M E M O

Discussion on Feb. 12, 1990 in the presence of Mr. Berry
Dr. Eibl
Mrs. Kunschak
Mrs. Jones
Dr. Igel
Dr. Schoppmann
Dkfm. Aschbauer
DD. Diernhofer
Mag. Henninger

The following summary of the current UK registration status was presented:

As to Kryobulin all expert reports and dossiers are now available. Everything will have to be reviewed and coordinated, since the data was prepared by different persons. After review, the pharmacological expert report will have to be signed by Dr. Eibl, the clinical report by Dr. Anderle.

It is anticipated that the abridged product license application will be ready for filing in about 3 to 4 weeks.

For the Feiba variation all documents are available except for Dr. Worofka's validation of the vapour heat treatment receptacle and the adjustment of moisture for vapour heat treatment. The pharmaceutical expert report is still missing. Dr. Weber who is going to prepare the report, had stated before the meeting that it would be ready within 2 months.

Concerning the Prothromplex variation, a redefinition of the product will be necessary due to the future specification of F X-units in international units. Probably the data collected so far will have to be revised.

The situation concerning the license application for TISSEEL KIT (vapour heated) is still unclear.

The following was discussed and agreed on the individual projects:

Feiba

Mr. Berry stressed that the variation for Feiba is of highest priority for Immuno Ltd. He cannot understand why it will take another 2 months till the pharmaceutical expert report will be ready and proposed to ask Mrs. Roberts to do the report. Since Dr. Weber has already prepared the report for Kryobulin, it was felt that he should also do the Feiba report on the same basis. Dr. Igel will check with Dr. Weber whether the report can be finalised at an earlier date. The situation should also be discussed with Dr. Schwarz after his return and Mr. Berry should be contacted at the end of this week and be given a definite date for the availability of the variation for filing with the DOH.

Prothromplex

In view of the problems that have arisen for this variation Mr. Berry proposed to drop it. In any case, Prothromplex is not sold in the UK but only required for overseas exports for which Immuno Ltd. does not need a product license.

Prothromplex-T and Factor VII are not licensed in the UK. According to Dr. Eibl product license applications should be considered for these products.

We could amend our presently licensed untreated Prothromplex to introduce either the total prothrombin complex (in 2 steps: first a variation concerning the composition, then another for further indications) or the purified F IX concentrate. Mr. Berry thinks that there is no market for the purified F IX concentrate.

For the time being Prothromplex-T could also be distributed on a doctor/named patient basis.

Tisseel Kit

Mr. Berry suggested that we should now apply for the vapour heated product using bovine thrombin to save time, since the waiting period is now already approx. 2 years before a new PLA is reviewed by the DOH. We could then make an amendment for human thrombin during the review period once all necessary data will be available.

Dr. Eibl stressed that we would have to prove a 15-log inactivation/partition of HIV in human thrombin.

Mr. Berry informed us that case reports on the use of vapour heated Tisseel are presently being collected in the UK.

As to Aprotinin, which is also of bovine origin, we could perhaps change over to the Bayer product. Generally, it seems to be best, however, rather to play down this problem for the time being.

Mr. Berry will try to get a UK expertise on B.S.E. (what is known, what is suspected).

High technology products

Mr. Berry will try and obtain some information on the filing mechanism of such products. It seems best to submit such an application either in the Netherlands or in the UK and have it then transferred to Brussels with a good assessment report. It would be interesting to get some information on UK rapporteurs.

GRO-C

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Dipl.Dolm. I. Diernhofer