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Fair pricing for medicines in the UK

'The Office of Fair Trading report clearly shows that the current system is flawed and cannot carry on'

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Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme (PPRS), which has existed in one form or another for nearly 50 years, is a voluntary agreement between the UK Department of Health and individual drug companies. Its aims are to secure access to medicines for the UK National Health Service (NHS) at reasonable prices and to promote a strong and profitable indigenous pharmaceutical industry. The PPRS covers all licensed, branded, prescription medicines (~80% by value of all NHS pharmaceutical expenditure) but not generics. Contrary to its title, it does little to regulate drug prices as companies are free to set prices at the time of launch. Instead, it regulates the level of profit that companies can make on their sales to the NHS, where a target profit of 21% return on capital (ROC) employed is allowed or, for those companies without a manufacturing base in the UK, 6% on sales with generous margins and allowances for costs and research. Companies with excessive profits of more than 40% above target are required to reimburse the Treasury but, in fact, such reimbursements have been rare.

The scheme has always been controversial. Many see an inherent contradiction in trying to get value for the NHS and support a local industry. Some have argued that the PPRS has done little to control the costs of medicines for the NHS [1], as by 1998 the UK prices were amongst the highest in the EU [2], nor was it clear what the UK gained in return. In recent years, the scheme has been scrutinized twice by the parliamentary Health Select Committee [3], but government responses to these inquiries have clearly always been swayed less by the costs to the NHS than by the apparent benefits of the pharmaceutical industry to the wider UK economy – pharmaceuticals are the UK's second largest export and the pharmaceutical industry is a major employer.

UK Office of Fair Trading report

The death knell for the present scheme may have been sounded by a recent report from the UK Office of Fair Trading (OFT), an independent statutory body charged with protecting consumers' interests in the UK [101]. Its overriding concern is that the PPRS does not secure good value for the NHS, with prices in the UK higher than in most European countries. Even within the UK market, and without too much effort, the OFT could identify huge price differences of up to 500% between near-substitute medicines, and possible savings of GB£500 million per year in a small number of therapeutic areas examined, especially cholesterol-lowering medicines, where £350 million could be saved just by switching from atorvastatin to simvastatin. The OFT states that it does not see any need to reduce overall NHS drug expenditure, but to redeploy it more efficiently. From an NHS perspective, it is hard to disagree with this, especially at a time when NHS budgets are difficult and the high rates of increase in NHS expenditure are set to slow.

On this basis, the OFT report concludes that the PPRS is no longer fit for purpose and should be reformed. It criticizes the failure to link prices to value for patients, and favors the introduction of a value-based pricing scheme. Under this, the value of a drug in terms of cost per quality-adjusted life year (QALY) would be assessed in a process similar to that used by the National Institutes for Health and Clinical Excellence (NICE), and then a price allowed that achieved an acceptable cost/QALY. A key

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here would be the comparator, which, as in NICE evaluations, would be current UK practice or existing medicines including generics.

The OFT considers several options for how to introduce value pricing – either before drug launch (its preference) or by allowing companies to retain free pricing at the time of launch then assessing and changing the prices afterwards. A premium price for the first marketed drugs in an innovative class would be allowed indefinitely, even when there were generic competitors, to reward innovation. Arguments that prelaunch assessments would delay launches are dismissed on the grounds that this is already practiced in other European countries (e.g., Sweden). The OFT acknowledges that uncertainty about a drug's true value at the time of launch means that reassessment of its value will be needed periodically. In exceptional cases, some form of risk-sharing scheme between government and company might be considered, perhaps as price/volume agreements or rebates.

This suggestion focuses strongly on the first aim of the PPRS, achieving value for the NHS, but what about the other aim of the PPRS, to support an indigenous industry? This is more complex: the OFT was unconvinced by arguments that the PPRS has encouraged pharmaceutical investment in the UK, either in manufacture or in research and development (R&D). It claimed that the aims of supporting an indigenous industry seem contrary to EU legislation on state support and competition. Value-based pricing, it says, would actually create greater incentives for companies to invest in areas of unmet clinical need rather than in areas already well served, with global benefits for patients and a more profitable industry overall.

'The PPRS is no longer fit for purpose, and should be reformed'

Regarding research, the OFT points out that the R&D allowances under the PPRS apply to R&D wherever it is undertaken, not just in the UK. The OFT undertook a series of interviews with companies that suggested costs and the PPRS were secondary factors for companies deciding whether or not to conduct research in the NHS and that their decisions were based more on the availability of highly skilled staff, good infrastructure, existing company R&D activities and public sector investment in R&D.

Assessments & institutions

The OFT praises NICE's activities and approach, and proposes an expansion of the role of NICE and similar agencies in Wales and Scotland. It does not make mention of the different standards used by these organizations, with NICE's assessments by far the most rigorous (and hence expensive). The OFT believes that a system to undertake the necessary evaluations would cost no more than £6.5 million per year (not counting the costs of industry submissions). A new unit within the Department of Health would negotiate prices and contracts with the companies on the basis of these assessments. Eventually, a new independent single agency, a Medicines Pricing Commission, might take on both assessments and negotiations.

Difficulties

The costs of the new proposal seem unrealistic for the number of assessments required and do not take account of industry costs or the cost of implementation that, so far, has been a major weakness of NICE, especially when it has tried to restrict the use of established medicines. It is not clear how, other than by complete refusal of reimbursement, the new approaches would tackle some of the current major barriers to more cost-effective prescribing (i.e., doctor inertia and both patient and doctor insensitivity to the costs of drugs). The assessments themselves might be more difficult than the OFT believes. It makes some sweeping assumptions regarding the equivalence of drugs within a class that will be hotly debated by clinicians and the pharmaceutical industry (e.g., simvastatin as a wholesale substitute for atorvastatin).

In recent years, the NHS drug bill has been influenced by the push to improve the management of cardiovascular disease (the use of the cholesterol-lowering statins has doubled in the past 3 years while, paradoxically, the costs have fallen by approximately £200 million/year [~25%] owing to the availability of generic simvastatin) and the activities of NICE. In its efforts to achieve cost-effective use of NHS resources, it has approved medicines that can deliver benefits within its threshold cost/QALY. So cost–effectiveness can be a two-edged sword, not serving to cut costs but to improve efficiency and perhaps to justify an increase in drug expenditure. Once approved, medicines may often be used outside the terms of NICE's recommendation and in groups where the cost–effectiveness is lower. Similar problems would occur in restricting the use of drugs to the indications assessed and approved under the OFT scheme.

The pharmaceutical industry has always enjoyed the security provided by the PPRS, although the report suggests that this security has already been eroded by the price cuts imposed within the scheme in recent years and by the lack of any guarantee of volume of use. Perhaps not coincidentally, at the same time as the OFT report appeared, the industry-sponsored Office of Health Economics released a report suggesting that the UK trade deficit would worsen substantially if the two big UK companies, GlaxoSmithKline and AstraZeneca were to move offshore [4]. It is clear that the industry will not welcome the changes proposed in the OFT report, however, so far (April 1st 2007), the Association of the British Pharmaceutical Industry (ABPI) has issued no formal comment.

Finally there are international political issues. The report argued that the UK, despite accounting for under 4% of global pharmaceutical sales, influences some 25% of world sales due to others benchmarking against it and, perhaps more as a result of the recognized excellence of its institutions, such as the Medicines and Healthcare products Regulatory Agency (MHRA) and NICE. This begs the question as to whether or not the UK would actually have the muscle to negotiate prices in this way with major international manufacturers: New Zealand has been able to do it as it can afford to be a price taker in international

markets, with no industry and little external influence. The very fact of the UK's influence would mean that major manufacturers would battle to retain higher prices.

In praising other countries, the report does not consider that New Zealand has no pharmaceutical industry, and that both the Canadian and Australian systems have recently come under severe pressure from the USA on the issue of pharmaceuticals. Even the current UK system may come under similar pressure, with a recent visit by the US Deputy Secretary of Health arguing that attempts to keep drug costs down, such as NICE, will stifle innovation [5]. Other US government officials have suggested that other countries freeload on the US medicine costs and its contributions to R&D; these arguments have been refuted [6]. Nevertheless, in dealing with a global industry, one can expect to see intense international lobbying, especially when other groups in Europe, such as the Pharmaceutical Forum of the European Commission, are more concerned with maintaining the competitiveness of the European pharmaceutical industry.

'The PPRS does not secure good value for the NHS, with prices in the UK higher than in most European countries'

Next steps

The OFT reports require responses from the government by the end of June. If this is considered unsatisfactory, the OFT can refer the matter to the Competition Commission, a statutory body that has the power to make and implement decisions. This, like the OFT itself, is independent of government, and political interference would be difficult if not impossible.

The report clearly shows that the current system is flawed and cannot carry on. The use of value-based pricing would be a radical change in relations between health systems and drug companies, not only in the UK but globally. This report is only the latest move towards cost–effectiveness that has been growing for many years internationally and of which NICE is the prime example. This particular leap may be too radical and before its time and the details are not well worked out, but the trend is unstoppable and industry must acknowledge this. In particular, there will need to be more assurance that such a move will not undermine the UK industry. Undoubtedly, big pharma will rattle that particular saber, in private at least.

The current PPRS agreement expires in 2010 – its renegotiation has been delayed by the expectation of the OFT report. The process of setting prices looks set to change radically, but these affairs are rarely managed in the UK by government diktat but by negotiation and one may be sure that, behind the scenes, there are many conversations between government officials and industry leaders. Thus, the final outcome may not be as drastic as the OFT proposes. One commentator stated that the report was "…sensible in its aims. Somewhat undercooked and perhaps a little naive in some of its conclusions" [7], which seems about right for the moment. There is much to praise in this report, and the PPRS in its present incarnation has had its day. The report brushes over many difficulties, though most of these can be resolved with time. It will be some time before we can say the last word on the effects of this earth-moving report.

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