From:

Sent: 15 September 2008 09:29

To:

Cc:

Subject: Appeal: Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF-a Inhibitor

Importance: High

15 September 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-α Inhibitor

Thank you for your letter of 11 September. This letter represents my final decision as to the validity of your appeal points.

Ground 3

Thank you for clarifying that the disability discrimination issue you wish to raise is the non-participation of people with learning difficulties in clinical trials. I agree that that is an arguable ground of appeal and that this should be considered by an appeal panel.

Under the ECHR, I agree that behaviour being challenged need only be within the ambit of a substantive right for Article 14 to apply. I am afraid that I do not agree that provision, or otherwise, of these treatments within the health service is within the ambit of any substantive ECHR right. This point was considered at some length by the appeal panel in the first appeal against the guidance concerning primary and secondary prevention of osteoporosis, in which the panel concluded that as a rule decisions as to general availability of treatments were not within the ambit of convention rights, a position which is being maintained in a current judicial review. Although I would be willing to consider arguments that any given treatment was an exceptional case, I do not think, in view of the Institute's position, that there is any prospect of this appeal ground succeeding.

This is of course a legal question and the Institute's view cannot be determinative. I am not allowing this argument to proceed, but this is without prejudice to your right to challenge the Institute's legal view in the usual way.

As to the transparency directive, much the same argument applies. The Institute has consistently taken the view that properly

worded guidance does not have the effect of a ban within the meaning of the directive. Again I would consider an argument that any particular guidance might have that effect because of its specific wording, but general claims under the transparency directive are not allowed to proceed. As you note, this issue is before the courts, and no doubt that case will give us a definitive answer. But, having considered the arguments carefully, NICE has a decided position on the issue and therefore there is no prospect of this appeal point succeeding.

Yours sincerely

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