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Wednesday 15th August 2007
Sent by email

Dear Sirs,

FAD Primary prevention of osteoporotic fragility fractures in postmenopausal women

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Thank you for appeal notice dated 9 July 2007 against these two FADs. This letter is my preliminary assessment of the validity of your appeal points, as required by NICE's appeal process.

I will adopt the numbering of your appeal notice. However, your numbering departs from the usual approach in NICE appeals, where appeals on the grounds of unfairness/failure to follow the Guide to Technology Appraisals (ground one) are listed first, and usually given numbers 1.1, 1.2. and so on, appeals under ground two are listed next, and usually numbered 2.1, 2.2, and so on, and ground three appeals (illegality) are listed at the end and numbered 3.1, 3.2 and so on. It would be a great help to the appeal panel if, after this initial scrutiny stage, you could reorder and renumber those of your appeal points which are to go forward in the usual way, and resubmit an amended appeal notice.

Paragraph 1.1

I note that the study referred to was submitted after publication and consultation on the ACD, and at the stage where an FAD was being prepared. At para 4.5.2.10 of the Guide to the Technology Appraisal Process, I note that new data are accepted at the ACD stage only if they are likely to have a material impact and only with prior agreement. Dealing with the situation after the ACD consultation has closed, para 4.5.4.4 of the same guide (which you cite) notes that in exceptional circumstances, for example if a relevant report is published while a FAD is being developed, further analysis may be undertaken. I am therefore minded to allow this appeal point to go ahead, but only on the basis that it was perverse not to conclude that that exceptional circumstances applied such that further analysis was necessary under para 4.5.4.4.

I note your argument under articles 8 and 14 ECHR. These arguments may belong more naturally under ground three, and I suggest that they should be considered under that heading. By way of guidance I would advise you to provide the appeal panel with legal argument on whether guidance on this treatment is within the scope of Article 8. I would draw your attention to the judgement in *R ota Eisai v NICE* (10/8/2007) in that regard.

Paragraph 1.2

I am not entirely clear whether (and if so how) this is a separate argument to the argument under paragraph 1.1. I am inclined to rule that they should be considered as one combined ground of appeal.

Paragraph 2

A valid ground two appeal

Paragraph 3

I am not convinced that this is not a ground one appeal point, rather than ground two. Could you reconsider which ground of appeal you feel this argument should be brought under before I make a final ruling. I would also point out as guidance that, for an argument of inconsistent treatment with other appraisals to succeed, you will need to satisfy the appeal panel that the appraisals you cite are properly comparable, such that consistent treatment can be said to be a requirement.

Paragraph 4

A valid ground one appeal point.

Paragraph 5

I am afraid I cannot see the unfairness/breach of procedures alleged here (although I have agreed above the point can go ahead under ground two). Could you detail the alleged internal inconsistency or unfairness, before I take a final decision.

Paragraph 6

A valid ground one appeal point.

Paragraph 7

Although I would agree that an alleged failure to act in accordance with para 4.5.4.4 of the Guide to the Technology Appraisal Process would be a valid ground of appeal, failure to adhere to the Social Values Judgement is not a valid ground of appeal. Depending on the facts of any case, it might be procedurally unfair (if, for example, you were led to believe that certain matters would be relevant and taken into account, which were not in fact considered), but this would need to be shown to be arguable.

If you can explain how the alleged failure to adhere to the social values judgement produced unfairness in this case, I would be willing to reconsider that the point should indeed be brought under ground one.

Nor is a breach of art8/14 ECHR a ground one ground of appeal, although as noted above it may be considered under ground three.

Paragraph 8

In light of the judgement of the High Court in *Rota Eisa v NICE*, 10/8/2007, I do not feel this is an arguable appeal point.

Paragraph 9

A valid ground one appeal.

Para 10

A valid ground three appeal.

As an appeal will take place in any event, the Institute will contact you to make the necessary arrangements. If you wish to make any further submissions on your points that I have queried or indicated that I would not be minded to accept, I would be happy to consider them before reaching a final decision on those issues. I would be grateful for any such reply within three weeks of this letter (COB Wednesday 5th September 2007)

Yours sincerely

Mark Taylor
Chair, Appeal Panel