DW/15

NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held on 14 September 1983

PRESENT

[redacted] (Chairman)

[redacted] (Medical Assessor)
[redacted] (Pharmaceutical Assessor)
[redacted] (Secretary)

ALSO PRESENT

[redacted] NIBSC

[redacted] DHSS

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 [redacted] and [redacted].

3. Minutes of the meeting held on 13 July 1983

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

4. Matters arising from the minutes

[redacted] informed the meeting that he had been appointed Chairman of the MRC Committee on AIDS.

5. Consideration of applications

5.1	PL/3400/0015-17	Serono Labs (UK) Ltd	TP-1
5.2	PL/0530/0127 and 0121	Harris Pharmaceuticals Ltd	Fluzone - inactivated influenza vaccine BP
5.3	PL/4500/0002	Biotest Pharma GmbH	Intraglobin

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

5.4 PL/0116/0011 Travenol Labs Ltd Hemofil

The Sub-Committee's recommendation on this application for a variation to the existing product licence is attached at appendix D.

6. Hearing

6.1 PL/1605/0011 Miles Labs Ltd Gamimune Immune Globulin

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

7. Items for information

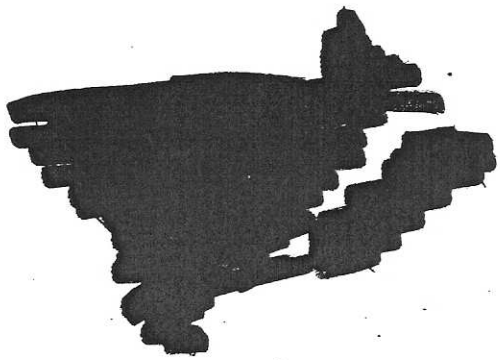
7.1 Statutory Instrument 1983 No 957 was circulated to members for information.

8. Any other business

The Chairman informed members that this was [redacted] last attendance at CSM(B) before his retirement. He thanked him for his many years of service to the Committee and remarked that his wisdom and knowledge would be greatly missed.

9. Date and time of next meeting

Wednesday 9 November 1983 at 10.30 am.



Appendix A

Number:

PL 3400/0015-17

Company:

Serono Labs Ltd

Product:

TP-1 Injection
10 mg, 25 mg, 50 mg

Therapeutic Class:

Hormone

Active Constituent:

Thymostimulin

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

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

The Sub-Committee considered that:

1. Further information should be provided on the identity, purity and consistency of the drug substance.

2. Further information should be provided on the methods used in establishing the stability of the dosage form, and on the stability of the standard.

3. Inadequate evidence of clinical efficacy had been provided.

4. Further information should be provided on the quality of the products used in all the Clinical Studies.

5. The labels and data sheets should be modified to the satisfaction of the Secretariat.

Remarks

1. In the event of a product licence being granted the Batch Release Procedure should apply to include the provision by the Company of bulk and in-process samples.

2. The Company should be encouraged to continue to evaluate the clinical and biological activity of the preparation.

Appendix B

Number:

PL 0530/0127, 0131

Company:

Harris Pharmaceuticals Ltd

Product:

Inactivated Influenza Vaccine BP

Therapeutic Class:

Viral Vaccine

Active Constituent:

A/Brazil/11/78
A/Bangkok/1/79
B/Singapore/222/79

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

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

The Sub-Committee considered that:

1. inadequate evidence of safety and efficacy had been presented for this product.

2. insufficient details had been given of the method and consistency of manufacture. The characterisation of the seeds should be described.

3. the quality control of the final product was inadequate in relation to material content, potency, pyrogenicity and stability.

4. in the event of a Product Licence being granted the proposed data sheet would require revision and the Batch Release Procedure should apply to include the provision by the Company of bulk and in-process samples.

Appendix C

Number:

PL 4500/0002

Company:

Biotest Pharma GmbH

Product:

'Intraglobin'

Therapeutic Class:

Immunoglobulin

Active Constituent:

Human Immunoglobulin (chiefly 1g G)

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

On the evidence before them the Sub-Committee recommended the grant of a Product Licence for this preparation in the single indication of replacement therapy for congenital agammaglobulinaemia and hypogammaglobulinaemia in patients who were unable to tolerate intramuscular administration, on condition that:

1. named sources for raw gamma globulin and human albumin were provided together with appropriate specifications and protocols.

2. further satisfactory information is provided on the content of antibodies against a representative range of bacterial and viral pathogens.

3. the specification for the end product should include not less than 80% monomer and not more than 10% aggregates or justification should be provided for different levels.

4. a satisfactory specification is provided for the content of IgG sub-classes and the levels of Kallikrein and pre Kallikrein activators.

5. in the event of a Product Licence being granted the Batch Release Procedure should apply to include the provision by the Company of bulk and in-process samples.

Appendix D

Number:

PL/0116/0011

Company:

Travenol Laboratories Ltd

Product:

Hemofil

Therapeutic Class:

Blood Product

Active Constituent:

Factor VIII

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

On the evidence before them the Sub-Committee on grounds of safety, quality and efficacy was unable to recommend that the Product Licence should be varied as indicated.

The Sub-Committee considered that

1. justification should be provided for the inclusion and choice of the heat treatment step.

2. the heat-treated product was inadequately characterised.

3. inadequate evidence of safety and efficacy was provided.

4. in the event of the grant of a variation to the licence, labels and data sheets should be modified to the satisfaction of the Secretariat.

REMARKS

1. Promotional letters making unjustified claims on improved safety margins in respect of infection and AIDS were seen by the Sub-Committee and strongly deprecated.

2. Evidence of the long-term safety in haemophiliac patients of treated products such as this is regarded as an important prerequisite of licensing.

Appendix E

Number:

PL 1605/0011

Company:

Cutter Laboratories Ltd

Product:

Gamimune Immune Globulin Intravenous 5%

Therapeutic Class:

Blood Product

Active Constituent:

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS 14 SEPTEMBER 1983

RECOMMENDATION

The Sub-Committee considered the additional data supplied by the Company to support their presentation at the forthcoming CSM Hearing and considered that the data was acceptable with regard to safety, quality and efficacy (points 1 to 8 of S21/1 letter) provided that the indications were restricted to the single indication of replacement therapy for congenital agammaglobulinaemia and hypogammaglobulinaemia, and that such use should be restricted to patients unable to tolerate intramuscular administration.

REMARK

The batch release procedure should apply, to include the provision by the Company of bulk and in-process samples.