Eingegangen am:
07. Okt. 1991
REGISTRIERUNG

IMMUNO LIMITED ARCTIC HOUSE RYE LANE DUNTON GREEN SEVENOAKS KENT TN14 5HB
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FAX TRANSMISSION NO. ...1076/91.. DATE ..04 October 1991.....

TO: Mrs. I Drenthen

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FROM: .....Mr R Nicholson.....

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NO. OF SHEETS INCLUDING THIS COVER SHEET: ..3.....

MESSAGE:

final Agenda as sent to MCA

Best Wishes

GRO-C: Robert Nicholson

SHOULD ANY PAGES NOT BE LEGIBLE, PLEASE PHONE: 0732-458101 (+44 732 458101)

A G E N D A

MCA Meeting, 8th October, 10.00 am. Persons attending:

Immuno Ltd.
Mr. P.J. Coombes, Managing Director
Mr. R. Nicholson, Director

Immuno AG
Mrs. I. Diernhofer, Head of Registration
It is possible a member of our technical staff may attend.

FEIBA P/L 215/0021-22

Variation applications dated 3rd and 4th July 1990. Ref. reply from MCA dated 19th July 1991 (copy attached).

Point 2

Vapour heat cycle monitoring. Data was supplied with the applications. What additional information is now required?

Point 4

Further discussions would be welcomed on the points of variance between the data submitted and the EP/CPMP guidance note on viral inactivation. In particular validity of the small scale spiking experiments, variation in the composition of the product, and parallel control assays to demonstrate the integrity of the various titre in the presence of product. Also who is responsible for the UK interpretation of this guidance on viral inactivation?

Point 5

We would like some indication of the Committee's current expectations in terms of demonstrable viral inactivation.

Point 9

For all 3 products "details regarding quality assurance of the assays for Hepatitis B and HIV antibodies used in donor screening" was requested. We currently supply to NIBSC details of kits used for testing for HIV and Hepatitis B. This information is kept up to date as kits are changed. Does this action cover the points raised by the Committee or is additional information needed?

PROTHROMPLEX P/L 0215/006-7

Variation applications dated 25 September 1990 and 26th September 1990. Ref. reply from MCA dated 22 July 1991 (copy attached).

The points raised for Prothromplex are similar to those for FEIBA. We may, however, decide not to proceed with a further Variation for this product as we have a new single Factor IX concentrate available, using additional purification steps.

We would like to discuss whether you feel that we can amend our existing licence, or whether we will require an abridged application for the new product.

KRYOBULIN PL0215/0027

Abridged Product Licence application. Ref. letter from MCA dated 8 July 1991 (copy attached).

Point 1

Clarification of this point in view of the International Factor Safety Study results showing no evidence of transmission of HIV or HBsAg and negative anti HCV tests in PUP (virgin patient) studies carried out since 1986 (further copy attached).

Point 2

Comment as to how the risk/benefit ratios are assessed would be helpful.

Point 4-2

We would like your comments on Aprotinin in relation to our ability to comply with CSM guidelines.

Point 4-6

Further clarification of this point.