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

Pro-forma Response

Executable Model

Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for the treatment of recurrent ovarian cancer (including review of technology appraisal no. 91 and technology appraisal no. 222) [ID468]

The economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by **BMJ-TAG.** 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. If asked, 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 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).

July 2013

Issue 1 Technical content

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
1) Pegylated Liposomal Doxorubicin Hydrochloride (Caelyx) We hope that there is capacity to deliver the required volume of PLDH to women who are suitable to receive it as a treatment option. Supplies of PLDH were severely disrupted at the end of 2011 and initially were not expected to resume till 2014. However production began again late last year, but we are not clear whether supplies are at capacity. 2) The number of women diagnosed with staged disease On pg 41 it is stated that 60% of women are diagnosed with stage III or IV disease. This data is from the Eastern Cancer Region and depicts that almost all women are staged. From the International Cancer Benchmarking Partnership study (Maringe et al, 2012), the UK presents quite differently. The data collected includes that of the Eastern Cancer region, but also includes UK data in addition to other international data and highlights that the proportions of unstaged tumours range from 4% (Norway) to 32% (UK). We would hope that the data from the International Cancer Benchmarking Study is used to ensure there are no misassumptions on the cost of treatments.	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 General

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
1) Title of the assessment report The title does not state that the focus is of women who have received prior platinum-based treatment 2) Categorisation of platinum sensitivity We noticed that at times in the document partial platinum-sensitive and fully platinum-sensitive were referred to as platinum-sensitive. It is important that the document is specific as to whether they are referring to partially platinum sensitive or fully platinum sensitive. Also we recommend that it is acknowledged early on in the document that some women are allergic to platinum in the first place. 3) Platinum allergic patients were not analysed separately (pg 15) We understand that platinum allergic patients were considered by the TAG, we also hope that the TAG consulted with clinical experts to come to the assumption that treatments for platinum allergic patients would respond in the same manner to other treatments. 4) The approach As far as we can determine, we regard the approach taken to develop 2 networks for platinum sensitive treatments as appropriate, and agree with the assumptions made, and most importantly with the need to acknowledge that for those women who are still platinum sensitive, some of them will not be able to tolerate further platinum treatment due to toxicity. 5) Overall survival and progression free survival	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

We welcome that the TAG consider both overall survival and progression free survival, as progression free survival vital for women as it is time without the cancer returning when women can live their lives as fully as they can.		

Issue 3 Suggested Research

Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
1) Suggestion for RCT to establish link between platinum sensitive network 1 and platinum sensitive network 2 We believe that conducting this research could limit women being involved in other trials of new treatments, and we are not clear this type of trials would be good use of resources. 2) Best supportive care We support future research on best supportive care as no one has quantified this yet. Knowledge of this would help decide what best supportive care looks like for clinicians. Due to the importance of this, we are funding the UK arm of an international prospective study investigating the clinical benefits of palliative treatments and also to establish how treatments affect quality of life.	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)