[redacted]
Health Economics and Strategic Pricing Director

15th April 2011

Dr Margaret Helliwell
Chair, Appeal Committee
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

RE: FINAL APPRAISAL DETERMINATION FOR ERLOTINIB MONOTHERAPY FOR THE MAINTENANCE TREATMENT OF ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER

Dear Margaret,

Thank you for your initial scrutiny letter in response to our notice of appeal against the FAD for the above Single Technology Appraisal. Our response to the matters raised in your letter is provided below.

If you require any further information or clarification then please do not hesitate to contact us.

Yours Sincerely,

[redacted]
Health Economics and Strategic Pricing Director

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

Noted and accepted.

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

In your letter you state your belief that this appeal point relates to ground 2 rather than ground 1 as 'it seems to me in substance to be a challenge to the conclusions drawn from the evidence'. We believe in essence this point relates to the fairness of the approach followed by the Appraisal Committee rather than simply the Committee's interpretation of the data and therefore suggest that it would be better placed under ground 1.

The Committee opted not to assess the cost-effectiveness of erlotinib in its whole EMA licensed maintenance indication based upon the data observed in that whole population. We believe that this constitutes unfairness and that the Committee should be obliged to consider the cost-effectiveness of a technology in its whole licensed population based upon the data observed in that population. The splitting of that EMA defined indication into numerous constituent parts without considering the clinical and cost effectiveness of the whole licensed population, could lead to spurious and illogical conclusions being drawn.

This approach is therefore unfair.

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.

Noted and accepted.

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.

Noted and accepted.

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

Noted and accepted.

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

Noted and accepted.

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

Noted and accepted.

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.

Noted and accepted.