

From: [REDACTED]
Sent: 03 June 2009 15:53
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Appeal - Initial scrutiny letter: renal cell carcinoma - bevacizumab, sorafenib, sunitinib and temsirolimus

Dear [REDACTED],

Thank you very much for your letter of 19th May regarding our appeal points for the above appeal.

In relation to point 3 (the basis for the committee's conclusions with regard to tolerability of bevacizumab plus IFNa is unclear) Roche would expand on this point by noting that the issue seems to be that the Committee has not explained in the FAD, adequately or at all, what evidence was relied upon for the conclusions drawn with respect to the incidence of adverse events associated with bevacizumab. Paragraph 4.3.8 of the FAD states that this was based on the evidence of "clinical specialists and patient experts"; however the written statements we can find in the Evaluation Report from such persons and published on NICE's website, do not support the conclusion drawn. The reasoning is unclear and, possibly, the evidence relied upon has not been disclosed (we cannot of course know that until we know what the evidence was).

In relation to point 4 (the conclusions reached on the side effect profile of bevacizumab plus IFNa are perverse) Roche would expand on this point by noting that we have made a "best guess" as to the basis for NICE's conclusions at paragraph 4.3.8 of the FAD and believe that reliance upon such evidence for the purposes of the conclusions drawn is perverse. Our interpretation of the adverse event data which is described by the Committee and that which was made available to the Committee suggests that the conclusion drawn is inappropriate. Roche submitted as part of the appraisal a side-by-side analysis of the adverse event profile of both bevacizumab and sunitinib and our point here is further reinforced by the contrasting conclusions drawn by the Committee about the adverse event profile for sunitinib.

We would therefore like to respectfully request that we are permitted to keep both appeal points 3 and 4 for further discussion at the oral hearing.

Best wishes.

