



Department
of Health



2014 PPRS: Heads of Agreement

Heads of Agreement for the 2014 Pharmaceutical Price Regulation Scheme

November 2013

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Chapter 1 – General and PPRS Payment

Overarching principles

- Provide stability and predictability to Government and industry.
- Support the NHS by ensuring that the branded medicines bill stays within affordable limits.
- Improve access to innovative medicines commensurate to outcomes they offer patients by ensuring that medicines approved by NICE are available widely in the NHS.
- Reduce bureaucracy and duplication.
- Support the Government's growth and innovation agenda for life sciences.

A. Status and length of the scheme

1. The new scheme will run for five years starting from 1 January 2014, and be non-contractual and voluntary, building on the current PPRS. The parties to these heads of agreement are the Department of Health (DH), acting on behalf of the UK Government and Northern Ireland, and the Association of the British Pharmaceutical Industry (ABPI).¹ The scheme will be 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 government and industry to enable certainty of planning. Both parties will work to ensure that the full text of the 2014 PPRS including annexes is written in accordance with these heads of agreement and is ready to be published by end November at the latest and implemented on 1 January 2014.
2. It is a fundamental condition of the scheme that it will continue to operate for five years starting from 1 January 2014.
3. The scheme as a whole applies to all branded, licensed NHS medicines as defined in the 2009 PPRS. The list of exclusions in the 2009 PPRS will continue to apply (e.g. OTC medicines etc.).

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 of availability of medicines, are devolved matters and it is for the Devolved Administrations to meet their policy and operational requirements.

4. The PPRS is the UK wide price regulation scheme. The UK Health Departments do not support additional or alternative initiatives by NHS organisations in respect of the pricing of branded, licensed NHS medicines in primary care.
5. All parties to the agreement will make their best endeavours not to manipulate or undermine the agreement in a way which conflicts with the overarching principles outlined above or in a way which makes the scheme ineffective as set out at paragraph 41. The mutual intent is that neither DH nor industry will seek to abuse this mechanism.

B. Design of the PPRS payment mechanism

6. The purpose of the scheme is to provide Government with surety on the level of NHS expenditure on all branded medicines supplied by companies in the voluntary scheme. A glossary of the key terms used to describe the PPRS payment mechanism is attached. The Allowed Growth Rates to calculate any payment due will be measured against the outturn of all sales of NHS branded medicines supplied by companies in the voluntary scheme, including new products, subject to the exclusions set out in paragraph 7 below.
7. 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. 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 company such as a parent company. Companies with sales of less than £5 million in the previous calendar year will not be required to make payments to the Department. Their sales will not be included in the Measured Spend or the Allowed Growth Rate of Measured Spend (i.e. the calculation of the overall sum to be repaid across all member companies). However some information will be required from these companies on sales. Further detail on eligibility and information requirements for the smaller companies exemption is set out in Annex C.
8. There will be a pre-agreed profile of payments for the five years of the scheme, derived from the forecast Growth Rate of Measured Spend and the Allowed Growth Rate of Measured Spend.
9. The PPRS payment will apply to sales of NHS branded medicines (calculated net of all discounts and excluding sales that relate to brand equalisation deals) except for the exclusions set out in paragraph 7 and new products. Annex C includes a definition of new products whose sales are not covered by the payment. The PPRS payment will

be set at a level to ensure that the Growth Rate of Measured Spend (sales of NHS branded medicines supplied by companies in the voluntary scheme, net of the exclusions set out in paragraph 7, but gross of sales of new products) is at the Allowed Growth Rate.

10. If the Measured Spend grows faster or slower than the initial forecast growth rate, the payment profile will be adjusted according to the process set out in Annex B 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.
11. The adjustments will be made to ensure that the Allowed Growth Rate of Measured Spend is not exceeded. If the outturn of the growth rate is lower than the Allowed Growth Rate and the payment for that year is set at zero, the Department will not make net payments to bring growth rate up to the Allowed Growth Rate.
12. There will be an independent reconciliation exercise completed during 2016 to compare company data with administrative data on outturn in 2014 and 2015, to follow up any inconsistencies and correct any errors (see Annex C for further details).
13. To meet the objective in paragraph 6, the Allowed Growth Rates for each year of the scheme are 0%, 0%, 1.8%, 1.8%, 1.9% and will remain fixed. The initial payment percentage for 2014 which applies to products as set out in paragraph 9 will be 3.74%.
14. Annex A sets out the Allowed Growth Rate of Measured Spend, and the initial profile of annual payment percentages which applies to the sales covered by the PPRS payment. Annex A also sets out the initial forecasts of growth rate in Measured Spend and the initial forecasts of new products share of Measured Spend. The PPRS payment profile will be adjusted as described in detail at Annex B. Annex C sets out the position on data sources and definition of sales.
15. The Department is seeking an opinion from HMRC on whether VAT is chargeable by DH on the PPRS payments.

C. Payments by companies

16. The PPRS payment percentage for each year, set in advance of that year, will apply uniformly to each company participating in the scheme (excluding smaller companies). The payment percentage will be applied to the sales covered by the PPRS payment, i.e. the company's sales during the relevant year of NHS branded medicines, net of all discounts and excluding sales that relate to brand equalisation deals, and with the

exclusions defined at paragraph 9. The company will pay the Department the resulting cash sum quarterly in arrears on submission of sales returns.

17. Government and industry have agreed that the baseline against which the payment is applied should be fair for all companies. Therefore the outturn of Measured Spend will be measured net of receipts to the Department from members of the 2009 and/or 2005 schemes that elected to deliver up to 2% of the price cuts in those schemes by making payments to the Department. This is spelt out in Annex C. Those members will remain responsible for delivering the value of those price cuts for the relevant products. They should continue to make the relevant payments according to the rules set out in the 2009 PPRS and should net them off their sales figures prior to the calculation of the PPRS payment.
18. The PPRS payment will be paid in quarterly instalments in cash by individual companies in arrears on submission of quarterly sales returns. The payment percentage will be applied to the company's sales covered by the PPRS payment (net of discounts) during the relevant quarter. Payment and quarterly returns of sales information will be due within one month of the end of each quarter of the calendar year. At the end of the calendar year an audited annual return will be submitted within nine months of the end of that year.
19. The scheme will also treat the sales of chemical entities on the market at 31 December 2013 which (a) are subsequently transferred or sold on, and (b) remain in the ultimate ownership of the company which held them on 31 December, as forming 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).
20. Government and industry have agreed strengthened arrangements for auditing annual company sales returns set out in detail at Annex C. Following the end of the calendar year there will be an independent audit of each company's sales return for that year. Any errors in individual company sales returns will be corrected following the audit and any amounts owed by either party as a result will be settled in cash. The calculation of adjustments to national PPRS payment percentages will take account of any corrections of outturn data following receipt of the independently audited figures as set out in Annex B.
21. Any adjustments to 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 to the scheme at the end of 2018, the payment for the final year will be adjusted based on 2014-2017 outturn actuals and over/underpayments. There will be no payment either by companies or the Department in the 2019 financial year to correct for differences between 2018 forecast and outturn for Measured Spend. Each company will make a final quarterly payment which will fall due in quarter one 2019 based on the percentage payment set in advance of year five. There will also be

an independent audit of each company's sales returns for year five. Any errors in individual company sales returns will be corrected following the audit and any amounts owed by either party as a result (relating to the 2018 sales year) will be settled in cash.

D. Provisions for smaller companies

22. Paragraph 7 above sets out the exemptions for smaller companies from the PPRS payments.
23. If a company in this category wishes to modulate the price of its products or apply for a price increase then it will have the same obligation to provide information as larger companies.

E. Pricing of new products

24. Rules on pricing of new products will remain as now (including free pricing of line extensions for five years as defined under paragraphs 7.31 to 7.40 of the 2009 PPRS), with pricing of new active substances priced at the discretion of the company on entering the market. The assumption is that prices at launch will be set at a level that is close to their expected value as assessed by NICE.
25. Subject to any agreed amendments the rules on flexible pricing will apply as now with companies given flexibility to increase or decrease the original list price only when significant new evidence is generated that changes the value of an existing indication or where a major new indication is proposed whose value to NHS patients is significantly different from the original indication. This will only apply when medicines are subject to NICE appraisal and a review by NICE will be required to determine whether the proposed revised price provides value to the NHS.
26. Companies will also retain the option of proposing a Patient Access Scheme as now for medicines subject to assessment by NICE. It is important that these schemes are sustainable and that they deliver the benefits expected of them. DH and ABPI will continue to work together to promote these objectives, and to ensure that Patient Access Schemes can continue to provide a vehicle 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 Patient Access Schemes, specifically including process costs and risks of under-delivery.

F. Price and profit control

27. There will be no change to the current target return on capital or return on sales, or the allowances set out in Chapter 8 of the 2009 PPRS. The margins of tolerance will be set at 50:50. The parties will discuss ways in which the administration of Annual Financial Returns (AFRs) might be made more efficient and effective. For the purposes of AFRs, companies will report sales net of the PPRS payment.
28. Companies are free to reduce their prices overall below the level at 31 December 2013 if they choose. As members of the scheme they will continue to be required to pay the PPRS payment percentage applying to all companies in the scheme as a percentage of their sales covered by the PPRS payment.
29. The scheme will allow price neutral modulation across the portfolio on the basis of list price in community and secondary care; and average selling price in secondary care based on prices at the end of December 2013. Scheme members will be able to modulate list prices of their PPRS products provided that the net result is less than or equal to a 0% increase. Modulation will be subject to prior agreement by the Department and there will be a 20% limit on the level to which prices could increase by the end of the scheme above the level that existed on 31 December 2013. Other rules restricting modulation will apply as now with any administrative changes necessary to reflect the change to the scheme.
30. Companies will need to provide evidence that modulation has produced a net result less than or equal to a 0% increase:
 - I. using NHS list price across primary care and the list price in secondary care; and
 - II. in secondary care companies must ensure and demonstrate that aggregate changes in average selling prices are equal to aggregate change in the list price of those products, or result in a lower average selling price than the changes in list price.
31. The rules on modulation in the last year of the scheme in the 2009 PPRS will apply to the last two years of the new scheme. The DH will not agree to any modulations proposed in the last two years of the scheme if they may cause the price neutrality delivered during the period of the scheme to be eroded in subsequent years.
32. If the list price of a product covered by a simple Patient Access Scheme discount is modulated downwards then the actual price of the product will also need to be modulated down in order to deliver a net 0% increase in prices across the portfolio of products covered by the scheme that the company supplies.

33. In exceptional circumstances, where a price increase is necessary to maintain security of supply, the Department may allow the company to increase the list price without offsetting reductions. The rules on profit control would be applied, i.e. the price increase would not be agreed unless the company's estimated and forecast profits are below 50% of the return on capital/return on sales target and the level of increase allowed would be no more than that required to achieve 50% of the ROC/ROS target. Any company asking for such a price increase (including a company to whom the smaller company exclusions apply) will be required to submit an AFR for the year in which the price increase is requested, and a forecast for the following year. The Department expects all scheme members to use their best endeavours to adhere to the best practice guidelines in the notification of product discontinuations, and in the notification and management of medicine shortages:

Notification and management of medicines shortages

Ensuring Best Practice in the Notification of Product Discontinuations

G. Distribution Margins

34. One of the objectives of this scheme is to encourage the efficient and competitive supply of medicines to the NHS. Individual companies are expected to follow good commercial practice in the distribution of their products.
35. 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.
36. DH will collect information on sales to retail pharmacy from companies annually and monitor any changes in the supply chain. This information will be considered as part of the independent reconciliation exercise to be carried out during 2016 and may result in corrective action.
37. If there are reasonable and objective grounds to believe that changes made during the lifetime of this scheme have, or would have, an adverse net impact on NHS expenditure in relation to the purchasing from that scheme member then the Department and the company will discuss and agree any adjustments to those distribution arrangements and where the company has influence on the pharmacy discount, this may include the company separately paying a sum of money to the Department equal to any additional costs to the NHS. This provision does not affect the right of companies unilaterally to offer or withdraw competitive trade discounts at any time, nor to determine individually how to distribute their own products.

H. General administrative arrangements

38. The 2014 scheme will continue to apply 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 to joining the scheme in the manner required by the Secretary of State. Such manufacturers and suppliers will be able to join the 2014 scheme at any time following from the publication of the point at which the full PPRS text for the 2014 scheme is published.
39. The parties will agree the detailed rules on disputes arising from previous schemes in the light of the following principles:
- The obligations arising from the 2009 or previous schemes will not roll forward into the 2014 scheme.
 - The new arrangements will ensure that 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.
 - The dispute resolution 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 PPRS giving rise to the dispute.
40. Exit by members from the 2014 scheme will require a 3-month written notice period. The Department intends to consult on amendments to the statutory scheme regulations to apply to companies that leave the voluntary 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 voluntary scheme.
41. Under the National Health Service Act 2006 the Secretary of State may serve notice on a manufacturer or supplier that the scheme is no longer to apply to it. The SofS may do this where any acts or omissions of the company 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 services medicines or limiting profits which may accrue in connection with the manufacture or supply of health service medicines. The provisions of the new scheme will be amended to make clear that this could include, but is not limited to, a case where a company which was a member of the scheme made any arrangements designed to reduce the amount of sales of that company's products on which the payment was due.

I. Review of scheme

42. 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 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.

Chapter 2 - Innovation and access to medicines

43. Further to the agreement set out above, the following provisions will apply in respect of England. As these provisions relate to matters where responsibility is devolved, it is for the Devolved Administrations to meet their policy and operational requirements in these areas.

NICE/HTA

- An objective of this agreement is to improve patient access and outcomes. NICE will undertake all elements of assessment for a broader definition of value.
- NICE will not negotiate, publicly set or publicly indicate prices.
- The basic cost-effectiveness threshold will be retained at a level consistent with the current range and not changed for the duration of the agreement.
- NICE will consult publicly before implementing changes arising from the DH Terms of Reference for value assessment.
- The Terms of Reference DH sets NICE for value assessment will not prevent NICE Appraisal Committees from applying deliberation in the assessment process. The Terms of Reference state that NICE should “encompass the different valuation of ‘End of Life’ treatments in the current approach within the system of Burden of Illness weights.”
- Companies may request value-based appraisal of their new medicines, and such requests will not be unreasonably refused.
- DH will work with 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.
- Timings for the NICE value assessment process are expected to be comparable with the current timetable for Single Technology Appraisals.
- DH supports the establishment of written ABPI working agreements with NICE and NHS England, a NICE Industry Council and an NHS England Industry Council.

Access to medicines and outcomes

- The role of NICE is well established in providing guidance and guidelines for medicines use and the NHS will not seek to duplicate this activity nor to further qualify, reinterpret or modify national guidance.
- Government will hold NHS England to account for its commitment to innovation, demonstrated both in 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 agreement.
- NHS England is committed to on-going implementation of the Innovation, Health and Wealth policy, which seeks to improve NHS use of innovative treatments for the benefit of patients. This commitment will be reflected in the Mandate for NHS England subject to the outcome of the current consultation. NHS England will be expected to demonstrate progress throughout the duration of this agreement and the Government will hold NHS England to account for doing so.
- 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.
- 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.
- With the exception of Patient Access Schemes as defined in this agreement, NHS England will 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.

Glossary of Key Terms to Describe the PPRS Payment Mechanism

Measured Spend

Definition: sales of NHS branded medicines supplied by companies in the voluntary 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;
- 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 company such as a parent company;
- Sales by companies with sales of NHS branded medicines of less than £5m in the previous calendar year.

Growth Rate of Measured Spend

Definition: the percentage growth in Measured Spend between one calendar year and the following calendar year.

Allowed Growth Rate of Measured Spend

Definition: 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 A and remain fixed for the duration of the scheme.

New products share of Measured Spend

Definition: The percentage of Measured Spend which is accounted for by sales of new products defined in paragraph 5 of Annex C.

Sales of NHS branded medicines

Definition: NHS branded medicines are defined in the 2009 PPRS paragraphs 4.16-4.21. Sales value is calculated net of all discounts and excluding sales that relate to brand equalisation deals.

Sales covered by the PPRS Payment

Definition: sales of NHS branded medicines, net of all discounts and excluding sales that relate to brand equalisation deals, and 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;
- 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 company such as a parent company;
- Sales by companies with sales of NHS branded medicines of less than £5m in the previous calendar year;
- Sales of new products defined in paragraph 5 of Annex C.

Annex A – 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 voluntary 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 (P1)	3.74%				
Estimated future annual payment percentages (2015-2018) (FP2, FP3, FP4, FP5)		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 applies to sales covered by the PPRS payment, i.e. sales of NHS branded medicines, net of all discounts and excluding sales that relate to brand equalisation deals, net of the exclusions set out at paragraph 7 of the main document above and also excluding new products as defined at Annex C.

4. As new products are exempt from the 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 Annex B.
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.

Annex B – 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 detailed in the Table below (paragraph 18).
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 18). 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 17 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 agreement, then DH 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 return completed by companies by the end of March 2014 broken down into quarters. This will be independently audited by September 2014.
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.
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 18 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 company, the company will adopt the methods recommended by the auditors for future sales returns.
15. Each time a company leaves or joins the voluntary 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 companies who are members of the scheme at the time the adjustment is carried out and only those companies. Companies that join the scheme after the end of the third quarter in any calendar year will need to submit a sales return for the last quarter of that year within one month and an audited annual return 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 companies 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) and that when audited data becomes available this will be used to make further corrections as necessary.
16. 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 Annex C.

17. These arrangements cover all companies with a financial year end of 31 December. Detailed arrangements for dealing with statutory accounts with a different end date will be agreed by the parties as part of the final scheme. These arrangements will follow the principle that 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) and that when audited data becomes available this will be used to make further corrections as necessary.

Timetable for Adjustments

18. 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	Unaudited 9 months ending 30/9/14	Nov 2014	Year 2 – 2015 (P2)
Year 1 - 2014	Years 3-5	Audited 12 months ending 31/12/14	Nov 2015	Year 3-2016
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
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
Year 4 - 2017	Year 5	Unaudited 12 months ending 30/9/17	Nov 2017	Year 5 – 2018 (P5)

Annex C – 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 have been agreed between DH and ABPI.

Data for PPRS payments

2. Individual payments by companies will be based on home sales data to the NHS provided by companies, which will be independently audited at year end. Sales data should be net of all discounts and exclude sales that relate to brand equalisation deals². A new pro-forma will be included in the revised scheme which should be used by companies to report their sales data for the PPRS payment.
3. The Department will treat as confidential information provided by companies on the estimated value of sales in the quarterly returns for quarters 1-3 of each year and the final audited end year sales data and payments. The Department cannot, however, guarantee that information provided would not be disclosable under Freedom of Information. Moreover the Department cannot undertake to keep the final audited end year sales data or payments confidential. DH 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 audited end of year annual sales returns for the payments 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 payment actually paid (i.e. including the value of the payment paid) but net of (i.e. after subtracting) any

² Sales where additional discounts are offered that result in branded products being dispensed against prescriptions written generically.

payments in lieu of price cuts under the 2005 or 2009 PPRS which companies are still paying.

5. Company quarterly and annual sales returns 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 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. Necessary outturn data will be provided by member companies both to the DH and, at the same time, on a confidential basis to an independent auditor, to be jointly agreed by ABPI and DH, to monitor the overall rate of growth of Measured Spend by member companies relative to the Allowed Growth Rate of Measured Spend. The ABPI will be provided with this data on a consolidated basis by the independent auditor following the auditor's receipt of the raw outturn data for the purposes of understanding the progress of the mechanism and changes to any payment values with the DH. Any changes to reported data that are made through subsequent discussion with DH or as a result of the reconciliation exercise must be reported by the company to the independent auditor.

Eligibility for smaller companies exemption

7. Companies with sales of branded medicines to the NHS of less than £5 million in the previous calendar year will not be required to make payments to the Department. In the case of companies with sales 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 do not grow above £1m. For companies with sales of over £1m but under £5m, eligibility for the exemption will be established at the start of each calendar year on the basis of the company's sales data for the previous calendar year and will apply for the whole of a calendar year concerned whether or not the sales 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.
8. Companies with sales of less than £1m will be required to submit a company declaration on the value of their NHS sales in 2013 by the end of March 2014. These companies will continue to be exempt for the period of the agreement subject to

submitting annual company declarations on the value of their NHS sales for the previous calendar year by end March in each subsequent year of the scheme.

9. Companies with sales of more than £1m and less than £5m in 2013 will be required to submit an unaudited return on sales of branded medicines to the NHS for the calendar year 2013 by March 2014. The Department will establish whether or not the company falls within the criteria for the exemption based on this data. If their sales total for 2013 is less than £5m then they will not be required to make PPRS payments or to submit quarterly sales returns or audited annual returns for 2014. The company will be required to submit an unaudited annual sales return for 2014 by the end of March 2015 and, if the company remains eligible for the exemption, for each subsequent year of the scheme by the end of March of the following calendar year.
10. If a company's sales total in the unaudited annual sales return 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 company's sales in 2014 were £5m or greater, then the Department will require the company to make PPRS payments for the whole of 2015, submitting the quarterly sales returns and payments and an annual audited sales return for 2015 according to the same procedure as other companies in the scheme. If a company has been making PPRS payments because its NHS sales were £5m or higher in the previous calendar year, but during the year its sales (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 company was at or above the £5m threshold according to its sales for 2013 and made PPRS payments for 2014, but the company's sales 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 return for 2014 submitted by end March 2015.

Auditing requirements

11. Government and industry have agreed that the arrangements for auditing the annual sales return should be strengthened with the following documents being incorporated into the final PPRS agreement:
 - **Audit Report** providing a Reasonable Assurance opinion in an agreed form performed by the statutory auditor of the statutory accounts performed under ISA805 and reported within nine months of the end of each year of sales applicable to the agreement including the baseline year sales (2013) against which the Growth Rate of Measured Spend will be measured;
 - **Engagement Letter** key terms including provision of a duty of care through a tri-partite engagement between each company, the Department of Health and

the auditor, key undertakings of the parties to the agreement, an appropriate limitation of liability agreed by all parties not less than £1m. Where the limitation of liability is to be based on a fee multiple, this will be a multiple of the statutory audit fee not just the fee for this audit. No additional limitation clauses will be permitted beyond the template;

- **Sales Report** reconciling each company's statutory sales to both the total NHS branded medicines sales and also NHS branded medicines sales covered by the PPRS payment;
- **Company Declaration** that the sales information provided has been accurately extracted from the company records and complies with the requirements of the scheme;
- **Guidance Notes** providing further guidance required for companies to undertake the completion of quarterly and annual sales returns.

In the event of an audit reporting a qualified opinion the Department of Health will at its discretion use the administrative data available to define NHS drugs sales for that company. Any resulting differential cost above those of the statutory audit associated with the Audit Report will be for each company's account.

Reconciliation exercise

12. There will be an independent reconciliation exercise in 2016 to compare company data with administrative data on outturn in 2014 and 2015. The exercise will identify any inconsistencies, examine the reasons for them and correct any errors in the company or administrative data that are discovered as a result. The Department will agree with the ABPI on the method to be followed in this exercise and will consult individual companies on any errors identified in their data. Companies and the Department will make good any sums owed as a result of errors in the data. If there are any corrections to individual companies' data which are agreed by the parties or determined following dispute resolution, this will lead to consequential corrections to the overall outturn data for 2014 and 2015. The Department will use the corrected outturn data in the calculation of the adjustment to the payments for year four and five (2017 and 2018) according to the methodology set out in Annex B.
13. As part of the reconciliation exercise there will be an examination of data available on parallel imports. If there are any unusual or unexplained increases in parallel imports for any member company's products the Department will investigate whether these are likely to have been as a result of arrangements by companies to reduce the amount of sales of that company's products on which the payment was due (sales covered by the PPRS payment). If this is the case then the Secretary of State may serve notice on a manufacturer or supplier that the scheme is no longer to apply to it,

in accordance with his powers under the NHS Act 2006 (as described at paragraph 41 of the main document above).

14. Any disputes arising out of the reconciliation exercise described in paragraph 13 above will be dealt with through the normal PPRS dispute resolution procedure. The DRP would need to consider whether the process adopted for the reconciliation process was accurate and comprehensive. This includes the right for companies to bring individual disputes or for the ABPI to bring a dispute that spans the interest of the broader membership, e.g. as regards the proposed correction of the outturn data or re-profiling of payments.
15. The ABPI will work with the Department to develop a methodology for how homecare sales are reported. The ABPI will write to all companies in the scheme encouraging companies 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 of Health.