SHTAC response to GSK comments on the assessment report produced for the appraisal of topotecan for the treatment of Small Cell Lung Cancer.

CLINICAL EFFECTIVENESS

GSK comment that the wording of the statement in the executive summary on IV amrubicin needs consideration given the limited internal and external validity of the clinical trial of this comparison. Our executive summary notes issues about the methodological quality and risk of bias in all of the included trials and the fact that the Inoue trial used a lower dose of topotecan is raised. This issue is also discussed more fully in the report.

COST EFFECTIVENESS

GSK raise two specific concerns regarding our cost analysis:

- the first is that some of the costs attributed to drug administration and monitoring (for patients receiving topotecan) are common to patients receiving BSC;

- the second is that we assumed that topotecan-treated patients would receive a CT scan every two cycles, but appear to have included a cost for each cycle.

With regard to the first concern our clinical advisors suggested that patients receiving BSC would not be subject to the same regime of monitoring as those undergoing active drug treatment. They specifically indicated that they would not expect to subject such patients to regular chest X-ray or CT - which would be used to monitor progression in patients undergoing active treatment. We assumed that any on-going monitoring of patients receiving palliative care (applied to patients in the BSC cohort and to topotecan-treated patients following disease progression) would be included under palliative care cost.

With regard to the second concern - some confusion may have arisen here as we did not explicitly state the unit cost for a CT scan in Table 28 or in the surrounding text. However Table 33 shows that the unit cost for a CT scan in the model is £94.68 (based on an uprating of 2006/07 NHS Reference Costs to 2007/08 prices). Hence the cost reported in Table 28 is £94.68 * 0.5, to reflect the fact that the CT is assumed to occur, on average, every two cycles.

GENERAL COMMENT

Please also note that GSK mistakenly refer to our centre as the Southampton Technology Assessment Group (SHTAG) which should be Southampton Health Technology Assessments Centre (SHTAC).