

# **THE PHARMACEUTICAL PRICE REGULATION SCHEME**

**JULY 1999**



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The text of this scheme and copies of the Schedules are available at:  
[www.doh.gov.uk/pprs.htm](http://www.doh.gov.uk/pprs.htm)

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## **INTRODUCTION AND OBJECTIVES**

The Health Departments 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. PURPOSES**

- 1.1 The 1999-2004 Pharmaceutical Price Regulation Scheme (PPRS) is an agreement for the purposes of Section 33 of the Health Act 1999. The objectives for 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 ABPI will support these policies, in the first instance, by collecting and sharing information about the industry’s competitiveness. 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. The Department and the ABPI are agreed that an assessment of the scope, pace of change and practical impact of competition in the supply and use of medicines for the NHS will contribute to an evaluation of progress against objectives.
- 2.4 Both parties agree that the performance of the PPRS cannot be assessed in isolation from the NHS environment with which it interacts.
- 2.5 Those factors, which influence the dynamics of medicine supply and use in the NHS, need to be analysed further. Both parties agree that the results of the analyses will be systematically evaluated and formally reported on from time to time in the Reports to Parliament and will inform the PPRS mid-term review. The potential for further deregulation of profit and price controls through the PPRS will be assessed at that time. The details of these arrangements will be agreed between the Department and the ABPI by January 2000.
- 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.

### **3 EFFECTIVE DATE OF THE SCHEME AND DURATION**

- 3.1 This scheme will operate for not less than five years from 1 October 1999, 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 April 2002.

### **4. MID-TERM REVIEW – DATE AND TERMS**

- 4.1. In the event of major changes affecting the supply of medicines to the NHS, either party may request an interim review after not less than 2½ years. Following such a review the terms of the scheme may be varied with the agreement of the ABPI and Secretary of State.
- 4.2 If the terms of this agreement 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 agreement as set out in Chapter 24.

## **5. APPLICATION OF THE SCHEME**

- 5.1 The scheme applies to manufacturers and suppliers (scheme members) as defined in the Health Act 1999 who have consented, in the manner required by the Secretary of State, as applying to them. 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 would also not apply if the scheme had been wound up following consultation between the parties as set out in Chapter 4.
- 5.2. The scheme sets out rules to determine the maximum prices which may be charged by any scheme member in respect of health service medicines, and the maximum profits to be made from the sale of medicines covered by the scheme.

## **6. ENTRY MECHANISM**

- 6.1 The scheme may apply to all manufacturers and suppliers of branded licensed NHS medicines that are prescribed by medical or dental practitioners, nurses or others qualified to prescribe. Companies which supply NHS medicines and do not elect to be scheme members, or cease to be scheme members under the procedure set out in Chapter 24, are liable to be treated under the arrangements relating to the control of the prices of medicines and profits set out in sections 34 to 38 of the Health Act 1999, referred to as the statutory scheme. Those sections do not apply to scheme members.
- 6.2 Those companies which elect to be scheme members shall signify their membership with the Certificate of Consent for Voluntary Scheme to be treated as applying as shown in Annex A.

### **Supply of medicines**

- 6.3 The scheme is intended to apply 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 market authorisation holder.

### **Non-ABPI members**

- 6.4 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**

- 6.5 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.

## **Obligations of companies**

- 6.6 Scheme members will supply the information set out in Chapter 8 subject to the following exceptions:
- 6.6.1 any scheme member with total home sales of NHS medicines not exceeding £1 million a 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;
- 6.6.2 any scheme member with total home sales of NHS medicines of more than £1 million and less than £25 million a year will be required to provide a copy of its audited accounts and a certificate signed by its managing director or chief executive, analysing its turnover for the year as between home sales of NHS medicines, export sales of NHS medicines and sales of other products. 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 21.

## **7. PRODUCTS COVERED**

- 7.1 The scheme applies to all branded, licensed NHS medicines.
- 7.2 For this purpose the term “NHS medicine” refers to any human pharmaceutical product for which marketing authorisation has been awarded 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 (INN) names, 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).
- 7.3 The scheme will apply to all packs (and dosage forms) of a NHS medicine except:
- 7.3.1 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);

- 7.3.2 sales of medicines which a company shows to be derived predominantly from private prescriptions.
- 7.4 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.
- 7.5 To avoid uncertainty, it is emphasised that the following products, provided they satisfy the criteria set out above, are covered by the scheme:
  - 7.5.1 branded generics (i.e. products which are copies of an out-of-patient product, but bear a brand name and therefore come within the overall definition at paragraph 7.2);
  - 7.5.2 vaccines;
  - 7.5.3 in-vivo diagnostics with a brand name and product licence;
  - 7.5.4 blood products that are licensed under the Medicines Act or Council Regulation No. (EEC) 2309/93;
  - 7.5.5 dialysis fluids;
  - 7.5.6 branded products supplied through tendering processes and on central or local contracts.
- 7.6 Products that are black-listed by brand name from NHS prescription and can only be prescribed on the NHS generically are excluded. In-vitro diagnostics are also excluded.

## **8. INFORMATION TO BE PROVIDED - ANNUAL FINANCIAL RETURN**

- 8.1 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.
- 8.2 AFRs, together with supporting information (see specimen in Annex B), will be completed annually and submitted to the Department as follows:
  - 8.2.1 scheme members with a UK registered name beginning with the letters A to K: within 6 months of the end of their financial year;

- 8.2.2 scheme members beginning with the letters L to P: within 9 months of the end of their financial year;
- 8.2.3 scheme members beginning with letters Q to Z: within 11 months of the end of their financial year.
- 8.3. Where a scheme member can demonstrate that for reasons beyond its control it cannot meet the time limits set out in paragraph 8.2, 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.
- 8.4 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.
- 8.5 The Department will acknowledge receipt within fourteen days of receiving an AFR and will advise companies in writing within 8 weeks of receipt if it also wishes to make further enquiries into the information submitted. The Department may require that any supplementary information requested should be independently audited when appropriate.
- 8.6 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.
- 8.7 Forecast financial returns will be completed annually and submitted to the Department within the first three months 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 is provided in Annex B.
- 8.8 If the prices of products have been modulated, there are additional information requirements which are set out in Chapter 21 and Annex D.
- 8.9 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 £500,000 or more and £100,000 or more in the AFR. For each product they should indicate the date of expiry of the active substance patent and any supplementary protection certificate. This will be used for:
- 8.9.1 confirming that the correct categories of product have been included and ensuring consistency between companies (see Chapter 7);

- 8.9.2 calculating allowable expenditure under the R&D formula (see Chapter 14);
- 8.9.3 calculating allowable expenditure under the sales promotion formula (see Chapter 16).

### **Small companies**

- 8.10 Any manufacturer or supplier relieved of the commitment to supply full financial information as in Chapter 6 will remain subject to the need to contain costs and the price restraint provisions (see Chapter 19). The Department reserves the right to call for a full AFR or forecasts or both at any time if circumstances warrant it.

### **Submission of AFRs in transition between 1993 scheme and this agreement**

- 8.11 Scheme members will be expected to submit AFRs without interruption over the transition between the 1993 PPRS and this agreement. Where a company's financial year covers both schemes (e.g. for a financial year ending 31 December 1999) costs, capital and sales will all be apportioned on a time basis. Months 1 to 9 will be dealt with under the rules for the 1993 agreement and months 10 to 12 under those of this agreement.

## **9. ALLOCATION OF COSTS AND CAPITAL**

- 9.1 The Department expects manufacturers and suppliers to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads.
- 9.2 Claimed costs and capital employed will be those normally included in the company's UK audited accounts. Any scheme member must be able to demonstrate that costs or capital included in its AFR are relevant to the supply of NHS medicines in accordance with this scheme. Overhead costs and shared assets utilised in both NHS home medicines and other business 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.
- 9.3 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 included in companies' AFRs are properly incurred in accordance with the scheme and they are reasonable in the light of accepted commercial practice. All other costs and capital not directly associated with the manufacture and supply of NHS medicines will not be allowed.

- 9.4 In its examination of the reasonableness of a company's costs and assets the Department will have regard to the following factors:
- 9.4.1 the trends in the data reported by the company over a number of years, including those for exports and other products;
  - 9.4.2 any special features of the company's operation;
  - 9.4.3 ratios inferred from the AFR for the company's non-PPRS business;
  - 9.4.4 each company's reported figures and the average of other similar scheme members;
  - 9.4.5 data from external sources that relate to the pharmaceutical industry across companies.
- 9.5 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 9.4. The Department will discuss the basis of any limitations with the company and will advise the company of its final AFR assessment.

## **10. LEVELS OF RETURN ON CAPITAL TARGET AND ALLOWANCES**

- 10.1 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 of the R&D of new medicines, and a commitment to a minimum of interference with companies' freedom to succeed in that activity.
- 10.2 There will be two levels of return on capital (ROC) targets and allowances:
- 10.2.1 level 1 will be used to decide price increase applications under the terms for such applications set out in Chapter 19;
  - 10.2.2 level 2 will be used to analyse scheme members' AFRs.
- 10.3 The ROC target and allowances for level 1 and level 2 are set out in paragraph 11.1.

## **11. RETURN ON CAPITAL**

- 11.1 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 17% per annum for level 1 and 21% per annum for level 2.
- 11.2 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.

## **12. MARGIN OF TOLERANCE**

- 12.1 The allowable returns referred to in paragraphs 11.1 and 11.2 will be associated with a margin of tolerance (MOT). Scheme members will be able to retain profits of up to 140% of the level 2 ROC target calculated by reference to level 2 allowances. Companies will not be granted price increases unless they are forecasting profits less than 50% of their level 1 ROC target calculated by reference to the level 1 allowances. Procedures for price increases are set out in Chapter 19.
- 12.2 The MOT will not be available to a scheme member for any year in which it has had a price increase agreed by the Department. Where a scheme member exceeds its level 1 target profit for a year in which it has received a price increase, all profits above the level 1 target will be repayable. Where a price increase is agreed by the Department in the second half of a year the Department may decide that the MOT will not be available to a scheme member for the year following the increase.
- 12.3 If the Department's assessment of an AFR shows profits in excess of the MOT, it will negotiate one or more of the following:
- 12.3.1 price reductions, during the accounting year following that covered by the return, to bring prospective profits down to an acceptable level, on the basis of available forecasts;
  - 12.3.2 repayments of that amount of past profits which are agreed to exceed the MOT;
  - 12.3.3 a delay or restriction of price increases agreed for the company or both.
- 12.4 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.

### **13. COMPANIES WITH LOW CAPITAL BASES**

- 13.1 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. This will enable some companies that have been assessed as return on sales (ROS) companies under the 1993 scheme to be assessed as ROC companies under this agreement.
- 13.2 Alternatively 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, a target rate of profit will be set by dividing the ROC target rate by a factor of 3.5. The assessment of the returns of scheme members that elect for the ROS option will take account of the MOT on transfer price profit.

### **14. RESEARCH AND DEVELOPMENT**

- 14.1 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. The allowance comprises two elements:
- 14.1.1 Flat rate:
- level 1: up to 17% of the value of NHS sales;
- level 2: up to 20% of the value of NHS sales.
- 14.1.2 Variable rate:
- an additional 0.25% of NHS home sales for each in-patent molecule above a threshold of £0.5 million of NHS home sales per annum up to a limit of 12 molecules. This is available on top of the level 1 and level 2 allowances.
- 14.2 These limits are allowable only where the scheme member can demonstrate within the AFR that the amount claimed relates to expenditure actually incurred.

## **15. UK FIXED COSTS**

- 15.1 When a company produces medicines for the NHS 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 would not take full account of the cost and asset base required in the UK to supply branded medicines to the NHS. To correct this distortion, companies will be allowed to apportion to the NHS 7.5% of their total net UK based NHS medicines fixed assets (excluding R&D assets and injected capital) and UK based manufacturing process costs, before an apportionment is made between the company's home and export business for the purpose of the scheme. The apportionment will be the same for levels 1 and 2.

## **16. SALES PROMOTION**

- 16.1 The sales promotion allowance will be calculated for each company on the following basis:
- 16.1.1 standard elements of 3% of home sales of NHS medicines for level 1 and 6% of same for level 2;
  - 16.1.2 a fixed element for levels 1 and 2 of £464,000;
  - 16.1.3 product servicing allowances 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.
- 16.2 Activities qualifying for the sales promotion allowance are set out in Annex E. Other expenditure will be disallowed.

## **17. TRANSFER PRICING**

- 17.1 Wherever possible, scheme members should seek to provide a breakdown of their transfer prices. The breakdown should be supported by an audit statement. The maximum permitted transfer price profit is 15% of accepted transfer price costs. "Accepted" means those costs allowed after negotiations. This amount will be converted into an equivalent amount of assets, using the scheme's target ROC, and added to scheme members' total capital employed (except in the circumstances in Chapter 13). This will have the effect of allowing the MOT on transfer price profits.

- 17.2 Whilst the Department encourages scheme members to provide a breakdown of transfer costs, it recognises that this may not be possible for all scheme members. In these circumstances, scheme members will be allowed to include transfer costs in their AFRs on an arm's length basis and paragraph 17.3 will apply. Scheme members will be required to state the basis of arm's length transfer pricing that has been adopted, and provide confirmation that the same basis has been used in the scheme member's corporation tax return. Where the reasonableness of transfer prices has been the subject of a ruling by the Inland Revenue or another Government department, the Department will take the ruling into account in its assessment of the scheme member's PPRS business.
- 17.3 Where a company only provides the total transfer price figure, it will be assumed to include an element of R&D costs, other relevant costs incurred outside the UK, and a reasonable profit margin. The Department will assume that 72% of the reported costs form the cost of goods, and will be treated as such in AFR Schedule 1. R&D costs will be assumed to be 15% of the total and the remainder will be assumed to be transfer price profit. If, when adding the R&D element to those R&D costs already within the AFR, the total exceeds the scheme member's R&D allowance, then the excess will be deducted from transfer price costs. If all, or part, of the R&D element is disallowed, then transfer price profits will be adjusted to 15% of accepted transfer price costs. As for scheme members that provide a breakdown of transfer costs, the assumed profit will be converted to an equivalent amount of assets, using the scheme's target ROC, and added to the scheme member's total capital employed.
- 17.4 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.

## **18. PRICE REDUCTION**

- 18.1 During the transition from the 1993 agreement, the prices of medicines covered by the PPRS will be reduced by 4.5% from 1 October 1999. The details of this reduction are set out in Annex C.
- 18.2 Prices will remain unchanged at the level of the cut for a period of 15 months until 1 January 2001, except where a cost-neutral modulation is agreed under Chapter 21. At the end of this period scheme members will be eligible to apply for price increases under Chapter 19.

## **19. PRICE RESTRAINT**

- 19.1 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 AFR business is up to date.

- 19.2 In all other cases, such as 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 a forecast for the year after that to which the most recent AFR relates and an estimate for the following year. Scheme members with NHS 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.
- 19.3 The Department will not agree to a price increase unless the company's forecast and estimated profits for the current and following financial years respectively, as assessed by the Department, are below 50% of the level 1 ROC target, calculated by reference to level 1 allowances.
- 19.4 If the Department is in any doubt as to whether prices are acceptable, or adjustments should be made, it may require further information. The Department may require that any supplementary information and data submitted to the Department should be independently audited, where appropriate.
- 19.5 Where price increases are agreed the level of the increases approved will be no more than that estimated as necessary for the company to achieve, in the following financial year, 80% of the level 1 ROC target calculated by reference to the level 1 allowances.
- 19.6 No company may be awarded a price increase within a period of twelve months after a preceding, authorised price increase.
- 19.7 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.

## **20. PRICING OF NEW PRODUCTS**

- 20.1 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. 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. This is conditional upon the requirement that this action will not cause forecast profits to exceed the MOT. The Department will also require that such an application to market the line extension has been submitted to the appropriate licensing authority during the term of five years from the grant of the original licence of the new product.

- 20.2 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.
- 20.3 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.
- 20.4 If a company considers, or the Department has reason to believe, that the rapid uptake of a new product will cause the company to exceed the upper 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.
- 20.5 Where a company wishes to add a further variation in formulation, presentation or pack size to an existing product, the Department should be given a minimum of four weeks notice of intention to launch. The company should provide a description of the product, including the current price of other presentations of the same medicine in the company's range if available, and a forecast of anticipated sales. If the Department has not responded to the notification within three weeks of its acknowledgement of the request, the scheme member is free to market at the price notified.

## **21. MODULATION**

### **Principles underlying modulation as an alternative to a price reduction of 4.5% on all products**

- 21.1 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 4.5%. Product list prices may be increased or decreased during the period 1 October 1999 to 31 December 2000, provided that they do not exceed those that prevailed on 1 August 1999. Modulation will be deemed to have occurred where:
- ◆ list prices have been reduced by a percentage other than 4.5%;
  - ◆ list prices remain unchanged from those that prevailed on 30 September 1999.
- 21.2 Companies can remodulate at any time from 1 October 1999, provided the Department is notified 21 days in advance of the implementation of the price change. The Department will have 14 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.
- 21.3 Companies will not be permitted to substitute discounts or contract prices already in place before 30 September 1999. Price reductions made on products where the patent or supplementary protection certificate expires after 1 July 1999 and before 1 January 2001 will not be allowed in calculations of modulations or overall adjustments made to achieve the price reduction.

### **Modulation principles after 1 January 2001**

- 21.4 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.
- 21.5 From 1 January 2001 list prices may be increased to a level no greater than 20% above the level that existed on 1 August 1999 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. The Department may withhold agreement to any price increase of 10% or more in any one year.
- 21.6 The prices of new products introduced after 1 October 1999 can be increased by up to 20% after 1 January 2001. Any reduction in the price of a new product cannot be used to offset price increases on other products until the new product has been on the market in the UK for two years.
- 21.7 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 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 2 years from the market entry of the competitor product.

### **Information requirements and monitoring**

- 21.8 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 establish monitoring procedures to ensure that scheme members that modulate prices deliver the 4.5% price reduction and that subsequent modulations are cost neutral. Details of the information requirements and the monitoring arrangements are set out in Annex D.

## **22. PRODUCTS SOLD ON**

- 22.1 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:

- 22.1.1 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;
- 22.1.2 the acquiring company may not increase the price for 3 months after acquisition;
- 22.1.3 if at the end of the 3 months the acquiring company wishes to increase the price of the product concerned, it should seek the Department's approval ;
- 22.1.4 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 Chapters 19 and 20. Where the increase would be more than 30%, the Department reserves the right to negotiate the increase over 3 years;
- 22.1.5 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.

## **23. ARBITRATION**

- 23.1 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.
- 23.2 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.

- 23.3 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.
- 23.4 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.
- 23.5 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.
- 23.6 The Secretariat to the panel will be provided jointly by the Department and the ABPI.
- 23.7 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.
- 23.8 The confidentiality of commercially sensitive information will be assured.

## **24. EXIT FROM AGREEMENT**

- 24.1 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 him. He 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 will have regard to any relevant decision of the arbitration panel when considering whether to serve a notice under that provision of that Act.

24.2 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.

24.3 A company may, at any time, withdraw consent for the voluntary scheme to be treated as applying to it.

## **25. AUDIT ARRANGEMENTS**

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

## **26. REPORT TO PARLIAMENT**

26.1 The Department will report to Parliament and provide aggregated details of the operation of this scheme. These details will include aggregated data submitted and adjustments made.

## **27. CONSULTATION ARRANGEMENTS**

27.1 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.

## **28. DISTRIBUTION MARGIN**

28.1 After appropriate consultation, the Department will from time to time indicate the level of margin normally allowable in published NHS prices of supplies distributed through wholesalers.

## ANNEX A

### **Section 33(2) and Section 33(6) of the Health Act 1999<sup>(a)</sup> 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<sup>(b)</sup> hereby consents to the voluntary scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State in July 1999 [(to which there are modifications/and additions made between [the company/partnership/[name] and the Secretary of State on.....<sup>(c)</sup>]] being treated as applying to it/him<sup>(b)</sup>.

2. I am duly authorised to sign this certificate.

Signed .....

Date .....

---

<sup>(a)</sup> 1999 c.8.

<sup>(b)</sup> delete as appropriate.

<sup>(c)</sup> insert date.

## 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<sup>(a)</sup> to the voluntary scheme made between the Secretary of State and the Association of British Pharmaceutical Industry in July 1999 being treated as applying to it is hereby withdrawn.
2. I am duly authorised to sign this certificate.

Signed .....

Date .....

---

<sup>(a)</sup> delete as appropriate.

## **ANNEX B**

### **NOTES ON COMPLETION OF THE ANNUAL FINANCIAL RETURN AND SCHEDULES**

#### **1. General**

- 1.1. The intention is that this return shall relate to business organisations that manufacture and supply medicines which ultimately are charged to the NHS. The return should normally cover, on a consolidated basis, the company to whom it is addressed 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 return should comprise consolidated figures for this sub-group. In such circumstances, references in the return 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 return; otherwise, they should be included in the return under “Other Products”.
- 1.2. 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 this return. It is not intended that reporting companies should produce additional audited accounts specially for the purpose of this return and where the accounting arrangements of the group are such that some other basis for the completion of the return is more appropriate, such other basis may be adopted by agreement between the reporting company and the Department of Health, which is acting on behalf of the Health Departments of the UK. 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.
- 1.3. The return 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 return and by a statement setting out the names of the companies, branches and divisions whose figures are included in the return 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 return.

- 1.4 The completed return should be signed by the Managing Director or Chief Executive of the reporting company and should be 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 return has been prepared on the basis required, and fairly reflects for the relevant financial year the capital employed in relation to NHS medicines and the profit earned from home sales of NHS medicines. A specimen is shown as Certificate 1 at the end of this Annex.
- 1.5 Schedule 1 should be completed in respect of the reporting company's financial year; Schedule 2 should relate to the Balance Sheet date at the end of the same financial year.
- 1.6 It is accepted that the accounting system employed by the reporting companies will result in some variation in the nature of expenses included under the various headings of the return. The purpose of these notes is to identify the main areas of consistency that are sought from all companies.
- 1.7 For the purpose of this return:
  - 1.7.1 an affiliated concern should include any parent company or fellow subsidiary company of the reporting company, any of its subsidiary companies, branches or divisions whose figures are excluded from the return and any other trading organisation under the same control as the reporting company (see also note 1.1 above);
  - 1.7.2 NHS medicines are the products defined in Chapter 7;
  - 1.7.3 all figures should be reported to the nearest £1,000;
  - 1.7.4 all figures for sales and costs should be stated net of UK Value Added Tax. Where a company 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.

### **Apportionment**

- 1.8 It is recognised that in many instances, the expenses incurred by the reporting entity and the related assets and liabilities cannot be directly allocated to its NHS home, exports and other products businesses and that various methods of apportionment can be adopted for these. Reporting companies are required to make such apportionments on the most realistic and reasonable basis possible, striking an equitable balance between the separate interests of the reporting entity 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 both appropriate in the circumstances and equitable as between the parties and to qualify his report in those cases where he is not satisfied with the bases adopted. The reporting entity will indicate in respect of each cost head, asset and liability the amounts involved and the bases used for apportioning figures, and whether these are in accordance with the accounting procedures

and corporate structure of its own organisation. If apportionment bases are changed from those adopted in the previous year in a way which affects the AFR this should be noted. The Department may ask for additional information on the method of apportionment if this is unclear. Where a material asset or liability is specifically allocated in total to NHS medicines, companies should give the amounts involved and explain the reasons for that allocation.

- 1.9 The schedules provide for figures to be given in respect of goods other than NHS medicines. This information is required only 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.

## **2. Schedule 1**

- 2.1 Separate information on home and export trade in NHS medicines should be provided as should information required under paragraph 8.9.
- 2.2 For Section A, discounts should be deducted from sales.
- 2.3 Dividends and interest received and trade investment income should be excluded from Schedule 1 and shown as an adjustment to Schedule 1A.
- 2.4 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 or other expenses which would be better included elsewhere in Schedule 1.
- 2.5 It is expected that costs included under Section B 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). The basis of allocations or apportionments should be indicated for all items. The Department will ask for additional information on apportionment if this is unclear.
- 2.6 Depreciation should be charged at historical cost. Any difference between the figure in the return and in the accounts should be shown in Schedule 1A.
- 2.7 Where Section B includes sums charged by affiliated concerns, the Department will require an audited breakdown of the transfer price under the cost headings included in AFR Schedule 1. In the event that the reporting entity is unable to provide such a breakdown, the Department will apply the default breakdown as provided for under Chapter 17 of the scheme.
- 2.8 Expenditure allowable as a charge on NHS prices under information expenses (Bvii) and sales promotion (Bviii) is set out in Annex E of the scheme. Expenditure (included in the audited accounts) not allowable should be shown in Schedule 1A as an adjustment in arriving at the AFR figures.

- 2.9 R&D expenditure (Bxii and E(i)) will include the salaries and wages of all staff engaged on R&D activities or supporting those activities by analytical, administrative and other services, and all materials and expenses incurred by these staff in carrying out their duties.
- 2.10 Where appropriate, R&D should be apportioned between NHS medicines and other products. The amount so apportioned to NHS medicines should cover all costs of carrying out or sponsoring:
- 2.10.1 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;
  - 2.10.2 formulation, investigations and clinical trials directed towards the production of a medical speciality product;
  - 2.10.3 costs of licensing, patent fees and registration fees for trademarks.
- 2.11 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 recorded 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.
- 2.12 Costs reported in Section E(i) and E(ii) are subject to a separate auditors’ report (see Certificate 2 at the end of this Annex) and will only be accepted in circumstances where it can be reasonably determined that costs incurred in the reporting entity’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.
- 2.13 The split of manufacturing process costs at line 9 should reflect the basic apportionment with no adjustment for the recognition of UK fixed costs (see Chapter 15). This will be shown separately at line 27 and can be calculated as 7.5% of the export allocation of manufacturing process costs shown on line 9. As this is an adjustment to both home and export costs, the amount in the home column will be shown as a cost and the same amount will be shown under exports as a negative cost.

### **3. Schedule 1A**

- 3.1 The sales, costs and profit shown in Schedule 1 of the return should be reconciled in Schedule 1A with the amounts disclosed in the audited accounts.

## **4. Schedule 2**

- 4.1 Fixed assets should be presented at historical cost. Any difference between the figures included in the return and the balance sheet should be shown in Schedule 2A. Assets should not include those investments the income from which has been excluded from Schedule 1.
- 4.2 Normally, Government Accounting conventions do not permit the inclusion of intangible assets in the computation of capital employed but there may be occasions on which the inclusion of such assets, (e.g. goodwill, patents and trade marks etc.) is justified, in which case reporting companies should provide an explanation of why they are included.
- 4.3 Any provision for future taxation should be excluded from current liabilities. For this purpose, future taxation is defined as any amount not payable within 12 months of the balance sheet date to which the return relates and “deferred” tax items should be excluded. 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).
- 4.4 The amount shown in Sections E and F should be the proportion of fixed and current assets less current liabilities appropriate to the operations covered by the return but not included in the audited accounts of the reporting company. Capital reported in this Section is subject to a separate auditors’ report (see Certificate 2 at the end of this Annex) and will only be accepted in circumstances where it can be reasonably determined that capital as shown in the reporting entity’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 in Section E(i) and E(ii) of Schedule 1. Conversely, a deduction should, if appropriate, be shown in Schedule 2A, calculated on the same principles, when the reporting company shows amounts excluded from the AFR on Schedule 1A.
- 4.5 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.
- 4.6 The figures of capital employed in relation to NHS medicines are not required to be divided between home and export trade.

## **5. Schedule 2A**

- 5.1 Items in Sections A, B and C of Schedule 2 should reconcile with the corresponding figures in the audited Balance Sheet, and where appropriate the reconciliation should be given in Schedule 2A.

**PPRS: SCHEDULE 1  
SALES, COSTS AND PROFIT**

**COMPANY:**

**AFR FOR YEAR ENDED:**

Section	Line Number	NHS Medicines Home	NHS Medicines Exports	Other Products	Total
		£000	£000	£000	£000
<b>A SALES</b>					
i To affiliated concerns	1				
ii To independent concerns	2				
<b>Total sales</b>	<b>3</b>				
<b>B COSTS AND EXPENSES</b>					
<i>Finished goods resold</i>					
i From affiliated concerns	4				
ii From independent suppliers	5				
<b>Total finished goods resold</b>	<b>6</b>				
<i>Own manufactured goods resold</i>					
iii Materials purchased from non AFR affiliates	7				
iv Materials purchased from independents	8				
v Manufacturing process costs	9				
<b>Total Manufacturing Cost of Goods Sold</b>	<b>10</b>				
<b>Total Cost of Goods Sold</b>	<b>11</b>				
vi Distribution costs	12				
vii Information expenses	13				
viii Sales promotion expenditure	14				
ix General & administrative expenses	15				
x Royalties payable - to affiliated concerns	16				
xi Royalties payable - to independent concerns	17				
xii Research and Development expenses in accounts	18				
xiii One - off costs & expenses	19				
<b>C TOTAL COSTS AND EXPENSES</b>	<b>20</b>				
<b>D TRADING PROFIT</b>	<b>21</b>				
<b>E SUPPLEMENTARY ITEMS</b>					
i Research and Development expenses - injected	22				
ii Other injected costs	23				
iii Other trading income less charges	24				
iv Royalties received - from affiliated concerns	25				
v Royalties received - from independent concerns	26				
vi UK fixed costs adjustment	27				
vii Other income/costs	28				
<b>F PROFIT BEFORE INTEREST AND TAXATION</b>	<b>29</b>				

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

**COMPANY:**

**AFR FOR YEAR ENDED:**

Section	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 per AFR
	£000	£000	£000	£000	£000
<b>A SALES</b>					
i To affiliated concerns					
ii To independent concerns					
<b>Total sales</b>					
<b>B COSTS AND EXPENSES</b>					
<i>Finished goods resold</i>					
i From affiliated concerns					
ii From independent suppliers					
<b>Total finished goods resold</b>					
<i>Own manufactured goods resold</i>					
iii Materials purchased from non AFR affiliates					
iv Materials purchased from independents					
v Manufacturing process costs					
<b>Total Manufacturing Cost of Goods Sold</b>					
<b>Total Cost of Goods Sold</b>					
vi Distribution costs					
vii Information expenses					
viii Sales promotion expenditure					
ix General & administrative expenses					
x Royalties payable - to affiliated concerns					
xi Royalties payable - to independent concerns					
xii Research and Development expenses in accounts					
xiii One - off costs & expenses					
<b>C TOTAL COSTS AND EXPENSES</b>					
<b>D TRADING PROFIT</b>					
<b>E SUPPLEMENTARY ITEMS</b>					
i Research and Development expenses - injected					
ii Other injected costs					
iii Other trading income less charges					
iv Royalties received - from affiliated concerns					
v Royalties received - from independent concerns					
vi UK fixed costs adjustment					
vii Other income/costs					
<b>F PROFIT BEFORE INTEREST AND TAXATION</b>					

**PPRS: SCHEDULE 2  
CAPITAL EMPLOYED**

**COMPANY:**

**AFR FOR YEAR ENDED:**

Section	Line Number	NHS Medicines	Other Products	Total
		£000	£000	£000
<b>A</b>				
<b>FIXED ASSETS (at historic cost)</b>				
Land & Buildings	30			
Plant & Machinery	31			
Other Fixed Assets	32			
<b>Total Fixed Assets</b>	33			
R & D Fixed Assets	34			
Non R & D Fixed Assets	35			
<b>Total Fixed Assets (to agree with line 33)</b>	36			
<b>B</b>				
<b>WORKING CAPITAL</b>				
<b>Current Assets</b>				
Cash and Bank balances	37			
Debtors – affiliates	38			
Debtors – other	39			
Stocks	40			
Other Current Assets	41			
<b>Total Current Assets</b>	42			
<b>C</b>				
<b>Current Liabilities</b>	43			
<b>D</b>				
<b>Net Working Capital</b>	44			
<b>E</b>				
<b>INJECTED CAPITAL</b>				
R & D Fixed Assets	45			
Non R & D Fixed Assets	46			
<b>F</b>				
Other Capital	47			
<b>Total injected capital</b>	48			
<b>G</b>				
<b>CAPITAL EMPLOYED</b>	49			

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

**COMPANY:**

**AFR FOR YEAR ENDED:**

Section	Total per audited accounts	Re - allocations between headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total per AFR
	£000	£000	£000	£000	£000
<b>A</b>					
<b>FIXED ASSETS (at historic cost)</b>					
Land & Buildings					
Plant & Machinery					
Other Fixed Assets					
<b>Total Fixed Assets</b>					
R & D Fixed Assets					
Non R & D Fixed Assets					
<b>Total Fixed Assets</b>					
<b>B</b>					
<b>WORKING CAPITAL</b>					
<b>Current Assets</b>					
Cash and Bank balances					
Debtors – affiliates					
Debtors – other					
Stocks					
Other Current Assets					
<b>Total Current Assets</b>					
<b>C</b>					
<b>Current Liabilities</b>					
<b>D</b>					
<b>Net Working Capital</b>					
<b>E</b>					
<b>INJECTED CAPITAL</b>					
R & D Fixed Assets					
Non R & D Fixed Assets					
<b>F</b>					
<b>Other Capital</b>					
<b>Total injected capital</b>					
<b>G</b>					
<b>CAPITAL EMPLOYED</b>					

**PPRS: SCHEDULE 1  
SALES, COSTS AND PROFIT**

**COMPANY:**

**ESTIMATE/FORECAST FOR YEAR ENDED:**

Section	Line Number	NHS Medicines Home	NHS Medicines Exports	Total
		£000	£000	£000
<b>A SALES</b>				
i To affiliated concerns	1			
ii To independent concerns	2			
<b>Total sales</b>	3			
<b>B COSTS AND EXPENSES</b>				
<i>Finished goods resold</i>				
i From affiliated concerns	4			
ii From independent suppliers	5			
<b>Total finished goods resold</b>	6			
<i>Own manufactured goods resold</i>				
iii Materials purchased from non AFR affiliates	7			
iv Materials purchased from independents	8			
v Manufacturing process costs	9			
<b>Total Manufacturing Cost of Goods Sold</b>	10			
<b>Total Cost of Goods Sold</b>	11			
vi Distribution costs	12			
vii Information expenses	13			
viii Sales promotion expenditure	14			
ix General & administrative expenses	15			
x Royalties payable - to affiliated concerns	16			
xi Royalties payable - to independent concerns	17			
xii Research and Development expenses in accounts	18			
xiii One-off costs & expenses	19			
<b>C TOTAL COSTS AND EXPENSES</b>	20			
<b>D TRADING PROFIT</b>	21			
<b>E SUPPLEMENTARY ITEMS</b>				
i Research and Development expenses - injected	22			
ii Other injected costs	23			
iii Other trading income less charges	24			
iv Royalties received - from affiliated concerns	25			
v Royalties received - from independent concerns	26			
vi UK fixed costs adjustment	27			
vii Other income/costs	28			
<b>F PROFIT BEFORE INTEREST AND TAXATION</b>	29			

**PPRS: SCHEDULE 2  
CAPITAL EMPLOYED**

**COMPANY:**

**ESTIMATE/FORECAST FOR YEAR ENDED:**

Section	Line Number	NHS Medicines: start of Year	NHS Medicines: end of Year
		£000	£000
<b>A</b>	<b>FIXED ASSETS (at historic cost)</b>		
	Land & Buildings	30	
	Plant & Machinery	31	
	Other Fixed Assets	32	
	<b>Total Fixed Assets</b>	33	
	R & D Fixed Assets	34	
	Non R & D Fixed Assets	35	
	<b>Total Fixed Assets (to agree with line 33)</b>	36	
<b>B</b>	<b>WORKING CAPITAL</b>		
	<b>Current Assets</b>		
	Cash and Bank balances	37	
	Debtors – affiliates	38	
	Debtors – other	39	
	Stocks	40	
	Other Current Assets	41	
	<b>Total Current Assets</b>	42	
<b>C</b>	<b>Current Liabilities</b>	43	
<b>D</b>	<b>Net Working Capital</b>	44	
<b>E</b>	<b>INJECTED CAPITAL</b>		
	R & D Fixed Assets	45	
	Non R & D Fixed Assets	46	
<b>F</b>	<b>Other Capital</b>	47	
	<b>Total injected capital</b>	48	
<b>G</b>	<b>CAPITAL EMPLOYED</b>	49	

## CERTIFICATE 1

**AFR 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 July 1999, 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 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.

**Name**.....**Signature**.....

**Address** .....**Date** .....

.....

.....

**Professional Qualification** .....

*(Delete italics as appropriate)*

## 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.

Name.....Signature.....

Address .....Date .....

.....

.....

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.

**SCHEDULE DETAILING THE UNDERLYING CALCULATIONS AND  
BASES OF APPORTIONMENT APPLIED IN PREPARING THE  
FIGURES FOR INJECTED COSTS AND/OR CAPITAL.**

## **ANNEX C**

### **PRICE REDUCTION**

1. During the transition from the 1993 agreement, the prices of medicines covered by the PPRS will be reduced by 4.5% from 1 October 1999.
2. This will be applied to the NHS list price of all products on the market on the day before the date of commencement of the new scheme. The price reduction will apply to all companies with NHS home sales above £1 million per annum in the financial year ending on or prior to 30 June 1999. Where the price of products covered by the scheme is reduced between 1 August 1999 and 1 October 1999, scheme members will be allowed to take account of these price reductions but not the savings that occur prior to 30 September 1999 in the delivery of the 4.5% reduction.
3. New products (i.e. those introduced following a major marketing authorisation and line extensions applied for within five years of the grant of the original licence) will retain freedom of pricing.
4. Where 30% or more by value of a scheme member's NHS home sales are made up of OTC products (i.e. not prescription only medicines), the member may elect to deliver the 4.5% price reduction by making a repayment to the Department of 4.5% of its ex factory sales of OTC products. To ensure equity with other members such repayments will continue for the duration of this agreement.
5. Products transferred between companies will remain subject to the price reduction.
6. The price reduction is subject to the provisions of the modulation rules in Chapter 21.
7. Prices will remain unchanged at the level of the cut for a period of 15 months until 1 January 2001, except where a cost-neutral modulation is agreed under the rules in Chapter 21. At the end of this period scheme members will be eligible to apply for price increases under the rules in Chapter 19.

## **ANNEX D**

### **MODULATION**

#### **Information requirements and monitoring by the Department**

##### **Information requirements**

1. 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).
2. **By 31 August 1999:**
  - 2.1 For all products the price of which is to be modulated:
    - ◆ a list of the products of which the price has been reduced since 1 August 1999 and the prices proposed from 1 October 1999, and those that prevailed prior to 31 July 1999;
    - ◆ the estimated quantities (i.e. the number of packs or units of each presentation of product) sold to the NHS for each product to be modulated for the following periods:
      - 1 October 1998 to 30 September 1999 (estimate)
      - 1 October 1999 to 31 December 1999 (forecast)
      - 1 January 2000 to 31 December 2000 (forecast)
    - ◆ the total net sales revenues for the following periods:
      - 1 October 1998 to 30 September 1999 (estimate)
      - 1 October 1999 to 31 December 1999 (forecast)
      - 1 January 2000 to 31 December 2000 (forecast)
  - 2.2 **21 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.

**2.3 By 28 February 2000**

- ◆ 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 October 1999 to 31 December 1999;
- ◆ quantities sold to the NHS for each product modulated for the period 1 October 1999 to 31 December 1999.

**2.4 By 28 February 2001 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 October 1999. Unit sales will be provided for each product for three complete calendar years after the date of modulation.

**Monitoring**

3. By 31 May for each year of the agreement the Department will analyse outturns for the previous 12 months ending 31 December (3 months for the analysis undertaken by 31 May 2000). 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.
4. Scheme members that report an overall price reduction of less than 4% for the period 1 October 1999 to 31 December 2000 will be required to make a payment to the Department to deliver the 4.5% reduction, including the wholesaler margin, and to remodulate prices so that this reduction is continued for the duration of the agreement.
5. Scheme members that report an overall price reduction of more than 5% for the period 1 October 1999 to 31 December 2000 will be able to remodulate prices so that the over delivery in that period is recovered by 31 December 2001.
6. The outcome of modulations made after 1 January 2001 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.

## ANNEX E

### SALES PROMOTION AND INFORMATION EXPENSES

1. Sales promotion and information expenditure in Schedules 1 and 1A include all expenditure incurred in the advertising and other promotion or presentation (other than packaging) of the company's NHS medicines in the UK market.
2. The following criteria are to be followed in deciding whether sales promotion and information expenditure will be allowable.
3. **Information expenses**
  - 3.1 *Samples for 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.
  - 3.2 *Summaries of Product Characteristics:* This covers the cost against this category and should cover all expenses incurred in the provision of data sheets including the direct labour and overhead and administration charges.
  - 3.3 *Medical Symposia* (not organised by company): This should include the cost of any support, including hospitality, given by the company for symposia originated and organised independently by the medical and allied postgraduate bodies. 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 Prescriptions Medicines Code of Practice, no part of the costs may be included in Schedule 1 of the AFR.
  - 3.4 Scheme members should note, however, that the Department cannot be expected to accept automatically unlimited levels of information costs, and that it may therefore wish to question any return with high levels of such costs.
4. **Sales promotion expenses**
  - 4.1 *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.

- 4.2 *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 visits to wholesalers or pharmacists for promotional purposes. Where the cost of representatives covers activities other than NHS medicines home, the cost should be apportioned on a suitable basis.
- 4.3 *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.
- 4.4 *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.
- 4.5 *Other Promotional Activities:* This should include the cost of films, lectures and discussion groups originated and organised by the company and journals or magazines not included under advertising, and other promotional services. It should include the cost of professional staff (including medical staff), contributing to these activities, in proportion to the amount of time spent in this way, and the contribution which they make to the other categories of expenditure (e.g. the training of representatives or supervision of literature, journals or advertisements) unless this is shown as part of one of the other categories.
- 4.6 Any element of sales representatives' costs which is included in any cost head other than the sales promotion cost head in the UK NHS Medicines Column of AFR Schedule 1 should be specifically identified, and an explanation given.

5. **Expenditure not allowable**

- 5.1 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)

6. If significant items of expenditure cannot be dealt with in accordance with paragraphs 3 and 4 above, the items involved, the expenditure on each item and, the method adopted to deal with it should be stated in an accompanying note.

## **ANNEX F**

### **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 34(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.