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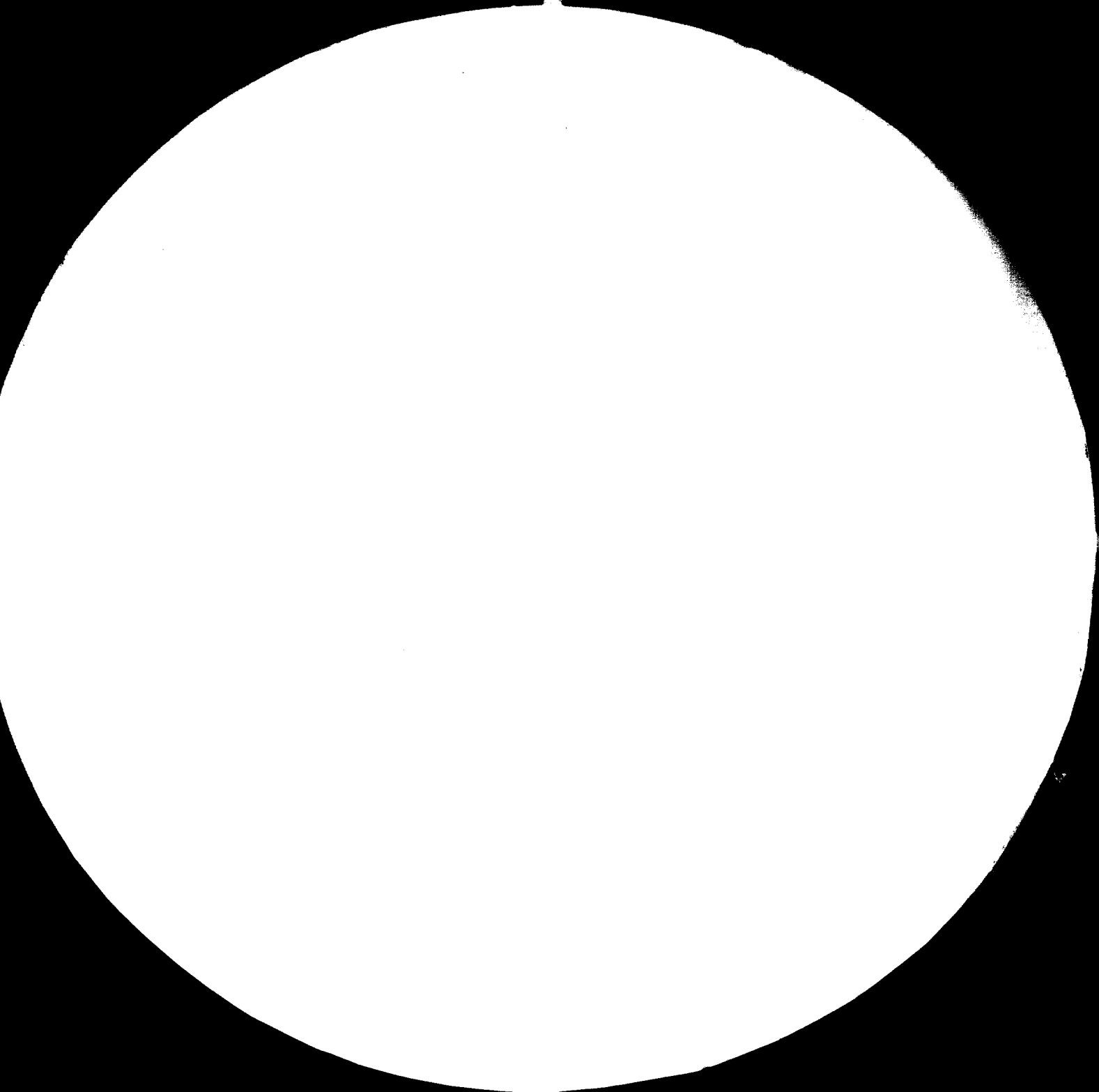
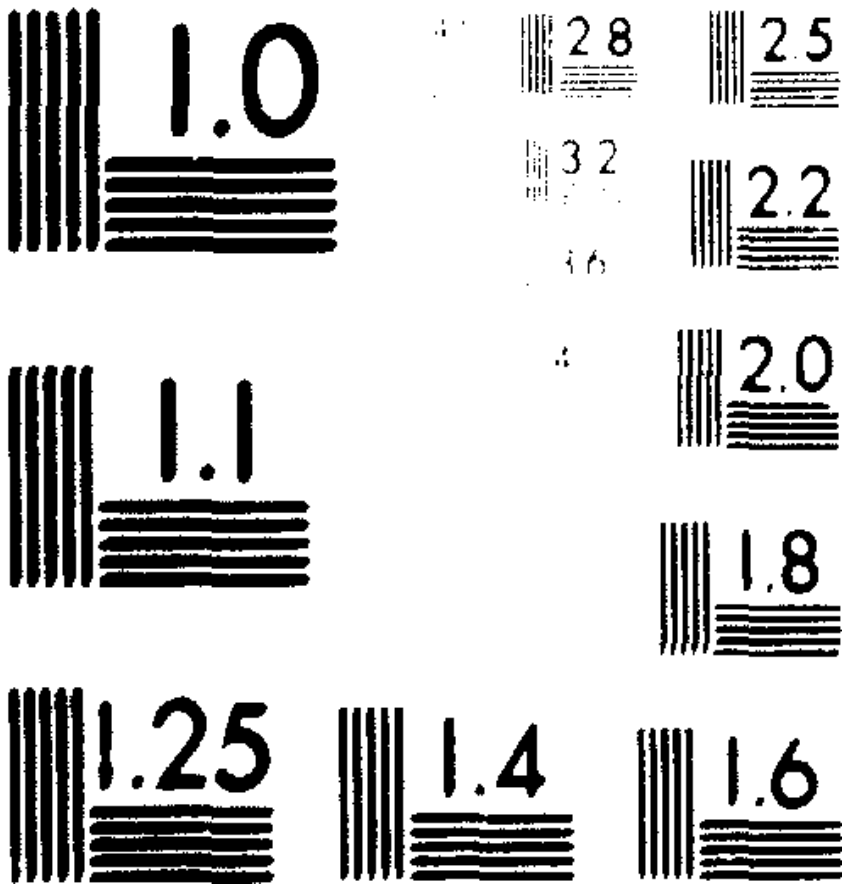
UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org





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Pharmaceutical Price Control Systems in the United Kingdom

Prepared by UNIDO Consultant
Mr. John WOODTHORPE

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PHARMACEUTICAL PRICE CONTROL SYSTEMS

OBJECTIVES

A price control system should have the following as its principle objective:-

(a) The provision of pharmaceutical products to the ultimate purchaser at reasonable and fair prices.

(b) The generation of adequate profit levels by locally based pharmaceutical manufacturing companies to the point where they remain financially viable. Profitability should also be sufficient to encourage such local companies to invest additional capital in expanded manufacturing facilities in line with market growth.

(c) The encouragement of new enterprises to establish local manufacturing plants.

(d) The establishment of a system which will enable the central government to maintain effective control over pharmaceutical prices with the minimum number of civil service personnel.

PRICE CONTROL SYSTEMS.

UNITED KINGDOM

1. Introduction.

(a) Prescription drugs in the United Kingdom whether distributed to the patient in hospitals or acquired by the patient from pharmacies are substantially financed by the DHSS (Department of Health and Social Security) That is to say the Government is the major and almost exclusive purchaser.

(b) The DHSS total expenditure on drugs is ca £1.000 millions per annum.

(c) Control is exercised over the annual profit of individual pharmaceutical companies either in relation to their level of capital investment, or in relation to annual sales value. Control is not ordinarily applied to the prices of individual products.

(d) Although pharmaceutical companies are generally free to fix or amend individual product prices, control over company profitability ensures that the DHSS annual expenditure on drugs is maintained within reasonable limits and, at the same time, that the national pharmaceutical industry remains financially viable.

(e) The United Kingdom price control system is not covered by statutory regulations, but is based on a voluntary arrangement or understanding between the DHSS and the pharmaceutical industry.

(f) There are, however, reserve statutory powers (National Health Service Act 1977 - see appendix I to this report) which can enable the Secretary of State to "control maximum prices to be charged for any medical supplies".

(g) These reserve powers, however, have not been applied in practice; primarily because of the good working relationship which has been established between the DHSS and the pharmaceutical industry, and the fact that the industry has in general brought its profitability into line with the requirements of the voluntary price regulation scheme.

(h) A key feature of the DHSS price control system is the absence of precise formulae for estimating permitted levels of company profitability or for controlling the selling prices of individual pharmaceutical products. The scheme, therefore, has considerable flexibility.

(i) The simplicity of the scheme enables the DHSS to achieve these objectives with a small staff at low administration cost.

2. The System.

(a) General.

(i) The companies supplying prescribed drugs to the DHSS cover a wide range of pharmaceutical activities from the more complex which undertake bulk drug synthesis from substantially basic raw materials, through formulation and packaging and including local research and development facilities; to companies wholely dependent upon the importation of prescribed drugs in finished pack form. There are, therefore, significant variations in the sales to capital ratios within the industry.

(ii) The DHSS price control scheme covers some 170 - 180 pharmaceutical manufacturers and suppliers. However, companies with sales of drugs prescribed under the DHSS of less than £200.000 per annum are generally excluded from control; although such companies may be included in the price control scheme in special circumstances.

(iii) The general guide lines for operation of the United Kingdom price regulation (control) scheme were developed and agreed jointly by the DHSS and the ABPI (Association of the British Pharmaceutical Industry) and issued in documentary form in April 1977 (see Appendix II)

(b) Definition of Capital.

(i) Capital for the purpose of computing profitability, includes fixed assets (land, buildings, plant and machinery) plus cash and bank balances, accounts receivable and total inventory; from which may be deducted accounts payable and other specified liabilities.

(ii) Fixed assets are recorded in terms of historical values. In the event that accounting practice in the United Kingdom adopt current (or replacement) values for capital assets, the criteria for acceptable profit on capital investment would require amendment (downwards)

(iii) The total capital investment in many pharmaceutical companies may be used only in part for the manufacture and distribution of prescribed drugs to the DHSS. The same common capital facility may also be employed in the servicing of the United Kingdom domestic market with "over the counter medicines" (not purchased or re-imbursed by the DHSS), pharmaceutical exports, and non - pharmaceutical products.

(iv) The annual financial returns submitted to the DHSS are designed to show total capital broken down into capital assigned to servicing DHSS medicines and capital assigned to other products. The "Sales, Costs and Profits" return also shows the break down of data for medicines purchased by the DHSS and for the same products sold into exports markets. The DHSS is, therefore, able to identify total profit on DHSS drug purchases and to relate that profit to the capital assignable to these purchases.

(v) The apportionment of total company capital between that assignable to DHSS purchases and assignable to other products can in some instances be a matter of judgement. The Department however, may request companies to provide additional information in support of this apportionment.

(vi) The capital assets recorded in the companies financial returns normally refer exclusively to assets located in the United Kingdom. However, in special circumstances the company may claim that capital assets located overseas should be taken into account in determining the percent profit on investment. In this event the company must submit detailed justification for inclusion of these capital assets in their financial statements.

(c) Definition of Profits.

(i) The annual sales, costs and profits statements submitted by pharmaceutical companies to the DHSS, in general, follow the standard accounting format; but special consideration is given to selected expense items.

(ii) Sales promotion expenses are deemed to include the cost of samples, data sheets, medical symposia, literature, advertising, salaries of the companie's marketing and sales personnel, and administration costs (which are required to be detailed in the financial returns to the DHSS)

The DHSS recognises that promotion expenses expressed as a percent of sales tend to be higher in smaller pharmaceutical companies than in larger organisations. In order to compensate for this disparity, allowable promotional expenses are calculated in accordance with a formula; this currently provides for a fixed allowance of £500,000 plus 7 per cent o' annual sales. The formula is normally reviewed annually. For 1982/83 the fixed allowance has been increased to £550,000; the 7 per cent of annual sales remains unchanged. Actual promotion expenses in excess of this level are not normally deductable from actural profit.

The DHSS, however, recognises that there may be special situations where a company may require to exceed the normally accepted level of expenditure on sales promotion for a transitory period (major new product introductions, entry of the company into the pharmaceutical industry for the first time, etc.) In such situations promotion expenses in excess of the normally permitted level may be accepted, subject to full justification being presented.

(iii) The cost of research and development activities carried out within the United Kingdom and, where appropriate and justified, an allocation of the cost of research and development from affiliated companies overseas, are allowable deductions from corporate profits.

The DHSS, however, may request explanation and justification from companies where research and development expenditure appears to be excessively high in relation to annual sales.

(iv) Profits are calculated before deduction of interest payments and corporate tax.

(d) Presentation of Corporate Financial Data.

(i) The format of financial returns required by the DHSS is set out in Appendix II (Pharmaceutical Price Regulation Scheme)

(ii) These returns follow substantially the layout of the standard financial reports prepared by the companies' accountancy department and, therefore, do not generate any significant work load within these companies.

(iii) Financial returns required by the DHSS cover the previous year's trading, together with a profit and loss forecast for the current year.

(iv) The returns are requested to be audited and signed by an independent accountant and signed by the Managing Director of the company.

(v) The information contained in these financial returns is treated by the DHSS as completely confidential.

(e) Profit to Capital Investment Relationships.

(i) A reasonable and acceptable percentage profit on capital employed will vary from company, depending upon the extent to which these companies have invested in pharmaceutical manufacturing operations and upon other factors. At one extreme a company may have a fully integrated chain of manufacturing facilities including bulk drug synthesis, formulation and packaging; at the other extreme the company may be solely an importer of finished packed products, with minimum capital investment except in local inventory.

(ii) The DHSS is assisted in its assessment of the reasonableness of profit levels by annual government reports which analyse and record the level of company profitability and the return on investment for British industry as a whole.

(iii) Broadly speaking the norm appears to be 20% profit on capital investment; or 10% profit on sales at the present time.

(f) Evaluation of Financial Returns.

(i) Financial returns for the previous years trading are required to be posted to the DHSS as soon as possible after the close of the year; but in any case no more than six months from that date. In the event that the DHSS requires additional supportive information or wishes to enter into discussions or negotiations with a company, notification will be made within two months of the receipt of the financial returns.

(ii) In their analysis of the annual financial returns the DHSS is concerned with arriving at a reliable assessment of the capital and the profits assignable to the manufacture and distribution of drugs purchased by the Department. It also checks the acceptability of expenditures by each company on sales promotion, research and development, etc.

(iii) Where significant quantities of raw materials, intermediates, or finished products are purchased by a company from affiliated sources (whether within or outside the United Kingdom) the company may be required to provide information to the DHSS on profits or on contributions to overheads, which may be contained within the transfer price for these materials.

(iv) Having arrived at an estimate of percentage profit on capital investment and percentage profit on sales, the Department then uses its best judgement as to whether or not these levels of profitability are fair and reasonable.

(v) The rigid application of fixed levels of profitability is regarded as unsatisfactory because of the differing circumstances of individual pharmaceutical companies, their varying contribution to the country's economy and export earnings, and their diverse policies with respect to new capital investment and expenditure on research and development.

However, the average profitability of British industry - see (e) (iii) - is used as a general guide.

(vi) In the event that the level of profitability is in the judgement of the DHSS excessive, discussions and negotiations between the Department and the company concerned will then be undertaken.

In the absence of any extenuating circumstances which might justify a temporary level of excessive profits, the Department will notify the company of the size of the adjustment which it considers necessary to reduce profitability to an acceptable level. Such an adjustment could take the form of price reductions in the current trading year or, in some circumstances, repayment to the Department of excess profits generated in the proceeding year.

The company is free, however, to decide where to make price reductions in its product range, provided the total cut back in company profit is in line with the sum indicated by the Department.

(g) Selling Prices.

(i) As explained earlier in this report the prime objective of the DHSS is to contain the cost to the government of drug purchases, by regulating the profitability level of the pharmaceutical industry.

The industry itself is left to fix individual product selling prices using its knowledge of commercial and competitive conditions, the impact of domestic prices on export prices, etc.

The philosophy of the DHSS in this matter is that if the total cost and profits in supplying prescription medicines are reasonable, then the prices as a whole charged by the company are accepted as being reasonable.

Furthermore, for the Department to become involved in the individual selling prices of the many thousands of product formulations and brands involved, it would be necessary to establish a large and expensive bureaucracy. The increased cost of imposing these additional control measures might be greater than any reduction in the national drug bill achieved by these measures.

(ii) Pharmaceutical companies are free to increase the selling prices of individual products (as they may need to do from time to time to off-set cost inflation,) but with certain restrictions.

Where a single product has annual sales exceeding £300,000 or 10% of the companies total sales to the DHSS, (which ever is the less,) the supplier must notify the Department ahead of time of his intention to raise the selling price and his justification for so doing. In the event that the proposed increase in selling price appears unwarranted, taking into account the company's forecasted financials for the current year, the Department may then intervene.

The supplier, however, is under the continuing constraint of not allowing selling price increases to rise to the point where the permitted limit of company profitability is exceeded, and "claw back" procedures initiated.

(iii) Pharmaceutical companies are free to launch new products into the market at initial selling prices of their own choice. However, if gross profit margins on such products are set too high, and profitability criteria levels are exceeded, "claw back" procedures may occur retrospectively.

(iv) In justification of the selling prices of drugs with annual sales to the DHSS exceeding £300,000, pharmaceutical companies may provide the Department with information on the selling prices of such products, or of comparable products, overseas. The mathematical procedures for evaluating such overseas prices are set out in the "Pharmaceutical Price Regulation Scheme" Appendix A attached. The Department, however, has not so far found cause to apply these procedures; probably because the existance of such procedures in writing is sufficient to induce pharmaceutical companies to avoid setting the selling prices of major drugs unreasonably high.

3. Selling Price Information.

(i) Since the DHSS Pharmaceutical Price Regulation Scheme does not directly control the selling prices of pharmaceutical products, considerable variations can arise in the selling prices of the same or comparable products.

(ii) The choice of products and product brands rest almost entirely with the medical practicioner in his preparation of prescriptions for his patients. The practicioner's choice, therefore, can have an important impact on the annual purchase bill for DHSS drugs.

The DHSS provides all medical practitioners with comprehensive information on the cost of drug therapy for all major areas of medical treatment (see examples attached to this report) However, it is emphasised that drugs grouped together for cost comparisons purposes do not necessarily have equal therapeutic values.

In his choice of prescription drugs, therefore, the medical practitioner is expected to take into account both the cost of treatment and the therapeutic efficiency of the different pharmaceutical preparations.

(iii) MIMS (Monthly Index of Medical Specialities) lists the trade prices of all pharmaceutical preparations (in each of their various packaged forms) available for prescription in general medical practice in the United Kingdom. The index is available on subscription from Medical Publications Ltd. 76 Dean Street, London. WIAIBU. The November 1981 index is included in this report package.

4. Departmental Organisation.

(a) The group responsible for regulating pharmaceutical prices within the DHSS has a total staff of ten people. All are "generalists"; that is to say, they do not necessarily hold academic qualifications in for example pharmacy, medicine or accountancy. They are, however, able to consult experts from these professions in other departments of the DHSS.

(b) It may seem unusual that such a small group of government officials can effect adequate control over the DHSS drug purchase bill (ca. £1,000 Million per annum), in a supply situation which involves a large number of pharmaceutical manufacturers and suppliers, and a vast range of pharmaceutical formulations.

(c) The DHSS has, however, successfully avoided the establishment of a large and expensive bureaucracy by concentrating its function upon basic and essential factors; primarily the profit levels generated by the pharmaceutical industry.

(d) Although a substantial number of company financial returns require evaluation by the Department each year, control is exercised by "exception". That is to say, where company profitability falls within acceptable limits (and many or most do so) no further work is required by the Department; the departmental work load being concentrated primarily on the exceptional situations where company profitability appears to be excessive.

(e) It has avoided involvement in secondary issues such as:-

(i) Small pharmaceutical manufacturers or suppliers with sales below £200,000. per annum.

(ii) The fixing or approval of individual selling prices of the many thousands of pharmaceutical preparations circulating in the British market.

(f) The regulation of such secondary issues would require vastly more personnel than at present employed.

(g) The operational cost of the DHSS department regulating pharmaceutical profits and price, is approximately 0.01percent of the total annual drug purchase.

A D D E N D U M

1. Address — Department of Health and Social Security
14 Russell Square
London WC1 B 5EP.

2. DHSS management met:-

Mr. John Long (Controller)
" Derek Iley
" Paul Bedy

Appendix II

PHARMACEUTICAL PRICE REGULATION SCHEME

April 1978

The Association of the British
Pharmaceutical Industry
162 Regent Street
London W1R 6DD

Tel: 01-734 9061

Department of Health and Social Security
14 Russell Square
London WC1B 5EP

Tel: 01-636 6811

Scottish Home and Health Department
St Andrew's House
Edinburgh
EH1 3DE

Tel: 031-556 8501

Ministry of Health and Social Services
Dundonald House
Upper Newtownards Road
Belfast
BT4 3SF

Tel: 0232-650111

Welsh Office
Pearl Assurance House
Greyfriars Road
CARDIFF

Tel: 0222-44151

PHARMACEUTICAL PRICE REGULATION SCHEME

1. INTRODUCTION

1.1 The Health Departments and the Association of the British Pharmaceutical Industry record their common interest in securing not only that safe and effective medicines are available on reasonable terms to the National Health Service, but also that a strong, efficient and profitable pharmaceutical industry in the United Kingdom is capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines, both for the National Health Service and for export.

1.2 As sponsor for the industry the Department of Health and Social Security recognises the industry's contribution to the economy of the United Kingdom as a whole and wishes further to encourage its competitive efficiency both at home and abroad. The Association of the British Pharmaceutical Industry recognises the desirability of securing in the public interest that the prices of pharmaceutical products supplied under the National Health Service are fair and reasonable.

1.3 With these objectives in mind, both parties have reviewed the operation of the Pharmaceutical Price Regulation Scheme and have agreed on the revised terms set out in succeeding paragraphs and the attached appendices. They also agree that the considerations set out above will be borne in mind by them in any interpretation of the provisions of the revised scheme and in any negotiations between the Departments and member companies of the ABPI which may arise from the scheme.

2. DURATION OF THE SCHEME AND PROVISION FOR REVIEW

2.1 The scheme as amended, unless varied by mutual consent, will continue unaltered subject to six months' notice of termination of the scheme in whole or in part to be given by either party not earlier than 1 October 1982. In the event of major changes taking place within the pharmaceutical services, either party has the right to give six months' notice of termination at any time.

3. EFFECTIVE DATE OF SCHEME

3.1 The scheme comes into operation on 1 April 1978 and all current and future negotiations will be in accordance with it.

4. SCOPE OF THE SCHEME

4.1 The scheme is intended to apply to all companies supplying medicines which are prescribed under the NHS by medical or dental practitioners. For this purpose the term NHS medicine means any human pharmaceutical, whether proprietary or non-proprietary, other than those advertised to the general public.

4.2 Small companies will be relieved of the commitment to supply full financial information as in paragraphs 5.1 to 5.4 to the extent set out in paragraphs 4.3 and 4.4, but they remain subject to the price restraint provisions in paragraphs 12.1-12.4. The Department reserves the right to call for a full annual financial return if circumstances appear to warrant it.

4.3 A company supplying NHS medicines with total home sales not exceeding £200,000 a year will be exempt from supplying financial information except when specifically called for.

4.4 A company supplying NHS medicines with total home sales between £200,000 and £1,500,000 a year will be asked to provide a copy of its audited accounts and a certificate signed by its managing director/chief executive showing a breakdown of its turnover for the year as between home sales of NHS medicines, export sales of NHS medicines and sales of other products.

4.5 The scheme will apply to all packs (and dosage forms) of a medicine except a pack which is intended for sale to the public without prescription and the price of which is not generally accepted as a basis for the pricing of FP10 prescriptions. Sales of medicines which a company shows to be derived predominantly from private prescriptions may by agreement be partially or wholly excluded.

4.6 The Association is prepared to offer advice and guidance to firms on any points of difficulty arising in the application of the scheme; the Association will maintain a constant liaison with the Department.

5 ANNUAL FINANCIAL RETURN

5.1 Financial returns will be completed annually and submitted to the Department as soon as possible after the end of the accounting year on which the return is based and in any event not later than six months from that date. The Department will notify companies within two months of receiving a return whether they wish to enter into negotiations based on that return. To simplify administration the Department will not seek amendment of any annual financial return or request additional information unless it has reasonable grounds for considering that the annual financial return may not correctly reflect the costs and capital involved to a material

extent and that for this reason prices may not be fair and reasonable. The Department and the company concerned will endeavour to complete negotiations and put any resulting adjustments into effect within 12 months of the end of the accounting year on which the annual financial return in question is based (see also paragraph 6.3 which deals with the effective date of negotiations). The time limits in this paragraph may be extended by agreement between the Department and the company and such agreement will not be unreasonably withheld. A specimen copy of an annual financial return is attached at Appendix B.

5.2 The annual financial return will form the basis for negotiations, but consideration will always be given to the contribution of the company to the economy as a whole. The Department reserves the right to seek clarification and the further information provided for in paragraphs 9.1 and 10.1. The Department will also take into consideration a company's financial returns for previous years. If after reviewing the annual financial returns the Department is in doubt as to whether prices are acceptable or adjustments should be made it may also require the further information provided for in paragraph 11.1.

5.3 In addition, companies will have the right to submit to the Department such additional evidence as is relevant to the consideration of their business, including the effects of cost inflation on the AFR figures being discussed. The Department will take account of such evidence notwithstanding the fact that it was not specifically called for in the annual financial return.

5.4 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 form, of the out-turn for the year preceding the forecast year. A specimen copy of the return is attached at Appendix C. The Department will not request additional information unless it has reasonable grounds for considering that the forecast return may not reasonably reflect the prospective sales, costs and capital involved.

6. EFFECTIVE DATE OF PRICE CHANGES OR OTHER ADJUSTMENTS

6.1 The purpose of the forecast annual return is to give an early indication of the company's prospective level of profits. If the return shows profits which in the view of the Department would be unacceptably high, it will notify the company of the adjustments which it considers would be required under paragraph 6.2 if the the annual financial return for the year showed such a level of profits in the outturn. Alternatively it will be open to the company and the Department to agree upon price reductions, to take effect during the forecast year, in order to reduce prospective profits to a level acceptable to the Department and as far as possible to remove the need for retrospective adjustments at the end of the year.

6.2 If the annual financial return shows profits which the Department considers to be unacceptably high, it will negotiate with the company one or more of the following:-

(1) Price reductions, during the accounting year following that covered by the return, to bring prospective profits down to an acceptable level, taking account of available forecasts.

(2) Delay in, or restriction of, price increases sought by the company.

(3) In clearance of the annual financial return, a repayment of that amount of past profits which the Department considers to be excessive.

6.3 Irrespective of the final date of settlement, any price reductions agreed as a result of negotiations based on the annual financial return will take effect from a date eight months after the end of the accounting year on which the return under discussion is based. 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 date on which a payment is to be made under (3) in paragraph 6.2 will be a matter for negotiation.

7. SALES PROMOTION AND INFORMATION

7.1 Members of the Association will each year review their expenditure on sales promotion and information with a view to effecting any further possible economies.

7.2 Where the expenditure of a company on sales promotion and information appears from a review of the annual financial returns to be unduly high, the Department may regard this as a factor to be taken into account in dealing with the returns.

7.3 The Department accepts that the ratio of expenditure on sales promotion and information to turnover will tend to be higher in the smaller companies. It also recognises that there are special circumstances which may justify a level of expenditure higher than that which would otherwise seem to be appropriate to the individual company. Such special circumstances may arise for example in connection with the introduction of a new medicine or medicines; recent entry to the industry (or expansion of a company's operations); recent merger or amalgamation of companies whose activities have not been fully rationalised; expenditure required by special or emergency product information.

8. PROFITABILITY

8.1 The reasonableness of the profits earned by individual companies in home sales of NHS medicines will be a matter for negotiation, having regard to the circumstances of the individual company, the contribution which it makes or is likely to make to the economy, including foreign earnings, investment, employment or research, the special characteristics of the pharmaceutical industry and the profitability of United Kingdom manufacturing industry as a whole. The Department reserves the right in assessing the reasonableness of profit, to take into account revenue foregone by a company which differentiates in selling prices between customers or classes of customers by providing free supplies or allowing discounts greater than are justified by normal commercial considerations.

9. TRANSFER PRICES

9.1 Where raw materials, intermediates or finished goods are supplied by an affiliated company, the receiving company will satisfy the Department that prices are at arms length, or where the Department is not so satisfied the company will on request use its best endeavours to inform the Department of any profit margins or contributions to overheads contained within the transfer prices of significant items.

10. TREATMENT OF OVERSEAS COST AND CAPITAL EMPLOYED

10.1 The costs and capital employed involved in price negotiations will be those normally included in the company's UK audited accounts. If the company considers that the amount shown in these accounts is not an adequate reflection of the total costs or capital involved, it will provide sufficient information about the size and nature of the items in question and the basis of their calculation as shown in the annual financial return to satisfy the Department that the amount should be accepted. The Department may also request companies to provide additional information in respect of figures included in their audited accounts but only if it has good reason to suppose that these may not appropriately reflect the costs and capital involved.

11. COMPARATIVE PRICE TESTS FOR INDIVIDUAL PRODUCTS

11.1 If required to do so under the provisions of paragraph 5.2 in respect of any medicine which is prescribed under the NHS by medical or dental practitioners and has annual home NHS sales in excess of £300,000 a year or 10% of the company's total annual home sales (whichever is the less) companies will provide: -

11.1.1 if the overseas sales amount to not less than 20% of the UK suppliers' total sales of that medicine in home and overseas markets, information in accordance with test 1 of Appendix A, or,

11.1.2. if the medicine does not qualify for scrutiny under test 1, information in accordance with test 2 of Appendix A.

11.2 Companies will be entitled to draw the attention of the Department to prices overseas, or to those of other closely comparable medicines, and due attention will be given, when reviewing the company's annual financial return, to cases where these reflect favourably on the company in question. Where there is a substantial volume of direct exports from the United Kingdom or of royalties from overseas licensees or of earnings from overseas subsidiaries, the Department will, where it is reasonable to do so and consistent with international obligations, seek a settlement which avoids adverse effect on those foreign earnings.

12. PRICE RESTRAINT

12.1 Members of the Association undertake that they will not increase the price of any medicine unless they are satisfied that a price increase is clearly justified (see paragraphs 12.2 - 12.4).

12.2 Where a supplier considers it necessary to increase the price of any branded medicine with annual NHS home sales exceeding £300,000 a year or 10% of the company's total annual NHS home sales (whichever is the less) he should give the Department (PP Branch) at 14 Russell Square London WC1B 5EP, not less than four weeks' notice of his intention, stating the amount of the proposed increase and the reason, in sufficient detail to satisfy the Department that the increase is justified. The manufacturer may assume that the Department are so satisfied unless he receives a reply to the contrary within two weeks.

12.3 If more than 6 months have elapsed since any price increase approved under paragraph 12.2 or any price decrease or similar adjustment proposed by the Department has been accepted a supplier may, subject to giving to the Department at least 7 days' notice, increase the price of a product with

annual home sales not exceeding the limits in paragraph 12.2 without the Department's prior approval provided that the increase does not raise the total value of the sales of the product beyond the limits in paragraph 12.2. The Department reserves the right to require the company to justify the increases if the company in any period of 6 months proposes to increase the price of more than one such product and the existing combined sales of the products exceed 10% of the company's total NHS home sales.

12.4 The Health Departments hope that, to simplify administration, suppliers will as far as possible continue their practice to date of not seeking to increase prices with every minor increase of costs. Where price increases are deferred because of a desire to avoid frequent fluctuations, however, the increase in costs at that stage will be taken into account when a later notification is made for any of the products of the company.

Appendix A

COMPARATIVE PRICE TESTS

In applying the tests in this Appendix it is recognised that the role of a new medicine and its sales possibilities in overseas markets cannot generally be established in under two years from the date of its first introduction for prescription by general medical practitioners in the United Kingdom.

TEST 1 - COMPARISON WITH OVERSEAS PRICES

1. This test is applicable in the circumstances outlined in paragraph 11 of the Scheme to any medicine whose sales in overseas markets, excluding sales in the United States of America, amount to not less than 20% by volume of the UK supplier's home and overseas sales of that medicine.

2. Sales in overseas markets as defined in paragraph 1 are represented by the sum of the following:-

2.1. direct sales of the medicine by the UK supplier in overseas markets;

2.2. sales of the main active ingredients of the medicine by the UK supplier to an overseas branch, affiliated company, associated establishment or agent, for processing into the same medicine sold under any proprietary name;

2.3. overseas sales (by volume) of the same medicine, sold under any proprietary name by a licensee, branch, affiliated company, associated establishment or agent, where royalties or profits accrue to the benefit of the UK supplier or to an affiliated company in respect of such sales (with proportionate reductions in the volume of sales where these firms are entitled only to a share of the royalties or profits).

PRICE CALCULATION

3. The price of the medicine to retail pharmacists in the UK shall be not greater than the weighted average market price after eliminating extremes as in paragraph 4, in the six most important similar overseas markets (or all markets where not more than six) excluding the continent of North America. The market price is the price paid by the wholesaler overseas, after adjustment to exclude sales taxes or similar taxes not having an equivalent in the UK, plus such percentage addition as will be equivalent to the current wholesale discount in the UK including any cash or settlement discount.

ELIMINATION OF EXTREMES

4. This shall be as follows:-

4.1. take the mean of the market prices;

4.2. eliminate any prices which are now more than 20% above or below the mean (except where a market accounts for more than 10% of the total sales of the medicine in the six markets);

4.3. determine the weighted average (weighted according to sales volume) of the remaining prices;

4.4. Where this method produces anomalies it may be modified in a manner to be agreed between the Department and the supplier.

SPECIAL CIRCUMSTANCES

5. Where the application of this test would create undue difficulties or be likely to lead to anomalies it may be modified in a manner to be agreed between the Department and the supplier.

TEST 2 - COMPARISON WITH CLOSELY COMPARABLE MEDICINES

6. In the circumstances outlined in paragraph 16 of the Scheme the Department may call upon the supplier to justify a differential between the price of his own medicine and that of closely comparable medicines in the UK market, provided his medicine does not qualify for scrutiny under test 1. It is recognised that there may be good reasons for differences in the price of such medicines. The degree to which medicines are comparable, and the grounds on which price differentials may be justified, (including differences between exact chemical equivalents, differences in formulation, standards of quality control, research or on other grounds) will vary and will be a matter for judgment and negotiation between the parties and agreement on these matters will not be unreasonably withheld.

DETAILS AND EXAMPLES OF TEST 1

COMPARISON WITH OVERSEAS SALES

1. Under the provisions of paragraphs 5 and 11 of the scheme the Department may apply test 1 to any medicine prescribed under the NHS by medical or dental practitioners with annual sales as defined in para 11, where the overseas sales of that medicine excluding sales in the USA amount to not less than 20% by volume of the UK supplier's home and overseas sales of that medicine.

2. For the purpose of reckoning the sales in overseas markets, each dosage form should normally be treated as a separate product. Sales of different dosage forms may be combined, with the agreement of the Ministry, where the various forms are reasonably comparable. Different strengths of the same dosage form may be regarded as one product (sales figures being combined in equivalent terms, eg one 200 mg = two 100 mg tablets).

3. Sales in overseas markets are the sum of the following:-

i. direct sales of the medicine by the UK supplier in overseas markets;

ii. sales of the main active ingredients of the medicine by the UK supplier to an overseas branch, affiliated company, associated establishment or agent, for processing into the same medicine sold under any proprietary name;

iii. overseas sales (by volume) of the same medicine sold under any proprietary name by a licensee, branch, affiliated company, associated establishment or agent, where royalties or profits accrue to the benefit of the UK supplier or to an affiliated company in respect of such sales (with proportionate reductions in the volume of sales where these firms are entitled only to a share of the royalties or profits).

4. The period with reference to which the overseas sales are to be calculated may be either

i. the last six months for which figures are available;

or

ii. where overseas sales are subject to market fluctuation for seasonal or other reasons, the last twelve months for which figures are available.

5. In order to calculate the volume of overseas sales:

i. take the sales in overseas countries, excluding the USA (as detailed in paragraph 3 above) and value them at the price to home wholesalers (the main active ingredient being represented in terms of the finished product);

ii. aggregate the resultant values;

iii. express this aggregate as a percentage of the supplier's total home and overseas sales (at prices to wholesalers) of the preparation under review; or (if preferred) as a percentage of the home and overseas sales revalued on the basis of typical packs.

Test 1 does not apply if this percentage is less than 20%.

CALCULATION OF THE OVERSEAS PRICE

6a. THE MOST IMPORTANT SIMILAR OVERSEAS MARKETS

Markets are normally distinct countries or territories. The relevant markets are the six similar overseas markets, excluding the continent of North America, in which the largest total sales were made during the review period (or all markets if less than six).

In determining the importance of a market, sales to Government Departments and Institutions at special prices are to be ignored. Such sales are, however, to be included in total overseas sales for the purpose of calculating the percentage sales as indicated in paragraph 5.

Each of the six most important markets should be weighted in accordance with its share of the total sales to the six markets. The weighting for use in the price calculations, should be calculated as in the following examples:-

Example i. Preparations presented in only one strength and one pack:-

Market	A	B	C	D	E	F	TOTAL
No. of packs	6,000	2,000	1.000	500	300	200	10,000
Therefore weighting	60	20	10	5	3	2	100

Example ii. Preparations presented in only one strength but in more than one pack:-

Market	A	B	C	D	E	F	
No. of tablets	8mn	6mn	2mn	3mn	2mn	-	
Ingredients converted to tablets	1mn	-	2mn	-	-	1mn	
Total	9mn	6mn	4mn	3mn	2mn	1mn	= 25mn
Therefore weighting	36	24	16	12	8	4	=100

Example iii. Preparations presented in two strengths and a number of packs, where the two strengths are to be combined under the terms of paragraph 2 of this Appendix:-

Market	A	B	C	D	E	F	
No. of 100 mg tablets	8mn	4mn	4mn	3mn	2mn	-	
Expressed as 50 mg tablets	16mn	8mn	8mn	6mn	4mn	-	
No. of 50 mg tablets	4mn	2mn	-	1mn	-	1mn	
Total	20mn	10mn	8mn	7mn	4mn	1mn	= 50mn
Therefore weighting	40	20	16	14	8	2	= 100

b. PRICES TO GOVERNMENT DEPARTMENTS, ETC

Special prices charged to Government Departments and to Institutions are to be excluded.

c. MARKET PRICES OVERSEAS

The market price of a medicine is the price paid by the wholesaler overseas, subject to an adjustment to exclude Sales Tax or similar tax not having an equivalent in the United Kingdom.

The weighted average of the prices is to be calculated as shown in the following examples which supplement those given in paragraph 6a:-

Example iv. Preparation presented in only one strength and one pack:

Name of Market	Six most important markets						
	A	B	C	D	E	F	
Weighting	60	20	10	5	3	2	100
Pack Size/ Strength	Price pence	Price pence	Price pence	Price pence	Price pence	Price pence	Weighted Average Price
100 x 10 mg	55	50	45	50	45	45	52 pence

Calculation: 60 x 55 = 3,300 + 20 x 50 = 1,000 + 10 x 45 = 450 + 5 x 50 = 250 + 3 x 45 = 135 + 2 x 45 = 90

5,225 ÷ 100

= 52.25 pence

Example v. Preparation presented in only one strength but in more than one pack:

Name of Market	Six most important markets						
	A	B	C	D	E	F	
Weighting	36	24	16	12	8	4	100
Pack Size/ Strength	Price pence	Price pence	Price pence	Price pence	Price pence	Price pence	Weighted Average Price
50 mg x 100	60	72	72	68	60	72	66 pence
50 mg x 250	144	-	-	156	144	174	148 pence

Example vi. Preparation presented in two strengths and a number of packs where the two strengths are to be combined under the terms of paragraph 2 of this Appendix:

Name of Market	Six most important markets						
	A	B	C	D	E	F	
Weighting	40	20	16	14	8	2	100
Pack Size/ Strength	Price pence	Price pence	Price pence	Price pence	Price pence	Price pence	Weighted Average Price
100 mg x 100	100	136	136	120	100	136	116 pence
100 mg x 250	260	-	-	280	260	300	266 pence
50 mg x 100	60	72	72	68	60	72	66 pence
50 mg x 250	144	-	-	156	144	174	148 pence

Note Each price in these examples is before addition of sales tax if any.

d. ELIMINATION OF EXTREMES

Calculate the mean of the market prices of the presentation as in examples i. to vi.

Eliminate any prices which are more than 20% above or below that mean, unless that market accounts for more than 10% of the total sales of the medicine in the six markets.

Determine the average (weighted according to sales volume) of the remaining prices.

Where anomalies result, the method should be discussed between the Department and the supplier.

Example vii

Market	A	B	C	D	E	F
Weighting	60	20	10	5	3	2
Price (in pence) net of sales tax	55	30	50	40	70	30

Calculation:

60 x 55 = 3300
20 x 30 = 600
10 x 50 = 500
5 x 40 = 200
3 x 70 = 210
2 x 30 = 60

4870

4870 ÷ 100 = 48.7 pence

Eliminate E (more than 20% above the mean)
Eliminate F (more than 20% below the mean)
But retain B because it exceeds 10% of the total sales in the six markets.

Take weighted average of A B C and D

$$\frac{3300 + 600 + 500 + 200}{95} = 48.5 \text{ pence}$$

7. DETERMINATION OF MAXIMUM HOME MARKET PRICE IN RELATION TO THE TEST 1 PRICE

The price charged to retail pharmacists in the home market for a particular pack size and strength of a product should not exceed the Test 1 price for the corresponding pack as sold overseas plus a percentage addition equivalent to the current wholesale discount in the United Kingdom.

Where a Test 1 price is not available for a particular home pack size, a notional Test 1 price for that pack size based on the supplier's normal commercial ratios should be agreed with the Ministry.

EXAMPLE - TABLET PRODUCT

Home packs: 25 and 100

Only pack sold in prescribed overseas markets: 50

Supplier's normal ratio between 25, 50 and 100 packs for product in similar price range: 1 : 1½ : 3

Test 1 price of 50 pack: 42 pence

Therefore, notional Test 1 prices of 25 and 100 packs would be 24 pence and 72 pence respectively.

8. MODIFICATION OF METHOD IN PARTICULAR CASES

Where the strict application of the Test would be attended by considerable practical difficulties (particularly where home sales are small), or be likely to lead to anomalies, suppliers may apply for the Department's agreement to special modification of the test.

EXAMPLES

a. SLIGHT VARIATIONS IN COMPOSITION BETWEEN HOME AND OVERSEAS PRODUCTS -

A product sold overseas may be substantially the same as one sold in the home market, a minor variation in formula having been made to suit the special circumstances of the overseas market. The supplier may apply for the home product to be considered under Test 1, the Test 1 price being adjusted to take account of the formula variation where necessary.

b. PRODUCTS MARKETED IN A RANGE OF SIZES AND/OR STRENGTHS

It may be difficult to calculate Test 1 prices where a product is marketed in a range of sizes and/or strengths, the sales of which may vary considerably in the home and in the several overseas markets. The supplier should apply for each such case to be treated on its merits. For example, it may be convenient and acceptable to fix a Test 1 price for the pack with the largest sale in overseas markets which approximates to the most popular NHS pack - other pack prices being fixed according to the supplier's normal ratios.

ANNUAL FINANCIAL RETURN

for the year ended .....

Company .....

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

Date .....

Affilated Companies consolidated in this Return -

1. .....
2. .....
3. .....
4. .....
5. .....
6. .....

INDEPENDENT ACCOUNTANTS' REPORT

I/We have examined the annexed Schedules 1, 2, 3 and 4, 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 April 1978, agreed between the Health Departments of the United Kingdom and the Association of the British Pharmaceutical Industry, and the explanatory notes;

ii. the methods of apportionment which have been used in preparing the figures relating to NHS medicines are appropriate in the circumstances and the figures in the Schedules fairly reflect on the bases defined above 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;

iii. *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)

APPENDIX B

ANNUAL FINANCIAL RETURN

Notes concerning the completion of the Annual Financial Return

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, within the Group organisation, audited accounts are prepared for a sub-Group which embraces all the group pharmaceutical business carried on in the United Kingdom(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. It is recognised, however, 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 and Social Security which is acting on behalf of the Health Departments of the United Kingdom. Where wholesaling and/or retailing activities are carried on in separate organisations for which separate figures of costs, sales and profits are available those figures may be either (a) excluded from the return, where they are covered by separate audited accounts, or otherwise, (b) included for the purpose of the return under "Other Products".

1.2 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. For this reason, figures in the "Other Products" and "Totals" columns need be entered against a heading only where the figure against that heading in the "NHS medicines" column includes an amount derived by a process of apportionment between "NHS medicines" and "Other Products". Other headings which do not involve any apportionments may be left blank.

1.3 Alternatively, the columns of the returns headed "Other Products" and "Totals" may be ignored altogether provided information is given about those items of costs and capital in respect of which the amounts included for NHS medicines have been derived wholly or in part from the apportionment of amounts common to those products and other sections of business. This information should be given by way of note in the following form:-

e.g. Schedule 1

Item D(iii) Distribution Cost	NHS Medicines £000's	Other Products £000's
Amounts apprortioned		
Other Amounts		
Total		

together with a full description of the bases of apportionment.

1.4 The return should be accompanied by a copy of the audited accounts 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.

1.5 Schedules 1, 3 and 4 should be completed in respect of the reporting Company's complete financial year; Schedule 2 should relate to the Balance Sheet date at the end of the same financial year.

1.6 It is recognised that, in many instances, the expenses incurred in the business and the assets and liabilities appropriate thereto cannot be apportioned precisely to the different headings required. Reporting Companies are asked to make such apportionments on the most realistic basis possible; they should indicate in respect of each main group of expenses the amounts involved and the bases used and whether these are in accordance with the accounting procedures and corporate structure of their own organisation.

1.7 For the purpose of this return, NHS medicines are all human pharmaceuticals, whether proprietary or non-proprietary, other than those advertised to the general public, whether or not the ultimate customer is the National Health Service, and irrespective of whether sold packaged or in bulk.

1.8 For the purpose of this return, 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).

1.9 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 if it has been practicable to show this, otherwise the profit earned from total sales of NHS medicines.

1.10 All figures should be reported to the nearest £1,000; percentages should be quoted to one decimal place.

2. Schedule 1

2.1 It is accepted that the accounting systems employed by the reporting Companies will result in variations in the nature of expenses included under the various headings of the return. It is expected that costs included under Section D will be on a cost centre basis, ie, salaries, wages, depreciation, materials and other expenses attributable to a function will be included in the cost of that function.

2.2 All figures for sales and costs should be stated net of United Kingdom 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.

2.3 Dividends and interest received and trade investment income should be excluded from Section B.

2.4 Research and development expenditure will include the salaries and wages of all staff engaged on research and development activities or supporting those activities by analytical, administrative and other services, and all materials and expenses incurred by this staff in carrying out its duties.

2.5 Where appropriate, research and development 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:-

(a) 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;

(b) formulation, investigations and clinical trials directed towards the production of a medical speciality product.

2.6 Reporting Companies who benefit from research and development expenditure borne by a parent Company or other affiliated concern, should include their appropriate share of such expenditure in the figures shown in Section D viii and should note the amount so included in Section I ia of Schedule 1 if the amount is not charged by the parent or affiliated concern. Similarly, any other items of expense that relate to the operations covered by the return and included in Section D but which have not been charged directly or indirectly in the audited accounts of the reporting Company, should be specified in Section I ib and the basis of calculation explained by way of a supporting statement. Conversely, expenditure charged in the audited accounts of a reporting Company could be attributable to an affiliated concern whose operations are not included in the return; in such cases, the amount thus attributed should be excluded from Section D and shown in Section I ii.

2.7 Separate information on home and export trade in NHS medicines should be provided where it is practicable to do so for particular items and where the volume of export business is such that the figures provided would be significant.

3. Schedule 1A

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

4. Schedule 2

4.1 Where reporting Companies elect to complete Section A2 (showing assets at current as distinct from Balance Sheet values), the basis on which current values of assets have been arrived at should be explained.

4.2 Assets should not include those investments, the income from which has been excluded from Schedule 1. 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, eg, goodwill, patents and trade marks, etc, is justified, in which case reporting companies should provide an explanation of why they are included. Where Government grants have been deducted from the value of fixed assets shown in Schedule 2, the amounts of such grants should be disclosed in a separate note.

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, eg bank borrowing, advances from affiliated concerns.

4.4 The amount shown in Section E a should be the proportion of fixed and current assets less current liabilities appropriate to the operations covered by the return and included in Sections A1-C but not included in the audited accounts of the reporting company. This net capital should generally correspond to the expense shown in Section I i of Schedule 1. The basis used in calculating this figure should be disclosed on an accompanying statement. Conversely, a deduction should if appropriate be shown against Section E b, calculated on the same principles, when the reporting Company shows an amount against Section I ii of Schedule 1.

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 medicine 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.

6. Schedule 3

6.1 Where the accounting system of the reporting Company does not conveniently allow analysis of Section D ii of Schedule 1 in the manner contemplated in Schedule 3, addressees may substitute an analysis more readily available provided that a similar degree of detail is disclosed.

7. Schedule 4

7.1 Schedule 4 should include all expenditure incurred in both sales promotion and information on NHS medicines in the UK market, including any company promotion expenditure which has to be allocated or otherwise apportioned to arrive at the total expenditure applicable to "NHS Medicines Home". Where the total expenditure includes apportioned items, the nature of these items and the bases of apportionment should be stated.

7.2 Sales promotion and information expenditure includes all expenditure incurred in the advertising and other promotion or presentation (other than packaging) of the company's NHS medicines in the UK market. All expenditure of a promotional nature should be included even though such expenditure is not specifically mentioned in the succeeding paragraphs.

7.3 The total expenditure on sales promotion and on information including, where appropriate, apportioned amounts, should be analysed into the expense categories shown in Schedule 4. The amounts against each category should include all expenses incurred in connection with that category. For example, literature and advertising would each include the cost of printing and distribution including postage, the commissioning of articles, the description of available medical products, whether in classified or other form, and all design, artwork, copy writing, agency block-making, stationery printing or photo work costs and charges as well as the cost of advertising space. Specific points on each category are set out overleaf:-

A. Sales (Invoice values less Returns and Discounts)

i. To affiliated concerns
ii. To independent customers

B. Other Trading Income less charges

C. Total Trading Income (A & B)

D. Costs and Expenses

i. Finished goods resold a. from affiliated concerns
b. from independent suppliers
ii. Manufacturing cost of goods sold (Schedule 3)
iii. Distribution costs
iv. Information expenses (Schedule 4)
v. Sales Promotion expenditure (Schedule 4)
vi. Royalties payable a. to affiliated concerns
b. to independent concerns
vii. General and administrative expenses
viii. Research and Development expenses

E. Total Costs and Expenses (D i.-viii.)

F. Trading Profits (C-E)

G. Royalties Receivable

a. From affiliated concerns
b. From independent concerns

H. Profits before Interest and Taxation

I. i. Costs not charged in the audited accounts if any, but charged in D above, and which are borne by affiliated concerns and which relate to the operations covered by this return.

a. Research and Development
b. Other costs

(To be specified in Schedule 1A)

ii. Costs charged in the audited accounts the benefit of which relates to affiliated concerns whose operations are not covered by this return, and are excluded from D above (to be specified in Schedule 1A).

J. Total Depreciation charged in D above.

Line Number	NHS Medicines				Other Products		Total	
	Home Trade		Exports					
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
24								

RECONCILIATION OF SCHEDULE 1 WITH AUDITED ACCOUNTS (TO BE COMPLETED IF APPROPRIATE)

	Total as per AFR		Adjustments to the AFR				Total as per Audited Accounts	
			Additions		Subtractions			
	£000	£000	£000	£000	£000	£000	£000	£000
A. SALES								
i. To Affiliated Concerns								
ii. To Independent Concerns								
B. OTHER TRADING INCOME								
C. TOTAL TRADING INCOME								
D. COST AND EXPENSES								
i. Finished Goods Resold								
a. From affiliated concerns								
b. From independent suppliers								
ii. Manufacturing Costs								
iii. Distribution Costs								
iv. Information Expenses								
v. Sales promotion Expenditure								
vi. Royalties Payable								
a. To affiliated concerns								
b. To independent concerns								
vii. General and Administrative Expenses								
viii. Research and Development Expenses								
E. TOTAL COSTS AND EXPENSES								
F. TRADING PROFITS (C-E)								
G. ROYALTIES RECEIVABLE								
a. From affiliated concerns								
b. From independent concerns								
H. PROFITS BEFORE INTEREST AND TAXATION								

CAPITAL EMPLOYED AT _____ (date)

Schedule 2

Gross and Net = Before and After Depreciation	Line Number	NHS Medicines		Other Products		Total	
		Gross	Net	Gross	Net	Gross	Net
		£'000	£'000	£'000	£'000	£'000	£'000
A[1] Fixed Assets (at balance sheet values)							
Land and Buildings	24						
Plant and Machinery	25						
Other Fixed Assets	26						
Total Fixed Assets	27						
B Current Assets							
Cash and Bank Balances	28						
Debtors - Affiliated Concerns	29						
- Others	30						
Stocks	31						
Other Current Assets	32						
Total Current Assets	33						
C Current Liabilities							
Trade Creditors - Affiliated Concerns	34						
Others	35						
Other Creditors - Affiliated Concerns	36						
Others	37						
Current Taxation	38						
Other Current Liabilities	39						
Total Current Liabilities	40						
D Capital Employed	41						
E a. Capital not shown in audited accounts but which is employed by a parent company or other affiliated concern and relates to the operations covered by this return	42						
b. Capital included in audited accounts but which is employed for the benefit of affiliated concerns and relates to operations not covered by this return	43						
A[2] Fixed Assets at Current Cost (if considered appropriate)		GROSS	NET	GROSS	NET	GROSS	NET
Land and Buildings	44						
Plant and Machinery	45						
Other Fixed Assets	46						
Total Fixed Assets	47						

Schedule 2A

RECONCILIATION OF SCHEDULE 2 WITH AUDITED ACCOUNTS (TO BE COMPLETED IF APPROPRIATE)

	Total as per APR		Adjustments to the APR				Total as per Audited Accounts	
			Additions		Subtractions			
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
A. Fixed Assets	GROSS	NET	GROSS	NET	GROSS	NET	GROSS	NET
Land and Buildings								
Plant and Machinery								
Other Fixed Assets								
Total Fixed Assets								
B. Current Assets								
Cash and Bank Balances								
Debtors - Affiliated Concerns								
- Others								
Stocks								
Other Current Assets								
Total Current Assets								
C. Current Liabilities								
Trade Creditors - Affiliated Concerns								
- Others								
Other Creditors - Affiliated concerns								
- Others								
Current Taxation								
Other Current Liabilities								
Total Current Liabilities								
D. Capital Employed (A + B - C)								

Schedule 3

MANUFACTURING COSTS OF GOODS SOLD

	Line Number	NHS Medicines		
		Total	Home Sales	Exports
		£000	£000	£000
Purchases from:— affiliates	48			
independents	49			
Direct Wages	50			
Manufacturing expenses:-				
Indirect wages	51			
Other Expenses	52			
Depreciation	53			
Total	54			
To reconcile with manufacturing costs of goods sold (Line 7 Schedule 1)	55			

Stocks: The following information should be given if readily available:-

	£000	Total	Home Sales	Exports
Opening Stock		£000	£000	£000
Raw materials				
Finished Goods				
Work in Progress				
	£000			
Closing Stock				
Raw materials				
Finished Goods				
Work in Progress				

Information Expenses

Samples for identification purposes:- the cost shown 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.

Data sheets:- the cost against this category should cover all expenses incurred in the provision of Data Sheets including the direct labour and overhead and administration charges.

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 professions, for example learned societies and postgraduate bodies.

Sales Promotion Expenses Allowable in NHS Prices

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 (eg, 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.

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 pharamacists for promotional purposes. Where the cost of representatives covers activities other than NHS medicines Home, the cost should be apportioned on a suitable basis.

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 free of charge.

Administration - Costs should include allthose 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.

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 (for example, the training of representatives or supervision of literature, journals or advertisements) unless this is shown as part of one of the other categories.

7.4 The following expenditure is not allowable as a charge in NHS prices and should not be included in Schedule 4:-

Samples (other than samples for identification purposes)
Gifts
Hospitality other than that provided for medical symposia.

7.5 If significant items of expenditure cannot be dealt with in accordance with paragraphs 7.1-7.4 above, the items involved in this way, the expenditure on each item and the method adopted to deal with it should be stated in an accompanying note.

CC

* FORECAST/ESTIMATE OF OUTTURN OF SALES, COSTS AND PROFITS

for the year ended .....

	Line Number	NHS MEDICINES			
		Home Trade		Exports	
		£'000	£'000	£'000	£'000
A. Sales at invoiced values, less returns and discounts					
To affiliated concerns	1				
To independent customers	2				
B. Other Trading income less charges	3				
C. Total Trading Income (A + B)	4				
D. Costs and Expenses					
a. Finished Goods resold, from affiliated concerns	5				
from independent suppliers	6				
Z b. Manufacturing Cost of Goods Sold	7				
c. Distribution Cost	8				
d. Information expenses	9				
e. Sales Promotion Expenses	10				
f. Royalties Payable, to affiliated concerns	11				
to independent concerns	12				
g. General and Administration Expenses	13				
h. Research and Development	14				
E. Total Costs and Expenses	15				
F. Trading Profits (C-E)					

* Delete as appropriate

Schedule 4

SALES PROMOTION AND INFORMATION EXPENSES

	Line	NHS Medicines (Home)
INFORMATION EXPENSES		
Samples for identification purposes	56	
Data sheets	57	
Medical Symposia (not organised by company)	58	
Total (lines 56-58) INFORMATION Cd to line 9	59	
SALES PROMOTION EXPENSES ALLOWABLE IN NHS PRICES		
Literature	60	
Representatives (including expenses)	61	
Advertising	62	
Administration of sales promotion and information	63	
Other promotion and information expenses	64	
Total (lines 60-64) SALES PROMOTION Cd to line 10	65	

APPENDIX C

FORM OF ANNUAL FINANCIAL RETURN

COMPANY .....

The annexed schedules are a forecast estimate of the company's sales, costs and profit for the year ended ..... for Home Trade in NHS Medicines and of the total Export sales of NHS medicines for the year, together with a similar estimate of the outturn for the year preceding the forecast year. All cost increases at present known have been included in the calculation of the forecast and estimate of outturn.

Since the Annual Financial Return for the year ended ..... was submitted, the total net assets employed have not materially changed/have changed as follows:-

(Signed) Managing Director/Chief Executive

.....

(Date) .....

[redacted]