DISPUTE RESOLUTION PANEL OF THE PHARMACEUTICAL PRICE REGULATION SCHEME

DECISION DATED 20 MAY 2013

IN THE MATTER OF **PPRSDRP/MAY/2013/02**

BAYER PLC

-and-

THE DEPARTMENT OF HEALTH

DECISION OF THE PPRS DISPUTE RESOLUTION PANEL

1. This is a decision of the PPRS 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. The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

2. Bayer initiated the dispute resolution procedure under the 2009 Scheme in June 2011. In February 2013 Bayer and the Department of Health ("the Department") agreed five issues which both wished the Panel to consider and determine. The parties then provided Reasoned Statements directed to those issues, and on the 27th March 2013 the Panel heard argument from both parties. The Panel is indebted to the advocates and also to the company representatives for their willingness not only to present, but to engage in constructive debate upon difficult issues which all agree reflect the inadequate drafting of both the 2009 and 2005 Schemes.

3. It is important to record at the outset that Bayer expressly brings these matters before the 2009 Panel rather than the Arbitration Panel under the 2005 Scheme. Accordingly, whilst the Panel is asked to consider the status of and conditions in the 2005 Scheme, this is done always through the prism of the 2009 Scheme and in the context of Chapter 7.49.1 of the 2009 Scheme which is central to the dispute between the parties.

4. Chapter 7.49 is concerned with modulation over and under deliveries and Bayer's concern is that the Department is not prepared to carry over from the 2005 Scheme to the 2009 Scheme significant over delivery (£XXX in 2008), because in the Department's view the 75% threshold set out in Chapter 7.49.1 has not been met: i.e. "*provided that enough under-delivering companies agree to repayment such that at least 75% by value of modulation under-deliveries will be repaid to the Department.*" Bayer contends that the Department's approach was "*fundamentally flawed, unfair and inconsistent with the requirements of the PPRS*."

5. **QUESTION 1: Is the 2005 Scheme a legally binding contract between the Department and Bayer?** The Panel's general reasoning is set out in the Merck Serono and Teva cases (PPRSDRP/MAY/2012/01 and PPRSDRP/MAY/2012/02 respectively), which in turn had regard to the 2007 *GlaxoSmithKline* decision of Cooke J decided in respect of the 1999 Scheme. The 2005 Scheme was not varied or added to when Bayer contracted and the Panel concludes that the answer to this question is 'yes'.

6. **QUESTION 2: Should the Department have treated the 2005 Scheme as legally binding for the purposes of enforcement?** Following discussion at the hearing, the Panel hopes it may help the parties to subdivide this question.

a) Did the Department have contracts in the terms of the 2005 Scheme with the companies judged to have under-delivered?

The Panel is able to respond 'probably', in view of its previous decisions, but not 'certainly', because the Panel has not taken evidence from those companies, and cannot exclude the possibility that their circumstances differ

from those of Teva, Merck and Bayer, for example because of modifications to the Scheme recorded when they joined.

b) If the Department had contracts with under-delivering companies, and therefore the contractual right to enforce delivery under the Scheme, did it have an obligation to exercise that right? Alternatively, whether or not there were contracts, did the Department have an obligation to take any disputes to the Arbitration Panel under the 2005 Scheme?

No. First, it was entitled to exercise reasonable judgment, and it seems to the Panel that there is likely to be a real difference between enforceability in general terms and assessing the certainty, the practical enforceability and any available remedy in respect of a particular alleged failure to comply with the terms of the Scheme. Second, an alternative was available, namely for over and under delivery to be carried forward into the 2009 Scheme - see (c) immediately below.

c) Was the Department required to deal with this under the 2005 Scheme?

No, because the 2008 and 2009 Schemes provided for over and under delivery to be carried forward for resolution under the 2009 Scheme. In effect, the Department, like Bayer, could and did postpone the issue. Notwithstanding the express provision in the 2009 Scheme that rights under earlier Schemes were "*neither waived nor extinguished*", both Bayer and the Department entered the 2009 Scheme and either could expect the other to proceed on the basis of Chapter 7.49. The Panel agrees with the Department that Chapter 7.49 "*is not couched in terms of enforcement*." The position under the 2009 Scheme is the subject of question 5 below.

7. **QUESTION 3: Was the Department able to calculate under-delivery in such a way as to have reasonable prospects of successfully enforcing recovery of such sums in the courts under the 2005 Scheme?** The Panel has insufficient information to determine whether any particular claim against an individual member company would have reasonable prospects of success. The calculations concern companies other than Bayer, and were not before the Panel in this case. In general, both parties accept that the calculations are necessarily approximations, and that this applies both to under- and to over-deliveries. They include sums arising in the year 2008, and thus governed partly by the 2005 Scheme and partly by the 2008 Scheme which states that it is non-binding. The Panel sees some force in Bayer's argument that the Department's calculations are either sufficiently robust to support enforcement (whether before the arbitration panel or in court) or alternatively "*are not sufficiently robust to be included in any calculation under 7.49.1 of the 2009 Scheme*."

8. **QUESTION 4: Under the 2005 Scheme (and taking account of the savings provisions at paragraph 1.3 and 4.7 of the 2009 Scheme), are Bayer's rights limited to consultation with the Department pursuant to Chapter 26.26 as the Department contends, or does Bayer have a right to carry forward its over-delivery in accordance with Chapter 26.17?** Whilst this question concerns interpretation of provisions of the 2005 Scheme, both parties approach the issue in the context of the subsequent 2009 Scheme to which they have both subscribed and which gives Bayer the right to carry forward its over-delivery subject to the 75% threshold in Chapter 7.49.

9. The Department argues that even if Bayer had brought issues to a head under the 2005 Scheme before the 75% threshold was in place, all it would have been entitled

to do was "*to consult with the Department on appropriate actions*" under Chapter 26.26 of the 2005 Scheme.

10. Bayer counters that 26.26 does not bring to an end the right in Chapter 26.17 that "*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*." If it was not intended to apply at the end of the Scheme (including if brought to an end prematurely as this was), it is argued, that should have been clearly stated. Further, the consultation in 26.26 is expressly "*To ensure that a 7% price cut is delivered by the Scheme as a whole*."

11. The Department responds that 26.17 cannot have been intended to confer an indefinite and unqualified right, if only because Chapter 26.27 provides that "*The Department may not agree to any modulations proposed in the last year of the Scheme if they may cause the savings delivered during the period of the Scheme to be eroded in subsequent years*."

12. On balance the Panel finds that, whatever the arguments might hypothetically have been at the end of the 2005 Scheme, Chapter 26.17 of the 2005 Scheme is not sufficient to override the 75% threshold in Chapter 7.49 of the 2009 Scheme. The right to "remodulate" in Chapter 26.17 of the 2005 Scheme suggests something within the modulation provisions of that Scheme; it says nothing about carrying forward modulation rights into a later scheme, independently of the rules of the later scheme; to imply such rights would require a very wide interpretation of "longer period" in 26.17.

13. Chapter 26.26 reads as if it was intended to conclude, in the words of the subheading, "*delivery of price cut by the end of the Scheme*". If it had been intended

that this specific entitlement to remodulation survived termination of the 2005 Scheme, then it could have been expressly stated to do so. Further, the saving provisions in Chapters 1.3 and 4.7 of the 2009 Scheme prevented extinguishment of accrued rights but did not, the Panel finds, extend the period for re-modulation beyond the life of the 2005 Scheme.

14. Accordingly, the Panel finds that Chapter 26.17 of the 2005 Scheme does not give Bayer a right to carry forward its over-delivery into the 2008 and 2009 Schemes, such opportunity being derived from those later schemes. Bayer acknowledged throughout that it entered the 2009 Scheme knowing and understanding that it contained the 75% threshold in 7.49.

15. QUESTION 5: For the purpose of Chapter 7.49.1 of the 2009 PPRS (and having regard to the obligation of good faith in Chapter 3.7):

[1] is the Department entitled to take into account only cash repayments by under-delivering companies and to disregard under-deliveries carried forward through adjustment under the 2009 Scheme in accordance with Chapter 7.49.2?

16. No. The Panel is persuaded by the company's argument that too narrow a construction could have absurd results: in the extreme, if companies were to make good all under-deliveries by setting prices lower than they would otherwise have been over the course of the 2009 Scheme, this would constitute a zero repayment on the Department's interpretation.

17. The Department argues that there is a "*clear distinction between repayment and adjustment in Chapter 7.49.2*". However, the Panel notes that Chapter 7.49.2

identifies two ways in which an under-delivery may be "*corrected*", either by "*cash payment*" or by "*adjustment during the lifetime of the new scheme*". The Panel finds that both methods of correction constitute "*repayment*" within the meaning of Chapter 7.49.1.

18. [2] is the Department entitled to treat repayment of under-deliveries under the 2005 Scheme as voluntary or is the Department required to take all reasonable steps to enforce the obligation of under-delivering companies to repay under-deliveries in accordance with Chapter 26.26 of the 2005 Scheme? Do such steps include court proceedings?

19. Enforcement under the 2005 Scheme is addressed in question 2. So far as the 2009 Scheme is concerned, The Department argues that Chapter 7.49.1 is not formulated in terms of enforcement and that agreement is the only relevant criterion. That, says Bayer, means that by refusing or failing to enforce, the Department can and has ensured retention of substantial over-deliveries as a consequence of relatively modest outstanding under-deliveries. Bayer contends that such a result is unfair.

20. Bayer accepts that it remains constrained by the terms of the Scheme and that Chapter 7.49 says nothing about enforcement. Bayer argues that there must be implied into Chapter 7.49.1 a requirement to take reasonable steps to enforce repayment of under-deliveries. The requirement to operate the Scheme in good faith set out in Chapter 3.7 is said to reinforce the implication of such a term.

21. The Panel agrees with the company that the obligation of good faith requires the Department to act fairly and reasonably, and among other things to give due consideration to available remedies (which might include court action) in relation to under-delivering companies. However, the Panel does not find Chapter 7.49

incomplete or inadequate as it stands, and does not find that the obligation of good faith is sufficient to add implied terms to Chapter 7.49 as Bayer suggests. Beyond this and previously published decisions, the Panel makes no findings as to the adequacy of steps taken by the Department against any particular under-delivering company.

22. The Panel acknowledges that an over-deliverer will regard as harsh any interpretation which leaves it to the Department to decide how far to take action against an under-delivering company when the over-deliverer can make no claim against that company. But it may also be seen as harsh to imply upon the Department an open-ended obligation to pursue under-deliverers in circumstances where the 2009 Scheme is expressed to be non-contractual, where Chapter 7.49 makes no reference to enforcement, and where sanctions under the 2005 Scheme are far from clear.

23. Ultimately, the Panel finds that it is not possible to extend Chapter 7.49.1 by implication in the manner suggested by the company. Even taking care not to limit interpretation to contractual principles, neither the wording of Chapter 7.49.1 nor the other provisions to which the Panel has been referred are sufficient to extend or depart from the relatively clear test of 'agreement' set out.

24. Bayer makes the additional point that companies may not agree whilst quantum is in dispute or at least in doubt, and that reference at least to the Arbitration Panel is required before assessing which companies have 'agreed'. Again the Panel concludes that no such requirement is expressed in or implied into Chapter 7.49.1. The Panel concludes that whether or not repayment of under-deliveries under the 2005 Scheme should be treated as 'voluntary', the test is the amount agreed to be

repaid by under delivering companies, whether in cash or by adjustment during the 2009 Scheme.

25. The Panel understands that this will disappoint Bayer. Both parties have told the Panel that Bayer and the Department co-operated well until these issues arose, and that Bayer has then handled these issues very constructively. That was evident at the hearing.

Panel members
Patrick Walker (Chairman)
Sir Robert Culpin
David Hill