COMMERCIAL IN CONFIDENCE CSM/BSC/82/1st Meeting

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICALS

Minutes of the meeting held on 22 January 1982

Dr J W G Smith (Chairman)		
Professor J A Dudgeon		
Prof G C Jenkins	Dr Schild	NIBSC
Prof H Lambert	Dr Sheffield	NIBSC
Prof J Melling	Mrs Michael	NIBSC
Dr D P Thomas	Dr Barnes	DHSS
Dr J Holgate (Medical Assessor)	Dr Andrews	DHSS
Mrs J C Archer (Secretary)	Dr Purves	DHSS
	Miss Hepburn	DHSS
	Dr Duncan	DHSS
	Dr Fowler	DHSS
	Mr Ayling	DHSS
	Miss Spencer	DHSS
	Mrs Harrison	DHSS
	Miss Draper	DHSS

1. CONFIDENTIALITY AND ANNOUNCEMENTS

1.1 The Chairman welcomed Professor Lambert and Professor Melling who were attending their first meeting of the Sub-Committee, he also welcomed Dr Thomas who was attending the meeting as a member for the first time.

1.2 The Chairman gave a brief description of the change in the structure of the Sub-Committee and how the new format was to operate.

1.3 The Chairman reminded members that the material they received was of a highly confidential nature and should not be made available to outside contacts.

2. APOLOGIES FOR ABSENCE

Apologies for absence had been received from Dr Lane, Dr Tyrrell, Dr Moir, Mr Watt and Dr Brinley Morgan.

3. MINUTES OF THE MEETING 11 NOVEMBER 1981

The minutes and appendices were agreed and signed by the Chairman as a correct record of the proceedings, subject to the inclusion of Miss Zoe Spencer in the list of those present at the meeting.

4. MATTERS ARISING FROM THE MINUTES

4.1 Members had been provided with a tabled paper detailing the decisions of the Committee on Safety of Medicines on two biological products which had been considered by the Sub-Committee at their previous meeting.

4.2 The Sub-Committee noted that the CSM had agreed that the applicants, LABORATOIRE DES STALLENGENES, should be notified in accordance with Section 21(1) of the Medicines Act, that on the evidence before them the Committee had reason to think that on grounds relating to safety, quality and efficacy they would be unable to advise the grant of a Product Licence for Penkit.

4.3 The Sub-Committee also noted that the CSM had agreed with the Sub-Committee's advice on the application for Solcotrichovac and had advised the Licensing Authority to issue a Clinical Trial Certificate on the conditions agreed by the Sub-Committee.

5. CONSIDERATION OF APPLICATIONS

The Sub-Committee considered four Product Licence applications, one application for the renewal of a Product Licence of Right and two Written Representations in connection with Product Licence applications. The preparations concerned and the recommendations of the Sub-Committee are details at Appendices A to G.

6. ITEMS FOR INFORMATION

Copies of the following had been circulated to members:-

Statutory Instruments 1981 No.'s 1633
1689
1690

7. ANY OTHER BUSINESS

There was no other business

8. DATE AND TIME OF NEXT MEETING

10 March 1982 at 10.30 am in Rooms 1612-14, Market Towers, Vauxhall.

GRO-C

10.3.82

GRO-C

PL/0215/0021-22

Coy.
Immuno Ltd

Product
Feiba Immuno-
Factor VIII
Inhibitor by passing
fraction human

Therapeutic Class
Anti-Hemophilia

Active Constituent
Feiba

500
25 units (± 30%)

1000
50 units (± 30%)

Sub-Committee on Biologicals - 22 January 1982

ADVICE

On the evidence before them the Sub-Committee, on grounds relating to quality and efficacy were unable to advise the grant of a Product Licence for this preparation.

The Sub-Committee considered that:-

1. No evidence of efficacy was provided for Haemophilia B patients with Factor IX inhibitors or Factor XIa inhibitor patients.

2. Inadequate evidence of efficacy was provided for Haemophilia A patients with Factor VIII inhibitors.

3. Adequate evidence of efficacy was not provided for all the indications claimed.

4. The following additional information was needed:-

i. Complete data on the manufacturing process.

ii. Stability data on reconstituted Feiba, held at room temperature.

iii. Details of the Immuno house standard for lyophilized inhibitor plasma.

iv. Product particulars, labels and data sheet.

REMARKS

1. In the event of a Product Licence being granted the Sub-Committee felt that information on the following should also be obtained:-

i. Complete details of the Kit provided for reconstitution of the product.

ii. A British approved name for the product.

iii. Batch release procedures for the product.

iv. Samples and protocols should be supplied to the NIBSC.

No.
PL/3132/0022-25

Coy.
NORDISK UK LTD

Product
Factor VIII
Nordisk 250, 350, 500, 1700

Therapeutic Class
Blood Product

Active constituents

Human coagulation factor VIII 250/350/500/700 IU

Sub-Committee on Biologicals 22 January 1982

ADVICE

On the evidence before them the Sub-Committee, on grounds relating to quality and efficacy were unable to advise the grant of a Product Licence for this preparation.

The Sub-Committee considered that:-

1. Inadequate evidence was provided to justify the claim that the product degraded more slowly than conventional Factor VIII preparations.

2. Futher information should be given on the controls exerted over plasma collection.

3. Futher information should be given on the manufacturing process.

4. Further information is required on the quality control of batches and Sub-batches.

5. Further information is required on the stability of the product.

REMARKS

1. A satisfactory inspectors report would need to be obtained to verify the plasma sources prior to the grant of a product licence.

2. In the event of a product licence being granted batch release procedures would be required.

3. Samples and protocols should be supplied to the NIBSC.

No.
PL/2777/0003

Coy.
Biotest Folex Ltd

Product
Dried Seralc VIII Antihaemophilic Factor (Human)

Therapeutic Class
Blood Product

Active Constituents
Antihaemophilic Factor (Factor VIII) Concentrate from Human Plasma

Sub-Committee on Biologicals 22 January 1982

ADVICE

On the evidence before them the Sub-Committee, on grounds of quality and safety in relation to quality were unable to advise the grant of a Product Licence for this preparation.

The Sub-Committee considered that:-

1. Further information should be given on the source and collection of plasma.

2. Further information on the manufacture and control of manufacture should be given.

3. Formal Finished Product Specifications should be presented for each of the four proposed strengths of this Product, and the product(s) should satisfy the criteria of the Ph Eur tests for abnormal toxicity, pyrogenicity and sterility.

4. The stability data presented was inadequate.

5. Information presented on the batch analysis of one lot as evidence of consistency of manufacture is inadequate.

REMARKS

1. Labels should comply with the Medicines (Labelling) Regulations (1976) and data sheets should comply with the Medicines (Data Sheet) Regulations(1972) and subsequent amendments.

2. The name of the qualified person responsible for the product in the UK should be provided

3. Samples and protocols should be supplied to the NIBSC