National Institute for Health and Clinical Excellence

Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (Review of TA 111)

The model must not be re-run for purposes other that 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).

September 2010

Lundbeck Response

Lundbeck would like to express their appreciation to the NICE Appraisal Committee and PenTAG for the opportunity to review the executable copy of the economic model developed by PenTAG. As described in the Lundbeck response to the Appraisal Consultation Document, we feel that the NICE review of AD treatments has been a transparent process that has ensured that patients in England and Wales will now get access to clinically effective medications that represent the most efficient use of NHS resources.

Lundbeck has undertaken a comprehensive review of the updated economic model and find it to be greatly improved in regard to both technical and face validity compared to the original evaluation. The cost-effectiveness estimates for memantine in the new model have improved in terms of robustness and validity. However, in the absence of a full technical report it is difficult to properly assess the relevance of some of the changes implemented in this revised model.

Although many of Lundbeck's comments on the original economic evaluation have been addressed some of the technical issues and model errors highlighted in our response to the technology assessment report (submitted in August 2010) remain. However, it is not anticipated that these issues and inaccuracies will have a substantial effect on the conclusions of the economic model and therefore Lundbeck have not detailed them further here.

Issue 1

Description of problem	**Description of proposed amendment**	**Result of amended model or expected impact on the result (if applicable)**
Give full details of the problem detected, if necessary, with explanation of why the issue is considered to be a problem.	Give details of any amendments/corrections made in sufficient detail to allow these to be reproduced	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

Issue 2

Description of problem	**Description of proposed amendment**	**Result of amended model or expected impact on the result (if applicable)**
Give full details of the problem detected, if necessary, with explanation of why the issue is considered to be a problem.	Give details of any amendments/corrections made in sufficient detail to allow these to be reproduced	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

Issue 3

Description of problem	**Description of proposed amendment**	**Result of amended model or expected impact on the result (if applicable)**
Give full details of the problem detected, if necessary, with explanation of why the issue is considered to be a problem.	Give details of any amendments/corrections made in sufficient detail to allow these to be reproduced	Insert ICER resulting from amended model. If the model has not been re-run, if appropriate, describe your expectations of how the problem might have an impact on the result

(please cut and paste further tables as necessary)