

COMMERCIAL IN CONFIDENCE

CSM/88/8th Meeting

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

Minutes of the Meeting held on Thursday 22 and 23 September 1988 in the 19th Floor Conference Room, Market Towers.

Present

Professor A W Asscher (Chairman)
Professor S S Bleehen
Professor T G Booth
Professor A M Breckenridge +
Professor P H Elworthy
Professor A T Florence
Professor H S Jacobs *
Dr W A Jerrett+
Professor M J S Langman +
Mr F E Loeffler Ø
Dr Elizabeth Mayne
Professor A McLean Ø
Professor G Nuki +
Dr S A Montgomery
Dr B L Pentecost +
Professor M D Rawlins

Ø 22 September am only
+ 22 September only
* 23 September only

Guest Members

Dr A McKay) - 22 September only
Dr G Schild)

Dr D Jefferys (Medical Assessor)
Dr J Purves (Pharmaceutical Assessor)
Miss A Simkins (Secretary)
Mr L R Whitbread (Assistant Secretary)
Dr J L Bem
Dr E G Brown +
Dr G Burton
Dr S Fawcett +
Dr K Fowler
Dr J Hilton
Dr R Lee
Dr M McGovern
Dr J A Nicholson +
Dr J C Ritchie
Dr F Rotblat
Dr A W M Scott
Mrs G Silvester +
Mr R Smith +
Dr H Stemplewski

Also Present

Mr D James
Mr D O Hagger +
Miss M Nash +
Dr A Watt

OBSERVER on 23 September

Dr Ture Sjoblom of the
Swedish Regulatory Authority

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 Lawson, McGee, Collee, Vessey, and Meadow for the 22nd and 23rd; from Professor Jacobs for the 22nd; and from Dr Jerrett, Professor Breckenridge, Professor Langman, Dr Pentecost and Dr Schild for the 23rd.
- 1.3 The Chairman welcomed Professor Stanley Bleehen, - Professor of Dermatology at Sheffield University, as a new member of the Committee.
- 1.4 The Chairman welcomed Dr A McKay and Dr G Schild as members for the day: Dr Schild was presenting the recommendations of the Biological Sub-Committee in the absence of Professor Collee.
- 1.5 The Chairman congratulated Dr Sue Wood, Medical Assessor in absentia on her appointment to replace Dr William Jenkins as Medical Assessor (Adverse Reactions).
- 1.6 The Chairman welcomed Dr Henry Stemplewski (SSO) who had recently joined the secretariat and thanked Dr June Raine for her work for the Committee and wished her well in her new post with the CDSM.
- 1.7 The Chairman welcomed Dr Ture Sjoblom of the Swedish Regulatory Authority who was attending as an observer on 23 September.
- 1.8 The Chairman congratulated Mr Whitbread and his team on coping valiantly with the effects of the postal strike.
- 1.9 The Chairman informed the Committee that he had received a letter of thanks from Mr Newton for CSM Annual Report for 1987.
- 1.10 The Chairman informed the Committee that he had had a meeting with British Medical TV who had offered to help CSM get urgent messages to doctors. After further discussion, the Committee agreed in principle the offer from British Medical TV, subject to resources being available on particular occasions.
- 1.11 The Chairman on behalf of the Committee wished Professor Jacobs well for his sabbatical.

2. Minutes of the Meeting held on the 28 July 1988

The minutes were agreed and signed by the Chairman as a true record of the meeting, after minor amendments had been made.

4. Applications

4.1 The Committee considered the applications listed and their advice is given at Annex A.

4.2

Professor Rawlins had not chaired SEAR because of a non-personal non-specific interest and took no part in the decision; Professor Breckenridge presented the SEAR recommendations.

4.3

Professor Asscher indicated that for personal reasons he would prefer to leave the chair; Professor Rawlins chaired the discussion on this item.

4.4

Professor Langman declared a personal non-specific interest and took no part in the decision.

4.5

Professor Florence and Dr Montgomery declared personal non-specific interests and took no part in the decision. The Committee noted tabled paper 5.

5. Written Representations

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

5.1.1

5.1.2

5.1.3

Professor Rawlins had not chaired SEAR because of a non-personal non-specific interest and took no part in the decision: Professor Breckenridge presented the SEAR recommendations.

5.1.4

Professor Florence declared a personal non-specific interest and took no part in the decision. The Committee noted tabled paper 4.

5.1.5

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

6. Hearings

6.1 The Committee considered written representations submitted in preparation for the following Hearings:-

6.1.1

The Committee noted tabled paper 7

6.1.2

Dr Montgomery declared a specific interest and left the Committee room. Professor Florence declared a personal non-specific interest and took no part in the decision.

The Committee noted tabled paper 8

6.1.3

6.1.4

6.1.5

The Committee noted tabled paper 6

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

7. The Pre-Clinical Biologicals Safety Testing of Medical Products derived from Biotechnology

The Committee noted this paper: Dr Schild invited members to send him any detailed comments.

8. Inadvertant use of Pregnancy

The Committee noted the paper on reports of congenital malformations in association with use of diethylpropin in early pregnancy. Professor Breckenridge reported that further review of the study by Dr Hill et al of congenital malformations and medicines had not resolved the uncertainties about diethylpropin or the extent of its use in pregnancy. The Committee endorsed the recommendations of SEAR and ARGOS that the Secretariat should negotiate with the licence holders on amendments to data sheets and for teratology studies in two animal species. Developments, would be reported in the Secretary's progress report.

9. Facts

The Committee noted this paper.

10.

11.

12. M

Professors Langman and Nuki declared personal non-specific interests and took no part in the decision.

The Committee considered the Company's submission and the Biologicals Sub-Committee recommendation.

The Committee were reassured as to the safety of the albumin used in this product and advised that the variation from Wellcome to market the MSD product should be approved.

13. Parliamentary Questions

The Committee noted with pleasure the PQ reporting the CSMS activities to promote ADR reporting.

14. _____

Professor Breckenridge declared a personal non-specific interest and took no part in the decision.

The Committee considered the Company's submission and confirmed their original request for additional mutagenicity testing.

15. Membership of the SEAR Sub-Committee - Tabled Paper 1

The Committee agreed to appoint Professor Hull as a member of the SEAR Sub-Committee.

16. Revised Fees for Chairman and Members of Committees - Tabled Paper 2

The Committee noted this information paper.

17. 1992 European International Market - Tabled Paper 9

The Committee noted this information paper.

18. Professor Stanley Bleehen - Tabled Paper 10

The Committee noted this information paper.

19. Current Problems 23

The Committee noted this item.

20. MAIL 55 and 56

The Committee noted these items.

21. Medical Assessor's/Secretary's Oral Report

21.1 Dr Jefferys informed the Committee, that so far this year 51 new active substances and 31 Hearings/written representations had been brought before the Committee.

21.2 Miss Simkins drew the Committees attention to the note that DHSS Research Management Division had said they were unable to fund Professor Vessey's research application on NSAIDs.

22. Any Other Business

None.

23. Date and Time of next Meeting

~~Thursday 20 October 1988 at 10 am.~~

Autscab

29/10/88