

Annexe J

Price control

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EXECUTIVE SUMMARY

The PPRS price control limits the price of existing medicines and has three main features:

- a series of agreed overall price reductions have accompanied the introduction of each of the last three PPRS agreements. Recent price cuts have been 2.5 per cent in October 1993, 4.5 per cent in October 1999 and most recently 7.0 per cent in January 2005
- at other times, PPRS companies are not permitted to increase the overall level of their prices, and
- the price control applies at a company level. Companies are able to vary prices of individual medicines within their overall limit and within certain constraints. Under the PPRS this is known as modulation.

The PPRS price control does not limit new drug prices. Indeed, companies may launch a product at a higher price than they otherwise would have done in anticipation of being required to make future price reductions. Although quantification is difficult, there is little doubt the PPRS price control does constrain primary care drug expenditure below the level it would otherwise have been. Comparing 2005 and 2004 shows savings in primary care of about seven per cent from the new PPRS agreement, although this will reduce over time as companies introduce new drugs at uncontrolled prices. The extent of savings in the hospital sector is uncertain as the price control constrains list prices but hospitals usually negotiate to purchase below list prices.

The PPRS price control, rather than the profit control, is currently the major instrument for controlling prices as all companies have reduced prices under the price control but most are not constrained by the profit control.

The level of price cuts is negotiated by the DH and the ABPI and is not clearly linked to a comparison of UK prices with those in other EU countries or to other observable variables. Nor, more importantly, does it link prices to patient benefits. One supplier's prices may be above average patient benefit while another's may be below, but under the PPRS price control both have to reduce their average prices by the same percentage.

In the short run, this potentially undermines the NHS's ability to secure value for money (that is, maximise health gains for a given health budget). Given the global importance of UK prices, it may also have important dynamic effects, since the scheme does not necessarily reward companies that produce drugs with a high therapeutic benefit over those that do not. While it is true that periodic price cuts at least reward companies for bringing out new products (since those launched more recently will have been subject to fewer (or no) price cuts), there is no necessary correlation between new products and products that are particularly valuable to patients. The price control therefore gives no clear incentives to pharmaceutical companies to compete by investing in the most innovative and effective drugs. We would also question whether seeking to control prices through price cuts, the size of which is not obviously related to objective criteria, represents a sustainable model of pricing in the future.

Companies make considerable use of modulation to vary the prices of individual drugs, especially at the time of overall price reductions. In January 2005, modulated products accounted for

almost two-thirds of total sales by value (around one-third by products where the price was left unchanged, rather than cut by seven per cent, and around one third by products where the price was cut but not by seven per cent).

Although not stated in the PPRS agreement, DH measures modulated price changes using a current-weighted price index with volume weights based on direct supplies in the UK. This provides strong incentives to companies to concentrate price reductions on drugs for which directly supplied volume is likely to increase in response to a reduction in the list price (that is, for which demand is price sensitive). In assessing the effects of modulation, it is necessary to distinguish between those associated with competition to secure prescriptions and those associated with competition to supply pharmacies/wholesalers.

Our survey of GPs suggests prescribers' demand is relatively insensitive to price changes. Nevertheless, there may be circumstances where price does affect prescribing decisions and there is consequently brand-on-brand competition (for example where a number of different brands of an off-patent drug are available). In these circumstances, modulation creates the incentive for a multi-product company to increase the price of products which are relatively price insensitive and reduce the price, possibly to below marginal cost, of products which are relatively price sensitive. This would be to the advantage of companies with many products with differing price sensitivity, but is to the disadvantage of the NHS (which experiences higher cost), smaller branded suppliers (which find it more difficult to modulate because of their smaller product range) and generic suppliers.

Modulation may also increase the incentive to reduce prices of branded products ahead of patent expiry in order to discourage generic entry (because the price cuts can be funded by price increases on other price insensitive drugs). This is most likely for products with small markets where entry is relatively costly for generic suppliers.

Pharmacies and wholesalers have a strong incentive to purchase drugs from the cheapest available source. In some circumstances, pharmacies are able to choose between a number of different brands or between one or more brands and generics, and similar issues may arise as with competition for prescriptions. Under the 1999 PPRS, a number of companies sought to exploit the rules of the PPRS to include, in modulation calculations, volumes supplied under 'brand equalisation' deals, that is supplies of branded goods discounted to the generic price to fulfil generic prescriptions. DH told us it had reached a satisfactory agreement with all but one company. Under the 2005 PPRS, brand equalisation volumes meeting generic prescriptions have been explicitly excluded from modulation volumes.

Pharmacies and wholesalers can also choose between direct supplies and parallel imports (which in the UK are reimbursed at the same price). Modulation creates a strong incentive for companies to target price reductions on brands with the highest penetration of parallel imports. Modulations at the time of the 2005 price cut seem to have led to a reduction in average parallel import penetration from about 22 per cent in 2004 to 18 per cent in 2005. The effects of modulations targeted on parallel imports are complex but overall are likely to be beneficial to the NHS, in particular because the advantages to companies make them willing to accept in negotiations a larger overall price reduction than in the absence of modulation. In the longer

term, lower parallel imports means a higher proportion of NHS payments going to the company which originally developed the product, and this may be expected to benefit innovation.

While the price control has constrained the overall level of prices, we have concerns about the lack of an objective basis for the level to which prices are constrained and the impact of modulation on competition both brand-on-brand and between branded suppliers and generics. We believe the PPRS should be changed to address the issues we have identified. We set out in Annexe L various options for reform. The key areas include:

- the lack of an objective basis for price levels and changes could be addressed by relating maximum reimbursement prices for each drug to therapeutic value
- such an approach (which would substitute for across the board price cuts) would also address concerns about the adverse effect of modulation on competition, and
- as regards off-patent medicines, branded versions of medicines with generic competition could be reimbursed at prices linked to category M prices.

1 INTRODUCTION

- 1.1 The PPRS is a 'voluntary' scheme under section 33 of the Health Act 1999, and has been agreed between DH and ABPI. The Health Act 1999 also gives the Secretary of State power to create a statutory scheme, and the PPRS states that companies not electing to join the 'voluntary' scheme, or denied membership, will be subject to statutory regulation. The PPRS includes controls on profits (considered in Annexe H) and prices (considered in this annexe).
- 1.2 The PPRS price control limits the prices of existing medicines and has three main features:
- a series of agreed overall price reductions have accompanied the introduction of each of the last three PPRS agreements
 - at other times, PPRS companies are not permitted to increase the overall level of their prices, although, under the PPRS profit control (see Annexe H), companies may increase prices if their profits fall below a certain level, and
 - the price control applies at a company level. Companies are able to vary prices of individual medicines within their overall limit. Under the PPRS this is known as modulation.
- 1.3 The PPRS price control does not explicitly limit the initial price at which new medicines can be introduced, but companies are required to inform the DH about new products. New products can be divided into three main categories:
- new medicines (products requiring the granting of EU or UK new active substance marketing authorisation): the PPRS places no limit on companies' initial price for new medicines. This also applies to line extensions submitted within five years of the original marketing authorisation
 - other new products (those which have not required the granting of EU or UK new active substance marketing authorisation)¹: the company must agree the price with the DH. If the company and the DH cannot reach agreement, the company may appeal to the PPRS Arbitration Panel. In considering prices of other new products, the DH takes into account factors such as the price of other presentations of the same medicine or comparable products, forecast sales and the effect on the NHS drugs bill, the clinical need for the products, and any exceptional costs
 - increased strengths of existing formulations: these may not be priced proportionately higher than existing strengths.
 - the PPRS also states that the freedom of pricing of reduced strengths of existing formulations should not be coupled with product deletions so as to achieve hidden price increases.

¹ These would include combination products containing active substances that have been marketed separately, active substances with new indications and variations in formulation, presentation or pack size.

- 1.4 The price control applies unless or until profits fall below the minimum under the PPRS profit control, at which point a price increase is permitted. In contrast to price controls on utilities, there is no explicit allowance for inflation in the PPRS price control (although rapid inflation might be expected to lead to profits falling below the minimum and a consequent price increase).
- 1.5 The PPRS price control, rather than the profit control, is the major instrument for controlling prices: all companies (except any with sales to the NHS of less than £1 million, which are exempt) have reduced prices under the price control but most are below the profit control ceiling (see Annexe H).
- 1.6 In this annexe, we first describe price controls in broad terms in chapter 2 and assess price cuts as a mechanism for delivering the high level objectives of the scheme in chapter 3. Chapter 4 and 5 discuss the impact of price modulation on competition within the primary care sector through substitution by pharmacies and by prescribers and assess its overall effects. Chapter 6 considers the savings in primary care expenditure, while chapter 7 considers the impact on the hospital sector. Conclusions on the price control are provided in chapter 8.

2 PRICE CUTS

Introduction

2.1 This chapter sets out the relevant PPRS rules, and considers issues associated specifically with the price cuts.

Overview of rules

2.2 The introduction of each of the last PPRS agreements has been accompanied by an overall price reduction agreed between the DH and the ABPI. The headline price reductions were:

- 2.5 per cent in October 1993
- 4.5 per cent in October 1999, and
- 7.0 per cent in January 2005.

2.3 The seven per cent price cut which took effect in January 2005 does not apply to companies with NHS sales of less than £1 million. The majority of companies with NHS sales of more than £1 million have agreed to the terms of the PPRS, including the price cut and the subsequent limits on price increases. Companies with sales of between £1 million and £10 million have to achieve a lower overall level of price reduction as they are exempt from the price cut on the first £1 million of sales.

2.4 As discussed in Chapter 3 (modulation), the overall level of price cuts must be maintained through the term of the PPRS agreement. This applies unless DH is satisfied a company's profits are falling below the minimum under the PPRS profit control. As set out in Annexe H, since 1999 none of the AFR companies have obtained an increase on grounds of inadequate profitability, but smaller companies have obtained 23 price increases with a combined full year value of about £10 million (just over 0.1 per cent of the total value of PPRS sales). DH told us that in some cases, larger companies had sold products on to smaller companies which had subsequently obtained price increases. These are included in the 23 increases with a combined full year value of about £10 million.

2.5 There are four methods by which PPRS participants can meet the price control under the current PPRS agreement:

- by reducing all list prices by seven per cent on 1 January 2005 and maintaining these prices throughout the duration of the agreement
- by modulating and/or re-modulating, so that some or all list prices are reduced by less or more than seven per cent but a price index for these drugs shows a reduction of seven per cent. The price index is not explicitly stated in the PPRS agreement but DH use a current-weighted index

- by making a payment to DH of seven per cent of sales at list price (applies only to companies where OTC products account for 30 per cent or more of sales)
- by making a payment to DH of up to two per cent of sales at list price and delivering the remainder of the price reduction by reducing prices with or without modulation (applies to all companies). Companies may make a cash payment because of unanticipated under-delivery of the price cut, rather than a deliberate wish to make a cash payment.

Level of price cut

2.6 The level of price cut is the outcome of a negotiating process between DH and the ABPI. Negotiations take in all aspects of the PPRS, including the profit control, but the price cut is the most important matter negotiated. On the DH side, the ultimate decision about an acceptable level of price cut is taken by Ministers. The ABPI have the option of rejecting a price cut, and individual companies have the option of not joining the scheme, but any company not joining the scheme on the terms offered by DH faces statutory regulation.²

2.7 The outcome of the 2004 negotiations which led to the current PPRS was a seven per cent price cut, which was subsequently accepted by all companies including non-members of the ABPI. The level of this price cut was not clearly linked to a comparison of UK prices with those in other EU countries, nor was it linked in any way to the therapeutic value of each company's drugs, company profitability or other observable parameters.

New drugs

2.8 As noted above, companies are free to set the initial price of new drugs. Over time, as new drugs replace existing drugs, each price cut affects a smaller and smaller proportion of the total branded drug bill. This is illustrated in Table 2.1 which shows the percentage of branded drugs expenditure in the fourth quarter of 2005 accounted for by drugs sold at various earlier dates.

Table 2.1: Percentage of 2005 Q4 drugs bill accounted for by products/chemicals sold in year and quarter shown

	Products	Chemicals
1991Q1	15.5%	37.9%
1993Q3	21.4%	51.0%
1999Q3	65.8%	89.8%

Source: OFT analysis of PPA data. PPA data covers primary care in England

² Sections 34-36 Health Act 1999

- 2.9 If we compare 2005 Q4 expenditure with 1993 Q3 (the quarter before the 1993 price cut), only about 21 per cent of 2005 Q4 expenditure was accounted for by products already sold in 1993 Q3, which were directly affected by the October 1993 price cut. The percentage increases to 51 per cent if all products with the same BNF chemical name as products sold in 1993 Q3 are included, as new formulations and/or delivery methods seem to have been significant.³
- 2.10 The extent to which prices of new formulations and/or delivery methods are affected by price cuts is uncertain so this analysis suggests that, by the fourth quarter of 2005, between 49 and 79 per cent of branded drug expenditure is unaffected by the 1993 price cut. The comparable figures for the 1999 price cut are 10 to 34 per cent. These figures suggest the percentage of expenditure unaffected by any price cut after five years of the current agreement could be 8 to 28 per cent,⁴ depending on the extent to which the price control constrains the price of new formulations and delivery methods.

Impact of price cuts on growth in prescription costs

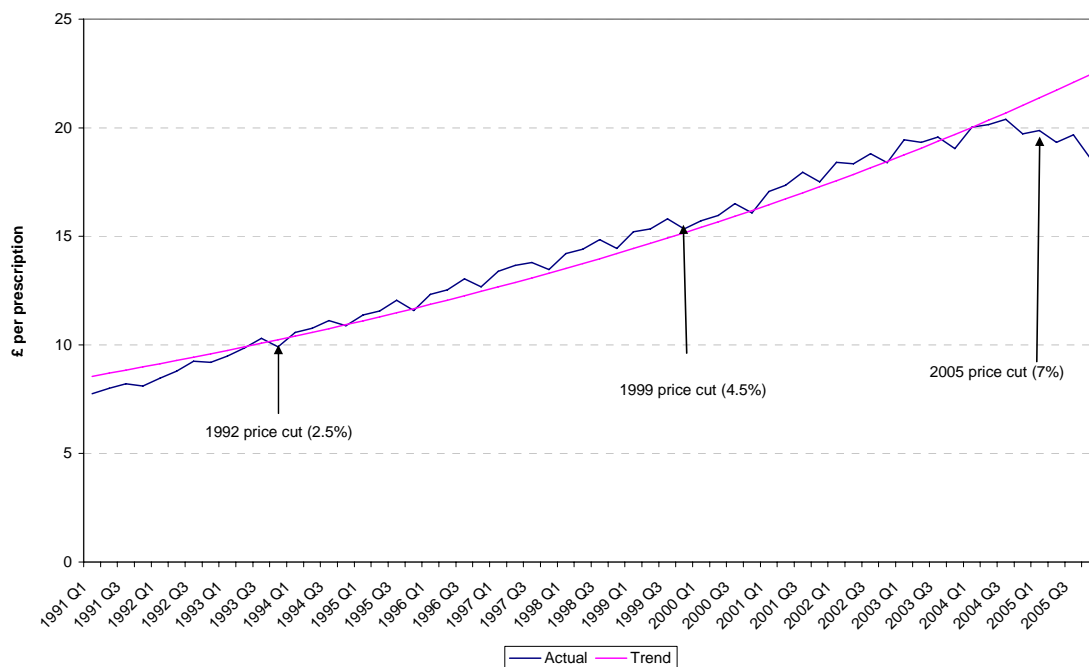
- 2.11 Average cost per branded prescription has increased by a trend rate of growth of about 6.7 per cent, as illustrated in Figure 2.1. This may reflect mix effects (a higher proportion of prescriptions being accounted for by higher priced drugs), pack sizes⁵ and strengths prescribed as well as higher prices of new drugs. The growth in average cost per prescription levelled off in 2005: this is likely to be due both to the 2005 price cut and the impact of generic substitution of some drugs with above-average prices.

³ The analysis may also be affected by product name changes.

⁴ The effect after six years of the 1999 agreement was 10 to 34 per cent, so the effect after five years of the current agreement may be expected to be five sixths of 10 to 34 per cent, that is, 8 to 28 per cent.

⁵ A DH analysis for 1992 to 1999 calculated that product quantity per prescription item increase by 1.1 per cent per year, Pharmaceutical Price Regulation Scheme – Fourth Report to Parliament, DH, 2001.

Figure 2.1 Average reimbursement price per branded prescription (primary care, England)



Source: OFT analysis of PPA data

Incentive effects of price cuts

- 2.12 As discussed elsewhere in the report, a fundamental concern we have about the scheme is that neither the profit cap nor the price cuts help to secure value-reflective prices. The one-off price cuts are imposed across all of a company's products, irrespective of their therapeutic value. One supplier's prices may be above average patient benefit while another's may be below, but under the PPRS both have to reduce their average prices by a similar percentage.
- 2.13 This has significant short run effects, undermining the NHS's ability to secure value for money (that is, maximise health gains for a given health budget), as discussed below. Given the global importance of UK prices, it may also have important dynamic effects, since the scheme does not provide any means of rewarding companies that produce drugs with a high therapeutic benefit over those that do not. It therefore gives no clear incentives to pharmaceutical companies to compete by investing in the most innovative and effective drugs.
- 2.14 It is true that the periodic cuts at least reward companies for bringing out new products (since those launched more recently will have been subject to fewer (or no) price cuts). However, there is no necessary correlation between new products and products that

are particularly valuable to patients. As discussed in Annexe M, the fact that a drug receives a New Active Substance marketing authorisation does not necessarily imply that it is more valuable in therapeutic terms than existing products on the market.⁶ Therefore this approach is at best a very blunt and indirect method of rewarding valuable innovation.

- 2.15 A further issue is that the price cuts, and in particular the prospect of future price cuts, may affect the price of new drugs. Companies set initial prices in the knowledge that there will be a price cut at the time of the renegotiation of the PPRS. While there may be other constraints on prices of new drugs, such as the prospect of NICE and SMC appraisals and parallel trading, firms are likely to take future price cuts into account when setting initial prices. The more these price cuts become a regular feature of PPRS, the more firms are likely to anticipate them in setting initial prices (by pricing above what they would otherwise have charged), particularly towards the end of a given PPRS period.
- 2.16 Under such an approach, price setting could become a strategic game in which firms attempt to guess the level of forthcoming price cuts and DH attempts to double guess this effect in setting the level of price cuts. We might expect the outcome of this game to be ever-increasing price cuts, which is consistent with what we have seen in practice (with cuts of 2.5 per cent, 4.5 per cent and 7 per cent over the last three schemes). Continuing to seek to control prices through the simple mechanism of an unsystematic price cut does not therefore appear to be a sustainable option for the future.
- 2.17 In Annexe L we set out some alternative options for controlling prices that avoid these effects. In the rest of this annexe, we consider two related issues connected to the use of modulation to deliver PPRS price cuts:
- whether modulation distorts competition in pharmaceuticals markets, and
 - whether the headline savings claimed for PPRS price cuts are achieved in practice.

⁶ Indeed, DH and other stakeholders have indicated to us that there are several branded drugs that are valuable to patients but for which, since they have been on the market for a long time and subject to several price cuts, price may be low relative to cost, making production relatively unattractive and contributing to supply difficulties.

3 MODULATION

- 3.1 Companies are able to deliver the initial price cut either by an across the board cut in all their prices or by varying the price cut across their products (modulation). Modulation gives rise to a number of issues and uncertainties which are covered in the PPRS rules.
- 3.2 This chapter discusses the PPRS rules on modulation, presents evidence collected on the extent of modulation and looks briefly at the competition effects of modulation. Such competition effects are examined in more depth in chapters 4 and 5.

PPRS rules on modulation

- 3.3 The rules on modulation in the current PPRS agreement state that companies are not permitted to:
- substitute discounts or contract prices in force during the six months prior to any modulation
 - include price reductions that may be necessary as a result of patent or SPC expiry. Price reductions cannot be included in modulation proposals where the patent/SPC has expired within one year before, or will expire within two years after, the date of modulation (six months and one year respectively for modulation at the time of a price cut such as 1 January 2005) ⁷
 - include sales volumes resulting from brand equalisation deals (deals involving additional discounts that enable branded products to be dispensed against generic prescriptions).⁸
- 3.4 The lower prices negotiated at the start of each PPRS agreement must be maintained during the term of each agreement companies may not increase any prices unless they re-modulate: under re-modulation the average level of their prices may not increase and individual price increases are limited to no more than 20 per cent compared to the last day of the previous PPRS agreement (31 December 2004 for the current agreement).⁹ Re-modulation can take place at any time but DH requires 28 days notice of companies' proposed price changes. It then has 21 days to respond but can only withhold agreement where it can show that remodulation would place the delivery of the price reduction in doubt.

⁷ Where a competitor product enters within two years of patent/SPC expiry, this is extended to two years after the entry of the competitor product.

⁸ This provision was not explicitly included in previous PPRS agreements (see discussion in chapter 4)

⁹ For new products (those introduced after the end of the previous agreement), price increases are limited to 20 per cent compared to the price at the date of introduction and price reductions can only be included in the modulated average price after two years.

Measurement of price changes

3.5 Where companies modulate, they reduce some prices by more than the headline price cut and others by less: it is then necessary to have some means of measuring the average price reduction. Although it is not explicitly stated in the PPRS, DH monitor delivery of the price cut by modulating companies using a current-weighted price index. More specifically, for each year of the price control:

- DH calculate savings for each modulated brand of drug by multiplying the price reduction for that brand (the difference between its current price and its price before the start of the control—31 December 2004 for the existing price control) by its current volume. Calculated savings therefore show the difference between actual current spend on the brand and what spend would have been at current volumes and 31 December 2004 prices
- DH then calculate percentage savings for that company's modulated drugs by adding up savings for each of its modulated drugs and dividing by total current spend plus calculated savings on all the company's modulated drugs.¹⁰

DH's formal monitoring of modulation under the PPRS uses audited data supplied by companies on the volume of their direct supplies to the NHS. It does not cover parallel imports of the same brands (on which PPRS members would not have precise information. However, as we explain below, DH also monitors total volumes using prescription pricing (PPA) data.

3.6 DH's use of a current-weighted, rather than a base weighted, index has advantages in aligning companies incentives with those of DH (see paragraphs 5.10 to 5.17) and avoiding any incentive for companies to gain by loading price increases on rapidly growing products and reducing prices of slowly growing products.¹¹ However, it also has the potential to add to distortions of competition between companies supplying the NHS, as discussed in chapter 4.

3.7 One result of using a current weighted index is that, as actual volumes are not known either to the company or DH until the end of the year in question, actual delivery of the price cut is uncertain at the time of any price modulation. During the course of each PPRS agreement, companies falling short of the savings target by more than 0.5 per cent (that is, achieving savings of less than 4.0 per cent for the 1999 PPRS and 6.5 per cent for the 2005 PPRS) are required to make a cash payment to DH. Companies

¹⁰ More formally, DH define proportionate savings as $\sum (p_0 - p_1) q_1 / (\sum p_1 q_1 + \sum (p_0 - p_1) q_1)$ for each modulating company. This may be rewritten as $1 - \sum p_1 q_1 / \sum p_0 q_1$, where the latter expression is the Paasche (current-weighted) price index, where summation is over all modulated branded medicines, p_0 is the list price before the price cut (31 Dec 2004 at present), p_1 is the list price in the current year and q_1 is the volume supplied by the company in the UK (excluding any parallel imports) in the current year. Where there is more than one modulation in a year, p_1 is the weighted average for the year. For second and subsequent years, new drugs can be included under some circumstances and p_0 for new drugs is the price at the time of introduction.

¹¹ Such an incentive occurs with a Laspeyres (base weighted) price index.

carry forward any under-delivery of less than 0.5 per cent and over-delivery (without interest) but must deliver the price control in full over the course of the scheme. Thus, under the 1999 PPRS, companies were required to deliver savings of at least 4.5 per cent compared to 30 September 1999 prices over the course of the scheme.¹² Any modulating companies which do not deliver the savings through price changes have to make up the under-delivery through a cash payment.

Modulation in 2005

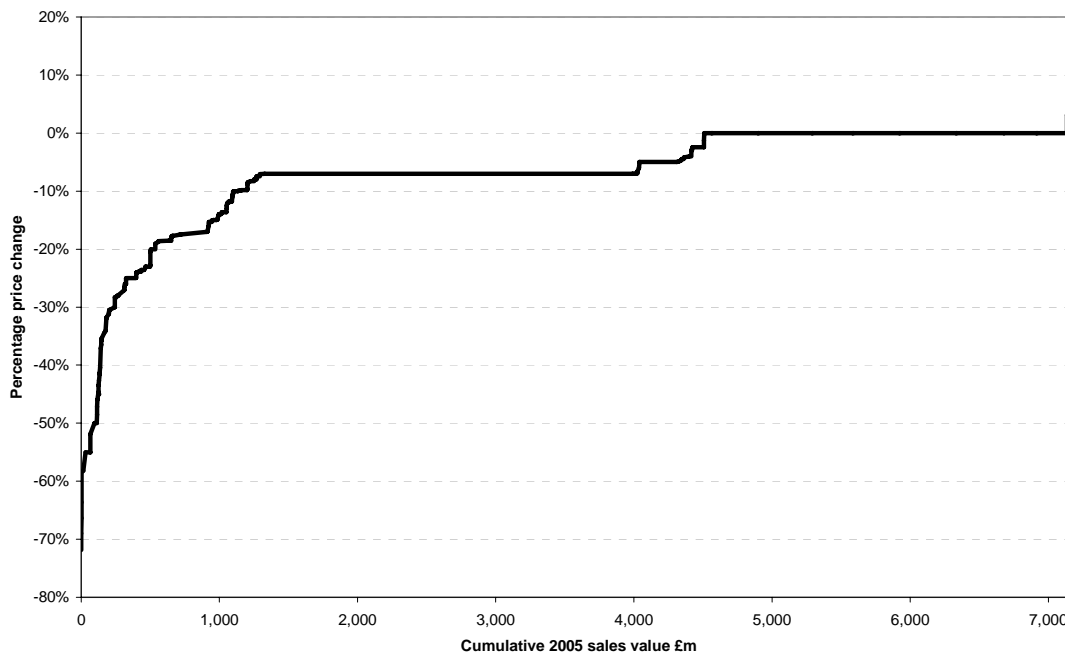
3.8 As stated in paragraph 3.2, there are four methods by which PPRS participants can deliver price cuts under the 2005 PPRS. For the 37 large AFR companies on which we have data, numbers in each of these categories for 2005 were:

- seven simply reduced all their list prices by seven per cent – did not modulate
- 26 modulated, of which 11 modulated on all their sales and 15 on only part of their sales
- none delivered the full price cut just by making a payment to DH, and
- four made a cash payment to deliver some, but not all, of the required price cut.

3.9 Figure 3.1, based on data reported by AFR companies to DH, shows the pattern of price reductions during 2005. Just over a third (36 per cent) of 2005 sales value was accounted for by products where prices were not modulated (reduced in price by exactly seven per cent) and a similar proportion by products where the prices were left unchanged, with one fifth of sales value reduced in price by more than seven per cent and around 14 per cent of sales value by more than 15 per cent. The price of around 20 drugs, accounting for a tiny proportion of sales, increased during the course of 2005 (although companies were not allowed to increase prices on 1 January 2005 a few did so later in the year). The data also suggest that, in total, the AFR companies delivered an average price reduction of 7.2 per cent: some companies over-delivered and others under-delivered but over-deliveries exceeded under-deliveries.

¹² Savings are defined as $\frac{\sum \sum (p_0 - p_1) q_1}{(\sum p_1 q_1 + \sum (p_0 - p_1) q_1)}$ where notation is as in previous footnote and the double summation is over modulated products and the 5.25 years that the 1999 PPRS was in force.

Figure 3.1: Comparison of prices at 31 December 2005 with prices at 31 December 2004



Source: OFT calculations based on information submitted by AFR companies to DH.

Modulation 1999-2004

- 3.10 For the 1999 price cut we have data on 32 large AFR companies which suggest:
- five companies did not modulate
 - 24 modulated, of which 15 modulated on all their sales and nine on only part of their sales
 - none delivered the price cut just by making a payment to DH, and
 - three companies made a cash payment to deliver some, but not all, of the required price cut.
- 3.11 Our analysis of AFR companies suggests that, in 1999, a somewhat higher proportion of sales value (than in 2005) was accounted for by products with unchanged prices—about 50 per cent. About 28 per cent of sales value was accounted for by non-modulated products (those where the price was reduced by exactly 4.5 per cent) and 21 per cent by products, the price of which was reduced by more than 4.5 per cent.
- 3.12 Table 3.1 shows the extent of modulation through the 1999 scheme. This suggests price modulations are greatest at the time of the initial price cut and lowest in the immediately following period. In the subsequent years, modulated products accounted for between 10 per cent and 14 per cent of sales revenue. Table 3.1 also shows that

cash payments accounted for a small proportion of the savings delivered by these companies under the 1999 scheme.

Table 3.1: Modulation and cash payments under the 1999 scheme

Year	Modulations			Cash payments	
	Number of products	Value £m*	% of sales value†	Value £m	% of savings‡
1999Q4	1,928	3,766	72%	0.4	0.2%
2000	75	389	7%	2.7	1.4%
2001	417	791	14%	3.2	1.4%
2002	336	616	10%	0.0	0.0%
2003	278	690	11%	0.0	0.0%
2004	219	809	13%	2.2	0.9%

* Value at 31 September 1999 list prices.

† Sales value of PPRS products at list prices is OFT estimate and is not available for all companies. Percentage is weighted average for those companies where sales value could be estimated.

‡ Cash payment as percentage of savings for the year.

Source: OFT calculations based on information submitted by 32 AFR companies to DH.

3.13 All but one of the 32 companies delivered 4.5 per cent savings across the period from October 1999 to December 2004 as required under the 1999 scheme.¹³ In eight cases, the savings included a cash payment. However, in most other cases, the companies over-delivered the required savings, and 10 companies significantly over-delivered savings.¹⁴ Total over-delivery of savings was about £200 million (at 31 September 1999 list prices), representing about 3.4 per cent of the 2004 sales for the 32 companies. Over the five and a quarter years of the scheme, this represents an average over-delivery of about 0.6 per cent per year.

3.14 Companies probably over-deliver savings because the volume of products with reduced prices increases more rapidly than expected at the time of modulation. Nevertheless, companies that significantly over-delivered savings forewent the opportunity to increase prices through re-modulation at some point before 31 December 2004. The reasons for this in individual cases are unclear, but the costs associated with price changes may discourage companies from making too many price changes.¹⁵

¹³ Based on company returns covering their direct supplies in the UK (excluding parallel imports). The volumes submitted by one company are disputed by DH as they include volumes dispensed generically under brand equalisation deals and DH are seeking a cash payment to obtain full delivery of savings excluding brand equalisation volumes (see paragraph 5.5).

¹⁴ These companies over-delivered by more than 1 per cent of the total sales value of modulated products and by more than 1 per cent of estimated total 2004 sales value (including both modulated and non-modulated products). In two of the 10 cases, over-delivery was more than 10 per cent of estimated total 2004 sales value.

¹⁵ The willingness of some companies to forego price increases towards the end of the 1999 PPRS does not indicate that they would have priced at the same level in the absence of the control, as companies would be unlikely to have reduced prices in the first place in the absence of the PPRS price control.

Effects of modulation on competition

- 3.15 As noted above, DH uses a current-weighted index for the purposes of price modulation. It should be emphasised that modulation applies to list as opposed to transaction prices, and it applies to volumes sold by the company in the UK rather than prescribed volumes (that is, it does not include parallel trade). Furthermore, because the index used is a current-weighted (Paasche) index it provides strong incentives for companies to concentrate reductions on drugs for which volume directly supplied is likely to increase in response to a reduction in the list price (that is, for which demand is price sensitive).
- 3.16 Modulation therefore has varying effects on competition according to the nature of the market. Accordingly, in considering the effects of modulation, it is useful to distinguish between medicines for primary care and for hospitals and, within primary care, between substitution by pharmacies and subscribers:
- in primary care, GPs (and in future others with relevant authority) make prescribing decisions, but pharmacies are responsible for supplying the appropriate medicine and are reimbursed by the NHS at list price (less a clawback). What this means in practice is that:
 - prescribers decide the medicine, but
 - pharmacies (and dispensing doctors) decide the supplier of that medicine, which they do presumably on the basis of which is on the market more cheaply at the time of purchase. For generic prescriptions of off-patent medicines pharmacies can usually choose between a number of manufacturers, while for on-patent medicines and branded prescriptions, pharmacies can choose between direct supply and parallel imports (the reimbursement price for both is UK list price less clawback)
 - in hospitals, doctors mostly prescribe according to formularies, which set down the hospital's preferred drug for treating many conditions, and the cost to the NHS is the price actually paid - list price less discount negotiated by the hospital.
- 3.17 The effects of modulation on competition in primary care are considered in greater detail in the next two chapters.

4 PRIMARY CARE: EFFECT ON COMPETITION TO SECURE PRESCRIPTIONS

Introduction

4.1 We turn now to consider the impact of changes in prices on the volume of medicines prescribed in NHS primary care. In order to focus on prescriber effects, we abstract in this chapter from the issue of parallel imports (see chapter 5) and also from other factors that affect prescribed volumes, for example time trends in prescribing (as such trends occur irrespective of any price changes). We first consider whether prescribers (GPs and, in future, others) are at all sensitive to price changes.

Price sensitivity of prescribers

4.2 A number of studies have found prescription drug use to be price inelastic: Kanavos and Cost-Font quote five studies which produced elasticity estimates between -0.02 and -0.33.¹⁶ As discussed in Annexe C, GPs are not generally very price aware or price sensitive. Typically they have limited awareness of prices of individual drugs and they do not have strong incentives to respond to price changes. Our findings are consistent with those of the joint DH/ABPI study into the extent of competition in the supply of branded medicines to the NHS, which summarised the situation as follows: 'overall the research suggests that prescribers prefer to select drugs on the basis of clinical efficacy, safety, tolerability and convenience to the patient in that order; cost is generally considered only when all of these are equal'.

4.3 While PCTs have the incentive to respond to relative price changes (for example where substitution of a cheaper for a more expensive drug leads to expenditure savings), they generally do not have strong levers to ensure GP compliance with budgetary constraints. In practice, PCTs seem to seek budgetary balance through curtailing expenditure on other (non drug) forms of healthcare intervention. PCTs do have specific means for constraining expenditure on high cost drugs but these are mostly prescribed in hospitals rather than in the primary care sector.

4.4 As is also discussed in Annexe C, however, the price sensitivity of GPs is likely to differ for different types of drug. Where a major event has occurred, for example, such as a drug going off patent leading to the availability of cheap generics, and where this is then reflected in their contractual incentives,¹⁷ GPs may be incentivised to respond by increasing overall prescribing. Similarly, price sensitivity may be greater where off-patent brands of the same chemical are competing (since therapeutic differences will be smaller than when broader substitutes are competing).

¹⁶ Kanavos, P and Costa-Font, J (2005) '*Pharmaceutical parallel trade in Europe: stakeholder and competition effects*', Economic Policy, October.

¹⁷ The Quality and Outcomes framework in the General Medical Services contract for GPs rewards specific clinical targets.

- 4.5 PCTs may also be more able to influence behaviour where GPs are not subject to strong countervailing marketing from pharmaceutical companies, for example several PCTs have been successful in persuading GPs to prescribe a branded generic instead of generic simvastatin, which is not specifically marketed to GPs by any one company (see paragraphs 4.26 to 4.29 below).
- 4.6 Moreover, price sensitivity may increase in future, at least for certain categories of drugs, with the advent of practice-based commissioning. It is therefore important to pursue the issues associated with price-related changes in demand, as they are relevant to assessing the effects of the price control both now and in the future.
- 4.7 Accordingly, in the rest of this chapter we consider two related issues: how demand effects, including prescriber substitution, may affect the results of modulation; and how the ability to modulate may affect competition between companies to secure GPs' prescription.

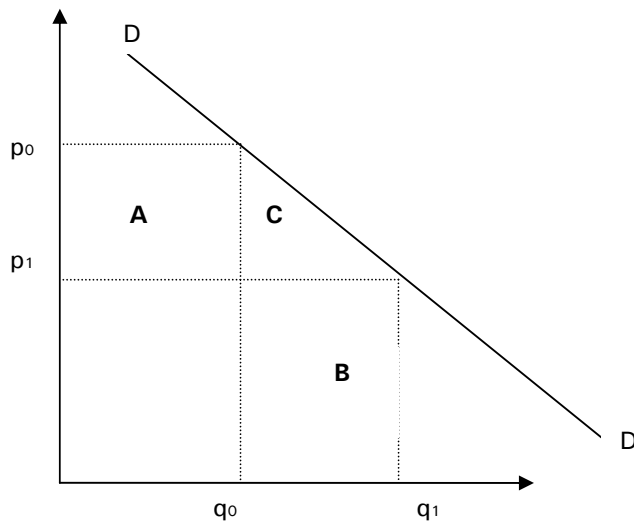
Demand effects

Across-the-board price cut

- 4.8 In general, a reduction in price makes a product more attractive for users, relative to alternatives, and may be expected to lead to an increase in its volume of use. The impact on expenditure then depends both on the extent of the price cut and on the extent of any resulting volume increase. This is illustrated in Figure 4.1: the impact of a cut in price (from p_0 to p_1) on expenditure is represented by area B (higher expenditure due to higher volume) minus A (lower expenditure due to lower price). If, as illustrated in Figure 4.1, demand is elastic (the slope of the demand curve DD is relatively shallow) a price reduction may lead to little change in expenditure, or even to an increase in expenditure, compared to the level that would otherwise prevail. Of course, where volume increases, users benefit from the additional volume and the benefit can generally be assumed to exceed the additional expenditure.¹⁸ Where demand is inelastic (the slope of the demand curve is near vertical), as is more likely to be the case for primary care drugs, a reduction in price will lead to reduction in expenditure.

¹⁸ In Figure 3, the net benefit to users is area C.

Figure 4.1: Impact of lower price on demand and expenditure



- 4.9 If an overall price reduction, such as the seven per cent price cut in January 2005, is delivered through an across-the-board reduction in all branded drug prices, both each individual drug and its alternatives are reduced in price by a similar percentage. Relative price levels would be maintained and, consequently, material volume effects for individual products from an across-the-board price cut seem unlikely.
- 4.10 Modulation, however, can lead to large changes in relative prices both at the time of an overall price cut and at other times. We therefore focus attention on modulation and its effects.

Modulated price changes

- 4.11 Where modulation is involved, Figure 4.1 does not represent a complete picture since it does not reflect that, in order to increase the price of one drug, a company has to reduce the price of one or more other drugs.
- 4.12 Figure 4.2 illustrates the situation for a company with one drug with elastic demand and another drug with inelastic demand. Under the assumptions in Figure 4.2 (which are exaggerated for illustrative effect), the company can maximise profits by reducing price on drug 1 and increasing the price of drug 2 to compensate (we ignore drug 3 for the time being). As a result of this, the company increases its revenue and the NHS its expenditure by $(D + B - A)$, which implies an increase in spending of $(B + 2C)$.¹⁹ However,

¹⁹ Since the rules on modulation imply that $D = A + 2C$

if the increase in volume of drug 1 is due to treatment of additional patients, there is also a benefit to patients from the additional prescriptions, which needs to be taken into account in assessing the net impact on the NHS.

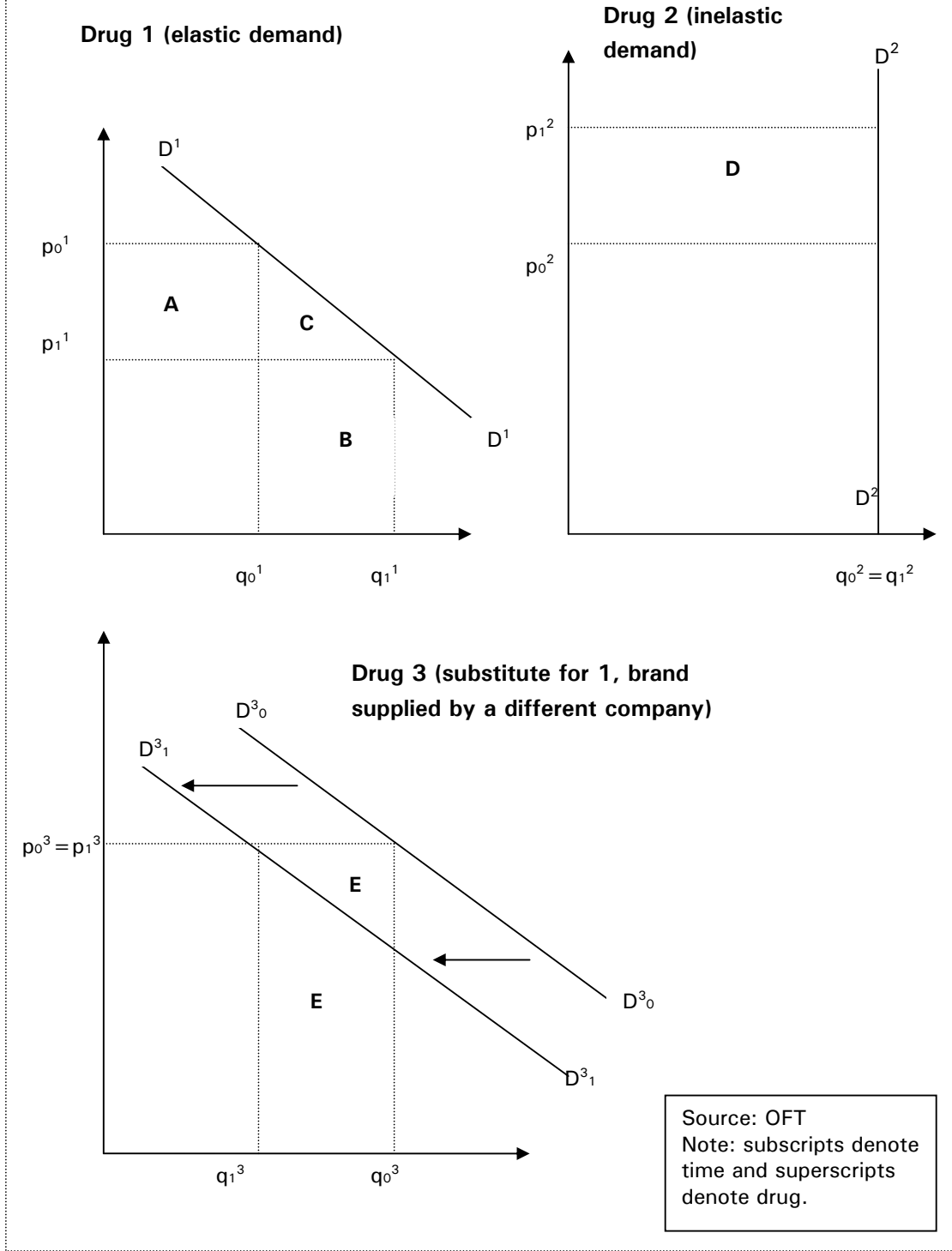
- 4.13 In Figure 4.2 this health benefit is $(B + C)$, so there is a net cost to the NHS of C .²⁰ More generally, the net cost to the NHS as a proportion of expenditure in the absence of the price changes lies between zero and the difference between a current-weighted (Paasche) price index and a base-weighted (Laspeyres) price index.²¹ The intuitive explanation for this is that a weighted average price change can be measured using volume weights before the price change (Laspeyres) and volume weights after the price change (Paasche). The PPRS uses the Paasche measure, which (assuming a downward sloping demand curve) gives a larger price reduction, but the true price change lies between the two indices.
- 4.14 Figure 4.2 assumes demand for drug 2 is perfectly inelastic (that is, demand does not respond at all to price changes) and, under this assumption, it is profitable for the company to reduce the price of drug 1 to zero (because increasing volume on drug 1 leads to a modulated increase in price on drug 2²²). If demand for drug 2 is much more inelastic than drug 1 but not perfectly inelastic (that is, demand responds in a very limited manner to price changes), it will not be profitable to reduce the drug 1 price all the way to zero, but it may still be profitable to reduce it below marginal cost (as long as the initial price of drug 1 is far enough above marginal cost and the difference in elasticity between drugs 1 and 2 is large enough).

²⁰ If the shape of the demand curve is not known (only the amounts prescribed with and without the price change are known), the net cost to the NHS lies between zero and $2C$.

²¹ The Laspeyres price index is $\sum p_1q_0 / \sum p_0q_0$ using the notation of previous footnotes.

²² As long as the initial price of drug 1 is in excess of marginal cost and demand for drug 2 is completely inelastic, cutting the price of drug 1 leads to an increase in revenue equal to the change in drug 1 volume times the difference between the initial price of drug 1 and marginal cost of drug 1.

Figure 4.2: revised impact of price changes on demand and expenditure



- 4.15 We turn now to the case where additional volume for drug 1 is at the expense of a third drug (which could also be a rival brand or generic supply of drug 1). This is illustrated in the lower part of Figure 4.2 where the price of drug 3 is assumed not to be changed. Now, there are expenditure savings on drug 3 (shown as area E in Figure 4.2) which partially offsets the additional expenditure on drugs 1 and 2.²³ Assuming the price of drug 3 lies between the old and new prices of drug 1, NHS expenditure increases. The extent of the increase lies between zero (if the price of drug 3 equals the old price of drug 1) and the difference between a current-weighted (Paasche) price index and a base-weighted (Laspeyres) price index (if the price of drug 3 equals the new price of drug 1). NHS expenditure increases because the use of current volumes in the modulation calculations means the modulating company can increase revenue from its inelastic drug 2 to cover both lost revenue due to the lower drug 1 price, and notional revenue at its previous drug 1 price on the volume it gains from other companies.
- 4.16 The substitute drug 3 may be another drug, a rival brand of the same drug or a generic. In all cases, the supplier of that drug is likely to experience lower revenue and profits as a result of modulation by the first company (which increases its revenue and profits). Where drug 3 is a brand, it will itself be covered by the PPRS and its supplier may itself be able to respond by modulating down the price of drug 3 and modulating up the price of its other drugs. If this is not possible, the supplier may be forced simply to reduce the price of drug 3 which would be disadvantageous to it (but beneficial to the NHS in reducing expenditure). On the other hand, if unable profitably to respond, a supplier of a substitute drug might be forced to withdraw from the market.
- 4.17 Summing up the analysis in Figure 4.2, a modulating company has the incentive to increase the price of products with relatively inelastic demand and reduce the price of products with relatively elastic prescriber demand (in some circumstances to below marginal cost), with the following effects:
- if lower prices generate additional prescriptions (rather than substitution by prescribers between drugs), there is additional cost to the NHS and a health benefit to patients
 - if lower prices generate substitution from another brand, there is additional cost to the NHS (see paragraph 4.15) and potentially a detrimental effect on the supplier of the substitute brand, and
 - if lower prices generate substitution from generics, there is again additional cost to the NHS and potentially an adverse effect on the generic market.
- 4.18 Thus, modulation may create perverse incentives to reduce price below marginal cost and may have effects on competition both between companies offering different

²³ The change in NHS costs is $(A - B - D + E)$. If the price of drug 3 is the same as the old price of drug 1 (as illustrated in Fig 4), this is zero since $D = (A + 2C)$ and $E = (B + 2C)$. If the price of drug 3 is equal to the new price of drug 1, this is $2C$ since $D = (A + 2C)$ and $E = B$.

branded drugs within the PPRS and potentially between companies offering branded drugs and generic suppliers. We consider these effects in the following two sections.

Competition between brands

- 4.19 As noted above, a large multi-product company may increase its profits through modulation but this may be at the expense of a smaller company with fewer products which is unable to benefit much from modulation. At the extreme, a company with one product could either lose much of its market or have to reduce prices in response to a large company modulating down the price of a drug which competes with that of the smaller company. This could have the result that the smaller company is unable to recover the costs of its R&D and the prospect of such an outcome could discourage smaller companies from launching new drugs. It is even possible that modulated price reductions by a larger company could mean that a smaller company (with just one or a small number of price sensitive products) is unable to cover its fixed costs and hence be forced out of the market. Such effects could affect either therapeutic competition between different medicines within a class with similar effects, or competition between brands of a single off-patent medicine. Effects in the latter area are probably more likely as price sensitivity is likely to be greater.
- 4.20 An extreme example of this is illustrated in Table 4.1. A large company and a small company both supply drug 1 and the large company also supplies drug 2 with inelastic demand. Table 4.1 illustrates that it is profitable for the large company to modulate down the price of drug 1 in order to gain market share from the small company and finance this through increasing the price of drug 2. This can even be the case, as illustrated in Table 4.1, if the large company reduces the price of drug 1 to below marginal cost.

Table 4.1: Illustration of modulation to reduce brand price to compete with another brand

	Quantity	Price	Spend	Row
Before modulation				
Drug 1				
Large company	50	1.00	50.00	1
Small company	50	1.00	50.00	2
Drug 2				
Branded supply by large company	100	1.00	100.00	3
Total supply by large company			150.00	4=1+3
Total cost to NHS			200.00	5=2+4
After modulation				
Drug 1				
Large company	90	0.20	18.00	5
Small company	10	1.00	10.00	6
Drug 2				
Branded supply by large company	100	1.72	172.00	7
Total supply by large company			190.00	8=5+7
Total cost to NHS			200.00	9=6+8
Modulation calculations for large company				
	Quantity	Price reduction	Saving	
Drug 1	90	0.80	72.00	10
Drug 2	100	-0.72	-72.00	11
Total saving			0.00	12=10+11
Extra cost and profit for large company				
	Extra quantity	Marginal cost	Value	
Drug 1	40	0.25	10.00	13
Drug 2	0	0.25	0.00	14
Extra cost			10.00	15=13+14
Extra profit			30.00	16=8-4-15

Source: OFT

4.21 The rules on modulation therefore have the potential to distort competition between firms with a large portfolio of drugs and those with a smaller portfolio and especially those with only a single drug. Two organisations while supportive of the PPRS generally, expressed concern about the effects of modulation on smaller companies:

- BIA (Biotechnology Industry Association) told us that, while it recognised the significant advantages that price modulation allows for larger pharmaceutical companies, it also recognised that price modulation can have a negative impact on smaller bioscience companies that typically have one or two products in their portfolios. It would normally take a smaller company many years to build up a portfolio where it could even begin to consider the possibility of price modulation, and

- EMIG (Ethical Medicines Industry Group) told us that, although it would not welcome the scrapping of modulation, it was concerned that price modulation has an effect on the R&D investment potential for many companies in the small pharmaceutical sector. EMIG said that small and emerging companies are not able to modulate in the same way as larger pharmaceutical companies, and that this imbalance in price adjustment gives rise to insecure financial planning in the small pharmaceutical sector due to the ability of larger pharmaceutical companies to modulate across a wider range of products and offset reductions accordingly. EMIG added that it could enable larger pharmaceutical companies to inadvertently price smaller competitors out of the market.

4.22 A small pharmaceutical company told us it derived most of its revenue from one of only two products it has on the market. This product is one of only two main products in a specific therapeutic niche, the other being supplied by one of the UK's larger pharmaceutical companies. The larger company has chosen to use modulation to reduce the price of its product by more than seven per cent, compensating by lower reductions on other products in its portfolio. For the smaller company this opportunity is not available because the product concerned is such a substantial part of its total business. Moreover, it believes that there is a significant degree of price sensitivity in the therapeutic niche – indeed it had only been able to enter the market by offering a lower price to GPs and PCTs. This leaves the small company with little option other than to reduce its price to maintain its competitiveness but it said this has had an adverse effect on its profitability and its smaller price advantage meant its growth slowed considerably, all of which had adversely affected its ability to research and develop new products.

Competition between brands and generics

4.23 The UK has a high rate of generic prescribing and competitive generic markets (see Annexe A). When medicines lose patent/SPC protection, suppliers of the originator brand have tended not to reduce its price to compete with generic supplies (see Annexe A). Possible reasons for this include a desire to prevent parallel exports from the UK and reputational damage to the brand,²⁴ and the fact that there is a small proportion of highly price insensitive GPs that continue to prescribe off patent drugs by brand even if the price remains high. Indeed, evidence reviewed in Annexe C suggests that a significant number of GPs appear to believe (wrongly) that brands do tend to drop their prices when going off patent.

4.24 While, for the major drugs, prices of originator brands have not generally been modulated down to compete with generics, one possibility is that the originator brand price is modulated down before patent expiry in order to discourage generic entry. This is more likely on lower volume drugs since any fixed costs of generic entry are a higher proportion of price on lower volume drugs. We noted that Procter and Gamble

²⁴ This might be avoided by launching a second brand ('pseudo generic') shortly before patent expiry.

modulated down by about 40 per cent the price of Didronel (disodium etidronate) tablets and Didronel PMO during 2005, ahead of patent expiry in June 2006.²⁵

- 4.25 Another situation of relevance is where a branded modified release product is an alternative to generic supply of the ordinary release product. Modulated reductions in the price of the modified release product could be financed by modulated increases in other products and, assuming prescriber price sensitivity, increase volume at the expense of generic supply of the ordinary release product. We noted above that in January 2005 Pfizer reduced by 55 per cent the price of Cardura XL, a modified release version of doxazosin, the patent of which expired in April 2002. As well as reducing parallel imports (see paragraph 5.21), this may have improved Cardura XL's market position relative to generic doxazosin – Cardura's XL's share of doxazosin continued to fall in 2005 but it may have declined less than in the absence of the price cut.²⁶

Margin arbitrage between brands and generics

- 4.26 It can be profitable for a branded drug to be priced so that it has a lower reimbursement price than generics. This can be profitable for a branded supplier because the reimbursement price for category M generics includes a substantial mark-up on the average pharmacy purchase price but branded drugs do not include a large mark-up (the disparity arises because of the arrangements for remunerating pharmacists, see Annexe A). The brand is marketed to PCTs on the grounds that it will save them money, and PCTs then persuade prescribers to prescribe the cheap brand rather than a generic. We describe this strategy as margin arbitrage.
- 4.27 Although there is an immediate benefit to some PCTs, the loss of margin by pharmacists can be recouped under the pharmacy contract and consequently the ultimate effect is likely to be increased costs for the NHS (we discuss this point in more detail in Annexe L) This adverse effect on NHS costs is compounded if modulation enables the branded supplier to set price reductions on brands, competing in this way with generics, against increases in prices on other brands, with inelastic demand.
- 4.28 We understand that initially margin arbitrage was used by suppliers of branded generics, but that more recently it has started to be used on originator brands.²⁷ This is of particular significance because price reductions on the originator brand, made more than two years after generic entry, could be included in modulation calculations, and set against increases in price on the company's other brands with inelastic demand. We were told that that one margin arbitrageur had accumulated substantial headroom under the price control as it had modulated down its prices to match generic price

²⁵ Didronel tablets were reduced in price from £34.69 to £20.69 and Didronel PMO from £37.39 to £21.12

²⁶ Cardura XL was introduced shortly before patent expiry and its market share may have been falling as prescribers reached the view that it offered little advantage over standard doxazosin.

²⁷ Another possibility would be for the originator company to introduce a second brand.

reductions. In principle this headroom could be used to increase prices of other products with inelastic demand, for instance if the margin arbitrageur was taken over.

4.29 Table 4.2 shows an illustrative example. Initially, 10 per cent of prescriptions for drug 1 are assumed to be for the brand and 90 per cent for the generic: generics are supplied at a price equal to marginal cost, which is assumed to be 25 per cent of the price of the brand. The table shows that it is profitable for the brand supplier to reduce its price to below marginal cost (20 per cent of the previous price) if it can increase branded prescriptions of drug 1 and recoup the notional loss of revenue by increasing the price of another drug with inelastic demand. The example in Table 4.2 therefore illustrates the following points:

- modulation can make it profitable for a brand supplier to reduce price of a brand with generic competition to below marginal cost to squeeze the share of generic suppliers
- such a strategy would lead to an increase in NHS expenditure (even without taking into account the impact on clawback via pharmacy margins).

Table 4.2: Illustration of modulation to reduce brand price to compete with generics

	Quantity	Price	Spend	Row
Before modulation				
Drug 1				
Branded prescriptions	10	1.00	10.00	1
Generic prescriptions	90	0.25	22.50	2
Drug 2				
Branded supply	100	1.00	100.00	3
Total supply by company			110.00	4 = 1 + 3
Total cost to NHS			132.50	5 = 2 + 4
After modulation (branded supplier gains half of generic market)				
Drug 1				
Branded prescriptions	55	0.20	11.00	5
Generic prescriptions	45	0.25	11.25	6
Drug 2				
Branded supply	100	1.44	144.00	7
Total supply by company			155.00	8 = 5 + 7
Total cost to NHS			166.25	9 = 6 + 8
Modulation calculations for company				
		Price		
	Quantity	reduction	Saving	
Drug 1	55	0.80	44.00	10
Drug 2	100	-0.44	-44.00	11
Total saving			0.00	12 = 10 + 11
Extra cost and profit for company				
	Extra	Marginal		
	quantity	cost	Value	
Drug 1	45	0.25	11.25	13
Drug 2	0	0.25	0	14
Extra cost			11.25	15 = 13 + 14
Extra profit			33.75	16 = 8 - 4 - 15

Source: OFT

5 PRIMARY CARE: EFFECTS ON COMPETITION TO SUPPLY PHARMACIES/WHOLESALERS

Introduction

- 5.1 In general, pharmacies and wholesalers have a strong incentive to purchase medicines from the cheapest available source. We can distinguish two types of competition to supply pharmacies and wholesalers:
- competition between one or more branded and/or generic suppliers. This occurs when prescriptions for off-patent brands are written generically and there are a number of suppliers of the prescribed medicines (that is, where the product is reimbursed generically). This is relevant to the PPRS when competition is between brands (with no generic supply) or when competition is between one or more brands and generic supply
 - competition between UK sourced products direct from the manufacturer (direct supply) and parallel imports. This occurs whenever a source of parallel imports is available. It is the only sort of competition when prescriptions are written for a brand, or prescriptions are written generically but there is only one brand available, for example on-patent drugs and off-patent drugs where the market is too small for generic supply (that is, whenever the product is reimbursed as a brand).

Effects of modulation: generic reimbursement

- 5.2 When an off-patent drug is prescribed using the generic name, the branded and generic manufacturers may compete to supply the pharmacy to dispense a drug against that prescription. The analysis of substitution in the previous chapter continues to be relevant: indeed, since pharmacies/wholesalers have strong incentives to obtain the cheapest supply, demand is likely to be more sensitive to price changes and consequently the impact of modulation greater.

Brand equalisation

- 5.3 Under brand equalisation deals, brand manufacturers supply pharmacies with branded drugs at a weighted average price to meet both branded and generic prescriptions. The branded supplier discounts the price to the pharmacy in order to compete with generic companies in supplying pharmacies to dispense against generic prescriptions.
- 5.4 Under the 1999 PPRS, a number of large firms tried to include, in their modulation returns to DH, brand equalisation volumes meeting generic prescriptions. These volumes do not yield genuine savings to DH (since they just substitute for generic volumes at the same price) and their inclusion would have enabled the companies to modulate up prices on other drugs at additional cost to the NHS. Moreover, as branded suppliers would have gained market share from generic suppliers at no cost, it could

also have had an adverse effect on competition, for instance by making generic suppliers less willing to enter the UK market.

- 5.5 DH took the view that brand equalisation volumes should be excluded from modulation. DH told us it had reached a satisfactory agreement with four of the five companies but the dispute with one went to the PPRS arbitration panel. The panel reached a decision on one matter but the issue had not yet been fully resolved.
- 5.6 Under the 2005 PPRS, brand equalisation volumes meeting generic prescriptions have been explicitly excluded from modulation volumes (see paragraph 3.2).

Drugs with branded competition but no generic supply

- 5.7 The effects of modulation are also relevant where drugs are prescribed generically but no true generic is available, and pharmacists choose between a number of branded products. This is the case, for example, with off-patent modified release products where MHRA regulations do not allow generic supply but a number of brands are available.²⁸ In these cases, pharmacists are reimbursed under category C of the drug tariff: category C products are priced on the basis of a particular brand, usually the originator brand. It is attractive for a manufacturer to modulate down the price of the brand on which category C prices are based: a reduction in list price enables profits to be increased by modulating up the price of other, price inelastic, products; and a reduction in transaction prices increases the volume of the price-reduced brand, enabling a larger upwards modulation in the price inelastic products and hence a larger profit gain.
- 5.8 Such a strategy might require manufacturers of competing brands to reduce their list prices as well if they wished to continue to compete for generic prescriptions. Such other manufacturers may or may not be able to use modulation to increase list prices of other drugs, depending on their individual circumstances. This may be to the disadvantage of the other manufacturers and consequently to the detriment of the competitive process (although it would not be to the short term disadvantage of the NHS, indeed the NHS would gain through lower prices overall if other manufacturers were not able to recover lost revenue by themselves modulating).
- 5.9 Data for 2005 suggests that the list prices of these drugs decreased more than the average: the weighted average reduction in price of drugs with branded competition but no generic supply was 11 per cent, compared to seven per cent for other branded drugs (see Table 6.1).
- 5.10 Felodipine provides an example of the process of price reduction for these drugs. During 2005 and up to June 2006, the list price of the originator brand (Plendil 10mg

²⁸ This reflects the view that modified release products are not generally substitutable. It is therefore surprising that some of these products have a high rate of generic substituting.

tablet) was £12.01 per pack, with two competitor brands (Cardiopen and Felotens) having list prices of £9.00 and £6.00 respectively. In June 2006 the manufacturer modulated down by 50 per cent the price of Plendil (10 mg tablet), to £6.01, and the manufacturers of these two competitor brands both subsequently reduced their price to £5.10

Effects of modulation: parallel imports

- 5.11 UK pharmacies and wholesalers can source branded medicines either directly from a UK supplier or from parallel imports.²⁹ Whichever source they use, pharmacies are reimbursed at the UK list price less clawback. The UK list price is set by the PPRS member (which in this annexe we refer to as the company or the manufacturer) and is limited by the PPRS price and profit controls.
- 5.12 A reduction in the list price of a branded medicine is likely to make UK-supplied medicines (direct supply) more attractive to pharmacies relative to parallel imports.³⁰ Assuming an upwards sloping supply curve for parallel imports,³¹ this will reduce the proportion sourced from parallel imports. Companies gain as they obtain a higher proportion of the list price³² when medicines are supplied directly than when they are supplied via parallel imports. Consequently, companies have an incentive to concentrate price reductions on those products where there is the greatest impact on parallel imports.
- 5.13 As the NHS pays the same price for parallel imports as for direct supply, it benefits from the lower price on overall prescribed volumes—both on the increased direct supply volume submitted by the company in PPRS returns and on the remaining volume of parallel imports.
- 5.14 Modulating companies deliver a reduction in weighted average prices, where the weights are based on direct rather than total supply (that is, they exclude parallel imports). Consequently, the weighted average price change to the NHS (that is, including parallel imports) may differ from that calculated under the PPRS. The weighted average price reduction to the NHS may be higher or lower than that calculated under the PPRS:

²⁹ Parallel trade relates almost entirely to branded drugs. Parallel imports account for less than one per cent of generic supply. Parallel importing of generics is unlikely to be attractive as supply of generics in the UK is highly competitive and prices are amongst the lowest in the EU.

³⁰ The price for UK sourced medicines paid by pharmacies will go down pro rata with the list price if the manufacturer's discount to the wholesaler and the wholesaler's margin remain unchanged (as a percentage of the list price). Generally branded drugs are sold to wholesalers at a discount of 12.5 per cent.

³¹ The supply curve may slope upwards because the cheapest supplies are limited and because the cost of reaching UK pharmacies differs between pharmacies.

³² Companies still obtain some revenues from parallel trade, since the parallel importers or their suppliers pay for the medicines in the country of origin. However, in order to make parallel trade profitable, revenues received in such countries must be considerably lower than those that would be received in the UK in the absence of parallel imports.

- the price reduction is greater if price reductions are concentrated on medicines with above-average parallel import penetration after the price reduction
- the price reduction is smaller if price reductions are concentrated on medicines with below-average parallel import penetration after the price reduction.

It is the parallel import penetration **after** the price reduction that is relevant because modulation is measured using a current-weighted price index (that is, using volumes after the price reduction).

5.15 Companies have the incentive to concentrate price reductions where they achieve the largest reduction in parallel imports (as they, or their affiliates, obtain a higher proportion of the list price when medicines are supplied directly than when they are supplied via parallel imports). This would seem to give them the incentive to try to equalise parallel import penetration across products. If this is difficult, for example because there are some products which are difficult to parallel import, price reduction would be likely to be concentrated on products which continue to have above-average parallel import penetration even after price modulation. There is some evidence following the 2005 price cut to support this (paragraph 5.20 below quotes evidence that the top 15 parallel imported products had both a larger than average drop in penetration and a higher than average penetration after the price reduction). This would suggest the price reduction to the NHS is likely to be greater than that calculated from company returns showing direct supply.

Table 5.1: Illustration of price reductions and parallel imports

	List price	PPRS supply volume	Parallel imports volume	NHS Expenditure*	Company revenue†
Pre-price cut position					
Drug A	1	150		150.0	124.5
Drug B	1	100	100	200.0	143.0
Total				350.0	267.5
Post-price cut position (no modulation)					
Drug A	0.93	150		139.5	115.8
Drug B	0.93	125	75	186.0	138.3
Total				325.5	254.1
Percentage reduction	7.0%			7.0%	5.0%
Post-price cut position (modulation)					
Drug A	1	150		150.0	124.5
Drug B	0.86	150	50	172.0	132.9
Total				322.0	257.4
Percentage reduction	7.0%‡			8.0%	3.8%
Company revenue as proportion of list price					
Drug A		0.83			
Drug B		0.83	0.60		

Note: Total volume is assumed constant at 150 for A and 200 for B

* Total volume times list price

† Volume times list price times company revenue as proportion of list price

‡ Under the PPRS the weighted average price reduction is calculated using post-price cut volume weights. As PPRS volume is the same for A and B, it is a simple average of the price reduction on A (0 per cent) and B (14 per cent) that is, 7 per cent

Source: OFT

5.16 This point is illustrated in the example in Table 5.1. In this example we assume a seven per cent price cut and a company with two products: A with no parallel imports and B with parallel imports, the level of which is sensitive to the UK list price. A non-modulated seven per cent reduction in prices of both drugs leads to a reduction in NHS expenditure of seven per cent and a reduction in company revenue of five per cent.³³ But a modulated price reduction leads to a reduction in NHS expenditure of eight per cent and a reduction in company revenue of 3.8 per cent, that is, modulation leads both to a greater reduction in NHS expenditure and to a smaller reduction in company revenue.

5.17 There are also two other positive effects to take into account:

³³ The percentage reduction in company revenue is less than the percentage increase in NHS expenditure because the company obtains a lower proportion of price from parallel imports than from direct supply but the NHS pays the same price for parallel imports as for direct supply (figure 5.1 includes revenue that the company's affiliates in other countries obtain from parallel imports.) We also note that a price cut would have a bigger impact on profits than revenue if a proportion of the company's costs are fixed.

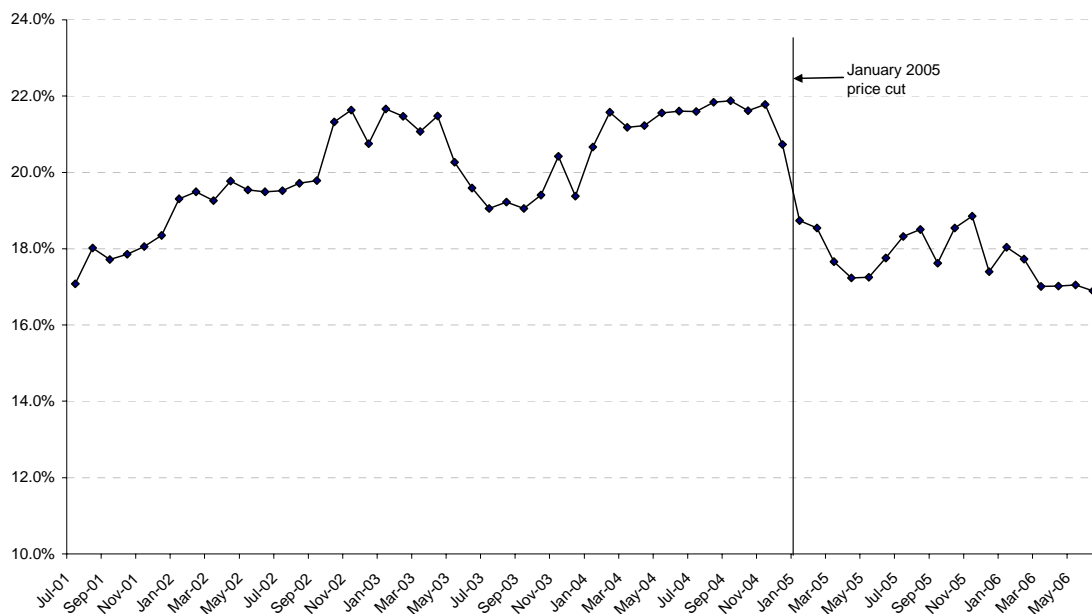
- the advantage to companies of reducing parallel imports may make them willing to accept in negotiations a larger overall price reduction than in the absence of modulation. We have seen some evidence to support this possibility—in particular, we were told that in the course of the 2004 re-negotiation the ABPI took the view that there was no case for changing the rules on modulation (because not to allow modulation would amount to regulation for its own sake), and that price cuts were unlikely to have been accepted if the principle of modulation had been removed from the scheme, and
- there may also be longer run effects associated with a reduction in parallel imports. For in-patent drugs, a reduction in parallel imports results in a higher proportion of NHS payments for drugs going to the originator company which originally developed the product. This may be expected to benefit innovation. The long run effects of parallel trade are considered in greater detail in Annexe L, which considers options for reform.

5.18 As against this, a reduction in parallel imports as a result of modulation may lead to a reduction in pharmacy margins. Assuming this shows up in the DH's margin inquiry it will feed through to a lower clawback against list price and a slightly higher reimbursement price paid by the NHS. The likely magnitude of this effect is considered in paragraph 6.7 below.

Impact of price cuts on parallel import penetration

5.19 Figure 5.1 shows monthly parallel import penetration over the last five years. Penetration dropped by about 4.5 per cent between November 2004 and April 2005 but then recovered to a small extent. Comparing calendar 2005 with 2004, the drop was about 3.5 per cent.

Figure 5.1: Parallel import penetration on branded medicines



Source: IMS (supplied by ABPI)

5.20 This is broadly consistent with figures quoted in a recent article by Janice Haigh of IMS,³⁴ which suggests a three per cent decline in overall parallel import penetration. It also states that, 'one of the key factors in reversing the growth of parallel imports in the UK was the impact in 2005 of the average seven per cent price cut under the PPRS. Many companies, continuing a trend started with the 1999 PPRS, used the opportunity to lower, disproportionately, the prices of products, packs and strengths with the greatest exposure to parallel imports. A year after the price cut, many companies achieved a significant reduction in their losses to parallel trade.' Janice Haigh's article also shows parallel import penetration of the top 15 parallel imported products dropped from 38.6 per cent in 2004 to 28.0 per cent in 2005.

5.21 At the individual company level, strategies differed. Pfizer cut the price of only four out of its 367 products - Cardura XL (both strengths were reduced in price by 55 per cent), Lipitor 20mg (price reduced by 17 per cent), Lipitor 40mg and 80mg (both prices reduced by five per cent) – with all others (including Lipitor 10mg) left unchanged. Both Cardura and Lipitor are in Haigh's list of the top 15 parallel imported products and, on her figures, parallel import penetration for Cardura fell from 32.6 per cent to 6.7 per cent and for Lipitor (all strengths including 10mg) from 42.5 per cent to 14.6 per cent. AstraZeneca followed a similar policy of concentrating price reductions on a small number of products where we estimate an apparent large fall in parallel imports.

³⁴ 'Parallel traders get smarter in declining market', Scrip magazine, May 2006.

Other large companies, however, followed different strategies: GlaxoSmithkline reduced all its prices by the standard seven per cent (it did not modulate), while SanofiAventis, Wyeth and EliLilly reduced some of their prices by seven per cent, some by more than seven per cent and some were kept constant (modulating on only part of their product portfolio).

6 SAVINGS IN PRIMARY CARE EXPENDITURE

6.1 In this chapter, we consider the savings in primary care expenditure as a result of the PPRS price control on branded drug prices.

6.2 The level of savings depends on the alternative against which current expenditure is compared. Conceptually, current expenditure might be compared with expenditure in the absence of the control. It is however difficult to know the level of prices in the absence of the control: prices would be constrained by factors such as parallel imports, PPRS profit control, NICE reviews and PCT budgetary limits but the precise quantitative impact of these factors is uncertain. We therefore focus on comparing the current PPRS agreement with continuation of the previous one, that is, no overall increase in prices. This is likely to understate the full impact of the price control as, in the absence of any control at all, companies are more likely to increase prices than lower them.

6.3 The discussion in previous chapters suggests there are a number of factors affecting the level of savings, defined as the percentage reduction in expenditure compared to expenditure if the previous PPRS agreement had continued:

- companies with sales of less than £1 million are excluded from the control and companies with sales of less than £10 million are excluded on the first £1 million of sales
- new drugs are excluded from the control and, as old drugs are replaced by new drugs, the impact of price cuts reduces over time
- Companies may anticipate future price cuts by pricing new drugs above the level they would otherwise have charged
- under modulation, companies can vary prices of individual drugs subject to the change in their average prices meeting the control, where average prices reflect direct supplies in the current year. The weights in the average price calculations may differ from the composition of NHS primary care expenditure in the absence of the price control because:
 - pharmacists meet prescriptions both from direct supplies and from parallel imports (hence the composition of NHS expenditure may differ from that of direct supplies)
 - modulated price changes may induce substitution between branded drugs and/or between branded drugs and generics (hence the composition of current NHS expenditure may differ from that in the absence of the price control)
- price changes to meet the control may induce changes (such as lower parallel imports) that reduce pharmacy margins, consequently reduce clawback on reimbursement prices, and thereby cause an increase in NHS expenditure
- price increases are allowed if a company's profits fall below the minimum under the PPRS profit control.

- 6.4 Apart from these issues, delivery of the savings depends on an effective system for verifying and monitoring companies' price changes. DH checks that companies are reimbursed through the prescription pricing authorities in line with their stated prices. DH also has extensive monitoring to ensure that modulating companies deliver the required savings. Companies are required to notify DH 28 days before any modulation and at this stage to provide information on estimated and actual sales of the products to be modulated. At the end of each year, companies are required to provide details of supplies to the NHS of all modulated products and to make a supplementary cash payment if the savings fall short of the required level by more than 0.5 percentage points.
- 6.5 DH also uses PPA reimbursement data for England to calculate average savings for each company. PPA data will not necessarily give exactly the same estimated savings (since PPA data includes parallel imports as well as direct supplies and relates only to England) but provides an independent check on company data and enables DH increasingly to pick up problems such as the inclusion of brand equalisation volumes in companies' returns under the 1999 PPRS (see paragraph 5.24). The NAO recently reviewed the calculation of the seven per cent price reduction at the start of the current PPRS. The NAO found that DH had met its target for price savings in the primary care sector in the first year of the scheme, from 1 January 2005 to 31 December 2005. The NAO considered that DH had effective procedures to assess and challenge forecast data and had validated the first year savings, but noted that individual NHS bodies would experience different levels of savings.

Savings in 2005

- 6.6 Table 6.1 shows DH's calculations of the effect of the 2005 price changes in primary care in England, based on PPA data for drugs reimbursed as a brand (excluding all drugs reimbursed as generics). The majority of 2005 spend in Table 6.1 is on drugs which were either prescribed as a brand or prescribed generically but where only one brand was available (mainly in-patent products): price reductions on these drugs were 6.96 per cent (7.31 per cent including cash payments). There are some drugs where no true generic is available and pharmacists are able to dispense one of a number of brands against generic prescriptions (see paragraphs 5.7 to 5.9). PPA data does not record accurately the value and volume of brands of these drugs dispensed against generic prescriptions³⁵ but DH carried out a special exercise which estimated savings of 11 per cent. As shown in Table 6.1, DH therefore estimated combined savings on both these categories, together with cash payments, at 7.49 per cent.³⁶ Spend in the Table is at list prices: allowing for clawback would reduce the savings in England to about

³⁵ Total value and volume for each drug are correctly recorded but the allocation between brands is incorrect.

³⁶ DH's analysis shows a total spend on medicines dispensed as brands of £5,129 million for the 12 months from January 2005. This is less than the total spend on medicines dispensed as brands shown in PCA data because the DH analysis excludes non PPRS products (for example, homeopathics and health food supplements) and out of pocket expenses.

£370 million. If savings in other parts of the UK were similar in percentage terms, the total UK savings would be about £450 million.

Table 6.1 DH's estimated savings on drugs reimbursed as brands for primary care in England, 2005 compared with 2004

	2005 Spend £ million	Savings compared to 2004 prices	
		£ million	%*
Branded prescriptions and generic prescriptions where only one brand is dispensed	4,829	361	6.96%
Cash payments		20	
Total	4,829	381	7.31%
Generic prescriptions where more than one brand is dispensed	237	29	10.96%
Total	5,066	410	7.49%
Effect of £1m exemption for small companies	41		
Total	5,107	410	7.43%
New products	22		
Total	5,129	410	7.40%

*Savings as a percentage of 2005 volumes at 2004 prices. For example, for branded prescriptions and generic prescriptions where only one brand is available, 2005 volumes at 2004 prices are £5,210 million (4829 + 381) and savings are therefore $381/5210 = 7.31$ per cent.

Source: DH calculations based on PPA data for 12 months from February 2005 (new reimbursement prices are implemented with one month's delay to allow for pharmacy stocks). Notes: Spend is shown at list prices; the table excludes drugs reimbursed as generics.

6.7 The factors listed above in paragraph 6.2 affect DH's estimated savings as follows:

- table 6.1 shows the exemption of the first £1 million of sales by small companies has a very small effect, reducing estimated savings from 7.49 to 7.43 per cent
- the exclusion of new drugs had a very small effect in 2005, reducing the savings from 7.43 to 7.40 per cent (see Table 6.1). This effect would however build up over time
- companies may have anticipated the 2005 price cut by pricing new drugs higher than they otherwise would but we have no quantification of this
- on the effects of modulation:
 - the PPA data cover both direct supplies and parallel imports, so the effect of parallel imports is included. Indeed, it may be a reason why estimated savings exceed the headline price cut of seven per cent
 - as discussed in chapters 4 and 5, substitution between brands or drugs causes the DH measure of savings to be overstated. The extent of overstatement is indicated by the difference between the Paasche (current weighted) price index used by DH and an alternative Laspeyres (base weighted) price index. In the Appendix, we consider these alternative price indices (but without adjusting for the misrecording of the value and volume of drugs where more than one brand is dispensed against generic prescriptions) but find very little difference for 2005

- the 2005 price cut appears to have been associated with a reduction of about four per cent in parallel import penetration (see paragraph 5.19). It is difficult to estimate the impact on expenditure via lower clawback as this depends on the impact of lower parallel import penetration on pharmacy margins
- West and Mahon³⁷ suggest that calculations for the clawback in 1999-2000 assumed pharmacy purchases of parallel imports to be at 17.43 per cent below list price (and this is similar to West and Mahon's own data which showed a 16.9 per cent weighted average level of discount for 2002 for the top 10 products). West and Mahon also suggest average clawback was 10.2 per cent which at the then parallel import penetration levels (11.9 per cent in 1999 and 13.6 per cent in 2000) implies a margin of about nine per cent on UK supplies and consequently savings from parallel imports compared to UK sourcing of about £50 million for 1999 and £60 million for 2000
- parallel imports increased markedly to 17.1 per cent in 2001 and 19.8 per cent in 2002 and these estimates therefore appear broadly consistent with a DH estimate of £100 million savings for 2001-2002, quoted in a study by Kanavos et al.^{38,39} Estimated savings of £60 million for 2000 represent 1.1 per cent of total sales at a time when parallel import penetration was 13.6 per cent, implying that a 13.6 per cent reduction in parallel imports would reduce margin by 1.1 per cent
- prorating these figures implies the four percentage point reduction in parallel import penetration from the 2005 price cut would reduce margin by about 0.3 percentage points ($1.1 * 4/13.6 = 0.3$).⁴⁰ A similar estimate would be obtained by prorating estimated savings of £50 million in 1999 and £100 million in 2001-2002. A more recent study⁴¹ indicates that parallel import prices increased relative to list prices between the beginning of 2002 and end of 2004, suggesting the impact might now be smaller than estimated by the studies based on earlier data. Overall, it seems fair to conclude the impact of lower parallel imports on margins ultimately offsets 2005 savings by around 0.3 per cent. This would reduce savings from 7.4 per cent to 7.1 per cent
- no companies obtained a price increase in 2005.

³⁷ 'Benefits to Payers and Patients from Parallel Trade' (report for the European Association of Euro-pharmaceutical companies), York Health Economics Consortium, May 2003.

³⁸ Kanavos, P, Costa-Font, J, Merkur, S and Gemmill, M (2004), 'The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis', LSE Special Research Paper, January.

³⁹ West and Mahon themselves quote parallel import savings for 2002 of £134 million but this seems to be just the effect of the clawback, which the NHS obtains on UK sourced supplies as well as parallel imports.

⁴⁰ A reduction in parallel imports will not necessarily have a pro rata effect on savings – it depends on the shape and slope of the supply curve for parallel imports - but detailed information on this is not available.

⁴¹ Enemark, U, Moller K and Sorensen J (2006), 'The economic impact of parallel import of pharmaceuticals', Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark, June. (Section 3.6.4).

6.8 Apart from these factors, estimated savings in primary care may differ from the headline price cut of seven per cent because companies in aggregate over- or under-deliver required savings (see paragraph 3.7), and because the control applies to all supplies, including supplies to hospitals (the average price change for primary care may differ from that for all supplies, including hospitals, as the composition of drugs used in primary care differs from the overall average). The impact of the price control on prices paid by hospitals is considered in the next chapter.

7 HOSPITALS

- 7.1 In this chapter we consider the effect of price cuts and modulation in the hospital sector.
- 7.2 The hospital sector differs from the primary care sector in that hospitals pay a net price and, for most drugs, are able to negotiate discounts and/or issue tenders to obtain the lowest cost drugs. To the extent there is effective competition between companies with therapeutically equivalent or similar drugs to supply hospitals, price control may be unnecessary, but this does not apply to all drugs.
- 7.3 The effect of price cuts in the hospital sector depends on whether transaction prices as well as list prices are reduced. There is a lack of clarity as to whether the PPRS requires transaction prices to be reduced in line with list prices— that is, requires discounts to be maintained when list prices are cut:
- while the 2005 PPRS states, 'the Department expects that the net effect of such changes [in discounts to hospitals] should not increase NHS costs', it also says that, 'the Department accepts fully the right of member companies to change discounts allowed on sales to hospitals'. The same paragraph states the Department requires advance information where, 'a member company intends to remove or reduce hospital discounts offered for PPRS medicines as a change in policy in all or the majority of the UK (other than those which may result from the outcome of a competitive tender)'⁴²
 - the 2005 PPRS also states, 'the Department accepts the right of member companies to change discounts allowed on sale. Paragraph 21.1 of the scheme sets out the basis of the expenditure savings on branded medicines covered by this agreement [the paragraph states the aim is to effect a seven per cent reduction in NHS expenditure on branded medicines]. The net effect of changes in discount allowed on the sales of these medicines should not affect the delivery of this aim'⁴³
 - as noted in chapter 2, the PPRS also states that modulating companies are not allowed to substitute discounts or contract prices in force during the six months prior to the date of any modulation.
- 7.4 From this and discussion with DH, it seems that companies are required to reduce transactions prices, as well as list prices, of any drugs that are modulated. However, as regards products where the price is not modulated, DH cannot insist on the headline reduction in transaction prices for drugs where the price results from a competitive tender. Where negotiated discounts rather than a competitive tender are involved, DH told us that any changes in discount structure should not affect delivery of the

⁴² Paragraph 22.8 of 2005 PPRS.

⁴³ Paragraph 21.11 of 2005 PPRS.

savings—hospitals can bring to DH's attention any changes in discount structure and DH investigates to ensure compensatory reductions are made elsewhere.

- 7.5 To the extent that the price control does lead to reductions in hospital transactions prices, the same considerations apply as in primary care: companies are likely to wish to focus price cuts where they can reduce parallel imports (see chapter 5) and where prescribing is sensitive to price (see chapter 4). Hospital demand is more likely to be price sensitive than primary care demand for two main reasons:
- hospital prescribers are generally more price aware and price sensitive than GPs, because:
 - hospitals can go bankrupt
 - prescriber compliance with the formulary is greater (prescribers are employees of the hospital), and
 - hospitals face incentives through National Tariff arrangements (hospitals directly bear drug prices rather than having them passed through to the PCT)
 - for high cost drugs (which are likely to be hospital drugs), PCTs have mechanisms to constrain expenditure (for example, requiring prior approval before prescribing or only agreeing to fund a certain level of prescribing over a given period). Consequently it is perhaps more likely that reducing the price of these may have a volume effect.

2005 savings in the hospital sector

- 7.6 Where companies modulate prices, DH seeks to ensure that reductions in list prices on hospital drugs are not used to justify upwards modulation on other drugs. We understand from DH that one company in 2005 modulated by cutting the list price by 18.75 per cent of one drug sold only to hospitals. Hospitals complained that the company subsequently reduced discounts and the company ultimately agreed with DH to measure average selling prices rather than list prices.

- 7.7 As hospitals purchase at below list prices, the extent of savings in the hospital sector is uncertain. The NAO report states that,

'It is not possible to demonstrate from the information collected by the Department that a seven per cent reduction in the total cost to the NHS, that is, across primary and secondary sectors combined, of medicines covered by the PPRS has been achieved. This is because the savings are calculated based on the reduction in the NHS list price, but the list price does not represent the cost to the NHS of medicines sold in the secondary sector (that is, to NHS trusts).'

- 7.8 The NAO made the point that the outturn for individual NHS bodies, such as hospitals, will vary depending on their product mix and volumes used and will also be affected by factors such as new medicines, cash payments instead of price reductions by PPRS

companies and parallel imports.⁴⁴ Similarly, in regard to the seven per cent price cut in 2005, we received evidence from several hospitals that their savings on branded medicines had been less than seven per cent: one group of hospitals calculated savings of around 1.3 per cent, another around 0.2 per cent and a third said it had experienced a slight increase in costs.

- 7.9 We estimated hospital discounts on list prices for nine drugs (27 products including different strengths) between April 2004 and November 2005, to assess the extent to which discounts declined after the 1 January 2005 reduction in list prices and hence the extent to which hospitals obtained real savings. The drugs were selected to cover a range of different types including drugs with therapeutic substitutes, drugs with no therapeutic substitutes and hospital only drugs. Our analysis showed a mixed picture concerning the impact of price reductions on hospital discounts.⁴⁵ In one case discounts dropped after the price cut but then increased sharply, in an apparently fairly clear effort to compensate for the earlier drop in discounts and meet the PPRS requirement that modulated cuts in list prices should not substitute for discounts or contract prices. In some other cases, discounts do seem to have declined following the reduction in list prices. However, discounts fluctuated throughout the period and the decline in discounts for these drugs might have occurred anyway, and discounts also declined on one drug where there was no change in list prices.

⁴⁴ Hospitals purchase directly from parallel imports and (unlike the primary care sector) do not pay UK list prices for parallel imports. Hence, the price hospitals pay for parallel imports will not necessarily go down even if prices of all UK suppliers are reduced.

⁴⁵ We have not included the details of the analysis in our report as hospital discounts on individual products may be regarded as commercially confidential information, the disclosure of which causes serious harm to the suppliers concerned.

8 CONCLUSIONS

- 8.1 The PPRS price control does constrain the prices at which branded drugs are reimbursed in the primary care sector. Although prices of new drugs are outside the control and the average reimbursement per prescription increased by almost seven per cent per year from 1991 to 2004, the level of increase would most likely have been even greater in the absence of the price control. DH's analysis suggests the January 2005 price cut yielded primary care savings of about seven per cent of expenditure compared to the alternative of continuing the previous PPRS agreement. Savings would be larger compared to the alternative of no price control, since companies would be likely to increase prices in the absence of any price control. However, the level of savings reduces during the course of each PPRS agreement as new drugs are introduced at uncontrolled prices and companies may anticipate future price cuts by increasing the level of new drug prices compared to the level they would otherwise charge. Hospitals purchase drugs at below the list prices that are the subject of the control, and the effect of the control on hospital prices is uncertain.
- 8.2 Although the price control constrains primary care prices, there is little or no objective basis for the level to which the PPRS constrains prices. The level of prices resulting from the PPRS is not clearly linked to a comparison of UK prices with those in other EU countries, nor is it linked in any way to the therapeutic value of each company's drugs, company profitability or other observable parameters.
- 8.3 An important feature of the price control is the arrangements for companies to modulate prices up and down as long as their average prices remain within the control. Modulation has advantages in providing companies with pricing flexibility and the ability to respond to parallel imports. Modulation therefore helps meet PPRS objectives by making companies willing to accept a larger price reduction than they otherwise would and, by reducing parallel imports, enabling a larger share of revenue to go to the innovating companies that developed the products.
- 8.4 However, modulation also creates incentives to distort competition. A company with a large number of products has the incentive to reduce the price of products with elastic demand to, or even below, marginal cost in order to gain market share as it can finance losses by increasing the price of products with inelastic demand. Its increases in market share could be at the expense of smaller companies with a small range of branded products or of generic suppliers. Modulation may also create the incentive to reduce prices of branded products ahead of patent expiry in order to discourage generic entry: this is most likely for products with relatively small markets where entry is relatively costly for generic suppliers. While we do not have evidence that such distortions are currently significant, it was not the purpose of this market study to pursue individual cases. Moreover, as a general principle, it is desirable to avoid even potential distortions to competition: for example, exploitation of modulation rules could increase in future.

8.5 We believe the PPRS should be changed to address the issues we have identified. We set out in Annexe L various options for reform. The key areas include:

- the lack of objective justification for price levels could be addressed by relating maximum reimbursement prices for each drug to therapeutic value
- such an approach (which would substitute for across the board price cuts) would also address concerns about the adverse effect of modulation on competition, and
- as regards off-patent medicines, branded versions of medicines with generic competition could be reimbursed at category M prices.

APPENDIX: ANALYSIS OF PRICE CHANGES IN PRIMARY CARE SECTOR

- A.1 In order to consider the overall effects of the price cuts on list prices of branded medicines, we have looked at PPA data for England which cover the cost of medicines in primary care. The PPA data excludes hospital sales (which may involve discounts on list prices) and includes parallel imports which however receive the same price as direct supplies. This analysis is relevant to quantifying the extent of substitution and to assessing how far expenditure has been reduced compared to the level that would otherwise prevail.
- A.2 PPA data do not accurately record the value and volume of drugs dispensed as a brand against generic prescriptions when more than one brand is available (for example modified release preparations of off-patent drugs). We have not been able to adjust for this problem and it represents an uncertainty in interpreting our results.
- A.3 We have looked at year-on-year changes in Paasche and Laspeyres price indices: any year-on-year difference between these indices may be the result of the impact on volume of price changes but it may also be the result of underlying volume trends, unrelated to the price changes. Different underlying growth rates of individual drug volumes, may result in a difference between the two indices. If price reductions are concentrated on medicines with fast growing volumes, the Paasche price index will weight these medicines relatively more than the Laspeyres price index and will show a greater average price reduction. And vice versa.
- A.4 Unfortunately, the impact of price on volume cannot be separated out. To the extent that any difference between Paasche and Laspeyres indices is due to underlying volume trends, the Paasche index (DH measure) is the better measure of savings (as it shows the change in expenditure compared to the level that would otherwise prevail). To the extent that volume changes result from the price changes themselves, the correct measure of savings would lie between the two measures.
- A.5 Table A1 shows our analysis of the 2005 price cut using the PPA data (but without adjusting for the problem with PPA data, which may explain the difference from DH results in table 6.1). The Paasche and Laspeyres price indices are similar indicating either that price-induced substitution between medicines was negligible or that any substitution was offset by price reductions being concentrated on slow-growing medicines.

Table A1: Analysis of 2005 price control

	Spend £million	Savings	Price reduction %
Paasche price index calculation			
2005 spend	5275.0		
2005 volumes at 2004Q4 prices	5637.6	362.6	6.4%
Delivered through repayments		19.9	0.4%
Total		382.5	6.8%
Laspeyres price index calculation			
2004 volumes at 2005 prices	5170.0		
2004 volumes at 2004Q4 prices	5534.7	364.7	6.6%
Delivered through repayments			0.4%
Total			6.9%

Note: only medicines with both a 2005 and a 2004 price are included. 2005 prices estimated from PPA data as value (net ingredient cost) divided by volume

Source: OFT calculations based on PPA data

- A.6 We carried out a similar exercise for the 1999 price cut of 4.5 per cent. In this case, we can see the effect through the whole PPRS period (see table A2). We looked at annual price changes and then calculated a cumulative price index by chaining the annual price indices. This does not reflect the impact of new drugs.
- A.7 The Paasche price reductions do exceed those on the Laspeyres measure indicating that the 1999 price cuts and subsequent modulation may have had an effect on demand, or alternatively that price reductions were concentrated on drugs with fast growing demand. Analysis at a more disaggregated level suggests that the difference between the two indices occurred within individual BNF sub-paragraphs rather than between them: this would be consistent with volume effects due to substitution between drugs.
- A.8 Our calculations of Paasche price indices up to 2002 suggest price reductions on the DH measure in excess of the target but a small upward movement in prices is evident in 2003 and 2004 (again however there is uncertainty about the effects because of the possibly inaccurate recording of the value and volume of individual brands when drugs are prescribed generically but dispensed through a number of brands).

Table A2: Analysis of 1999 price control

	Price indices		Coverage*
	Paasche	Laspeyres	%
			in year
	Price reduction		
2000	4.8%	3.9%	98.3%
2001	0.0%	0.0%	98.5%
2002	0.5%	0.3%	99.4%
2003	-0.4%	-0.6%	99.3%
2004	-0.8%	-1.0%	99.6%
	Cumulative price reduction		
2000	4.8%	3.9%	
2001	4.8%	4.0%	
2002	5.3%	4.2%	
2003	4.9%	3.7%	
2004	4.2%	2.7%	

Note: price reduction for 2000 is compared to the 12 months before the price cut (Oct 1998 to Sep 1999). The comparison of 2000 with 1998/99 excludes one product for which there were anomalous results.

*Spend on medicines where information was available for previous year as per cent of spend on all medicines in that year.

Source: OFT calculations based on PPA data.