

[REDACTED]
Chief Executive
Birmingham East and North Primary Care Trust
4th Floor, Waterlinks House
Richard Street
Aston
B7 4AA

11 October 2007

Sent by email

Dear [REDACTED]

Final Appraisal Determination: Pemetrexed for the treatment of malignant pleural mesothelioma

Thank you for your letter dated 13 September 2007 amending Birmingham East and North PCT's appeal against the above Final Appraisal Determination (FAD).

As I noted in my letter to you dated 24 August 2007, the Institute's appeal procedures allow for an initial scrutiny of points raised by an appellant to confirm that they are at least arguably within the permitted grounds of appeal. Birmingham East and North PCT's initial points of appeal have been subject to this initial scrutiny process. The PCT has now elected to re-work its appeal document quite substantially. This letter comments on the amended points of appeal raised and confirms which points of appeal will be referred to the Appeal Panel. To clarify, it is this amended appeal document and not the PCT's initial appeal document (received under cover of letter dated 20 July 2007) that will be the basis of the PCT's appeal before the Appeal Panel.

Upon receipt of this letter, it will not be necessary for you to comment further on your appeal points or on my comments on those points prior to the Appeal Panel hearing.

As you are aware, there are three permitted grounds of appeal:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared guidance which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

Points of Appeal

Your amended appeal document makes two points of appeal under Ground 1 (appeal points 1A and 1B), two points of appeal under Ground 2 (appeal points 2A and 2B) and one point of appeal under Ground 3 (appeal point 3).

Your appeal point 1A contains a number of limbs. In so far as it asserts that the Appraisal Committee should have used a comparison between pemetrexed with cisplatin and active symptom control to assess cost-effectiveness rather than a comparison between pemetrexed with cisplatin and cisplatin monotherapy, I consider it to be a valid point of appeal.

Appeal point 1A then goes on to make various arguments in relation to paragraph 4.3.11 of the FAD. My understanding is that, combined, they amount to the contention that the Appraisal Committee has failed fully to explain in the FAD the reasoning behind its recommendation. However, I do not regard all of the arguments made in favour of this contention as supporting it. The points made at paragraphs 11 (a), (b), (f), (g), (h) and (i) do not appear to demonstrate how the Committee has failed to explain its reasoning but instead focus on areas in which the PCT believes the Committee's reasoning to be in error. I do not, therefore, regard those points to be valid arguments under Ground 1 and consider that they would be more appropriate as Ground 2 points (discussed below). To the extent that the points made at paragraphs 11(c), (d) and (e) argue that the Committee's reasoning was unclear, I believe them to be valid Ground 1 points.

Your appeal point 1B essentially argues that the Institute's document *Social Value Judgments* indicates that occupational exposure should not be taken into account when developing NICE guidance. As you may recall, in my response to your initial appeal document, I accepted this as a valid point of appeal but suggested that you might like to reframe it as a Ground 2 point (that is, that failure to act in accordance with *Social Value Judgments* and/or taking into account occupational exposure is perverse in light of the evidence submitted) on the basis that the document is not part of the Institute's published procedures for appraisals and failure to act in accordance with it will not, of itself, trigger Ground 1.

The initial section of your appeal point 1B asks me to reconsider my position on the relevance of *Social Value Judgments* to this appeal. To clarify, my initial scrutiny letter did not argue that *Social Value Judgments* is not relevant to this appeal; my point was simply that, as it is not part the Institute's published procedures for appraisals, the PCT's argument may not be appropriate as a Ground 1 point and may sit better within Ground 2. However, I invited you to maintain it as a Ground 1 point if your argument essentially amounted to a contention that it was unfair that the Appraisal Committee failed to consider *Social Value Judgments* as the PCT had put forward specific arguments based on it or that it was unfair that the Committee failed to consider the document because you did not know that the cause of Mesothelioma might be considered by the Committee.

Your amended appeal document appears to have focused your argument regarding *Social Value Judgments* on the discrimination that allegedly arises as a result of taking occupational exposure into account in technology appraisals. I am still minded to consider this as a Ground 2 point as I believe that your argument is focused on the consequences of taking into account occupational exposure rather than on the procedural question of whether the Appraisal Committee should have taken into account *Social Value Judgments*.

To the extent that appeal point 1B focuses on the rule of rescue, I consider it to be a valid point of appeal under Ground 1.

Your appeal point 2A states that to the extent that any of the points made in relation to Ground 1 tend to perversity, they are repeated as a Ground 2 point. Unfortunately, I am of the view that this does not sufficiently explain the arguments that the PCT intends to make under Ground 2 and that it can not be for the Appeal Panel or the Institute to determine which of the PCT's Ground 1 points it also intends to make under Ground 2. Crucially, the Appeal Panel can not prepare properly for the hearing unless the PCT clearly identifies which points it intends to make under each Ground. Consistent with the view I have taken above, I have taken the points made at paragraphs 11(a), (b), (f), (g), (h) and (i) to be Ground 2 points and consider them all to be valid.

Point 2A then specifically focuses on the argument that it was perverse for the Appraisal Committee to have assessed the cost-effectiveness of pemetrexed against cisplatin rather than against best supportive care. I regard this to be a valid point of appeal.

I consider your appeal point 2B (the Appraisal Committee has based its recommendation on the availability of a 100mg pemetrexed vial that is not yet available in the NHS) to be a valid point of appeal. As an aside, I note that you have stated that it was perverse for the Appraisal Committee to mandate PCTs to make funding available for pemetrexed when the vial size recommended is not available in the NHS. I wish to clarify that NICE does not direct PCTs to make funding available although I acknowledge that the Secretary of State's directions may oblige PCTs to do so.

Your appeal point 3 has two limbs. The first limb is that it is beyond the powers of the Institute to recommend a treatment in a form (a 100mg vial) that presently is unavailable. I regard this to be a valid point of appeal.

The second limb of appeal point 3 is that it is beyond the powers of the Institute to "seek to use the NHS as a form of quasi-statutory compensation for occupationally contracted diseases." In your original appeal document, you argued that it was outside the powers of the Institute to introduce occupational exposure as a differentiating factor. I accepted this as a valid point of appeal but indicated that the Appeal Panel would want to hear argument as to why introducing occupational exposure as a factor was unlawful. Having read your amended appeal document, I interpret the new

contention that the effect of the Appraisal Committee's recommendation is to try to use the NHS as a quasi-statutory compensation mechanism to be an attempt to extrapolate on your original argument, as I had requested. I am minded to allow this second limb as a point of appeal but suggest that you will need to explain to the Appeal Panel precisely how the FAD does in fact generate a compensatory mechanism as you suggest.

Preliminary Conclusion

As indicated, I regard appeal points 1A (in part under Ground 2), 1B (in part under Ground 2), 2A, 2B and 3 to be valid points of appeal.

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence