

[REDACTED]

Mr Mark Taylor  
Appeal Committee Chair  
National Institute of Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
LONDON  
WC1V 6NA

19th August 2008

Dear Mr Taylor

**RE: Final Appraisal Determination: Alendronate etidronate risedronate and strontium ranelate for the primary and secondary prevention of osteoporotic fragility fractures in post menopausal women**

Thank you for your letter of 6 August 2008.

As previously stated in my letter of 4 August 2008, Servier Laboratories ("Servier") disagrees with the refusal to allow the appeal panel to reconsider all of the appeal points raised by Servier in relation to the osteoporosis final appraisal determinations.

In particular I note your position in relation to the issue of the failure of the Institute to provide consultees with a fully-executable version of the economic model (appeal point 9). However, Servier disagrees with your analysis and I take this opportunity to make Servier's position clear.

The fact that the Institute has petitioned the House of Lords for permission to appeal the Court of Appeal's decision in the *Eisai* case does not alter the fact the current judgment of the Court of Appeal in that decision is the law as it presently stands. The Institute is therefore wilfully continuing to act unfairly in failing to provide a copy of the economic model in full knowledge of the law as set out in this judgment.

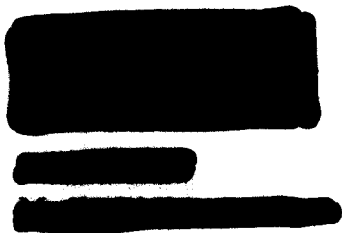
You also state that there are considerations applying to the economic model in this case that did not apply in the *Eisai* case. However, you cannot deny that as far as the issues of confidentiality and the practicality of providing a fully-executable version of the model are concerned, the Court of Appeal in the *Eisai* case, as set out in my letter of 4 August, had these in consideration when it made clear that it had borne in mind the wider significance of its decision, i.e. the general implications for the work of the Institute if it was required to release fully-executable versions of its economic models to consultees. Nevertheless, the

Court held that fairness requires the release of the economic model to consultees, which the Institute has failed to do in the present case.

I also refer to the Appeal Panel's initial decision in relation to this guidance that the Institute should request permission from the World Health Organisation to release it from its confidentiality undertakings in respect of the data used to populate the economic model such that a copy of the model could be provided to consultees. Servier has not received any confirmation that this request has even been made.

I note that you state that your response of 6 August represents your final decision on the validity of the points Servier has raised on appeal. Servier respectfully requests that you reconsider allowing the appeal panel to hear all of the points raised by Servier in this appeal, as it continues to contest that the decision of the appraisal committee was unlawful for all of the reasons raised on appeal. If you are not minded to agree to this request, Servier will have no option but to bring to the court's attention the refusal to hear these appeal grounds again, including the continuing refusal by the Institute to provide the economic model, both in the ongoing judicial review proceedings and in any potential claim for judicial review of the reappraised guidance Servier may elect to bring following the conclusion of the current appeal.

Yours sincerely

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