

7 March 2007



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Dear

FAD Pemetrexed Disodium for the treatment of non-small cell lung cancer

Thank you for your letter dated 1 March 2007. This letter is my preliminary assessment of the validity of your appeal points, as required by NICE's appeal process.

On an initial point, your letter refers to appeals under grounds one, two and three of NICE's appeal process. However it only details appeals under grounds one and three. Could you confirm that your letter contains all of the grounds on which you wish to appeal?

Ground one

In my view these are all valid ground one appeal points, and will be considered at an appeal hearing in due course.

Ground three

In my preliminary view this is not a valid appeal point. First, the FAD appears to state the conclusion of the CHMP. Second, whereas I would agree that NICE would act outside its remit if it moved into the area of product licensing, (where it must accept the view of the CHMP), it is a logical non-sequitur that it must, as a jurisdictional issue, accept findings of fact of the CHMP, when it is acting within its own remit of assessing clinical and cost effectiveness. I am therefore not minded to allow this ground of appeal to proceed.

As an appeal will take place in any event, the Institute will contact you to make the necessary arrangements. If you wish to make any further submissions on your point on ground three, I would be happy to consider them before reaching a final decision on that issue. I would be grateful for any such reply within fourteen days of this letter.

Yours sincerely

Mark Taylor
Appeals Committee Chair