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GRO-C

Eingegangen am:

7th July 1988

PJC/BMC 15. Juli 1988

Dr. O.F. Schwarz,
Immuno AG,
Vienna.

cc: DR. Eibl REGISTRIERUNG

*Fr. Henninger b. Bericht.
Hr. Kulkarni
Dr. Schuppert*

Dear Dr. Schwarz,

We have been informed this week that the Regional Haemophilia Directors in the U.K. have sent a circular letter to all the Haemophilia Centres informing them that the only Factor VIII products to be used in the U.K. are as follows, in order of priority:

1. Factor VIIIY - BPL
2. Haemate P - Behring
3. Profilate - Alpha

A customer of ours who has constantly been in touch with us to establish when we are going to obtain a Licence, has contacted one of the Regional Haemophilia Director's in response to this letter and has been informed that if she uses unlicensed products then she will not have any backing from the Haemophilia Directors and must take sole responsibility for its use. She is, therefore, now having to decide whether to change to another product. We will have to be very careful that this situation does not extend to Feiba as this currently provides a very important part of our turnover.

As you are aware, it is now nearly a year since we had the meeting with the Ministry of Health concerning our steam treated products and I think they are becoming concerned that we have not submitted the necessary data as requested. I understand from Mrs. Henninger that the Kryobulin Application is well under way, but we are still waiting for the expert reports which seem to be an ongoing problem. However, I understand that as yet the Feiba and Prothromplex data has not been prepared. It is now vitally important that we submit the data on these 3 products at the earliest opportunity as I feel that we shall be called to another meeting at the Ministry and they will express their concern at the large amount of unlicensed products which we are importing into the U.K.

Yours sincerely,
for IMMUNO LTD.

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P.J. Coombes
Managing Director