National Institute for
Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Tel: 0845 003 7780
Fax: 0845 003 7784

Email: nice@nice.org.uk
www.nice.org.uk

Sent by email

[redacted]

GlaxoSmithKline UK Ltd

5 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 of 2 June.

There may be a misunderstanding. I am aware that the clinical guideline and the technology appraisal guidance are issued by the same body, and that was not the point being made. The point is that it is the guidance only which is being appealed. The panel is not in a position to evaluate the guideline. To consider your argument would first require a detailed consideration of the guideline to see if it is or is not truly inconsistent, and second an evaluation of the work of the GDG to see what the reasons for any inconsistency were, bearing in mind that an appraisal and guideline development are two different processes producing two different products. That is outside the scope of the appeal process.

Furthermore your concern that trastuzumab should have been accepted as a comparator has already been agreed to be a valid appeal point, on the basis that (you argue) it is a standard treatment. If the appraisal committee argue that trastuzumab is in fact not a standard treatment then the guideline would seem to be relevant to support your case, and no doubt the chair of the panel would let you make that point if it becomes relevant, but otherwise it seems to me to be very much a side issue. Even were it not outside the scope of the appeal I would strongly question whether it would be proportionate to embark on a consideration of the guideline when the appeal stands or falls on its own merits.

I do not feel this is a case where you are being prevented from putting the gist of your complaint. Rather, I am trying to prevent you taking what is at best a side issue, (in good faith I am sure), which I do not think would help you or the appeal panel.

Yours sincerely

[redacted]

Appeals Committee Chair
National Institute for Health and Clinical Excellence