IN THE MATTER OF

DEPARTMENT OF HEALTH

-and-

ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY

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 ("PPRS") to consider and provide reasoned Decisions in respect of disputes arising under the 2009, 2008 and 2005 Schemes. This dispute arises only under the 2009 Scheme ("the Scheme"). The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

2. The Panel is grateful to the parties’ representatives for their submissions both in writing and at the hearing, which was assisted by succinct and compelling advocacy. The Association of the British Pharmaceutical Industry ("ABPI") provided a Reasoned Statement dated the 5th October 2011 with annexes and a revised Statement dated the 15th November. The Department of Health ("the Department") provided a Reasoned Statement dated 2nd September 2011.

3. The ABPI originally asked the Panel to consider three matters, but the issue relating to classification of sales between primary and secondary care was not pursued so that in accordance with paragraph 7.7 of Annex Q to the Scheme, that point was "conceded". This does not affect the ability of an individual Scheme member (whether a member of the ABPI or not) to raise the same or a similar issue before the Panel, nor does it preclude interested parties from referring to or relying upon observations of the Panel in an earlier case, in so far as such observations are relevant, unless and until the issue is further considered by the Panel.

4. The remaining issues are outlined in the ABPI’s second Reasoned Statement, and the second issue was reformulated during the hearing, so that in essence, the issues the Panel is invited to consider are:

   i. Should the Decision of the Panel concerning GlaxoSmithKline UK Ltd made in May 2011¹ ("the May 2011 Decision") be limited to its own particular facts, namely the stockpiling of medicines by the NHS Purchasing & Supply Agency (PASA) [now called the Commercial Medicines Unit], in anticipation of need?

¹ PPRSDRP/May/2011//02 published at
http://www.abpi.org.uk/our-work/commercial/pprs/Pages/dispute-resolution.aspx
http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH_128747
ii. Does the Panel agree that price modulation returns should continue to include only UK sales of branded licensed prescription medicines used at the direction of and funded by the NHS?

5. The Department agreed that the reformulated issue was a helpful one for the Panel to consider. The Panel notes that the terms of the reformulated issue are different from those contained within the Scheme and that neither party put forward evidence as to precisely what does or does not constitute “at the direction of the NHS”. However both parties regarded this wording as a reasonable description of the understanding that had prevailed for many years.

6. The issues were prompted by a letter from the Department dated 10 August 2011 which set out changes to modulation calculations said to result from the May 2011 Decision and from the Department’s understanding that “there should be compliance with the agreement on the basis of a reasonable interpretation of the terms as drafted.”

7. In respect of issue 1, the Panel is quite clear that the May 2011 Decision was made in the context of a particular dispute relating to stockpiling, but is equally clear that the findings in it cannot be wholly disregarded when considering further modulation cases. For example, the observation that parties have an “obligation…to seek to place a reasonable interpretation on the terms as drafted” clearly has wider application. The Panel considers it may assist the ABPI, the Department, and individual Scheme members seeking to reach terms with the Department to be aware of the following:

i. The May 2011 Decision was made in the context of a dispute where “it was common ground that the products were within the scope of the Scheme”.

ii. The issue relating to primary and secondary care, and in particular the finding that these two categories are “exhaustive” arose in the context of a product found to be “within a class eligible for modulation and not within any sub-class which is expressly or impliedly excluded”.

iii. The Panel considered and still considers that the correct approach is to find a reasonable interpretation of the terms of the Scheme as drafted. That approach requires consideration of all of the terms and in their context.

iv. The Panel does not expect any party either to apply the May 2011 Decision without regard to its particular facts or to ignore it altogether.

8. The Department concluded that the effect of the May 2011 Decision and a reasonable reading of the terms of the Scheme including paragraphs 4.16, 4.17 and 7.51 requires modulation to take account of all sales of branded licensed NHS Medicines as widely defined in paragraph 4.17 unless expressly excluded, and that in consequence no distinction should be made between medicines supplied to and paid for by the NHS, and those not supplied to and/or not
paid for by the NHS. The Department accepted that the Scheme had not been so operated previously, and defended the interpretation as the necessary consequence of interpreting the terms of the Scheme strictly, in accordance with the Department's view of the May 2011 Decision, rather than operating a more flexible approach.

9. Dr Williams for ABPI argued with tenacity and courtesy that the provisions relied on by the Department must be read in context so that:

i. paragraph 3.4 of the Scheme makes it clear that the Scheme is a price regulation scheme “for branded prescription medicines supplied to the NHS”.

ii. Further support is provided by paragraph 7.58 (referring to “NHS sales”), 8.1 and 8.9 (supply “to the NHS”), 9.6 (“NHS home sales”) and 9.11 and Annex J paragraph 1.3 (“sales…to the NHS”).

iii. “paragraph 3.4 of the PPRS determines the parameters of the PPRS (i.e. supply to the NHS) then, within that scope, the medicinal products covered by the Scheme are defined as paragraphs 4.16 and 4.17...”

iv. Regard should also be had to relevant legislation including the Health Service Medicines (Information Relating to Branded Medicines etc) Regulations 2007 (as amended) and the Health Act 1999 (explanatory notes).

v. Regard should be had to the way in which the Scheme has been previously administered throughout its fifty year history during which the Scheme has not been applied to "sales that do not involve the NHS".

10. The Panel agrees with the Department that the parties should rely on a reasonable reading of the Scheme and considers that the previous course of dealing is no guarantee of correct interpretation.

11. The Panel also acknowledges that the Department’s approach was prompted by what the Department perhaps regarded as an inflexible and precise interpretation of the Scheme in the May 2011 Decision, but that Decision should not be so construed. Rather it reflected the need for both parties to look first to see if the 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.

12. In the May 2011 Decision it was a reading of the Scheme as a whole and in context which resulted in the rejection of the Department’s argument. In this case the Department’s approach effectively seeks to apply the definition at paragraph 4.16 without the full context of paragraph 3.4 and other provisions of the Scheme.
13. The Panel considers that because in the earlier case the Department cited parallel exports as an example in addition to stockpiling of sales which were neither primary nor secondary care, it is understandable how the May 2011 Decision came to be regarded by the Department as extending to parallel exports by implication. But such inference presumes that all parallel export sales volumes fall within the parameters of the PPRS price regulation described in paragraph 3.4 of the Scheme and no evidence was taken upon that point and no finding was made on it.

14. The Panel considers that, applying the approach set out above, the more compelling interpretation is that put forward by the ABPI.

15. On the issue of good faith, the Panel notes that the ABPI’s Reasoned Statement stated that the Department’s interpretation was “inconsistent with the DH’s obligation to operate the Scheme ‘in good faith’”. This assertion was withdrawn at the hearing, and the Panel considers rightly so. It considers that both parties have acted in good faith throughout and that each understandably struggles to apply a Scheme which the Panel has already described as ‘inadequate’ and having a number of unhelpful gaps and inconsistencies.

16. Having regard to the matters set out above, the Panel thanks both parties for their helpful submissions and finds in answers to questions 1 and 2:

i. No. The Decision, like many, was made on particular facts, but will have some relevance in other cases.

ii. The second question was reformulated at the invitation of the Panel and at short notice. The Panel was and remains grateful for the assistance provided by the parties in attempting to so summarise the past approach. Nonetheless the Panel has some concern as to the terms included in the question. For example there are circumstances in which a medicine may be purchased by and / or supplied to the NHS but not used by it. Having regard to those concerns the Panel’s conclusion is necessarily limited to saying that, subject to paragraph 3 above, nothing in the May 2011 decision nor any matter on which the Panel has expressed a view to date should preclude or discourage the parties from continuing to agree price modulation returns upon the basis prevailing immediately before the change in approach evidenced by the 10 August 2011 letter from the Department.