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Sir Michael Rawlins  
Chair  
National Institute of Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
LONDON  
WC1V 6NA

4<sup>th</sup> August 2008

Dear Sir Michael

**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 29 July 2008 and your initial view on the points raised by Servier Laboratories on appeal.

We are pleased to note that you consider some of the points raised by Servier to be valid appealed points and that you are minded to pass Servier's appeal to the Appeal Panel for consideration.

We also note, however, that you do not propose to allow Servier's appeal points numbered 1, 3, 4, 6, 7, 9 and 10 to be presented to the Appeal Panel. As has been noted in both our appeal submission of 21 July and your letter of 29 July, these points were raised by Servier in its appeal against the previous versions of the Final Appraisal Determinations published in June 2007, and were allowed to be presented to the Appeal Panel as they were considered to be valid (as being arguably within the permitted grounds of appeal). Although Servier has indicated that it anticipates that the Appeal Panel may feel itself bound by the previous decision of the Appeal Panel to reject these points, we nevertheless disagree with the conclusion that these points should not go forward to the Appeal Panel for consideration at all. The appeal will be heard by a newly-constituted panel, which may choose to take a different view from that of the previous panel, and we request that these points are also forwarded to the Appeal Panel for its consideration.

As a final point, we consider that there has been a material change in the legal circumstances in relation to numbered point 9. Since the Appeal Panel's decision of 11 December 2007 to reject Servier's point that it was unfair to withhold a copy of the economic model, the Court of Appeal has ruled, in the *Eisai v NICE* case<sup>1</sup>, that it is procedurally unfair for NICE not to provide a full version of the economic model underpinning the technology appraisal to consultees. The Court also made it quite clear that the decision was not restricted to the particular facts of that case. The judgment of

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<sup>1</sup> *Eisai v NICE* [2008] EWCA Civ 438

Lord Justice Richards referred not only to the administrative considerations advanced by the Institute to support its claim that procedural fairness did not require disclosure of the fully-executable model, but also to the wider significance of the decision reached. It is clear that the law recognises that procedural fairness requires the disclosure of the fully-executable version of the economic model to consultees, and the Appeal Panel should have the opportunity to correct, following the exposition of the law by the Court of Appeal, its earlier decision not to require this disclosure. We therefore request that, in any event, appeal point 9 be forwarded to the Appeal Panel for consideration.

Yours sincerely

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