

### **Addendum to the 2014 Pharmaceutical Price Regulation Scheme**

The Department of Health and the Association of the British Pharmaceutical Industry (“ABPI”) have agreed the following amendment of the 2014 Pharmaceutical Price Regulation Scheme (“PPRS”) in accordance with paragraph 3.4 of the Scheme.

Actual expenditure on branded health service medicines, by or through the National Cancer Drugs Fund (“NCDF”), up to the maximum amount specified below in relation to each year of the Scheme (“the Included CDF Spend”), will be included in the calculation of PPRS Payments in the way set out in chapter 6 and Annexes 3-7 of the Scheme as originally published on 3<sup>rd</sup> December 2013 without amendment.

<b>NHS Financial Year</b>	<b>Maximum NCDF expenditure included in PPRS Payment Mechanism (£million) (i)</b>
2013/2014	200 (ii)
2014/2015	280
2015/2016	340
2016/2017	320
2017/2018	300
2018/2019	280 (ii)

- (i) Figures to be adjusted to remove VAT paid by the NCDF.
- (ii) Figures to be pro-rated to reflect the part of the NHS Financial Year<sup>1</sup> covered by the Scheme.

Any expenditure on branded health service medicines, by or through the NCDF, in excess of the amounts specified above (“the Excluded CDF Spend”), will be excluded from the PPRS Payment Mechanism by adding the excluded amounts to the Allowed Spend (Annex 5 of the PPRS sets out how the Allowed Spend is to be calculated).

The mechanism for calculating PPRS Payments in accordance with this amendment to the Scheme is set out in the Appendix to this Addendum.

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<sup>1</sup> “Financial Year” means any of the financial years set out in the above tabulation

## Appendix

### **Mechanism for calculating PPRS Payments in accordance with the amendment to the Scheme**

#### **Timing and scheme methodology**

1. Starting in November 2015 for the calculation of the final 2016 Payment Percentage<sup>2</sup>, the Excluded CDF Spend is added to the Allowed Spend for each year for which outturn growth is included in the calculation prior to applying the Scheme Payments<sup>3</sup> calculation to set the next Payment Percentage; this is carried out each time the Payment Percentage is adjusted after that point. Allowed Spend is calculated following the methodology set out in Annex 5 of the Scheme.
2. No further change is made to the Scheme methodology. In particular there is no reduction in net sales from any individual Scheme members as a result. Also the correction and re-forecasting methodology in the Scheme remain unchanged.
3. To the extent that the agreed amounts have been exceeded during 2014 or 2015, the excess will be taken into account in calculating the PPRS Payment Percentage for 2016 and, if necessary, subsequent years.

#### **Value Added Tax**

4. As CDF payments include Value Added Tax (VAT), whereas the Measured Spend is net of VAT, a net Excluded CDF Spend figure must be derived. The Parties agree to further refine this position to take account of any of the Excluded CDF Spend which does not attract VAT.

#### **Data**

5. Estimated gross CDF spend for 2015-16 onwards will be based on NHS England's best estimate at the time. The gross outturn CDF spend will be accounted for on a Financial Year basis, based on NHS England information on invoiced CDF spend for each relevant financial year. Corrections of estimates will be made as outturn CDF data become available according to the following table:

<b>Subtraction of the excess amount from the PPRS Payment Mechanism</b>	
<b>2016 Payment Percentage Calculated in November 2015 correcting the following calculations of Allowed Spend</b>	
<b>Payment Percentage calculations</b>	<b>CDF subtraction</b>
Correction of 2014 Allowed Spend:	Add to the 2014 Allowed Spend the final net excluded CDF spend for 2014

<sup>2</sup> "Payment Percentage" has the meaning given in Chapter 6 of the Scheme

<sup>3</sup> "Scheme Payments" is to be construed in accordance with paragraph 6.3 of the Scheme

Calculation of estimated 2015 Allowed Spend	Add to the 2015 Allowed Spend the initial net excluded CDF spend for the 12 months ending Q3 2015
<b>2017 Payment Percentage Calculated in November 2016 correcting the following calculations of Allowed Spend</b>	
Correction of 2014 Allowed Spend:	Add to the 2014 Allowed Spend the final net excluded CDF spend for 2014
Correction of 2015 Allowed Spend:	Add to the 2015 Allowed Spend the final net excluded CDF spend for 2015
Calculation of estimated 2016 Allowed Spend:	Add to the 2016 Allowed Spend the initial net excluded CDF spend for 12 months ending Q3 2016
<b>2018 Payment Percentage Calculated in November 2017 correcting the following calculations of Allowed Spend</b>	
Correction of 2014 Allowed Spend:	Add to the 2014 Allowed Spend the final net excluded CDF spend for 2014
Correction of 2015 Allowed Spend:	Add to the 2015 Allowed Spend the final net excluded CDF spend for 2015
Correction of 2016 Allowed Spend	Add to the 2016 Allowed Spend the CDF final net excluded CDF spend for 2016

Calculation of estimated 2017 Allowed Spend	Add to the 2017 Allowed Spend the initial net excluded CDF spend for 12 months ending Q3 2017
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### **Steps to reach net excess amount**

6. The gross Included CDF Spend is calculated on a Financial Year basis. The gross Excluded CDF Spend will then be calculated on a Financial Year basis by subtracting the gross Included CDF Spend from the gross outturn CDF spend. The Financial Year net Excluded CDF Spend will be derived by subtracting any VAT.

### **Conversion of results into different time periods**

7. The net Excluded CDF Spend must be calculated on a calendar year basis and on a 12 months ending September basis in each current (Scheme) year's growth calculation. The financial year net Excluded CDF Spend amount will be divided into four equal quarters and those quarters (or quarter in the case of 2013/14) will be assigned to the correct calendar year or 12 months ending September.  
Financial Year to calendar year

8. To convert the Financial Year net Excluded CDF Spend into a calendar year excess the last quarter of one Financial Year is added to the first three quarters of the following Financial Year. For example, to calculate 2014 calendar year take the Financial Year net Excluded CDF Spend for quarter 4 of 2013-14 plus quarters 1-3 of 2014-15.

Financial Year to year ending September

9. To convert the Financial Year net Excluded CDF Spend into a figure for the year ending September, the last two quarters of one Financial Year are added to the first two quarters of the next. For example to calculate year ending September 2015 take the Financial Year net Excluded CDF Spend for Quarters 3 and 4 2014-15 plus Quarters 1 and 2 2015-16. (NB This calculation does not apply to 2014).