbursement

Whereas progress in the regulatory area is undeniable, the main issue impacting the economics of the industry has not been addressed. In many instances, pricing and reimbursement still remains an “unpredictable lottery”. The debate on an industrial policy for the pharmaceutical industry in Europe has led to a broad agreement that inadequate reward for innovation and significant delays in patient access to new medicines play a major role in Europe’s declining competitiveness as a location for pharmaceutical R&D. However, it is obvious that progress will only be possible if a balance can be struck between the objectives of rewarding innovation, improving patient access to innovative medicines and controlling health care budgets.

The first issue is how to put value to a new medicine? In principle, market-based pricing is the most efficient way to allocate resources and reward innovation. However, where there is a single government payer, there is no functioning market. Thus, alternatives to market-based pricing are needed. To an economist the recurrent theme of cost-based pricing is amazing. Critics of the industry ask how can we put a price on a product if one does not know the cost of manufacturing, or the cost of research and development? Cost-plus pricing was used historically in a number of countries such as Spain, Italy and Japan. This method not only creates controversies about the measurement of costs but is neither efficient, nor effective. Cost-based pricing rewards input (investments) rather than outcomes (better cures). Whereas market-based pricing rewards the successful innovator handsomely and penalises failure, cost-plus pricing inherently favours risk-averse research and can lead to perverse results.

Other methods to value new medicines include therapeutic comparison (value based pricing), where clinical relevance and cost effectiveness are taken into consideration, or country baskets (price comparison with certain reference countries). Such country baskets are primarily driven by political considerations, since a comparison with prices in other countries is always a comparison of different pricing and reimbursement policies based on the concern that a country does not want to pay more than a neighbour or an economically comparable country. Companies naturally adjust to pricing signals. If they know, for example, that rich countries are unlikely to accept a higher price than poor countries, they will adjust their European price bands accordingly. This also leaves open the question of how to determine prices in the ‘first’ Member States that will serve later as the reference point.

Accepting the reality of administered pricing in most European countries, value-based pricing, i.e. reimbursement on the basis of comparative effectiveness is certainly the most interesting and politically relevant approach. Criteria which should be considered when assessing value include:

- Does the innovation address a high unmet medical need?
- Does it reflect a major, important or moderate clinical improvement?
- Is there an alternative treatment available and if so, is the superiority of the new treatment plausibly demonstrated?
- Is there sufficient choice to allow all patients to be treated?
- Is there a favourable cost-benefit ratio?
- What is the impact on public health?
- What is the broader societal benefit and cost?

Added value merits reward

The pharmaceutical industry has to accept that it can only receive a higher price for better value. Whereas a patent, by defi-
nition, equals an innovation from a technical perspective, a patent is not necessarily equivalent for added therapeutic value. A consequence of therapeutic comparison and value-based pricing is that major reward will be limited to significant innovation. However, the industry concern today is probably less the reward for breakthrough innovation which tends to receive a market price within a fairly narrow global band but the unwillingness in some countries to acknowledge incremental innovation. Medical progress rarely occurs in big leaps, small steps are the norm rather than the exception. Whereas the immunosuppressant Cyclosporine was a historic breakthrough for transplant surgery, the tremendous progress in transplant surgery since the first application of cyclosporine in 1978, was the result of many small steps in surgery as well as pharmaceutical research.

Without the acceptance of reward for incremental innovations, patients might not have received the benefits of step-by-step medical progress so important in many disease categories. However, negative examples of how innovation is valued in Europe today include the mixing of patented and off-patent products under reference price systems (‘Jumbo’ groups in Germany) which by definition pull up the price of generics and penalise patented medicines. Furthermore, in some cases health technology assessment is not used to identify value but to put up new hurdles. And in some countries with arbitrary budget thresholds or payback mechanisms, the pharmaceutical industry is often seen as the lender of last resort.

Huge differences in patient access
Valuing and rewarding innovation does not mean much if patients have no access to innovative medicines. In reality, not only costs vary from country to country, but also access to new drugs is subject to substantial differences. For example, the Karolinska report shows that the uptake of new cancer drugs is above average in Switzerland, Spain, Austria, and, more recently also in France, but is below average in countries such as UK, Norway or Poland. The IMS/EFPIA Patients WA.T. Indicator shows that patients in some countries have to wait more than a year longer than patients in other European countries before they have access to new medicines. Do such differences matter given that there are critics from epidemiology who challenge the statistical approach of the Karolinska study? It may be a subjective view but if I were a patient, I would not want to wait until somebody has proven the Karolinska study with epidemiological and statistical data beyond doubt. Personally, I believe that the Eurocare data on cancer survival do show significant differences in survival rates across European countries. There may be multiple factors but access to innovative treatments is most likely one of them.

Guiding principles – a fair balance
Industry is aware that finding solutions to the questions of value and affordability of innovation needs a willingness for dialogue from all stakeholders. While emphasising the need for reward and patient access to innovation, the budgetary implications and constraints cannot be ignored. The Pricing Working Group of the High Level Pharmaceutical Forum has worked out a set of guiding principles which demonstrate that dialogue between Commission, Member States and multiple stakeholders is possible. These guiding principles attempt a fair balance trying to meet the needs of patients, payers and industry alike. In particular, the principles recognise the need to not only reward breakthrough innovation but to also reward incremental innovation. The problem of uncertainty at the time of market approval is acknowledged and patient-friendly solutions are advocated. Furthermore, the paper contains an important conclusion regarding national pricing policies. In short, it states that national price controls are not meant to have an extraterritorial impact and that affordable prices for different countries in Europe should allow differentiation. The consensus on the ‘guiding principles’ was only possible because participants in the dialogue knew that they had to look for a fair balance between the potentially conflicting objectives of reward for innovation, improved patient access and the need for sustainable funding. More of this kind of dialogue is needed, in particular at Member States’ level, to find new solutions to old problems.

Innovation is crucial to Europe and its economy. Pharmaceutical innovation brings benefits to patients and wealth to society. A balance between industrial policy and health policy needs to be maintained. In this respect, pricing is an indicator of society’s willingness to pay for health benefits. Dialogue, openness and more flexible arrangements are required from governments and industry when it comes to pricing decisions. Value-based pricing means a significant reward for breakthrough innovation and an incremental reward for incremental innovation. A common understanding of what constitutes value will remain a challenge. However, it was a comforting experience for an industry participant in the High Level Pharmaceutical Forum’s Pricing Working Group that agreement on fairly broad “characteristics of innovation” was reached without much controversy.

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