UNDERSTANDING THE 2009 PPRS

INDUSTRY BRIEFING

CONTENTS

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THE PHARMACEUTICAL PRICE REGULATION SCHEME

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 medicines supplied to the NHS 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. However, the Department of Health has also published a new statutory scheme to control the prices of branded NHS medicines alongside the latest voluntary scheme.

Subsequent versions on 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 2005 Scheme increased the level at which companies routinely had to report financial data, eliminating some small companies from the whole process, except that their prices could only be increased after prior agreement with the Department of Health.

The 2009 Scheme contains a number of initiatives aimed at encouraging and rewarding innovation to continue to provide a choice of treatments for the benefit of patients and assisting the uptake of new medicines. The Department and the ABPI have agreed mechanisms on flexible pricing and patient access schemes which aim at better reflecting the value of medicines.

A new Statutory Scheme – The Health Service Branded Medicines (Control Of Prices And Supply Of Information) (No. 2) Regulations 2008) – is also in place for companies who are members of the voluntary PPRS.

The pharmaceutical industry plays a key role 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 in 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 first introduced in 1957 and is generally renewed every five years or so. The current Scheme runs for five years from January 2009.

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

Understanding the 2009 PPRS aims to describe 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 2009. The precise workings of the Scheme are complex, and the full text of the 2009 PPRS is available on the Department of Health's website at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825

THE VALUE OF THE PHARMACEUTICAL INDUSTRY

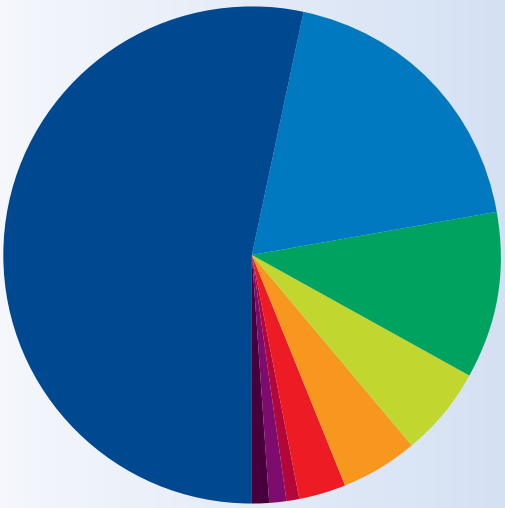
For many years the UK has been a world leader in the development of new medicines. A fifth of the world's top medicines were discovered in British laboratories – second only to the USA and as many as the rest of Europe put together.

Yet medicines spending in this country is low compared to the value of medicines discovered and developed here, and lower than in most other countries in the rest of Europe. The Government has set a target in its NHS Plan of raising health expenditure in Britain to the European average.

Currently, the pharmaceutical sector invests £10.6m a day in the research and development of medicines – nine per cent of the worldwide total. In 2007, the pharmaceutical industry contributed £4.3bn to the UK trade surplus.

Employment in the sector was about 67,000 in 2007. Among those employed by the industry are scientists that have historically been a strength of the UK, particularly those with skills associated with the discovery and development of new medicines.

SALES SHARE OF THE TOP 100 PRESCRIPTION MEDICINES 2007



USA	54%
GREAT BRITAIN	19%
CHINA	11%
JAPAN	6%
FRANCE	5%
GERMANY	3%
BELGIUM	1%
DENMARK	1%
ISRAEL	1%

THE OBJECTIVES OF THE PPRS

The Health Departments of the United Kingdom and the ABPI have a common interest in ensuring that safe and effective medicines are available at reasonable terms to the NHS and in a strong, efficient and profitable pharmaceutical industry.

The Scheme aims to strike a balance to ensure that the interests of patients, the NHS, industry and the taxpayer are promoted for each other's mutual benefit. The objectives of the Scheme are that it should:

- **Promote access and uptake for new medicines**
  The Department and industry are committed to increasing uptake and patient access for new clinically and cost effective medicines in the NHS in a sustainable manner.

- **Deliver value for money**
  The PPRS must deliver value for money for the NHS by securing the provision of safe and affective medicines at reasonable prices, and encouraging the efficient development and competitive supply of medicines.

- **Encourage innovation**
  The Scheme aims to promote a strong and profitable pharmaceutical industry that is both capable and willing to invest sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and industry in this and other countries.

- **Provide stability, sustainability and predictability**
  To help the NHS and industry develop sustainable financial and investment strategies, the UK must remain a stable and predictable market that does not place unforeseen burdens on either party over the coming years.

NHS MEDICINES SPENDING

The annual cost of the NHS across the UK is around £105 billion (2007). The greatest proportion of this goes on salaries and other staff costs. Health service expenditure on medicines stands at around £10.8 billion – about 10.3 per cent of the total NHS bill.

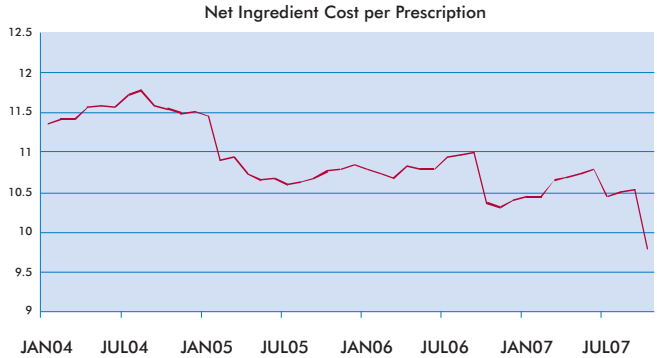
More prescriptions are being issued every year. Over the past decade, the annual total of prescription items per person in the UK has risen from 10 to more than 15.

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

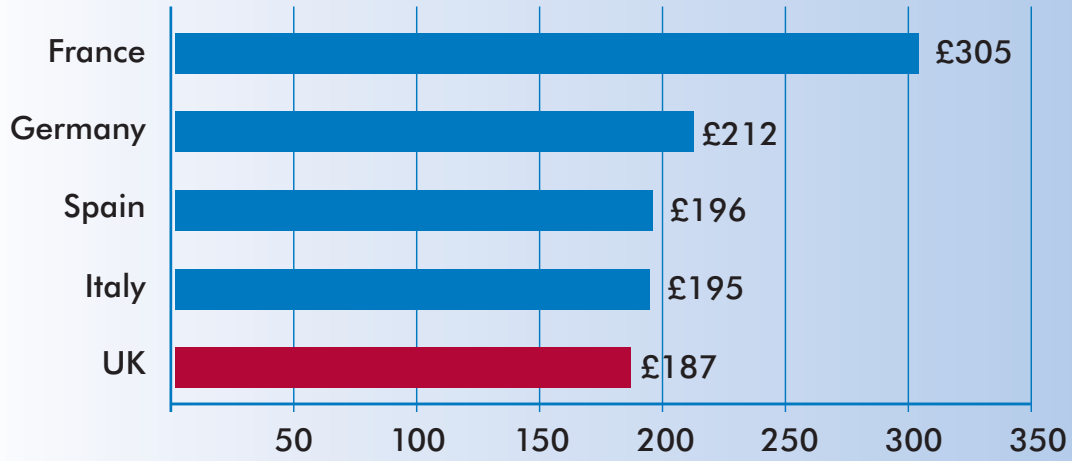
- The introduction of innovative new medicines, creating fresh treatment opportunities for previously untreatable conditions, and bringing improved existing treatments.
- An ageing population, leading to a greater number of people needing both short and long term medical care.
- An increasing number 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.

At the same time, the average net ingredient cost of medicines has actually fallen over the past few years.

Modern healthcare relies increasingly on a greater use of medicines to prevent or treat early-stage illness and to limit the need for more costly and radical forms of treatment such as surgery.

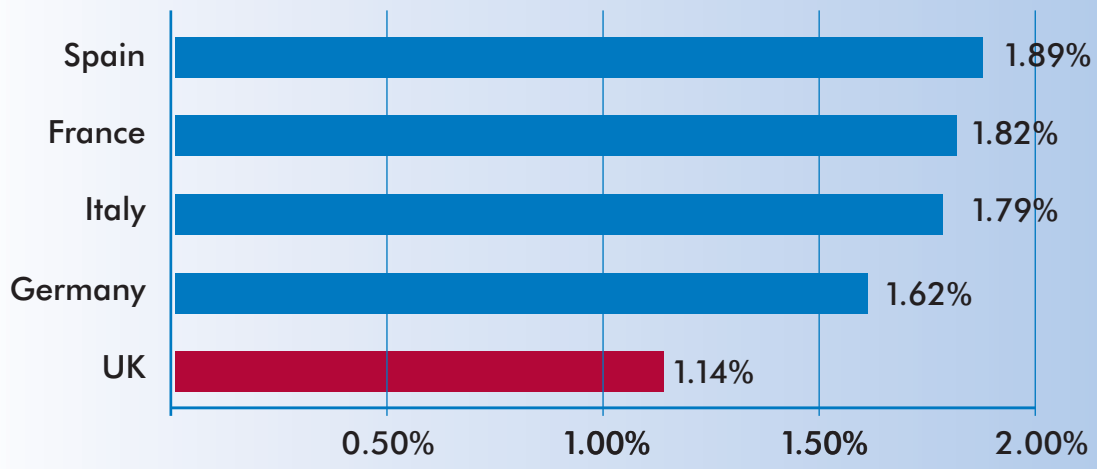


MEDICINES SPEND PER HEAD (2006)



Source: ABPI estimate from 2006 IMS World Review

MEDICINES EXPENDITURE AS % OF GDP (2005)



Source: ABPI estimate from 2006 IMS World Review

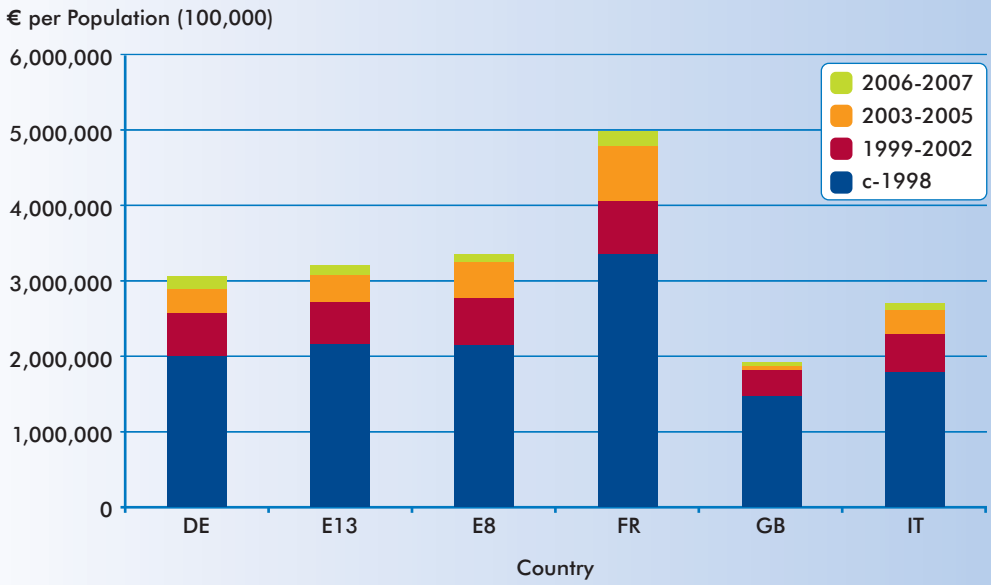
PROMOTING ACCESS AND UPTAKE FOR NEW MEDICINES

The Department of Health will refresh and extend good practice guidance in England so that it is clear that absence of NICE guidance is not a reason for refusing funding. Medicines should be provided in the NHS on the basis of clinical need and cost-effectiveness where no guidance exists.

The Government remains fully committed to ensuring NHS implementation of NICE Technology Appraisals, and will ensure that there is consistency between NICE recommendations and broader policy on the NHS. Industry and the Department of Health will work together to define a set of measures that allow comparison of the uptake of all new medicines with major EU economies and provide international benchmarks and trends for the uptake of NICE approved technologies.

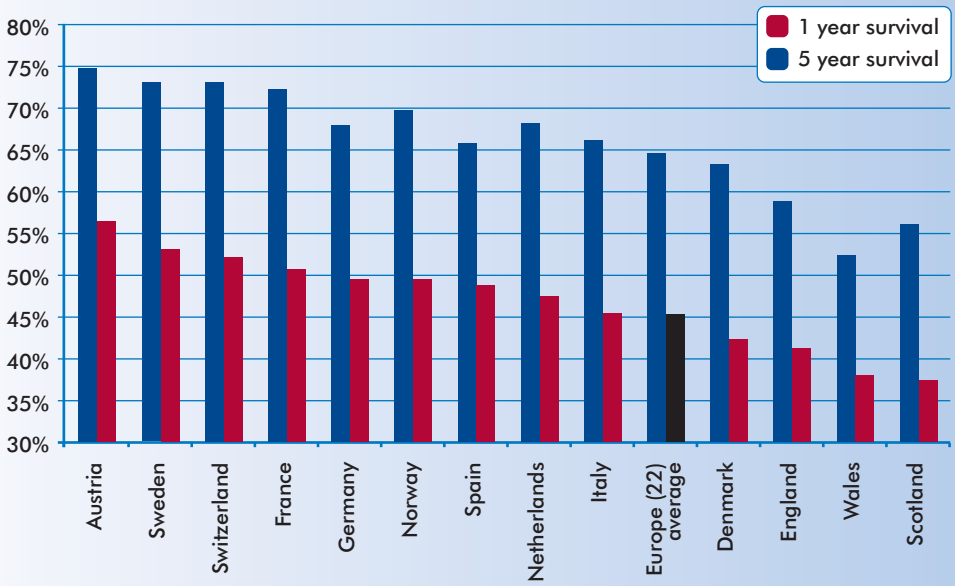
Take cancer for example:
The UK medicines spend is lower than comparable European countries as shown in the graph below.

SALES OF CANCER DRUGS IN 2007 IN E13, FRANCE, GERMANY, ITALY, SPAIN AND THE UK, IN (€)/100,000

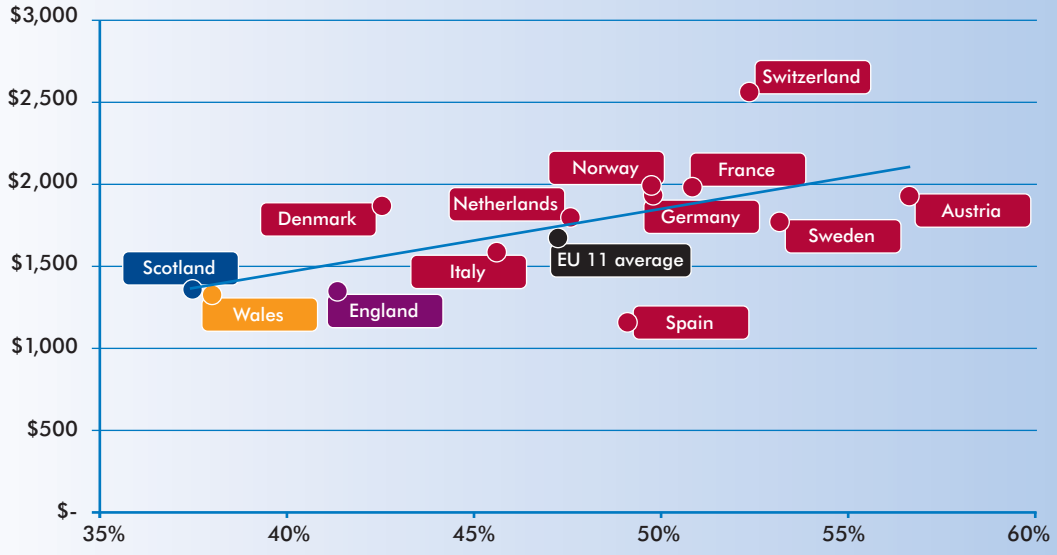


Patients outcomes are also low, as shown in the chart below:

ALL CANCERS – 1 AND 5 YEAR SURVIVAL



5 YEAR SURVIVAL ALL CANCERS DIAGNOSED 1990-1994 vs AVERAGE ANNUAL HEALTHCARE EXPENDITURE US$ PER PERSON (1990-1999)



DELIVERING VALUE FOR MONEY

Industry recognises the need to continually improve the value for money that is achieved by the use of medicines.

Over the years, investment in the use of medicines has added value by enabling improved patient care and allowing delivery of that care in low cost, primary care settings, avoiding unnecessary use of expensive specialist resources.

While the number of prescriptions has risen, the "pooling of risk" through the NHS continues to allow this increase in use of medicines to be achieved at a reducing average cost, which is currently less than £10 per prescription and declining. The National Audit Office confirmed in 2007 that the price of medicines in real terms had declined in the last decade. Spend on medicines within the NHS has been a stable element of the cost base, 9.2% for 2007, and remains among the lowest spend per head in comparable European countries, as mentioned in the UK context part of this document.

The Ninth PPRS Report to Parliament, in 2006 stated that branded prescription medicine prices in the UK were 5th out of 12 comparator countries. Updated to 2008, industry analysis indicates that UK prices are now 9th out of 12. The UK is also one of the highest users of cheap generic medicines, and achieves considerable savings through rapid conversion of the market from branded to generic medicines following the loss of exclusivity of the innovator.

Continuing competitive pressure combined with payor demands for increased value, and wider use of various forms of Health Technology Appraisal have been clearly reflected in the pricing of new products in recent years and established stronger links between pricing and estimated "value", within the limited definition of value that currently exists.

For the first time, Patient Access Schemes are included in the PPRS. These are aimed at improving patient access to medicines which have not initially been assessed as cost or clinically effective by NICE.

These new initiatives will be reviewed after two years.

Provision is made in the new PPRS for generic substitution to be introduced in 2010, subject to discussion during 2009. Certain types of medicines and certain conditions are not suitable for this approach. However, experience in other countries suggests that with appropriate safeguards for patient safety and an option for doctors to override the system, pharmacists can safely dispense an identical generic medicine against a branded prescription. This could produce cost reductions for the NHS without compromising patient care, but in a way that does not harm innovation.

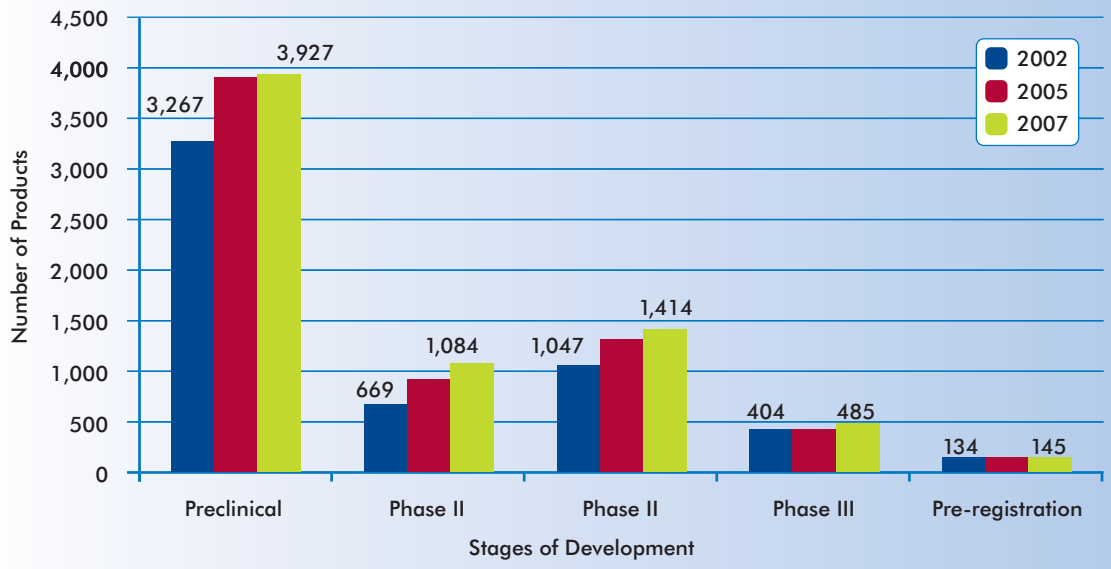
ENCOURAGING INNOVATION

The role of the pharmaceutical industry in the development of healthcare and medical advances is of crucial importance. It is in the interest of patients, the NHS, Government and the industry that any pricing system encourages research and reward innovation which delivers valuable new treatments.

The Department will establish a single, unified horizon scanning process to identify new technologies in development by industry. Industry will play its part in the design and development of a database to capture new technologies.

The 2009 PPRS confirms a commitment to recognising the cost of R&D within the prices paid for NHS disease treatments through the R&D allowance. The R&D allowance is variable, with an element providing for innovation and children's medicines. This is intended to reflect a contribution to the worldwide cost of the R&D undertaken by companies developing human medicines and a desire tor reward and provide an incentive for success in R&D.

A HEALTHY GLOBAL PIPELINE FOR PHARMACEUTICALS



2,210 for cancer (from blood to solid tumours), **530** for heart disease and stroke, **1,445** for CNS including **261** for Alzheimer's disease including new mechanisms of action and **109** for Parkinson's disease, **383** for arthritis, **169** for multiple sclerosis, **90** for osteoporosis.

PROVIDING STABILITY, SUSTAINABILITY AND PREDICTABILITY

The 2009 PPRS saw an end to one of the most turbulent periods for pricing and reimbursement of medicines in the UK. The Government and the ABPI will continue to work together under the aegis of the Ministerial Industry Strategy Group (MISG) Long Term Leadership Strategy for Medicines in a continuing programme of action aimed at supporting the objectives of the Scheme and the industry's global competitiveness.

Medicines are expensive to develop, both in terms of money and development times. It takes on average more than £500 million and 10 to 12 years to bring a new medicine to market, so more stability in the market is a welcome development.

Stability will be restored under the 2009 PPRS as there is a clear Government commitment in the Scheme that the agreement cannot be terminated or re-negotiated for 5 years.

The PPRS has created a stable environment attractive for innovation and investment.

PHARMACEUTICAL BALANCE OF TRADE (AMOUNTS IN £MILLION)

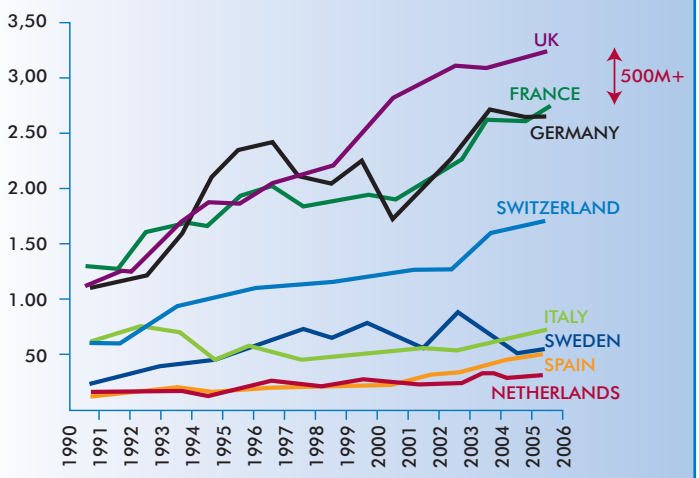
	Exports	Imports	Trade Balance
1980	745	222	523
1985	1,426	590	1,184
1990	2,258	1,158	1,100
1995	4,939	2,812	2,123
1996	5,386	3,107	2,279
1997	5,455	3,192	2,262
1998	5,910	3,447	2,462
1999	6,332	4,260	2,072
2000	7,275	4,902	2,373
2001	9,144	6,405	2,739
2002	10,185	7,549	2,636
2003	11,935	8,374	3,561
2004	12,354	8,642	3,750
2005	12,272	8,758	3,514
2006	13,905	9,461	4,444
2007	14,567	10,291	4,276

SOME STATISTICS ABOUT THE PHARMACEUTICAL INDUSTRY

- Medicines account for little over 10 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 are 24 per cent lower than ten years ago (2007) and make up a lower proportion of the overall NHS budget.
- Around a third of total UK pharmaceutical industry sales returns is reinvested in research and development – far more than in any other UK industry sector.
- The pharmaceutical industry provides around 63,000 jobs directly and about 250,000 more in related sectors.
- Pharmaceutical exports in 2007 were £14.6 billion, creating a trade surplus for the UK economy of £4.3 billion.

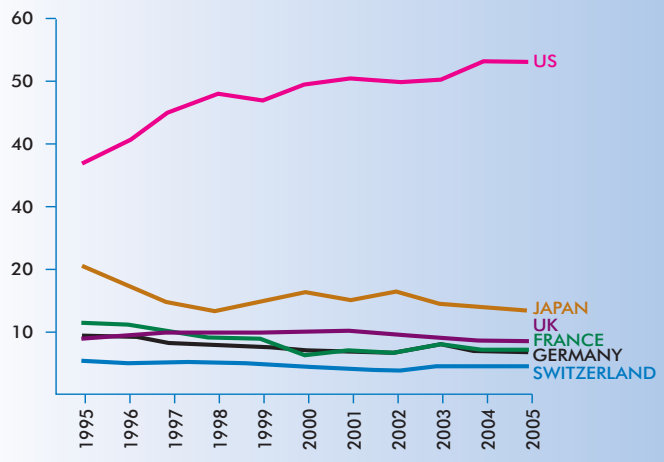
UK attracts more R&D investment than other EU markets, but this position is declining and fragile

R&D INVESTMENT IN KEY EUROPEAN MARKETS (£M)



Source: ABPI

GLOBAL MARKET SHARE OF R&D INVESTMENT (%)



Source: National trade associations.
Collated by ABPI and agreed with DH

THE MECHANISMS OF THE PPRS

The PPRS covers all branded NHS medicines. For this purpose, a branded NHS medicine is defined as a human pharmaceutical product for which a marketing authorisation has been granted and to which the owner applies a brand name that enables the product to be identified without reference to its generic name.

Membership of the PPRS is not confined to member companies 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, a new statutory scheme would prevail. The Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 limit the maximum price of prescription only, branded medicines supplied to the National Health Service and require manufacturers and suppliers of branded pharmaceutical companies to provide the Department of Health with information on sales income and discounts. Details of the statutory scheme can be found at: http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/PPRSlegislation/DH_092413. 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 a balance sheet. This must be submitted annually by companies with a relevant annual turnover of more than £35 million, 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.

Scheme members with a turnover of less than £5 million are exempt from submitting an AFR. However, companies with a turnover of less than £35 million 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.

Limiting (or controlling) profits

The PPRS sets a ceiling on companies' profits on NHS sales, but does not guarantee them. The Scheme sets a target of 21 per cent on a company's Return on Capital Employed from home sales of NHS medicines.

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 target by more than 40 per cent (the upper margin of tolerance) is required to repay the excess or reduce prices by an equivalent amount. The upper margin of tolerance is not available in year in which the member has been granted a price increase. Only if a member's assessed profit falls short of the target by more than 60 per cent may the company apply for a price increase.

Price Changes

In addition to existing freedom of pricing for new active substances, for the first time a system of flexible pricing will be introduced, which in carefully defined circumstances will help to ensure that prices can change to reflect the value that the medicines deliver. Once new or additional data about a medicine is known, a company can apply for a price increase. NICE will then reassess the medicine's price.

The 2009 imposed an immediate price reduction of 3.9 per cent, with a further 1.9 per cent reduction a year later. From 2011, small price increases will be allowed. This applies to all Scheme members with an annual turnover of more than £5 million.

DATE	PRICE ADJUSTMENT
February 2009	-3.9%
January 2010	-1.9%
January 2011	+0.1%
January 2012	+0.2%
January 2013	+0.2%

The price reduction on individual products may be applied differentially, some products being reduced by more and others by less, or even increased, but audited reporting systems are in place to ensure that each member's reduction amounts to the equivalent overall price reduction across its product range.

Monitoring And Enforcing The Scheme

Monitoring procedures are required to ensure that Scheme members deliver the required price reduction across primary and secondary care over the lifetime of the Scheme. In addition to the annual financial reporting set out in the Independent Accountants Review Arrangements, the PPRS provides for regular consultation between the ABPI, representing Scheme members, and the Department of Health, representing the four UK Health Departments, as well as an arbitration process and an annual report to Parliament, available on the Department's website.

CONCLUSION

The 2009 Scheme encompasses a much broader agenda than previous schemes and includes elements that have not been included previously in the PPRS. Both the Government and the ABPI welcome these developments, which help ensure that the PPRS provides for a fair and balanced package by incorporating measures that reward innovation, increase uptake of clinically and cost effective medicines and increase patients' access to medicines at prices that better reflect their value.

The Government asked for a renegotiation of the 2005 PPRS when it still had two more years to run. Measures have been taken to avoid an early termination of the 2009 Pharmaceutical Price Regulation Scheme and the new Scheme will run for five years. The Government's commitment to this should bring a more stable and predictable period where the pharmaceutical industry in the UK can continue to develop and produce innovative medicines for patients in the UK and other countries around the world.