DISPUTE RESOLUTION PANEL OF THE PHARMACEUTICAL PRICE REGULATION SCHEME

DECISION DATED 5 JUNE 2013

IN THE MATTER OF **PPRSDRP/MAY/2013/03**

TAKEDA UK LIMITED

-and-

THE DEPARTMENT OF HEALTH

DECISION OF THE PPRS DISPUTE RESOLUTION PANEL

1 This is a decision of the Dispute Resolution Panel ("the Panel") appointed under the Pharmaceutical Price Regulation Scheme 2009 ("the 2009 Scheme") to consider and provide reasoned decisions in respect of disputes arising under the 2009, 2008 and 2005 Schemes. This dispute arises and is referred to the Panel only under the 2009 Scheme. The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

2 The Panel is grateful to both parties' representatives for their helpful and pragmatic approach. The issue is whether, having regard to bullet point 2 of Chapter 7.59 and to the 2009 Scheme as a whole, where over-deliveries are in excess of 0.5% in a particular year of the 2009 Scheme, over-deliveries may be carried forward to the following year, as Takeda UK Limited ("Takeda") contends.

3 Chapter 7.59 provides as follows:

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

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- *where the cumulative price reduction remains within 0.5% of that required the under or over-delivery will be carried forward to the following year;*

- *where the cumulative price reduction exceeds the required figure by more than 0.5% the scheme member may remodulate as set out in paragraphs 7.42 to 7.49 above;*

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

4 Takeda summarises modulation as follows: *"Modulation is the mechanism whereby differential price cuts across the portfolio are implemented in such a way that in aggregate a company delivers the required price reduction. It is designed to be a cost neutral alternative for a company and the NHS to an across the board list price reduction, a principle that is of paramount importance to Takeda's position in the dispute."*

5 The Department assessed an over-delivery of £4.7 million for Takeda's 2009 year and Takeda agrees the amount. It is also agreed that the amount represents a sum in excess of the 'required figure' for that year by more than 0.5%.

6 Takeda has explained that the over-delivery was caused not by any material change in its forecast sales volumes since the implementation of its modulated prices in February 2009 but rather by a particular product which *"unexpectedly came back within the Takeda portfolio."* However, the Panel does not consider that the 2009

Scheme provides for different methods of calculation according to the cause of over-delivery, and Takeda did not argue otherwise. Its point appeared to be to demonstrate that it was not seeking to manipulate the Scheme, and the Department does not suggest to the contrary. The company and the Department agreed that Takeda could have corrected the over-delivery by remodulating in 2009 to take account of the product in question.

7 Takeda decided to remodulate in 2010 relying on bullet point 2 in Chapter 7.59. It expected to do so in exactly the manner provided for in Chapter 26.17 of the 2005 Scheme, namely *"A scheme member may re-modulate its prices, with the Department's agreement, so that the member may recover any over delivery in the following year, or over a longer period if the member so wishes*."

8 The Department argues that Chapter 7.59 is in contrast to the provisions of the 2005 Scheme and is a *"clear and unequivocal description of the consequences for companies choosing to deliver the price reduction by modulation"* so that the Panel is asked to *"find that Takeda forfeits the excess delivery in 2009 within the terms of the 2009 PPRS."*

9 Both parties have referred to the 2005 Scheme but are agreed that the 2009 Scheme should be interpreted having regard to its own terms. Takeda summarised its position as follows: *"In any event, in the context of this dispute, the 2005 PPRS is irrelevant. The wording of the 2009 Scheme stands alone and changes in wording should not be construed to interpret the intention of the parties when negotiating the 2009 Scheme."*

10 The Panel agrees that reference to the 2005 Scheme is not particularly helpful, partly because it is easy for Takeda to argue that what was omitted from the 2009 Scheme

was only that which was implicit, and equally convenient for the Department to proceed on the basis that the omission represented a clear and intentional change. The Panel proceeds, as it did in the ABPI decision in December 2011 *"to look first to see if the [2009] Scheme read as a whole and in context provides an unequivocal answer, and second if it does not, to interpret the Scheme and address its shortcomings in a way which is both reasonable and consistent with its terms and which allows the considerable gaps in the scheme to be plugged with common sense."*

11 The Department says that Chapter 7.59 is clear and unequivocal. Three bullet points describe different outcomes according to the degree of under or over-delivery. Where the delivery is within the 0.5% margin (either way), it is carried forward. Where under-delivery exceeds the margin, the company must make payment and remodulate. Where over-delivery exceeds the margin, it is forfeit and cannot be carried forward, but the company may remodulate for the future.

12 Takeda points out that Chapter 7.3 provides the *"price cut…will have the effect of reducing NHS expenditure on branded medicines…over the lifetime of the scheme"* and argues this is inconsistent with the 'year by year' approach contended for by the Department. Takeda accepts that bullet point 2 *"is silent on the issue of carry forward in such circumstances but is equally silent on the subject of forfeiture"* but goes on to argue *"Given the significance of the matter Takeda assert that the 2009's Scheme's silence on the point of forfeiture is such as to prevent the Department making this assumption in its assessments."*

13 The Panel does not consider that bullet point 2 of Chapter 7.59 is clear and unequivocal on its face, and looks to the Scheme as a whole, and particularly Chapter 7, so as to interpret the provision in context.

14 The Panel considers that the difficulty with Takeda's approach is an assumption that unless forfeiture is expressed or implied, the 'default' position should be that there is a right to carry forward. That assumption is based on *"precedent under previous PPRS schemes", "achieving symmetry between under- and over-delivering companies" and "fair treatment of over-delivering companies just within and just outside the 0.5% corridor."* Whilst the Panel understands each of these arguments, and accepts that they might provide the basis for negotiation of a different scheme, the Panel finds that none is sufficient to determine the interpretation of the provisions of Chapter 7.59.

15 There are indications within Chapter 7 that Chapter 7.59 must be read within the concept of a scheme intended to reduce expenditure *"over the lifetime of the scheme"* (see for example Chapters 7.3 ,7.5 and 7.50). Further Chapter 7.59 itself refers to delivery within range *"throughout the agreement",* and bullet point 1 expressly refers to carrying forward to the following year. All these factors, it may be argued, point towards carrying forward and consideration of the position through the whole lifetime of the Scheme, with the 'reckoning' at the end of the Scheme, set out in Chapter 7.70.

16 But there are also indications that whilst the objectives are to be achieved over the lifetime of the Scheme, the manner in which they are achieved involves a discrete annual assessment of price adjustment. The percentages are set out year by year in Chapter 7.7 and Chapter 7.57 sets out the way in which price adjustment savings will be analysed *"for the previous 12 months"*. Chapter 7.57 continues *"It is recognised that it will be difficult for scheme members to deliver exact outturns matching the scheme's required outcome in each year. Consequently a margin of 0.5% in each year will be permitted against both measurement methods."*

17 Where there is ambiguity in Chapter 7.59 and some conflicting indicators within the Scheme as a whole, the Panel returns to Chapter 7.59 and looks for an interpretation which is both reasonable and consistent with its terms. It is noted that bullet point 1 makes express reference to carrying forward (under or) over-delivery, whereas bullet point 2 does not. (Chapter 7.49 provides another example of express reference to carrying forward.) The Panel finds that this, on its own, is not enough to reject Takeda's interpretation, particularly having regard to the onerous consequences.

18 However, taking account of all the points above, and having regard to the terms of Chapter 7.57, the Panel concludes, by a majority, that bullet point 2 of Chapter 7.59 neither expresses nor implies an ability by a company to carry forward an over-delivery from one year to the next. Chapter 7.57 makes it clear those signing up to the Scheme:

(i) Acknowledged that it would be difficult for scheme members to deliver exact outturns.

(ii) Expressly referred to *"the scheme's required outcome in each year."*

(iii) Agreed a *"permitted"* margin.

19 The margin appears to the Panel to be quite narrow, but that was not an issue in the dispute, and in any case the Panel can find no ambiguity about the figure of 0.5 per cent. References to 'required' and 'permitted' emphasise that scheme members were expected to make every effort to stay within that margin. Takeda's interpretation of Chapter 7.59 would apply no sanction against a member over-delivering outside the margin. The Panel finds, by a majority, that the better interpretation of Chapter 7.59 is that whilst neither over nor under-delivery within margin will attract any

sanction, greater under-delivery gives rise to an obligation to make payment to the Department and greater over-delivery carries no right to carry forward.

20 The Panel has considered the argument raised by the Department that if the position was otherwise, modulating members could reduce prices sharply at the beginning of the Scheme and benefit by having higher prices at the end of the scheme than those that cut prices across the board and those that stay within the 0.5% margin. Neither Chapter 7.48 nor Chapter 7.71 would provide a total answer to this risk. However, the clearer point is that members agreed to deliver within the stated margin, and it is reasonable to interpret the Scheme in a way consistent with its provisions and in a way which encourages delivery within that margin.

21 The Panel has much sympathy with the point that this result may appear particularly harsh for companies over-delivering just outside the 0.5% margin, but cannot find any provision within the Scheme to address this. The Panel accepts the Department's view that the *"administrative efficiency"* referred to in Chapter 7.59 is a reference to the 0.5% margin, and it is clear from bullet point 2 that *"if you don't get within that target, there are consequences."*

22 The Panel finds, by a majority, that in the circumstances of this case and upon a proper interpretation of Chapter 7.59, where over-delivery in a particular year of the 2009 Scheme exceeded the 0.5% margin, the over-delivery cannot be carried forward.

Panel members

Patrick Walker (Chairman)
Sir Robert Culpin
David Hill