



Eingegangen am:

- 6. Aug. 1991

REGISTRIERUNG

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

31st July 1991

PJC/BMC

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

Dear Dr. Schwarz,

KRYOBULIN - Abridged Licence Application
FEIBA, PROTHROMPLEX - Variations

You will no doubt have heard from Mrs. Diernhofer concerning our recommendations in relation to the Section 21(1) letter for Kryobulin.

I feel that the two main pharmaceutical problems still remain from our last licence application:

1. Viral inactivation studies as per EP/CPMP Guidelines including validation of small scale spiking studies.
2. Vapour heat cycles - continuous monitoring by relative humidity recorders.

Both of these points were very important when we had discussions with the Department of Health several years ago.

I feel, however, that we are now faced with another very serious problem concerning the viral inactivation studies relating to Kryobulin Vapour Heated. They are asking for comparative data with the dry heat product. I suspect that 6 log steps is no longer acceptable to the licensing authorities and we will not be able to show a significant improvement from dry heat.

We have informed the CSM of our intention to attend a Hearing to present our case. The written data will have to be submitted before the Hearing. We will now have to arrange a meeting with the assessors to discuss in more detail the contents of the Section 21(1) letter. If we decide that we cannot provide the required data we should then consider cancelling our Hearing and withdraw our application. This would prevent the licence being turned down and would save the company being placed in an embarrassing situation.

We have been in contact with Dr. Rotblat the Medical Assessor concerning a proposed meeting. The feeling which Mr. Nicholson obtained from the conversation was that we are going to have great difficulty registering Kryobulin Vapour Heated. They now regard it as an old product and feel that we should be presenting them with applications for new generation products in the same way as other companies.

The products recently being licensed such as Monoclade are able to claim over 15 log steps HIV inactivation. The methods of treatment favoured are pasteurisation and more recently SDI. The situation, therefore, does not look very encouraging.

We are meeting Professor Preston on 19th August to discuss the matter and obtain his opinion. In the meantime the licensing authorities have refused our recent request to import Kryobulin for stock on a doctor/patient basis. This will not affect our business as the small amount sold is for export - however it is of great concern.

Please could you let me know as soon as possible who will attend the meeting with the assessors. I would suggest no more than two from Immuno AG with two members of Immuno Ltd. It would appear that the following periods may be suitable in order of preference:

Weeks commencing: 9th September, 16th September, 12th August and 19th August.

Please could you let me have a selection of dates.

You are now aware that the Feiba and Prothromplex Variations have been turned down and there is no Appeal. If we are unable to obtain the Kryobulin Licence then there will be little point in submitting a further Variation for Prothromplex.

However, as far as Feiba is concerned they are taking a slightly different view and we feel that if we can answer the pharmaceutical points in their letter we could be successful. We are informed that Dr. Rotblat would have agreed to the Variation but the pharmaceutical assessor was not in favour. It was felt that as Feiba was a specialist product and received an extra vapour treatment it could be viewed in a different light.

It is, therefore vital that we submit a new Variation for Feiba as soon as possible following our meeting with the assessors. Sales of Feiba represent a considerable part of our turnover and we do not want the licensing authority to prevent us importing for stock. I feel, however, that this is unlikely at the present time. We have in fact, been granted permission this week for a consignment.

Kind regards,

Yours sincerely,
for IMMUNO LTD.

GRO-C

P.J. Coombes
Managing Director

cc Mrs. Diernhofer