

The National Osteoporosis Society
*For and on behalf of the National Osteoporosis Society, the Society for Endocrinology, the
British Society for Rheumatology and the Bone Research Society*

7 September 2007
Sent by email

Dear [REDACTED]

FAD Primary prevention of osteoporotic fragility fractures in postmenopausal women
FAD Secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for your letter dated 22 August 2007. This letter is my final assessment of the validity of your appeal points, as required by NICE's appeal process.

Paragraph 1.2

I repeat that ground one appeals must be brought on the basis that " The Institute has failed to act fairly and in accordance with its procedures as set out in the Guide to the Technology Appraisal Process". The social values judgements document is not part of the guide to the technology appraisal process. Therefore, we have to ask, on the facts of any case, it is arguable that a failure to adhere to the guide is procedurally unfair. (At this preliminary stage I would assume that any allegations you made would be proved in due course, unless they were patently hopeless.)

Your letter still gives me no indication of why the alleged failure to consider this document can be said to have produced unfairness. For example, you have not identified any submission which you made, expecting it to be relevant by virtue of the social values judgement, but which you say was in fact disregarded, or any other matter of that sort. I therefore conclude that the appeal point should be considered as a matter of perversity, not procedural fairness.

Paragraph 1.3

Contrary to your submission, I do not regard the judgement of the High Court in *R ota Eisai v NICE* as narrowly confined to its facts. Clearly, it must to a degree depend on the facts of that case, but in my opinion it has established a general rule that NICE's published procedures and settled practice of not releasing an executable model is not unfair. Only if an appellant demonstrated some exceptional feature taking an appraisal outside the *Eisai* precedent would this point be arguable. In my judgement you have not done so, and I conclude this appeal point should not proceed.

However, I should inform you that another appellant, Servier laboratories, has raised the different issue of whether as a matter of fact the non-executable model released in this appraisal contained sufficient information to enable intelligent comment. I have agreed that that point is not settled by the *Eisai* case and should be considered by the appeal committee. Notwithstanding my ruling on the validity of your appeal point 1.3, I would expect that the appeal committee would consider any submissions you may wish to make on Servier laboratories point.

Paragraph 1.5

On consideration of your further points, I agree that an allegation of inconsistency of approach or methodology in an appraisal may be a ground one matter, (albeit inconsistency in outcome would be a ground two matter) and that the appeal should proceed under ground one.

Paragraph 1.6

I remain unclear as to how it is that you say the alleged lack of transparency has produced unfairness. However, I am assuming that you will argue that you were not able to make relevant submissions due to uncertainty as to the reasons for the conclusions in the FAD, and on that basis I will agree that the point should continue under ground one.

Paragraph 1.7

Possibly my earlier letter was unclear. Failure to follow the methods guide is not of itself a ground of appeal. It may, of course, lead to unfairness, and that would be a valid ground of appeal.

On consideration of your further submissions, it seems to me you are arguing that, as a result of the guide, you expected certain calculations to be carried out, and certain factors to be weighed in considering the results of those calculations. Whether you are right that that is the effect of the methods guide will be a matter for the appeal panel, but I do agree that it would be right for them to consider the point under ground one.

Paragraph 1.8

I noted above that an inconsistency in approach could be a valid ground one matter. It still appears to me that your complaint here is an inconsistency in outcome, and I remain of the view that that is better considered as a question of perversity. If in fact it transpires during the investigation of this point that the primary and secondary prevention appraisals were conducted in a different way, then I would expect the appeal panel to feel able to explore that matter in the context of ground one, if it felt that was appropriate.

Paragraph 1.9

I still can see no evidential basis for arguing that innovation has not been taken into account. I do not think it is sufficient to infer from a failure to recommend a more innovative treatment, that innovation has been ignored. However, as you are in a sense seeking to prove a negative, it may be that an appeal panel would wish to put the point to the appraisal committee for its response. I therefore agree the point should proceed.

Para 2.1

Thank you for your clarification

Paragraph 2.2

I remain unconvinced that this is a valid appeal point, and my decision is that it should not proceed.

Yours sincerely

Mark Taylor
Chair, Appeal Panel