



26.03.1990
REGISTRIERUNG

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21st March 1990
PJC/BMC

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

Dear Mrs. Diernhofer,

Please could you let me have an update on the proposed submission dates for Kryobulin, Feiba and Prothromplex.

We have now passed the second date on which licence fees have been increased. Companies have submitted a large number of licence applications prior to the increase in fees which, as you will see from the attached article, is now causing further delays in the licensing system.

We need to obtain our place in the queue as soon as possible. I am still concerned that our current licences could be cancelled if the DHSS realise that Kryobulin and Feiba are dry heat and Prothromplex is non heat treated. In the case of Feiba and Prothromplex this would mean new applications. I think the Feiba licence is due for renewal in October this year and if they decide not to renew it we will become involved in a lot more registration work.

I have checked our records and it appears that it will be three years in August since the famous meeting with Mr. Sloggem and it is nearly four years since the Kryobulin amendment was turned down and the Feiba and PPK amendments withdrawn.

As we have stated recently, we must now submit the data we have available - even if it is not adequate. If the DHSS ask us why we have waited nearly four years, I am not sure what we can tell them.

We continue to find ourselves in a very difficult situation at major conferences where we cannot promote any of our coagulation products.

Please can we have a confirmed date for this registration data which we desperately need.

Kind regards,

Yours sincerely,
for IMMUNO LTD.

GRO-C

P.J. Coombes
Managing Director