



*Pharmaceutical Price
Regulation Scheme*

Ninth Report to Parliament

Pharmaceutical Price Regulation Scheme

Ninth Report to Parliament

July 2006

Introduction

This is the ninth Report to Parliament on the Pharmaceutical Price Regulation Scheme (PPRS). The first report was published in May 1996 following a recommendation by the Health Committee¹ that the ‘Department of Health should introduce greater transparency into the PPRS by publishing an annual report on the scheme’. Since then the Department has published a report to Parliament on the operation and management of the scheme most years². The Department published the eighth report in March 2005.

The prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (NHS) are regulated by the PPRS. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI) – under Section 33 of the Health Act 1999. There have been a series of voluntary agreements with the industry since 1957 to limit branded medicine prices and profits, each lasting five years or so, although the details of these agreements have evolved over time.

A new five-year scheme negotiated with the ABPI commenced on 1 January 2005 in succession to the 1999 scheme. It includes a price reduction of 7% in the prices of branded prescription medicines supplied to the NHS as part of a package of measures, which provide stability for the industry and reward innovation and research whilst keeping public expenditure under control.

The objectives for the 2005 scheme are unchanged from those for the 1999 scheme and, as stated in the agreement, continue to be to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices;
- Promote a strong and profitable pharmaceutical industry capable of such sustained research and development as should lead to the future availability of new and improved medicines;
- Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter (OTC) medicines) except when prescribed. It is a UK wide scheme and covers around 80% by value (some £8 billion) of the medicines used in the NHS in both primary and secondary care.

1 House of Commons: Session 1993-94: Health Committee: Second Report: Priority Setting in the NHS: The NHS Drugs Budget: Volume I: 80-1: London HMSO

2 1997, 1999, 2000, 2001, 2002, 2003, 2004 and 2005

In summary, the PPRS:

- Allows companies freedom of pricing for new medicines (new active substances)
- Requires companies to seek the Department's agreement for price increases, which are only granted if the reasons for the application meet the criteria for increases set out in the agreement
- Requires companies with NHS sales of more than £25 million a year to submit annual data on sales, costs, assets and profitability and to repay the excess where profits exceed the agreed return on capital threshold
- Provides significant support for research and development (R&D) and innovation through improved allowances for R&D.

The agreement seeks to achieve reasonable prices for the NHS, whilst recognising that the industry needs to be profitable to enable it to develop and market new and improved medicines.

This report highlights that in 2005:

- All major companies elected to join the new PPRS, which started on 1 January 2005, and all companies reduced prices as required under the scheme
- The majority of scheme members required to submit Annual Financial Returns (AFRs) under the 1999 PPRS did so in accordance with the agreed timetable but for those 2003 AFRs not received on time there was a significant increase in the average delay in submitting returns
- The price reduction under the 1999 scheme continued to deliver annual savings to the NHS of some £250 million in 2004
- The improved allowances for R&D continued to provide significant support for R&D and innovation.

However, there remain concerns about whether submitted AFRs meet the degree of transparency required by the scheme. The Department rigorously examines and questions such returns, which led to an increase in the average time taken to clear the 2003 AFRs. Two returns remain uncleared.

The Department has referred a disagreement with one company regarding the full delivery of the 4.5% price reduction required under the 1999 PPRS to the independent arbitration arrangements provided by the scheme.

In September 2005, the Office of Fair Trading (OFT) announced a market study of the PPRS to assess whether the scheme is the most effective means of securing value for money for the NHS, whilst offering appropriate incentives for pharmaceutical companies to invest in new medicines for the future. The OFT have said that a final report is due to be published in the first quarter of 2007.

Contents

1. The 2005 Scheme	3
• New agreement	3
• Scheme membership	4
• ‘Standard’ branded generics	4
• Distribution margin	4
2. The 1999 Scheme	5
• Government’s objectives	5
3. Management and Operation of the Scheme	6
• Management of the PPRS	6
• Operation of the PPRS	6
• Submission and clearance of company financial returns	7
• Outturn data	9
• Arbitration	10
4. Pricing	11
• 4.5% Price reduction	11
• 7% Price reduction	11
• Price increases	12
5. International Price Comparisons	13
6. Contribution to the Economy	16
7. Office of Fair Trading Study into the PPRS	18
Annex A Summary of the 2005 PPRS	19
Annex B Scheme members of the 2005 PPRS	24

1. The 2005 Scheme

This section describes the 2005 PPRS, which replaced the 1999 PPRS from 1 January 2005, following negotiations between the Department of Health and the ABPI.

New agreement

The new agreement is a package of measures, which provides stability for the pharmaceutical industry and rewards innovation and research but also keeps public expenditure under control.

The main points of the new agreement are:

- A price reduction of 7% in the prices of branded prescription medicines supplied to the NHS from 1 January 2005, which will deliver expenditure savings of more than £1.8 billion over the next five years for the NHS in England
- Increased support for R&D through allowances for R&D to a maximum of 28% of NHS sales (up from 23%) with greater incentives for R&D of innovative medicines and those for children
- Continues to allow companies freedom of pricing for new medicines (new active substances) launched in the UK
- No change to target rate of return on capital (21%)
- A number of concessions for small companies including exempting the first £1 million of sales from the price cut for companies with PPRS turnover of less than £10 million
- The recognition of marketing and information costs in a way that is more acceptable to both sides than the provisions under the 1999 scheme
- An improved basis for the treatment of transfer prices
- Companies that elect not to join the new PPRS will be subject to a statutory scheme under sections 34 to 38 of the Health Act 1999.

All companies with sales of branded medicines to the NHS of more than £1 million have reduced prices from 1 January 2005 as required under the scheme.

The first AFRs under the 2005 scheme are due to be submitted at the end of June 2006.

Further information on the 2005 PPRS is at annex A.

Scheme membership

All large companies and the majority of smaller companies have elected to join the 2005 scheme. A list of the 161 scheme members is at annex B.

'Standard' branded generics

In January 2005, the Department carried out a consultation on proposals that:

- 'Standard' branded generics³ should be removed from the PPRS and transferred to the new arrangements for the reimbursement of generic medicines⁴; and
- The future reimbursement price of 'standard' branded generic medicines will be the lesser of either the revised Drug Tariff price of the comparable true generic or the list price of the 'standard' branded generic medicine.

Many of the responses received supported the proposals but comments included concerns about the accurate identification of 'standard' branded generic medicines that are not in oral solid dose (OSD) form.

The Department, therefore, published a further consultation letter in September 2005 seeking views on detailed proposals to remove OSD forms of 'standard' branded generic medicines from the PPRS. The Department is analysing responses to this second consultation.

Distribution Margin

The 2005 PPRS provides for the Department in consultation with the ABPI and others as required to review the appropriateness of the provisions relating to the distribution margin for supplies distributed through wholesalers.

In 2005, the Department of Health discussed the implementation of this provision with the ABPI and others in the supply chain. It was agreed with the ABPI that the Department would write to all member companies with total home sales of NHS medicines of £5 million or more a year to provide information on the percentage distribution margin including, where appropriate, any prompt settlement discount that they allow.

3 A 'standard' branded generic is defined as an out of patent product to which the manufacturer/supplier, who is not the originator company, has applied a brand name and that is directly comparable to a true generic that is readily available. Branded products sold on by the originator company to another company remain within the scheme. Other branded generics (e.g. modified release preparations and 'complex' branded generic products) remain within the scheme.

4 In April 2005, the Department introduced new long-term arrangements for the reimbursement of generic medicines. The Drug Tariff introduced a new Category M of generic medicines under Part VIII. The basic prices of Category M medicines reflect the average manufacturers' market prices after discount and data to amend prices in line with market changes is provided by members of two new voluntary Schemes (M and W), backed by section 33 of the Health Act 1999. Scheme M applies to manufacturers and Scheme W applies to wholesalers. Category M will remove some £300 million from the distribution chain to be channelled back to pharmacy services as part of the new pharmacy contract arrangements. The new arrangements replace the Maximum Price Scheme, which had secured annual savings of some £330 million when compared with expenditure that would have been incurred if prices had remained at March 2000 levels.

2. The 1999 Scheme

This section outlines the extent to which the Government's objectives for the 1999 scheme have been achieved.

Government's objectives

In addition to the stated objectives for the 1999 PPRS, the scheme was devised to:

- Be more transparent in terms of its operational framework
- Deliver greater compliance than previous PPRS agreements
- Provide greater support to R&D, innovation and competition.

The fifth year's operation of the 1999 scheme indicates that:

In terms of Transparency: the scheme is more easily understood than its predecessor with a common return on capital (ROC) target and a common basic allowance for research and development (R&D). The ABPI accepts that it has been equally applied to all members. However, despite the ABPI re-emphasising to its members the need for full compliance with the terms of the agreement, some companies have not readily provided detailed information about the allocation and apportionment of costs and capital claimed as utilised in NHS home medicines business.

In respect of Compliance: the average delay for those companies submitting AFRs for 2003 late increased significantly from 43 to 57 days and some companies are continuing to fail to submit all the required information. The speed of response to subsequent enquiries has, in most cases, been acceptable but some companies remain reticent to provide substantive replies.

Research and Development: the Department has continued to support R&D expenditure by means of additional allowances and has extended procedures for the recognition of capital employed for both manufacturing and R&D.

3. Management and Operation of the Scheme

This section reports on the operation of the 1999 scheme, and comments upon the submission by companies of the principal information required under the scheme.

Management of the PPRS

A team in Medicines Pharmacy and Industry Group of the Department of Health administer the scheme on behalf of the UK Health Departments. The team also has responsibility for the prices of generic medicines and the resolution of medicine supply issues. 8.5 full time equivalent staff manage the PPRS. The team includes accountants, responsible for handling a portfolio of companies' returns, and pharmacists and analysts, responsible for policy issues.

Operation of the PPRS

The PPRS operates at the level of the individual company and regulates the overall profits made by the company from its sales of branded prescription medicines to the NHS. There is a common profit target, usually expressed as a return on capital (ROC) employed of 21% for assessing profits and 17% for assessing price increase applications. If a company exceeds its target profit by more than 40%, it must repay the excess to the Department and/or reduce prices. Where a company's profit is 50% or less of the ROC target, it may apply for a price increase to take it to 80% of the target.

Some companies that undertake little manufacturing or research in the UK may have insufficient capital in the UK in relation to their sales for it to be feasible to express their target in terms of return on capital. In these circumstances, companies may have their PPRS business assessed on a return on sales (ROS) basis.

The profit target does not guarantee that each company will achieve this profit and it exists only as a basis for assessing company profits made under the scheme and a framework within which companies set prices for their products.

Members of the scheme are expected to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads. 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 submitted under the scheme are reasonable in the light of commercial practice.

In assessing the reasonableness of a company's costs and assets, the Department examines:

- The trend in data submitted by the company over a number of years, and where applicable any special features
- Ratios inferred for the company's PPRS and non-PPRS business
- Data relating to other similar pharmaceutical companies and from external sources that relate to the pharmaceutical industry.

The 1999 scheme contains specific provisions for R&D, sales promotion costs and the recognition of UK fixed costs.

Research and Development: all companies that submit an AFR have an R&D allowance of 20% of NHS sales for assessing profits or 17% of NHS sales for assessing price increase applications, plus an additional 0.25% of NHS sales for each in-patent molecule with annual sales of more than £0.5 million, up to a limit of 12 molecules. These allowances (up to 23% of NHS sales) are available only where companies can demonstrate within the provisions of the scheme that the amounts claimed relate to expenditure actually incurred.

Sales promotion: there is a formula for the calculation of allowable sales promotion costs, which equates to an average of 7% of NHS sales for the assessment of profits and 4% for considering price increase applications.

UK fixed costs: companies are allowed to apportion to the NHS up to 7.5% of their total net UK based fixed assets (net of R&D capital) and UK based manufacturing costs before an apportionment is made between PPRS and non-PPRS assets and costs for the purposes of the scheme.

The text of the 1999 PPRS is available at www.dh.gov.uk/pprs

Submission and clearance of company financial returns

The 1999 PPRS specifies that companies are required to submit Annual Financial Returns (AFRs) to the Department within six, nine or eleven months after the end of the company's financial year. The date depends on the first letter of the company's name. In the majority of cases, this is at the end of the following June, September or November.

Table 1: Submission and clearance of company financial returns

Company financial years ending in calendar years shown	Annual Financial Returns		
	2002	2003	2004
Total number of AFRs	36	38	38
Received from companies by:			
June 2003	12	n/a	n/a
September 2003	24	n/a	n/a
November 2003	33	n/a	n/a
June 2004	36	13	n/a
September 2004	36	27	n/a
November 2004	36	36	n/a
June 2005	36	38	13
September 2005	36	38	22
November 2005	36	38	33
January 2006	36	38	35
Percentage not received 1 year after end of AFR year	6%	5%	11%
Cleared by the Department by:			
September 2003	6	n/a	n/a
November 2003	9	n/a	n/a
June 2004	30	0	n/a
September 2004	32	3	n/a
November 2004	35	4	n/a
June 2005	36	25	0
September 2005	36	30	1
November 2005	36	34	7
January 2006	36	35	15
Percentage cleared as % of number of companies	100%	92%	39%
Percentage cleared of AFRs received	100%	92%	43%

Three-quarters of companies submitted their 2003 AFRS on time but there was a significant increase in the average delay for those companies submitting late AFRs. The average delay increased to 57 days for 2003 AFRs from 43 days for 2002 AFRs and 23 days for 2001 AFRs. The increase was due mainly to two companies. Early indications show that this trend in late submissions has continued with an increase in delays for the submission of 2004 AFRs. The Department has raised its concerns with the ABPI.

The process of AFR clearance by the Department is taking longer with the average time taken increasing from an average of 183 days for 2001 and 2002 AFRs to 223 days for 2003 AFRs. The increase is due to the Department having to request from more companies information, which should have been submitted with the AFR (in some cases, requiring the submission of revised AFRs), and to question companies about the underlying assumptions and calculations in order to satisfy itself that it is in a position to make a valid judgement on companies' profitability. Two 2003 AFRs remain uncleared and are excluded from the above figures.

Outturn data

The contents of AFRs include commercially sensitive information, so it is not possible to publish detailed data on individual companies. Previous reports have included aggregated information for ROC and ROS companies from 1995 to 2002. This report updates that information with the results of the returns for 2003. The information submitted to the Department by companies is shown in the 'company' columns, whilst the 'outturn' columns show the position reached after assessment of the AFRs by the Department and negotiations with each company. The results of these analyses for 2003 are shown in tables 2 and 3 below along with the results for 2002. Note that the data for 2003 includes estimated figures for two companies, whose AFRs are not yet settled.

For 2003, for the 38 companies, which submitted AFRs, sales to the NHS were some £5.3 billion at the *factory gate* on which the industry made an assessed profit of £786 million.

Table 2: Summary aggregate data for ROC companies on PPRS capital, sales, costs and profit for 2002 and 2003

£,000s	2002		2003	
	Company	Outturn	Company	Outturn
Sales	2,882,422	2,882,422	3,094,510	3,094,510
Sales promotion	515,610	194,279	546,495	205,489
R&D	759,492	638,887	807,137	689,169
Other costs	1,917,825	1,521,435	2,217,502	1,693,651
Total costs	3,192,927	2,354,601	3,571,134	2,588,309
Total profit	(310,505)	527,821	(476,624)	506,201
Capital employed	3,693,188	2,559,969	3,399,701	2,570,003
Return on capital	(8.4%)	20.6%	(14.0%)	19.7%

Table 3: Summary aggregate data for ROS companies on PPRS sales, costs and profit for 2002 and 2003

£,000s	2002		2003	
	Company	Outturn	Company	Outturn
Sales	1,860,043	1,871,835	2,196,845	2,211,274
Sales promotion	234,876	131,464	303,111	153,911
R&D	312,024	383,268	357,141	436,175
Other costs	1,491,900	1,146,681	1,763,710	1,341,414
Total costs	2,038,800	1,661,413	2,423,962	1,931,500
Total profit	(178,757)	210,422	(227,117)	279,774
Return on Sales	(9.6%)	11.2%	(10.3%)	12.7%

Arbitration

Membership of the arbitration panel established under the 1999 PPRS agreement remains unchanged. Lord Peston of Mile End is the Chairman, Mr Ian Burns CB, a retired senior civil servant, is the Department's nominee on the panel and Dr Peter Read CBE, a former President of the ABPI, is the industry's nominee. For the first time, a matter has been referred to the arbitration panel to resolve a disagreement between the Department and one company concerning delivery of the full 4.5% price cut under the 1999 scheme.

4. Pricing

This chapter gives information on the price reductions and price increases under the PPRS.

4.5% Price reduction

With effect from 1 October 1999, scheme members were required to reduce the prices of their medicines covered by the PPRS by 4.5%. Subsequently no scheme member has increased the price of any medicine without the Department's prior approval.

Companies were allowed to achieve the 4.5% price reduction by variable reductions to the prices of different products (modulation) to achieve the overall reduction, or in some limited circumstances as specified in the scheme by cash repayment, provided that the overall effect of this was a price reduction of 4.5%.

With one exception, all companies have complied with their responsibilities to deliver the 4.5% price reduction and, where required, have provided audited data to confirm the value of their delivery. There has been a disagreement between the Department and one company regarding the delivery of the full 4.5% price reduction required under the 1999 PPRS. As the issue remains unresolved, the Department has referred the matter to the independent arbitration arrangements provided by the scheme.

During the sixty-three months ending 31st December 2004, the 4.5% price reduction has produced estimated savings to the NHS of £1.3 billion.

7% Price reduction

As part of the 2005 PPRS, scheme members were required to reduce prices of branded prescription medicines by 7% from 1 January 2005. It is estimated that the price reduction will deliver expenditure savings of £370 million a year for the NHS in England. All companies reduced prices as required under the scheme. Companies were required to submit audited data to the Department on the actual savings achieved in 2005 by the end of February 2006. The Department is currently analysing this data.

Price increases

The PPRS requires companies to seek the Department's agreement for price increases, which are only granted if the reasons for the application meet the criteria for increases set out in the agreement.

The price increases in table 4 are those agreed through the proper operation of the PPRS.

Table 4: Number and value of price increases 2001 to 2005

Year	Number of price increases (of which AFR companies)	Full year value of price increase (£ million)
2001	4 (0)	3.0
2002	2 (0)	0.1
2003	8 (0)	1.7
2004	9 (0)	4.7
2005	0	0

5. International Price Comparisons

This section compares the prices of branded medicines in the UK with a range of European countries and the USA. It updates the information included in the previous reports and is based on an annual exercise carried out by the Department of Health. It compares the prices of all preparations for the top 150 branded medicines⁵ in the UK with other countries, depending on the availability of matching preparations elsewhere⁶.

International price comparisons for medicines need to be interpreted with some caution, particularly when they are used to compare prices over time. The comparisons can be significantly affected by the relative level of sales in each country of the products used in the comparison, movement in exchange rates and the proportion (and mix) of medicines expenditure included in the analysis. These will vary from country to country and over time. Relative positions, particularly between European countries, will also be affected by the development of different price control policies in these countries. Annex B of the Second Report to Parliament gave a fuller account of these factors.

In addition, the prices used do not, in the main, take account of rebates paid by manufacturers in some countries as part of cost containment policies. This means that prices in some countries may be overstated relative to the true position.

Prices can be compared between the UK and one other country (a bilateral comparison) or between the UK and a number of other countries (a multilateral comparison). In practice, few medicines are available in the same form and strength in all countries, resulting in the multilateral comparison being based on a much smaller sample of medicines than with the bilateral comparisons. In some countries, the index is driven by price differences in a small number of brand/form/strength matches. The market coverage in this year's analysis ranged between 27% and 48% of expenditure in England on branded medicines, with a median coverage of 33%, a similar coverage to last year.

Previous reports showed that UK prices were in the middle range of the European countries in this study over the period 1992 to 1996 but the UK's position has changed since 1996, largely as a result of sterling appreciation. Last year we reported that the value of sterling had

5 More specifically, the data relates to all the branded products covered by the chemical name to which the top selling brands relate where there is a match for the form and strength. Rather than just taking the best selling brand for comparison, the analysis uses all matches found. The number of brands covered therefore exceeds the number of chemical entities covered (see footnote below). This method was used last year but differs from that in previous years.

6 For 2004, there were 1137 molecules for which data were available and at least one other country match for form and strength was found. This covered 211 brands (though some of these are not very significant in terms of sales).

depreciated against the Euro by about 9% since 2002 accounting for a large proportion of the change in the indexes from 2002 to 2003. However, the Euro exchange rate has been fairly stable from 2003 to 2004. This is not true for the position with respect to the USA where the fall in price relative to the UK from 2003 to 2004 is largely due to the depreciation of the dollar.

The bilateral comparisons, based on 2004 market exchange rates, showed the weighted index of prices in the UK to be:

- Significantly lower than those in the USA
- Higher than those in the other European comparator countries except Germany⁷ and Ireland, where prices are broadly comparable.

However, if the longer-term five-year average exchange rate is used UK prices remain significantly lower than those in the USA but are higher than all other European countries except Germany. This demonstrates the influence that exchange rates have on the estimates of price relativities.

Table 5: Bilateral comparisons of ex-manufacturer prices

Country	2000	2001	2002	2003	2004	5 year* average
France	80	81	81	91	84	78
Germany	91	94	95	102	106	98
Italy	79	82	86	90	78	72
Netherlands	81	84	88	93	92	86
Spain	64	67	75	81	80	74
UK	100	100	100	100	100	100
USA	209	217	201	190	176	192
Austria	77	81	86	94	94	87
Belgium	78	81	86	91	90	84
Finland	83	84	88	98	96	89
Ireland	83	88	93	N/A	99	N/A

* Uses 2004 price information but converted to sterling, for this comparison, using the average exchange rate for the period 2000–2004.

7 Note that these price relativities do not take account of refunds paid by manufacturers in Germany as part of cost containment policies.

Table 6: Multilateral comparisons of ex-manufacturer prices at market exchange rates

Country	2000	2001	2002	2003	2004	5 year* average
France	83	81	83	91	91	85
Germany	94	90	94	102	103	95
Italy	82	85	86	99	83	77
Netherlands	83	84	92	97	96	89
Spain	70	72	77	85	89	82
USA	241	205	194	189	175	192

* Uses 2004 price information but converted to sterling, for this comparison, using the average exchange rate for the period 2000-2004.

The figures are average prices and there exists a wide range of international price variances. Some UK prices for branded medicines are above the European average and some below. The price comparisons are based on 2004 data and do not take account of the 7% price reduction in the UK from 1 January 2005.

6. Contribution to the Economy

The global pharmaceutical industry's presence within the UK is a major aspect of our economy. The Government is determined to help the industry maintain its competitive advantage during a period of industry consolidation and increasing globalisation by creating a stable and competitive economic environment, and working in international settings for an environment favourable to a successful industry, which serves patients' needs. Highlights include:

- In 2004, the industry employed in excess of 73,000 people directly in the UK, with 27,000 working in R&D and with an estimated 250,000 employed in related activities.
- In 2004, the pharmaceutical industry invested over £3.2 billion in R&D or nearly £10 million a day. This investment represents around a quarter (24%) of the UK's total manufacturing industry expenditure on R&D, and accounts for 9% of global R&D spending.
- In 2004, the value of exports was an estimated £12.3 billion, creating a trade surplus of some £3.7 billion.
- Eighteen of the world's 75 top-selling medicines in 2004 were discovered and developed in the UK; only the U.S. accounts for a higher share.
- Research and development in the pharmaceutical sector has benefited from the extension of R&D tax credits to large companies. Since its inception, the tax credit has provided over £300 million for the pharmaceutical sector.
- The UK has a particularly successful biotech sector with UK companies accounting for 43% of products in late-stage clinical trials in Europe. There are around 455 specialist UK biotech companies employing nearly 22,500 people.
- The Department of Trade and Industry (DTI), the Department of Health and the BioIndustry Association (BIA) collaborated on the Bioscience Innovation and Growth Team (BIGT) initiative whose report 'Bioscience 2015' was published in November 2003, making recommendations on how the UK should secure its position as a global leader in bioscience. The Bioscience Leadership Council (BLC) took forward this work for two years; a smaller successor body will meet annually to review progress, leading to a mid-term BIGT review in 2007/8.
- The UK Government is increasing funding for NHS R&D by an additional £100 million a year by 2008. This investment underpins the UK Clinical Research Collaboration (UKCRC), a partnership between Government, the voluntary sector, patients and industry. UKCRC is building the research infrastructure, working to enhance clinical research careers, develop incentives for research in the NHS and streamline the regulatory and governance framework. The recently announced Department of Health R&D Strategy "Best Research for Best Health" sets out measures

to establish a world class environment for medical research, development and innovation, through a programme of investment and reforms which will enable medicines to be developed more quickly and more cheaply.

- The UK remains well-placed in terms of the number of patents filed per £ invested in R&D although there has been some evidence of pharmaceutical companies concentrating R&D investment in the US, the largest single national market.
- The Pharmaceutical Industry Competitiveness Task Force (PICTF) reported in March 2001 (available with subsequent publications on <http://www.advisorybodies.doh.gov.uk/pictf/index.htm>). Government/industry dialogue is continued through the Ministerial Industry Strategy Group (MISG). MISG's focus is on the discussion of strategic issues. It is taking a strategic look at the environment for the industry in 5-10 years through the Long Term Leadership Strategy. This aims to ensure that the UK remains an attractive option for the pharmaceutical industry.
- The Strategy is being taken forward through three workstreams:
 - Partnership Working Group – partnerships between the NHS and pharmaceutical industry
 - European Working Group – provide a mechanism for the Government and industry to develop proposals to assist the aims of the European Commission's Pharmaceutical Forum to improve European competitiveness.
 - Regulatory Working Group – looking at new methods for safe introduction of medicines and safety of licensed medicines, whilst maintaining patient access to innovative medicines.
- The model of PICTF was taken up at European level in the 'G10 High Level Group on Innovation and the Provision of Medicines' of which industry leaders and EU Member State Ministers are members. At the Health Council on 3 June, Commissioner Verheugen announced that the Commission would establish the Pharmaceutical Forum to look at those areas in the G10 report that have not been implemented, and to consider how to engage all Member States to achieve this. In addition, there will be a Steering Committee, which will facilitate, monitor and ensure progress.
- There will be three working groups on:
 - Public Private Partnership on Information to patients: to consider practical ways to improve information on medicines to the public
 - Pricing: to examine alternative pricing mechanisms to allow fast market access for new medicines and control of pharmaceutical budgets
 - Relative effectiveness: to examine potential areas for sharing experiences and building common approaches between Member States
- The UK was heavily involved in the G10 process, and endeavours to have an increased role in this new strategy, and be represented at all levels.

7. Office of Fair Trading Study into the PPRS

The Office of Fair Trading (OFT) announced a market study of the PPRS on 13 September 2005.

The remit of the study is to assess whether the scheme provides the most effective means of meeting its stated objectives, which are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices;
- Promote a strong and profitable pharmaceutical industry in the United Kingdom capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
- Encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The OFT has held stakeholder meetings with government, the NHS, industry associations, scheme members etc. It has also reviewed information submitted by scheme members to the Department under the PPRS.

Following the initial phase of the study, the OFT announced in March 2006 that it will continue with its study with a final report due to be published in the first quarter of 2007. The decision to continue with the study rather than to make a reference to the Competition Commission reflects the positive levels of cooperation received to date by the OFT from Government and industry.

Annex A

Summary of the 2005 Pharmaceutical Price Regulation Scheme

Objectives

The objectives of the 2005 Pharmaceutical Price Regulation Scheme (PPRS) continue to be to:

1. secure the provision of safe and effective medicines for the NHS at reasonable prices;
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;
3. encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

Term

The new scheme commenced on 1st January 2005 and will operate for at least five years subject to six months' notice of termination of the scheme by either party after 1st July 2007.

Entry to the Voluntary Scheme

Participation in the scheme is open to companies (usually marketing authorisation holders or those that discharge the obligations of marketing authorisation holders) supplying branded licensed NHS medicines. Companies need not be ABPI members.

Exit from the Scheme

A company may leave the voluntary scheme at any time. A company that is clearly non-compliant, or that fails to implement a decision of the arbitrator, will cease to be a member of the voluntary scheme. A company may re-enter the voluntary scheme provided all its obligations under the scheme have been fully discharged.

Scope

The scheme applies to all branded licensed prescription medicines sold to the NHS with the exception of 'standard' branded generics, which subject to public consultation, will no longer be covered by the PPRS and will be transferred to the new arrangements for the reimbursement of generic medicines. A 'standard' branded generic is defined as an out of patent product to which the manufacturer/supplier, who is not the originator company, has applied a brand name and that is directly comparable to a true generic that is readily available.

Price Reduction

Companies with sales of branded prescription medicines to the NHS above £1 million in 2004 were required to reduce prices by 7% from 1 January 2005. Thereafter, no price may increase before 31st December 2005. The price cut applies to the NHS list price of all products covered by the scheme on the market at 31st December 2004. For companies with NHS home sales of £10 million or less in that year, the first £1 million of sales are exempt from the price cut. Alternatively, companies may make variable reductions (price modulation) provided that the company can show that the aggregate effect is equivalent to an overall reduction of 7%. Scheme members may opt to deliver up to 2% of the price cut by making a payment to the Department.

Allocation of Costs and Capital

In the audited annual financial return (AFR), companies are required to indicate for each cost and capital item the bases of allocation between Home, Export and Other Products. In addition, scheme members will include in the 'NHS Medicines Home costs claimed' column only those costs that it is expected that the Department will accept rather than costs irrespective of limitations to R&D, marketing and information.

Limitation of Costs and Assets

As in previous schemes, the Department will need to satisfy itself that the costs incurred and assets employed by companies are reasonable in all the circumstances.

Profit Target

All scheme members have a common Return on Capital (ROC) target of 21%. For those scheme members, who are assessed on a Return on Sales (ROS) basis, the target is 6%.

Margin of Tolerance

The upper margin of tolerance remains at 140% of the target return on capital and the lower margin of tolerance at 40%. Where a company's profit falls short of 40% of target, it may apply for a price increase to achieve 65% of the ROC target.

Transfer Prices

Where possible, scheme members should provide an audited breakdown of their transfer prices from overseas affiliates. If they cannot, but can confirm that the prices have been reported to be at arm's length for tax purposes, a default breakdown will be applied. In such cases, the Department will assume that transfer prices comprise 59% manufacturing, 21% research and development (R&D) and 20% profit. Where the default breakdown is applied, the maximum acceptable manufacturing costs i.e. total cost of goods sold will be restricted to 45% of home NHS sales.

Research and Development

The R&D allowance is increased to a maximum of 28% of NHS sales. It comprises three elements:

1. Flat rate – up to 20% of the value of NHS home sales for assessing profits (up to 15% for assessing price increase applications).
2. Variable rate for innovation – up to 5% of NHS home sales (0.25% of NHS home sales for each in-patent active substance protected by a basic preparation patent (and SPC where one exists) above a threshold of £300,000 of NHS home sales a year up to a limit of 20 active substances. Or for a period of 10 years after the grant of the first marketing authorisation for a new active substance where no patent exists).
3. Variable rate for paediatrics – 1% of NHS home sales in the year in which a product is first generally available on prescription in the UK under the terms of a marketing authorisation that includes a paediatric indication, up to a limit of three products in any one year (not for assessing price increase applications).

Marketing Allowance

The marketing allowance is calculated for each company on the following basis:

- Standard element of up to 4% of home sales of NHS medicines for assessing profits (2% for price increases);
- A fixed element of £1 million for assessing profits (£500,000 for price increases);
- Product servicing allowance for each active substance with sales to the NHS of £100,000 or more. 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.

Information Allowance

The information allowance is calculated for each company as a maximum of 4% of home sales of NHS medicines for assessing profits (2% for price increases).

New Product Pricing

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.

Products Sold On

Where one company proposes to transfer a PPRS product to another, the transferring company must inform the Department. The acquiring company may not increase the price for three months. Thereafter, it may apply for an increase, although this may have to be phased.

AFR Submission

Companies with relevant turnover above the threshold of £25 million are required to submit AFRs. Companies below £25 million may be required to submit an AFR when it appears to be necessary, and generally will be required to do so in the event of a price increase application.

Companies with NHS home sales below £5 million are not normally required to submit any financial information to the Department.

Other Provisions

Other provisions, including price restraint and recognition of UK Fixed Assets and Costs are broadly similar to the 1999 Scheme.

Arbitration

Disputes between a company and the Department (on such matters as agreeing an AFR outturn) may be referred by either party to an independent arbitration panel. The decision of the arbitrator will not constitute a precedent for future referrals.

The Alternative

Companies that choose not to become members of the 2005 PPRS will be subject to the statutory price control under section 34 of the Health Act 1999.

PPRS: GLOSSARY OF TERMS

R&D	Research and Development
ROC	Return on Capital
ROS	Return on Sales
AFR	Annual Financial Return
Upper Margin of Tolerance	The area in the agreement where companies can retain additional profit.
Lower Margin of Tolerance	The threshold below which profit levels need to drop before price rises will be considered.
Transfer Prices	Charges for products, ingredients or other services made by an overseas affiliate to a UK-based company.

Annex B

Scheme Members of the 2005 PPRS

3M	Boehringer Ingelheim
A.Menarini Pharma	Borg Medicare
Abbott Laboratories Ltd	Bracco UK Limited
Acorus Therapeutics Ltd	Bristol-Myers Squibb
Actelion Pharmaceuticals UK Ltd	Britannia Pharmaceuticals Ltd
Alcon Laboratories (UK) Ltd	Cambridge Laboratories Ltd
Alk-Abello (UK)	Castlemead Healthcare Ltd
Allergan Ltd	Cephalon UK
Allergy Therapeutics Ltd	Chemidex Pharma Ltd
Alliance Pharmaceuticals Ltd	Chiron Biopharmaceuticals Ltd
Alpharma Pharmaceuticals Ltd	Chiron Vaccines Ltd
Alphashow Ltd	Chugai Pharma UK Ltd
Altana Pharma Ltd	Clinimed Ltd
Amdipharm Plc	Concord Pharmaceuticals Ltd
Amersham Plc	CP Pharmaceuticals Ltd
Amgen Ltd	Crookes Healthcare Ltd
Ardana Bioscience Ltd	Deproco Ltd
Arden Healthcare Ltd	Derma UK
Ashbourne Pharmaceuticals Ltd	Dermal Laboratories
Astellas	Dexcel Pharma Ltd
AstraZeneca	Discovery Pharmaceuticals
B. Braun Medical Ltd	Dr Faulk Pharma UK Ltd
Baxter Healthcare Ltd	EC De Witt & Company Ltd
Bayer Plc	Ecolab
Beacon Pharmaceuticals	Eisai Ltd
Beiersdorf UK Ltd	Elan Pharma Ltd
Bioenvision Ltd	Eli Lilly & Company Ltd
Biogen Limited	Exelgyn Laboratories
BioMarin Europe Ltd	Ferndale Pharmaceuticals Ltd

Ferring Laboratories Ltd	Lundbeck
Florizel Ltd	Martindale Pharmaceuticals
Flynn Pharmaceuticals Ltd	MASTA Ltd
Forest Laboratories UK	Meda Pharmaceuticals
Fournier Pharmaceuticals Ltd	Merck Pharmaceuticals
Fresenius Kabi Ltd	Merck, Sharp & Dohme Ltd
Galderma (UK) Ltd	Napp Pharmaceutical Holdings
Galen Ltd	Neolab Limited
GE Healthcare	Nordic Pharma
Geistlich & Sons Ltd	Norgine Pharmaceuticals Ltd
Generics (UK) Ltd	Novartis Consumer Health
Genus Pharmaceuticals	Novartis Pharmaceuticals Ltd
Genzyme Therapeutics	Novex Pharma Ltd
Gilead Science Ltd	Novo Nordisk
GlaxoSmithKline	Nycomed UK Limited
GlaxoSmithKline Consumer Healthcare	Organon Laboratories Ltd
Glenwood Laboratories Ltd	Orion Pharma
Goldshield Group plc	Orphan Europe (UK) Ltd
Grifols UK Ltd	Paines & Byrne Ltd
Grunenthal Ltd	Pantheon Healthcare Ltd
Hansam Healthcare Ltd	Peckforton Pharmaceuticals Ltd
Hawgreen Ltd	Pfizer Ltd
Helios Healthcare Ltd	Pharmion Limited
HK Pharma Ltd	Pierre Fabre Ltd
INO Therapeutics	PLIVA Pharma Ltd
Intrapharm Laboratories Ltd	Procter & Gamble
Ipsen Ltd	Profile Pharma Ltd
IVAX Pharmaceuticals UK Ltd	ProStrakan Pharmaceuticals Ltd
Janssen-Cilag	Provalis Healthcare Ltd
JHC Healthcare Ltd	Ranbaxy (UK) Ltd
Kestrel Ophthalmics Ltd	Recordati Pharmaceuticals Limited
King Pharmaceuticals Ltd	Resource Medical UK Ltd
Kyowa Hakko UK Ltd	Roche
LABS Ltd	Rosemont Pharmaceuticals Ltd
Leo Pharmaceuticals Ltd	Sandoz Ltd
Link Pharmaceuticals Ltd	Sankyo Pharma UK Ltd

Sanochemia UK Ltd
Sanofi Pasteur MSD
Sanofi-Aventis
Schering Health Care Ltd
Schering Plough Ltd
Schwarz Pharma
Serono Pharmaceuticals Ltd
Servier Laboratories
Seven Seas Ltd
Shire Pharmaceuticals Ltd
Smith & Nephew Healthcare Ltd
Solvay Healthcare Ltd
Sovereign Medical
SSL International plc
STD Pharmaceuticals Ltd
Stiefel Laboratories (UK) Ltd
Strakan Pharmaceuticals Ltd
Syner-Med
Takeda UK Ltd
Thornton & Ross Limited
Tillomed Laboratories Ltd
Transdermal Ltd
Trinity-Chiesi Pharmaceuticals Ltd
Tyco Healthcare
Typharm Ltd
UCB Pharma Ltd
Valeant Pharmaceuticals International
Vitaline Pharmaceuticals UK Ltd
William Ranson & Son Plc
Wyeth
Zeneus Pharma Ltd
Zeroderma Limited
ZLB Behring UK Limited



© Crown copyright 2006
275889 1p 350 July 06 (CWP)
Produced by COI for the Department of Health

Copies available from
Department of Health,
Pricing and Supply,
456D Skipton House,
80 London Road,
London SE1 6LH.
Email: Jamilla.Rogers-Wright@dh.gsi.gov.uk

Tel: 020 7972 2827
Fax: 020 7972 2932

Also available on the department's website at www.dh.gov.uk/pprs

275889/*Pharmaceutical Price Regulation Scheme* can also be made available on request in braille, on audio cassette tape, on disk and in large print.

www.dh.gov.uk/publications