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 6th November 1985.

Present

Dr J.W.G. Smith (Chairman)
Professor J.E. Banatvala
Professor J.G. Collee
Professor G.C. Jenkins
Professor J. Melling
Dr D.P. Thomas
Dr A.J. Isaacs (Medical Assessor)
Dr J. Purves (Pharmaceutical Assessor)
Mr K.L. Fowler (Secretary)
Mr K.J. Ayling
Mr J.P. Betts
Mr J.P. Digings
Dr M.E. Duncan
Dr S. Grieve
Dr W. Jenkins

Also present

Mr D. Hagger
Dr A. Meager )
Mrs R. Michael ) NIBSC
Dr G. Schild )
Dr Thorpe )

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 introduced and welcomed Dr Isaacs who was attending his first meeting as Medical Assessor. The Sub-Committee wished to thank Dr Mann for his assistance as Medical Assessor, and wished him success in his new post of PMO for the Adverse Reactions section.

1.3 The Chairman introduced and welcomed Dr Jenkins who was attending his first meeting of the Sub-Committee.

2. Apologies for absence

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

3. Minutes of the meeting held on 4th September 1985

These 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 decisions of the CSM, at its September meeting, regarding products previously considered by the Biologicals Sub-Committee. The applications for Wellferon Injection and Roferon-A had been deferred for consideration by the SEAR Sub-Committee, and the Committee had been unable to advise the grant of a PL for Konyne-HT. The Hearing for Merieux Human Albumin had resulted in the Committee advising the grant of a PL provided certain conditions were satisfied.

5. Consideration of Applications

5.1 The Sub-Committee considered applications for the following products:

5.1.1 Orthoclone OKT3 Sterile Solution : PL 0076/0128 : Ortho-Cilag Pharmaceuticals Ltd.

The Sub-Committee were informed that NIBSC were consulting with the Licensing Authority to prepare guidelines for the pre-clinical testing of new biological products. The Chairman asked for a paper to be presented to the Sub-Committee when the guidelines were prepared.

5.1.2 Arteparon Injection : CT 0481/0009 : Luitpold-Werk

5.1.3 Intron A : PL 0201/0063-8 : Kirby-Warrick Pharmaceuticals Ltd

Professor Jenkins declared a non-specific interest.

5.2 The recommendations of the Sub-Committee regarding these applications are given at Annex A.

6. Disclosure of Interests

Mr Hagger introduced this paper, which was discussed and noted.

7. Items for Information

The following items for information were noted:

Calendar of meetings for 1986

MAIL 44

S.I. 1403
S.1. 1539
S.I. 1540

8. Any Other Business

Screening for HTLV III

Dr Schild raised this matter, and after discussion the Sub-Committee requested that, with the agreement of the CSM, the following remark should be passed to the Licensing Authority:

'The Committee are anxious that individual donations for all blood products should be screened for HTLV III from the earliest possible date. Manufacturers should be requested to confirm that donations are being screened and to provide information about the nature of the screening tests used.'

9. Date and Time of Next Meeting

Wednesday 8th January 1986.

GRO-C

GRO-C

8.1.86