NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held on 4 January 1984

PRESENT	ALSO PRESENT	
Dr J W G Smith (Chairman)	Dr G C Schild	NIBSC
Professor W J Brammar	Dr F W Sheffield	NIBSC
Professor G C Jenkins	Mr K J Ayling	
Professor H Keen	Dr J Barnes	
Dr R S Lane	Mr J P Betts	
Professor J Melling	Dr M E Duncan	
Dr D P Thomas	Dr L K Fowler	
Dr D A J Tyrrell	Mr T J Kirkley	
	Miss Z Spencer	
	Mr G Wade	

Dr J Purves (Pharmaceutical Assessor)
Mr H M Morgan (Secretary)

1. Confidentiality and Announcements

The Chairman informed the Sub-Committee that two new members had been appointed and that they were Professor Collee and Professor Banatvala. He explained that Professor Banatvala was unable to attend meetings until August 1984.

The Chairman paid tribute to the work of Professor Dudgeon and Dr Pollock as members of the Sub-Committee. Both these members retired from CSM(B) at the end of 1983.

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 had been received from Professor McMichael, Mr Watt and Professor Collee.

3. Minutes of the Meeting held on 14 September 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 the CSM's advice on applications previously seen by the Sub-Committee.

5. Consideration of applications

5.1 PL/1317/0001-Solco Basle Ltd - Solcotrichovac

5.2 CT/5467/0001 - Crinos SpA - Defibrotide Injection 200mg/2.5 ml

5.3 CT/0015/0101 - Boehringer Ingelheim - Berofor Nasal Spray

Dr Tyrrell declared a non-specific interest in this application.

5.4 PL/3478/0090-95 - Warrick Pharmaceuticals Ltd - Alpha-2 Interferon

5.5 PL/3473/0011 - Common Services Agency - Human Immumoglobulin.

The Sub-Committee's recommendations on these applications are at appendices A-E.

6. Written representation

PL/4447/0004 - Alpha Therapeutic - Antihaemophilic Factor (Human) Wet Paste (Bulk) Cryoprecipitate)

The Sub-Committee's recommendation on this written representation is attached at appendix F.

7. Items for Information

MLX 149 + 149 Corrigendum, MLX 150, Statutory Instrument 1983 No 1212

MAIL 38

These were circulated to Members for their information

8. Any other business

The Chairman informed Members that this was Miss Spencer's last attendance at CSM(B) and thanked her for her help and guidance.

9. Date and Time of next meeting

Wednesday 7 March 1984 at 10.30 am.

GRO-C

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7.3.84

No

PL/4447/0004

Coy

Alpha Therapeutic Corporation

Product

Antihaemophilic Factor (Human)

Wet Paste (Bulk Cryoprecipitate)

Therapeutic Class

Blood Product

Active Constituent

Human Factor VIII

Sub-Committee on Biological Products 4 January 1984

RECOMMENDATION ON WRITTEN REPRESENTATION

The Sub-Committee considered the additional data supplied by the Company in support of their written representation against the CSM's provisional conclusion but they were unable to recommend the grant of a Product Licence for this product.

The Sub-Committee considered that:

1. the Company were unable to confirm that the bulk cryoprecipitate would be prepared by Alpha Therapeutic only from source plasma (Human) derived from their own licensed plasmapheresis centres and their arguments for an alternative arrangement were not accepted (point 1 of the Section 21(1) letter),

2. satisfactory evidence had not been provided to show that the cryoprecipitate is at leas equivalent in quality to that used for the manufacture of Alpha Therapeutic's US licensed factor VIII (point 2 of the Section 21(1) letter),

3. the information presented on the control of the material during transport to the UK was inadequate (point 3 of the Section 21(1) letter),

4. a satisfactory undertaking had been provided, by the Company, to supply donor lists to the manufacturer of any finished dosage form (point 4 of the Section 21(1) letter),

5. 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. The Sub-Committee did not accept the Company's argument that the batch release procedure should not apply (point 5 of the Section 21(1) letter),

6. satisfactory details of the manufacturing process had been provided (point 6 of the Section 21 (1) letter).

Therefore points 1, 2, 3 and 5 of the Section 21(1) letter remained outstanding.