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27th September 1988
PJC/BMC

Mrs. I. Diernhofer,
Immuno AG,
Industriestrasse 72,
A1220,
Vienna.

Dear Mrs. Diernhofer,

We are now very concerned at the time it has taken to prepare the data for the Abridged Application for Kryobulin and the Licence Variations for Feiba and Prothromplex.

We do appreciate the problems in obtaining the data but the situation has now become very embarrassing to our company. It is over a year since our meeting with the DHSS when they gave us detailed information on the data required to obtain these Licenses. They have asked us on a number of occasions for the data and this has still not been submitted.

The Haemophilia Centres in the U.K. are no longer really interested in discussing our products because they have been told for such a long time that we are attempting to change our Licenses. The DHSS have either Licensed or are in the process of considering new Licences for all our competitors and they are not be very impressed with the time it has taken us to provide the required data. The U.K. Haemophilia Directors' meeting is being held this week and as one of the main sponsors it is particularly difficult for our staff to continue to give excuses to them concerning the delays in licensing our products. The Haemophilia Directors have already told the U.K. hospitals that they should only use licensed Factor VIII products and we are now also seeing hospitals reducing their purchases of Feiba. In many Haemophilia Centres they will not use the product because it is no longer licensed.

Could you please, therefore, process the Kryobulin Application and the Prothromplex and Feiba Variations as soon as possible and let me have the dates when the data will be available for submission. I would also like to know whether you have any specific problems in obtaining the documentation you require.

We are also anxious to obtain the data for the Irish Endobulin Application. We have been selling the product for several years on an unlicensed basis and the authorities will stop us importing if they see we have no intention of applying for a licence. If this is likely to take a long time to prepare, we may be able to assist by trying to put an application together based on the U.K. application if necessary.

We have been informed now that we will be granted a licence for Endobulin once we have supplied the remaining data required.

The Tisseel Appeal is not looking very encouraging because of the dry heat treatment process. We will, however, have to wait for the official reply to find out whether we need to prepare a completely new application which I assume will be the vapour product. We will have to discuss this in detail when the situation has been clarified.

I look forward to hearing from you as soon as possible concerning the dates on submission of the data required.

Yours sincerely,
for IMMUNO LTD.

P.J. Coombes
Managing Director

cc Dr. O.F. Schwarz
Dr. H. Igel
Mrs. I. Henninger