

NOT FOR PUBLICATION

CSM/BSC/75/4th Meeting.

November

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICALS

Meeting to be held on Wednesday 12 November 1975 at 10.30am in
Room B03, Finsbury Square House, 33/37A Finsbury Square, London EC2A.

A G E N D A

1. Apologies for absence.
2. Confidentiality.
3. Minutes of the last meeting.
4. Matters arising from the minutes.
 1. Report on biological products considered at the last meeting.
(Paper CSM/BSC/75/10)
5. Consideration of applications.

Proplex Factor IX Complex (Human)	PL/ 0116/0049
Buminate - Human Albumin Fraction	PL/0116/0051
Buminate - Human Albumin Salt-Poor	PL/0116/0053
Factorate (Factor V111)	PL/0231/0038
Octobulin - Human Factor V111	PL/3070/0004
Sisomicin	CT/0010/0052-56
Symmetrel	PL/0001/0067
Factor X111 Concentrate	PL/0086/0047

6. Applications previously deferred.

Calcitonin - Sandoz	PL/0101/0095-96
Glucagon	PL/0542/0016

7. Integration of Viral Genomes (Paper CSM/BSC/75/9) Distributed 28.10.75
8. Any other business.
9. Date and time of next meeting.

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICALS

Minutes of the meeting held on Wednesday 12 November 1975.

PRESENT

Sir Eric Scowen (Chairman)
Dr D R Bangham
Professor J A Dudgeon
Professor D G Evans
Dr J W Lightbown
Dr G D W McKendrick
Dr W D'A Maycock
Dr T M Pollock
Dr D A J Tyrrell

Mr G E W Kenwood (Secretary)
Dr J A Holgate (Medical Assessor)

ALSO PRESENT

Dr R D Andrews
Mr J S Bird
Dr M Duncan
Mr A C Law
Dr A T B Moir
Mrs M Pratt
Mr W J W Price
Mr T R M Simon

1. APOLOGIES FOR ABSENCE

An apology was received from Professor O'Grady.

2. CONFIDENTIALITY

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

3. MINUTES OF THE MEETING HELD ON WEDNESDAY 10 SEPTEMBER 1975

The minutes were agreed and signed by the Chairman.

4. MATTERS ARISING FROM THE MINUTES

(a) Paper CSM/BSC/75/10 was presented showing the recommendations of the Sub-Committee on Toxicity, Clinical Trials and Therapeutic Efficacy and the decisions of the Main Committee on those biological products which had been considered at the last meeting of the Sub-Committee. Members were advised that the application in respect of Arvin (Ancrod) PL/0152/0099 had been referred to the last meeting of the TCF Sub-Committee but had been withdrawn from the agenda pending clarification of the indications for use.

(b) Professor Evans reported that the Immunological Products Advisory Committee had considered the control procedures in respect of Human Diploid Cell Rabies Vaccine (PL/0012/0106) and Tick-borne Encephalitis Virus Vaccine (PL/0487/0001) and had forwarded their views to the Secretariat for discussion with the manufacturers concerned.

5. CONSIDERATION OF APPLICATIONS

Applications for six product licences and one clinical trial certificate were considered. The preparations concerned and the Sub-Committee's recommendations are set out in Appendix A to these minutes. The application in respect of Symmetrel (PL/0001/0067) was withdrawn from the agenda, since the company had decided to omit the indications of influenza in children.

6. APPLICATIONS PREVIOUSLY DEFERRED

Two applications that had been deferred for further information at the meeting of 12 March 1975 were considered. The preparations concerned and the Sub-Committee's recommendations are included in Appendix A to these minutes.

7. INTEGRATION OF VIRAL GENOMES (Paper GEM/BSC/75/9)

This paper drew the attention of members to an article by V M Zhdanov that had appeared in 'Nature' on 7 August 1975 suggesting that certain autoimmune diseases were manifestations of viral information integrated into host cells through the co-operation of latent cucornaviruses.

A comment by Dr Schild, together with several other references, was tabled.

Members agreed to consider Dr Schild's comment individually for discussion at a later date.

8. ANY OTHER BUSINESS

There was no other business.

9. DATE AND TIME OF NEXT MEETING

The next meeting would be held on Wednesday 7 January 1976 at 10.30am.

GRO-C

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