National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

ERG report

Edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

You are asked to check the ERG report from **BMJ-TAG** to ensure there are no factual inaccuracies contained within it.

If you do identify any factual inaccuracies you must inform NICE by **5pm** on **8th May 2015** using the below proforma comments table. All factual errors will be highlighted in a report and presented to the Appraisal Committee and will subsequently be published on the NICE website with the Evaluation report.

The proforma document should act as a method of detailing any inaccuracies found and how and why they should be corrected.

Issue 1 Description of model structure and assumptions

Description of problem	Description of proposed amendment	Justification for amendment	ERG response
Regarding the approach to modelling CTEPH and PTS, the ERG report (page 18) states that patients should be at risk of these events at all times.	We would like to qualify these statements as follows: Only those patients who have experienced a PE should be at risk of developing CTEPH. Only these patients should be at risk of CTEPH at all times. Only those patients who have experienced a DVT should be at risk for PTS. Only these patients should be at risk of PTS at all times.	This is necessary to address comments on the consistency of the modelling approach.	Not a factual error. Patients in the model should be at risk of experiencing these conditions at all times since both conditions are VTE related (and not treatment related as suggested by the company) and all patients have had an index VTE event. Therefore all patients are at risk of experiencing recurrent VTE (DVT or PE). Furthermore the company has assumed that all VTE patients can experience PTS which was corroborated by clinical opinion provided to the ERG.

Issue 2 Tornado diagrams

Description of problem	Description of proposed amendment	Justification for amendment	ERG response
On page 223 it is stated that the Tornados haven't been provided in our model and that the macros don't work.	After extensive testing, we find that the tornado diagrams appear after running the macro, and after checking the final version of the models, the sensitivity analysis runs well on our computers. Could it be a software problem? We are happy to offer technical guidance.	We believe our model is robust and would like to ensure that the sensitivity analyses in our submission are fully evaluated.	The ERG agrees that the current text is inaccurate and has amended the text on page 223. This change does not affect any other content in the ERG report.