

**From:**  
**Sent:** 21 August 2008 20:01  
**To:**  
**Cc:**  
**Subject:** Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF- $\alpha$  Inhibitor  
**Importance:** High

21 August 2008

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Dear

**Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF- $\alpha$  Inhibitor**

Thank you for your letter of 1 August, lodging Schering-Plough Limited's appeal against the above Final Appraisal Determination (FAD).

**Introduction**

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are least arguable within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- 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 a FAD which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

I normally write to appellants with my initial view of the points of appeal they have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Since, however, I consider all your points of appeal to be valid, you may take it that they will all be referred to the Appeal Panel.

**Appeal Points**

You have raised two points of appeal under Ground 1 (1.1 and 1.2), two points of appeal under Ground 2 (2.1 and 2.2) and one point of appeal under Ground 3 (3.1).

I consider your appeal points 1.1, 2.1, 2.2 and 3.1 to be valid. With regard to your appeal point 1.2, the Court of Appeal's decision in Eisai is currently under appeal to the House of Lords. Nevertheless, it seems to me appropriate that the Appeal Panel should consider this point in case there are considerations applying to the release of the model in this case that were not

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present in the Eisai case. I therefore consider that your appeal point 1.2 is also valid.

**Conclusion**

Since I have concluded that all your appeal points are valid, an appeal hearing will take place. The Institute will contact you to arrange this in due course.

Yours sincerely

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