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8<sup>th</sup> October 2015

Dear ,

*Re. Initial scrutiny: FAD - 'Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed' (ID537)*

Thank you for your letter dated 25th September 2015.

MSD are grateful for the opportunity to have our appeal points considered at an oral hearing.

We note that at this time you consider that point 1.2(a), our assertion that NICE has failed to follow process which has led to unfairness, and that NICE has failed to allow proper comment on the issue of biosimilars, are valid grounds for appeal.

We note also that you consider that 1.1(a) does not represent a valid ground for appeal, and as such are not minded to refer this point to an appeal panel. With respect to point 1.1(a) relating to the FAD unfairly discriminating against Remicade, MSD would like to challenge the current position that this is an invalid ground for appeal.

In your response you have agreed grounds for appeal around the inappropriate use of contract prices, and the late inclusion of biosimilars into the MTA. The consequence of using contract prices in this way, and a failing to consult with MSD on this topic has resulted in the FAD containing a published ICER for biosimilar infliximab which implies it is the only cost effective infliximab and should be used in preference over Remicade. This is the clear impression that we have when reading the FAD and the feedback we have from physicians and commissioners supports this interpretation. For this reason MSD believe that the FAD will unfairly discriminate against Remicade. We request that this aspect of our appeal forms part of the discussions during the oral hearing. If necessary, we feel that this could be covered during the discussion of our existing point 1.2(a).

Please do not hesitate to contact me if you have any comments or queries.

Yours sincerely,

Senior HTA & OR Manager