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of Health



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The Pharmaceutical Price Regulation Scheme 2014

Prepared by the Department of Health and the Association of the British Pharmaceutical Industry

This document published on 17 December 2013 contains corrections to typographical errors in the PPRS document published on 3 December 2013. These corrections have been agreed between the Department and the ABPI and are as follows:

1. Chapter 6, paragraph 6.7, line 2: the reference to the paragraph that contains the definition of "Sales of PPRS Products" was incorrect. It has been amended to read "6.5" instead of "6.4".
2. Chapter 8: the title has been amended to "Levels of Return and Allowances" (chapter title and index) to make clear that this refers to both Return on Sales Targets as well as Return on Capital Targets.
3. Chapter 8, paragraph 8.31.2.1, fourth bullet: the reference has been corrected to read "3.19" instead of "3.18".
4. Chapter 10, paragraph 3: the third sentence has been amended to refer to "Scheme Products" not "PPRS Products" in order to be consistent with Chapter 6.
5. Annex 6, paragraph 1: for completeness, the term "(NP%)" has been inserted after "New Products Share of Measured Spend"
6. Annex 12, note 4: the reference period for average selling price in secondary care for the purposes of monitoring price neutral modulation has been corrected so that it refers to 1 January 2013 to 31 December 2013, which is the correct reference period, instead of 1 October 2013 to 31 December 2013.
7. Annex 18, paragraph 5.3: the paragraph reference in the last line has been corrected from "5.2.6" with "5.2.7" to make clear that paragraph 5.3 should be read in conjunction with paragraph 5.2.7 and not with paragraph 5.2.6.

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1. Purpose, Principles and Objectives

- 1.1. The 2014 Pharmaceutical Price Regulation Scheme (the scheme) is a non-contractual voluntary scheme effective from the termination of the 2009 Pharmaceutical Price Regulation Scheme (the 2009 PPRS) on 31 December 2013. The parties to the scheme are the Department of Health (the Department), acting on behalf of the UK Government and Northern Ireland which includes the Health Departments of England, Wales, Scotland and Northern Ireland, and the Association of the British Pharmaceutical Industry (the ABPI).¹
- 1.2. The Health Departments of England, Scotland, Wales and Northern Ireland 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 Government and the ABPI are committed to strengthening the UK environment for life sciences. The Government has set out a broad range of policy initiatives, including the Life Sciences Strategy, to support a sustainable industry based on innovation and the Innovation, Health and Wealth initiative addresses the importance of early adoption and diffusion of clinically and cost effective innovative medicines in the NHS. This scheme should be seen in the context of wider life science policy and its shared objectives. The Government and the ABPI believe it is vitally important that there is a continuing supply of innovative treatments that benefit NHS patients. Continuous research and development and competitive efficiency should be the keys to any company's success in a research-based industry.
- 1.4. A number of important principles and objectives underpin this scheme. It is important to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer. The overarching principles and objectives of the scheme are to:

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

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

¹ The pricing of medicines is reserved to the UK Government, with the exception of Northern Ireland. Many other aspects of health policies, including those affecting the use and availability of medicines, are devolved matters, and it is for the Devolved Administrations to meet their policy and operational requirements.

1.4.2. Support the NHS by ensuring that the branded medicines bill stays within affordable limits

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

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

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

1.4.4. Reduce bureaucracy and duplication

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

1.4.5. Support the Government's growth and innovation agenda for life sciences.

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

1.5. It is a fundamental condition of the scheme that it will continue to operate for five years starting from 1 January 2014.

2. Introduction

- 2.1. 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 Health Departments of England, Scotland, Wales and Northern Ireland, recognise that continuous innovation is the key to competitive success in a research-based industry and wish to encourage the research, development and supply of innovative treatments for the benefit of NHS patients.
- 2.2. 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 Health Departments of England, Scotland, Wales and Northern Ireland will facilitate the industry's participation in government initiatives relevant to the further development of the sector.
- 2.3. The ABPI recognises that it is in the public interest that the prices of medicines supplied to 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.
- 2.4. Both parties agree that the performance of the scheme cannot be assessed in isolation from the NHS environment with which it interacts. The scheme is the UK-wide price regulation scheme for branded, licensed Health Service medicines. It applies across the four nations of the UK.
- 2.5. The Health Departments of England, Scotland, Wales and Northern Ireland do not support additional or alternative initiatives by NHS organisations in respect of the pricing of branded, licensed NHS medicines in primary care.
- 2.6. NHS bodies and providers to the NHS must comply with EU and UK law on procurement and competition. However, the outcome of any tender in England is not a barrier to patient access to medicines recommended in NICE appraisals or highly specialised technology evaluations.
- 2.7. With the exception of Patient Access Schemes as set out in Chapter 5 of this scheme, NHS England has agreed to seek to bring to an end initiatives by NHS commissioners (NHS England or clinical commissioning groups) to arrange for rebates to be paid by manufacturers to the commissioning body for the supply of medicines with a positive NICE technology appraisal to providers of NHS services in primary or secondary care.
- 2.8. The Health Departments of England, Scotland, Wales and Northern Ireland will use their best endeavours to ensure that the scheme is fully implemented and sustained throughout the NHS during the lifetime of the scheme.
- 2.9. The Government and the ABPI will continue to work together through the Ministerial Industry Strategy Group (MISG) in a programme of action aimed at supporting the objectives of the scheme and the industry's global competitiveness.

- 2.10. All parties will operate the scheme in good faith and recognise that there should be compliance with the scheme. All parties to the scheme will use their best endeavours not to manipulate or undermine the scheme in a way which conflicts with the overarching purpose, principles and objectives set out in Chapter 1 or in a way which makes the scheme ineffective as set out at paragraph 3.13. The mutual intent is that neither the Department, the ABPI, nor members of the scheme will seek to abuse this scheme.
- 2.11. 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.
- 2.12. The Department will use best endeavours to ensure the confidentiality of commercially sensitive information submitted by scheme members. However, the Department cannot provide any absolute guarantees that information submitted would not be subject to disclosure under the provisions of the Freedom of Information Act 2000 (“FOI”) unless there is a valid exemption within the legislation that would prevent disclosure. The Department will take reasonable steps to notify the scheme member promptly of the relevant content of any FOI request which pertains to that scheme member’s sales.

3. Status and Membership of the Scheme

- 3.1. The scheme is a voluntary scheme which is not binding under the law of contract. Any supplier or manufacturer 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. Annex 2 summarises the provisions contained in sections 261-266 of the National Health Service Act 2006.

Effective Date and Duration

- 3.2. The Department and the ABPI are committed to ensuring stability, sustainability and predictability for scheme members. The scheme will operate for five years from 1 January 2014 until and including 31 December 2018. It is a fundamental condition of the scheme that it will continue to operate for five years starting from 1 January 2014 and ending on 31 December 2018. In the scheme, a period ending or terminating on a given date shall have effect until midnight on that given date.
- 3.3. The scheme replaces all previous Pharmaceutical Price Regulation Schemes. The obligations arising from the 2009 or previous schemes will not roll forward into the scheme. However any disputes as to the obligations under the 2005, 2008 or 2009 Pharmaceutical Price Regulation Schemes between the scheme member and the Department shall not be extinguished by virtue of said schemes being terminated and shall continue to be dealt with under the dispute resolution arrangements pertinent to the scheme under which the dispute arises. The Dispute Resolution Panel (“the panel”) will make a decision as to the content of the dispute and provide a resolution constituting a cash payment from one party to the other. If the parties agree that a cash payment does not provide an appropriate resolution, the parties shall use their best endeavours to agree an alternative resolution. If the parties are unable to agree on the type of resolution or the quantum, these matters shall be determined by the panel, under the terms of the Pharmaceutical Price Regulation Scheme giving rise to the dispute.

Amendment of the Scheme

- 3.4. The provisions of the 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 paragraph 3.12).

Interpretation

- 3.5. Without prejudice to the requirements of paragraph 3.4 (amendment of the scheme), the Department and the ABPI may from time to time discuss and agree the correct application of provisions of the scheme that lend themselves to different interpretations and to notify scheme members of such an agreement.

Review of Administration

- 3.6. There will be a review of the administration of the scheme completed during 2016. This will not review the Allowed Growth Rates, nor the methodology for setting or adjusting PPRS Payments. It will cover other aspects of administering the scheme, such as information requirements or dispute resolution. Any changes to the scheme as a result would have to be agreed by both parties in line with paragraph 3.4 above.

Application to Manufacturers and Suppliers

- 3.7. 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 1. 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.

Entry Mechanism

- 3.8. Suppliers and manufacturers may consent to join this scheme at any time from 3 December 2013 by completing Form A at Annex 1. In order for suppliers and manufacturers to avoid being subject to regulations (see paragraph 3.9), they should aim to submit Form A to the Department by 13 December 2013. Membership will be effective from the start of the scheme (1 January 2014) provided that the Department receives a completed Form A by 31 December 2013. A completed Form A may validly be submitted by email to the Department. The date of receipt will be deemed to be the date that the Department sends an email to the supplier or manufacturer acknowledging receipt of Form A. Thereafter, suppliers or manufacturers may join the scheme at any time after 1 January 2014 by completing Form A. Their membership will be effective from the first day of the calendar quarter following the date of receipt of Form A by the Department or such other date as is agreed between the supplier or manufacturer and the Department.
- 3.9. Manufacturers and suppliers that either elect not to join this scheme or exit the scheme under paragraphs 3.12 or 3.13 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

- 3.10. Although the scheme is the result of negotiations between the ABPI and the Department, it is open to suppliers and manufacturers that are not members of the ABPI to be scheme members.

Supply of Medicines

- 3.11. 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

- 3.12. A scheme member may at any time give notice of their intention to withdraw consent for the scheme to be treated as applying to it, by completing Form B at Annex 1. Exit by scheme members will require a three-month written notice period. At the end of the notice period, the scheme will no longer be treated as applying to that scheme member. The Department intends to consult on amendments to the statutory scheme regulations to apply to companies that leave the scheme at any stage from the time that new regulations applied to ensure that the price cuts applied to those new members of the statutory scheme reflect at a minimum the level of payment they would otherwise have paid in the scheme.
- 3.13. Under the National Health Service Act 2006 the Secretary of State may serve notice on a scheme member that the scheme is no longer to apply to it. The Secretary of State may do this where any acts or omissions of the scheme member have shown that, in the scheme member's case (or through the actions of their parent company or subsidiaries based in other countries), 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. This could include, but is not limited to, a case where a scheme member made any arrangements designed to reduce the amount of sales of that scheme member's products on which the payment was due. 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 scheme 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 the 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.

Products Covered

- 3.14. Scheme Products are branded, licensed health service medicines (as defined at paragraph 3.15 below) supplied by scheme members with the exceptions set out at paragraph 3.17 below.
- 3.15. A health service medicine as defined at s. 266(6) of the National Health Service Act 2006, is a medicinal product used to any extent for the purposes of the health service. For these purposes, health service has a technical meaning that encompasses not only the NHS in all parts of the United Kingdom (whether the services are provided by public or private sector providers) but also services provided (whether by public or private

sector providers) pursuant to the public health functions of the Secretary of State under the National Health Service Act 2006 and the equivalent legislation in the devolved administrations. The scheme does not apply to any medicinal product which is not used for the purposes of the health service in the UK. 'Medicinal product', sometimes known as 'human pharmaceutical product', is defined in the Human Medicines Regulations 2012 (SI2012/1916).

- 3.16. A branded medicine means any medicinal 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-propriety Names (rINN), or any list of similar standing.
- 3.17. The scheme does not apply to the following:
 - 3.17.1. Sales of medicines for supply on private prescription or other use outside the health service in England, Scotland, Wales, or Northern Ireland;
 - 3.17.2. Products that cannot be ordered under a General Medical Services Contract as listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004 in relation to England and Wales;
 - 3.17.3. Products specified in any directions given by the Scottish Ministers under section 17N(6) (other mandatory contract terms) of the Scotland Act 1978 as being drugs, medicines or other substances which may not be ordered by a GMS contractor for patients in the provision of primary medical services under a general medical services contract made under section 17J (health boards power to enter into general medical services contracts) of the Scotland Act 1978 in relation to Scotland;
 - 3.17.4. Products listed in Schedule 1 to the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 in relation to Northern Ireland;
 - 3.17.5. Dental anaesthetics;
 - 3.17.6. Over the counter (OTC) sales.
- 3.18. Where a medicine is sold over the counter (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.
- 3.19. For clarification, the scheme applies to the following products (although the list is not exhaustive), provided that they are licensed and have a brand name and marketing authorisation:
 - 3.19.1. branded generics;
 - 3.19.2. vaccines;
 - 3.19.3. in vivo diagnostics;

- 3.19.4. blood products;
- 3.19.5. dialysis fluids;
- 3.19.6. branded products supplied through tendering processes and on central or local contracts;
- 3.19.7. biotechnology products;
- 3.19.8. biosimilars.

4. Access and Outcomes

- 4.1. 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. It is an objective of the Department and NHS England to improve overall outcomes for patients including through access to effective medicines. Innovation, Health and Wealth (IHW) set out an ambition subscribed to by the Department and NHS England “for an NHS defined by its commitment to innovation, demonstrated both in its support for research and its success in the rapid adoption and diffusion of the best, transformative, most innovative ideas, products, services and clinical practice.” This is reflected in NHS England’s statutory duties to promote research and innovation which are in turn translated into a specific requirement in the NHS England Mandate. To these ends, the Department, NHS England and the industry have committed to a number of specific initiatives aimed at encouraging and rewarding innovation and assisting better access to effective medicines. This chapter summarises the key elements of the actions to support better access and usage of effective medicines.
- 4.2. With the exception of UK Pharmscan, the horizon scanning database, all other initiatives relate to the Department of Health in England and NHS 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. Policy regarding the pricing of branded health service medicines however remains the sole preserve of the Department of Health.

Horizon scanning, UK PharmaScan

- 4.3. The Department and the industry have jointly established UK PharmaScan, a single, unified horizon scanning database to identify new technologies in development by the industry. This database, a 2009 Pharmaceutical Price Regulation Scheme commitment, was developed in co-operation with key stakeholders including the National Institute for Health and Care 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). Uses of the database include supporting Health Technology Assessment (HTA) topic selection, scoping of appraisals and providing timely information to all NHS organisations for planning and budgeting purposes. The database, operational from summer 2010, is hosted by NICE Evidence with responsibility for governance overseen by an Oversight and Governance Committee.
- 4.4. There is a shared objective to move towards a single source for horizon scanning through the extended use of UK PharmaScan. Therefore, those responsible for horizon scanning in NHS England will be given access to the database in order to promote consistency and minimise duplication in the NHS. The Department will continue to

maintain UK Pharmscan, and scheme members will continue to commit best efforts to supply accurate, complete, and timely information about such new technologies.

Valuing Innovation in New Medicines

- 4.5. NICE will undertake all elements of assessment for a broader definition of value. The Department has given NICE Terms of Reference for this activity. NICE will discharge this responsibility through the development of its technology appraisal programme. This includes provisions for the engagement of the industry, along with other stakeholders, in the ongoing development of both methodology and process, including periodic public consultations.
- 4.6. The Terms of Reference the Department sets NICE for value assessment of new medicines will not prevent NICE Appraisal Committees from applying deliberation in the assessment process. The Terms of Reference state that NICE should “encompass the differential valuation of ‘End of Life’ treatments in the current approach within the system of burden of illness weights”. NICE will consult publicly before implementing changes arising from the Terms of Reference for value assessment.
- 4.7. Prompt appraisal by NICE of significant new medicines is an important element of the Government’s approach to ensuring that patients can access innovative cost-effective medicines quickly and consistently. The Government is committed to ensuring that the majority of NICE appraisals of new medicines result in final guidance within a few months of a medicine’s marketing authorisation.
- 4.8. Timings for the NICE value assessment process are expected to be comparable with the current timetable for Single Technology Appraisals. Companies may request value-based appraisal of their new medicines, and such requests will not be unreasonably refused. The Department will work with the industry and NICE to support further consideration of issues and potential resolutions around the use of unlicensed comparators and optimising the contribution to NICE’s work of independent Evidence Review Groups.
- 4.9. The basic cost-effectiveness threshold used by NICE will be retained at a level consistent with the current range and not changed for the duration of the scheme.

Improving Outcomes through Access to Effective Medicines

- 4.10. 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 technology appraisal guidance and highly specialised technology (“HST”) guidance, it is implemented consistently across England. The Department, NHS England and NICE recognise their roles in supporting this implementation. The Government remains fully committed to ensuring NHS implementation of NICE technology appraisal and HST guidance, supported by ongoing commitment to the statutory three-month funding requirement.

- 4.11. NHS England is committed to ongoing implementation of IHW, which seeks to improve NHS use of innovative treatments for the benefit of patients, including:
- Supporting the prompt implementation of NICE guidance, ensuring that NHS patients have access to clinically and cost-effective drugs and technologies. This includes the establishment with the pharmaceutical industry and other stakeholders of a NICE Implementation Collaborative (NIC) and a commitment that NICE appraisal guidance is promptly delivered throughout the NHS. There should be no local barriers to accessing technologies recommended in NICE appraisals, beyond a clinical decision relating to an individual patient.
 - Requiring that all NICE technology appraisal recommendations are incorporated into relevant local NHS formularies in a planned way that supports safe and clinically appropriate practice. This process should take place within 90 days to support compliance with the three month funding requirement and the NHS Constitution.
 - Publishing on a regular basis an innovation scorecard to track adoption of NICE technology appraisals at local level.
- 4.12. This ongoing commitment to IHW is reflected explicitly in the NHS England Mandate. NHS England will be expected to demonstrate progress throughout the duration of the scheme and the Government will hold NHS England to account through the Mandate for doing so.
- 4.13. The Government and NHS England will continue to evaluate whether patients consistently achieve better access to cost effective medicines, including via continuation of the NHS England Innovation Scorecard.
- 4.14. In addition, the NHS Constitution 2012 specifically provides that:
- “You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.”
 - “You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.”
- The Government has reaffirmed its commitment to both rights.
- 4.15. An implication of the first of these rights is that national guidance in NICE technology appraisals and highly specialised technology evaluations takes precedence in full over regional or local guidance, that the NHS will not seek to duplicate this activity, and that there will be no further qualification, reinterpretation or modifications made to national guidance, while recognising the freedom of clinicians to prescribe as they see most appropriate for patients. Although the NHS Constitution right does not apply to NICE clinical guidelines, the NHS should not seek to duplicate NICE guideline development activity.
- 4.16. In the context of the second of these rights, the absence of NICE guidance is not in itself seen as 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. NICE has published good practice guidance on updating local formularies.

- 4.17. The Government will hold NHS England to account through the Mandate for its commitment to innovation, demonstrated in both its support for research and development and for its success in promoting the rapid adoption and diffusion of innovative medicines and to other commitments in the scheme.
- 4.18. NHS bodies will retain their responsibilities to promote innovation in the provision of health services.
- 4.19. Academic Health Science Networks (“AHSNs”) have a goal to improve patient and population health outcomes by translating research into practice and NHS England will support them in this. As part of this goal AHSNs will work with the industry to jointly develop solutions to key health challenges.

Comparative Information

- 4.20. The Department, NHS England 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.
- 4.21. To this end, the Department, NHS England and the industry will work together to deliver a single transparent programme of activities looking at comparative medicines use in the NHS, to evaluate whether patients consistently achieve better access to cost-effective medicines. This will include a number of medicines positively appraised by NICE (either fully or with restrictions). Information on comparative medicines usage needs to be relevant to the NHS, service users and the industry and take account of the anticipated impact of NICE technology appraisal guidance relative to actual use and include coverage of both newer and more recently appraised medicines and more established medicines, across a range of NHS organisations. Information should be published through suitable channels on at least an annual basis and will be proactively communicated through the NHS.
- 4.22. The UK should compare itself with other countries if it is to deliver a world-class NHS. Information on medicines use is an important dimension of such comparisons, but to be of most value it needs to be set alongside information on other aspects of system performance including available resourcing information and evidence on outcomes. The industry, NHS England and the Department will work together to develop and evolve an approach to the analysis and publication of comparative information on international medicines use on a periodic basis that incorporates this context, with a first report to be published by the end of 2014. A joint Department of Health, industry and NHS England working group will oversee this activity with a particular focus on NICE-approved technologies and with the objective of complementing parallel activity to understand domestic patterns of medicines use.
- 4.23. In addition, the Department and the industry will refresh and recommit to updated annual indicators arising from the Pharmaceutical Industry Competitiveness Task Force (PICTF) in a new initiative as agreed in the Medicines Access Group of the Ministerial Industry Strategy Group (MISG).

Monitoring, Assurance and Cooperation

- 4.24. As independent statutory bodies NHS England and NICE are responsible to the Secretary of State for the delivery of their agreed work programmes. NHS England will be held to account for delivery of its work programme through the Mandate accountability mechanisms.
- 4.25. The Department supports the establishment of written bilateral working agreements between the ABPI and both NICE and NHS England, along with a NICE Industry Council and an NHS England Industry Council. These arrangements will enable industry engagement in ongoing delivery of the actions set out in this chapter.
- 4.26. In addition to these arrangements, the Government will retain the Ministerial Industry Strategy Group (MISG) which is the main forum for Government interaction with the bio-pharmaceutical industry on joint issues of strategic importance.

5. Value and Pricing: Flexible Pricing and Patient Access Schemes

A Pricing System that Reflects Value to the NHS

- 5.1. Progress has been made since the creation, in 1999, of the organisation now known as the National Institute for Health and Care Excellence (NICE) in ensuring that patients have benefited from innovative cost-effective medicines that are of value to patients. The NICE process and PPRS are already indirectly linked as companies consider the likely outcome of a NICE appraisal when setting the price of a medicine. *The Coalition: our programme for government* included a commitment to move to a system of value-based pricing (VBP). VBP establishes a closer link between the prices the NHS pays for innovative medicines, and their value to patients and society, while retaining freedom of pricing on new active substances on entering the market (paragraph 7.14).
- 5.2. NICE's assessment of value is not exclusively driven by cost per Quality Adjusted Life Year (QALY) analysis, but also takes into account other factors in order to come to a view on whether or not a treatment is likely to be good value for the NHS. The Government has given NICE terms of reference for the value assessment of medicines under VBP, and NICE is developing methods for value assessment under VBP which are intended to allow the consideration of wider factors in a more consistent, systematic, transparent and predictable way. NICE will not negotiate or publicly set or publicly indicate prices.
- 5.3. The Department and the ABPI agreed to introduce two different mechanisms aimed at better reflecting value as part of the 2009 PPRS:
 - Flexible Pricing – where a scheme member can apply for an increase or decrease to a product's original list price in light of new evidence or a different indication being developed.
 - Patient Access Schemes – which can facilitate patient access to a medicine where NICE's assessment of value, on the current evidence base, is unlikely to support the list price.
- 5.4. These pricing flexibilities will continue to be available as part of the value-based approach to pricing, giving scheme members flexibility to better reflect the value of their medicines, within a framework that preserves the independence of NICE.
- 5.5. The Department and the ABPI will continue to work together to ensure that the pricing flexibilities can continue to provide a sustainable vehicle within the scheme for supporting patient access to new medicines on terms that represent value to the NHS. The operation of the provisions on flexible pricing and patient access schemes may need to be reviewed in due course. The timing of any such review will be jointly agreed but, if a review is carried out, it will be initiated not later than two years after the commencement of the scheme.
- 5.6. Whilst pricing is a reserved matter, the value assessment of medicines, and decisions about the prioritisation of NHS resources, 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 industry and with the Department where appropriate in relation to this chapter.

Flexible Pricing

- 5.7. Flexible pricing recognises that the initial launch price of a medicine may not fully reflect its longer-term value to patients in the NHS. It therefore allows a scheme member to propose an initial price for a medicine that reflects value that can be demonstrated at launch, while retaining the freedom to apply 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.
- 5.8. The Department and the ABPI acknowledge that this more flexible approach is a logical consequence of taking a more value-based approach to pricing. However, no applications were received under the flexible pricing mechanism within the 2009 PPRS, and this remains a novel approach with a number of practical challenges in implementation. The initial proposals set out in this document may therefore need to be reviewed in due course, for example, if there have been no applications under these provisions within two years of the commencement of this scheme. As per paragraph 5.5, the timing of any such review will be jointly agreed but may be initiated not later than two years after the commencement of this scheme.
- 5.9. There are two circumstances in which flexible pricing may be relevant:
- When significant new evidence is generated that changes the value of an existing indication; and
 - Where a significant new indication is proposed.
- 5.10. The Department and the ABPI agree that the potential for flexible pricing will only apply 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.
- 5.11. 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 scheme.

New Evidence for Existing Indications

- 5.12. Scheme members 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.
- 5.13. In the case of products launched after 1 January 2009, a scheme member will be able to indicate directly to NICE that it believes 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, in line with its technology appraisal process guide. 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.

- 5.14. 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 scheme member will be able to propose a price change linked to new evidence only where NICE itself initiates a review.
- 5.15. In all cases, scheme members will only be able to request one price increase after 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 scheme member will have the freedom to propose a new price up to the maximum and subject to NICE review. The 30% limit may be reconsidered as part of any review of the flexible pricing provisions carried out under paragraph 5.8, in the light of experience at that point.
- 5.16. 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 medicine 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.
- 5.17. In the event of a price rise, the scheme member 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

- 5.18. 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 scheme member 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.
- 5.19. 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, the scheme member may apply for an increase or decrease in price for the new indication as compared to the old.
- 5.20. 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 have reference to the topic selection criteria, which were consulted on in 2009, in relation to any determination of a major new indication.

- 5.21. The scheme member 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 unless the relevant indication was selected for appraisal and:
- Until after NICE final guidance had been issued; or
 - After twelve months from the date of licensing of the relevant indication (or twelve months after the scheme member proposed the price change if the proposal is made post licensing of the relevant indication);

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. Consistent with the principle that companies' requests for value-based review of their new medicines will not be unreasonably refused, scheme members' requests for NICE appraisal of a major new indication of a medicine as part of a flexible pricing application will not be unreasonably refused.

- 5.22. For new indications for products first launched in the UK on or after 1 January 2009, 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 only be expected to have one price change per active substance during its lifetime. For products launched before 1 January 2009, no price increases will be available under the terms of this part of the scheme.
- 5.23. In the event of a price increase, a scheme member 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 straightforward 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.
- 5.24. The NICE appraisal will review and decide whether to recommend the new indication at the proposed price for the medicine and, as per its methodological approach applicable at the relevant time, decide whether this provides value for money for the NHS. The scheme member will be able to proceed with the price increase (with the timing determined by paragraph 5.21) and NICE will issue guidance to the NHS on use of the product.

Patient Access Schemes

- 5.25. A Patient Access Scheme (PAS) is a scheme proposed by a scheme member and agreed between the Department (with input from NICE) and the scheme member in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines (see below for further information on the

types of PAS). This section of the scheme relates to England and Wales, as different HTA arrangements are in place in Scotland and Northern Ireland. In Scotland, Wales and Northern Ireland, separate arrangements may be available under which proposals may be considered as part of an assessment of a medicine by a relevant Health Technology Assessment (HTA) body (e.g. the Scottish Medicines Consortium or the All Wales Medicines Strategy Group). Where arrangements for considering PAS proposals are in place and a scheme member decides to offer a PAS for a product, where possible, it may be simplest for the scheme member to offer the same PAS across the UK.

- 5.26. The Department and the ABPI recognise that there are potential benefits to be derived from PAS. In England and Wales, prior to the introduction of these provisions, NICE and the Department were 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. Many products are now being referred to NICE by the Department prior to their launch, which may have increased the numbers of requests for PAS.
- 5.27. While welcoming moves for greater flexibility where this can facilitate access for NHS patients in England and Wales to new medicines 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 PAS are adopted. Patient Access Schemes should therefore be the exception rather than the rule. The following paragraphs outline different types of PAS, those which are preferable to 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

- 5.28. A number of principles for Patient Access Scheme proposals were 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.
 - PAS proposals 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 PAS.
 - The full costs to the NHS of any such arrangements should be included in the costs considered by the Appraisal Committee.
 - PAS 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 PAS 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 PAS 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 PAS 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 PAS proposals. Priority is likely to be given to PAS proposals that deliver the greatest benefits to patients, for example in enabling the NHS to address a previously unmet need.
 - PAS should be consistent with existing financial flows in the NHS and with commissioning arrangements (e.g. payers must be able to calculate the effective price for their patient population, so the costs and savings accrue to those services making commissioning and treatment decisions.)
 - The NHS in England and Wales must be consulted on PAS proposals, 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 patient’s condition over and above that for the normal management of a patient. The Patient Access Scheme Liaison Unit (PASLU) at NICE has been established to advise the Department on the feasibility of Patient Access Scheme proposals, and the PASLU process includes arrangements for consultation with the NHS.
- 5.29. It is important that Patient Access Schemes are sustainable and deliver the benefits expected of them. In line with paragraph 5.5, the Department and the ABPI will continue to work together to ensure that PAS can continue to provide a sustainable vehicle within this scheme for supporting patient access to new medicines on terms that represent value to the NHS. This will include measures to monitor actively the costs and benefits of PAS, specifically including process costs and risks of under-delivery. In order to maintain confidence in PAS and ensure that their cumulative impact on the NHS remains manageable, the operation of these provisions may need to be reviewed, for example, to ensure that PAS remain the exception rather than the rule. As per paragraph 5.5, the timing of any such review will be jointly agreed but will be initiated not later than two years after the commencement of this scheme.

Types of Patient Access Scheme

- 5.30. Experience of Patient Access Scheme proposals under the 2009 PPRS has enabled the development of a typology for Patient Access Schemes where there are:
- Simple discount schemes; and
 - Complex schemes
- 5.31. **Simple discount schemes** must meet the simple discount criteria which ensure that a PAS imposes no significant ongoing additional burden on the NHS, as set out in the PASLU process guide and the relevant PAS proposal template. The other option for a scheme member would be to change the list price of the product.

- 5.32. The Department and the ABPI note that simple discount schemes are the simplest type of PAS and are the preferred model because they place the least burden on the NHS and manufacturers.
- 5.33. **Complex schemes** include all other types of PAS. This could potentially incorporate a wide range of models. To date, components of PAS have included:
- Rebates;
 - Stock supplied at zero cost;
 - Dose capping;
 - Outcome-based schemes.
- 5.34. In contrast to simple discount PAS, complex PAS may be specific to one or more indications of a medicine. However, a PAS should only modify the cost of a single product. Further, the Department is unlikely to agree to more than one PAS for a single medicine, because of the complexity this would introduce for the NHS. In view of this, PAS proposals should be designed so that the same PAS could apply across all relevant indications.
- 5.35. Experience within the 2009 PPRS demonstrated that complex PAS are burdensome for industry and the NHS. This means that, to an even greater degree than simple discount patient access schemes, they are likely only to be appropriate in exceptional circumstances.
- 5.36. There are added issues to consider around patient access schemes in primary care. A PAS is unlikely to be suitable for a medicine widely used in primary care.

Potential Timing of Proposals for Patient Access Schemes

- 5.37. While Patient Access Schemes are intended to help to secure access for NHS patients to medicines that might otherwise not have been deemed cost-effective, it is important that arrangements for proposing and agreeing PAS 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 PAS proposals does not encourage “gaming” of the appraisal system by any party.
- 5.38. In that context, the Department and the ABPI have concluded that, where scheme members wish to bring forward PAS proposals in the context of a NICE appraisal, 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 submission to the Department should precede the scheme member’s submission to NICE; 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, under the rapid review facility (described in NICE’s Guide to the Process of Technology Appraisal).

- 5.39. In exceptional circumstances, a PAS proposal assessed as meeting the simple discount criteria may be accepted at additional times in the NICE process, but this would not be possible for complex PAS proposals.
- 5.40. Where a scheme member submits a PAS proposal through the rapid review facility following an MTA, other scheme members whose products were appraised in the same appraisal would also have a single opportunity to propose a PAS.

Transparency

- 5.41. The concerns of scheme members for commercial confidentiality of PAS proposals whilst they are being considered by the Department and PASLU will be respected. However, the arrangements applicable at the relevant time for consultation and disclosure will apply to PAS proposals when they are considered as part of the NICE appraisal process. In particular, when NICE consults on draft appraisal guidance, this must provide stakeholders with an opportunity to comment on the full content of the appraisal including information on any proposed PAS.
- 5.42. The decision on whether to submit PAS proposals is a commercial decision for the individual scheme member concerned. It is not therefore appropriate, where a scheme member makes a PAS proposal, for an alert to be given by the Department or NICE to other company stakeholders before a PAS proposal is referred to NICE for consideration as part of a technology appraisal.
- 5.43. PAS proposals submitted through the rapid review facility will remain confidential until such time as NICE needs to consult, as set out in NICE's Guide to the Technology Appraisal Process.
- 5.44. The Department and the Health Departments of Scotland, Wales and Northern Ireland and their bodies responsible for the assessment of medicines may exchange information on Patient Access Scheme proposals. Unpublished information shared in this context will not normally be made publically available, subject to the provisions of paragraph 2.12.
- 5.45. The Department's general position is that all operational Patient Access Schemes should be transparent. The only exception to this principle is in the context of a simple discount PAS, where Ministers have agreed, in response to a specific request from the scheme member made at the time of submission of their PAS proposal, that the discount rate can be treated as commercial-in-confidence.
- 5.46. Where a discount level as part of a simple discount PAS is not published in final NICE guidance, the NHS must have access to the discount price, so providers and commissioners are able properly to account for the PAS. Where agreed, this will be within appropriate arrangements to safeguard confidentiality.
- 5.47. In publishing guidance, NICE must be satisfied that sufficient information can be communicated to stakeholders to explain an appraisal recommendation. In this regard, what constitutes a sufficient level of transparency is a matter for NICE to determine in developing its guidance.

- 5.48. It is important that these arrangements do not have a perverse effect on the appraisal of other technologies. Where a medicine recommended by NICE with a PAS is used as a comparator for the appraisal of another treatment, NICE must be able to make relevant details of the PAS available to relevant consultees and commentators.

Process for Consideration of PAS Proposals

- 5.49. The Patient Access Scheme Liaison Unit (PASLU) at NICE has been established to advise the Department on the feasibility of PAS proposals, and the PASLU process includes arrangements for consultation with the NHS. Details of how PASLU assesses the viability of PAS proposals are set out in PASLU's Process for advising on the feasibility of implementing a patient access scheme. NICE's Guide to the Methods of Technology Appraisal sets out how PAS proposals are taken into account in the context of appraisals, following a referral by the Department.

Arrangements Offered Outside or Prior to NICE Appraisals and Link to Other Sections in this Scheme

- 5.50. None of these provisions stops scheme members from reducing their prices at any time or offering local discounts to the NHS in order to improve their competitive position. In addition, the agreement of a PAS is not a substitute for, nor excludes a medicine from any provisions under the other sections in this scheme. If the list price of a medicine covered by a simple discount PAS is modulated downwards then the actual price of the medicine will also need to be modulated down in order to deliver a net 0% increase in prices across the relevant scheme member's portfolio of medicines covered by the scheme.
- 5.51. Scheme members may continue to offer local discounts or other arrangements to the local NHS outside NICE appraisals as long as these do not contravene any aspect of the scheme, but decisions on whether to participate in such arrangements and the terms on which they are offered are matters for the relevant scheme member and the local NHS. In England and Wales only a scheme that is included in final NICE appraisal guidance should be described as a Patient Access Scheme or PAS. A different term should be used for arrangements offered outside NICE appraisals.

Monitoring and Review of Operational PAS

- 5.52. In order to maintain confidence in Patient Access Schemes, it is essential to ensure that their full value to patients and the NHS is realised, and their individual and cumulative impact on the NHS remains manageable.
- 5.53. When submitting a proposal for a new PAS, scheme members should set out information on the expected level(s) of uptake of the proposed PAS, and data they would share with the Department, NICE and the NHS to enable periodic monitoring of the PAS' operation (including in relation to uptake of the PAS). The expectation is that scheme members will make such information available.
- 5.54. Where periodic monitoring indicates problems with the operation of a PAS, including greater than expected administrative burdens and/or under-delivery of benefits, the scheme member should work with the NHS to urgently identify the underlying causes,

and, in discussion with the Department and, where appropriate, NICE, make proposals to address the problems. This may include measures, which must be consistent with existing financial flows, to ensure that the NHS realises the full expected financial benefits of the PAS.

- 5.55. NICE Technology Appraisal Guidance includes a date at which NICE will consider whether to review the guidance. Where guidance includes a PAS, this provides a useful opportunity to review how the PAS is operating and consider whether it would be appropriate to make any changes to the PAS to simplify and improve its operation. Any changes to an operational PAS are subject to discussion with, and agreement by, the Department.
- 5.56. The expectation is that an operational PAS will remain in place for the lifetime of the relevant NICE guidance, and that there should not normally be any changes that fundamentally alter the nature of the PAS once it is operational. Where significant changes are proposed to an operational PAS (for example, change of scheme type or extension to a new indication), a submission will need to be made to the Department, for consideration in the same way as a new PAS proposal.

6. PPRS Payment Mechanism

Note

The contents of Chapter 6 and Annex 7 have been amended in accordance with paragraph 3.4 with effect from [1st January 2017] by mutual agreement between the ABPI and the Secretary of State for Health. This has been done to reflect some changes to the payment mechanism.

Introduction

- 6.1. Recognising the current state of the global economy, the Department and ABPI have agreed that instead of the headline price adjustments which have been a feature of recent PPRSs a limit is introduced on growth in the overall cost of the branded medicines purchased by the NHS from members of the scheme. An important purpose is to provide Government with surety on the level of NHS expenditure on branded health service medicines supplied by scheme members. The scheme remains a portfolio-wide profit regulatory scheme which permits modulation in the market.
- 6.2. In outline and without prejudice to the requirements set out in paragraphs 6.4A-6.47 below, scheme members will make percentage payments. The percentage will be derived from the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines and, for the years 2017 and 2018 on a set of agreed payment percentage figures as set out in paragraph 6.4A. The percentage payments will apply to products on the market at 31 December 2013 subject to the exemptions set out below. Allowed percentage growth has been agreed for the five years of the scheme. The difference between the allowed percentage growth and an agreed forecast percentage growth gives an initial estimate of percentage payments. An initial percentage payment has been set for the first year and this will not change. In subsequent years, the actual percentage growth will be reviewed versus the forecast and the initial estimate of payment percentages for the future years will be adjusted to reflect actual percentage growth, any over or underpayment from the previous year and a revised forecast percentage growth for the following years. In the last year, the payment percentage will be based on the forecast percentage growth calculated at the end of the previous year and there will be no adjustment and/or payment to reflect the actual percentage growth in the last year. This is known as the “basic PPRS Payment Mechanism”.
- 6.3. The key terms used to describe the PPRS Payment Mechanism are set out in paragraphs 6.4A-6.10 below. This scheme sets out the Allowed Growth Rate of Measured Spend for each year of the scheme. Scheme members will make payments (“PPRS Payments”) to the Department for Measured Spend which is above the Allowed Growth Rate of Measured Spend, according to the rules set out in the scheme.

Definitions

- 6.4A Modified meaning of “PPRS Payment Percentage”—

References to the PPRS Payment Percentage which relate to the years 2017 and 2018 must be construed in accordance with the following:

- for 2017 the PPRS Payment Percentage is 4.75%
- for 2018 the PPRS Payment Percentage is to be calculated in accordance with the basic PPRS Payment Mechanism but with the following conditions:
 - where the payment percentage produced by applying the Mechanism is less than 2.38%, the payment percentage shall be 2.38%;
 - where the payment percentage produced by applying the Mechanism is more than 7.80%, the payment percentage shall be 7.80%.

- 6.4. **“Sales of Scheme Products”** means: sales of all products covered by the scheme (as defined at paragraphs 3.14-3.19), including central procurements. Sales of Scheme Products will be calculated net of all discounts, but including sales that relate to Brand Equalisation deals and excluding parallel imports i.e. medicines which are imported and supplied to the NHS by a party other than the scheme member or a company that is affiliated to the scheme member such as a parent company.
- 6.5. **“Sales of PPRS Products”** means: Sales of Scheme Products as defined in paragraph 6.4 above, but excluding sales that relate to Brand Equalisation deals. Brand Equalisation occurs where a scheme member offers dispensing contractors, whether directly or through wholesalers, additional discounts or rebates on branded medicines that result in them dispensing their brand against a generic prescription where there is a competitor generic presentation available.
- 6.6. **“Measured Spend”** means: Sales of PPRS Products as defined at paragraph 6.5 above supplied by scheme members in the scheme, including sales of new products, but excluding the following:
- The following central procurements:
 - Exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation);
 - Procurements of centrally supplied vaccines;
 - Sales by smaller companies, defined as companies with Sales of Scheme Products of less than £5m in the previous calendar year.
- 6.7. **“Sales Covered by the PPRS Payment”** means: Sales of PPRS Products as defined at paragraph 6.5 above including biosimilars and line extensions of products originally introduced before 31 December 2013 but excluding the following:
- The following central procurements:

- Exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation);
 - Procurements of centrally supplied vaccines;
 - Sales by smaller companies defined as companies with Sales of Scheme Products of less than £5m in the previous calendar year;
 - Sales of new products as defined in paragraph 6.10 below.
- 6.8. **“Growth Rate of Measured Spend”** means: the percentage growth in Measured Spend between one calendar year and the following calendar year.
- 6.9. **“Allowed Growth Rate of Measured Spend”** means: The Allowed Growth Rate of Measured Spend in each year of the scheme. The Allowed Growth Rates for each year of the scheme are set out in Annex 3 and remain fixed for the duration of the scheme.
- 6.10. **“New Products Share of Measured Spend”** means: The percentage of Measured Spend which is accounted for by sales of new products. For this purpose, new products are defined as follows: products introduced after 31 December 2013 following the granting of an EU or UK new active substance marketing authorisation from the appropriate licensing body. This does not include biosimilars or line extensions of products originally introduced before 31 December 2013.

Summary of Methodology

- 6.11. To meet the objective set out in paragraph 6.1, the Allowed Growth Rate for 2014 is 0% and then for each subsequent year is 0%, 1.8%, 1.8%, 1.9%. The Allowed Growth Rates for each year of the scheme will remain fixed. There is a pre-agreed profile of PPRS Payment percentages for the five years of the scheme (expressed as percentages of the Sales Covered by the PPRS Payment) derived from the initial forecast Growth Rate of Measured Spend and the Allowed Growth Rate of Measured Spend. Annex 3 sets out the Allowed Growth Rates of Measured Spend, and the initial profile of PPRS Payment percentages. Annex 3 also sets out the initial forecasts of Growth Rate of Measured Spend and the initial forecasts of New Products Share of Measured Spend.
- 6.12. The PPRS Payment percentage which applies in 2014 is 3.74%. If the Measured Spend grows faster or slower than the initial forecast Growth Rate, the payment percentage profile will be adjusted according to the process set out in Annex 4 and applied to the remaining period of the scheme. The first adjustment will apply to year two (2015) based on outturn Growth Rate of Measured Spend for year one (2014). The adjustments will be based on actual growth rates compared to forecast, and corrections for any previous under or over-payments will be pro-rated over the remaining period. Annex 5 sets out the detailed methodology and calculation formulas for calculating PPRS Payments in each year of the scheme.
- 6.13. Any adjustments to the profile of PPRS Payment percentages for future years will be set in advance of the year concerned and communicated in quarter four of the previous year. In order to ensure a prompt closure of the scheme, the PPRS Payment for the final year will be adjusted based on 2013-2017 outturn actuals and over or underpayments from those years.....Omitted.

- 6.14. Omitted.....
- 6.15. Annex 6 provides further details on the data sources that will be used for the PPRS Payment Mechanism. There will be an independent reconciliation exercise completed during 2016 to compare company data with administrative data on outturn in 2013, 2014 and 2015, to follow up any inconsistencies and correct any errors.

Arrangements for Making PPRS Payments

- 6.16. Each scheme member will make a payment to the Department of Health which is the PPRS Payment percentage multiplied by their Sales Covered by the PPRS Payment. The PPRS Payment percentage for each year, set in advance of that year, will apply uniformly to each scheme member (excluding smaller companies, defined at paragraph 6.31 below). The PPRS Payment percentage will be applied to the company's Sales Covered by the PPRS payment as defined at paragraph 6.7 above.
- 6.17. The PPRS Payment will be paid in quarterly instalments by individual companies at the same time as the Quarterly Sales Reports are submitted. Payment and Quarterly Sales Reports will be due within one month of the end of each quarter of the calendar year. The Quarterly Sales Report should be completed in accordance with the guidance at Annex 7 and using the Sales Report pro-forma at Annex 7, appendix 1).
- 6.18. In the case of chemical entities on the market at 31 December 2013 which are subsequently transferred or sold on, and remain in the ultimate ownership of the company which held them on 31 December those sales should form part of that company's sales for the purposes of calculating and making payments by scheme members, unless already captured elsewhere in the industry-wide calculations (i.e. there will be no double counting of sales when it comes to PPRS Payments).

Sales Reports

- 6.19. At the end of each calendar year, following the statutory audit of the company's statutory accounts, an Audited Annual Sales Report will be submitted by the company in accordance with the requirements for audit of the PPRS Payments set out at paragraphs 6.24-6.30 below. The Audited Annual Sales Report must be submitted within nine months of the end of the company's financial year end. For companies with a year end of 31 December the deadline is therefore 30 September in the following calendar year.
- 6.20. Annex 7 provides guidance notes on completion of PPRS Payments Sales Reports together with the following appendices:
1. A pro-forma for the PPRS Payments Sales Reports;
 2. A Company Declaration for the PPRS Payments Sales Reports;
 3. The Independent Auditor's report on the PPRS Payments Sales Report.
- 6.21. In addition to the Annual Audited Sales Report an unaudited Annual Presentation Level Sales Report should be submitted using the pro-forma at Annex 8 and the Company Declaration at Annex 9. This is to allow the Department to compare company sales data with administrative data on spend on branded medicines. This does not itself need to be

audited, but the data should reconcile with the Annual Audited Sales Report. For the purpose of completing Annex 8 the following data should be included:

- Under Primary Care Sales: those presentations which are dispensed by community pharmacists or dispensing doctors;
 - Under Homecare Sales: those presentations that are sold direct to Homecare providers;
 - Under All Other Customers: all other sales (including wholesaler sales to homecare providers).
- 6.22. The Company Declarations will declare that the sales information provided has been accurately extracted from the company records and complies with the requirements of the scheme.
- 6.23. All Quarterly and Annual Sales Reports for the PPRS Payments(as described in Annex 7) should also be submitted to the independent third party, as soon as they have been appointed by ABPI (such appointment subject to the Department's reasonable right of veto) and details of whom have been confirmed to scheme members.

Audit Arrangements

- 6.24. Government and industry have agreed the following arrangements for auditing company Audited Annual Sales Reports for the PPRS Payments set out below.
- 6.25. Following the end of the calendar year there will be an independent audit of each scheme member's Audited Annual Sales Report for that year.
- 6.26. The auditor for the purposes of the Audited Annual Sales Report will be the auditor of the statutory accounts. There will be a tripartite engagement between each scheme member, the Department of Health and the auditor. Any resulting differential cost above those of the statutory audit associated with the Audited Annual Sales Report will be for each scheme member's account provided such costs are incurred in order to comply with the requirements of the scheme at the reasonable request of the Department.
- 6.27. The engagement letter with the auditor must include the key terms set out in paragraph 8.2 of Annex 7 and must be signed by the scheme member, the auditor and the Department of Health.
- 6.28. The Audited Annual Sales Report must show how the reported Sales of Scheme Products, and the reported Sales Covered by the PPRS Payment relate to the sales figures set out in the scheme member's Statutory Accounts submitted under the Companies Act 2006. The Annual Audited Sales Report must be accompanied by an Audit Report as set out in Annex 7, appendix 3). This Audit Report will provide a Reasonable Assurance opinion in an agreed form performed by the auditor of the statutory accounts performed under ISA805 and reported for each year of sales applicable to the scheme including the baseline year sales (2013) against which the Growth Rate of Measured Spend will be measured. Annex 7 sets out further guidance required for auditors to undertake the engagement only to the extent that this does not override applicable accounting or auditing standards.

- 6.29. Any differences between the PPRS Payment by an individual company derived from the Quarterly Sales Report and Annual Audited Sales Report will be corrected following the audit. Any amounts owed by either party as a result will be settled in cash. The calculation of adjustments to the PPRS Payments for the scheme as a whole will take account of any corrections of outturn data following receipt of the independently audited figures as set out in Annexes 4 and 5. In the case of years four and five (2017 and 2018) the company level reconciliation between audited and unaudited sales reports will be carried out and any sums owed by either party settled in cash. But the audited figures for years four and five will not be available in time for adjustments to PPRS Payment percentages for the scheme as a whole.
- 6.30. In the event of an audit reporting a qualified opinion, the Department will at its discretion use the administrative data available to define Sales of PPRS Products for that scheme member.

Smaller Companies

- 6.31. Scheme members with Sales of Scheme Products of less than £5 million in the previous calendar year will not be required to make PPRS Payments to the Department. In the case of scheme members with Sales of Scheme Products of less than £1m in 2013, eligibility for the exemption will be established at the start of the scheme and will continue throughout the period of the scheme provided that annual Sales of Scheme Products do not grow above £1m.
- 6.32. For scheme members with Sales of Scheme Products over £1m but under £5m, eligibility for the exemption will be established at the start of each calendar year on the basis of the scheme member's sales data for the previous calendar year and will apply for the whole of a calendar year concerned whether or not the Sales of Scheme Products during that calendar year are above or below the threshold. This eligibility will be reassessed at the start of the following calendar year in the same way.
- 6.33. Scheme members with Sales of Scheme Products of less than £1m will be required to submit a company declaration on the value of their Sales of Scheme Products in 2013 by the end of March 2014 using the company declaration at Annex 10. These scheme members will continue to be exempt for the period of the agreement subject to submitting annual company declarations on the value of their Sales of Scheme Products for the previous calendar year by end March in each subsequent year of the scheme.
- 6.34. Scheme members with Sales of Scheme Products of more than £1m and less than £5m in 2013 will be required to submit an unaudited Annual Sales Report of Sales of Scheme Products for the calendar year 2013 by March 2014 using the Sales Report at Annex 7 appendix 1 and the company declaration at Annex 11. The Department will establish whether or not the scheme member falls within the criteria for the exemption based on this data. If their total Sales of Scheme Products for 2013 is less than £5m then they will not be required to make PPRS Payments or to submit Quarterly Sales Reports or Audited Annual Sales Reports for 2014. The scheme member will be required to submit an unaudited Annual Sales Report for 2014 by the end of March 2015 and, if the scheme member remains eligible for the exemption, for each subsequent year of the scheme by the end of March of the following calendar year.

- 6.35. If a scheme member's total Sales of Scheme Products in the unaudited Annual Sales Report is £5m or greater, then the exemption will cease to apply for the following calendar year. So if the sales total for 2014 submitted by end March 2015 shows that the scheme member's Sales of Scheme Products in 2014 were £5m or greater, then the Department will require the scheme member to make PPRS Payments for the whole of 2015, submitting the Quarterly Sales Reports and PPRS Payments and an Annual Audited Sales Report for 2015 according to the same procedure as other members of the scheme.
- 6.36. If a scheme member has been making PPRS Payments because its Sales of Scheme Products were £5m or higher in the previous calendar year, but during the year its Sales of Scheme Products (gross of the PPRS Payment) dip below the £5m threshold, then it will become eligible for the smaller companies exemption in the following calendar year. For example if a scheme member was at or above the £5m threshold according to its Sales of Scheme Products for 2013 and made PPRS Payments for 2014, but the scheme member's Sales of Scheme Products gross of the PPRS Payment in 2014 fell below the £5m threshold, then it could apply for a smaller companies exemption for 2015 based on an unaudited Sales Report for 2014 submitted by the end of April 2015.

Reconciliation Exercise

- 6.37. Omitted.....
- 6.38. Omitted.....
- 6.39. Omitted.....
- 6.40. Omitted.....

Historic Cash Payments

- 6.41. Government and industry have agreed that the baseline against which the PPRS Payment is applied should be fair for all scheme members. Therefore members of the 2009 PPRS that elected to deliver up to 2% of the price cuts in that scheme by making payments to the Department should remain responsible for delivering the value of those price cuts for the relevant products and should continue to make the relevant payments and net them off of their sales figures prior to the calculation of the PPRS Payment.
- 6.42. These payments will be known as Historic Cash Payments. The process for calculating Historic Cash Payments is set out at paragraphs 6.43-6.45 below.
- 6.43. Using information from the 2013 modulation exercise under the 2009 PPRS, the Department will establish the percentage level of cash payment made by scheme members in the last year of the 2009 PPRS. This will be calculated by dividing the amount of a scheme member's total cash payment in 2013 by the total level of their sales of Scheme Products at NHS list reference prices. The percentage result, known as the Historic Cash Payment Percentage, will be capped at 2%.
- 6.44. For 1 January to 31 December for each year of the scheme, scheme members required to make Historic Cash Payments will complete a Price Neutral Modulation Monitoring Form (Annex 12), annotating it appropriately so that sales against which the Historic

Cash Payment Percentage will be applied can be identified. The completed Annex 12 should be submitted to the Department by 31 March of the following year. The presentations annotated will be those that were on the market on 31 December 2008 (and any subsequent line extensions of those presentations) and that continue to be sold by the scheme member. Only modulation exemptions under Chapter 7 of this scheme (the 2014 Pharmaceutical Price Regulations Scheme) will apply to such sales. The total sales at NHS list prices of these presentations will be known as Annual Historic Cash Payment Sales.

- 6.45. The Historic Cash Payment for each year of the scheme will be calculated by applying the Historic Cash Payment Percentage against the respective year's Annual Historic Cash Payment Sales.
- 6.46. Scheme members will be required to estimate the Historic Cash Payment in advance of each year of the scheme. 25% of the annual estimate of the Historic Cash Payment should be paid each quarter at the same time that the PPRS Payment is made. Any balancing amount following the Department's assessment of each company's Annual Historic Cash Payment Sales will be made in the quarter following the issue of the Department's assessment.
- 6.47. Scheme members that elected to deliver price cuts on OTC products under the 2009 PPRS by making a payment to the Department will be required to make a one off payment to the Department that equates to 10% of the value of NHS sales of the relevant products for the period 1 January 2013 to 31 December 2013. This payment should be based on sales at NHS list prices and will be in addition to the PPRS Payments. Scheme members should make this payment no later than 31 March 2014.

7. Pricing

- 7.1. No scheme member may increase the NHS list price of any Scheme Product without the Department's prior approval other than an NHS list price change subsequent to the requirements of Chapter 5 on flexible pricing. An NHS list price increase will not be granted unless a scheme member's PPRS business is up to date.
- 7.2. Where a scheme member wishes to increase the NHS list price of any Scheme Product or make an NHS list price change other than pursuant to the rules on flexible pricing in Chapter 5, or through modulation as provided for under paragraphs 7.27-7.53, 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. Scheme members, including those with NHS home sales below the threshold for submitting annual financial returns (AFRs) routinely, will be required to provide an estimate AFR for the current year and a forecast AFR for the year following that in which the proposed price increase will have effect. If a price increase is awarded, the scheme member will provide a full audited AFR for the year the price increase is awarded and an AFR for one year following the price increase.
- 7.3. The Department will not agree to an NHS list price increase unless the scheme member's estimated and forecast profits for the current and following financial years respectively, as assessed by the Department, are below 50% of the return on capital or return on sales (ROC/ROS) target.
- 7.4. Where an NHS list price increase is agreed, the level of the increase approved will be no more than that required for the scheme member to achieve 65% of the ROC/ROS target.
- 7.5. No scheme member may be awarded an NHS list price increase within a period of 12 months after a preceding, authorised NHS list price increase.
- 7.6. If a scheme member is awarded an NHS list price increase, it will continue to be required to pay the PPRS Payment at the rate applying to all scheme members as a percentage of their Sales Covered by the PPRS Payment and in accordance with the²Chapter 6.
- 7.7. The Department accepts fully the right of scheme members 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 or affect the delivery of price neutrality. Accordingly, if a scheme member intends to remove or reduce hospital discounts offered for Scheme Products as a change in its 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:

² Words omitted as a consequence of amendments made to Chapter 6 as from 1st January 2017.

- 7.7.1. notify the Department at least 28 days before the date of any proposed reduction or removal of hospital discounts;
 - 7.7.2. identify the presentations of Scheme Products affected;
 - 7.7.3. quantify the volume of sales of the presentations concerned, the extent of the discount involved and the extra cost to the NHS; and
 - 7.7.4. indicate the action it proposes to take to counterbalance the extra cost to the NHS.
- 7.8. The Department will respond to such communication within 28 days of receipt of a scheme member's letter and may reject the proposal where it concludes that the change in hospital discount and any counter-balancing action that the scheme member proposes to take is not cost neutral.

Temporary Reductions to NHS List Prices

- 7.9. Scheme members may make temporary reductions to an NHS list price, outside the arrangements for modulation or those for the settlement of an AFR, and increase the NHS list price to a level no more than the NHS list 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.
- 7.10. Where temporary reductions in NHS list prices have been made, scheme members will continue to be required to pay the PPRS Payment at the rate applying to all scheme members as a percentage of their Sales Covered by the PPRS Payment and in accordance with³ Chapter 6.

Pricing of New Medicines

Medicine Launches

- 7.11. A scheme member wishing to launch a branded medicine in the UK market is required to give the Department a minimum of 28 days' notice before the date of launch. A scheme member may not launch a medicine until it has received confirmation from the Department either that it has freedom of pricing or that the proposed price is acceptable.
- 7.12. As part of its submission the scheme member should supply the Department with details of the medicine including the proposed NHS list price and the Summary of Product Characteristics (or draft thereof). The scheme member may give such notice prior to receipt of the marketing authorisation in order to avoid patient access delays. The Department may provisionally respond to a scheme member on a medicine which is awaiting the grant of a marketing authorisation.

³ Words omitted as a consequence of amendments made to Chapter 6 as from 1st January 2017.

- 7.13. The Department will acknowledge the submission and seek confirmation of the marketing authorisation status from the appropriate licensing authority.

New Active Substances

- 7.14. New medicines launched in the UK market 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 scheme member on entering the market. It is assumed that prices at launch will be set at a level that is close to their expected value as assessed by NICE.
- 7.15. Line extensions relating to such new medicines, granted on the basis of an abridged application, may also be priced at the discretion of the scheme member 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 marketing authorisation of the new medicine.
- 7.16. 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.
- 7.17. Once the Department has established that a medicine is a new active substance it will write promptly, and in any event within five working days, to the scheme member confirming that the product has freedom of pricing.
- 7.18. If forecast sales of any new medicine in any one year of the first five years following launch are expected to exceed £20 million, a scheme member must inform the Department of both the price and the anticipated level of sales in each of the first five years.
- 7.19. If a scheme member considers that the rapid uptake of a new medicine will cause the scheme member to exceed the upper margin of tolerance (MOT) used in the assessment of AFRs, 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 medicine will cause a scheme member to exceed the upper MOT.
- 7.20. Freedom of pricing at the time of launch of these new medicines is conditional on it not causing forecast profits to exceed the target profit MOT.

All Other Products and Their Line Extensions

- 7.21. Where a new product does not have freedom of pricing the following applies.
- 7.22. In reaching a decision on the acceptability of a proposed price, the Department may take into account factors such as the following:
- 7.22.1. the price of other presentations of the same medicine or comparable products;
 - 7.22.2. forecast sales and the effect on the NHS drugs bill;

- 7.22.3. the clinical need for the medicine; and
 - 7.22.4. any exceptional costs.
- 7.23. As part of its assessment, the Department may request additional information from the scheme member.
- 7.24. The Department will consider the acceptability of the price and provide the scheme member with its decision within 28 days of receipt of the original notification or from the receipt of any additional information it has requested from the scheme member.
- 7.25. If, following discussions, agreement cannot be reached on the NHS list price of the medicine, a scheme member may decide to refer the issue to the dispute resolution procedure (see Chapter 11).

Scheme Products Sold On

- 7.26. The requirements set out in this paragraph refer to the treatment of Scheme Products sold in respect of the rules on price and profit control, and modulation. Scheme members sometimes need to change the structure of their product portfolios. In some cases the original scheme member 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 scheme member continues, for example, to manufacture the Scheme Product. It is important that, as in other circumstances, there should not be disproportionate NHS list price increases. Accordingly, when a Scheme Product covered by the PPRS is sold on:
- 7.26.1. the scheme member transferring the Scheme Product and the acquiring scheme member should notify the Department of the Scheme Product and the name of the acquiring scheme member within 14 days of the transfer;
 - 7.26.2. the acquiring scheme member will revert the NHS list price to that applying on 31 December 2013, but may make an application to the Department, in accordance with paragraphs 7.27-7.53, to remodulate on a price neutral basis in their own right; and
 - 7.26.3. where the original scheme member continues to manufacture or supply the Scheme Product, information may be needed by the Department from that scheme member to justify an NHS list price increase.

Modulation

- 7.27. The scheme will allow price neutral modulation across the portfolio from 1 March 2014 of presentations (and any subsequent line extensions of those presentations) of Scheme Products on the market on 31 December 2013. Modulation will be deemed to have occurred when a scheme member's NHS list prices have changed other than as permitted under paragraphs 7.2-7.6 or paragraphs 7.9-7.10.
- 7.28. Modulation will be measured on the NHS list prices of Primary Care Sales and Secondary Care Sales referenced to NHS list prices at 31 December 2013.

- 7.29. For modulation purposes, Primary Care Sales are those modulated presentations which are dispensed by community pharmacists or dispensing doctors. Secondary Care Sales are all other sales of modulated presentations.
- 7.30. Where a presentation is modulated, the Department will also monitor the volume weighted mean selling price (known as the average selling price (ASP)) of the presentation's Secondary Care Sales. The Secondary Care Sales reference ASP will be based on Secondary Care Sales covering the period 1 January 2013 to 31 December 2013.
- 7.31. Scheme members will be allowed to modulate with the following conditions:
- 7.31.1. no modulation on presentations 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 NHS list price or not) and where there is more than one proprietary available. The Department will publish a list of these presentations. The NHS list price of these presentations must not be changed as compared to the NHS list price on 31 December 2013 unless the scheme member can demonstrate that there is no resulting increase in NHS expenditure;
 - 7.31.2. no substitution of discounts in force during the six months prior to the date of any proposed modulation;
 - 7.31.3. no NHS list price reductions that may be necessary as a result of patent or Supplementary Protection Certificate expiry to justify an NHS list price increase on other NHS presentations. Consequently, scheme members will not be allowed to include NHS list price reductions made on presentations 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. 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;
 - 7.31.4. no inclusion of volumes of sales defined as Brand Equalisation, using the definition of Brand Equalisation at paragraph 6.5; or
 - 7.31.5. no reductions in the NHS list price of a new active substance as part of modulation until the new active substance has been on the market in the UK for two years.
- 7.32. 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 jeopardise price neutrality, where new formulations or pack sizes of presentations that are modulated are launched after 31 December 2013, the new formulation or pack size will also be subject to the modulation rules. In such cases the Department will advise the scheme member of the notional reference price (i.e. the price that would have been in place before the scheme began were the presentation on the market at that time), 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).

- 7.33. If the NHS list price of a presentation covered by a simple discount PAS is modulated downwards then the ASP of the presentation will also need to be modulated downwards in order to avoid a net increase in prices across the relevant scheme member's portfolio of Scheme Products.
- 7.34. From 1 March 2014, NHS list prices may be increased through modulation to a level no greater than 20% above the level that existed on 31 December 2013 subject to the agreement of the Department. The Department will consider applications for increases greater than 20% for products with NHS sales of £250,000 or less where the cost can be justified on the basis of a medical need.
- 7.35. 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 reserves the right, following discussions with the scheme member, to refuse the proposed modulation.
- 7.36. The Department is keen to minimise interference in the conduct of scheme members' commercial affairs consistent with safeguarding public expenditure. Scheme members can modulate or remodulate at any time from 1 March 2014 provided the Department is notified 28 days in advance of the implementation of the NHS list 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 price neutrality in doubt.
- 7.37. The Department will not agree to any modulations proposed in the last two years of the scheme if it may jeopardise price neutrality in subsequent years.

Ensuring Price Neutrality from Modulation

- 7.38. Where a scheme member opts to modulate NHS list prices, the Department will monitor a scheme member's modulations to ensure that they deliver the required price neutrality across Primary Care Sales and Secondary Care Sales over the lifetime of the scheme. To do this, the Department will require information for modulated presentations.
- 7.39. Companies will need to provide evidence that modulation has produced a net result less than or equal to 0% using a two-stage process:
- Stage 1 – NHS list price: scheme members should demonstrate that they have delivered price neutrality using NHS list prices on all sales; and
 - Stage 2 – Secondary Care Sales ASPs: for Secondary Care Sales, scheme members must align aggregate percentage changes in ASPs with aggregate percentage changes in the NHS list prices of modulated products.
- 7.40. The Department will validate data provided by scheme members against other data sources.

Information Required from Scheme Members before a Presentation is Modulated

- 7.41. Scheme members should supply the following information to the Department with every request to modulate a presentation.

- 7.41.1. The name of the presentation (including strength and pack size) to be modulated.
 - 7.41.2. The NHS list price of the presentation at 31 December 2013.
 - 7.41.3. The current NHS list price.
 - 7.41.4. The proposed modulated NHS list price.
 - 7.41.5. Net Secondary Care Sales and volumes sold for the period 1 January 2013 to 31 December 2013.
 - 7.41.6. The estimated quantities sold to the NHS in the 12 months before and after the proposed modulation split across Primary Care Sales and Secondary Care Sales.
- 7.42. Item 7.41.5 will be used to establish a reference Secondary Care Sales ASP to enable monitoring of Secondary Care Sales ASPs for modulated presentations.

Annual Outturn Information from Modulating Scheme Members – Required By 31 March Following Each Year of the Scheme

- 7.43. Scheme members should provide the following information for all modulated presentations for the period 1 January to 31 December of the previous year:
- 7.43.1. For Primary Care Sales: volumes sold differentiated by period where NHS list prices have changed within the year.
 - 7.43.2. For Secondary Care Sales: volumes sold and net sales.

This information should be sent to the Department in electronic format using a copy of the Excel spreadsheet provided by the Department to scheme members and replicated at Annex 12.

- 7.44. The data submitted for the purposes of monitoring the delivery of NHS list price neutrality and Secondary Care Sales ASPs will be independently reviewed (see Annex 13), and this review must include an independent verification of reference NHS list prices and reference Secondary Care Sales ASPs. A Company Declaration (Annex 14) should also accompany the data submitted.

Calculation of Modulation Outturn Delivery

- 7.45. By 30 June following each year of the scheme, the Department will analyse the outturn of NHS list price neutrality for modulated presentations for the previous 12 months ending 31 December. Whether a scheme member chooses to modulate on a price neutrality basis is a commercial decision for individual scheme members. The commercial risk associated with modulation will, therefore, be solely the scheme member's.

Stage 1 – Calculation of Delivery of NHS List Price Neutrality

- 7.46. The delivery of NHS list price neutrality is calculated using NHS list prices on Primary Care Sales and Secondary Care Sales. A separate calculation for both of these categories will be made. For each category, the calculation will be determined, in any given period, by subtracting the total unit value (volume) of sales of modulated presentations at in-year NHS list prices from the same total unit value (volume) of sales of modulated presentations at NHS list reference prices (i.e. as at 31 December 2013). The result of each calculation will be divided by the respective category's total unit value (volume) of sales of modulated presentations at NHS list reference prices. This result will be expressed as a percentage known as the Stage 1 Outturn Percentage.
- 7.47. A Total Stage 1 Outturn Percentage, combining both Primary Care Sales and Secondary Care Sales will be calculated using the same method used at paragraph 7.46 for all sales. For price neutrality the Total Stage 1 Outturn Percentage is 0%.

Stage 2 – Calculation of Delivery of Secondary Care Sales ASP Neutrality

- 7.48. The Secondary Care Sales ASP calculation will be determined, in any given period, by subtracting the total unit value (volume) of Secondary Care Sales of all modulated presentations at in-year ASPs from the same total unit value (volume) of Secondary Care Sales of all modulated presentations at reference ASPs (for the year 1 January 2013 to 31 December 2013 (see paragraph 7.42)). The result will be divided by the total unit value (volume) of the Secondary Care Sales of all modulated presentations at reference ASPs. This result will be expressed as a percentage known as the Stage 2 Outturn Percentage.

Secondary Care Sales NHS list Price/ASP Comparison and Adjustments

- 7.49. To give the Department assurance of NHS list price neutrality happening on Secondary Care Sales, a comparison of delivery of modulated presentations in this category at NHS list prices and ASPs will be undertaken. This will be achieved by comparison of the Stage 1 and Stage 2 calculations for Secondary Care Sales.
- 7.50. For Secondary Care Sales, where the Stage 1 Outturn Percentage is greater than 0.5% above the result of the Stage 2 Outturn Percentage, the Department will make an adjustment, known as the Secondary Care Adjustment. The value of the Secondary Care Adjustment will be incorporated into the Department's final annual assessment of a scheme member's delivery of price neutrality measured by the Total Stage 1 Outturn Percentage. The Value of the Secondary Care Adjustment is calculated as follows:

$$(A - B) - (A \times C\%)$$

Where:

A = The total unit value (volume) of Secondary Care Sales of all modulated presentations at reference ASPs.

B = The total unit value (volume) of Secondary Care Sales of all modulated presentations at in-year ASPs.

C = Secondary Care Sales Stage 1 Outturn Percentage.

In all other cases, the Department will not make an adjustment to a scheme member's Total Stage 1 Outturn Percentage.

Actions to be taken after Modulation Outturn Calculation

- 7.51. For assessment of price neutrality in respect of 2014, 2015 and 2016 there are three possibilities.
- 7.51.1. Where the cumulative annual Total Stage 1 Outturn Percentage is greater than 0.5% scheme members will only be allowed to carry forward a maximum of 0.5% over-delivery to the following year and any excess above 0.5% will be forfeit. Scheme members will be allowed to remodulate NHS list prices subject to the rules on modulation.
 - 7.51.2. Where the cumulative annual Outturn Percentage is a negative percentage which is less than minus 0.5% (e.g. minus 0.6%), scheme members will be required to make an immediate payment of the under-delivery to the Department and must remodulate NHS list prices subject to the rules on modulation to ensure future price neutrality.
 - 7.51.3. In all other cases, the under or over-delivery may be carried forward into the following year.
- 7.52. For assessment of price neutrality in respect of 2017 there are three possibilities.
- 7.52.1. Where the cumulative annual Total Stage 1 Outturn Percentage is greater than 0.5% scheme members will not be allowed to carry forward any over-delivery to 2018. Scheme members will be allowed to remodulate NHS list prices subject to the rules on modulation.
 - 7.52.2. Where the cumulative annual Outturn Percentage is a negative percentage which is less than minus 0.5% (e.g. minus 0.6%), scheme members will be required to make an immediate payment of the under-delivery to the Department and must remodulate NHS list prices subject to the rules on modulation to ensure future price neutrality.
 - 7.52.3. In all other cases, the under or over-delivery may be carried forward into the following year.
- 7.53. For assessment of price neutrality in 2018 (the last year of the scheme) there are two possibilities.
- 7.53.1. The scheme member must repay to the Department the amount of any under-delivery accruing as a result of a Total Stage 1 Outturn Percentage of less than 0% immediately following receipt of the Department's assessment.
 - 7.53.2. The scheme member will forfeit any over-delivery when the Total Stage 1 Outturn Percentage is greater than 0%.

Scheme Members Awarded an NHS List Price Increase

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

Products Transferred and Fostering Arrangements

- 7.55. This section and the section below on company mergers apply to price and profit control, and modulation but not to the PPRS Payment Mechanism in Chapter 6. Where a scheme member transfers ownership of a Scheme Product to another scheme member, the acquiring scheme member will revert the NHS list price to that applying on 31 December 2013, but may make an application to the Department, in accordance with paragraphs 7.27-7.53, to remodulate on a price neutral basis in the scheme member's own right.
- 7.56. Occasionally a scheme member may enter into a product fostering arrangement with another scheme member. Usually, in these instances, the marketing authorisation remains with the original scheme member and the second (fostering) company assumes responsibility for sales and marketing of the product. In this case, the original scheme member will report sales of the fostered products in its own AFR and will retain responsibility for delivering price neutrality in respect of the Scheme Product. However, if sales are reported in the AFR of the scheme member fostering the Scheme Product, then the foster scheme member will assume responsibility for that Scheme Product for modulation purposes.
- 7.57. When scheme members enter into such fostering arrangements with another company, it is essential that the Department be informed in writing. The scheme members should clearly state which scheme member is to include sales of the Scheme Product in its AFR and is therefore also responsible for delivering price neutrality with respect to that Scheme Product.

Company Mergers

- 7.58. Where presentations have been modulated, the combined portfolios of products belonging to the merged scheme member will be reviewed to establish a revised target with reference to the original NHS list prices of 31 December 2013 and Secondary Care Sales reference ASPs. In cases where the cumulative portfolio results in a failure to deliver price neutrality as required by the scheme, the combined scheme member will be required to make a payment in accordance with paragraphs 7.51-7.53.

8. Levels of Return 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 the scheme, there is encouragement for the research and development (R&D) of new medicines, and a commitment to a minimum of interference with scheme members' freedom to succeed in that activity.
- 8.2. There will be one level of return on sales target (ROS) and one level of return on capital (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 ROS and ROC targets, and R&D, marketing and information allowances for level 1 and level 2 are set out in paragraphs 8.12, 8.13, 8.14, 8.31, 8.35 and 8.38 respectively and summarised at Annex 15.

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 scheme member'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 scheme member, 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 scheme member 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. Scheme members 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 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 scheme member's costs and assets the Department will have regard to the following factors:
- 8.10.1. the trends in the data reported by the scheme member over a number of years, including those for exports and other products;
 - 8.10.2. any special features of the scheme member's operation;
 - 8.10.3. ratios inferred from the AFR for the scheme member's non-PPRS business;
 - 8.10.4. each scheme member'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 scheme member'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 may discuss the basis of any limitations with the scheme member.

Rates of Return

- 8.12. 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.
- 8.13. The allowable ROS that may be earned by individual scheme members from home sales of NHS medicines will be 6% of sales a year.
- 8.14. The allowable ROC that 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.

- 8.15. 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. Scheme members 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.
- 8.16. Where a scheme member is satisfied that it will be assessed as a return on sales company, schedule 2 of the AFR is not required to be submitted.

Margin of Tolerance

- 8.17. The allowable return referred to in paragraphs 8.13 and 8.14 will be associated with a margin of tolerance (MOT). Scheme members will be able to retain profits of up to 150% of target. Scheme members will not be granted price increases unless they are forecasting profits less than 50% of target. Procedures for price increases are set out in Chapter 7.
- 8.18. 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.
- 8.19. If the Department's assessment of an AFR shows profits in excess of the MOT, it will negotiate one or more of the following:
- 8.19.1. repayments of that amount of profits which exceed the MOT;
 - 8.19.2. 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;
 - 8.19.3. a delay or restriction of price increases agreed for the scheme member or both.
- 8.20. 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.

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 scheme 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 4 qualifying products, 0.5% for the next 4 qualifying products and 0.25% of NHS home sales for qualifying products in excess of 8 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, which has been granted a new active substance marketing authorisation. The allowance will be given for a period of 10 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 3.19, 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:

- 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 scheme member 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:

- 2.0% of NHS home sales for each of active substance 1 and 2;
- 1.0% 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 scheme member'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 at Annex 16.
- 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 scheme member 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 scheme member'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 at Annex 16.
- 8.38. The information allowance will be calculated for each scheme member on the following basis:
- 8.38.1. Standard elements of 2% of home sales of NHS medicines for level 1 and 4% of home sales of NHS medicines for level 2.

9. Information Requirements for Annual Financial Returns (AFR)

9.1. Any scheme member with total home sales of NHS medicines of £50 million or more in its financial year will be required to provide an Annual Financial Return (AFR). The Department will select approximately 20% of qualifying scheme members for submission of a full, independently reviewed AFR each year, whilst other scheme members will be required to submit the following:

- AFR schedule 1 for all companies and schedule 2 if an ROC company;
- the product list set out in paragraph 9.5;
- Statutory accounts on which the AFR is based;
- Company declaration.

Scheme members required to complete the full return will be advised by the 31 January of the year that the full return is due.

9.2. AFRs as required by paragraph 9.1, together with supporting information (see specimen in Annex 16), will be completed annually and submitted to the Department by 30 September following the company year end.

9.3. Where a scheme member can demonstrate that for reasons beyond its control it cannot meet the time limits set out in paragraph 9.2, 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.

9.4. The Department will only recognise that an AFR has been submitted by a scheme member when all components of the AFR including relevant supporting documents have been submitted (see paragraph 9.1 or Annex 17 as appropriate). 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.

9.5. Scheme members should provide a list of the NHS home products that have been included within their AFR with NHS home sales of £100,000 or more (after discounts and rebates but gross of PPRS payments) for which variable rate (innovation and paediatric) R & D allowances or Marketing Product Servicing Allowances are sought. 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:

- calculating allowable expenditure under the R&D formula (see paragraphs 8.28 to 8.32);

- calculating allowable expenditure under the marketing formula (see paragraphs 8.33 to 8.35);
- 9.6. The Department will acknowledge receipt within fourteen 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.
- 9.7. If an assessment of the information submitted indicates that a payment is due to the Department, then this will be discussed with the company and a date for payment will be agreed. That date will be no later than one month after the date of the completion of the negotiations on an assessment.
- 9.8. The Department will use best endeavours to ensure the confidentiality of commercially sensitive information submitted by scheme members.

Small Companies

- 9.9. Any scheme member with total home sales of NHS medicines not exceeding £50 million in its financial year will be exempt from supplying financial information. However, the Department reserves the right to call for a full Annual Financial Return (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 16;
- 9.10. Any scheme member relieved of the commitment to supply full financial information as in paragraph 9.9 will remain subject to the need to contain costs and the price restraint provisions covered in Chapter 7. The Department reserves the right to call for a full AFR at any time if circumstances warrant it.
- 9.11. Subject to the provisions of paragraph 9.10 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

Distribution Margin

- 10.1. One of the objectives of the scheme is to encourage the efficient and competitive supply of medicines to the NHS. Individual scheme members are expected to follow good commercial practice in the distribution of their products.
- 10.2. Any scheme member that intends to change its overall distribution arrangements during the lifetime of this scheme 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.
- 10.3. The Department will collect information on sales to retail pharmacy from scheme members annually and monitor any changes in the supply chain as per this paragraph. This information will be considered as part of the independent reconciliation exercise to be carried out during 2016 and may result in corrective action. Information is required from scheme Members with Sales of Scheme Products to the NHS of £5 million or more a year in the form of the unaudited Annual Presentation Level Sales Report. This information should be sent to the Department in electronic format using a copy of the Excel spreadsheet provided by the Department to scheme members and replicated at Annex 8 within nine months of the financial year end. A company declaration (Annex 9) should accompany the data submitted.
- 10.4. 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 scheme member will discuss and agree any adjustments to those distribution arrangements and where the scheme member has influence on the pharmacy discount, this may include the scheme member separately paying a sum of money to the Department equal to any additional costs to the NHS.
- 10.5. This provision does not affect the right of scheme members 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

- 10.6. The Department and the ABPI have published guidelines to ensure best practice in the notification of product discontinuations, and in the notification and management of medicines shortages. The guidelines are available at <https://www.gov.uk/government/publications/notification-and-management-of-medicines-shortages-abpi> and at <https://www.gov.uk/government/publications/notification-of-product-discontinuations-pharmaceuticals> and at www.abpi.org.uk.

- 10.7. 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 scheme to patient care.

Patent Expiry and Generic Market Entry

- 10.8. As products near the end of their patent lives, the Department does not expect scheme members 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 6 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.

Information on Homecare

- 10.11. The ABPI will work with the Department to develop a methodology for how homecare sales are reported. The ABPI will write to all scheme members encouraging them to write to all the homecare providers whom they supply with medicines to confirm that they have no objection to those homecare companies sharing sales value and volume data pertaining to their company's products with the Department.

11. Dispute Resolution

- 11.1. The Department and individual scheme members undertake to operate the scheme so that issues arising between any scheme member(s) and the Department are normally resolved by discussion between the scheme member(s) 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 refer to the panel matters that span the interests of the broader membership and not just an individual member. For example, if there is a dispute arising out of the reconciliation exercise for PPRS Payments (described at paragraphs 6.37 – 6.40) as regards the proposed correction of the outturn data and re-profiling of PPRS Payments, then it would be more appropriate for the ABPI and the Department to seek resolution through the Dispute Resolution Panel than for an individual scheme member or members to do so. However, the provisions in Chapter 4 ('Access and Outcomes') are excluded from dispute resolution as they will be monitored through MISG. The provisions relating to the process to be followed when referring a dispute to the panel will apply to a dispute referred by the ABPI in the same way as a dispute referred by a scheme member.
- 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 28 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 party instigating the dispute must provide the Dispute Resolution Panel with a reasoned statement of its position with regard to the dispute within 28 days of the notice of dispute. A reasoned statement of position shall consist of a reasonably detailed account of that party's position which captures the scope of the discussions to be had in front of the panel with regard to the event in dispute. The non-instigating party will then have a further 28 days in which to provide a reasoned statement of position in response. Statements will be made available to the parties. They may be supplemented in response to questions arising during the dispute resolution procedure. For administrative ease each reasoned statement of position should be sent to the secretariat.
- 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 arrange the date of the hearing within 20 days of the receipt of the non-instigating party's reasoned statement of position and to hold the hearing within 45 days

of the receipt of same. 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 or such other timeframe as the parties and the panel shall agree. All information provided to the panel members and the panel members' 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 formal hearing before the panel. The parties will be offered the opportunity of an informal meeting with the Chairman of the panel sitting alone following receipt of reasoned statements of position from the parties to explore the possibility of a compromise and settlement of the dispute in question. That process will be considered independent of any formal hearing before the panel.
- 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 practice 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 in respect of a dispute will be shared equally by the parties to that dispute. The parties to each dispute will be responsible for paying their own costs.
- 11.11. The Department and the ABPI shall publish on their websites the decision of the panel after the redaction of commercially sensitive information. The parties to any dispute shall have an absolute right to see the decision of the panel in their case before publication. In determining what is commercially sensitive for the purposes of publication of the decision on the respective websites only, the parties have a right of veto in deciding which details of a decision are commercially sensitive in relation to their own data. This does not affect any legal obligation to publish information, such as pursuant to the FOI.

- 11.12. The Department, the ABPI, scheme members and the members of the Dispute Resolution Panel as a condition of their appointment as members of the panel 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 18.

Annex 1: 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 THE SCHEME) REGULATIONS 1999

CERTIFICATE OF CONSENT FOR THE SCHEME TO BE TREATED AS APPLYING

Name.....

[name of company, partnership etc.]

Address

.....

.....

1. I [name of person signing & capacity in which signing, (e.g. director, partner or other)] certify that the above named company/partnership/person¹ hereby consents to the scheme made between the Association of the British Pharmaceutical Industry and the Secretary of State in December 2013 (known as the 2014 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/him³.

2. I am duly authorised to sign this certificate.

Signed

Date

¹ Delete as appropriate

² Only insert date where a modification to the Scheme has been agreed

³ Delete as appropriate

FORM B

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

CERTIFICATE OF NOTICE OF WITHDRAWAL OF CONSENT FOR THE 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 & capacity in which signing (e.g. director/partner/other)] certify that the consent of the above named company/partnership/person¹ to the scheme made between the Secretary of State and the Association of British Pharmaceutical Industry in December 2013 (known as the 2014 PPRS) being treated as applying to it will be withdrawn with effect from:

Date (*must be not less than three months after the date that this certificate is signed*).

2. I am duly authorised to sign this certificate.

¹ Delete as appropriate

Annex 2: 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 3: Forecasts, Allowed Growth Rates and Initial Profile of Payment Percentages

1. The table below sets out for each year of the scheme the agreed:
 - initial forecast Growth Rate of Measured Spend (F%);
 - Allowed Growth Rate of Measured Spend (AGR);
 - initial forecast of New Products Share of Measured Spend (NP%);
 - initial annual payment percentage for companies in the scheme (P1);
 - estimated future annual payment percentages (FP2-5).

	2014	2015	2016	2017	2018
Initial forecast Growth Rate of Measured Spend (F%)	3.87%	3.52%	3.86%	2.14%	3.09%
Allowed Growth Rate of Measured Spend (AGR)	0%	0%	1.8%	1.8%	1.9%
Initial forecast of New Products Share of Measured Spend (NP%)	0.47%	1.85%	3.37%	5.13%	7.01%
Initial annual payment percentage (P%1)	3.74%				
Estimated future annual payment percentages (2015-2018) (FP%2, FP%3, FP%4, FP%5)		7.13%	9.92%	9.92%	9.92%

2. The Allowed Growth Rate of Measured Spend percentage (AGR) figures will remain fixed as above for the whole period of the scheme and will not be revised.
3. The payments apply to Sales Covered by the PPRS Payment, as defined at paragraph 6.7 of Chapter 6.
4. As new products are exempt from the PPRS Payments, but are included in the Measured Spend, the payment percentage is proportionately increased to take account of the percentage of new products and the resulting payment shortfall.

5. The first annual payment percentage (P1) will be 3.74% of Sales Covered by the PPRS Payment in 2014. This is based on the agreed forecast Growth Rate of Measured Spend for 2014 and will deliver a 0% growth rate for 2014 for those sales. All other payment percentages (P2, P3, P4 and P5) depend on how the forecast growth rate compares to outturn for the remaining years of the scheme, and will be adjusted on an annual basis, as explained in Annexes 4 and 5.
6. The second annual payment percentage (FP2) is expected to be 7.13% of Sales Covered by the PPRS payment in 2015. The actual payment percentage (P2) will depend on how the outturn compares to the joint forecast, but will be set such that there is a 0% Growth Rate of Measured Spend for 2015.
7. There is a smoothed payment percentage for the last three years of the scheme, and that is why the last three payment percentages (FP3, FP4 and FP5) are expressed as a constant percentage of 9.92% for 2016, 2017 and 2018. The smoothed forecast payment percentage for these last three years of the scheme is calculated as the sum of the forecast Measured Spend for the last three years of the scheme minus the sum of the forecast allowed Measured Spend for the last three years. This number is expressed as a percentage of forecast Sales Covered by the PPRS Payment.
8. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used.

Annex 4: Adjustments to Profile of Payments

Adjustment of forecast growth rates

1. The forecast growth rates for the remaining years of the scheme are adjusted to take account of the outturn for the previous year. The adjustments are outlined in the Table below (paragraph 17). Annex 5 sets out the methodology in more detail and the calculation formulae which will be used in each year of the scheme.
2. The forecast Growth Rate of Measured Spend (F%) is adjusted following the methodology set out below. In order to avoid volatility, and only for the first adjustment of the scheme in year two the correction of the forecast growth rate is half of the difference between the actual growth rate for year one and the forecast growth rate for year one. The difference could be a positive or negative figure and is expressed as a percentage. This is added to the initial forecast growth rate for each of the subsequent years to produce the adjusted forecast growth rate for each year.
3. For years three and following the correction is the average of the differences between actual growth rate and forecast growth rate for each previous year of the scheme. This is added to the initial forecast growth rate for each of the subsequent years to produce the adjusted forecast growth rate for each year.

Adjustment of forecast New Products Share of Measured Spend

4. The first adjustment to the New Products Share of Measured Spend will be in November 2014, which will affect the forecasted New Products Share of Measured Spend for 2015 to 2018. The original forecasted New Products Share of Measured Spend for 2015 to 2018 will be adjusted in an additive way based on the difference between the original forecasted share and the outturn share. The outturn share will be based on company reported sales for new products in quarter two 2014 and quarter three 2014 multiplied by two. This will give a first estimate for the sales of new products for 2014.
5. In November 2015, the first outturn data for the New Products Share of Measured Spend in 2015 will be available. The forecast sales of new products for 2015 will be estimated based on company reported sales for new products in quarter two and quarter three of 2015 multiplied by two. The New Products Share of Measured Spend for 2016, 2017 and 2018 will then be adjusted in percentage terms (i.e. in a multiplicative way) based on the average ratio in 2014 (based on audited data) and 2015 (based on first outturn data for this year).
6. For the last three years of the scheme, the New Products Share of Measured Spend will be adjusted based on a rolling two year average. Thus, for example, in November 2016 the forecast New Products Share of Measured Spend for 2017 and 2018 will be adjusted based on the average error for 2015 (based on audited data) and 2016 (based on first outturn – quarter two and quarter three multiplied by two).

Adjustment of payment percentages

7. The 'error' in the payment due in a given year is the difference between the actual cash payment made, and the payment that would have been made had the forecast been accurate. This figure could be either positive or negative. For each year there is an initial error figure calculated on the basis of unaudited outturn data and a revised error figure calculated on the basis of audited outturn data. This is illustrated in the table below (paragraph 17). Due to end year dates for Statutory Accounts, it is possible that audited outturn will not cover the full year for the year in question. What follows assumes that all audited data is available the following year. How differing end year statutory accounts are dealt with is covered in paragraph 16 below.
8. The error is spread equally over the remaining scheme years, and the new payment percentage takes this and the revised forecast growth rates into account.
9. The smoothed payment percentages for 2016, 2017 and 2018 is the total forecast payment for the remaining years of the scheme divided by the sum of the adjusted forecast net spend on sales covered by the PPRS payment adjusted for the payment error for each of the remaining years of the scheme. This number is expressed as a percentage of the revised spend on sales covered by the PPRS payment.
10. In the event that the outturn of the Growth Rate of Measured Spend is lower than the Allowed Growth Rate of Measured Spend, the payment for that year is set at zero. If adjustments to the future payment cannot compensate for Industry overpayments during the early stages of the scheme, then the Department will refund companies the full amount of the payment each company has made for the years when the payment percentage is adjusted to zero.

Timing of the adjustments

11. The initial base 2013 calendar year Measured Spend outturn will be captured in a Sales Report completed by scheme members by the end of March 2014 broken down into quarters. This will be independently audited by September 2014. Scheme members will use the Sales Report pro-forma at Annex 7, Appendix 1) for both the quarterly and annual report of sales in the baseline year. The annual baseline year sales report will be audited according to the requirements set out at paragraphs 6.24-6.30 of Chapter 6.
12. Outturn of Measured Spend is calculated following the close of the third quarter of each calendar year. The outturn is the actual Measured Spend for the twelve months ending in September – i.e. including the fourth quarter of the previous calendar year. This is in order that the adjustments can be calculated and set in advance of the following calendar year. For the adjustment to the 2015 payment percentage in November 2014 this will be based on January to September 2014 versus the same period in 2013. Once the Audited Annual Reports for 2013 and 2014 have been received, the outturn Growth Rate of Measured Spend for 2014 will be calculated by comparing the twelve months 1 January 2013 to 31

December 2013 with the twelve months 1 January 2014 to 31 December 2014. This will apply to the calculation of the year 3 (2016) payment.

13. Following the independent audit of the accounts after the end of each year (expected to be completed by September of the following year) any corrections necessary to the aggregated outturns are then fed into the calculation of the adjustment of the payment percentage for the year after. So for year one (2014) any corrections to the outturn following the audited accounts received by September 2015 in year two will be fed into the adjustment calculations for the payment percentage for years three and following (2016, 2017 and 2018). See table in paragraph 17 for more details.
14. Where the auditors recommended approach for accounting for Sales Covered by the PPRS Payment differs from the approach adopted by the scheme member, the scheme member will adopt the methods recommended by the auditors for future Sales Reports.
15. Each time a scheme member leaves or joins the scheme and/or exceeds/falls below the smaller company exemption the baseline outturn figures will be adjusted to include the outturn sales for all of the scheme members who are members of the scheme at the time the adjustment is carried out and only those scheme members. Scheme members that join the scheme after the end of the third quarter in any calendar year will need to submit a Sales Report for the last quarter of that year within one month and an Audited Annual Sales Report for that year within nine months of the end of that year in order for their sales to be included in the baseline year in which they joined the scheme. The calculation of the outturn Growth Rate of Measured Spend for any year will exclude any scheme members where there is not sales data for both that and the previous year. The best available data will be used at each point that adjustments are made (this could include part year audited and part year unaudited data). When audited data becomes available this will be used to make further corrections as necessary.
16. All scheme members will be required to submit their Audited Annual Sales Report within nine months of the end of the scheme member's financial year. Where the financial year end date differs from the end of the calendar year (31 December) the best available data will be used at each point that adjustments are made (this could include part year audited and part year unaudited data). When audited data becomes available this will be used to make further corrections as necessary. This also covers data relating to the baseline period (2013). It is also possible that information may come to light, for example during the reconciliation exercise, that means that additional adjustments are required to the Measured Spend and therefore the forecasts and payment percentages, which are not set out in the table at paragraph 17. This will be agreed with the auditors on the basis of how to best represent measured spend historically and for future adjustments.

Timetable for adjustments

17. The payment percentages are adjusted each year to the attached timetable. There is a reconciliation exercise with administrative data carried out in 2016 as described in paragraphs 6.37-6.40 of Chapter 6. Bracketed adjustments are calculated and applied in the same exercise and result in a single adjustment to the payment percentage for the year they apply to (plus knock on adjustments to the profile for expected payment percentages for the remaining years of the scheme).

Outturn year	Payment percentage profile adjusted for Years	Based on actual spend for	Calculated when	Applies to payment in Year
Year 1 - 2014	Years 2-5	Audited 9 months ending 30/9/13 Unaudited 9 months ending 30/9/14	Sept 2014 Nov 2014	Year 2 – 2015 (P2)
Year 1 - 2014	Years 3-5	Audited 12 months ending 31/12/13 Audited 12 months ending 31/12/14	Sept 2014 Nov 2015	Year 3-2016 (P3)
Year 2 - 2015	Years 3-5	Unaudited 12 months ending 30/9/15	Nov 2015	Year 3 – 2016 (P3)
Years 1 & 2 – 2014 & 2015	Years 4-5	Audited & reconciled 12 months ending 31/12/14 Audited & reconciled 12 months ending 31/12/15	Nov 2016	Year 4 – 2017 (P4)
Year 3 - 2016	Years 4-5	Unaudited 12 months ending 30/09/16	Nov 2016	Year 4 – 2017 (P4)
Year 3 - 2016	Year 5	Audited 12 months ending 31/12/16	Nov 2017	Year 5 – 2018 (P5)
Year 4 - 2017	Year 5	Unaudited 12 months ending 30/9/17	Nov 2017	Year 5 – 2018 (P5)

Annex 5: Payment Scheme Calculation Formulae

1. The following tables and formulae outline the inputs and methodology used to calculate the scheme’s payments. The first year’s payment is based on the forecast below. All subsequent payment percentage estimates are based on adjustments to the agreed initial forecast Growth Rate of Measured Spend (F%) and the initial forecast of new products (NP%).
2. The initial forecast measured spend, F, is calculated using baseline spend in 2013 (Year 0) grown in line with the initial forecast Growth Rate of Measured spend (F%). The allowed spend, AS, is estimated by growing 2013 baseline spend in line with allowed growth rate of measured spend (AGR). The values of F%, NP% and AGR are presented in the table below:

Table 1

	2014	2015	2016	2017	2018
Initial forecast growth rate of measured spend (F%)	3.87%	3.52%	3.86%	2.14%	3.09%
Initial forecast of new products (NP%)	0.47%	1.85%	3.37%	5.13%	7.01%
Allowed Growth Rate of Measured Spend (AGR)	0.0%	0.0%	1.8%	1.8%	1.9%

3. The key parameters to calculate are the five payment percentages for 2014 to 2018 (P%₁, P%₂, P%₃, P%₄ and P%₅). For year 1, this is set already. Once data becomes available, the payment percentages for years 2 to 5 are adjusted. The methodology to re-calculate these percentages is broadly the same (although there are slight differences, for example, on how to adjust for revisions in the forecast to reduce volatility, and how to incorporate payment errors), and several steps are taken. All the algebra is shown below.
4. First, the forecast growth rates for the remaining years of the scheme are adjusted to take account of the outturn for the previous year. Second, the forecast new products share of measured spend is adjusted. This gives us the adjusted forecast measured spend and the adjusted forecast measured spend excluding new products. Thirdly, a correction is made to compensate for any over or under payment in previous years once the most recent outturn data has been incorporated. Based on these three adjustments, a correction for the error in the payment is calculated, which is spread

across the remaining years of the scheme. This information is then used to calculate the payment percentages.

- Please note that any reference to latest outturn estimate (L_O) below refers to the latest estimate of outturn that will be available when the payment is calculated for a particular year. The latest estimate of outturn may be based on audited company returns or provisional company returns and will vary from year to year i.e. L_{O1a} , when calculating the year 2 payment is not the same as L_{O1b} when calculating the year 3 payment¹ etc. The same applies to estimated outturn New Product Shares (e.g. $L_{NP\%01a}$), and error corrections of payments made (e.g. L_{O1a}).

Throughout the annex, the algebra is shown for the cells highlighted in green in the tables below.

2014 payment percentage calculation

- The agreed scheme requires an unsmoothed payment percentage, estimated to be 3.74% in 2014 ($P\%_1$ below).

In year 1 the following inputs are required for calculation of the payment percentage: ($P\%_1$)

	Year 1	Year 2	Year 3	Year 4	Year 5
Initial forecast growth rate of measured spend, $F\%$	$F\%_1$	$F\%_2$	$F\%_3$	$F\%_4$	$F\%_5$
Initial forecast measured spend, F	F_1	F_2	F_3	F_4	F_5
Initial forecast measured spend excluding new products, F_{NP}	F_{NP1}	F_{NP2}	F_{NP3}	F_{NP4}	F_{NP5}
Allowed spend, AS	AS_1	AS_2	AS_3	AS_4	AS_5
Initial forecast share of new products spend, $NP\%$	$NP\%_1$	$NP\%_2$	$NP\%_3$	$NP\%_4$	$NP\%_5$
Annual payment percentage, $P\%$	$P\%_1$				
Estimated future annual payment percentages (2015-2018), $FP\%$		$FP\%_2$	$FP\%_3$	$FP\%_4$	$FP\%_5$

¹ Note that revisions to outturn data could occur for a number of reasons, and therefore adjustments to the payment percentage may incorporate revised outturn estimates for any previous year, right up to 2017 when the final adjustment is made. The PPRS explicitly accounts for seven adjustments between 2014 and 2018 but there might be further adjustments for individual companies if their financial year end date differs from the end of the calendar year. Post 2017, individual company adjustments will be made to compensate for any error that has occurred in the payments, resulting from revisions to their sales data right up to their final year audited figures being available.

7. Calculation of allowed spend:

$$AS_1 = F_0 * (1 + AGR_1)$$

$$AS_2 = AS_1 * (1 + AGR_2)$$

$$AS_3 = AS_2 * (1 + AGR_3)$$

$$AS_4 = AS_3 * (1 + AGR_4)$$

$$AS_5 = AS_4 * (1 + AGR_5)$$

8. Similarly, the estimates of the initial forecast measured spend and the initial forecast measured spend excluding new products is as follow:

$$F_1 = F_0 * (1 + F\%_1)$$

$$F_{NP1} = F_1 * (1 - NP\%_1)$$

Therefore the payment percentage for year 1 is:

$$P\%_1 = (F_1 - AS_1) / F_{NP1}$$

The results from these equations, using the values presented in Table 1, give a value of P%₁ equal to 3.74% as above.

2015 payment percentage calculation

9. The agreed scheme requires a payment percentage in 2015. Based on the initial values presented in Table 1, the payment percentage for 2015 is currently estimated to be 7.13% (FP%₂).

In year 2 the calculation of payments requires adjustments due to the availability of indicative outturn estimates for year 0 (the base year, L₀₀) and year 1 (both available in Q3 of year 1).

	Year 1	Year 2
Initial forecast growth rate of measured spend, F%	F% ₀₁	F% ₀₂
Initial forecast measured spend, F	F ₁	F ₂
Initial forecast measured spend excluding new products, F _{NP}	F _{NP1}	F _{NP2}
Allowed measured spend, AS	AS ₁	AS₂
Initial forecast share of new products spend, NP%	NP% ₀₁	NP% ₀₂
Annual payment percentage, P%	P% ₀₁	P%₀₂
Latest outturn estimate growth rate, L _O %	L _O % _{1a}	
Latest outturn estimate of measured spend, L _O	L_{O1a}	
Latest share of new product estimate, L _{NP} %	L _{NP} % _{1a}	
Latest outturn estimate excluding new products, L _{ONP}	L_{ONP1a}	
Error correction of payments made	Ec₁	
Adjusted forecast growth rate of measured spend, Fa%		Fa%₀₂
Adjusted forecast measured spend, Fa		Fa₂
Adjusted forecast share of new product spend, NPa% ₀₂		NPa%₀₂
Adjusted forecast measured spend, excluding new products, Fa _{NP}		Fa_{NP2}

10. The forecast growth rate of measured spend (adjusted) takes into account the following adjustments:

Latest outturn estimates:

$$L_{O1a} = L_{O0a} * (1 + L_{O\%1a})$$

$$L_{ONP1a} = L_{O1a} * (1 - L_{NP\%1a})$$

Adjustment for forecast error:

$$Fa\%_2 = F\%_2 + (L_{O\%1a} - F\%_1)/2$$

Adjustment for error in forecasting new products²:

$$NPa\%_2 = NP\%_2 + (L_{NP}\%_{1a} - NP\%_{01})$$

11. These adjustments are used to calculate the following variables:

Adjusted forecast measured spend:

$$Fa_2 = LO_{1a} * (1 + Fa\%_2)$$

Adjusted forecast measured spend, excluding new products:

$$Fa_{NP2} = Fa_2 * (1 - NPa\%_2)$$

12. Correction for error in payment (amortised to remaining years of the scheme)³:

$$EC_1 = ((LO_{1a} - AS_1) - (L_{ONP1a} * P\%_{01}))/4$$

13. Therefore the payment percentage for year 2 is:

$$P\%_2 = (Fa_2 - AS_2 + EC_1) / Fa_{NP2}$$

2016 payment percentage calculation

14. The agreed scheme requires a smoothed payment percentage in 2016. This smoothing effect will take into account the payment percentages due in 2016, 2017 and 2018 given the latest outturn (and resulting payment errors). Based on the initial values presented in Table 1, the smoothed payment percentage in 2016 is currently estimated to be 9.92%.

In year 3 the calculation of payments requires adjustments due to the availability of audited outturn data for year 0 and year 1 and indicative outturn for year 2.

² Please note that this adjustment for new products is additive, whereas adjustments for 2016 – 2018 are multiplicative and use a two year moving average.

³ The division by 4 is because this is the number of remaining years (2015, 2016, 2017, 2018)

	Year 1	Year 2	Year 3	Year 4	Year 5
Initial forecast growth rate of measured spend, F%	F% ₀₁	F% ₀₂	F% ₀₃	F% ₀₄	F% ₀₅
Initial forecast measured spend, F	F ₁	F ₂	F ₃	F ₄	F ₅
Initial forecast measured spend excluding new products, F _{NP}	F _{NP1}	F _{NP2}	F _{NP3}	F _{NP4}	F _{NP5}
Allowed measured spend, AS	AS ₁	AS ₂	AS₃	AS ₄	AS ₅
Initial forecast share of new products measured spend, NP%	NP% ₀₁	NP% ₀₂	NP% ₀₃	NP% ₀₄	NP% ₀₅
Annual payment percentage, P%	P% ₀₁	P% ₀₂	P%₀₃		
Latest outturn estimate growth rate, L _O %	L _O % _{01b}	L _O % _{02a}			
Latest outturn estimate of measured spend, L _O	L_{O1b}	L_{O2a}			
Latest share of new product estimate, L _{NP} %	L _{NP} % _{01b}	L _{NP} % _{02a}			
Latest outturn estimate of spend excluding new products, L _{ONP}	L_{ONP1b}	L_{ONP2a}			
Error correction of payments made	EC ₁	EC₁₋₂			
Adjusted forecast growth rate of measured spend, Fa%			Fa%₀₃	Fa%₀₄	Fa%₀₅
Adjusted forecast measured spend, Fa			Fa₃	Fa₄	Fa₅
Adjusted forecast share of new product spend, NPa%			NPa%₀₃	NPa%₀₄	NPa%₀₅
Adjusted forecast measured spend, excluding new products, Fa _{NP}			Fa_{NP3}	Fa_{NP4}	Fa_{NP5}

15. The forecast growth rate of measured spend (adjusted) takes into account the following adjustments:

Latest outturn estimates:

$$L_{O1b} = L_{O0b} * (1 + L_{O}\%_{01b})$$

$$L_{ONP1b} = L_{O1b} * (1 - L_{NP}\%_{01b})$$

$$L_{O2a} = L_{O1b} * (1 + L_{O}\%_{02a})$$

$$L_{ONP2a} = L_{O2a} * (1 - L_{NP}\%_{02a})$$

Adjustment for forecast error:

$$Fa\%_3 = F\%_3 + \text{Average}(L_{O\%1b} - F\%_1, L_{O\%2a} - F\%_2)$$

$$Fa\%_4 = F\%_4 + \text{Average}(L_{O\%1b} - F\%_1, L_{O\%2a} - F\%_2)$$

$$Fa\%_5 = F\%_5 + \text{Average}(L_{O\%1b} - F\%_1, L_{O\%2a} - F\%_2)$$

Adjustment for error in forecasting new products:

$$NPa\%_3 = NP\%_3 * \text{Average}(L_{NP\%1b} / NP\%_1, L_{NP\%2a} / NP\%_2)$$

$$NPa\%_4 = NP\%_4 * \text{Average}(L_{NP\%1b} / NP\%_1, L_{NP\%2a} / NP\%_2)$$

$$NPa\%_5 = NP\%_5 * \text{Average}(L_{NP\%1b} / NP\%_1, L_{NP\%2a} / NP\%_2)$$

16. These adjustments are used to calculate the following variables:
Adjusted forecast measured spend:

$$Fa_3 = L_{O2a} * (1 + Fa\%_3)$$

$$Fa_4 = Fa_3 * (1 + Fa\%_4)$$

$$Fa_5 = Fa_4 * (1 + Fa\%_5)$$

Adjusted forecast measured spend, excluding new products:

$$Fa_{NP3} = Fa_3 * (1 - NPa\%_3)$$

$$Fa_{NP4} = Fa_4 * (1 - NPa\%_4)$$

$$Fa_{NP5} = Fa_5 * (1 - NPa\%_5)$$

17. Correction for error in payment⁴:

$$EC_{1-2} = [\sum((L_{O1b} - AS_1), (L_{O2a} - AS_2)) - \sum((L_{ONP1b} * P\%_1), (L_{ONP2a} * P\%_2))] / 3$$

18. Therefore the smoothed payment percentage for year 3 is:

$$P\%_3 = \sum((Fa_3 - AS_3 + EC_{1-2}), (Fa_4 - AS_4 + EC_{1-2}), (Fa_5 - AS_5 + EC_{1-2})) / \sum(Fa_{NP3}, Fa_{NP4}, Fa_{NP5})$$

2017 payment percentage calculation

19. The agreed scheme requires a smoothed payment percentage in 2017. This smoothing effect will take into account the payment percentages due in 2017 and 2018. Based on the initial values presented in Table 1, the smoothed payment percentage in 2017 is currently estimated to be 9.92%.

In year 4 the calculation of payments requires adjustments due to the availability of audited outturn data for years 1 and 2 and indicative outturn for year 3.

⁴ The division by 3 is because this is the number of remaining years (2016, 2017, 2018). EC_{1-2} is used instead of EC_2 as the error correction covers both years 1 & 2.

	Year 1	Year 2	Year 3	Year 4	Year 5
Initial forecast growth rate of measured spend, F%	F% ₀₁	F% ₀₂	F% ₀₃	F% ₀₄	F% ₀₅
Initial forecast measured spend, F	F ₁	F ₂	F ₃	F ₄	F ₅
Initial forecast measured spend excluding new products, F _{NP}	F _{NP1}	F _{NP2}	F _{NP3}	F _{NP4}	F _{NP5}
Allowed measured spend, AS	AS ₁	AS ₂	AS ₃	AS₄	AS ₅
Initial forecast share of new products measured spend, NP%	NP% ₀₁	NP% ₀₂	NP% ₀₃	NP% ₀₄	NP% ₀₅
Annual payment percentage, P%	P% ₀₁	P% ₀₂	P% ₀₃	P%₀₄	
Latest outturn estimate growth rate, L _O %	L _O % _{01c}	L _O % _{02b}	L _O % _{03a}		
Latest outturn estimate of measured spend, L _O	L_{O1c}	L_{O2b}	L_{O3a}		
Latest share of new product estimate, L _{NP} %	L _{NP} % _{01c}	L _{NP} % _{02b}	L _{NP} % _{03a}		
Latest outturn estimate of spend excluding new products, L _{ONP}	L_{ONP1c}	L_{ONP2b}	L_{ONP3a}		
Error correction of payments made ⁵	EC ₁	EC ₁₋₂	EC₁₋₃		
Adjusted forecast growth rate of measured spend, Fa%				Fa%₀₄	Fa%₀₅
Adjusted forecast measured spend, Fa				Fa₄	Fa₅
Adjusted forecast share of new product spend, NPa%				NPa%₀₄	NPa%₀₅
Adjusted forecast measured spend, excluding new products, Fa _{NP}				Fa_{NP4}	Fa_{NP5}

⁵ This error incorporates the over-delivery of payments due to smoothing as well as any error because outturn has changed.

20. The forecast growth rate of measured spend (adjusted) takes into account the following adjustments:

Latest outturn estimates:

$$L_{O1c} = L_{O0c} * (1 + L_{O\%01c})$$

$$L_{ONP1c} = L_{O1c} * (1 - L_{NP\%01c})$$

$$L_{O2b} = L_{O1c} * (1 + L_{O\%02b})$$

$$L_{ONP2b} = L_{O2b} * (1 - L_{NP\%02b})$$

$$L_{O3a} = L_{O2b} * (1 + L_{NP\%03a})$$

$$L_{ONP3a} = L_{O3a} * (1 - L_{NP\%03a})$$

Adjustment for forecast error:

$$F_{a\%4} = F_{\%4} + \text{Average}(L_{O\%01c} - F_{\%01}, L_{O\%02b} - F_{\%02}, L_{O\%03a} - F_{\%03})$$

$$F_{a\%5} = F_{\%5} + \text{Average}(L_{O\%01c} - F_{\%01}, L_{O\%02b} - F_{\%02}, L_{O\%03a} - F_{\%03})$$

Adjustment for error in forecasting new products:

$$NP_{a\%4} = NP_{\%4} * \text{Average}(L_{NP\%02b} / NP_{\%02}, L_{NP\%03a} / NP_{\%03})$$

$$NP_{a\%5} = NP_{\%5} * \text{Average}(L_{NP\%02b} / NP_{\%02}, L_{NP\%03a} / NP_{\%03})$$

21. These adjustments are used to calculate the following variables:

Adjusted forecast measured spend:

$$F_{a4} = L_{O3a} * (1 + F_{a\%4})$$

$$F_{a5} = F_{a4} * (1 + F_{a\%5})$$

Adjusted forecast measured spend, excluding new products:

$$F_{aNP4} = F_{a4} * (1 - NP_{a\%4})$$

$$F_{aNP5} = F_{a5} * (1 - NP_{a\%5})$$

22. Correction for error in payment⁶:

$$EC_{1-3} = [\sum((L_{O1c} - AS_1), (L_{O2b} - AS_2), (L_{O3a} - AS_3)) - \sum((L_{ONP1c} * P_{\%01}), (L_{ONP2b} * P_{\%02}), (L_{ONP3a} * P_{\%03})]/2$$

23. Therefore the smoothed payment percentage for year 4 is:

$$P_{\%4} = \sum((F_{a4} - AS_4 + EC_{1-3}), (F_{a5} - AS_5 + EC_{1-3}))/ \sum(F_{aNP4}, F_{aNP5})$$

⁶ The division by 2 is because this is the number of remaining years (2017, 2018). EC₁₋₃ is used instead of EC₃ as the error correction covers both years 1, 2 & 3.

2018 payment percentage calculation

24. As this is the final year no smoothing is possible. In year 5 the calculation of the payment percentage requires adjustments due to the availability of audited outturn data for years 1 to 3 and indicative outturn for year 4.

	Year 1	Year 2	Year 3	Year 4	Year 5
Initial forecast growth rate of measured spend, F%	F% ₀₁	F% ₀₂	F% ₀₃	F% ₀₄	F% ₀₅
Initial forecast measured spend, F	F ₁	F ₂	F ₃	F ₄	F ₅
Initial forecast measured spend excluding new products, F _{NP}	F _{NP1}	F _{NP2}	F _{NP3}	F _{NP4}	F _{NP5}
Allowed measured spend, AS	AS ₁	AS ₂	AS ₃	AS ₄	AS₅
Initial forecast share of new products measured spend, NP%	NP% ₀₁	NP% ₀₂	NP% ₀₃	NP% ₀₄	NP% ₀₅
Annual payment percentage, P%	P% ₀₁	P% ₀₂	P% ₀₃	P% ₀₄	P%₀₅
Latest outturn estimate growth rate, L _O %	L _O % _{01d}	L _O % _{02c}	L _O % _{03b}	L _O % _{04a}	
Latest outturn estimate of measured spend, L _O	L_{O1d}	L_{O2c}	L_{O3b}	L_{O4a}	
Latest share of new product estimate, L _{NP} %	L _{NP} % _{01d}	L _{NP} % _{02c}	L _{NP} % _{03b}	L _{NP} % _{04a}	
Latest outturn estimate of spend excluding new products, L _{ONP}	L_{ONP1d}	L_{ONP2c}	L_{ONP3b}	L_{ONP4a}	
Error correction of payments made ⁷	EC ₁	EC ₁₋₂	EC ₁₋₃	EC₁₋₄	
Adjusted forecast growth rate of measured spend, Fa%					Fa%₀₅
Adjusted forecast measured spend, Fa					Fa₅
Adjusted forecast share of new product spend, NP _a %					NP_a%₀₅
Adjusted forecast measured spend, excluding new products, Fa _{NP}					Fa_{NP5}

⁷ This error incorporates the over-delivery of payments due to smoothing as well as any error because outturn has changed.

25. The forecast growth rate of measured spend (adjusted) takes into account the following adjustments:

Latest outturn estimates:

$$L_{O1d} = L_{O0d} * (1 + L_{O\%01d})$$

$$L_{ONP1d} = L_{O1d} * (1 - L_{NP\%01d})$$

$$L_{O2c} = L_{O1d} * (1 + L_{O\%02c})$$

$$L_{ONP2c} = L_{O2c} * (1 - L_{NP\%02c})$$

$$L_{O3b} = L_{O2c} * (1 + L_{O\%03b})$$

$$L_{ONP3b} = L_{O3b} * (1 - L_{NP\%03b})$$

$$L_{O4a} = L_{O3b} * (1 + L_{O\%04a})$$

$$L_{ONP4a} = L_{O4a} * (1 - L_{NP\%04a})$$

Adjustment for forecast error:

$$Fa\%_5 = F\%_5 + \text{Average}(L_{O\%01d} - F\%_1, L_{O\%02c} - F\%_2, L_{O\%03b} - F\%_3, L_{O\%04a} - F\%_4)$$

Adjustment for error in forecasting new products:

$$NPa\%_5 = NP\%_5 * \text{Average}(L_{NP\%03b} / NP\%_3, L_{NP\%04a} / NP\%_4)$$

26. These adjustments are used to calculate the following variables:

Adjusted forecast measured spend

$$Fa_5 = L_{O4a} * (1 + Fa\%_5)$$

Adjusted forecast measured spend, excluding new products

$$Fa_{NP5} = Fa_5 * (1 - NPa\%_5)$$

27. Correction for error in payment::

$$EC_{1-4} = \sum((L_{O1d} - AS_1), (L_{O2c} - AS_2), (L_{O3b} - AS_3), (L_{O4a} - AS_4)) - \sum((L_{ONP1d} * P\%_1), (L_{ONP2c} * P\%_2), (L_{ONP3b} * P\%_3), (L_{ONP4a} * P\%_4))$$

28. Therefore the payment percentage for year 5 is:

$$P\%_5 = (Fa_5 - AS_5 + EC_{1-4}) / Fa_{NP5}$$

Annex 6: Data Sources

Initial forecasts

1. The initial forecast for Growth Rate of Measured Spend (F%) and the forecast of New Products Share of Measured Spend (NP%) have been agreed between the Department and the ABPI.

Data for PPRS payments

2. Individual payments by scheme members will be based on data on sales of health service medicines provide by scheme members, which will be independently audited at year end. Sales data should be net of all discounts. Scheme members will report their sales data for the PPRS Payment using the Quarterly Sales Reports and the Annual Audited Sales Reports as described at Annex 7.
3. The Department will treat as confidential information provided by companies on the estimated value of sales in the Quarterly Sales Reports. The Department cannot, however, guarantee that information provided would not be disclosable under Freedom of Information. Moreover the Department cannot undertake to keep the Audited Annual Sales Report or final annual payment confidential. The Department will notify a company promptly of the relevant content of any FOI request which pertains to that company's sales.

Outturn data

4. The Department of Health will use the Annual Audited Sales Reports in order to calculate the:
 - Outturn Measured Spend (including new products) in the base year (2013) and in each subsequent year of the scheme;
 - Outturn New Products Share of Measured Spend in the base year (2013) and in each subsequent year of the scheme.

The outturn spend figures will be calculated gross of the PPRS Payment actually paid (i.e. including the value of the PPRS Payment paid) but net of (i.e. after subtracting) any Historic Cash Payments (i.e. payments in lieu of price cuts under the 2009 PPRS which companies are still paying).

5. Scheme member Quarterly and Audited Annual Sales Reports will need to include sales of new products so that the outturn Measured Spend can be calculated. Sales of new products will be excluded from the sales used to calculate the PPRS Payment by each company. New products are defined as products introduced after 31 December 2013 following the granting of an EU or UK new active substance marketing authorisation from

the appropriate licensing body. This does not include biosimilars or line extensions of products originally introduced before 31 December 2013. Biosimilars and line extensions of products originally introduced before 31 December 2013 will be included in net sales for the purposes of calculating Sales Covered by the PPRS Payments.

6. All Quarterly and Annual Sales Reports for the PPRS Payments will be provided by scheme members to the Department and, at the same time, on a confidential basis to an independent third party, who will be appointed by the ABPI (such appointment subject to the Department's reasonable right to veto), to monitor the overall rate of growth of Measured Spend by scheme members relative to the Allowed Growth Rate of Measured Spend. The ABPI will be provided with this data on a consolidated basis by the independent third party following their receipt of the raw outturn data for the purposes of understanding the progress of the mechanism and changes to any payment values with the Department. Any changes to reported data that are made through subsequent discussion with the Department or as a result of the reconciliation exercise must be reported by the scheme member to the independent third party.

Annex 7: Guidance Notes on Completion of PPRS Payment Sales Reports

1. General

- 1.1. This annex sets out guidance on the completion of Quarterly and Annual PPRS Payments Sales Reports (Sales Reports) which are required to calculate the Growth Rate of Measured Spend. They also provide the mechanism for member companies to pay the Quarterly PPRS Payment to the Department.
- 1.2. The Sales Reports must show how the reported Sales of Scheme Products, Sales of PPRS Products, Measured Spend and the reported Sales Covered by the PPRS Payment relate to Turnover set out in the scheme member's Statutory Accounts submitted under the Companies Act 2006 (Audited Annual Sales Report) or underlying accounting records (Quarterly Sales Report). For the avoidance of doubt, Sales Covered by the PPRS Payment includes sales to NHS hospitals (unless subject to one of the exclusions set out section 3 below).
- 1.3. The "Turnover per audited Statutory Accounts" figure included in the Audited Annual Sales Report must be included in the primary statements or supporting notes of the applicable UK company Statutory Accounts. The UK company Statutory Accounts should be submitted with the Audited Annual Sales Report.
- 1.4. The Quarterly Sales Reports should be used by companies to calculate the PPRS Payment for each quarter. For 2014 the PPRS Payment should be 3.74% of Sales Covered by the PPRS Payment, i.e. Sales of PPRS Products (calculated net of all discounts and excluding sales that relate to brand equalisation deals¹) less the exclusions set out in section 3 below. The percentages applicable in subsequent years will be notified in the fourth quarter of the preceding year. A payment (BACS electronic transfer) should be completed at the same time as each Quarterly Sales Report is provided.
- 1.5. Given the importance of the Sales Reports to the operation of the 2014 PPRS and given that the Audited Annual Sales Report needs to reconcile to the company's UK Statutory Accounts, the auditor of the Statutory Accounts should also audit the Audited Annual Sales Report under International Standards on Auditing (ISAs) and report under ISA 805 – Special considerations – Audits of single financial statements and specific elements, accounts or items of a financial statement.
- 1.6. In the event that the Audited Annual Sales Report shows that there is an under payment, an adjustment payment (BACS electronic transfer) should be made at the point the Audited Annual Sales Report is submitted. In the event that the Audited Annual Sales Report shows there is an over payment, this amount should be deducted from the next Quarterly payment to correct this position.

¹ Brand Equalisation occurs where a scheme member offers dispensing contractors, whether directly or through wholesalers, additional discounts or rebates on branded medicines that result in them dispensing their brand against a generic prescription where there is a competitor generic presentation available.

- 1.7. Quarterly and Annual Sales Reports should be submitted to the Department and also to the independent third party, as set out in paragraph 6.23 of the scheme, details of whom will be confirmed to scheme members.

2. Information requirements and deadlines

- 2.1. The PPRS Payment will apply to Sales of PPRS Products (net of all discounts and excluding sales that relate to brand equalisation deals) less the exclusions set out in section 3 below. These are referred to as Sales Covered by the PPRS Payment.....² .
- 2.2. The information required to support these calculations will be provided in the PPRS Payments Sales Report, as shown in Appendix 1. The Sales Report (both Annual and Quarterly) should be accompanied by a Company Declaration as set out in Appendix 2. The Audited Annual Sales Report should be accompanied by an Independent Auditor's Report as set out in Appendix 3. The schedule starts with the total UK entity Turnover then deducts non-pharmaceutical sales, then deducts sales that are not classified as Scheme Products (the definition of Scheme Products is set out in paragraphs 3.14-3.19) and sales that relate to brand equalisation deals to arrive at net sales of PPRS Products. Net sales of PPRS Products should include sales of branded medicines to NHS hospitals. The net sales of PPRS Products, less the exclusions set out in section 3 below, but gross of sales of new products will then be aggregated to calculate the actual Growth Rate of Measured Spend. Sales of new products (as set out in paragraph 3.8) should then be deducted from Measured Spend to arrive at a net sales value for calculating the PPRS Payment due for the quarter. All Reports should be based on calendar quarters and years.
- 2.3. In order to calculate the actual Growth Rate of Measured Spend for 2014 to 2018 information is required for 2013. An analysis is required for the calendar year and for each calendar quarter. The annual information will need to be audited since it provides the baseline number for the calculation of medicines bill growth for 2014 versus 2013. This will be used to calculate the PPRS Payment percentage for 2015. Companies should use the Sales Report template at Appendix 1 to complete both the Quarterly and Audited Annual Sales Reports for 2013. The Audited Annual Sales Report for 2013 should be accompanied by a Company Declaration as set out in Appendix 2 and an Independent Auditor's Report as set out in Appendix 3.
- 2.4. The unaudited quarterly information for each quarter of 2013 is required no later than 31 March 2014. This will enable the Department and the ABPI to measure actual growth in Measured Spend on a quarterly basis from quarter one 2014. The audited annual information is required no later than nine months after the end of the scheme member's financial year (i.e. by 30 September 2014 if the financial year ends on 31 December 2013).
- 2.5. The unaudited Quarterly Sales Report for quarter one 2014 will be required no later than 30 April 2014. For each subsequent quarter the Quarterly Sales Report and payment is required no later than one calendar month after the quarter end.

² Words omitted as a consequence of amendments made to Chapter 6 as from 1st January 2017.

- 2.6. The Audited Annual Sales Report, which is in the same format as the Quarterly Sales Report, is required no later than nine months after the financial year end to allow time for the Statutory Accounts to be finalised.
- 2.7. In the event that a company has a financial year-end other than 31 December the Sales Report will need to analyse sales by calendar year. If the financial year end is not the end of a calendar quarter (i.e. 31 March, 30 June, 30 September or 31 December) the sales Report will need to analyse sales so that sales applicable to complete calendar quarters within the financial year can be identified. For example if a company has a November year-end the Sales Report would need to separately report December sales, January-September Sales and October-November sales. For the avoidance of doubt these sales when combined will still reconcile to the Turnover per the Statutory Accounts.
- 2.8. Where the scheme member's financial year end is not the end of a calendar year, the Department will use the best available data to calculate the PPRS Payment percentages. This could include audited data covering part of the year and unaudited data for the remainder. When the audited data becomes available this will be used to make further corrections as necessary.

3. Exclusions

- 3.1. Scheme members with Sales of Scheme Products of less than £5 million in the previous calendar year will not be required to make PPRS Payments to the Department. Their sales will not be included in the Measured Spend or the Allowed Growth Rate of Measured Spend.
- 3.2. In the case of scheme members with Sales of Scheme Products of less than £1m in 2013, eligibility for the exemption will be established at the start of the scheme and will continue throughout the period of the scheme provided that annual Sales of Scheme Products do not grow above £1m.
- 3.3. For scheme members with sales of Scheme Products over £1m but under £5m, eligibility for the exemption will be established at the start of each calendar year on the basis of the scheme member's sales data for the previous calendar year and will apply for the whole of a calendar year concerned whether or not the Sales of Scheme Products during that calendar year are above or below the threshold. This eligibility will be reassessed at the start of the following calendar year in the same way.
- 3.4. The arrangements for reporting by scheme members with sales of Scheme Products of less than £5 million in the previous calendar year are set out in section 4 below.
- 3.5. The Measured Spend and the Allowed Growth Rate of Measured Spend will not include the following central procurements: exceptional central procurements out-with the normal Annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation) and procurements of centrally supplied vaccines. These sales are excluded from the Measured Spend and the Sales Covered by the PPRS Payment.
- 3.6. The Measured Spend and the Allowed Growth Rate of Measured Spend will not include parallel imports i.e. medicines which are imported and supplied to the NHS by a party

other than the scheme member or a company that is affiliated to the scheme member such as a parent company.

- 3.7. Sales of new products launched after 31 December 2013 will need to be included in the Measured Spend but will be exempt from the PPRS Payment. Company Quarterly and Annual Reports will need to include sales of new products so that the total Measured Spend can be calculated. Sales of new products will be excluded from the Sales Covered by the PPRS Payment for each company.
- 3.8. For the purposes of the basic³ PPRS Payments Mechanism, new products are defined as products introduced after 31 December 2013 following the granting of an EU or UK new active substance marketing authorisation from the appropriate licensing body. This does not include biosimilars or line extensions of products originally introduced before 31 December 2013. Biosimilars and line extensions of products originally introduced before 31 December 2013 will be included in net sales for the purposes of calculating Sales Covered by the PPRS Payments.

4. Reporting by smaller companies

- 4.1 Scheme members with Sales of Scheme Products of less than £1m will be required to submit a company declaration on the value of their Sales of Scheme Products in 2013 by the end of March 2014 using the company declaration at Annex 10. These scheme members will continue to be exempt for the period of the scheme subject to submitting annual company declarations on the value of their Sales of Scheme Products for the previous calendar year by end March in each subsequent year of the scheme.
- 4.2 Scheme members with Sales of Scheme Products of more than £1m and less than £5m in 2013 will be required to submit an unaudited Annual Sales Report for the calendar year 2013 by March 2014 using the Sales Report pro-forma at Appendix 1 of Annex 7 and the company declaration at Annex 11. The Department will establish whether or not the scheme member falls within the criteria for the exemption based on this data. If their total Sales of Scheme Products for 2013 is less than £5m then they will not be required to make PPRS Payments or to submit Quarterly Sales Reports or Audited Annual Sales Reports for 2014. The scheme member will be required to submit an unaudited Annual Sales Report for 2014 by the end of March 2015 and, if the scheme member remains eligible for the exemption, for each subsequent year of the scheme by the end of March of the following calendar year.
- 4.3 If a scheme member's total Sales of Scheme Products in the unaudited Annual Sales Report is £5m or greater, then the exemption will cease to apply for the following calendar year. So if the sales total for 2014 submitted by end March 2015 shows that the scheme member's Sales of Scheme Products in 2014 were £5m or greater, then the Department will require the scheme member to make PPRS Payments for the whole of 2015, submitting the Quarterly Sales Reports and PPRS Payments and an Annual Audited Sales Report for 2015 according to the same procedure as other members of the scheme.

³ The word 'basic' has been inserted as a consequence of amendments made to Chapter 6.

- 4.4 If a scheme member has been making PPRS Payments because its Sales of Scheme Products were £5m or higher in the previous calendar year, but during the year its Sales of Scheme Products (gross of the PPRS Payment) dip below the £5m threshold, then it will become eligible for the smaller companies exemption in the following calendar year. For example if a scheme member was at or above the £5m threshold according to its Sales of Scheme Products for 2013 and made PPRS Payments for 2014, but the scheme member's Sales of Scheme Products gross of the PPRS Payment in 2014 fell below the £5m threshold, then it could apply for a smaller companies exemption for 2015 based on an unaudited Sales Report for 2014 submitted by the end of April 2015.

5. Defining Sales of PPRS Products

- 5.1. The reported net Sales of PPRS Products (defined at paragraph 6.5 of the scheme) should only include branded, licensed health service medicines supplied by scheme members (calculated net of all discounts and excluding sales that relate to brand equalisation deals).
- 5.2. There are four categories identified on the Sales Report as out of scope, namely non-UK sales, sales to non-health service customers (where the medicine is not for health service use), sales of products which are not covered by the scheme and brand equalisation deals.
- 5.3. Non-UK sales include:
- Sales to markets outside of the UK, including the Channel Islands and the Isle of Man. The UK legal entity could cover a wider geographical area than the UK, for example the UK and Ireland, so non UK sales need to be identified and excluded.
 - Direct exports from the UK to third parties.
 - Direct exports from the UK to affiliated companies.
 - Parallel Export sales which are sold by the UK entity but are not reimbursed by the NHS. See methodology section for more details.
- 5.4. Sales to non-health service customers: branded, licensed prescription medicines may be sold to customers other than the NHS providers or public health service providers so should be excluded in the Sales Report. This list may include:
- Over the Counter (OTC) products – some OTC medicines may be partially prescribed so those units do need to be included in net sales of PPRS Products. PCA and IMS provide prescription data. See methodology section for more details.
 - Private hospitals
 - Other private medicine sales – for example flu vaccines sold to retailers
 - Ministry of Defence
 - Clinical trial companies
 - Contract manufacturers
 - Other non-health service concerns such as cruise and holiday companies, occupational health practices or veterinary practices

The category of non-health service customer does not apply where service is provided by private or third sector providers for the NHS or for public health functions e.g. homecare providers.

- 5.5. Products which are not covered by the scheme: there are various product categories that are not covered. The definition of products covered is set out in paragraphs 3.14-3.15 of the scheme. Products which are not covered include generics, medical appliances and products listed at paragraph 3.17 of the scheme. The MHRA product licence states the product category. Other sources of information to determine product category include the British National formulary (BNF), the Prescription Cost Analysis (PCA) and the prescription drugs database MIMS.
- 5.6. Brand equalisation deal sales – these are recognised by the Department as part of the generic medicines bill rather than the branded medicines bill so should be excluded from the net sales of PPRS Products. See methodology section for more details.
- 5.7. If the PPRS Payment (under the scheme) is recognised in the Statutory Accounts and underlying accounting records as a reduction in turnover it needs to be added back in the Sales Report to arrive at the net sales of value that is used to calculate the Measured Spend and the Sales Covered by the PPRS Payments used to calculate the Quarterly PPRS Payment.

6. Methodology

- 6.1. There are certain calculations that need to be made where reliance is placed on data sources other than the scheme member's underlying accounting records. The following methodologies are recommended to help ensure that Sales Reports are as accurate as possible and within the materiality levels outlined in section 8.
- 6.2. Scheme members may consider that they have a more precise methodology. If that is the case then individual scheme member should agree an alternative methodology with the Department and agree this in writing so that it can form part of the audit trail.
- 6.3. Parallel exports – can be identified in several ways including IMS or PCA data versus ex-factory comparisons, irregular retail pharmacy ordering patterns and specific information from overseas affiliates. Depending on what distribution arrangements are in place companies may also have visibility of customer stock movements. Where possible parallel export units should be supported by the scheme member's accounting and supply chain records. Where IMS or PCA data is used scheme members should compare available year to date IMS or PCA units with ex-factory units for the same period. Given the time delay in receiving IMS and PCA data there will be a timing difference in quarters 1 to 4 but this can be corrected for in the Annual Report which has a 9 month deadline. Scheme members should ignore parallel export adjustments if they cannot provide a clear audit trail using company records and IMS or PCA data.
- 6.4. OTC prescription sales – if there is evidence that some OTC units are prescribed then companies should use either the latest available IMS or PCA data to calculate the percentage of OTC sales that are prescribed and therefore reimbursed by the NHS. This may result in an adjustment in the Annual Report versus the sum of the four quarters if the amount is material.

- 6.5. Brand Equalisation occurs where a scheme member offers dispensing contractors, whether directly or through wholesalers, additional discounts or rebates on branded medicines that result in them dispensing their brand against a generic prescription where there is a competitor generic presentation available. The deal value should be supported by internal records and financial transactions with customers.
- 6.6. Private medicine sales – if there is evidence that such sales are being sold privately and are therefore not reimbursed by the NHS, for example flu vaccines sold to retailers, then these sales should be excluded. Where possible private medicine sales should be supported by the company's accounting and supply chain records. Alternatively, latest available IMS or PCA data should be compared with ex-factory data to calculate the value of non-NHS sales.
- 6.7. Adjustments that rely on 3rd party information and an agreed methodology should be disclosed in Accounting Policies.

7. Other guidance

- 7.1. The number reported in the Audited Annual Sales Report as “Net sales of Scheme Products” should equal to the sales number in the NHS Medicines home column of the AFR Schedule 1.
- 7.2. Co-promotions - scheme members should agree in advance who is going to report sales in any co-promotion arrangements and disclose in Accounting Policies.
- 7.3. These guidance notes may be updated from time to time by way of a supplementary note, if further information comes to light that would help improve the accuracy of the Sales Reports.

8. Audit arrangements

- 8.1. As noted in paragraph 1.5, the appointed auditor of the Statutory Accounts should audit the Audited Annual Sales Report under International Standards on Auditing (ISAs) and the report issued under ISA 805 – Special considerations – Audits of single financial statements and specific elements, accounts or items of a financial statement.
- 8.2. In contracting with the scheme member and the Department to audit the Audited Annual Sales Report, the auditor must include the following required terms in relation to the audit engagement:
 - Limit of liability no less than £1m;
 - Materiality as per statutory audit, provided it is in the range of 0.5%-1.2% of Turnover. In the event that:
 - Materiality used for the statutory audit is in this range it can therefore be used.
 - Materiality used for the statutory audit is above this range 1.2% of Turnover is to be used (to ensure sufficient auditing of the sales Report).
 - Materiality used for the statutory audit is below this range 0.5% of Turnover is to be used (to avoid expensive over auditing of the sales Report);

- De minimis reporting threshold set at 10% of materiality.
- Each scheme member to meet PPRS Audited Annual Sales Report audit fees; and
- Audit plan (including details of materiality and reporting timetable) and report to those charged with governance (including an update on the materiality used and any unadjusted errors) to be provided to the Department at the same time they are provided to the scheme member.

Appendix 1: PPRS Payment Sales Report

COMPANY:

PERIOD COVERED:

	£'000
TURNOVER PER AUDITED STATUTORY ACCOUNTS (Annual Return) or TURNOVER PER MANAGEMENT ACCOUNTS (Quarterly Returns) (net of any Historic Cash Payments or PPRS Payments) LESS NON PHARMACEUTICAL SALES PHARMACEUTICAL TURNOVER	0
LESS ADJUSTMENTS:	
NON-UK Sales (For Example: Sales in markets outside of the UK, Direct Exports & Parallel Exports) This adjustment includes: Parallel Exports*	0
CUSTOMER EXCLUSIONS (For Example: OTC Medicines, Private Sales, MoD & Clinical Trial Companies) This adjustment includes: OTC non-prescription sales* Private medicine sales*	0
PRODUCT EXCLUSIONS (For Example: Generics & Medical Appliances)	0
Total Adjustments	0
NET SALES OF SCHEME PRODUCTS LESS: BRAND EQUALISATION SALES NET SALES OF PPRS PRODUCTS	0
ADD BACK: PPRS Payments under 2014 PPRS	
DEDUCT: Procurements of centrally supplied vaccines and stockpiled medicines	0
NET SALES SUBJECT TO MEDICINES BILL GROWTH CALCULATION (MEASURED SPEND)	0
DEDUCT: New products launched since 1st January 2014	
NET SALES COVERED BY THE PPRS PAYMENT	0
PPRS PAYMENT Full Year Less payments made in respect of: Q1 Q2 Q3 Q4 Correction Payments (please specify which quarter they relate to)	0
PPRS PAYMENT - (Over) / Under Payment for the Year	0
	3.74%**

*Adjustments that rely on 3rd party information and an agreed Methodology to be disclosed separately

** 2014 PPRS Payment. Percentages for future years will be set in the fourth quarter before the year concerned.

Appendix 2: Company Declaration

Statement of directors' responsibilities

The directors are responsible for complying with the 2014 Pharmaceutical Price Regulation Scheme and for designing, implementing and maintaining systems and controls which enable their preparing the [insert name of schedule] in accordance with the basis of preparation and accounting policies in [note 1 below] and the guidance notes in Annex 7 of the 2014 Pharmaceutical Price Regulation Scheme . The directors must not approve the [insert name of schedule] unless they are satisfied that they have been properly prepared, in all material respects, in accordance with the basis of preparation and accounting policies in [note 1] to the [insert name of schedule]. In preparing the [insert name of schedule], the directors have:

- selected suitable accounting policies and then applied them consistently;
- made judgements and accounting estimates that are reasonable and prudent;
- stated the basis of preparation and accounting polices applied;
- prepared the [insert name of schedule] on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the company's transactions and disclose with reasonable accuracy at any time the financial position of the company. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

PPRS Payment Sales Report sign off

The [insert name of schedule] was approved by the board of directors on [insert date] and signed on their behalf by:

[insert name]

[Director]

Note 1

Basis of preparation of the PPRS Payment Sales Report

[insert details of the basis of preparation e.g. The schedule has been prepared in accordance with the Pharmaceutical Price Regulation Scheme and the Guidance Notes in Annex 7 to the scheme.]

Accounting policies

[insert details of accounting policies used in preparing the schedule, including details of any estimates and source data used in these estimates and confirmation that the revenue recognition policy is consistent with the Statutory Accounts]

Appendix 3: Independent Auditors' Report

We have audited the Pharmaceutical Price Regulation Scheme (PPRS) PPRS Payments Audited Annual Sales Report, hereafter referred to as the 'special purpose financial information' of (name of entity) for the [year/period] ended [period end date] which comprise the [state the primary financial statements] and the related notes¹. The financial reporting framework that has been applied in its preparation is the basis of preparation and accounting policies in note 1 to the special purpose financial information.

Directors' responsibilities for the special purpose financial information

As explained more fully in the Company Declaration [set out [on page]] the directors are responsible for the preparation of the special purpose financial information in accordance with the basis of preparation and accounting policies in [note 1] to the special purpose financial information. This includes determining that the basis of accounting is an acceptable basis for the preparation of the special purpose financial information and for such internal control as management determines is necessary to enable the preparation of the special purpose financial information that is free from material misstatement, whether due to fraud or error.

Auditor's responsibilities

Our responsibility is to express an opinion on the special purpose financial information based on our audit. We conducted our audit in accordance with International Standards on Auditing. Those standards require us to comply with the ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the special purpose financial information is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the special purpose financial information. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the special purpose financial information, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the special purpose financial information in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates, if any, made by management, as well as evaluating the overall presentation of the special purpose financial information.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion

¹ This is a private report to the directors and as such we would not allow it to be published on the client's website. Auditor's reports of entities that do not publish their non-statutory financial statements on a web site may continue to refer to the non-statutory financial statements by reference to page numbers.

This report, including the opinion, has been prepared for and only for the directors and the Secretary of State for Health in respect of the PPRS Audited Annual Sales Report in accordance with our engagement letter dated [date] and for no other purpose. This report, including opinion, should not be given to any other party or referred to without our prior written consent. We do not, in giving this opinion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come including without limitation under any contractual obligations of the company, save where expressly agreed by our prior consent in writing.

Opinion

In our opinion the special purpose financial information for the year ended [period end date] has been properly prepared, in all material respects, in accordance with the basis of preparation and accounting policies in [note 1] to the special purpose financial information.

Basis of preparation

Without modifying our opinion, we draw attention to Note X to the special purpose financial information, which describes the basis of preparation. The special purpose financial information is prepared to for the purposes of the PPRS Payments Audited Annual Sales Report reporting. As a result, the special purpose financial information may not be suitable for another purpose.

[Auditor²]

[Chartered Accountants]

[Location]

[Date]

² The report is signed in the firm's name.

Annex 9: 2014 PPRS – Company Declaration for the Unaudited Annual Presentation Level Sales Report

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 6.

Signature..... Date.....

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

Signature..... Date.....

Name..... *(Finance Director/senior financial executive)*

Annex 10: 2014 PPRS – Company Declaration Covering Sales of Scheme Products less than £1m

Company:

Year ended:

Affiliated Companies consolidated in this Return:-

1.....

2.....

3.....

4.....

5.....

We can confirm that our Sales of Scheme Products for the above period amount to the total sum of

£.....

Signature..... Date.....

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

Signature..... Date.....

Name..... *(Finance Director/senior financial executive)*

Annex 11: 2014 PPRS – Company declaration covering unaudited Annual Sales Report for Sales of Scheme Products between £1m and £5m

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 6.

Signature..... Date.....

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

Signature..... Date.....

Name..... (*Finance Director/senior financial executive*)

Annex 12: 2014 PPRS Monitoring of Price Neutral Modulation

Company:	
Year or Year/Quarter:	
PPRS Reference¹:	

Code Number ²	Product Description	Strength	Pack Size	Historic Cash Payment Yes/No	Reference NHS List Price (£) ³	SECONDARY CARE SALES		NHS List Price (£) ⁵	SECONDARY CARE SALES		PRIMARY CARE SALES	
						Reference Average Selling Price (£) ⁴	Date From		Date To	Average Selling Price (£) ⁶	Quantity	Net Sales (£) ⁷

Notes:

1. PPRS company reference number
2. PPRS database presentation number
3. NHS list price at 31 December 2013
4. Average selling price for the period 1 January 2013 to 31 December 2013: net sales/quantity
5. NHS list price for a presentation during the relevant period
6. Spreadsheet calculation (average selling price for relevant period): net sales/quantity
7. Net Secondary Care Sales

Annex 13: 2014 PPRS – Independent Accountant’s Supplementary Report Covering Price Neutral Modulation

[headed paper]

The Directors
Company Address

INDEPENDENT ACCOUNTANT’S SUPPLEMENTARY REPORT COVERING PRICE NEUTRAL 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 price neutral modulation for the period as required under the Pharmaceutical Price Regulation Scheme 2014.

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 and net sales in secondary care 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 31 December 2013;
- 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 14: 2014 PPRS – Company Declaration Covering Price Neutral 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 15: 2014 PPRS - Schedule of Rates and Allowances

ROCE	Target	21%
ROS	Target	6%
MOT	Upper limit	150%
	Lower limit	50%

			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	Flat rate		12%	20%
	Variable Rate ⁽¹⁾	Innovation ⁽²⁾	<p>To a maximum of 28 active substances with NHS sales of £100,000 or more.</p> <p>The first four products at 0.75% of sales.</p> <p>The next four products at 0.50% of sales.</p> <p>The next 20 products at 0.25% of sales.</p>	<p>To a maximum of 28 active substances with NHS sales of £100,000 or more.</p> <p>The first four products at 0.75% of sales.</p> <p>The next four products at 0.50% of sales.</p> <p>The next 20 products at 0.25% of sales.</p>
		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 10 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 16: Guidance on Completion of the Annual Financial Return and Schedules

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 scheme member's figures, as provided for in chapter 8 of the scheme.
- 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, with 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 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 scheme members enter into a partnership, joint venture or other joint commercial arrangement relating to the sales of an NHS medicine to the NHS, the scheme members involved should each notify the Department when submitting their AFR. Each scheme member's notification should include for each NHS medicine involved, details of how sales to the NHS and associated expenses have been reported within their 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 scheme members 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 basis 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 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 to 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 this Scheme 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/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 professional judgement to ensure that the bases adopted are adequately explained in the accompanying notes and to qualify his 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 Home, NHS Export 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 formula. 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 home will also be excluded from NHS 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 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 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' to tie back to the accounts and then excluded in the column 'Items in audited accounts excluded from AFR.'
- 5.4. The 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 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 a mirror of 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, PPRS payments 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 3 of the scheme. 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, whilst 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 with sales in excess of £100,000 for which a innovation R & D allowance or paediatric allowance is claimed should be provided. For each product for which a variable rate innovation R&D allowance is claimed, the list should 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	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

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 has 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 to 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 or 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 paragraphs 7.8-7.10 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 & 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 & 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
		£0	£0	£0	£0	£0
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 & 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
	£0	£0	£0	£0	£0
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 & 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
		£0	£0	£0	£0	£0
FIXED ASSETS (at historic cost)		-	-	-	-	-
Land & Buildings	30					
Plant & 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 34)	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
	£0	£0	£0	£0	£0
FIXED ASSETS (at historic cost)	-	-	-	-	-
Land & Buildings 30					
Plant & 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

Company Declaration

AFR 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 2013 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, exports 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.

Signed.....

(Managing Director/Chief Executive)

Date.....

Signed.....

(Finance Director/senior financial executive)

Date.....

Pharmaceutical Price Regulation Scheme

[headed paper]

The Directors
Company
Address

Independent Accountant’s Report

AFR 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 give 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 2013, 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. ¹transfer 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

Annex 16: Guidance on Completion of the Annual Financial Return and Schedules

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 exist¹.

(Delete italics as appropriate)

Signature **Date**

Name

Address

.....

Professional Qualification

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

Annex 17: Checklist of Items to be Submitted for a Full AFR

Accounts

- ❑ Published accounts of UK company supplying medicines to 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.
- ❑ 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 products included in NHS home medicines 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 18: Dispute Resolution

- 1 Introduction
- 2 The law
- 3 Dispute Resolution Panel membership
- 4 Secretariat
- 5 Events giving rise to dispute resolution
- 6 Dispute resolution timetable
- 7 Conduct of hearings
- 8 Powers of the panel
- 9 Disputes arising from the 2005, 2008 and 2009 Pharmaceutical Price Regulations Schemes
- 10 After dispute resolution
- 11 Conclusion

1. Introduction

- 1.1 This annex is a broad outline of the functions of the scheme 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 scheme is such a voluntary scheme.

- 2.3 Membership of the scheme 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 scheme, 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 do not have access to the panel, save for the sole exception described in paragraph 5.2.6.
- 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 scheme⁵. 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. Dispute Resolution Panel membership

- 3.1 The panel will comprise:
 - 3.1.1 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
 - 3.1.2 two members, one appointed by the Secretary of State and the other by the ABPI.
- 3.2 The panel will sit as the Chairman and both members. The Chairman may not sit alone for any formal hearing before the panel.

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

² The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013. SI 2013/2881 coming into force on 1st January 2014.

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

⁴ As defined in section 265(7) of the National Health Service Act 2006 (c. 41)

⁵ An event within the meaning of chapter 11.4 of the scheme, and see also paragraph 5.2 of this annex.

- 3.3 In the event that the Chairman is not legally qualified as described in paragraph 11.7.1 a solicitor or barrister qualified to practice 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.

4. Secretariat

- 4.1 Chapter 11 of the scheme provides that the secretariat shall be provided jointly by the Department and the ABPI.

- 4.2 Communications to the secretariat shall be addressed to:

The Secretariat
Department of Health
456.D
Skipton House
80 London Road
London SE1 8LH
Tel: 020 7972 2879

and to:

The Secretary to the Association of the British Pharmaceutical Industry
7th Floor, Southside,
105 Victoria Street,
London SW1E 6QT
Tel: 0870 890 4333

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

- 4.3 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 the panel.
- 4.4 Similarly, it shall be the duty of the secretariat to make available to parties to a dispute communications from the panel.
- 4.5 The duties described in paragraphs 4.3 and 4.4 shall be discharged as soon as possible after receipt of a communication and, in any event, not later than two working days from receipt.

5. Events giving rise to dispute resolution

- 5.1 Within the terms of chapter 11 of the scheme, the Department and scheme members will have the right to dispute resolution.
- 5.2 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 comprehensive. In each case, it will be for the scheme member to comply with the Department's view or to seek dispute resolution.

- 5.2.1 Failure to agree the value of sales of a company which are covered by the PPRS Payment.
 - 5.2.2 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.
 - 5.2.3 Refusal to allow a general price increase or limitation to such an increase.
 - 5.2.4 Refusal to allow a price modulation within the meaning of Chapter 7 of the scheme.
 - 5.2.5 Failure to agree allowed prices of products sold on from one company to another.
 - 5.2.6 A request to provide information required by the Department in connection with the operation of the scheme.
 - 5.2.7 Notice given by the Secretary of State (other than under paragraph 10.1.3 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.
- 5.3 A company that has been refused scheme membership of the scheme shall not have any right of dispute resolution under paragraph 5.2.7.

6. Dispute resolution timetable

- 6.1 The Department shall give detailed written notice to the scheme member of any view falling within the ambit of paragraphs 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5 and 5.2.6 or of any other view or decision that might give rise to a scheme member seeking dispute resolution under the scheme. This notice should explain the Department's position fully so as to assist the scheme member in deciding whether to proceed to dispute resolution.
- 6.2 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 4.2).
- 6.3 Within 28 days of such notice given under paragraph 6.2, the party instigating the dispute must provide the panel with a reasoned statement of its position. A reasoned statement of position shall consist of a reasonably detailed account of that party's position which captures the scope of the discussions to be had in front of the panel with regard to the event in dispute. The non-instigating party will then have a further 28 days in which to provide a reasoned statement of position in response. For administrative ease each reasoned statement of position should be sent to the secretariat.
- 6.4 Insofar as possible the panel shall be expected to arrange the date of the hearing within 20 days of the receipt of the non-instigating party's reasoned statement of position and to hold the hearing within 45 days of the receipt of same. 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.

- 6.5 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 or such other timeframe as the parties and the panel shall agree.
- 6.6 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.
- 6.7 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.
- 6.8 The parties should comply with the effective date given by the panel in its decision.

7. Conduct of hearings

- 7.1 Hearings will be informal and shall not be bound by strict rules of evidence or legal procedure.
- 7.2 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.
- 7.3 Information submitted pursuant to the hearing shall be restricted as in paragraph 7.2.
- 7.4 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.
- 7.5 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.
- 7.6 The conduct of the hearing will be for the panel Chairman to decide in matters such as order of business, questions and evidence.
- 7.7 Each party shall be responsible for its own costs.
- 7.8 The ABPI shall be entitled to circulate the number and in broad terms, the nature of cases that have been referred to dispute resolution, to scheme members at regular intervals.

8. Powers of the panel

- 8.1 The panel may request any information from either party that it considers necessary to determine any point of fact.

- 8.2 The panel may call any expert witness whom it considers necessary to determine any point of fact.
- 8.3 The panel may not, without the express consent of the parties, extend any of the time limits given in Chapter 11 or paragraphs 6.2 to 6.8.
- 8.4 The panel shall either refer a matter to the Department for reconsideration under direction or substitute its own decision in respect of that matter.
- 8.5 The panel may decide an effective date as appropriate for any substituted decision in the case of the following (such list is not exhaustive):
 - 8.5.1 value of the sales by a company which are covered by the PPRS Payment, the date that the payment fell due;
 - 8.5.2 payment of excess profits, the original date;
 - 8.5.3 refusal of a general price increase, any date on or after the date of the panel's decision;
 - 8.5.4 referral of a price modulation, any date on or after the panel's decision;
 - 8.5.5 allowed price of products sold, any date on or after the panel's decision; and
 - 8.5.6 information required by the Department, the original date, where the original date is the date of the notice specified in paragraph 6.1.

9. Disputes arising from the 2005, 2008 and 2009 Pharmaceutical Price Regulation Schemes

- 9.1 Any disputes as to the obligations under the 2005, 2008 or 2009 PPRSs between the company and the Department shall not be extinguished by virtue of said schemes being terminated and shall continue to be dealt with under the dispute resolution arrangements pertinent to the scheme under which the dispute arises. Further information as to disputes arising under any previous scheme is provided in Chapter 3.

10. After dispute resolution

- 10.1 Given the voluntary nature of the scheme it is intended that any decision of the panel will not give rise to any action pursuant to the Arbitration Act 1996. Unless a court adjudicates to the contrary, this means that the company has, in practice, three options:
 - 10.1.1 follow the panel's decision;
 - 10.1.2 withdraw from membership of the scheme; or
 - 10.1.3 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.

10.2 In cases covered by paragraphs 10.1.2 and 10.1.3 the company will no longer be a scheme member 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 4.2 above).



Department
of Health

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