

Sent by email

██████████
Head of Health Economics and Strategic Pricing
Roche Products Limited

2 September 2014

Dear ██████████

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

Thank you for lodging Roche's appeal against the above Final Appraisal Determination.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- 1(a) NICE has failed to act fairly,¹ or
- 1(b) NICE has exceeded its powers;²
- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

I can confirm that there will be an oral hearing of the appeal.

¹ formerly ground 1
² Formerly ground 3

Initial View

Ground 1 (a)

The Appraisal Committee's refusal to take into account the Pharmaceutical Price Regulation Scheme ("PPRS") in the context of its consideration of trastuzumab emtansine was procedurally unfair

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

A valid appeal point.

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

A valid appeal point.

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

Without expressing a view as to whether this may be fair or unfair, it seems to me it is not a criticism that can be directed at the appraisal committee. The appraisal committee's remit is to appraise technologies referred to it in accordance with the scope and NICE's procedures and to produce recommendations. Appeals are appeals against recommendations.

The task of stating how any given factor should be taken into account in appraisals would fall to NICE corporately rather than an appraisal committee, and would be contained in a process guide or instruction to all appraisal committees, rather than a technology recommendation. An appraisal committee would not be able to comment on whether this should have been done or why it was not.

If the absence of that explanation has produced unfairness in this particular appraisal it seems to me that that can be explored under (i) or (ii) above, but at present I do not think this point is available as a standalone point in the appeal process.

As I agree some of your appeal points are valid they will be passed to an appeal panel for consideration. There will be an oral hearing. I would be grateful to receive your comments on the point I am presently not minded to treat as valid within 10 working days of this letter, no later than **Tuesday 16 September 2014**, whereupon I will take a final decision.

Yours sincerely

Dr Maggie Helliwell
Vice Chair
National Institute for Health and Care Excellence