DISPUTE RESOLUTION PANEL OF THE PHARMACEUTICAL PRICE REGULATION SCHEME

DECISION DATED 18 MAY 2012

IN THE MATTER OF: **PPRSDRP/MAY/2012/01**

DEPARTMENT OF HEALTH

- and –

MERCK SERONO LIMITED

1. This is a decision of the Dispute Resolution Panel appointed under the Pharmaceutical Price Regulation Scheme 2009 to consider and provide reasoned decisions in respect of disputes arising under the 2009, 2008 and 2005 Schemes. Further, so far as may be necessary, the Panel is also appointed to carry out the functions of the 2005 PPRS Arbitration Panel and at the start of the hearing the parties, Merck Serono ("the Company") and the Department of Health ("the Department") agreed that the panel members could and should decide matters in the capacity they saw fit. The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

2. **THE ISSUE:** The Company advances a number of arguments against the Department and says remedies should be available whether under the 2005 or 2009 Schemes. However the parties agreed that the approach was likely to differ depending on whether membership of the 2005 Scheme constitutes a contract, and this question was identified as an appropriate preliminary issue. In the event, other preliminary issues were not argued because investigations into records of decision-making were incomplete. Accordingly, the sole issue for the Panel was whether on entering the 2005 Scheme, the Company entered into a contract ("the Issue"). The Company argues that it did: the Department contends there is no contract. If there is a contract, the parties may seek to enforce it as a binding agreement, but it was no part of the application and is no part of this decision to determine whether every or

any particular provision within the Scheme gives rise to a particular enforceable contractual remedy.

3. **BACKGROUND:** The Panel does not approach the issue in a vacuum. It notes that the 2009 Scheme is expressly stated to be *"a voluntary scheme which is not binding under the law of contract"* (Chapter 4.1). That provision was included in the knowledge that in June 2007 Cooke J, sitting in the Commercial Court, had decided that the 1999 Scheme does constitute a 'commercial contract' ("the 2007 GSK Decision"[1]) . By the date of that decision the 2005 Scheme had been drafted by agreement between the Department and the Association of the British Pharmaceutical Industry ("the ABPI"), and a number of companies, including this Company, had entered the Scheme. It is common ground that Cooke J did not determine whether the 2005 Scheme constitutes a contract. In considering the issue the Panel has had the benefit of careful argument presented on behalf of the Company, and at a separate hearing, submissions on the same issue made by another company.

4. **INDICATORS OF A CONTRACT OR UNENFORCEABLE ARRANGEMENT, THE OBJECTIVE APPROACH AND THE BURDEN OF PROOF:**

4.1 Before turning to comparisons between the 1999 and 2005 Schemes and the judgment of Cooke J, the Panel considers it helpful and appropriate to look directly at the terms of the 2005 Scheme with a view to ascertaining whether those terms support the existence of a contract. The Panel accepts that insofar as those terms replicate those in the 1999 Scheme, it may be re-visiting matters already considered by Cooke J, but since the terms read together are not identical, the Panel does not regard itself as constrained from so doing.

1 [2007] EWHC 1470 (Comm).

4.2 The Panel seeks to ascertain the intention of the parties, but in accordance with what both parties appear to accept is established law, that intention is to be considered in the light of objective impression or appearance, to be ascertained principally if not entirely from the terms of the Scheme itself. Furthermore, care must be taken not to rely on subjective beliefs evidenced after the Scheme was entered into. For example, it would be a mistake to conclude that because the parties agreed to the 2009 Scheme which is expressly stated to be non-contractual, the 2005 Scheme must be treated in the same way. Equally unhelpful, in the Panel's view, would be to rely on the observations of the then spokesperson for health in the House of Lords on the 21st October 2008, to which one company referred, suggesting that the 2005 Scheme was *"essentially the same as the 1999 PPRS, was therefore also a contract."*

4.3 The Panel also proceeds on the basis, accepted by the Department, that where the subject-matter of the agreement is commercial, as it clearly is here, the burden of proof lies on the party denying the existence of a contract, and that such burden is a heavy one: see for example the comments of Megaw J in Edwards –v- Skyways Ltd (1964) 1 WLR 349 at 355. The clearest but not the only way of establishing that no contract exists would be by reference to terms expressly so providing, but it would also be possible, in an appropriate case, for the same conclusion to be inferred from provisions inconsistent with the existence of a contract.

4.4 Without reference to the interpretation suggested by Cooke J, the Panel considers that Annex H to the 2005 Scheme includes terms which are at least surprising to find within and arguably inconsistent with the existence of a contract. In paragraph 10.1 it is recited that *"the Department and scheme members are expected to abide by the*

Panel's decision" whereas a contract might have been expected to either assume obligatory compliance or state that members will abide by decision of the Panel.

4.5 Paragraph 10.2 also sits uneasily with the existence of a contract because, on its face, it suggests that it is open to a company to *"ignore the Panel's decision"* and that the appropriate and arguably the only remedy is the removal of the company from the Scheme.

4.6 Chapter 21.1 includes the words *"In imposing this reduction, the aim is to effect a corresponding reduction in the NHS expenditure on branded medicines."* This stated aim (not included in the predecessor Scheme) also sits uneasily with the existence of a contract, particularly as it appears within a specific price reduction provision rather than within the context and aspirations summarised in Chapters 1 and 2 ('Objectives' and 'Introduction').

4.7 Chapter 26.26 provides that members who have overdelivered upon the 7% price cut *"should consult with the Department on appropriate actions"*. This leaves it very unclear what if any contractual remedy is open to a company.

4.8 Form B in Annex A provides that a company *"consents to the voluntary scheme…being treated as applying to it".* In the case of a contract, it might have been expected that the company simply 'agree to the terms of the Scheme'.

4.9 The Department further points out that the Scheme *"is not complete nor, indeed, was it intended to be"* and that the Panel commented on such incompleteness (though not intention) in its decision PPRSDRP/APRIL/2011/1. Relevant parts of the decision include these observations: *"The Panel considers that the 2005 provisions, insofar as they relate to Mid-sized Companies, are inadequate and difficult to*

construe, and King's ability to comply was hindered by the inadequacy of the provisions."[2] *"The Panel agrees that the Scheme's provisions are incomplete and require interpretation and the addition of implied terms in some instances."*[3]

4.10 Against these examples, it may be and has been argued on behalf of two companies that the 2005 Scheme contains terms consistent with and tending to suggest a contract. The Panel notes:

4.10.1 The overtly commercial purpose of the Scheme is to agree pricing or at least formulae for pricing.

4.10.2 In Chapter 5.1, the Scheme has a fixed term *"unless varied or terminated as set out below".*

4.10.3 There are repeated references to *"obligations"* under the "*agreement*": see for example Chapters 8.2, 8.5, 8.7.2, 24.5, 26.15 and 26.16.

4.10.4 The Scheme includes detailed arbitration provisions (Chapter 30). The *"right"* to arbitration is confirmed in paragraph 2.7 of Annex H.

4.1.1 The Department was unable to point to any provision indicating expressly that the parties do not intend to be contractually bound.

4.11 Whilst this last point is unhelpful to the Department's case, ultimately, the Panel is driven to consider whether the terms of the Scheme as a whole point to a commercially binding agreement, or are more in the nature of guidance notes with no effective sanction, save removal of a company from the Scheme, if a company should ignore a decision of the Arbitration Panel (Annex H, paragraph 10.2.3).

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2 Paragraph 6(i).

3 Paragraph 7(iii).

4.12 It would be possible to conclude that the terms are incomplete, and whilst incorporating some terms with a contractual 'flavour', overall they are insufficient to evidence or give rise to a binding agreement. However, the alternative view, preferred by the majority of the Panel, is that though some terms appear inadequate and incomplete, overall, and in the context of the approach and burden summarised above, they are consistent with parties choosing to agree in such a way as to be 'obliged' or bound.

5 COMPARISON OF SCHEMES AND THE EFFECT OF THE 2007 GSK DECISION:

5.1 Many of the terms of the 2005 Scheme are very similar to those of the 1999 Scheme, and the Company argues, in common with another company, that the Schemes are not materially different. The Department points to a number of characteristics of the 2005 Scheme which it says support the view that the Scheme is not a contract, but with its usual candour and succinct written argument, concedes that most of its observations also apply to the 1999 Scheme so that they cannot be sufficient if the Panel is bound by the decision of Cooke J. The Panel does accept that by reason of the learned judge's decision, it is not reasonably open to the Panel to find that the 1999 Scheme is other than a binding contract.

5.2 The Panel accepts that the term 'voluntary scheme' should be read in the context of the alternative of a statutory scheme, and does not, of itself, point away from a contractually binding arrangement. As Cooke J commented[4]: *"It is clear that the 1999 Health Act distinguishes between 'voluntary schemes' into which a pharmaceutical company may enter and 'statutory schemes' which are applicable to those who do not choose to enter into such 'voluntary schemes'. Schemes are 'voluntary' in the sense that there is a choice whether or not to enter into them. There is nothing in the*

[4] Paragraph 10.

Act which suggests that a voluntary scheme is a non-binding scheme once entered into, although a pharmaceutical company or the Minister can in certain circumstances bring it to an end as between themselves."

5.3 The Department seeks to identify and rely on differences between the wording of the 1999 and 2005 Schemes, particularly (a) the introduction in Chapter 21.1 of the words *"In imposing this reduction, the aim is to effect a corresponding reduction in the NHS expenditure on branded medicines"* and (b) the addition to the 2005 Scheme in Annex H of provisions previously contained in 'Occasional Note 3', a note considered by Cooke J and which it is agreed was (i) drafted after parties entered the 1999 Scheme (ii) drafted between the Department and the ABPI and (iii) not agreed with individual companies.

5.4 Clause10 of Annex H to the 2005 Scheme is headed "After Arbitration" and provides as follows: -.

> *"10.1 The Department and scheme members are expected to abide by the Panel's decisions.*
>
> *10.2 The voluntary nature of the 2005 PPRS means that a company has, in practice, three options:*
>
> *10.2.1 Follow the Panel's decision;*
>
> *10.2.2 Withdraw from membership of the 2005 PPRS; or*
>
> *10.2.3 Ignore the Panel's decision. In such circumstances, the Secretary of State will conclude that the scheme is no longer effective in the particular member's case and he will therefore remove the member from scheme membership.*

10.3 In cases 10.2.2 and 10.2.3 the company will no longer be a scheme member of the 2005 PPRS and shall thenceforth be subject to any statutory controls in place pursuant to sections 34 to 38 of the Act".

5.5 The same terms but contained in Occasional Note 3 were relied on by the Department to support the proposition that the 1999 Scheme was not a contract. Cooke J rejected that approach; expressing the view that clause 10 describes *"a range of options open to the member with regard to scheme membership following an Arbitration Award against it. It does not state the Arbitration Award is not binding or enforceable...What is being spelt out in 10.2.3 is the effect of ignoring the Panel's decision in the context of membership and not in the context of enforcement of any kind. Indeed it is plain that, if regulations provide for penalties, penalties could be payable."*

5.6 Whilst the Company would argue that these observations represent the final nail in the coffin of any attempt by the Department to rely on Annex H to distinguish the 2005 Scheme from its 1999 predecessor, the Panel does not consider the matter to be so straightforward for the following reasons:

5.6.1 Cooke J considered the provisions expressly in the context that they were not included in the Scheme and not even negotiated by anyone with agency authority to bind the company (see paragraph 22 of the Judgment). In contrast, in the 2005 Scheme the provisions were expressly included and agreed to at the outset by the Department and by the Company. Cooke J's findings that *"it is in the context of scheme membership that clause 10 of Occasional Note 3 has to be read"* and that *"what is being spelt out in 10.2.3 is the effect of ignoring the Panel's decision in the context of membership and not in the context of enforcement of any kind"* appear to the Panel to suggest

the Court considered whether the Occasional Note issued after the Scheme had been agreed could be read as consistent with a finding that the 1999 Scheme was contractual. Where the same terms are incorporated at the outset, a different approach is arguably appropriate. The Panel considers that Cooke J was too ready to dismiss the interpretation of clauses 10.2.2 and 10.2.3 as alternatives to a company complying with the Arbitration Panel's decision.

5.6.2 The Judge held that *"the whole tenor of the PPRS and the arbitration provisions militate against"* the interpretation contended for by the Department. Under the 2005 Scheme Clause 10 of the Occasional Note effectively becomes part of the arbitration provisions, including clause 10.1 containing the statement that the parties *"are expected to abide by the Panel's decision".* As considered above, the Panel considers that this provision would be unusual and otiose in and arguably inconsistent with a binding contract.

5.6.3 Because the Occasional Note was not incorporated in the 1999 Scheme (held to be a contractual agreement), comments upon interpretation of the Note were not a necessary part of the decision and were arguably obiter comment.

5.7 Is then Clause 10 an explanation of the administrative membership options open to a company after an arbitration decision or is its incorporation in the 2005 Scheme sufficient to negate all the other terms of the Scheme which closely follow the wording of the 1999 Scheme and which the High Court has already determined to be a binding contract? As Cooke J noted, that wording includes the provision that the Scheme is *"an agreement for the purpose of section 33 of the Health Act 1999"* and

(unlike the 2009 Scheme) contains no express provision stating it is a non-binding agreement.

5.8 As set out above, where commercial parties enter into an agreement, there is a heavy burden to show that objectively, the parties did not intend to be bound. Cooke J thought it *"hard to see why the parties would want to enter into an agreement which did not bind then to fulfil its terms"* although the 2009 Scheme suggests the parties do wish to, or at least are prepared to, do precisely that.

6. CONCLUSIONS

Ultimately, the Panel considers that:

6.1 Whilst both the 1999 and 2005 Schemes include ambiguities which make interpretation challenging, that challenge is presented to the parties and on occasions to the Panel, whether or not a scheme is a contract. A similar challenge is presented by the ambiguities in the 2009 Scheme which is expressed not to be contractual.

6.2 Although there are some distinctions between the 1999 and 2005 Schemes, those distinctions are insufficient to conclude that the 2005 Scheme should be construed other than as terms capable of constituting a commercial contract.

6.3 Even though the Panel has some reservations about the decision of Cooke J, that decision is respected, considered binding in respect of the 1999 Scheme and highly persuasive in respect of the similarly worded 2005 Scheme.

6.4 The Panel, sitting both as the 2009 Panel and the 2005 Arbitration Panel, finds that when the Company and the Department agreed to the Company's entry into the 2005 Scheme, and on the assumption that they did so without any relevant modification of the terms of the Scheme, the parties entered into a commercial contract in the terms of the 2005 Scheme.

PANEL MEMBERS:-

Patrick Walker (Chairman)
Sir Robert Culpin
David Hill