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

2 June 2009

Dear [redacted]

Final Appraisal Determination: lapatinib for the treatment of women with previously treated advanced or metastatic breast cancer

Thank you for your letter dated 1 May 2009, in which you notified GSK of your decision in relation to the admissibility of the Company's points of appeal. We have noted your conclusions and are preparing our appeal as you have indicated. However, while we understand that your decision is final, we should be grateful if you would please clarify an issue arising from your letter, as set out below.

The point of appeal at paragraph 2.2 of our appeal letter was based on the fact that the approach of the Appraisal Committee to the use of lapatinib in patients who have CNS metastases is inconsistent with that followed in the Clinical Guideline on Breast Cancer in relation to trastuzumab, and creates a situation that is arbitrary and therefore perverse. In your letter of 1 May, you advised us of your conclusion that this point would be permitted to proceed to the oral hearing "on the simple basis that the decision vis a vis patients with CNS metastases is perverse". However you said that you did "not think that the comparison with a different treatment and a different body [could] be relevant or capable of resolution in this process and that part of the argument should not be advanced". This response suggests to us that there may have been a misunderstanding in relation to the issue we sought to raise at paragraph 2.2:

Your letter appears to suggest that the Clinical Guideline and Technology Appraisal Guidance are issued by different bodies and that it is not therefore inappropriate for them to adopt a different approach to evidence or to issue guidance that is inconsistent. With respect, we do not believe this is correct. NICE's functions, as provided by regulation, include the preparation of Clinical Guidelines and Technology Appraisal Guidance. While NICE may delegate the preparation of Clinical Guidelines to a GDG and the preparation of Technology Appraisal Guidance to an Appraisal Committee, it is the Institute that issues any Clinical Guideline or Guidance and the Institute is responsible for those documents. This is not therefore a situation where two independent bodies have produced conflicting

recommendations, but rather where recommendations issued by the same body are inconsistent - namely the fact that NICE has (a) adopted a different standard for the evidence that may form the basis for a recommendation in a Guideline and in draft Guidance on the same therapeutic area and (b) has stated in the context of its Clinical Guideline that trastuzumab should be used after disease progression, in a sub set of patients, but then has maintained, in the Technology Appraisal Guidance for lapatinib, that trastuzumab treatment may not be regarded as an appropriate comparator even in the same population of patients. These inconsistencies in two sets of recommendations issued by the Institute, within a day of each other, undermine the credibility of both and are unhelpful to the NHS. We believe this situation is a strong indicator of perversity.

For completeness, we would say that we do not believe the decision of the appeal panel that considered the first appeal against the guidance on primary and secondary prevention of osteoporosis, of assistance in this regard. In the osteoporosis case, the appeal panel was asked to consider whether an appraisal committee may properly delegate part of its functions to a guideline development group. No consideration was given, in that case, to the issue now raised by GSK in this appeal.

We believe that these are important points of principle and are grateful to you for considering them. We would ask you please to provide the requested clarification either in correspondence before the appeal or at the start of the appeal hearing.

Thank you for your assistance with respect to this matter.

Yours sincerely

[redacted]
GlaxoSmithKline UK