NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held on 9 March 1983

PRESENT:	ALSO PRESENT:	
Dr J W G Smith (Chairman)	Mr T W Barrowcliffe)	
Professor J A Dudgeon	Ms A Ford)	
Professor H Keen	Dr G C Schild)	NIBSC
Professor H Lambert	Dr F W Sheffield)	
Dr R S Lane	Mrs R Michael)	
Mr J G Watt		
Mr H M Morgan (Secretary)	Mr K J Ayling)	
	Mr J P Betts)	
	Dr M E Duncan)	
	Dr L K Fowler)	DHSS
	Mrs S Kelly)	
	Dr J Purves)	
	Dr D W Zutshi)	
	Dr Brinley Morgan	MAFF
	Miss Z Spencer)	DHSS
	Mr T J Kirkley)	

1. Confidentiality

The Chairman reminded members that the material they received was confidential and should not be disclosed outside the meeting.

2. Apologies for Absence

Apologies for Absence were received from Professor Jenkins, Professor Melling and Dr Tyrrell.

3. Minutes of the meeting held on 12 January 1983

These were agreed and signed by the Chairman as a correct record of the proceedings.

4. Matters arising from the minutes

The Sub-Committee noted that the application for a product licence for Tetavax was seen by the CSM at its meeting held on 20 January 1983 and that the CSM had endorsed the Sub-Committee's recommendation. (Minutes of the meeting 20/1/83 refer).

5. Consideration of Applications

5.1	PL/0002/0106-8	Smith, Kline and French	Moniarix
5.2	PL/0512/0054	Duphar Laboratories Ltd	Influvac
5.3	PL/4447/0004	Alpha Therapeutic (UK) Ltd	Antihaemophilic Factor (Human) Wet-Paste (Bulk Cryoprecipitate)

The Sub-Committee's recommendations on these applications for product licences are attached at appendices A-C.

5.4	CT/3070/0006	Speywood Laboratories Ltd	Mono-VIII:C

Prior to the consideration of this application Dr Lane and Mr Watt declared a non-specific interest in the application.

The Sub-Committee's recommendation on this application for a clinical trials certificate is attached at appendix D.

5.5	PL/3262/0015	CIS (UK) Ltd	Fibrinocis (TCK-19)

The Sub-Committee's recommendation on this application for a product licence is attached at appendix E.

5.6	PL/4029/0001	Alpha Therapeutic	Profilate
5.7	PL/0093/0041	Servier Laboratories Ltd	Imotest Tuberculin

The Sub-Committee's recommendation on these applications for a variation to the existing product licences is attached at appendices F-G.

6. Hearing

PL/4534/0001	Laboratoire des Stallergenes	Penkit

The Sub-Committee's recommendation on this hearing is attached at appendix H.

7. Items for information

Mail 36 and the PHLS Surveillance on BCG Vaccine - Thirteenth Report (Tabled Paper 1) were circulated to members for information.

8. Any Other Business

None.

9. Date and Time of Next Meeting

Wednesday 11 May 1983 at 10.30 am.

GRO-C

GRO-C

11.2.83

SUB-COMMITTEE ON BIOLOGICALS 9 MARCH 1983

No.

PL/4447/0004

Coy.

Alpha Therapeutic (UK) Ltd

Product

Antihaemophilic Factor (Human) Wet-Paste (Bulk Cryoprecipitate)

Therapeutic Class

Blood Product

Active Constituent

Human Factor VIII

RECOMMENDATION

On the evidence before them the Sub-Committee, on grounds of safety and quality, were unable to recommend the grant of a Product Licence.

The Sub-Committee considered that:

1. the bulk cryoprecipitate should be prepared by Alpha Therapeutics only from Source Plasma (Human) derived from their own licensed plasmapheresis centres,

2. there were inadequate details on the manufacturing process,

3. evidence should be provided to show that the cryoprecipitate is at least equivalent in quality to that used for the manufacture of Alpha Therapeutic's US licensed Factor VIII,

4. inadequate information was presented on the control of the material during transport to the UK,

5. an undertaking should be given that donor lists should be available to the manufacturer of the finished dosage form,

6. in the event of a licence being granted for this product, the batch release procedure should apply, to include the provision of protocols and samples of bulks, as required.

Remarks

1. The Licensing Authority is asked to consider the legal implications of licensing this bulk blood product as an ingredient rather than as a finished product, especially in view of the great difficulties foreseen for the manufacturer of the finished dosage form in exercising full control going back to the source material.

2. The Sub-Committee advised that special attention be given to the inspection of the Company's premises in the USA.

3. The Sub-Committee noted that no evidence of efficacy was presented as the product was only as an ingredient.

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RECOMMENDATION

No.

CT 3070/0006

Coy.

Speywood Laboratories Ltd

Product

Mono-VIII C

Therapeutic Class

Blood Product

Active Constituent

Human Factor VIII

On the evidence before them the Sub-Committee, on grounds of safety and quality, were unable to recommend the issue of a Clinical Trial Certificate.

The Sub-Committee considered that:

1. the bulk cryoprecipitate should be prepared by Alpha Therapeutics only from Source Plasma (Human) derived from their own licensed plasmapheresis centres,

2. there were inadequate details on the manufacturing process,

3. evidence should be provided to show that the cryoprecipitate is at least equivalent in quality to that used for the manufacture of Alpha Therapeutic's US licensed Factor VIII,

4. inadequate information was presented on the control of the material during transport to the UK,

5. inadequate information had been provided on the control of the quality of the material on arrival in this country and throughout its transit in the UK,

6. donor lists should be available to Speywood Laboratories Ltd as manufacturer of the finished dosage form,

7. full details should be supplied on the manufacturing and control methods. This should include definitive information on in-process sterilisation methods and microbiological control,

8. reverse osmosis water should not be used in the preparation of this product,

9. bubble-point testing should be carried out on the sterilising filter before and after filtration,

10. the FPS should include tests and limits for Loss on Drying, Isoagglutinins and Pre Kallikrein Activator,

11. full information should be supplied on the manufacture and quality control of the 5 ml diluent supplied with the injection,

12. in the event of a Clinical Trials Certificate being issued the study should be limited to 10 patients and to no more than one bleeding episode in each patient,

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No.

PL 4029/0001

Coy.

Alpha Therapeutic

Product

Profilate

Therapeutic Class

Factor VIII -
Human Blood Product

Active Constituent

Dried Human
Antihaemophilic
Factor

RECOMMENDATION

On the evidence before them the Sub-Committee were unable to recommend that the product licence should be varied as indicated in the application.

The Sub-Committee considered that inadequate information had been presented by the Company to assess this variation.