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Sent via email

Health Economics and Strategic Pricing Director Roche Ltd

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Dear

Final Appraisal Determination: Erlotinib monotherapy for maintenance treatment of advanced or metastatic non-small cell lung cancer.

Thank you for your response to the initial scrutiny of your appeal lodged against this FAD. This letter represents the final decision on initial scrutiny.

1.2 Failure to consider the authorised indication for erlotinib as a whole rather than only as squamous and non-squamous subgroups is inappropriate and unfair

I have carefully considered both your original point and the further explanation you have provided. However it still seems to me that the essential complaint here is not that the appraisal was opaque, or otherwise procedurally unfair, but that the decision to generate ICERs for subgroups rather than for the total patient population was wrong.

I have understood that part of your argument is that the committee's decision introduced uncertainty, and that uncertainty was a factor in its overall decision not to recommend treatment. Assuming for the purpose of this letter that you are right, I can understand how that could be described as "unfair", in the colloquial sense. However I am confident that the appeal panel will be fully able to consider that issue as an aspect of the overall reasonableness of the conclusions reached in light of the evidence submitted.

Therefore I still consider that the appropriate ground for this complaint is ground two.

## Conclusion

This is the final decision on initial scrutiny. I have accepted all of the appeal points raised as valid, but have reallocated points 1.1, 1.2 and 1.5 to be considered under ground 2.

Yours sincerely

Appeal Committee Chair
National Institute for Health and Clinical Excellence