



**National Institute for
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16 December 2011

Dear [REDACTED]

Final Appraisal Determination: Dabigatran etexilate for the prevention of stroke or systemic embolism in people with atrial fibrillation (AF)

Thank you for lodging your comments on my initial scrutiny letter. As you have significantly restructured your appeal, I will work from your letter of 8 December 2011 as the appeal document to be considered by the panel. Your earlier letter will not be directly considered.

Ground 1

I had previously agreed and I now confirm that these are valid ground one appeal points.

Ground 2

I will agree that the whole of this point is valid under ground 2. To assist you in preparing for the hearing, I would expect that an appeal panel would want to deal with each of points A-D in turn.

Ground 3: The Institute has exceeded its powers

I am still not persuaded that this point raises a stand-alone appeal point. It seems to me that, once the fairness of the process which generated the guidance has been looked at, and the reasonableness of the guidance also considered, there is no stand-alone content to this point. Put another way, the arguments you wish to make here can be accommodated within the grounds of appeal which I have agreed should go forward.

For this reason I do not agree that the panel should consider this point.

Conclusion

This is the final decision on initial scrutiny. The valid appeal points are the points set out under grounds one and two in your letter of 8 December 2011. Thank you for your comment on the need for an oral hearing. The Institute will contact you to make arrangements for the hearing in due course. As you will not have attended an appeal hearing before, you might find it helpful to contact the appeals project manager, [REDACTED], for an overview of how appeal hearings are usually conducted. She can be reached on [REDACTED]

Yours sincerely

[REDACTED]
For the Appeals Committee Chair
National Institute for Health and Clinical Excellence