Roche

[redacted]
Centre for Health Technology Evaluation
National Institute for Health and Care Excellence
10 Spring Gardens
London SW1A 2BU

28 July 2015

Re: NICE technology appraisal - Breast cancer (HER2 positive, unresectable) - trastuzumab emtansine (after trastuzumab and taxane) [ID603]

Dear [redacted]

Thank you for your letter of 02 June 2015 inviting us to comment on the NICE position statement "Pharmaceutical Price Regulation Scheme 2014 – implications for NICE".

We continue to believe it is unfair to disregard the consideration of PPRS payments within the appraisal process and are deeply disappointed that the conclusion reached by NICE is that "the 2014 PPRS payment mechanism should not be regarded as a relevant consideration in its assessment of the cost-effectiveness of branded medicines".

We acknowledge that there are significant and complex challenges to implementing a workable solution; however it is discouraging that attempts to identify a solution have not been more vigorously pursued.

We remain firm in our belief that the principle issue raised in our appeal (namely that it is unfair and unreasonable to fail to take the PPRS payments into account in the context of NICE appraisals) has not been fully answered, and contend that failure to identify a solution is insufficient reason for the Committee disregard the impact of the PPRS scheme on their appraisal process.

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We ask NICE to consider a pragmatic solution where the Committee issue positive guidance conditional upon the following points:

- Roche remain within the 2014 PPRS scheme
- The spend level within the 2014 PPRS scheme remains above the agreed growth levels
- Guidance is reviewed at the commencement of the 2019 PPRS scheme

While the branded drugs spend within the PPRS scheme remains above the defined growth levels there is no additional cost to the healthcare system of this action, making this a justifiable solution. This action would allow patients the opportunity to benefit from significant new therapies such as trastuzumab emtansine, whilst still offering surety of branded drug spend to the NHS.

Finally, I would like to request a copy of the full statement provided by The Department of Health referred to in the NICE position paper, which not previously been made available to us.

Yours sincerely,

[redacted]

[redacted] Head of Health Economics and Strategic Pricing

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