

**DISPUTE RESOLUTION PANEL OF THE PHARMACEUTICAL PRICE
REGULATION SCHEME**

DECISION DATED 7 APRIL 2015

IN THE MATTER OF

PPRSDRP/APRIL/2015/01

PFIZER LTD

-and-

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 2009 and 2014 Pharmaceutical Price Regulation Schemes to consider and provide reasoned decisions in respect of disputes arising under the 2014, 2009, 2008 and 2005 Schemes. This dispute arises and is referred to the Panel under the 2009 and 2014 Schemes. The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

- 2 This dispute arises out of the over-payment of the cash component (PPRS 2009 7.14) of price reductions made by Pfizer Ltd ("Pfizer") under the 2009 Scheme and the Department of Health's ("the Department") subsequent decision to decline Pfizer's request for repayment of or opportunity to carry forward the overpayment into the 2014 Scheme. Further, Pfizer takes issue with the fact that the Department's calculation of the company's Historic Cash Payments for the purposes of the 2014 Scheme is based on the percentage level of cash payment actually made by Pfizer in 2013, without regard to the fact that this represented an overpayment.



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REPAYMENT IN RESPECT OF OVER DELIVERY UNDER THE 2009 SCHEME

- 3 The first question upon which the Panel's decision is required arises out of the 2009 Scheme. Paragraph 7.14 of the 2009 Scheme permits companies to deliver up to 2% of the required price cut by making payment to the Department: 90% of the estimated amount by the end of January in each year, with the balance payable by 31st March in the following year. In February 2013 Pfizer made a payment of £xxxx and it is now agreed that this represented an over-delivery in excess of £xxxx. Estimates are no more than that, and Paragraph 7.70 expressly provides that members who have delivered less than the required price cut overall will be required at the end of the Scheme to make a cash payment equating to the under delivery.
- 4 Paragraph 7.70 provides that *"To ensure that that price cut is delivered by the Scheme as a whole, those members that have delivered more than the price reduction required should consult with the Department on appropriate actions."* It is right to say that nothing in the paragraph precludes arrangements for return of monies following over-delivery.
- 5 Pfizer now seeks a direction from the Panel that the Department should *"participate in consultations with Pfizer regarding 'appropriate actions'...to address the over-delivery...through a cash payment."* The Department's argument by letter dated 5th August 2014 concluded: *"The PPRS Decision Committee acknowledges that paragraph 7.70 of the 2009 PPRS gives no guidance on what "appropriate action" is in these circumstances. However, the Committee has noted that there are no specific provisions within either the 2009 PPRS or the 2014 PPRS to allow over-deliveries of the price reduction under the 2009 scheme to be either repaid to the scheme member or carried forward to the 2014 scheme. The Committee also considers that*

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modulation of a price reduction is undertaken by a scheme member at its own commercial risk and that risk should not be underwritten by the Department.”

- 6 The arguments have been well rehearsed in more than one Reasoned Statement of Position from each party and in detailed and helpful oral submissions to the Panel. The Panel does not consider the position to be straightforward. From Pfizer's point of view the words *"to ensure that a price cut is delivered by the Scheme as a whole"* may have given rise to some hope of repayment or carrying forward, particularly when the Department could expect further payments in respect of under-delivery. Against this, there are clearly winners and losers at particular stages of a Scheme, and the Panel must be wary of re-writing the provisions, rather than simply giving them a practical and reasonable interpretation. Furthermore, as the Panel has previously noted in a number of reported decisions, its task is not to rewrite, but to interpret reasonably the words of a particular provision in context, including of the Scheme as a whole.
- 7 On its face, paragraph 7.70 records an obligation to consult, and does not commit either party to a particular result. Pfizer argues that the obligation must be read together with the obligation of good faith, that 7.70 does not preclude repayment and that the provision should be construed as a route to recovery of its overpayment to the Department. The Department argues that there is no substantive obligation to make such repayment.
- 8 The Panel has considered whether the factors identified by Pfizer, taken together, are sufficient to show that the Department has an obligation to 'restore' Pfizer's over-delivery by one means or another. It may be pointed out that a cash payment made in advance is not analogous to over-delivery due to differential modulation, and that retrospective payment would reasonably be based on actual sales rather than a

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forecast. But whilst such reasoning might support re-drafting so as to favour Pfizer, the Panel takes account of all the relevant circumstances including the following:

- 8.1 The 2009 Scheme does not require repayment following over delivery, but nor does it preclude it.
- 8.2 The Scheme does require further payment following under delivery. The Scheme could have but did not make reciprocal provision in respect of over delivery.
- 8.3 Paragraph 7.14 makes express provision for payment of the balance following payment of the 90% estimate, but makes no suggestion that any sum should be refunded if the 90% estimate was over-generous.
- 8.4 The stated purpose of paragraph 7.70 is *“to ensure that the price cut is delivered for the scheme as a whole”*. It is common ground that Pfizer over-delivered. The Panel does not know, and neither party based an argument on, the position for the scheme as a whole.
- 8.5 The 2009 Scheme was drafted, and signed up to by members, in contemplation that it would probably end after 5 years but not knowing what if any scheme might follow and what it would provide for matters outstanding.
- 8.6 By way of example, Pfizer agreed to become a member of the 2014 Scheme in December 2013, and pursuant to paragraph 3.3 of the 2014 Scheme expressly acknowledged that any earlier over deliveries would not be carried forward into that 2014 Scheme, so that at least one and perhaps the most obvious contemplated 'appropriate action' would no longer be considered.

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- 8.7 Pfizer argues not just that such acknowledgement carries with it a reasonable expectation that a cash repayment would be made but that *“the effect of the 2014 (Panel’s emphasis) Scheme is that these (over deliveries) should be dealt with by way of a cash payment by the Department.”* The Panel considers that it would require much clearer and express provision in the 2009 Scheme or the 2014 Scheme to give effect to this important consequence. The Panel agrees with the Department that paragraph 3.3 of the 2014 Scheme (relied on by Pfizer) cannot be read as importing into the 2009 Scheme an entitlement to repayment not included in that earlier scheme.
- 9 The Panel concludes that the Department is not obliged by the scheme to repay or otherwise restore Pfizer’s over-delivery.
- 10 Pfizer then argues for a lesser remedy of requiring the Department to consult further. The Panel has considered whether there has been sufficient consultation on ‘appropriate actions’ to comply with the scheme. Firstly, the Panel rejects the Department’s contention that the consultation obligation in Paragraph 7.70 is only upon the company. Secondly, it is clear, at least with the benefit of hindsight, that the Department could have been more forthcoming in its discussions about its reasoning. Thirdly, although all stages of the process could have been improved, the Panel concludes from the emails, correspondence and record of calls that the Department did consult with Pfizer and did consider whether there was any appropriate remedy for the company, including by referring to a committee.
- 11 It was further suggested by the Department that it should not or at least would not volunteer any repayment but the parties do not ask the Panel, and it is not the Panel’s task, to comment in respect of the exercise of any such discretion.

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- 12 The Panel finds that Pfizer has not shown a failure by the Department to comply with paragraph 7.70. If the Panel were wrong on this, it would add that during the course of the hearing it became apparent that the Department's consideration had been rather fuller than disclosed in correspondence, and that it is very apparent that if further consultation were ordered, the end result would be the same in terms of refusing to make repayment to Pfizer.
- 13 For these reasons the Panel concludes that the Department did have an obligation to consult (and that it did so) but that no obligation to repay arises in the circumstances of this case, expressly or impliedly, and whether by reason of the provisions of the 2009 Scheme, or of the 2014 Scheme or otherwise. In these circumstances the Panel concludes that it is not appropriate to make the direction for further consultations sought by Pfizer.

CALCULATION OF HISTORIC CASH PAYMENTS UNDER THE 2014 SCHEME

Issues

- 14 Under the 2014 Scheme, Pfizer is required to make "Historic Cash Payments". The issue is whether these include or exclude its over-delivery in 2013. This turns on the interpretation of paragraphs 6.41-6.43 of the 2014 Scheme, which only apply to companies which chose to make payments under paragraph 7.14 of the 2009 Scheme.
- 15 Paragraph 6.41 records that "*Government and industry have agreed that the baseline against which the PPRS Payment is applied should be fair for all scheme members*".

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16 Paragraph 6.41 continues: *“Therefore members of the 2009 PPRS that elected to deliver up to 2% of the price cuts in that scheme by making payments to the Department should remain responsible for delivering the value of those price cuts for the relevant products and should continue to make the relevant payments and net them off of their sales figures prior to the calculation of the PPRS payment.”*

17 Such payments, described as Historic Cash Payments, are calculated in accordance with paragraph 6.43, and it is the interpretation of this provision which gives rise to the dispute between the Department and Pfizer. Paragraph 6.43 provides:

“Using information from the 2013 modulation exercise under the 2009 PPRS, the Department will establish the percentage level of cash payment made by scheme members in the last year of the 2009 PPRS. This will be calculated by dividing the amount of the scheme member’s total cash payment in 2013, by the total level of their sales of Scheme Products at NHS list reference prices. The percentage result, known as the Historic Cash Payment Percentage, will be capped at 2%.”

18 The Department’s position is that Historic Cash Payments depend under paragraph 6.43 on *“cash payment made by scheme members in the last year of the 2009 PPRS,”* which further depend on *“a scheme member’s total cash payment in 2013”*. These phrases mean what they say, and therefore include Pfizer’s over-delivery.

19 The Department also argues that there is no need or justification for considering what is ‘fair’, because the wording is unambiguous, and says further that if there is any relevant ambiguity, there is no unfairness – see paragraph 22.7 below.

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- 20 Pfizer's starting point is that the Department's interpretation is "*procedurally unfair*" and inconsistent with paragraph 6.41 because it would require Pfizer to do more than "delivering the value of those price cuts" for which it made a payment under the 2009 Scheme and would therefore not give a "*baseline... fair for all scheme members.*"
- 21 The Panel's approach is to look first at whether the provision has a clear obvious interpretation which makes sense in the 'real' commercial world. Secondly, if there is any ambiguity, to seek to construe the relevant wording reasonably, and in the context of the provision and the Scheme as a whole. If and only if the language of a provision is ambiguous and admits of clear alternatives as to the sense the parties intended to achieve, then consideration must be given to whether the interpretation contended for is commercially sensible or leads to an apparent absurdity. This approach is consistent with the Panel's own published decisions.
- 22 The Panel has considered all the points advanced on behalf of each party including the following:
- 22.1 Paragraph 6.43 includes the words "*total cash payment in 2013.*" It does not refer to sums calculated to be due at the end of the period. This is the foundation of the Department's case.
- 22.2 The Department argued in its reasoned statement of position that "*there is no basis therefore to argue that 6.43 should be construed contrary to its natural meaning, in effect by replacing 'the amount of a scheme member's total cash payment in 2013' with the obviously different text 'the amount that, retrospectively determined, a scheme member would have had to have paid by cash payment in order to deliver the required price reduction.'*"

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Nonetheless, the Department acknowledged in discussion that paragraph 6.43 as a whole is not absolutely clear.

- 22.3 Paragraph 6.43 provides that the calculation of Historic Cash Payments is made “*using information from the 2013 modulation exercise.*” Pfizer’s cash payment in 2013 depended on a forecast made in early 2013, as required by paragraph 7.14 of the 2009 Scheme. By the time the modulation exercise concluded in 2014, forecasting was no longer necessary and was overtaken by audited outturns (meaning in this context, subject to the independent accountant’s supplementary report covering price cut/modulations (Annex G)).
- 22.4 Both parties agree that the calculation of Historic Cash Payments establishes a payment as a percentage of NHS home sales; that the measure of NHS home sales used in this calculation is the audited outturn, established at the end of the “*modulation exercise*” in 2014, not the forecasts or estimates made in the course of 2013; and that the payment required to deliver a price cut depends on NHS home sales. Their disagreement is whether Pfizer’s Historic Cash Payments should be the payment derived from a forecast of NHS home sales made in early 2013 or the amount shown in 2014 to have been necessary given the audited outturn for NHS home sales.
- 22.5 Pfizer’s case is that the Department’s interpretation is inconsistent with paragraph 6.41, which provides that the “*baseline should be fair for all scheme members.*” This does not say what the authors of the scheme would regard as fair, nor for example does it require equal financial consequences for all companies.

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- 22.6 Paragraph 6.41 also says that members who made cash payments under the 2009 Scheme "should remain responsible for delivering the value of those price cuts for the relevant products and should continue to make the relevant payments and net them off of their sales figures prior to the calculation of the PPRS Payment." This does not say "the value of those price cuts and only those price cuts". Nor does it say that scheme members should deliver "more than the value of those price cuts". It seems to the Panel that the more natural reading is that 'value' is achieved by reference to the audited sum found to be necessary to deliver the required price cuts, rather than the actual sum paid within the relevant (2013) year, whether that sum was too much or too little.
- 22.7 Both parties argued that their approaches would produce a baseline fair to all members. Pfizer's case is that it would be unfair to repeat for 5 years an over-delivery deriving from a forecasting error in one year, when outturn figures are available and agreed. The Department responds not only that this is what the scheme provides but also that it puts companies which over-deliver through payments to the Department in the same position as companies which over-deliver through modulation and cannot recover their over-delivery in the 2014 Scheme. Pfizer in turn responds that companies which over-deliver through modulation will see this disadvantage erode, for example as patents expire, but no such relief is available to those which over-deliver by paying too much. The Panel has very limited opportunity to test these arguments, because no other modulating company is party to the dispute, and the Panel has no independent knowledge of the possible implications for other scheme members.

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22.8 Both parties agreed that in most circumstances, the level of cash payment would not exceed 2%, so that the cap would be redundant. However, the parties agreed that in some circumstances, the figure could exceed 2%, so the Panel considers that the provision for the cap does not significantly assist in interpretation of the whole.

Conclusions

- 23 Following helpful and open discussion at the hearing, both parties agreed that paragraph 6.43 as a whole is not completely clear or consistent, especially when read with paragraph 6.41. The terms at issue are new and untested in the 2014 Scheme, and the Panel is mindful that it has only heard from one company and does not know the position of others.
- 24 Both parties agreed in particular that if Historic Cash Payments are based entirely on cash payments in 2013, and that phrase is taken entirely at face value, Historic Cash Payments would include Pfizer's over-delivery but exclude any sum due for 2013 but not paid until after the end of the year. Thus, a consequence could be that no account would be taken of any additional sum found due from a company to the Department as a result of the audit, so that a company which paid a grossly inadequate estimated cash sum would enter into the 2014 Scheme without any consideration of that inadequacy. That is an interpretation for which not even the Department contends: it would mean that companies with payments outstanding at the end of 2013 could not "remain responsible for delivering the value of those price cuts" to which they committed, as required by 2014 paragraph 6.41.
- 25 As a specific example, paragraph 7.14 of the 2009 Scheme requires companies making a payment in respect of 2013 to pay 90% of the estimated amount in 2013

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and the balance in 2014: a strict construction would exclude from Historic Cash Payments the balancing payment in 2014. The Department argued in discussion that *"where a further 10% payment is made in 2014, that would be in respect of 2013 and fall for inclusion into the calculation of the on-going historic cash payment."* The Department fairly pointed out there is a distinction between such a situation in which all the sums paid are taken into account, and the present case which is concerned with a calculation of a lesser sum found to be due. Nonetheless, this is clearly not the same as the argument that "cash payment in 2013" means just what it says. The Department's approach in this regard is consistent with an interpretation which takes account of payments in respect of 2013.

- 26 Building on this discussion between the parties, the Panel finds that when Historic Cash Payments and 'total cash payment' are considered within the whole context of paragraphs 6.41-43, 'total cash payment in 2013' is best construed in the circumstances of this case as 'cash payable in respect of 2013'. As explained below, this interpretation takes proper account of the purpose of delivering value as set out in paragraph 6.41 and of the requirement to use information from the 2013 modulation exercise.
- 27 What then is cash payable in respect of 2013 for Pfizer? The decision on the first question gives the Panel's answer under the 2009 Scheme. The Panel finds the 2014 Scheme different particularly in two relevant respects.
- 28 First, as already noted, paragraph 6.41 says that *"members of the 2009 PPRS that elected to deliver...price cuts...by making payments...should remain responsible for delivering the value of those price cuts"*. If Historic Cash Payments include Pfizer's over-delivery in 2013, the company would over-achieve this objective. The Panel accepts that paragraph 6.41 does not exclude that possibility; and the Department

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argues that it is the position of companies which over-delivered through modulation and therefore consistent with establishing a “*baseline...fair for all scheme members*” (paragraph 6.41).

- 29 The second relevant provision is that paragraph 6.43 says that Historic Cash Payments should be calculated “*using information from the 2013 modulation exercise under the 2009 PPRS*”. This can be interpreted in two ways:
- a. “*The modulation exercise under the 2009 PPRS*” concluded that Pfizer’s cash payable in respect of 2013 included its over-delivery. All the 2014 Scheme does is to use this information in further calculations: it does not change the conclusion reached under the 2009 Scheme. On this interpretation, Pfizer’s Historic Cash Payment includes its over-delivery.
 - b. “*The modulation exercise under the 2009 PPRS*” determined the amount by which Pfizer over-delivered in 2013. That amount was agreed and audited in “the 2013 modulation exercise” and so is “*information from the 2013 modulation exercise*” which should be taken into account in calculating Historic Cash Payments.
- 30 The Panel finds the second more persuasive, because it satisfies the test in paragraph 6.41 that companies should “*deliver the value*” of the price cuts to which they committed, and because it uses all the evidence produced in the modulation exercise rather than excluding some of it.
- 31 The Panel finds that there is no requirement to repay over-deliveries in the 2009 Scheme or to perpetuate them in the 2014 Scheme. The Panel has considered whether its two findings are consistent, and concludes that it is appropriate to consider each question and the provisions of each scheme in its own context.

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32. In Pfizer's case, therefore, the Panel reads paragraph 6.43 to mean that the company's Historic Cash Payments should be calculated by reference to the cash payable in respect of 2013 ascertained through the 2013 modulation exercise. It concludes that Historic Cash Payments, so construed, take account of the new evidence available in 2014 that Pfizer over-delivered by an amount which has been agreed and audited, and in the circumstances of Pfizer's case, its Historic Cash Payments should be calculated excluding its over-delivery in 2013.
33. On both the issues in this case, the Panel finds it entirely understandable that disputes have arisen, has found merit in arguments from both parties, and has found no evidence that either party has behaved improperly or unreasonably.
-