[redacted]
Appeals Committee Chair
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

13 January 2010

Dear [redacted]

Final Appraisal Determination: Sorafenib for the treatment of advanced Hepatocellular Carcinoma

Thank you for your letter dated 11 December 2009, providing your preliminary view on the admissibility of Bayer's appeal against the above final appraisal determination. We now provide our response, for your consideration before a final decision is made on admissibility.

Appeal Point 1.1

Noted

Appeal Point 1.2

Noted

Appeal Point 1.3

Noted

Appeal Point 1.4

While we note that you are willing for this point of appeal to proceed, we provide further clarification of our case in relation to this issue.

In our appeal letter, we referred to the fact that NICE's procedures (including the Guide to the Single Technology Appraisal Process) require the Appraisal Committee to take into account "the longer term interests of the NHS in encouraging innovation in technologies that will benefit patients" in formulating guidance to the NHS. NICE itself has clarified this procedural requirement in its response to Sir Ian Kennedy's

report: Appraising the Value of Innovation, referenced in our appeal letter. It is Bayer's case that the Appraisal Committee has failed to adhere to the Institute's own procedures and standards in taking into account the innovative nature of sorafenib for hepatocellular carcinoma in this appraisal.

The decision of Mr Justice Simon in Fraser & Short, referenced in your letter of 11 December, may be distinguished from the situation in this appraisal. In that case, the Court was asked to consider the assessment by a Guideline Development Group in the context of a Clinical Guideline, rather than, as in this case, an Appraisal Committee conducting a Technology Appraisal. The purpose of a Clinical Guideline is substantially broader than that of Technology Appraisal Guidance and the associated procedures are less detailed, with greater discretion to the GDG as to how the process should be conducted and less structured participation by stakeholders. In contrast, the procedures for Technology Appraisal are defined in detail and allow for less discretion by the GDG as to the appropriate procedures; they involve participation by stakeholders throughout the process and impose a high standard of fairness. Furthermore the case in Fraser & Short involved an argument by the Claimants that the relative weight attached by the GDG to various sources of evidence, was incorrect. This is a very different situation from the appeal advanced by Bayer that a particular factor (innovation) should be given weight by the Appraisal Committee considering an STA, in circumstances where NICE's own procedures provide that this factor should be taken into account and the approach of the Appraisal Committee is not consistent with the Institute's own explanation of how it is expects that is to be achieved.

Appeal Point 1.5

Your comments in relation to this point of appeal are noted. While Bayer does not agree with your conclusions, we do not propose to pursue the matter further in the context of this appeal.

Appeal Point 1.6

As explained in our appeal letter, NICE is required to take into account the degree of clinical need of patients with the disease under consideration, in formulating guidance to the NHS. This requirement is also reflected in the approach set out in NICE's supplementary advice on end of life treatments.

In circumstances where patients with hepatocellular carcinoma clearly have an extremely high clinical need and where sorafenib is the only treatment with proven efficacy for this condition, a fair procedure requires that the Appraisal Committee explains how it is has considered the clinical need of patients with the condition. There is however no explanation of such an assessment provided in the FAD and accordingly, Bayer believes the procedure is unfair.

Appeal Point 1.7

Under this point, Bayer appeals on the basis that the approach by the Appraisal Committee to the difference between independent and investigator assessments of time to disease progression in the SHARP trial, is inappropriate and unfair. Two reasons for this conclusion are set out in the appeal letter:

a) that the Appraisal Committee failed to record an ICER that took account of the patient access scheme for sorafenib and therefore were unable to estimate the potential implications of the difference in measurement of time to disease progression; and

b) the fact that the Appraisal Committee seemingly failed to recognise that the approach of the trial investigators was likely to reflect that of treating physicians in clinical practice and therefore the most appropriate basis for the formed appraisal of cost effectiveness in this case.

We believe there may have been some misunderstanding in relation to this part of our appeal as your letter of 11 December simply states that Bayer was able to understand the approach followed by the Appraisal Committee, but does not respond to the allegations of unfairness made in our appeal.

Appeal Point 1.8

In your letter of 11 December, you expressed the view that there is no inconsistency in relation to the approach adopted to lenalidomide and sunitinib in the context of the application of NICE's end of life criteria. However, with respect, we disagree. In particular, while, as you say, the Appraisal Committee did not feel able to give a specific ICER for sunitinib, they said that it "could" be less than £50,000 (paragraph 4.3.10 of the Guidance for sunitinib) rather than "was" less than £50,000 as stated in your letter and that this figure "might" be at the upper end of any plausible valuation of such benefits, presumably in the context of that apparisal. On any view therefore the figure for sunitinib is little different to that for sorafenib and the positions for the two products are comparable. For this reason fairness requires that the Appraisal Committee should explain its conclusion that the magnitude of additional weight to be applied to the QALY benefits for sorafenib would be too great.

We hope that the additional clarification provided in this letter will assist you to consider our appeal and that you will agree that the additional points, addressed in this letter, may also proceed to an oral appeal hearing.

Yours sincerely

[redacted]