



IMMUNO LIMITED ARCTIC HOUSE RYE LANE DUNTON GREEN NR SEVENOAKS KENT TN14 5HB  
TELEPHONE: SEVENOAKS (0732) 458101 TELEX: 95413 FAX: (0732) 455175

15th February 1988

PJC/BMG

Mrs. I. Diernhofer,  
Immuno AG,  
Vienna.

Dear Mrs. Diernhofer,

Further to our recent telephone conversation concerning registration for the U.K. I would like to make the following comments:

1. KRYOBULIN / PROTHROMPLEX / FEIBA - Steam Treated

I understood after our visit to Vienna that the inactivation data for these products would be ready by mid March and that the full data for submission to the Ministry would be ready shortly after this date. As you are aware we need to have the information to answer all the questions raised by the DHSS, particularly relating to the technical validation. After talking to Mr. Berry, however, I now understand that it was only the Kryobulin data that will be ready in mid March and Feiba and Prothromplex will follow. Please could you, therefore, give us estimated dates when we are likely to receive the data for these applications. It is now 6 months since our meeting with Mr. Sloggem at the DHSS and we really should have submitted the data by this time. We will have to submit all the data requested as they will not process it if we only answer certain of the questions.

2. As far as the licence renewal for Kryobulin dry heat is concerned, as agreed we wish to send in the renewal documents for this product, but we do not intend to sell the product. These documents are required by the end of February. As you know, Dr. Schwarz agreed to us applying for this renewal.

3. You mentioned in a telefax to me that the pasteurisation data would take about one month which is why Mr. Nicholson gave a date of mid February. If this is not so then please give a revised date. We are still trying to sort out the other PPT variations with the DHSS so that we can try and have them all approved before the licence renewal in May.

4. PARTOBULIN

Please can you give us a date when the answers to the Section 44 letter can be replied to. The DHSS have agreed to give this application priority as there is a growing shortage of this product in the U.K. and there is no other licensed product. We must, therefore, answer these points as soon as possible.

- 2 -

## 5. KYROBULIN STEAM 3 (IRELAND) - Variation from steam 2 to steam 3

We discussed this in Vienna and you gave a provisional date of end of February. If this cannot be achieved, please advise.

## 6. ENDOBULIN for IRELAND - New Application

We agreed in Vienna to a provisional date of end of April. If this cannot be achieved, please advise.

We need to have dates when we can expect to receive the documents for all the above items, otherwise we cannot make any future plans for selling our products in the U.K. Unless we show the DHSS that we can provide the additional information required in a reasonable time, they will feel that we are not regarding these licence applications as a priority issue.

Our sales of unlicensed products are increasing, particularly Tisseel and Feiba and unless we can start to obtain some licenses, the DHSS will, I am sure, start restricting import of these products or even stop imports.

The situation is becoming very serious in the U.K. and we really need to try and make some progress in our attempts to obtain product licences.

Please could you discuss these points with Dr. Schwarz and Dr. Eibl as both Mr. Berry and myself understood that certainly for Kryobulin Steam 3 the inactivation data would be available by mid March and answers to the remaining queries raised by Mr. Sloggen would also be available. Feiba and Prothromplex would follow shortly afterwards, although I think it would be advisable to submit all three applications at around the same time.

We do appreciate your efforts to try and provide us with the required data but I hope we can formulate a definite schedule for delivery of the information on the points raised above so that we can make a determined effort to try and clear some of these problems this year.

Kind regards,

Yours sincerely,  
for IMMUNO LTD.

GRO-C

P.J. Coombes  
Managing Director

Eingegangen am:

16. Feb. 1988

I M M U N O L T D

REGISTRIERUNG

TELEFAX NO: 55/88/PJC NUMBER OF PAGES  
INCLUDING COVER SHEET: 3

DATE: 16th February 1988

TO: Mrs. I. Diernhofer - Immuno AG

FROM: Mr. P. Coombes

SUBJECT: Registration situation

FAX No: GRO-C

TEL No: GRO-C