National Institute for
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26 August 2008

[redacted], Health Outcomes
GlaxoSmithKline
Stockley Park West
Uxbridge
UB11 1BT

Dear [redacted],

Single Technology Appraisal – Lapatinib for the treatment of previously treated women with advanced, metastatic or recurrent breast cancer

The Decision Support Unit and the technical team at NICE have now had an opportunity to take a look at your submission and have formulated requests for further clarification.

We ask you to provide a written response to this letter to the Institute by noon on 29 August 2008 at the latest. Two versions of this written response should be submitted; one with academic/commercial in confidence information clearly marked and one from which this information is removed.

If you present data that is not already referenced in the main body of your submission and that data is seen to be academic/commercial in confidence information, please complete the checklist for in confidence information.

Yours sincerely

Meindert Boysen, Pharmacist MScHPPF
Associate Director Centre for Health Technology Evaluation

Section A. Points for clarification

1. Please provide a copy of the poster presented at ASCO 2.
2. Please provide copies of the abstract and poster presented at SABCS
3. Please confirm what amendments have been made to the dose adjustments (relative dose intensity) for trastuzumab in the updated model and provide a rationale for any changes.
4. Please clarify in more detail which exact criteria were used in the modelling of the access programme, where they were sourced from, what impact the rules had on the patient distribution through the model, what relevance these criteria have with clinical practice, how you established the relevance, how you envisage the criteria to be used in NICE recommendations might the Committee want to use the access programme for final recommendations.