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IN CONFIDENCE

Mr C Feinmann
National Institute for Health and Clinical Excellence
Peter House
Oxford Street
Manchester
M1 5NA

14th January 2008

Dear Mr Feinmann

This letter sets out Baxter Healthcare's response to the Technology Assessment Report on routine antenatal anti-D prophylaxis (RAADP) for rhesus-negative women dated 28th November 2007.

Baxter Healthcare is broadly in agreement with the majority of information contained within the report, but would like to raise the following points.

- On page 39, it should be noted that WinRho SDF is also subject to a multi-step chromatographic fractionation method of production, resulting in a liquid-stable anti-D preparation being available in some countries. However in the UK Baxter supplies the lyophilised product.

- The 'Pivotal' Study referred to in the first line on page 58 was used to gain licensure for WinRho SD (Solvent Detergent) for treatment of Rh isoimmunisation in 1993. The nanofiltration step to make it WinRho SDF was added into the manufacturing process in 1999. The statement that this is "implicitly WinRho SDF" is therefore incorrect.

- The cost section on page 88 incorrectly states that the single-dose regimen uses more anti-D than the two-dose regimen. This is not true when comparing with Partobulin SDF which is used at doses of 1000 – 1650 IU and therefore uses more anti-D than the single-dose regimen.

  Within the same section, Partobulin SDF is incorrectly referred to as a single-dose regimen. Baxter believes the report should refer to Rhophylac in this case.

- In the section on availability of donor plasma on page 89, the report states that

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"an argument can be made for those strategies which minimise the volume of plasma required. These include:

- The use of a two-dose 500 IU regimen, as this uses two-thirds the quantity of anti-D used by the single-dose regimen…"

It is Baxter's opinion that this is not a valid argument since if supply problems arise, an alternative formulation is required, which renders choice of dosing largely irrelevant. Baxter also notes that in the most recent past, the majority of supply problems have been associated with D-Gam.

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 Technology Assessment Report for RAADP, and welcomes further communication should additional information or clarification of points arising from this letter be required.

Yours sincerely,