OFT, VBP: QED?

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SUMMARY

The report by the Office of Fair Trading (OFT) on the UK pharmaceutical price regulation scheme (PPRS) recommends the reform of the current scheme, which is a combination of profit and price controls, to one where price is based on the health benefits offered by a pharmaceutical. On closer examination some of the more commonly expressed concerns about these proposals do not seem to be well founded.

In principle, the OFT's recommendations may contribute to allocative and dynamic efficiency in the NHS. However, there are some dangers and the details of how it will be implemented are crucial. For example, value-based pricing with an inappropriate threshold for cost-effectiveness, or an inappropriate pricing structure, could lead to technologies being adopted at prices where their benefits, in terms of health outcome, do not offset the health displaced elsewhere in the NHS, a situation in which the NHS is damaged rather than improved by innovation. A failure to account for uncertainty and the value of evidence in negotiating prices and coverage could also undermine the evidence base for future NHS practice. Whatever view is taken, the OFT report will inevitably shape the scope of future policy debates about value, guidance, price and innovation. Copyright © 2007 John Wiley & Sons, Ltd.

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INTRODUCTION

The report by the Office of Fair Trading (OFT) on the UK pharmaceutical price regulation scheme (PPRS) recommends the reform of the current scheme, which is a combination of profit and price controls, to one based on value-based pricing (VBP) (OFT, 2007). The report provides a detailed examination of the PPRS and disposes of many of the myths associated with it. It provides a clear and coherent rationale for pricing based on the health benefits of pharmaceuticals. The OFT claims that the recommended reform would, ‘provide major benefits to NHS patients and to innovative companies in the short and longer run’ (OFT, 2007).

The principal expectations are that in the short run technologies will be adopted for use in the NHS only at prices that ensure that the expected health benefits exceed the health predicted to be displaced elsewhere in the NHS due to their additional cost; that is, such technologies will be cost-effective. In the longer run prices based on value to the NHS will provide a clear signal and incentives to invest in the development of technologies which are more likely to be able to demonstrate their cost-effectiveness. Achieving both these objectives of static and dynamic efficiency requires the NHS, through an assessment authority such as NICE, to provide a clear and predictable signal of value to the private sector, i.e. it specifies what regulators will regard as cost-effective at particular prices. It is then for the
private sector to choose to invest in those developments which it believes will be both sufficiently cost-effective for the NHS and provide a satisfactory return on investment, assuming that intellectual property rights continue to be protected through patent protection.

The responsibilities of the NHS, through assessment authorities like NICE, are to signal clearly and predictably what is of value, to assess cost-effectiveness and to provide a secure basis for price/coverage negotiation. It is for other parts of government and the public sector, through tax incentives, infrastructure investment, publicly funded research and patent law, to ensure that the private sector can respond to this ‘NHS demand curve’ and to encourage inward research and development investment, assuming that also to be an industrial policy objective.

**SOME COMMON OBJECTIONS**

A number of objections have already been raised during the consultation period, many of which are reflected in media coverage of the report (Economist, 2007; The Guardian, 2007; The Times, 2007; The Independent, 2007). It is worth briefly dealing with these first before considering some more substantive and critical issues of how a VBP scheme could be implemented.

**Inward research and development**

There may be a fear that VBP could be regarded as the ‘last straw’ for those companies which have located research and development activities in the UK so that its implementation will cause them to relocate. This perception seems to be based on a misunderstanding of the current PPRS as well as a belief that the domestic market incentivises inward investment and that the proposed reform will necessarily reduce the NHS spend on pharmaceuticals.

It is a common myth that the current PPRS scheme incentivises domestic pharmaceutical companies and inward investment. In fact, however, the scheme does not, and legally cannot, distinguish between research and development located in the UK and that located elsewhere. Firms locating their activities in the UK or elsewhere are treated in exactly the same way under the current scheme. Of course VBP would not provide any direct incentives for domestic research and development either. Again, it would be illegal to do so, as it would require premium prices for those products associated with companies which invest in the UK. It also seems inappropriate to use NHS resources as a tool of industrial policy rather than for the improvement of health, particularly when other more effective, targeted (and legal!) policy levers are available to government.

Another argument has been that domestic research and development requires a buoyant (subsidised) local market for the industry’s products. This seems ill founded in both theory and practice. The pharmaceutical industry is global, so technologies developed in one location are marketed worldwide. Choice of location will be directly influenced by the tax treatment of R&D, infrastructure investment and the degree of public investment in research, but it is difficult to conceive of any situation in which the size of a subsidy in a local market will directly influence decision about location. If such ‘incentives’ currently exist they seem remarkably ineffective and hardly explain why we observe such substantial activity located in Switzerland and Ireland.

Lobbyists have nonetheless sought to link dissatisfaction with NICE decisions with the migration of domestic investment and this has been well documented. The Guardian reported the lobbying of Ministers by 10 pharmaceutical companies about a range of NICE decisions during 2006, which also included warnings about investment in the UK. For example Pfizer, when lobbying Ministers about the restrictive NICE guidance on drugs for Alzheimer’s disease, ‘noted that there is some complacency in Whitehall regarding their continued investment in the UK’ (The Guardian, 2006a).

The concern expressed seems more readily explicable as a simple and crude threat: provide easy access to a subsidised domestic market or research and development will be relocated. Whether or not such
threats are credible and whether public policy should respond, even if they are, is for others to judge. However, it is important to understand that such threats are at odds with the real incentives at work.

**NHS spend on pharmaceuticals**

Some commentators appear to believe that VBP will necessarily lead to a lower spend on drugs in the NHS. Although the UK market is small (3% of the world pharmaceuticals market) it has influence on many other European markets which reference UK prices (25% of the world market) (OFT, 2007). VBP in the UK could, it therefore seems, significantly reduce revenues and reduce the resources available for research and development wherever it is located. This analysis seems to be both a misreading of the report and a misunderstanding of the principles of VBP. VBP would lead to higher prices for some products and involve a reallocation of revenue from products which are less valuable to those products which are more valuable. Of course this would mean a reduction in price for some drugs, e.g. premium priced branded drugs when, in the absence of evidence of additional benefit, an equivalent generic is available. The OFT report identifies £500 m of immediate NHS savings that could be made in this way. However, these savings do not necessarily imply a reduction in the NHS drugs spend as a whole. It is perfectly possible that the overall NHS spend on drugs will increase, particularly if the productivity of new and innovative pharmaceuticals grows faster than that of other NHS activities. Incumbent firms that are unable to innovate and produce valuable products will lose, but others, including future new entrants, who are able to respond to these new incentives will benefit, as will the NHS.

**The value of innovation**

There has also been a concern that VBP will not recognise the potential value of an innovative technology, i.e. a new technology likely to lead to the development of other more valuable future technologies. This was a view clearly expressed by Alex Azar, the US Deputy Health Secretary, when lobbying Ministers on behalf of the US pharmaceutical industry, who said ‘attempts to use rationing mechanisms such as NICE to cut soaring drugs bills would stifle innovation... In all of our systems it is so easy to make the decision to cut costs today by going after drug prices, and to not focus on what will be the impact on long term innovation.’ (The Guardian, 2006b).

In other markets the private sector anticipates the benefits of innovation and the future market returns which flow from better products and the higher prices they can command. As long as society protects the intellectual property rights associated with innovation (as it does through patent protection) then the private sector will continue to invest if it anticipates that the product will be purchased at prices that provide a return on the investment. If not, the investment will not be made because the innovation is not worthwhile neither to the private sector nor to society. No one, least of all Mr Azar, would suggest that consumers should be compelled to buy products at prices higher than their valuation of the benefits merely to incentivise further innovation! The same must be true in health care. Why should the NHS pay more than the value of the benefits from a new technology in the hope that a future technology which is more valuable will be developed? To do so would be to pay twice for the innovation and to incentivise innovations which are not worthwhile (the research and development resources could have been used to provide greater health or other benefits elsewhere).

**Decentralised assessment of value?**

What is different in health care is that individual consumers (patients) or their agents (doctors) are not best placed to identify and synthesise all relevant evidence and undertake the computation required fully to assess value. In a collectively funded health-care system, even if such assessments were possible, it is very unlikely that they would lead to decisions that were consistent with collectively agreed objectives and that met the resource constraints, because neither doctors nor patients face the same constraints.
and perfect incentive compatible contracts cannot be specified. A more efficient approach, and the one taken by the UK Department of Health, is to give an independent assessment authority such as NICE the responsibility for assessing value and effectively signalling the market demand curve for pharmaceutical technologies on behalf of the NHS. As well as being an efficient solution to information asymmetry and imperfect agency, this arrangement leaves patients free to communicate their history, circumstances and preferences to their doctor and doctors free to establish relationships with their patients through which they can take account of individual characteristics in selecting interventions from the range of cost-effective procedures that are available for use in the NHS.

In summary, many commonly expressed concerns do not seem to be well founded. However, other concerns need to be considered alongside the more detailed issues of how a VBP scheme could be implemented.

**CRITICAL ISSUES FOR IMPLEMENTATION**

The type of VBP recommended in the OFT report offers great opportunities which are consistent with the intentions of the Cooksey (2006) report and likely to improve health outcomes with a given NHS budget in both the short and longer run. To achieve this, *ex ante* assessment of value at launch followed by periodic *ex post* assessment is envisaged for new technologies. In addition, *ex post* assessments of existing on patent drugs will be undertaken (OFT, 2007). However, there are also some real dangers which turn critically on the detail. For example, VBP with an *inappropriate threshold* for cost-effectiveness, an *inappropriate pricing structure*, or that fails to account for the value of evidence could lead to technologies being adopted at prices where their benefits, in terms of health outcome, do not offset the health displaced elsewhere in the NHS. In such cases, not only would the NHS not benefit from innovation but could actually be damaged by it. It is also possible that decisions could disincentivise evaluative research and undermine the evidence base for future NHS practice. Each of these issues is explored in the following sections.

**What is the appropriate threshold for VBP?**

If the purpose of a health-care system is to improve the health of the population it serves, subject to a budget that is fixed by some socially legitimate process, then an assessment of value requires an estimate of the cost-effectiveness of the technology, often summarised as an incremental cost-effectiveness ratio (ICER). However, this must be compared to some threshold for cost-effectiveness. Since the budget for the NHS is fixed by a political process, the threshold should represent the health forgone due to other NHS activities which will be displaced by the additional costs of the technology, i.e. it can be thought of as the ICER of the activities displaced or the shadow price of the budget constraint (Culyer *et al*., 2007). If the budget is set by a socially legitimate process then the threshold also represents the implicit social valuation of health. In principle, with full information about the cost and effect of all possible NHS activities, it would be possible to solve this allocation problem and establish the shadow price of the budget constraint (Stinnett and Paltiel, 1996; Epstein *et al*., 2007). However, the informational requirements indicate that neither NICE nor any other decision-making entity, including a practising physician, can know precisely which NHS activities will be displaced by their guidance or prescribing decisions nor exactly who will forgo which specific health benefits.

Therefore, the threshold of £20,000–£30,000 per QALY used by NICE, represents an informed estimate of the health forgone, based on the evidence that is available about the productivity of other NHS activities (Culyer *et al*., 2007). Of course more precise estimates are possible and empirical work is being undertaken (NICE, 2007; Martin *et al*., 2007). The indications are that £30,000 per QALY is too high and that even £20,000 may be too high. The point is that the appropriate threshold for VBP is not
some negotiated or societal value of a QALY but an empirical question based on the productivity of existing NHS activities and the budget set by parliament.

**Implications for VBP.** Choosing a price so that the ICER within a particular indication and patient group is just equal to such a threshold would mean that the health benefits of the technology for these patients would just offset the health displaced elsewhere in the NHS, i.e. a VBP for a technology with a single indication and a single population will provide no net health benefit to the NHS. All the benefits of the technological innovation would be captured by private rent.

However, if the threshold is based on some political negotiation with the pharmaceutical sector (as suggested in footnote 58 in the OFT report) or on some alternative societal value of a QALY, based on individual preferences (and this is higher than the shadow price of the budget constraint), then pricing up to such a threshold will mean that the health benefits of the technology will be more than offset by the health outcomes forgone due to displaced NHS activity. Technological innovation will reduce overall health for the NHS population if prices are set in such a way.

Therefore, clarity on what the cost-effectiveness threshold ought to represent is crucial. Once it is agreed that the threshold should represent the value of displaced NHS activities it is then possible to search for more secure empirical estimates. It also means that a key determinant of value is removed from the heat of political negotiation and becomes a transparent and explicit question subject to scientific analysis.

**Price structure**

With a single indication and a single population group (Q*), if price is set at P* so that the ICER is just equal to the threshold, then there will be no net benefit of the technology to the NHS. In essence, the NHS demand curve for this technology is perfectly price elastic and all rent goes to the producer (see Figure 1(a)). In these circumstances the NHS may only benefit in the longer run following patent expiry, if there is competitive generic entry and, if newly patented technologies at that time are priced relative to the cheaper generic versions of the old branded technology. At this point the surplus from the generic versions of the old technology is appropriated by the NHS, while all the incremental benefits of the new patented drug will still go to its manufacturer.

However, even within a single indication the cost-effectiveness of a technology will differ by subgroup (where there are differences in relative effect, base line risks or other characteristics related to expected cost and outcomes). For example, imagine three subgroups (S1, S2, S3) within the original population in Figure 1(a), where the technology is most cost-effective for S1 and least cost-effective for S3. This is illustrated in Figure 1(b). Now there are a number of choices. The private sector can choose P1 but will only get coverage or approval for use in S1 and will sell Q1, or they can choose P2, get wider approval

![Figure 1](https://example.com/figure1.png)

**Figure 1.** (a) VBP at average cost-effectiveness and (b) VBP at cost-effectiveness of the marginal subgroup
for both S1 and S2, and sell $Q_2$, or choose a low price ($P_3$) and get unrestricted coverage for this indication (S1, S2 and S3) and sell $Q_3$ (equal to $Q^*$ in Figure 1(a)).

The analysis of cost-effectiveness by subgroup provides the demand curve for the NHS and the price structure that can be used in VBP negotiations.

**Pricing at the margin.** It is now apparent that the only way the NHS can get net health benefit from technological innovation in the short and medium term is by pricing at the margin, i.e. at the least cost-effective subgroup within the claimed coverage. For example, if the manufacturer chose price $P_2$ they would be given restricted coverage for this indication (use in S1, S2 would be approved but not in S3). However, the benefits of the technology for S2 just outweigh the health displaced elsewhere (there is no net health benefit from using the technology in this group). But for groups S1 there is positive net benefit (ICER < threshold) and the NHS would get some of the surplus (area A) from technological innovation. The manufacturer receives revenue $P_2 \cdot Q_2$ and appropriates surplus depending on their average costs (since they chose $P_2$ this is likely to be greater than their average costs). Alternatively, if the manufacturer chose $P_3$, $Q_3$ they would be given unrestricted approval (groups S1, S2 and S3), the net benefit to the NHS will be larger (area A, B and C) and the manufacturer’s revenue ($P_3 \cdot Q_3$) increases in this case.

**Dynamic efficiency.** It is important that manufacturers should be allowed to appropriate some share of the surplus (monopoly rent) to incentivise investment in research and development, as they would with the type of marginal pricing described above. However, concern for dynamic efficiency does not mean that they ought to take it all (as in Figure 1(a)). Firstly, the public sector subsidises research and development in a number of ways, through publicly funded research, tax incentives and infrastructure investment. Therefore, even if society was unconcerned about who benefits from innovation (NHS patients or the pharmaceutical industry) it would not be efficient to allow full appropriation. In other markets, where innovation is protected, society simply offers monopoly rent during patent protection but does not allow full appropriation by, for example, facilitating perfect price discrimination (see below). Finally, it is appropriate for the society to be concerned about who receives the benefits and it is reasonable that at least some of the benefits of innovation should accrue to NHS patients.

**Incentives for subgroup analysis.** The OFT report suggests that VBP will provide incentives for the manufacturers to conduct subgroup analysis. In some circumstances this may be true, but in general with a single branded on patent drug there is a strong incentive to only report the average cost-effectiveness across all the subgroups within the indication, avoiding pricing at the marginal subgroup ($P_2$) thereby achieving price $p^*$ but with full coverage of the indication $Q^* = Q_3$. Now the entire surplus is captured by the manufacturer, i.e. pricing at average cost-effectiveness will ensure that the NHS never benefits from technological innovation, at least before patent protection expires.

But the NHS will tend to get more net health benefit by considering finer definitions of subgroups. For example, if six rather than three subgroups can be identified in Figure 1(b) then the NHS may get a better deal from VBP at the margin. This suggests that the definition and analysis of subgroups cannot be left in the hands of the manufacturer, as currently within single technology assessments (STAs) for NICE. The assessment and price negotiating body must have either the power to demand that cost-effectiveness analysis by subgroups be conducted by the manufacturer or have the resources and the access to commercial in confidence (CIC) data to conduct the analysis itself.

**Price, guidance and price volume.** There are three ways to use the NHS demand curve depicted in Figure 1(b). Firstly, a price volume or rebate contract could be specified based on Figure 1(b). However, this may be inefficient as it would be difficult to know whether it was the high- or low-value subgroups who received the drug. In reality, it will be these groups that are easiest to market for uptake. It would also
facilitate perfect price discrimination. For example, in Figure 1(b) the manufacturer would be able to charge $P_1$ for $Q_1$, $P_2$ for $Q_2 - Q_1$ and $P_3$ for $Q_3 - Q_2$, appropriating the entire surplus, an outcome equivalent to pricing based on average cost-effectiveness illustrated in Figure 1(a)).

Second, it may be better to link the price to explicit and mandatory guidance on which subgroups are covered. This requires the same information as price volume contract and is what NICE generally does in issuing guidance. If the guidance could be perfectly implemented then marketing would be disincentivised and no further regulation would be needed.

A third option is most appealing. The combination of price linked to guidance or coverage but with an additional marginal price volume or rebate agreement based on the same analysis would be a ‘belt and braces’ approach, ensuring that the most valuable subgroups are treated but disincentivising marketing even if guidance is ‘leaky’ at the edges. For example, if the manufacturer chose $P_2$ in Figure 1(b) then this price would be charged up to $Q_2$, but any prescribing outside of guidance (beyond $Q_2$) would either be reimbursed at less than $P_3$ (up to $Q_3$) or not reimbursed at all.

These distinctions are not quite clear in the OFT report and although a link between price and guidance is made in the recommendations, the analysis in Chapter 5 of the report does not clearly link the cost-effectiveness of subgroups to price and guidance and to price volume agreements. However, VBP provides an opportunity to disincentivise marketing of pharmaceuticals, thereby reducing costs to the industry estimated to be 18% of costs (OFT, 2007) and to the NHS.

**Price negotiation.** There are a number of different ways the price negotiation could take place based on the type of NHS demand curve represented in Figure 1(b). The manufacturer could be offered a free choice from the menu of prices and the associated coverage. Assuming that there is only one patented product for this indication, this approach amounts to offering a monopoly position to the manufacturer, where they choose to locate on the market (NHS) demand curve. In general, they will tend to choose a higher price with narrower coverage than society would want. For example, imagine a manufacturer chose to locate at $P_2, Q_2$ but the NHS would prefer lower price with greater coverage $P_3, Q_3$. One option is not to allow a free choice but simply offer a ‘take it or leave it’ deal of full coverage at $P_3$ or nothing at all. For this to be credible, the regulatory authority must be willing to say no even though the $P_2, Q_2$ deal would be better. However, this is unlikely to be credible for a public body given the political consequences of no deal outcome. It could also undermine the appropriate monopoly returns which incentivise further innovation and lead to suspicions about the commitment of the regulator to allow manufacturers to retain surplus, undermining dynamic efficiency.

Analogously, even if the manufacturer was willing to freely choose $P_3, Q_3$ they will know that up to $P^* \text{ coverage } Q^* = Q_3$ is still worthwhile for the NHS. They could then offer an ‘all or nothing’ deal to the NHS of a price just below $P^*$ with $Q_3$ or nothing. To avoid this, the marginal pricing rules would need to be explicit and it must also be credible that the regulator has the political independence to say no to the ‘all or nothing deal’ and bear the heat of such a decision. This is not to suggest that the regulator should game with manufacturers (given the political context they are likely to lose and if they won it may undermine dynamic efficiency). Rather the rules must be explicit and clear (price at the marginal subgroup) so that the manufacturer cannot game the regulator and reassure manufacturers of the regulator’s commitment not to undermine anticipated monopoly returns. This suggests that a pricing authority that is politically independent is essential in the longer run.

**Price elasticity.** Of course where the manufacturer will choose to locate on the NHS demand curve will depend on their costs and the price elasticity of demand. Since almost all pharmaceutical costs are sunk, manufacturers may simply try to maximise revenue. If the NHS demand curve is price elastic (as illustrated in Figure 1(b)) there will be an incentive to choose lower prices and greater coverage to increase their revenue. If the assessment authority is in control of how subgroups are defined then it may be possible to construct price elastic demand curves.
Multiple indications. Figure 1(b) is easily extended to represent an NHS demand curve for a pharmaceutical which has multiple indications, each of which may have multiple subgroups. In principle, price discrimination by indication will not be possible. Therefore, a manufacturer that already has a VBP for a more valuable indication may choose not to negotiate a lower price at *ex ante* assessment and forego coverage for the new indication if at a lower price overall revenue is reduced. Alternatively, if the extant indication already has a low VBP (it is less valuable) then this might already be less than the marginal VBP for the new indication and full coverage would be granted. The OFT report proposes that renegotiation of VBP and coverage across all the indications will take place at the subsequent *ex post* assessments. It should be noted that in practice there will be incentives to attempt to discriminate between indications by making marginal changes to products (dosage, administration, etc.) even if they are of little therapeutic value.

Multiple comparators. So far the discussion has considered an indication where only one technology is available. However, in most instances there will be a number of patented competitors as well as other drugs and interventions which are available. Now the question of cost-effectiveness and VBP requires a comparison of the cost and effect of each, not to some common generic comparator, current NHS practice or to no treatment, but to each other.

The approach to establishing cost-effectiveness for multiple alternatives and the appropriate ICERs to use is well established (Johannesson and Weinstein, 1993; Stinnett and Mullahy, 1998). The question to ask is: Does the value of the health gained by moving from a less costly (but less effective) to the more costly but more effective alternative exceed the additional cost? It should be clear that the VBP of technology A now depends on the price of technology B. For the *ex ante* assessment of A this may be fine, the other competitor B will already have a VBP which can be taken as fixed. However, at the subsequent *ex post* assessment the negotiation will not be bilateral (regulator and the manufacturer of drug A) but multilateral (A and B together). The menu of prices now involves the combinations of prices for A and B and the associated coverage, e.g. if A chooses a low price then B must also choose a low price to be cost-effective relative to A. The monopoly problem described above (manufacturers locating at higher prices and lower coverage than society would want) may be overcome as the manufacturers of A and B engage in price competition to get the right price and coverage deal. However, such price competition during patent protection could undermine the incentives for dynamic efficiency as their share of the surplus is reduced.

‘Me too’ incentives and winner takes all. It is not quite clear that the issue of multiple comparators and the potential complexity of multilateral price and coverage negotiation has been anticipated in the OFT report or how multilateral price negotiation will take place. One approach might be described as ‘winner take all’ where the manufacturer who negotiates the best VBP will get coverage but the others will be excluded. This will not necessarily be the lowest price if the product has additional benefits or lower non-acquisition costs than the competitors. This type of approach would certainly sharpen incentives for price competition but would undermine the incentives for dynamic efficiency provided by patent protection. Indeed this is not what seems to be envisaged by OFT, possibly because it may also be beneficial to have access to a range of interventions when individual patients may respond to some drugs rather than others, but also the substantial shift of risk to the manufacturers would make the proposals even less likely to command their support.

The alternative to ‘winner take all’ would be to negotiate a set of VBP which would make each of the comparators equally cost-effective within a particular subgroup. This does not necessary mean that all would be cost-effective for all subgroups, e.g. A and B might be recommended for use in subgroups S1 and S2 but only B would be recommended for use in S3 as well. This is closer to what appears to be proposed, where the VBP of the first entrant is not renegotiated on subsequent entry but the new entrants must establish a VBP relative to the incumbent. The renegotiation of all prices could take place
at \textit{ex post} assessment (which is suggested after 5 years) or at patent expiry. Under any scheme there will be dangers of outright or tacit collusion, but as long as the NHS is able to insist on marginal prices, control the analysis of subgroups and present price elastic demand to manufacturers there will be incentives for both to choose greater coverage with lower prices.

It seems clear that those products which are second to market or those that might be described as ‘me too’ are at no disadvantage despite concerns that have been expressed (Economist, 2007). The second to market will be able to offer the same VBP as the incumbent (if they are equivalent) and get the same coverage or undercut the price and get wider coverage. If it offers greater benefits then a higher VBP and/or wider coverage will be possible. In fact, the second movers have the advantage between the \textit{ex ante} and \textit{ex post} assessments because they have more information. However, those second to market do have a shorter period to generate revenue before generic entry. If they are relying on being able to continue to sell at premium prices once an equivalent generic becomes available then VBP or a NICE appraisal or any other policy to encourage rational prescribing will undermine these expectations. If this is the concern, it seems a very precarious approach to business planning, resting, as it does, on continued inappropriate prescribing in the NHS. If the introduction of VBP prompts more realistic expectations and more secure business plans based on known patent life and innovation valuable to the NHS, then industry will benefit along with the NHS. Of course it is possible that current patent protection is inadequate. If so, the case needs to be made for reform of patent law rather than relying on inappropriate prescribing to support the revenue stream.

\section*{Price and the value of evidence}

The recommended \textit{ex ante} assessment at licence, like the STA process at NICE, means decisions will be made when the evidence base to support the use of a technology in the NHS is least mature, with substantial uncertainty surrounding cost-effectiveness. It should be recognised that a decision to approve a technology will inevitably have an impact on the prospects of acquiring evidence to support its use in the future. This is because the incentives on manufacturers to conduct evaluative research (for the claimed indication), once coverage has been granted, are removed, the clinical community is unlikely to regard further experimental research to be ethical and, even if ethical approval was granted, any randomised controlled trial is unlikely to recruit NHS patients once positive guidance provides mandatory access to the technology.

Therefore, the decision to approve a technology at a particular price ought to take account of both the value of the technology (the expected net health benefits) and the value of the evidence that may be forgone for future NHS patients (Griffin \textit{et al}., 2007). Evidence is valuable because it allows better decisions to be made which improve net health benefits for future patients. Methods are available which can establish the net health or monetary value evidence in a way that is consistent with the valuation of the technology itself. These methods have firm foundation in statistical decision theory (Pratt \textit{et al}., 1995) and are increasingly established in health technology assessment (they are also recommended although not required in the NICE methods guidance) (Ades \textit{et al}., 2004; Claxton and Sculpher, 2006).

This general issue of balancing the value of evidence about the performance of a technology and the value of access to a technology can be seen as central to the critical path for the early adoption of innovative technologies envisaged in the Cooksey report but it is also a critical issue for VBP.

\section*{Risk sharing and coverage with evidence}

In some circumstances the additional evidence needed may be provided by the manufacturer or by publicly funded research, while at the same time granting approval for an apparently cost-effective technology. In principle, this would be an efficient solution to the problem; where patients get early access but the evidence is also generated so that the decisions can be reconsidered at an \textit{ex post} assessment. This question of ‘coverage with evidence’ or some form of ‘risk sharing’ seems to be envisaged within Cooksey. The OFT report considers risk sharing to be the
exception rather than the rule at *ex ante* assessment. However, by setting a VBP at launch so that the ICER is close to the threshold will mean that the decision to approve (at least in the marginal subgroup) will be most uncertain. This, combined with an immature evidence base, suggests that additional evidence will be needed more often than not.

If risk sharing or coverage with evidence decisions are to become a policy tool formal methods will be needed to establish when they are viable and what evidence should be acquired, i.e. is additional evidence needed, if so, what type of evidence is required and will the type of evidence, which is possible to gather with concurrent coverage, be valuable and meet these needs? For example, if the key uncertainty is evidence about relative effect then the type of observational registry data that is often envisaged will be unable to provide more precise estimates as a comparable control group will not be available. Early access will have been allowed but the promise of the type of evidence needed will not be fulfilled. In these circumstances *ex ante* assessment would mean that the evidence base for future NHS practice will be undermined.

*Pricing, evidence and uncertainty*. If the type of evidence needed cannot be provided once coverage is granted then the decision to grant approval and agree a VBP ought to take account of both the value of the technology (the expected net benefits) and the value of the evidence that may be forgone (also measured in terms of net benefit). Figure 2(a) illustrates a situation where a technology would be regarded as cost-effective, a threshold of £30,000 per QALY, when only considering the net health benefits of the technology itself (here expressed in monetary terms). However, the value of the evidence (also expressed in monetary terms) that would be forgone for future patients (the opportunity cost of approval) exceeds the net benefits of approval. The NHS would better off by withholding approval, acquiring the evidence needed before reconsidering approval once the evidence is available (Griffin

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Figure 2. (a) Price and the value of evidence; (b) more evidence is provided; and (c) price is reduced
et al., 2007), i.e. by NICE issuing an ‘only in research recommendation’, despite the technology being priced below the threshold (ICER = £25 000).

Integrating consideration of uncertainty and the value of evidence in this way provides appropriate incentives for manufacturers to either provide the evidence needed to support use in the NHS or price in such a way that the cost-effectiveness of the technology is not uncertain. Figure 2(b) illustrates the same technology at the same price but now with more evidence to support its use. The value of additional evidence is reduced and now, at a threshold of £30 000 per QALY, the net benefits of early approval are greater than the value of evidence which will be forgone. Approval should be granted at the manufacturers offered price.

Figure 2(c) illustrates the same technology as 2(a), with the same evidence to support its use but with a lower price (the ICER has fallen from 25 000 per QALY to 10 000 per QALY). By reducing price the uncertainty surrounding cost-effectiveness is reduced and the value of additional evidence is also somewhat lower. However, the benefits of early approval have substantially increased (the net benefits to the NHS at a lower price are much higher). Now, at a threshold of £30 000 per QALY, the net benefits of approval exceed the value of additional evidence which may be forgone. The technology should be approved at the lower price.

Implications for VBP. This has clear implications for VBP. Price is not only a function of expected cost-effectiveness (as described in Sections 3.1 and 3.2), but also of the uncertainty and the value and type of evidence that are needed to support NHS practice. This link between price and the value of evidence provides appropriate incentives for manufacturers to invest in the type of evidence needed by the NHS early in the development of their products. Other things equal, those that do and come to ex ante assessment with less uncertainty surrounding cost-effectiveness will be rewarded with higher prices than those that do not. This may also provide incentives for manufacturers to continue to invest in evaluative research once a product has approval. Those who do, will be able to claim a higher VBP at ex post assessment if the evidence suggests that the technology is more cost-effective than it appeared ex ante or if there is less uncertainty surrounding the initial estimates. The OFT report does not deal explicitly with these issues. If VBP based only on expected cost-effectiveness is introduced there will be a real danger that the evidence base for future NHS practice will be undermined. In addition, an opportunity to incentivise early evaluative research during the critical path of drug development as outlined in the Cooksey (2006) report will be lost. The recommendations made within this report, for the reform of UK health research funding, have been accepted by the UK Treasury and were supported by Ministerial Industry Strategy Group, which includes the Minister of Health for Quality and representatives from UK Department of Health and The Association of the British Pharmaceutical Industry.

Assessment vehicle and institutional arrangements

A robust assessment of cost-effectiveness is critical and there are a number of detailed issues of methods, processes and institutional arrangements which would need to be resolved. The more significant issues deserve mentioning.

STA as an assessment vehicle. The report rightly points out that much of the assessment needed to implement VBP is already being conducted by NICE. Indeed, VBP seems the natural extension of these processes and methods. The OFT suggests that STA might provide a suitable basis for VBP negotiation at ex ante assessment. However, the current STA would need to be strengthened in a number of respects if it were to form a suitable vehicle for VBP negotiation.

STA places assessment in the hands of the manufacturer. The committee, in the light of an independent review of the manufacturer’s submission must decide, on balance, whether the technology is cost-effective. It does not need to demonstrate what it believes the ICER to be, only that it is likely to
be under or over the threshold. However, VBP will require much more. The assessment authority will need to establish its preferred analysis which generates the ICER for VBP negotiation. This will have to be defensible and will tend to shift the burden of proof from the manufacturer to the assessment authority. Comparability between analysis from different manufacturers at different times for the same indication or disease area will be required. For example, the type of assumptions and modelling used in one submission must be consistent with another. This will require more control over submissions than the current STA process.

Some comparators will also be branded on patent drugs where other manufacturers hold relevant CIC data. In these common circumstances the manufacturer preparing the submission simply cannot access all relevant evidence. This already poses a problem for STA at NICE. The solution is to have an independent assessment of all the technologies together. However, this would require a process much more like the multiple technology assessment (MTA) at NICE or the ex post assessment described in the OFT report. The periodic ex post assessment of all the technologies relevant to an indication is critical. However, this will include all the indications relevant to the set of products all of which are comparators in some or all of the indications. This will substantially expand the scope of assessment compared to either STA or MTA which has focused on a single indication.

Again, the definition and exploration of cost-effectiveness by subgroups is critical (see Section 3.2). Currently, within STA this is in the hands of the manufacturer. The assessment process must be able to specify which cost-effectiveness analysis by subgroup should be conducted by the manufacturer or provide the resources and the access to (CIC) data to conduct the analysis itself.

Explicit and robust analysis of cost-effectiveness, uncertainty and its consequences has opportunity costs, but it also has the benefits of leading to better decisions for the NHS and reducing the chance of particularly bad ones. Those who wish to see more explicit and robust methods adopted, believe that the costs are relatively small compared to these expected benefits. However, in the current climate it is incumbent to demonstrate what appears to be self-evident.

Institutional arrangements. The appropriate institutional arrangements seem to follow naturally from the principles, methods and process required to properly implement VBP. These principles suggest arrangements that have certain key characteristics. Firstly, the threshold for VBP is an empirical question based on the productivity of existing NHS activities and the budget set by parliament. Therefore, establishing an appropriate threshold should be the responsibility of an independent assessment authority based on explicit and transparent analysis. Secondly, since price and guidance are intrinsically linked and based on the same analysis of cost-effectiveness, either a single authority should assess cost-effectiveness, negotiate VBP and issue guidance to the NHS, or these functions should be very closely linked. Finally, it is critical that pricing at the marginal subgroup is maintained and that attempts by manufacturers to game the regulator by offering all or nothing deals at average prices will be rejected. This suggests that a pricing authority that is politically independent is essential in the longer run.

CONCLUSIONS

Many of the more commonly expressed concerns about the OFT recommendations do not seem to be well founded and appear to be based on either a misunderstanding of the current PPRS, a view that the domestic market incentivises inward investment, or an assumption that VBP will necessarily reduce the NHS spend on pharmaceuticals. The possibility of establishing a fixed budget for drugs and then allocating resources within it, rather than specifying a cost-effectiveness threshold for VBP negotiations is discussed in the OFT report. This would not be feasible or efficient for a variety of more and less obvious reasons. However, each technology with a negotiated VBP and associated guidance across its
indications implies an expected revenue over a budgetary period. It also implies a total on patent drug spend when considered across all technologies with a VBP. An agreement to monitor this total NHS spend and the revenue expected for a particular technology might provide reassurance to industry that the introduction of VBP will not simply mean a cut in revenue but a reallocation. Such monitoring could be linked to a rebate agreement, where lower than expected total spend would lead to a transfer from the NHS to industry (possibly allocated by share of value, i.e. expected revenue). Equally higher than expected spend would lead to a transfer from industry to the NHS. This would reassure the Treasury and Department of Health that the introduction of VBP will not lead to uncontrolled rises in spending, and industry that there will not be dramatic cuts. It would offer industry some reduction in risk and also some protection from parallel trade where a valuable technology is able to negotiate a VBP in the UK that is higher than prices in other European countries.

Concerns expressed about the value of innovation and disincentives for those second to market are not really related to VBP at all but to an implicit claim that the current protection of intellectual property is inadequate. If so, the case needs to be made for reform rather than relying on inappropriate NHS prescribing to support revenue. In the absence of any real disincentives from VBP and some evidence about the nature of lobbying that has taken place, the expressed concerns may reflect a simple threat to relocate research and development. If such threats are being made then others must judge whether they are credible and whether public policy should respond to them even if they are.

The OFT report provides a clear and coherent rationale for a move to VBP. The opportunities it offers are consistent with the intentions of the Cooksey (2006) report and the tasks undertaken by NICE on behalf of the NHS. However, there are some dangers and the details of how it will be implemented are crucial. For example, VBP with an inappropriate threshold for cost-effectiveness, or an inappropriate pricing structure, could lead to technologies being adopted at prices where their benefits, in terms of health outcome, do not offset the health displaced elsewhere in the NHS, a situation in which the NHS is damaged rather than improved by innovation. A failure to account for uncertainty and the value of evidence in negotiating prices and coverage could also undermine the evidence base for future NHS practice. Nevertheless, in principle the OFT’s recommendations could indeed, ‘provide major benefits to NHS patients and to innovative companies in the short and longer run’ (OFT, 2007).

It is not yet clear if all the recommendations of the OFT report will be accepted at the end of the consultation period or what compromises might be made by those responsible for making such decisions. What is clear is that this report cannot be ‘disappeared’. The OFT has put down an important marker which will inevitably shape the scope of future policy debates about value, guidance, price and innovation.

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