Understanding the 2005 PPRS

Industry briefing

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Medicines for a healthy future

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The Pharmaceutical Price Regulation Scheme

The pharmaceutical industry plays a key part in enhancing both the health and wealth of the UK. Over the years, patients in the National Health Service have been major beneficiaries of the many therapeutic advances made by the pharmaceutical companies operating in this country.

The Health Departments of the United Kingdom and the Association of the British Pharmaceutical Industry have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the NHS and in maintaining a strong, efficient and profitable pharmaceutical industry in the United Kingdom.

To ensure the future availability of new and improved medicines in this and other countries, the industry must be capable of sustained research and development.

The Pharmaceutical Price Regulation Scheme is a voluntary agreement between the Government and the pharmaceutical industry aiming to create an environment where both these objectives can be achieved.

The Scheme was introduced in 1957 and is generally renewed every five or six years. The current Scheme runs for five years from January 2005.

The PPRS has played a significant role in the relationship between the industry, the NHS and the wider economy since its introduction in the early days of the NHS, but its mechanisms are complex and have not always been set out clearly and perhaps not widely understood.

Understanding the 2005 PPRS aims to outline the rationale behind the Pharmaceutical Price Regulation Scheme and to give a broad outline of the structure and working of the current agreement introduced in January 2005. The precise workings of the Scheme are complex – the full text of the 2005 PPRS is available on the Department of Health’s website at www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/PharmaceuticalPriceRegulationScheme/ThePPRSScheme.

THE HISTORY OF THE PPRS

The transformation of the original Voluntary Price Regulation Scheme, first agreed in 1957, into the modern PPRS began during Labour’s administration in the 1960s. An inquiry chaired by Lord Sainsbury established the principle of limiting the profits made on NHS medicines by identifying the relevant capital employed, restricting the associated costs and limiting the allowable return.

The PPRS has remained a negotiated agreement between the ABPI and the Department of Health, rather than a statutory arrangement, though the Secretary of State for Health has powers to invoke a statutory scheme.

Subsequent versions of the Pharmaceutical Price Regulation Scheme introduced progressively more sophisticated ways of regulating promotional spending and other costs, including those incurred outside the UK in relation to the production of NHS medicines. In the early 1990s, the Scheme was further changed to exclude the supply of generic medicines. This shift reflected NHS developments such as the creation of enhanced financial incentives for prescribers, practices and hospitals to minimise their medicine costs.

The Health Act 1999 gave the Government reserve powers independent of the PPRS to intervene if and when necessary to control NHS pharmaceutical prices and profits.

The 2005 Scheme increases the level at which companies routinely have to report financial data, eliminating some small companies from the whole process, except that their prices may only be increased after prior agreement with the Department of Health.
The value of the pharmaceutical industry

For many years Britain has been a world leader in the development of new medicines. A quarter of the world’s top medicines were discovered and developed in British laboratories – second only to the USA and as many as the rest of Europe put together.

Yet the UK’s spending on medicines is low compared to the value of medicines discovered and produced here, and lower than in most other countries in Europe, although the Government has set a target in its NHS Plan of raising health expenditure in Britain to the European average by the year 2008.

Sales share of the world’s top 100 prescription medicines 2004

- USA - 49%
- UK - 24%
- Switzerland - 13%
- France - 6%
- Japan - 5%
- Germany - 3%

Annual sales of medicines per person 2003

The objectives of the PPRS

The objectives of the PPRS, agreed between the Government and industry, are 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 expenditure 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 applies across the four nations of the United Kingdom. The UK Health Departments do not support additional or alternative initiatives by local Health Authorities in respect of the pricing of branded prescription medicines in primary care.

In essence, the PPRS operates by restricting each company’s profit to a target Return on Capital Employed (ROCE), after taking into account a series of allowances for expenses including research, marketing and administration. But profits are not guaranteed and there are tight restrictions on the circumstances in which the prices of medicines may be increased.

NHS MEDICINES SPENDING

The annual cost of the NHS across the UK is around £85 billion (2004). Of this, the greatest proportion – about two-thirds – goes on salaries and other staff costs. Health service expenditure on medicines stands at around £10.7 billion - about 12.5 per cent of the total NHS bill.

More prescriptions are being issued every year. Over the past decade, the annual number of prescription items per person in the UK has risen from 9 to more than 12.

A range of factors affect the growth in the number and cost of prescriptions.

• The introduction of innovative new medicines, creating fresh treatment opportunities for previously untreatable conditions, and bringing improvements on existing treatments
• An ageing population, leading to a greater number of people needing both short and long term medical care
• An increasing number of patients treated, with less use of institutional care and in-patient therapy and more interventions such as day surgery, often made possible through the use of medicines.

Modern healthcare relies increasingly on a greater use of medicines to prevent or treat early-stage illness and to reduce the need for more costly and radical forms of treatment such as surgery.
Companies operating within the PPRS are in competition to supply an increasingly cost-conscious NHS. Market forces ensure that their costs and prices are held down. No company in the PPRS is guaranteed its target earnings, and less efficient companies or those with less successful products cannot simply put up their prices in an attempt to achieve their allowable profits. Apart from the restraints put on price rises by the PPRS itself, such companies would incur further competitive disadvantage against their commercial rivals.

Under the agreement, companies may charge up to 4 per cent of turnover to marketing expenses and a further 4 per cent for information expenses, such as the provision of information to health professionals, government and health technology bodies and where appropriate, non-product specific information to patients and the public.

Appropriate expenditure on providing information on new medicines is not only in the interest of innovative pharmaceutical companies, but in the public interest too. The healthcare professionals who work in the Trusts in England, the Health Boards in Scotland, the Local Health Boards and Trusts in Wales and in the Health Boards in Northern Ireland can serve their patients better if they have access to the latest information about new medicines. Clearly, the company that has discovered and developed a medicine is the primary source of expertise as to its characteristics and use.

In other countries in the EU, different methods are used to control the prices of medicines and to influence their use. Typically, dossiers on costs and product benefits relating to individual products have to be submitted to Government-appointed committees. The committees consider whether a proposed price should or should not be approved. In some countries, price levels elsewhere in Europe are taken into account; in others, the price of competitor products available domestically is a critical issue.

The system in the UK is different in that it leaves innovators free to price new products at market-determined levels, but within the overall constraints of a company’s PPRS profit cap.

*International R&D investment*
Market share for products launched in the previous five years (International)

SOME STATISTICS ABOUT THE PHARMACEUTICAL INDUSTRY

• Medicines account for only about 12.5 per cent of total NHS costs, despite a constant growth in the number of prescriptions issued.

• Modern medicines offer good value for money - in real terms, NHS medicines prices are 18 per cent lower than ten years ago.

• Around a third of total UK pharmaceutical industry sales returns is reinvested in research and development - three times more than any other industry sector in the UK. Highly skilled R&D staff make up a large proportion of the total industry workforce. Although medicines undergo a long and complex development process, the finished products are relatively easy to copy, and so they are different in their nature from other ‘high-tech’ products such as aircraft, which typically have many thousands of discrete parts.

• The average return for pharmaceutical companies on their NHS sales, 17 to 18 per cent return on capital, is in line with the average profit of leading UK companies in other sectors.
The mechanisms of the PPRS

The PPRS covers all branded NHS medicines. For this purpose, a branded NHS medicine is a human pharmaceutical product for which a marketing authorisation has been granted and to which the proprietor applies a brand name that enables the product to be identified without reference to its generic name. The situation regarding the application of the PPRS to certain branded generic products has yet to be decided.

Membership of the PPRS is not confined to members of the ABPI. Any supplier of NHS medicines may join the Scheme. A company may choose not to become a member, or may be excluded by the Secretary of State for Health if, for example, it has failed to comply with the requirements of the Scheme. In such circumstances, the Health Act 1999 empowers the Secretary of State for Health to apply a statutory scheme and to limit prices and impose price reductions. Members of the PPRS are exempt from such statutory powers.

Annual Financial Return

The core reporting mechanism of the PPRS is the Annual Financial Return (AFR), a set of audited accounts in a prescribed format, comprising primarily a profit and loss account and balance sheet. This must be submitted annually by companies with a relevant turnover of more than £25m, together with their published statutory accounts, to which the AFR must be reconciled. In the case of subsidiaries of overseas companies, the published accounts of the ultimate holding company must also be submitted. Companies with a turnover below £25m may be required to submit an AFR if the Department of Health is of the view that circumstances warrant it.

The AFR is used as the basis of assessment of the revenues, costs, profits and net capital employed appropriate to the supply of medicines to the NHS, as distinct from export and other business.

Measuring Profits

The PPRS sets a ceiling on companies’ profits on NHS sales, but does not guarantee them.

Scheme members are subject to a profit cap of 21 per cent, measured as the return on net capital employed (ROCE). Fixed assets are valued on a historical cost basis. Companies with low capital bases are subject to an equivalent cap on return on sales (ROS).

In the assessment of a Scheme member’s profit for the year, almost all cost categories are restricted. Research and development, marketing and information expenses are capped at published percentage levels; other cost categories may be restricted by negotiation. Disallowed costs are added back to profit, with the result that the assessed PPRS profit is generally higher than the profit reported by the Scheme member.

A Scheme member whose assessed profit exceeds the cap by more than 40 per cent (the upper margin of tolerance) is required to repay the excess or reduce prices by an equivalent sum. The upper margin of tolerance is not available in a year in which the member has been granted a price increase i.e. repayment applies at the lower level. Only if a member’s assessed profit falls short of the cap by more than 60 per cent (the lower margin of tolerance) may it apply for a price increase.

Price changes

No PPRS member, irrespective of size of turnover, may increase the price of an NHS medicine without the prior approval of the Department of Health.

The 2005 Scheme imposed a price reduction on all members with a relevant turnover of more than £1m. For members whose turnover exceeds £10m, the level of the reduction was 7 per cent. The price reduction on individual products may be applied differentially, some products being reduced by more and others by less, but audited reporting systems are in place to ensure that each member’s reduction amounts to the equivalent of 7 per cent across its product range.

Monitoring and enforcing the Scheme

In addition to the audited financial reporting arrangements, the PPRS provides for regular consultation between the Association of the British Pharmaceutical Industry, representing the Scheme members, and the Department of Health, representing the four United Kingdom Health Departments, as well as an arbitration process and an annual report to Parliament, available on the Department’s website (see page 6).

A formal review of the PPRS may be conducted by agreement midway through the term of the current Scheme, in mid 2007.
Prospects for the future

Since the agreement of the 1999 Pharmaceutical Price Regulation Scheme, the NHS has continued to undergo constant change, and the 2005 Scheme has been modernised to reflect this. In economic terms, the PPRS acts on the supply side of the NHS medicine cost equation. On the demand side, innovations have increased the ability of the NHS to purchase medicines in a more cost-sensitive way.

Some of these developments are listed below.

• The National Institute for Clinical Excellence (NICE), which assesses the value of medicines and issues guidance on best practice, with a focus on cost-effectiveness. NICE has a major potential influence in encouraging or discourageing the use and availability of medicines.

• The growth of a new NHS culture more sympathetic to concepts such as evidence-based medicine, the increasing use of properly-developed clinical guidelines, and the value of cost-effectiveness and other forms of economic analysis in the provision of healthcare.

• The emergence of distinct health policies in Scotland, Wales and Northern Ireland. This will influence how health provision is delivered in all four countries. However, the 2005 PPRS applies equally to all four health services.

• Changes in the organisation of primary care and the introduction of local prescribing incentive schemes. The latter offers practices financial rewards for keeping medicines costs down, creating pressures on prescribers to economise.

• Generic prescribing targets. Around three-quarters of all NHS prescriptions are written generically, compared with about a third in the mid 1980s. The PPRS does not cover generic medicines.

NHS prescriptions dispensed in the United Kingdom

<table>
<thead>
<tr>
<th>Year</th>
<th>Prescriptions millions</th>
<th>Prescriptions per head</th>
<th>Net Ingredient Cost £m</th>
<th>£ per head</th>
<th>Net Ingredient Cost £ per prescription</th>
<th>Total cost £m</th>
<th>Total cost £ per head</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>393.1</td>
<td>6.9</td>
<td>1,536</td>
<td>27.06</td>
<td>3.91</td>
<td>1,875</td>
<td>33.15</td>
</tr>
<tr>
<td>1990</td>
<td>446.6</td>
<td>7.8</td>
<td>2,563</td>
<td>44.78</td>
<td>5.74</td>
<td>2,984</td>
<td>52.13</td>
</tr>
<tr>
<td>1995</td>
<td>544.8</td>
<td>9.3</td>
<td>4,179</td>
<td>72.14</td>
<td>7.67</td>
<td>4,711</td>
<td>81.33</td>
</tr>
<tr>
<td>2000</td>
<td>637.5</td>
<td>10.7</td>
<td>6,335</td>
<td>108.03</td>
<td>9.94</td>
<td>6,723</td>
<td>114.64</td>
</tr>
<tr>
<td>2001</td>
<td>676.7</td>
<td>11.3</td>
<td>6,920</td>
<td>117.61</td>
<td>10.23</td>
<td>7,299</td>
<td>124.06</td>
</tr>
<tr>
<td>2002</td>
<td>712.2</td>
<td>12.1</td>
<td>7,723</td>
<td>130.88</td>
<td>10.84</td>
<td>8,059</td>
<td>136.57</td>
</tr>
<tr>
<td>2003</td>
<td>748.8</td>
<td>12.7</td>
<td>8,487</td>
<td>142.81</td>
<td>11.33</td>
<td>8,787</td>
<td>147.86</td>
</tr>
<tr>
<td>2004</td>
<td>789.3</td>
<td>13.2</td>
<td>9,110</td>
<td>152.37</td>
<td>11.54</td>
<td>9,442</td>
<td>157.93</td>
</tr>
</tbody>
</table>
The United Kingdom is a major player in the world’s pharmaceutical sector in terms of research, manufacturing and exporting, despite relatively low spending on medicines in its National Health Service. The pharmaceutical industry contributes more than £3.4 billion in trade surplus to the UK economy, directly providing more than 73,000 jobs, especially in the high technology area.

A wide range of factors influences the competitiveness of the pharmaceutical industry in the UK, and the Department of Health recognises that effective policies need to be developed to continue the industry’s success. For its part, the industry recognises that it is in the public interest that the prices of pharmaceutical products supplied under the NHS are fair and reasonable. The PPRS aims to encourage the pharmaceutical industry in its research and development work to deliver new and improved medicines for patients, especially for children, for example. The five-year agreement offers a degree of stability that is essential to an industry that works very much in the long term.

The 2005 Pharmaceutical Price Regulation Scheme covers a broad range of objectives, with the overall aim of achieving more effective and efficient healthcare in the UK and bringing significant benefits to patients, the NHS and the pharmaceutical industry.

**Conclusion**

**R&D Expenditure in the UK by the pharmaceutical industry**

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditure £ million</th>
<th>Pharma R&amp;D as a % of turnover</th>
<th>Pharma R&amp;D as a % of all industry R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>546</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>1990</td>
<td>1,140</td>
<td>17</td>
<td>14</td>
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<tr>
<td>1995</td>
<td>1,813</td>
<td>19</td>
<td>20</td>
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<td>2000</td>
<td>2,846</td>
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<td>25</td>
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<td>2001</td>
<td>3,040</td>
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<tr>
<td>2003</td>
<td>3,241</td>
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<td>24</td>
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