JANSSEN-CILAG Ltd

Ustekinumab for the treatment of adults with moderate to severe psoriasis

Janssen-Cilag Ltd's Response to the Appraisal Consultation Document

Following on from your letter dated 11th May 2009, please find below Janssen-Cilag Ltd's response to the Appraisal Consultation Document (ACD).

Overall, Janssen-Cilag Ltd agrees with the Appraisal Committee's preliminary recommendation of ustekinumab being recommended as a treatment option for adults with plaque psoriasis based on the specific criteria stated in section 1.1 of the ACD. In addition, we agree with the recommendation of the 16 week assessment of response, where treatment with ustekinumab is stopped if people with psoriasis have not responded adequately.

We have some comments on the wording of some of the sections of the ACD which are addressed below.

Section 2.3

In section 2.3, it states that *'The cost of ustekinumab for the two loading doses (at 0 and 4 weeks) is £4,294. The cost in the first year is £12,882, with an annual cost thereafter of £9,335'*. The cost of a 6th dose falls at the end of year 1/start of year 2 and is actually more likely to occur in the second year of treatment. Therefore, in our view, the cost would be better stated as being £10,735 based on five injections in the first year for those patients who continue on treatment beyond the trial period.

Section 3.5

In section 3.5, it states that '*DLQI data were not reported in the ACCEPT trial*'. We would like to clarify that these data were not collected in the ACCEPT trial rather than were not reported. We propose that the wording is amended to: 'DLQI data were not collected in the ACCEPT trial' to reflect this.

Section 3.11

In this section, it states that the assessment point for infliximab was 14 weeks. We can confirm that the assessment point was actually 10 weeks for infliximab.

Section 3.17

In section 3.17, it states '*SF-36 values collected in the PHOENIX trials'*. We would like to clarify that SF-36 values were collected only in the PHOENIX 1 trial.

Section 3.20

In relation to the text featured in section 3.20, we would like to clarify that the mixed treatment comparison (MTC) used in the appraisal of efalizumab and etanercept (TA103) is identical to our MTC as described in the main body of the text in the Woolacott review. This analysis was previously accepted by NICE in the Multiple Technology Appraisal of efalizumab and etanercept. The differences lie within the WinBUGS code that appears in the appendix to the original appraisal group report that incorrectly included a random effect baseline. The main body of the report states a fixed effects baseline was used and consultation with the original authors has confirmed that this was indeed the analysis used for the appropriate methodological reasons stated in our submission.

Section 3.23

Whilst the results referred to in section 3.23 are rather redundant given the acceptance of the scheme, we appreciate that it may provide context to help the NHS understand why one was proposed in the first place. However, the statement '*the probability of ustekinumab being cost-effective was zero*' could be misinterpreted by those who are unfamiliar with PSA methods (who will form the majority of the audience). If you have a zero chance of being cost-effective, people may conclude that there would be no circumstances under which the 90mg dose could be cost effective. It sounds like an immovable fact and yet we know that this is not the case when one considers the scheme. We would therefore prefer an amended sentence that conveys the intent of the paragraph whilst averting the potential for misinterpretation. We would suggest the following wording would achieve this:

"*When the ERG repeated the analysis assuming that the cost of ustekinumab 90mg was twice that of 45mg, the PSA results showed that ustekinumab would not be considered cost-effective at conventional thresholds*".

Section 4.6

In section 4.6, it is noted that there is uncertainty about whether the MTC had used a random or fixed effects baseline. We can confirm that as per section 6.6 or our original submission we used a fixed effects baseline, which was the same approach as that used in the Multiple Technology Appraisal of efalizumab and etanercept (TA103).

Section 4.12

Section 4.12 – same comment as in section 3.17 above.

10th June 2009