Department of Health

The Pharmaceutical Price Regulation Scheme

Twelfth Report to Parliament

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The Pharmaceutical Price Regulation Scheme

Twelfth Report to Parliament

Prepared by the Pricing and Supply PPRS Policy Team

This is the 12th report to Parliament on the Pharmaceutical Price Regulation Scheme (PPRS). 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 between the Department of Health and the branded pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI).

Contents

1. Introduction

1.1. In 2011/12, the UK NHS spent approximately £11.3 billion on branded prescription medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism which is used to control the prices of these medicines and limit the profits that companies can make on their NHS sales.

1.2. This is the twelfth Report to Parliament on the PPRS.[1] The PPRS is a voluntary scheme agreed between the Department of Health (acting on behalf of the UK Health Departments) and the branded pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI). The Secretary of State's powers in relation to the scheme are set out in sections 261 and 265 and 266 of the National Health Service Act 2006. The eleventh Report to Parliament was published in February 2012.

1.3. This report covers the 2009 PPRS which lasted from the 1st of January 2009 to the 31st of December 2013. It also describes the 2014 PPRS which began on the 1st of January 2014.

1.4. Chapter 2 reports on the operation of the 2009 scheme. Chapter 3 of the report outlines and reports on the early operation of the 2014 PPRS. Chapter 4 provides an update on the innovation provisions under the 2009 scheme; and describes the Government's commitment to holding NHS England to account for the ongoing implementation of *Innovation, Health and Wealth* as laid out in the 2014 PPRS. Chapter 5 gives an overview of the Government's broader support for the life science industry.

1.5. The Prescriptions, Pricing and Supply team within the Medicines, Pharmacy and Industry Group of the Department of Health administers the scheme throughout the UK. The team includes negotiators, pharmacists, an accountant and policy officials. Together, they are responsible for the operation of the scheme as well as other key aspects of pharmaceutical policy, such as medicine supply, in the NHS.

1.6. In previous Reports the Department have provided international medicines price comparisons (e.g. Chapter 6 of the Eleventh Report to Parliament). As previous reports have noted, there are a number of reasons why these comparisons are problematic, so that they may not reflect the actual prices paid in many countries.

[1] The Department of Health published its first report in May 1996 following a recommendation by the Health Committee that 'Department of Health should introduce greater transparency into the PPRS by publishing an annual report on the scheme in their report' (Priority Setting in the NHS: the NHS drugs budget (1994)). Since then, the Department has published a report in the following years: 1997, 1999, 2000, 2001, 2003, 2004, 2005, 2006, 2009 and 2012

2. Management and operation of the 2009 PPRS

2.1. This chapter describes the operation of the 2009 PPRS, which replaced the 2005 PPRS and the 2008 interim schemes. The 2009 agreement was a package of measures that provided stability, sustainability and predictability in pharmaceutical pricing.

2.2. The major components of the 2009 PPRS were:

- Price adjustments on the list price of branded prescription medicines sold to the NHS of 3.9% in 2009, 1.9% in 2010 and then small increases in the following three years.
- A target rate of return on capital of 21% and a target rate of return on sales 6%.
- A more systematic basis for Patient Access Schemes
- Action to support innovation so that patients had faster access to new medicines that are clinically and cost effective.

Operation of the 2009 PPRS

2.3. The 2009 PPRS operated at the level of the individual company, and regulated the overall profits made by the company from its sales of licensed, branded prescription medicines to the NHS. It did not cover products that do not have a brand name (generics) or branded products that are available without prescription (over-the-counter medicines) except when prescribed. Although the 2009 PPRS has terminated, there are still a number of outstanding requirements to be fulfilled such as submitting Annual Financial Returns (AFRs) for the final year of the scheme.

Information requirements

2.4. In assessing the reasonableness of a company's profits, any scheme member with total home sales of NHS medicines of £35 million or more in its financial year was required to provide an AFR.

2.5. Any scheme member with total home sales of NHS medicines of more than £5 million and less than £35 million in its financial year was required to provide a copy of its audited accounts and a certificate signed by its managing director or chief executive, giving a breakdown of turnover for the year between home sales of NHS medicines, export sales of NHS medicines and sales of other products.

2.6. Those scheme members with total home sales of NHS medicines not exceeding £5 million in its financial year were exempt from supplying financial information.

Profit targets and allowances

2.7. There was a common profit target for assessing profits, either expressed as a Return on Capital (ROC) employed of 21% or a ROS (Return on Sales) of 6% for companies with low capital bases in the 2009 PPRS. 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 ROC. In these circumstances, companies may either inject capital in their financial return or elect to have their PPRS business assessed on an ROS basis.

2.8. 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 40% or less of target, it may apply for a price increase to take it to 65% of the target. 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.

2.9. In assessing the profitability of scheme members' AFRs, the scheme sets out allowances for R&D, information and marketing expense.

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

- the trends in the data reported by the company over a number of years,
- including those for exports and other products;
- any special features of the company's operation;
- ratios inferred for the company's PPRS and non-PPRS business;
- each company's reported figures and the average of other similar scheme members; and
- data from external sources that relate to the pharmaceutical industry

2.11. Members of the 2009 PPRS were expected to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads. The industry accepts that the scheme was 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.

Submission and clearance of company financial returns

2.12. This section provides amalgamated details on the submission and clearance of AFRs for the years 2009 to 2011 as at 13 February 2014, all submitted under the rules of the 2009 PPRS.

2.13. The 2009 PPRS changed submission date requirements (when compared to the 2005 PPRS) by spreading them more evenly throughout the year. Depending on the first letter of the company's name, submissions are required between six and twelve months after the end of the company's financial year.

2.14. Table 1 provides the statistics related to these submissions for the AFR submissions from 2009 to 2011.

Table 1: Submission and clearance of company financial returns

AFR Year	2009	2010	2011
Total number of AFRs	35	33	31
Number of AFRs received from companies on time	14 (40%)	7 (21%)	10 (32%)
Number of AFRs not received one year after the end of the financial year	8 (23%)	17 (52%)	6 (19%)
Number of AFRs cleared	35	33	29
Number of AFRs received but not cleared	0	0	1
Percentage cleared of AFRs received	100%	100%	97%

2.15. There has been a gradual decline in the number of companies required to submit AFRs over the period 2009 to 2011. The reduction is due to a combination of factors, including some companies opting to leave the 2009 PPRS to be covered by the statutory alternative, which does not have AFR provisions, and company merger and acquisition activity.

2.16. The average time it has taken the Department to process AFRs to clearance has varied over the period of this report – 2009: 185 days; 2010: 216 days; 2011: 176 days. The amount of time taken is a reflection on the additional information that has been required from companies (sometimes including revised AFR submissions) to enable the Department to satisfy itself that it is in a position to make a valid judgement on companies' profitability. All AFRs have been cleared for 2009 and 2010, whilst one AFR remains uncleared in 2011, and the Department is continuing to negotiate its position on this AFR with the relevant scheme member.

Outturn data

2.17. The previous report included aggregated information for ROC and ROS companies for 2004 to 2007. This report updates the information for 2009 and adds data for 2010 and 2011, the latest year for which AFRs have been received and assessed. The results of these analyses are shown in Table 2. The 2012 AFRs are being received and processed so to the Department cannot present meaningful figures. This will be presented in the next report.

2.18. In accordance with paragraph 2.3, it will be seen that 2013 AFRs are not yet due in.

Table 2: Summary of aggregate data for all companies of sales, costs, and profit for 2009 to 2011

Year	2009		2010		2011	
Number of companies	35		33		31	
	Company £000	Outturn £000	Company £000	Outturn £000	Company £000	Outturn £000
Sales	8,294,305	8,175,889	8,128,189	8,123,572	7,859,947	7,859,947
Marketing costs	394,189	379,579	384,098	371,441	369,279	358,253
R & D costs	1,359,599	2,071,764	1,162,609	2,085,429	982,984	1,970,349
Other costs	6,691,590	4,235,883	6,454,785	4,162,246	6,587,369	4,174,420
Total costs	8,445,378	6,687,226	8,001,492	6,619,116	7,939,632	6,503,022
Profit	-151,073	1,488,663	126,697	1,504,456	-79,685	1,356,925
Return on sales	-1.8%	18.2%	1.6%	18.5%	-1.0%	17.3%

2.19. The 2011 figures include AFRs in respect of 31 companies with sales to the NHS at factory gate prices of £7.9 billion. This compares with 35 AFRs received for 2009 that showed sales to the NHS of £8.3 billion.

2.20. Although there have been some additional companies who were required to submit AFRs under the various schemes, the number of AFRs received has declined over the period as a result of mergers. The number of companies choosing to be assessed as ROS rather than ROC has further increased and it is no longer feasible to include separate schedules for ROC and ROS companies in view of the confidential nature of the information submitted. A single schedule is presented, therefore, covering all companies and showing the overall return on sales.

2.21. As in previous reports, the information submitted to the Department by companies is shown in the ‘company’ columns, while the ‘outturn’ columns show the position reached after assessment of the AFRs by the Department and negotiation with each company. Where companies purchase goods from affiliates on transfer prices, these are reallocated between cost of goods sold (59%), R&D (21%) and profit (20%). This split of the transfer price has been agreed with the industry and is set down in sections 8.21–8.27 of the 2009

PPRS. The split is identical to that under the 2005 scheme. It is for this reason that R&D costs allowed in the assessments seem to be higher than those being claimed by the companies. The transfer price profit element of the transfer prices is not treated as a cost in arriving at assessed profit but is added to target return and is the major reason why outturn profit is significantly higher than that apparently claimed by the companies in their submissions.

Price increases

2.22. The PPRS requires companies to seek the Department's agreement for price increases (other than pursuant to paragraph 7.6 (iii) of the 2009 scheme that lays out the automatic permitted price increases under that scheme) which are only granted if the reasons for the application meet the criteria for increases set out in the agreement.

2.23. Table 3 shows the number of companies that were allowed to increase prices through the operation of the PPRS and the full year of the price increases. No major companies were allowed to increase prices.

Table 3: number of companies with price increases and value of price increase

Year	Number of companies with price increases (of which AFR companies)	Full year value of price increase (£ million)
2009	11(0)	3.3
2010	8 (0)	1.8
2011	2 (0)	0.2
2012	4 (0)	0.4
2013	0	0

Delivery of the price adjustments

2.24. With effect from 1 February 2009, scheme members (companies with sales of £5 million or more) were required to reduce the prices of their medicines covered by the PPRS by 3.9%. A further price cut of 1.9% followed in January 2010. In January 2011 prices could increase by 0.1% and in January 2012 they could increase by 0.2%.

2.25. The Department operates monitoring procedures to ensure that companies deliver the required price adjustment as set out in the lifetime of the scheme. According to the latest data, the Department the price cuts are broadly being delivered. However there are a number of outstanding disputes which could have an impact on the savings delivered by the price cuts.

Over- and under-deliveries from the 2005 and 2008 PPRS

2.26. Some companies that chose to deliver price cuts under the 2005 and 2008 schemes by modulation reported under- or over-deliveries carried forward for resolution in the 2009 scheme. This scheme stated that the Department would recognise modulation over-

deliveries under these schemes provided that enough under-delivering companies agree to repayment such that at least 75% by value of modulation under-deliveries was repaid to the Department. At present, this matter is being disputed by several companies under the Dispute Resolution process.

Flexible pricing

2.27. The flexible pricing provisions introduced in the 2009 PPRS enable scheme members to propose an increase or decrease to a medicine's list price in light of new evidence or a major new indication.

2.28. There are two circumstances in which flexible pricing may be relevant:

- where significant new evidence is presented that changes the value of an existing indication of a medicine; and
- where the value of a major new licensed indication for a medicine is shown to be significantly different from the value of the initial indication.

2.29. To date no proposals for price changes have been submitted under the flexible pricing provisions in the 2009 or 2014 schemes.

Patient access schemes

2.30. A patient access scheme (PAS) is a scheme proposed by a scheme member and agreed with the Department (with input from NICE) in order to improve the cost-effectiveness of a medicine in the context of an appraisal by NICE. PAS can help to facilitate greater access for NHS patients to medicines that may not initially be found to be cost-effective by NICE.

2.31. To date, including PAS agreed under arrangements in operation prior to the 2009 PPRS, 32 PAS have been incorporated by NICE as part of 42 sets of technology appraisal guidance. A list of medicines that have been recommended by NICE with a PAS can be found on NICE's website at: http://www.nice.org.uk/aboutnice/howwework/paslu/ListOfPatientAccessSchemesApprovedAsPartOfANICEAppraisal.jsp

2.32. PAS can impose additional administrative costs and burdens on the NHS and it is important that any such burdens are minimised and that the cumulative burden on the NHS is manageable. Since November 2009, the Patient Access Scheme Liaison Unit (PASLU) at NICE, and its Expert Panel, which includes representatives of the NHS, patients and the public and the pharmaceutical industry, has provided advice to the Department on the feasibility of implementing PAS proposals in the NHS. Since its establishment, the Expert Panel has been reappointed with expanded representation for patients, the NHS and the industry.

2.33. Following a review carried out jointly by the Department and the ABPI in 2011, additional guidance was developed for companies considering making a PAS proposal. This is available at: https://www.gov.uk/government/publications/patient-access-scheme-guidance-for-companies-considering-a-proposal-in-england--2

Dispute resolution

2.34. The 2009 PPRS has provisions for resolving disputes that arise during the operation of the PPRS. Under these provisions, the ABPI has the right to dispute resolution on matters that span the interest of the broader membership.

2.35. The Dispute Resolution Panel consists of a chair (a part-time judge) appointed by the Secretary of State for Health subject to agreement of the ABPI, and two members, each appointed by the Secretary of State and the ABPI.

2.36. Decisions of the Panel in dispute resolution cases are published on the ABPI and Department websites in accordance with the 2009 agreement. Further information can be found at https://www.gov.uk/search?q=2014+pharmaceutical+price+regulation+scheme&tab=government-results

3. The 2014 Scheme

3.1. This chapter describes the 2014 PPRS, which replaced the 2009 PPRS from 1 January 2014, following negotiations between the Department of Health and the branded pharmaceutical industry.

3.2. The 2014 scheme responds to the current financial challenges by providing greater certainty on the maximum the NHS will spend on branded medicines while continuing to provide timely access to medicines for patients. The scheme also includes a number of measures to improve access to innovative medicines commensurate with the outcomes they offer patients and to support innovation and growth.

Objectives and Principles

3.3. The overarching principles and objectives for the 2014 scheme, as set out in the agreement,[2] are as follows:

- **Provide stability and predictability to the Government and the industry**

  The scheme is a single, holistic, UK pricing agreement covering all the relevant key issues that underpin the pricing of NHS branded medicines. Importantly, it is intended to provide stability and predictability to both the Government and the industry to enable certainty of planning and to help the NHS and the industry develop sustainable financial and investment strategies.

- **Support the NHS by ensuring that the branded medicines bill stays within affordable limits**

  Support the NHS by ensuring that the branded medicines bill stays within affordable limits and deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices, and encouraging the efficient development and competitive supply of medicines.

- **Improve access to innovative medicines commensurate with the outcomes they offer patients by ensuring that medicines approved by NICE are available widely in the NHS**

  Improve outcomes for patients by improving access to and appropriate use of clinically and cost-effective medicines and, in England, encourage the NHS to promote the rapid adoption and diffusion of innovative medicines and treatments recommended by NICE commensurate to the outcomes they offer patients.

- **Reduce bureaucracy and duplication**

  The scheme aims to reduce bureaucracy and duplication and avoid unforeseen burdens on either party over the coming years.

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2 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/266539/2014_PPRS_Final_corrected_at_1530_16_Dec.pdf

- **Support the Government's growth and innovation agenda for life sciences**

  Encourage innovation and the development of high value treatments by promoting a strong and profitable pharmaceutical industry that is both capable of and willing to invest in sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and the industry in this and other countries.

PPRS Payment Mechanism

3.4. The 2014 scheme introduces a PPRS Payment Mechanism, which limits the amount that the NHS spends on branded medicines supplied by members of the PPRS. The key features of this are:

- pre-agreed levels of allowed growth rate for spend on branded medicines included in the mechanism for each year of the scheme at 0% in 2014 and for each subsequent year 0%, 1.8%, 1.8% and 1.9%;
- payments by companies direct to the Department once the allowed growth rate is exceeded;
- the initial payment percentage for 2014 is fixed at 3.74% and is based on the difference between the allowed growth rate for 2014 and an agreed joint forecast of the growth rate branded bill;
- payment percentages for subsequent years will be adjusted based on actual outturn, and smoothed in the last three years of the scheme;
- payment will be paid quarterly in cash in arrears by companies on submission of quarterly returns of UK net sales to the NHS; and
- payment will be applied to net sales of products on the market on 31 December 2013, subject to exclusions.

3.5. The following exclusions were agreed to the spend which is measured and controlled by the allowed growth rates:

- exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation);
- procurements of centrally supplied vaccines;
- parallel imports; and
- companies with NHS sales under £5m in the previous year.

3.6. The spend which is measured and controlled by the allowed growth rates includes sales of new products (products launched after 31 December 2013). However sales of new products are not themselves subject to the PPRS Payments.

Sales reports and audits

3.7. The 2014 PPRS requires companies making PPRS Payments to provide quarterly sales reports with their payments and to provide an audited annual sales report within nine months of the end of the company's financial year. There are considerably strengthened audit arrangements under the new scheme. There will be an independent audit of the annual sales report carried out by the auditor of the company's statutory accounts. There will be a tripartite audit arrangement between each company, the Department and the auditor which must include specified key terms. Any errors found in the audit will be corrected and settled in cash.

3.8. There will also be an independent reconciliation exercise in 2016 to compare company data with administrative data and correct any errors discovered as a result. This will include an examination of data on parallel imports and distribution margins and the Department will investigate any unusual or unexplained changes which may have an impact on the effectiveness of the scheme. Under the National Health Service Act 2006 the Secretary of State may serve notice on a scheme member that the scheme is no longer to apply to it where the scheme is ineffective in that scheme member's case.

3.9. The first sales report covering the first quarter are due to be received in April 2014. The audited annual sales reports for the baseline year 2013 are due by end September 2014. Annual financial returns (AFRs) will be due in September 2015.

PPRS price control

3.10. Under the 2014 PPRS, there are a number of mechanisms which directly affect prices.

3.11. Like the 2009 scheme, the 2014 scheme allows for price neutral modulation across a scheme member's portfolio from 1 March 2014 of presentations (and any subsequent line extensions of those presentations) of Scheme Products on the market on 31 December 2013. The detailed rules for price modulation are set out in the PPRS.

3.12. Additionally, scheme members may increase the NHS list price of any Scheme Product or make an NHS list price change other than pursuant to the rules on flexible pricing or through modulation subject to the Department's prior approval. The Department will not agree to an NHS list price increase unless the scheme member's estimated and forecast profits for the current and following financial years, as assessed by the Department, are below 50% of the return on capital or return on sales (ROC/ROS) targets set out in the scheme. Where a price increase is agreed, the level of the increase approved will be no more than that required for the scheme member to achieve 65% of the ROC/ROS target.

3.13. If a scheme member is awarded an NHS list price increase, it will continue to pay the PPRS Payment at the rate applying to all scheme members as a percentage of their Sales Covered by the PPRS Payment and in accordance with the PPRS Payment mechanism. Information on these is set out in chapters 5, 6 and 7 of the 2014 PPRS.

Annual Financial Returns

3.14. There has been an increase in the Annual Financial Returns (AFR) threshold in the 2014 PPRS. Any scheme member with total home sales of NHS medicines of £50 million (previously £35 million) or more is required to provide an Annual Financial Return (AFR).

3.15. All companies will now submit AFRs by 30 September rather than the suggested submission dates of the previous scheme. Furthermore, this change is accompanied by a reduced audit requirement in that only 20% of companies submitting AFRs each year will

be required to submit the full AFR information and have it audited. The other 80% of companies will have a much reduced submission requirement and no audit requirement.

3.16. The 2014 PPRS makes no change to the target rate of return on capital (ROC) (21%) or return on sales (ROS) (6%). However, there is an increase in the margin of tolerance (MOT) threshold to 50% of the target up from 40% in the previous scheme.

Access and outcomes

3.17. It is an objective of the Department of Health and NHS England to improve overall outcomes for patients including access to effective medicines. The scheme also includes an important commitment to the ongoing implementation of *Innovation, Health and Wealth* (IHW) as reflected explicitly in the NHS England Mandate.

Flexible pricing and patient access schemes

3.18. Two new pricing flexibilities, flexible pricing and patient access schemes, were introduced in the 2009 PPRS with the aim of making a closer link between the value of medicines and what the NHS pays for them. The 2014 PPRS confirms that the flexible pricing mechanism, which is yet to be used, continues to be available as an option for scheme members, on similar terms to those set out in the 2009 scheme. Within the 2014 PPRS, scheme members also retain the option of proposing a patient access scheme (PAS) for medicines subject to assessment by NICE, though the scheme confirms that PAS should continue to be the exception rather than the rule. It is important that PAS are sustainable and deliver the benefits expected of them, and the 2014 PPRS includes new provisions on the monitoring and review of operational PAS.

Implementing the 2014 Scheme

3.19. Most companies have signed up to the 2014 PPRS. Those companies that have not signed up to the voluntary scheme are subject to statutory controls (see below).

3.20. To date, 134 companies have elected to join the 2014 scheme. A list of the members of the 2014 PPRS is available on the Department's website at https://www.quickrplaces.dh.gov.uk/LotusQuickr/pprsinformation/Main.nsf/h_RoomHome/8cf7804fd9fad6b080257c6e005b3a6b/?OpenDocument

Statutory scheme

3.21. A company supplying the NHS with branded medicines which has not joined the 2014 PPRS will fall under the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013. The Regulations form the statutory alternative to the voluntary arrangements of the 2014 PPRS. As of January 2014, 109 companies had been notified that they are subject to the price controls under the statutory scheme.

3.22. Further information on the 2014 PPRS is available on the Department's website at https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

4. Innovation, access and outcomes

4.1. This chapter sets out the progress that has been made on the pharmaceutical innovation package in the 2009 PPRS and discusses the commitments to access and outcomes in the 2014 PPRS.

2009 PPRS

4.2. The 2009 PPRS set out a range of initiatives to strengthen up take and innovation. As the eleventh Report to Parliament noted, seven of the initiatives have been completed. These include, examining if Payment by Results (PbR) affected medicine up take, providing greater clarity to the NHS on the reasons why technologies have (or have not) been prioritised for NICE review and the Department facilitating meetings between NICE and industry. More detailed discussion of these initiatives is set out in the eleventh Report.

4.3. There are three initiatives from the 2009 PPRS that are on going and have been developed further in the 2014 PPRS.

4.4. The 2009 PPRS agreed that:

> **A joint industry, Department and NICE working group should be established with immediate effect to define principles and criteria for metrics; to identify NICE-appraised medicines on which to pilot this new approach; to identify data sources and ongoing reporting; and information management processes, including publication channels and methods, and governance mechanisms, with a view to starting to publish annual indicators in summer 2009.**

4.5. The Metrics Oversight Group (MOG) oversees and provides strategic leadership to the development, delivery and communication of this work. MOG includes members from the Department of Health, the Association of the British Pharmaceutical industry, the National Institute for Health and Care Excellence, the Health and Social Care Information Centre and the NHS.

- The first report of this work was published on 9 September 2009 by the Health and Social Care Information Centre and can be found at www.hscic.gov.uk/catalogue/PUB01400.
- The second report of this work was published on 26 January 2011 and can be found at www.hscic.gov.uk/catalogue/PUB01470.
- The third report of this work was published on 17 October 2012 and can be found at www.hscic.gov.uk/catalogue/PUB07985.
- The fourth report of this work was published on 21 January 2014 and can be found at www.hscic.gov.uk/catalogue/PUB13413.

4.6. Each report compares actual usage data with an estimate of the eligible population for NICE-recommended medicines within the NHS in England (where possible) and shows variation between organisations.

4.7. Following on from the 2009 PPRS, the 2014 PPRS commits the Department, NHS England and the industry to working together to deliver “a single transparent programme of activities looking at comparative medicines use in the NHS, to evaluate whether patients

consistently achieve better access to cost-effective medicines. This will include a number of medicines positively appraised by NICE (either fully or with restrictions)."

4.8. A second on-going commitment in the 2009 PPRS was that:

> **The industry and the Department will work together to define a set of measures that allow comparison of the uptake of all new medicines with major EU economies and, additionally and more specifically, to provide international benchmarks and trends for the uptake of NICE-approved technologies. It is important that these metrics focus on individual medicines as well as trends rather than on just absolute uptake. The metrics also need to recognise the differences between different health systems and countries. Baseline data collection should commence in September 2008, with a view to starting to publish annual indicators, and contextual commentary from April 2009 onwards.**

4.9. Following agreement with the pharmaceutical industry, this work was taken forward as part of a wider project led by Professor Sir Mike Richards, National Cancer Director, looking at both the extent and causes of international variations in drug usage. Professor Richards' report was published in July 2010 and can be found at www.gov.uk/government/publications/extent-and-causes-of-international-variations-in-drug-usage .

4.10. Following on from the 2009 PPRS, the 2014 PPRS commits the industry, NHS England and the Department to working together "to develop and evolve an approach to the analysis and publication of comparative information on international medicines use on a periodic basis". A first report is to be published by the end of 2014.

4.11. In addition it was agreed in the 2009 PPRS to:

> **Establish and populate a horizon scanning database for use by all horizon scanning organisations, the NHS, and pharmaceutical companies to provide a single source for this data.**

4.12. The Department and the Association of the British Pharmaceutical Industry (ABPI) have jointly established *UK Pharmascan*, a single unified horizon scanning database to identify new technologies in development by the industry. This database, a 2009 PPRS commitment, was developed following a successful collaboration with key stakeholders including the National Institute for Health and Care Excellence (NICE), the National Horizon Scanning Centre (NHSC),the Scottish Medicines Consortium (SMC), the All Wales Medicines Strategy Group (AWMSG), UK Medicines Information (UKMi) and the National Prescribing Centre. Uses of the database include supporting Health Technology Assessment (HTA) topic selection, scoping of appraisals and providing timely information to all NHS organisations for planning and budgeting purposes. The database, operational from summer 2010, is hosted by NICE.

4.13. Over 130 pharmaceutical companies have now registered to use the database and nearly 700 technology records for medicines, which are either in phase III clinical trials or within three years of launch in the UK market, have been entered onto the database. The database is more or less fully populated, with the remaining companies which have yet to register or enter data largely those based outside of the UK with either none or a very small number of future pipeline products.

4.14. All horizon scanning organizations are using the data on *UK Pharmascan* to support their horizon scanning activities although use varies between organizations depending on specific local business processes.

4.15. There is an on-going programme of work to encourage companies to actively engage and to enter high quality data on the database. The current focus is:

- A communications plan to encourage wider awareness and usage of the database by organizations responsible for advising the NHS on forward planning; and
- Activities focusing on improving the quality, comprehensiveness and completeness of the data provided by companies.

4.16. Following on from the 2009 PPRS, the 2014 PPRS includes the following commitment: "The Department will continue to maintain UK Pharmascan, and scheme members will continue to commit best efforts to supply accurate, complete, and timely information about such new technologies".

2014 PPRS

4.17. In the 2014 PPRS the Department, NHS England and industry have committed to a number of specific initiatives aimed at encouraging and rewarding innovation and assisting better access to effective medicines, including further work in relation to the three continuing initiatives from the 2009 PPRS. The 2014 PPRS also reflects NHS England's continuing commitment to implementation of *Innovation:Health and Wealth*, which seeks to improve NHS use of innovative treatments for the benefit of patients. This commitment is reflected explicitly in the NHS England Mandate and NHS England will be held to account for delivery of its work programme through the Mandate accountability mechanisms.

5. Government support for the life science industry

5.1. The UK is home to a world-class pharmaceutical industry, which makes significant contributions not only to developing new medicines, and to the economy, but also to the UK research capacity within and beyond the NHS.

5.2. Highlights[3] include:

- the pharmaceutical sector in the UK has 477 companies, employing over 70,000 people and generating a turnover of £29 billion, the majority of this from sales of medicines still under patent.
- the pharmaceutical sector continues to make a major contribution to the UK economy as a strong exporter generating a positive trade balance of over £5bn per annum for the last 5 years.
- all of the top 20 global pharmaceutical companies have activities in the UK accounting for 67% of turnover and 57% of sector employment.

5.3. The UK remains one of the world's leading locations for pharmaceutical R&D as highlighted by the:

- £11.5 million invested every day in R&D by the pharmaceutical sector in the UK[4].
- R&D expenditure by the pharmaceutical sector accounted for almost 25% of all R&D expenditure in the UK in 2012.
- UK's first-class research and science base which is contributed to and supported by the industry.

5.4. However, the industry has seen significant changes in the commercial environment. The Government has, therefore, made a series of important announcements to help the life sciences sector maintain its key position in the UK economy:

- *The Plan for Growth*, announced in March 2011, identifies life sciences as a key potential growth sector and sets out a number of initiatives for life sciences, many of which are to be achieved within the short to medium term.
- *The Strategy for UK Life Sciences* and *Innovation Health and Wealth – Accelerating Adoption and Diffusion in the NHS,* published in December 2011, contain a package of more long-term measures building on those included in the *Plan for Growth*. Both aim to enable the UK to capitalise on strengths such as its world-class science and

[3] Source: HMG Strength and Opportunity 2013 Annual Update, February 2014 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/279854/bis-14-p90-strength-opportunity-2013.pdf

[4] Source: ONS UK Business Enterprise Research and Development, 2012 http://www.ons.gov.uk/ons/rel/rdit1/bus-ent-res-and-dev/2012/stb-berd-2012.html

clinical research, talent base of pioneering life science researchers and first rate universities.

Plan for Growth

5.5. The Department of Health (working closely with HMT and BIS) developed a package of 16 actions aimed at supporting growth in the healthcare and life sciences sector. Pharmaceutical companies as well as biotechnology and medical technology companies will directly benefit from many of these actions. *Plan for Growth* actions address a variety of issues in health research, procurement, social care and the uptake of assistive technologies. The actions include improving the UK's competitiveness as a location for clinical trials by reducing the regulatory burden, improving speed and cost-effectiveness and encouraging collaboration and innovation in the life sciences sector.

5.6. Good progress is being made in delivering the Healthcare and Life Sciences commitments with most completed or on track. The latest implementation update was published alongside the Budget on 20 March 2013[5].

Strategy for UK Life Sciences

5.7. *The Strategy for UK Life Sciences*[6] is a strategy for the next 10–15 years building on many of the actions in the *Plan for Growth*. The strategy is based on three overarching objectives:

- Building a life sciences ecosystem
- Attracting, developing and rewarding the best talent
- Overcoming barriers and creating incentives for the promotion of health care innovation.

5.8. Twelve months on from launch, the '*Strategy for UK Life Sciences: One Year On'*[7] report was published in December 2012 showing the key progress made. Since then, quarterly newsletters[8] have highlighted the continued good progress in delivering the strategy.

Key achievements include:

- publication by the **National Institute for Health Research** (NIHR) of information on performance in initiation and delivery of clinical trials against benchmarks, including an initial benchmark of 70 days or less for approving trials and recruiting the first patient (this compares to the 142 days median as reported by the ABPI in 2009);
- establishing the Clinical Practice Research Datalink (CPRD) in April 2012 within the Medicines and Healthcare products Regulatory Agency (MHRA) as a joint £60 million investment between the NIHR and MHRA to service the specialised needs of the research and life sciences communities. CPRD provides a unique opportunity for

[5] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200019/growth_implementation_update_mar2013.pdf

[6] www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences

[7] https://www.gov.uk/government/news/life-sciences-strategy-one-year-on

[8] https://www.gov.uk/government/organisations/office-for-life-sciences

life sciences research by offering access to data that supports clinical trials and population observational studies. Since April 2012, studies using CPRD have resulted in over 300 research papers and abstracts. The Independent Scientific Advisory Committee has approved 388 studies. CPRD is providing data via its on-line access system to 18 leading pharmaceutical companies for approved research studies. Currently there are over 40 discussions on-going about potential new projects, observational and clinical trials with pharmaceutical, biotech and medical devices companies.

- establishing the UK Clinical Trials Gateway (UKCTG) website and app as a resource where patients and clinicians can identify trials that may be of interest to them. Since the launch in April 2012, over 250,000 unique users have visited the UKCTG site and over 11,000 copies of the UKCTG smartphone and tablet app have been downloaded.
- establishing the **NIHR website** as the principal mechanism for making information on clinical research available to researchers and research funders, promoting collaboration and innovation. Since the beginning of 2013, over 490,000 visits to the site have been made.
- establishing translational research partnerships from the £800 million investment in NIHR Biomedical Research Centres and Units;
- introducing a **Patent Box** providing 10% Corporation Tax rate on profits from patents.
- supported by the Technology Strategy Board, establishing a **Cell Therapy Catapult** and secured funding for a **National Biologics Manufacturing Centre** and a Cell Therapy Manufacturing Centre.

MISG

5.9. The Government values the on-going close working between Government and industry to explore issues and develop solutions through the Ministerial (biopharmaceutical) Industry Strategy Group (MISG). It views the strategic discussions with the research-based bio-pharmaceutical industry as being crucial in guiding policy in this area to ensure that the UK environment is attractive to the industry. The high-level nature of these discussions is recognised through the Secretary of State for Health co-chairing the meetings with the Chairman of the British Pharma Group and through the membership of other ministers from the Department of Health, the Department for Business, Innovation and Skills (BIS) and HM Treasury (HMT).

Joint Government Office for Life Sciences

5.10. The Government has announced the establishment of a new joint Government Office for Life Sciences that will bring together all the DH and BIS officials working on life sciences policy to strengthen delivery of the S*trategy for UK Life Sciences*.