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4th November 1991
PJC/BMC

Dr. O.F. Schwarz,
Immuno AG,
PO Box 30,
Industriestrasse 67,
A1221 Vienna.

Dear Dr. Schwarz,

Following our discussions in Vienna concerning the current registration situation in the UK, I am writing to confirm the decisions which were made concerning both current and future applications.

1. Kryobulin Vapour Treated - it was decided to cancel our appeal and withdraw the current Abridged Application.

2. The variation for Feiba and Prothromplex Vapour Treated would be submitted as soon as possible. A timescale of 2 months was suggested but it was agreed that we should improve on this if possible.

   The Feiba Variation was a high priority to prevent us losing the current dry heat licence at the review.

3. An Abridged Application for Immunine would be prepared as soon as possible also taking into account the comments made on the vapour heat process at the recent meeting with the Department of Health.

4. It was agreed that we should attempt to register Immunate as soon as the data was available. It was stated that Immuno Ltd. had been excluded from the UK Factor VIII market since the early 1980's and it was important that we re-entered the market as soon as possible.

5. It was stated that the Tetabulin Abridged Product Licence Application was being compiled and this should be submitted to the UK Authorities as soon as possible. If we did not obtain a Product Licence before mid 1992 it was likely that all sales of Tetanus Immunoglobulin would be lost as Wellcome would be forced to stop supplying Humotet at the end of the contract period.

6. As far as Tisseel was concerned, we could not apply for a new licence application until a meeting had been held with the UK Authorities to discuss their interpretation of the EEC Guidelines on viral inactivation.

7. It was agreed that the meeting to discuss the EEC Guidelines would be arranged after the Product Licence Variations for Prothromplex and Feiba had been submitted.

It would be necessary to submit a detailed paper to the Department of Health in advance of our visit giving details of our interpretation of the Guidelines and how we intended to comply with them.

We all look forward to our success in 1992 in registering our vapour treated products.

Kind regards,

Yours sincerely,
for IMMUNO LTD.

GRO-C

P.J. Coombes
Managing Director

cc Mrs. Diernhofer
Mr. Nicholson