

COMMERCIAL IN CONFIDENCE

CSM 88/10th Meeting

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

Minutes of the Meeting held on Thursday 17 November 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 J G Collee
Professor P H Elworthy
Dr W A Jerrett
Professor M J S Langman
Professor D H Lawson
Mr F E Loeffler
Dr Elizabeth Mayne
Professor A E M McLean
Professor J O D McGee⁺
Professor S R Meadow
Professor G Nuki
Dr B L Pentecost
Professor M D Rawlins
Professor M P Vessey

Dr D Jefferys (Medical Assessor)
Dr S Wood (Medical Assessor Adverse Reactions)
Mr A G Stewart (Pharmaceutical Assessor)
Miss A Simkins (Secretary)
Mr L R Whitbread (Assistant Secretary)
Dr J L Bem
Dr E G Brown
Dr G Burton
Dr K Fowler
Mrs J Hampton
Dr J Hilton
Dr D Looi
Dr R Lee
Dr M McGovern
Dr J A Nicholson
Dr A Nath
Miss S Norton
Dr F Rotblat
Mrs G Silvester
Dr A W M Scott
Dr H Stemplewski

⁺ am only

Also Present

Dr G Jones
Mr C Wilson
Mr P Nilsson
Mrs S Armstrong
Mrs J Alderman

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 and Florence and Drs Montgomery and Watt.

1.3 The Chairman welcomed Mr P Nilsson who would be advising the Committee on legal matters in Mr James' absence and Mr A G Stewart who was acting as Pharmaceutical Assessor in Dr Purves absence.

1.4 The Chairman on behalf of the Committee thanked Dr G Burton for his contributions to the work of the Committee, in particular for seeing through the mianserin episode and wished him well on his appointment with Upjohn. He also thanked Mrs J Hampton (pharmaceutical assessor) for her contributions to the work of the Committee and wished her well on her appointment with Merrell Dow.

88/11.17/9.1

1.5 The Chairman referred to the enjoyable visit to NIBSC on 11 November, which he and other members of the Committee and Medicines Commission members had made.

1.6 The Chairman referred to the letter of apology he had received from Baxter Health Care with regard to the Gammagard application seen by the Committee at its September meeting: the file would be used by the company for training purposes.

2. Minutes of the Meeting held on 20 October 1988

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

3. Matters Arising

None.

4. Applications

4.1 The Committee's advice and reasons for that advice are given in Annex A.

4.2

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

4.3

Professor Breckenridge declared a personal non-specific interest and took no part in the discussion except in relation to general issues of medical practice.

4.4

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

4.5

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

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

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

6. Hearings

6.1 The Committee considered a written representation on the following hearing.

6.1.1

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

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

7. Bovine Spongiform Encephalopathy

7.1 The Committee discussed the paper and endorsed the recommendations of the SEAR and Biologicals Sub-Committees.

7.2 The Committee also noted the letter from Sir Richard Southwood (Tabled Paper 4). The Committee agreed that the Chairman should reply to Sir Richard Southwood detailing the view of the Committee and referring to preliminary consideration of this matter by CRM and CDSM.

8. Adroit Computer System - Progress Report

The Committee noted this paper with interest.

9. CSM Video Action by MSD

The Committee noted the letter sent to the CSM from MSD's Solicitors in which they indicated that the matter was now regarded as closed.

10. 1 Tabled Paper 1

The Committee noted the advice of the Medicines Commission.

11. Tabled Papers 2 and 6

The Committee took note of the tabled papers and of advice from Mr Nilsson, Mr Wilson, Dr Jones and Dr Wood. The Committee did not accept the allegations against them in the anonymous Lancet editorial of 5 November, and wished to publish a short letter of refutation which referred to the legal action against the Committee and did not comment on issues relevant to that action. The letter must be cleared legally.

12. Current Problems - I, Rash and Pulmonary Eosinophilia -
Tabled Paper 3

The Committee endorsed the ARGOS and SEAR recommendations and agreed the draft articles.

13. Secretary's Progress Report

Miss Simkins drew attention to the note in the written report that 670 adverse reactions reports were awaiting coding and said that this backlog had now been reduced to about 100.

14. Any Other Business

None.

15. Date and Time of Next Meeting

Thursday 15 December 1988 at 10 am.

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15/12/88