

REGULATING PRICES PAID BY THE NHS FOR MEDICINES SUPPLIED BY THE UK-BASED PHARMACEUTICAL INDUSTRY

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I. INTRODUCTION

Expenditure on pharmaceuticals by the National Health Service (NHS) amounted to £4.7 billion in 1995, making up about 12 per cent of total expenditure on the NHS (McGuigan, 1997).

Moreover, public expenditure on pharmaceuticals is one of the fastest growing components of NHS expenditure in real terms – up by more than 60 per cent on a per capita basis in the 1980s. This growth of expenditure arises from both demand and supply-side pressures – notably increased longevity, and the increasing costs and risks of developing new pharmaceuticals, which mean that improvements in the quality of medicines are accompanied by higher real prices.

Over the last few years, the UK Government has given increasing attention to controlling public pharmaceutical expenditure. Many of its efforts have been directed at the 'demand side' of the market, limiting the range of medicines which doctors may prescribe through an extension of the Selected List Scheme, and setting target budgets with financial incentive schemes for non-fundholding GPs and cash budgets for fundholders. But attention has also focused on control of prices. In 1993, the profit and price control mechanism, the Pharmaceutical Price Regulation Scheme or PPRS, was renegotiated, and a 2.5 per cent reduction in prices agreed. The NHS drugs budget has also been the subject of detailed scrutiny by the House of Commons Health Committee (Health Committee, 1994). Its report, published in July 1994, included some criticisms of the PPRS and elicited a response by the Government (Department of Health, 1994).

The aim of this paper is to review alternative methods of regulating the price of pharmaceuticals bought by the NHS from the perspective of the experience of the economic regulation of other industries in the UK, notably the privatised utilities. The NHS procures medicines in a variety of ways, subject to different methods of price control, but the main control is on profits via the PPRS (see Box 1). The emphasis in privatised utility regulation in the UK

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Table 1: Structure of Utility Regulation

	Telecoms	Gas	Electricity	Water	Airports
Regulator	Director General of OFTEL Also MMC	Director General of OFGAS Also MMC	Director General of OFFER Also MMC	Director General of OFWAT Also Environmental Agency, MMC	Civil Aviation Authority (CAA) Also MMC
Main aspects of activity subject to price control	Most residential, international and domestic calls, line rentals and connection charges	Transmission, Distribution, Supply to Domestic Customers	Transmission, Distribution, Supply to Domestic Customers	Supply of water and sewerage services	Airport charges and services
Main Price Control Mechanism	RPI-X	RPI-X	RPI-X	RPI+K	RPI-X

Source: Adapted from Baldwin (1995), Table 1

has been on the use of incentive regulation in the form of an RPI-X price control (combining an increase for inflation with an efficiency target) and, where possible, the creation of market conditions which allow competition and so reduce or remove the need for regulation. Table 1 gives an overview of utility regulation. There has been a widespread assumption that profit control based on 'cost-plus' regulation is less effective in getting value-for-money for the consumer because it does not create the same incentives for efficiency. As the current PPRS is due to expire in October 1998 it is timely to consider whether experience elsewhere suggests it should be replaced by a different type of regime.

The paper evaluates the PPRS scheme against possible alternative types of economic regime, given the assumptions underlying UK privatised utility regulation and competition policy. The experience of other major European countries in regulating pharmaceuticals is also considered. It is structured as follows:

- **Section 2** outlines the objectives we believe appropriate for price control regimes in general, and pharmaceuticals in particular;
- **Section 3** sets out the types of price control methods used in the utility sector and the nature of the implicit contract between the regulator and the companies;
- **Section 4** then examines whether these alternative price control regimes could be efficiently applied in the case of pharmaceuticals, looking at overall price levels and, drawing on experience of pharmaceutical regulation elsewhere, relative price levels;
- **Section 5** discusses the transparency with which the current PPRS scheme operates;
- **Section 6** gives our conclusions.

BOX 1

PRICE CONTROL FOR GENERIC AND BRANDED MEDICINES SOLD TO THE NHS

There are separate systems of price control. Generic medicines are subject to a form of price control designed to prevent pharmacists being paid above an average price for that category of medicine. The system embodies an elegant device known as yardstick or comparative competition, (Shleifer, 1985) which gives each pharmacist an incentive to 'beat the average' and thus should bring average prices down. Technically there are two incentive mechanisms at work. The Drug Tariff is a set of published prices at which the NHS will reimburse pharmacists for meeting generic prescriptions. Where more than one generic is available, the Tariff is set by reference to the average market price of the major wholesalers. Pharmacists have an incentive to buy below the Drug Tariff price, and so wholesalers compete to supply at lower prices. This will in turn reduce the Drug Tariff price when it is periodically recalculated.

In addition to the Drug Tariff, the Government operates a Discount Clawback, which applies to all NHS medicine purchases made by retail pharmacists. An assumption about the discounts pharmacists can obtain from wholesalers is made and deducted, or 'clawed back' from the sums reimbursed by the NHS. The clawback is based on surveys of the discounts obtained by pharmacists. Thus pharmacists have an incentive to beat the average, and this in turn will lead to a higher clawback in due course.

The bulk of NHS expenditure consists of branded prescription medicines and these have been subject to a regime of price control first introduced on a voluntary basis in 1957. The purposes of the Pharmaceutical Price Regulation Scheme (PPRS) are to:

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

Under current rules all companies selling branded medicines to the NHS are subject to the PPRS. However, most regulation focuses on the large companies. In the case of companies whose annual sales to the NHS are more than £20 million a year a return on capital target is set within a 17 per cent to 21 per cent range, although in some cases companies have relatively little capital investment in the UK and are given a return on sales target. The 17-21 per cent range was agreed by reference to the average profitability of all sectors of UK industry as measured by the FT500. An Annual Financial Return (AFR) to the Department of Health has to be completed within six months of the end of the accounting year. This contains information about the breakdown of the company's turnover between sales of NHS medicines, export sales of medicines and sales of other products. The company also provides copies of its accounts.

Companies are entitled to price individual new medicines (i.e. those with a new active chemical or biological substance) as they wish providing turnover from the new medicine is not expected to exceed £20m in any of the first 5 years after launch or to cause the company to exceed its return on capital target by more than 25 per cent. Pricing freedom is also allowed on line extensions within the first five years of a new products' life. Once launched, however, products cannot normally be increased in price. This means that the PPRS contains a reasonably strong form of price control within it by preventing price increases for established products. This is equivalent to an RPI-X price control as used by regulators in the utility sector and discussed later in the paper.

On the basis of the information provided in the AFR the company's capital and expenditure is assessed to see if it is reasonable, and adjustments made if necessary. Separate formulas for allowable expenditure are applied to R&D and to promotional expenditure. Provided the company's profits are then within 25 per cent of their target value, no further action is taken. If they fall above the range, the company may be required either to reduce its prices subsequently or to repay the excess profit. If profits are below the range the company is allowed to seek price increases. The Tables below show the extent of such interventions. We should note, however, that these predate the 1993 revisions to the Scheme which reduced the allowable excess profit from 50 per cent to 25 per cent and reduced the scope for seeking price increases. The current PPRS falls into the form of price regulation (described further below), known as a banded profit control system.

PRICE INCREASES, PRICE REDUCTIONS AND REPAYMENTS OF EXCESS PROFIT UNDER THE PPRS, 1988 TO 1992

A – Price increases

The following price increases were permitted to companies with sales to the NHS above £4 million per annum, providing detailed annual financial returns.

Year	Price increases	Value of increases (£m)	Per cent PPRS sales
1988	23	36	2.9
1989	14	12	0.6
1990	11	11	0.5
1991	13	20	0.8
1992	18	10	N/A

Source: Health Committee, (1994)
N/A=not available

B – Price reductions and repayments of excess profits and sales promotion

Year	Number of companies			
	With excess profits Company view	With excess profits DoH view	Making price reductions	Making excess payments
1988	11	38	1	23
1989	9	38	2	24
1990	8	32	1	27
1991	9	43	0	17
1992	N/A	N/A	1	–

Source: Health Committee, (1994)
N/A=not available

The 1993 Scheme also introduced a one-off 2.5 per cent price cut, which is outside of the return on capital formula (i.e. the revenue is added back before profit is calculated). This was meant to unwind after 3 years (i.e. in October 1996) but the government decided it was to remain in place until October 1998 when the present PPRS ends. For further information on the PPRS see Department of Health (1996), Health Committee (1994), and Pharma Pricing Review (1996a, 1996b).

2. OBJECTIVES AND EVALUATION CRITERIA

The natural questions to ask of a price control regime are the following:

- Does it promote 'static efficiency', in the sense that it gives firms an incentive to minimise the costs of reducing their existing range of outputs and to set prices at levels which will encourage desirable levels of consumption?
- Does it promote 'dynamic efficiency', in the form of creating incentives to develop new products and bring them to the market at appropriate times?

- Does it encourage the generation of profits from exports and royalties from overseas, which would be in addition to benefits which accrue to domestic consumers?

- Is it capable of meeting social policy and equity objectives? These are particularly important in the health care sector.

We can note that these evaluation criteria broadly match the stated purposes of the PPRS, as set out in Box 1, to obtain medicines for the NHS at reasonable prices, and create a profitable industry that can innovate and export. We briefly discuss these criteria in turn.

2.1 Static Efficiency

Static efficiency has two components – efficient production and efficient pricing. Efficient production is relatively easy to define, although difficult both to measure and to achieve. Efficient pricing is more complex and we therefore concentrate below on the capacity of different price control regimes to achieve an efficient set of prices.

The primary requirement of static efficient pricing is that domestic prices should be set in a manner which encourages optimal current levels of consumption. As is well known, in informed markets, this is normally achieved by marginal cost pricing. In the case of pharmaceutical products marginal cost is substantially below average total cost because of the considerable sunk research and development costs and fixed production capacity cost, and the imposition of marginal cost pricing would obviously impose losses upon the companies. One possibility, pursued in some countries, is to free-ride on others' R&D, and concentrate on manufacturing generic medicines, by setting prices that cover production and selling costs but not R&D costs. Given the evidence (see 2.3 below) of the high economic value of the UK-based industry as presently organised, it would not make sense for Britain to throw away its lead in pharmaceutical research, and take the 'generic' route. Even if such an option were attempted, it could fail to achieve expected net gains for the NHS. This is because companies may withdraw products from the UK market in order to avoid low-priced products being exported to other EU markets. Alternatively, low UK prices may lead to low prices elsewhere through their inclusion in price comparisons used for price setting by purchasers in other countries, so reducing global R&D expenditures, which in turn will reduce the flow of new products offering benefits to NHS patients.

What is therefore required is a system or market structure which allows firms to recover efficiently incurred R&D costs without, on average, making excessive rates of profit (i.e. above the risk adjusted cost of capital). However, the definition of 'efficiently incurred' is complex. Clearly it does not mean that only R&D expenditure incurred on substances ultimately prescribed to patients should be recovered; it is well known that much R&D goes on unsuccessful developments which nonetheless are worth a try. Yet to provide an incentive for efficient R&D, firms must bear some risks. The problem is that, in any pricing regime, the rate of profit it allows and the appropriate level of R&D are interlinked. In other words, we are dealing with a complex

set of trade-offs in which profits are likely to be uncertain: the system should aim to provide incentives, and not to allow firms to hit a pre-ordained profits target irrespective of their performance in terms of innovation and cost control.

Another requirement for static efficiency in pricing is that, in making prescribing decisions, doctors ensure that relative prices do not exceed their valuations of relative therapeutic merits. Thus in an ideal world prices should carry both information about relative costs and relative benefits. Medical practitioners, acting as agents both for the Government (as the funder of the NHS) and for patients, would then prescribe appropriately depending on their assessment of relative benefits and this would in turn influence companies' prices. We discuss below how far it is possible to capture relative benefits in the price system. But even if this is possible, for the process to work it is essential that prescribers take account of the prices of alternative treatments. Despite Government policy intended to disseminate information on costs, it is still quite likely that many doctors do not respond to price signals in the way required to ensure price competition between companies, although Towse (1997a) reported evidence that greater price competition was occurring in the 1990s.

A study of GP price awareness (Ryan et al, 1992), predating the NHS reforms of 1991, showed limited knowledge of prices, and the Audit Commission (Audit Commission, 1994) criticised GPs for prescribing medicines with 'convenience' price premiums that were not justified by any extra clinical benefit. It may well be that GPs do not share the Audit Commission's view of the appropriate trade-off between extra cost and extra patient convenience. We return to this trade-off later in the paper in our discussion of the role of health economics. However, we would expect the Governments' 'demand side' measures to increase price awareness and price sensitivity over time and a recent survey of 600 GPs (Silcock et al, 1997) found that most GPs believed that prescribing costs should be taken into account when determining the appropriate treatment for an individual patient. When asked to price 31 products, the GPs got one third right, (49 per cent of expensive products) with fundholders being significantly more knowledgeable than non-fundholders about cheap (<£10) and very cheap (<£1) medicines.

2.2 Dynamic efficiency

The requirement of dynamic efficiency is that appropriate incentives should be present to encourage competitive research and

development. Several authors have argued that, given the opportunities which exist for competition with product differentiation, dynamic efficiency is best achieved by the Schumpeterian process of permitting excess profits to serve as an entry signal. (For a discussion, see Teeling-Smith, 1992.) This argument has also been employed by 'Austrian School' critics of the price controls on UK privatised utilities. For example, Beesley and Laidlaw, (1989) argued that imposing price controls on BT, so reducing the profitability of the UK telecoms market, would slow down the rate of entry by competitors, and reduce the incentive to innovate. Alternatively, it can be argued that, in the case of the incentive to develop new medicines, since pharmaceutical companies derive only a proportion of their revenues from the NHS, and because considerable pricing freedoms exist in other markets, it is possible to introduce a considerable degree of price control in the UK regulated market (to help achieve static efficiency) without discouraging innovation – provided that the UK market makes an appropriate contribution to R&D costs and does not set prices at a level that, if replicated in other markets, would substantially reduce the returns to innovation.

It has also been suggested that much R&D involves needless duplication of research into chemical entities with almost identical therapeutic properties. There is some anecdotal evidence in favour of the duplication of R&D effort by companies ('tit for tat' strategies), and several models have been constructed in which the desire to win 'patent races' leads to excessive investment in R&D. But other models yield different results, and a quantitative study by Cockburn and Henderson (1994) (see Box 2) of competition in ethical drug discovery provides evidence against the existence of single-prize patent races. Companies that are first to introduce a new 'breakthrough' medicine are followed by competitors with similar products. Indeed the first entrant will usually introduce modified versions of its original product.

These additional products are often called 'me-too' products. A more appropriate term might be 'incremental chemical extensions' (Wells, 1988). In principle this should lead to more choice for doctors as new entrants provide a different profile of product characteristics, and, to the extent that products are similar, to price competition, so improving 'static' efficiency. Concerns arise however because, as we noted above, doctors have not traditionally been price sensitive customers, and subsequent entrants

BOX 2

According to the standard model of 'duplicative investment' in R&D, pharmaceutical firms are seen as being engaged in a race in which there is only one prize – the award of a patent which offers control of the relevant market. Late-comers get nothing, or more accurately their reward is so much delayed through patents that they get next to nothing.

In order to test this hypothesis, Cockburn and Henderson examined R&D expenditure by 10 firms in 38 detailed research areas for a period of up to 30 years.* They were concerned to establish whether R&D investment by product type across firms is highly correlated, suggesting participation in races, and how R&D outputs by product type are related: if there were only one prize, one firm's outputs would be uncorrelated with others', whereas if there were several interdependent prizes, a success by one firm would increase the chances of success by others.

They found that firms' expenditures on R&D are only weakly correlated, after adjustments to common shocks such as changes in the underlying science base are taken into account. This is shown by the failure of competitors' expenditures, current or lagged, to contribute to the explanation of each firm's expenditure, which is dominated by its own past history.

On the output side, they found that one firm's success in gaining an important patent (defined as one issued in two of the major markets – Europe, Japan and the United States) is positively correlated with success on the part of other firms. The finding that outputs are positively correlated suggests that there are significant spill-overs of knowledge across firms' research programmes and that races to discover new entities have several prizes, casting doubt upon some of the conclusions of the literature on patent races.

*Cockburn and Henderson, 'Racing to Invest? The Dynamics of Competition in Medical Drug Discovery', *Journal of Economics and Management Strategy*, Vol. 3, No 3, Fall 1994, pp 481-520.

have charged higher prices than the incumbent, rather than lower. This is starting to change, particularly in the USA, where Health Maintenance Organisations and other insurers are seeking to impose price driven formularies, and well informed Pharmacy Benefit Managers exercise purchasing power in market segments where there are competing products with similar chemical actions and therapeutic effects. As noted earlier there is now some evidence that price competition may be increasing in the UK also (Towse, 1997a). This type of competition reduces the incentives to bring new products into a crowded market place. Thus the existence of large numbers of products in some established therapeutic classes (for example NSAIDS, beta blockers and ACE inhibitors) may have been a consequence of lack of past price-quality sensitivity on the part of doctors.

It is practically impossible to identify optimal levels of innovation in any industry. A regime which allows unsuccessful as well as successful R&D expenditures to be recovered in prices runs the risk of encouraging excessive levels of R&D expenditure (i.e. where the marginal research project undertaken has an expected social benefit below its costs). But it is not the case that a profit control mechanism necessarily provokes more R&D spending than alternative regimes which leave the recovery of such costs more uncertain. If a successful innovation confers huge benefits on the firm in question, without any accompanying control of resulting profits, the prospect of such gains may cause firms to invest more heavily than they might under profit control. Moreover, as discussed in Box 1 there is an effective cap under the PPRS on allowable R&D expressed as a percentage of NHS sales and only companies with successful products will generate NHS sales to cover allowable PPRS R&D costs.

2.3 Profits from overseas

In the case of the pharmaceutical industry, efficiency will also embrace the objective of maintaining a competitive and profitable UK-based industry, generating producer surplus from overseas, as the economic benefits of doing this are currently high. One estimate put these at £2bn per annum (Hale and Towse, 1995), and concluded that 'under all reasonable assumptions the industry is making a net contribution to the UK economy of several hundreds of £millions per annum.' Of course, it could be argued that these benefits could be maintained irrespective of the prices paid by the NHS for pharmaceuticals – perhaps by other targetted incentives. However, as we discuss in sections 2.1 and 2.2 above, NHS price levels and attitudes to rewarding innovation send important signals to the industry and to purchasers in other countries.

2.4 Social policy and equity objectives

Social objectives relating to the provision of health care are achieved most directly through the mechanisms by which health care is made available to patients by the NHS, rather than through the pricing of pharmaceuticals to the NHS. Prescription charges will have an impact on the utilisation of medicines by patients (and also on the overall resources available to the NHS), but as these charges are flat rate, and not related to the prices paid by the NHS for medicines, we do not discuss these further in this paper. (For a discussion of international evidence on charging and utilisation, see Mattison, 1995,

and on the impact of UK prescription charges see Hughes and McGuire, 1995.) Nonetheless, both the overall level of prices, and relative prices, have an impact on the treatment patients receive, as a result of the cash limit that covers most NHS expenditure, and the annual NHS financial settlement.

The detailed implications of these arrangements are not straightforward, because GP prescribing is not cash limited and upward pressure on the medicines bill will increase the realistic settlement for NHS expenditure. However, once set, there is great pressure to contain expenditure on pharmaceuticals to ensure overall NHS spending limits are met, and GPs with budgets or incentive schemes can use savings to provide more of other NHS services. Given effective NHS cash limits, patients are likely to have a preference for low prices. But they also have an interest in ensuring that new therapeutically valuable medicines come onto the market and are available to NHS patients. The difficulty of making these trade-offs was apparent in the debate about the 1992 extension of the Selected List to restrict the medicines available on NHS prescription in 10 therapeutic areas. Patient groups involved in the disease areas affected were worried that more expensive products with some unique clinical effects would be delisted, and that the possibility that new products might not be listed would reduce the incentive to innovate in these disease areas.

3. REGULATION OR CONTRACTING?

Most price regulation in the UK occurs in the utilities sector. Because there is a dominant national or local supplier in the relevant industry (telecoms, water, electricity, gas and airports) the Government has created a regulatory body, as set out in Table 1 on page 2, which can control the prices which the regulated firms may charge to domestic and business customers. These customers include the Government itself, but most of them are households or businesses. This is an important difference between the utilities and NHS pharmaceuticals, where the Department of Health is the only paying customer. Most utility regulation is based on different types of 'RPI-X' price control where prices in aggregate can rise by inflation (RPI) less an element for efficiency improvement (X). These are devised and applied in different ways. There are, however, alternative approaches, such as those used in the PPRS. For a summary of some of the major elements of price regulation, see Box 3.

VARIETIES OF PRICE CONTROL

Prices can be regulated in various ways. This box identifies some of the dimensions of price regulation and gives examples from the field of utilities.

1. Methods of Control

Who decides upon the necessity for, and operates the price control regime? This can be either a Government department (such as the Department of Health in the case of the PPRS) or an independent regulatory agency such as the Office of Telecommunications (OFTEL).

2. Coverage of the Price Control

It is normal for price control to be restricted to those goods or services where the supplier exercises market power, and for other prices to be unregulated, except by normal competition law. For example, in the UK telecommunications sector, equipment sales and value added services are competitive and unregulated, whereas quarterly rental and call charges for most residential customers are controlled by BT's retail price-cap, set by OFTEL.

3. Mode of Operation

Prices can be set at a specified level and remain there until a review, or a price control formula, such as a five year price-cap, can be imposed: firms can then vary prices according to the formula. Thus whilst US utilities normally have to have each individual price increase approved by their State or Federal regulators, in the UK four or five year review periods have usually been used (the current PPRS agreement is a five year one, with an interim three year review point). There are differences in length. The National Grid, for example, was given a three year price cap in 1990, although the subsequent caps have been for four years. UK water companies are subject to a formula for price rises over ten years, but with an option to review after five, which has so far been taken up on both occasions when the opportunity has arisen.

4. How Are Prices Set?

The two principal alternatives are either cost-plus techniques or the setting of 'target' prices. Under the former, companies justify price increases by cost increases, where costs include an allowable rate of return. Under the latter, target prices are set for a period of years, and companies can 'keep' as extra profit the benefits of any cost reductions over and above those assumed for the period for which the 'target' prices were set. Intermediate cases are also possible, in which companies are only allowed to seek price increases, or are required to lower prices, when their rates of return go outside pre-specified bounds.

5. Disaggregation of Price Control

The regulator can set prices either for particular products, as in many US jurisdictions where utility prices are controlled individually, or, as in the UK, control average price levels or average increases in prices. Intermediate variants are also possible, with 'subcaps' on particular groups of products.

6. Resetting the Price-Cap

Price control formulae typically have a limited life, because unpredictable events may otherwise make profits too high or too low. For example, BT's price-cap has, since 1989, been set for four year periods. At the end of that period, the cap is reviewed in the light of BT's current and expected levels of profitability, with a view to restoring a normal rate of return (equal to the company's cost of capital) at the end of the following control period. This delayed feedback retains incentives to improve efficiency. In other industries, the regulator has chosen to bring prices more into line with costs at the start of a new price control period by making a substantial one-off reduction. This policy, if anticipated by the regulated firm, may give it a diminished incentive to cut costs.

7. Determining the Allowed Rate of Return

This is typically done on a basis of comparisons with other 'equivalent' industries, or by the use of financial models which, as a starting point, identify the cost of capital (i.e. the rates of return required by shareholders given the degree of risk in the sector in question). In some regulatory systems, the allowed rate of return is specified in real terms and then has to be translated into a nominal rate on the basis of observed and expected inflation. In others, as with the PPRS, it is specified in nominal terms – i.e. it already incorporates inflation. Although the cost of capital and allowed rate of return for many utilities has been the subject of heated debate, it appears to have been a less controversial issue in the case of the PPRS.

8. Profit Sharing

A hybrid, combining elements of price caps and rate of return regulation, is known as profit-sharing. Under this system, a firm is subject to price cap but in addition has to lower prices further if its profits or rate of profit exceeds some pre-specified threshold. Above this level, profits are shared between investors and consumers. In addition, if profits fall below a certain level, the firm may be entitled to raise prices (loss sharing). Profit-sharing avoids high 'excess' profits but cuts incentives to lower costs. However, this effect can be counterbalanced by extending the period between reviews of the price cap.

For further details on utility regulation see Armstrong et al. (1994), Baldwin (1996), Oxford Review of Economic Policy (1997), Oxford Review of Economic Policy (1996), and Mayer and Vickers (1996).

Price regulation of this kind balances two concerns. Firstly, it is necessary to control the monopoly power potentially held by the dominant incumbent. Secondly, however, it is recognised that, for the industry to develop effectively, some kind of lower bound on prices is also required. The technologies of network utilities are often characterised by the need to make long-term non-salvageable or 'sunk' investments. Investors subject to price control

may fear that the regulator will hold down prices to a degree which effectively expropriates their assets. Concern about such an outcome will discourage investment and undermine the sustainability of the regulated firm. In order to provide some comfort to investors, a system of regulation has thus been established which imposes upon regulators (typically the Secretary of State, the industry specific regulator and the Monopolies and Mergers Commission) a balanced

set of obligations – on one hand to protect consumers, and on the other hand to ensure the capacity of the incumbent to satisfy its obligations, finance its functions, or maintain an ability to attract capital investment.

This arrangement is sometimes referred to as a regulatory contract, formed between the regulator as a representative of consumers and the firm on behalf of its investors. Clearly, it is not a contract in a formal sense, and doubts have been expressed about the reliability of its enforcement mechanism, particularly since the decision of the electricity regulator in March 1995 to revisit a price control proposal he had made only a short time before – which many regarded as already being part of the ‘contract’. It is usually acknowledged that the need for such an informal contract arises from the length of the asset lives and the impossibility of specifying in advance a contract which would take account of all possible contingencies over such a long period.

In the pharmaceutical case, similar problems exist. Companies with new patent protected products are in a position to exploit temporary monopoly power – indeed this is the point of patent protection. Equally, R&D is akin to infrastructure investment; the Government is in a position to use its monopsony power as NHS purchaser to a degree which may prevent the recovery of sunk R&D expenditure, just as a harsh price control regime on a utility may expropriate the value of shareholders’ sunk investments. However, in the pharmaceutical case, the Department of Health plays several roles. As a regulator, it sets an overall profit ceiling and creates a framework for decentralised purchasing. As a customer, it sets limits for pharmaceutical expenditure. It is thus subject, as a customer, to an important budget constraint, to which we return below. It is also the government sponsor of the industry. These roles could be kept organisationally separate, with (say) an OFPHARM regulator, Department of Trade and Industry sponsorship of the industry, and a Department of Health concerned only with overall expenditure. However, these activities are not conceptually separate. Effective regulation involves oversight of market structure, yet organising and incentivising NHS purchasers and prescribers is crucial to Department of Health attempts to contain expenditure and get value for money from it. Likewise purchasing is an important part of sponsorship. The Department of Health has an interest in ensuring not simply that it gets the lowest possible prices today, but that the industry is around to develop and supply new products in the future. The factors that will determine the international competitive success

of the UK-based industry are also those that will determine its ability to meet the future requirements of NHS patients.

In their roles as supplier and customer, the pharmaceutical industry and the NHS are therefore in a situation not dissimilar from those of the owners of a mine and of a nearby power station. The value of either asset to its owner depends critically upon the availability of a suitable contract with the owner of the other. Yet because of the duration of the assets, it is difficult to formulate a detailed contract. In this case, the ‘standard solution’ is to agree some form of indexed price contract with break clauses and – possibly – a provision for arbitration (Joskow, 1987). In a similar way, the Department of Health and pharmaceutical companies are mutually dependent. The industry wants a contract to supply the NHS and the NHS cannot meet its obligations to provide health care to its citizens without contracts to obtain medicines. Because of the complexity of the purchases, a standard indexed price contract is impracticable. Instead, the Department of Health in its role as regulator has the capacity to offer a voluntary agreement which limits to a reasonable return the profits available to companies on the (as yet unknown) quantities and ranges of goods they will supply.

However, the key point is that all the examples noted here – utility pricing, contracting between ‘tied’ companies and the PPRS – have in common the feature that they embody some kind of implicit or explicit contract in the form of a pricing or expenditure control mechanism which offers comfort to both sides. Thus the distinction between the PPRS and utility regulation noted above (that the Government is the budget-constrained purchaser in the former case, but not in the latter) does not prevent lessons being learnt from their price control regimes. In both cases, what is sought is a regime which is efficient, provides incentives, and some security for both parties, avoids opportunism and shares the benefits it creates. In our judgement this effectively rules out simple cost-plus pricing.

4. METHODS OF PRICE REGULATION

We first consider four alternative methods for regulating (or not regulating) the overall level of pharmaceutical prices (in subsections 4.1 to 4.4), and then discuss the implications of the NHS’s budget constraints (section 4.5) and the issue of relative prices within an overall expenditure control (section 4.6).

4.1 Deregulation

The first issue is whether regulation of prices or profits is routinely required. The natural approach to this question, as embodied in general competition policy, is no – unless a supplier has market power in respect of a particular product. In many cases of the supply of medicines, notably those involving generic medicines, no company will have significant market power as entry is relatively easy or there are already many competitors. Hence no regulation of prices is needed to prevent monopolistic exploitation.

In the case of products still protected by patent, there will be a considerable range of possible outcomes. At one end of the range, no effective substitute will exist, and the company will have considerable market power. At the other end of the range a product may have close substitutes which deprive the company of significant market power.

Even where market power exists, there are two factors that may make it unnecessary, and even counterproductive, to regulate prices and profits.

Firstly, purchasers may also be powerful. The Department of Health is the major budget-constrained purchaser of pharmaceuticals in the UK. As discussed earlier, this situation has some of the characteristics of a bilateral monopoly, with the outcome much influenced by the Department's need to control its overall expenditure. (We return to this point in Section 4.5 below). NHS primary care prescribers currently have target budgets or cash limits depending on their fundholding status, but the prices of pharmaceuticals are set nationally. If they were able to negotiate prices and discounts (as in the hospital sector), then price sensitivity might increase, and result in more cost-effective prescribing. However, if many companies had strong market positions, then prices might be higher than under the PPRS regime. There would certainly be a different pattern of prices – some lower and some higher – and different NHS buyers would pay different prices for the same product. The efficiency and incentive effects for the industry would be positive, but the Department of Health may be concerned that prices on average could be higher, with some buyers paying excessive prices.

Secondly, even in the absence of purchaser bargaining power, there is a very respectable tradition of economic analysis, to which we referred above, originating with Joseph Schumpeter, which emphasises the role of temporary monopoly profits as the engine of

innovation and technical progress (see Schumpeter, 1961; Teeling-Smith 1992). A monopoly position will ultimately be eroded by new entrants attracted by the high returns. Indeed patent rights are only temporary, and it could be argued that the point of the patent system is to provide firms with a window of opportunity to exploit intellectual property which has been acquired at considerable expense and which would otherwise be appropriated costlessly, or at lower cost, by competitors. Price controls diminish the ability to exploit the full commercial potential of the patent.

This case was recently put by Scherer (Scherer, 1995), who, whilst accepting that 'the UK model (of regulation) seems particularly intelligent', went on to say that 'regulation is a clumsy instrument for fashioning the delicate trade off between securing competitive prices on the one hand, and maintaining incentives for investment in new product discovery on the other hand. Because new drugs yield substantial consumers' surplus untapped by their developers, even when profits are high, consumers would lose along with producers with price or profits regulation. Should a trade-off be required between modestly excessive prices and profits versus retarded technical progress, it would be better to err on the side of excessive profits.' He argued that stimulating post-patent expiry generic competition would help to bring down medicine costs and ensure companies had to continue seeking important new drugs to earn substantial profits. This has been happening – the NHS has been more effective in recent years in increasing the rate of generic prescribing, and, when major products come off-patent, the speed and size of loss of originator market share can be dramatic.

The choice between no price regulation and price regulation is not a dichotomous one, as intermediate variants exist. These might take the form, for example, for a backstop control preventing any real or nominal price, or set of prices, rising above a specified level. Thus OFTEL has recently introduced a 'safeguard cap' on certain telecommunications services, the markets for which lay in an intermediate position between competitive and non-competitive (OFTEL, 1995, 1996). Controls of this kind would not normally be binding, as competition would normally drive prices below the level chosen. They do, however, protect consumers against unpleasant surprises.

It could be argued that continuing lack of price sensitivity on the part of prescribers (brought about in part by medical ethics and the commitment that NHS patients will receive the medicines they need) together with the inevitably

crude trade-off between dynamic and static competition represented by patent law, requires some form of economic regulation to prevent 'excessive' profits being made by some companies. However, companies exploiting patents are already subject to ordinary competition law, and the Department of Health has other, non-PPRS, powers. The next issue we consider is therefore whether there is a need for a comprehensive PPRS or other price control type scheme, or whether the powers already available to the Department of Health, outside of the PPRS, are sufficient. These are (i) Fair Trading Act referrals to competition bodies, (ii) compulsory licensing powers under patent legislation, and (iii) reserve powers to set maximum prices under NHS legislation. We discuss these briefly in turn.

(i) Fair Trading Act referrals

One of the bases for a company to be referred to the Monopolies and Mergers Commission (MMC) under the Fair Trading Act is excessive prices arising from a dominant market position. Within the pharmaceutical industry, the best known example of this is the MMC report on Chlordiazepoxide and Diazepam (House of Commons Papers, 1972-73, 197). In that report the MMC concluded that Hoffman La Roche's prices for Librium and Valium in the UK had been too high over a number of years. The MMC considered the price of Librium should be reduced to not more than 40 per cent of the 1970 price level and that of Valium to not more than 25 per cent. After much litigation, the company refunded a sum of money to the Department of Health and Social Security and reduced its prices.

More generally, under the Fair Trading Act 1973 or the Competition Act 1980 the MMC can consider all aspects of a firm's behaviour, including the way in which it exploits its patents. (See Whish, 1993, pp 494-495 and 643-644.) This suggests that, in the absence of specific price controls for pharmaceuticals, a company would not be able to charge what it liked for a medicine, even in the absence of competition. Companies would balance increased profit against the risk of investigation and referral, and the likely outcome.

(ii) Compulsory Licensing

In an earlier case in 1962, involving Cyanamid and Pfizer, the Minister for Health, Enoch Powell, failed to obtain a price reduction on patented branded broad spectrum antibiotics, and granted compulsory licences for generic production and importation, using Section 46 of the 1949 Patents

Act. The Act allowed arbitrated compensation for the patent holders. Compulsory licences can also be used were a company to refuse to sell a product because it did not believe it was getting a reasonable price.

(iii) Setting Maximum Prices

The Secretary of State for Health retains a power, which has never been used, now included under section 57 of the National Health Service Act 1977, to issue an order to control the maximum price of any medical supply. There is also a power to require a company to keep financial and other records and provide financial and other information. This was used prior to the referral of Roche to the MMC. These powers predate the establishment of the NHS, dating back to Defence of the Realm Acts.

An obvious issue that arises in looking at these 'backstop' arrangements is whether in practice competition plus the 'backstop' is likely to strike a better balance between reward for innovation and affordability for the NHS than a PPRS or other comprehensive price control in the meeting of the objectives and evaluation criteria set out in section 2 of this paper.

A key consideration is whether regulation should have a narrow focus on products that enjoy substantial monopoly power. This is the approach taken in general competition policy, and (as set out in Box 3) by utility regulators. Indeed in these cases, although it is tempting to go for an overall price control regime that covers all of a company's activities, it is important to avoid placing products facing competition within such a control. This is because if a firm is subject to an overall price control covering both competitive and non-competitive products, it can recoup any losses it makes in competitive markets by charging above cost prices in monopolistic markets. Predatory pricing in competitive markets may thus become more likely, forcing out competitors. When market circumstances change and competitors enter, it is therefore usually desirable to exclude competitive products from price control arrangements at the earliest opportunity, not only to reduce administrative costs but also to remove incentives for anti-competitive practices. The utility regulators have therefore explored the potential for removing price controls. Indeed most licences provide for all price control to lapse at the end of a price cap period unless renewed by the regulator with either the agreement of the company or the sanction of the MMC. In practice, there have been examples of price control being extended in scope and of it being reduced in scope. For a discussion, see Box 4.

REMOVING PRICE CONTROLS

One of the duties imposed upon the regulators of utilities in the United Kingdom is to promote competition. Where competition develops, the regulator faces the issue of when it is safe to withdraw from price control, and to allow customers to be protected from excessive pricing through the ordinary processes of competition. Not surprisingly, the scope for developing competition varies from sector to sector, with the greatest potential in telecommunications and in the supply of energy, and the least in water and the transmission and distribution of gas and electricity. Rail transport falls somewhere in the middle.

As a result, regulators have been forced to address the question of whether and when to abandon price controls. This can be best illustrated from the telecommunications industry. In 1984, BT was subject to price controls on its provision of lines and on local and long distance calls in the UK. Subsequently, this was extended to leased lines and international calls.

However, OFTEL now takes the view that competition in the sector has developed to the extent that from 1997 it is safe to restrict retail price controls to services provided to a subset of residential customers, leaving BT much greater freedom, subject to competitive pressures, to set its own prices for business customers and for those residential customers with the largest bills (OFTEL, 1996). (The company is, however, still subject to certain 'safeguard' controls which prevent it from raising prices.) Moreover, it is proposed that BT should have expanded freedom to set the prices of services which it provides to other operators on a wholesale basis. From the end of 1997, about half of these in value terms will be deregulated (OFTEL, 1997).

In deciding whether to deregulate prices, OFTEL has gone through the procedure of analysing the level of competition in each market for broadly defined services. This has involved collection and analysis of information on such things as:-

- Market shares and their rate of change

- The extent and distribution of excess capacity
- Entry to and exit from the market
- Pricing behaviour in the market

In other words, OFTEL has sought to apply a standard competition policy analysis to identify the markets for various telecommunications services and to evaluate BT's power in each market. The decisions taken have shown a willingness to deregulate prices, sometimes subject to a 'safeguard' control, even in circumstances where BT enjoys relatively high market shares, of 70 per cent or more.

In the energy sector, competition has come through successive liberalisation of both energy and gas supply. This will culminate in 1998 when the Regional Electricity Companies and British Gas' former trading division (now known as Centrica) lose their monopolies in residential markets. However, some form of price control will continue to operate. In the gas industry, a distinction is made between the initial stages of competition and a situation where competition has been established. In areas where competition has not been established, the dominant supplier is subject to a rigorous restriction on undue preference and undue discrimination. Where it has been established, the dominant supplier may offer to supply gas on terms which are reasonably necessary to meet established competition, provided that prices are not predatory and satisfy certain other conditions.

These examples show that price deregulation or partial liberalisation can be achieved when competition develops. Of the two examples given above, telecommunications is closer to the pharmaceutical industry in the sense that it produces a variety of differentiated products (as contrasted with gas and electricity, where the service is more homogeneous). The telecommunications experience has shown that a case by case analysis of the competitive situation in each market can lead to decisions to deregulate. For a recent survey of competition in regulated utilities, see Oxford Review of Economic Policy (1997).

In the case of the pharmaceutical industry, generic medicines were excluded from the PPRS in 1986, because the market was deemed competitive. The Government did not want companies to cross-subsidise generic prices from branded sales by allowing poor profitability on generics to be offset against higher profitability from branded sales within the PPRS. This would disadvantage generic companies as well as the NHS. The 1993 PPRS includes Clause 3.4 that provides for additional classes of NHS medicines to be excluded from the Scheme 'where there is evidence that there is price competition that enables this to be done without additional cost to the NHS'. However, to date no classes have been proposed for exclusion.

It may, however, be important to include the whole portfolio of patented pharmaceutical products within the price or profit control. There are significant joint costs in R&D activity and whilst it may be worthwhile bringing products to

the market because they will cover incremental cost and so make a contribution to R&D costs, companies are disproportionately dependent on 'blockbuster' products which represent major therapeutic breakthroughs, and so enjoy market power. The results of an US market analysis by Grabowski and Vernon (Grabowski, 1995), indicated that only 30 per cent of new products earned net revenues that covered average R&D costs. There is therefore a danger that a piecemeal discretionary approach to regulation, although intended to provide a 'light hand', will in practice target the highly innovative products for which NHS patients have most need, and in the process hit both the ability of companies to fund R&D and the incentive for them to do so. The need to look at returns to the whole portfolio of R&D based products was, however, recognised by the MMC in its report on Chlordiazepoxide and Diazepam (House of Commons Papers, 1972-73,

197). It accepted that R&D expenditure and returns to R&D had to be considered in relation to the portfolio of current products of a company, rather than on a product by product basis (although the MMC found that even on this basis prices for these products were too high, and that the company's R&D was also too high, being inflated by the use of excessive profits.)

Our overall view of the 'deregulation' option is that it should be fully explored and then assessed on three criteria:

- the empirical evidence. How much price competition is there and how quickly after a blockbuster innovation are profits eroded by 'Schumpeterian' innovative follower entry? How price sensitive are doctors and could they be made more so?
- the policy judgement. Where should the trade-off lie between obtaining the benefits of static and dynamic competition, and how in practice would the competition authorities and Department of Health operate a 'backstop' intervention policy?
- the political judgement. What degree of 'protection' would the public expect the NHS to have to ensure that it was able to buy medicines for NHS patients at reasonable prices?

Such an assessment will determine to what extent deregulation is likely to be mutually beneficial to industry and government.

If some kind of price control is considered, there are a number of alternatives which we now move on to evaluate. We first discuss three methods for controlling the average level of prices – price caps, profit control and banded rates of return.

4.2 Price-Caps

The conventional wisdom is that a price-cap or RPI-X regulation is to be preferred to cost-based rate of return regulation because of its better incentive properties. Under a price-cap the producer is entitled to keep as profit any extra cost savings made between successive impositions of the cap. Pure cost-plus rate of return regulation obviously lacks this advantage as it allows all costs, efficiently incurred or otherwise, to be recovered through revenues.

It is now widely recognised that this distinction is rather unrealistic, principally because of the necessity to reset the cap at regular intervals. Resetting the cap typically involves identifying a firm's revenue requirements over the subsequent period (necessary for it to recover its costs, including a return equal to the cost of capital) and setting prices – or price changes – at a level

calculated to satisfy the revenue requirement. If this were done in an automatic way, allowing the company to recover all the costs it projected for itself, the distinction between price caps and rate of return controls would be negligible. However, price caps can be set in a forward looking way, in which a projection is made of the company's costs and a judgement made about achievable efficiency improvements. If the productivity growth target is determined exogenously, the price cap retains its incentive properties.

How might a price cap operate in practice for a firm in the pharmaceutical sector? For a company with a range of medicines already purchased by the NHS, there would be little technical difficulty in establishing and operating such a cap. Given the heterogeneity of output, a natural approach to adopt would be that based on a 'tariff basket' or basket of product prices. This would mean that in each year the average real price of the company's regulated outputs (weighted by the previous period's expenditure shares) would rise or fall by some prespecified amount.

The system proposed would be broadly the same as that operating in the case of BT's tariffs (see OFTEL, 1995) except that the number of products would probably be greater. The BT experience demonstrates that it is possible, although not simple, to combine more complicated charging schemes, including quantity discounts, in the arrangement.

Thus a price cap seems a practicable method for regulating the bundle of existing products. However, new products create a challenge to such regimes. The key difficulty with inserting new products in a price cap is that of determining their 'initial' price. To establish whether a company has satisfied a price cap, the regulator has to calculate whether the weighted average change in price of all products in the basket satisfies the price control. If a new product enters the basket at a very high initial price, the company will be able to satisfy the price control condition relatively easily by subsequently reducing the price of the new product. Provided that the quantities sold are not negligible, such a price cut may allow the company to satisfy its overall price control without having to reduce the prices of its other products. In order to guard against this, the regulator might have to control the initial price at which a product enters the basket.

But there might be a case for deferring the incorporation of a new product or service in a price control regime until it has been subject to market testing. OFTEL recognises that the main

telecommunications supplier, BT, should have an incentive to introduce innovative products or services. In the nature of things, such offerings will not face competition and this creates a dilemma:

'BT may thus be in a position, at least in the short term, to exploit the customer. On the other hand, such profits act as both a reward for the introduction of new services which benefit the customer and as a signal for competitors to enter the market. In such cases, control of markets may stifle entry and discourage innovation, to the detriment of the customer in the long run. For this reason, OFTEL believes that new services should not be included in the price cap. Other mechanisms will be used to deal with any unfair cross-subsidy or other anti-competitive behaviour which might be identified in relation to such services.'

(OFTEL, 1995, pp 28-29)

This argument applies equally to the pharmaceutical sector, and one possible way forward, analogous to that proposed by the House of Commons Health Committee, is to offer new products a period of grace in which their prices are not directly controlled within the price cap. (There would still be a need for companies to justify the prices of new products to purchasers and prescribers by reference to their therapeutic benefits.) At the end of that period, if there continues to be a demand for them, both revenues and the direct costs associated with them would be incorporated in the price control (although the Committee was not proposing a price cap of this form, but a form of individual price control). To avoid excessive administrative costs, if a price cap were in operation, this incorporation might take place only when the price cap is reset, except in the cases of new products with particularly high initial sales. To a significant extent, the case for a price cap of this form rests on whether or not there is a practicable way of bringing new products into the formula at some point. We consider in section 4.6 below some of the issues involved in trying to set individual product prices.

4.3 Profit Control/Rate of Return Regulation

Rate of return regulation in its simplest form is a method of cost plus pricing which generates few incentives for efficiency and encourages over-investment wherever the allowed rate of return exceeds the cost of capital. This is the type of control formerly used in the US utility sector, and, in the UK by the Ministry of Defence. The best regulatory or market argument in its favour may be that the security of return which it

provides reduces risks and hence the cost of capital. Martin has argued (Martin, 1995) that the PPRS does fund R&D in this way, and so the rate of return allowed under the PPRS should be lower. We do not address rate of return issues in this paper, but we do not see the PPRS as guaranteeing profits or R&D costs. This is because the PPRS only permits companies to fund R&D out of current NHS sales to an agreed limit, as discussed in section 2. Companies are being rewarded for the success of past R&D (if this has led to products the NHS wants to buy) by being allowed to charge prices for those products that enable them to continue financing R&D. It is true that companies have to continue investing in R&D to get the R&D allowance, but the allowance is related to current sales performance which reflects past R&D investment.

In a capital intensive industry, the effect on costs of a lower cost of capital might conceivably outweigh the resulting productive inefficiency of a cost-plus regime. Alternatively the regulator might seek to 'strip out' inefficiencies in determining recoverable costs, although this raises risk. There is, however, an information asymmetry, which may allow the company to conceal inefficiency from the regulator. Where several comparable firms are operating in a sector, it might be possible to subject them to some kind of 'yardstick' competition, based upon comparative cost data. The current PPRS contains the potential for a system of this kind because the Department of Health collects comparative information on costs and establishes a differentiated target level of return for each firm. If it believed a firm was behaving inefficiently, it could adjust the target rate of return downwards or refuse to accept all expenditures for the purposes of calculating profits in the financial returns. In fact, however, if the procedures whereby such target expenditure levels are set, or disallowances made, are opaque, it is unlikely that firms have sufficient knowledge of how any such mechanism of yardstick comparison will impact upon them to have the desired incentive effect. To provide effective incentives the yardstick measure should be clear to the company and determined exogenously (for example by reference to industry aggregate performance). We thus reach a poor evaluation of the pure rate of return approach to price setting unless target costs are linked to a yardstick, which will produce some incentive effects.

4.4 Rate of Return Regulation Within Bands

There are, in addition, a number of mechanisms intermediate between price cap and rate of return regulation. These can involve a sharing

mechanism, such that when the rate of return rises beyond a specified level a proportion of the gains are kept as profit, while a proportion are taken in price reductions, possibly with a symmetrical arrangement when the rate of return falls below the target level. Several US utilities are now regulated in this way.

Alternatively, prices may be pre-set, with no adjustment occurring unless the rate of return falls outside a specified band. Under this arrangement, shareholders keep all gains from efficiency and innovation up to a certain threshold (the 'dead band') and none thereafter. The impact of this arrangement clearly depends upon the width of the band. In the case of the PPRS, the upward band of allowable returns was reduced by one half in the 1993 review (from 50 per cent to 25 per cent), thus generating more limited incentives for efficiency or innovation. In the limit, with a very narrow band, the system would approach pure rate of return regulation. The choice of an appropriate band is thus critical. Under a combined system, profits outside the 'dead band' could be shared between consumers and investors. For a discussion of profit sharing see Mayer and Vickers (1996).

It has been argued (Health Committee, 1994, Martin, 1995) that the ceiling and floor threshold or banding mechanism of the PPRS works to the disadvantage of the NHS, because if doctors save money by, for example, prescribing more off-patent generic medicines (which are not in the Scheme) then companies whose profits are hit and so fall more than 25 per cent below their target rate of return are entitled to increase their prices. The Government's response (Department of Health (1994), Department of Health (1996)) was to argue that falling sales volumes would lead to downward adjustments to allowable capital employed, R&D expenditure, promotional costs, and manufacturing and distribution costs. The PPRS Report (Department of Health, (1996)) includes an example of how this could operate so that ROCE remained within the 25 per cent band below the target, although clearly in other hypothetical cases (e.g. Martin, (1995) pp50-51) ROCE could fall below the band. Should it do so the Department of Health may, of course, still refuse a price increase. The Scheme has a clause which allows the Department of Health to ensure NHS cost saving measures are not undermined by price increases elsewhere. It is also quite likely that a company losing sales volume to the extent that it falls beneath the band around the target rate will not enjoy the market power to enforce a price increase were it to be permitted one, although, of course, other parts of its product portfolio may be in stronger market position. In principle, however, any form of

banded profit control should permit price increases if an efficient regulated company's profitability falls outside the bottom of the band. It is the quid pro quo for the cap at the top end of the band. The ceiling on the PPRS upper band means that doctors know that if their prescribing of higher value products pushes a company's profitability up above the cap, then prices will be cut or the NHS will get a rebate.

Finally, there is the important question of whether a margin of 25 per cent above or below the target rate of return is an appropriate one. On the face of it, the current spread, which amounts to a range of 14.25 per cent to 23.75 per cent (taking the mid point of the PPRS target level of 17-21 per cent as the starting point), looks rather small in relation to the variation in rates of return reported by large UK companies. An analysis of FT500 data on the return on capital employed for 1996 for the top 500 companies in the UK shows that over 40 per cent exhibited a rate of return in excess of this band and 30 per cent a return below it. Of course, such calculations are only suggestive. They ignore differences in risk (and hence in the cost of capital) between the pharmaceutical industry and other sectors, as well as differences in accounting practice, and variations within each FT500 sector may be lower. Nonetheless, they suggest that the largest firms in the UK as a group exhibit substantially more variation in returns than those allowed to pharmaceutical companies supplying the NHS, before those returns trigger a response under the terms of the Scheme. A bigger margin would both enable successful companies to earn more and further reduce the ability of companies performing poorly to increase prices.

4.5 Expenditure Control

A utility regulator is concerned primarily with controlling prices, leaving it to millions of customers to make purchasing decisions subject to their individual budget constraints. In some cases, the regulator may be concerned with providing subsidies for particular categories of customers through the pricing system, but these are the exception rather than the rule. In the case of the National Grid a total revenue constraint was imposed on the company, but this reflected the fixed nature of its cost structure, rather than a concern about the expenditure of its electricity supply company customers.

The Department of Health, as the major customer of pharmaceutical products in the UK, cannot ignore the financial consequences for the NHS of its overall regulatory framework for prescribing by focusing entirely on the control of average prices and profits, ignoring the volume

and mix of prescribing and the resulting cost, because, like other Departments, it is subject to expenditure limits.

Nor is the United Kingdom unique in this regard. In other European countries, controls over public spending impose an additional downward pressure on pharmaceutical prices. Thus the German reference pricing scheme, which we discuss below, has been accompanied by across the board reductions in pharmaceutical prices. The French Government's controversial 1996 plans for controlling social security expenditure involved a 'contribution' from the pharmaceutical industry in the form of a tax on total sales and the French 'Accord Cadre' (discussed in Box 6) can be seen as a total revenue constraint. The decision of the UK government to include a 2.5 per cent price reduction in the 1993 PPRS was thus not unusual by European standards.

As a result, a regulatory framework for pharmaceuticals is likely to be of considerable conceptual, as well as practical complexity. The Government will seek to control not only average prices, in order to avoid excess returns; but also to limit overall expenditure in a way which depends partly on general economic conditions and constraints on public spending, and partly on the extra demands for pharmaceuticals generated by technological advance. In terms of our criteria for evaluating price control regimes, this is likely to have a mixed effect. It keeps prices down, but may have a substantial adverse effect on incentives for R&D, especially if reductions are applied arbitrarily and unpredictably and hit new products.

Of course, it could be argued that it would be more efficient to focus on overall NHS expenditure rather than on pharmaceutical expenditure per se, with the pharmaceutical regime concentrating on ensuring that prices are reasonable (which may or may not require price or profit control, as we discuss above), as the Government does not know what level of pharmaceutical expenditure gives value for money. However, as with any 'deregulation' option, the Government would have to be confident that decision makers had information and bargaining power to extract value for money before letting go of levers to control pharmaceutical expenditure.

4.6 Individual Product Price Controls

The price control options discussed above do not directly affect the price of any individual product, but control average prices, revenues or aggregate profits. In this section we discuss how the price of

an individual product could be set, relative to the price of other medicines, non-pharmaceutical treatments, and other related goods.

The four options we consider are:

- (i) No control of individual product prices
- (ii) Use of health economic evaluations
- (iii) Cost plus/therapeutic benefit criteria
- (iv) Reference pricing

We discuss these in turn.

(i) No Product Level Price Control

This option leaves companies free to set product prices. It could be within an RPI-X, profit control or free market overall framework. Under the PPRS companies can set relative prices of new chemical entities at launch. Companies will set product prices looking at the potential value of the product to doctors treating patients. This 'willingness to pay' will be influenced by the prices of any existing products also available to treat the condition, and by the extent to which the product is seen by doctors to have unique characteristics. Cost of production will not be a factor, except in so far as there is price competition. For example, in the case of a generic market, with different versions of the same active chemical ingredient, price competition will push price towards marginal cost.

We can conjecture what structure of relative prices might emerge from first principles. Interestingly, it turns out that individual pricing freedom might generate a desirable set of relative prices.

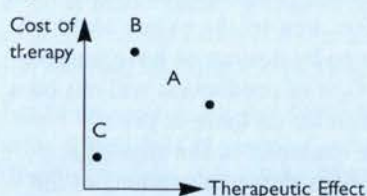
When an overhead such as R&D expenditure has to be recovered from a range of products so that marginal cost pricing is not possible, it should be done in such a way as to minimise distortions in the structure of consumption. This is achieved by allocating the overhead disproportionately to products where the price elasticity of demand is low, thus keeping down the prices of goods where demand is very sensitive to price changes. Deviations from marginal cost are thus inversely proportionate to the price elasticity of demand. Such prices are known, after their discoverer, as Ramsey prices. It is known that a price-cap system, where the cap is set in a way calculated to avoid excessive profits, will under certain conditions encourage a monopolist firm to move towards Ramsey pricing, and this is an argument for favouring some flexibility in relative prices under the price control regime, rather than the imposition of a common mark-up (Vickers, 1997).

PRINCIPLES AND PRACTICE OF HEALTH ECONOMIC EVALUATION BASED PRICING

If the therapeutic effectiveness of alternative treatments of an illness could be measured, it would be possible to record the price and effectiveness of each treatment as in Figure 1. Note that the relevant price is that of the overall therapy, not of the medicine which forms part of it. The availability of such information would make it possible to show that, for example, treatment A dominated treatment B, as it is both cheaper and more effective than B. However, the diagram does not enable us to make any judgement as between A and C or as between B and C.

Two jurisdictions, Australia and the Province of Ontario in Canada, have introduced a requirement for economic evaluation submissions to be made by manufacturers. Some European countries accept health economic evaluation submissions from companies. France has recently published guidelines for use in preparing submissions for use in reimbursement listing decisions and price setting decisions. (This was agreed as part of the Accord Cadre – see Box 6).

Figure 1



Essentially, if the price cap is set at an appropriate level, the monopolist will only achieve break-even by choosing the price set which maximise its profits given the average price constraint of the cap. The result thus relies upon the well-known similarity in the structure of monopolistic and efficient pricing: in both cases, margins above cost are greater where the price elasticity of demand is higher, although the monopolist maximises profit, while a firm subject to Ramsey pricing is normally constrained to, at best, break even. (See Armstrong et al, 1994, pp 51-53, 79-83).

However, when a firm operates in a market subject to competition, its price setting behaviour is guided not by the market price elasticity of demand, relevant to Ramsey pricing, but by its perception of the responsiveness of its own demand for price changes. This depends upon competitive responses. Models can be constructed in which a price-capped firm subject to competition of a certain form will still be driven to Ramsey pricing (Laffont and Tirole, 1994). However it appears that these results require a particular specification of the nature of the competitive process, which may not always apply in practice.

In the UK (as in the USA), cost-effectiveness studies are aimed at prescribers and purchasers, and have to confirm with rules governing all promotional activity. For a comparison of the Australian, Canadian and UK approaches to the use of health economics see Towse, (1997b). As discussed below, cost-effectiveness analysis can only set a price ceiling, or, for a given price, answer the question as to whether it is cost-effective. By implication, when countries use health economic evaluation evidence to consider reimbursement, they are implicitly or explicitly both assuming the price that will be charged and adopting a hurdle or threshold cost-per-effect to ration the availability of treatment. For example, the Health Select Committee (Health Select Committee, 1994) proposed a national formulary with companies having pricing freedom for the initial five years of a product's life, and then submitting a health economics study to demonstrate the product's cost-effectiveness. The companies would choose the price, but the formulary committee would decide whether it was cost-effective at that price, and hence whether or not it should continue to be available to NHS patients at the end of the five year period. This committee would thus be making a central judgement as to the cost-effectiveness 'hurdle' ratio that would need to be exceeded for a treatment to be accepted.

(ii) Use of Health Economic Evaluations

An alternative approach involves use of techniques by which economists and clinicians measure the cost-effectiveness of products. Effectiveness can be measured using a clinical measure, such as reduction in blood pressure, episode-free days or loss of symptoms, indicating a cure, or by a more patient-oriented measure of the improvement in their health related quality of life. However, this will only allow decisions to be made about use where one treatment dominates another, i.e. it gives the same or a greater effect for less cost. Where we can get more effect, but at more cost (as illustrated in the example in Box 5), we have to be able to answer the question 'Is it worth it – does it represent value for money?' Health economists have developed a technique called 'cost utility analysis' which typically uses an outcome measure of Quality Adjusted Life Years (QALYs) to enable improvements to be 'valued' and so compared across patients and across therapy areas. However, unless we assume everyone has an objective of maximising society's health gain, or the Department of Health takes a view of the NHS's willingness to pay for an incremental QALY by setting a cost-per-QALY threshold,

irrespective of how it is distributed, then individual patients, doctors and citizens will take differing views as to how much it is worth paying to achieve a particular effect for a particular patient. Even if we had such a view, economic evaluation does not then determine how much should be paid for the medicine. Society's willingness to pay for health gain is a ceiling, the cost of supply is a floor. How a pharmaceutical should be priced between the ceiling and the floor, i.e. how the benefits of the innovation should be divided between the supplier and the customer requires a judgement about the balance between static and dynamic efficiency. (For a discussion of this issue see Drummond et al, (1997)).

(iii) Cost Plus/Therapeutic Benefit Criteria

Most countries in Europe use either reference pricing (discussed below) or a set of criteria which combines elements of 'cost plus' and 'therapeutic benefit'. The implication is that prices should reflect the value of the product to the patient, in particular its ability to deliver better health, but should also meet reasonable costs and allow reasonable but not excessive profit. Therapeutic benefit is usually determined by expert clinical and pharmacological assessment, and the prices of products already available in the disease area are an important determinant, together with the price of the product in other markets. (Examples of this type of system are set out in the discussion of France and Spain in Box 6).

These systems could be viewed as crude versions of the type (ii) system using health economic evaluations discussed above. Rules of thumb are used to establish relative therapeutic merit and cost information is used to place the price towards the bottom end of the range of prices at which there would be net benefit to the health care system. The rewards for innovation are thus relatively low, and, not surprisingly, some companies are submitting health economic evaluation information, as part of their pricing application, to try and increase the agreed value of the therapeutic benefit and also make a case for a larger share of the benefit to go to the company in the form of a higher product price.

(iv) Reference Pricing

Reference pricing was first introduced in Germany, and is now also used in Sweden, Denmark, the Netherlands and Italy. As used in Phase I of the German system, and in Sweden and Denmark, it is a form of yardstick competition for off-patent medicines, which we discussed earlier in the context of the use of the

Drug Tariff to set NHS generic reimbursement prices. A price is set for reimbursement, linked to a market price, and suppliers charging above this price then have the option of cutting their price, or asking patients to pay the extra out of their own pockets. Those companies pricing below the reference price may, however, increase their prices. The extent to which this will happen depends on the price sensitivity of the prescribing doctor or the dispensing pharmacist. In Germany, the price is set by reference to that of the leading generic, in Denmark by using the average price of the two cheapest chemically identical products (including parallel imports), and in Sweden at 110 per cent of the cheapest generic.

Phases II and III of reference pricing in Germany, and the system in the Netherlands, go beyond this to set a reference price for a therapeutic group or a cluster of products with similar therapeutic actions, indications and side effects (such as many Non Steroidal Anti Inflammatory Drugs). This reduces the incentive for innovation within product clusters, although Germany has now removed products still under patent from the reference price system. The stated objective in the Netherlands was to promote breakthrough innovation, but not 'me-too' medicines, by excluding breakthrough products from the reference price system. However, 'List 6' which should include all new products for which no other medication is available has been closed since July 1993, preventing such new products from being reimbursed. The introduction of a requirement for health economics information for such breakthrough products is now being discussed in the Netherlands.

A number of countries have taken into account prices in other EU countries when setting prices. In Italy and Holland the reference pricing regimes set prices by reference to prices in other EU countries (France, Germany, Spain and the UK in the case of Italy, and France, Germany, Belgium and the UK in the case of the Netherlands). In the case of Italy, the scheme replaces existing price controls, while in the case of the Netherlands it is on top of the existing set of controls. The impact of such regimes depends on which countries are chosen for comparison and on the basis of calculation. There are prima facie economic reasons, however, for expecting an efficient set of prices that recover R&D costs to involve different prices for the same product in different countries, depending on per capita income, per capita pharmaceutical consumption and other factors. For a discussion of this issue see Danzon, (1997).

We should note that all of the mechanisms for

BOX 6

PHARMACEUTICAL INDUSTRY PRICE CONTROLS IN FOUR MAJOR EU MARKETS

FRANCE

The Government appointed Transparency Commission decides whether a new medicine will be available to patients of the social insurance funds. It does so using seven criteria (such as the nature and severity of the disease, and the degree of innovation) to assess its medical benefit and score the product at one of six levels on the Medical Benefit Assessment Scale (ASMR), ranging from 'major therapeutic improvement' to 'no improvement'. Products representing 'no improvement' may still be listed, because the Transparency Commission considers economic as well as therapeutic evidence. It encourages companies to present health economic evidence of cost effectiveness, i.e. that the price they are seeking represents value for money to the system. If inclusion is recommended, then the papers are passed to the Economic Committee, which fixes the price. It takes account of the ASMR rating, the prices of other products, the research and development commitment of the company, other information about the company's financial performance, employment plans and strategic direction, the promotional plans and the sales forecast. Once relative prices have been set, the levels of all pharmaceutical prices are increased or reduced by the government on an annual basis depending on economic circumstances.

The Economic Committee is responsible for acting within the 'Accord-Cadre' or Convention negotiated between the government and the industry. Initially set for a three year period to the end of 1996, it has been renegotiated for a second term, although this draft Convention has yet to be finalised and agreed by both parties. Under the Convention companies sign contracts or 'conventions' setting out overall sales targets. The objective is to reduce volumes of consumption, by lowering promotional activity and encouraging better use of medicines, whilst allowing prices to increase to Northern European levels. Conversely, if sales exceed agreed targets then prices must be reduced. In this sense the agreement is an expenditure control. The agreement also requests provision by companies of health economic evaluation information to support price increases. This is voluntary and guidance has recently been agreed through a consultative process. More than 100 companies have signed conventions covering 90 per cent of the market, and in September 1995 price reductions were imposed on 28 products.

In 1996, the Juppe plans for welfare reform led to a global 'levy' on the industry equivalent to 2 per cent of sales as its contribution to health care savings.

GERMANY

Reference pricing was introduced in 1989. Phase I covered off-patent products with the reference price set using a formula linking it broadly to the price of the generic market leader. Companies could charge above the reference price and ask the patient to pay the difference. However, there was patient resistance to this, and few companies now price above the reference price level.

In 1993, the next two phases were introduced, and the scheme covered 70 per cent of the social insurance funds' pharmaceutical expenditure. Phase II covers prices for products in the same therapeutic category, e.g. ACE inhibitors, and Phase III sets prices for products with the same therapeutic function (e.g. anti-hypertensives, whether ACE inhibitors or beta blockers). There was a general price reduction of 5 per cent in 1993 for products not subject to reference pricing. In 1996 products still in patent were

removed from the reference price system to restore incentives for innovation. Other reference prices were cut in April 1997 by between 1.25 and 25 per cent.

However in 1993, the impact of reference pricing was overshadowed by the impact of a further measure, - a global doctors' budget for pharmaceutical expenditure was introduced, with financial penalties for doctors and the pharmaceutical industry if they exceeded them. This procedure was repeated in 1994 and 1995. In 1996 the global budget ended and expenditure rose. Discussions continue as to whether doctors should be penalised for this. The 1993 policy package also included proposals to establish a 'positive list'. Products not on the list would not be reimbursed. However this element of the plan has effectively been dropped.

ITALY

From 1990 to 1993, a pricing formula was used by the Price Commission for new products to be listed on the public health care system. It used production, overhead, and promotion costs with adjusting coefficients, to take account of the size of the market, the degree of innovation, and the company's contribution to the economy. Prices in other EU countries were also taken into account.

From 1994 a reference pricing system was introduced, covering new and existing products, using an 'average European price' for products with the same active ingredient (including generics). For most products the Italian price will be set by the Interministerial Committee for Economic Planning (CIPE) using the average of prices in France, Spain, Germany, and the UK, adjusted by a purchasing power parity (PPP) index, and weighted by sales value in each of these countries. Price reductions would take immediate effect, price increases would be phased over 5 years. It is taking some time to establish the reference prices and in early 1997 the State Council (the supreme administrative court) upheld industry complaints about the use of only 4 countries, the use of PPPs rather than market exchange rates and the asymmetrical treatment of price increases and price decreases.

From 1994, co-payment rates were increased substantially. Medicines were classified into list A 'life saving' with low flat rate co-payment, list B (products with demonstrated therapeutic advantages), with 50 per cent co-payment, and list C of other products, with full cost borne by the patient.

Price levels were cut by 2.5 to 5 per cent in 1995 (depending on company sales growth), and public spending targets for pharmaceuticals suggest that further ad hoc measures will be taken, irrespective of the coherence of the reference pricing system.

SPAIN

The price of a new product to be available within the public health care system is set using a combination of:

- a cost plus formula, including production, distribution, sales and marketing and administrative overhead, and a profit mark up;
- reference to the prices of similar therapies, and to the price of the product in other countries.

Overall prices move up or down by royal decree. A three year 'pact' was signed in 1995, by the government and the industry association, providing for some price increases, but limiting overall revenue growth to 7 per cent per annum, with industry paying back around half of the value of any sales exceeding the agreed limit.

setting relative prices discussed in (i) to (iv) above are normally integrated with a system for controlling overall expenditure on pharmaceuticals by the health care system. Having chosen a rule for setting individual product prices, governments need an aggregate mechanism of the sort discussed in sections 4.1 to 4.5 above in order to manage overall price levels. In practice, many European governments announce annual amounts by which all prices will be raised (or reduced). We present our overall conclusions on the various options we have discussed in the final section of the paper.

5. TRANSPARENCY

One of the major concerns of the House of Commons Health Committee revolved around what the Committee regarded as lack of transparency in current arrangements for pharmaceutical price control. In particular, the Committee proposed that:-

Greater transparency should be introduced into the scheme by the publication of an Annual Report which would specify (i) the aggregate profit made by each company under the scheme; (ii) its allowances for research and promotion; (iii) its shortfall or excess of profits compared with target either inside or above margin of tolerance; (iv) overall profits declared under the scheme by all companies, together with the total value of all repayments to the Department of Health as a result of excess profits and the total value of any price reduction.

The Department of Health (1994) replied that:

'The Government opposes publication of company-specific information. It will, however, publish in future a report on each year's operation of the scheme.'

Transparency has also played a prominent role in discussions of utility regulation. But there the issues have been rather different. The physical inter-relatedness of network industries requires competitors to use one another's infrastructure, or the infrastructure of the dominant provider. Thus BT and Mercury terminate the calls of one another's subscribers, and gas shippers utilise British Gas' transportation network. In order to satisfy competitors' suspicions that the dominant operator is over-charging them for access to infrastructure, regulators have mandated successively greater disclosures of costs and revenues of the network business, including in some cases a requirement for separate accounting (see Carey et al, 1994). However, some data are still withheld on confidentiality

grounds, and new entrants' suspicions are not fully assuaged.

A principal motive in seeking transparency in the case of utility regulation is to reassure competitors who are also customers. Under the PPRS, the customer is the Department of Health, which administers the Scheme and thus has access to the requisite data. However, this is not seen by the Health Committee as being adequate. Arguments are made in favour of greater public disclosure to reassure the public that the Department is doing its job properly. While we acknowledge the desire for maximum disclosure including of individual companies' performance, we are chiefly interested here in the issue of what data are required to be made public to maintain the efficient operation of, and public and industry confidence in, the overall price control scheme.

The data required to operate the current Scheme are the following:

- Company-specific target rates of return within the overall range
- The costs, revenues and asset base relevant to the Scheme for each company
- The consequential effects of the Scheme, in terms of pay-backs, price reductions or price increases.

At present none of these data is publicly available in company-specific form. Aggregate data on consequences were, however, provided by the Department of Health to the Committee.

It is acknowledged that the target rates of return are generated by a process which takes account of a number of considerations, summarised as the company's long-term commitment to the UK pharmaceutical market and the risk associated with that. This means that firms undertaking high levels of R&D investment in the United Kingdom will receive a higher target return than if the investment were elsewhere.

If there were a simple formula, the argument for its publication would be strong. However, the Department of Health may establish individual target rates on the basis of judgement, taking into account a variety of considerations. An analogy is provided by the obligation on a utility regulator to establish an allowed rate of return for regulated firms, which may differ in terms of scale, profile of activities and other characteristics including the cost of capital. This task ultimately involves a regulator in making a judgement, which probably cannot be captured by a simple arithmetic formula. Thus utility

regulators issue discussion papers on the factors to be taken into account in setting the formula, in particular how efficiency comparisons are to be made and used, and how the rate of return or cost of capital should be set, but do not publish a formula for setting the price control formula, (see for example OFTEL (1996) and (1997)).

In the utility regulator's case, however, the result of the judgement is typically published. While we see no overriding confidentiality objection to the publication of individual pharmaceutical companies' target rates of return, we do not regard it as necessary to demonstrate the efficient functioning of the Scheme. It would, however, be helpful to outsiders for the Department either to publish an average figure (weighted by asset base), or to publish the number of firms in bands between the floor and the ceiling. There is a danger that such publication would lead to pressure to narrow the range of target rates of return around the mean as companies with low targets lobbied for higher ones and industry critics pressed for high targets to be reduced. Our view is that the degree of innovative success should be a major factor influencing the setting of targets by the Department. This is inevitably an area of judgement (although the factors taken into consideration can be – and are in outline already – published) and we would not expect target rates of return to converge over time.

The next issue concerns the publication of outcomes including – in the limit – relevant revenues, costs, asset base and rates of return of named companies, together with the action taken by the Department of Health in cases where the target has been departed from by more than 25 per cent.

Here the claims of commercial confidentiality are even stronger. It would, however, be quite practicable to publish the data in suitably anonymised form. These could include, for example, the distribution of the departure of actual returns from target, with an indication of relevant asset base in each category. Alternatively, publication of the overall average return would provide outsiders with an indication of how closely firms in aggregate achieve their target rates. Outturn information that enabled observers to understand something of the distribution of returns would, in addition, inform judgement as to the extent to which the PPRS did distinguish in practice between 'successful' and 'unsuccessful' companies.

Finally, the Department of Health could usefully disclose on a more regular basis information on actions taken as a result of firms reporting results outside the relevant 25 per cent band. The

information presented should include the number of firms outside the band (both above and below); the aggregate level of excess and deficient return; the relevant asset base; and the actions taken, in the form of repayments, subsequent price reductions or price increases – each valued appropriately. A start in this regard was made in the Department of Health's evidence to the Health Committee (see the Tables in Box 1), but more data could usefully be published and included in the Annual PPRS Report.

6. CONCLUSION

This paper has been concerned with mechanisms which can be employed to regulate the prices of medicines, and in particular with what lessons can be drawn for the pharmaceutical sector from other UK industries in which price control has been practised, notably the utilities. We have argued that both pharmaceuticals and utilities have a crucial element in common – the necessity on the part of the companies to make sunk investments in, respectively, research and development and the laying down of distribution networks. Investors have to be confident of recovering these expenditures through a pricing regime which allows mark-ups over marginal costs: otherwise the investible funds will dry up.

A prior question is whether a price control formula is required at all. Competition is a more efficient discipline for companies and their customers than regulation. Some pharmaceutical products, notably generics, are traded in nationally and internationally competitive markets, and there is no need for price regulation. It can be argued, moreover, that in the long-term a company's monopoly power in any pharmaceutical market will be eroded by entry, and that it is precisely the availability of such temporary monopoly profits (which in any case are subject to investigation under UK competition law) which brings advances to the sector as a whole. In such an environment, the Department of Health's overall cash limits and budgets for purchasers and prescribers would impose a real constraint on pharmaceutical expenditure. Price and quality sensitive doctors will put price pressure on 'me-too' products, especially if practices were able to negotiate prices and keep discounts. There are counter arguments which we discuss in the paper. Nonetheless, the case for deregulation should be carefully assessed and efficiency arguments imply that price control should be as parsimonious as possible: if it can be removed, it should be.

If options for price control within all or part of the sector are considered, it is useful for analytical

purposes, to distinguish between controls on the aggregate or average level of pharmaceutical prices and expenditure and individual price setting, although the latter – if universally applied – will also imply an aggregate control.

At the individual product level, a number of alternative approaches can be distinguished, ranging from no individual price setting as in existing PPRS (although under that Scheme companies are prevented from raising prices except in special circumstances, and may be required to reduce prices as part of an agreement to return excess profits) to price controls based on reference prices, health economic evaluations, cost-plus, therapeutic benefit, or some combination of these.

If prescribers were fully informed, the operation of the market would impose a broadly similar structure of relative prices to that implied by therapeutic benefit-based pricing. This would arise because one medicine could only trade at a higher price than another similar one if, in the eyes of patients or their doctors, it were preferable. In fact, however, the market is not fully informed, and relatively ineffective treatments might be chosen. (The likelihood of this depends in part upon the overall system of price control and the incentives to innovate which it creates – which are discussed below.)

However, existing techniques of therapeutic benefit-based pricing used by governments in the EU are rough and ready at best, and the health economics approach to evaluating effectiveness is an imperfect tool for price setting. The choice between relative pricing freedom and individual price setting thus becomes a choice between alternative second best solutions. We are not persuaded that it is desirable for government to set individual prices across the board, although where reliable studies of comparative effectiveness are available, there is a case for incorporating them in any price setting process that is in place.

As far as the overall form of price control is concerned, we have identified three main options: price caps, rate of return regulation and intermediate forms such as banded rate of return (the system adopted in the current PPRS).

Most observers agree that price-caps have the desirable incentive property that, for the duration of the cap, companies are allowed to benefit from increases in efficiency. Rate of return considerations are, however, likely to intrude whenever the cap is reset. The distinction between the two forms is thus not absolute. Moreover, as with other forms of cost plus price setting, rate of return regulation can

operate in the manner which prevents costs which are inefficiently incurred from being recovered in prices.

In the case of existing products, a company-based aggregate price control regime could be implemented. Setting the cap would require an allocation of costs between those incurred in producing medicines sold by the company to the NHS, and those incurred on other products or on the same medicines sold elsewhere. If the price cap could be set to permit the recovery only of necessary costs, there would be an incentive for cost reduction. However, difficulties arise in incorporating new products in the price cap as they must enter at an exogenously determined initial price. This problem could be resolved, however, if new products were incorporated in the price cap at the regular intervals when the cap is reset. Their direct costs would then enter the cost-base, and recoverable revenues from both old and new products would permit the company to make, on an ex ante basis, the allowable rate of return. The practicability of adding new products or services to a price cap has already been demonstrated on a small scale in the telecommunications industry (OFTEL, 1995). It could, however, create considerable difficulties in the pharmaceutical industry where many firms would have to be subject to detailed price control, each of them producing many regulated products.

In our view, this aspect could make the use of the price cap unduly complicated. Of the remaining alternatives, the arguments against pure cost-plus regulation seem strong: the adverse effects on incentives to efficiency are likely to be too great, notwithstanding the possible use of cost 'yardsticks' to determine allowable cost.

This leaves intermediate forms such as profit sharing or banded rate of return regulation. The current PPRS is an example of the latter, and in our view it has demonstrated its practicability and performed adequately for the NHS and the industry in aggregate over what is now a fairly long history.

There is, however, a case for changes both in the PPRS itself and in the publication of information about how it works. The current band of 25 per cent above or below each firm's target rate of return is unduly restrictive. It represents a disincentive for successful firms and a safety net for the unsuccessful ones. There is of course an argument for a safety net at some level, because if companies exit from the market this may reduce competition. We believe, however, there is a case for restoring the band to its earlier level of 50 per cent, but this time to apply below the target rate as well as above the target rate. The

expected impact of such a change on the overall weighted average return to the industry and hence cost to the NHS would obviously have to be taken into consideration in any negotiations.

There is also a case for excluding new products from the Scheme in their early years. This would offer an additional incentive to go for major innovations, rather than incremental changes which are designed to maintain a firm's market share within the permitted range of returns. The Department of Health would have to be confident, however, that it had in place arrangements to ensure purchasers and prescribers were able to assess value-for-money.

At the same time as firms obtain these greater freedoms they should accept more disclosure of the effects of the overall operation of the Scheme and of target rates around which it is based. The argument for disclosure of individual firm targets and outcomes is not convincing. But public confidence will be enhanced by the publication of more aggregated data about the average level of the target rate of return, the overall performance of firms within the PPRS and consequential effects of the Scheme such as price increases and reductions or repayment of profits, and by the disclosure of bands of target and actual profitability. In order for the disclosures to have value, it would be essential that they are made in a timely way.

In summary, our conclusions and recommendations are as follows:

(1) It should be an objective of policy to limit the scope of pharmaceutical price control as far as possible in favour of competition. The case for full or partial deregulation should be fully explored.

(2) Where overall price levels or profits are controlled, the firms should have a degree of freedom in setting relative prices; new products should remain outside the control for a period of three to five years and individual price control should be avoided.

(3) Were the current PPRS to be maintained in some modified form then: (a) the size of the permitted band should be increased, (b) the Department of Health should publish more information about the operation of the Scheme.

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