MEMORANDUM

To: Dr. R.S. Lane

From: T.J. Snape

Date: 22nd August 1986

Observations on Dr. Harris' letter of 1.8.86

You will have received a copy of my letter of 13.8.86 to Dr. Schild outlining proposals for submission of samples to NIBSC in accordance with Dr. Harris' letter (my letter to Dr. Schild was also copied to Alison Smithies). These proposals no longer stand, following discussion at NIBSC on 18.8.86 between Dr. Schild, Dr. Thomas, Dr. Thorpe and myself. Dr. Schild proposed, and I was happy to agree, the following:-

i. Finished product samples (precise number to vary according to product) will be submitted to NIBSC from every batch of all products (BPL and PFL).

ii. In addition BPL will submit in advance a full batch manufacturing record for each type of product (factor VIII, factor IX, Albumin and Immunoglobulin), this to increase NIBSC awareness of the nature of the manufacturing process.

iii. NIBSC will perform at least anti-HIV, and at their discretion, any other analytical/microbiological procedures consistent with establishing compliance with specification, on every batch.

iv. Dr. Schild is discussing with Medicines Division (meeting agreed for 18th September - should we be represented) an appropriate format for reporting results. In the interim an informal arrangement has been agreed whereby results of testing for anti-HIV will be reported directly to BPL. No batch will be released from BPL/PFL without at least telephoned advice from NIBSC.

v. The procedure will be put into effect as soon as possible but will be effective for all products released from October 1986.

With regard to Dr. Harris' comments on licensing, I am confident that Manufacturing Licence Applications will be lodged for both manufacturing facilities (BPL and PFL) by the end of 1986. Product Licence Applications for factor VIII and IX will be lodged during first half of 1987; other PLAs will follow during 1987.

GRO-C

T.J. SNAPE

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