

COMMERCIAL IN CONFIDENCE
NOT FOR PUBLICATION
COMMITTEE ON SAFETY OF MEDICINES

CSM/89/3rd Meeting

Minutes of the Meeting held on Thursday 30 March 1989 in the 19th Floor
Conference Room Market Towers.

Present

Professor A W Asscher (Chairman)	Dr D Jefferys (Medical Assessor)
Professor S S Bleehen	Dr S Wood (Medical Assessor, Adverse Reactions)
Professor A M Breckenridge	Dr J Purves (Pharmaceutical Assessor)
Professor J G Collee	Mr J Bewley (Secretary)
Professor P H Elworthy	Mr L R Whitbread (Assistant Secretary)
Professor A T Florence	Dr K Fowler
Dr W A Jerrett	Dr J Hilton
Professor D H Lawson	Dr M McGovern
Mr F E Loeffler	Dr J A Nicholson
Professor J O D McGee	Dr A Nath
Professor A E M McLean	Dr J Ritchie
Professor S R Meadow	Dr L Robinson
Dr S A Montgomery	Dr F Rotblat
Professor G Nuki	Dr A W M Scott
Dr B Pentecost	Dr H Stemplewski
Professor M D Rawlins	Dr K Winship
Professor M P Vessey	

Also present

Mr D James
Mr D Hagger
Dr B Matthews
Mr P Adams
Dr A Watt (SHHD)

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 Jacobs, Langman and Booth and Dr Mayne.

1.3 The Chairman informed members that as from 10 April the Director of the Medicines Control Agency would be Dr Keith Jones lately Executive Director of Merck, Sharp and Dohme Inc (USA) responsible for Clinical Pharmacology.

1.4 The Chairman announced that Dr Gerald Jones would be leaving Medicines Division and on behalf of the Committee thanked him for his support over the years and wished him success in his new post.

1.5 The Chairman on behalf of the Committee sent best wishes to Dr R Lee for a speedy recovery.

1.6 The Chairman on behalf of the Committee thanked Dr Lena Robinson for her contributions to the work of the Committee and wished her success in her new job as a microbiologist in Food Safety.

1.7 The Chairman informed the Committee that in May there would be a one day meeting on the 25th.

1.8 The Chairman advised the Committee of a successful meeting with ABPI on 29 March.

1.9 The Chairman informed the Committee that Dr Robert Mahler (the Editor of Journal of the Royal College of Physicians) had suggested that a rapporteur should be appointed for the seminar on Drug Toxicity on 19 October 1989. Members agreed to recommend the appointment of Dr Sandy Scott.

2. Minutes of the Meeting held on 23 February 1989

2.1 The minutes were agreed and signed by the Chairman as a true record of the meeting subject to the following amendment being made.

2.2 At 3.2.1 "excepted" should read "accepted".

10. Evans-Cumliffe Recommendations relevant to CSM and Sub-Committees

10.1 The Committee noted the paper and Mr Wilson's oral presentation.

10.2 Professor Breckenridge announced that in 1988, a record number 19,000 yellow cards had been received.

10.3 Mr Wilson said that a paper on the release of yellow card data to outside bodies would be put to the Committee as soon as legal advice had been received.

11. SKF Judgement

The Committee noted this paper.

12. Code of Practice on Declaration of Interest

12.1 Mr Wilson said that the revised Code had been endorsed by the Secretary of State, who favoured openness in matters of this kind and would robustly defend members.

12.2 Mr Bewley said that he was prepared to see draft declarations if members found that completion was particularly difficult. He would take a note of any problems of interpretation which might arise: it might be possible to go back to Ministers at some future stage with proposals for further revision.

12.3 Members pointed out that it was essential to keep abreast of commercial developments and difficult to do this without involvement. There was concern about media interest and about some definitions, eg "Competitor".

Members hoped that Ministers would express their complete confidence in the membership whenever necessary.

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13.

The Committee noted this item and said that the issue of companies withdrawing from Hearings at short notice should be raised with the ABPI at its meeting with CSM on 29 March 1989.

14. (TABLED PAPER III) AND CURRENT PROBLEMS 25 (TABLED PAPER V)

14.1 The Committee noted Tabled Paper III and Mr Nilsson's oral presentation.

14.2 Mr Nilsson thanked the Committee and in particular Professors Asscher and Rawlins for their assistance in preparing the defence.

14.3 The Committee noted the Current Problems article (Tabled Paper V) which had been prepared for publication.

15. Medical Assessor's and Secretary's Written Report.

15.1 The Committee noted the Secretary's progress report.

16. Any other Business

Dr Rotblat informed the Committee that in May there would be a full day meeting on the Thursday and that there might be a hearing on the Wednesday afternoon.

17. Date and time of next meeting

Thursday 30 March 1989 at 10am.

Walter Asscher
30/3/89

3. Matters Arising

3.1 Item 1.5 - CSM annual dinner

The Chairman informed the Committee that the college would not be available for the CSM annual dinner to be held on 18 October 1989, and was now planned for the Reform Club. Members were asked to complete the availability forms.

3.2 Item 8 Bovine Spongiform Encephalopathy

Dr Jefferys reported that the press conference (held by Ministers on 27 February) had been successful. Mr Kenneth Clarke had referred to the advice of the CSM in his statement. Members noted this.

4. Applications

4.1

The Committee noted Tabled Paper I. Professor Meadow declared a personal non-specific interest and took no part in the decision.

4.2

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

4.3

Professors Bleeheh and McGee declared personal non specific interests and took no part in the decision. Professor McGee left the Committee room.

4.4

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

4.5

Professor McLean declared a non-personal non-specific interest, but this did not debarr him from taking part in the decision.

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89/03.30/4.5

4.6

The Committee noted tabled paper III.

4.7 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 a written representation on the following product:-

5.1.1

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

6. Pre-Hearings

6.1 The Committee considered written representations in preparation for the following hearings

6.1.1

6.1.2

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

7. Hearings

7.1 The Committee considered representations in preparation for the following hearing:-

7.1.1

The Committee noted Tabled Paper V.

7.2 The Committee's advice and reasons for that advice are given at Annex D.

8.

9.

The Committee noted the paper and following a detailed discussion the Committee endorsed the recommendations in full as at Annex E. Dr Matthews to take necessary action.

10. Liquid Paraffin

10.1 The Committee considered the draft recommendations and endorsed 1.2, 1.3, 1.4, 1.6 and 1.7 as at Annex F.

10.2 The Committee did not feel that there was a risk for oral products containing liquid paraffin as an excipient.

10.3 The Committee also commented that the Sub-Committee on Chemistry, Pharmacy and Standards should review the quality aspects of Liquid Paraffin BP.

10.4 The Committee also commented that these recommendations should be brought to the attention of the Committee on the Review of Medicines.

11. The Development of Resistance

The Committee noted the paper and agreed that no further regulatory action was necessary.

12. - ADR Monitoring/Data Sheet Amendments

The Committee noted the paper and endorsed the recommendations for changes to the Data Sheet.

13. Research Studies Involving Patients with ADRs Reported in Yellow Cards.

13.1 The Committee noted the paper and endorsed the modified guidelines as at Annex G.

13.2 The Committee also endorsed the SEAR recommendation that wide use of yellow card data for research purposes was not appropriate at the moment.

14. in Pregnancy - Company's response

14.1 The Committee noted the paper and endorsed the recommendation for Data Sheet changes and agreed that no further action was necessary.

14.2 The Committee also commented that it wished to be kept informed of further developments.

15. Draft CSM Annual Report for 1988

The Chairman welcomed the style and content of the report. Members were asked to submit written comments to the Secretary by 7 April 1989.

16. Draft Current Problems Articles

16.1

The Committee noted Tabled Paper IV and endorsed the article with amendments.

16.2

The Committee endorsed the article with amendments.

16.3

The Committee endorsed the article with amendments.

17. _____

The Committee noted the information paper.

18. Medical Assessor's and Secretary's Report

18.1 Dr Jefferys paid tribute to the work of Dr Gerald Jones both on the CSM and in Europe and said that over the last 10 years Dr Jones had made a major contribution to European Drug Regulation.

18.2 Mr Bewley advised that a paper on confidentiality would be put to the Committee in May.

19. Any other Business

None.

20. Date and Time of Next Meeting

Thursday 27 April 1989 at 10 am.

Handwritten signature: A. Assch

*27 April 1989
Aust.*