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

ERRATA

This report was commissioned by the NIHR HTA Programme as project number 14/60

BMJ Technology Assessment Group

This document contains errata in respect of the ERG report in response to the manufacturer's factual inaccuracy check.

The table below lists the page to be replaced in the original document and the nature of the change:

Page No.	Change
223	Removed text "Additionally, there is a lack of transparency in the OWSA reported. Not only have the tornado diagrams not been provided in the Excel model, but the macros running the OWSA in the model don't work. Furthermore,"

based on the assumption that the probability of these events might be different depending on the treatment received. As would be expected, when the probability of CTEPH or stroke is varied just in one arm of the economic model, the ICER changes substantially as these are expensive and serious conditions. However, varying the probability of these events in only one arm of the model doesn't have face validity, as there is no clinical rationale for CTEPH or stroke to be linked to the type of treatment received. By including irrelevant parameters in the analysis (but with a substantial impact on the ICER), and by presenting only the eight most influential parameters in the model, the company rendered their OWSA largely irrelevant. During clarification the ERG also asked the company to present total costs, total QALYs, and ICERs for the upper and lower value for each input listed; however these were not provided.

The ERG manually ran the scenario where the probability of VTE recurrence with edoxaban was changed to its upper limit on the 95% Confidence Interval range (1.174) and obtained an ICER of £7,181. This hasn't been reported in the list of inputs with "noteworthy" impact, which included ICERs from around £10,000 to around £5,000.

For utility values and utility decrements the company estimated 95% Confidence Intervals as low and high values, however the ERG is not clear how the standard deviations in the calculation presented were obtained. This was not reported by the company.

The ERG questions the appropriateness of varying the overall health state costs by +/-20%. The ERG believes this approach loses granularity because the specific costs or resource use within each health state that influence the results cannot be identified. The ERG notes that the resource use associated with warfarin monitoring should have been explicitly varied between plausible values, as this is expected to be a key model parameter.

Finally, it seems somewhat implausible that no parameter would influence the ICER of edoxaban vs rivaroxaban.

5.1.1.1 Probabilistic sensitivity analysis (PSA)

Parameter uncertainty was explored using PSA. Individual parameters within the model were assigned a distribution and the model was run for 2,000 simulations to generate total costs and QALYs. The inputs reportedly varied in the PSA and the assigned distributions are outlined in Table 94 the Appendix.

Probabilities, such as VTE-related death rate and event rates, were sampled from a beta distribution (bounded by 0 and 1). ORs were assumed to be distributed according to a lognormal distribution