National Institute for Health and Clinical Excellence Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

Pemetrexed for the maintenance treatment of non small cell lung cancer

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by **Eli Lilly & Co**. It has been sent to you for information only. It cannot be used for any other purpose than to inform your understanding of the appraisal. Accordingly, neither the model nor its contents should be divulged to anyone other than those individuals within your organisation who need to see to them to enable you to prepare your response. Those to whom you do show the documents must be advised they are bound by the terms of the Confidentiality Acknowledgement and Undertaking Form that has already been signed and returned to the Institute by your organisation.

You may not make copies of the file and you must delete the file from your records when the appraisal process, and any possible appeal, are complete. You must confirm to us in writing that you have done so. You may not publish it in whole or part, or use it to inform the development of other economic models.

The model must not be re-run for purposes other than the testing of its reliability.

Please set out your comments on reliability in writing providing separate justification, with supporting information, for each specific comment made. Where you have made an alteration to the model details of how this alteration was implemented in the model (e.g. in terms of programme code) must be given in sufficient detail to enable your changes to be replicated from the information provided. Please use the attached pro-forma to present your response.

Please prepare your response carefully. Responses which contain errors or are internally inconsistent (for example where we are unable to replicate the results claimed by implementing the changes said to have been made to the model) will be rejected without further consideration.

Results from amended versions of the model will only be accepted if their purpose is to test robustness and reliability of the economic model. Results calculated purely for the purpose of using alternative inputs will not be accepted.

No electronic versions of the economic model will be accepted with your response.

Responses should be provided in tabular format as suggested below (please add further tables if necessary).

December 2009

Issue 1 Number of cycles of maintenance Pemetrexed

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
Page 17 4.14 Decision to cap the number of cycles of maintenance pemetrexed at 17 (Mean plus one standard deviation). The distribution of the number of cycles is almost certainly not normal. In fact only 23% of patients received more than 10 cycles.	The median number of cycles (5.0) should be used or at very most 10 but not 17	This will have to be recalculated

Issue 2 Utility estimates

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
The adjustment of the utility scores in 4.15 is unjustified as the toxicity of this drug is very low and indeed the utility scores may improve in some patients as an additional 5% had a further partial response which should alleviate their lung cancer related symptoms	The original utility scores should be used	This will have to be recalculated

This response is submitted by RCP on behalf of the NCRI/RCP/RCR/ACP/JCC. We are grateful for the opportunity to comment.