2ND DECEMBER 1985

E.L. GREENE

M.W. TATT

NIBSC MEETING TWO

MEETING HELD AT NIBSC ON THURSDAY 28TH NOVEMBER, 1985 TO DISCUSS THE CSM DECISION ON KONYNE-HT AND THE QUESTION OF GAMIMUNE BATCH RELEASE

PRESENT : Dr. G. Schild
Dr. D. Thomas
Dr. R. Thorpe
Dr. T. Barrowcliffe
Dr. Philip Minor (Head of Virology)
M.W. Tatt

MT explained the reason for the meeting. Our product licence application for Konyne-HT had been considered by the CSM and they had advised against the grant of a licence. MT had discussed their reasons for this decision with the DHSS but they were unable to comment on one point, i.e., "Inadequate evidence had been provided of virus inactivation", and had suggested that we discuss this with Dr. Schild.

GS said that they were tightening up on blood products and required more detailed information concerning screening of donors for HTLV III, including how the selected test is applied, whether the test has been validated and by whom, details of the reference serum used, etc. (Obviously, he knows that it has been tested in the U.K. and found unacceptable by the DHSS). GS wished to see results of viral inactivation studies which used a range of relevant marker viruses, he could provide a list if we wished (this will be sent next week).

DT pointed out that our application did not include studies showing inactivation of HTLV III. Although the heat-treatment step appeared to have been accepted here because a product licence for Koate-HT had been granted, in fact it had never been approved by the CSM (Koate-HT was given fast-track approval). We could not have known that. (DT explained later that we had been unlucky to have been caught at a time when a screening test had been approved by the DHSS).

GS said they also want to know about elimination of viruses during purification.

/Continued ...

With regard to Gamimune, GS would not say whether they would be prepared to release the product if we supplied all the information requested by the DHSS. He stressed that they wanted comprehensive data on the screening of donors for HTLV III antibodies and details of the source of plasma. RT pointed out that we have already supplied information to the DHSS on the source of supply and had informed them that we were screening all donations. GS made no comment.

DT said that he had asked for information on the protocol about HTLV III screening. GS said that yes, they needed confirmation of this with every batch submitted and he would want a sample of the bulk plasma pool. MT queried why they wanted these samples. GS said they would be looking for contamination. MT queried what contamination. GS said they would be testing for HTLV III antibodies.

GS also said that we should test the final product for HTLV III antibodies.

Regards,

Marie.