

Sent by email

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

22 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 your letter of 16 September 2014 2014. This letter is my final decision on initial scrutiny.

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

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

Both already agreed to be valid.

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

I have considered the additional points you make.

The relevant of the past appeals to the point you are seeking to advance was not immediately apparent. I struggled to identify any where the unfairness complained of was not of the appraisal committee. In any event, although NICE seeks to be broadly consistent in its actions, it is informed rather than bound by its past decisions. (In passing, I would agree that the slightly changed wording of our Regulations is not intended to have restricted our ability to correct any actual unfairness in the production of guidance, although as a statutory body we are bound by the wording of the statutory instrument.)

I am clear that an appeal may be brought against any unfair action (or inaction) of the appraisal committee conducting an appraisal. That is so whether the appraisal committee's action is taken of its own motion, or whether it was simply following a policy or process set by NICE corporately. Therefore there may have been appeals where an appraisal committee has followed a corporate policy or process and that has been found to be unfair (perhaps TA111 and the former policy of not releasing an executable model is an example).

Any complaint you have about the Committee's treatment of the PPRS is already accepted as a valid ground of appeal. (ii) deals with the substantive complaint, essentially that the new PPRS was relevant and was not considered. (i) deals with the procedural complaint, that the Committee did not explain why the PPRS was disregarded. As far as the Committee's actions are concerned these two challenges seem to be exhaustive: they did not do what they should have done, and they did not explain why. If there is alleged unfairness in dealing with the PPRS in this appraisal, however arising, then it will be considered by the Appeal Panel. For that reason I expect the Appeal Panel to take a relatively broad rather than a narrow approach to (i) and (ii) and indeed to recall that both are merely subpoints of your one substantive point and that they should not be prevented from correcting any unfairness they may find by the precise wording of those subpoints. I welcome the chance to make this clear.

Your point (iii) does go further. (iii) is necessarily addressed not to the committee, but only to NICE corporately. It is not a challenge to this guidance, or to the way in which this guidance was produced, but to the way in which NICE administers itself. It complains not, or not only, of unfairness, but that a specific step by NICE which it is said would have avoided unfairness was not taken. In the interests of proper management of the appeal process it is important to be clear that complaints about a failure to act by any body other than the appraisal committee cannot be within the scope of the appeal process, because they are not complaints about a failure to act fairly in making the assessment that preceded the

recommendation, as required by our governing Regulations. The assessment preceding the recommendation is the exclusive business of the appraisal committee.

I therefore confirm the valid appeal points as (i) and (ii), to be understood as I have explained above.

Yours sincerely

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