



Department  
of Health &  
Social Care

# **Changes to the statutory scheme to control the costs of branded health service medicines**

**Clarification note**

Published 5 October 2018

# Statutory scheme payment calculations

On 7 August 2018 the Department published a consultation paper and impact assessment setting out proposed changes to the Branded Health Service Medicines (Costs) Regulations 2018 (“the statutory scheme”). As part of the consultation, respondents have asked for additional information relating to -

1. The expected 2018 baseline for forecast relevant sales and allowed relevant sales
2. The calculation of the payment percentages for 2019 to 2021

This document provides additional information in relation to these two issues to help respondents understand how the Department calculated the proposed payment percentages.

This document also clarifies some further points in the consultation document and impact assessment in order to accurately describe the method used by the Department to calculate the proposed payment percentages. The proposed payment percentages set out below are unchanged from those in the consultation document.

## 1. The expected 2018 baseline

As set out in chapter 4 of the consultation document, the Department proposes to set the payment percentage based on the difference between forecast relevant sales of branded health service medicines and allowed relevant sales of branded health service medicines as calculated from the expected spend on branded health service medicines as at 2018 (“the expected 2018 baseline”).

The expected 2018 baseline for **allowed relevant sales for England**, which the Department used to determine the payment percentages proposed in the consultation, is **£9,105 million**. The calculation to determine payment percentages used estimates of sales in England, as described below. Each figure can be scaled up by a factor of 1.25 to give a UK estimate; this scaling does not affect the proposed payment percentages.

At paragraph 96 of the impact assessment the expected 2018 baseline (given as £9,081 million) was misstated.

The expected 2018 baseline for allowed relevant sales was determined by first estimating:

- total sales of branded health service medicines made by companies in the 2014 PPRS in 2017, excluding sales by small companies, based on PPRS company sales returns up to Q3 2017;
- total sales of branded health service medicines made by companies subject to the statutory scheme in 2017, excluding sales by small companies, based on 2016 statutory scheme company sales returns; and
- total sales of parallel imports in 2017, based on parallel import volume data obtained from IQVIA up to Q3 2017, with prices adjusted for brand-level discounts observed in PPRS company returns.

The 2017 estimated relevant sales were then uplifted by a forecast growth rate for 2018 of 3.8%, which was derived from the forecasting model described in chapter 8 of the consultation. This calculation yields an estimate for total **forecast relevant sales for England** in 2018 of **£9,577** million.

From this number, the estimated payment received from companies under the 2014 PPRS for the year 2018 (£471 million for England) is deducted, as described in paragraph 96 of the impact assessment. This calculation yields an estimate of the expected 2018 baseline for allowed relevant sales for England of £9,105 million.

## 2. The payment percentage calculation

The forecast model is described in chapter 8 of the consultation and applied to forecast relevant sales. The allowed growth level is applied to the expected 2018 baseline to determine the allowed relevant sales. The payment percentage in each year is then given by the difference between forecast relevant sales and allowed relevant sales, divided by the forecast relevant sales.

The table below sets out the relevant figures (in £ millions) which have been used to determine the proposed payment percentages from 2019 to 2021:

<b>England, £ million</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>
1. Forecast % growth <sup>1</sup>	3.8%	6.7%	8.2%	8.8%
2. Forecast growth		9,577*6.7%	10,217*8.2%	11,051*8.8%
3. Forecast relevant sales	9,577	10,217	11,051	12,023
4. Allowed relevant sales <sup>2</sup>	9,105	9,206	9,307	9,409
5. Difference [ 3 – 4 ]		1,011	1,744	2,613
6. Payment % [ 5 / 3 ]		9.9%	15.8%	21.7%

**Note:** figures may not sum due to rounding

Please note that at paragraph 19 of the impact assessment, the calculation to derive payment percentages was misstated. The correct formula is given by:

$$\text{Payment percentage} = \left( 1 - \frac{\text{Allowed relevant sales}}{\text{Forecast relevant sales}} \right) * 100$$

<sup>1</sup> See paragraph 21 of the impact assessment

<sup>2</sup> As described in paragraph 96 of the consultation, the 2018 baseline for allowed sales takes into account the expected 2018 payment received from members of the 2014 PPRS, expected to be £471 million for England.

Further, contrary to what is stated in paragraph 4.4 in the consultation document, the 2018 estimate of **forecast relevant sales does include sales of presentations supplied under extant contracts with a contracting authority based on a framework agreement or under extant public contracts** (entered into on the basis of an invitation to tender that closed on or before 1 April 2018) for the statutory scheme (collectively ‘extant framework sales’). To exclude these would have the effect of increasing the payment percentage for 2019 onwards. This is because in 2018, forecast relevant sales, and thus allowed relevant sales, would be approximately £453m less, but in 2019, we estimate that £307m worth of sales would no longer qualify as extant framework sales because of the proposed changes to the treatment of sales under framework agreements set out in chapter 6 of the consultation document, so the difference between forecast relevant sales and allowed relevant sales would increase by a further £307m. The Department considers that such an increase would be artificial rather than an actual increase in sales and that it would not be fair on companies to increase the payment percentage in such a way.

For the avoidance of doubt, the proposed payment percentages in the consultation document have been derived with the inclusion of all sales under framework agreements in the expected 2018 baseline, and are therefore unaffected by this clarification. This clarification also does not change the proposed treatment of framework agreements in the payment mechanism outlined in chapter 6 of the consultation document.

Additionally, paragraphs 96 to 100 of the impact assessment describe a scenario where all branded medicines spend is controlled by the statutory scheme. These paragraphs described the impacts on sales in England. To determine the final impacts to the UK as a whole, each figure should be increased by a factor of 1.25.

## **Consultation question:**

As part of the consultation, you were asked whether you had any comments on the proposed payment percentages or the methodology used in determining the payment percentages. You are asked to provide any further comments you may have on this question or any other questions included in the consultation document as a result of the information provided in this document.

## **Responding to this consultation:**

You can respond to this consultation via email to [statutory\\_scheme\\_consultation@dh.gsi.gov.uk](mailto:statutory_scheme_consultation@dh.gsi.gov.uk) or by sending your responses by hard copy to

C/o Samuel Jackson  
Medicines Pricing Team  
39 Victoria Street  
London

SW1H 0EU

Any responses received as during the original consultation period are still being taken into account by the Department and do not need to be re-submitted. You therefore only have to respond to this consultation if you want to submit additional comments on the contents of the note or if you would like to amend a response submitted in the original consultation period.

This consultation closes on 19 October 2018, 23:59. Please direct any questions regarding this consultation to [statutory\\_scheme\\_consultation@dh.gsi.gov.uk](mailto:statutory_scheme_consultation@dh.gsi.gov.uk).

© Crown copyright 2018

Published to GOV.UK in pdf format only.

[www.gov.uk/dhsc](http://www.gov.uk/dhsc)

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit [nationalarchives.gov.uk/doc/open-government-licence/version/3](http://nationalarchives.gov.uk/doc/open-government-licence/version/3)

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

