NHS
National Institute for
Health and Clinical Excellence

1 December 2008

[redacted]

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Dear Mr [redacted],

Single Technology Appraisal – Lenalidomide for multiple myeloma

Thank you for your response to the ACD. We have read your response and have noted that your have proposed a price capping scheme. We would like to request clarification on a number of points listed below. However, please note that NICE has not been instructed by the Department of Health to consider the appraisal of lenalidomide within the proposed scheme. As you probably know, the Department of Health has to approve any pricing scheme before NICE can consider it. As such, this letter is purely for the purposes of requesting clarification on your response.

1. Could you provide us with details of how you have calculated your estimates of the cost effectiveness of lenalidomide with the price capping scheme. This does not appear to have been calculated in the updated economic model you sent with your response.

2. For all analyses please state clearly all assumptions, and detail any inputs that have been changed between the ICER without the scheme, and the ICER with the scheme. For example, please confirm whether any costs that would be expected to be incurred by the NHS beyond 24 months of treatment with lenalidomide, such as for the management of adverse effects due to lenalidomide and follow up appointments, have been included. Please also clarify what assumptions have been made regarding operational costs to the NHS of administering the price capping scheme.

3. Could you provide us with details of the number of people in the trial who had not relapsed at 24 months (in the original treatment arm and following crossover) and details of how many further cycles of lenalidomide were required. Could you please provide us with the mean per patient cost for lenalidomide with and without the price capping scheme.

4. If using a model to extrapolate the relapse rate on lenalidomide beyond 24 months please provide us with details of how closely the model predicts the trial results.

5. Whilst I note you have set out in your response reasons why you do not agree with fitting the dexamethasone overall survival curve to the mean from the MRC trial, I would draw your attention to section 4.9 of the ACD, which highlights that the Appraisal Committee considered this approach was valid and would result in more plausible estimates of cost effectiveness than using the median. Could you please provide us with an analysis (both with and without the proposed scheme) using the mean of the overall survival data.

6. When responding to this clarification letter with your updated analyses please note that we cannot accept the entirety of the details of the proposed price capping scheme and related ICERs to be marked as confidential. If NICE is requested by the Department of Health to appraise lenalidomide within the proposed price capping scheme, it will be necessary for sufficient information to be available in the public domain to ensure transparency in evidence, decision making and recommendations. If your response still contains any confidential data, two versions of your response should be submitted; one with academic/commercial in confidence information clearly marked and one from which this information is removed. We also ask you to complete the attached checklist for in confidence information.

We request you to provide a written response to this letter to the Institute by 8th December, 2008.

Yours sincerely

Meindert Boysen, Pharmacist MScHPPF
Associate Director - STA
Centre for Health Technology Evaluation

Encl. checklist for in confidence information

cc. [redacted]
Department of Health