

COMMERCIAL IN CONFIDENCE

CSM/89/8th Meeting

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

Minutes of the Meeting held on Thursday 28 September 1989 at 10.00 am in the
19th Floor Conference Room Market Towers.

Present

Professor A W Asscher (Chairman)
Professor S S Bleehen
Professor T J Booth
Professor A M Breckenridge
Professor J G Collee
Professor P H Elworthy
Professor A T Florence
Professor H S Jacobs +
Dr W A Jerrett
Professor D H Lawson
Professor A E M McLean
Dr S Montgomery
Dr B L Pentecost
Professor M D Rawlins

Dr D Jefferys (Medical Assessor)
Dr S Wood (Medical Assessor, Adverse
Reactions)
Dr J Purves (Pharmaceutical Assessor)
Mr J Bewley (Secretary)
Mr L R Whitbread (Assistant Secretary)
Dr G Bem
Dr E Brown
Dr B Davis
Dr J Dunne
Dr K Fowler
Dr S Galton
Dr J Hilton
Dr M James
Dr R Lee
Dr A Nath
Dr J A Nicholson
Dr J Raine
Dr J Ritchie
Dr F Rotblat
Dr R Shah
Dr J Sims
Mr H Stemplewski

+ am only

Also present

Dr K Jones
Mr D Hagger
Mr D James
Mr C Freedman
Dr D Looi
Mrs D Leahey

Observer

Monsieur Jean Bacou
(French Ministry of Health)

1. Apologies and Announcements

- 1.1 The Chairman reminded the Committee that the papers and proceedings were confidential and should not be disclosed.
- 1.2 Apologies had been received from Professors McGee, Nuki, Vessey, Meadow, Langman, Dr Mayne and Mr Loeffler and from Professor Jacobs for the afternoon session.
- 1.3 The Chairman welcomed Dr Simon Galton (SSO) who had recently joined the Secretariat.
- 1.4 The Chairman welcomed Monsieur Jean Bacou of the French Ministry of Health and Clive Freedman of the legal section who were attending as observers.
- 1.5 The Chairman informed the Committee that he had received a letter from - in response to a Chairman's letter sent in July - in which the Company apologised for the state of their application.
- 1.6 The Chairman informed the Committee that this was David James last meeting as legal advisor to the CSM and that he would be transferring to another Department: the Committee thanked David James for his work for the Committee.
- 1.7 The Chairman drew attention to an invitation to members from the PAGB, to a joint DOH/PAGB symposium to be held on 30 November.

2. Minutes of the Meeting held on 27 and 28 July 1989

2.1 The minutes were agreed and signed by the Chairman as a true record of the meeting.

3. Matters Arising

None.

4. Applications

4.1

Dr Montgomery declared a non-personal non-specific interest but this did not debar him from taking part in the decision.

4.2

The Committee noted Tabled Paper V.

4.3 The Committee's advice and reasons for that advice, on these and all other applications considered, are given at Annex A.

5. Written Representations

5.1 The Committee considered written representations on the following products:-

5.1.1

5.1.2

5.1.3

5.2 The Committee's advice and reasons for that advice are given at Annex B.

6. Hearings

6.1

The Committee noted Tabled Paper I.

6.2 The Committee's advice and reasons for that advice are given at Annex C.

7. Chairmanship of the Sub-Committees of CSM, ARGOS and the Working Party on Bovine Spongiform Encephalopathy

7.1 The Committee noted the paper and endorsed the recommendations that

- a. Professor M D Rawlins should continue to chair SEAR Sub-Committee.
- b. Professor A T Florence should chair the CPS Sub-Committee.
- c. Dr D A J Tyrrell should chair the Biologicals Sub-Committee.
- d. Professor A M Breckenridge should continue to chair ARGOS.
- e. Professor J G Collee should continue to chair the Bovine Spongiform Encephalopathy Working Party.

7.2 The Chairman and members of the Committee paid tribute to Professor P H Elworthy who had chaired the CPS Sub-Committee for the last ten years and to Professor J G Collee who had chaired the Biologicals Sub-Committee for the last three years.

8. Data Sheet Statement on Te

The Committee noted the paper and concluded that the present data sheet pregnancy warning was adequate.

13. Bovine Spongiform Encephalopathy

The Committee noted Professor Collee's oral report and Tabled Paper III (attached at Annex D) and endorsed the recommendations of the Working Party.

14. Mumps, Meningitis Associated with MMR Vaccine

14.1 The Committee noted Professor Collee's oral report of the Biologicals Sub-Committee meeting and concluded that they were re-assured as to the safety of the vaccines.

14.2 The Committee noted that there had been ten cases for mumps meningitis following meningitis reactions of MMR vaccination of which three were causally related to the MMR vaccine, set against 2.5 million doses in the UK.

14.3 The Committee noted that the ARVI Sub-Committee would continue to monitor the position and that Professor Collee would report to the Committee as and when necessary.

15.

15.1 Professor McLean declared a personal, specific interest and took no part in the discussions.

15.2 The Committee noted the paper and re-affirmed their provisional conclusion to advise the licensing authority not to renew the product licence.

15.3 The Committee's findings advice and reasons for that advice is at Annex E.

16.

19. CSM Annual Report 1988

The Committee noted this item.

20. Tabled Paper II

The Committee noted this information paper.

21. Mianserin

The Committee noted Mr James' oral report of the hearing before the court of Appeal and noted that judgement had been reserved.

22. Tabled Paper VIII

The Committee noted this information paper.

23. Proposed Amendment of the GSL Order 1984 - Tabled Paper VI

The Committee noted this information paper.

24. Secretary's Progress Report

The Committee praised coding staff on the low numbers of Yellow Cards outstanding.

25. Any other business

None.

26. Date and time of next meeting

Thursday 26 October 1989 at 10 am.

Alf Asscher

26/10/89