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IN CONFIDENCE

Mr C Feinmann
National Institute for Health and Clinical Excellence
Peter House
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28th March 2008

Dear Mr Feinmann

This letter sets out Baxter Healthcare's response to the Appraisal Consultation Document (ACD) on routine antenatal anti-D prophylaxis (RAADP) for rhesus-negative women dated March 2008.

Baxter Healthcare broadly welcomes the Appraisal Committee's preliminary recommendations, however would like to raise the following points.

- Section 2.6: The ACD states that 'recent survey evidence suggests that the single-dose regimen is increasingly preferred for logistical reasons.' From reading the Assessment Report, this appears to be based only on anecdotal evidence. Baxter believes this statement misleadingly favours the single-dose regimen without mention of there being no evidence of difference in efficacy between the two regimens or of previously stated concerns from the Royal College of Nursing (RCN), and that it should be removed or amended to reflect a more balanced point of view.

- Section 3.4: The word 'autoimmune' is incorrect and should be replaced either by 'immune' or 'idiopathic'. Baxter also requests that the fact that WinRho SDF is marketed in the UK *solely* for the treatment of idiopathic/immune thrombocytopenic purpura be made more explicit, preferably at the start of the section.

- Section 3.6: The final sentence should be amended to 'Costs are likely to vary…' as locally negotiated procurement discounts will mean prices will invariably differ from list price.

- Section 4.1.6: Baxter believes that the phrase '…and no evidence of a difference in efficacy between these regimens' should be removed, or re-worded as per the Assessment Report which states that the studies 'do not provide any evidence to suggest that two 500 IU doses of anti-D at 28 and 34 weeks are more, or less, effective than a single dose of 1500 IU at 28 weeks.'

- Section 4.3.8: In the Assessment Report, there was mention of concerns by the RCN regarding protection at 28 and 39 weeks. However there is no mention of such concerns within the ACD. Baxter believes that this section also gives a mis-leading impression in favour of the single-dose regime and that the RCN concerns are valid and important for consideration in this section.

- Also within this section, Baxter believes that the paragraph on supply constraints is of such importance that it should be addressed in its own separate section and that the concluding statement again should be addressed as a separate paragraph.

In light of the comments above, Baxter asks for any factual errors to be corrected, and for consideration to be taken of other comments noted.

Baxter Healthcare thanks NICE for the opportunity to comment on the ACD for RAADP, and welcomes further communication should additional information or clarification of points arising from this letter be required.

Yours sincerely,