IF IT AIN’T BROKE, DON’T PRICE FIX IT:
THE OFT AND THE PPRS

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SUMMARY
The Office of Fair Trading (OFT) Report on the UK Pharmaceutical Price Regulation Scheme (PPRS) recommends that when the current five-year PPRS expires in 2010 it be replaced with ‘value-based pricing’ which involves pre-launch centralised government price setting based on a cost-per-QALY threshold plus periodic ex post reviews. I examine the validity of the OFTs criticisms of the existing PPRS, review its proposals and propose an alternative way forward. I conclude that PPRS has performed well as a procurement bargain between industry and the UK government. It does not, however, incentivise efficient relative prices. That is not its job. I identify a number of problems with the OFT proposals. I recommend that key elements of a reformed UK pharmaceutical environment for 2010 should include an expanded role for HTA but with companies retaining freedom to set prices at launch; HTA use targeted via a contingent value of information approach; a retained backstop PPRS, perhaps moving to an RPI-X type control; the use of risk sharing and non-linear pricing arrangements; measures to ensure more effective therapeutic switching at local level; and measures to improve the take up of cost-effective treatments.

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One of the UK’s two competition bodies, the Office of Fair Trading (OFT), has produced over 1000 pages of analysis of the UK Pharmaceutical Price Regulation Scheme (PPRS) in an 18-month ‘market study’ (OFT, 2007a). The study is one of a number in public procurement (DotEcon, 2004). It examines whether the PPRS is effective in meeting its high-level objectives, or whether there is a case for reform (para 1.2). Another key objective for the OFT was to improve the terms of debate about ‘pharmaceutical pricing and reimbursement, not just in the UK, but internationally’ (para 1.16). The OFT concludes that more regulation is needed because there are demand side problems in the NHS, not because of an absence of competition on the supply side. This case for regulation is therefore very different from that found in regulated activities in economic sectors such as communications, energy, transport and water where lack of competitive supply is the problem.

The OFT proposes the abandonment of the 50-year-old PPRS in 2010 in favour of a new regime of government ‘product-by-product’ price setting based on ‘value’ which it claims will incentivise companies to undertake R&D to find the cost-effective treatments NHS patients need. It sounds promising but is the OFT analysis accurate and is there any ‘beef’ in these proposals? A number of questions arise which can be grouped into the following:

- What are we trying to achieve?
- Is the ‘old’ PPRS failing to do this?
- Will the OFT’s proposals help?
- Given the answers to these questions, what is the way forward?

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WHAT ARE WE TRYING TO ACHIEVE?

Health-care systems and their pricing and reimbursement systems (which typically focus on input price and recommendations for or against the use of specific medicines in some or all groups of patients) should be trying to achieve two things from the use of pharmaceuticals:

- an efficient use of the medicines currently available – static efficiency. This involves addressing questions such as:
  - are the prices ‘right’, i.e. do they reflect opportunity costs?
  - given prices and budgets, are pharmaceuticals being used within a condition or patient group in the most cost-effective way, i.e. are we achieving productive efficiency?
  - are we treating the conditions and patients that society most cares about, i.e. given input prices and cost-effectiveness are we achieving allocative efficiency? For those who believe a QALY is a QALY there is no distinction between productive and allocative efficiency; for the rest of us this matters.

- to stimulate the development of new cost-effective medicines – dynamic efficiency. This requires a combination of:
  - revenues (i.e. price multiplied by volume) for current medicines that send the appropriate signals about the revenues the system is willing to spend on valuable new treatments;
  - any other incentives (or disincentives) to compensate for any under- or overpayment through the pricing and reimbursement system.

Estimating the cost of R&D is a particular problem for pharmaceuticals because of high failure rates, long development times (10–12 years) and the global joint sunk cost characteristics of R&D. Not only is there a large divergence between short-run marginal costs (Philipson and Jena, 2005) and long-run marginal costs for individual drugs, it is necessary to account for the resource cost of failures and early development work that was not product specific (DiMasi et al., 2003). Revenues from individual drugs tend therefore to bear little relation to their short-run costs and returns are highly skewed (Grabowski et al., 2002). From a societal perspective what matters is the ability of companies to achieve ex post returns on product portfolios where social value exceeds social cost, or for enough companies to keep believing ex ante that they will achieve a return on socially useful R&D investments.

More controversial issues are: (1) the role if any that P&R systems should play in trying to attract pharmaceutical industry investment to a specific location; and (2) the extent to which it is appropriate to reward innovation per se.

IS THE ‘OLD’ PPRS FAILING?

Context

The UK government does not set drug prices or (with a few exceptions) dictate use via positive or negative lists. It uses indirect methods. The PPRS acts as a constraint on branded drug prices and profits. Local prescribers informed by HTA seek to maximise health outcomes given local budgets. In recent years, new HTA institutions (the National Institute for Health and Clinical Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG)) have been put in place to provide strong direction on the cost-effective use of drugs and (in the case of NICE) other technologies. However, there is often slow take up of technologies that are recommended for use. There are high rates of generic prescribing and a strong competitive generics industry.
The PPRS is a unique scheme both in the realm of pharmaceutical price regulation and more generally of government regulation and procurement. The objectives of the scheme (DoH, 2004) are to:

- secure the provision of safe and effective medicines for the NHS at reasonable prices;
- promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
- encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The PPRS is an agreement negotiated every 5 years between industry and government, within a statutory framework. It includes periodic price cuts. The last one-off price cut (part of the 2005 Scheme) was 7%. Key elements are:

1. A profit cap with banded upper (lower) rates of return to provide for paybacks and price cuts (increases).
2. Price freedom for NCEs at launch followed by a price freeze, i.e. once set the price cannot be increased in nominal terms. This means NHS prescribers can begin using the product as soon as the company launches it following licensing approval.
3. Price modulation, which allows companies to increase the prices of some products provided they reduce the prices of others such that the expected overall volume-weighted revenue is the same. (This enables companies with product portfolios to adjust to competitive circumstances – i.e. their revenues would otherwise be falling – at cost neutrality to the NHS.)

Theoretical problems

It is thus a hybrid scheme combining a profit cap and a price control. It is easy for economists to dislike it – and many do. The major theoretical problems are:

1. Return on capital (profit cap) regulation can lead to inefficiency around the allowable rate of return and the treatment of costs.

   (a) There is an incentive to overinvest (‘gold plate’) capital if the return offered exceeds the cost of capital (Averch and Johnson, 1962). But the PPRS regulates accounting rates of profit, not economic rates of return, (Edwards et al., 1987). As R&D is not capitalised but expensed, the largest asset of the industry does not appear on the balance sheet. The accounting rate of profit needs to be above the economic return. It cannot be assumed (as the OFT implies) that the 21% accounting rate of profit is above the cost of capital.

   (b) Any rate of return set is an average. Different R&D projects will in reality have different (systematic and hence undiversifiable) risks. This may reflect the science, the chances of successful commercialisation or the stage at which the project is at – ‘operational gearing’ (Myers, 1999). The OFT argues that an average return encourages low-risk, low-value product investment. This ignores the impact of competition and of HTA as I discuss below.

   (c) There is a danger of ‘cost plus’, as costs are allowed before profit. However, as the OFT notes the PPRS uses a combination of allowances not related to actual spend and costs that the DH can disallow. It benchmarks companies against each other in a form of yardstick competition (Shliefer, 1985). OXERA modelled the potential impact on accounting and economic returns of different levels of costs and allowances, and treatments of R&D (OFT, 2007b). It found some offsetting effects which suggests that the DH and industry are well aware of the ‘swings and roundabouts’ when they negotiate.
2. Regulating an industry with joint costs in only one of its geographical markets produces cost allocation issues (verification of costs and of allocations). The OFT identifies particular issues around the treatment of transfer pricing. These clearly need to be tackled.

3. Danger of ‘regulatory capture’ i.e. the DH is too close to the industry to do its job properly. The OFT does not explicitly address this, but it looks at component parts which might include:
   
   (a) There is not enough challenge. The OFT does not suggest this – and indeed congratulates the DH on its application of the Scheme.
   
   (b) DH is compromised by its desire to keep UK investment – I return to this.
   
   (c) The profit cap does not bite – to a large part reflecting the issue with transfer pricing referred to above. The OFT assumes that because no company has been in ‘payback’ since 2005 this means that the cap is ineffective. The reverse could also be the true – a desire to avoid profit cap penalties influences pricing behaviour or another binding constraint (e.g. the impact of HTA on new product pricing) means the profit cap is providing a ‘backstop’.
   
   (d) Overall UK price levels. The OFT implies that UK brand prices are high. The DH figures for 2005 (in the OFT Report) show the UK as the fourth highest out of 10 EU countries. (These figures exclude Sweden which has brand prices above the UK derived from an HTA process the OFT supports.) The OFT ignores the key driver of relative prices identified by the DH – exchange rate movements. A recalculation of the 2005 numbers using the Treasury-commissioned estimate of a sterling/euro equilibrium exchange rate of 1.37 euros to the £ (Wren-Lewis, 2003) puts the UK as the eighth lowest out of the 10 EU countries. This makes sense. A combination of parallel trade and restrictions on UK price increases after launch means companies set UK launch prices with a view to expected euro/£ exchange rates over the lifetime of the product. We are also yet to assess the impact of UK HTA on UK relative prices. Recent work (Danzon and Furukawa, 2006) on biological drug prices concludes ‘that prices for biologics are relatively low in the United Kingdom...’

4. Modulation links markets. A company competing in more than one market could ‘cross subsidise’ price at the expense of companies competing in only one. However, existing competition law protects companies from predatory pricing by competitors, irrespective of PPRS rules.

Nature of competition for innovation

The OFT argues that in the UK, companies choose to bring ‘me too’ type products to the NHS market because they are low risk and get an excessive reward under the PPRS. This reflects a misunderstanding of the R&D process and implies that the PPRS somehow guarantees a return irrespective of the quality of the product – which it does not. R&D processes have changed. There is plenty of R&D-based competition with many new entrants into the R&D process (Cockburn, 2004). Evidence shows potential market size has a direct impact on drug and vaccine development (Acemoglu and Linn, 2003; Finkelstein, 2003; Lichtenberg and Walsfogel, 2003). Scientific advances in the understanding of disease mechanisms now lead to several companies competing to find ways of exploiting that knowledge. Competition in translational research is stimulated by advances in basic research. This can lead to several products getting to a new therapy market shortly after one another. This change is reflected in the reduced time between the first and the subsequent entrants (Towse and Leighton, 1999).

DiMasi and Paquette (2004) found that by the time the first-in-class product enters most ‘follow-on’ products are already in late stages of clinical development. They concluded that ‘The development histories of entrants to new drug classes suggest that development races better characterise new drug development than does a model of post hoc imitation. Thus, the usual distinctions drawn between breakthrough and ‘me-too’ drugs may not be very meaningful.’ A science-driven competitive process leads
to companies seeking breakthrough products but often ending up with *de facto* ‘me toos.’ These drugs do, however, provide value to payers and to patients through one or more of: competing in the provision of information; competing on price; or competing for different sub-groups of patients within the disease area (Wertheimer et al., 2001; OHE, 2005). Of course this requires a ‘demand side’ that sends the right signals and is able to exploit these effects.

**Attracting investment**

The OFT argues that the PPRS has not been effective in attracting R&D and manufacturing investment as ‘*the scheme does not contain any systematic incentives to locate investments within the UK.*’ (para 3.35), and any attempt to incorporate such goals would ‘be contrary to EC legislation’ (para 3.70). This is not a new finding – the EU Commission, other Member State governments and companies have all been through the wording of the Scheme to check this.

Is it legitimate to use a P&R regime to attract investment? Will it be successful? Claxton has argued it is not legitimate (Claxton, 2007). It is not obvious why this is the case. Government procurement often has an industrial policy objective. Industrial policy is often misguided – witness 50 plus years of intervention in the UK motor industry – but in pharmaceuticals it has assisted the UK in getting 10% of global R&D investment with only 3% of global sales. It could be argued that any industrial policy funding should be identified separately, and not come out of the health budget. There is a case for this in principle. But when the P&R climate influences investment this is difficult.

The OFT concludes that it will not be successful in practice. Only the science base and clinical research infrastructure matter. It does not recognise the ‘intangible’ value of the PPRS. The long-term ‘sunk’ nature of pharmaceutical investment means that there are opportunities for governments as buyers to behave opportunistically. The stability of the PPRS reinforces the reputation of the UK government as not prone to opportunistic ‘hold up’ of the pharmaceutical industry once it has sunk costs into R&D and the UK economy. Most R&D investment is ‘footloose.’ There are other places it could go. For rational reasons, companies will seek to avoid rewarding countries with regulatory regimes that have policy instability, or attempt free riding on R&D, provided it does not cost them (the companies) too much. When good science can be found in more than one country the business environment will become a factor in investment location (NERA, forthcoming).

**Relative prices**

The OFT sees the central problem with the PPRS as being no mechanism for ensuring that relative prices reflect value – ‘*neither the profit cap nor the price cut helps to secure prices that reflect the therapeutic value of the drugs...to the NHS.*’ This is true – assessing value is done elsewhere in the system – although not well according to the OFT.

The reality is that the PPRS has performed well as a procurement bargain between industry and the UK government. It does not incentivise efficient *relative* prices. That is not its job. Will the OFT’s proposals tackle this efficiently?

**WILL THE OFT’S PROPOSALS HELP?**

The OFT proposes that when the current five-year PPRS expires in 2010, government and industry work towards a new one replacing profit control with a version of something it calls ‘value-based pricing’ (VBP), which involves *ex ante* centralised government price setting based on a cost-per-QALY threshold plus periodic *ex post* reviews. More specifically the OFT proposes:

1. All new products are subject to a NICE/SMC/AWMSG *ex ante* review, i.e. before launch. The review identifies appropriate prices given evidence on expected costs and effects and an agreed cost-per-QALY threshold.
2. Prices are set by the Department of Health on the basis of this review. At a later stage the OFT envisage the HTA and pricing roles would be combined in a new independent UK-wide body.
3. When a therapy class has significant new evidence, a new entrant, or a patent expiry, a new review is conducted and prices adjusted accordingly.
4. Prices can go down or up as a consequence of the review.
5. At a patent expiry of product A:
   (a) The price of the originator brand of A is reduced automatically to 25% above the price of generic versions of A.
   (b) The prices of competing brands (B, C) go down to 50% above the generic price of A, unless they can show advantages over drug A.
6. The use of risk sharing and non linear pricing agreements to help set the right prices.
7. Continuation of the PPRS as a negotiated 5-year agreement in order to maintain stability, albeit with the existing profit cap/price control arrangements replaced by an agreed VBP framework (reflecting (1)–(6) above) including a cost-per-QALY threshold.
8. A fixed drug budget.

The OFT also considers a purely *ex post* version of VBP, in which companies are free to set prices subject to post-launch reviews at which point the government adjusts prices. It rejected this option because it anticipates poor take up of products by the NHS in the absence of a review at launch.

I have a number of concerns about the OFT’s recommendations.

**What is value-based pricing?**

Prices need to reflect appropriate resource costs. In normal markets companies set prices to maximise profits. The prices customers are prepared to pay reflect the value to them. The marginal group of customers pays prices more or less equal to the value they receive. Intramarginal customers gain consumer surplus. Companies remain in the market in the long run if all costs are covered. Investment takes place if *ex ante* revenues are expected to provide a return that takes account of the risk associated with the project. Competition reduces prices towards costs. How close prices get to costs depends on the degree of competition which in part depends on product differentiation. Products with unique attributes can command premium prices – limited by consumer willingness to pay for these attributes given where else they can spend their money. In this sense, it is hard to think of prices not reflecting value for very long. Customers will walk away.

In the case of pharmaceuticals, the NHS provides insurance cover to patients. There are principal–agency problems. Patient demand will tend to be inelastic. They are not paying. Prescribers have budgets and so should look for value to exceed or equal price. HTA is intended to provide a payer assessment of cost-effectiveness, i.e. of NHS willingness to pay. The real issue is how NHS medicine markets should adjust to bring price and value into line, i.e. through price or through volume or a combination. The OFT assumes adjustment should or can only take place through price. If prices do not reflect value at current volumes, it assumes prices rather than volumes are wrong.

**Demand side failures**

As the OFT recognises ‘*The PPRS works in conjunction with a wide range of mechanisms and institutions designed to encourage cost effective prescribing at local and national level.*’ The problem is that the OFT thinks these mechanisms do not work. Hence, it sets out an agenda that replaces them with central price setting. GPs can carry on handing out the pills but no one expects them to have any responsibility for getting value for money. The OFT’s main plank of evidence is a GP survey of 1000 GPs testing their awareness of the relative prices of medicines within six major therapeutic groups. It found that ‘GP’s
ability to rank branded drugs in order of price proved to be no better than chance.’ (Box 2.3 and Annexe C). This is quite consistent with previous studies on the subject (DH/ABPI, 2002; Ryan et al., 1992, 1996; Silcock et al., 1997) and while discouraging does not, contrary to OFT’s evident belief, prove a lack of price sensitivity on the demand side of the NHS medicines market. English GPs are influenced in their prescribing by NICE, practice formularies and Primary Care Trust (PCT) advisers, among other factors. As long as someone with influence in this process understands cost-effectiveness it is unnecessary for individual GPs to be price aware.

Of course the demand side is a long way from working as well as it needs to. The NAO (2007) Report on prescribing identified the characteristics of PCTs that had been successful in pursuing value for money prescribing. The OFT is right to point out that centralisation of HTA reduces duplication of effort and provides scale economies. But local awareness of value for money remains essential for three reasons:

- HTA recommendations are implemented locally. Prescribing volumes have to adjust up or down. UK take up of new medicines identified by NICE as cost-effective is slow. The OFT, unfortunately, has nothing to say on the take up of products that are recommended under its VBP system. Cooksey (2006) proposes the use of ‘Knowledge Transfer’ teams within the NHS to speed uptake of cost-effective technologies. Adelphi Consulting (2006) in its work on take up for the MISG identified what successful PCTs did.
- Central guidance cannot cover everything. Even if it did local choices still have to be made. There will not be enough money in the budget to do everything that is deemed cost-effective or necessary by the centre. Hence, the debate over the relevant cost-effectiveness threshold to use (Culyer et al., 2007) and renewed interest in Programme Budgeting techniques to help understand efficient choice at the (local) margin.
- Centralisation can lead to information loss (local experience of the product, local priorities and opportunity cost in terms of the projects given up to fund central decisions are unknown or ignored) with consequential errors.

The OFT implies that an inefficient demand side is wasting money. It states ‘we identified over £500m of expenditure in 2005 that could have been put to more cost effective uses. For one drug alone we estimate that the use of more value-reflective prices could potentially have saved £350million in that year’ (page 4). Yet the OFT knew at the time of writing (February 2007) that the savings from substituting use of generic simvastatin in the place of Lipitor were much lower. NHS statin prescribing had become more efficient through national (incentivised) targets following NICE guidance in January 2006, a subsequent BMJ editorial, and more aggressive PCT pursuit of generic substitution. The NHS was driving a search for savings that was not dependent on increased knowledge of the relative prices of all statins by individual GPs (Keyworth and Yarrow, 2007).

Government price setting

Government price setting introduces major additional uncertainty into the R&D process. The UK has slow product uptake. Now price is to be subject to potential opportunistic (but understandable) attempts by the government to keep NHS costs down. This is not a stable business environment. The OFT draws on a number of other countries where it thinks there are working models the UK can adapt. Its prime candidate is the LFN in Sweden. However, LFN states that ‘another important aspect of the Swedish reimbursement system is that we do not negotiate prices. We look upon the price as an integrated part of the cost-effectiveness analysis. If the price is too high there will be no cost-effectiveness’ (LFN, 2007).

LFN also argues it is not eager to force the price down as much as possible, for three reasons. First, they do not believe that it is really possible for a government agency to efficiently set prices. Second, they do not want to regulate the pharmaceutical market more than necessary. And third, a reimbursement system that uses cost-effectiveness from a societal perspective can play an important role when it comes to
stimulating innovations. It makes far more sense to let companies set prices in the knowledge that the NHS will use HTA effectively to decide whether or not to use products and in which groups of patients.

**Use of QALYs**

The OFT proposals mean that the cost-per-QALY calculation would become the sole criterion for price determination and drug rationing within the NHS. It is not clear that QALYs are ready to move from being a key influencer to sole determinantal. Concerns include:

- how to derive a cost-per-QALY threshold? If this is to reflect societal preferences these may vary between disease area and patient group. If it is to reflect the opportunity cost of the health gain from interventions efficiently displaced (i.e. those that are least efficient) in the NHS by funding a new treatment then there has to be a way of discovering this information. However, as the OFT suggests, some element of stability is required if the threshold is to provide long-term signals of society’s willingness to pay for innovation. There are trade-offs to be made which can in part be informed by research currently underway on societal preferences and the cost-effectiveness of existing NHS programmes. The resulting figure has to be ‘sold’ to the public as well as to industry and the NHS;
- the ability of the QALY to accurately reflect the impact on patient morbidity and willingness to ‘trade’ quality and length of life – particularly in disease areas such as cancer where life expectancy may be short. The QALY assumption of a constant willingness to trade length of life against quality of life does not seem to hold in these circumstances;
- the need to take a more societal perspective on costs and benefits, including the productivity benefits of getting people back to work. The OFT indicate NICE should move in this direction – and it is right to do so, but this is not straightforward. There are difficult methodological and measurement issues;
- the consistency of QALY estimates depending on the method of elicitation used. As Kind puts it ‘The research agenda remains substantial.’ (Kind, forthcoming).

**Efficient use of HTA**

HTA resources in the UK are scarce and the NHS has many needs. The Cooksey (2006) Report identified priorities, recommending (page 102) ‘expanding the HTA programme to:

- strengthen the commissioned workstreams for primary research, clinical trials and themed call programmes;
- diagnostic tests;
- follow up on research recommendations from NICE (see 35);
- medical devices…;
- improve Knowledge Transfer…;
- augment HTA clinical trials infrastructure.’

The OFT’s desire to significantly expand the use of HTA to cover all new drugs is hard to justify. Indeed any detailed consideration of proportionality is absent. HTA should be expanded and used where it can offer greatest value – that may well involve more effort with drugs but the OFT proposal to cover all drugs not just ‘at launch’ but with regular re-reviews is unlikely to make sense. I recommend below a contingent value of information approach to the use of HTA.

**Pre-launch emphasis**

The OFT opt for a pre-launch review. Yet even with improved Phase III development programmes or adoption of the Cooksey (2006) proposal for a ‘new drug development pathway’ with ‘conditional
licensing’ at the end of Phase II giving earlier access to the market, earlier review by NICE followed up by ‘the use of real-world data’ through use of NHS IT and patient registries, it is hard to see how definitive and quick decisions can be made at launch. Claxton (2007) and Griffin et al. (2007) argue that more has to be done pre-launch because manufacturers have little incentive to undertake additional work if their product has been authorised and because there are issues around conducting RCTs when products have already been recommended for use in the NHS. Within a formal value of information framework they argue that if there is no opportunity to collect information post-launch to resolve uncertainties around the mean cost-effectiveness estimate then manufacturers must either supply information pre-launch that reduces this uncertainty or accept a lower price that provides an acceptable expectation that the product will be cost-effective in use. However, it is not obvious that post-launch data collection is of limited value and most RCTs are conducted post-launch. The challenge is to find an acceptable level of data to enable a pre-launch view to be taken where needed and to enable requirements for post-launch assessment to be specified.

Static versus dynamic efficiency

The OFT propose that prices should reflect cost-effectiveness at the marginal patient group using the cost-per-QALY threshold. Where there are choices, i.e. different sub-groups have different cost-effectiveness ratios, then the DH and the company would negotiate whether to go for a lower price and serve all patient sub-groups or a higher price and restrict use to a subset of patients. This is of course what happens now – except that companies decide the price and HTA bodies recommend which patient sub-groups it should be used in. Claxton (2007) argues that this could lead to perfect price discrimination (for example, by a refusal to undertake sub-group analysis and the setting of price at the cost-per-QALY threshold) and the appropriation of all the value of the innovation by the manufacturer until patent expiry, at which point prices fall if there is a competitive generic market and all of the surplus comes to the NHS. The reality is that sub-group analysis can be done on an ad hoc basis by HTA bodies, and companies take a high risk if they refuse to undertake it. More importantly:

- it is highly unlikely that all of the consumer surplus will accrue to the innovator during patent life;
- there is no right answer as to where to draw the line. The more of the surplus that accrues to the innovator, the greater the incentives for future innovation and health gain. However, the greater the surplus that accrues to the NHS, the greater the immediate health gain. Evidence suggests that the societal gains from pharmaceuticals and other health technologies have been high (Philipson and Jena, 2005; Murphy and Topel, 2003).

Therapeutic reference pricing?

The post-launch reviews proposed by the OFT resemble a form of therapeutic reference pricing (TRP) in which price regulation refuses on principle to recognise any differential value of products within a therapy class. The impact of this on the innovation process I set out earlier cannot be overstated. Subsequent entrants cannot get a price premium even if their products are better for patients, and once the first product comes off-patent the prices of follow-on products are forced down by an automatic formula so reducing the effective patent life of the follow-on product. As Pammolli and Riccaboni (2004) put it:

some cost containment initiatives recently implemented or under study across the world could permanently and adversely affect competition in the industry. For example, convergence toward price control schemes such as reference pricing for on patent drugs within broad equivalency classes would reduce expected revenues from horizontal product differentiation and would reinforce first-mover advantages, which would in turn lead to higher concentration....All in all, international convergence toward price control and reference pricing for innovative drugs would have negative
effects on industry structure and innovation. A new industry landscape would take shape, but one that might look quite different from what policy makers originally had in mind.

The OFT would no doubt argue that its proposals to force down all brand prices in a therapeutic category to a small premium over the first off-patent generic is not TRP, because if there are differences they can be reflected in price premiums. The evidence from elsewhere in the world is that this is rarely done. The fundamental problem is the OFT’s insistence that all adjustment should be through price. If a product is no longer value for money across a broad spectrum of patients because a competitor product is now off-patent, then volume should adjust and use be restricted to any patient sub-groups where it is still cost-effective. The company may choose to reduce price to retain competitiveness in the broader population. That is a commercial judgement for it to make.

**Treatment of off-patent products**

As we have noted above, the UK has a competitive generics market and its continuation is essential if the NHS is to maximise the benefits of innovation. The OFT’s proposals to bring down originator and competitor brand prices reduce the incentives for generic companies. Indeed Sweden and Australia have moved away from linked systems because they impacted on their ability to get low price generics.

**Rewarding innovation per se**

The OFT argues that it would not be efficient to reward products with higher prices than justified on cost-per-QALY grounds alone just because they were innovative per se, i.e. pioneering in a disease area. It seems to argue this on grounds of practicality – how could an efficient mechanism be designed – rather than principle. This is important as there is a case for such an approach. In all markets there are externalities from use. Early adopters typically pay high prices and the experience gained enables better products to be developed or existing ones to be better used. These benefits accrue to subsequent users. Suppose there were no early adopters? If there are (on average) systematic later benefits from use of (say) a first-in-class product, then it makes sense to subsidise early use. Use is (in effect) buying an option on access to future technology. An analogous situation is where we know that evaluative research on one product will almost provide an externality in terms of building up a knowledge base from which it then becomes easier to assess the value of other products. Of course, there is a difference between knowing that in principle an effect could be there and finding evidence to support a credible policy rule.

**Fixed drug budget**

The OFT proposal for a fixed drug budget is nonsensical. Maximising overall NHS efficiency requires switching input mix as required to maximise health gain (Garrison and Towse, 2003). It claims that such an arrangement may be helpful to companies because innovations will only compete with other innovations for access to treatment. (In effect there will be a shadow cost-per-QALY for medicines that is different – higher or lower depending on where the threshold is set – from the rest of the NHS.) It seems more likely that it sees such a fixed budget as protection for the NHS from increased pharmaceutical spend. This suggests a lack of confidence in its proposed VBP system to deliver efficient relative prices and use of drugs.

**WHAT IS THE WAY FORWARD?**

**Strengthening the ‘demand side’**

The UK NHS needs to improve its arrangements for medicines procurement and use by continuing to tackle the ‘demand side’ failures that led to the development of the PPRS as a regulatory procurement...
tool. This involves not only more use of HTA but enabling PCTs and prescribers to get better value for money, both through local priority setting and through effective use of medicines deemed cost-effective.

A backstop PPRS

The PPRS should remain as a ‘backstop’ control but only until it is clear that the ‘demand side’ is robust enough to ensure value for money use of drugs. Those products subject to HTA reviews could be treated differently within the PPRS. The option of moving from a profit cap/price control scheme to an RPI-X type control as used in UK utility regulation could be explored (Vickers and Yarrow, 1988). It had previously been thought unsuitable for pharmaceuticals because it cannot address new products (Cave and Towse, 1997; Bloom and Van Reenen, 1998). Use of a separate HTA process could leave a residual RPI-X control on older and niche medicines.

A contingent appraisal process

A critical issue is the effective use of HTA given the resource constraints and the availability of information at launch and post-launch (Buxton, 2006). Towse and Buxton (2006) identified the need for more analyses of a wider range of technologies within the resource constraints on appraisals (financial and/or the availability of time and of skilled researchers). They set out several actions, in particular the:

- ‘development of a more contingent appraisal process where the level of analytical effort is more closely related to the nature of the decision problem;
- use of value of information (VoI) methods to determine the relevant level of complexity in particular cases;
- use of VoI to determine which technologies to appraise;
- use of ‘MS type’ risk sharing schemes involving additional data collection with payment contingent on actual patient outcomes. This can allow adoption of technologies despite high levels of remaining uncertainty.’

Elements of reform

Key elements of a reformed UK pharmaceutical environment for 2010 should therefore include:

- an expanded role for HTA but with companies retaining freedom to set prices at launch and HTA use targeted at major products with a mix of at-launch and post-launch reviews. The choice of products to review, and timing of reviews to be determined using a contingent approach;
- the retention of a backstop profit cap/price control PPRS scheme perhaps moving to an RPI-X type control;
- the use of risk sharing and non-linear pricing arrangements. These could be negotiated centrally or locally;
- measures to ensure more effective therapeutic switching at local level when new products enter, there is new information about cost-effectiveness, or a major product comes off-patent. The NHS is getting better, but there is still substantial health gain and cash savings to be made from a more rapid adjustment of prescribing volumes;
- measures to improve the take up of cost-effective treatments. This has to involve a combination of support for local priority setting and for more effective use of clinical guidelines for the management of patients.
The objective is to tackle relative prices, volumes (efficient levels of use) and the absolute level of prices, within a framework that provides rewards for innovation and a stable procurement environment for the industry – albeit one where there is a determined search for value for money.

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REFERENCES


