Department of Health

The Pharmaceutical Price Regulation Scheme

Eleventh Report to Parliament

February 2012

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Department of Health

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Contents

Chapter 1 – Introduction

1.1 This is the eleventh Report to Parliament on the Pharmaceutical Price Regulation Scheme (PPRS).[1] The PPRS is a voluntary scheme agreed between the Department of Health and the branded pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI) under section 262 of the National Health Service Act 2006. The tenth Report to Parliament was published in December 2009.

1.2 This report covers the current 2009 PPRS, the conclusion of the 2005 PPRS, which lasted from 1 January 2005 to 31 August 2008, and the 2008 interim PPRS, which operated from 1 September to 31 December 2008.

1.3 In 2010/11, the NHS spent approximately £10 billion on branded prescription medicines in the UK. The PPRS is the mechanism which the Department of Health (acting on behalf of the UK Health Departments) uses to control the prices of these medicines by regulating the profits that companies can make on their NHS sales.

1.4 The current 2009 scheme negotiated with the pharmaceutical industry commenced on 1 January 2009 and provides for a fair and balanced package that seeks to reward innovation and also increases patient uptake and access to cost-effective new medicines.

1.5 The objectives for the 2009 scheme, as set out in the agreement,[2] are as follows:

Deliver value for money

1.5.1 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.

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1 The Department of Health published its first report in May 1996 following a recommendation by the Health Committee that the '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, 2002, 2003, 2004, 2005, 2006 and 2009

2 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091825

Encourage innovation

1.5.2 Promote a strong and profitable pharmaceutical industry that is both capable 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 industry in this and other countries.

Promote access and uptake for new medicines

1.5.3 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.

Provide stability, sustainability and predictability

1.5.4 In order 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.

1.6 Based on these four objectives, the 2009 PPRS introduced some key new provisions. These were:

- a price cut of 3.9% in the first year of the agreement, a further price cut of 1.9% in January 2010, followed by three successive annual price increases of 0.1%, 0.2% and 0.2%;
- an innovation package aimed at encouraging and rewarding innovation and assisting the uptake of clinically and cost-effective new medicines; and
- two different mechanisms aimed at better reflecting the value of medicines: flexible pricing, which allows a company to increase (or decrease) its original list price in light of new evidence or a different indication being developed, and patient access schemes (PAS) that enable patients to receive access to cost-effective innovative medicines.

1.7 Chapter 2 of the report outlines the current 2009 PPRS scheme. Chapter 3 reports on the operation of the 2009 scheme, the conclusion of the 2005 scheme and the 2008 interim scheme. Chapter 4 provides an update on the innovation provisions under the 2009 scheme and Chapter 5 gives an overview of the Government's support for the life science industry. Chapter 6 gives an update of international medicines price comparisons.

1.8 In summary, this report highlights the following:

- 167 companies are signed up to the 2009 scheme and 64 companies are subject to statutory controls under the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008;
- three innovation package initiatives are still ongoing but the remaining seven have now been completed;
- to date, 17 PAS have been incorporated as part of 20 pieces of National Institute for Health and Clinical Excellence (NICE) appraisal guidance and these schemes are operational in the NHS;
- there have been no proposals for price changes submitted under the flexible pricing provisions;
- the number of scheme members submitting Annual Financial Returns (AFRs) in accordance with the agreed timetable has continued to decline. In 2009, 23% of AFRs were not received by the Department one year after the end of the financial year; and
- a comparison of the prices of branded medicines in the UK with prices in a range of European countries and the USA and Australia for 2010 shows that the UK is among the lowest compared to other European comparator countries. However, the picture is more mixed when a five-year average exchange rate is used.

Chapter 2 – The 2009 scheme

2.1 This chapter describes the 2009 PPRS, which replaced the 2005 PPRS and the 2008 interim scheme from 1 January 2009, following negotiations between the Department of Health and the branded pharmaceutical industry.

2.2 The 2009 agreement is a package of measures that provides stability, sustainability and predictability in pharmaceutical pricing but also keeps NHS expenditure on branded prescription medicines under control.

2.3 The main components of the 2009 scheme are:

- a 3.9% cut in the list price of branded prescription medicines sold to the NHS from 1 February 2009 and a further price cut of 1.9% in January 2010;
- action to support innovation so that patients have faster access to new medicines that are clinically and cost-effective;
- new and more flexible pricing arrangements that will enable pharmaceutical companies to supply medicines to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date; and
- a more systematic basis for PAS, which allow pharmaceutical companies to offer discounts or rebates that reduce the effective cost of a medicine to the NHS.

2.4 The scheme also:

- continues to allow companies freedom of pricing for new medicines (new active substances) launched in the UK;
- makes no change to the target rate of return on capital (ROC) (21%) or return on sales (ROS) (6%);
- increases support for research and development (R&D) through allowances for R&D to a maximum of 30% of NHS sales;
- increases the AFR threshold to £35 million; and
- increases the exemption from the price cut to companies with sales of prescription medicines to the NHS of £5 million or less (up from £1 million in 2005).

Price adjustments

2.5 The 2009 PPRS includes provision for two separate price cuts (a price cut of 3.9% in February 2009 and a further price cut of 1.9% in January 2010) followed by three successive price increases of 0.1% in January 2011, 0.2% in January 2012 and 0.2% from January 2013.

2.6 Pharmaceutical manufacturers can deliver the price adjustments by across-the-board reductions, variable price reductions across their product portfolio (modulation) and/or a cash payment to the Department of up to 2% of the price cut. Manufacturers with sales of branded prescription medicines to the NHS of £5 million or less in 2007 are exempt from the price adjustments.

2.7 Companies are required to submit independently reviewed annual outturn information to the Department each year to support the price monitoring procedures that the Department operates, in order to ensure that companies deliver the required price reduction over the lifetime of the scheme.

Scheme membership

2.8 Most companies have signed up to the 2009 PPRS. Those companies that have not signed up to the voluntary scheme are subject to statutory controls (see below).

2.9 To date, 167 companies have elected to join the 2009 scheme. A list of the members of the 2009 PPRS is available on the Department's website at www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS/DH_090499

Statutory scheme

2.10 A company supplying the NHS with branded medicines which has not joined the 2009 PPRS will fall under the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008. The regulations form the statutory alternative to the voluntary arrangements of the 2009 PPRS. As of January 2012, 64 companies had been notified that they are subject to the price controls under the statutory scheme.

2.11 Further information on the 2009 PPRS is available on the Department's website at www.dh.gov.uk/pprs

Chapter 3 – Management and operation of the scheme

3.1 This section reports on the operation of the PPRS, covering the conclusion of the 2005 scheme (from 1 January 2007 to 31 August 2008), the 2008 interim scheme (which operated from 1 September to 31 December 2008) and the first year of the 2009 scheme.

Management of the PPRS

3.2 The Prescriptions, Pricing and Supply team within the Medicines, Pharmacy and Industry Group of the Department of Health administers the scheme on behalf of the UK Health Departments. 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.

Operation of the PPRS

3.3 The PPRS operates at the level of the individual company and regulates the overall profits made by the company from its sales of licensed, branded prescription medicines to the NHS. It does 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.

Information requirements

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

3.5 Any scheme member with total home sales of NHS medicines of more than £5 million and less than £35 million in its financial year is 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.

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

Profit targets and allowances

3.7 There is a common profit target for assessing profits, either expressed as an ROC employed of 21% or an ROS of 6% for companies with low capital bases. 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.

3.8 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.

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

3.10 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 across companies.

3.11 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.

Submission and clearance of company financial returns

3.12 This section provides amalgamated details on the submission and clearance of AFRs for the years 2007 to 2009. AFR submissions for 2007 and the first eight months of 2008 were covered by the 2005 PPRS, which ended on 31 August 2008; 2009 AFR submissions were the first under the 2009 PPRS.

3.13 The 2005 PPRS specified that companies were required to submit AFRs to the Department within 6, 9 or 11 months after the end of the company's financial year. The date depended on the first letter of the company's name.

3.14 The 2009 PPRS changed submission date requirements by spreading them more evenly throughout the year. Depending on the first letter of the company's name, submissions are required between 6 and 12 months after the end of the company's financial year.

3.15 Table 1 provides the statistics related to these submissions for the AFRs from 2007 to 2009.

Table 1: Submission and clearance of company financial returns[3]

AFR year	2007	2008	2009
Total number of AFRs	38	33	35
Number of AFRs received from companies on or before deadline	21 (55%)	18 (55%)	14 (40%)
Number of AFRs not received one year after the end of the financial year	4 (11%)	3 (9%)	8 (23%)
Number of AFRs cleared	32	31	32
Number of AFRs received but not cleared	6	2	2
Percentage cleared of AFRs received	84%	94%	94%

3 An apparent inconsistency between this table and tables included in previous Reports to Parliament may arise because of the change in the AFR reporting timetable and companies' financial year-ends

3.16 The number of companies required to submit AFRs has remained relatively constant over the period 2007 to 2009. The 2009 PPRS raised the threshold for submission of AFRs to £35 million of NHS sales compared to £25 million under the 2005 PPRS. This has reduced the number of companies required to submit an AFR. A reduction has also occurred because some companies with substantial NHS sales did not join the 2009 PPRS, opting instead to be covered by the alternative statutory arrangements.

3.17 Between 2007 and 2009, the average number of days' delay that the Department experienced in receiving AFRs rose from 50 days to 88 days: an increase of 76%. In 2009, 23% of AFRs were not received by the Department one year after the end of the financial year – a marked increase on earlier years.

3.18 The average time it has taken the Department to process AFRs to clearance has varied over the period of this report – 2007: 281 days; 2008: 331 days; 2009: 169 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. Six AFRs remain uncleared in 2007, the majority due to the submission of non-standard audit certificates. The Department continues to negotiate with some companies about their 2008 and 2009 AFRs, which remain uncleared pending agreement.

Outturn data

3.19 The contents of AFRs include commercially sensitive information so it is not possible to publish detailed data on individual companies. The previous report included aggregated information for ROC and ROS companies for 2004 to 2007. This report updates the information for 2007 and adds data for 2008 and 2009, the latest year for which AFRs have been received and assessed. The results of these analyses are shown in Table 2. The data includes the latest figures for those companies whose AFRs are not yet settled, but no data is included for the one 2009 AFR that has not yet been received. This is an agreed delay; there were a number of matters arising from previous AFRs and it was decided to finalise those assessments and delay submission of the 2009 AFR.

Table 2: Summary of aggregate data for all companies of sales, costs, and profit for 2007 to 2009

Year	2007		2008		2009	
Number of companies	38		33		34	
	Company £000	Outturn £000	Company £000	Outturn £000	Company £000	Outturn £000
Sales	6,548,741	6,548,741	7,031,201	4,764,281	7,709,033	7,590,617
Marketing costs	328,156	322,989	331,248	223,406	368,694	353,831
R&D costs	971,420	1,482,879	1,043,119	1,083,478	1,289,489	1,928,288
Other costs	5,100,412	3,502,139	5,534,219	2,525,799	6,192,755	3,917,297
Total costs	6,399,988	5,308,007	6,908,586	3,830,282	7,850,938	6,199,278
Profit	148,753	1,240,734	122,615	931,598	-141,905	1,391,201
Return on sales	2.3%	18.9%	1.7%	19.6%	-1.8%	18.3%

3.20 The 2009 figures include AFRs in respect of 34 companies with sales to the NHS at factory gate prices of £7.7 billion. This compares with 38 AFRs received for 2007 that showed sales to the NHS of £6.5 billion. The growth in the value of company sales for those AFRs processed was 7.4% in 2008 over 2007 and 9.6% in 2009 over the sales of 2008.

3.21 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. Additionally, six companies that would otherwise have submitted AFRs have elected to join the statutory scheme. 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.

3.22 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.

3.23 The figures presented cover three different schemes: 2007 AFRs were assessed under the 2005 PPRS; the period September to December 2008 was covered by the 2008 interim scheme and was not profit assessed; while 2009 AFRs fall to be assessed under the 2009 PPRS. This meant that for companies with a December year-end, one third of the full year AFR submitted in respect of 2008 was not profit assessed and it is this that explains the significant differences between the 2008 company submissions and the outturn figures. As not all companies have a December year-end, there was a limited impact on the figures for 2009 when, usually, only one month of the 2009 AFR fell into the 2008 interim scheme and, therefore, was not profit assessed.

3.24 There were no differences in the rules for the marketing allowance under the 2005 and 2009 schemes and this is reflected in the allowance being a similar percentage of sales for the period reviewed: 4.9% of sales for 2007 and 4.7% for 2008 and 2009. The increased R&D allowance negotiated as part of the 2009 scheme shows up in the R&D allowance coming through at 25.4% of sales in 2009 compared to 22.6% and 22.7% for 2007 and 2008 respectively.

Price increases

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

3.26 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

Delivery of the price adjustments

3.27 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%. The Department operates monitoring procedures to ensure that companies deliver the required price reduction over the lifetime of the scheme. As a result of disputes, the Department is continuing to assess the delivery of the price adjustments in 2009 and 2010.

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

3.28 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 states that the Department will 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 will be repaid to the Department. At present, this matter is being disputed by several companies under the Dispute Resolution process.

Flexible pricing

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

3.30 Flexible pricing arrangements can take two forms:

- where significant new evidence is presented that changes the value of a medicine under an existing indication; 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.

3.31 To date no proposals for price changes have been submitted under the flexible pricing provisions.

Patient access schemes

3.32 Patient access schemes (PAS) are schemes proposed by a pharmaceutical company and agreed with the Department in order to improve the cost-effectiveness of a medicine. They can enable NHS patients to access medicines that may not initially be found to be cost-effective by NICE.

3.33 The Department is responsible for assessing PAS proposals in line with the principles set out in the PPRS. The Department does not assess whether a PAS proposal will make a medicine cost-effective for the NHS, as this is a decision for NICE through the appraisal process. If the Department agrees that a PAS proposal can be considered, NICE will assess the impact of the proposed PAS as part of the relevant appraisal process.

3.34 At the time of publication, 17 PAS had been incorporated as part of 20 pieces of NICE appraisal guidance and these schemes are now operational in the NHS.

3.35 PAS can impose additional administrative requirements and it is important that any such burdens are minimised. Since November 2009, the Patient Access Scheme Liaison Unit 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 scheme proposals in the NHS.

Review of PAS and flexible pricing

3.36 The 2009 PPRS made provision for a review into the more systematic use of PAS and flexible pricing, to begin within two years of the commencement of the scheme.

3.37 The Department and the ABPI agreed terms of reference for the review in late 2010, and the review was carried out in 2011.

3.38 The purpose of the review was to explore experiences of PAS and the flexible pricing provisions to date, and to consider whether there was scope for improvements to be made to the use of such provisions for the remaining lifetime of the 2009 PPRS.

3.39 The key findings of the review included:

- PAS have proven a useful tool within the 2009 PPRS in facilitating patient access to some medicines that might not otherwise have been recommended by NICE;
- no flexible pricing applications have been made but this option is seen by companies as potentially useful and remains open to them within the terms of the 2009 PPRS; and
- learning and experience over time have led to a trend towards proposals that are simpler and easier to implement.

3.40 Following the review, the Department, the ABPI and NICE will work together to produce further guidance for companies on proposing PAS.

Generic substitution

3.41 The 2009 PPRS agreement stated that *'subject to discussion with affected parties, the Department of Health will introduce generic substitution in primary care. This will enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine. Provision will be made to allow the prescriber to opt out of substitution where, in his clinical judgment, it is appropriate for the patient to receive a specific branded medicine. In these circumstances, the named brand must be dispensed. Provision may also be made to exclude certain categories of medicines for clinical reasons in the interests of patient safety'*.

3.42 In England in 2008 (in primary care), 83% of prescription items were prescribed generically, made up of:

- 65% of prescription items that could be dispensed generically;
- 18% of prescription items that, although prescribed generically, were only available as a branded product so they were dispensed as the brand; and
- the remaining 17% of prescription items were prescribed and dispensed by the brand name. The great majority of these drugs are available only as a branded product, but 5% of prescription items were prescribed by brand where the drug concerned is available as a generic.

3.43 Therefore, the generic prescribing rate could have potentially been 88% (i.e. 83% plus this additional 5%) assuming there were no clinical reasons why the patient needed a specific manufacturer's product. Closing this 5% gap was the key driver behind the implementation of 'generic substitution'. Furthermore, realisation of savings will be most significant in relation to products that have very recently come off patent, when prices fall.

3.44 Accordingly, the Department issued a public consultation that ran from 5 January to 30 March 2010 and undertook a series of meetings with key stakeholders in order to discuss the commitment in the PPRS agreement. These discussions and representations considered the following three options:

- do nothing;
- introduce generic substitution with specific exclusions (i.e. exclude specific items from generic substitution); or
- introduce generic substitution for a selected number of products only.

3.45 In total, 423 organisations and individuals submitted written responses. In addition, 107 delegates attended Department of Health listening events, and their comments were recorded as part of the consultation.

3.46 The analysis of responses showed no clear consensus with regards to a preferred option going forward. Three key points were apparent:

- there was a strongly held perception by respondents that generic substitution posed a threat to patient safety. If the proposals were to be implemented, these concerns would arise in the frontline delivery of NHS services, impacting on the workload of healthcare professionals;
- the position on the cost-effectiveness of generic substitution implementation was inconclusive. There is a strong sense that the effort involved in implementing a formal generic substitution scheme was simply too great for the scale of the potential gain; and
- other, less nationally prescriptive, mechanisms for further supporting the use of generic medicines could be explored.

3.47 In the light of the public consultation findings, the Department decided not to progress any further the implementation of generic substitution. Instead, the Written Ministerial Statement published alongside the response to the consultation indicated that the Department would look at further ways to support the use of generic medicines in a way that is acceptable to patients, recognising that there are still some savings that can potentially be delivered in this area.

3.48 The consultation and the report on responses can be found on the Department's website at www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_120431

Distribution margin

3.49 Individual companies are expected to follow good commercial practice in the distribution of their products according to their individual needs. Any scheme member that intends to change its overall distribution arrangements during the lifetime of this scheme in a manner that is likely to increase costs to the NHS is expected to notify the Department of such changes as early as possible, and at least four months in advance of any such change being made operational.

3.50 In addition, the 2009 PPRS provides for companies that have sales of branded medicines to the NHS of £35 million or more a year to supply additional information to the Department on sales of those medicines. The information required is the net value of sales of branded medicines to the NHS quarterly by product and the gross value of the same sales (i.e. at NHS list price). Net value of sales means income from sales of branded products after deduction of all trade and other discounts (howsoever named) including settlement discounts, rebates and sales taxes. The information is required to be split into sales into three channels – wholesalers/retail pharmacists; NHS hospitals; and other (which includes dispensing doctors and General Medical Services/Personal Medical Services contractors). Companies are also required to provide information about discounts given that cannot be specifically attributed to a particular branded product.

3.51 Companies that are not members of the voluntary PPRS are subject to the Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2011, and are required to supply the Department with similar information, where their relevant sales exceed £25 million per annum.

3.52 The Department continues to use the quarterly information that it receives on discounts to monitor the impact of changes to the supply chain.

Dispute resolution

3.53 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.

3.54 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.

3.55 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 www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH_128747

Chapter 4 – Pharmaceutical innovation package

Update on the ongoing innovation package initiatives

4.1 This section reports on the delivery of the proposals in the pharmaceutical innovation package. Seven of the initiatives have been completed and good progress has been made on the three continuing initiatives. These are outlined in bold, below:

4.1.1 **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.**

4.1.2 A Metrics Working Group consisting of the Department, NICE, the Health and Social Care Information Centre and pharmaceutical industry was established in May 2008. 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.ic.nhs.uk/pubs/niceappmed. The second report of this work was published on 26 January 2011 and can be found at www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/use-of-nice-appraised-medicines-in-the-nhs-in-england--2009-experimental-statistics. Both reports compare actual usage data with an estimate of the eligible population for NICE-recommended medicines within the NHS in England (where possible) and show variation between organisations. Work is underway on a third report, overseen by the Metrics Oversight Group, a new group established by the Department of Health to provide strategic leadership and direction to this work.

4.1.3 **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.**

4.1.4 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.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117962. The findings in Professor Richards' report supported the Government's plans for a Cancer Drugs Fund and informed its development. In response to the report's publication, the Government announced that a further £50 million would be made available from October 2010 to help cancer patients access additional drugs in advance of the launch of the Cancer Drugs Fund. The £200 million a year Cancer Drugs Fund was launched on 1 April 2011 for three years.

4.1.5 **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.**

4.1.6 UK Pharmascan, a single comprehensive database of horizon scanning information for new medicines, has been developed following a successful collaboration between the Department of Heath, the ABPI and key stakeholders. These included all the major horizon scanning bodies in the UK (National Horizon Scanning Centre, Scottish Medicines Consortium, All Wales Medicines Strategy Group), UK Medicines Information, NICE, National Prescribing Centre, representatives of the NHS and officials from Scotland, Wales and Northern Ireland. The database is hosted by NHS Evidence under the auspices of NICE.

4.1.7 Over 100 pharmaceutical companies have now registered to use the database and over 400 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 being largely those based outside of the UK with either none or a very small number of future pipeline products.

4.1.8 All horizon scanning agencies are using the data on UK Pharmascan to support their horizon scanning. Next steps include:

- communications about UK Pharmascan to encourage wider awareness and usage of the database by NHS planning organisations; and
- ongoing activities focusing on improving the quality, comprehensiveness and completeness of the data held about medicines.

Completed innovation package initiatives

4.2 The following innovation package initiatives have been completed:

4.2.1 **Three case-based reviews undertaken on uptake of NICE guidance in Payment by Results (PbR) in order to promote better understanding or possible use of existing levers within PbR to support and where possible incentivise uptake, and to further promote the effective use of existing tariff flexibilities.**

4.2.2 As previously reported, the group drawn from industry, the Department and NICE concluded that PbR was not a key issue affecting the uptake of the medicines in the case studies. It was agreed that there might be scope for a separate piece of work looking at the relationship between PbR and innovative technologies more generally. This has, in effect, been superseded by the NHS Chief Executive's 2011 Innovation Report, *Innovation Health and Wealth: Accelerating adoption and diffusion in the NHS,* which sets out a delivery agenda for spreading innovation at pace and scale throughout the NHS.

4.2.3 The report includes a range of measures, some of which are specifically aimed at reducing variation in the NHS and driving greater compliance with NICE-appraised medicines and technologies across the NHS. We have introduced a NICE Compliance Regime for the funding direction attached to NICE technology appraisals, to ensure rapid and consistent implementation throughout the NHS. In addition, we have committed to publishing information on compliance locally through the Innovation Scorecard and we will establish a NICE Implementation Collaborative which will bring together all key stakeholders to support rapid and consistent implementation of NICE guidance throughout the NHS. This will reduce variation and assure patients of their access to the clinically and cost-effective technologies and medicines that their doctors believe they need.

4.2.4 **The Department and NICE will provide greater clarity to the NHS on the reasons why technologies have (or have not) been prioritised for NICE review.**

4.2.5 As previously reported, this has been successfully completed. NICE has published this information on its website and it is also available through NHS Evidence. It can be found at www.nice.org.uk/getinvolved/topicselection/TADecisions.jsp

4.2.6 **Pilot prescribing incentives to promote uptake of innovative medicines.**

4.2.7 This work commenced with the identification of a number of potential primary care trust pilot sites but was overtaken by the development of guidance on *Strategies to Achieve Cost-Effective Prescribing* (DH, October 2010), which covered incentive schemes. In view of this, and in the context of wider health system reforms, this specific action was not progressed further.

4.2.8 **Address the anomaly whereby the funding direction does not apply to NICE technology appraisal recommendations, which are subsequently updated in a clinical guideline.**

4.2.9 As previously reported, the Department and NICE have agreed that, where a technology appraisal is reviewed in the context of a clinical guideline and the recommendations are unchanged as a result, the original technology appraisal will remain in place and the funding direction will continue to apply to recommended technologies.

4.2.10 **The Department to refresh and extend good practice guidance by April 2009 or earlier if possible to:**

- **provide best practice advice and guidance on local and regional arrangements where national advice is not (not yet) available;**
- **update and re-enforce guidance to the NHS that medicines should be provided on the basis of clinical need and cost-effectiveness where no NICE guidance exists, and that absence of NICE guidance should not be a reason for refusing funding; and**
- **reinforce the principle that national guidance from NICE technology appraisals takes precedence in full over regional or local guidance (similar to the principle recently embodied in the mandatory directions to the NHS regarding the National Framework for NHS Continuing Healthcare) and that there should be no further qualification, re-interpretation or modifications made to national guidance at local levels; while recognising the individual freedom of clinicians to prescribe as they see most appropriate for patients.**

4.2.11 As previously reported, the NHS Constitution gives patients a right 'to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence'. It also sets out patients' right 'to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you'. In February 2009, the National Prescribing Centre published *Supporting rational local decision-making about medicines (and treatments): A handbook of good practice guidance; First Edition: February 2009*.

4.2.12 **Focus groups are being held with Government, industry, patient groups and other stakeholder involvement to look at the economic perspective that the Department sets for NICE. These groups will produce outputs and report to Government.**

4.2.13 As previously reported, the University of York report, published in January 2010, did not present a clear mandate for change, concluding that incorporating a wider economic perspective into NICE's work would be a complex task which would raise a significant number of practical problems.

4.2.14 **The Department facilitate a number of bilateral NICE and industry meetings to discuss key concerns of industry with NICE processes.**

4.2.15 As previously reported, the Department facilitated a number of meetings between NICE, industry and relevant stakeholders to discuss the perceived lack of academic incentive for conducting health technology appraisals. NICE ran a series of 'master classes' for industry and academic stakeholders to share best practice.

Chapter 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 Key points include:

- the pharmaceutical sector in the UK has 365 companies, employing nearly 78,000 people, with combined annual sales of around £31.8 billion.[4] This represents an estimated 4% of global sales;
- of the top 50 global pharmaceutical companies, 37 companies have a total of 60 sites in the UK, employing 52,000 staff, representing 83% of the total sector turnover;[5] and
- the pharmaceutical sector continues to make a major contribution to the UK economy. In 2009, UK exports totalled around £20 billion while imports were around £13 billion, resulting in a trade surplus of some £7 billion.[6]

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

- £4.3 billion invested in the UK in 2008;[7]
- 25% of UK business R&D investment (the level of pharma industry investment which makes up 25% of the total industrial R&D investment across all sectors of the UK economy);
- UK's first-class research and science base which is contributed to and supported by the industry; and
- development in the UK of some 20% of the world's 75 top-selling medicines in 2007 – second only to the USA.

4 Source: HMG Strength and Opportunity 2011 Annual Update, December 2011 (www.bis.gov.uk/assets/biscore/innovation/docs/s/11-p90-strength-and-opportunity-2011-medical-technology-sectors)

5 Source: HMG Strength and Opportunity 2011 Annual Update, December 2011 (www.bis.gov.uk/assets/biscore/innovation/docs/s/11-p90-strength-and-opportunity-2011-medical-technology-sectors)

6 Source: OECD (STAN Bilateral Trade Database); HMRC Trade Statistics (www.uktradeinfo.com)

7 Source: ONS UK Business Enterprise Research and Development, 2009 (www.ons.gov.uk/ons/rel/rdit1/bus-ent-res-and-dev/2009-edition/index.html)

5.4 The Government wishes to ensure that the UK remains a leading location for life sciences investment, and a strong base from which to export. It very much values the ongoing close working between Government and industry to explore issues and develop solutions through the Ministerial (bio-pharmaceutical) Industry Strategy Group. It views the strategic discussions with 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 and through the membership of the Business Secretary and other ministers from the Department of Health, the Department for Business, Innovation and Skills (BIS) and HM Treasury (HMT).

5.5 Close working between the industry and the NHS is also crucial – the NHS Life Sciences Innovation Delivery Board brings together leaders from the NHS, industry and Government in a way that will make a difference at local level.

Plan for Growth

5.6 The Government's *Plan for Growth*[8] was launched alongside the Budget on 23 March 2011. One of the areas selected for particular focus in this process was 'healthcare and life sciences'. The Department of Health (working closely with HMT and BIS) developed a package of 16 actions aimed at supporting growth in the life sciences and social care sectors. Pharmaceutical companies will directly benefit from many of these actions, as will biotechnology and medical technology companies. *Plan for Growth* actions address a variety of issues in health research, procurement, social care and the uptake of assistive technologies.

5.7 The actions include:

- improving the UK's competitiveness as a location for clinical trials by reducing the regulatory burden, improving speed and cost effectiveness through:
  - establishing a Health Research Authority in 2011, working closely with the Medicines and Healthcare products Regulatory Agency to create a unified approval process and proportionate compliance and inspection;
  - from 2012, publication by the National Institute for Health Research (NIHR) of clinical trials outcomes against benchmarks, including an initial benchmark of 70 days or less for approving trials and recruiting

8 http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf

the first patient (this compares to the 142 days median as reported by the ABPI in 2009); and

- encouraging collaboration and innovation in the life sciences sector by:
  - establishing translational research partnerships from the £775 million investment in NIHR Biomedical Research Centres and Units;
  - taking forward a range of measures to encourage innovation in NHS procurement, including a £10 million investment over two years in the Small Business Research Initiative on healthcare challenges;
  - asking the NHS Chief Executive to publish a report by November 2011 on accelerating innovation across the NHS; and
  - launching a competition to form a Cell Therapy Technology and Innovation Centre.

5.8 A progress document was published on 29 November 2011, alongside the Government's Autumn Statement.[9]

Life Sciences Strategy

5.9 *Strategy for UK Life Sciences*[10] was launched by the Prime Minister on 5 December 2011. This was launched alongside the NHS Chief Executive's review on *Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS*[11] and sets out how the Government will support closer collaboration between the NHS, industry and our universities, driving growth in the economy and improvements in the NHS.

5.10 The Government has developed this strategy for the next 10–15 years. It will build on many of the actions of the Growth Review. Its key aims are to:

- promote new links between researchers, clinicians and business;
- improve the UK's performance on clinical R&D;
- ensure that the UK is supplying the high-skilled individuals required by industry;
- do better at translating research ideas into treatments for patients quickly and safely; and
- back the major new scientific advances.

9 http://cdn.hm-treasury.gov.uk/autumn_statement.pdf
10 www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences
11 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131299

Chapter 6 – International medicines price comparisons

6.1 This chapter compares the prices of branded medicines in the UK with prices in a range of European countries, the USA and Australia. It updates the information included in the previous reports and is based on an annual exercise carried out by the Department.

Broad methodology

6.2 The comparison is based on prices of the top-selling 250 branded products in primary care in England. From this, identical formulations that are prescribed in England and in other comparator countries are identified. As product availability, strengths, formulations and delivery routes can vary across countries, this restriction reduces the number of products included in the sample for each country.

6.3 An index is created by weighting product prices by their share of England community prescribing. Hence the index indicates what expenditure would be if these products were purchased at the prices existing in the comparator countries.

6.4 In some previous years, two sets of comparisons have been made:

- bilateral comparisons, where matches are found between the UK and the other country considered, e.g. UK and France, UK and Germany etc; and
- multilateral comparisons, where products included in the comparisons are restricted to those available in all the comparator countries.

6.5 As the list of comparator countries has expanded over the years, the number of multilateral matches declines, resulting in too few matches and hence too small a sample size to make this exercise viable. Therefore this report focuses on bilateral comparisons only.

6.6 As the number of matches in each bilateral comparison varies, the market coverage will vary. The market coverage in this year's analysis ranged between 43% and 75% of expenditure in England on branded medicines, with a median coverage of 53%.

6.7 Many countries regulate the wholesaler and pharmacy margins, and in some countries, prices reimbursed to pharmacies include a margin that counts towards the bulk of remuneration. These arrangements can vary considerably across countries. As this comparison is an attempt to estimate the prices paid to pharmaceutical companies, ex-factory prices have been used. However, for many countries, only reimbursement prices are known, therefore assumptions may have to be made in order to adjust to ex-factory prices. This adds another layer of uncertainty.

Changes over time

6.8 These price comparisons are undertaken every year. Year-on-year changes in the price indices for other countries should be treated with caution as changes may be due to any of the following:

- actual price changes relative to the UK;
- changes in the sample of products;
- movements in exchange rates; or
- changes in UK prescribing patterns, which alter the weights attached to each product/price.

Interpreting the results

6.9 International price comparisons for medicines need to be interpreted with some caution, particularly when they are used to compare prices over time.

6.10 There are a number of issues that relate to the methods that confound comparisons:

- 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 (see below). International comparisons must use an exchange rate conversion factor. Market exchange rates have been used for these comparisons. However, these can be subject to short and medium-term fluctuations. The results presented below use market exchange rates pertinent to the time of the comparison, and also a five-year average (as a means of 'smoothing out' short-term fluctuations);
- the proportion (and mix) of medicines expenditure included in the analysis. These will vary from country to country and over time;

- minor changes in the methods used over the years, though these are not expected to markedly affect the results; and
- use of ex-factory price estimates in the comparison, which can only be approximated for some countries.

6.11 In addition to these technical factors, there are a number of cost containment policies that significantly affect prices and the cost borne by state funders, which will not be reflected in the price comparisons shown in Table 4 because:

- 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 is becoming an increasing feature in many countries, particularly in recent years as countries have faced serious economic pressures. This means that prices in some countries may be overstated relative to the true position; and
- some countries have adopted reference pricing arrangements. Under these arrangements, reimbursement is capped at the price of a therapeutic comparator, often a much cheaper generic. If patients want the brand, they have to make a substantial co-payment. In essence, this means that the price used in this analysis may not always reflect the price paid by the respective health service or insurer, which can be substantially less in some instances. This means that the price indices quoted below may significantly overstate the prices that are paid by state or social insurance funders.

Results

6.12 Table 4 below shows figures for 2004 to 2010.[12]

Table 4: Bilateral comparisons of ex-manufacturer prices

Country	Price indices							
	2004	2005	2006	2007	2008	2009	2010	2010 indices using five-year* average exchange rate
Australia	–	–	–	94	94	126	139	106
Austria	94	96	94	96	111	125	117	107
Belgium	90	95	97	101	122	132	122	112
Finland	96	101	96	99	119	113	105	96
France	84	96	89	92	108	115	104	95
Germany	106	108	105	113	142	169	155	142
Ireland	99	103	105	112	134	144	133	122
Italy	78	84	78	83	101	120	113	103
Netherlands	92	95	94	99	115	–	–	–
Spain	80	84	85	88	109	118	106	97
Sweden	–	–	103	105	116	126	130	114
UK	100	100	100	100	100	100	100	100
USA	176	198	188	183	252	249	281	254

* Uses 2010 price information but converted to sterling, for this comparison, using the average quarter 4 exchange rate for the period 2006 to 2010.

6.13 The comparisons for 2010 (based on quarter 4 2010 market exchange rates) showed the weighted index of prices in the UK to be:

- significantly lower than those in the USA; and
- lower than those in the other European comparator countries.

12 Please refer to previous Reports to Parliament for figures going further back

6.14 However, if the longer-term five-year average exchange rate is used, the picture is more mixed. UK prices are significantly lower than those in the USA; lower than those in Australia, Austria, Belgium, Germany, Ireland and Sweden; and higher than those in Finland, Spain and France. This demonstrates the influence that exchange rates have on the estimates of price relativities.

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