Dr Margaret Helliwell
Chairman Appeals Committee
National Institute for Health and Care Excellence
10 Spring Gardens
London SW1A 2BU

BY EMAIL

16 September 2014

Re: Appeal against Final Appraisal Determination – Trastuzumab emtansine for treating HER2- positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane

Dear Margaret,

Thank you for your letter dated 2 September 2014 setting out your initial view as to the admissibility of Roche's appeal in respect of the Final Appraisal Determination (FAD) for the above appraisal and confirming that this will be heard by NICE's Appeal Panel.

Our responses to your initial view of our points of appeal, which raise various issues concerning the fact that the Appraisal Committee did not take into account the 2014 Pharmaceutical Price Regulation Scheme ("PPRS") in the context of this appraisal, are set out below:

(i) The reasoning set out in the FAD to justify disregarding the 2014 PPRS is inadequate and does not explain the conclusion reached

Noted

(ii) The Appraisal Committee has failed to take into account relevant matters when reaching the decision set out in the FAD

Noted

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(iii) NICE has issued no guidance or statement explaining how the 2014 PPRS should be taken into account during appraisals

In your letter you express the view that this is not a criticism that may be directed towards the Appraisal Committee whose remit is, you say, to appraisal technologies in accordance with the scope and NICE's procedures. You therefore suggest that this issue should not be permitted to proceed to a hearing as a stand-alone point of appeal.

Roche strongly disagrees with the preliminary view expressed in your letter, both as a point of principle and in the particular context of this appraisal. Our further clarification in relation to this issue is as follows:

- The wording of Ground 1a as set out in NICE's Guide to the technology appraisal and highly specialised technologies appeal process is:

  "Ground 1: In making the assessment that preceded the recommendation, NICE has:

  a) failed to act fairly....."

  The scope of unfairness is therefore not limited to acts or omissions by the Appraisal Committee but extends to acts or omissions by NICE corporately which impact "the assessment which preceded the recommendation". This is clearly recognised in the Guide to the Technology Appraisal and Highly Specialised Technologies Appeal Process which refers expressly to appeals under Ground 1a based on unfair treatment "by NICE or the advisory committee....".

- The scope of an appeal based on procedural grounds is inevitably broader than one based on the reasonableness of the conclusions set out in the FAD. While substantive determinations in the FAD represent (or should represent) conclusions of the Appraisal Committee alone (and appeals based on Ground 2 may be considered in that context), the procedures that have led to those conclusions are variously decided and applied by NICE corporately as well as by the Committee and any challenge may not, as a matter of natural justice, be limited to those aspects of procedure decided by the Committee.

- The position as described above is one that NICE has accepted since its inception. Accordingly appeals have been accepted (and have in some cases succeeded) based on procedural unfairness arising from acts or omissions of NICE corporately and not simply the Appraisal Committee. The following cases are a few examples of those where an appeal has been advanced, based on procedural unfairness by NICE corporately (i.e. not unfairness by the Appraisal Committee) and this has

been successful either at appeal or subsequent judicial review (there are of course many more cases, where similar issues were permitted to proceed to an appeal hearing, but the point was not upheld by the Panel):

- TA32 (MS treatments) 2000 - Administrative error by Institute
- TA33 (irinotecan etc) 2001 - Failure to disclose economic model
- TA68 (photodynamic Therapy) 2003 - Failure to disclose information provided to Appraisal Committee
- TA68 (photodynamic Therapy) 2003 - Failure to disclose economic model
- TA103 (efalizumab etc) 2006 - Failure by Institute to apply normal processes on disclosure of evidence
- TA111(Alzheimer's disease treatments) 2006 - Refusal to disclose economic model
- TA129 (bortezomib) 2007 - Interim STA process did not provide for Scope
- TA162 (erlotinib) 2007 - Refusal to disclose economic model
- TA162 (erlotinib) 2007 - Refusal to disclose software used by ERG
- TA160 (osteoporosis treatments) 2007 - Refusal to disclose algorithm developed by third party
- TA195 (adalimumab etc) 2008 - Failure to develop Scope
- TA195 (adalimumab etc) 2008 - Refusal to disclose economic model
- ID20(lapatinib) 2009 - Failure to amend procedure to take account of supplementary advice on end of life
- TA228(bortezomib and thalidomide) 2010 - Failure to disclose revised economic model

- For the avoidance of doubt, while the precise wording of the text of Ground 1a (previously Ground 1) in NICE's process guides, has been subject to some minor changes over time, there is no reason to believe that associated modifications are intended to restrict the scope of the matters of procedural unfairness which may be subject to appeal.

In summary therefore, procedural unfairness and appeals under Ground 1a may relate to acts or omissions by NICE corporately as well as by the Appraisal Committee and, in these circumstances, Roche believes that point (iii) of our appeal, which relates to a failure by the Institute to issue guidance to stakeholders and the Appraisal Committee, reflecting the 2014 PPRS, should be considered by the Appeal Panel as a stand-alone point.

Yours sincerely,

[redacted]

[redacted] Head of Health Economics and Strategic Pricing

Roche Products Limited