GRO-C 580/398 GRO-C

NOT FOR PUBLICATION

CSM/BIOLS/86/2nd Meeting

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held in Room 1611/12, Market Towers on Wednesday 5th March 1986.

Present

Dr. J.W.G. Smith (Chairman)
Professor J.G. Collee
Professor G.C. Jenkins
Dr. R.S. Lane
Dr. G. Schild
Dr. D.A.J. Tyrrell
Mr. J.G. Watt
Dr. A.J. Isaacs (Medical Assessor)
Mr. J.P. Betts (Pharmaceutical Assessor)
Mr. K.L. Fowler (Secretary)
Mr. K.J. Ayling
Dr. J. Barnes
Mr. J.P. Digings
Dr. S. Grieve
Mrs. J.A. Hampton
Dr. W. Jenkins
Dr. J. Purves
Dr. F. Rotblat
Mr. G. Wade
Miss B. Woollett

Also Present

Dr. D Bangham )
Dr. T.W. Barrowcliffe ) NIBSC

1. Confidentiality and Announcements

1.1 The Chairman reminded members that the papers and proceedings are confidential and should not be disclosed.

1.2 The Chairman informed members that Mr. Betts was now Pharmaceutical Assessor to the Sub-Committee, and Mrs. Hampton was Deputy Pharmaceutical Assessor. Mrs. Hampton was attending her first meeting of the Sub-Committee.

2. Apologies for Absence

Apologies for absence had been received from Professor Banatvala, Dr. Brinley-Morgan, Professor Keen, Professor Melling, and Dr. Thomas.

3. Minutes of the Meeting held on 8th January 1986

3.1 The pharmaceutical conditions were added to the Sub-Committee's recommendation for Pneumovax (PL 0025/0213 : Merck, Sharp & Dohme).

3.2 Following this amendment, the minutes were agreed and signed by the Chairman as a true record of the meeting.

4. Matters Arising from the Minutes

The Sub-Committee noted the advice of the CSM regarding items previously considered by the Sub-Committee.

5. Consideration of Applications

The Sub-Committee considered applications for the following products, and their recommendations are at Annex A :

5.1 Intraglobin F : PL 4500/0004 : Biotest Pharma

5.1.1 In connection with this application, the Sub-Committee noted three tabled appendices.

5.1.2 Dr. Lane offered to prepare a paper for the future consideration of the Sub-Committee on immunoglobulin sub-classes and their effects.

5.2 Lupron : PL 0037/0184 : Abbott Laboratories

5.3 Roferon-A : PL 0031/0201-2 : Roche Products

5.3.1 Dr. Tyrrell declared a specific interest. The Chairman decided that he should contribute to the discussion.

5.3.2 During the consideration of this application the point was raised by Dr. Tyrrell that the science relating to interferons was rapidly developing, and it was important to ensure that benefits to patients were not inhibited by unnecessary requirements to repeat efficacy data for closely related molecules. It was agreed that NIBSC should prepare a paper on this.

5.3.3 Arising from the consideration of this application Dr. Schild agreed that NIBSC would prepare a paper on the principle of requiring access to bulk and in-process samples.

6. Written Representations

The Sub-Committee considered written representations on the following products, and their recommendations are at Annex B :

6.1 Defibrotide Injection : CTC 5467/0001 : TIL (Medical) Ltd

6.2 Fibrin Adhesive Kit : CTC 0086/0106 : Hoechst UK Ltd

7. Hearing

The Sub-Committee considered the additional written data for a Hearing on the following product, and their recommendation is at Annex C :

ORG 10172 : CTC 0065/0076 : Organon Laboratories Ltd

8. Further Information on the Safety of Immunoglobulins

The Sub-Committee considered this paper and made the following recommendations:

8.1 The Sub-Committee was glad to see that the use of donor screened plasma was rapidly being introduced. It was hoped that at its next meeting the data submitted on inactivation of virus by the manufacturers' processes would be available.

8.2 The Sub-Committee advised that the information from the manufacturers should include data on the reliability of the methods used for HTLV-III antibody screening.

8.3 It was agreed that the whole question should be kept under review.

9. Any Other Business

The Safety of Heat Treated Factor VIII (tabled paper 1)

The Sub-Committee considered this paper and made the following recommendations:

9.1 The Sub-Committee were glad to receive this data on the follow up of alleged transmission of HTLV-III by heat treated Factor VIII. The Sub-Committee agreed that there was insufficient evidence for action to be taken on any specific product.

9.2 Close surveillance should be maintained on the two possible cases of HTLV-III transmission in recipients of Armour material.

9.3 The Sub-Committee advised that, if any of the data provided by manufacturers on viral inactivation suggested a danger, urgent consultation should be sought with appropriate members.

10. Date and Time of Next Meeting

Wednesday 7th May 1986, at 10.30 a.m.

GRO-C