The Association of the British Pharmaceutical Industry

Department of Health

The Pharmaceutical Price Regulation Scheme

November 2004

The Pharmaceutical Price Regulation Scheme 2005

The Association of the British
Pharmaceutical Industry
12 Whitehall
LONDON
SW1A 2DY
Tel: 020 7930 3477

Department of Health
Medicines, Pharmacy and Industry Group
Eileen House
80-94 Newington Causeway
LONDON
SE1 6EF
Tel: 020 7972 2827

Scottish Executive
Health Department
St. Andrew's House
EDINBURGH
EH1 3DE
Tel: 0131 556 8400

Department of Health
and Social Services
Dundonald House
Upper Newtownards Road
BELFAST
BT4 3SF
Tel: 02890 650 111

National Assembly of Wales
Health and Social Care Department
Pharmaceutical Services Branch
New Crown Building
Cathays Park
CARDIFF
CF10 3NQ
Tel: 029 2082 3251

The text of this scheme and copies of the schedules are available at:
www.dh.gov.uk/pprs

Contents

Introduction and Objectives

The Health Departments of the United Kingdom (UK) and the Association of the British Pharmaceutical Industry (ABPI) have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the National Health Service (NHS), and in a strong, efficient and profitable pharmaceutical industry in the United Kingdom (UK). Such an industry must be capable of sustained research and development (R&D) leading to the future availability of new and improved medicines in this and other countries.

1 Objectives

1.1 The 2005 – 2010 Pharmaceutical Price Regulation Scheme (PPRS) is an agreement for the purposes of section 33 of the Health Act 1999. The objectives of the scheme are that it should continue to:

1.1.1 secure the provision of safe and effective medicines for the NHS at reasonable prices;

1.1.2 promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines;

1.1.3 encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

2 Introduction

2.1 The Department of Health ('the Department'), on behalf of the UK Health Departments, recognises the industry's contribution to the economy of the UK and wishes to continue to encourage its competitive efficiency, both at home and abroad. The Department recognises that continuous innovation is the key to competitive success in a research based industry and wishes to encourage the research, development and supply of innovative treatments for the benefit of NHS patients.

2.2 The Department recognises that a wide variety of factors influences the competitiveness of the pharmaceutical industry in the UK and that effective industrial policies need to be developed, incorporating European and global issues. These need to be managed alongside health policy. The Department will facilitate the industry's participation in Government initiatives relevant to the further development of the sector.

2.3 The ABPI recognises that it is in the public interest that the prices of pharmaceutical products supplied under the NHS are fair and reasonable. The ABPI shares the Government's objective of ensuring that medicines are supplied and used effectively and efficiently and that expenditure on medicines is managed and understood within the context of NHS spending as a whole.

2.4 Both parties agree that the performance of the PPRS cannot be assessed in isolation from the NHS environment with which it interacts. The PPRS is the UK-wide price regulation scheme for branded prescription medicines supplied to the NHS. It applies across the four nations of the United Kingdom.

The UK Health Departments do not support additional or alternative initiatives by Health Authorities in respect of the pricing of such supplies in primary care. Subject to any future decisions of the UK or devolved Parliaments, or Ministers to adopt a different policy with regard to the pricing of branded prescription medicines, the Health Departments will do all they can to ensure that the scheme is fully implemented and sustained throughout the NHS during the lifetime of the scheme.

2.5 The Government and the ABPI share a common goal in promoting uptake of effective new medicines, in particular those that have received a positive appraisal from the National Institute for Clinical Excellence (NICE). In addition to the Government's commitment to the existing work of the Pharmaceutical Industry Competitiveness Task Force (PICTF), including its role in producing information on uptake of new drugs, Ministers announced in June 2004 a specific programme of work to improve the uptake of NICE guidance by the NHS. This includes work on topic selection, additional support from NICE for implementation, dissemination to appropriate clinical audiences, local NHS planning for implementation and development of better comparative information to aid improvement of local performance. The Department of Health values the important contribution that the pharmaceutical industry can make in this area, and looks forward to working constructively with the ABPI to this end.

2.6 Both parties will operate the PPRS in good faith within the parameters of this agreement. The ABPI recognises that there should be compliance with the agreement and has agreed the range of measures to secure such compliance. The Department agrees to raise any issues relating to the management and operation of the PPRS over the life of the scheme during regular review meetings. The Department assures the confidentiality of commercially sensitive information submitted by scheme members.

3 Ensuring best practice in the notification of product discontinuations

3.1 In 2001, the Department and the ABPI drew up guidelines to ensure best practice in the notification of product discontinuations. The Department expects all scheme members to use their best endeavours to adhere to the best practice guidelines as a demonstration of the importance of the agreement to patient care. The guidelines are available at www.dh.gov.uk and www.abpi.org.uk.

4 Patent expiry and generic market entry

4.1 Under the PPRS, companies have freedom of pricing for new active substances on market entry (paragraph 24.1). As products near the end of their patent lives, the Department does not expect companies to take any unreasonable action to delay or discourage generic entry to the market.

Membership of the Scheme

5 Effective Date of the Scheme and Duration

5.1 This scheme will operate for not less than five years from 1 January 2005 unless varied or terminated as set out below. It will continue to operate subject to six months' notice of termination of the scheme in whole or in part given by either party to take effect after 1 July 2007.

5.2 This scheme replaces all previous PPRS agreements.

6 Mid-Term Review – Date and Terms

6.1 In the event of major changes affecting the supply of medicines to the NHS, either party may request an interim review after two and a half years. Following such a review the terms of the scheme may be varied with the agreement of the ABPI and Secretary of State.

6.2 If the terms of this scheme are altered with the agreement of the ABPI and Secretary of State, companies will be invited to accept the new terms. They will have the option of leaving the scheme as set out in chapter 9.

7 Application to manufacturers and suppliers

7.1 The scheme applies to manufacturers and suppliers (scheme members) as provided by section 33(2) of the Health Act 1999 who have consented, in the manner required by the Secretary of State. The scheme is set out in this document and the terms of consent in annex A. The scheme will apply as long as the scheme member has not withdrawn its consent in the manner required by the Secretary of State and the Secretary of State has not given written notice that the scheme is not to apply to the scheme member. It will also not apply if the scheme has been wound up following consultation between the parties as set out in chapter 6.

7.2 The Department and any manufacturer or supplier moving from the 1999 PPRS to this scheme will continue to meet their respective obligations arising from the 1999 PPRS, that is to say: a scheme member will submit an Annual Financial Return (AFR) (if so required) in respect of any business year ending in 2004; deliver the 4.5% price reduction; provide any required supporting information; and meet any other outstanding commitments under the 1999 PPRS.

8 Entry Mechanism

8.1 Members of the 1999 PPRS may join this scheme by completing the forms at annex A at any time from 3 November 2004. Form A effectively removes a supplier or manufacturer from membership of the 1999 PPRS and form B is the consent to membership of this scheme. Companies, which were not members of the 1999 PPRS may join this scheme by completing form B.

8.2 A manufacturer or supplier having been a member of the 1999 PPRS, but which ceased to be a member of the agreement because of unfulfilled obligations under that agreement will be required to meet those unfulfilled obligations before membership of this scheme is confirmed by the Secretary of State.

8.3 Manufacturers and suppliers which either elect not to join this scheme or which are denied membership under the terms of paragraph 9.1 shall be subject to any regulations or directions made by the Secretary of State pursuant to his powers under sections 34 to 36 of the Health Act 1999. Those sections do not apply to members of this scheme.

Non-ABPI members

8.4 Although this scheme is the result of negotiations between the ABPI and the Department, it is open to companies that are not members of the ABPI to be scheme members.

Re-entry to the scheme

8.5 A company, which manufactures or supplies NHS medicines, has the right to be a scheme member unless, having ceased to be a scheme member for whatever reason, any of its obligations under the scheme remain undischarged.

Supply of medicines

8.6 The scheme applies to the manufacturers of medicines and, in the case of suppliers with affiliates outside the UK, the subsidiary company with a place of business in the UK. In cases of doubt, the holder of the marketing authorisation for the NHS medicine is likely to be treated as the supplier for PPRS purposes, or the company discharging the responsibilities of the marketing authorisation holder, or of the EU marketing authorisation holder.

Obligations of companies

8.7 Scheme members will supply the information set out in chapter 27 subject to the following exceptions:

8.7.1 any scheme member with total home sales of NHS medicines not exceeding £5 million in its financial year will be exempt from supplying financial information. However, the Department reserves the right to call for a full Annual Financial Return (AFR) if circumstances appear to warrant it. In particular, in the case of an application for a price increase, the Department may demand financial information in the format specified in annex B;

8.7.2 any scheme member with total home sales of NHS medicines of more than £5 million and less than £25 million in its financial year will be required to provide a copy of its audited accounts and a certificate signed by its managing director or chief executive, giving a breakdown of turnover for the year between home sales of NHS medicines, export sales of NHS medicines and sales of other products. This information should be submitted annually to the Department within nine months of the end of its financial year. If a company in this category wishes to modulate the price of its products, it will have the same obligation as larger companies as set out in chapter 26.

9 Exit From the Agreement

9.1 Under the Health Act 1999, the Secretary of State may serve notice on a manufacturer or supplier that the scheme is no longer to apply to it. The Secretary of State may do this where any acts or omissions of the company have shown that, in the scheme member's case, the scheme is ineffective either for the purpose of limiting prices for the supply of health service medicines or limiting profits which may accrue in connection with the manufacture or supply of health service medicines. The Secretary of State may also consider the scheme to be ineffective where a scheme member significantly fails to comply with the requirements of the agreement more generally. The Secretary of State will have regard to any relevant decision of the arbitration panel when considering whether to serve a notice under that provision of that Act.

9.2 The Secretary of State would also normally regard it as relevant if it had been necessary to impose penalties or take other enforcement action provided for in regulations for breaches of provisions under regulations or directions made under that Act, particularly where this appeared to show a pattern of behaviour.

9.3 A company may, at any time, withdraw consent for the voluntary scheme to be treated as applying to it by completing form A at annex A.

10 Products Covered

10.1 The scheme applies to all branded, licensed NHS medicines. There will be a public consultation on the position of 'standard' branded generics (see paragraph 10.6.2).

10.2 For this purpose the term 'NHS medicine' refers to any human pharmaceutical product for which a marketing authorisation has been granted and to which the proprietor applies a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International Non-proprietary Names (rINN), or any list of similar standing, and which brand name is not excluded from prescription on Form FP10 (GP10 in Scotland; HS21 in Northern Ireland).

10.3 The scheme will apply to all packs and dosage forms of a NHS medicine except:

10.3.1 a pack that is intended for sale to the public without a prescription and the price of which is not generally accepted as a basis for the pricing of FP10 prescriptions (GP10 in Scotland; HS21 in Northern Ireland);

10.3.2 sales of medicines that can be shown to be derived predominantly from private prescriptions.

10.4 Where a medicine is sold under the same brand name on prescription and over the counter (OTC), only the proportion that is prescribed shall be subject to the provisions of the scheme.

10.5 For clarification, the scheme applies to the following products, provided they have a brand name and marketing authorisation:

10.5.1 branded generics excluding, subject to consultation, 'standard' branded generics (see paragraph 10.6.2);

10.5.2 vaccines;

10.5.3 in-vivo diagnostics;

10.5.4 blood products;

10.5.5 dialysis fluids;

10.5.6 branded products supplied through tendering processes and on central or local contracts;

10.5.7 biotech products.

10.6 The scheme does not apply to the following:

10.6.1 products that cannot be prescribed under the NHS Pharmaceutical Services (Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004);

10.6.2 'standard' branded generics;
Subject to public consultation, 'standard' branded generics will no longer be covered by the PPRS and will be transferred to the new arrangements for the reimbursement of generic medicines. A 'standard' branded generic is defined as an out of patent product to which the manufacturer/supplier, who is not the originator company, has applied a brand name and that is directly comparable to a true generic that is readily available. Branded products sold on by the originator company to another company remain within the scheme. Other branded generics (e.g. modified release preparations and 'complex' branded generic products) remain within the scheme.

10.6.3 in-vitro diagnostics;

10.6.4 unlicensed products supplied on a 'named patient basis'.

Levels of Return on Capital Target and Allowances

11 Introduction

11.1 The scheme provides a framework for determining reasonable limits to the profits to be made from the supply of medicines to the NHS. In keeping with the principles set out in the introduction to this scheme, there is encouragement for the research and development (R&D) of new medicines, and a commitment to a minimum of interference with companies' freedom to succeed in that activity.

11.2 There will be one level of return on capital (ROC) target.

11.3 There will be two levels of allowance for R&D, information and marketing expenses:

11.3.1 level 1 will be used to decide price increase applications under the terms for such applications set out in chapter 22;

11.3.2 level 2 will be used to assess the profitability of scheme members' AFRs.

11.4 The ROC target, and R&D, marketing and information allowances for level 1 and level 2 are set out in paragraphs 13.1, 17.4, 18.3 and 19.3 respectively and summarised at annex D.

12 Allocation of Costs and Capital

12.1 The Department expects manufacturers and suppliers to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads.

12.2 Costs and capital employed claimed in the AFR submission will be those normally included in the company's UK audited accounts. For R&D and information and marketing expenses, the value and costs entered in the 'claimed' column in schedule 1 of the AFR should represent no more than the specified allowance for a company, as permitted by the Department under the PPRS.

12.3 The Department may specify other arrangements where the supply of NHS medicines in the UK arises from overseas sources and comprehensive financial information is not available in the accounts of the UK trading entity. In particular, it is expected that, where trade in the UK is conducted on a principal-commissionaire basis, the AFR will be based on the audited accounts of the overseas entity. If such arrangements are not feasible or cannot be agreed between the company and the Department, then the company's NHS business will be regulated as directed by the Secretary of State under section 35 of the Health Act 1999.

12.4 Any scheme member must be able to demonstrate that costs or capital included in its AFR are appropriate to the supply of NHS medicines in accordance with this scheme. Overhead costs and shared assets utilised in both NHS medicines and other products must be reasonably apportioned. Companies will provide reasonable details of costs and capital either directly allocated or apportioned to home NHS medicines, together with explanations supporting any apportionment.

12.5 The industry accepts that the scheme is not a cost plus scheme and that the Department is entitled to satisfy itself that costs and capital claimed for medicines supplied to the NHS are properly incurred in accordance with the scheme and they are reasonable in the light of accepted commercial practice. Excess costs and capital will be disallowed from the assessment.

12.6 In its examination of the reasonableness of a company's costs and assets the Department will have regard to the following factors:

12.6.1 the trends in the data reported by the company over a number of years, including those for exports and other products;

12.6.2 any special features of the company's operation;

12.6.3 ratios inferred from the AFR for the company's non-PPRS business;

12.6.4 each company's reported figures and the average of other similar scheme members;

12.6.5 data from external sources that relate to the pharmaceutical industry across companies.

12.7 Where the Department does not receive an adequate explanation of costs and capital claimed in a company's AFR, it may limit the costs and capital to a level that is reasonable in the light of its analysis of the company's figures as set out in paragraph 12.6. The Department will discuss the basis of any limitations with the company and will advise the company of its final AFR assessment.

13 Return on Capital

13.1 The allowable ROC, which may be earned by individual scheme members from home sales of NHS medicines, will be based on the historical value of average capital employed. This target will be 21% a year.

13.2 Companies will be allowed to inject costs or capital on the condition that they provide audited evidence that these injections are appropriate and are not duplicated in any way by other entries in the AFR.

14 Margin of Tolerance

14.1 The allowable return referred to in paragraph 13.1 will be associated with a margin of tolerance (MOT). Scheme members will be able to retain profits of up to 140% of the ROC target. Companies will not be granted price increases unless they are forecasting profits less than 40% of the ROC target. Procedures for price increases are set out in chapter 22.

14.2 The MOT will not be available to a scheme member for any year in which it has implemented a price increase agreed by the Department. Where a scheme member exceeds its target profit for a year in which it has received a price increase, all profits above the target will be repayable. Where a price increase is agreed by the Department in the second half of a year, the MOT will not be available to a scheme member for the year following the increase.

14.3 If the Department's assessment of an AFR shows profits in excess of the MOT, it will negotiate one or more of the following:

14.3.1 repayments of that amount of profits which exceed the MOT;

14.3.2 price reductions, during the accounting year following that covered by the AFR, to bring prospective profits down to an acceptable level, on the basis of available forecasts;

14.3.3 a delay or restriction of price increases agreed for the company or both.

14.4 Irrespective of the final date of settlement, any agreed price reductions will take effect from a date three months after the scheme member's AFR is due. In the event of negotiations not being completed by the effective date, any price reductions resulting from the review will in any case be made effective as if they had been operative from that date, if necessary by payment or other adjustment having equivalent effect. The Department will specify the date on which a payment is to be made. That date will be no later than one month after the date of settlement.

15 Companies with Low Capital Bases

15.1 Scheme members will be able to include capital employed in their AFR on the basis of its inclusion in UK statutory accounts, by injection or by imputation in the transfer price.

15.2 For scheme members whose AFR home sales exceed their average assessed home capital employed (excluding any capital imputation from the transfer price) by a factor of 3.5 or more, sales rather than capital will be used to determine the profit target. The target rate of profit will be set by dividing the ROC target rate by a factor of 3.5 and applying this rate to home sales. The target will be 6% Return on Sales (ROS). The assessment of the returns of scheme members that are subject to the ROS option will take account of the transfer price profit and the MOT on transfer price profit.

15.3 Where a company is satisfied that it will be assessed as a return on sales company, schedule 2 of the AFR (and forecast and estimate) is not required to be submitted.

16 Transfer Pricing

16.1 Where possible, scheme members should seek to provide an audited breakdown of their transfer prices (purchases from affiliates, lines 4 and 7 of schedule 1).

16.2 Where a member provides no breakdown of transfer price costs, it will be required to confirm that its transfer prices are at arm's length, to indicate the basis on which such arm's-length prices are set, and to confirm that the transfer prices reported in the AFR are as reported in the member's corporation tax computation. In such cases, the Department will assume that transfer prices comprise 59% manufacturing, 21% R&D and 20% profit.

16.3 The maximum permitted transfer price profit allowed in the assessment is 25% of accepted costs. 'Accepted costs' means the costs allowed after negotiation. In the case of a member assessed on a ROC basis, the allowed profit will be converted to an equivalent amount of assets, using the scheme ROC target, and added to the member's total capital employed. In the case of a member assessed on a ROS basis, the allowed profit will be added to the member's ROS profit target.

16.4 In an AFR year in which a member is subject to the default transfer price breakdown and 20% or more of claimed NHS home manufacturing costs i.e. total cost of goods sold (line 11, AFR schedule 1) is derived from the transfer price, the maximum acceptable manufacturing costs i.e. total cost of goods sold (line 11) will be restricted to 45% of home NHS sales in the assessment (after re-assignment of costs to take account of the transfer price analysis).

16.5 Where a scheme member's manufacturing costs i.e. total cost of goods sold are restricted to 45%, the excess will first be disallowed from the transfer price component, thus reducing accepted transfer price costs and consequently the transfer price profit allowed.

16.6 Where a scheme member's claimed total R&D, including the R&D component from the transfer price, exceeds its R&D allowance for the year, the excess will first be disallowed from the transfer price component, thus reducing accepted transfer price costs and consequently the transfer price profit allowed.

16.7 Where significant currency movements occur, the Department may seek clarification from scheme members on the effects of these movements on transfer prices, including information on the sources of transfers. The Department may also look at the consistency of transfer prices from one year to another.

17 Research And Development

17.1 The Department confirms its commitment to recognising the cost of R&D within the prices paid for NHS medicines. The amount allowed reflects both a contribution to the worldwide cost of R&D undertaken by companies developing human medicines and a desire to reward and provide an incentive for success in R&D.

17.2 The maximum R&D allowance is 20% of NHS home sales for assessing price increases (level 1) and 28% of NHS home sales for assessing AFRs (level 2).

17.3 These R&D allowances are allowable only where a scheme member can demonstrate within the AFR that the amount claimed relates to expenditure actually incurred.

17.4 The R&D allowance comprises three elements:

17.4.1 Flat rate:

- level 1: up to 15% of the value of NHS home sales;
- level 2: up to 20% of the value of NHS home sales.

17.4.2 Variable rate for innovation:

- 0.25% of NHS home sales for each in-patent active substance protected by a basic preparation patent (and Supplementary Protection Certificate (SPC) where one exists) above a threshold of £300,000 of NHS home sales a year up to a limit of 20 active substances. The maximum allowance for this component is, therefore, 5% of NHS home sales and is additional to the level 1 and level 2 flat-rate allowance.
- Where no patent exists, the additional component may apply to each substance, which has been granted a new active substance marketing authorisation. The allowance will be given for a period of 10 years after the grant of the first marketing authorisation for that new active substance. For clarification, this provision is intended to cover all branded licensed NHS medicines including those in paragraph 10.5, which are not patentable. This is subject to them being recognised by the Licensing Authority as a new active substance, in that a full (major) marketing authorisation is required.
- During the first three years that a company is included in the scheme as a full AFR company, the allowance, for assessing AFR profits only, is increased as follows:
  - 2.0% of NHS home sales for active substance 1;
  - 1.0% of NHS home sales for active substance 2;
  - 0.25% of NHS home sales for each active substance thereafter.

  This additional flexibility for new entrant AFR companies is subject to a maximum allowance of 5%.

17.4.3 Variable rate for paediatrics

- 1% of NHS home sales in the year in which a product is first generally available on prescription in the UK under the terms of a marketing authorisation that includes a paediatric indication, up to a limit of three products in any one year. This additional element for paediatric indications may not be utilised for applying for a price increase under the scheme.

18 Marketing Allowance

18.1 Marketing expenditure should include the cost of all advertising, selling and sales promotion of a company's NHS medicines in the UK as well as the administrative support to such activities. Further guidance on the activities qualifying for the marketing allowance is at annex B.

18.2 The following expenditure is not allowable as a charge in NHS prices and must be excluded from the AFR on schedule 1A:

- samples (other than samples for identification purposes);
- gifts;
- hospitality (other than that provided for eligible medical symposia).

18.3 The marketing allowance will be calculated for each company on the following basis:

18.3.1 standard elements of 2% of home sales of NHS medicines for level 1 and 4% of home sales of NHS medicines for level 2 (see paragraph 11.3 for an explanation of levels 1 and 2);

18.3.2 a fixed element of £500,000 for level 1 and £1,000,000 for level 2;

18.3.3 product servicing allowance for each active substance with sales to the NHS of £100,000 or more (in the year to which the AFR relates). These will be set at £58,000 for each of the first three eligible products, £46,000 for each of the next three, £35,000 for each of the next three, and £23,000 each for all others.

19 Information Allowance

19.1 Information expenses should include the costs of the provision and dissemination of factual information on a company's NHS medicines in the UK. This includes information whether or not required by statute or regulation or requested by a public body, the provision of non-product-specific information, support for the development, implementation or monitoring of protocols, guidelines, service standards or frameworks, and the provision to patients of support and information as required or permitted by law and the relevant Code of Practice. Information expenses will also include the costs of samples for identification purposes, summaries of product characteristics and medical symposia.

19.2 Further guidance on the activities qualifying for the information allowance is at annex B.

19.3 The information allowance will be calculated for each company on the following basis:

19.3.1 standard elements of 2% of home sales of NHS medicines for level 1 and 4% of home sales of NHS medicines for level 2.

20 UK Fixed Costs

20.1 When a company produces medicines for the NHS home and export markets net assets have to be allocated between these two markets. The ABPI recognises that the NHS should bear only its fair share of costs and capital as a result of this apportionment. At the same time, the Department acknowledges that a straight apportionment on the basis of the value of NHS and export sales may not take full account of the cost and asset base required in the UK to manufacture branded medicines for the NHS. To correct this potential distortion, additional costs and capital will be apportioned to NHS home medicines. The additional benefit will be calculated as 7.5% of UK based NHS exports medicines manufacturing process costs as shown in AFR schedule 1 and 7.5% of the total net fixed assets allocated to exports (excluding R&D assets and injected capital) as shown on AFR schedule 2. The apportionment will be the same for levels 1 and 2.

Pricing

21 Price Cut

21.1 The prices of medicines covered by the PPRS will be reduced by 7% from 1 January 2005. In imposing this reduction, the aim is to effect a corresponding reduction in the NHS expenditure on branded medicines.

21.2 The price cut will apply to the NHS list price of all products on the market on 31 December 2004, the day before the date of commencement of the new scheme. The price cut will apply to all companies with NHS home sales above £1 million in the company's financial year ending in 2004. For companies with NHS home sales of £10 million or less in that year, the first £1 million sales will be exempt from the price cut.

21.3 No price increases will be permitted for a period of 12 months until 31 December 2005, except as part of a cost-neutral modulation agreed under chapter 26. At the end of this period, scheme members will be eligible to apply for price increases under chapter 22.

21.4 New products introduced following the granting of an EU or UK new active substance marketing authorisation and line extensions applied for within five years of the grant of the original authorisation retain freedom of pricing on entering the market (see chapter 24)

21.5 As an alternative to an across the board reduction, scheme members may opt to deliver the price cut by modulating the prices of some or all of their products covered by the PPRS (see modulation rules in chapter 26).

21.6 Scheme members may also opt to deliver up to 2% of the price cut by making a payment to the Department. By the end of January each year, a scheme member should notify the Department of its estimated NHS home sales for the period 1 January to 31 December and make a payment of 90% of the estimated amount with the balance payable to the Department by 28 February the following year. The payment should be based on sales at NHS list price.

21.7 Where 30% or more by value of a scheme member's NHS home sales are made up of OTC products (i.e. medicines intended for sale to the public without a prescription), the member may elect to deliver the 7% price cut by making a payment to the Department. This payment should be made quarterly in arrears no later than three months following the end of the quarter. In order to ensure equity with scheme members delivering the price cut by modulation, where a company is also delivering the 4.5% price cut under the 1999 scheme by payment, the payments should be 11.2% of NHS sales at list price. The payments should continue for the duration of this agreement.

21.8 Products transferred between companies will remain subject to the price reduction (see chapter 25).

21.9 Scheme members should notify the Department by 19 November 2004 of how they wish to deliver the price cut and the list of prices proposed from 1 January 2005. The information required for companies, which choose to modulate, is given in paragraph 26.12.

21.10 Both parties acknowledge that the price cut may affect the cost-effectiveness evaluation and advice to the NHS communicated by Health Technology Assessment bodies. In circumstances where the price cut materially alters the Budget Impact Statement or assessed Cost per QALY (Quality Adjusted Life Year), the member may request a review of this element.

21.11 The Department accepts the right of member companies to change discounts allowed on sales. Paragraph 21.1 of the scheme sets out the basis of the expenditure savings on branded medicines covered by this agreement. The net effect of changes in discount allowed on the sales of these medicines should not affect the delivery of this aim.

21.12 The Department will be operating monitoring procedures to ensure that the reduction in NHS expenditure on branded medicines is achieved.

21.13 In addition to the information arrangements set out in chapter 26, to enable the Department to monitor the delivery of expenditure savings the following additional information should be submitted by all scheme members with NHS home sales of more than £1 million by 28 February of each year, starting on 28 February 2006:

Modulating companies

- Total sales revenues at list price for all those products where prices have not been modulated for the period 1 January to 31 December in the previous year.

Non-modulating companies

- Total sales revenues at list price for all those products where prices have not been modulated for the period 1 January to 31 December in the previous year.
- Total net sales revenues for all those products where prices have not been modulated for the period 1 January to 31 December in the previous year.

21.14 The Department reserves the right to call for the information specified in paragraph 21.13 from any scheme member at any time if circumstances warrant it. Where it can be demonstrated as a result of a member's action that a member is not delivering the required reduction at paragraph at 21.1, the member will be expected to rectify the position and discuss with the Department how this will be achieved.

21.15 The data submitted for the purposes of monitoring the delivery of expenditure savings delivered under this agreement will be independently audited (see annex F).

22 Price Restraint

22.1 No scheme member may increase the price of any medicine without the Department's prior approval. This will not be granted unless a scheme member's PPRS business is up to date.

22.2 Where a scheme member wishes to increase the price of any branded medicine it should give the Department not less than eight weeks' notice of this request. This notice should state the amount of the proposed increase and the reason in sufficient detail to satisfy the Department that the increase is justified. Companies must submit an estimate for the year after that to which the most recent AFR

relates and a forecast for the following year. Scheme members with NHS home sales below the threshold for submitting AFRs routinely, will be required to provide an AFR for the year a price increase is awarded and for one year following the price increase.

22.3 The Department will not agree to a price increase unless the company's estimated and forecast profits for the current and following financial years respectively, as assessed by the Department, are below 40% of the ROC target.

22.4 If the Department is in any doubt as to whether costs and capital are acceptable, or adjustments should be made, it may require further information. The Department may require that any supplementary information and data submitted should be independently audited, where appropriate.

22.5 Where a price increase is agreed, the level of the increase approved will be no more than that required for the company to achieve 65% of the ROC target.

22.6 No company may be awarded a price increase within a period of twelve months after a preceding, authorised price increase.

22.7 PPRS member companies may from time to time review their discounts on sales to NHS hospitals. The outcome of any such reviews may result in the overall reduction or removal of discounts that are not a result of competitive tendering in the open market.

22.8 The Department accepts fully the right of member companies to change discounts allowed on sales to hospitals. At the same time, the Department expects that the net effect of such changes should not increase NHS costs. Accordingly, if a member company intends to remove or reduce hospital discounts offered for PPRS medicines as a change in company policy in all or the majority of the UK (other than those which may result from the outcome of a competitive tender) then it must:

- notify the Department at least 28 days before the date of any proposed reduction or removal;
- identify the product or products concerned;
- quantify the volume of product concerned, the extent of the discount involved and the extra cost to the NHS;
- indicate the action it proposes to take to counterbalance that extra cost to the NHS.

22.9 The Department will respond to such communications within 28 days of receipt of a member's letter and may reject the proposal where it concludes that the change in hospital discount and any counter-balancing action that the scheme member proposes to take is not cost neutral.

23 Price Reductions

23.1 Scheme members may make temporary reductions to a price, outside the arrangements for modulation or those for the settlement of an AFR, and increase the price to a level no more than the price before the reduction without the agreement of the Department. Scheme members must inform the Department at least 21 days before the changes take effect and provide information on the existing and new prices, and the expected duration of the reduction.

24 Pricing Of New Products

24.1 New products introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Licensing Authority, may be priced at the discretion of the company on entering the market.

24.2 Line extensions relating to such new products, granted on the basis of an abridged application, may also be priced at the discretion of the company provided that the application to market the line extension has been submitted to the appropriate licensing authority within five years of the grant of the original authorisation of the new product.

24.3 Increased strengths of existing formulations may not be priced at a level greater than pro-rata to existing formulations. The freedom of pricing of reduced strengths should not be coupled with product deletions so as to achieve hidden price increases.

24.4 If forecast sales of any new product in any one year of the first five years following launch is expected to exceed £20 million, a company must inform the Department of both the price and the anticipated level of sales in each of the first five years.

24.5 If a company considers that the rapid uptake of a new product will cause the company to exceed the upper margin of tolerance (MOT), then it is obliged to inform the Department immediately and negotiate a reduction in profitability for the current year to the upper level of the MOT. Similarly, the Department will negotiate a reduction in profitability if it has reason to believe that the rapid uptake of a new product will cause a company to exceed the upper MOT.

24.6 Freedom of pricing at the time of launch of these new products is conditional that it will not cause forecast profits to exceed the target profit MOT.

24.7 A company wishing to introduce a product to the UK market should give the Department a minimum of four weeks notice before the intended date of introduction. The company should supply the Department with details of the product including the NHS list price and Summary of Product Characteristics. The Department will acknowledge the letter and seek confirmation of the new active substance marketing authorisation status from the appropriate licensing authority.

24.8 Once the Department has confirmed the new active substance marketing authorisation status, it will write to the company confirming that the product has freedom of pricing. Where a new product has not been subject to a new active substance marketing authorisation, a company must seek the Department's agreement to the price of the new product. This can include new products regarded by a company as innovative but which are not classified by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMEA) as new active substances; combination products containing active substances that have been marketed separately; active substances with new indications; 'complex' branded generics; and variations in formulation, presentation or pack size to existing products.

24.9 In reaching a decision on the acceptability of a price for a new product that is not introduced following the granting of an EU or UK new active substance marketing authorisation, the Department may take into account factors such as the following:

- 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 product;
- any exceptional costs.

24.10 If, following discussions, agreement cannot be reached on the price of the product, a company may decide to go to arbitration (see chapter 30).

25 Products Sold On

25.1 Companies sometimes need to change the structure of their product portfolios. In some cases the original company has no further interest in the product, having transferred intellectual property rights, manufacture, name and distribution network; in others the change will be minimal, and the original company continues, for example, to manufacture the product. It is important that, as in other circumstances, there should not be disproportionate price increases. Accordingly, when a product covered by the PPRS is sold on:

25.1.1 The company transferring the product and the acquiring company should notify the Department of the product and the name of the acquiring company within 14 days of the transfer;

25.1.2 The acquiring company will assume responsibility for delivering the price reduction on the acquired product and may not increase the price for three months after acquisition. This condition will not apply where the acquiring company is forecast to have NHS sales of less than £1 million in the 12 months following the date of acquisition;

25.1.3 If at the end of the three months the acquiring company wishes to increase the price of the product concerned, it should seek the Department's approval;

25.1.4 The Department will consider the application against the company's overall PPRS position and will only approve the increase if it is justified under the terms for price increases in chapter 22. Where the increase would be more than 20%, the Department reserves the right to negotiate the increase over three years;

25.1.5 Where the original company continues to manufacture or supply the product, information may be needed by the Department from that company to justify the increase.

26 Modulation

Principles underlying modulation as an alternative to a price reduction of 7% on all products

26.1 As an alternative to an across the board price reduction, scheme members may modulate the list price of their PPRS products by reductions that equate to an overall level of 7%. Modulation will be deemed to have occurred where:

- list prices have been reduced by a percentage other than 7%;
- list prices remain unchanged from those that prevailed on 31 December 2004.

26.2 Companies can remodulate at any time from 1 January 2005 provided the Department is notified 28 days in advance of the implementation of the price change. The Department will have 21 days in which to respond to modulation notifications and will only withhold agreement where it can be shown that the effect would place the delivery of the price reduction in doubt.

26.3 Companies will not be permitted to:

- substitute discounts or contract prices in force during the six months prior to the date of any proposed modulation;
- include price reductions made on products where the patent or supplementary protection certificate expires after 1 July 2004 and before 1 January 2006 in any calculations of modulations or overall adjustments made to achieve the price reduction;
- include volumes of sales where additional discounts are offered that result in branded products being dispensed against prescriptions written generically; commonly known as brand equalisation deals.

Modulation principles after 1 January 2006

26.4 The Department is keen to minimise interference in the conduct of companies' commercial affairs consistent with safeguarding public expenditure. Companies are permitted to modulate the prices of products provided that the effect of the modulation is cost neutral.

26.5 From 1 January 2006, list prices may be increased to a level no greater than 20% above the level that existed on 31 December 2004 subject to the agreement of the Department. The Department will consider applications for increases of more than 20% for products with NHS sales of £100,000 or less where a medical need can be justified. If the Department has reasonable grounds to believe that a proposed modulation may have a significant negative effect on a part or parts of the NHS, it may require the company concerned to discuss the proposed modulation prior to it being implemented.

26.6 The prices of new products introduced after 1 January 2005 can be increased by up to 20% after 1 January 2006. Any reduction in the price of a new product cannot be used to offset price increases on other NHS products until the new product has been on the market in the UK for two years.

26.7 Scheme members will not be permitted to use price reductions that may be necessary as a result of patent or supplementary protection certificate expiry to justify a price increase on other NHS products. Consequently, scheme members will not be allowed to include in their modulation proposals price reductions made on products where the patent or supplementary protection certificate has expired within one year before, or will expire within two years after, the proposed date for modulation. Where a competitor product enters the market within two years of patent or supplementary protection certificate expiry, the exclusion period for modulation purposes will be extended to a maximum of two years from the market entry of the competitor product.

Information requirements and monitoring

26.8 Scheme members will provide the Department with information on the estimated and actual unit sales of NHS medicines in respect of each product where prices are to be modulated and the estimated and actual total net sales revenues of all such products. The Department will operate monitoring procedures to ensure that scheme members that modulate prices deliver the 7% price reduction and that subsequent modulations are cost neutral.

26.9 By 31 May for each year of the agreement, the Department will analyse outturns for the previous 12 months ending 31 December. It is recognised that it will be difficult for scheme members to deliver a cost neutral outcome in each year. Consequently, a margin in each year of 0.5% either side of a cost

neutral outturn will be permitted. Where modulations are outside the range of 0.5% either side of a cost neutral outturn the following arrangements will apply to ensure that companies deliver an outcome within the agreed margin.

26.10 The outcome of modulations made after 1 January 2005 that is not cost neutral for the NHS will be rectified by remodulation so that any cost to the NHS or the scheme member can be recovered within 12 months.

26.11 Companies that decide to modulate the list prices of some or all of their products to deliver the price reduction will provide the Department with the following information (that for the outturn data will be independently audited – see annex F).

By 19 November 2004:

26.12 For all products, the price of which is to be modulated:

- a list of the NHS prices proposed from 1 January 2005 and the prices at 31 December 2004;
- the estimated quantities (i.e. the number of packs or units of each presentation of product) forecast to be sold to the NHS for each product in the years ending 31 December 2004, 2005 and 2006;
- the total net sales revenues for those years.

26.13 Companies, which have not provided details of their modulation proposals to the Department by 19 November 2004, will be unable to modulate prices from 1 January 2005 and the Department will notify the PPA of a 7% reduction in prices across the board.

28 days before any additional or subsequent modulation

- the name of the product (including dosage, pack size etc.,) to be modulated and the pre and post modulation prices;
- the estimated quantities sold to the NHS in the 12 months before and after modulation;
- the estimated total net sales revenues for all the modulated product(s) before and after modulation.

By 28 February 2006 and by 28 February in each subsequent year

- total net sales revenues for all those products where prices have been modulated and those where prices have not been modulated for the period 1 January to 31 December in the previous year;
- quantities sold to the NHS for each product modulated since 1 January 2005 for the period 1 January to 31 December in the previous year. Unit sales will be provided for each product for three complete calendar years after the date of modulation (see annex E).

26.14 If the Department has reasonable grounds to believe that a product proposed for downward modulation is a brand equalisation product, the company will be required to report unit and cash sales and identify the volume sold into the generics market. Only the volume sold into the branded market will count in the computation of the modulation.

Calculation Of Delivery

26.15 Scheme members with sales of NHS medicines in excess of £1 million in the year ending 31 December 2004 are obliged to deliver an overall price reduction of 7% from 1 January 2005 as part of their conditions of membership of the 2005 PPRS.

26.16 In determining whether a company has met this obligation the Department will examine sales for each year ending 31 December for the remainder of the lifetime of the 2005 PPRS. The Department will by 31 May of each year from and including 2006 categorise deliveries as follows:

- delivery of more than 7.5%;
- delivery of less than 6.5%;
- delivery of 6.5% or more but no more than 7.5%.

Action to be taken where modulation does not deliver a 7% reduction

Delivery of more than 7.5%

26.17 A scheme member may re-modulate its prices, with the Department's agreement, so that the member may recover any over delivery in the following year, or over a longer period if the member so wishes.

Delivery of less than 6.5%

26.18 For each year, ending 31 December during the duration of the scheme where modulation has delivered a reduction of less than 6.5% scheme members will be required to make a payment to the Department to deliver the full 7% reduction for that period. Scheme members will also be required to re-modulate prices so that the 7% reduction is delivered for the remainder of the agreement.

Delivery of 6.5% or more but no more than 7.5%

26.19 For the sake of administrative efficiency, scheme members that achieve a modulation outcome within the range of 6.5% to 7.5% will not be required to re-modulate or to make a repayment. To ensure that delivery remains within the 6.5% to 7.5% range throughout the agreement, the quantum of the under or over delivery will be added to that achieved in the following year to calculate the percentage delivery in that year and treated as follows:

- where the cumulative modulation remains within the 6.5% to 7.5% range the under or over modulation will be carried forward to the following year;
- where the cumulative modulation exceeds 7.5% the scheme member may re-modulate as set out in paragraph 26.17 above;
- where the cumulative modulation is below 6.5% the scheme member will be required to take action as set out in paragraph 26.18 above.

26.20 All modulations will be monitored over the duration of the scheme.

Companies Awarded A Price Increase

26.21 Scheme members will be required to make a payment to the Department to deliver any shortfall of the target 7% savings before an agreed price increase may be implemented. Where a scheme member has over-delivered against the 7% target it will be expected to re-modulate before applying for a price increase and then to apply for such an increase only if after re-modulation it meets the required conditions. The value by which any price increase erodes the target saving will be recorded and agreed with each company.

Products Transferred and Fostering Arrangements

26.22 Where a company transfers ownership of a product to another company, details of sales should be removed from the vendor's modulation and included in the purchaser's modulation from the date of the transfer. There may be a consequent requirement for remodulations to correct any resultant under or over delivery of the 7% price reduction.

26.23 Occasionally a company may enter into a product fostering arrangement with another company. Usually, in these instances, the marketing authorisation remains with the original company and the second (fostering) company assumes responsibility for sales and marketing of the product. In this case, the original company will report sales of the fostered products in its own AFR and will retain responsibility for delivering the saving in respect of the product. However, if sales are reported in the AFR of the company fostering the product, then the foster company will assume responsibility for that product for modulation purposes.

26.24 When companies enter into such fostering arrangements, it is essential that the Department be informed in writing. The companies should clearly state which company is to include sales of the product in its AFR and is therefore responsible for delivering the 7% saving with respect to that product.

Company Mergers

26.25 The combined portfolios of products belonging to the merged company will be reviewed to establish a revised target with reference to the original prices of 31 December 2004. In cases where there is a cumulative shortfall below 7%, the merged company will be required to make a payment to deliver the 7% reduction calculated to be due on the date of the merger. In all other instances, the value of the cumulative delivery to be carried forward will be calculated and agreed with the company.

Delivery of Price Cut by the end of The Scheme

26.26 To ensure that a 7% price cut is delivered by the scheme as a whole those members that have delivered more than a 7% price cut should consult with the Department on appropriate actions. Those members who have delivered less than a 7% price cut overall will be required at the end of the scheme to make a cash payment to the Department that equates to the under delivery against the 7% price cut specified in the agreement.

26.27 The Department may not agree to any modulations proposed in the last year of the scheme if they may cause the savings delivered during the period of the scheme to be eroded in subsequent years.

Information Requirements

27 Annual Financial Return (AFR)

27.1 The Department has to satisfy the needs of public accountability by the scrutiny of each company's AFR and price increase applications under the terms of the scheme. There is a balance to be struck between recognising the costs to companies of providing information and the level of detail necessary to enable the Department to reach reasonable conclusions on each company's PPRS position.

27.2 AFRs, together with supporting information (see specimen in annex B), will be completed annually and submitted to the Department as follows:

27.2.1 scheme members with a UK registered name beginning with the letters A to F: within six months of the end of their financial year;

27.2.2 scheme members beginning with the letters G to O: within nine months of the end of their financial year;

27.2.3 scheme members beginning with letters P to Z and any others: within 11 months of the end of their financial year.

27.3 Where a scheme member can demonstrate that for reasons beyond its control it cannot meet the time limits set out in paragraph 27.2, the deadline for the submission of its AFR may be extended with the agreement of the Department. The Department will not grant an extension to the deadline for the submission that would result in an AFR being received later than 12 months after the end of a company's financial year.

27.4 The Department will only recognise that an AFR has been submitted by a scheme member when all components of the AFR including relevant audit certificates have been submitted (see checklist at annex C). It is recognised by both parties that the scheme depends on information being supplied promptly. The Department will monitor the submission and processing of AFRs closely and bring the results to the attention of the ABPI, which will use its best endeavours to ensure that deadlines are adhered to.

27.5 Scheme members should provide a list of the NHS home products that have been included within their AFR, identifying those with NHS home sales of £300,000 or more and £100,000 or more (after discounts and rebates). For each product, they should indicate the date of expiry of the active substance patent and any supplementary protection certificate or where no patent exists, the date of grant of the first marketing authorisation for that new active substance. This will be used for:

27.5.1 confirming that the correct categories of product have been included and ensuring consistency between companies (see chapter 10);

27.5.2 calculating allowable expenditure under the R&D formula (see chapter 17);

27.5.3 calculating allowable expenditure under the marketing formula (see chapter 18);

27.5.4 calculating allowable expenditure under the information formula (see chapter 19).

27.6 The Department will acknowledge receipt within fourteen days of receiving an AFR and will advise companies in writing within eight weeks of receipt if it also wishes to make further enquiries into the information submitted. The Department may require that any supplementary information requested is independently audited. Scheme members will be expected to provide supplementary information within 28 days of the date of the request.

27.7 Upon completion of its enquiries, the Department will issue an assessment. If this assessment indicates that a payment is due to the Department then a date for payment will be specified. That date will be no later than one month after the date of the completion of the negotiations on an assessment.

27.8 Forecast financial returns will be completed annually and submitted to the Department within the first three months of the start of the accounting year to which they relate. Each return will be accompanied by an estimate, in the same format, of the outturn for the year preceding the forecast year. A specimen copy of the forecast/estimate is provided in annex B.

27.9 To enable the Department to monitor the delivery of expenditure savings from the price cut, the information specified at paragraph 21.13 should be submitted by 28 February each year. If the prices of products have been modulated, there are additional information requirements, which are set out in chapter 26.

27.10 The confidentiality of commercially sensitive information submitted to the Department will be assured.

28 Small companies

28.1 Any manufacturer or supplier relieved of the commitment to supply full financial information as in paragraph 8.7 will remain subject to the need to contain costs and the price restraint provisions (see chapter 22). The Department reserves the right to call for a full AFR or forecasts or both at any time if circumstances warrant it.

28.2 Subject to the provisions of paragraph 28.1 above, in assessing the AFR or other financial information provided by a small company, the Department may exercise a degree of discretion in relation to such matters as the levels of costs or capital employed allowed. In particular, the levels of allowances for R&D, marketing and information, set out in paragraphs 17 to 19 respectively are not necessarily applicable to small companies. The Department will continue to look at these flexibly with regard to the circumstances of the individual company, including the level of its NHS turnover.

29 Submission of AFRs in transition between 1999 scheme and this agreement

29.1 Scheme members will be expected to submit AFRs without interruption over the transition between the 1999 PPRS and this agreement. AFRs will be assessed on the basis of where the majority of the accounting period to which the AFR relates falls. Thus AFRs based on company financial years ending up to 30th June 2005 will be assessed under the 1999 scheme and AFRs based on accounting periods ending after 1 July 2005 will be assessed under the 2005 scheme. There will be no split year assessments as there have been under previous schemes.

Other Matters

30 Arbitration

30.1 The Department, the ABPI and individual scheme members undertake to operate this agreement so that issues arising between the company and the Department are normally resolved by discussion between the scheme members and the Department. Nevertheless, significant issues between the member and the Department may arise that cannot be resolved in this way. These issues may be referred to the arbitration procedure set out below by either party.

30.2 Where a scheme member or the Department decides to go to arbitration it must give written notice to the other party of its intention within 21 days of an event. Examples of 'events' in this context would be refusal by the Department to agree a price increase under the scheme or the failure of both parties to reach agreement on the extent, if any, to which excess profits are repayable to the Secretary of State. Both parties to the dispute must provide the arbitration panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of arbitration. Statements will be made available to both parties. They may be supplemented in response to questions arising during the arbitration procedure.

30.3 The arbitration panel will give each party to the disagreement the opportunity to put forward its case on the issue(s) that is (are) in dispute at an oral hearing. The panel will be expected to hold the hearing within 30 days of the receipt of the written statements from both parties. Both parties are free to decide their representation at the oral hearing.

30.4 Prior to, or at the hearing, the panel may request supplementary written information from either party to the dispute where it considers this necessary to properly understand the issues. The parties will be required to provide this information within 15 days of the request. All information provided to the arbitrators and the arbitrators' reasoned opinion and decision will be available to all parties. The panel will be expected to make its decision known to both parties within 30 days of the oral hearing or within 45 days where it has been necessary to obtain additional written information from either party. The decision will not be relied upon in the future operation of the scheme.

30.5 The arbitration panel will comprise:

30.5.1 a Chairman appointed by the Secretary of State with the agreement of the ABPI;

30.5.2 two members, one appointed by the Secretary of State and the other by the ABPI.

30.6 The Secretariat to the panel will be provided jointly by the Department and the ABPI.

30.7 The costs of the arbitration panel will be shared equally by the Department and the ABPI. The parties to each dispute will be responsible for paying their own costs.

30.8 The confidentiality of commercially sensitive information will be assured.

30.9 A description of the functions of the Arbitration Panel and its work is at annex H.

31 Audit Arrangements

31.1 Information supplied by scheme members must be audited as provided in this agreement, and supported by audit certificates in the form set out in annex B.

32 Report To Parliament

32.1 The Department will publish a report to Parliament on the scheme and provide aggregated details of the operation of this scheme. These details will include aggregated figures for data submitted and adjustments made.

33 Consultation Arrangements

33.1 Apart from the mid-term review, meetings will take place between the ABPI and the Department every six months to consider the operation of the scheme. This is in addition to any formal process of consultation required in relation to procedures referred to in the Health Act 1999.

34 Distribution Margin

34.1 One of the objectives of this scheme is to encourage the efficient and competitive supply of medicines to the NHS. Individual companies are expected to follow good commercial practice in the distribution of their products according to their individual needs.

34.2 With that objective in mind the Department in consultation with ABPI and others as required will review the appropriateness of the provisions relating to the distribution margin for supplies distributed through wholesalers as set out in the 1999 PPRS. The process for this review will be agreed by January 2005.

Annex A

PPRS MEMBERSHIP FORMS

FORM A

CERTIFICATE OF WITHDRAWAL OF CONSENT FOR VOLUNTARY SCHEME TO BE TREATED AS APPLYING

Name ----------
[of company/partnership, etc.]

Address ----------

Date on which the consent now being withdrawn was given

---

1. I ---------- [name of person signing & capacity in which signing (e.g. director/partner/other) certify that the consent of the above named company/partnership/person(a) to the voluntary scheme made between the Secretary of State and the Association of British Pharmaceutical Industry in July 1999/November 2004(a) being treated as applying to it is hereby withdrawn.

2. I am duly authorised to sign this certificate.

Signed ----------

Date ----------

(a) delete as appropriate

FORM B

SECTION 33(2) AND SECTION 33(6) OF THE HEALTH ACT 1999[1]

CERTIFICATE OF CONSENT FOR VOLUNTARY SCHEME TO BE TREATED AS APPLYING

Name ----------
[name of company, partnership etc.]

Address ----------

---

1. I ---------- [name of person signing & capacity in which signing, (e.g. director, partner or other)] certify that the above named company/partnership/person[2] hereby consents to the voluntary scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State in November 2004 [(to which there are modifications/and additions made between [the company/partnership/[name] and the Secretary of State on---------- [3])] being treated as applying to it/him[(a)].

2. I am duly authorised to sign this certificate.

Signed ----------

Date ----------

1 1999 c.8.
2 delete as appropriate.
3 Insert date.
(a) delete as appropriate

Annex B

GUIDANCE ON COMPLETION OF THE ANNUAL FINANCIAL RETURN AND SCHEDULES

1 General

1.1 This annex sets out guidance on the completion of Annual Financial Returns (AFRs) and the approach that the Department will adopt in assessing the returns. It is not intended to be comprehensive in its approach and does not cover all the issues that may arise in the assessment of AFRs. The Department will continue to discuss AFRs with scheme members bilaterally and may limit costs and capital to a level that is reasonable in its analysis of the company's figures, as provided for in chapter 12 of the agreement.

1.2 The AFR should relate to business organisations that manufacture and supply licensed branded medicines that ultimately are charged to the NHS. The AFR should cover, on a consolidated basis, the company and its subsidiaries, and should include business done through branches or divisions. Where, however, with the group organisation, audited accounts are prepared for a sub-group which embraces all the group pharmaceutical business carried on in the UK (though not necessarily confined to such business), the AFR should comprise consolidated figures for this sub-group. In such circumstances, references in the AFR to affiliated concerns should be regarded as extending to such excluded units as overseas subsidiaries, and non-pharmaceutical UK subsidiaries, branches or divisions. Where wholesaling and/or retailing activities are carried out in separate organisations for which separate figures of costs, sales and profits are available those figures should, where they are covered by separate audited accounts, be excluded from the AFR; otherwise, they should be included in the AFR under 'Other Products'.

1.3 It is recognised that the availability of consolidated and/or audited accounts will be a matter of corporate organisation and will not necessarily coincide with the requirements of the AFR. It is not intended that scheme members should produce additional audited accounts especially for the purpose of the AFR and where the accounting arrangements of the group are such that some other basis for the completion of the AFR is more appropriate, such other basis may be adopted by agreement between the scheme member and the Department. Nevertheless, the Department requires a reconciliation to the UK audited accounts or to audited and published segmental accounts (or analyses) – either for a pharmaceutical sector or for the geographical segment which includes the UK, depending on the basis used in the annual report.

1.4 The AFR should be accompanied by a copy of the audited accounts or audited and published segmental accounts (or analyses) of the company, group or sub-group whose figures form the basis of the AFR and by a statement setting out the names of the companies, branches and divisions whose figures are included in the AFR with a broad indication of the business activities of the major units. Published financial accounts of the ultimate holding company and of any relevant intermediate holding company should accompany the AFR.

1.5 The completed AFR should be signed by the Managing Director or Chief Executive of the scheme member and accompanied by a report from independent, qualified auditors to the effect that (subject to such reservations as they consider necessary), in their opinion, and in accordance with the explanations

given them, the AFR has been prepared on the basis required, and fairly reflects for the relevant financial year the capital employed in relation to NHS home medicines and the profit earned from home sales of NHS medicines (See certificate 1 at the end of this annex).

1.6 Schedule 1 (Sales, Costs and Profit) should be completed in respect of the reporting company's financial year and schedule 2 (Capital employed) should relate to the balance sheet date at the end of the same financial year. Where a scheme member is satisfied that it does not qualify to be assessed as a return on capital company owing to its home sales to capital ratio being greater than 3.5:1, there is no requirement to submit schedule 2.

1.7 It is accepted that the accounting system employed by the scheme members will result in some variation in the nature of expenses included under the various headings of the AFR. The purpose of these notes is to identify the main areas of consistency that are sought from all companies.

1.8 For the purpose of the AFR:

1.8.1 an affiliated concern should include any parent company or fellow subsidiary company of the scheme member, any of its subsidiary companies, branches or divisions whose figures are excluded from the AFR and any other trading organisation under the same control as the scheme member (see also note 1.2 above);

1.8.2 all figures should be reported to the nearest £1,000;

1.8.3 all figures for sales and costs should be stated net of UK Value Added Tax. Where a scheme member has been unable to recover input tax or a proportion of it, thus making it a cost to the business, it should be treated as such.

2 Apportionment

2.1 The Department recognises that scheme members cannot always allocate costs and capital directly to its NHS home, NHS exports and Other Products businesses and that various apportionment techniques have to be used to attribute shared costs and capital to the three businesses. Scheme members are required to make such apportionments on the most realistic and reasonable basis possible, striking an equitable balance between the separate interests of the scheme member in reporting the lowest possible profitability/ROC employed on its NHS home business and that of the taxpayer in reporting the highest possible profitability/ROC employed. It is expected that the auditor will use his professional judgement to ensure that the bases adopted are appropriate in the circumstances and to qualify his report in those cases where he is not satisfied with the bases adopted.

2.2 The scheme member will include with the AFR, notes identifying, with amounts, those items that have been specifically allocated against each cost and capital heading and those that have been apportioned. For those items that have been apportioned scheme members should give the amounts involved and explain the reasons for that allocation. If apportionment bases are changed from those adopted in the previous year, this should be declared in the notes and the AFR lines identified. The Department may ask for additional information on the method of apportionment if this is unclear.

3 Schedule 1: Sales, Costs and Profit

3.1 Columns are provided for separate information on home and export trade in NHS medicines. Sales of products not falling within the definition of NHS medicines should be shown under Other Products. This information is required to assist the Department in forming an independent judgement on the reasonableness of any methods of apportionment used in preparing the NHS figures and to reduce to a minimum the requests for additional information in individual cases.

3.2 The strict apportionment or allocation of costs may result in home costs that are greater than the Department is likely to accept, or are restricted by formula. To avoid claiming excessive costs and distorting published statistics, scheme members should include in the 'NHS Medicines Home costs claimed' column only those costs that it is expected that the Department will accept.

3.3 It is expected that costs and expenses (lines 4 to 20) will be on a cost centre basis i.e. salaries, wages, depreciation, materials and other expenses attributed to a function will be included in the cost of that function.

3.4 Depreciation should be charged at historical cost. Any difference between the figure on schedule 1 and in the accounts should be shown in the appropriate column on schedule 1A.

3.5 Where costs and expenses (lines 4 and 7) include sums charged by affiliated concerns, the Department will apply the default breakdown as provided for under chapter 16 of the scheme if the scheme member is unable or unwilling to provide an audited breakdown of the transfer price under the cost headings included in schedule 1.

4 Schedule 1A: Reconciliation of Schedule 1 with audited accounts

4.1 Columns on schedule 1A provide for a reconciliation of sales, costs and profit shown in schedule 1 with the amounts disclosed in the audited accounts on which the AFR is based.

4.2 Figures from the accounts should be transferred directly into the first column 'Total per audited accounts'. If the cost headings used in the accounts are incompatible with the AFR, then sales, total costs and profit before interest and taxation should be shown.

4.3 The second column 'Reallocations between cost headings' provides for cost reallocation where cost heads in the accounts are not the same as in the AFR. Details of costs reallocated should be explained, together with reasons for the reallocation, in notes accompanying the AFR.

4.4 The third column 'Items in audited accounts excluded from AFR' is where costs that are not appropriate to PPRS should be shown. Home costs reported in Schedule 1 will exclude certain items of non-PPRS income and expenditure that are normally recognised for published accounts purposes. It is expected that items which are omitted from the figures reported for NHS home will also be excluded from NHS exports and Other Products so that the three businesses may be compared on a basis which is as close as possible to like-with-like. Non-PPRS items should be eliminated consistently and in their entirety on schedule 1A. Examples of costs that should be excluded from schedule 1 and shown in column 3 of schedule 1A include amortisation of intangible assets, dividends and trade investment income received, interest paid and received and charitable and political donations.

4.5 The fourth column of schedule 1A 'Items not in audited accounts included in AFR' allows for costs that are not in the accounts that form the basis of the AFR to be brought in if they are dealt with through the accounts of other group companies but are directly relevant to the supply of medicines to the NHS. The usual cost that is brought in under this column is R&D that has been done by or has been recharged to affiliate companies.

4.6 Costs reported in this column at lines 22 and 23 are subject to a separate auditors' report (see certificate 2 at the end of this annex). These will only be accepted where it can be reasonably determined that costs incurred in the scheme member's accounts do not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating these costs.

4.7 The final column of schedule 1A must agree with the total column on schedule 1.

5 Schedule 2: Capital employed

5.1 Fixed assets should be presented at historical cost. Any difference between the figures included in the AFR and the balance sheet should be shown in schedule 2A. Assets should not include investments the income from which has been excluded from schedule 1.

5.2 PPRS does not permit the inclusion of intangible assets in the computation of capital employed.

5.3 Any provision for corporate taxation, including deferred taxation, should be excluded from current liabilities. Also excluded from current liabilities are items which do not represent normal trading balances but are of a long-term nature representing, in reality, part of the reporting company's capital structure (e.g. bank borrowing; advances from affiliated concerns). Such items should be entered in the column 'Total per audited accounts' to tie back to the accounts and then excluded in the column 'Items in audited accounts excluded from AFR'.

5.4 The amounts shown in lines 45 to 47 should be the proportion of fixed and current assets less current liabilities appropriate to the operations covered by the AFR but not included in the audited accounts of the scheme member. Injected capital reported at lines 45 to 47 is subject to a separate auditors' report (see certificate 2 at the end of this annex) and will only be accepted where it can be reasonably determined that capital, as shown in the scheme member's accounts, does not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating this capital. This net capital should generally correspond to the expenses shown at lines 22 and 23 of schedule 1. Conversely, a deduction should, if appropriate, be shown in schedule 2A, calculated on the same principles, when the scheme member shows amounts excluded from the AFR on schedule 1A.

5.5 If the average capital employed during the year would not be fairly represented by averaging the capital employed at the beginning and at the end of the year, a statement should be attached indicating the appropriate adjustment.

5.6 Under the 2005 scheme, the figures for capital employed in relation to NHS medicines are required to be divided between home and export trade. Opening home capital for the 2005 assessment will be the average home capital as used for the 2004 assessment.

6 Schedule 2A: Reconciliation of Schedule 2 with audited accounts

6.1 Schedule 2A should be used to reconcile items on schedule 2 with the corresponding figures in the audited Balance Sheet. The columns are a mirror of schedule 1A and comments above in respect of schedule 1A also apply to schedule 2A.

7 Definitions and explanatory notes on cost and capital headings

Sales

7.1 Sales should be shown net after deduction of all trade and other discounts (whether allowed to wholesalers, NHS authorities, trusts or others) and all rebates, return allowances and sales taxes. Discounts include settlement discounts where these are allowed as part of the normal wholesalers' discount.

7.2 NHS medicines should include only those products covered by the scheme as set out in chapter 10 of the agreement. To qualify as NHS medicines, products must be in the same form and packaging as used for filling prescriptions. Thus, sales of intermediate products and bulk supplies will not be classified as NHS medicines. This means that, whilst NHS home sales can include products that are not included under NHS export sales, NHS export sales cannot include products that are not included in NHS home sales.

7.3 Other Products sales include all products that are not specifically NHS products including contract manufacture for third parties, production of intermediates (except where they are used by the AFR company for conversion into finished products) and sales of bulk chemicals (whether in the form of tablets or not). The recharge of service costs and other intangibles (including R&D) should be excluded from the AFR on Schedule 1A through the exclusion of both the income and cost being recharged.

7.4 A list of all products included under home NHS medicines should be provided, identifying those with sales greater than £300,000 and £100,000 (after discounts and rebates). For each product, the list should also show the date of expiry of the active substance patent and any supplementary protection certificate or where no patent exists, the date of grant of the first marketing authorisation for that new active substance. This information is used to calculate the R&D and marketing allowances (paragraph 27.5)

Cost of goods sold

7.5 Materials purchased from affiliates and independents should be on a materials consumed basis. Manufacturing process costs should include all direct and indirect labour costs, depreciation of manufacturing fixed assets and other related manufacturing overhead expenses. Costs should not include any one-off costs (line 19) or other expenses that would be better included elsewhere in schedule 1.

7.6 The split of manufacturing process costs (line 9) should reflect the basic apportionment with no adjustment for the recognition of UK fixed costs (see chapter 20). Where there is both home and export manufacturing, this should be shown separately at line 28, calculated as 7.5% of the export allocation of

manufacturing process costs (line 9). As this is an adjustment to both home and export costs, the amount in the home column should be shown as a cost and the same amount shown under exports as a negative cost.

7.7 In all cases where there are products being licensed in or out, or contract manufacturing is being undertaken for either other independent companies or for affiliated companies, which impact in a material way on the sales of NHS medicines, all costs and revenue shall be included in the AFR, together with a brief description of the arrangement and of how expenditure and income has been treated in the AFR. Where a company manufactures a product for marketing by another, the relevant costs should be shown under 'Other Products' in the AFR of the producing company and the purchase price recorded under 'NHS Medicines' in the AFR of the marketing company.

Distribution costs

7.8 Distribution costs should normally cover only those costs directly associated with the physical warehousing of finished products and their distribution to wholesalers, hospitals etc.

Marketing costs

7.9 Marketing expenses in schedules 1 and 1A includes all expenditure incurred in advertising and other promotion of the sale of the company's NHS medicines in the UK market. The following are the criteria by which marketing expenditure will be allowable.

7.9.1 *Literature:* The cost against this category should cover all expenses incurred and include the direct labour and overhead charges attributable to operations concerned with such promotion (e.g. insertion and addressing) but not the cost of samples. If mailing is undertaken by an agency the relevant charges should be entered in this section.

7.9.2 *Representatives:* The cost should include the salaries and wages and overhead costs of representatives and supervisors, the running and replacement costs of vehicles and all travelling and subsistence expenses. The cost incurred in visits to hospitals as well as to general practitioners should be included, as should the cost of promotion to wholesalers or pharmacists. Where the cost of representatives covers activities other than NHS medicines home, the cost should be apportioned on a suitable basis.

7.9.3 *Advertising:* The cost of advertising in professional journals should cover all expenses incurred whether the journals are placed on sale, are issued by subscription, or are free of charge.

7.9.4 *Administration:* Costs should include all those incurred in the organisation, control, supervision and assessment of promotional activities in so far as it is not reasonably possible to allocate these costs to the other categories.

Information expenses

7.10 The activities allowable under the heading Information Expenses are set out at chapter 19 of the scheme. For clarification, the following criteria apply to the specific costs listed below:

7.10.1 *Samples or Identification Purposes:* The cost included should be for those samples provided specifically to enable prescribers to identify a particular product and should include the factory cost of the materials in final packed form, distribution, handling, postal charges and overhead and administration charges.

7.10.2 *Summaries of Product Characteristics:* This covers the cost against this category and should cover all expenses incurred in the production of data sheets including the direct labour and overhead and administration charges.

7.10.3 *Medical symposia:* This should include the cost of any support, including hospitality, given by the company for medical symposia. The ABPI Code of Practice Authority will be particularly concerned with the conduct of such symposia, which should not be the occasion for conspicuous extravagance. Where a symposium has been found to be in breach of the Prescription Medicines Code of Practice, no part of the costs may be included in schedule 1 of the AFR.

Expenditure not allowable

7.11 The following expenditure is not allowable as a charge in NHS prices and should not be included in schedule 1.

- samples (other than samples for identification purposes);
- gifts;
- hospitality (other than that provided for eligible medical symposia).

7.12 If significant items of expenditure cannot be dealt with in accordance with paragraphs 7.9 and 7.10 above, the items involved, the expenditure on each item and, the method adopted to deal with it should be stated in an accompanying note.

General & Administrative (G&A) costs

7.13 G&A expenses include the administrative costs of running a business including the salaries and employment costs of administrative staff, accommodation costs and the associated costs of general management.

Research & Development (R&D) costs

7.14 R&D covers the costs incurred by a company in carrying out R&D in its own facilities as well as R&D bought in, whether from affiliate companies or third parties. It includes.

- investigation, the object of which is to discover new therapeutic agents or processes in the manufacture of new agents or new methods of producing known agents;
- formulation, investigations and clinical trials directed towards the production of a medicine;
- costs of licensing, patent fees and registration fees for trademarks.
- salaries and associated costs of all staff engaged on R&D activities or supporting those activities by analytical, administrative and other services;
- all materials and expenses incurred by these staff in carrying out their duties and related accommodation costs.

One off costs

7.15 One off costs (line 19) by their very nature will not occur every year. This heading should be used for any large but infrequent costs that would distort other cost heads if they were included within them.

Recognition of UK Fixed Costs

7.16 The split of non R&D Fixed assets (line 36) should reflect the basic apportionment with no adjustment for the recognition of UK fixed costs. This should be shown separately at line 38, calculated as 7.5% of the export allocation of non-R&D fixed assets. As this is an adjustment to both home and export fixed assets, the amount in the home column should be shown as an additional asset and the same amount should be shown under exports as a negative asset.

PPRS: SCHEDULE 1

SALES, COSTS AND PROFIT

COMPANY:

AFR FOR YEAR ENDED:

	Line number	NHS Medicines Home	NHS Medicines Exports	Other products	Total	NHS Medicines Home costs claimed
		£000	£000	£000	£000	£000
SALES						
To affiliates	1					
To independent	2					
Total sales	3					
COSTS AND EXPENSES						
Finished goods bought in						
From affiliates	4					
From independents	5					
Total finished goods resold	6					
Own manufactured goods resold						
Materials purchased from affiliates	7					
Materials purchased from independents	8					
Manufacturing process costs	9					
Total MCOGS	10					
Total COGS	11					
Distribution costs	12					
Information expenses	13					
Marketing expenses	14					
General & administrative expenses	15					
Royalties payable – to affiliates	16					
Royalties payable – to Independents	17					
R & D expenses in accounts	18					
One–off costs and expenses	19					
Total costs and expenses	20					
TRADING PROFIT	21					
Supplementary items						
R & D expenses – injected – UK recharged	22					
R & D expenses – injected – overseas costs	23					
Other injected costs	24					
Other trading income less charges (–)	25					
Royalties received – affiliates (–)	26					
Royalties received – independents (–)	27					
UK fixed costs adjustment	28					
Other income (–)/costs (+)	29					
PROFIT BEFORE INTEREST AND TAX	30					

PPRS: SCHEDULE 1A
RECONCILIATION OF SCHEDULE 1 WITH AUDITED ACCOUNTS

COMPANY:

AFR FOR YEAR ENDED:

	Line number	Total per audited accounts	Re–allocations between cost headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total
		£000	£000	£000	£000	£000
SALES						
To affiliates	1					
To independents	2					
Total sales	3					
COSTS AND EXPENSES						
Finished goods bought in						
From affiliates	4					
From independents	5					
Total finished goods resold	6					
Own manufactured goods resold						
Materials purchased from affiliates	7					
Materials purchased from independents	8					
Manufacturing process costs	9					
Total MCOGS	10					
Total COGS	11					
Distribution costs	12					
Information expenses	13					
Marketing ex;penses	14					
General & administrative expenses	15					
Royalties payable – to affiliates	16					
Royalties payable – to independents	17					
R & D expenses in accounts	18					
One–off costs and expenses	19					
Total costs and expenses	20					
TRADING PROFIT	21					
Supplementary items						
R & D expenses – injected – UK recharged	22					
R & D expenses – injected – overseas costs	23					
Other injected costs	24					
Other trading income less charges (–)	25					
Royalties received – affiliates (–)	26					
Royalties received – independents (–)	27					
UK fixed costs adjustment	28					
Other income (–)/costs (+)	29					
PROFIT BEFORE INTEREST AND TAX	30					

PPRS: SCHEDULE 2
CAPITAL EMPLOYED

COMPANY:

AFR FOR YEAR ENDED:

	Line number	NHS Medicines Home	NHS Medicines Export	Other Products	Total
		£000	£000	£000	£000
FIXED ASSETS (at historic cost)					
Land & Buildings	31				
Plant & Machinery	32				
Other Fixed Assets	33				
Total Fixed Assets	34				
R & D Fixed Assets	35				
Non R & D Fixed Assets	36				
Total Fixed Assets (to agree with line 34)	37				
UK fixed costs adjustment	38				
WORKING CAPITAL					
Current Assets					
Cash and bank balances	39				
Debtors – affiliates	40				
Debtors – other	41				
Stocks	42				
Other Current Assets	43				
Total Current Assets	44				
Current Liabilities	45				
Net Working Capital	46				
INJECTED CAPITAL					
R & D Fixed Assets – UK	47				
R & D Fixed Assets – overseas	48				
Non R & D Fixed Assets	49				
Other Capital	50				
Total Injected Capital	51				
CAPITAL EMPLOYED	52				

PPRS: SCHEDULE 2A
RECONCILIATION OF SCHEDULE 2 WITH AUDITED ACCOUNTS

COMPANY:

AFR FOR YEAR ENDED:

	Line number	Total per audited accounts	Re–allocations between cost headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total
		£000	£000	£000	£000	£000
FIXED ASSETS (at historic cost)						
Land & Buildings	31					
Plant & Machinery	32					
Other Fixed Assets	33					
Total Fixed Assets	34					
R & D Fixed Assets	35					
Non R & D Fixed Assets	36					
Total Fixed Assets	37					
UK fixed costs adjustment	38					
WORKING CAPITAL						
Current Assets						
Cash and bank balances	39					
Debtors – affiliates	40					
Debtors – other	41					
Stocks	42					
Other Current Assets	43					
Total Current Assets	44					
Current Liabilities	45					
Net Working Capital	46					
INJECTED CAPITAL						
R & D Fixed Assets – UK	47					
R & D Fixed Assets – overseas	48					
Non R & D Fixed Assets	49					
Other Capital	50					
Total Injected Capital	51					
CAPITAL EMPLOYED	52					

PPRS: SCHEDULE 1

SALES, COSTS AND PROFIT

COMPANY:

ESTIMATE/FORECAST FOR YEAR ENDED:

	Line number	NHS Medicines Home	NHS Medicines Exports	Total	NHS Medicines Home costs claimed
		£000	£000	£000	£000
SALES					
To affiliates	1				
To independents	2				
Total sales	3				
COSTS AND EXPENSES					
Finished goods bought in					
From affiliates	4				
From independents	5				
Total finished goods resold	6				
Own manufactured goods resold					
Materials purchased from affiliates	7				
Materials purchased from independents	8				
Manufacturing process costs	9				
Total MCOGS	10				
Total COGS	11				
Distribution costs	12				
Information expenses	13				
Marketing expenses	14				
General & administrative expenses	15				
Royalties payable – to affiliates	16				
Royalties payable – to independents	17				
R & D expenses in accounts	18				
One–off costs and expenses	19				
Total costs and expenses	20				
TRADING PROFIT	21				
Supplementary items					
R & D expenses – injected – UK recharged	22				
R & D expenses – injected – overseas costs	23				
Other injected costs	24				
Other trading income less charges (–)	25				
Royalties received – affiliates (–)	26				
Royalties received – independents (–)	27				
UK fixed costs adjustment	28				
Other income (–)/costs (+)	29				
PROFIT BEFORE INTEREST AND TAX	30				

PPRS: SCHEDULE 2
CAPITAL EMPLOYED

COMPANY:

ESTIMATE/FORECAST FOR YEAR ENDED:

	Line number	Start of year			End of year		
		NHS Medicines Home	NHS Medicines Export	Total	NHS Medicines Home	NHS Medicines Export	Total
		£000	£000	£000	£000	£000	£000
FIXED ASSETS (at historic cost)							
Land & Buildings	31						
Plant & Machinery	32						
Other Fixed Assets	33						
Total Fixed Assets	34						
R & D Fixed Assets	35						
Non R & D Fixed Assets	36						
Total Fixed Assets	37						
UK fixed costs adjustment	38						
WORKING CAPITAL							
Current Assets							
Cash and bank balances	39						
Debtors – affiliates	40						
Debtors – other	41						
Stocks	42						
Other Current Assets	43						
Total Current Assets	44						
Current Liabilities	45						
Net Working Capital	46						
INJECTED CAPITAL							
R & D Fixed Assets – UK	47						
R & D Fixed Assets – overseas	48						
Non R & D Fixed Assets	49						
Other Capital	50						
Total Injected Capital	51						
CAPITAL EMPLOYED	52						

CERTIFICATE 1

Annual Financial Return for the year ended ----------

Company ----------

Signed ----------
(Managing Director/Chief Executive)

Date ----------

Affiliated Companies consolidated in this Return:

1 ----------

2 ----------

3 ----------

4 ----------

5 ----------

AUDITORS' REPORT

I/We have examined the annexed schedules 1 and 2, which *I/we* have initialled for the purpose of identification, together with the accompanying notes and reconciliations. *I/We* have obtained such explanations and carried out such tests as *I/we* have considered necessary.

On the basis of *my/our* examination and of the explanations given to *me/us, I/we* report that, in *my/our* opinion and subject to the reservations mentioned below.

i. the figures set out in the Schedules are based on audited accounts and have been compiled on the basis required for the purpose of the Pharmaceutical Price Regulation Scheme dated November 2004, agreed between the Health Departments of the United Kingdom and the Association of the British Pharmaceutical Industry;

ii. the methods of apportionment, which have been used in preparing the figures relating to NHS medicines are fair and reasonable in the context of the PPRS. The figures in the schedules fairly reflect, on the bases of apportionment defined, the income, costs and profits relating to home sales of NHS medicines/total sales of NHS medicines for the financial year and the capital employed in relation to NHS home medicines at the close of the financial year;

I/We have seen acceptable evidence to support the inclusion in the schedules of items dealt with in the accounts of affiliated companies.
(Delete italics as appropriate)

Signature ---------- **Date** ----------

Name ----------

Address ----------

Professional Qualification ----------

CERTIFICATE 2

ANNUAL FINANCIAL RETURN

For the year ended ----------

Company: ----------

AUDITORS' SUPPLEMENTARY REPORT COVERING INJECTED COSTS AND/OR CAPITAL

On the basis of *my/our* examination and of the explanations given to *me/us*, there is, in *my/our* opinion and subject to the reservations mentioned below, a reasonable level of assurance that:

(i) fair and reasonable methods of apportionment, the details of which are given on the attached schedule, have been employed in calculating the amounts of injected costs and/or capital attributed to NHS medicines;

(ii) injected costs have not been specifically included in the transfer price paid for goods or services received;

(iii) injected costs exclude profit where the associated capital has also been injected into AFR schedule 2.

(Delete italics as appropriate)

Signature ---------- **Date** ----------

Name ----------

Address ----------

Professional Qualification ----------

Note: Where an overseas operation is audited by a company, which is not responsible for certifying the AFR, this certificate, or part of it, will be accepted from the overseas auditor.

CERTIFICATE 3

ANNUAL FINANCIAL RETURN

For the year ended ----------

Company: ----------

INDEPENDENT ACCOUNTANTS' SUPPLEMENTARY REPORT: TRANSFER PRICE

A. COMPANIES SUBMITTING A TRANSFER PRICE BREAKDOWN

On the basis of our examination and of the explanations given to us, there is, in our opinion *and subject to the reservations mentioned below*, a reasonable level of assurance that the following average transfer price breakdown applies to the company's purchases of Finished Goods and Raw Materials from affiliated companies:

	% of Transfer Price
Manufacturing	
Distribution	
Information	
Sales Promotion	
Administration	
Research & Development	
Transfer Price profits	
Total	

B. ARMS LENGTH TRANSFER PRICES

Transfer prices in the annual financial return are as included in the company's corporation tax return *except as set out overleaf* and are set on the following basis:

Basis adopted:

Signature ---------- **Date** ----------

Name ----------

Address ----------

Professional Qualification ----------

(Delete italics as appropriate)

Note: Where an overseas operation is audited by a company, which is not responsible for certifying the AFR, this certificate, or part of it, will be accepted from the overseas auditor.

Annex C

Checklist of items to be submitted for a full AFR

Accounts

- ☐ Published accounts of UK company supplying medicines to NHS.
- ☐ Published accounts of UK holding company (if applicable).
- ☐ Published accounts of ultimate holding company.

Audit

- ☐ AFR signed on behalf of company and including a list of companies, branches and divisions included in the AFR.
- ☐ Certificate 1 (including independent accountant's report).
- ☐ Certificate 2 (covering injected costs and/or capital).
- ☐ Certificate 3 (independent accountant's supplementary report: transfer price)

Schedules and Supporting Information

- ☐ AFR schedules 1, 1A, 2 and 2A. Companies assessed as return on sales may omit schedules 2 and 2A.
- ☐ Details of reallocations between cost headings (schedules 1A and 2A).
- ☐ Details of items in the accounts excluded from the AFR.
- ☐ Details of items injected into the AFR.
- ☐ Details of apportionments for all cost and capital headings either directly allocated or apportioned to NHS home medicines with explanations of the apportionments.
- ☐ AFR Home Sales/Net Modulation Sales reconciliation.

Product Information

- ☐ List of *all* products included in NHS home medicines separately identifying those with sales over £300,000 and £100,000 (after discounts and rebates) for which PSA is claimed and also indicating whether they are considered to be eligible for a variable rate (innovation) R&D allowance.
- ☐ Date of expiry of the active substance patent for each product and any SPC, or where no patent exists, the date of grant of the first marketing authorisation for that new active substance.
- ☐ List of products with relevant details for which variable rate R&D paediatric allowances are claimed.

Annex D

2005 PPRS: Schedule of Rates and Allowances

ROCE	Target	21%
ROS	Target	6%
MOT	Upper limit	140%
	Lower limit	40%

			Level 1	**Level 2**
Marketing Allowance	Fixed element		£500,000	£1,000,000
	Standard element		2%	4%
	Product Servicing Allowances	For each active substance with sales to the NHS of £100,000 or more	• £58,000 for each of the first three eligible products • £46,000 for each of the next three • £35,000 for each of the next three • £23,000 each for all others	
Information Allowance	Standard element		2%	4%
Research and Development Allowance	Flat rate		15%	20%
	Variable Rate[1]	Innovation[2]	20 active substances (NHS sales of £300,000 or more) at 0.25% each	20 active substances (NHS sales of £300,000 or more) at 0.25% each
		Paediatrics		1.0% per product (up to 3%) in any one year.
	Maximum Total		20%	28%

Default Transfer Pricing	Manufacturing	59%
	R&D	21%
	Profit	20%
	Allowed TP Profit	25% of accepted costs
	Total Manufacturing Costs	45%

[1] Definition of 'in patent' to include 10 years from date of marketing authorisation for new active substances where no patent exists

[2] or New Entrant Flexibility (for 1st 3 years in the AFR):
- 2.0% of NHS Home sales for active substance 1
- 1.0% for active substance 2
- 0.25% for each active substance thereafter

= 5% max

Annex E

Modulation information required by February 2006

Products with NHS prices unchanged during 2005

A Product Description including form, strength and pack size	B NHS Price (31/12/2004)	C New NHS price	D Quantity Sold (total number of packs or units of each presentation specified at A)	F OTC as % of NHS Sales	G Date of Patent Expiry or SPC
			1/1/2005 to 31/12/2005		
e.g. ABCDE Tabs 100mg x 56	£100.00	£93.00	2000	0%	31/12/07

Products with NHS prices changed during 2005

A Product Description including form, strength and pack size	B NHS Price (31/12/2004)	C New NHS price	C? Price effective during:	D Quantity Sold	F OTC as % of NHS Sales	G Date of Patent Expiry or SPC
e.g. WXYZ Tabs 100mg x 56	£100	£96	1/1/2005 to 31/12/2005	1000	0%	31/12/07
e.g. WXYZ Tabs 100mg x 56	£100	£93	1/6/2005 to 31/12/2005	1000	0%	31/12/07

(Please use additional pages if required)

Total net sales revenue (actual) of modulated products 1 January 2005 to 31 December 2005	£000s

Total net sales revenue (actual) of unmodulated products 1 January 2005 to 31 December 2005	£000s

Notes:
1. To include all modulated products that were on sale at 1 January 2005
2. Total net sales are the aggregate figures for those products where prices have been modulated and those where prices have not been modulated
3. Enter the date of expiry of the SPC in Column G. However, if no SPC has been granted then this is the Product patent expiry date. Indicate if an SPC has been applied for but not yet granted.
4. Information should be returned to Mr Richard Hambrook, PPRS Branch, Department of Health by 28 February 2006 (e-mail: richard.hambrook@dh.gsi.gov.uk).
5. This form is available for downloading as an Excel or Lotus 123 file on the Department's website www.doh.gov.uk/pprs.

Annex F

Auditor's Supplementary Report Covering Price Cut/Modulation

Company: ----------

Year ended: ----------

We have examined the attached schedules (which we have initialled for the purpose of identification) that set out the information relating to modulation for the period ---------- *[insert dates]* as required under the Pharmaceutical Price Regulation Scheme 2005.

In our opinion [and subject to the reservations mentioned below] we have concluded that:

(i) the information contained in the schedules has been properly extracted from the records of the company;

(ii) in compiling the schedules the company has complied with the requirements of the scheme as set out in paragraphs 21.13 and chapter 26.

Signature ---------- **Date** ----------

Name ----------

Address ----------

Professional Qualification ----------

ANNEX G

Powers of the Secretary of State Deriving from the Health Act 1999

A summary of the provisions contained in sections 33 to 38.

1 Section 33 enables the Secretary of State, after making a scheme with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. This scheme (with additions or modifications agreed in individual cases) would apply only to those companies who consent (subsection (2)). Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the scheme is no longer to apply to him. This can be done where the acts or omissions of the manufacturer or supplier have shown the scheme is ineffective in his case. Subsection (7) read with section 38 gives the Secretary of State power by regulations or direction to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State.

2 Section 33(8) read with section 38 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State's approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.

3 In addition to powers to secure compliance with a voluntary scheme, the Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme.

4 Section 34 read with section 38 provides for the Secretary of State, after consultation with the industry body, by regulations or direction, to limit any price which may be charged by any manufacturer or supplier and for payment of the excess to the Secretary of State within a specified period. This power is only exercisable in relation to companies who are not "scheme members" as defined in section 33(4). This section replaces section 57 of the NHS Act 1977 with respect to controlling the maximum price of health service medicines. Section 38(5) therefore provides that section 57 shall cease to have effect in relation to health service medicines but this does not affect any other powers of the Secretary of State to control profits or prices.

5 Section 35 read with section 38 enables the Secretary of State, after consultation with the industry body, by regulations or direction to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Section 35(3) provides that such a scheme may in particular require any manufacturer or supplier to whom it applies to record and keep information and provide information to the Secretary of State. Section 35(5) provides for payment to the Secretary of State of profits in excess of the limits determined under the scheme. Section 35(6) enables the Secretary of State to prohibit any manufacturer to whom the scheme applies from increasing prices without his approval and to require a sum representing the amount of that excess to be paid to him. Section 35(7) excludes "scheme members" from any statutory scheme.

6 Section 36 read with section 38 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.

7 Section 37 provides for enforcement. Section 37(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of regulations or directions made under sections 33 to 36. Section 37(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 37(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50%. Section 37(4) enables the Secretary of State to provide for interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.

8 Section 37(5) enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 37(7) defines the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.

9 Section 37(8) provides that any requirement, prohibition or limit under sections 33 to 35 may only be enforced under this section and not relied on in any other proceedings. Section 37(9) requires the Secretary of State to consult the industry body before making regulations under section 37. Section 37(10) provides for the maxima set out in section 37(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 62(8).

10 Section 38 deals with supplementary matters. In particular section 38(1) provides how the powers in sections 33(6) to (8) and 34 to 36 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions, and that regulations may give power to give directions in such particular cases. Section 38 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. The Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of R&D.

11 The provisions in sections 33 to 38 enable the Secretary of State to make regulations in respect of England, Scotland, Wales and Northern Ireland. The operation of a PPRS in respect of Northern Ireland is a transferred matter under the Northern Ireland Act 1998. In practice, therefore, the Secretary of State will only make regulations which extend to Northern Ireland with the consent of the Northern Ireland Assembly.

Annex H

Arbitration

1 Introduction

1.1 This annex is a broad outline of the functions of the 2005 PPRS Arbitration Panel ('the Panel') and describes its work in practice.

2 The law

2.1 The Health Act 1999 ('the Act') provides for voluntary schemes, which may:

- limit the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines; or
- limit the profits, which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines.

2.2 The Act also provides for statutory price and profit controls. These powers can only apply to companies who are not members of a voluntary scheme. The 2005 PPRS is such a voluntary scheme.

2.3 Membership of the 2005 PPRS is established when a company has consented to be a member of the scheme[1] and the Secretary of State has notified that company that it is a member.

1 In accordance with the Health Service (Consent to Voluntary Scheme) Regulations 1999, SI 1999/2229.

2.4 Under the statutory price controls[2] presently in force, there is a right of appeal to the NHS Medicines (Control Of Prices And Profits) Appeal Tribunal[3] against *enforcement decisions*[4] made by the Secretary of State.

2.5 Under the 2005 PPRS, the Panel will be the body to which a company might go if it wishes to dispute views taken by the Department of Health in respect of its prices or profits. There is no recourse to the NHS Medicines (Control Of Prices And Profits) Appeal Tribunal except in the case where there is in existence statutory provision for the imposition of penalties for late delivery of information and an enforcement decision is made under that provision.

2.6 Companies who are not scheme members of the 2005 PPRS do not have access to the Panel, save for the sole exception described in paragraph 6.2.6.

2.7 There is, therefore, a fundamental distinction to be made between an enforcement decision made by the Secretary of State in accordance with statute and a view taken by the Department of Health after negotiation within the 2005 PPRS[5]. In the first case, there is a right of appeal to the NHS Medicines (Control Of Prices And Profits) Appeal Tribunal. In the second case, there is a right of arbitration by the Panel.

3 2005 PPRS Provisions

3.1 Chapter 30 of the 2005 PPRS deals with arbitration. That chapter is reproduced here for ease of reference:

30.1 The Department, the ABPI and individual scheme members undertake to operate this agreement so that issues arising between the company and the Department are normally resolved by discussion between the scheme members and the Department. Nevertheless significant issues between the members and the Department may arise that cannot be resolved in this way. These issues may be referred to the arbitration procedure set out below by either party.

30.2 Where a scheme member of the Department decides to go to arbitration it must give written notice to the other party of its intention within 21 days of an event. Example of "events" in this context would be refusal by the Department to agree a price increase under the scheme or the failure of both parties to reach agreement on the extent, if any, to which excess profits are repayable to the Secretary of State. Both parties to the dispute must provide the arbitration panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of arbitration. Statements will be made available to both parties. They may be supplemented in response to questions arising during the arbitration procedure.

30.3 The arbitration panel will give each party to the disagreement the opportunity to put forward its case on the issue(s) that is (are) in dispute at an oral hearing. The panel will be expected to hold the hearing within 30 days of the receipt of the written statements from both parties. Both parties are free to decide their representation at the oral hearing.

30.4 Prior to, or at the hearing, the panel may request supplementary written information from either party to the dispute where it considers this necessary to properly understand the issues. The parties will be required to provide this information with 15 days of the request. All information provided to the arbitrators and the arbitrators' reasoned opinion and decision will be available to all parties. The Panel will be expected

2 Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000, SI 2000/123.
3 Health Service Medicines (Price Control Appeals) Regulations 2000, SI 2000/124
4 As defined in Section 37(7) of the Act
5 An event within the meaning of chapter 30.2 of the 2005 PPRS

to make its decision known to both parties within 30 days of the oral hearing or within 45 days where it has been necessary to obtain additional written information from either party. The decision will not be relied upon in the future operation of the scheme.

30.5 The arbitration panel will comprise:

30.5.1 a Chairman appointed by the Secretary of State with the agreement of the ABPI;

30.5.2 two members, one appointed by the Secretary of State and the other by the ABPI.

30.6 The Secretariat to the panel will be provided jointly by the Department and the ABPI.

30.7 The costs of the arbitration panel will be shared equally by the Department and the ABPI. The parties to each dispute will be responsible for paying their own costs.

30.8 The confidentiality of commercially sensitive information will be assured.

4 Tribunal Membership

4.1 The arbitration panel will comprise:

23.5.1 a Chairman appointed by the Secretary of State with the agreement of the ABPI;

23.5.2 two members, one appointed by the Secretary of State and the other by the ABPI.

4.2 The Panel may sit either as:

4.2.1 the chairman and both members; or

4.2.2 with the express permission of both members, the chairman alone.

5 Secretariat

5.1 Chapter 30 of the 2005 PPRS provides that the secretariat shall be provided jointly by the Department and the ABPI.

5.2 Communications to the secretariat shall be addressed to:

The Secretariat
Department of Health
Room 611
Eileen House
80-94 Newington Causeway
London SE1 6EF
Tel: 020 7972 2983
Fax: 020 7972 2932

and to:

The Secretary to the Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY
Tel: 020 7930 3477
Fax: 020 7747 1414

The cost of the secretariat shall be born jointly and equally by the Department and the ABPI.

5.3 It shall be the duty of the secretariat to ensure that communications from one party to an arbitration shall be made available to the other party and to all members of the Panel.

5.4 Similarly, it shall be the duty of the secretariat to make available to parties to an arbitration communications from the Panel.

5.5 The duties described in paragraphs 5.3 and 5.4 shall be discharged as soon as possible after receipt of a communication and, in any event, not later than two working days from receipt.

6 Events Giving Rise to Arbitration

6.1 Within the terms of chapter 30 of the 2005 PPRS, both the Department and scheme members have the right to arbitration.

6.2 The following is a list of events, which might give rise to a scheme member seeking arbitration by the Panel. The list is not necessarily comprehensive. In each case, it will be for the scheme member to comply with the Department's view or to seek arbitration.

6.2.1 Payment of excess profit to the Secretary of State. A scheme member might disagree that there is any requirement to pay to the Secretary of State sums representing excess profit or the amount of the sum to be paid.

6.2.2 Refusal to allow a general price increase or limitation to such an increase.

6.2.3 Refusal to allow a price modulation within the meaning of chapter 26 of the 2005 PPRS.

6.2.4 Failure to agree allowed prices of products sold on from one company to another.

6.2.5 A request to provide information required by the Department in connection with the operation of the 2005 PPRS.

6.2.6 Notice given by the Secretary of State (other than under 10.2.3 below) that a company's membership of the scheme is to cease as a result of the Secretary of State concluding that the membership is ineffective in that member's case. At such an arbitration, the ostensible matter will be scheme membership, but the substantive matter will be the event giving rise to the decision that the company is no longer a scheme member

6.3 A company, which has been refused scheme membership of the 2005 PPRS, shall not have any right of arbitration under 6.2.6.

7 Arbitration Timetable

7.1 The Department shall give written notice of any view falling within the ambit of paragraphs 6.2.1, 6.2.2, 6.2.3, 6.2.4 and 6.2.5 to the scheme member.

7.2 The scheme member shall have 28 days from and including the date of that written notice in which to give notice that it wishes to seek arbitration by the Panel. For administrative ease this should be sent to the secretariat (see paragraph 5.2).

7.3 Within 28 days of such notice given under paragraph 7.2, reasoned statements of position by the Department and the scheme member must be submitted to the secretariat.

7.4 Insofar as possible a hearing by the Panel shall be arranged within 30 days of the receipt of the later statement of reasons.

7.5 Information requested by the Panel before or at the hearing shall be supplied to the secretariat by the relevant party within 15 days of the request.

7.6 Insofar as possible, the Panel shall make known it decision to the parties within 30 days of either the date of the hearing or of receipt of information whichever is the later.

7.7 At any time until the Panel's decision, either party shall have the right to withdraw from the arbitration and thereby concede the point or points at issue.

7.8 The parties should comply with the effective date given by the Panel in its decision.

8 Conduct of Hearings

8.1 Hearings will be informal and shall not be bound by strict rules of evidence or legal procedure.

8.2 Hearings will be held in camera to protect matters of commercial confidentiality. The notes of proceedings kept by the secretariat shall be made available only to:

- the Panel,
- the scheme member;
- the Department.

8.3 Information submitted pursuant to the hearing shall be restricted as in paragraph 8.2.

8.4 It is open to each party to the arbitration to be represented as that party sees fit and to call such witnesses as it sees fit.

8.5 The conduct of the hearing will be for the Panel Chairman to decide in matters such as order of business, questions, evidence and so on.

8.6 Each party shall be responsible for its own costs.

9 Powers of the Panel

9.1 The panel may request any information from either party, which it considers necessary to determine any point of fact.

9.2 The Panel may call any expert witness whom it considers necessary to determine any point of fact.

9.3 The Panel may not, without the express consent of both parties, extend any of the time limits given in paragraphs 7.2 to 7.8.

9.4 The Panel shall either refer a matter to the Department for reconsideration under direction or substitute its own decision in respect of that matter.

9.5 The Panel may decide an effective date for any substituted decision as follows in respect of:

9.5.1 payment of excess profits, the original date;

9.5.2 refusal of a general price increase, any date on or after the date of the Panel's decision;

9.5.3 referral of a price modulation, any date on or after the Panel's decision;

9.5.4 allowed price of products sold, any date on or after the Panel's decision;

9.5.5 information required by the Department, the original date, where the original date is the date of the notice specified in paragraph 7.1.

10 After Arbitration

10.1 The Department and scheme members are expected to abide by the Panel's decisions.

10.2 The voluntary nature of the 2005 PPRS means that a company has, in practice, three options:

10.2.1 follow the Panel's decision;

10.2.2 withdraw from membership of the 2005 PPRS; or

10.2.3 ignore the Panel's decision. In such circumstances, the Secretary of State will conclude that the scheme is no longer effective in the particular member's case and he will therefore remove the member from scheme membership.

10.3 In cases 10.2.2 and 10.2.3 the company will no longer be a scheme member of the 2005 PPRS and shall thenceforth be subject to any statutory controls in place pursuant to sections 34 to 38 of the Act.

11 Conclusion

11.2 Questions concerning this annex should be directed to the secretariat (see para 5.2 above).

265758 1p 1k Dec 04 (CWP)

First published: November 2004

Copies available from:

Department of Health
Pricing and Supply
Room 626
Eileen House
80-94 Newington Causeway
London SE1 6EP
Telephone: 020 7972 2827
Fax: 020 7972 2932
or email Jamila.Rogers-Wright@dh.gsi.gov.uk

08700 102 870 – Textphone (for minicom users) for the hard of hearing
8am-6pm Monday to Friday

265758/*Pharmaceutical Price Regulation Scheme* can also be made available on request in braille, on audio cassette tape, on disk and in large print.

The Pharmaceutical Price Regulation Scheme is available on the department's website at www.dh.gov.uk/pprs