[redacted]

Thursday 26th March 2009

Laura Malone
Technology Appraisal Project Manager
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
LONDON
WC1V 6NA

BY E-MAIL

Dear Laura,

SINGLE TECHNOLOGY APPRAISAL –
Tenofovir disoproxil for the treatment of chronic hepatitis B

Thank you for sending us the Appraisal Consultation Document (ACD) for the above technology appraisal. Please find below comments from Roche presented under the three standard headings.

1 WHETHER YOU CONSIDER THAT ALL OF THE RELEVANT EVIDENCE HAS BEEN TAKEN INTO ACCOUNT

Roche believe that all relevant evidence has been taken into account.

2 WHETHER YOU CONSIDER THAT THE SUMMARIES OF CLINICAL AND COST EFFECTIVENESS ARE REASONABLE INTERPRETATIONS OF THE EVIDENCE AND THAT THE PRELIMINARY VIEWS ON THE RESOURCE IMPACT AND IMPLICATIONS FOR THE NHS ARE APPROPRIATE

Roche believe that the evidence given by the manufacturer have been generally interpreted satisfactorily by the ERG and the Appraisal Committee.

Roche is concerned about the basis of the conclusions drawn about the HBeAg-negative subgroup of patients. The manufacturer points out that there can be no meaningful analysis due to lack of data but presents an analysis combining HBeAg-negative and HBeAg-positive and using the HBeAg-negative results as a covariate. Inferring clinical results based on this analysis may lead to an overestimation or underestimation of the results. In turn this may impact the cost-effectiveness of tenofovir disoproxil in this subgroup.

3 WHETHER YOU CONSIDER THAT THE PROVISIONAL RECOMMENDATIONS OF THE APPRAISAL COMMITTEE ARE SOUND AND CONSTITUTE A SUITABLE BASIS FOR THE PREPARATION OF GUIDANCE TO THE NHS

Roche believe that the provisional recommendations are sound.

Yours sincerely.