

Description of problem	Description of proposed amendment	Justification for amendment	ERG's response
<p>On page 56 of the ERG report it is stated 'The databases specified by NICE as a minimum for cost-effectiveness are: Medline, Embase, Medline in Process, EconLIT and NHS EED'. The report then proceeds to state that 'it appears one of the required resources, EconLIT, was not used' when referring to the economic evaluation search conducted in section 7.1.</p> <p>At the time of submission the template utilised stated that the databases searched should include at least Medline, Embase, Medline in Process, NHS EED, HEED and ISPOR Research Digest. EconLit was not stated in the template used. All of the 'required resources' stated in the template used were searched. As EconLit was not listed as a required resource it was not searched.</p>	<p>The ERG report should be amended to reflect the fact that in the economic evaluation search Roche utilised all resources stated in the template used.</p>	<p>This amendment will make no difference to the conclusion of the analysis but will clarify that the economic evaluation search conducted by Roche was carried out using all the resources detailed in the template used.</p>	<p>The ERG used the October 2009 template "Specification for manufacturer/sponsor submission of evidence for STA" provided by NICE ¹. However, the ERG acknowledges that the manufacturer may have used an earlier version of the template.</p> <p>The ERG is happy to amend the report to reflect this.</p>
<p>On page 52 of the ERG report Table 14 lists the activity cost of 'Drug delivery. 1st attendance. Output/day case' used in the model as £581.45. In the model and in the economic section of the submission the figure used was £281.45.</p>	<p>Table 14 should be amended to reflect the fact that a cost of £281.45 and not £581.45 was used in the cost-minimisation analysis</p>	<p>The ERG report contains a factual inaccuracy and therefore should be amended. The figure appears to be a simple isolated typographical error as the figure of £581.45 was used to derive the other results presented. The amendment of this figure will therefore have no impact on conclusions of the cost-effectiveness of capecitabine but nevertheless should be corrected in order to accurately portray the analysis carried out.</p>	<p>The ERG agrees that this typographical error should be amended. The correct activity cost of 'Drug delivery. 1st attendance. Output/day case' is £281.45.</p>

<p>On page 14 of appendix 2 table 4 notes that the incremental administration cost of CF over CX is - £3801. This figure should be £3801. Roche acknowledge that this table is simply a replication of the one submitted as part of our response to the ERG's clarification questions in which we mistakenly placed a negative sign in front of the £3801.</p>	<p>This table should be amended. The negative sign should be removed.</p>	<p>Whilst this error was typographical in nature and clearly played no part in further analysis it should be amended to reflect the fact that administration costs are cheaper with the CX regimen than the CF regimen.</p>	<p>The ERG agrees that this typographical error should be amended. The correct administration cost of CF over CX is £3801.</p>
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<p>Section 3.3 states that : “The manufacturer had conducted market research which indicated that these represented the chemotherapy regimes used in the UK, with the exception of some usage of epirubicin plus cisplatin alone and a small proportion of patients treated with other regimes”.</p> <p>Roche does not believe that epirubicin and cisplatin is a likely treatment regimen for gastric cancer, nor that there is anything in our original submission to suggest that this is the case.</p>	<p>It should be made clear within the ERG report what regimens relate to evidence presented within the MS and those assumed by the ERG via other research.</p>		<p>The ERG accepts that the MS does not suggest that epirubicin and cisplatin is a likely treatment regimen for gastric cancer, this confusion arose because of a lack of clarity in Figure 2 of the submission which was subsequently rectified in the response to the letter of clarification; the ERG’s report was not amended to reflect this.</p> <p>This section should be amended to read “The manufacturer had conducted market research which indicated that these represented the chemotherapy regimes used in the UK, with the exception of some usage of a small proportion of patients treated with other regimes.”</p>
<p>States that “Follow-up times were not reported in the MS”.</p> <p>Roche would point out that median follow-up times for patients in the two RCTs were reported in Section 6.3.6 of our original submission</p>	<p>ERG report to reflect reporting of follow-up duration within MS</p>		<p>The ERG accepts that overall median follow-up is reported in the submission; this should be amended to state that while median overall follow-up was reported, the duration of follow-up for the individual trial arms was not reported.</p>

¹at (<http://www.nice.org.uk/aboutnice/howwework/devnicetech/singletechnologyappraisalsubmissiontemplates.jsp?domedia=1&mid=4D9D8C83-19B9-E0B5-D4B0E148B3FE727F>)