

The ERG has sent us an additional point for clarification about the ipilimumab submission as stated below:

"The mean body surface area (BSA) used in the manufacturer's model (1.93 square metres) is inconsistent with all the other patient characteristics used as parameters in the model. In particular the mean body weight (78.83kg) used for costing ipilimumab is derived from the pivotal trial combined with the compassionate use programme. However, the BSA value incorporates data from a separate CLL trial of rituximab, and is clearly much larger than is compatible with the other data.

Please would the manufacturer provide the mean and standard deviation of BSA for patients in the Hodi trial, split between males and females, and the mean and standard deviation of BSA for patients in the compassionate use programme also split between males and females."

If time permits, can you please provide a response to this additional question alongside the other points for clarification which were sent to you on Monday (by 26th July). If this is not possible, it would be most helpful if you could provide your response to this question at your earliest convenience.

Please do not hesitate to contact me if you need any further information.

Best wishes,

Fiona