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M E M O

FEIBA - Registration Project Team / United Kingdom

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As a result of a meeting on December 11, 1991 Dr. Eibl and Dr. Schwarz have requested that a project team be established to address the problems associated with FEIBA registration in the UK.

BACKGROUND

FEIBA sales in the UK are currently in the region of £ 2 million (40 million AS) per year and contribute significantly to the profitability of the UK company. FEIBA was licenced in the UK in 1986 as the dry heat treated product. Since this time two attempts have been made to licence the vapour treated product.

Both applications have failed for essentially similar reasons:

- Failure to provide reassurance on the consistency of the vapour heating process and that the production process is under full control with particular reference to variable parameters such as composition of bulk, water content, etc.

- Failure to provide reassurance that the preclinical data on viral inactivation truly reflects the full scale production process.

It is intended to submit a further application in the first week February 1992 to change the current licence to allow the vapour heated product to be freely supplied. If we do not meet this date there is a real danger of the existing licence being lost because of the review (revision) procedures being applied to all blood product licences as a result of EC directives.

The loss of this licence would have a major impact on sales of FEIBA in the UK with a resultant loss of profit to the UK company. It may also have repercussions in other EC countries.

A project team has been set up to address this problem and a more detailed list will be circulated addressing those topics we identify as being of prime importance. It is, however, realised that the short time frame means it will be difficult if not impossible to carry out any additional studies. The submission to the UK licencing authorities must therefore make the best use of the data currently available to address their concerns.

The basic philosophy must be to prove:

- The manufacturing process is well controlled and reproducible.

- The preclinical viral inactivation data is valid and fully relevant to full scale production.

  Both these items must address the potentially variable parameters of composition, dew point (relative humidity) and also the kinetics of inactivation.
  It is important to be able to demonstrate that the variable parameters of the preclinicals are similar to full scale production.

- The risk/benefit ratio for FEIBA treatment is acceptable.

- It is important that all previously unsubmitted data be reviewed as this may well provide justification for the decisions that have been taken in the development of vapour heated FEIBA. In some instances explanation of decisions taken during the pharmaceutical development may provide important reassurance to the UK authorities.

- The project team by necessity must draw on the expertise of many different departments. It is hoped and indeed encouraged that any member will feel free to comment on any topic even if it does not directly fall within their normal departmental role.

- The first meeting of small groups will be held Wednesday/ Thursday 18th/19th December and regular meetings will be held during the coming 6 weeks to review progress and plan necessary action. Please, however, feel free to contact the co-ordinator in Vienna, Dr. Schoppmann, or myself if you have any comments or suggestions.

- Finally I would ask for your full co-operation in the project team tackling this important issue which has the full backing of Dr. Eibl and Dr. Schwarz.

GRO-C

R. Nicholson
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Director
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