

A single European market for pharmaceuticals: could less regulation and more negotiation be the answer?

Jim Attridge

After almost two decades of tripartite discussions between the EU Commission, member states and the pharmaceutical industry, in parallel with a process of attrition through the European courts, a satisfactory model for a single market for medicines has neither been agreed in principle, nor emerged in practice. This article reviews the current position and offers some suggestions as to where possible compromises might arise in long established policies in the hope of making more effective progress for the benefit of all stakeholders.



Jim Attridge, The Business School, Imperial College London

The debate between the EU Commission, member states and the pharmaceutical industry on how to create a single market for medicines, which is compatible with member states retaining their competence over medicines funding and provision, which strictly adheres to the EU principles of free movement of goods, and which promotes an inter-

nationally competitive R&D based industry, has shown little progress over the past twenty years (European Commission, 1996, 2003).

Whilst there has been significant progress in harmonising the process for technical approval of medicines, through the establishment of the European Medicines Agency (EMA), finding a mutually agreeable formula for economic regulation continues to prove elusive.

This paper reviews economic regulation of the pharmaceutical sector at the EU member state level and proposals that have been advanced to promote a more effective single market. It suggests that the key to breaking the impasse at the EU level may lie in further convergence of the principles which underpin frameworks for control of reimbursed prices at the member state level. This would be a precursor to market mechanisms at the EU level, which fairly balance the interests of the relevant stakeholders over the long term. It is further proposed that this convergence should be towards systems which allow greater scope for flexible negotiation of prices between suppliers and state health purchasers and away from rigid, legally enforced formulae.

Address for correspondence: Jim Attridge, Research Fellow, Health Policy Group, The Business School, Imperial College London, South Kensington Campus, London SW7 2AZ, UK. E-mail: jimattridge@aol.com

In that context the paper also then addresses future contractual relationships in the supply chain in an enlarged EU and the implications for free movement of goods in this sector.

In the overview of alternative national pricing systems, the emphasis is upon the principles involved rather than the minutiae of current regimes, or reforms in individual countries. Particular attention is given to assessing the degree to which there is evidence of convergence of approach. In the light of the aims of the primary stakeholders, the analysis will conclude with a suggestion as to which combinations of member state and EU approaches might offer the best way forward.

Markets and prices

Pricing transactions in commercial and industrial markets can be broadly classified into three categories (Simon, 1989).

Consumer markets

These are markets with many customers, often the general public, or a large section of it. Typical are retail markets, such as food and clothing. Also, they are usually markets in which the value of individual transactions is low, but subject to regular repeat purchases. Prices are arrived at in these markets by suppliers posting a price, which consumers either accept or reject, when they visit shops. For the most part there is no process of price negotiation. Prices are effectively kept in check, or 'regulated' by 'volume switching', i.e. consumers signal to suppliers that their prices are too high by switching their purchases to other alternative cheaper competitor products, leading to a decline in sales and profits. Normally suppliers adjust prices in response to these signals, until equilibrium prices are established between customers and alternative competing suppliers.

Industrial markets

These are markets in which there are relatively few customers and suppliers, the value of individual purchases is high and they are made relatively infrequently. Typical examples would be aircraft, property and industrial plant and equipment. In these markets prices are arrived at by negotiations by individuals or small teams, and the outcomes (including prices and payment terms) are enshrined in contracts.

Government fixed price markets

There are markets where, either because governments decide that in the public interest, market

mechanisms for arriving at prices do not work well, or because the state is a major party to the transactions, either as customer (military equipment) or supplier (utilities, such as water, gas or electricity), prices are fixed and periodically adjusted by government. Often formulae are devised or employed by government-appointed regulators and experts. For example, in the UK utilities prices are subject to 'Rp - X' formulae, where increases are limited to Rp, which is the retail price inflation index, minus X, a downward adjustment factor.

National price and reimbursement systems

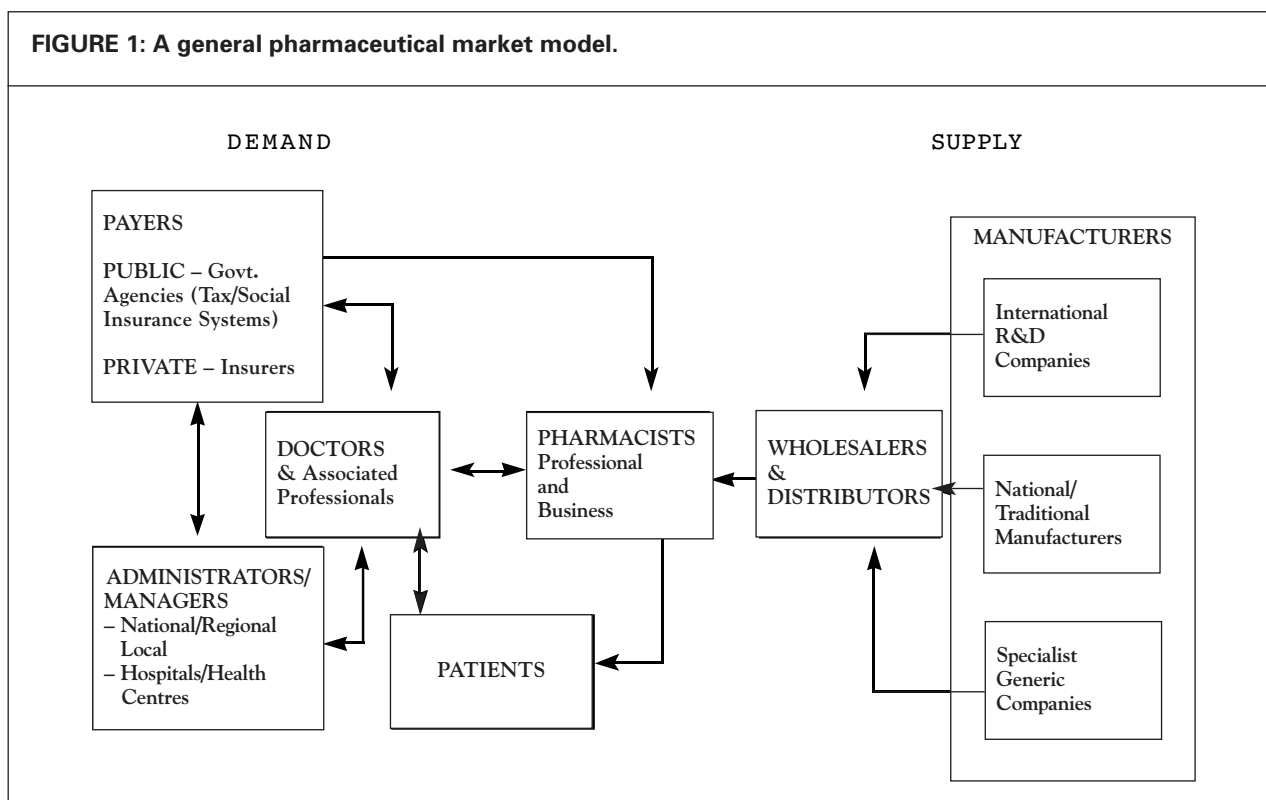
Demand-supply relationships

This section evaluates the principles upon which national systems are based, using the framework in the previous section, but does *not* analyse in detail the complex systems of laws, regulations and processes deployed to enforce them.

An essential prerequisite to understanding these price and reimbursement systems lies in understanding the changing configurations of demand and supply side actors, who participate in decision-making processes for individual national markets. For those not familiar with the sector, a general diagram illustrating the main participants and the relationships between them, which are common to most countries, is given in Figure 1.

On the demand side there are three distinct groups – doctors, patients and payers. The term 'payer', whilst a convenient shorthand term for a wide range of administrators and managers, who may operate in quite different local situations, needs to be used with some caution. Furthermore, whereas, taking a global view, payers might be in public or private sector entities, for the purposes of this analysis, our prime concern is with the predominant majority who operate within state systems.

Within the general classification of markets above, doctors constitute a consumer market group. There are large numbers of them (up to 50 000 in major EU countries), they write prescriptions for low-value individual packs of medicines, and there are many repeat prescriptions, or purchases. Their primary concern is the welfare of their patients and for the most part they do not engage either individually, or collectively in negotiating medicines prices. However, of all the customers, they can exert the most powerful impact on the revenues of suppliers, by switching, or shifting the volume of prescriptions from one product to another.

FIGURE 1: A general pharmaceutical market model.

In contrast payers, working in large public, or quasi-public health systems, with a designated responsibility for medicines are relatively few. Many will be career bureaucrats, or professionally qualified health service officials. They carry an onerous responsibility, firstly to obtain budget allocations for health, in competition with other state agencies (education, defence, etc.), then they must allocate funds between many diverse healthcare activities on an annual basis, and finally they are held accountable for ensuring that actual expenditures conform as closely as possible to the budgets.

Despite much public debate, the third distinct customer group, patients, although the ultimate beneficiaries of medical treatments, in reality still have relatively little direct power or involvement in decision-making in the choice of medicines.

patients, although the ultimate beneficiaries of medical treatments, in reality still have relatively little direct power or involvement in decision-making in the choice of medicines

There are two exceptions to this. Firstly, disease sector specific patient groups, who lobby for a bigger share of the total funding 'cake' for their area, can be influential in some EU countries in putting pressure on governments to reimburse valuable new medicines. Secondly, under the 'reference price' systems operated by some EU countries, in principle patients may have a choice of medicines, which require them to make different levels of direct copayment of a proportion of the cost. However, this is often more hypothetical rather than a real option.

Integrated demand side organisational forms

Over recent years, it has been argued that the key to improving the efficiency and effectiveness of healthcare funding and provision lies in improving the organisation of these demand side participants, rather than in directly regulating the suppliers. However, achieving effective change in practice faces formidable barriers.

In the evolution of demand side systems for pricing and reimbursement of medicines there has been a constant search for better organisational forms, in which the power of payers over costs and prices and the power of doctors over prescription volumes can be brought together more effectively (Reinhardt, 2001).

Broadly these fall into two categories. The first is for the payers to create systems, which, through

budgets and formularies, seek to manage access of products to state reimbursement, thereby constraining doctors' prescribing choices. The second is to create structures within which doctors become an integral part of the financial, or budgetary management of the system, so that they become directly accountable for expenditure at a local level, and for making 'trade-off' decisions between therapeutic value and costs, across a wide range of interventions for the patient population for which they are responsible. Regulatory reform in countries such as France, Italy and Spain have concentrated on the first of these, whereas in the UK and Germany the prime focus has been on the latter.

In terms of the pricing regimes, in France, Italy and Spain there is a strong reliance on 'command and control' systems, where legally based government-fixed formulae offer limited scope for suppliers to negotiate. In the UK and Germany, where the tradition has been for health authorities not to fix individual product prices, the emphasis has been on cascading down budget responsibility, and thereby decision-making, to practitioners on the front line. However, many clinicians have resisted being made responsible for integrated clinical and cost management systems. In these systems the emphasis is upon better informed doctors, who at a local level can make value judgements based upon both clinical and cost effectiveness. Thus these markets resemble consumer markets but still with an overlay of central payer controls.

This latter policy taken to its logical conclusion could lead to a *de facto* 'dis-aggregated' consumer pricing model, in which local operating units, or 'mini health firms', within the overall state framework, would have considerable independence to determine the prices they paid for medicines. This could be done by volume switching strategies, or also possibly through new forms of local price negotiation.

The residual relationships with the larger system would be twofold: firstly, an allocated budget and accountability to operate within it; and secondly, conformity to central guidance and performance 'norms', as defined by national expert guidelines, which would safeguard the principle of equity of patient access to medicines across the community. Thus they would be subject to both clinical and financial audits. Since 1999 the UK has sought to do this through the National Institute of Clinical Excellence (NICE), a concept which may also be introduced shortly in Germany.

These distinctions between EU countries are at best broad indications of policy trends. In reality, current regulatory and organisational reform is, in many

EU countries, in a constant flux, with multiple sets of criteria and methodologies being used, often based upon taking ideas from their neighbours.

Whilst this may be seen as reflecting a positive trend over the past decade in which EU countries look outwards to garner the potential benefits of the experience of other nations, it can result in rapid cascades of diverse piecemeal reforms, causing confusion and uncertainty in the market on both the demand and supply side. However, this process may provide the springboard for a consensus view across Europe, as to how to best organise the demand side at the member state level. It may be argued therefore that this is an inevitable interim phase, between inward-looking health systems, confident in the appropriateness, if not inherent superiority of their own approach, and a convergence towards an EU, or even possibly an OECD, norm.

From the perspective of this paper the interesting questions are, 'Where may this turbulent interactive process of national reforms lead to, in terms of a common approach, over what timescale and will it facilitate the completion of a single market for medicines?'

Supply side infrastructure and product classes

Before reviewing forms of regulation it is important to understand the competitive dynamic of the market which they seek to control. On the supply side, competition between manufacturers occurs primarily at the 'disease sector – product class' level, where products are available for specific disease states, for which to varying degrees the products may be regarded as substitutable. Any of the following four sub-market situations may exist:

1. A *class of one, or a genuine monopoly situation*, in which a single innovative patented product has emerged from R&D and which has no similar competitors. Such situations are rare and constitute a small part of the market, they are relatively short-lived and in this case, the innovators face the considerable challenge of changing established medical practice.
2. A *patented only class* – here a cluster of maybe 3–6 distinct molecules, for the same disease and with the same mode of action, compete.
3. A *mixed patented-generic class* – in these the patent has expired on one or more of the products from class 2, and multiple generic copy versions of it are available and compete, both with the original innovative product and with other patented members of the class.

4. A *generic, or commodity class*, in which there is a wide choice of competing brand generic or generic products.

As shown in Figure 1, the delivery of medicines involves a complex series of supply chain relationships, whereby manufacturers deliver to wholesalers, who in turn supply large numbers of pharmacies, who dispense prescriptions to patients. It is the wholesaling element in this chain that provides the main opportunity for arbitrage, or parallel trade of medicines between EU member states. Parallel trade in an EU context is the term commonly used to describe the situation in which a wholesaler buys in a low price EU country, where the price may be subject to strict government control, and the medicine is then sold on with the necessary approvals and relabelling into the wholesaler-pharmacy distribution chain in another EU country where the government reimbursed price is higher.

For the purposes of this paper, the role of pharmacies of relevance is for dispensing the prescriptions written by doctors. In practice across Europe this function is performed by a remarkable range of organisations. In Sweden, for example, all pharmacies are state owned and so there is effectively no competition, whereas in many other countries by law each pharmacy must be owned by a registered pharmacist, who is not allowed to own more than one outlet. Commercial chains such as the UK Boots group are still relatively rare in the EU. Pharmacies in most countries are rewarded through contracts negotiated collectively with state health services, in the form of a combination of fixed fees and allowable margins.

Wholesalers, who are increasingly large and operate on a pan-EU basis, have relatively low margins. However, as we will discuss later, any single market model has to take careful account of both the roles and regulations governing these players country by country.

Types of national price and reimbursement systems

As part of their overall healthcare strategy, all governments have legislation, regulations and methodologies for determining which products they will pay for (reimburse) and at what price (or cost) to them. Price and reimbursement systems may be designed to cap or limit expenditure for all products, or may selectively target product classes, or individual ones.

General interventions

Contract systems

These seek to limit sales growth or profitability at the overall company level by negotiating agreed annual targets (France Spain, and UK) and requiring retrospective pay-backs by the company to the health system, if they are exceeded.

General price cuts

These are imposed from time to time by state health systems for all products, using legislative powers, and are commonly in the range of 3–10% (UK, Italy, Spain, Belgium, France).

Specific controls

New product launch price fixing

The majority of EU countries have procedures for fixing new product prices by a formula and a central review/negotiation process, with a particular emphasis upon innovative patented products with significant sales potential.

Cost effectiveness appraisal

These take the form of mandatory or voluntary requirements for manufacturers to submit appraisals of products using agreed methodologies. Again the primary focus is upon determining the value of innovative products.

Reference pricing schemes

This increasingly common approach sets a general limit as to what the state will pay for treatment on a product class basis. In principle higher prices can be charged, but the patient must then pay the difference. In practice in most cases the reference price just becomes a maximum price, because the 'patient-doctor' duo does not function effectively as a discriminating purchasing agent. It is widely used for class 4 products and there is a growing tendency to extend its use to class 3 products. For a review see Lopez-Casasnovas and Jonsson (2001).

Generic competition incentives

These are measures that seek to encourage greater demand side usage of, and supply side company participation in selling, cheap generic versions of patent-expired products.

Class based price reviews

If in a class 2 or 3 situation the growth in sales of the class as a whole or one leading product is high, authorities may review prices and enforce reductions on an ad hoc basis from time to time.

In practice in most cases the reference price just becomes a maximum price, because the 'patient-doctor' duo does not function effectively as a discriminating purchasing agent

There are many complex and sophisticated national variations on these and most countries apply them in combinations. However, in summary there has been a degree of convergence in recent years across the EU towards four main methodological approaches:

- new product price fixing mechanisms,
- reference pricing systems,
- corporate contracts, and
- cost-effectiveness appraisals.

It appears likely that the future evolution, or possible convergence, of national market regulation will be based upon these four approaches. These, in turn therefore, will be the platform from which a future, improved single market will have to be launched.

Pricing in a single EU market

Stakeholders and principles

The primary stakeholders in the debate over price and reimbursement regulation and the formation of a single market are the EU Commission, the EU member states and the pharmaceutical industry. The key to any proposal for a more effective single market lies in seeking compromises which reflect their different interests. This is not to suggest that the other key stakeholders shown in Figure 1 are not also of importance.

Also in Figure 1, we have identified three categories of supplier: R&D based companies, national or traditional companies and specialist generic companies. A full account of the structure of these manufacturing segments is beyond the scope of this paper, but the industry leaders, in terms of global market share and intensity of R&D investment, are unquestionably the top 20–30 multinational companies, such as Pfizer, GlaxoSmithKline, Merck &

Co and Novartis. However, in recent years in Europe, as in the USA, there has been a significant shift in the usage of medicines away from brand products towards cheaper generics and the companies who specialise in this area are likely to have a more prominent voice in the future. However, for the purposes of this discussion, the primary industry protagonist will be taken to be the leading R&D based international companies.

The dominant issue of principle for the Commission is respect for EU competition and in particular the laws governing the free movement of goods. The foundation of the EU market in economic terms rests upon the principle of free and open competition across the whole of the territory, for which the free movement of goods is a vital element. In the context of innovative markets, such as pharmaceuticals, where products are protected by patents and trademarks, the principle of international exhaustion applies within the EU, i.e. these *national* intellectual property rights cannot be used to limit free movement.

Also in the interest of all EU consumers, the Commission promotes broad health policy aims, insofar as this is possible within its limited competence.

The Commission also has a responsibility to promote and encourage a European pharmaceutical industry that is competitive in world markets and to attract inward investment. It is widely recognised (EU Commission, 2003) that only innovation-led and hence R&D intensive companies are likely to succeed in this context.

The member states' prime concern is to optimise healthcare funding and provision for their populations within the confines and constraints of national economic and social circumstances. Member states are unanimous in their commitment to this remaining a national competence, which includes regulating the pharmaceutical sector, a key aspect of which is mechanisms for control of pricing and state reimbursement.

The R&D based pharmaceutical industry ideally would like both the freedom to set its own individual product prices across the whole EU, not just UK and Germany as at present, and some degree of constraint on parallel trading of products across national boundaries between high and low price markets. Ideally it would prefer some form of 'consumer market', where competition relied upon the volume switching behaviour of doctors, or integrated 'doctor payer' operating units.

A prime concern for the R&D based industry is to ensure that the relatively small numbers of inno-

vative products entering the market each year are priced at levels that fairly recognise their long-term social and economic value and the risks and costs associated with R&D.

Price differentials between countries

A central issue for the future of pharmaceutical prices in the EU is whether it is feasible to think in terms of a more or less, single price across all EU countries, or whether it is inevitable that significant price differentials, or what is technically called 'discrimination' between national markets, will be a continuing feature of the EU market.

In economic theory, there are a number of definitions of degrees, or forms of price discrimination, based upon different principles (Phlips, 1994; Danzon and Chao, 2000). For the purposes of this analysis it is useful to distinguish three of these, which are used in support of differential pricing of medicines between EU countries.

Prices and income differences

In principle a fundamental shared objective of all stakeholders is that all EU citizens should have access to the best available modern medicines, regardless of personal ability to pay for them, i.e. the principle of 'social solidarity', which underpins most state systems. At present it must be acknowledged that this is a national, rather than a pan-European preoccupation.

However, if we accept the reality that the state is effectively the surrogate customer for its national population, and that some states are distinctly more affluent than others, then prices may need to reflect these income, or 'ability to pay' differences.

It is self-evident, that as one ranges across the future EU say, from Sweden to Spain to Greece to Poland, there will continue to be substantial differences. So it can be argued that optimising welfare in terms of access is best served by poorer state health systems paying less than richer ones.

Prices and value

There is considerable debate, even with the latest clinical and cost-effectiveness comparison techniques now available, as to how far it is possible to assess the relative value of medicines one against another and then use that as a basis for relative pricing. Clearly this is an area of great interest to both government regulators or negotiators and industrial innovators.

Most would acknowledge that prospectively agreeing prices will continue to be a matter of judgement, rather than one of applying quantita-

tive scientific methods. In that context, differences in national cultures and value systems, in cost structures and health system infrastructures, when taken together, suggest that for any new medicine, there will be significant differences in the value placed upon it in one national context compared to another, and hence the price that would be acceptable. This again therefore would suggest that cross-country price differentials will persist.

Prices and quantities consumed

It is a well-understood concept, in many contexts, that the unit price paid for an item, should reduce as the number of units that a particular customer buys increases – the volume discount principle. Applying this simple market principle to medicines leads to the question, 'Can a large EU country reasonably argue that, all other things being equal, that it should pay lower unit prices, because collectively it consumes much greater volumes than its smaller neighbours?'

Concluding comments on differential pricing determinants

These are not just theoretical considerations. Government health payers in Greece, Spain, Portugal and the new entrant Central and Eastern European (CEE) countries commonly defend enforcing or offering lower prices on the grounds of being less affluent countries than those in northern Europe. In Italy lower prices proposed for drugs for mental illness have been justified on the basis that the incidence of such conditions is low in Italy and hence it is a low priority area for allocating expenditure. In the past in France low prices have been defended on the grounds of the large volume consumption of medicines by the state system, compared to other countries.

Also because the balance of power between government customer and company suppliers at the nation state level is in favour of the former, the reality of the EU market is that industry suppliers are largely 'price takers' and not 'price makers', i.e. individual companies must take the price offered by host governments or, effectively, not sell the product in that country.

In conclusion, therefore, based upon these considerations member states insist, and much of the pharmaceutical industry acknowledges, that any future EU market must allow national customers flexibility to negotiate their own prices.

Convergence to a single EU price

An alternative view could be that, taking the EU market for medicines as a whole, there has been a

considerable convergence of prices during the 1990s, as in many other industrial sectors. Currency variations, an important force for creating price differentials, have largely disappeared. Also the market discipline of active parallel trade will continue to exert pressure to ensure that new products in particular are constrained to relatively narrow price bands.

So, it can be argued that, even under present regimes, there will be further progress towards a single market at relatively uniform *and lower* prices, which overall is in the EU consumer interest. Clearly this is an attractive vision for both member states and the EU Commission healthcare administrators. All member state health authorities see themselves as under extreme pressure to contain costs. Therefore they would all see a short-term benefit from leveraging down prices to the lowest level that the least affluent entrant country from CEE can afford.

Also from the EU Commission perspective, superficially this can be construed as an example of the EU single market working to the benefit of consumers and, furthermore, there would be no need to address the parallel trade issue through exceptions to EU competition law, which could set dangerous precedents for other sectors.

However, from an EU industrial policy-makers' perspective and that of the R&D based industry, this does not look like a viable scenario for a globally competitive industry. Both point out that a combination of *downward* price convergence and increasing levels of parallel trade continue to erode margins for innovative products. Particularly for companies whose prime source of revenue comes from EU markets this will clearly leave them at a disadvantage opposite predominantly US-based companies, in sustaining long-term investment.

Thus from the viewpoint of industrial competitiveness in an increasingly global market, this amounts to 'eating the innovation seed corn' in return for short-term alleviation of the healthcare cost escalation problem. Not only would this be a short-sighted industrial policy, but insofar as retrospective analysis suggests that innovative medicines have made major contributions to cost containment in healthcare, as well as improved patient outcomes, it is also likely to be bad health policy over the long term.

There is undoubtedly a need to continue to seek a fair balance between these two positions, which must, however, recognise the wider realities, beyond health and industrial priorities at the individual country level.

Creating a more effective EU market

This section summarises relevant policy reform proposals. These are classified into the following three categories:

- constraints on EU trade,
- reform of national price and reimbursement systems,
- interactive reforms at both the member state and EU levels.

Constraints on EU trade

There have been extensive discussions and interminable court cases on what constitutes a restriction on free movement of pharmaceuticals, which infringes Article 81 of the Treaty of Rome. The best that can be said, after a very expensive and exhaustive process, is there has been a recognition from the European Court of Justice (ECJ) that this sector is a special case, in which there is an inherent conflict between Article 81 and the member states' rights to regulate medicine prices.

In the late 1990s the ECJ suggested that the EU Commission should take appropriate measures to resolve this conflict. Unfortunately no acceptable form of agreement, or easement, or reinterpretation has emerged which would *de facto* constrain the scope of parallel trade. In fact to the contrary, current statistics show that levels of trade between lower and higher price markets continue to increase.

The obvious measure would be a sector-specific exemption from Article 81 for selected categories of prescription medicines, for selected countries. Many proposals, which directly or indirectly might have such an effect, have been put forward over the years and rejected by the EU competition authority. The following are currently still under consideration and might yet possibly feature in some future EU regime.

In the context of EU enlargement, it has been suggested that for CEE entrant countries, whose per capita GNP is less than 70% of the EU average, exports of medicines to other EU countries should not be allowed.

Another similar proposal was to allow selective exemption from free movement for new patented products into the market from a given point in time. This was based upon the argument that the impact upon the market would be very small and only increase slowly over a period of years.

Most recently, a number of companies have notified the Commission of initiatives to improve

the efficiency of their product distribution systems in Europe, by introducing national quotas for volume supplies to individual countries, which *inter alia* might constrain EU trade.

Reform of national price and reimbursement systems

Both government customers and industry suppliers agree in principle that their common aim is to provide patients with the best available modern medicines at fair and reasonable prices.

In many countries there is a reasonably amicable dialogue between them as to which forms of consumer or industrial market based competition would work to their mutual satisfaction. A full account of these is beyond the scope of this article, but the distinction which we made above between industrial or negotiated price regimes and government fixed price systems is particularly pertinent to this debate. In many EU countries there are combinations of these, which operate within legislative frameworks, with specified criteria or formulae, but which also allow scope for companies to negotiate individually with pricing authorities.

It can be argued that the flexibility needed for a more efficient EU market lies in a shift away from, 'one size fits all' national regulations, towards negotiated prices with individual companies. The following developments are of interest in that they could provide the basis of at least better interim combinations of national and EU models of that type.

An important area of common ground, which emerged from the EU Commission-led dialogues in the 1990s, was the idea of creating 'budgetary headroom'. In effect this suggested that the key to affording modern innovative medicines within capped budgets was to 'delist' from reimbursement, or pay considerably lower prices for, older long established products.

Much has been achieved in many member states with a three-pronged set of reforms in this area. Firstly, a stronger line has been taken in delisting really old products of doubtful efficacy or with serious side effects for which there are much better modern alternatives. Secondly, well-proven modern products with a good margin of safety have been transferred out of state funding into the 'over the counter' (OTC) sector. Thirdly, reforms have been undertaken to provide demand side incentives for prescribing and dispensing cheaper generic products and to create more competitive generic markets in which manufacturers of these products can gain and hold a position in the market.

In highly regulated markets, such as France where a transition to a market based approach has proved more difficult, useful progress has been made within an industrial negotiating setting, whereby individual companies have obtained higher prices for new products, more in line with those in Germany and the UK in return for price reductions on older ones.

A less attractive feature of the company contract model for industry in France and Spain has been its use to effectively capture companies within the state budgeting system, by holding them responsible for 'overspending' against fixed allocated annual budgets. This approach requires companies to make repayments at the end of the year to the health system according to government devised and enforced formulae. In 2002 in the face of a budgetary crisis this model was also adopted in Germany. Current proposals now suggest that it may become a permanent feature of that market, with much larger retrospective pay-backs in 2004.

This illustrates well how the attractiveness of such approaches hinges greatly upon the balance of negotiating power between the parties and the spirit in which they are deployed in practice.

Integrated EU and member state reforms

Of the many ideas that have been debated over the years, the following three strands of thinking appear most likely to feature in any future integrated approach.

For the EU Commission and some member states, a key issue is a common approach to assessing the value of new medicines, which is rooted in both medical science and health economic concepts, and which would provide a better basis for agreeing prices at a national level.

It can be argued that if industry wants to get away from arbitrary national pricing systems, which do not take adequate account of the value of innovations, it should support proposals to establish a common set of principles for techno-economic, or cost-benefit analysis. Industry has two concerns regarding such proposals. Firstly, that any EU approach of this type would result in a *force majeure* EU position linking value to price in a way that would make medicines fully accessible to the poorest countries, i.e. lowest common denominator pricing across the EU. Secondly, it could be a step along the path to some form of EU federal price and reimbursement authority, which would have vastly enhanced negotiating power relative to the current state purchasers.

From the industry side an attractive idea is to follow the US practice of manufacturers posting consumer market style list prices for the EU as a whole. It would seem sensible that this price would equate to the prices currently set in the UK and Germany. In other more restricted markets, negotiation, in industry market mode with state customers, to agree a contract price, would be necessary. Such contracts could be corporate, or product specific.

Existing dedicated EU legislation on pharmaceutical price and reimbursement is limited to the directive on price transparency, which aims to ensure that national systems are operated using objective and verifiable criteria. It has been suggested that any significant shift to a more orderly or coherent approach at national level would be unlikely to work in practice unless this directive was redrafted, or replaced with a new one, in order to limit the scope for highly restrictive government fixed price regimes, backed by national law.

A contrary view is that further EU legislation is unnecessary but that member states should proactively use the existing directive and its associated committee process to develop and refine a set of principles and processes as to how prices should be negotiated in member states. Ideally such a process would seek to achieve greater consistency and continuity of approach, leading to more stable market conditions.

Convergence to a negotiation based model

The challenge

Looking ahead to an enlarged EU post 2004, for the market of the future to operate more effectively, there must be greater flexibility, which allows purchasers, distributors and suppliers of medicines scope to negotiate and periodically renegotiate agreements to suit local circumstances, without becoming embroiled in endless disputes in national courts, or the ECJ.

In the previous section, we have identified a number of strands of thinking which contribute to improving the EU medicines market, but the question is: 'How might they be integrated into a framework, such that the primary stakeholders could agree on acceptable policy compromises, which, whilst inevitably involving a degree of risk, would offer the prospect of real progress?'

The following combination, whilst by no means offering an instant or easy solution, could at least provide the basis for movement in the right direction.

Reform and convergence of national systems

The first element of such a plan would be to agree a set of principles and if possible a common outline framework for a national regulatory system towards which member states would seek to converge over, say, a five-year period.

Based upon the foregoing discussion, it is proposed that the appropriate 'middle ground' for discussion should be moving towards an essentially negotiation based model. This would involve phasing out rigid formula models enshrined in legislation and agreement, to avoid further piecemeal regulation in response to periodic short-term budget crises. In particular, the model should address the temptation to use government legislative power to impose general price reductions. The emphasis would be upon incremental changes in individual national legal frameworks, to give more flexibility, which would allow state purchasers and company suppliers to negotiate prices, using the agreed principles outlined above.

From the industry side this will require acceptance that the very nature of future integrated demand side systems will preclude the possibility of going back to a consumer style market, in which the only restraint on prices would lie with individual clinicians switching products. This will require some rethinking of industry positions and rhetoric on the concept of 'free pricing'.

In some countries, such as France, this could be based upon an evolution of the present company level annual contract, which allowed flexible trade-offs between individual products. Whilst year-end retrospective rebates might well continue to be a feature of such models, this should be regarded as the exception rather than the rule and should not penalise successful innovators by artificially constraining competition in the market. Other bureaucratic supply side controls, such as limiting promotional activities, which are difficult to administer in practice might also be reviewed in this context.

A promising and positive trend is that many regulators are now committed to reforming incentives in the supply chain, which will enable a transition away from complex and inefficient reference price systems towards genuinely market based generic competition. This should make it easier to develop in parallel, less complex and more liberal frameworks of incentives for patented products.

The essential thrust of government strategy, whilst recognising the need to work within defined expenditure limits, would be to 'streamline' national price and reimbursement systems to minimise the

burden of bureaucratic complex multiple control mechanisms. Effective and acceptable levels of state expenditure growth should be possible with a balanced mixture of pro-market based generic competition, pro-creation of headroom and pro-innovation strategies.

An EU list price set by manufacturers as a basis for negotiation

From the industry side, companies should establish EU level list prices for new products, from which they would negotiate discounted contract prices with individual member states, where necessary. The EU list price would fully reflect the innovative nature of the product and the need to obtain a fair reward for R&D activities.

It appears increasingly likely that in future prices will be related to commonly agreed principles for determining the relative value of products, based upon their clinical and cost-effectiveness and, in consequence a reasoned justification of that list price based upon price–value relationships will be necessary and become the starting point for negotiations at a national level.

Much interest has been shown by other EU countries in the role played in the UK by the National Institute of Clinical Excellence (NICE), which was established as a national agency in 1999 to assess the clinical and cost-effectiveness of all new medical technologies including medicines. However, in progressing the use of ‘NICE style’ assessments, through agreed principles and guidelines at the EU level, it should be clear that each member state, cognisant of its own national priorities and environment, would be solely responsible for making its own national assessment of value, as a basis to engage in negotiations with individual companies.

Differential prices and the EU single market

The consequence of this model would be a continuation of a regime in which, with a combination of freely set prices in some markets plus discounted prices in national contracts in others, there would be, *de facto*, price differentials across the EU, between the richer countries of the north and the less affluent ones in the south and east.

This inevitably must be the case if less affluent countries, particularly the new entrant CEE countries, are to have any reasonable hope of widening and deepening their population’s access to modern medicines at prices they can afford. Thus scope for wholesalers or other third parties to engage in par-

allel trade will continue to be an issue.

This brings us to our third main protagonist, the EU Commission. Here also if progress is to be made a more flexible recognition of the peculiar nature of this sector will be necessary. It has been clear for many years that a simple across-the-board-exemption from free movement of medicines is unacceptable to the EU competition authority.

However, currently over 50% of the value of the EU market consists of non-patented products. There is no reason why, as national price systems are rationalised, this should not lead to a fully open and efficient single market for such products through more widespread generic competition.

The bulk of the remaining smaller patented class sectors is in the uniformly affluent major northern and central European countries, for which an EU list price which equates to the current UK and German prices could be used by manufacturers, through modest periodic adjustments to maintain prices in very narrow ranges.

The R&D based pharmaceutical industry ... cannot be globally competitive if prices across the whole EU are driven down to the lowest level that the poorest member states can afford

This leaves us with the market segment attributable to patented products in a fringe of southern and eastern EU markets, which in value terms currently only accounts for maybe 10–15% of the total EU market. It will of course grow with economic progress in these countries. These countries undoubtedly have a case that if they are to achieve volume consumption levels which would be in line with the principle of EU social solidarity, giving their populations equal access to medicines with other member states, they could not afford to pay the EU list price. It remains to be seen in future to what extent social solidarity and equity of access will be embraced as EU concepts rather than just national ones.

Correspondingly, the R&D based pharmaceutical industry has a case that it cannot be globally competitive if prices across the whole EU are driv-

en down to the lowest level that the poorest member states can afford.

In the light of these interests of key stakeholders, it would seem reasonable to ask the EU competition authority to agree upon a limited constraint on free movement for a selected subset of products, for a selected subset of countries, for a limited period.

There is therefore a case for an EU level agreement that would constrain export of low price patented products from this group of countries, based upon some rational principle such as relative per capita national GNPs. Such an approach would carry with it the automatic scope to phase out such constraints over time as these countries became more affluent.

Wholesaler and pharmacy contracts

Future scope for parallel trade in this sector will also depend upon the rapidly evolving multiplicity of national laws and practices which characterise the roles and relationships of wholesalers and pharmacists.

There has been considerable progress since 1992 in improving the efficiency of wholesaling across the EU, by concentration of the sector into international companies and deployment of modern IT and communications technologies.

In contrast, change in the pharmacy sector has been more limited. There is still the full range of situations, from countries, such as Sweden, where all pharmacies belong to a single state organisation, to others where legislation enforces single ownership of pharmacies by individual pharmacists. Neither of these appears to be compatible with achieving enhanced efficiency through competitive market forces.

For both wholesalers and pharmacists there has been significant movement towards more rational forms of contracting for the services which they provide. This has taken the form of formulae, with a much greater emphasis on fees for services, rather than a straight percentage mark-up on the acquisition price.

As further concentration occurs across the EU, a logical evolution of the manufacturer-wholesaler relationship would be manufacturers contracting with maybe only one or two major pan-European wholesalers. Insofar as prices vary from country to country at the state health system level, such arrangements, might also involve transaction prices at an EU average level, with some form of flexible rebate system based upon the volumes consumed.

Such trends towards long-term contracts between major companies could possibly limit the scope for casual small-scale arbitrage by smaller companies, who lack economies of scale.

Whether such new contractual forms would be acceptable to the EU competition authority, based upon a more flexible interpretation of EU law, remains to be seen.

Summary and conclusions

This paper has provided an overview of the complex issues that have been at the core of a decade-long running battle between the EU Commission, the member states and the pharmaceutical industry. It offers some insights into the ideas, principles and policies that have led to this impasse.

Based upon current trends it outlines the sort of system that might be feasible and work better in the interests of all parties in a future enlarged union. The essence of this is a more flexible approach to price negotiations at a national level, an EU list price based upon a realistic assessment of the value of products, a cascade of price discounts leading to differential prices and some very modest transitional constraints upon exports of patented products from the least affluent countries.

However, it does suggest that if effective progress is to be made, all three of the main protagonists must stand back, take a pragmatic view and be willing to compromise a little on dearly held principles.

Member states, whilst safeguarding their autonomy to set budgets and manage expenditure on medicines to suit national priorities, should seek to converge the principles of national price and reimbursement in the direction of negotiation based systems and streamline the very different and complex patterns of national legislation.

The pharmaceutical industry needs to back away from long cherished ideals about 'free pricing' in a consumer context and acknowledge that if the government is *de facto* the paying customer, then it is the government with whom they must negotiate prices.

And finally the EU Commission must take a more unbending view of what is in the long-term interest of all the parties in this case, rather than hiding behind formal rigidities of free market legislation. There would already seem to be a reasonable basis to constrain exports from poorer countries in CEE, which could be extended also to a limited

number of member states in the south for a longer transitional period to allow for both economic convergence and regulatory and infrastructure reforms.

References

- Danzon PM, Chao L (2000) *Prices, Competition and Regulation in Pharmaceuticals: A Cross-national Comparison*. Office of Health Economics Monograph, BSC Print, London.
- European Commission (1996) Council Resolution of 23rd April 1996 designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union. *Official Journal of the European Communities*, 96/C 136/04.
- European Commission (2003) Communication from the Commission to the Council, The European Parliament, The Economic and Social Committee and the Committee of the Regions, A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, Brussels 1.7.03, COM(2003)383 final, available at <http://pharmacos.eudra.org/F3/g10/p11.htm>.
- Lopez-Casasnovas G, Jonsson B (eds) (2001) *Reference Pricing and Pharmaceutical Policy*. Barcelona: Springer-Verlag Iberica.
- Phlips L (1994) *The Economics of Price Discrimination*. Cambridge, UK: Cambridge University Press.
- Reinhardt UE(2001) Perspectives on the pharmaceutical industry. *Health Affairs* 20(5): 891.
- Simon H (1989) *Price Management*. Amsterdam: Elsevier Science Publishers.

Copyright of European Business Journal is the property of Whurr Publishers Ltd and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.