IMPACT ASSESSMENT REVIEWS

Review of the Office of Fair Trading's Market Study of the Pharmaceutical Price Regulation Scheme

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Regulatory Policy Institute

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Assessment of the OFT's Market Study of the PPRS

Preface

Market studies

The Office of Fair Trading undertakes market studies in a variety of different policy contexts. The Office's interest may lie in assessing features of a market that might be expected to have adverse effects on competition and/or to give rise to consumer detriments, or the focus might be on potentially problematic business practices that are to be found across a range of different markets. Guidance on the OFT's approach to market studies under the Enterprise Act 2002[1] also makes explicit reference to their use in assessing *"the effect of government regulations"* (para 1.3).

There is a range of possible outcomes of a study including:

- giving the market a clean bill of health (i.e. a decision that intervention is not appropriate on the evidence available);
- publishing information to help consumers;
- encouraging firms to take voluntary action;
- encouraging a consumer code of practice;
- making recommendations to the Government or regulators;
- investigation, or enforcement action against companies or individuals suspected of breaching consumer law or competition law; and
- a market investigation reference to the Competition Commission.[2]

Studies can vary substantially in terms of scope and duration, although most are classified by the OFT as either short studies (often of a fact-finding nature) or full studies.

Given this diversity, it is perhaps unsurprising to find that the OFT does not operate according to a standard set of rules of procedure that applies across all the relevant exercises, for example in the manner of the rules of procedure that the Competition Commission (CC) adopts for its own market investigations. It could, for example, be disproportionate for the processes that are used for a large-scale, full study to be applied to an exercise that is much more limited in its scope, and which might only be a precursor to a larger exercise to be undertaken by a body such as the CC.

[1] *Market Studies: Guidance on the OFT approach*, November 2004.
[2] The OFT may also accept undertakings in lieu of making such a reference.

Such flexibility in processes can, however, give rise to problems. Consider, for example, situations in which there is a concern that some or other aspect of government regulation might be having the effect of unnecessarily preventing, restricting or distorting competition. If the focus is solely on effects on competition, the function being carried out is broadly equivalent to that discharged by other parts of government when carrying out the 'competition assessment' component of a wider regulatory impact assessment (RIA). On the other hand, if the exercise involves a wider (than competition) evaluation of the effects of public regulation, and/or if it results in the OFT making specific recommendations for regulatory reform, then the market study will, in effect, be broadly similar in nature to a full regulatory impact assessment or to the remedies stage of a Competition Commission market investigation. And where such broad equivalence exists, it is to be expected that the conduct of a market study is, or should be, subject to the same kinds of disciplines faced by other parts of government when they are engaged in similar activities.

It might be argued, in response to this last point, that the OFT does not make policy in the manner of government departments and of the CC (when implementing remedies), and hence that there is no pressing requirement for equivalence in procedural disciplines. The OFT does, however, negotiate undertakings in lieu of possible references to the CC, which is a form of policy implementation; market studies often absorb considerably more administrative resource than departmental RIAs; and market studies also sometimes contain strong and definite recommendations to government on regulatory policy. Given these points, the view that the outputs of market studies are no more than a preliminary input into later RIAs appears to be unsustainable. Many longer studies are manifestly intended to have substantial influence on policy outcomes; the scale of resource involved is unlikely to be justified for a preliminary exercise; and the strength of recommendations made in relation to particular policy choices would be inappropriate (because prejudicial) at a preliminary stage of policy assessment.

On this basis, we think that it is appropriate that, in the context of 'full' market studies and when dealing with matters that are primarily to do with the evaluation of possible adverse effects on competition, and with recommendations directed at eliminating those adverse effects, the OFT's approach and procedures can properly be compared with the approach and procedures adopted by the Competition Commission in its market investigations. Similarly, when full studies deal with matters that are more broadly regulatory in nature, it is appropriate to assess them according to criteria established for the evaluation of regulatory impact assessments. The OFT Report on the Pharmaceutical Price Regulation Scheme (PPRS) falls into the latter category.

Assessment criteria

Three sources of evaluation criteria are relied upon in this and other Regulatory Policy Institute assessments of regulatory policy documents. They are:

Regulatory Impact Assessment Guidance

Guidance for regulatory impact assessment has been developed in a number of organisational and jurisdictional contexts, including the OECD, the EU, and most of the member nations of those institutions. This guidance covers both technical aspects

of the relevant policy analysis and aspects of the process by which policy is developed. As in many other policy development contexts, effective process and effective analysis are seen as complementary activities. The UK has been both an advocate and early adopter of the relevant principles.

Although guidance differs in some of its details among jurisdictions and implementations, there exist a number of core principles that are widely shared. These include the high importance of early and clear identification of relevant problems and issues that motivate the contemplation of new regulation; the clarification of relevant objectives; the construction and evaluation of multiple options including a 'do nothing' option; detailed assessment of the likely effects of implementing each option; consideration of the various risks that might be involved; testing for potential unintended consequences of regulation; consideration of equity and fairness issues; and the central importance of consultation, both as a means of acquiring and verifying information, and of discharging responsibilities owed to those who will potentially be affected by any exercise of public (monopoly) power that is in contemplation. Dimensions of policy assessment that have been considered important in UK government guidance, but which have sometimes not featured as prominently elsewhere, include the evaluation of possible impacts on small businesses and on competition.

Principles of better regulation

As in relation to guidance, there are now multiple versions of the list of 'principles of better regulation'. In the UK the principles are, as explained (relatively informally) on the Better Regulation Executive website, as follows:

- *"Proportionality: policy solutions should be appropriate for the perceived problem or risk: you don't need a sledgehammer to crack a nut!*

- *Accountability: regulators/policy officials must be able to justify the decisions they make and should expect to be open to public scrutiny.*

- *Consistency: government rules and standards must be joined up and implemented fairly and consistently*

- *Transparency: regulations should be open, simple and user friendly. Policy objectives, including the need for regulation should be clearly defined and effectively communicated to all stakeholders.*

- *Targeting: regulation should be focused on the problem. You should aim to minimise side-effects and ensure that no unintended consequences will result from the regulation being implemented."*

Judicial standards

Judicial supervision of administrative processes has become an increasingly significant factor in public policy over recent years, particularly in the enforcement of competition law. A good example of the contribution of the courts to the setting of standards in assessment is the European Court of Justice's judgment in *Tetra Laval v*

Commission (February 2005), which was concerned with a European Commission decision under the Merger Regulation and which stated, among other things, that:

"Whilst the Court recognises that the Commission has a margin of discretion with regard to economic matters, that does not mean that the Community Courts must refrain from reviewing the Commission's interpretation of information of an economic nature. Not only must the Community Courts, inter alia, establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it."

In testing whether or not the requisite standard of analysis has been reached in a particular case, therefore, the following questions might be asked:

- Is the evidence relied upon factually accurate, reliable and consistent?

- Is it sufficiently comprehensive, or are there significant/substantial areas of evidence that are relevant to the assessment but which have not been considered?

- More specifically, have 'inconvenient facts' (i.e. evidence that might cast doubt on arguments/reasoning being presented) been neglected, ignored or avoided?

- Do the reasoning and conclusions 'flow from the facts'? Are the conclusions adequately substantiated?

In consequence of the increasing role of the courts, we expect, over time, that these quite basic evaluation criteria or standards will come to exert a greater influence on the conduct of regulatory policy assessments.

ASSESSMENT

Summary of the OFT Report

The OFT Report on the PPRS[3] is 114 pages long and, collectively, the annexes add up to 924 pages. As might be expected of a text of this length, it contains a large number of different strands of argument/reasoning and covers a wide range of issues. Almost inevitably, there are inconsistencies in places, and, more avoidably (but also a very common tendency in this type of document), there are many points at which the reasoning drifts off into economic theorising that is only loosely related to the principal issues and evidence at hand.

For obvious reasons it is impossible in a review such as this to assess each and all of the elements of the Report, and some selection mechanism or filter must be applied to the material. The most straightforward way to deal with this issue is to focus upon those aspects of the analysis which the OFT itself considers to be the most significant, as indicated/revealed by what is said in the main text of the Report, and, in particular, by what is said in the opening Summary, the introductory chapter (chapter 1), and the recommendations made at the opening of the final chapter (chapter 6).

On this basis, the following appear to be among the most important points made or conclusions reached (with direct extractions from the Report in italics):

The remit of the study *is to assess whether the PPRS is effective in meeting its high level objectives, or whether there is a case for reform* (para 1.2).

The objectives of the scheme 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* (para 1.2).

These objectives are interpreted by the OFT as meaning that *the scheme aims both to secure value for money for the NHS and to provide companies with good incentives to invest in beneficial medicines in the future* (para 1.3).

Another key objective of the market study is *to improve the terms of debate about pharmaceutical pricing and reimbursement, not just in the UK, but internationally* (para 1.16).

[3] *The Pharmaceutical Price Regulation Scheme*, Office of Fair Trading, 2007.

The OFT concludes that the rationale for a national pricing scheme of some form derives from *demand side problems in other parts of the NHS*, not from an absence of competition on the supply side such as is found in some activities in economic sectors such as communications, energy, transport and water (para 1.9).

Evidence for the existence of demand side problems is to be found in a survey of 1000 GPs which *suggests they have weak knowledge of the prices of some of the most widely-prescribed drugs in the UK* (Summary).

The PPRS works in conjunction with a wide range of mechanisms and institutions designed to encourage cost effective prescribing at local and national level (Summary).

UK prices are found to have a particularly important effect on investment incentives, largely through the influence they have on prices in other parts of the world (Summary).

The PPRS is found to have a number of positive features, including:

- Companies value the stability it affords in the market environment.

- It *allows drugs to come on to the UK market rapidly without the need for lengthy up front price negotiations*.

- *The scheme is also light on direct administration costs for the public purse* (Summary).

However, it is also concluded that *neither the profit cap nor the price cut helps secure prices that reflect the therapeutic value of the drugs companies are supplying to the NHS* (Summary). This is considered to be a major shortcoming.

More specifically, it is concluded that:

- Regulating profits is *ill-suited to an innovative industry such as pharmaceuticals*, although it is noted that *there has been a significant reduction in the importance of profit controls within the past few years*, and further that *profit controls are therefore not a binding constraint for most companies* (although some small companies *might* be adversely affected).

- The PPRS price cuts *imposed across a company's products … take no account of the value of these products to patients*, which *is not consistent with value for money or good investment incentives.* Further, the price cuts may impact unevenly on different companies and the overall level of the cut *is unrelated to objective criteria.*

- There is a risk that, over time, the price cuts will give rise to an unsustainable game in which, anticipating price cuts, companies will set ever higher prices at product launch and, anticipating higher prices at launch, the DH will press for ever deeper price cuts (Summary).

Reviewing *some major drug categories on an indicative basis,* it is concluded that the market study has *identified over £500 million of expenditure in 2005 that could have been put to more cost effective uses* (Summary). The effects of this are that some patients have *reduced access to both drugs and other forms of healthcare.*

In relation to effects of the PPRS on investment, it is concluded that:

- *More value reflective prices in the UK could … bring major gains over time as they drive investment in areas of clinical need.*

- *The Government has much more effective instruments at its disposal for attracting investment into the UK, such as investing in the science base or improving the environment for clinical trials* (Summary).

In relation to the overall level of drugs prices in the UK, no firm conclusion is reached as to how this compares with price levels in other countries (Summary).

A number of options for reform are considered, and it is concluded that *there is a compelling case for reform of the scheme toward a value-based pricing system that would relate the prices of products to their clinical value relative to existing treatments.*

More specifically, the market study recommends that:

- *Government work towards reforming the PPRS, replacing the existing profit cap and price caps with a value-based approach to pricing.*

- Given this, the best option would be *to replace PPRS profit controls and price cuts with an ex-ante value-based approach to pricing* and with *ex post reviews to be conducted on all drug categories over a five year period.*

- Standard branded generics should be reimbursed at the generic price.

- Originator brands with a generic (Category M) equivalent should be reimbursed at the generic price, plus a premium of up to 25% (paras 6.1 – 6.4 and 6.9).

In addition, the Report takes the view that *much could be achieved by allowing for more flexible price structures than at present such as price volume agreements and rebate systems*, particularly *for drugs for which cost effectiveness differs markedly by indication and patient subgroup* (Summary).

A possible legal and institutional framework to administer the recommended option for reform is discussed in Chapter 6, although the points in this chapter are made more tentatively than elsewhere in the document, particularly in relation to longer term institutional developments. There is nevertheless a strong theme to the effect that the determination of the value of medicines is essentially a technocratic exercise. For example:

- *In principle, it seems reasonable to strive to remove political influence from essentially technocratic decisions on the consistent pricing of the clinical value of medicines – which can only properly be determined by specialists* (para 6.56).

- *A value-based PPRS would clearly be a different sort of document to the present agreement, containing high level principles for the conduct of reviews* (of the value of medicines) *and setting out certain key parameters. Perhaps the most important of these would be the cost/QALY [4] threshold that should apply to assessments* (para 6.63).

There is some ambiguity on the critical issue as to whether, in any reformed arrangements, maximum prices are to be imposed by Government or negotiated with suppliers.

Objectives of the market study

In announcing the market study in September 2005, the then Chairman of the OFT said that:

"We want to examine whether the PPRS works well to ensure that pharmaceuticals markets meet the needs of patients by offering adequate rewards to pharmaceutical companies for developing new and useful drugs, while providing the taxpayer with value for money."

The press release at that time stated:

"The decision to launch the study follows a previous study by the OFT looking at the impact of public procurement on competition. The study will last at least until spring 2006 and may continue until the end of that year, depending on the findings. Possible outcomes include:

- *recommendations that Government consider changes to the scheme*
- *a reference to the Competition Commission for it to investigate the matter further*
- *enforcement action by the OFT*
- *a clean bill of health for the scheme."*

Comparing with what is said in the Report, there is some indication of a tightening of the relevant assessment criteria (a test based on the notion of 'good incentives' is substituted for a test based on the notion of 'adequate rewards') and of mission creep (*"to improve the terms of debate about pharmaceutical pricing and reimbursement, not just in the UK, but internationally."*) Much more important, however, is that, whereas the declared intent is to consider whether there is a case for reform of the PPRS and whether the OFT should recommend that the Government consider changes to the scheme, the Report itself goes significantly further and adopts a position of advocating particular reforms.

[4] Cost per quality adjusted life-year.

Although the two exercises (assessing whether there is a case for reform and assessing what any reform should look like) are not unrelated – it would not be sensible to recommend that the Government consider reform without at least considering whether or not feasible, potentially advantageous reform options were likely to exist – they are different in nature and scope. To the extent that the intention is to make specific recommendations, and thereby to seek to exercise a greater influence over the development of public policy, it is appropriate that the market study process is subject to the process disciplines that have been developed more generally for the conduct of regulatory impact assessments. With greater influence/power should come proportionally greater responsibility and enhanced checks and balances – a principle to be found in the European Treaty (e.g. Article 82), the movie Spiderman 2,[5] and many places in between.

There is no explicit recognition of this point in the PPRS Report, and the conduct of the study appears to have been governed by the kind of processes most regulators, including the Competition Commission, have now left behind. That is, the evaluation process has occurred largely behind closed doors and with very limited public discourse, giving rise to 'surprises' on publication (a persistent criticism of the old, unreformed Monopolies and Mergers Commission). Precisely because the OFT can change/adjust the objectives of market studies in mid stream, for example by choosing to turn an initially limited exercise into something much more ambitious, existing procedures seem to us to give rise to the risk that such flexibility can potentially be used to weaken discourse, (within-study-period) scrutiny, and accountability.

Understanding the relevant economic/political/social background

Scattered throughout the body of the Report and its annexes, there is a considerable amount of accurate and informative material about the background context that is relevant for any assessment of public policy in relation to pharmaceuticals pricing. However, this part of the analysis appears to us to exhibit weaknesses that would likely have been be more transparent, and hence more likely to have been addressed in the course of the study, if the relevant material had been gathered together in the manner indicated in Cabinet Office guidelines for impact assessment documents.

On the positive side, the OFT recognises, as part of its background understanding, that:

- Notwithstanding the label, the rationale for the continued existence of the PPRS does not lie in monopolisation on the supply-sides of the relevant product markets, but rather in a knot of incentive and information problems on the demand side.

- UK prices are of rather greater significance for returns to R&D activities than might be expected on the basis of the share of the UK in world demand, because of the UK's significance as a benchmark/comparator for other countries.

[5] Uncle Ben to young Peter: *"Remember, with great power comes great responsibility."*

- Empirically, the profit cap element of the PPRS has become a less constraining influence on prices over recent years.

The Report is also correct to highlight the fact that "*The PPRS works in conjunction with a wide range of mechanisms and institutions designed to encourage cost effective prescribing at local and national level"* (Summary, page 2), but it subsequently tends to focus only on those bodies responsible for formal evaluation of the cost effectiveness of drugs and other medical interventions – NICE, SMC and AWMSG – and to neglect other of the 'wide range of mechanisms and institutions'. This reflects the apparent attractive pull felt by the authors toward formal cost-effectiveness analysis (CEA), and it represents a first move toward narrowness and abstraction in the analysis. Yet without a wider understanding of the full context in which the PPRS operates, any analysis of the scheme, of its effects, and of the likely impact of reforms risks superficiality. In particular, it would be a mistake – and a mistake of large magnitude – to assume that the only way of promoting cost effectiveness is to engage in formal cost-effectiveness analysis. Such a mistaken assumption would be an example of the 'fallacy of misplaced concreteness'.[6]

Having found from its assessment of financial returns that the profit cap is not binding for many companies, the OFT does not go on to consider the question: given that companies have freedom of pricing at launch, what factors are determining/influencing the relevant price setting behaviour of companies? The question is a rather important one, since (a) therapeutic effectiveness is one of the obvious, possible influences on new product prices, and (b) any inability to answer the question would strongly suggest a lack of understanding of the current situation in relation to NHS procurement. The question is, however, not addressed in the Report. We will return to the significance of this point below.

Other potentially important aspects of the contextual background that receive relatively little attention in the market study include:

- The interactions between the pricing of branded pharmaceuticals (governed by the PPRS) and the pricing of generics. This is also a matter of some importance since, to the extent that the current PPRS, or some hypothetical alternative, has impacts on price determination for generics it will have indirect effects/impacts on value for money achieved by the NHS. Moreover, any such effects/impacts are potentially appreciable in magnitude by virtue of the significance of generics markets in the UK.

  What might be at stake here is illustrated by a recently published Eurostat comparison of the price levels of pharmaceutical products in 33 countries in 2005.[7] The results are of particular interest because the relevant price indices include generic as well as branded products, and they show the UK price level lying 7% <u>below</u> the EU 25 average, and about 27% below the German level (a

[6] The most familiar, textbook illustration of the fallacy in economics is the false belief that those (very many) companies that, when setting prices, do not engage in formalistic evaluations of marginal revenues and marginal costs can not be setting prices that maximise their profits. See Sir Derek Morris, "The Enterprise Act: Aspects of the New Regime", *Economic Affairs*, 22, 4, 2003.

[7] "Pharmaceutical products – comparative price levels in 33 European countries in 2005", *Eurostat*, Statistics in focus, Economy and Finance, 45/2007.

much used comparator for the UK). It would appear that generic pricing contributes significantly to this favourable position, and hence, by implication, that there is potentially much to lose (relative to current outcomes) if poorly designed reform of the PPRS inadvertently harms the effectiveness of generics markets. RIA guidance on the need to consider risks and unintended consequences is, therefore, particularly appropriate in relation to the assessment of potential effects of possible reforms on generics.

- There is little sense of the historical performance of the PPRS over the fifty year lifetime of the scheme and its forerunners. Thus, for example, analysis of past international price relativities for branded drugs over extended time periods would have given the OFT much stronger indications of the significance of exchange rate movements, which in turn would have assisted in assessing the factors driving the substantial improvement in the relative position (internationally) of the UK between 2000 and 2005 that is plainly exhibited in figure 3.6 of the Report, and which is potentially highly relevant to any subsequent impact assessment.[8] Longer-term analysis is of particular relevance given the long lead times typically associated with the development of new products, the relatively long periods over which companies typically seek to recover R&D costs, and the relative fixity of product prices (e.g. the price of a product launched in the mid 1990s, when sterling was weak, might have appeared low relative to EU benchmarks at the time of launch, but might have appeared high relative to the same benchmarks five years later, when sterling was much stronger).

- Although the OFT does not rule out the existence of a link between market conditions, including the framework of public policy, and incentives to invest in the UK, it is clearly sceptical that such a linkage exists. The importance of the 'regulatory climate' for investment decisions is, however, a rather widely agreed point in other economic sectors (egs. energy, financial services). It is currently one of the sets of issues being explored by a House of Lords Select Committee inquiry into regulators, and quantities of oral and written evidence are available from that exercise. It is unclear, therefore, why the OFT team appears to have had difficulties with this point, although it may be connected with the fact that the relevant linkages are much more difficult to analyse in terms of formal theory (the 'games' are too complex to be handled analytically) than empirically.

- There are similar weaknesses of reasoning and analysis in relation to potential links between the regulatory climate, of which the PPRS can be considered a part, and the level of R&D activity in the UK. The bare facts of the matter are that, compared to other economic sectors, the UK has an unusually good international record in pharmaceuticals R&D, an unusually good record in pharmaceutical manufacture and exporting, and an unusually light-touch and flexible regulatory environment. It is, of course, possible that this conjunction of factors results from chance/coincidence, but, *prima facie*, it is more likely

[8] Exchange rate effects are considered in Annexe F, and the relevance of exchange rate movements is recognised, but the analysis is restricted to a very short period and earlier, potentially relevant information/evidence is not taken into account in the assessment.

that these things are related in some way or another. Thus, whilst it is clearly possible to argue that "*The Government has much more effective instruments at its disposal for attracting investment into the UK, such as investing in the science base or improving the environment for clinical trials"* (Summary, pages 4 and 5), the argument, as it appears in the Report, is no more than an unsubstantiated assertion.

The unsafeness of the assertion can be illustrated by the thought experiment of turning the clock back 50 years to the genesis of the voluntary agreements between government and pharmaceutical companies. As now, the UK had a fine science base in pharmaceuticals R&D. It also had a fine science base in civil nuclear power. Most analysts looking for explanations of the decline in the latter would, we think, conclude that the set of significant factors includes regulatory/political decisions in downstream electricity markets. Arguably, the negative effects on of such decisions on the science base could have been offset by alternative instruments at the disposal of successive governments, but the historical evidence suggests that such a countervailing course of action is rather easier to follow in theory than in practice. The OFT therefore errs when it (too easily) dismisses the contribution to R&D investment of what might loosely be labelled the 'pull through' effects of downstream economic activity and its regulation.

In summary, whilst the PPRS Report contains a significant amount of informative material about the relevant background context, as the above points illustrate there appear to be some very major gaps in the OFT's understanding of that context.

Since regulatory impact assessment builds cumulatively from the foundations of an initial understanding of the relevant market or context, such gaps should serve as a warning light, flashing red, in relation to what is to follow, since errors and omissions made at the outset can also have cumulative effects. The consequences in this case will be explored further below.

Identification of the 'problems'

Precise and early (in the process) 'identification of the problems' is of critical importance for well-conducted impact assessment. The relevant stage in RIA is mirrored in Competition Commission procedures, in that the first phases of CC market investigations are heavily focused on determining whether or not there exist features of the relevant market that might be expected to have adverse effects on competition. Moreover, both RIA and CC market investigation processes provide for the publication of initial views on the relevant set of identified issues/problems.

Without precise identification of problems, there is obviously a much increased risk that regulatory measures in contemplation might be poorly targeted, and thus fail to satisfy one of the high-level principles of better regulation. By the same token, without clear sight of the problem to be addressed, it will likely be much more difficult to assess the proportionality of alternative courses of action.

Proportionality is of particular importance, since it will typically be possible to point to performance deficiencies in more or less any economic context. Markets and

market rules are in a constant state of flux, and what might have been judged efficient with yesterday's knowledge base and technologies might be judged inefficient with today's. There is continuing discovery, learning, adaptation and correction in these matters. In general, therefore, the presence of performance deficiencies at any one point in time is not a sufficient ground, and indeed is nowhere near to being a sufficient ground, for concluding that there is a potential 'problem' that is so serious as to warrant the consideration of further regulatory intervention.

The PPRS Report contains many detailed points of criticism about existing arrangements for the procurement of drugs by the NHS. A substantial proportion of these points appear to be of relatively limited significance, relating to the kind of distortions that are an almost inevitable feature of any arrangement for controlling or supervising prices, and it is particularly notable that the OFT does not identify major problems associated with (a) the <u>average</u> level of UK drug prices or (b) the level of remuneration available to sustain an appropriate <u>level</u> of investment, including in R&D. As we interpret matters, the OFT's concerns appear to revolve around the <u>structure</u> of relative prices – although we say this relatively tentatively because the reasoning is not entirely clear, and at some points in the Report and its annexes there is a tendency toward conflation of price level and price structure issues. The absence of any clear 'identification of the problems' sub-exercise in the evaluation process may well be a contributor to the resulting ambiguities.

So far, so good, in that distinctions between price level and price structure issues are a standard aspect of systems of price regulation. In practice, most regulatory effort goes into the 'on average' (or price level) issues. Thus, for example, in regulated utilities the great bulk of price review activity is concerned with determining the overall 'revenue allowance', which is intended to strike a balance between shareholders and consumers, and to provide an adequate level of remuneration for investment. The determination of the relative prices of different products/services, within this overall settlement, is frequently left to companies, perhaps subject to regulatory approval of the methodologies to be used in setting those prices (and, of course, always subject to competition law).

The current PPRS arrangements accord with this now familiar template. The major interest of the DH has centred on the 'on average' settlement with manufacturers. Subject to compliance with the overall bargain, companies are left with freedom to set the initial prices of their products, although there are secondary constraints at the individual product level in the form of the rules concerning price changes, including modulation.

Compared with what is at stake in the overall bargain, the economic significance of the relative price issues are normally considered to be a function of the relevant demand and supply cross-elasticities. Put very simply, if demand and supply are relatively unresponsive to relative prices, the issues in this area can be expected to be of minor significance. The reason is that it is volume/quantity changes that give rise to changes in economic efficiency. Again speaking fairly loosely, if the volume effects are likely to be small, relative prices can be expected not to matter very much (for economic efficiency).

Once these high level distinctions and points are recognised, the OFT analysis immediately begins to look slightly eccentric. The major problem identified appears to be summarised in the following extract:

"... we have an overriding concern with the scheme as it is currently designed: neither the profit cap nor the price cut helps secure prices that reflect the therapeutic value of the drugs companies are supplying to the NHS. For a scheme that sets out to deliver value for money for the NHS and give companies the right incentives to invest, we consider this to be a major shortcoming, particularly in view of the demand side problems we have identified in the rest of the NHS."

However, if 'demand side problems' include 'insensitivity of demand to relative prices', the normal economic implication of such inelasticity is that the relative prices of different products might be expected not to matter very much. (Supply elasticities/responses, including in the long-term, are also relevant, but the Report offers neither reasoning nor evidence on the likely quantitative significance of such effects.) To put it relatively mildly, there is a tension between the OFT team's general pessimism on demand side responsiveness to relative prices and its views on the economic and financial importance of the structure of (relative) prices.

More fundamentally, there is a prior question to be asked and answered: why should it be considered a problem that certain features of the existing PPRS arrangements do not *"help secure prices that reflect therapeutic value"*? At the risk of undue repetition, it can be noted again that the OFT Report states (correctly) that *"The PPRS works in conjunction with a wide range of mechanisms and institutions designed to encourage cost effective prescribing at local and national level."* If that is so, what matters for policy is how the various mechanisms and institutions work together, not whether or not particular components (e.g. profit caps, price cuts) of one element of policy (the PPRS) make specific, direct contributions to one aspect of objectives (e.g. value for money). At a minimum, then, the OFT's *"overriding concern"* appears somewhat mis-directed.

Notwithstanding this conclusion, and whatever the linkages to individual strands of health policy, the more general question of whether or not the existing structure of prices can be expected to lead to inefficient outcomes is an important one. It is in addressing it that the OFT Report comes to its most striking conclusion, which is that *"we have identified hundreds of millions of pounds of expenditure per year that could be used more effectively under value-based pricing."* This is the claim that was highlighted in media coverage of the Report, but unfortunately it is a claim that, upon detailed examination of the Report, is simply not substantiated.

There are a number of different points that have bearing on the relevant issues here and, since the matters are central to the outcome of the market study, we will consider several of the most important.

The determinants of current prices

The implication of the OFT reasoning is that there are serious problems with the existing price structure because it does not adequately reflect estimates of therapeutic value that would eventuate from the systematic use of formal, cost-effectiveness

analysis. This conclusion is reached, however, without any attempt to explain what it is that determines existing prices. There is, for example, no evidential basis for concluding that current prices set at product launch do not adequately reflect therapeutic values. The profit cap and the price cuts of the PPRS are targeted at average price levels, not at the structure of relative prices, which companies can vary, both via pricing decisions at product launch and, subsequently, via modulation.

Given that there is *"a wide range of mechanisms and institutions* (other than the PPRS) *designed to encourage cost effective prescribing at local and national level",* it might reasonably be expected that companies will take account of assessments of therapeutic values when determining their pricing and marketing policies. In effect, the PPRS Report implies, or comes very close to implying, that these other mechanisms and institutions have been comprehensively unsuccessful; but no evidence is presented in relation to launch prices of products that would support that conclusion. Indeed the evidence, although still limited and not completely conclusive, points the other way, to some success in increasing demand-side influences on the relative prices of drugs. For example, having looked at the financial data, the OFT concludes that the profit cap has not been constraining for most companies over recent years, and companies do not appear to have been able to use the available 'headroom' to hike up new product prices to any great extent: product launch prices in the UK over recent years and UK prices for biopharmaceuticals both appear to be reasonable, and in some cases keen, by international standards.[9] What else but the price-sensitivity of demand could be constraining price determination for new products? The question remains unanswered in the Report – because it is not addressed.

For pricing of new products then, no problem (of inadequate 'value-reflectivity' in prices) has actually been clearly identified by the OFT, although it might be argued that the Report does, indirectly and implicitly, suggest that product launch prices in the UK are 'too low'. This would follow if the Report is interpreted as suggesting that (a) UK prices are reasonable on average but that (b) the prices of long-established products are 'too high'; but putting things this way would reveal the next weakness in the reasoning.

Invalid estimation procedure

The PPRS Report postulates a hypothetical, unspecified price structure based upon some notion of "value-based pricing", which is assumed to be different from the price structure that is currently observed. If, consistent with the evidence examined by the OFT, UK drugs prices are not excessive on average, it might be expected that some product prices will be higher under this alternative system and some will be lower.

The approach taken by the OFT is to examine a number of well-established, existing products (i.e. not new products) where the hypothetical, alternative prices can be expected to be lower than current prices because, for these cases, there is an alternative, substantially cheaper, generic product that provides a benchmark for

[9] See, for example, the evidence discussed at 7.13 – 7.17 of Annexe F, and also P.M. Danzon and M.F. Furukawa, "Prices and Availability of Biopharmaceuticals: An International Comparison", *Health Affairs*, 25, No. 5, 2006.

determining "value".[10] The differences between expenditures at the actual prices of the relevant products and hypothetical expenditures at the hypothetical, "value-based" prices are calculated, are added up, and are claimed to provide estimates of potential savings in expenditure that would be made as a result of introducing "value-based" pricing.

What are not examined are drugs for which the alternative, hypothetical prices might be expected to be higher than current prices, and, quite manifestly, the procedure is therefore an invalid method of estimating the potential effects on expenditure of an alternative pricing system – if, for any policy change that produces winners and losers, only winners are counted, the change will always look beneficial. A few potential expenditure reductions have been cherry picked, when what is required is an assessment based upon the complete price structure (or, if that is infeasible within available resources, based on some appropriate sampling procedure).

Had the OFT's approach to this issue been open and transparent, in conformity with principles of better regulation, the error could have been highlighted and subsequent, mis-leading claims could have been avoided.

The trade-off between pricing and R&D

There is also a more subtle, but quite fundamental, economic point that is missed in the PPRS Report's analysis. It is always possible to cut expenditure on drugs in the short-run by reducing prices for some or all existing drugs. A quick way of achieving the effect would be to reduce the duration of patent protection by, say, a year, which, since it would tend to lead, product by product, to earlier generic entry, could be expected to reduce the drugs bill by hundreds of millions of pounds per annum.

It should be obvious, however, that any such recommendation would not necessarily be a good thing, for the simple reason that its effects on incentives for R&D and innovation would be adverse: in the longer-term, the supply of new, higher quality medicines would be harmed. The latter effects must, therefore, be weighed in the balance. Moreover, if the patent life is about 'right' in its duration, the short-term benefits of the price cut will be approximately equal to the loss of long-term benefits from R&D and innovation, since it is by balancing off the short- and long-term costs and benefits of extra patent life that the most efficient duration of patent protection is determined. Again, the conclusion that there exists a substantial pot of benefits to be had from adjustments to relative prices depends upon illegitimately ignoring adverse, longer-term effects on R&D and innovation.

The correct trade-offs are implicitly recognised in the existing PPRS arrangements and past negotiations. Thus, as footnote 17 of the Report states, the DH has already taken steps – including via RIA and consultation – toward removing 'standard

[10] There is clearly a hornet's nest of problems here, since the degree of substitutability among different pharmaceuticals is not parametric (i.e. a given) but can be expected to depend on product volumes. Thus, drug B may be a good substitute for drug A for many patients. But if drug A is used only to treat patients for whom drug B is, for some reason or other, inappropriate, B will no longer be a good substitute for A. The OFT Report does not address the issues, but anyone familiar with the realities of regulation will recognise a potentially rich source of headaches (to regulators), complexity, cost, and litigation.

branded generics' from the PPRS and remunerating their supply at the lesser of the list price of the relevant drug or the Drug Tariff price of the comparable (unbranded) generic. 'Standard branded generics' are products that, typically, have been developed without the levels of R&D effort associated with 'originator brands', and hence where lower prices can be expected to have a much lesser impact on longer-term incentives and supply responses. The trade-offs are different from those surrounding 'originator' brands and, hence, reasonably and proportionately, the DH has proposed different treatment for these drugs. It is one of the (less transparent) costs of the OFT's market study that it has led to delay in this particular reform/adaptation of the existing PPRS arrangements.

Use of arbitrary assumptions regarding generics prices

In estimating potential expenditure reductions by comparing existing brand prices with existing generics prices, the OFT is making an implicit assumption that generics prices would be unaffected by the introduction of the hypothetical, "value-based" price structure for branded pharmaceuticals. However, speaking broadly, if the relevant products really were fairly close substitutes, it might be expected, on general economic grounds, that changing the pricing arrangements for branded products would have implications for the prices set for generics. In the absence of any reasoning on this point, the Report's number-work is necessarily arbitrary.

The potential issue is noted in passing at para 4.20 of Annexe M (in a section concerned with statins prescribing, for more about which see below), where it is explained that in Australia, where the reimbursement price of atorvastatin (on-patent) has been linked to the price of simvastatin (off patent), simvastatin is more expensive than in the UK. The explanation offered is that Australia *"lacks a well developed generics market"*. Para 4.20 goes on to say that *"We understand that recent policy proposals have aimed at securing more competitive reimbursement prices for generics and will in the future de-link the price of simvastatin and atorvastatin"*. By implication, then, Australian policy makers appear to have concluded that linkage between the two prices has had an upward effect on generics prices, or, put another way, that the generics price can not be expected to be invariant to the linkage. The OFT may disagree with this view but, at a minimum, the issue should have been addressed rather than ignored.

The statins

The bulk of the short-term, potential expenditure reductions claimed in the Report are associated with one group of products, the statins. More specifically, the claimed reductions, which are based on 2005 data, are closely associated with the growth in prescriptions of the branded medicine Lipitor (atorvastatin) in a period when an alternative generic (simvastatin) was available at a much lower price.

We are not qualified to speak on the therapeutic properties of the drugs concerned, but what it is possible to say is that the matters raised in the Report (in February 2007) were hardly news, as the Report itself rightly recognises. Issues surrounding the therapeutic properties of the relevant drugs and their relative prices had received prominent coverage within the NHS, including in a BMJ editorial (in mid 2006), and NICE guidance was issued in January 2006. The statins case therefore provides an

opportunity to study the reactions of the demand side to new information and to changes in relative prices. More specifically, given the publication date of the Report, the OFT had the opportunity to study NHS purchasing patterns for the statins in the period following the issuing of the NICE guidance, at the beginning of 2006.

The OFT also had an opportunity to compare what was happening in the UK with what was happening in other countries. The market study is concerned with the PPRS, a drugs procurement regime that has unique features. In table 5.1, the Report compares features of the PPRS with features of other regimes, and suggests that the PPRS is unusual in its lack of provision for 'pricing relative to substitutes', both *ex ante* and *ex post*. Given this, an obvious question to ask is: how has the UK been doing relative to these other systems (which are claimed to 'price relative to substitutes') in relation to the pattern of statins prescribing and expenditure? Clearly this question has significant, potential relevance to the task at hand (evaluation of the PPRS).

Finally, given the very large contribution of statins prescribing to the claimed "hundreds of millions" of expenditure savings (see table 5.3), we think it was incumbent on the OFT to consider the question of whether recent circumstances in this market could be considered relatively unusual (e.g. because of a conjunction of the timing of flows of new evidence on therapeutic effectiveness, the timings of patent expiries, and the large and fast-growing volumes of prescriptions for these particular products) or whether similar situations could be expected to arise on an ongoing basis. This is another important aspect of the 'identification of the problem' exercise, which, as pointed out above, is required if any policy responses are to be well targeted. To illustrate the point at the most basic level, there will usually be little point in going to great effort to implement regulatory reforms aimed at dealing with a one-off problem that has occurred in the past but that is highly unlikely to occur again. More generally, an assessment of the frequency or risk of 'problematic' circumstances is required to ensure proportionality in policy responses (and this is one component of the risk-based approach to regulation favoured by the government, and advocated in particular by the Treasury).

The PPRS Report fails to engage systematically with any of the above questions.

In relation to market developments in 2006, it is simply noted (para 2.64) that:

"While volumes of some on-patent statins may have fallen somewhat since this analysis was undertaken, the extent of inefficiency (sic) *remains significant."*

This is a telling sentence. Did the volumes referred to 'fall somewhat' or not during 2006? If so, by how much, and over what period? What implications does the 2006 evidence have for estimates of potential expenditure reductions going forward? If changes in the pattern of purchasing were occurring in 2006, why did the OFT persist in advertising over £500 million pounds of potential savings, based on 2005 numbers, when it might reasonably be expected that, looking at the position at the beginning of 2007, this figure could be misleading – or, at a minimum, that it would likely be widely misinterpreted?

There is a hint at para 4.31 of Annexe M that the lack of attention given to the most recent developments in the market might have been due to lack of publicly available data. However, given the significance of what is claimed in the Report, if such was the case it was incumbent on the OFT to seek to gather the relevant data itself and, if that proved to be a difficult task because of the Office's limited information gathering powers, to refer the matter to the Competition Commission. The failure to proceed in this manner leaves the reader with a strong sense that there was a reluctance to address discoverable facts that might have proved potentially inconvenient for arguments in the course of development and for claims in contemplation.

A similar conclusion follows from the absence of any reference to international comparisons in relation to statins. Paragraph 2.64 refers to a lack of UK price and volume responses from on-patent brands, particularly Lipitor, in the period following the introduction of generic simvastatin, but table 3.1 indicates that Lipitor increased its sales and maintained its market share at a global level in 2005. The UK market position does not, therefore, appear unusual. Indeed, looking at the relative magnitudes and movements of the Lipitor and simvastatin numbers in table 3.1, and comparing with the picture painted for the UK in Figures 2.5 and 2.6, it is arguable that this material might be suggesting that the UK achieved rather earlier expenditure reductions following the introduction of generic simvastatin than countries which, according to the OFT, have 'pricing to substitutes' as part of their reimbursement arrangements. At a minimum, this possibility needed to be explored and assessed, which it wasn't.

As to the likely frequency of market circumstances in which an on-patent brand continues, for a significant period, to sell in large volumes in the presence of a much lower priced generic alternative, the Report is, once more, silent. In consequence, the subsequent analysis of policy options is impeded for want of a clear specification of the nature of the problem to be addressed.

In summary then, there are major failings in the OFT's identification of the problems to be addressed. Since the issues involved are relatively complex, some errors and gaps in understanding might reasonably be expected at the early stages of any review of this kind. The discipline – as envisaged by RIA guidance and by CC market investigation procedures – of a requirement to publish initial views on where problems are thought to lie is intended (among other things) to provide a means of reducing the likelihood of such errors being carried forward in to the assessment of potential regulatory options or (in the case of the CC) remedies. The assessment process is therefore structured so as to have sequential and iterative elements. In relation to the PPRS market study, however, OFT views on the identification of problems only emerged at the same time as specific proposals/recommendations were presented – when, so to speak, the study has been 'done and dusted' – allowing no within-review opportunities for other parties to point out the errors and omissions, including those highlighted above.

Identification of the relevant policy objectives

The OFT identifies the relevant objectives as those set out in the PPRS agreement itself, namely

- *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* (para 1.2)

It then interprets these objectives as implying that *the scheme aims both to secure value for money for the NHS and to provide companies with good incentives to invest in beneficial medicines in the future* (para 1.3).

Whilst there is considerable overlap between the stated objectives of the PPRS and this shorter statement of aims, they are nevertheless not the same.

The point is worth noting because there has been a tendency, in a number of regulatory contexts, for economists to reinterpret objectives (which in some cases are statutory) in terms of promoting economic efficiency. However, whilst economic efficiency or cost-benefit assessments should certainly inform the policy process, it is illegitimate to substitute efficiency or cost-benefit tests for the relevant objectives, and to do so would undermine the more general system of devolved policy making, which, by design, relies on constraining delegated objectives to be more specific, and narrower, than "Go forth and maximise net benefits".

That said, we think that it is reasonable that the OFT should raise questions about relevant objectives, and that this is an area where a market study might differ in scope from a typical regulatory impact assessment. Particularly given that the PPRS is only one piece in a much larger policy jigsaw, there is reason to ask whether or not its existing objectives are appropriate in the wider, evolving health policy context. Appropriate specification of objectives for different parts of the wider system is part and parcel of getting all the parts working together well.

It would have been better, however, if the 'objectives issues' had been clearly identified as such, and had been discussed more explicitly. As it is, they are addressed implicitly and in a scattered way, for example via the initial reinterpretation of aims and then later via sniping at 'industrial policy' interpretations of the PPRS.

Identification of regulatory/policy options

The PPRS Report identifies a number of broad policy options that might be adopted going forward, but, for the purposes of this review, it will be sufficient to assess the approach to the main elements of the preferred option, namely the introduction of what is referred to as "value-based pricing" on a universal basis (i.e. for all drugs, not just for some).

The missing option/baseline

First, however, it can be noted that there is no systematic analysis in the Report of the 'do nothing' option.

Guidance on impact assessment, reflecting general public policy, now places great stress upon the importance of this exercise, which is considered to be one of the available antidotes that can be used to help calm hyper-active regulators or would-be regulators. Analysis of the benchmark, 'do nothing' option is very much bound up with the 'identification of the problem' stage of policy impact assessment. In fact, 'identification of the problem' can be viewed as a kind of first phase of the 'do nothing' option evaluation, with more detailed consideration of potential impacts/effects to come later.

As discussed above, there are a number of flaws in the Report in the way that potential problems are identified and specified. Explicit analysis of a 'do nothing' option would likely have made these weaknesses more transparent, and hence could have helped prevent them in the first place (another example of how good procedures can promote better, substantive policy analysis). Consider again, for example, the case of the statins. Explicit analysis of the 'do nothing' option would have almost certainly led to the conclusion that the 'problems' identified in relation to statins could be expected to be of declining quantitative significance over time, first in consequence of price and volume adjustments for on-patent brands – which were already plainly observable by the time of publication of the Report – and later in consequence of the expiry of currently existing patents.

"Value-based pricing"

There is an immediate problem with the OFT's advocacy of "value-base pricing" (its preferred option) since, although this notion may make a useful sound-bite for media presentations, it is not a concept usually to be found in general economics. Indeed, given that the price of a product or service can be interpreted as one measure or as one definition of value – and references to the 'theory of value' in economics usually just mean the theory of price determination – there is a tautologous feel to the whole notion of "value-based prices".[11]

What the OFT appears to have in mind is some process of setting prices, or at least maximum prices, by reference to assessments of the "therapeutic value" of drugs, but that still leaves puzzles. In most markets it is to be expected that cost factors, as well as demand side assessments of the worth/value of a product, will influence price. Is the OFT really saying that costs should have no bearing on price? Further, markets are places where the valuations of products/services are discovered and revealed, is the OFT saying that information discovery and revelation are relatively straightforward exercises for technocrats faced with the task of making cost-effectiveness estimates?

[11] In places, particularly near the beginning (e.g. on page 1), the Report refers to "value-reflective prices" rather than "value-based prices". Although this takes us no further forward on the question of what is meant by 'value', the word 'reflective', implying something like 'influenced by', is perhaps more precise and accurate terminology than 'based', with its connotations of 'predominant influence'.

Overall, in the OFT's advocacy of "value-based pricing" there is a strong impression of argumentation that is skating on thin ice, and of a tendency to beg questions that should not be begged. For example, there appears to be inadequate explicit recognition of the duality between prices and volumes/quantities in the determination of value. Figure 1 below illustrates. It shows the marginal values associated with different levels of usage of a drug, ranked from highest to lowest. As noted at para 5.78 of the Report, valuation differences of the type exhibited may be associated with the existence of different indications, different patient groups, and of differences in individual responses to particular drugs. In a decentralised decision-making system the value-volume relationship might be called a demand curve, but, whatever the name, it can reasonably be expected to slope downwards: the higher the volume of product in use, the lower can be expected to be the marginal valuation.

Figure 1.

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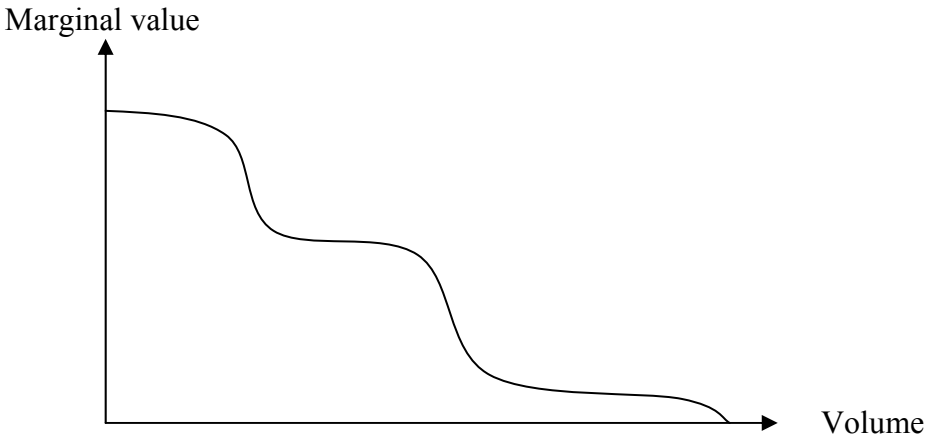


Even if it is assumed that all the marginal valuations are accurately known or can be accurately estimated – which is a very, very large assumption indeed[12] – it is not at all obvious what is meant by <u>the</u> "value-based price". How do we get from the therapeutic valuation information assumed in the construction of this diagram to a price? Plainly, something has to be said about quantity/volume to make sense of the situation, and even then we are left with the question of what has happened to costs in all of this. Some drugs cost more to develop and produce than other drugs, and it might reasonably be expected that this will be reflected in price determination. And, if it is so reflected, in what sense is it helpful to talk about value-<u>based</u> pricing?

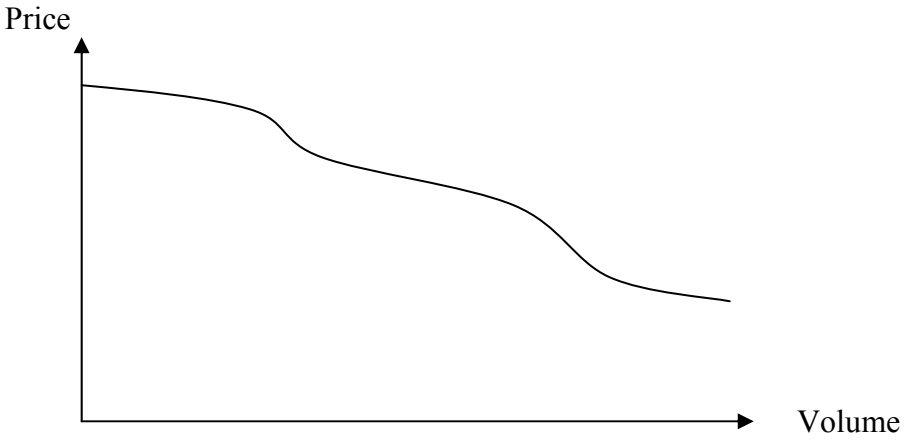
At paras 5.64 and 5.65, the Report suggests that the preferred approach is to make use of the incremental cost-effectiveness ratio (ICER), defined as the incremental cost of using a drug relative to some specified comparator divided by the incremental increase in health benefits resulting from the use of the drug, relative to the same comparator. The suggestion is that health benefits be measured in terms of estimated

[12] One of the principal activities that takes place in the NHS is information discovery, and approaches to health policy that assume that things that remain to be discovered are things that are already known should properly be treated with some scepticism.

quality-adjusted life years (QALYs). It is stated that *"Under a value-based pricing approach, a maximum ICER would be set for all drugs. The price of a branded good could not exceed the level at which its ICER (relative to the comparator product) reaches this threshold."* A figure of £20,000 per QALY is suggested in the annexe material.

There are multiple problems with this suggestion, but here we focus on just one (others will be noted later, below). The price at which the ICER is equal to the value-of-a-QALY threshold depends upon the anticipated quantity of the drug that will be used, as shown in Figure 2. This follows by virtue of the downward sloping marginal valuation curve, as illustrated in Figure 1.

Figure 2



Put simply and non-technically, there may be some patients who would benefit very substantially from a new drug. If the drug is restricted to these patients, a very high price may be determined from the suggested approach. If the drug is to be prescribed more widely, a lower price will be determined. Which of these prices is the more appropriate? The OFT's preferred option does not say.

If price were determined via a market, the indeterminacy would be resolved by supply side valuations, otherwise known as costs. Multiple demand side valuations (emanating from the diverse individuals consuming the product in differing quantities) and multiple supply side valuations (the costs of competing suppliers) would interact to determine, simultaneously, market price/value and market quantity/volume. However, in the OFT's preferred option, it would appear, at first sight, that the supply side influence on price determination has been abolished. As one commentator has put it, such "value-based pricing" is a kind of mirror image of Marx's labour theory of value: one abolishes the demand side, the other abolishes the supply side.

The price/quantity duality can not, however, be abolished in practice; and it keeps popping up throughout the Report, in a non-systematic way. It is precisely when this relationship is most explicitly recognised that economic analysis in the Report is at its

most coherent, as for example in the discussions of non-linear pricing in Annexe L, which contain suggestions for developments in policy that certainly merit further exploration (the potential benefits of price-volume agreements are obvious, and, as is often the case for discriminatory pricing schemes – and non-linear pricing is a form of price discrimination – the trickier issues lie chiefly in whether feasible implementations can be found.)

If, however, one wanted to explore the notion of "value-based pricing" further in a 'single-price' context, so far as we can see on a preliminary inspection the only way of making sense of it (without introducing supply-side information) is to determine the maximum price as the price at which the relevant ICER is equal to the designated value-of-a-QALY for that patient, or that group of patients, who would derive the *maximum* estimated benefit from the medicine. Any lower level for the maximum price would potentially discourage the supply of drugs in circumstances where supply would be both profitable and (net of costs to the NHS) beneficial to some patients. In a very obvious and direct meaning of the expression, such an approach would be anti-competitive – it would tend to deter beneficial supplies – and this is, of course, the classic outcome of price controls that are excessively stringent (which serves as a reminder that, whatever the euphemisms used, price control is price control, and it comes with a well-understood family of problems of its own.)

Impact assessment

The lack of explicit identification of a 'do nothing' option has been noted above, and it follows that the Report contains no focused, comprehensive assessment of the consequences of allowing the PPRS to operate and to evolve in the ways that have characterised its previous history. There are a variety of insights scattered throughout the Report and its annexes that are potentially relevant for the missing exercise, most particularly in sections dealing with limitations of the PPRS, but the material is not pulled together and there are some major omissions (see the earlier discussion of statins, particularly in relation to the neglect of relevant evidence for 2006).

Similar problems occur in relation to the OFT's assessment of the effects of its preferred, "value-based pricing" option, which includes both *ex ante* and *ex post* valuation exercises. The view might have been taken that it was not the responsibility of the OFT to engage in detailed assessment of the potential impacts if implementing the preferred option, since all that was being done at this stage was to put a possible line of policy development on to the policy agenda, for further consideration by other parts of government. Such a view might have been sustainable if the Report had been presented in a low-key way, and if the proposals had been subject to appropriate 'health warnings'. The tone of the Report is, however, much more evangelical and enthusiastic than that, and, in effect, seeks to 'sell' a very particular approach. We think, therefore, that a rather greater level of responsibility is required: if particular policy proposals are to be enthusiastically advocated by a public body, in a way that is likely to exert significant influence on later assessments, that body should be required to ensure that the favoured proposals are well founded in evidence and reason.

Assessment of ex ante aspects of the OFT's preferred "value-based pricing option"

The most fundamental weakness of the PPRS Report's proposals is that they fail to recognise what would almost certainly have been much more apparent if a more structured and open assessment process had been followed: that relatively mechanistic, technocratic price-setting of the sort that seems to be implied by the favoured ICER methodology could, with a relatively high probability, turn into a public policy disaster.

There are so many points to be made here that they could fill a book; but there is no need for that since the books and papers have already been written, and all that it is needful to do is to read them. For brevity, we here consider just one theoretical point and just one major piece of evidence, but emphasise that these are just the tips of very large icebergs.

The theoretical point is that the QALY, which is intended to be a measure of output, is not a 'value free' measure.[13] It depends upon assumptions about public values and, at a minimum in current implementations (though, in our view, also in all likely feasible implementations), it is not based on 'values' consistent with those of patients or doctors or taxpayers. What we mean by this is that, mechanistic application of a cost-per-QALY measure to ration resources would lead to NHS decisions that could be expected to meet with widespread, almost consensual, opposition.

To be clear, this is not a point about public resistance to the inevitability of rationing. It is a point about the *form* of rationing. Rationing is a fact of life, and its existence is widely, albeit usually implicitly, accepted (notwithstanding rationing, the NHS enjoys considerable public legitimacy). But certain ways of rationing would not be acceptable, and mechanistic rationing via ICERs is, in all likelihood, one of them.

Immediate corroboration of this point is available from Sweden, a country with a political culture in which experts/technocrats arguably command rather more respect than they do in the UK. Contrary to impressions that might be given by one or two sections of the PPRS Report, *ex ante* assessments of therapeutic effects in Sweden do not lead to prices being set on the basis of value-per-QALY estimates. As is correctly explained in Annexe K of the Report, the assessment body (the LFN) takes prices indicated by pharmaceutical manufactures and, given these prices, forms views about the appropriate *usage* of the relevant products. That is, the LFN is <u>not</u> a price setting agency. More importantly, the criteria to be used by the LFN include, but are not restricted to, cost-effectiveness analysis (CEA) thresholds. The criteria (see Annexe K) are:

- human value: respect for equality
- need and solidarity: those in greatest need take precedence, and

[13] Similarities with central planning, particularly in relation to the considerable efforts made to develop <u>single</u> output indicators that can be used to measure and reward performance, are worth noting in passing here, not least because 'soviet economics' is much less taught than it used to be, and things can get forgotten that should not be forgotten … such as the story of the chandeliers. Question: how should the output of chandeliers be measured? Planners' answer: by weight. Outcome: lots of ceiling reinforcement work required.

• cost effectiveness.

What the broad terms in this list (human value, equality, need, solidarity) mean in practice is a matter for determination in each individual context. They are not precisely defined, and quite deliberately so, because any attempt at an acceptable definition would almost certainly fail, for the same reason as the QALY is not a good measure of NHS output: values differ, they are impossible to aggregate, and, necessarily, they have to be reconciled by social, market and political processes that are accepted as legitimate by the public. In practice, the LFN has approved applications for particular medicines which, on the therapeutic assessments, imply a cost-per-QALY well in excess of any threshold that might be deemed appropriate as a general benchmark for the health sector as a whole.

Many of the issues of relevance to an assessment of the OFT's preferred option are explored in a recent book, *Using Cost-Effectiveness Analysis to Improve Health Care: Opportunities and Barriers* by Peter J. Neumann (New York: Oxford University Press, 2005), which examines possible reasons for the relative failure of CEA in the USA, or what is referred to as *"the persistent failure of rational intentions."*. A good sense of the debate can be gained by reading Neumann's short book together with a review ("What Politics May Be Telling Us About Cost-Effectiveness Analysis", *Health Affairs*, 24, No. 4, 2005) by a fellow Harvard Professor, Daniel Carpenter. Neumann is an enthusiastic advocate of CEA: Carpenter is, like us, more sceptical, and concludes as follows:

"Peter Neumann has, then, provided students of health policy with a commencement of sorts, a guide into understanding the political and economic failure of CEA. Yet he fails to persuade us of his fundamental message, that "the United States' failure to use CEA is driven more by its own cultural, political and institutional conditions than by the technique's inherent methodological shortcomings." If politics is telling us something informative, and if the message of CEA critics is less about resistance to limits and more about resistance to centralization and formalization, then CEA's "methodological shortcomings" may be more deeply implicated in its failure than academics want to believe." [14]

Our own views are closer to those of Carpenter, but the detail of the debate is not the important thing here. Rather, the 'take-home' points to be noted are that:

- There is a reasonable consensus about the failure of CEA in the US, though not about the causes of that failure. The most famous failure occurred in Oregon; and assessing prospects for CEA in the UK without reference to Oregon is a little like assessing energy market reforms without reference to California (a spectacular policy disaster which, for better or worse, had career

[14] We think this last reference to academics is a little too generalised. The inherent shortcomings of central planning, in all its various guises, were well exposed in the course of twentieth century economic debates – of which the exchanges between Lange and von Hayek are probably the most famous – and the periodic resurgences of enthusiasm for the *deus ex machina* of the social planner are nowadays found only in relatively isolated pockets of the academies, and are largely confined to those who have never seen administrative price fixing up close (never a pretty sight).

enhancing effects for Governor Schwarzenegger, but not for his Democratic predecessor).

- There is a reasonable consensus that CEA should not be used rigidly/mechanically, and should be viewed as just one of the inputs into health policy decisions. Neumann concludes: *"Leaders in the field have always warned against using CEA rigidly, but it took the Oregon plan's misadventures to drive home the lesson. That experience should dissuade others from attempting to use CEA in a mechanical fashion. The Oregon experience should also caution policy makers to lower expectations in the first place."* Similarly, the US Panel on the Cost-Effectiveness in Health and Medicine has said that *"cost-effectiveness analyses are an aid to decision making, not a complete procedure for making decisions, because they cannot incorporate all the values relevant to the decisions."* To which all that needs to be said is 'precisely so'.

None of this is taken into account by the PPRS Report, which, on this count, reads like a doctoral thesis which has omitted to include, even in its extensive bibliography, any reference to material which is of central importance for what it is that is being argued. This is, therefore, a very major deficiency of the market study. There is a wealth of experience and evidence that is directly relevant to an assessment of the likely effects of the OFT's preferred option for reform, which lies toward the rigid/mechanical end of the spectrum of approaches to the use of CEA, but it just has not been considered.

Assessment of ex post aspects of the OFT's preferred "value-based pricing option"

We end by noting that, surprisingly given that this is an OFT exercise, the PPRS Report's proposals for *ex post* cost-effectiveness assessment are developed and advocated with relatively little regard to their potentially adverse effects on competition in general, and on generics competition in particular.

It is suggested in the PPRS Report that where a generic product is available that is similar in its therapeutic effects to a branded drug the maximum price of the latter should be set at some premium – 25% and 50% being the numbers mentioned – to the relevant generic price.[15] It can be noted that, in some cases, the latter may be a very low market price indeed, and hence that the commercial value of any premium to the brand owner may likewise be very modest. Although the OFT argues that the premium is designed to offset any anti-competitive effects of the maximum price, the small tolerances involved when the benchmark price is very low suggest that this may be no more than wishful thinking. There is no attempted quantification of effects in the Report, and no objective basis is given for the choice of a 25% or 50% threshold.

[15] The incoherence of the notion of value-based pricing is again evident in the proposed 25%/50% premium. It may be the case, for example, that whilst a generic is a good therapeutic alternative to a branded product for many patients, there are individual patients or patient groups for whom it is not. The 'value' of the brand for these latter patients, measured relative to the generic, might therefore be much higher than is allowed for in the proposed premium.

If the proposed pricing rule – e.g. the branded product price to be no more than 25% higher than a comparator generic price – is restated in an alternative, economically equivalent way – e.g. the generic price can be no less than 20% below the relevant brand price – some of the potentially anti-competitive effects of the proposed rule are more easily grasped. Specifically, the proposal would render deep discounting (relative to a 'competing' brand) of generics infeasible. Particularly if there are problems of limited price sensitivity on the demand side, the effect may be that generic penetration would be impeded.

More generally, excessively tight price controls serve as a disincentive to supply. This may be a short-run effect (withdrawal of existing products from the market because of lack of profitability) or a long-run effect (fewer new products of the relevant type coming on to the market in the first place). The significance of these effects can be expected to vary with context. In some markets, restriction to a 25% premium over a comparator product may have little economic effect; in other markets it might have highly negative effects. Unless the premium is set sufficiently high, across-the-board standardisation in price setting, which reduces the flexibility of prices to respond to variations in market contexts, is in itself one of the potentially adverse features of price control; and potentially unwanted consequences certainly stand to be assessed. Pharmaceuticals markets vary from product to product, and there is no *prima facie* reason to believe that a 'one-size-fits-all' approach will be appropriate. Since, in this case, the possible adverse effects concern potential restrictions of competition, it might have been expected that the OFT would have given them particular attention, but the competition assessment is extremely limited.

Depending upon how it is implemented, the OFT's preferred option might sometimes be expected to lead to very rapid, downward movements in branded drug prices when comparator generics are introduced into the market.[16] That seems to be the intention, since great play is made in the Report of the expenditure savings that might be achieved in the short term (and, if significant lags between generic entry and subsequent price adjustments for branded products were to be allowed, it becomes more difficult to see how resulting expenditure reductions could be expected to amount to very much).

It is, however, a standard proposition in industrial economics that highly reactive pricing conduct on the part of incumbents serves to reduce the payoffs from new entry, and hence can serve to limit new entry (because the newcomer is unable to establish a sufficient price advantage over established suppliers). The OFT's preferred option therefore introduces an obvious risk that generic entry could be harmed, and, once again, that is potentially a highly material risk that stands to be assessed. There is currently nothing in the Report that gives comfort on the point.

The relative neglect of the possible anti-competitive effects of the introduction of a standard, across-all-markets pricing constraint might be justified if there were reason to believe that the effects were not likely to be appreciable; but no grounds for such a belief are provided. The intensity of generics competition varies considerably across pharmaceuticals markets, depending in part on the size of the relevant market: in

[16] We say 'sometimes', because one of the potential effects of the proposal is to cause higher initial generic prices, since there will be restrictions on maximum levels of discount against existing products.

some markets generic competition strong, in others it is relatively weak, and in some markets there is no generic entry at all.

Where competition is already weak, special responsibility falls upon those who might do things that could weaken it further. The OFT knows that, because that is a principle that the courts have enunciated in relation to the application of Chapter 2 of the Competition Act and Article 82 of the European Treaty, which the OFT enforces. Yet here in the PPRS market study, when advocating benchmarking of on-patent brands on generics, the OFT appears, by virtue of the thinness of its analysis of likely consequences for competition, to pay scant heed to that principle.

Whilst the above comments place particular emphasis on potential negative implications for competition, the more general issue that stands to be assessed here is the potential for unintended consequences to follow from implementation of the preferred policy approach. The prominence that RIA guidance typically gives to the explicit assessment of any risks and unintended consequences that might flow from the implementation of a particular policy option is an attempt – through the use of procedural requirements – to counter known tendencies to neglect, or to give inadequate attention to, the assessment of such potential impacts.

The PPRS Study exhibits these known tendencies, in that very little attention is given to the consideration of risks and unintended consequences that might be caused by the preferred approach. This is particularly surprising given the economic, political and social significance of the matters under investigation; the good performance track-record of existing UK policies; and the plentiful availability of evidence on practical experiences with the kind of CEA approach that appears to underpin the OFT's preferred option, including on pitfalls to be avoided. However, whether surprising or not, the relative neglect of the relevant considerations is another, significant failing of the market study.

Conclusions

Had the OFT restricted itself to a Report that was designed to *"improve the terms of the debate"* on pharmaceutical pricing, we would have judged the exercise to have been useful and thought-provoking. The weaknesses identified would still, of course, have been there, but they would not have weighed more heavily in the balance against the variety of interesting points raised in what is a very long document. Indeed mistakes and errors are all part of any regulatory discourse, and a 'good mistake' can often be very productive in promoting clearer thinking and analysis.

In the event, however, the OFT has not so restricted itself. The Report claims to have identified hundreds of millions of pounds in savings that could be made from reform of current pharmaceutical pricing arrangements, and seeks to promote a particular way forward, under the label of "value-based pricing". Assessment against higher standards is appropriate, therefore, and against these standards – which are required of other parts of government when seeking to promote regulatory reform – the Report comes up badly short.

The claims concerning savings are unsubstantiated: evidence has been ignored, the accounting counts pluses but not minuses, and the relevant economic trade-off

between short-term and long-term efficiency effects, around which any successful drug reimbursement system must necessarily be built, has not been properly recognised or assessed

A preferred course of action has been identified which, so far as we can see, rests upon an approach to the use of cost-effectiveness assessment with a history of failure behind it. Literature and evidence on these failures – which are matters of record, and can be discovered by simple internet search – are simply not considered in the Report.

Surprisingly, the preferred approach rests upon what is, at bottom, a central planning system, with prices determined, or at least heavily influenced, by experts/technocrats/ planners, and with a strong emphasis on centralisation and an exploitation of (state) market power. It might have been expected that the OFT would have been more sympathetic to decentralisation, competition and the values of patients, doctors and taxpayers, in part because this is the kind of (rebuttable) presumption it more typically works with in other contexts, and in part because this is the (widely supported) current direction of government policy.

These are strong criticisms, but they are intended to be constructive. The OFT has highly skilled staff, and we think that the underlying weaknesses have more to do with process deficiencies that with any lack of capability to address regulatory issues. Good regulation depends to a substantial degree on good regulatory discourse. Keynes famously said that *"It is astonishing how many foolish things one can temporarily believe if one thinks too long alone",* and the same might be said of small groups of experts which have become detached, or semi-detached, from wider discourses. That is, group-think can be foolish too.

This raises something of a difficulty for public agencies entrusted with competition law duties (and this includes sectoral regulators, as well as the OFT). For good legal reasons, enforcement of the Competition Act and of Articles 81 and 82 of the European Treaty tends to be organised around small case teams who, in relation to many of the relevant matters, operate in a way that (formalistically) limits interactions with the rest of the world. The process model (which might be characterised loosely as 'closed') is therefore rather different from the wider discourse, dialogue and consultation ('open') procedures that are advocated, with good cause, by those parts of government seeking to promote better regulation. In our view, the 'closed' approach is deficient for the purposes of regulatory impact assessment, and that deficiency shows in the PPRS Report.

Given these various points, we have two broad-brush recommendations for the OFT:

- Be cautious not to exaggerate the value of the output of the Office. Claiming to have identified hundreds of millions of pounds worth of value added may play well in the media, and may appear to help in the next round of government budget allocations, but, in the absence of adequate substantiation, it might be viewed as a form of mis-selling, a practice that is not always good for business and that, whether good for business or not, should not be tolerated by the OFT.

- Consider whether the conduct of market studies, or at least what are referred to as 'full' market studies, should be subject to procedures that are more in line with those required of other parts of government when conducting similar sorts of exercises (or, in the case of the Competition Commission, rules of procedure that have been developed, without formal requirement, to improve openness, dialogue and discourse).

Whilst these are matters of process and presentation, the importance of the points for substantive outcomes should not be underestimated. The initiation of a market study in relation to any given area of economic activity can – at least if the OFT is to be listened to in the way that it would like to be listened to – potentially give rise to significantly increased uncertainties about the conduct of future regulatory policy for businesses engaged in the relevant activities. Defined procedures – of the kind set out in RIA guidelines, and by the CC in relation to market investigations – can be understood as providing a form of 'right' to parties that may be affected by subsequent decisions: they can expect that relevant issues will be assessed in a structured and transparent manner that should provide opportunities to respond at different stages of the process. These procedures can thus help to reduce the likelihood of 'surprises' and guard against 'opportunistic' public policy interventions, and, in doing so, can limit some of the uncertainties that are inevitably generated by review processes.

The PPRS Report explicitly recognises the central importance of having institutions that are able to withstand pressures to engage in opportunistic price cutting behaviour, in order to avoid undermining incentives to invest in valuable drugs in the future. However, at the same time, the Report itself is presented as having identified *hundreds of millions of pounds of expenditure per year that could be used more effectively under value-based pricing.* The potential impact of this and other rather grand (unsubstantiated) claims on policy/regulatory credibility/uncertainty appears to have been wholly ignored (or least treated as of little significance). Indeed, given the multiple, and rather obvious, problems associated with the 'efficiency savings' estimates, one potential interpretation of the Report is that it might mark a shift toward more opportunistic NHS procurement policies in the future. Although we do not think that that is at all what the OFT intends, it needs to be borne in mind that policy credibility can take a long while to establish, and that it can be lost very quickly.

In relation to substantive issues raised in the PPRS Report, our views are that the following points are well made by the OFT:

- That the profit cap has not recently been a significant constraint for many companies – although we would suggest that this is indicative evidence of some success in demand-side reforms in the NHS, and that the profit-cap can still potentially serve as a precautionary, back-stop control to protect against risk of serious problems in the future.

- That the price cut aspect of the PPRS is problematic and lacks 'objective justification' – although here we note that there is some protection against adverse effects by virtue of the voluntary nature of the scheme, and further that it is possible to envisage incremental reforms, possibly including inputs

from CEA, that could increase regulatory certainty/credibility at the cost of a modest expansion of resources devoted to the problems within the DH.

- That price-volume agreements or other forms of 'non-linear' pricing have potential to enhance the effectiveness of the PPRS – although the difficulties lie largely in developing practical implementations, and significant, further work would be necessary to test feasibility.

On the other hand, we consider the following conclusions of the Report to be unsubstantiated and unsafe:

- That the OFT has *"identified hundreds of millions of pounds of expenditure per year that could be used more effectively under value-based pricing"*. The relevant assessment exercises are manifestly flawed.

- That current profit and price controls be replaced with a *"value-based approach to pricing"* – which is a notion that lacks coherent, economic meaning and seems to ignore the fact that prices should, and most probably actually already do, reflect both demand- and supply-side factors.

- That the determination of value is an activity that is best done technocratically, by a small group of experts, via cost-effectiveness analysis – there is no need to look into the crystal ball on this, since the book of relative failure can easily be read, and such an approach flies in the face of current health policy.

- That *ex post* benchmarking of on-patent drugs prices to generic alternatives could be expected, other than at a very high allowed price premium, to have no harmful effects on competition in its various dimensions (e.g. inter-brand competition, generic competition, and competition in R&D and innovation) – relevant assessment is missing from the Report.

- That the proposed OFT reforms would lead to better incentives to invest – the pursuit of unsustainable policies could only inject considerable regulatory uncertainty into a policy area characterised by steady evolution over a fifty year period, and is unlikely to be positive for investment incentives.