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14th October 2015

Dear

Re. Initial scrutiny: FAD - 'Ankylosing spondylitis and axial spondyloarthritis (non-radiographic) adalimumab etanercept infliximab and golimumab (inc rev TA 143 and TA 233) ID 694

Thank you for your letter dated 2nd October 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 the points:

- 1.1) NICE has inappropriately used contract prices, and
- 1.2) biosimilars are not mentioned in the appraisal scope, are valid grounds for appeal.

We note also that with respect to aspects of point 1.2, specifically our concerns around the wording of the recommendation in paragraph 1.1 of the FAD, you are not presently minded to allow these points to proceed. As you state in your letter, the caveat that treatment should be started with the least expensive product does not single out any product by brand, and which product might be least expensive might vary from time to time and place to place. However, the wording currently states:

"Infliximab is recommended only if treatment is started with the least expensive infliximab product".

When read in conjunction with paragraphs 4.46 and 4.67, this infers that the least expensive infliximab product will *always* be the biosimilar infliximab. It is for this reason and to avoid misinterpretation of the guidance that we suggest the wording is changed to:

"Start treatment with the least expensive drug (taking into account administration costs, dose needed, and product price per dose). Costs may vary in different settings because of negotiated procurement discounts",

This wording also accounts for the fact that all biologics in this appraisal are recommended for use. MSD would be satisfied that such a change to the wording would ensure that the guidance is clear, and no longer open to misinterpretation. The current wording is a direct result of elements of a process that MSD deems to be unfair as described in our grounds for appeal. However making these simple changes to the wording in paragraph 1.1 would address the unintended consequence that the FAD is open to misinterpretation.

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

Yours sincerely,

Senior HTA & OR Manager