



## Regulating Drug Prices and Stimulating Pharmaceutical Innovation in Europe: How to Resolve the Dilemma?

El objetivo de este artículo es establecer algunas propuestas para ayudar a alcanzar el consenso entre los diferentes agentes implicados en el sector farmacéutico europeo. Estas propuestas hacen referencia a la necesidad de mayor transparencia en los procesos de decisión sobre precios y reembolso, sustituyendo el control de precios ex-ante por un control ex-post. Delimitar el sistema de fijación de precios a fármacos directa o indirectamente financiados con recursos públicos, focalizando la competición por parte de genéricos a aquellos fármacos que han perdido la patente. Modernizar los canales de distribución, por ejemplo a través de la autorización de las cadenas de farmacias. Estas reflexiones no pretenden dar soluciones, pero si ofrecer caminos para llegar a ellas.

*The objective of this note is to frame some proposals that could win consensus among relevant stakeholders in the context of the ongoing EU reflection on drug pricing. They relate to transparency of decisions, to switching from ex-ante to ex-post price controls; to controlling prices only of drugs that are directly or indirectly paid by public health insurance, to limiting generic competition to out of patent products; and to modernizing distribution channels, for instance through authorizing pharmacy chains. These suggestions do not pretend to provide comprehensive solution to the overall problems of enhancing Europe's competitiveness in medicine and biology, or improving healthcare policies or funding. However they do offer some possibility for progress.*

**Key words:** Pharmaceutical innovation, pricing and reimbursement systems, pharmaceutical european market.

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### The current European operating context

The pharmaceutical industry is - yet again - being expected to pay a heavy price to compensate for overruns in public health expenditure in France. Recent financial reform proposals threaten drug firms with a revenue cut-back of €1.4 billion in 2006 alone, to help remedy a projected health insurance deficit of more than €6 billion for the year. And this will come on top of a previously-negotiated plan to cut €2.1 billion from drug reimbursement across 2004-2007. This is a far-from-isolated case in Europe. Italy, Germany, Spain, Belgium and the Netherlands have recently either cut

pharmaceutical prices, raised barriers to public reimbursement (through delisting drugs, or through patients' co-payment), or imposed special taxes. Most countries face the same equation: public health care expenditures are growing faster than GDP. And most of them are reluctant to raise payroll or general taxation rates at a time when countries are in fiscal competition over the location of increasingly volatile industrial activity.

At the same time, obvious political considerations make governments reluctant to constrain the other components of health care expenditures - such as doctors' fees and hospital budgets. As a result, the pharmaceutical industry becomes a relatively easy target as the

main source of savings - and it is generally required to contribute much more to cost containment policies than would be justified by its share in public health expenditures.

### But not just cost-cutting

Paradoxically, Europe is simultaneously becoming increasingly aware - at least in formal terms - of the merits of preserving and developing a competitive pharmaceutical industry. In 2003 the EU Council noted "the need to reinforce the competitiveness of the European-based pharmaceutical industry vis-à-vis its competitors, particularly by enhancing Europe's attractiveness as a location for innovative high tech industry and for maintaining a high quality science base".

The Council also emphasised "the need for a balance between competitiveness and public health policies". This key sentence is not only a recognition that cost containment policies may be harmful to competitiveness, but also implies that this is probably the case. Those public health policies cannot, of course, be blamed as the sole cause of the demonstrable loss of productivity of the European pharma-

ceutical industry compared to the US, where the industry has never been so powerful and creative. The Pammolli report, commissioned by the EU in the late 1990s, identified other factors, including the limited links between academic and industrial research, the excessive fragmentation of the European market, the lack of venture capital, and the unpredictability of national health policies. But it is equally clear that obliging the pharmaceutical industry to contribute more than its share to rescue the finances of those public health policies - and for the sole reason that the industry is a politically easy target - has contributed to the decline of a strategically vital industry.

### Action is long overdue

Despite the rhetoric about competitiveness, little has been done to improve the functioning of the European market for pharmaceuticals since the 1989 Transparency Directive, which established rules for national pricing and reimbursement procedures. There is a striking contrast between the enormous volume of statements, motions, declarations, roundtables, working groups and other mechanisms for identifying problems and discussing solutions; and the extremely limited number of concrete steps that have been taken. The contradiction is perfectly illustrated by the issue of parallel trade - where profit-seeking wholesalers benefit from the possibilities of arbitrage among European markets, by buying drugs in low-priced countries and selling them in high-priced countries. The European Court of Justice has urged the European Commission to take measures to stop the practice, which is legally correct but economically disruptive. But apart from numerous speeches and documents, no progress has been made in solving the problem. The Commission has tried repeatedly, mainly by focusing on the possibility of dissociating a freely-set European market price from national reimbursement procedures. But these attempts have all failed, principally because of opposition from member states.

Another example is provided by the discussions of value-based pricing - the use of pharmacoeconomic techniques to decide prices. Basing the price on a drug's intrinsic value, measured both in economic terms (such as hospital care savings) and in terms of medical outcome (patients' health status improvement), would certainly be an efficient approach to reconciling public health objectives and competitiveness. But most European

countries and governments rely instead on price comparisons with existing drugs in the same country or with the same drug in other countries - which raises many unanswered questions about the relevance of the prices used as comparators. Most member states also employ systems that make them insensitive to any real pharmacoeconomic approach: their reliance on "silo budgeting" procedures, in which drugs and hospitals expenditures are recorded into separate budgets, prevent the health care system capturing the full economic effect of a drug, for instance in terms of hospital stay reduction. As a result, the cost of health innovations is over-estimated, leading to sub-optimal allocation of resources between the various health system components.

### Adjusting the perceptions

The statement that cost-containment policies can be harmful to competitiveness should not be interpreted as implying an automatic opposition or contradiction between the interests of patients and of the industry. Maintaining a strong pharmaceutical activity in Europe ultimately serves the patient. The direct benefit of innovative treatments is complemented by the indirect benefits that come - for instance - from the engagement of hospitals and doctors in clinical research, from related medical training and education, from research contracts with local public or private organisations, or from the definition of research priorities that take account of local epidemiological needs.

There can be no vigorous pharmaceutical research without a vigorous medical environment. And the medical community at large derives an obvious advantage from dynamic pharmaceutical research. Patients and the health care system benefit not only from the products of innovation, but also from the process of innovation. Nor is there any intrinsic contradiction between the interests of the health-care system and the broader economy. The same innovation that can improve health-care provision will also feed into general economic activity, both by promoting high-technology activity and employment (with benefits for exports too), and by making health-care provision more efficient (not only boosting the availability of economic actors, insofar as improved health means less time off work, but also reducing the need for extensive and expensive hospital care, and thus helping keep spending down). Only by deliberately adopting a limited and short-term view - that

innovation increases health-care costs - is it possible to overlook the obvious longer-term synergies. Discussion is also clouded by misunderstandings over the nature of pharmaceutical innovation. There is an urgent need to remedy the widespread but inaccurate perception that innovation springs mainly from small and creative biotech start-up companies which deserve encouragement, while large pharmaceutical companies (so-called "Big Pharma") are producing ever-fewer innovative products, but constantly increasing their share of national drug bills.

This dichotomised view does not correspond to the reality that the industry is large, complex, and in many respects complementary. Innovative start-ups invariably need "Big Pharma" - and vice versa. Biotech start-ups rarely have the capacity to develop and market their innovative products in a significant number of countries; they usually need the assistance of some larger traditional drug company. And there is nothing new in this cooperative approach. Long before the emergence of biotechnologies, drug companies routinely adopted combined strategies, developing their own products, and licensing them out to small companies specialized in new drug design and discovery processes. The vigorous diversity and interdependence of this many-faceted sector cannot be arbitrarily segmented and separated: over-regulation of any one part is likely to have repercussions elsewhere. Certainly, it will be no benefit to biotech start-ups if regulation aims to weaken large companies.

### Balancing competitiveness and public health policies

The failure to make tangible progress on topics of such vital concern to the pharmaceutical industry certainly calls for reflection on how decisions are made at the European level. Even if the urgent short-term task of containing health care costs (including through price cuts) depends directly on individual governments, the involvement of all member states is demanded for the longer-term and more strategic task of promoting a strong and innovative pharmaceutical sector in Europe (especially through prices that reward innovation). Progress at a strategic level has frequently been impeded by a non-cooperative approach that has become almost institutionalised. Many European governments act as if pharmaceutical innovation was a public good whose existence and availability can be taken for granted, utterly independent of national

policies, on the assumption that someone else will always be ready to pay for it. This situation is analogous to the choice between defection and cooperation in the famous “prisoners’ dilemma” game, which is familiar to game theorists. In this game, each player’s best interest is to defect provided others cooperate!

Of course, the final outcome is that nobody cooperates although each player would be better off if they all cooperate. Because each country currently has access to the fruits of innovation, there is a tendency to forget that innovation will continue only as long as some other countries are ready to fund it through the drug prices they allow. The temptation is to restrict national drug prices, declining to pay a share of the costs of innovation, and relying on the others to achieve the common goal. However, if all governments adopted the same reasoning, innovation would not be financed at all - even though every government was in favour of continued innovation. This non-cooperative model is ultimately unsustainable, since its individual strategies are in conflict with the common goal. It also runs counter to the very nature of the EU and its principles of solidarity and burden-sharing in pursuit of shared values.

### Concrete steps within easy reach

To improve the situation for pharmaceuticals, a better balance can be achieved without calling into question the basic features that are considered as part of our common culture, such as universal public health insurance, fiscal financing, or government regulation - in other words, without jeopardizing the basic principles governing provision, distribution and financing of health care in Europe.

It is possible to stimulate innovation without deregulating the market for pharmaceuticals beyond what would be acceptable for most member states. Some elementary - almost common-sense - measures can achieve the goal. Moreover, some of these changes are likely to improve accountability and sustainability of health care systems as a whole. These proposals are in no way revolutionary. They constitute no more than the application of existing regulation. They relate to transparency of decisions; to switching from ex-ante to ex-post price controls; to controlling prices only of drugs that are directly or indirectly paid by public health insurance; to limiting generic competition to out-of-patent products; and to modernizing distribution

channels, for instance through authorizing pharmacy chains.

### Transparency

The basic European legislation for the economics of pharmaceuticals is still the old 1989 “Transparency” directive, which recognizes the right of member states to regulate drug prices and reimbursement, on condition that decisions are made within six months and are based on “objective and verifiable criteria”. Despite several attempts, this measure has not been revised. However, before any updating takes place, the priority should be to make the existing rules function effectively - which, at present, they don’t. In the first place, decisions are not fully transparent in several countries, especially in the new member states. Procedures and criteria remain too often obscure.

Secondly, time limits for pricing and reimbursement decision are not enforced in many countries - and these include “old” member states, notably Portugal, France, Italy, and the Netherlands. The only countries in which a product can be launched as soon as it is authorised are Germany and the UK. In a few other countries, including Austria and Sweden, the review by local pricing and reimbursement committees takes place within the six-month legal limit. But in all other countries, the average delay between the marketing authorization and the effective market access exceeds by far the official deadline. Some member states claim that they comply with the directive, and back their assertions with subtle arguments or suggestions, for instance that compliance depends on how time is evaluated. The European citizens have sharply unequal access to pharmaceutical innovations for reasons that are purely institutional. Applying the existing legislation would greatly improve the functioning of the market, support innovation, and meet citizens’ expectations.

### Separating price controls from launch

In practically all countries with price regulation, medicines are not launched as long as reimbursement and pricing decisions are pending. Delays in market access are considered as the logical and unavoidable consequence of the price regulation that many member states remain firmly attached to. But it is possible to dissociate price regulation and product launch. Under a “price notification” procedure, for instance, products can be marketed as soon as marketing authorization is granted, and at a price set by the manufacturer. Public authorities are informed of the price and are entitled, within a given time frame, to accept it

or refuse it. If the price is refused, a negotiation follows, and if no agreement can be reached, a price may be fixed by the authorities.

A procedure of this type exists in Switzerland, and was recently introduced in France. Somewhat timidly, the eligibility in France is limited to products classed as “innovative”, and the price set by the manufacturer has to be aligned with the prices in other designated countries (the UK, Germany, Italy and Spain). But this is progress, nevertheless. It speeds up market access, promotes the idea of a European price for innovation, and introduces a fundamental change in the spirit of price fixing, with a shift from ex-ante control to ex-post control. It could be expanded to cover the entire EU as a recommended model for pharmaceutical price fixing. Even if it does not constitute a major departure from existing practices, the results in terms of market access would be significant.

### Freeing pricing for non-reimbursed drugs

One obvious way to improve “the balance between competitiveness and public health policies” is to abolish price controls on non-reimbursed medicines. These products already enjoy price freedom in most European countries, but some member states - Austria, Belgium, Greece, Luxembourg, Portugal and the Czech Republic - still fix prices of non-reimbursable medicines. Pricing legislation in these countries does not distinguish between reimbursable and non-reimbursable drugs.

The consistency of such practices with EU principles is legally complex. It might be argued that price regulation is a disguised import restriction - but as this argument would also apply to reimbursed drugs, it is unlikely to be accepted. As is invariably the case in matters of pharmaceutical economics, the essential problem is less legal than political. So a simple recommendation to exclude non-reimbursable drugs from price control, as it is the case in most countries, would be a step towards more harmonization and more flexibility, without any consequences for public finances. Precise definitions relating to reimbursement also merit attention because grey areas currently confuse the picture and inhibit the market unduly. For instance, in France and other countries, some self-medication drugs, such as aspirin or paracetamol, can be reimbursed provided a physician has prescribed them. For that reason they are considered as “reimbursable” drugs - and in consequence have a regulated price, even if a large share of the sales are for self-medication, and therefore neither prescribed nor reimbursed. It should

be the rule that price regulation applies only to drugs that are actually reimbursed - and not to drugs that are reimbursable but not reimbursed. Such a provision would not imply radical change, since non-reimbursable and non-reimbursed products constitute only a small share of the total drug market. But it is a change that would have the merit of provoking potentially valuable reflection on the justification for price controls.

### Real generic competition

Generic drugs have acquired a reputation in many circles as a miracle cure: they can cut health care budgets without diminishing service to patients, and at the same time can promote competitiveness, because the savings they offer can permit insurance funding of innovative products. For these reasons, it is argued, generic competition should be clearly encouraged, by creating appropriate incentives at the level of physicians, pharmacists and patients. But some governments have adopted measures that fail to maximise the potential of generics - and at the same time risk inflicting damage on the entire drug sector. For instance, some countries have aligned the price of the branded reference drug with that of the generic product. Although it may provide some short-term savings, this measure is harmful not only to the branded industry, but also to the generic industry: if the price is the same, the consumer will generally choose the branded reference product to which he is accustomed.

Another measure extremely destructive to competitiveness is to apply generic pricing not only to the out-of-patent molecule but also to all other patented products judged to be similar. Germany and other countries have created large drug groups (known as “jumbo groups”) including patented as well as non-patented products, for which a common “reference price” is fixed for reimbursement, at the level of the price of generic drugs. This application of generic prices to products still under patent is an assault on intellectual property rights (IPR), and obviously counterproductive to the goal of promoting innovation. If governments

really wish to promote innovation, they must defend IPR, which means that generic pricing should be applied only to drugs that are effectively off-patent, and not to what are -often questionably- deemed similar drugs.

### Distribution divergences

A discussion of pharmaceutical prices is incomplete if it ignores the distinct levels of pricing along the distribution chain. Divergences between ex-manufacturer prices are only a part of the true picture: the “public price” that health insurance agencies pay or reimburse is much higher, since it includes distribution costs incurred by wholesalers and retailers, and VAT. So even if ex-manufacturer prices were harmonised across Europe, wide divergences would remain in public prices, since distribution margins and VAT rates differ sharply from one country to another.

VAT harmonisation is beyond the scope of the present paper, as it concerns the European economy as a whole and not only the pharmaceutical sector. But the sensitive question of harmonising distribution margins is ripe for examination, since it represents 20-30% of the public price.

Some potential large productivity gains in distribution have been identified. In some countries, for instance, “short line” sales that by-pass wholesalers are taxed on the pretext that wholesalers assume a general interest mission - such as maintaining sufficient stock to face emergencies. In other countries, this kind of wholesaler mission simply does not exist. Harmonizing the mission of wholesalers and determining the cost of any constraints imposed on them would be a useful first step towards realising potential productivity gains.

The way retail distribution is organised and controlled also deserves attention, especially monopolies on drug distribution, ownership requirements for pharmacies, restrictions on the number of pharmacies in individual ownership, geographical restrictions on the number and location of pharmacies, and the level of state-regulated margins. The legal environment for retail pharmaceutical distribution varies widely across Europe. Pharma-

cies in France, for instance, are subject to numerous controls (including all those above), while in the UK, for instance, pharmacies chains are authorised - and the current entry controls were recently challenged by an Office of Fair Trading recommendation that competition should be stimulated in the retail pharmaceutical distribution. The national character of the economics of drug distribution are likely to make rapid convergence improbable. But some limited steps are possible. One is to authorize multiple pharmacy ownership. Denmark and Portugal have recently abolished legal prohibitions on pharmacy chains, and even in countries where chains are still formally prohibited, pharmacists often spontaneously form groups to boost efficiency and save costs. Further integration would certainly offer some productivity gains, without challenging the role of pharmacists in health care.

These limited suggestions do not pretend to provide comprehensive solutions to the overall problems of enhancing Europe’s competitiveness in medicine and biology, or of improving health care policies or funding. However, they do offer some possibilities for progress without requiring a revolution in the sensitive relationships between member states or between member states and the EU. They are consistent with principles underlying health insurance in Europe. They are designed to improve cooperation, and to shift the balance slightly in the direction of supporting pharmaceutical innovation - and therefore responding to patients’ interests. In the current situation, given the complexity of the task and the lack of consensus about more significant changes, that would not be a bad start!

But even these limited changes will not occur without strong and determined action from the Commission. And there is also an important lesson from the “prisoners’ dilemma” game: the best outcome cannot be reached and maintained if each member state is allowed to define its own strategy entirely independently. After more than ten years of discussions and debates at the highest level, the time for real action has come.

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