National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

30 May 2012

Dear,

RE: Belimumab for the treatment of systemic lupus erythematosus

Thank you for your letter dated 17 May 2012, providing your initial view in relation to the admissibility of our appeal. In this letter, we respond only to your preliminary view that point 1.3 of our appeal should be considered under ground 3 of NICE’s procedures, rather than under ground 1, as drafted.

Point 1.3 of our appeal arises from the approach followed in this appraisal in relation to the comparison of belimumab with a product which is not authorised for the indication under consideration. NICE’s Methods of Technology Appraisal expressly provide that comparator technologies may include those that do not have a marketing authorisation for the indication defined in the Scope (paragraph 2.2.4) but do not specify whether or, if so, how the authorisation status of such technologies should be taken into account during the appraisal. We believe that, while it may be appropriate to consider a comparison with a product used outside the licensed indication in the context of this appraisal, it is unfair to require that superior clinical and cost effectiveness be demonstrated in circumstances where the data relating to use of the comparator may be limited. As a matter of fairness, where the available data do not establish that a comparator, used outside the terms of its marketing authorisation, is more clinically effective than the product which is the subject of appraisal, NICE should not issue a negative recommendation based on cost, which will inevitably support continued off-label use of the comparator. This view is consistent with the decision of the European
Court in Case C-185/10, which also found that a recommendation in favour of an unlicensed product rather than a licensed alternative on costs grounds, is unlawful. In summary therefore, it is GSK's position that point 1.3 of our appeal raises questions of fairness as well as excess of powers and therefore may properly be brought under either ground 1 or ground 3. GSK would prefer to argue the point under ground 1 and requests your agreement to this arrangement.

In your letter you indicate that we should respond to your initial view in relation to 1.3 of our appeal by 1 June and should provide legal submissions by 5 June 2012 (we assume 6 June, in view of the bank holiday). However, in circumstances where the focus of our legal submissions will change, depending on whether you agree that point 1.3 may proceed under ground 1 or maintain your current view that it should be considered under ground 3, we would respectfully request that the date for provision of legal submissions should be extended to 5 working days after receipt of your final decision in response to this letter.

Yours sincerely,

VP Health Outcomes and Regulatory Affairs
GlaxoSmithKline UK Ltd