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 7 May 1986.

Present

Dr J W G Smith (Chairman)
Professor J E Banatvala
Professor J G Collee
Professor J Melling
Dr D P Thomas
Dr D A J Tyrrell
Dr G Schild
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
Mr J P Digings
Dr S Grieve
Mrs J A Hampton
Dr S Fawcett
Dr J Purves
Dr F Rotblat
Mr J Sloggem

Also Present

Dr D Bangham )
Ms A W Ford )
Mrs R Michael ) NIBSC
Dr R 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 Ms Ford from NIBSC, who was attending to advise members with regard to her paper "A proposal for the use of international units for the expression of potency in certain allergenic extracts".

1.3 The Chairman introduced and welcomed Dr Fawcett and Mr Sloggem who were attending their first meeting of the Sub-Committee.

2. Apologies for Absence

Apologies for absence had been received from Professor Jenkins, Professor Keen, Dr Lane, Professor McMichael, Professor Moxon and Dr Brinley-Morgan. Apologies had also been received from Dr Jenkins of the Secretariat.

3. Minutes of the Meeting held on 5 March 1986

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 Gamimune-N: PL 0055/0109: Miles Laboratories Ltd.

5.1.1 Mr Watt declared a non-specific interest

5.1.2 The Sub-Committee considered that the name Gamimune-N was not appropriate for this product.

5.2 Imunox Injection: PL 0076/0131: Ortho-Cilag Pharmaceuticals Ltd.

5.3 Lutrelef Injection: PL 3194/0025-6: Ferring Pharmaceuticals Ltd.

6. Manufacture of Blood Products from Plasma Derived from Unscreened Donors

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

6.1 All imported albumin preparations and the other products listed in this paper should be prepared from plasma individually tested for HBSAg and anti-HTLV-III. The Companies involved should be asked to apply for variations to their Product Licences to cover this point, as soon as possible.

6.2 Details of the method of testing of HBSAg and HTLV-III antibody should be supplied.

6.3 All preparations not subject to the batch release procedure should be required to comply with it.

6.4 BIOLOGICALS REMARK TO CSM

The attention of the Elstree and Edinburgh Fractionation Centres should be drawn to these recommendations.

7. A Proposal for the use of International Units (IU) for the Expression of Potency in Certain Allergenic Extracts.

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

7.1.1 The potency of the final formulations of allergens be expressed in International Units where calibrated international standards exist.

7.1.2 The potency and its method of measurement must be given on the label or the Data Sheet. Eg potency = 10,000 IU per ampoule by RAST inhibition.

7.1.3 For an interim period of possibly 5 years it is suggested that the potency of extracts should be expressed in both IU and the currently used units, to accustom the user to the internationally accepted new units.

7.1.4 The Data Sheet should make it clear that there is no fixed ratio between international standard units and the various empirical units in use at present.

7.2 The Sub-Committee expressed concern about the lack of international standards for formulations containing mixed allergens. Ms Ford agreed to consider whether an assay should be required for such applications, and to provide a paper for future consideration by the Sub-Committee.

8. Guidelines on the Pre-clinical Testing of Biological Products

The Sub-Committee considered this paper. They considered that there was a need for a document of this type and were in general in agreement with its contents. The following suggestions wre put forward:

8.1 It should be emphasized that guidelines are flexible and it would be of value to include examples illustrating where the guidelines may not be applicable.

8.2 Consideration should be given to providing a section on genetically engineered products.

8.3 The general introduction should include details of the problems specific to biological products.

8.4 It was suggested that allergens should not be included in the guidelines.

8.5 It was noted that this document does not include guidance on the conduct of clinical studies.

9. Any Other Business

None.

10. Date and Time of Next Meeting

Wednesday 2 July 1986, at 10.30 am.

GRO-C