nras
National Rheumatoid Arthritis Society

Mr Mark Taylor,
Appeals Committee Chair,
National Institute for Health and Clinical Excellence,
MidCity Place,
71 High Holborn,
London WC1V 6NA.

3rd September 2008

Dear Mr. Taylor

Thank you for your email dated 21st August 2008. We are naturally extremely disappointed that you did not consider valid the points of appeal that we raised and welcome the opportunity to come back to you to raise any additional points for your consideration.

In regard to our first point which refers to data which you claim is new data and has not been before the Appraisal Committee before, I would like to draw to your attention the following information which may not have been clear.

The Appeal panel's decision was released in June of 2007 and it recommended that the issue of switching must be referred back to the Appraisal Committee for reconsideration. In fact we wrote to NICE on 2nd November, 2007 to register our concern over the delay by NICE in advice to the stakeholder community of a date of the new Review which in fact did not take place until April 2008. We therefore assumed that the Appraisal Committee would re-appraise the originally available information and any new data which had come to light up to early 2008.

We felt and still believe that it was entirely legitimate to point out that where there is new and compelling evidence that has come to light that it would be perverse indeed to let a flawed conclusion stand for some years on the basis of a decision made in the light of incomplete evidence. The data referred to in our appeal dated 1st August relates to a systematic review and meta analysis of data presented from January 1995 – November 2007 which included Eular and ACR abstracts presented from 2004 – June 2007 which surely meets the Institute's criteria regarding the timeframe of availability of relevant information to inform their decision-making and must, therefore, include data already familiar to the Appraisal Committee even if they had not seen the meta-analysis.

In regard to our second point, you have rightly pointed out that the ECHR is not part of the law of the United Kingdom. I apologize for this oversight and would like to re-state our point underThe Human Rights Act 1998 which became UK law in 2000, Article 14 which covers PROHIBITION OF DISCRIMINATION which says that:

'In the application of the Convention rights, you have the right not to be treated differently because of your race, religion, sex, political views or any other status, unless this can be justified objectively.'

You also state that sero-negative and sero-positive patients are not distinguished in the recommendation. That may be true in regard to the 'recommendation' but we are claiming that this is inappropriate on the part of the Institute, particularly as the Appraisal Committee acknowledge that Rituximab is less likely to be effective in sero-negative disease (4.3.20, pages 33 – 34), and have then failed to include this in their subsequent analyses.

As far as we are able to determine, the current recommendations would be discriminatory against a substantial sub-set of rheumatoid patients if they were denied an efficacious therapy on the grounds that NICE decision making caters for another subset only. It is entirely reasonable to make pathobiological distinctions between sero-negative and sero-positive patients, both of which are associated with a disability with similar patterns of expression (although not identical patterns).

We believe NICE, by their current recommendations, are discriminating against a sub-set of RA patients and do not believe that this has been objectively justified.

I would be grateful if you would review our appeal again in the light of the above further explanation and look forward to hearing from you in this regard.

Yours sincerely