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Wyeth

Sent by email

[redacted]
Appeals Committee Chair
National Institute for Health and Clinical Excellence

17 June 2009

Dear [redacted]

Re:- Final Appraisal Determination – Bevacizumab (first-line), sorafenib (first- and second-line), sunitinib (second-line) and temsirolimus (first-line) for the treatment of advanced and/or metastatic renal cell carcinoma

Thank you for your further correspondence of 11th June with regard to Wyeth's appeal against the FAD for the above-mentioned appraisal.

I acknowledge your acceptance of point 1.1 and the need to develop the argument further but note that you are still not minded to agree that point 1.3 is a valid ground for appeal.

I would be grateful if you would be prepared to reconsider your decision in light of the following comments aimed at addressing your outstanding concerns with regard to the validity of point 1.3.

Whilst you suggest it is difficult to see that the Appraisal Committee did not consider the clinical need of patients with poor prognosis, Wyeth can find no evidence to suggest that they acknowledged or gave particular consideration to the greater value patients with shorter life expectancy place on the increased survival they experience compared with the same period of survival in patients with a better prognosis. In the event that the Appraisal Committee did consider this, it is not known what weight, if any, they were prepared to attribute to this benefit when considering the cost effectiveness of temsirolimus in the context of the End of Life Supplementary Guidance. This is important when considered alongside the impact the other points of appeal may have on the Appraisal Committee's decision not to recommend temsirolimus.

Wyeth maintain that the Appraisal Committee is required to consider the above-mentioned issue because the Secretary of State's Directions to the Institute require that in the appraisal of the clinical benefits and the costs of interventions, NICE should consider the degree of clinical need of patients with the disease under consideration and the Institute's Citizens Council identified length of life as a feature of disease which should be taken into account when considering clinical need.

The Secretary of State's Directions to the Institute do not stipulate that the degree of clinical need should only be considered in the case for supporting the use of a technology. To do so would imply that the Appraisal Committee first makes its decision and then puts together a justification which includes those considerations which support it. Indeed it could be argued that it is as important to ensure such factors

are taken into consideration in the event that the Appraisal Committee is minded not to recommend the use of a technology.

Furthermore the requirement for enough information and justification to enable the reader of the Guidance to understand what evidence the Appraisal Committee considered and the need to summarise the various issues which have been debated as well as the rationale for the conclusions drawn (Section 6.1.4 of the Methods Guide) does not appear to be dependent on the recommendation made.

Wyeth maintain that by not ensuring that the Appraisal Committee considered the greater clinical need and hence the greater value poor prognosis patients (treated with temsirolimus) place on improvements in overall survival, compared with the patients with good to intermediate prognosis with a greater anticipated overall survival (eligible for treatment with the other technologies considered in this appraisal), the Institute has failed to act fairly and in accordance with its published procedures.

Many thanks in anticipation.

Yours sincerely,

p.p.

[redacted]
Medical Director