



*The Pharmaceutical Price
Regulation Scheme
2009*

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1 Purpose

- 1.1 The 2009 Pharmaceutical Price Regulation Scheme (the scheme) is a non-contractual scheme, effective from the termination of the 2008 Pharmaceutical Price Regulation Scheme (the 2008 PPRS) on 31 December 2008. The parties to this agreement are the Department of Health (the Department), acting on behalf of the Health Departments of England, Wales, Scotland and Northern Ireland and the Association of the British Pharmaceutical Industry (the ABPI).
- 1.2 The Health Departments of the United Kingdom (UK) and the ABPI have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the National Health Service (NHS), and in a strong, efficient and profitable pharmaceutical industry. Such an industry must be capable of sustained research and development (R&D) leading to the future availability of new and improved medicines in this and other countries.
- 1.3 The Department, on behalf of the UK Health Departments, acknowledges that in consenting to the terms of this 2009 scheme all rights and obligations accrued by members of the 2008 PPRS and the Department pursuant to the 1999 Pharmaceutical Price Regulation Scheme (the 1999 PPRS) and/or the 2005 Pharmaceutical Price Regulation Scheme (the 2005 PPRS) and/or the 2008 PPRS are neither waived nor extinguished by entry into the scheme. Rights in this regard include the right of both the Department and the scheme member to refer disputes to arbitration as provided for in the 1999 PPRS and/or the 2005 PPRS and/or the 2008 PPRS and to appeal an award to the High Court under the 1999 PPRS and/or the 2005 PPRS.

2 Objectives

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

2.1.1 **Deliver value for money**

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.

2.1.2 **Encourage innovation**

Promote 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.

2.1.3 **Promote access and uptake for new medicines**

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

2.1.4 **Provide stability, sustainability and predictability**

To help the NHS and the 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.

3 Introduction

- 3.1 The Government recognises the industry's contribution to the economy of the UK and wishes to continue to encourage its competitive efficiency, both at home and abroad. The Department, on behalf of the UK Health Departments, recognises that continuous innovation is the key to competitive success in a research-based industry and wishes to encourage the research, development and supply of innovative treatments for the benefit of NHS patients.
- 3.2 The Department recognises that a wide variety of factors influences the competitiveness of the pharmaceutical industry and that effective industrial policies need to be developed, incorporating European and global issues. These need to be managed alongside health policy. The UK Health Departments will facilitate the industry's participation in government initiatives relevant to the further development of the sector.
- 3.3 The ABPI recognises that it is in the public interest that the prices of pharmaceutical products supplied under the NHS are fair and reasonable. The ABPI shares the Government's objective of ensuring that medicines are supplied and used effectively and efficiently and that expenditure on medicines is managed and understood within the context of NHS spending as a whole.
- 3.4 Both parties agree that the performance of the PPRS cannot be assessed in isolation from the NHS environment with which it interacts. The PPRS is the UK-wide price regulation scheme for branded prescription medicines supplied to the NHS. It applies across the four nations of the UK. The UK Health Departments do not support additional or alternative initiatives by health authorities in respect of the pricing of such supplies in primary care. Subject to any future decisions of the UK or devolved parliaments, assemblies or ministers to adopt a different policy with regard to the pricing of branded prescription medicines, the Health Departments will do all they can to ensure that the scheme is fully implemented and sustained throughout the NHS during the lifetime of the scheme.
- 3.5 This scheme encompasses a much broader agenda than previous schemes and includes elements that have not been included previously in the PPRS. The Government and the ABPI welcome these developments, which help to ensure that the PPRS provides for a fair and balanced package by incorporating measures that reward innovation, increase uptake of clinically and cost-effective new medicines and increase patients' access to medicines at prices that better reflect their value. Further information on these new elements is set out in chapter 5 on uptake and innovation and chapter 6 on flexible pricing and patient access schemes.
- 3.6 The Government and the ABPI will continue to work together under the aegis of the Ministerial Industry Strategy Group's (MISG) Long-Term Leadership Strategy for medicines in a programme of action aimed at supporting the objectives of the scheme and the industry's global competitiveness.
- 3.7 Both parties will operate the PPRS in good faith and recognise that there should be compliance with the agreement. The Department agrees to raise any issues relating to the management and operation of the scheme over its lifetime during regular review meetings with the ABPI. The Department will ensure the confidentiality of commercially sensitive information submitted by scheme members.

4 Status and membership of the scheme

Status

- 4.1 This scheme is a voluntary scheme which is not binding under the law of contract. Any company which participates in this scheme will not be subject to a statutory scheme, as under sections 262(2) and 263(7) of the National Health Service Act 2006, there is no power to make statutory scheme regulations as regards members of voluntary schemes.

Effective date and duration

- 4.2 The Department and the ABPI are committed to ensuring stability, sustainability and predictability for scheme members. This scheme will operate for not less than five years from 1 January 2009. Either the Department or the ABPI may request a termination or renegotiation of the scheme after four years. The scheme will continue to operate subject to at least 12 months' notice given by either party not earlier than 31 December 2012. In this agreement, a period ending or terminating on a given date shall have effect until midnight on that given date.
- 4.3 This scheme replaces all previous PPRS agreements, save that all rights and obligations accrued by members of the 2005 PPRS and the Department pursuant to the 1999 PPRS and/or the 2005 PPRS and/or the 2008 PPRS are neither waived nor extinguished by entry into this scheme.

Amendment of the scheme

- 4.4 The provisions of this scheme may only be amended by the mutual agreement of the ABPI and the Secretary of State for Health. If the terms of this scheme are amended, existing scheme members will be invited to accept the new terms and will have the option of leaving the scheme as set out below (see paragraphs 4.13–4.15).

Application to manufacturers and suppliers

- 4.5 The scheme applies to manufacturers and suppliers (scheme members), as provided for by section 261(2) of the National Health Service Act 2006 and The Health Service Medicines (Consent to Voluntary Scheme) Regulations 1999, who have consented in the manner required by the Secretary of State. The scheme is set out in this document and the terms of consent are in annex A. The scheme will apply as long as the scheme member has not withdrawn its consent in the manner required by the Secretary of State and written notice by the Secretary of State has not taken effect.
- 4.6 Subject to paragraph 4.3 above, the Department and any manufacturer or supplier moving from the 2005 PPRS or the 2008 PPRS to this scheme will continue to meet their respective obligations arising from the 1999 PPRS, 2005 PPRS and 2008 PPRS. In the case of a scheme member, they will submit an Annual Financial Return (AFR) (if so required) in respect of any business year or part year up to and including the end of 2008, provide the additional information relating to sales of branded medicines

(if so required), provide any required supporting information, and meet any other outstanding commitments under the 1999 PPRS, the 2005 PPRS and the 2008 PPRS.

Entry mechanism

- 4.7 Members of the 2008 PPRS may join this scheme at any time from 11 December 2008 by completing form A at annex A, and their membership will be effective from the start of this scheme. Form A is the consent to membership of this scheme. Companies, which were not members of the 2008 PPRS, may join this scheme by completing form A and their membership will be effective from the date of receipt of form A by the Department or such other date as is agreed between the company and the Department. Consent to join this scheme neither implies nor constitutes waiver or extinguishment of any rights or obligations accrued by either the Department or the scheme member pursuant to the 1999 PPRS, the 2005 PPRS and 2008 PPRS.
- 4.8 A manufacturer or supplier having been a member of the 2005 PPRS and/or 2008 PPRS, but which ceased to be a member of either of those agreements because of unfulfilled obligations under those agreements, will be required to meet those unfulfilled obligations before membership of this scheme is confirmed by the Secretary of State. Members of the 1999 PPRS and/or 2005 PPRS will not be barred from joining this scheme by virtue of having filed a non-standard audit certificate under either or both the 1999 PPRS and 2005 PPRS.
- 4.9 Manufacturers and suppliers that either elect not to join this scheme or that are denied membership under the terms of paragraph 4.13 shall be subject to any regulations or directions made by the Secretary of State pursuant to his powers under sections 262 to 264 of the National Health Service Act 2006. Those sections do not apply to members of this scheme.

Non-ABPI members

- 4.10 Although this scheme is the result of negotiations between the ABPI and the Department, it is open to companies that are not members of the ABPI to be scheme members.

Re-entry to the scheme

- 4.11 A company that manufactures or supplies NHS medicines has the right to be a scheme member unless, having ceased to be a scheme member for whatever reason, any of its obligations under the scheme remain undischarged.

Supply of medicines

- 4.12 The scheme applies to the manufacturers of medicines and, in the case of suppliers with affiliates outside the UK, the subsidiary company with a place of business in the UK. In cases of doubt, the holder of the marketing authorisation for the NHS medicine is likely to be treated as the supplier for PPRS purposes, or the company discharging the responsibilities of the marketing authorisation holder, or of the EU marketing authorisation holder.

Exit mechanism

- 4.13 Under the National Health Service Act 2006, the Secretary of State may serve notice on a manufacturer or supplier that the scheme is no longer to apply to it. The Secretary of State may do this where any acts or omissions of the company have shown that, in the scheme member's case, the scheme is ineffective either for the purpose of limiting prices for the supply of health service medicines or limiting profits which may accrue in connection with the manufacture or supply of health service medicines. The Secretary of State may also consider the scheme to be ineffective where a scheme member significantly fails to comply with the requirements of the agreement more generally. The Secretary of State will have regard to any relevant decision of the Dispute Resolution Panel when considering whether to serve a notice under that provision of that Act. A scheme member on whom notice has been served under this paragraph may appeal against said notice, and any notice so appealed shall not become effective unless and until the Dispute Resolution Panel has concluded its proceedings and found in favour of the Secretary of State.
- 4.14 The Secretary of State would also normally regard it as relevant if it had been necessary to impose penalties or take other enforcement action provided for in regulations for breaches of provisions under regulations or directions made under that Act, particularly where this appeared to show a pattern of behaviour.
- 4.15 A scheme member may, at any time, withdraw consent for the voluntary scheme to be treated as applying to it by completing form B at annex A.

Products covered

- 4.16 The scheme applies to all branded, licensed NHS medicines.
- 4.17 For this purpose the term 'NHS medicine' refers to any human pharmaceutical product for which a marketing authorisation has been granted and to which the proprietor applies a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International Non-proprietary Names (rINN), or any list of similar standing, and which brand name is not excluded from prescription on form FP10 (GP10 in Scotland, WP10 in Wales, HS21 in Northern Ireland).
- 4.18 The scheme will apply to all packs and dosage forms of a NHS medicine except:
- 4.18.1 a pack that is intended for sale to the public without a prescription and the price of which is not generally accepted as a basis for the pricing of FP10 prescriptions (GP10 in Scotland, WP10 in Wales, HS21 in Northern Ireland);
 - 4.18.2 the proportion of sales of medicines that can be shown to be derived predominantly from private prescriptions or over-the-counter (OTC) sales.
- 4.19 Where a medicine is sold predominantly OTC or on private prescription and its NHS prescription sales are below £50,000, the Department may exercise discretion to exclude such sales from the requirements of the scheme.

- 4.20 For clarification, the scheme applies to the following products, provided that they have a brand name and marketing authorisation:
- 4.20.1 branded generics;
 - 4.20.2 vaccines;
 - 4.20.3 in-vivo diagnostics;
 - 4.20.4 blood products;
 - 4.20.5 dialysis fluids;
 - 4.20.6 branded products supplied through tendering processes and on central or local contracts;
 - 4.20.7 biotech products.
- 4.21 The scheme does not apply to the following:
- 4.21.1 products that cannot be prescribed under the NHS Pharmaceutical Services (Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004);
 - 4.21.2 in-vitro diagnostics;
 - 4.21.3 unlicensed products supplied on an individual patient supply basis;
 - 4.21.4 dental anaesthetics.

5 Uptake and innovation

- 5.1 The role of the pharmaceutical industry in the development of healthcare and medical advances is of crucial importance. It is in the interests of patients, the NHS, the Government and the industry that any pricing system encourages research and rewards innovation that delivers valuable new treatments. The Department is committed to increasing the uptake of new cost-effective medicines in the NHS. To this end, the Department and the industry have committed to a number of specific initiatives aimed at encouraging and rewarding innovation and assisting the uptake of new medicines. This chapter summarises the key elements of the actions on innovation and uptake. Details of the package as a whole are set out at annex B (which has equal status with this chapter). With the exception of the horizon scanning process, all other initiatives relate to the Department of Health in England. It is for the devolved administrations to meet their policy and operational requirements. The Health Departments of Scotland, Wales and Northern Ireland will work with the industry on making progress in these areas, and working with the Department where appropriate.

Horizon scanning

- 5.2 The Department will establish a single, unified horizon scanning process to identify new technologies in development by the industry. This process will be developed in co-operation with the National Institute for Health and Clinical Excellence (NICE), the Scottish Medicines Consortium (SMC), the All Wales Medicines Strategy Group (AWMSG), the National Prescribing Centre (NPC), UK Medicines Information (UKMi) and the National Horizon Scanning Centre (NHSC). The industry will play a full part in the design and development of a database to capture such new technologies. Uses of the database will include supporting Health Technology Assessment (HTA) topic selection, scoping of appraisals and providing timely information to all NHS organisations for planning and budgeting purposes.

Uptake of innovation

- 5.3 It is the Department's intention that implementation of NICE technology appraisals should continue to be performance managed through mainstream NHS systems. It is important that when NICE issues guidance it is implemented consistently across England, and the Department and NICE recognise their roles in supporting this implementation. The Government remains fully committed to ensuring NHS implementation of NICE technology appraisals, supported by the statutory three-month funding direction that the Department put in place in 2002. In addition, the draft NHS Constitution issued for consultation in 2008 included a patient right to NICE-approved drugs.
- 5.4 By no later than April 2009 the Department will:
- refresh and extend good practice guidance in England so that it is clear that absence of NICE guidance is not a reason for refusing funding. Medicines should be provided in the NHS on the basis of clinical need and cost-effectiveness where no guidance exists. By no later than April 2009 the Department will provide new best practice advice and guidance on local and regional arrangements where national advice is not, or not yet, available;

- reinforce the principle that national guidance in NICE technology appraisals takes precedence in full over regional or local guidance and that there should be no further qualification, reinterpretation or modifications made to national guidance at local levels, while recognising the freedom of clinicians to prescribe as they see most appropriate for patients; and
- address the anomaly whereby the funding direction does not apply to NICE technology appraisal recommendations, which are subsequently updated in a clinical guideline. The Department will establish the optimum mechanism to achieve this.

5.5 The Department will ensure that there is consistency between NICE recommendations and broader policy on the NHS. This will include, for example:

- The Department will work with some primary care trusts (PCTs) to pilot extension of prescribing incentive schemes to promote the uptake of innovative products. Potential volunteer PCTs were identified by October 2008.
- The Department will continue to ensure alignment between the Quality and Outcomes Framework (QOF) and NICE guidance.
- The Department and the industry will undertake jointly three case-based reviews proposed by the industry on uptake of NICE guidance in Payment by Results (PbR) to promote better use of existing levers in PbR to further promote and incentivise uptake. The review will be completed by December 2008 with a way forward identified by April 2009.

Comparative information

5.6 The Department and the industry agree that new guidance and an effective use of system levers need to be supported by an effective use of benchmarking and monitoring to achieve sustained change. To this end:

- a joint industry, Department of Health and NICE working group has been established to define metrics, pilot products, data sources, publication channels and governance mechanisms. Analysis will commence in September 2008 with a view to commencing publication of annual indicators by summer 2009. The Department commits to publication of strategic health authority (SHA), PCT and network-level metrics for uptake of a number of positively approved NICE appraisals (approved either fully or with restrictions). The metrics will be published through suitable channels on an ongoing basis.

5.7 The UK should compare itself with other countries if it is to deliver a world-class NHS. 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, more specifically, to provide international benchmarks and trends for the uptake of NICE-approved technologies. To that end:

- a joint Department of Health and industry working group will be set up immediately. Baseline data collection will commence in September 2008 with a view to publishing annual indicators and contextual commentary from April 2009.

NICE and HTA

5.8 The Department recognises concerns that the industry has raised regarding the importance of incremental innovation in the discovery process, and the issues that the industry has highlighted regarding particular aspects of NICE's work. The Department will, while recognising and respecting the fundamental independence of NICE, facilitate ongoing meetings to discuss and address these issues.

The Government confirms that it is committed to transparency, consistency in decision-making and support for innovation.

- 5.9 The Government is committed to continuing to explore the key issue of the economic perspective that the Department sets for NICE. This is a complex issue, which is of interest to key stakeholders, including the industry, and the Government recognises the concerns that the industry has raised.

Monitoring arrangements

- 5.10 The Department and the industry agree that it is important that progress in these areas is monitored in future years with a view to ensuring effective implementation. This monitoring will be through MISG and the Health Innovation Council (HIC), although the details of this monitoring role will be dependent on the future composition and role of HIC. Implementation of these measures will not be subject to the dispute resolution procedures set out in chapter 11.

6 Flexible pricing and patient access schemes

A pricing system that reflects value to the NHS

- 6.1 Progress has been made since the creation of NICE in 1999 in ensuring that patients have benefited from innovative cost-effective drugs that are of value to patients. The NICE process and the PPRS are already indirectly linked as companies consider the likely outcome of a NICE appraisal when setting the price of a drug. Thus, the price of a drug and its potential value are already linked to an extent while retaining freedom of pricing on new active substances on entering the market (paragraph 7.31). NICE will not negotiate or publicly set or publicly indicate prices.
- 6.2 NICE's assessment of value is not exclusively driven by cost per Quality Adjusted Life Year (QALY) analysis, but instead is based on a deliberative process that also takes into account other factors in order to come to a view on whether or not a treatment is likely to be cost-effective.
- 6.3 It is important that value is reflected in the PPRS. While there are already measures in place aimed at reflecting the value of medicines in their prices, more could be done to ensure that value is further reflected and better systematised in the PPRS.
- 6.4 The Department and the ABPI have therefore agreed two different mechanisms aimed at better reflecting value that now form part of the PPRS:
 - Flexible pricing – where a company can increase or decrease its original list price in light of new evidence or a different indication being developed.
 - Patient access schemes – which will facilitate earlier patient access for medicines that are not in the first instance found to be cost and clinically effective by NICE within a framework that preserves the independence of NICE.

While pricing is a reserved matter, a number of the proposals are devolved matters and the Department's scope of influence is limited to the NHS in England and NICE. It is for the devolved administrations to meet their policy and operational requirements. The Health Departments of Scotland, Wales and Northern Ireland will work with the industry on making progress in these areas, and working with the Department where appropriate.

Flexible pricing

- 6.5 Flexible pricing recognises that the initial launch indication of a medicine may not fully reflect its longer-term value to patients in the NHS. It therefore allows a company to propose an initial price for a medicine that reflects value at launch, while retaining the freedom to increase or decrease this original list price either as further evidence or as new indications for the medicine emerge and change the effective value that the medicine offers to NHS patients.
- 6.6 The Department and the ABPI acknowledge that this more flexible approach is a natural consequence of taking a more value-based approach to pricing. However, this is a novel approach and a number

of practical challenges remain in implementation. The initial proposals set out in this document will therefore need to be reviewed in due course. The timing of such a review will be jointly agreed but will be initiated not later than two years after the commencement of this agreement.

- 6.7 There are two circumstances in which such a flexible approach to pricing will be relevant:
- when significant new evidence is generated that changes the value of an existing indication; and
 - where a significant new indication is proposed.
- 6.8 The Department and the ABPI agree that the potential for flexible pricing will apply only when medicines are subject to NICE appraisal. A review by NICE will be required to determine whether the revised price provides value to the NHS.
- 6.9 For medicines not selected for NICE review the potential to increase prices via modulation will remain an option. The flexible pricing arrangements are additional to and not a substitute for options available under the other pricing sections in this agreement.

New evidence for existing indications

- 6.10 Companies will have the opportunity to use flexible pricing for existing indications where new evidence has the potential to significantly change the expected value to NHS patients when compared with the value at the original review of the medicine. In some cases, the potential for such new evidence will have been identified as part of the original NICE appraisal.
- 6.11 In the case of products launched after 1 January 2009, a company will be able to indicate directly to NICE that it believes that the existence of significant new evidence warrants a decision by NICE to review the product. NICE will retain the responsibility to decide whether a review is appropriate using its current process involving input from stakeholders. NICE will consider these review criteria in its review of its technology appraisal process guide, due to be completed by mid 2009. Where significant new evidence is available and a price change is proposed, then the review will form part of a Single Technology Appraisal (STA) or Multiple Technology Appraisal (MTA) review and will not be updated as part of a clinical guideline.
- 6.12 The Department is concerned about the ability of the NHS to plan for any future price increases and is also concerned about the impact on NICE's workload of reviews. Therefore, for products that were launched before 1 January 2009, a company will be able to propose a price change linked to new evidence only where NICE itself initiates a review.
- 6.13 In all cases, companies will be able to request only one price increase after the launch of the list price for any individual product under the terms of this chapter (regardless of launch date and assuming that the requirement for significant new evidence is met). In all cases, any price increase will be restricted to a maximum of 30%. In these circumstances, the company will have the freedom to propose a new price up to the maximum and subject to NICE review.
- 6.14 The NICE appraisal will review the revised price for the medicine, and as per its current approach decide whether this provides value for money for the NHS. In doing this NICE will apply its standard methodological approach as outlined in the *Guide to the Methods of Technology Appraisal*. NICE's assessment of cost-effectiveness will be consistent with that used in the previous appraisal. This will address ABPI concerns that by definition the medicine will always be more cost-effective at the (old) lower price, and the Department's concerns about the potential for drug prices to be pushed to the

margins of cost-effectiveness. As before, NICE will not negotiate or publicly set or indicate prices when undertaking this review.

- 6.15 In the event of a price rise, the company will not be permitted to implement the price increase until and unless positive guidance covering similar numbers of patients is obtained from NICE. In the event of a negative NICE appraisal, the price will remain at the original price.

New indications

- 6.16 Any medicine may have a number of indications developed over its lifetime. For many of these the value to patients may be within a similar range and therefore it will be feasible for the company to propose an original launch price that is likely to provide sufficient value to the NHS to enable NICE to issue positive guidance on each indication.
- 6.17 However, there are occasions where the value to NHS patients of the new indication may be significantly different from the original indication. In these circumstances, an increase or decrease in price may be sought by the company for the new indication as compared with the old.
- 6.18 As in the case of new evidence for existing indications, the Department is concerned about the ability of the NHS to plan for price increases and is also concerned about the impact on NICE's workload of reviews. To this end, these provisions are restricted to major new indications that are likely to result in a significantly different value to patients. The Department and NICE will set out the criteria relevant to any determination of a major new indication after seeking input from stakeholders as part of work being undertaken by NICE and the Department on NICE topic selection.
- 6.19 The company could signal its intention to propose a higher price in advance of or as part of the topic selection process but the price increase would not come into effect until after NICE final guidance had been issued or after 12 months from the date of licensing (or 12 months after the company proposed the price change if the proposal is made post licensing), whichever date is reached first. Many major new indications of medicines are already likely to be subject to NICE appraisal so it is not anticipated that this will result in any major increase in the number of appraisals required.
- 6.20 For new indications for products first launched in the UK on or after 1 September 2007, there will be no limit on the price increase. However, to limit the number of applications to a manageable level and to facilitate implementation in the NHS for any medicine, it will normally be expected to have only one price change per active substance during its lifetime. For products launched before 1 September 2007, no price increases will be available under the terms of this part of the agreement.
- 6.21 In the event of a price increase, a company must make arrangements to provide the product at the old price for the original indication. This will have to be done through the application of a simple discount, introduced on the day that any new price commences. In order not to invalidate an existing NICE appraisal and associated funding direction, the price of the original indication must remain the same. There are added issues to consider around discount schemes in primary care. Proposals in primary care will therefore need to be considered on a case-by-case basis.
- 6.22 The NICE appraisal will review and decide whether to recommend the new indication at the proposed price for the medicine, and as per its current methodological approach decide whether this provides value for money for the NHS. The company will be able to proceed with the price increase (with the timing determined by paragraph 6.19) and NICE will issue guidance to the NHS on use of the product.

Patient access schemes

- 6.23 Patient access schemes are schemes proposed by a pharmaceutical company and agreed between the Department (with input from NICE) and the pharmaceutical company in order to improve the cost-effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines (see below for further information on the types of scheme). This section of the PPRS document relates to England and Wales, as different HTA arrangements are in place in Scotland and Northern Ireland.
- 6.24 The Department and the ABPI recognise that there are potential benefits to be derived from these schemes. In England and Wales, NICE and the Department are already facing ad hoc requests from companies for approval for 'schemes' to secure a positive NICE appraisal where that might not be forthcoming on the basis of published list price and currently available evidence. More products are being referred to NICE by the Department prior to their launch, which may increase the numbers of requests for schemes.
- 6.25 While welcoming moves for greater flexibility where this can facilitate access for NHS patients in England and Wales to new drugs on cost-effective terms for the NHS, the Department and the ABPI recognise the need to ensure that the cumulative burden on the NHS is manageable and the need to ensure that there is proper consultation with the NHS before such schemes are adopted. These schemes should therefore be the exception rather than the rule. The following paragraphs outline different types of scheme, those that are preferable for the ABPI, the Department and the NHS, and the principles that will be applied in administering them.

Key principles for implementation in England and Wales

- 6.26 A number of principles have been developed through discussions between the Department and the ABPI. These include the following:
- Arrangements must respect the role of NICE in providing the NHS with an independent assessment and appraisal of the evidence on an intervention.
 - Schemes are to be discussed first and agreed in principle by the Department and the company. NICE's principal role is to assess the impact of such proposals on cost-effectiveness taking into account the details of the proposed scheme.
 - The full costs to the NHS of any such arrangements should be included in the costs considered by the Appraisal Committee.
 - Schemes should be clinically robust, clinically plausible, appropriate and monitorable (e.g. if it is a responder scheme, there must be a relatively straightforward way to measure a patient's clinical response).
 - Any scheme should be operationally manageable for the NHS without unduly complex monitoring, disproportionate additional costs and bureaucracy. Any burden for the NHS should be proportionate to the benefits of the scheme for the NHS and patients. Clarity is also required on the exact duration of any agreement and the circumstances in which it might be terminated.
 - It is important that the cumulative administrative burden of such schemes remains manageable for all parties involved in their operation, including front-line NHS staff. It is reasonable for the Department to take this issue into account when considering the viability of individual schemes. Priority is likely to be given to schemes that deliver the greatest benefits to patients, for example in enabling the NHS to address a previously unmet need.

- Schemes should be consistent with existing financial flows in the NHS and with local commissioning (e.g. payers must be able to calculate the effective price for their patient population, so the costs and savings accrue to those local services making commissioning and treatment decisions).
- The NHS in England and Wales must be consulted on patient access schemes, in particular where these involve additional data collection beyond that associated with the conventional purchase of medicines – for example in relation to patient numbers, or the monitoring and recording of a patient’s condition over and above that for the normal management of a patient. The Department will set out in more detail the nature of that consultation.
- The more systematic use of such schemes will need to be reviewed in light of experience. The timing of such a review will be jointly agreed but will be initiated not later than two years after the commencement of this agreement.

Types of patient access scheme

6.27 The Department and the ABPI have agreed a typology for patient access schemes whereby there are:

- financially-based schemes; and
- outcome-based schemes.

6.28 **Financially-based schemes** are where:

- the company does not alter the list price of the drug, but offers effective discounts or rebates that may be linked to (for example) the:
 - numbers or type of patients treated (e.g. price/volume arrangement that may or may not be linked to use in different patient sub-groups);
 - response of patients treated (there is, of course, also an ‘outcome’ dimension to such schemes); and
 - numbers of doses required;
- the other option for a company would be to change the list price of the product.

6.29 Within these schemes, the Department and the ABPI note that the simplest type of scheme is one involving some sort of an adjustment to the price that the NHS pays without a need for additional reporting of patient data as this places the least burden on the NHS.

6.30 **Outcome-based schemes** can be split into three sub-groups:

- **Proven value: price increase.** The company seeks agreement to a later increase in price subject to a re-review of the drug in the light of additional evidence collection as agreed with NICE. The company will normally be responsible for the collection of the additional evidence.
- **Expected value: rebate.** The company seeks agreement to a price subject to the collection of additional evidence as agreed with NICE. Such an arrangement will be subject to a rebate and subsequent reduction in list price in the event of the additional evidence not supporting the current price in a re-review in the light of the additional evidence. The company will normally be responsible for the collection of the additional evidence.

- **Risk sharing.** Outcomes are measured, be these patient reported outcomes or clinical outcome measures and price adjustments and/or cash transfers are made in one or both directions (between the company and the NHS) in the light of the outcomes identified relative to those anticipated in line with the terms of the scheme.

6.31 The Department and the ABPI agree that outcome-based schemes, particularly risk sharing schemes, are likely to be more burdensome on the industry and the NHS because of complexities in designing and measuring outcomes. This means that, to an even greater degree than patient access schemes in general, they are likely to be appropriate only in exceptional circumstances.

Potential timing of proposals for patient access schemes

6.32 Prompt appraisal by NICE of significant new drugs is an important element of the Government's approach to ensuring that patients can access innovative cost-effective medicines quickly and consistently. *High Quality Care For All* underlines the Government's commitment to ensuring that the majority of NICE appraisals of new drugs result in final guidance within a few months of a drug's marketing authorisation.

6.33 While patient access schemes are intended to help to secure access for NHS patients to drugs that might otherwise not have been deemed cost-effective, it is important that arrangements for proposing and agreeing such schemes do not in turn jeopardise the timeliness of NICE appraisal guidance, which is in itself designed to provide guidance to the NHS on the cost-effective provision of treatment to patients. It is also important that the timing of discussions on schemes does not encourage 'gaming' of the appraisal system by any party.

6.34 In that context, the Department and the ABPI have concluded that, where companies wish to bring forward scheme proposals in the context of a NICE STA, they should do so at one of two stages in the process, either:

- at the outset, when making their initial evidence submission to NICE. This implies that any discussions with the Department should precede the company's submission; or
- at the end of the appraisal process, once any appeals have been heard and NICE's final guidance has been issued to the NHS.

NICE will consider how best to implement this provision in its review of its technology appraisal process guide, due to be completed by mid 2009. It is anticipated that the process review will consider the provision of a short fixed period following the issuing of NICE guidance during which the company can approach the Department with a proposal for a patient access scheme and, if the scheme is acceptable to the Department, a review of the guidance by NICE.

6.35 There is no guarantee that patient access schemes will be considered at other stages in the NICE process.

Application to the MTA process

6.36 NICE MTAs are, in future, likely to be used primarily as a mechanism for reviewing groups of drugs that have previously been assessed individually. Patient access schemes may also play a role here in facilitating patient access for medicines that may not, in the first instance, be found to be cost and clinically effective by NICE in an MTA. If the company wishes to propose a patient access scheme, they should submit proposals to NICE (post discussions with the Department) at the start of the MTA

process. Because of the complexity of the MTA process, there must be a very clear presumption against proposing or accepting schemes at additional times in the NICE process.

- 6.37 Subject to the requirements of NICE's published appraisal processes, details of any patient access scheme will, if the submitting company wishes, be listed as 'commercial in confidence' when the submissions are published. NICE will of course need to make relevant details of proposals clear when it issues its Appraisal Consultation Document and subsequently.
- 6.38 In the event of NICE recommending significantly restricted use or no use of a company's product, a company would have the opportunity as in the case of an STA to initiate the process for submission of a patient access scheme. In this situation, a company whose drug was approved in the original NICE MTA would also have the option of proposing a scheme. However, companies will have only one opportunity to do this following NICE guidance. The issuing of any revised guidance following NICE consideration of one or more patient access schemes will not be followed by a further opportunity for any company to submit such a scheme or any additional post-guidance review. In consideration of the principles set out in paragraph 6.26 above, any judgement made by the Department in relation to a proposed scheme on the burden for the NHS being proportionate to the benefits of the scheme for the NHS and patients will, in the context of an MTA, take into account NICE's view on the potential for significant additional benefit to patients.
- 6.39 The decision on whether to submit patient access scheme proposals is a competitive decision for the individual companies concerned. It is not therefore appropriate for any 'early alert' to be given by the Department or NICE to other companies when a scheme is proposed.
- 6.40 None of these provisions stops companies from reducing their prices at any time or offering local discounts to the NHS in order to improve their competitive position.

Conditional licensing/earlier access

- 6.41 There may be links between these proposals and the pricing aspects of the 'conditional licensing' recommendation of the Cooksey Report and current work on earlier access. Further work will be taken forward with MISG and the Medicines and Healthcare products Regulatory Agency (MHRA) on this point.

Transparency

- 6.42 The concerns of companies about commercial confidentiality will be respected. However, the existing arrangements for consultation and disclosure will apply in relation to schemes proposed at the start of the NICE appraisal process.
- 6.43 The proposals for a new post-guidance stage mean that the content of a scheme submitted under this provision will remain confidential until such time as NICE needs to consult the NHS. At that point, only the information necessary to enable the NHS to comment or operate any revised guidance would be published.

Consultation

- 6.44 It has been established that where schemes are proposed, they must be agreed in principle by the Department before NICE can incorporate them into its appraisal guidance. To enable it to take an

informed view on the implementability of scheme proposals, the Department needs to be able to validate them with NHS stakeholders or a representative group. Similarly, when NICE consults on draft appraisal guidance, this must provide stakeholders with an opportunity to comment on the full content of the appraisal including the details of any proposed pricing scheme. The Department and NICE will put in place processes to validate and consult on proposals with NHS stakeholders.

Schemes offered outside or prior to NICE appraisals

- 6.45 Pharmaceutical companies may continue to offer schemes or discounts to the local NHS outside NICE appraisals as long as these do not contravene any aspect of the PPRS, but decisions on whether to participate in such schemes and the terms on which they are offered are matters for the relevant pharmaceutical companies and the local NHS.

Links with NICE process review

- 6.46 The process implications of the approaches this document sets out will be addressed by NICE through its established mechanisms for periodic review of its appraisal process, due to be completed by mid 2009. The wording in this chapter applies from 1 January 2009 but full implementation will be dependent on the conclusion of the scheduled NICE appraisal process review.

7 Pricing

Introduction

- 7.1 In consideration of a five-year agreement and delivery of the commitments set out elsewhere in this scheme, a package of measures will be implemented to secure further efficiencies in NHS medicines expenditure.
- 7.2 The measures set out below are consistent with the principles and objectives of the scheme. They are intended to encourage and reward innovation while also supporting normal market competition, and providing greater value following loss of exclusivity and entry of generic equivalents.
- 7.3 Provision is made 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) and the introduction of generic substitution in the NHS. It is intended that the initial price cut and the introduction of generic substitution will have the combined effect of reducing NHS expenditure on branded medicines by an average of 5% per annum over the lifetime of the scheme compared with expenditure on 31 December 2008 on products on the market on that day (with an additional 1% price cut being applied from 1 January 2010). Efficiencies achieved from generic substitution are expected to increase over the lifetime of the scheme, so provision is also made for price increases in each year from 2011.

Price cuts

- 7.4 The NHS list prices of medicines covered by the PPRS in primary and secondary care will be adjusted from 1 February 2009 with further adjustments from 1 January 2010 and annually thereafter as set out in paragraph 7.7 below. In imposing this reduction, the aim is to effect a corresponding reduction in NHS expenditure on branded medicines. An exact savings calculation is not possible because of changes in market behaviour following price reductions. For the purposes of this agreement we use the term 'price adjustment savings' where delivery is measured according to the rules of this chapter.
- 7.5 The price cuts in primary and secondary care will be delivered by a combination of measures. These measures are aimed at delivering a price cut of 5% over the lifetime of the scheme (with an additional 1% price cut being applied from 1 January 2010). As the price cut will not deliver 5% in the first year and the amount of savings delivered by generic substitution vary with time, the profile of the price cut varies with time as set out below in paragraph 7.7.
- 7.6 The combined measures that will be introduced are:
- (i) A 3.9% price cut will be introduced starting in February 2009 (NB the scheme will still start on 1 January 2009, but the price cut will take place a month later to allow further time for arrangements to be put in place).

- (ii) Subject to discussion with affected parties, the Department 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 their clinical judgement, 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.
- (iii) There will be further price adjustments on 1 January of each year, starting with a reduction of 1.9% in January 2010. There will be automatic permitted price increases of 0.1% from 1 January 2011, a further 0.2% increase from 1 January 2012 and a final increase of 0.2% from 1 January 2013. Such increases are not subject to underlying PPRS provisions regarding price increases in other circumstances.

7.7 In summary, therefore, the following price changes will apply:

Date	Price adjustment
February 2009	-3.9%
January 2010	-1.9%
January 2011	+0.1%
January 2012	+0.2%
January 2013	+0.2%

- 7.8 As the precise effect of generic substitution is unknown, the expected savings have been modelled. However, as it is unlikely that the package overall will deliver the expected savings exactly, the Department and the ABPI will each be able to call for a review to be undertaken with a view to adjustments being made to correct any under or over-delivery. No adjustment would be made in respect of loss of savings that arose because implementation of generic substitution was delayed later than January 2010. Any review could not take place before 1 January 2012. The review and calculation of any adjustment would be carried out according to methodologies to be agreed between the Department and the ABPI. The Department and the ABPI may agree that an independent organisation carry out an audit of any review of over and under-delivery and adjustment.
- 7.9 The price adjustments will apply to the NHS list prices of all products on the market on 31 December 2008, the day before the date of the commencement of the new scheme.
- 7.10 Scheme members have a right under the 2005 and 2008 schemes to restore prices reduced temporarily since 21 June 2007 under those schemes, so that those temporary price reductions can be restored prior to the 3.9% price reduction becoming effective under the 2009 scheme, subject to the terms of the 2009 scheme. Notice required under paragraph 7.30 for temporary price reductions is not applicable in this case. Scheme members opting to restore temporary price reductions must notify the Department as part of the information on the price reduction provided under paragraph 7.52.
- 7.11 The price adjustments will apply to all companies with NHS home sales above £5 million in the company's financial year ending in 2007. For companies with NHS home sales of £25 million or less in that year, the first £5 million of sales will be exempt from the price adjustments.
- 7.12 No price increases will be permitted for a period of eight months until 31 August 2009, except as part of a modulation agreed under paragraph 7.42, but scheme members may make temporary price reductions (see paragraph 7.30) and also seek the Department's agreement to increase prices in exceptional

circumstances in order to ensure the supply of medicines to patients. At the end of this period, scheme members will be eligible to apply for price increases under paragraphs 7.22 to 7.29.

- 7.13 As an alternative to an across-the-board reduction, scheme members may opt to deliver the price cuts by modulating the prices of some or all of their products covered by the PPRS (see modulation rules in paragraphs 7.42 to 7.49).
- 7.14 Scheme members may also agree with the Department to deliver up to 2% of the price cut by making a payment to the Department. By the end of January each year, a scheme member wishing to do so should notify the Department of its estimated NHS home sales for the period 1 January to 31 December and make a payment of 90% of the estimated amount with the balance payable to the Department by 31 March the following year. The payment should be based on sales at NHS list price. Scheme members who previously elected to make such payments remain responsible for delivering the value of the 7% price cut under the 2005 scheme for the relevant products.
- 7.15 Where 30% or more by value of a scheme member's NHS home sales of a product are OTC (i.e. medicines intended for sale to the public without a prescription), the member may elect to deliver the price cut by making a payment to the Department. This payment should be made quarterly in arrears no later than three months following the end of the quarter. In order to ensure equity with scheme members delivering the price cut by modulation, scheme members who previously elected to make such payments remain responsible for delivering the value of the 4.5% price cut under the 1999 scheme and/or the value of the 7% price cut under the 2005 scheme, for relevant products. The payments should continue for the duration of this agreement. Annex C helps illustrate what the effect would be for a company that had maintained the same portfolio.
- 7.16 Products transferred between companies will remain subject to the price reduction (see paragraph 7.41).
- 7.17 Scheme members should notify the Department by 6 January 2009 of how they wish to deliver the 3.9% price cut and the list of prices proposed from 1 February 2009. Scheme members should also notify NHS Prescription Services of new prices by 6 January 2009. The information required is given in paragraph 7.52.
- 7.18 Scheme members should notify the Department by 20 November 2009 of how they wish to deliver the 1.9% price cut and the list of prices proposed from 1 January 2010. Scheme members should also notify NHS Prescription Services of new prices by 20 November 2009.
- 7.19 Both parties acknowledge that the price cut may affect the cost-effectiveness evaluation and advice to the NHS communicated by Health Technology Assessment bodies. In circumstances where the price cut materially alters the Budget Impact Statement or assessed Cost per QALY, the member may request a review of this element.
- 7.20 The Department accepts the right of member companies to change discounts allowed on sales. At the same time, the Department expects that the net effect of such changes should not increase NHS costs. Paragraph 7.4 sets out the basis of the expenditure savings on branded medicines covered by this agreement. The net effect of changes in discount allowed on the sales of these medicines should not affect the delivery of this aim.
- 7.21 The Department will be operating monitoring procedures to ensure that the reduction in NHS expenditure on branded medicines is achieved (see paragraphs 7.50 to 7.64).

Price restraint

- 7.22 No scheme member may increase the price of any medicine without the Department's prior approval other than pursuant to paragraph 7.6 (iii) above or a price change subsequent to the requirements of chapter 6 on flexible pricing. This will not be granted unless a scheme member's PPRS business is up to date.
- 7.23 Where a scheme member wishes to increase the price of any branded medicine other than pursuant to paragraph 7.6 (iii) above or a price change subsequent to flexible pricing under chapter 6, it should give the Department not less than eight weeks' notice of this request. This notice should state the amount of the proposed increase and the reason in sufficient detail to satisfy the Department that the increase is justified. Companies must submit an estimate for the year after that to which the most recent AFR relates and a forecast for the following year. Scheme members with NHS home sales below the threshold for submitting AFRs routinely will be required to provide an AFR for the year a price increase is awarded and for one year following the price increase.
- 7.24 The Department will not agree to a price increase unless the company's estimated and forecast profits for the current and following financial years respectively, as assessed by the Department, are below 40% of the return on capital (ROC) target.
- 7.25 Where a price increase is agreed, the level of the increase approved will be no more than that required for the company to achieve 65% of the ROC target.
- 7.26 No company may be awarded a price increase within a period of 12 months after a preceding, authorised price increase.
- 7.27 PPRS member companies may from time to time review their discounts on sales to NHS hospitals. The outcome of any such reviews may result in the overall reduction or removal of discounts that are not a result of competitive tendering in the open market.
- 7.28 The Department accepts fully the right of member companies to change discounts allowed on sales to hospitals. At the same time, the Department expects that the net effect of such changes should not increase NHS costs nor affect the delivery of the price adjustment savings. Accordingly, if a member company intends to remove or reduce hospital discounts offered for PPRS medicines as a change in company policy in all or the majority of the UK (other than those that may result from the outcome of a competitive tender) then it must:
- notify the Department at least 28 days before the date of any proposed reduction or removal;
 - identify the product or products concerned;
 - quantify the volume of product concerned, the extent of the discount involved and the extra cost to the NHS; and
 - indicate the action it proposes to take to counterbalance that extra cost to the NHS.
- 7.29 The Department will respond to such communications within 28 days of receipt of a member's letter and may reject the proposal where it concludes that the change in hospital discount and any counterbalancing action that the scheme member proposes to take is not cost neutral.

Temporary price reductions

- 7.30 Scheme members may make temporary reductions to a price, outside the arrangements for modulation or those for the settlement of an AFR, and increase the price to a level no more than the price before the reduction without the agreement of the Department. Scheme members must inform the Department at least 21 days before the changes take effect and provide information on the existing and new prices, and the expected duration of the reduction.

Pricing of new products

- 7.31 New products introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate licensing authority may be priced at the discretion of the company on entering the market.
- 7.32 Line extensions relating to such new products, granted on the basis of an abridged application, may also be priced at the discretion of the company provided that the application to market the line extension has been submitted to the appropriate licensing authority within five years of the grant of the original authorisation of the new product.
- 7.33 Increased strengths of existing formulations may not be priced at a level greater than pro rata to existing formulations. The freedom of pricing of reduced strengths should not be coupled with product deletions so as to achieve hidden price increases.
- 7.34 If forecast sales of any new product in any one year of the first five years following launch are expected to exceed £20 million, a company must inform the Department of both the price and the anticipated level of sales in each of the first five years.
- 7.35 If a company considers that the rapid uptake of a new product will cause the company to exceed the upper margin of tolerance (MOT), then it is obliged to inform the Department immediately and negotiate a reduction in profitability for the current year to the upper level of the MOT. Similarly, the Department will negotiate a reduction in profitability if it has reason to believe that the rapid uptake of a new product will cause a company to exceed the upper MOT.
- 7.36 Freedom of pricing at the time of launch of these new products is conditional on it not causing forecast profits to exceed the target profit MOT.
- 7.37 A company wishing to introduce a product to the UK market should give the Department a minimum of four weeks' notice before the intended date of introduction. The company may give such notice prior to receipt of the marketing authorisation in order to avoid patient access delays. The Department reserves the right to approve a product that is awaiting marketing authorisation, as it will need to await confirmation of the marketing authorisation before being able to confirm new active substance status. The company should supply the Department with details of the product including the NHS list price and Summary of Product Characteristics or draft thereof. The Department will acknowledge the letter and seek confirmation of the new active substance marketing authorisation status from the appropriate licensing authority.
- 7.38 Once the Department has confirmed the new active substance marketing authorisation status, it will write to the company confirming that the product has freedom of pricing. Where a new product has not been subject to a new active substance marketing authorisation, a company must seek the Department's agreement to the price of the new product. This can include new products regarded by a company as innovative but which are not classified by the MHRA or the European Medicines Agency (EMA) as

new active substances; combination products containing active substances that have been marketed separately; active substances with new indications; 'complex' branded generics; and variations in formulation, presentation or pack size to existing products.

7.39 In reaching a decision on the acceptability of a price for a new product that is not introduced following the granting of an EU or UK new active substance marketing authorisation, the Department may take into account factors such as the following:

- the price of other presentations of the same medicine or comparable products;
- forecast sales and the effect on the NHS drugs bill;
- the clinical need for the product; and
- any exceptional costs.

7.40 If, following discussions, agreement cannot be reached on the price of the product, a company may decide to refer the issue to the dispute resolution procedure (see chapter 11).

Products sold on

7.41 Companies sometimes need to change the structure of their product portfolios. In some cases the original company has no further interest in the product, having transferred intellectual property rights, manufacture, name and distribution network; in others the change will be minimal, and the original company continues, for example, to manufacture the product. It is important that, as in other circumstances, there should not be disproportionate price increases. Accordingly, when a product covered by the PPRS is sold on:

7.41.1 The company transferring the product and the acquiring company should notify the Department of the product and the name of the acquiring company within 14 days of the transfer.

7.41.2 The acquiring company will assume responsibility for delivering the price reduction on the acquired product and may not increase the price for three months after acquisition. This condition will not apply where the acquiring company is forecast to have NHS sales of less than £5 million in the 12 months following the date of acquisition.

7.41.3 If at the end of the three months the acquiring company wishes to increase the price of the product concerned, it should seek the Department's approval.

7.41.4 The Department will consider the application against the company's overall PPRS position and will approve the increase only if it is justified under the terms for price increases in this chapter. Where the increase would be more than 20%, the Department reserves the right to negotiate the increase over three years.

7.41.5 Where the original company continues to manufacture or supply the product, information may be needed by the Department from that company to justify the increase.

Modulation

- 7.42 As an alternative to an across-the-board price reduction, scheme members may modulate the list price of their PPRS products by changes that equate to an overall level of 3.9% in 2009 (and agreed levels in subsequent years (see paragraph 7.6 above)).
- 7.43 Modulation will be deemed to have occurred where:
- list prices have been reduced (rounded to the nearest penny) by a percentage other than 3.9% in 2009 (and agreed levels in subsequent years); or
 - list prices remain unchanged or have been increased from those that prevailed on 31 December 2008.
- 7.44 Scheme members will be allowed to modulate all in patent and out of patent products with the exception that they will not be permitted to:
- 7.44.1 modulate products where the generic title is listed as Category C in Part VIII of the NHS England and Wales Drug Tariff (irrespective as to whether the product is the Category C reference price or not) and where there is more than one proprietary available. The Department will publish a list of these products on its website. These products will need to be reduced by 3.9% in 2009 (and agreed levels in subsequent years) unless the scheme member can demonstrate that there is no resulting increase in NHS expenditure;¹
- 7.44.2 substitute discounts in force during the six months prior to the date of any proposed modulation;
- 7.44.3 use price reductions that may be necessary as a result of patent or Supplementary Protection Certificate expiry to justify a price increase on other NHS products. Consequently, scheme members will not be allowed to include price reductions made on products where the patent or Supplementary Protection Certificate has expired within one year before, or will expire within two years after, the proposed date for modulation in any calculations of modulations or overall adjustments made to achieve the price reduction. Where a competitor product enters the market within two years of patent or Supplementary Protection Certificate expiry, the exclusion period for modulation purposes will be extended to a maximum of two years from the market entry of the competitor product;
- 7.44.4 include volumes of sales where the NHS list price of the brand is reduced below the reimbursement price of the equivalent generic, or where additional discounts are offered (commonly known as brand equalisation deals), that result in branded products being dispensed against prescriptions written generically; or
- 7.44.5 use reductions in the price of a new product to offset price increases on other NHS products until the new product has been on the market in the UK for two years.
- 7.45 To ensure that very simple changes in product formulations (such as a change from tablets to capsules or vice versa, or a change in flavouring of a product) or pack sizes do not erode the price cut, where new formulations or pack sizes of products that are subject to the price cut are launched after 31 December 2008, the new formulation or pack size will also be subject to the price cut. In such cases, the Department will advise the company of a notional reference price (i.e. the price that would have been in place before the scheme began), based on the ratio of the agreed price of the new presentation and the price(s) of the existing formulation(s) or pack size(s).

¹ For example, an increased price that does not exceed the reimbursement price would not result in an increase in NHS expenditure.

- 7.46 From 1 February 2009, list prices may be increased to a level no greater than 20% above the level that existed on 31 December 2008 subject to the agreement of the Department. The Department will consider applications for increases of more than 20% for products with NHS sales of £100,000 or less where a medical need can be justified. If the Department has reasonable grounds to believe that a proposed modulation may have a significant negative effect on a part or parts of the NHS, it may require the scheme member concerned to discuss the proposed modulation prior to it being implemented.
- 7.47 The Department is keen to minimise interference in the conduct of scheme members' commercial affairs consistent with safeguarding public expenditure. As well as modulation to deliver the required price adjustment savings, scheme members are also permitted to modulate the prices of products provided that the effect of the modulation will produce an overall price adjusted saving of 3.9%.
- 7.48 Scheme members can remodulate at any time provided the Department is notified 28 days in advance of the implementation of the price change. The Department will have 21 days in which to respond to modulation notifications and will only withhold agreement where it can be shown that the effect would place the delivery of the price adjustment savings in doubt.
- 7.49 The 2008 scheme provided that the position of companies that had reported under or over-modulations as at 31 December 2008 would be carried forward for resolution in the 2009 scheme. The following arrangements have been agreed:
- 7.49.1 The Department will recognise modulation over-deliveries under the 2005 scheme and the 2008 scheme and will carry these forward to the 2009 scheme, 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. The adjustments to take account of over-delivery will be made over the full five years of the 2009 scheme.
- 7.49.2 Scheme members that have under-delivered will agree with the Department their plans to correct the position either through adjustment during the lifetime of the new scheme or by making a cash payment.
- 7.49.3 Companies that undertook temporary price reductions shall be entitled to include such reductions in the assessment of that scheme member in determining whether the member reduced prices in line with the requirements of the 2005 scheme and the 2008 scheme, subject to the provision that the value shall be determined only on the basis of temporary price reductions introduced after 21 June 2007. Where scheme members opt to use relevant temporary price reductions in this way, they will not be permitted to restore those temporary price reductions in accordance with paragraph 7.30 of the 2009 scheme.
- 7.49.4 The Department and the ABPI will review this matter at the regular review meetings provided for in paragraph 10.9.

Monitoring the price reduction and price adjustment savings

- 7.50 Monitoring procedures are required to ensure that scheme members deliver the required price reduction across primary and secondary care over the lifetime of the scheme. Price adjustment savings in secondary care will also be monitored by the Department. The Department will require information for all presentations covered by the price reduction if scheme members have reduced prices across the board or through modulation. In summary, the method used will be a two-stage process:

- **Stage 1 – Price reduction:** scheme members should demonstrate that they have delivered a price reduction using NHS list prices across both primary and secondary care.
- **Stage 2 – Price adjustment savings in secondary care:** in order to provide the Department with assurance of verifiable price adjustment savings happening in secondary care, a parallel calculation will be undertaken on secondary care data using net sales and volume data in that sector to establish that the required level of price adjustment savings has been achieved. This calculation will help the Department establish that scheme members have not reduced discounts in the secondary care sector to offset the price cut.

7.51 When reporting data into primary care, companies should include sales only to wholesale and retail pharmacies, net of any volumes and values of such sales appropriate to secondary care. When reporting data into secondary care, companies should include sales to NHS hospitals and other customers, whether made directly by the scheme member or through a wholesaler, agent or distributor, at prices controlled by the scheme member. The Department will validate data provided by scheme members against other data sources.

Initial information – required by 6 January 2009

7.52 For all presentations required to deliver the price reduction in primary care and in secondary care:

- a list of the NHS prices proposed from 1 February 2009 and the NHS prices at 31 December 2008.

This information should be sent to the Department in electronic format using a copy of the Excel spreadsheet found on the Department's website, and replicated at annex D for ease of reference.

Secondary care information – required by 31 March 2009

7.53 For all presentations required to deliver the price reduction in secondary care:

- NHS list prices; net sales; and volumes sold for the period 1 October 2008 to 31 December 2008.

This data will be used to establish a reference price to enable monitoring of price adjustment savings in secondary care.

This information should be sent to the Department in electronic format using a copy of the Excel spreadsheet found on the Department's website, and replicated at annex E for ease of reference.

Information required before any additional or subsequent modulation – required 28 days before price change

7.54 Scheme members should supply the following information before any additional or subsequent modulation:

- the name of the product (including strength and pack size) to be modulated and the pre and post-modulation prices; and

- the estimated quantities sold to the NHS in the 12 months before and after modulation split across primary and secondary care.

Annual outturn information – required by 31 March 2010 and by 31 March in each subsequent year

7.55 Scheme members should provide the following information for all presentations required to deliver the price reduction for the period 1 January to 31 December of the previous year (1 February to 31 December for 2009):

- **For primary care:** volumes sold differentiated where NHS list prices have changed within the year.
- **For secondary care:** volumes sold and net sales.

This information should be sent to the Department in electronic format using a copy of the Excel spreadsheet that will be available on the Department's website at the appropriate time in the form of annex F.

7.56 The data submitted for the purposes of monitoring the delivery of price reductions and price adjustment savings in secondary care will be independently reviewed (see annex G).

Calculation of delivery

7.57 By 30 June for each year of the agreement, the Department will analyse both the outturn of the price reduction and the price adjustment savings in secondary care for the previous 12 months ending 31 December. It is recognised that it will be difficult for scheme members to deliver exact outturns matching the scheme's required outcome in each year. Consequently, a margin of 0.5% in each year will be permitted against both measurement methods. The delivery will take account of deliveries across both primary and secondary sectors.

Stage 1 – Calculation of delivery of price reduction

7.58 The delivery of the price reduction is calculated using NHS list prices across both primary and secondary care. It will be determined, in any given period, by comparing the total unit value (volume) of NHS sales of all products at NHS list reference prices (i.e. as at 31 December 2008) with the total value of the same unit value (volume) of NHS sales at in-year NHS list prices.

Action to be taken where price reduction does not meet that required under the scheme

7.59 For the sake of administrative efficiency, scheme members that achieve a price reduction outcome within 0.5% of what is required each year will not be required to remodulate or to make a payment. To ensure that delivery remains within the 0.5% range throughout the agreement, the quantum of the under or over-delivery will be added to that achieved in the following year to calculate the percentage delivery in that year and treated as follows:

- where the cumulative price reduction remains within 0.5% of that required the under or over-delivery will be carried forward to the following year;
- where the cumulative price reduction exceeds the required figure by more than 0.5% the scheme member may remodulate as set out in paragraphs 7.42 to 7.49 above;

- where the cumulative price reduction is below the required figure by more than 0.5% the scheme member will be required to make a payment to the Department to deliver the full reduction required and to remodulate prices so that the required reduction is delivered for the remainder of the scheme.

Stage 2 – Verification of price adjustment savings in secondary care

- 7.60 To give the Department assurance of verifiable price adjustment savings happening in secondary care, a parallel calculation will be made using the net sales and volume data in the secondary care sector provided by companies.
- 7.61 The secondary care verification calculation will be determined, in any given period, by comparing the total unit value (volume) of secondary care sales of all products at reference prices (see paragraph 7.53; for the quarter 1 October 2008 to 31 December 2008) with the total value of the same unit value (volume) of secondary care sales at in-year average selling prices.

Action to be taken where price adjustment savings in secondary care are below the assessment of list price reductions in that sector

- 7.62 The Department recognises that there could be a difficulty for scheme members achieving price adjustment savings in secondary care that match the percentage delivery of list price reductions in that sector. For this reason, the Department will adopt a margin of 0.5% when comparing the outcomes of the two calculations.
- 7.63 Where the calculation of price adjustment savings (i.e. based on net sales) is below the 0.5% margin when compared with the delivery of the price reduction in secondary care (i.e. based on NHS list prices), the Department will undertake further investigations with individual scheme members to establish a correct level of price cut. Where necessary scheme members may be required to make further adjustments to prices and/or make a payment to the Department to deliver the price reduction.
- 7.64 As well as the Department entering into bilateral discussions with individual scheme members about the delivery of the price cut, paragraph 7.8 of the 2009 agreement includes a provision by which either the Department or the ABPI will be able to call for a review to be undertaken of the price adjustment savings being delivered with a view to adjustments being made to correct any under or over-delivery of the price reduction over the lifetime of the scheme. The Department will exercise this right where it believes that the price adjustment savings were not being achieved.

Companies awarded a price increase

- 7.65 Scheme members will be required to make a payment to the Department to deliver any shortfall in the price reduction before an agreed price increase may be implemented. Where a scheme member has over-delivered against the price reduction it will be expected to remodulate before applying for a price increase and then to apply for such an increase only if after remodulation it meets the required conditions. The value by which any price increase erodes the target saving will be recorded and agreed with each company.

Products transferred and fostering arrangements

- 7.66 Where a company transfers ownership of a product to another company, details of sales should be removed from the vendor's modulation and included in the purchaser's modulation from the date of the transfer. There may be a consequent requirement for remodulations to correct any resultant under or over-delivery of the price reduction.
- 7.67 Occasionally a company may enter into a product fostering arrangement with another company. Usually, in these instances, the marketing authorisation remains with the original company and the second (fostering) company assumes responsibility for sales and marketing of the product. In this case, the original company will report sales of the fostered products in its own AFR and will retain responsibility for delivering the saving in respect of the product. However, if sales are reported in the AFR of the company fostering the product, then the foster company will assume responsibility for that product for modulation purposes.
- 7.68 When companies enter into such fostering arrangements, it is essential that the Department be informed in writing. The companies should clearly state which company is to include sales of the product in its AFR and is therefore responsible for delivering the price reduction with respect to that product.

Company mergers

- 7.69 The combined portfolios of products belonging to the merged company will be reviewed to establish a revised target with reference to the original prices of 31 December 2008. In cases where there is a cumulative shortfall below the required reduction, the merged company will be required to make a payment to deliver the reduction calculated to be due on the date of the merger. In all other instances, the value of the cumulative delivery to be carried forward will be calculated and agreed with the company.

Delivery of price cuts by the end of the scheme

- 7.70 To ensure that the price cut is delivered by the scheme as a whole, those members that have delivered more than the price reduction required should consult with the Department on appropriate actions. Those members who have delivered less than the required price cut overall will be required at the end of the scheme to make a cash payment to the Department that equates to the under-delivery against the price reduction specified in the agreement.
- 7.71 The Department may not agree to any modulations proposed in the last year of the scheme if they may cause the price adjustment savings delivered during the period of the scheme to be eroded in subsequent years.

8 Levels of return on capital target and allowances

Introduction

- 8.1 The scheme provides a framework for determining reasonable limits to the profits to be made from the supply of branded medicines to the NHS. In keeping with the principles set out in the introduction to this scheme, there is encouragement for the research and development (R&D) of new medicines, and a commitment to a minimum of interference with companies' freedom to succeed in that activity.
- 8.2 There will be one level of ROC target.
- 8.3 There will be two levels of allowance for R&D, information and marketing expenses:
- 8.3.1 level 1 will be used to decide price increase applications under the terms for such applications set out in chapter 7;
- 8.3.2 level 2 will be used to assess the profitability of scheme members' AFRs.
- 8.4 The ROC target, and R&D, marketing and information allowances for level 1 and level 2 are set out in paragraphs 8.12, 8.31, 8.35 and 8.38 respectively and summarised at annex I.

Allocation of costs and capital

- 8.5 The Department expects manufacturers and suppliers to achieve all reasonable economies in the costs of pharmaceutical production and supply, and related overheads.
- 8.6 Costs, capital employed and any related receipts or income claimed in the AFR submission will be those normally included in the company's UK audited accounts. For R&D and information and marketing expenses, the value and costs entered in the 'claimed' column in schedule 1 of the AFR should represent no more than the specified allowance for a company, as permitted by the Department under the PPRS.
- 8.7 The Department may specify other arrangements where the supply of NHS medicines in the UK arises from overseas sources and comprehensive financial information is not available in the accounts of the UK trading entity. In particular, it is expected that, where trade in the UK is conducted on a principal-commissionaire basis, the AFR will be based on the audited accounts of the overseas entity. If such arrangements are not feasible or cannot be agreed between the company and the Department, then the company's NHS business will be regulated as directed by the Secretary of State under section 266(1) of the National Health Service Act 2006.
- 8.8 Any scheme member must be able to demonstrate that costs or capital included in its AFR are appropriate to the supply of NHS medicines in accordance with this scheme. Overhead costs and shared assets utilised in both NHS medicines and other products must be reasonably apportioned. Companies will provide reasonable details of costs and capital either directly allocated or apportioned to home NHS medicines, together with explanations supporting any apportionment.

- 8.9 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 claimed for medicines supplied to the NHS are properly incurred in accordance with the scheme and that they are reasonable in the light of accepted commercial practice. Excess costs and capital will be disallowed from the assessment.
- 8.10 In its examination of the reasonableness of a company's costs and assets the Department will have regard to the following factors:
- 8.10.1 the trends in the data reported by the company over a number of years, including those for exports and other products;
 - 8.10.2 any special features of the company's operation;
 - 8.10.3 ratios inferred from the AFR for the company's non-PPRS business;
 - 8.10.4 each company's reported figures and the average of other similar scheme members;
 - 8.10.5 data from external sources that relate to the pharmaceutical industry across companies.
- 8.11 Where the Department does not receive an adequate explanation of costs and capital claimed in a company's AFR, it may limit the costs and capital to a level that is reasonable in the light of its analysis of the company's figures as set out in paragraph 8.10. The Department will discuss the basis of any limitations with the company and will advise the company of its final AFR assessment.

Return on capital

- 8.12 The allowable ROC, which may be earned by individual scheme members from home sales of NHS medicines, will be based on the historical value of average capital employed. This target will be 21% a year.
- 8.13 Companies will be allowed to inject costs or capital on the condition that they provide evidence (signed off by an independent accountant) that these injections are appropriate and are not duplicated in any way by other entries in the AFR.

Margin of tolerance

- 8.14 The allowable return referred to in paragraph 8.12 will be associated with a margin of tolerance (MOT). Scheme members will be able to retain profits of up to 140% of the ROC target. Companies will not be granted price increases unless they are forecasting profits less than 40% of the ROC target. Procedures for price increases are set out in chapter 7.
- 8.15 The MOT will not be available to a scheme member for any year in which it has implemented a price increase agreed by the Department. Where a scheme member exceeds its target profit for a year in which it has received a price increase, all profits above the target will be repayable. Where a price increase is agreed by the Department in the second half of a year, the MOT will not be available to a scheme member for the year following the increase.

- 8.16 If the Department's assessment of an AFR shows profits in excess of the MOT, it will negotiate one or more of the following:
- 8.16.1 repayments of that amount of profit which exceeds the MOT;
 - 8.16.2 price reductions, during the accounting year following that covered by the AFR, to bring prospective profits down to an acceptable level, on the basis of available forecasts;
 - 8.16.3 a delay or restriction of price increases agreed for the company or both.
- 8.17 Irrespective of the final date of settlement, any agreed price reductions will take effect from a date three months after the scheme member's AFR is due. In the event of negotiations not being completed by the effective date, any price reductions resulting from the review will in any case be made effective as if they had been operative from that date, if necessary by payment or other adjustment having equivalent effect. The Department will specify the date on which a payment is to be made. That date will be no later than one month after the date of settlement.

Companies with low capital bases

- 8.18 Scheme members will be able to include capital employed in their AFR on the basis of its inclusion in UK statutory accounts, by injection or by imputation in the transfer price.
- 8.19 For scheme members whose AFR home sales exceed their average assessed home capital employed (excluding any capital imputation from the transfer price) by a factor of 3.5 or more, sales rather than capital will be used to determine the profit target. The target rate of profit will be set by dividing the ROC target rate by a factor of 3.5 and applying this rate to home sales. The target will be 6% return on sales (ROS). The assessment of the returns of scheme members that are subject to the ROS option will take account of the transfer price profit and the MOT on transfer price profit.
- 8.20 Where a company is satisfied that it will be assessed as an ROS company, schedule 2 of the AFR (and forecast and estimate) is not required to be submitted.

Transfer pricing

- 8.21 Where possible, scheme members should seek to provide an independently reviewed breakdown of their transfer prices (purchases from affiliates, lines 4 and 7 of schedule 1).
- 8.22 Where a member provides no breakdown of transfer price costs, it will be required to confirm that its transfer prices are at arm's length, to indicate the basis on which such arm's-length prices are set and to confirm that the transfer prices reported in the AFR are as will be reported in the member's corporation tax computation. In such cases, the Department will assume that transfer prices comprise 59% manufacturing, 21% R&D and 20% profit.
- 8.23 The maximum permitted transfer price profit allowed in the assessment is 25% of accepted costs. 'Accepted costs' means the costs allowed after negotiation. In the case of a member assessed on a ROC basis, the allowed profit will be converted to an equivalent amount of assets, using the scheme ROC target, and added to the member's total capital employed. In the case of a member assessed on a ROS basis, the allowed profit will be added to the member's ROS profit target.

- 8.24 In an AFR year in which a member is subject to the default transfer price breakdown and 20% or more of claimed NHS home manufacturing costs, i.e. total cost of goods sold (line 11, AFR schedule 1), is derived from the transfer price, the maximum acceptable manufacturing costs, i.e. total cost of goods sold (line 11), will be restricted to 45% of home NHS sales in the assessment (after re-assignment of costs to take account of the transfer price analysis).
- 8.25 Where a scheme member's manufacturing costs, i.e. total cost of goods sold, are restricted to 45%, the excess will first be disallowed from the transfer price component, thus reducing accepted transfer price costs and consequently the transfer price profit allowed.
- 8.26 If, in the assessment of an AFR, a scheme member's claimed total R&D, including the R&D component from the transfer price, exceeds its R&D allowance for the year, any R&D costs derived from the transfer price will be allowed first, unless the scheme member indicates otherwise when submitting the AFR.
- 8.27 Where significant currency movements occur, the Department may seek clarification from scheme members on the effects of these movements on transfer prices, including information on the sources of transfers. The Department may also look at the consistency of transfer prices from one year to another.

Research and development

- 8.28 The Department confirms its commitment to recognising the cost of R&D within the prices paid for NHS medicines. The amount allowed reflects both a contribution to the worldwide cost of R&D undertaken by companies developing human medicines and a desire to reward and provide an incentive for success in R&D. The Department expects this allowance to contribute towards the R&D of new and improved medicines.
- 8.29 The maximum R&D allowance is 22% of NHS home sales for assessing price increases (level 1) and 30% of NHS home sales for assessing AFRs (level 2).
- 8.30 These R&D allowances are allowable only where a scheme member can demonstrate within the AFR that the amount claimed relates to expenditure actually incurred.
- 8.31 The R&D allowance comprises three elements:
- 8.31.1 *Flat rate:*
- level 1: up to 12% of the value of NHS home sales;
 - level 2: up to 20% of the value of NHS home sales.
- 8.31.2 Variable rate allowances to a maximum of 10% of NHS sales comprising a variable rate for innovation and a variable rate for paediatrics as follows:
- 8.31.2.1 *Variable rate for innovation:*
- An allowance for each in-patent active substance protected by a basic preparation patent (and Supplementary Protection Certificate (SPC) where one exists) with NHS home sales above a threshold of £100,000, up to a limit of 28 active substances.

- The allowance shall be 0.75% of NHS home sales for the first four qualifying products, 0.5% for the next four qualifying products and 0.25% of NHS home sales for qualifying products in excess of eight and up to a maximum of 28.
- The maximum allowance for this component is, therefore, 10% of NHS home sales and is additional to the level 1 and level 2 flat-rate allowance.
- Where no patent exists, the additional component may apply to each substance that has been granted a new active substance marketing authorisation. The allowance will be given for a period of ten years after the grant of the first marketing authorisation for that new active substance. For clarification, this provision is intended to cover all branded licensed NHS medicines, including those in paragraph 4.20, which are not patentable. This is subject to them being recognised by the Licensing Authority as a new active substance, in that a full (major) marketing authorisation is required.

8.31.2.2 Variable rate for paediatrics

- An allowance of 1% of NHS home sales in the year in which a product is first generally available on prescription in the UK under the terms of a marketing authorisation that includes a paediatric indication, up to a limit of three products in any one year. The combined maximum allowance for the variable rate for paediatrics and the variable rate for innovation is 10% of NHS home sales. This additional element for paediatric indications may not be utilised for applying for a price increase under the scheme.

8.32 During the first three years that a company is included in the scheme as a full AFR company, the variable rate for innovation allowance, for assessing AFR profits only, is increased as follows:

- 2% of NHS home sales for each of active substance 1 and 2;
- 1% of NHS home sales for active substance 3;
- 0.25% of NHS home sales for each active substance thereafter.

This additional flexibility for new entrant AFR companies is subject to a maximum allowance of 10%.

Marketing allowance

8.33 In addition to all costs associated with the operation of marketing departments, marketing expenditure should include the cost of all advertising, selling and promotion of a company's NHS products as well as the administrative support to such activities. Costs and activities that are expected to fall within marketing include market research and marketing strategy. Further guidance on the activities qualifying for the marketing allowance is in annex J.

8.34 The following expenditure is not allowable as a charge in NHS prices and must be excluded from the AFR on schedule 1A:

- samples (other than samples for identification purposes);
- gifts;
- hospitality (other than that provided for eligible medical symposia).

- 8.35 The marketing allowance will be calculated for each company on the following basis:
- 8.35.1 standard elements of 2% of home sales of NHS medicines for level 1 and 4% of home sales of NHS medicines for level 2 (see paragraph 8.3 for an explanation of levels 1 and 2);
 - 8.35.2 a fixed element of £500,000 for level 1 and £1,000,000 for level 2;
 - 8.35.3 product servicing allowance for each active substance with sales to the NHS of £100,000 or more (in the year to which the AFR relates). These will be set at £58,000 for each of the first three eligible products, £46,000 for each of the next three, £35,000 for each of the next three, and £23,000 each for all others.

Information allowance

- 8.36 Information expenses should include the costs of the provision and dissemination of factual information on a company's NHS medicines. This includes information whether or not required by statute or regulation or requested by a public body, the provision of non-product-specific information, support for the development, implementation or monitoring of protocols, guidelines, service standards or frameworks, and the provision to patients of support and information as required or permitted by law and the relevant Code of Practice. Information expenses will also include the costs of samples for identification purposes, Summaries of Product Characteristics and medical symposia.
- 8.37 Further guidance on the activities qualifying for the information allowance is in annex J.
- 8.38 The information allowance will be calculated for each company as standard elements of 2% of home sales of NHS medicines for level 1 and 4% of home sales of NHS medicines for level 2.

9 Information requirements

Annual Financial Return (AFR)

- 9.1 Any scheme member with total home sales of NHS medicines of £35 million or more in its financial year will be required to provide an Annual Financial Return (AFR).
- 9.2 The Department has to satisfy the needs of public accountability by the scrutiny of each scheme member's AFR and price increase applications under the terms of the scheme. There is a balance to be struck between recognising the costs to scheme members of providing information and the level of detail necessary to enable the Department to reach reasonable conclusions on each scheme member's PPRS position.
- 9.3 AFRs, together with supporting information (see specimen in annex J), will be completed annually and submitted to the Department as follows:
 - 9.3.1 scheme members with a UK registered name beginning with the letters A to E: within six months of the end of their financial year;
 - 9.3.2 scheme members with a UK registered name beginning with the letters F to J: within seven months of the end of their financial year;
 - 9.3.3 scheme members with a UK registered name beginning with the letters K to M: within eight months of the end of their financial year;
 - 9.3.4 scheme members with a UK registered name beginning with the letters N to R: within ten months of the end of their financial year;
 - 9.3.5 scheme members with a UK registered name beginning with the letters S to T: within 11 months of the end of their financial year; and
 - 9.3.6 scheme members with a UK registered name beginning with letters U to Z and any others: within 12 months of the end of their financial year.
- 9.4 Where a scheme member can demonstrate that for reasons beyond its control it cannot meet the time limits set out in paragraph 9.3, the deadline for the submission of its AFR may be extended with the agreement of the Department. The Department will not grant an extension to the deadline for the submission that would result in an AFR being received later than 12 months after the end of a scheme member's financial year.
- 9.5 The Department will recognise that an AFR has been submitted by a scheme member only when all components of the AFR including relevant supporting documents have been submitted (see checklist at annex K). It is recognised by both parties that the scheme depends on information being supplied promptly. The Department will monitor the submission and processing of AFRs closely and bring the results to the attention of the ABPI, which will use its best endeavours to ensure that deadlines are adhered to.

- 9.6 Scheme members should provide a list of the NHS home products that have been included within their AFR, identifying those with NHS home sales of £100,000 or more (after discounts and rebates) and including those products with sales below £100,000. For each product, they should indicate the date of expiry of the active substance patent and any Supplementary Protection Certificate or, where no patent exists, the date of grant of the first marketing authorisation for that new active substance. This will be used for:
- 9.6.1 confirming that the correct categories of product have been included and ensuring consistency between companies (see paragraphs 4.16 to 4.21);
 - 9.6.2 calculating allowable expenditure under the R&D formula (see paragraphs 8.28 to 8.32);
 - 9.6.3 calculating allowable expenditure under the marketing formula (see paragraphs 8.33 to 8.35); and
 - 9.6.4 calculating allowable expenditure under the information formula (see paragraphs 8.36 to 8.38).
- 9.7 The Department will acknowledge receipt within 14 days of receiving an AFR and will endeavour to advise scheme members in writing within eight weeks of receipt if it also wishes to make further enquiries into the information submitted. The Department may require that any supplementary information requested is independently reviewed where information in the original submission is found to be incorrect or further explanations on such matters as apportionment are required and revised or additional information is submitted. Scheme members will be expected to provide supplementary information within 28 days of the date of the request.
- 9.8 Upon completion of its enquiries, the Department will issue an assessment. If this assessment indicates that a payment is due to the Department then a date for payment will be specified. That date will be no later than one month after the date of the completion of the negotiations on an assessment.
- 9.9 Forecast financial returns will be completed annually and submitted to the Department within the first three months of the start of the accounting year to which they relate. Each return will be accompanied by an estimate, in the same format, of the outturn for the year preceding the forecast year. A specimen copy of the forecast/estimate is provided in annex J.
- 9.10 The confidentiality of commercially sensitive information submitted to the Department will be assured.

Provision of information relating to sales of branded medicines

- 9.11 Information is required from companies with sales of branded medicines to the NHS of £35 million or more a year. 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. 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 (GMS)/Personal Medical Services (PMS) contractors). Companies should also provide information about discounts given that cannot be specifically attributed to a specific branded product. The information will be required to be independently reviewed. A schedule illustrating the requirement is attached at annex L, a company declaration is attached at annex M and an independent accountant's report is attached at annex N. The information should be submitted electronically and a form is available for downloading as an Excel file on the Department's

website at www.dh.gov.uk/pprs. A hard copy of the information reviewed by an independent accountant should also be supplied to the Department by 28 February each year. Companies are required to submit information within one calendar month of each quarter end.

Transitional arrangements for submission of AFRs

- 9.12 As advised in the joint letter of 21 October 2008 to scheme members from the Department and the ABPI, scheme members should provide AFRs for a 12 month period based on statutory accounts for years ending in 2008 and 2009. Details are at annex O.

Small companies

- 9.13 Any scheme member with total home sales of NHS medicines not exceeding £5 million in its financial year will be exempt from supplying financial information. However, the Department reserves the right to call for a full AFR if circumstances appear to warrant it. In particular, in the case of an application for a price increase, the Department may demand financial information in the format specified in annex J.
- 9.14 Any scheme member with total home sales of NHS medicines of more than £5 million and less than £35 million in its financial year will be 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. If a company in this category wishes to modulate the price of its products, it will have the same obligation as larger companies as set out above. Where NHS sales occur in more than one company under the same ultimate common ownership (whether part of a UK group or not), e.g. sales of branded OTC prescription medicines by a consumer healthcare company within the group, these sales should be added together to determine whether or not it is required to provide this information. This information should be submitted annually to the Department within nine months of the end of its financial year.
- 9.15 Any scheme member relieved of the commitment to supply full financial information as in paragraph 9.13 will remain subject to the need to contain costs and the price restraint provisions (see paragraphs 7.22 to 7.29). The Department reserves the right to call for a full AFR or forecasts or both at any time if circumstances warrant it.
- 9.16 Subject to the provisions of paragraph 9.15 above, in assessing the AFR or other financial information provided by a small company, the Department may exercise a degree of discretion in relation to such matters as the levels of costs or capital employed allowed. In particular, the levels of allowances for R&D, marketing and information, set out in paragraphs 8.28 to 8.38, are not necessarily applicable to small companies. The Department will continue to look at these flexibly with regard to the circumstances of the individual scheme member, including the level of its NHS turnover.

10 Other matters

Independent accountant's review arrangements

- 10.1 Information supplied by scheme members must be reviewed by an independent accountant as provided in this agreement, and supported by an independent accountant's report in the form set out in annexes G, J and N.

Distribution margin

- 10.2 One of the objectives of this scheme is to encourage the efficient and competitive supply of medicines to the NHS. Individual companies are expected to follow good commercial practice in the distribution of their products according to their individual needs.
- 10.3 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 will notify the Department of such changes as early as possible, and at least four months in advance of any such change being made operational. Scheme members would not be required to notify routine commercial transactions that would not be expected to have a cost to the NHS.
- 10.4 The Department will use the quarterly information it receives on discounts (see paragraph 9.11) to monitor the impact of changes to the supply chain.
- 10.5 If there are reasonable and objective grounds to believe that changes made during the lifetime of this scheme have, or would have, an adverse net impact on NHS expenditure in relation to the purchasing from that scheme member then the Department and the company will discuss and agree any adjustments to those distribution arrangements.
- 10.6 This provision does not affect the right of companies unilaterally to offer or withdraw competitive trade discounts at any time, nor to determine individually how to distribute their own products.

Ensuring best practice in the notification of product discontinuations and in the notification and management of medicines shortages

- 10.7 The Department and the ABPI have developed guidelines to ensure best practice in the notification of product discontinuations, and in the notification and management of medicines shortages. The Department expects all scheme members to use their best endeavours to adhere to the best practice guidelines as a demonstration of the importance of the agreement to patient care. The guidelines are available at www.dh.gov.uk/medicinesupply and www.abpi.org.uk.

Patent expiry and generic market entry

- 10.8 Under the PPRS, companies have freedom of pricing for new active substances on market entry (paragraphs 7.31 to 7.40). As products near the end of their patent lives, the Department does not expect companies to take any unreasonable action to delay or discourage generic entry to the market.

Liaison between the Department and the ABPI

- 10.9 Meetings will take place between the ABPI and the Department every six months to consider the operation of the scheme. This is in addition to any formal process of consultation required in relation to procedures referred to in the National Health Service Act 2006.

Report to Parliament

- 10.10 The Department will publish a report to Parliament on the scheme and provide aggregated details of the operation of this scheme. These details will include aggregated figures for data submitted and adjustments made, and publication of comparative data on uptake of new medicines alongside international price comparisons.

11 Dispute resolution

- 11.1 The Department and individual scheme members undertake to operate this agreement so that issues arising between any scheme member(s) and the Department are normally resolved by discussion between the scheme members and the Department. Such discussions may be escalated at the option of the scheme member and the Department to a more senior level within that organisation. Nevertheless, significant issues between the scheme member and the Department may arise that cannot be resolved by discussion. These issues may be referred to the dispute resolution procedure set out below by the scheme member or the Department.
- 11.2 The ABPI will have the right to dispute resolution on matters that span the interests of the broader membership and not just an individual member. For example, should there be a dispute as to a review of the reductions or price adjustment savings delivered and whether a further price adjustment is required (paragraph 7.8) then it would be more appropriate for the ABPI and the Department to seek resolution through the Dispute Resolution Panel than for an individual company or companies to do so. However, the provisions in chapter 5 ('Uptake and innovation') are excluded from dispute resolution as they will be monitored through MISG and the HIC. The provisions relating to the process to be followed will apply in the same way to a dispute involving the ABPI.
- 11.3 It is intended that the use of the dispute resolution process shall not entail any forfeiture of any other judicial remedy available to either party.
- 11.4 Where a scheme member or the Department decides to go to dispute resolution it must give written notice to the other party of its intention within 21 days of an event. Examples of 'events' in this context would be refusal by the Department to agree a price increase under the scheme or the failure of the parties to reach agreement on the extent, if any, to which excess profits are repayable to the Secretary of State. The parties to the dispute must provide the Dispute Resolution Panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of dispute. Statements will be made available to the parties. They may be supplemented in response to questions arising during the dispute resolution procedure.
- 11.5 The Dispute Resolution Panel will give each party to the dispute the opportunity to put forward its case on the issue(s) that is (are) in dispute at an oral hearing. Each party to the dispute shall be allowed a reasonable period within which to make oral representations which shall in no case be less than two hours. The panel will be expected to hold the hearing within 30 days of the receipt of the written statements from the parties. The parties are free to decide their representation at the oral hearing.
- 11.6 Prior to or at the hearing, the panel may request supplementary written information from any party to the dispute where it considers this necessary to properly understand the issues. The parties will be required to provide this information within 15 days of the request. All information provided to the panel members and the panel members' reasoned decision will be available to all parties. The panel will be expected to make its decision known to the parties within 30 days of the oral hearing or within 45 days where it has been necessary to obtain additional written information from any party.

- 11.7 The panel for any given dispute resolution shall comprise:
- 11.7.1 a Chairman appointed by the Secretary of State subject to the agreement of the ABPI, a representative of which shall sit on the interview panel for the post of Chairman and shall have the right of veto over any appointment. The Chairman should ideally be a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland of at least seven years' standing and/or a person who has at least seven years' experience of heavyweight mediation or dispute resolution; and
 - 11.7.2 two members, one appointed by the Secretary of State and the other by the ABPI.
- 11.8 The Chairman may not sit alone for any part of a dispute resolution.
- 11.9 The secretariat to the panel will be provided jointly by the Department and the ABPI. In the event that the Chairman is not legally qualified as described in paragraph 11.7.1 a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland shall be appointed jointly by the Department and the ABPI (with both having the right of veto over such appointment) to advise the panel on any aspects of its role in a particular dispute and shall be entitled to be present throughout the dispute proceedings.
- 11.10 The costs of the panel will be shared equally by the parties. The parties to each dispute will be responsible for paying their own costs.
- 11.11 The reasoned decision of the panel shall be published on the website of the Department and the ABPI after the redaction of commercially sensitive information. The parties to any dispute shall have an absolute right of veto in deciding which details of a decision are commercially sensitive in relation to their own data.
- 11.12 The Department, the ABPI, scheme members and the members of the Dispute Resolution Panel as a condition of their appointment undertake to keep commercially sensitive information confidential.
- 11.13 A description of the functions of the Dispute Resolution Panel and its work is at annex Q.

Annex A: PPRS membership forms

Form A

SECTION 261(2) AND SECTION 261(6) OF THE NATIONAL HEALTH SERVICE ACT 2006 AND THE HEALTH SERVICE MEDICINES (CONSENT TO VOLUNTARY SCHEME) REGULATIONS 1999

CERTIFICATE OF CONSENT FOR THE 2009 VOLUNTARY SCHEME TO BE TREATED AS APPLYING

Name.....

[name of company, partnership etc.]

Address

.....

.....

1. I *[name of person signing and capacity in which signing (e.g. director/partner/other)]* certify that the above-named company/partnership/person¹ hereby consents to the voluntary scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State in December 2008 (known as the 2009 PPRS) [to which there are modifications/and additions made between..... *(the company/partnership/name)* and the Secretary of State on.....²] being treated as applying to it/him.³

2. I am duly authorised to sign this certificate.

Signed

Date.....

1 Delete as appropriate.

2 Only insert date where a modification to the 2009 PPRS has been agreed.

3 Delete as appropriate.

Form B

CERTIFICATE OF WITHDRAWAL OF CONSENT FOR VOLUNTARY SCHEME TO BE TREATED AS APPLYING

Name.....
[name of company/partnership etc.]

Address

.....

.....

Date on which the consent now being withdrawn was given

1. I *[name of person signing and capacity in which signing (e.g. director/partner/other)]* certify that the consent of the above-named company/partnership/person¹ to the voluntary scheme made between the Secretary of State and the Association of the British Pharmaceutical Industry in December 2008 being treated as applying to it is hereby withdrawn.

2. I am duly authorised to sign this certificate.

Signed.....

Date.....

1 Delete as appropriate.

Annex B: Uptake and innovation package¹

Action on Health Technology Assessment (HTA) and uptake of new medicines to support innovation and patient access to new medicines

The Cooksey Report² highlighted the issue that innovation is only sustainable if innovative products are made available to NHS patients. Studies carried out through the Long-Term Leadership Strategy show that UK uptake was relatively high for anti-obesity, sepsis and smoking cessation medicines, low in the case of drugs for hepatitis C, dementia, osteoporosis and each of the four cancer medicines studied. For the other three groups (anti-TNFs, glitazones and anti-psychotics), UK uptake was high overall but not always within three years from launch. While the situation may be improving in some areas, the UK lags behind other OECD countries in the uptake of new technologies of proven clinical and cost-effectiveness. As part of this Pharmaceutical Price Regulation Scheme (PPRS) agreement, we propose that the Department of Health and the industry commit to a number of specific initiatives covering both uptake and HTA in order to support more effective diffusion and adoption of clinically and cost-effective medicines and technologies across England and the devolved nations. It is for the devolved administrations to meet their policy and operational requirements. The Health Departments of Scotland, Wales and Northern Ireland will work with the industry on making progress in these areas, and working with the Department where appropriate.

Uptake

The goal is to ensure that positive National Institute for Health and Clinical Excellence (NICE) guidance is implemented in practice and that all eligible patients are able to access medicines and treatments in a timely manner when they need them. We propose the following:

The Department to establish a single horizon scanning and planning process for new technologies

Current horizon scanning information and processes are fragmented, with duplication of information requests and syntheses and analyses of information being undertaken by numerous different bodies. There is agreement in principle between the Department, NICE, the National Prescribing Centre, UK Medicines Information, the National Horizon Scanning Centre, the Scottish Medicines Consortium and the All Wales Medicines Strategy Group for a single unified horizon scanning database. The Association of the British Pharmaceutical Industry (ABPI) strongly supports this and will play a full part in the design and development of the database, and will encourage companies to populate it. Uses would include supporting NICE topic selection, scoping of appraisals and providing timely information to all NHS organisations for pre-launch planning and budgeting purposes.

We propose that as part of the PPRS agreement:

- The Department and the ABPI will renew their commitment to ensuring the delivery of the single horizon scanning database, with a view to developing specifications; processing change requirements; agreeing funding; going through the tendering process; and developing an

¹ Timescales for these pieces of work were agreed in June 2008 and work has already commenced in a number of these areas.

² Sir David Cooksey, *A review of UK health research funding*, December 2006.

implementation plan by April 2009. An implementation plan will be agreed with the successful tenderer with a deadline to complete development of the database covering pharmaceuticals by no later than October 2009, and companies will fully populate it by the end of December 2009.

- As part of the design and development work, an analysis is undertaken to understand how horizon scanning data can be translated into actionable information nationally on drugs bill evolution and locally for the NHS to include in commissioning plans and budgets.
- The ABPI will strongly encourage companies to populate the database and keep it up-to-date with timely horizon scanning product pipeline information.
- A single unified system will provide benefits to those companies that contribute to the database, and as such the ABPI anticipates that pharmaceutical companies will wish to populate the database.
- The PPRS agreement will commit members to accept the horizon scanning database as a recognised method by which relevant and timely horizon scanning information that they are willing and able to share, will be exchanged between a scheme member and the NHS.
- The Ministerial Industrial Strategy Group (MISG) will work with the Health Innovation Council (HIC) to retain oversight of delivery against agreed milestones for the pharmaceutical aspects of these initiatives.

A number of actions will be taken to further promote the uptake of cost-effective innovative treatments

In his interim report,³ Lord Darzi has reaffirmed the principle that healthcare should be ‘equally available to all’. However, NICE ‘blight’ and inconsistent uptake of NICE guidance continue to be issues that impact patients’ access to medicines. The Department and the ABPI agree that a package of measures is needed, including renewed guidance and improved awareness of existing flexibilities together with incentives to promote uptake of innovative products. Our proposals cover funding directions, regional/local drug evaluation best practice, implementation of guidance and application of NICE processes, and communication from topic selection processes.

We propose that as part of the PPRS agreement:

- the Department to refresh and extend good practice guidance by April 2009 or earlier if possible to:
 - (a) provide best practice advice and guidance on local and regional arrangements where national advice is not yet available;
 - (b) update and reinforce 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 the absence of NICE guidance should not be a reason for refusing funding;
 - (c) reinforce the principle that national guidance in 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, reinterpretation 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;

3 Lord Darzi, *Our NHS our future: NHS Next Stage Review Interim Report*, October 2007.

- address the anomaly whereby the funding direction does not apply to NICE technology appraisal recommendations, which are subsequently updated in a clinical guideline. The Department will establish the optimum mechanism to achieve this;
- the Department and the industry agree that the purpose of NICE's short clinical guideline process is to examine a small number of clinical questions on a small part of a clinical pathway rather than to be used as a vehicle to appraise new medical technologies;
- 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 through improved communication and access to information generated by the NICE topic selection process to all NHS organisations by April 2009;
- the Department and the industry will undertake jointly, with support from NICE, three case-based reviews brought forward by the industry on the 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. The review should be completed by December 2008, with a way forward identified by April 2009;
- in consultation with NICE and the industry, the Department will work with some primary care trusts (PCTs) to pilot an extension of prescribing incentive schemes, to promote the uptake of innovative products. Volunteer PCTs will be identified by October 2008. Following the pilots, PCTs across the country would have the option of using such schemes to incentivise the uptake of specific innovations in primary care where these drive up the quality of patient care;
- the Department will continue to ensure alignment between the Quality and Outcomes Framework and NICE guidance;
- the need to plan for NICE guidance is highlighted in the world class commissioning competencies, which have been developed by the Department in partnership with the NHS. The Department will ensure that NICE guidance continues to link in with the wider world class commissioning agenda; and
- MISG will work with HIC to retain oversight of delivery against agreed milestones for these initiatives.

The Department and the industry agree that new guidance and an improved use of system levers needs to be supported by effective use of benchmarking and monitoring to achieve sustained change. To this effect:

The Government acknowledges that NICE guidance is likely to be highly relevant to the implementation of the Bill's⁴ provisions on standards. The Department and the industry recognise that it is important to work through future consultations which are planned on the work of the Care Quality Commission and the quality standards which the Bill will allow the Secretary of State to set for the NHS.

It is the Department's intention that implementation of NICE technology appraisals should continue to be performance managed through mainstream NHS systems.

It is important that when NICE issues guidance it is implemented consistently across England, and the Department and NICE recognise their roles in supporting this implementation. The Government remains fully committed to ensuring NHS implementation of NICE technology appraisals, supported by the statutory three-month funding direction that we put in place in 2002. Compliance with NICE's technology appraisals is a core standard for the NHS. NHS organisations are required to demonstrate

⁴ Health and Social Care Act 2008.

for the Healthcare Commission's annual health checks that they are providing funding for NICE recommended treatments within three months of guidance being issued. The Department has made it clear that if evidence comes to light that a particular body is failing to comply with a statutory funding direction to put in place funding for NICE technology appraisals within three months of their publication, it will expect the relevant strategic health authority (SHA) to ensure that action is taken to address the situation.

In the future, the new Care Quality Commission should provide independent assurance on this activity in the performance of its functions. The Care Quality Commission will have a high degree of operational independence and will, for example, decide which criteria to use to assess compliance with the registration requirements that are set for registered services. However, ministers retain the powers to ask the Commission specifically to assure performance in NICE technology appraisals, and would be prepared to use these powers if required.

An identified organisation to publish comparative information annually on the uptake of NICE-approved medicines

Exposure of variation is a powerful driver of change, particularly where NICE can provide benchmarks of successful implementation. We believe this is possible with existing data sources and propose immediate action, with a view to future refinement (for example in response to opportunities generated through Connecting for Health). In addition, we will expand the dedicated resources within NICE to support implementation and associated financial planning at the local level in order to support diffusion of benchmark data and promote NICE guidance.

We propose that as part of the PPRS agreement:

- 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. A number of agencies may be involved in fulfilling these roles (e.g. NICE, the NHS Institute for Innovation and Improvement, the NHS Information Centre). Building on existing industry and NHS data sources and work carried out through the Long-Term Leadership Strategy, analysis should commence in September 2008, with a view to starting to publish annual indicators in summer 2009.
- The industry will support this initiative through sharing appropriate datasets on medicines uptake.
- The Department commits to publication of SHA, PCT and network-level metrics for uptake of a number of positively approved NICE appraisals (approved either fully or with restrictions). The exact number of metrics will be determined by the experience of pilots and other issues such as the availability of data. However, the Department is committed to extending metrics to further NICE-approved medicines once the pilots have been carried out. These metrics will allow PCTs to compare uptake against their peers and against NICE expected uptake. Suitable, influential channels should be used to publish these metrics.
- It is agreed that any work on metrics should support effective performance management systems. If, as a result of these metrics, it is evident that there are significant problems with and/or unacceptable variations in NHS implementation of NICE appraisals which are not being adequately addressed, the Department commits to revisiting this issue through the Care Quality Commission, the NHS Operating Framework, the commissioning assurance system or some other suitable mechanism.

- MISG will work with HIC to retain oversight of delivery against agreed milestones for these initiatives.

A report from MISG or another suitable source to include comparative international data on uptake of new medicines, alongside existing international price comparison data

Pharmaceutical Industry Competitiveness Task Force (PICTF) indicators have demonstrated that, while there may be some exceptions, the UK is generally slower than other developed healthcare economies in the uptake of new technologies. While any international comparisons are subject to interpretation, we believe that the UK should compare itself with other markets if it is to deliver on a 'vision for a world class NHS focused relentlessly on improving the quality of care' (Lord Darzi, *Our NHS our Future*).

We propose that as part of the PPRS agreement:

- 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. A joint Department and industry working group should be set up immediately – under the aegis of the Office of Health Economics (OHE) – to design and agree the metrics and data collection methods. 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. The indicators should also be published by MISG or through another suitable source.
- MISG will work with HIC to retain oversight of delivery against agreed milestones for these initiatives.

Health Technology Assessment

The industry agrees with the Office of Fair Trading and the Government's response to the Health Select Committee that prices should reflect the value of medicines to patients and society. We also acknowledge that NICE has an important role to play in determining whether the manufacturer's price represents value for money.

Defining value

- Focus groups are being held with the Government, the industry, patient groups and other stakeholders to look at the economic perspective that the Department sets for NICE. These groups will produce outputs and report to the Government.
- The Department is holding focus groups on value, as agreed with the industry and referenced in the Government's response to the Health Select Committee, to explore the cost/benefit perspective that the Department sets for NICE. These groups will produce outputs and report to the Government. This is a complex area and the implications of adopting a broader perspective on costs and benefits could be substantial. In particular, in the context of a fixed healthcare budget there will be both 'winners' and 'losers' from any shift in NICE's economic perspective. The focus groups are an attempt to begin an informed debate, without any preconceptions on the Government's part as to the outcome. We agree that it would be quite wrong to pre-empt such discussions, and any significant changes would in any event need

to be preceded by a far broader consultation. It is also important that stakeholders are aware of flexibilities in the current system. Some of these issues have also been raised in the recent consultations on NICE's methods and social value judgments.

Resolving issues with current HTA processes

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

The industry has expressed its concerns regarding the fitness of specific aspects of the current NICE appraisal process. The Department can play a valuable facilitating role to ensure an effective dialogue between the industry and NICE, and to ensure that the concerns of the industry as key stakeholder are fairly considered, recognising the necessity to maintain the independence of NICE. This facilitated dialogue can also provide NICE with the opportunity to deepen the industry's understanding of its process and decisions.

We propose that as part of the PPRS agreement:

- The Department creates a platform for ongoing dialogue and engagement on common HTA issues between industry, NICE and academic groups to ensure the quality and consistency of HTA submissions to NICE and with a view to providing the best possible evidence for appraisal committees.
- NICE facilitate a number of meetings between industry and other parties:
 - (a) NICE/industry preparatory meetings to identify industry issues that are relevant to the upcoming NICE process review.
 - (b) The industry table briefing documents prior to the joint NICE/industry preparatory meeting to identify issues relevant to the upcoming review of NICE appeal processes.
 - (c) There are several issues relating to topic selection. These are being looked at through a separate part of the PPRS negotiations and discussions are ongoing in this area.
- Any changes resulting from any of the above proposals would be implemented as necessary and appropriate.

Monitoring delivery of these proposals

This document is part of overall discussions on PPRS, and agreement to this package is subject to agreement being reached in other areas. The Department and the industry agree that it is important that progress is monitored in future years. This monitoring will be through MISG and HIC, although the details of this monitoring role will be dependent on the future composition and role of HIC.

Annex C: Cash payments

Where a scheme member wishing to deliver the price reduction by payments to the Department is also delivering the 4.5% price reduction under the 1999 scheme by payment and/or the 7% price reduction under the 2005 scheme, the payments should be percentages of NHS sales at list price as in the table below.

Cash payment under 2005 and/or 2008 PPRS	2009 payment	2010 payment	2011 payment	2012 payment	2013 payment
No previous cash payment	3.9%	5.8%	5.7%	5.5%	5.3%
7% (2005 PPRS)	10.6%	12.4%	12.3%	12.1%	11.9%
11.2% (incorporating 4.5% under 1999 PPRS)	14.7%	16.4%	16.3%	16.1%	15.9%

Annex D: 2009 PPRS – Price reduction information required by 6 January 2009

Company name:

A	B	C	D	E	F	G	H
Product description (including form)	Strength	Pack size	NHS price (31 December 2008) (known as reference price)	Current NHS price (if different from D)	Proposed new NHS price (with effect from 1 February 2009)	OTC as % of NHS sales	Date of patent expiry or SPC
e.g. ABCDE Tablets	100mg	56	£100.00		£90.00		31/12/2015

Notes:

1. Column A should include all products on sale at 31 December 2008.
2. Enter the date of expiry of the Supplementary Protection Certificate (SPC) in Column H. However, if no SPC has been granted then this is the product patent expiry date. Indicate if an SPC has been applied for but not yet granted.
3. Information should be returned to Jamila Rogers-Wright, MPIG-PS, Zone 456D, Skipton House, 80 London Road, London SE1 6LH.

Annex E: 2009 PPRS – Price reduction information for secondary care sector required by 31 March 2009

Company name:

A	B	C	D	E	F
Product description (including form)	Strength	Pack size	NHS price (31 December 2008)	Quantity sold 1 October to 31 December 2008	Net sales (£) 1 October to 31 December 2008
e.g. ABCDE Tablets	100mg	56	£100.00		

Notes:

1. To include all products on sale at 31 December 2008.
2. Information should be returned to Jamila Rogers-Wright, MPIG-PS, Zone 456D, Skipton House, 80 London Road, London SE1 6LH.

Annex F: 2009 PPRS – Monitoring of price cut and price adjustment savings

Company name:

Year:

Code number	Product description	Strength	Pack size	Reference NHS list price (£)	SECONDARY CARE		NHS list price (£)	SECONDARY CARE			PRIMARY CARE	
					Reference average selling price (£)	Date from		Date to	Average selling price (£)	Quantity	Net sales (£)	Quantity

Notes:

1. Code number – PPRS database presentation number.
2. Reference NHS list price (£) – NHS list price at 31 December 2008.
3. Reference average selling price (£) – average selling price for the period 1 October to 31 December 2008: net sales/quantity.
4. NHS list price (£) – NHS list price prevailing for a presentation during the relevant period.
5. Average selling price (£) – spreadsheet calculation (average selling price for relevant period): net sales/quantity.
6. Net sales (£) – net sales into secondary care.

Annex G: 2009 PPRS – Independent accountant's supplementary report covering price cut/modulation

[headed paper]

The Directors
Company
Address

INDEPENDENT ACCOUNTANT'S SUPPLEMENTARY REPORT COVERING PRICE CUT/MODULATION

Company:

Year ended:

We have examined the attached schedules (which we have initialled for the purposes of identification) that set out the information relating to modulation for the period XXXXXX as required under the Pharmaceutical Price Regulation Scheme 2009.

In our opinion (and subject to the reservations mentioned below) we have concluded that the information contained in the schedules has been accurately extracted from the records of the company in that we have:

- i. agreed the extraction of the quantity figures set out in the modulation schedule from the company's underlying accounting records;
- ii. agreed the reference price figures set out in the modulation schedule to the company's price list that was in effect at XXXX;
- iii. agreed the extraction of the modulated price figures to the company's published price list and to the underlying record of the company.

This engagement is separate from, and unrelated to, our audit work on the financial statements of the company which was carried out solely for the purposes of Section 235 of the Companies Act 1985/Sections 495 and 496 and 497 of the Companies Act 2006 and nothing herein creates any additional obligations or liabilities regarding our statutory audit work, our statutory audit report or the opinions we have formed in respect of that statutory audit, which would not otherwise exist.¹

[Delete italics as appropriate]

Signature..... **Date**

Name.....

Address

Professional qualification

¹ This paragraph should be included only where the same audit firm provides both statutory audit and PPRS services.

Annex H: 2009 PPRS – Company declaration covering price cut/modulation

Company:

Year ended:

Affiliated companies consolidated in this return:

1

2

3

4

5

We can confirm that:

- i. the figures set out in the schedules have been accurately extracted from the records of the company;
- ii. in compiling the schedules, the company has complied with the requirements of the scheme as set out in chapter 7.

Signature..... **Date**

Name..... (Managing Director/Chief Executive)

Signature..... **Date**

Name..... (Finance Director/Senior Financial Executive)

Annex I: 2009 PPRS – Schedule of rates and allowances

ROCE	Target	21%
ROS	Target	6%
MOT	Upper limit	140%
	Lower limit	40%

			Level 1	Level 2
Marketing allowance	Fixed element		£500,000	£1,000,000
	Standard element		2%	4%
	Product servicing allowances	For each active substance with sales to the NHS of £100,000 or more	<ul style="list-style-type: none"> • £58,000 for each of the first three eligible products • £46,000 for each of the next three • £35,000 for each of the next three • £23,000 each for all others 	
Information allowance	Standard element		2%	4%
Research and development allowance^{(1) (2)}	Flat rate		12%	20%
	Variable rate	Innovation	To a maximum of 28 active substances with NHS sales of £100,000 or more. The first four products at 0.75% of sales. The next four products at 0.50% of sales. The next 20 products at 0.25% of sales.	
		Paediatrics	N/A	1.0% per product (up to 3%) in any one year.
	Maximum total			22%

Default transfer pricing	Manufacturing	59%
	R&D	21%
	Profit	20%
	Allowed TP profit	25% of accepted costs
	Total manufacturing costs	45%

(1) Definition of 'in patent' to include ten years from date of marketing authorisation for new active substances where no patent exists.

(2) New entrant flexibility: during the first three years as a full AFR company, when assessing profits only, higher rate allowance will be given as follows: 2% for substances 1 and 2, 1% for substance 3, with 0.25% of NHS home sales for each active substance thereafter to an overall maximum of 10%.

Annex J: Guidance notes on completion of the Annual Financial Return and schedules, company declaration and independent accountant's report

1 General

- 1.1 This annex sets out guidance on the completion of Annual Financial Returns (AFRs) and the approach that the Department will adopt in assessing the returns. It is not intended to be comprehensive in its approach and does not cover all the issues that may arise in the assessment of AFRs. The Department will continue to discuss AFRs with scheme members bilaterally and may limit costs and capital to a level that is reasonable in its analysis of the company's figures, as provided for in chapter 8 of the agreement.
- 1.2 The AFR should relate to business organisations that manufacture and supply licensed branded medicines that ultimately are charged to the NHS. The AFR should cover, on a consolidated basis, the company and its subsidiaries, and should include business done through branches or divisions. Where, however, within the group organisation, audited accounts are prepared for a sub-group which embraces all the group pharmaceutical business carried on in the UK (though not necessarily confined to such business), the AFR should comprise consolidated figures for this sub-group. In such circumstances, references in the AFR to affiliated concerns should be regarded as extending to such excluded units as overseas subsidiaries, and non-pharmaceutical UK subsidiaries, branches or divisions. Where NHS sales occur in more than one company under the same ultimate common ownership (whether part of a UK group or not), e.g. sales of branded over the counter (OTC) prescription medicines by a consumer healthcare company within the group, these sales should be added together. However, where management of the companies is entirely separate, it may be more appropriate for companies to submit separate returns. Companies wishing to do this should notify the Department in writing by 31 March of the year in which they intend to provide separate submissions. Where wholesaling and/or retailing activities are carried out in separate organisations for which separate figures of costs, sales and profits are available, those figures should, where they are covered by separate audited accounts, be excluded from the AFR; otherwise, they should be included in the AFR under 'Other products'.
- 1.3 Where two or more companies enter into a partnership, joint venture or other joint commercial arrangement relating to the sales of an NHS medicine to the NHS, the companies involved should each notify the Department when submitting their AFR. Each company's notification should include, for each NHS medicine involved, details of how sales to the NHS and associated expenses have been reported within its own PPRS return. The information provided should assist the Department to satisfy itself that all sales of the NHS medicine to the NHS and associated expenses are included in the PPRS returns of the companies involved.
- 1.4 It is recognised that the availability of consolidated and/or audited accounts will be a matter of corporate organisation and will not necessarily coincide with the requirements of the AFR. It is not intended that scheme members should produce additional audited accounts especially for the purpose of the AFR and where the accounting arrangements of the group are such that some other basis for the completion of the AFR is more appropriate, such other bases may be adopted by agreement between the scheme member and the Department. Nevertheless, the Department requires a reconciliation to the UK audited accounts or to audited and published segmental accounts (or analyses) – either for a pharmaceutical sector or for the geographical segment which includes the UK, depending on the basis used in the annual report.

- 1.5 The AFR should be accompanied by a copy of the audited accounts or audited and published segmental accounts (or analyses) of the company, group or sub-group whose figures form the basis of the AFR and by a statement setting out the names of the companies, branches and divisions whose figures are included in the AFR with a broad indication of the business activities of the major units. Published financial accounts of the ultimate holding company and of any relevant intermediate holding company should accompany the AFR.
- 1.6 The completed AFR should be signed by the Managing Director or Chief Executive and the Finance Director or appropriate senior financial executive of the scheme member (see the company declaration at the end of this annex). The AFR should be accompanied by a report from independent accountants to the effect that (subject to such reservations as they consider necessary), in their opinion, and in accordance with the explanations given them, the AFR has been prepared on the basis required, and fairly reflects for the relevant financial year the profit earned from home sales of NHS medicines and, where appropriate, the capital employed in relation to NHS home medicines (see 'Independent accountant's report' at the end of this annex).
- 1.7 For the purposes of the PPRS an independent accountant is any member of the Consultative Committee of Accountancy Bodies (CCAB) who, under the rules of that body, is entitled to engage in public practice, and would be eligible for such an appointment. An individual, body corporate or firm may be appointed as an independent accountant.
- 1.8 Schedule 1 (Sales, Costs and Profit) should be completed in respect of the reporting company's financial year and schedule 2 (Capital Employed) should relate to the balance sheet date at the end of the same financial year. Where a scheme member is satisfied that it does not qualify to be assessed as a return on capital company owing to its home sales to capital ratio being greater than 3.5:1, there is no requirement to submit schedule 2.
- 1.9 It is accepted that the accounting system employed by the scheme members will result in some variation in the nature of expenses included under the various headings of the AFR. The purpose of these notes is to identify the main areas of consistency that are sought from all companies.
- 1.10 For the purpose of the AFR:
 - 1.10.1 an affiliated concern should include any parent company or fellow subsidiary company of the scheme member, any of its subsidiary companies, branches or divisions whose figures are excluded from the AFR and any other trading organisation under the same control as the scheme member (see also note 1.2 above);
 - 1.10.2 all figures should be reported to the nearest £1,000;
 - 1.10.3 all figures for sales and costs should be stated net of UK Value Added Tax. Where a scheme member has been unable to recover input tax or a proportion of it, thus making it a cost to the business, it should be treated as such.

2 Apportionment

- 2.1 The Department recognises that scheme members cannot always allocate costs and capital directly to its NHS home, NHS exports and other products businesses and that various apportionment techniques have to be used to attribute shared costs and capital to the three businesses. Scheme members are required to make such apportionments on the most realistic and reasonable basis possible, striking an equitable balance between the separate interests of the scheme member in reporting the lowest possible profitability/return on capital (ROC) employed on its NHS home business and that of the taxpayer in reporting the highest possible profitability/ROC employed. It is expected that the independent accountant will use his/her professional judgement to ensure that the bases adopted are adequately explained in the accompanying notes and to qualify his/her report in those cases where he is not satisfied that this has been the case.
- 2.2 The scheme member will include with the AFR notes identifying, with amounts, those items that have been specifically allocated against each cost and capital heading and those that have been apportioned. For those items that have been apportioned, scheme members should give the amounts involved and explain the reasons for that allocation. If apportionment bases are changed from those adopted in the previous year, this should be declared in the notes and the AFR lines identified. The Department may ask for additional information on the method of apportionment if this is unclear.
- 2.3 Employee-related items (whether a cost or credit) included in the profit and loss account of the audited accounts, such as accounting for pension, stock options and other post-retirement benefits, should be apportioned in the AFR in line with the salary costs of the relevant employees. Where this is not possible (e.g. when the item does not in full relate to current employees such as pensions accounting for retired or deferred members), a realistic alternative basis of allocation across the various businesses and relevant cost heads should be used and the basis of apportionment used should be fully explained in notes to the AFR.
- 2.4 In accordance with paragraph 8.6, schedule 1 and schedule 1A should be completed in a manner that ensures that incomes and associated expenditures are matched within an AFR line. The scheme member should ensure that when sales are allocated between AFR headings ('NHS medicines home', 'NHS medicines exports' and 'Other products'), all relevant costs are considered and apportioned in an appropriate and consistent manner.

3 Schedule 1: Sales, Costs and Profit

- 3.1 Columns are provided for separate information on home and export trade in NHS medicines. Sales of products not falling within the definition of NHS medicines should be shown under 'Other products'. This information is required to assist the Department in forming an independent judgement on the reasonableness of any methods of apportionment used in preparing the NHS figures and to reduce to a minimum the requests for additional information in individual cases.
- 3.2 The strict apportionment or allocation of costs may result in home costs that are greater than the Department is likely to accept, or are restricted by formulae. To avoid claiming excessive costs and distorting published statistics, scheme members should include in the 'NHS medicines home costs claimed' column only those costs that it is expected that the Department will accept.
- 3.3 It is expected that costs and expenses (lines 4 to 20) will be on a cost centre basis, i.e. salaries, wages, depreciation, materials and other expenses attributed to a function will be included in the cost of that function.

- 3.4 Depreciation should be charged at historical cost. Any difference between the figures on schedule 1 and in the accounts should be shown in the appropriate column on schedule 1A.
- 3.5 Where costs and expenses (lines 4 and 7) include sums charged by affiliated concerns, the Department will apply the default breakdown as provided for under chapter 8 of the scheme if the scheme member is unable or unwilling to provide an independently reviewed breakdown of the transfer price under the cost headings included in schedule 1.

4 Schedule 1A: Reconciliation of schedule 1 with audited accounts

- 4.1 Columns on schedule 1A provide for a reconciliation of sales, costs and profit shown in schedule 1 with the amounts disclosed in the audited accounts on which the AFR is based.
- 4.2 Figures from the accounts should be transferred directly into the first column, 'Total per audited accounts'. If the cost headings used in the accounts are incompatible with the AFR, then sales, total costs and profit before interest and taxation should be shown.
- 4.3 The second column, 'Reallocations between cost headings', provides for cost reallocation where cost heads in the accounts are not the same as in the AFR. Details of costs reallocated should be explained, together with reasons for the reallocation, in notes accompanying the AFR.
- 4.4 The third column, 'Items in audited accounts excluded from AFR', is where costs that are not appropriate to PPRS should be shown. Home costs reported in schedule 1 will exclude certain items of non-PPRS income and expenditure that are normally recognised for published accounts purposes. It is expected that items which are omitted from the figures reported for 'NHS medicines home' will also be excluded from 'NHS medicines exports' and 'Other products' so that the three businesses may be compared on a basis which is as close as possible to like-with-like. Non-PPRS items should be eliminated consistently and in their entirety on schedule 1A. Examples of costs that should be excluded from schedule 1 and shown in column 3 of schedule 1A include amortisation of intangible assets, dividends and trade investment income received, interest paid and received and charitable and political donations.
- 4.5 The fourth column of schedule 1A, 'Items not in audited accounts included in AFR', allows for costs that are not in the accounts that form the basis of the AFR to be brought in if they are dealt with through the accounts of other group companies but are directly relevant to the supply of medicines to the NHS. The usual cost that is brought in under this column is research and development (R&D) that has been done by or has been recharged to affiliate companies.
- 4.6 Costs reported in this column at lines 22 and 23 are subject to the independent accountant's report (see the independent accountant's report at the end of this annex). These will only be accepted where it can be reasonably determined that costs incurred in the scheme member's accounts do not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating these costs.
- 4.7 The final column of schedule 1A must agree with the total column on schedule 1.

5 Schedule 2: Capital employed

- 5.1 Fixed assets should be presented at historical cost. Any difference between the figures included in the AFR and the balance sheet should be shown in schedule 2A. Assets should not include investments the income from which has been excluded from schedule 1.
- 5.2 PPRS does not permit the inclusion of intangible assets in the computation of capital employed.
- 5.3 Any provision for corporate taxation, including deferred taxation, should be excluded from current liabilities. Also excluded from current liabilities are items which do not represent normal trading balances but are of a long-term nature representing, in reality, part of the reporting company's capital structure (e.g. bank borrowing; advances from affiliated concerns). Such items should be entered in the column 'Total per audited accounts' on schedule 2A to tie back to the accounts and then excluded in the column 'Items in audited accounts excluded from AFR'.
- 5.4 The injected capital amounts shown in lines 45 to 48 should be the proportion of fixed and current assets less current liabilities appropriate to the operations covered by the AFR but not included in the audited accounts of the scheme member. Injected capital reported at lines 45 to 48 is subject to the independent accountant's report (see the independent accountant's report at the end of this annex) and will only be accepted where it can be reasonably determined that capital, as shown in the scheme member's accounts, does not fully reflect the level of worldwide group services it receives and that appropriate bases of apportionment have been applied in calculating this capital. This net capital should generally correspond to the expenses shown at lines 22 and 24 of schedule 1. Conversely, a deduction should, if appropriate, be shown in schedule 2A, calculated on the same principles, when the scheme member shows amounts excluded from the AFR on schedule 1A.
- 5.5 The strict apportionment or allocation of capital may result in home capital that is greater than the Department is likely to accept. This is most likely to occur where costs being claimed are less than initially allocated to home, such as R&D, marketing or information. Scheme members should include in the 'NHS medicines home capital claimed' column, only that capital that it is expected that the Department will accept.
- 5.6 If the average capital employed during the year would not be fairly represented by averaging the capital employed at the beginning and at the end of the year, a statement should be attached indicating the appropriate adjustment.

6 Schedule 2A: Reconciliation of schedule 2 with audited accounts

- 6.1 Schedule 2A should be used to reconcile items on schedule 2 with the corresponding figures in the audited balance sheet. The columns are the same as those on schedule 1A and comments above in respect of schedule 1A also apply to schedule 2A.

7 Definitions and explanatory notes on cost and capital headings

Sales

- 7.1 Sales should be shown net after deduction of all trade and other discounts (whether allowed to wholesalers, NHS authorities, trusts or others) and all rebates, return allowances and sales taxes. Discounts include settlement discounts where these are allowed as part of the normal wholesalers' discount.
- 7.2 NHS medicines should include only those products covered by the scheme as set out in chapter 4 of the agreement. To qualify as NHS medicines, products must be in the same form and packaging as used for filling prescriptions. Thus, sales of intermediate products and bulk supplies will not be classified as NHS medicines. This means that, while NHS home sales can include products that are not included under NHS export sales, NHS export sales cannot include products that are not included in NHS home sales.
- 7.3 Other products sales include all products that are not specifically NHS products including contract manufacture for third parties, sales of intermediates and sales of bulk chemicals (whether in the form of tablets or not). The recharge of service costs and other intangibles (including R&D) should be excluded from the AFR on schedule 1A through the exclusion of both the income and cost being recharged.
- 7.4 A list of all products included under home NHS medicines should be provided, identifying those with sales less than £100,000 and more than £100,000 (after discounts and rebates). For each product, the list should also show the date of expiry of the active substance patent and any Supplementary Protection Certificate or, where no patent exists, the date of grant of the first marketing authorisation for that new active substance. This information is used to calculate the R&D and marketing allowances (chapter 8) and might be submitted in the following format:

Company:

Product information

(Year)							
			Home sales <£100k	Home sales >£100k	Qualifying for PSA	Qualifying for innovation allowance	Qualifying for paediatric allowance
PRODUCT	PATENT DETAILS						
a							
b							
c							
d							
e							
etc							
Total			0	0	0	0	0

Cost of goods sold

- 7.5 Materials purchased from affiliates and independents should be on a materials consumed basis. Manufacturing process costs should include all direct and indirect labour costs, depreciation of manufacturing fixed assets and other related manufacturing overhead expenses. Costs should not include any one-off costs (line 19) or other expenses that would be better included elsewhere in schedule 1.
- 7.6 In all cases where there are products being licensed in or out, or contract manufacturing is being undertaken for either other independent companies or for affiliated companies, which impact in a material way on the sales of NHS medicines, all costs and revenue shall be included in the AFR, together with a brief description of the arrangement and of how expenditure and income have been treated in the AFR. Where a company manufactures a product for marketing by another, the relevant costs should be shown under 'Other products' in the AFR of the producing company and the purchase price recorded under 'NHS medicines' in the AFR of the marketing company.

Distribution costs

- 7.7 Distribution costs should normally cover only those costs directly associated with the physical warehousing of finished products and their distribution to wholesalers, hospitals etc.

Marketing costs

- 7.8 In addition to all costs associated with the operation of marketing departments, 'Marketing expenses' in schedules 1 and 1A includes all expenditure incurred in advertising, selling and promotion of a company's NHS products as well as the administrative support for such activities. Cost and activities that are expected to fall within marketing include market research and marketing strategy. The following are the criteria by which marketing expenditure will be allowable:
- 7.8.1 **Literature:** The cost against this category should cover all expenses incurred and include the direct labour and overhead charges attributable to operations concerned with such promotion (e.g. insertion and addressing) but not the cost of samples. If mailing is undertaken by an agency, the relevant charges should be entered in this section.
- 7.8.2 **Representatives:** The cost should include the salaries and wages and overhead costs of representatives and supervisors, the running and replacement costs of vehicles and all travelling and subsistence expenses. The cost incurred in visits to hospitals as well as to general practitioners should be included, as should the cost of promotion to wholesalers or pharmacists. Where the cost of representatives covers activities other than 'NHS medicines home', the cost should be apportioned on a suitable basis.
- 7.8.3 **Advertising:** The cost of advertising in professional journals should cover all expenses incurred whether the journals are placed on sale, are issued by subscription, or are free of charge.
- 7.8.4 **Administration:** Costs should include all those incurred in the organisation, control, supervision and assessment of promotional activities in so far as it is not reasonably possible to allocate these costs to the other categories.

- 7.9 The following expenditure is not allowable as a charge in NHS prices and should not be included in schedule 1:
- samples (other than samples for identification purposes);
 - gifts;
 - hospitality (other than that provided for eligible medical symposia).

Information expenses

- 7.10 The activities allowable under the heading 'Information expenses' are set out at chapter 8 of the scheme. For clarification, the following criteria apply to the specific costs listed below:
- 7.10.1 **Samples for identification purposes:** The cost included should be for those samples provided specifically to enable prescribers to identify a particular product and should include the factory cost of the materials in final packed form, distribution, handling, postal charges and overhead and administration charges.
- 7.10.2 **Summaries of Product Characteristics:** This covers the cost against this category and should cover all expenses incurred in the production of data sheets including the direct labour and overhead and administration charges.
- 7.10.3 **Medical symposia:** This should include the cost of any support, including hospitality, given by the company for medical symposia. The ABPI Code of Practice Authority will be particularly concerned with the conduct of such symposia, which should not be the occasion for conspicuous extravagance. Where a symposium has been found to be in breach of the Prescription Medicines Code of Practice, no part of the costs may be included in schedule 1 of the AFR.
- 7.11 If significant items of expenditure cannot be dealt with in accordance with notes 7.8 and 7.10 above, the items involved, the expenditure on each item and the method adopted to deal with it should be stated in an accompanying note.

General and administrative (G&A) costs

- 7.12 G&A expenses include the administrative costs of running a business including the salaries and employment costs of administrative staff, accommodation costs and the associated costs of general management.

Research and development (R&D) costs

7.13 R&D covers the costs incurred by a company in carrying out R&D in its own facilities as well as R&D bought in, whether from affiliate companies or third parties. It includes:

- investigation, the object of which is to discover new therapeutic agents or processes in the manufacture of new agents or new methods of producing known agents;
- formulation, investigations and clinical trials directed towards the production of a medicine;
- costs of licensing, patent fees and registration fees for trademarks;
- salaries and associated costs of all staff engaged on R&D activities or supporting those activities by analytical, administrative and other services;
- all materials and expenses incurred by these staff in carrying out their duties and related accommodation costs.

One-off costs

7.14 One-off costs (line 19) by their very nature will not occur every year. This heading should be used for any large but infrequent costs that would distort other cost heads if they were included within them.

PPRS: SCHEDULE 1: SALES, COSTS AND PROFIT

COMPANY:

AFR FOR YEAR ENDED:

	Line number	NHS medicines home	NHS medicines exports	Other products	Total	NHS medicines home costs claimed
		£000	£000	£000	£000	£000
SALES						
To affiliates	1					
To independents	2					
Total sales	3					
COSTS AND EXPENSES						
Finished goods bought in						
From affiliates	4					
From independents	5					
Total finished goods resold	6					
Own manufactured goods resold						
Materials purchased from affiliates	7					
Materials purchased from independents	8					
Manufacturing process costs	9					
Total MCOGS	10					
Total COGS	11					
Distribution costs	12					
Information expenses	13					
Marketing expenses	14					
General and administrative expenses	15					
Royalties payable – to affiliates	16					
Royalties payable – to Independents	17					
R&D expenses in accounts	18					
One-off costs and expenses	19					
Total costs and expenses	20					
TRADING PROFIT	21					
Supplementary items						
R&D expenses – injected – UK recharged	22					
R&D expenses – injected – overseas costs	23					
Other injected costs	24					
Other trading income less charges (-)	25					
Royalties received – affiliates (-)	26					
Royalties received – independents (-)	27					
Other income (-)/costs (+)	28					
PROFIT BEFORE INTEREST AND TAX	29					

PPRS: SCHEDULE 1A: RECONCILIATION OF SCHEDULE 1 WITH AUDITED ACCOUNTS

COMPANY:

AFR FOR YEAR ENDED:

	Line number	Total per audited accounts	Re-allocations between cost headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total
		£000	£000	£000	£000	£000
SALES						
To affiliates	1					
To independents	2					
Total sales	3					
COSTS AND EXPENSES						
Finished goods bought in						
From affiliates	4					
From independents	5					
Total finished goods resold	6					
Own manufactured goods resold						
Materials purchased from affiliates	7					
Materials purchased from independents	8					
Manufacturing process costs	9					
Total MCOGS	10					
Total COGS	11					
Distribution costs	12					
Information expenses	13					
Marketing expenses	14					
General and administrative expenses	15					
Royalties payable – to affiliates	16					
Royalties payable – to independents	17					
R&D expenses in accounts	18					
One-off costs and expenses	19					
Total costs and expenses	20					
TRADING PROFIT	21					
Supplementary items						
R&D expenses – injected – UK recharged	22					
R&D expenses – injected – overseas costs	23					
Other injected costs	24					
Other trading income less charges (-)	25					
Royalties received – affiliates (-)	26					
Royalties received – independents (-)	27					
Other income (-)/costs (+)	28					
PROFIT BEFORE INTEREST AND TAX	29					

PPRS: SCHEDULE 2: CAPITAL EMPLOYED

COMPANY:

AFR FOR YEAR ENDED:

	Line number	NHS medicines home	NHS medicines export	Other products	Total	NHS medicines home capital claimed
		£000	£000	£000	£000	£000
FIXED ASSETS (at historic cost)						
Land and buildings	30					
Plant and machinery	31					
Other fixed assets	32					
Total fixed assets	33					
R&D fixed assets	34					
Non-R&D fixed assets	35					
Total fixed assets (to agree with line 33)	36					
WORKING CAPITAL						
Current assets						
Cash and bank balances	37					
Debtors – affiliates	38					
Debtors – other	39					
Stocks	40					
Other current assets	41					
Total current assets	42					
Current liabilities	43					
Net working capital	44					
INJECTED CAPITAL						
R&D fixed assets – UK	45					
R&D fixed assets – overseas	46					
Non-R&D fixed assets	47					
Other capital	48					
Total injected capital	49					
CAPITAL EMPLOYED	50					

PPRS: SCHEDULE 2A: RECONCILIATION OF SCHEDULE 2 WITH AUDITED ACCOUNTS

COMPANY:

AFR FOR YEAR ENDED:

Line number	Total per audited accounts	Re-allocations between cost headings	Items in audited accounts excluded from AFR	Items not in audited accounts included in AFR	Total
	£000	£000	£000	£000	£000
FIXED ASSETS (at historic cost)					
Land and buildings	30				
Plant and machinery	31				
Other fixed assets	32				
Total fixed assets	33				
R&D fixed assets	34				
Non-R&D fixed assets	35				
Total fixed assets	36				
WORKING CAPITAL					
Current assets					
Cash and bank balances	37				
Debtors – affiliates	38				
Debtors – other	39				
Stocks	40				
Other current assets	41				
Total current assets	42				
Current liabilities	43				
Net working capital	44				
INJECTED CAPITAL					
R&D fixed assets – UK	45				
R&D fixed assets – overseas	46				
Non-R&D fixed assets	47				
Other capital	48				
Total injected capital	49				
CAPITAL EMPLOYED	50				

PPRS: SCHEDULE 1: SALES, COSTS AND PROFIT

COMPANY:

ESTIMATE/FORECAST FOR YEAR ENDED:

	Line number	NHS medicines home	NHS medicines exports	Total	NHS medicines home costs claimed
		£000	£000	£000	£000
SALES					
To affiliates	1				
To independents	2				
Total sales	3				
COSTS AND EXPENSES					
Finished goods bought in					
From affiliates	4				
From independents	5				
Total finished goods resold	6				
Own manufactured goods resold					
Materials purchased from affiliates	7				
Materials purchased from independents	8				
Manufacturing process costs	9				
Total MCOGS	10				
Total COGS	11				
Distribution costs	12				
Information expenses	13				
Marketing expenses	14				
General and administrative expenses	15				
Royalties payable – to affiliates	16				
Royalties payable – to independents	17				
R&D expenses in accounts	18				
One-off costs and expenses	19				
Total costs and expenses	20				
TRADING PROFIT	21				
Supplementary items					
R&D expenses – injected – UK recharged	22				
R&D expenses – injected – overseas costs	23				
Other injected costs	24				
Other trading income less charges (-)	25				
Royalties received – affiliates (-)	26				
Royalties received – independents (-)	27				
Other income (-)/costs (+)	28				
PROFIT BEFORE INTEREST AND TAX	29				

PPRS: SCHEDULE 2: CAPITAL EMPLOYED

COMPANY:

ESTIMATE/FORECAST FOR YEAR ENDED:

Line number	Start of year			End of year		
	NHS medicines home	NHS medicines export	Total	NHS medicines home	NHS medicines exports	Total
	£000	£000	£000	£000	£000	£000
FIXED ASSETS (at historic cost)						
Land and buildings	30					
Plant and machinery	31					
Other fixed assets	32					
Total fixed assets	33					
R&D fixed assets	34					
Non-R&D fixed assets	35					
Total fixed assets	36					
WORKING CAPITAL						
Current assets						
Cash and bank balances	37					
Debtors – affiliates	38					
Debtors – other	39					
Stocks	40					
Other current assets	41					
Total current assets	42					
Current liabilities	43					
Net working capital	44					
INJECTED CAPITAL						
R&D fixed assets – UK	45					
R&D fixed assets – overseas	46					
Non-R&D fixed assets	47					
Other capital	48					
Total injected capital	49					
CAPITAL EMPLOYED	50					

Pharmaceutical Price Regulation Scheme 2009

COMPANY DECLARATION

Annual Financial Return for the year ended:

Company:

Affiliated companies consolidated in this return:

1

2

3

4

5

We confirm that:

- i the figures set out in the annexed schedules 1, 1A, 2 & 2A ('the schedules'), together with the accompanying notes and reconciliations ('the AFR') have been reconciled to the audited accounts and have been compiled on the basis required for the purpose of the Pharmaceutical Price Regulation Scheme dated December 2008 agreed between the Health Departments of the United Kingdom and the Association of the British Pharmaceutical Industry.
- ii where apportionment of costs has been necessary, an appropriate method of apportionment has been selected and this has been adequately disclosed in the accompanying notes. Those bases of apportionment are fair and reasonable in the context of PPRS and the figures in the schedules fairly reflect the income, costs and profits relating to home sales of NHS medicines, export sales of those products and the rest of the business as represented by other products for the financial year and the capital for each of those businesses at the close of the financial year.
- iii *Where injected costs and/or capital have been included, an appropriate method of apportionment has been selected in calculating the amounts of injected costs and/or capital attributed to NHS medicines, and has been adequately disclosed in the accompanying notes. To the best of our knowledge, the injected costs have not been included in the transfer price paid for goods or services received and exclude profit where the associated capital has been injected into AFR schedule 2.*
[Delete italics as appropriate]

Signature..... **Date**

Name..... (Managing Director/Chief Executive)

Signature..... **Date**

Name..... (Finance Director/Senior Financial Executive)

Pharmaceutical Price Regulation Scheme 2009

[headed paper]

The Directors
Company
Address

INDEPENDENT ACCOUNTANT'S REPORT

Annual Financial Return for the year ended:

Company:

Affiliated companies consolidated in this return:

1

2

3

4

5

I/we have examined the annexed schedules 1, 1A, 2 & 2A ('the schedules'), together with the accompanying notes and reconciliations ('the AFR') which *I/we* have initialled for the purpose of identification.

On the basis of *my/our* examination and of the explanations given to *me/us*, *I/we* report that, in *my/our* opinion and subject to the reservations mentioned below:

- i The figures set out in the AFR have been reconciled to audited accounts and have been compiled on the basis required for the purpose of the Pharmaceutical Price Regulation Scheme dated December 2008, agreed between the Health Departments of the United Kingdom and the Association of the British Pharmaceutical Industry.
- ii Where apportionment of costs has been necessary, the Schedules have been prepared in accordance with the basis of allocation set out in the accompanying notes.
- iii Transfer prices in the AFR are on the same basis as those the company expects to include in its corporation tax return and are consistent with those used in the previous corporation tax return *except as set out overleaf* and are set on the following basis:

Basis adopted:

- iv *Where injected costs and/or capital have been included I/we have seen acceptable evidence to support the inclusion in the schedules of items dealt with in the accounts of affiliated companies. The method of apportionment to NHS medicines has been adequately disclosed in the accompanying notes.*

This engagement is separate from, and unrelated to, our audit work on the financial statements of the company which was carried out solely for the purposes of section 235 of the Companies Act 1985/sections 495/and 496 and 497 of the Companies Act 2006 as appropriate and nothing herein creates any additional obligations or liabilities regarding our statutory audit work, our statutory audit report or the opinions we have formed in respect of that statutory audit, which would not otherwise exist.¹

[Delete italics as appropriate]

Signature..... **Date**

Name.....

Address

Professional qualification

¹ This paragraph should be included only where the same audit firm provides both statutory audit and PPRS services.

Annex K: Checklist of items to be submitted for a full AFR

Accounts

- Published accounts of UK company supplying medicines to the NHS.
- Published accounts of UK holding company (if applicable).
- Published accounts of ultimate holding company.

Schedules and supporting information

- Company declaration signed on behalf of company and including a list of companies, branches and divisions included in the AFR.
- Independent accountant's report.
- AFR schedules 1, 1A, 2 and 2A. Companies assessed as return on sales may omit schedules 2 and 2A.
- Details of reallocations between cost headings (schedules 1A and 2A).
- Details of items in the accounts excluded from the AFR.
- Details of items injected into the AFR.
- Details of apportionments for all cost and capital headings either directly allocated or apportioned to NHS home medicines with explanations of the apportionments.
- NHS medicines home costs and capital claimed columns completed.
- AFR home sales/net modulation sales reconciliation.
- Details of partnerships, joint ventures and other joint commercial arrangements relating to sales of an NHS medicine to the NHS included in this return.

Product information

- List of all products included in NHS home medicines identifying those with sales over £100,000 (after discounts and rebates) for which PSA is claimed and indicating whether they are considered to be eligible for a variable rate (innovation and paediatrics) R&D allowance.
- Date of expiry of the active substance patent for each product and any SPC, or where no patent exists, the date of grant of the first marketing authorisation for that new active substance.

Annex M: 2009 PPRS – Company declaration covering additional information relating to sales of branded medicines

Company:

Year ended:

Affiliated companies consolidated in this return:

1

2

3

4

5

We can confirm that:

- i the information contained in the schedules has been accurately extracted from the records of the company; and
- ii in compiling the schedules the company has complied with the requirements of the scheme as set out in paragraph 9.11.

Signature..... **Date**

Name..... (Managing Director/Chief Executive)

Signature..... **Date**

Name..... (Finance Director/Senior Financial Executive)

Annex N: 2009 PPRS – Independent accountant’s supplementary report covering additional information relating to sales of branded medicines

[headed paper]

The Directors
Company
Address

INDEPENDENT ACCOUNTANT'S SUPPLEMENTARY REPORT COVERING ADDITIONAL INFORMATION RELATING TO SALES OF BRANDED MEDICINES

Company:

Year ended:

We have examined the attached schedules (which we have initialled for the purposes of identification) that set out the information relating to the 12 months ended 31 December 20XX, as required under the Pharmaceutical Price Regulation Scheme 2009.

The information has in part or whole been extracted from information systems that have not been an integral part of the statutory audit process. Those systems have not been separately reviewed by us for the purposes of the report. However, on the basis of our examination and of the explanations given to us there is in our opinion and subject to the reservations mentioned below, a reasonable level of assurance that:

- i the information contained in the schedules has been accurately extracted from the records of the company; and
- ii in compiling the schedules the company has complied with the requirements of the scheme as set out in paragraph 9.11.

This engagement is separate from, and unrelated to, our audit work on the financial statements of the company which was carried out solely for the purposes of section 235 of the Companies Act 1985/sections 495/and 496 and 497 of the Companies Act 2006 and nothing herein creates any additional obligations or liabilities regarding our statutory audit work, our statutory audit report or the opinions we have formed in respect of that statutory audit, which would not otherwise exist.¹

[Delete italics as appropriate]

Signature **Date**

Name.....

Address

Professional qualification

¹ This paragraph should be included only where the same audit firm provides both statutory audit and PPRS services.

Annex O: Submission of AFRs in transition between the interim scheme and the 2009 PPRS

Scheme members should provide an audited AFR for a 12 month period based on statutory accounts for the year ending in 2008 and independently reviewed AFRs for a 12 month period based on statutory accounts for the year ending in 2009.

The Department will exclude from the profit assessment the period 1 September to 31 December 2008 and will apportion full year figures on a time basis unless otherwise agreed (see below). The amounts to be excluded under the interim scheme will be the relevant proportion (number of months/12) of the full year totals. For ROC companies with an accounting year that ends during the interim scheme, the year-end capital will be used as a proxy for capital employed at 31 August 2008 and this will also be used as the opening capital for the 2009 scheme. The provision of a full year AFR for 2008 and 2009 means no change from current arrangements for scheme members and avoids detailed apportionment of figures between periods.

The following schedule shows the basis of apportionment of AFRs based on accounting years ending in 2008 and 2009.

Company year end/ 12 month AFR to	Proportion to be assessed under 2005 PPRS	Proportion to be excluded under interim scheme	Company year end/12 month AFR to	Proportion to be assessed under 2005 PPRS	Proportion to be assessed under 2009 PPRS	Proportion to be excluded under interim scheme
31 December 2008	8/12	4/12	31 December 2009	0/12	12/12	0/12
30 November 2008	9/12	3/12	30 November 2009	0/12	11/12	1/12
31 October 2008	10/12	2/12	31 October 2009	0/12	10/12	2/12
30 September 2008	11/12	1/12	30 September 2009	0/12	9/12	3/12
31 August 2008	12/12	0/12	31 August 2009	0/12	8/12	4/12
31 July 2008	12/12	0/12	31 July 2009	0/12	8/12	4/12
30 June 2008	12/12	0/12	30 June 2009	0/12	8/12	4/12
31 May 2008	12/12	0/12	31 May 2009	0/12	8/12	4/12
30 April 2008	12/12	0/12	30 April 2009	0/12	8/12	4/12
31 March 2008	12/12	0/12	31 March 2009	8/12	0/12	4/12
29 February 2008	12/12	0/12	28 February 2009	8/12	0/12	4/12
31 January 2008	12/12	0/12	31 January 2009	8/12	0/12	4/12

Where a 12 month AFR covers three schemes (2005, interim and 2009), then the eight-month period to be assessed will be assessed under the PPRS in which the majority of the AFR falls. This will avoid assessing two short periods separately under different schemes.

Should a time-based apportionment become a problem for an individual scheme member (e.g. if assessed as having profits in excess of the margin of tolerance under the PPRS), then the specific circumstances of that scheme member will be considered when the need arises. This may result in the scheme member providing additional information to enable the apportionment of income and costs on an alternative/ actual basis.

These arrangements are a simple and practical solution that will generally mean no change for scheme members and a single assessment for each AFR submitted.

Annex P: Powers of the Secretary of State deriving from the National Health Service Act 2006

A summary of the provisions contained in sections 261 to 266

- 1 Section 261 enables the Secretary of State, after making a scheme with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. This scheme (with additions or modifications agreed in individual cases) would apply only to those companies that consent (subsection (2)). Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the scheme is no longer to apply to them. This can be done where the acts or omissions of the manufacturer or supplier have shown that the scheme is ineffective in their case. Subsection (7) read with section 266 gives the Secretary of State power by regulations or directions to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State.
- 2 Section 261(8) read with section 266 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State's approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.
- 3 In addition to powers to secure compliance with a voluntary scheme, the Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme.
- 4 Section 262 read with section 266 provides for the Secretary of State, after consultation with the industry body, by regulations or directions, to limit any price that may be charged by any manufacturer or supplier and for payment of the excess to the Secretary of State within a specified period. This power is exercisable only in relation to companies who are not 'scheme members' as defined in section 261(4).
- 5 Section 263 read with section 266 enables the Secretary of State, after consultation with the industry body, by regulations or directions to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Section 263(3) provides that such a scheme may in particular require any manufacturer or supplier to whom it applies to record and keep information and provide information to the Secretary of State. Section 263(5) provides for payment to the Secretary of State of profits in excess of the limits determined under the scheme. Section 263(6) enables the Secretary of State to prohibit any manufacturer to whom the scheme applies from increasing prices without his approval and to require a sum representing the amount of that excess to be paid to him. Section 263(7) excludes 'scheme members' from any statutory scheme.
- 6 Section 264 read with section 266 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.

- 7 Section 265 provides for enforcement. Section 265(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of regulations or directions made under sections 261 to 264. Section 265(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 265(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50%. Section 265(4) enables the Secretary of State to provide for interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.
- 8 Section 265(5) enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 265(7) defines the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.
- 9 Section 265(8) provides that any requirement, prohibition or limit under sections 261 to 263 may only be enforced under this section and not relied on in any other proceedings. Section 265(9) requires the Secretary of State to consult the industry body before making regulations under section 265. Section 265(10) provides for the maxima set out in section 265(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 272.
- 10 Section 266 deals with supplementary matters. In particular section 266(1) provides for how the powers in sections 261(6) to (8) and 262 to 264 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions, and that regulations may give power to give directions in such particular cases. Section 266 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. The Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of R&D.
- 11 The provisions in sections 261 to 266 enable the Secretary of State to make regulations in respect of England, Scotland, Wales and Northern Ireland. The operation of a PPRS in respect of Northern Ireland is a transferred matter under the Northern Ireland Act 1998. In practice, therefore, the Secretary of State will only make regulations that extend to Northern Ireland with the consent of the Northern Ireland Assembly.

Annex Q: Dispute resolution

1	Introduction
2	The law
3	2009 PPRS provisions
4	Tribunal membership
5	Secretariat
6	Events giving rise to dispute resolution
7	Dispute resolution timetable
8	Conduct of hearings
9	Powers of the panel
10	After dispute resolution
11	Conclusion

1 Introduction

1.1 This annex is a broad outline of the functions of the 2009 PPRS Dispute Resolution Panel ('the panel') and describes its work in practice.

2 The law

2.1 The National Health Service Act 2006 ('the Act') provides for voluntary schemes, which may:

- limit the prices that may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines; or
- limit the profits that may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines.

2.2 The Act also provides for statutory price and profit controls. These powers can apply only to companies that are not members of a voluntary scheme. The 2009 PPRS is such a voluntary scheme.

- 2.3 Membership of the 2009 PPRS is established when a company has consented to be a member of the scheme¹ and the Secretary of State has notified that company that it is a member.
- 2.4 Under the statutory price controls² presently in force, there is a right of appeal to the NHS Medicines (Control of Prices and Profits) Appeal Tribunal³ against enforcement decisions⁴ made by the Secretary of State.
- 2.5 Under the 2009 PPRS, the panel will be the body to which a scheme member might go if it wishes to dispute views taken by the Department in respect of its prices or profits. There is no recourse to the NHS Medicines (Control of Prices and Profits) Appeal Tribunal except in the case where there is in existence statutory provision for the imposition of penalties for late delivery of information and an enforcement decision is made under that provision.
- 2.6 Companies that are not scheme members of the 2009 PPRS do not have access to the panel, save for the sole exception described in paragraph 6.2.6.
- 2.7 There is, therefore, a fundamental distinction to be made between an enforcement decision made by the Secretary of State in accordance with statute and a view taken by the Department after negotiation within the 2009 PPRS.⁵ In the first case, there is a right of appeal to the NHS Medicines (Control of Prices and Profits) Appeal Tribunal. In the second case, there is a right of dispute resolution by the panel.

3 2009 PPRS provisions

- 3.1 Chapter 11 of the 2009 PPRS deals with dispute resolution. That chapter is reproduced here for ease of reference:

11.1 The Department and individual scheme members undertake to operate this agreement so that issues arising between any scheme member(s) and the Department are normally resolved by discussion between the scheme members and the Department. Such discussions may be escalated at the option of the scheme member and the Department to a more senior level within that organisation. Nevertheless, significant issues between the scheme member and the Department may arise that cannot be resolved by discussion. These issues may be referred to the dispute resolution procedure set out below by the scheme member or the Department.

11.2 The ABPI will have the right to dispute resolution on matters that span the interests of the broader membership and not just an individual member. For example, should there be a dispute as to a review of the reductions or price adjustment savings delivered and whether a further price adjustment is required (paragraph 7.8) then it would be more appropriate for the ABPI and the Department to seek resolution through the Dispute Resolution Panel than for an individual company or companies to do so. However, the provisions in chapter 5 ('Uptake and innovation') are excluded from dispute resolution as they will be monitored through MISG and the HIC. The provisions relating to the process to be followed will apply in the same way to a dispute involving the ABPI.

11.3 It is intended that the use of the dispute resolution process shall not entail any forfeiture of any other judicial remedy available to either party.

1 In accordance with the Health Service Medicines (Consent to Voluntary Scheme) Regulations 1999, SI 1999/2229.

2 The Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008, SI 2008/1938.

3 The Health Service Medicines (Price Control Appeals) Regulations 2000, SI 2000/124, as amended.

4 As defined in section 265(7) of the Act.

5 An event within the meaning of paragraph 11.4 of the 2009 PPRS.

- 11.4 *Where a scheme member or the Department decides to go to dispute resolution it must give written notice to the other party of its intention within 21 days of an event. Examples of 'events' in this context would be refusal by the Department to agree a price increase under the scheme or the failure of the parties to reach agreement on the extent, if any, to which excess profits are repayable to the Secretary of State. The parties to the dispute must provide the Dispute Resolution Panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of dispute. Statements will be made available to the parties. They may be supplemented in response to questions arising during the dispute resolution procedure.*
- 11.5 *The Dispute Resolution Panel will give each party to the dispute the opportunity to put forward its case on the issue(s) that is (are) in dispute at an oral hearing. Each party to the dispute shall be allowed a reasonable period within which to make oral representations which shall in no case be less than two hours. The panel will be expected to hold the hearing within 30 days of the receipt of the written statements from the parties. The parties are free to decide their representation at the oral hearing.*
- 11.6 *Prior to or at the hearing, the panel may request supplementary written information from any party to the dispute where it considers this necessary to properly understand the issues. The parties will be required to provide this information within 15 days of the request. All information provided to the panel members and the panel members' reasoned decision will be available to all parties. The panel will be expected to make its decision known to the parties within 30 days of the oral hearing or within 45 days where it has been necessary to obtain additional written information from any party.*
- 11.7 *The panel for any given dispute resolution shall comprise:*
- 11.7.1 *a Chairman appointed by the Secretary of State subject to the agreement of the ABPI, a representative of which shall sit on the interview panel for the post of Chairman and shall have the right of veto over any appointment. The Chairman should ideally be a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland of at least seven years' standing and/or a person who has at least seven years' experience of heavyweight mediation or dispute resolution; and*
- 11.7.2 *two members, one appointed by the Secretary of State and the other by the ABPI.*
- 11.8 *The Chairman may not sit alone for any part of a dispute resolution.*
- 11.9 *The secretariat to the panel will be provided jointly by the Department and the ABPI. In the event that the Chairman is not legally qualified as described in paragraph 11.7.1 a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland shall be appointed jointly by the Department and the ABPI (with both having the right of veto over such appointment) to advise the panel on any aspects of its role in a particular dispute and shall be entitled to be present throughout the dispute proceedings.*
- 11.10 *The costs of the panel will be shared equally by the parties. The parties to each dispute will be responsible for paying their own costs.*
- 11.11 *The reasoned decision of the panel shall be published on the website of the Department and the ABPI after the redaction of commercially sensitive information. The parties to any dispute shall have an absolute right of veto in deciding which details of a decision are commercially sensitive in relation to their own data.*
- 11.12 *The Department, the ABPI, scheme members and the members of the Dispute Resolution Panel as a condition of their appointment undertake to keep commercially sensitive information confidential.*

4 Tribunal membership

4.1 The Dispute Resolution Panel will comprise:

4.1.1 a Chairman appointed by the Secretary of State subject to the agreement of the ABPI, a representative of which shall sit on the interview panel for the post of Chairman and shall have the right of veto over any appointment. The Chairman should ideally be a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland of at least seven years' standing and/or have at least seven years' experience of heavyweight mediation or dispute resolution; and

4.1.2 two members, one appointed by the Secretary of State and the other by the ABPI.

4.2 The panel will sit as the Chairman and both members. The Chairman may not sit alone for any part of a dispute resolution.

4.3 In the event that the Chairman is not legally qualified as described in paragraph 11.7.1 a solicitor or barrister qualified to practise in England and Wales, Scotland or Northern Ireland shall be appointed jointly by the Department and the ABPI (with both having the right of veto over such appointment) to advise the dispute panel on any aspects of its role in a particular dispute.

5 Secretariat

5.1 Chapter 11 of the 2009 PPRS provides that the secretariat shall be provided jointly by the Department and the ABPI.

5.2 Communications to the secretariat shall be addressed to:

The Secretariat
Medicines, Pharmacy and Industry Group
Department of Health
Skipton House
80 London Road
London SE1 8IH
Tel: 020 7972 2879
Fax: 020 7972 2932

and to:

The Secretary to the Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY
Tel: 0870 890 4333
Fax: 020 7747 1400

The cost of the secretariat shall be borne jointly and equally by the Department and the ABPI.

5.3 It shall be the duty of the secretariat to ensure that communications from one party to a dispute shall be made available to the other party/parties and to all members of the panel.

- 5.4 Similarly, it shall be the duty of the secretariat to make available to parties to a dispute communications from the panel.
- 5.5 The duties described in paragraphs 5.3 and 5.4 shall be discharged as soon as possible after receipt of a communication and, in any event, not later than two working days from receipt.

6 Events giving rise to dispute resolution

- 6.1 Within the terms of chapter 11 of the 2009 PPRS, the Department and scheme members will have the right to dispute resolution.
- 6.2 The following is a list of events that might give rise to a scheme member seeking dispute resolution by the panel. The list is not necessarily comprehensive. In each case, it will be for the scheme member to comply with the Department's view or to seek dispute resolution.
- 6.2.1 Payment of excess profit to the Secretary of State. A scheme member might disagree that there is any requirement to pay to the Secretary of State sums representing excess profits or with the amount of the sum to be paid.
- 6.2.2 Refusal to allow a general price increase or limitation to such an increase.
- 6.2.3 Refusal to allow a price modulation within the meaning of chapter 7 of the 2009 PPRS.
- 6.2.4 Failure to agree allowed prices of products sold on from one company to another.
- 6.2.5 A request to provide information required by the Department in connection with the operation of the 2009 PPRS.
- 6.2.6 Notice given by the Secretary of State (other than under paragraph 10.2.3 below) that a company's membership of the scheme is to cease as a result of the Secretary of State concluding that the membership is ineffective in that member's case. At such a dispute resolution, the ostensible matter will be scheme membership, but the substantive matter will be the event giving rise to the decision that the company is no longer a scheme member.
- 6.3 A company that has been refused scheme membership of the 2009 PPRS shall not have any right of dispute resolution under paragraph 6.2.6.

7 Dispute resolution timetable

- 7.1 The Department shall give written notice of any view falling within the ambit of paragraphs 6.2.1, 6.2.2, 6.2.3, 6.2.4 and 6.2.5 to the scheme member.
- 7.2 The scheme member shall have 28 days from and including the date of that written notice in which to give notice that it wishes to seek dispute resolution by the panel. For administrative ease this should be sent to the secretariat (see paragraph 5.2).
- 7.3 Within 28 days of such notice given under paragraph 7.2, reasoned statements of position by the Department and the scheme member must be submitted to the secretariat.

- 7.4 Insofar as possible a hearing by the panel shall be arranged within 30 days of the receipt of the later statement of reasons. Directions for the conduct of the hearing shall be notified by the Chairman of the Dispute Resolution Panel to the parties in writing at least 14 days in advance of the hearing.
- 7.5 Information requested by the panel before or at the hearing shall be supplied to the secretariat by the relevant party within 15 days of the request.
- 7.6 Insofar as possible, the panel shall make known its decision to the parties within 30 days of either the date of the hearing or of receipt of information, whichever is the later.
- 7.7 At any time until the panel's decision, either party shall have the right to withdraw from the dispute resolution and thereby concede the point or points at issue.
- 7.8 The parties should comply with the effective date given by the panel in its decision.

8 Conduct of hearings

- 8.1 Hearings will be informal and shall not be bound by strict rules of evidence or legal procedure.
- 8.2 Hearings will be held in camera to protect matters of commercial confidentiality. The notes of proceedings kept by the secretariat shall be made available only to:
- the panel;
 - the scheme members; and
 - the Department.
- 8.3 Information submitted pursuant to the hearing shall be restricted as in paragraph 8.2.
- 8.4 It is open to each party to the dispute resolution to be represented as that party sees fit and to call such witnesses as it sees fit.
- 8.5 Each party to the dispute resolution shall be allowed a reasonable period within which to make oral representations, which shall in no case be less than two hours.
- 8.6 The conduct of the hearing will be for the panel Chairman to decide in matters such as order of business, questions and evidence.
- 8.7 Each party shall be responsible for its own costs.

9 Powers of the panel

- 9.1 The panel may request any information from either party that it considers necessary to determine any point of fact.
- 9.2 The panel may call any expert witness whom it considers necessary to determine any point of fact.
- 9.3 The panel may not, without the express consent of the parties, extend any of the time limits given in paragraphs 7.2 to 7.8.

- 9.4 The panel shall either refer a matter to the Department for reconsideration under direction or substitute its own decision in respect of that matter.
- 9.5 The panel may decide an effective date for any substituted decision as follows in respect of:
- 9.5.1 payment of excess profits, the original date;
 - 9.5.2 refusal of a general price increase, any date on or after the date of the panel's decision;
 - 9.5.3 referral of a price modulation, any date on or after the panel's decision;
 - 9.5.4 allowed price of products sold, any date on or after the panel's decision; and
 - 9.5.5 information required by the Department, the original date, where the original date is the date of the notice specified in paragraph 7.1.

10 After dispute resolution

- 10.1 The Department and scheme members are expected to abide by the panel's decisions.
- 10.2 The voluntary nature of the 2009 PPRS means that a company has, in practice, three options:
- 10.2.1 follow the panel's decision;
 - 10.2.2 withdraw from membership of the 2009 PPRS; or
 - 10.2.3 ignore the panel's decision. In such circumstances, the Secretary of State may conclude that the scheme is no longer effective in the particular member's case and he will therefore remove the member from scheme membership.
- 10.3 In cases covered by paragraphs 10.2.2 and 10.2.3 the company will no longer be a scheme member of the 2009 PPRS and shall thenceforth be subject to any statutory controls in place pursuant to sections 262 to 266 of the Act.

11 Conclusion

- 11.1 Questions concerning this annex should be directed to the secretariat (see paragraph 5.2 above).



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