

Drug reimbursement harmonisation in Europe

by Claire Dadou-Willmann and Jean-Michel Peny

In Europe, cost-cutting programmes intended to reduce the burden of healthcare expenditure on national budgets will have to comply not just with national priorities, but with the EU objective of healthcare system harmonisation by 1997.

Although drug costs in Europe represent an average 16% of healthcare expenditure, against more than 40% for hospital costs, EU governments have focused their attention on reducing the drugs bill – most favouring price cutting as a cost containment measure. It is likely, therefore, that EU healthcare harmonisation will lead to drug price convergence across the Community, with prices, according to EU Commissioner Sir Leon Brittan, moving towards those of the lower-priced member states.

The assumption that drug prices and levels of consumption will converge across EU countries, the analysis of government measures that may be implemented to reduce expenditure, and the assessment of their impact on drug markets' size and growth are key elements in forecasting the potential size of the drug market, and the risks to pharmaceutical companies posed by EU-wide harmonisation.

Of course, no-one can accurately predict the European drug market given the potential differences in key variables. The 'convergence' of drug consumption levels proposed on these pages is a theoretical model, based on strong hypotheses. Nevertheless, knowledge of the range of 'uncertainties' may help pharmaceutical companies

prepare future strategies and become proactive participants in defining the new market.

Healthcare budgets

Healthcare expenditure as a percentage of gross domestic product (GDP) varies significantly from one country to another – from 6% in the UK to 8.8% in France. Moreover, figures for 1990 indicate that the drugs bill, as a percentage of total healthcare spending, ranged from 9.1% in Denmark, to 19.3% in Italy, to 22% in Germany.

Recent measures adopted by the Italian and German governments to control health expenditures show that the higher the drug/healthcare cost ratio, the harder the government drive to reduce drug prices and consumption. Over the past three years the gap between drug spending per capita among EU member states, excluding France, has narrowed. In 1990, for instance, the average amount spent on drugs per capita in Italy and the UK – the countries with the highest and the lowest ratios respectively – was US\$179 compared with US\$85. In 1993 the gap narrowed to US\$158 in Italy versus US\$92 in the UK. Both countries' policies have contributed to this convergence (Figure 1).

Unlike most European countries, however, France has increased its consumption per capita – from US\$193 in 1990 to US\$213 in 1993. When looked at in units consumed per capita, the range between consumption in France and other EU countries is even greater.

Past and current differences in drug consumption within the countries of Europe explain

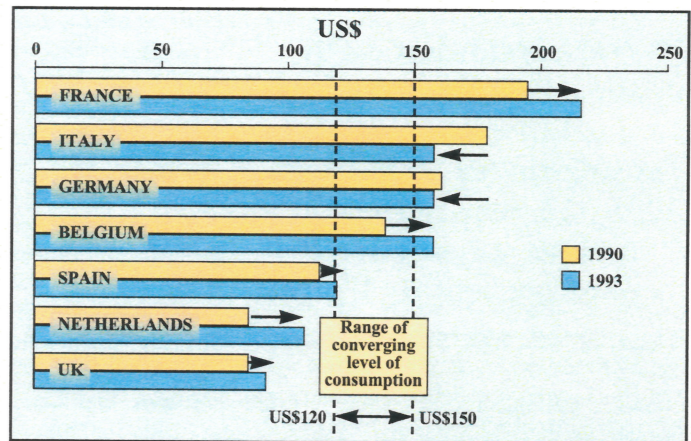


Figure 1: Per capita drug consumption in seven European countries in 1990 and 1993.

why various combinations of cost containment measures have been adopted by different EU member states.

Government action

The ministries of health of the European countries have a clearly defined, common objective: to control national drug expenditures without altering the quality of care delivered. Governments have three main courses of action, or 'levers', available to meet this challenge:

- They can control the level of drug reimbursement (share of drug expenditures covered by the government) at the patient level.
- Control drug prices which affect the distribution chain at the level of drug manufacturers, wholesalers and retailers.
- Control drug volume which affects the prescription chain at the level of drugmakers and prescribers – general practitioners (GPs) or specialists.

Drug reimbursement

Withdrawing certain drugs or therapeutic classes from reimbursement lists may result in

direct savings in these drugs or classes of drug. But past experiences have shown that there is a 'purchase transfer' from delisted drugs to other products with similar therapeutic properties that are still reimbursed. Moreover, the efficacy of delisting can also be impaired by the adverse reactions induced by a transfer of prescriptions, as witnessed in Portugal, where the anti-asthenics delisting has caused a significant increase in the consumption of antidepressant drugs.

To obtain a realistic picture of the economic impact generated by delistings, a cost savings analysis would need to be carried out involving both the product and the disease treated, or alternatively, in the Portuguese case, a macro-economic analysis, taking into account the impact of this measure on work productivity.

While there are other methods by which governments can shift drug costs to patients, drug delisting is the major tool. The effects of drug reimbursement on the 'convergence' theory should have limited repercussions, as average reimburse-

ment levels are relatively similar – from 59% in France to 67% in Germany in 1991. However, while the introduction of measures affecting the reimbursement level may reduce government drug spend, it will not necessarily significantly reduce total national drug expenditures. Today, many patients are not ready to com-

introduced in Sweden, Denmark and Belgium, and the Spanish are also seriously studying this option.

In the UK product prices are indirectly controlled by a limitation of company profits. In southern countries like France, Italy or Spain, drug prices are directly controlled product by product.

Certain governments have also enforced price reductions. This is the case in Germany where prices were cut by 5% for all drugs in January 1993. In Spain a 3% price reduction was negotiated in November 1993 between the government and the Spanish pharmaceutical industry.

Other measures that affect drug prices are the simplification of generic registration procedures (such as in the US), the right for pharmacists to substitute doctors' prescriptions (practised in the Netherlands), and parallel imports of drugs from countries with lower prices (as in the UK). These measures have had an impact only in northern countries, however, where drug prices are relatively high.

Although drug price differentials are still important across most European countries (in 1992 the drug price index in the Netherlands was still twice the price index in France) the gap between European countries has been reduced significantly

since 1988, and the convergence trend is continuing, with the exception of France.

For several years, governments have also squeezed wholesale and retail margins of reimbursed drugs and today all retailer (pharmacy) margins, excluding those of Portugal, Spain and Greece, are below 28%. Further pressure on margins will force many players out of business. This represents a political risk for governments. The pressure on wholesale margins has spawned a consolidation trend in Germany, the Netherlands, France and the UK (where the top three players control more than 75% of the market share). In Italy, Spain and Belgium wholesaling concentration has not really started, but margins are very small.

The same phenomenon could also happen at the retailing level with a proliferation of chain pharmacies like Boots in the UK, which accounts for 25% of the retail sales. Such a concentration will generate economies of scale and therefore protect margins, but concentration will increase unemployment.

It would seem, however, that actions on wholesaler and retailer margins can only be complementary measures for governments in the difficult task of curbing drug expenditures.

Drug volume

The two key players in the prescription chain are drug manufacturers and prescribers, who are prime targets in the governments' drug expenditure control strategies.

In the last 30 years medical demography has changed completely: the number of doctors increased twelvefold in Europe. If today most European countries limit the number of prescribers through a system of *numerus clausus*, countries like France and Germany will still have an excess of practising doctors.

Another parameter, the number of consultations per prescriber, cannot be modified easily, and is very much dependent on patient habits. Moreover, in the UK, patient access to specialists is limited by GPs acting as a filter, which is not the case in France.

Prescribing rate, also as a result of doctor and patient habits, varies widely between European countries: in France the prescribing rate per visit is as high as 84% (versus only 74% in the UK and 56% in the Netherlands).

Regulations, doctor practices and patient demands have created very different habits in medical practices across Europe. But changing behaviour can only be a long term objective; as a short-term objective it may be politically dangerous and very unpopular. Short term cost reductions must therefore be found through other measures.

All European countries have introduced more or less coercive systems to limit doctor prescribing. The most coercive measure is no doubt the German one. The total amount of reimbursed drugs prescribed is determined annually at the national level and then at the regional level. If this amount is exceeded, the regional medical associations must pay the difference. If the difference is too high the drug manufacturers pay as well.

To a lesser extent in the UK, the National Health Service collects explanations from 'over-prescribers', and in the Netherlands, an incentive scheme for pharmacists allows them to keep one-third of the savings they make when a generic or parallel import is dispensed rather than a brand.

Some additional measures to control drug volume have also

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promise on health and will themselves pay for what they are not reimbursed.

Price controls

The strategies adopted to control national drug expenditure will obviously depend on differences in national conditions, but there is a noticeable split in Europe between the 'northern' countries (ie Denmark, Germany, Ireland, the Netherlands and the UK), whose governments appear to favour total market value controls above other actions, and those in the 'south' (ie Luxembourg, France, Italy, Portugal, Spain and Greece) which appear to favour individual drug price control (Figure 2). There is also a clear split between the drug pricing systems of 'northern' and 'southern' countries of Europe.

In Germany and the Netherlands, a fixed payment system, also called reference pricing, has been set up whereby, irrespective of the drug's selling price, the patient will be reimbursed a fixed amount defined by the therapeutic class. The fixed payment system seems to be proliferating throughout Europe. It has recently been

	REIMBURSED PRODUCT PRICE					VOLUMES AND AMOUNT		
	Laboratory prices		Intermediaries margin		Patient reimbursement levels	Prescription control	Pharmacist substitution	Product reimbursements
	Existing products	NCE	Wholesalers	Pharmacists				
Germany	●	●			●			●
UK		●						
Netherlands	●	●		●	●			
France						●	●	
Italy		●		●		●	●	●
Spain				●		●	●	

● Primary levers
● Secondary levers

Figure 2: Key 'levers' by which governments can control national drug expenditures.

been implemented. The sale of drugs by unit (eg tablet by tablet) such as in the UK and the Netherlands, or a standardisation of therapeutic approaches to limit waste and unnecessary prescriptions (now being implemented in France), are examples. Although useful as a complement, these measures are not sufficient to slow down an ever-increasing patient demand.

It seems, therefore, that even if they are politically dangerous, measures limiting the total amount of drugs prescribed will have to be implemented through actions which will affect doctor's prescribing habits.

Promotional costs

By limiting the promotional expenditures of pharmaceutical companies, EU governments expect to reduce the pressure on doctors to prescribe a particular drug over another one, and therefore contain the volume growth of drugs prescribed. Several approaches have been adopted already:

- A limit on the amount spent on promotional expenditures (UK).
- Taxes on promotional expenses (France).
- Limitation of the number of medical calls per company per doctor (UK, Sweden).

The average annual number of calls per doctor in the south is also twice that of the north. A harmonisation of medical call practices could lead to a downsizing of salesforces by between 30% and 50% in the south, making a reduction in salesforce activity likely. This will depend, however, on the choice made by EU governments between the cost of additional unemployment linked to salesforce reduction, and the cost of 'overconsumption' of drugs linked to call excesses.

Market impact

In order to decide on future strategies, pharmaceutical companies may base their estimation of European drug market evolution on the convergence hypothesis. If this hypothesis is confirmed, the relative size of the different European drug markets

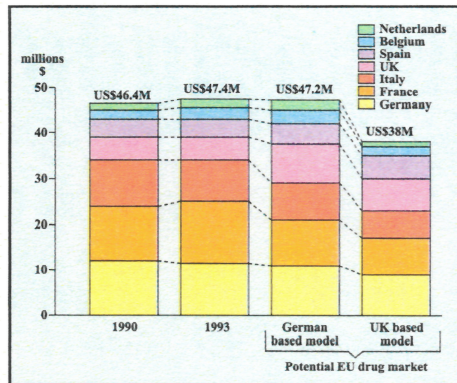


Figure 3: Potential European drug market size.

should change dramatically.

Between 1990 and 1993, the total market size of the top seven European markets (Germany, France, Italy, UK, Spain, Belgium, and the Netherlands) hardly changed (US\$47.4 billion in 1993 versus US\$46.4 billion in 1990). However, important variations occurred in certain markets. France, with 28% fewer people than in Germany, has reached the same market size as Germany. At the same time, the Italian market shrank 20% last year.

The two hypotheses within the convergence theory are:

- Governments want to reduce healthcare costs and index further growth to GDP.
- Comparison of healthcare practices and treatment habits among European countries will point European governments in the general direction of harmonisation.

To estimate the future value of the European market, it is assumed that this convergence will happen, and that the choice is between two models:

The German model of consumption based on price control (through reference pricing) and volume control (through 'ceilings' on prescribing). In that case, following historical trends, we have assumed that the average consumption value could still decrease and be around US\$150 per capita in the near future.

The UK model of consumption, based on a control of patient access to doctors (volume effect) and pharmaceutical companies' pricing (through the pharmaceutical price regulation scheme). In that case we have assumed that average consumption in the UK

will increase and reach US\$120 per capita (Figure 1).

With the first hypothesis (convergence of all European consumption per capita towards that of the German model) the value of the top seven European markets would remain close to the current value at US\$47.2 billion,

but with a UK market increase and a French market decrease. With the second hypothesis, the drug market of the top seven European countries could be reduced to US\$38 billion (that is a 20% reduction). The largest reduction would be in France, Germany and Italy (Figure 3).

These two estimates of the future European drug market assume that all governments will try not only to slow down drug expenditures growth but reduce it before trying to stabilise growth.

In the case of France, however, as no measures have yet been taken to reduce consumption, the range for potential market size is even bigger. The French drug market could reach US\$13.8 billion in 1998, (slow growth hypothesis without any cost reduction), US\$8.5 billion (convergence hypothesis: German model), or US\$6.8 billion (convergence hypothesis: UK model).

Pharmaceutical companies must anticipate a potentially drastic reduction in the size of the European drug market and be ready to re-evaluate their sales and development strategies. Potential changes are the most important for France, where readjustment in volume could be considerable. Pharmaceutical companies should be well prepared and organised for this reduction and should have built up enough goodwill to get the necessary price increases when consumption limits are introduced.

There will be an increasing challenge for marketing managers as pharmaceutical products will move from a well defined environment to a more traditional

consumer goods environment. The marketing mix will include new elements such as new distribution channels and new promotional approaches, including direct to patients communication, specific information packages for institutions, and so on.

For sales people, marketing efforts will increasingly involve economic rationale, and pharmacists will be approached more and more as their role in prescribing increases.

Healthcare expenditure control at a realistic level (expenditure growth limited to GDP growth) will not be achieved in the largest European markets without the implementation of measures influencing the entire range of players. The entire medico-economic environment will be affected by, and have to adapt to, these changes. For example, the reduction of prescription volumes by doctors will be accompanied by the education of patients in self-medication and prevention.

Pharmaceutical companies have an important role to play in this area. They could use their marketing capabilities to recommend to doctors the proper usage of products as well as communicating a product's cost/benefit advantage.

In order to really succeed in reducing drug expenditures, the array of measures undertaken by the governments must convince all the players involved to contribute to the elimination of drug waste and over-consumption.

These measures will not, however, prevent governments from being faced in the very near future with certain key ethical questions. What is the price of a human life? Up to how much can the collective healthcare system continue to spend on an individual? And should there be different accessibility levels for expensive therapies based on age, profession, potential quality of life? SM

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