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[redacted]
Merck Sharp Dohme Ltd
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By email to [redacted]

21 October 2015

Dear [redacted]

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 of 14 October. This is my final decision on initial scrutiny.

Ground 1 (a)

1.1 NICE has inappropriately used contract prices in analyses.

Already accepted as a valid appeal point save in respect of the observation in [redacted]'s letter of 25 September that "there is no transparency on how the "highest NHS Contract price"...was determined." Paragraph 4.46 of the FAD seems to state clearly that the assessment group took the cheapest of the biosimilar products, and then used the highest price that might need to be paid for that product as a result of the tendering process. This description is not so unclear as to cause unfairness.

1.2 The FAD lacks transparency.

There are several subpoints here. The first is your complaint that contract prices were not used for Remicade (or for the other products) but were used for biosimilar infliximab. I do not consider this to be a valid appeal point for the reasons given in my letter of 2 October.

Second, that paragraphs 4.46 and 4.67 should be deleted. I take this to be a consequence of your argument under heading 1.1 above, and it seems to me it stands or falls with it. It is not a valid appeal point in itself as I noted in my letter of 2 October.

Third, that paragraph 1.1 of the FAD should be amended. Your letter of 14 October made some further points in support of your view that paragraph 1.1 should be subject to appeal and amended. I have considered carefully what you say but am not persuaded that this is a valid appeal point. I consider that the FAD is clear in what it says as I set out in my letter of 2 October. Also, the wording of the FAD will depend on the outcome of your appeal under 1.1 above and on the point immediately below (that biosimilars were not included in the original scope). However, the Guidance Executive may also consider drafting amendments to the final guidance if they consider the FAD unclear.

Fourth, that biosimilars are not mentioned in the appraisal scope. Already accepted as a valid appeal point.

In summary therefore, I have concluded that there are two valid points for appeal under ground 1(a). First, on the use of contract prices in the analysis. And second, that biosimilars are not mentioned in the appraisal scope.

Grounds 1(b) and Ground 2

No points raised

There will be an oral hearing to consider two points under ground 1(a).

Yours sincerely

[redacted]

National Institute for Health and Care Excellence