



BALANCING COST, INNOVATION AND AVAILABILITY IN HEALTH CARE

- A GUIDE TO THE ISSUES

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Introduction

Healthcare regulation in Europe, especially in terms of medicine, is a maze. The following is an attempt to give a short overview.

Health care today is predominantly about somebody else making decisions about our lives; and that somebody is government. If we were free to choose, things would be very different. Therefore, we need to think at a more basic level about what brings value to us as consumers of health services. How, in other words, is innovation correctly rewarded; and is it the government's job to achieve this goal?

The paper begins with a brief tour of pricing in the five major EU markets (France, Germany, Spain, Italy and the UK) to get a glimpse of the issues involved, with an emphasis on the policies designed to favour innovation. Then follows a review of the arguments for cost-containment versus innovation. Finally, it looks at the recent debate on value-based pricing to see whether this is a way forward and what it means within a regulated environment.

In conclusion, some thoughts on how we could move towards more consumer-based options.

1 – Pricing and reimbursement (P& R) policies - European Union

Average health expenditure per capita:

(USD, PPP, 2005)

EU 5: 2,654

US: 6,102

Canada: 3,165

Japan: 2,249 (2003)

Pharmaceutical spend as percentage of total health care spending

EU 5: 18.5

US: 12.3

Canada: 18.2

Japan: 18.9 (2003)

(Source: OECD Health Data 2006; data refer to 2004, except Japan. NB: last available figure for pharmaceutical expenditure for the UK is from 1997.)

Pharmaceutical sales in the five largest EU markets (UK, France, Germany, Italy and Spain) make up the world's second largest market after the United States.

Whereas the EU 5 total health care spending is much lower than the US, the share of medicines is 50% higher in the EU compared to the US. We should remember also that the US market is divided almost equally between branded medicines and generic products; this is not the case in Europe, where generics are a lot more expensive.

In these circumstances, branded medicines provide an ideal target for government policies aiming at cost containment. Their proportion is also significantly higher in the EU than in the United States (although very similar to Canada's). This is worth mentioning, as we may establish a direct link between the amount of money spent on medicines and improvements in health outcomes, which is difficult to measure in other areas of health care.

So we could say that medicines in a budget perspective are exposed to a degree which is inversely proportional to both their share of the total expenditure and their effectiveness compared to alternative solutions.

1 – Overview of pricing and reimbursement policies

Pricing and reimbursement (P & R) policies vary considerably between countries. The European Union countries use a wide array of P&R tools which are primarily designed to control health care spending. In contrast, the United States has no price controls but instead uses reimbursement controls, and the use of patient co-payment is larger than in Europe.

Price controls (2006)

	Definition	Examples
Cost-plus pricing	Development costs + profits	Few (Poland, Columbia)
Reference pricing	Price based on an average of 1) lower-priced medicines in the therapeutic basket (national RP or 2) medicines in another country (international RP)	France, Spain, Germany, Norway ...
Profit controls	Price based on producer profits	Few (UK)
Price cuts, ceilings or freezes	Price is reduced or fixed at a given anniversary	Cuts (Japan, UK, France, Germany, Spain), Ceilings (NL and some US states), Freezes (UK, Germany, Canada, Sweden)

Source: Datamonitor (Sept 2006)

In Europe, the reference pricing model has been the most widely used tool over the past 15 years, since it was introduced in Germany in 1989. It has been debated extensively in the past few years, especially in Germany because of the so-called jumbo groups which put branded and generic products together. This reduces the price of branded medicines much faster, as price cuts are implemented by using the parameters of reference pricing.¹

A quick reminder on the definition: medicines with similar therapeutic effect are put together and a reference price is set, based on the average of a small number (e.g. three) of 1) lower-priced drugs in the basket or 2) drugs in another country. But as Valentin Petkantchin has pointed out, reference pricing is a misnomer: it is not a pricing system as such but simply a tool to restrict reimbursement and to redistribute a subsidy. A more

correct name would be “a fixed reimbursement drug policy”.¹ The practice of reference pricing is subject to substantial national preferences and variations.

Profit controls: at a certain level, companies will have their excess profit taxed, or else reduce their prices accordingly. The best-known example is the UK Pharmaceutical Price Regulation Scheme (PPRS).

A report released by the Office of Fair Trading in the UK (20 Feb 2007) recommends a major overhaul of this system of relatively free pricing, essentially eliminating the previous framework and introducing so-called “value-based pricing” where the price of medicines will be assessed by the added therapeutic value. This will be discussed in conclusion.

Price cutting and freezing are used extensively in the EU: one recent example occurred in the UK in 2004. Until then companies were required to reduce their prices by 4.5 per cent per year; this was raised to 7 per cent in 2005.² This is one of the more systematic examples; in other European countries, price cuts tend to be more a reflection of budgetary pressures and are applied as needed.

France is one of the clearest exponents of the cost-containment approach. In 2005, several health agencies merged to create the *Haute Autorité de Santé* (HAS). Its claim to fame in terms of promoting innovation has been to reduce the waiting time for market access of innovative products from 150 to 100 days. In fairness, seven new products in 2006 received their marketing approval within a record time ranging from 27 to 83 days. (So anybody dying in that interval was at least aware that government reform was speeding up.)

Reimbursement controls

	Definition	Example
Physicians	Ceiling on prescriptions	UK
Co-payment	Relative patient contribution to cost of medicines	Sweden, Spain
De-reimbursement/delisting	Positive/negative formularies	France, UK, Germany, US
Taxes on reimbursed products	Selective taxation on medicines	France
Pharmacoeconomic studies (PE) to justify cost		EU: UK, Denmark, Portugal, the Netherlands
Risk-sharing agreements/value-based pricing	Establishing the precise value added through long-term studies	UK, Italy
Pharmacist substitution	Substitution of branded products for cheaper/generic medicines	Germany, France

Source: Datamonitor (Sept 2006)

The second part is the reimbursement scheme, which is perhaps the most important, given that reimbursement largely determines the incentive to bring new products to market in the EU.

Let us briefly review the national contexts and look at the mechanisms which provide some reward for innovative products.

2 – Innovation within P & R systems

France

As mentioned previously, the HAS has made efforts to put a premium on innovation by reducing the marketing approval procedure for new products. The HAS is the key authority for pricing and reimbursement.

Reimbursement is determined using SMR (*Service médical rendu*, i.e. benefits) and ASMR (*Amélioration du service médical rendu*, i.e. additional benefit compared to other medicines for the same indication). The SMR is then evaluated in categories A (major or considerable), B (moderate) or C (low but still reimbursed). Re-evaluations are made every five years.

The ASMR rating goes from 1 to 6, based on how innovative the product is. Few products achieve the rating 1 or 2, but those which do enjoy flexible pricing. Once the SMR and ASMR ratings have been submitted, the pricing authority (CEPS) negotiates with the manufacturer before setting the price.

On the other side, more than 150 medicines were taken off the list of reimbursed products in 2006; another 80 were taken out in 2003.

Germany

Although Germany nominally enjoys free pricing, the reference pricing scheme and various other government programmes affect market access for innovative products.

The German system, including the 16 Länder, is decentralized. Sickness funds have a significant clout in negotiating prices with suppliers: there are some 250 sickness funds which have been in competition since 1996 (although there is little competition on price which is set on the federal level). On the other hand, the Bundestag decides on patient co-payment (which is modest and has little impact on medicines) and on negative lists. Reference pricing levels are decided jointly by the sickness funds and the federal committee of physicians.

Given the high barrier to proving innovation, new products are effectively excluded, or in some cases exit the German market because of the reference pricing system.

As mentioned, the jumbo reference pricing system is certainly not a driver of innovation, as it effectively eliminates patent protection by pushing the general price level towards the generic price. Further, because of the EU directive which bans advertising of medicines, companies may not communicate with patients who could be interested in having a choice and paying a higher price. There were price cuts in 2004 involving 223 drug groups.

Spain

The Spanish market will be shaped in coming years by the new medicines bill, approved in July 2006. Notwithstanding a number of regulations (new reference pricing, price cuts, generic substitution and taxes on pharmaceuticals), there are two interesting features:

- 1) Innovative medicines benefit from a 15 per cent reimbursement premium relative to the basic price. The only problem is that “innovation” has not been defined, nor incremental innovation.
- 2) A “let-out clause” allows companies which face patent expiry for an innovative drug to escape inclusion into the reference pricing system. This is meant to encourage post-patent R & D.

Italy

The Italian medicines agency (AIFA) created in 2004 controls both product approval, pricing and reimbursement.

P & R is essentially contingent on negotiations, and price cuts are implemented at will: in the past five years, there have been no less than 10 price cuts. Policies are clearly geared to cost-containment, and the decentralized nature of providers with 20 regional authorities makes it difficult to provide a coherent picture.

Innovation is further complicated by the fact that branded medicines have a marginal price difference with generics; and in view of the general instability of Italian politics, predicting future policies remains hazardous, to say the least. Italy uses European Reference Pricing (ERP) based on the four other major countries (but other countries have been added since the ERP was introduced). Like Spain, it is highly decentralized, and like France it has three levels of reimbursement.

We should also remember that there was no patent protection for pharmaceuticals in Italy until 1992; thus these concerns are rather new to policy makers.

UK

The PPRS is based since 1957 on five-year agreements between the Department of Health and the industry association (ABPI). All companies with sales to the NHS of more than £ 1 million participate in the PPRS. 80 per cent (in value) of medicines bought by the NHS are covered by the system.

PPRS also allows for tailoring prices within the range of products for any given company. The manufacturer may lower the price for medicines which face significant competition, and put a premium on those which have a stronger position.

The OFT report (20 February 2007) recommends that the current system (operated through profit controls and price cuts) be replaced by value-based pricing to “ensure the price of drugs reflect their clinical and therapeutic value to patients and the broader NHS”.

What does this mean? The proposal will be subject to negotiations, but the two models proposed are briefly:

- 1) “ex-post value-based pricing” = pricing remains free for new medicines, but subject to reviews of the cost-effectiveness. A maximum price would be set based on the clinical benefits relative to an existing drug, pending new clinical data.
- 2) “ex ante value-based pricing” = this would include ex post reviews for existing products, plus a “fast track ex ante assessment” of cost-effectiveness of new products. Again, approval would be dependent on additional benefits relative to existing products.

If experience is a guide in this context, it seems likely that, apart from the encouraging noise on innovation, this means in effect adding a new layer of bureaucracy for evaluating new medicines, presumably through increased use of HTAs.

It is obviously too early to offer an evaluation; but clearly this is far from a consumer-based assessment of technology. If implemented, price controls using HTAs would also have a European impact since UK prices are used for reference pricing in other EU countries.

3 – Containing costs and promoting innovation

The battle is essentially between cost effectiveness and cost containment, and it hinges on how governments define and evaluate innovation. Unfortunately, in most countries there seems to be no “official” definition of what really constitutes innovation.

In addition to price controls, we also have to consider the following tools.

1) Pharmaco-economics – cost/benefit analysis of the value of a medicine – is increasingly an integral part of the clinical trials.

2) Health technology assessment (HTA): this is defined as “The systematic evaluation of the benefits, costs and wider consequences of drugs, equipments and procedures involved in healthcare, with the aim of supporting evidence-based decisions about their use.”³

3) Evidence-based medicine (EBM)

The objective of EBM is to provide cost-effective access to state-of-the art therapies and medicines, using “the current best evidence in making decisions about the care of individual patients”.⁴ In practice however, I would argue that both EBM (the approach) and HTA (the tool) are increasingly used in Europe for cost containment. Moreover, these policies concentrate on what has worked in the past, an approach which is not particularly conducive to innovation. Last but not least, the outcome is often to ignore practice variations, i.e. a belief that one-size-fits-all. In terms of medicines, this leads to restricting choice and cutting costs while disregarding individual differences.

So-called “me-too” drugs are often in the line of fire coming from HTA and EBM. But these products are very useful in terms of catering to different individual needs: a product may be very similar to another of the same class, but personal features, notably allergies, side-effects, contra-indications and other characteristics, are essential for finding the right medicine for the right person. (As my colleague Peter Pitts would say, “there are no me-too drugs because there is no such thing as a me-too patient”.)

To illustrate the dangers of EBM, let me quote an article published in the British Medical Journal in 2003⁵. The issue concerned the use of parachutes, and this is what the authors concluded:

“As with many interventions to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised control trials. Advocates of evidence-based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.”

Conclusion

Innovation is a long haul business, as is product approval - the key to patient access to medicines.

But how could we define innovation? I have a particular fondness for the concept of serendipity, which is characteristic for innovation overall: meaning that the procedure of discovery is a constant source of surprise and above all unexpected benefits. Naturally, we would all be delighted if scientists and industry came up with the equivalent of penicillin twice a year. But that is hardly likely. All the same, we have benefited from enormous breakthroughs in the past 30 years, notably on HIV-AIDS and cancer; but progress in the medical field otherwise remains essentially incremental, although it is impossible to predict the developments of biologics. Integrating these new developments into current P&R arrangements will certainly prove a great challenge in the near future, to governments and industry alike.

But this also means that research and innovation include features which, by definition, cannot be foreseen, dictated or regulated by government: the cancer drug Avastin is currently in clinical trials for some 20 different uses. Could any single person, or indeed a health bureaucracy, predict this? It is highly unlikely; had this been the case, we would all be much better off today.

Thus, to make sense any definition of innovation and its price must be decentralized, i.e. subject to a market framework. What represents a value to one health consumer may well be viewed as a waste of money by another. Therefore, the very definition of innovation is contingent on individual choice, in health care or for any other service.

The global free market has provided huge savings to consumers in recent years; this has not been achieved by government intervention. There is no reason why health care should be excluded from this positive trend. Yet today, health care remains captive of Soviet ideology.

As public health systems are increasingly determined not by patient satisfaction but by budgetary constraints, we as patients and taxpayers should look for alternative options and voice our opinion, as well as using the interesting possibility of doing both through so-called health tourism.

The current discussion of pharmaceutical pricing needs more imagination. In theory, every EU citizen retains the right to opt out of public health insurance and seek private coverage. In practice, however, this right is not enforced by courts, e.g. in France where the author lives. The reason is obvious: were French taxpayers allowed to desert the public insurance scheme for private insurance, which offers the equivalent (or better) coverage at an equivalent or cheaper price, this would be the death knell to the current system. Nevertheless, to resolve the conundrum of public financing, patient rights must be respected.

We could try to revive Recommendation 6 put forth by the G 10, whereby free pricing should be allowed for de-listed and non-reimbursed medicines. This would make for an embryonic free market of medicines which would likely be fuelled, paradoxically, by a growing number of products which governments all over Europe are no longer willing to pay for. (This option is currently being reviewed by one working group within the EU High Level Pharmaceutical Forum which is supposed to deliver a report in 2007.)

Rewarding innovation is key in this context; but it is hard to see how the current system in Europe can possibly satisfy this goal. Given a choice, would anyone put her personal health in the hands of an institution which may hardly be trusted for delivering mail?

In conclusion, a quote by Arne Björnberg of the Health Consumer Powerhouse: “Far from being a cost, we should look at health care as a growth industry for the 21st century”. But to make this happen we have to make innovation in health care a business for the first stakeholders, the patients.

¹ For a more detailed discussion, cf. the recent presentation by Valentin Petkantchin from the CNE website (Nov 2006).

¹ “Economic effects of Germany’s reference pricing policy for drugs”, Centre for the New Europe, November 2006.

² “Pharmaceutical Price Regulation Scheme: Ninth Report to Parliament”, UK Department of Health (July 2006)

³ HTAi conference 2004 (cited in Datamonitor, Sept 2006).

⁴ D. Sackett, BMJ, 1996; 312, 71-72 (13 January).

⁵ “Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials”, G.C.S. Smith, J.P. Bell (British Medical Journal, vol. 327, 20-27, Dec. 2003.