

Editorial

In this bulletin Don Macarthur carefully and in an unbiased way critiques the report from the UK Office of Fair Trading (OFT) investigating brand drug pricing and the PPRS.

OFT recommends the dismantling of the PPRS to be replaced by a "value-based" pricing authority. OFT make their case by stating that NHS is ripped off by £500M due to overpriced drugs. However, almost the entire premise of their report is flawed. Several reasons include:

- Who sets prices in the UK?

The PPRS doesn't really set prices in the UK. There are a whole host of other supply- and demand-side mechanisms (many value related) that keep UK prices reasonable, which the OFT report has mostly ignored.

- Value based pricing or therapeutic referencing

The £500M savings that OFT identify do not come from value based pricing. The majority are based on therapeutic referencing to cheaper priced generics. The OFT assumes that every drug should be similarly priced to cheap generics once one is launched in a new class. However, generics are generally priced using a "cost-plus" approach, which has nothing to do with the value that they give to the NHS.

When the first brand in a class loses patent protection in the UK generics will enter the market and compete with each other on price. But that doesn't mean that overnight all of the other drugs in the class are no longer priced according to their value. It simply means that a very cheap alternative is now available for doctors to use. A good pharmacist in control of a Primary Care Trust formulary should make sure that doctors know cheaper versions are available

In general, all pricing authorities should take advantage of cheap generics because, to some extent, this enables them to afford branded drugs priced according to their value (known as headroom for innovation). No system is perfect, but the UK one is among the best at taking advantage of generics to the envy of much of Europe.

- Value and the Incremental Cost Effectiveness Ratio
Value is a very difficult thing to quantify and clinical value often most difficult. OFT has used an economic assessment of value to base its calculations on. This is controversial. The UK has adopted the incremental cost effectiveness ratio (ICER) based upon a notional threshold of £30,000 (based on Quality Life Adjusted Years - QALYs). This threshold is "unofficial" and set by academics within NICE. It was initially set many years ago (at least 20). If it had been adjusted by general

inflation it would be over £60,000 today. This means we value life less now than when this threshold was first established and despite everyone recognising that the cost to develop drugs has increased, the value of them to society has effectively been halved.

Having used this threshold, OFT believes many drugs are overpriced, but it has ignored the hundreds of drugs that are priced well below the threshold. If these drugs had their prices increased until they reached the £30,000 threshold the cost to the NHS would more than offset the savings estimated.

- Encouraging Investment

OFT says it wants to encourage investment in real unmet need. The impact would probably be the opposite. If drugs are going to be priced according to therapeutic referencing to generics, there is hardly any chance for a company to see a return on investment in those circumstances. The industry will stay clear of disorders where there are old, cheap drugs that would be used as references. Often these are the disorders where unmet need is highest.

- Assuming OFT Are Right

Assuming that OFT was right in their assessment, £500M is a lot of money. But, in the pharmaceutical budget of £11Bn it represents less than 5% of the total and would probably be within the sensitivity limits of a health economist's calculations.

Even if it were possible to save the £500M, because the proposal is so highly bureaucratic, the cost of running the OFT scheme would again offset any savings.

Perhaps the most unfortunate outcome of the OFT report is that an industry, which does so much good, was publicly paraded as having ripped off the NHS. To date there has only been a muted case in reply put by the pharmaceutical manufacturers. Having worked within and for this industry for over 30 years, for me it was a very sad day when this report was published.

Please read Don's review below. Don gives his own thoughts in his commentary and we lay out the main implications for strategy development.

We welcome your comments.

Introduction

The Office of Fair Trading (OFT), the UK's antitrust watchdog, believes there is a "compelling case" for replacing the 50-year old Pharmaceutical Price Regulation Scheme (PPRS) with a "value-based approach to pricing", under which a maximum incremental cost-effectiveness ratio (ICER) would be set for all drugs.

During its 17-month investigation, the OFT identified £500 million of brand spend among some major categories in 2005 alone, out of the £11 billion NHS drug bill that could have been used more cost effectively under value-based pricing, thus allowing patients access to drugs and other healthcare benefits they are currently being denied.

According to OFT, change in 2010 when the current PPRS is due to expire, would lead to a stable, sustainable system for government and industry. It would avoid reliance on 'increasingly arbitrary profit and price controls' that fail to reflect the therapeutic value of drugs to the NHS, and would give companies more incentives to invest in R&D to meet unmet patient needs.

Why OFT says change is needed

OFT says the basics of the PPRS – the profit cap on companies – is 'ill suited' to an innovative sector such as pharmaceuticals. There are also practical difficulties in making profitability assessments. Companies have an increasingly global cost base and a high level of intangible capital. Also profit controls cannot be binding on transfer-priced products that now account for more than 70% of sales.

The allowable return on capital has progressively increased from 15-17% in 1984 to 29.4% today (including the upper margin of tolerance), and the OFT hints the profit cap no longer functions effectively as a cap at all. Profit repayments in the 1999-2004 Scheme represented a mere 0.01% of company PPRS revenues over this period.

While the 7% price cut in 2005 delivered £450 million savings that year in primary care costs, the impact fell over time as new drugs were launched to replace older ones at uncontrolled prices. OFT fears firms will increasingly anticipate price cuts by setting launch prices correspondingly higher.

Neither doctors nor patients are price sensitive. OFT points out that there was a high level of prescribing for some products that cost much more than available substitutes but deliver very similar benefits. Price differences of 500% or more were identified for 'very close substitutes'.

When simvastatin and pravastatin lost patent protection, competition did not impact the prices of other statins, which retained significant volume and market shares.

OFT did find some benefits in the PPRS, reflecting industry thoughts over the years that it was 'the least worst option' should government intervention be needed at all. These benefits were.

- Companies like the freedom to set prices and launch without lengthy negotiations, though OFT believe this is offset by the subsequent low uptake of new drugs in the UK.
- The five years of relative stability during the life of each agreement is also widely appreciated, though this is offset by the arbitrary nature and increasing size of price cuts over the three most recent ones, i.e. 7% in 2005, 4.5% in 1999 and 2.5% in 1993. (In contrast, there was only one government-mandated price cut – mid term in the 1983 PPRS – during the lifespan of all previous six agreements.)
- The Scheme is highly efficient and operated at minimum cost by the Department of Health (just 10 staff)

OFT Proposals

OFT says that where access is restricted on cost-effectiveness grounds, it is 'vitaly important' that all drugs (old and new) are assessed on the same basis. It offers two main options for reform:

ex post value-based pricing

Free launch pricing for medicines containing new active substances would continue but the PPRS' company-wide profit controls and periodic price cuts would be replaced by a rolling series of five-yearly reviews of the cost-effectiveness of individual drugs or drug classes. These reviews would set the maximum price of a product in accordance the clinical benefit it delivers relative to an appropriate comparator.

ex ante value-based pricing

Retaining the ex post reviews of existing drugs (as above), this option would also involve a fast-track assessment of a new drug's cost-effectiveness (starting during the marketing authorization application review process) and an upfront negotiation of price. Especially in the case of chronic-use products, when pre-launch data are deemed insufficient for an assessment to be made, a risk-sharing approach could be adopted, though this would be exceptional.

The majority of companies interviewed preferred the ex-post method, the report indicates, though ex-ante is the OFT's preference. As the introductory price would not be 'once and for all' it dismisses fears of launch delays and 'NICE blight' would be avoided.

The OFT also thinks more could be done with price/volume agreements and rebates, especially for products for which cost-effectiveness differs markedly by

indication and patient subgroup. Rebates in lieu of price changes would also help minimize parallel trade, it said.

Raising fears of therapeutic class referencing, innovation should not be rewarded *per se*, says the OFT. When considering cost-effectiveness of a patented brand the comparator might be a generic, it argues, though in order to capture benefits to patients that have not been demonstrated formally in trials a brand premium of up to 50% may apply.

The preferred approach for an off-patent original brand is to reimburse at the Drug Tariff generic price plus 25% (as long as there is a Category M Tariff listing for the active ingredient). Standard branded generics would receive just the Tariff price, in line with a recent Department of Health proposal.

Fears that companies would withdraw their investment in the UK if the P&R environment turned more hostile are dismissed. While the OFT emphasized its focus was not on whether the aggregate level of prices or the overall amount spent on medicines in the UK was too high, it 'saw merit in considering a fixed annual budget for the NHS drugs bill'.

Envisaged Method of Operation

Under OFT's preferred option manufacturers would submit a suggested price, along with cost effectiveness evidence, which would differ across indications.

An analysis of value-reflective prices would then be undertaken, with existing HTA bodies – the National Institute for Health and Clinical Excellence (NICE), the Scottish Medicines Consortium and the All Wales Medicines Strategy Group – considered 'the natural candidates' for doing this. NICE assessments are seen as 'the gold standard' for HTA around the world, the OFT adds.

Coordination might be achieved by a new 'Commission on the Value of Medicines'. Longer term, a new 'Medicines Pricing Commission' would replace this.

As a phasing-in step, the OFT suggests *ex ante* reviews on all new active substances and *ex post* reviews on all drug categories over a five-year period

NICE would seem to need a large boost in resources and budget to it perform the new tasks the OFT envisages for it. Even with the new single technology appraisal (STA) process, the average time span from topic selection to publication approaches two years.

Several countries, including Sweden, Australia and Canada, have successfully implemented value-based P&R systems. Sweden in particular is held by the OFT as an example of a country much smaller than the UK that routinely demands evidence of cost effectiveness with all new active substance reimbursement applications. The Pharmaceutical Benefits Board (LFN) has a staff of just 30 persons of whom five are health economists, but unlike NICE its appraisals are limited to examination of the economic evidence the applicant

company itself provides. Decisions must be made by law within 180 days, but internally the target is 60-120 days, a spokesman confirmed.

Commentary

Some will question why a competition body is making recommendations on what value drugs bring to healthcare, and why the emphasis is on cost effectiveness and not clinical effectiveness. Others will highlight that the cost of medicines per head in the UK is already among the lowest in Europe.

The OFT's remit was limited to brands, as unbranded generics were removed from the PPRS in its 1986 revision, but it is difficult to separate generics from the overall value equation in the UK as this segment is highly competitive, low priced relative to other markets in western Europe, and accounts for over half of all prescriptions dispensed.

Another problem if deciding on radical supply side changes to part of the market at this time is that there is already too much turbulence. Many other changes have recently taken place, are happening now, or are pending. These include NICE's STA process, changes to generic reimbursement, the new pharmacy contract, inquiries into the distribution margin and the prescription charge, major companies reviewing their distribution channels, and the ongoing research by the National Audit Office into value for money from primary care prescribing. With demand side controls potentially strong in the UK this last-named review is important so as to obtain the overall view.

Several factors are also interconnected. Category M generic reimbursement prices, which under the OFT's proposals could be used to set prices of patented drugs in the same therapeutic category, are artificially adjusted by the Department of Health to ensure pharmacies retain the level of procurement discounts they are contractually entitled to, for example

The two main price control methods used elsewhere in Europe – geographic reference pricing and internal reference pricing - get barely a mention. Fears of politically unpopular higher charges on patients may explain omission of the latter. However, at just 5% of the drugs bill, co-payments in the UK are amongst the lowest in the EU.

Some statements seem odd. The OFT says the PPRS 'does not contain any systematic incentives to locate investments in the UK', yet its whole basis is return on capital assets employed in the UK. The country 'is almost unique (*sic*) in this world in not taking explicit account of the therapeutic benefits of drugs in its pricing system', but the UK does not currently have a pricing system.

The 120-page report '*The Pharmaceutical Price Regulation Scheme: An OFT Market Study*', published February 20th 2007, can be downloaded from www.of.gov.uk.

Implications for Strategy

Development

Any pricing reform in the UK would impact globally. While it represents just 4% of world demand for prescription medicines, other countries that set prices with reference to those in the UK together account for 25% (Japan, France, Italy, Canada, Belgium, Switzerland, Poland, Netherlands, Finland, Hungary, Norway and Ireland are mentioned).

The PPRS has been written off several times before, but has always survived with some tinkering around the edges after lengthy and sometimes heated discussions. The OFT's proposals are only a recommendation to ministers, and other reports from this body not been adopted. Their plan for total liberalisation of community pharmacy NHS contracts was not implemented, for example. Given the difficult financial situation the NHS currently faces, with hospital closures and staff lay-offs regularly in the news, it will however be politically very difficult for the government to totally ignore the OFT's recommendations on the PPRS, unless the ABPI has a reasoned alternative of its own.

The industry must make a robust, reasoned rebuttal of the OFT report. The industry must make sure that it works within the spirit of the PPRS; in the past some liberties have been taken.

Most importantly, the industry must ensure that it develops drug pricing strategies that give a rational justification for the price asked and that this justification is fully communicated.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific expertise on a wide range of policy matters and detailed knowledge of P&R rules in all major markets worldwide.

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