DRUG PRICE REFORM IN THE UK: DEBUNKING THE MYTHS

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SUMMARY

The OFT report into the Pharmaceutical Price Regulation Scheme (PPRS) called for reform of the scheme, replacing existing profit and price controls with a system of value-based pricing (VBP). The report argued that VBP would be much more effective than the current PPRS both at providing value for money for the NHS and giving pharmaceutical companies the right incentives to invest in drugs in the future.

The report has sparked a widespread debate about drug pricing in the UK and has been controversial in some quarters. Some of the more negative responses are, however, based on fundamental misconceptions about the OFT recommendations. In particular, contrary to some claims, the recommended system would provide strong incentives for incremental innovation and the right balance of rewards for first in class and follow-on products. Nor, as is sometimes argued, would VBP have an adverse effect on investment in the UK.

Certainly, real challenges lie ahead if VBP is to be implemented. These concern the definition of value, particularly where patient benefits differ significantly by subgroup or indication, and the level of resource required to implement VBP. The OFT report contains proposals for addressing each of these areas. Perhaps the most difficult challenge is the political one: securing acceptance for a reform package that would create winners and losers among pharmaceutical companies according to their success in producing valuable drugs. Ultimately, however, only a scheme that does precisely this can hope to meet the needs of patients, the NHS and innovative companies in the long run. Copyright © 2007 John Wiley & Sons, Ltd.

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It has been seven months since the OFT published its report into the Pharmaceutical Price Regulation Scheme (PPRS) (OFT, 2007a), which called for reform of the scheme, replacing existing profit and price controls with a system of value-based pricing (VBP). The report argued that VBP would be much more effective than the current PPRS at delivering short and long-run efficiency – that is, providing value for money for the NHS and giving pharmaceutical companies the right incentives to invest in drugs in the future. In support of these arguments, it identified over £600m of expenditure on drugs in 2005 that could have been used more cost effectively under alternative pricing arrangements, giving patients better access to the treatments they need and innovative companies better incentives to invest in the most valuable drugs in the future.

Since publication, the recommendations have been debated in a variety of forums, with participation from senior levels of Government, the NHS and the pharmaceutical industry. Understandably, with such large sums of money at stake, the report has been controversial and led to a wide range of responses, with positions for and against the OFT proposals apparently entrenched. The previous editorials in this journal are no exception, with Claxton (2007) supportive of a move towards VBP and Towse (2007) markedly less enthusiastic.

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However, many of the more negative responses to the OFT report are based on fundamental misconceptions about the recommendations it makes. Once these ‘myths’ are dispelled, it becomes clear that, behind the apparently polarised positions, there is in fact a considerable degree of consensus on the key issues to be addressed in moving in the direction of VBP.

This article attempts to expose some of the key myths, in order to focus attention instead on the real challenges that lie ahead in implementing an effective UK drug pricing system for the long term. To provide context for the discussion, I first summarise the case for reform of the PPRS and give a brief overview of the OFT recommendations.

THE CASE FOR REFORM

What is the PPRS?

The PPRS is one of the main mechanisms employed by the UK Health Departments to influence expenditure on branded prescription drugs. It comprises two main types of control:

- profit controls, which set maximum and minimum levels of profits that companies can earn from the sale of branded drugs to the NHS;
- price controls, which give companies freedom to set the price of new active substances on launch but impose restrictions on subsequent price increases. In addition, price cuts are imposed at the time of renegotiations of the scheme (roughly every five years). Companies have some flexibility in deciding which products to target in cutting prices, a system known as price modulation.

The scheme is best thought of as an attempt to exercise buyer power in the purchase of prescription pharmaceuticals by the NHS across the UK. In doing so, it aims to meet the interests of patients in the short run – by helping to maximise benefits from available resources – and the long run – by giving companies good incentives to supply new and useful drugs in the future.

Problems with profit and price controls

The report argued that the current scheme is not the best way of meeting either of these goals because PPRS profit and price controls take no account of the value to patients of the drugs companies are producing. Exploring this theme further, it is possible to identify both principled and practical problems with each type of control (OFT, 2007b).

The standard concern about profit controls is that by focusing on inputs rather than outputs they undermine static and dynamic efficiency. This applies to a much greater extent to a sector such as pharmaceuticals, which is characterised by a high degree of innovation, such that outputs produced differ very significantly between companies. Since PPRS profit controls fail to take account of the value of products produced, they do not attempt to address this problem, with the perverse result that the maximum allowed profitability for a company producing many highly valuable drugs is no different to that for a company that has been a less successful innovator. There are also major practical difficulties in measuring profitability in the pharmaceutical sector, arising from the fact that companies have an increasingly global cost base and a high level of intangible capital.

The importance of profit controls within the PPRS has clearly reduced significantly in recent years. Profit repayments in the 1999–2004 scheme were negligible, with repayments representing only about 0.01% of company PPRS revenues over the period. Towse (2007) suggests that this might reflect the fact that companies adjust their prices so as to avoid profit repayments, but in truth, the rules have changed significantly: cost allowances have been made more generous and the band between maximum and minimum allowed profit levels has been widened.

The most important issue – and one recognised by Towse – relates to transfer pricing from affiliates abroad, which now covers about 70% of sales to the NHS. Where companies use ‘resale minus’ transfer...
pricing (as the majority now do) PPRS profit controls cannot be binding irrespective of the prices they charge to the NHS, since higher prices simply lead to higher assessed costs, not higher PPRS profits. Indeed, ironically given the purported benefits of the scheme for UK investment, the companies for which current profit controls are most likely to bite are small, R&D-intensive manufacturers based mainly in the UK (and which are therefore less able to benefit from transfer pricing arrangements).

PPRS price cuts again take no account of the value of medicines to patients – one supplier may be producing drugs that are particularly beneficial to patients while another may not, but under PPRS both will have to reduce their average prices by the same amount. This is not consistent with value for money or good investment incentives.

The report also questioned the sustainability of a system based increasingly on arbitrary price cuts. Since companies have freedom to set prices initially under the PPRS, the more price cuts become a regular feature of the scheme, the more firms are likely to anticipate them in setting their prices (at the optimal price plus the anticipated price cut) particularly towards the end of the PPRS period. Under such an approach, pricing risks becoming a strategic game in which firms attempt to guess the level of forthcoming price cuts and DH attempts to second guess this effect in setting the level of price cuts. One would expect the outcome to be increasing price cuts or even price cuts imposed at random intervals. This is not a sustainable model of pricing for the future.

**Inefficiencies under the current system**

It became clear in the course of the study that, to make a compelling case for reform, we could not rely on principled arguments alone, but would have to assess the extent to which, under current arrangements, prices reflect value. Reviewing the price and clinical data of a small sample of drugs, we identified over £600m of primary care expenditure in 2005 that would have been used more cost effectively under a VBP regime that set the maximum price of a product at a level that reflected its value to patients. It is worth reiterating that these are resources that could be used in giving patients better access to treatments and companies better returns for producing cost effective products.

The analysis is a snapshot as of 2005, as this was the most recent year for which there was publicly available information. It covered a small number of drugs and did not include hospital expenditure, suggesting total benefits from reform would be larger. Nevertheless, some have claimed that the savings the report estimated in 2005 are unlikely to be replicated in the future. Towe, for example, suggests that the savings for one of the drugs we assessed – atorvastatin – fell dramatically after 2005, and indeed the report itself anticipated that savings in 2006 would fall due to efforts by the NHS to curb prescribing of this drug. In the event, however, while growth rates fell, this did not transpire: potential savings for atorvastatin in 2006 were virtually unchanged. It is also worth noting that using data from 2005 is likely to paint the PPRS in its most positive light in cost reduction terms, since this was the year the price cut was imposed.

It is clearly true that potential savings from VBP will change year on year, as new drugs come onto the market and old drugs come off patent. Further analyses of the kind we undertook in the study would be useful, perhaps covering a greater time span, wider samples of drugs and expenditure in hospitals.

A simple conclusion we can draw, however, is that in the absence of VBP, there is clearly a greater possibility of drugs continuing to be prescribed in the future at prices that do not reflect their value.

**Proposed reforms**

On the basis of these arguments, the report recommended reform of the PPRS from 2010, replacing profit and price controls with a system based on VBP, in which the maximum price of a product reflects the incremental benefits it produces relative to an appropriate comparator (OFT, 2007c). The main features are:

- all new active substances would be assessed *ex ante* (that is, before they come onto the market) through a fast-track appraisal process;
the existing stock of drugs would be assessed on a rolling basis through *ex post* reviews;
- risk sharing contracts could be agreed in principle if there is insufficient information up front to
  reach a robust view on the cost effectiveness of a drug;
- non-linear pricing arrangements could be negotiated to accommodate situations in which value
  differs by indication and/or subgroup; and
- for off-patent brands with a bioequivalent generic comparator, the price would adjust once a
  Category M price was established following generic entry.

Where a brand has not demonstrated benefits over a generic comparator the recommendations allow in
principle for a small ‘brand premium’ to reflect potential plausible but unproven benefits over the
generic.

**MYTHS**

Since the study was published, a number of myths have arisen concerning the report’s recommendations
and the analysis informing them. While they may serve a useful rhetorical purpose for those who oppose
an aspect of the recommendations, they are clearly unhelpful in progressing the debate. There are
several variants, but the key arguments appear to be that the recommendations:

- represent a heavy-handed ‘regulatory’ solution;
- fail to recognise and reward incremental innovation;
- unfairly disadvantage follow-on products in a class of drugs; and
- would undermine pharmaceutical investment in the UK.

It is important to identify and dispel these myths up front, as this allows for a clearer analysis of the real
challenges involved in implementing VBP.

**Regulation**

Some have expressed the view that VBP would represent a heavy-handed ‘regulatory’ approach to
improving value for money, which is typically contrasted with approaches based on improving the
demand side. This is a fundamental misconception – in many markets the ability to negotiate on price
and volume is a key feature of an active demand side. It is not clear why the NHS should be uniquely
precluded from doing so on the basis that this is regulation (and therefore ‘a bad thing’).

The report analysed a range of measures currently used at a local level to improve value for money in
the prescription of branded drugs. While recognising the importance of these measures, it noted that the
information to which GPs have access and the incentives to which they were subject do not always lead
to cost effective prescribing. Further, there are strong arguments for the centralisation of certain
functions within the NHS, such as the assessment of cost effectiveness (these are economies of scale
arising from the complexity of the analysis involved) and the negotiation of prices (in order to make
effective use of NHS buyer power). These conclusions were not drawn on theoretical grounds but
empirical evidence, relating to GP price awareness and, most importantly, current inefficiencies in
prescribing behaviour (OFT, 2007d and e).

The truth is that central VBP would supplement more local measures attempting to improve cost
effectiveness in prescribing behaviour. They are both instruments of the demand side and are both
articulated towards the same aim – helping ensure prescribing behaviour delivers value for money for
the NHS. Of course, some – for example, companies whose products are not cost effective at prevailing
prices – might be concerned that VBP in conjunction with local demand side measures will be more
effective in securing value for money than local demand side measures alone. We would agree.
In his article, Towse (2007) introduces a novel element to this debate. He states that the report recommended replacing local demand side initiatives with VBP.

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.

The OFT study did not assume, much less recommend this. Indeed, the report stressed the importance of guidance to prescribers (on the appropriate use of medicines) as a necessary component of any VBP scheme. The choice is not, therefore, between VBP and local initiatives to improve the cost effectiveness of prescribing. They are complementary measures in achieving a more active demand side. The choice, rather, is between VBP and the current PPRS – that is, between an approach to pricing that takes account of the value of medicines and one that does not.

**Incremental innovation**

A further argument that has been made is that the OFT recommendations ignore or fail to reward ‘incremental innovation’, that is, small benefits to all patients or differential benefits to different patient subgroups or in different indications. Towse (2007) is typical of the views expressed when he suggests,

> 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 [...] cannot be overstated.

It will be clear to anyone who reads the report that the claim that its recommendations refuse on principle to account for incremental innovation is entirely false. The report rejects such an approach in favour of one that takes full account of any innovation that provides benefits to patients, whether incremental or otherwise. Indeed, the recommendations regarding non-linear pricing are specifically designed to ensure that benefits in different indications or subgroups can be accommodated (OFT, 2007c). It is this aspect of the report’s proposals that causes Claxton (2007) to conclude that they would provide overly generous rewards to companies for incremental innovation – concerns that I consider below.

One factor that may have encouraged some to perpetuate the view voiced above by Towse is the fact that the report reviewed clinical data on certain high-profile on-patent drugs and concluded that there was no evidence that they deliver greater benefits to patients (either in specific subgroups or particular indications) than available generic alternatives (OFT, 2007e). Some of the companies concerned may wish to contest these claims and they are of course within their rights to do so – if the report failed to take account of important facts this should be pointed out. But the OFT analysis is supported by publicly available trials and used NHS experts to help ensure the data were not misinterpreted. Anyone with an interest should read Annexe M of the report and draw their own conclusions, but we should at least be clear about the nature of the debate here – it concerns the clinical evidence in relation to particular drugs, not the principle of accounting for incremental benefits under VBP. Incremental benefits should be rewarded under a reformed scheme and this is a point about which the report is abundantly clear.

**Follow-on products**

A variant of the above view is that our recommendations would unfairly favour ‘first in class’ drugs over follow-on products. Again, this is a critique that does not bear scrutiny. To understand why, it is helpful to give some background on the pharmaceutical innovation process. Towse, citing a variety of research, notes that,

> 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 reduced time between 1st and subsequent entrants.

Under such a scenario, which DiMasi and Paquette (2004) refer to as a ‘development race’, it seems fair to argue that products arriving on the market shortly after the first entrant should not be penalised unduly. Only when a product arrives on the market several years after the first in class without offering major benefits over it is the process more likely to be one of ‘post hoc imitation’ as DiMasi and Paquette term it. Under this scenario, the rewards should be lower to improve incentives for dynamic efficiency.

The OFT recommendations secure both of these outcomes. Under the proposed approach, only when the first in class product goes off patent can prices be expected to fall significantly. It therefore would allow products a longer period of premium pricing if they arrive soon after the first in class and a shorter period if they arrive several years after the first in class without offering major additional benefits. Notably, unlike some other pricing systems in the world, the report does not propose an arbitrary premium for first in class products. Neither as Claxton notes does it favour a ‘winner takes all’ system, in which only the product offering the most cost-effective price would get coverage.

Investment in the UK

The impact of the OFT recommendations on investment in the UK has been one of the most hotly debated topics in the follow up to the report. The report explores the arguments in considerable detail (OFT, 2007f), yet the key issues can be dealt with in short order.

In brief, Government interest focuses on attracting and retaining ‘footloose’ investments (that is, investments that can be carried out anywhere in the world where a suitable investment environment exists, regardless of where final sales are made). In relation to the pharmaceutical sector, these are primarily R&D and some manufacturing investments.

It is now generally agreed that the PPRS does not contain incentives to invest in the UK (although some in industry appeared to hold a different view at the beginning of the study). Further, a pricing and reimbursement scheme could not legally contain any such incentives under EC rules relating to the free movement of goods and state aids. Therefore, amending the PPRS would not affect incentives to invest in the UK. On practical and legal grounds, Governments wishing to attract investment should focus on factors that do, such as a skilled workforce.

As a second-order argument, some have argued that there is an indirect link between prices and location of investment, since companies can use the threat of withdrawing investments as a means of encouraging countries to pay high prices. Are these threats credible? No one, to my knowledge, has been able to establish a relationship between overall price levels and success in attracting investment. Further, such threats do not appear to be incentive compatible, since they rely on companies withdrawing investments even if the investment environment itself is attractive.

But even if such arguments did hold water, they would be irrelevant to an assessment of the merits of the OFT proposals, since, as both Claxton and Towse note, VBP is not about reducing overall expenditure on drugs but making best use of expenditure. Therefore, even if there is a loose link between market conditions and incentives to invest in the UK, reform in the direction of VBP should attract investment by innovative companies, who would prosper under new arrangements, just as much as it would reduce the attraction of the UK for those companies who would not.

CHALLENGES AHEAD

All this is not to downplay the real challenges that lie ahead if a move in the direction of VBP is to be made. But I have been encouraged by the serious, mature discussions that have taken place in debates
concerning the report about how to address these challenges – once the ‘myths’ about our recommendations have been dispelled. I touch on a few of the key issues below, relating to the definition of value, informational requirements and institutional design, the level of prices and the choice of comparators.

**Definition of value**

The basic definition of value we advocate in the report – that it should capture extensions of life and improvements to the quality of life – should not in itself be controversial. The report supports the principle that, in addition to patient benefits, account should also be taken of any significant non-patient benefits (e.g. to carers) delivered by medicines.

There is of course an extensive methodological debate about the use of QALYs and how they should be derived, focusing particularly on the methods used to identify and weight quality of life parameters. The simple point I would like to make here is that one does not avoid these issues – as is sometimes implied by those opposed to VBP – by failing to take account of cost/QALY or other cost-effectiveness measures. The rationing decisions that are made every day in the NHS entail implicit cost/QALY thresholds, whether they are made explicit or not. Our argument is that only by focusing explicitly on cost effectiveness can we move towards making best use of available resources for patients.

**Value that differs by subgroup and indication**

The value of medicines can differ significantly by patient subgroup and by indication and is therefore not linear over total volumes prescribed. Figure 1, which is a variant of the graph presented in Claxton (2007), helps to illustrate the arguments. As in the original graph, S1, S2 and S3 are three subgroups, where the technology delivers greatest incremental benefit for S1 and least incremental benefit for S3.

This sort of scenario motivated the report’s recommendation of non-linear pricing, in which different prices could be negotiated for different volumes of prescribing, for example a high maximum price for volumes reflecting estimates of the subgroup in which a drug is particularly effective (a maximum price of P1 up to Q1) and a lower price for volumes in excess of that (P2 from Q1 to Q2 and P3 from Q2 to Q3). In practice, on grounds of practicability, this would be achieved through rebates between payers and companies rather than changes to the list price. All such agreements would be supported by relevant guidance to prescribers.

These proposals would secure value for money for the NHS while offering companies efficient rewards for value in different indications and subgroups. They would also help eliminate the inefficient incentives companies are given under current linear pricing arrangements to engage in marketing

![Figure 1. Non-linear pricing under VBP.](image-url)
expenditure (amounting to £850m according to 2004 PPRS Annual Financial Returns), which would bring major benefits to both the NHS and industry.

Towse is in favour of this approach but Claxton, as noted, is concerned that it is too generous to companies, by effectively allowing for the possibility of perfect price discrimination. Claxton prefers instead a system in which companies are asked to choose a single price and the corresponding level of coverage (e.g. P1 with coverage Q1 or P3 with coverage Q3). He also suggests a ‘punitive’ price volume component (my term not his), by effectively proposing no reimbursement for quantities prescribed beyond estimates of the relevant subgroup (so that if, for example, a company has offered P1, they would get no reimbursement for quantities in excess of Q1). I address Claxton’s concerns below.

First, it is worth reiterating that the thresholds that would be in place under the OFT recommendations are the maximum prices that could in principle be negotiated with the pricing authority. Companies may choose to price below the threshold for a number of reasons. A company bringing a new product onto the market might, for example, choose P3 Q3 in order to avoid the need for price negotiations and the associated risk of delay. Companies may also choose to price below the threshold for promotional reasons (to gain market share). The report noted that this does sometimes occur and the recommended approach to pricing was designed specifically to retain incentives for such competitive discounting (OFT, 2007c).

Second, in assessing the claim that the recommendations are overly generous to companies (and insufficiently generous to the NHS) it is important to consider the status quo. As already discussed, under current arrangements, some of the largest selling drugs in the NHS are almost certainly not cost effective over all quantities supplied. One key reason for this is that under current arrangements – in contrast to the OFT proposals – prices of on-patent drugs do not adjust when the price of close therapeutic substitutes fall following patent expiry. Relative to that benchmark, our proposals would deliver significant benefits to the NHS.

It is true that, under the OFT proposals, companies could get high returns for demonstrating benefits in defined subgroups and indications. That is necessary in order to incentivise incremental innovation. It should be stressed that premium prices would only be paid if benefits and associated volumes could clearly be demonstrated. In contrast, if I read Claxton’s proposals of price volume agreements accurately, they would offer much lower rewards for one drug that had a given clinical effect in two subgroups than the combined returns offered to two drugs that delivered the same overall clinical effectiveness between them, each addressing one of the subgroups. It is not easy to reconcile this with static or dynamic efficiency.

Third, it is important to consider the likely response of companies faced with the choice Claxton’s proposals would give them. He suggests they may choose P3, Q3, which would be good news for the NHS. While this is plausible, they may also choose P1, Q1 if, as in Figure 1, this is the revenue-maximising option. Indeed they may choose P1, Q1 even if it is not the revenue-maximising option in the UK due to the importance of UK prices in international reference pricing schemes. P1, Q1 is an inferior outcome in efficiency terms to perfect price discrimination, since companies are worse off but the NHS is no better off. In short, I would suggest our proposals offer a better balance of static and dynamic efficiency.

I have spent some time exploring the details, as this is one of the more complex and challenging areas of potential reform. It would be wrong to overstate the differences between the OFT proposals and those Claxton makes – the difference relates purely to our respective conceptions of price volume agreements. However, these differences can have important effects, particularly on the incentives companies face to invest in and demonstrate incremental value.

**Information requirements**

To be effective, VBP must be based on robust information and give manufacturers the right incentives to provide that information. The report recognised that there may be situations in which it may not be
feasible to give a comprehensive demonstration of value at the time of launch. This might particularly be the case for medicines for chronic conditions, where information on clinical endpoints may only be available after several years.

To accommodate this, the report recommends *ex post* reviews of cost effectiveness and the possibility of risk sharing contracts being agreed (in which a price would be agreed contingent on the claimed benefits of a medicine being demonstrated in practice). I think there is a strong consensus between Claxton, Towse and the OFT report on the benefits in principle of these approaches. It is clear, however, that the specifics of contract design and governance are key to ensuring that risk sharing delivers benefits in practice. The UK’s only other experience with a national risk sharing scheme (that for interferon beta and glatiramer for the treatment of multiple sclerosis) suggests some key lessons in this respect (Sudlow and Counsell, 2003).

Such obstacles are not insurmountable in an appropriately designed scheme, however, and it is encouraging that NICE recently published draft guidance recommending that a risk sharing type contract be agreed for bortezomib (Velcade) for the treatment of multiple myeloma following a proposal of the manufacturer, Janssen-Cilag (NICE, 2007). This development confirms that aspects of the changes the report proposes can be mutually beneficial – for patients, the NHS and companies. It also suggests that, quite outside of the formal Government response to OFT recommendations, incremental changes are taking place to existing arrangements that are consistent with the broad path of reform we have set out.

**Resources and institutional design**

Another aspect of the report that has received scrutiny relates to the level of public resource required to implement the recommendations post 2010, which call for assessment of all new active substances at launch and *ex post* reviews of therapeutic groups over a five-year cycle. In aggregate, the report made a compelling argument that the benefits of the proposals would exceed the costs by a very considerable degree. But the costs and benefits of conducting each individual appraisal will vary significantly and there is clearly little benefit in spending a large amount of resource conducting an appraisal on an area of low expenditure about which there is little controversy.

This raises an important question – to what extent should the level of resource required vary per appraisal? If VBP is to work, companies and patients must of course have confidence that the system is fair and robust. But this should not mean that the level of resource should be the same for each appraisal. A fair and consistent approach would, rather, involve resourcing in accordance with the complexity and size of the task. NICE currently carries out appraisals on the most controversial areas, but if VBP were extended to all drugs, less controversial or complex areas would also be covered, suggesting a lighter touch approach may be more appropriate.

This approach is also consistent with the report’s proposal to make best use of the resources of each of the HTA bodies across the UK, since SMC and AWMSG have traditionally adopted a more rapid, less-resource intensive approach to reviews than NICE, while, importantly, retaining the confidence of key stakeholders. Of course, greater coordination than at present would be required to make the system work across the UK – not just to avoid duplication between the bodies, but to ensure that appropriate standards are adhered to by each.

**Setting the cost/QALY or budget**

The report noted that VBP could be implemented either by fixing a cost/QALY threshold in advance (and allowing the budget to be determined *ex post*) or by fixing the budget in advance and allowing the threshold to be determined *ex post* (in practice this would be achieved through payments between companies and the NHS at the end of the year).
Claxton and Towse are, unusually, united in rejecting the latter approach, Towse describing it as ‘nonsensical’ on the basis that it would result in a maximum cost/QALY for medicines that would be different to that for other health interventions. Curiously, however, Towse does seem to be in favour of setting the threshold for drugs in part to signal ‘society’s willingness to pay for innovation’, which would presumably result in the same outcome. Claxton, in contrast, is clear in rejecting any approach other than one that attempts to derive the threshold from the overall level of NHS expenditure. Three points made in the report are relevant here.

First, it is clear that if the only policy objective targeted is securing value for money from the overall NHS budget, then there should be a single maximum cost/QALY threshold for drugs and non-drugs and there is no case for a separate drugs budget. Indeed, there would be no need to hold negotiations on drug expenditure or the overall level of drug prices – the only political decision that would need to be made would be to set the overall level of the NHS budget, as Culyer et al. (2007) argue.

Second, it is equally clear that this is not the world we are currently in. If Government wanted to make a higher (or lower) contribution to the global costs of R&D, for example, it would not feel constrained to do so only through increasing or decreasing the size of the NHS budget. The periodic negotiations through the PPRS about the overall level of prices demonstrate the keen interest from both industry and Government – in the level and trend of drug expenditure. Furthermore, as Claxton notes, the current cost/QALY threshold may well be higher than the level consistent with maximising health gains from overall NHS expenditure. Recent research suggests that the threshold should possibly be capped at £20,000 per QALY – a lower level than that currently employed by NICE (Martin et al., 2007).

Third, and most importantly, the report shows that VBP could be implemented using either approach.

**Choice of comparators**

Without doubt, the most controversial aspect of the report’s recommendations concerns the use of generic comparators. Some companies have argued strongly that existing on-patent brands should not be compared against generics in assessing cost effectiveness for VBP purposes. The report clearly disagreed with this argument. Given the limited resources the NHS has at its disposable, it cannot afford, on grounds of both efficiency and fairness to patients, to ignore relevant comparators on the grounds that they are ‘too cost effective’. If the best available treatment is a generic, then treatments must demonstrate their benefits in relation to the generic to receive higher prices. This principle is a key element in ensuring not just static but dynamic efficiency: only a scheme that takes explicit account of the availability of cost effective alternatives can hope to give companies the right incentives to invest, by encouraging them to target areas of greatest patient need.

Some companies have understandably been hostile to this one element of the report’s recommendations, since they would have significant short-term financial implications for them. This in turn has raised political obstacles to reform – since those who would lose out in the short term always shout louder than those who stand to gain – but I have yet to hear a convincing argument against what the report proposes.

If one abstracts away from short-term financial implications and focuses instead on the design of scheme in the long run, the arguments are thrown into starker relief. The essential question is this – in designing a scheme for the long run, can we systematically turn a blind eye to the availability of cost effective substitutes? Quite apart from the fact that such an approach would build significant static and dynamic inefficiency into the system, it is scarcely credible that a payer today can commit not to take into account cost effective substitutes in assessing value-based prices for existing products in the future. This would amount to an explicit policy of restricting access to new products while ignoring inefficiencies in current expenditure and would be untenable.
CONCLUSION

At the time of writing, the UK Government has just issued an interim response to the study, indicating that the PPRS will be renegotiated (Department of Health, 2007; Department for Business, Enterprise and Regulatory Reform, 2007). This is a positive development, but given the range of interests at stake, it is difficult to speculate at this stage what form the renegotiated scheme will take. A substantive response to the report’s recommendations is expected by the end of 2007, which will give a clearer indication of the future direction of travel.

This article has focused on the challenges ahead should Government decide to move in the direction the report has suggested. These relate to the principles and rules governing VBP and the resources and institutions required to implement the new system. If, on the other hand, the renegotiation process leads only to minor changes to the scheme, an obvious question presents itself – is the current PPRS a sustainable model of pricing branded drugs in the future? Clearly, the arguments set out above suggest that it is not.

Resistance to reform within some parts of Government has tended to be based on the notion that the current scheme is popular with industry. However, none of the apparently vigorous defences of the PPRS that have appeared post-publication provides arguments as to why the specific instruments it comprises – profit controls and price cuts – are a good idea. Most critiques of the OFT proposals tend, rather, to compare them against the ideal world (from an industry point of view) of no pricing scheme at all. This, clearly, is not the correct counterfactual – if the current scheme is retained, price cuts will remain the principal instrument for controlling expenditure.

The choice facing companies – between the OFT proposals and the status quo – will therefore be starkest at the time of the next price cut. Those companies that are producing particularly cost-effective products, for example, would lose out by accepting a price cut that is applied equally to all companies irrespective of the value of their products (as opposed to one that is targeted on areas of inefficient expenditure). It is worth noting that in 2005 – when the last price cut was imposed – the potential savings the report estimated from a handful of drugs far outweighed the impact of the price cut, implying that, for the same level of savings to the Exchequer, the vast majority of companies would not have had to accept a cut.

Whatever the short-term response of Government to the recommendations in the OFT report, these fundamental truths will not go away. Pricing on the basis of value is in the interests of patients, the NHS and innovative companies. In the long term I believe that reform will follow the broad direction set out in the OFT report.

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