National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Tel: 0845 003 7780
Fax: 0845 003 7784

Email: nice@nice.org.uk
www.nice.org.uk

Sent via email

[redacted]
Health Economics and Strategic Pricing Director
Roche Ltd

1 April 2011

Dear [redacted]

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

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:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

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.

Initial View

Ground 1

1.1 The Appraisal Committee's conclusion that the benefit of maintenance treatment with erlotinib seen in the SATURN trial was likely to be lower in routine clinical practice is not evidence based and is therefore unfair

I agree that this is a valid appeal point, but an allegation that a conclusion is not evidence based can only be an allegation that it cannot be justified in the light of the evidence submitted.

I am therefore minded to allow this appeal to go forward, but under appeal ground two.

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

Again, although I agree this is a valid appeal point, it seems to me in substance to be a challenge to the conclusions drawn from the evidence.

I am therefore minded to allow this appeal to go forward, but under appeal ground two.

1.3 The Appraisal Committee's failure to investigate adequately the potential uncertainty surrounding the cost-effectiveness of erlotinib compared to pemetrexed in those patients eligible for both treatments is unfair.

A valid ground one appeal point.

1.4 NICE's approach to the calculation of small patient populations, to which the end of life criteria may be applied, lacks transparency and is unfair, both in general and in the context of this appraisal.

A valid ground one appeal point. For guidance, in considering point (a), I would expect the appeal panel to consider its comments in the appeal in TA 178, and I would expect it to treat points (b) and (d) as essentially the same complaint, and likewise points (c) and (e).

1.5 The Appraisal Committee's determination that the evidence for erlotinib does not demonstrate an extension to life of at least three months is inadequately explained in the context of the available data

Again, although I agree this is a valid appeal point, it seems to me in substance to be a challenge to the conclusions drawn from the evidence.

I am therefore minded to allow this appeal to go forward, but under appeal ground two.

1.6 It is unfair for the Appraisal Committee to decline to make a recommendation on the use of an intervention relative to a comparator described in the Scope for the appraisal because they conclude that the use of the comparator is declining

A valid ground one appeal point.

Ground 2

2.1 The Appraisal Committee's conclusion that the results from the licensed stable patient population in the SATURN study are too uncertain, simply because they are based on *post hoc* analyses is not reasonable

A valid ground two appeal point.

2.2 The decision of the Appraisal Committee not to recommend an intervention which, when assessed by the independent Evidence Review Group using consistent methodology is more cost-effective than the recently NICE-approved alternative, pemetrexed is perverse.

A valid ground two appeal point.

Conclusion

As I am minded to agree your appeal points are valid I will pass them to an appeal panel for consideration.

If you wish to make any further comment on the points I believe should be reclassified as falling within ground two, please provide to me this within 10 working days from the date of this letter **no later than Friday 15 April**.

Yours sincerely

[redacted]

Appeals Committee Chair
National Institute for Health and Clinical Excellence