CSM/Mins/85/10

GRO-C: A Goldberg

19/12/85

CSM/85/10th Meeting

NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

Minutes of the meeting held on Thursday 21 November 1985, in the 19th Floor Conference Suite, Market Towers.

Present

Professor Sir Abraham Goldberg (Chairman)
Professor A W Asscher
Professor A M Breckenridge
Dr C M Castleden
Mr W M Darling
Professor J W Dundee
Professor P H Elworthy
Professor A T Florence
Professor D G Grahame-Smith
Professor M W Greaves
Dr J M Holt
Professor D Hull
Professor M D Rawlins
Dr J W G Smith
Professor M P Vessey
Dr D M B Ward
Professor H K Weinbren

Dr A J Isaacs (Medical Assessor)
Dr J Purves (Pharmaceutical Assessor)
Mr J Grimshaw (Secretary)
Mr K L Fowler (Assistant Secretary)
Dr P N Adams
Mr A C Cartwright
Miss R Coulson
Mr J Digings
Dr M E Duncan
Dr S Fawcett
Dr L K Fowler
Dr A M Glen-Bott
Dr S Grieve
Dr W Jenkins
Dr G Jones
Dr R Littlewood
Dr R Mann
Mr M Pinel
Dr J Ritchie
Dr F Rotblat
Dr D I Slovick
Mr A Stewart
Dr K Winship
Dr S M Wood

Also Present

Dr G Burton
Mr D Dunleavy
Mr D Hagger
Mr N Hale
Dr D Jeffreys
Dr A T B Moir
Mr P Nilsson
Dr H Pickles
Mrs L Smulders

1. APOLOGIES AND ANNOUNCEMENTS

1.1. The Chairman reminded members that the papers and proceedings are confidential and should not be disclosed.

1.2. Apologies had been received from Professor Jacobs and Dr Pentecost.

1.3. The Chairman informed members that Dr Isaacs was attending his first meeting as Medical Assessor to the Committee, and Dr Mann was attending as PMO for the Adverse Reactions section. The Chairman thanked Dr Mann for his work as Medical Assessor, and wished them both success in their new posts.

1.4. The Chairman introduced and welcomed Dr Rotblat who was attending her first meeting as a member of the Secretariat.

2. MINUTES OF THE MEETING HELD ON THURSDAY 24 OCTOBER 1985

2.1. The following amendments were made to the minutes:

2.1.1. Page 13 - ULTRAVIST: in item 1 the words "unilateral or bilateral" were deleted.

2.1.2. Page 29 - HEARING FOR GAMMA VINYL GABA: in item 5.2. the first paragraph was amended to read:

"The Committee would be reassured, by the additional written data and the Company's presentation, that the possible therapeutic advantage of the drug might outweigh the potential risk to man provided that:"

2.2. Following these amendments, the Chairman and Professor Grahame-Smith (acting Chairman of the October meeting) signed the minutes as a true record of the meeting.

3. MATTERS ARISING FROM THE MINUTES

Professor Hull said he wanted it minuted that he had not been able to read and assimilate all the papers sent to him for the meeting. He thought that members were expected to undertake far too much reading for meetings. Other members expressed concern that, whereas the Opren case showed them to be potentially liable for their advice, it was in practice impossible for them to be fully informed about all aspects of subjects on which they were asked to give advice.

Dr Castleden suggested that business might be organised as for CRM, so that all members were not asked to consider all papers. Professor Grahame-Smith said he did not think that a sub-group approach would work satisfactorily.
Professor Rawlins said that the Committee had adopted a multi-disciplinary approach to its work, with members taking each others' advice. He thought this approach provided a satisfactory basis for the Committee's work.

Professor Grahame-Smith said that an important problem facing the Committee was the tendency for companies to submit premature applications which required a great deal of work by the Secretariat and by members, particularly in checking rejection points. Professor Greaves said that he thought that the standard of applications would improve if companies were given a clearer idea of what data should be provided, for example on skin preparations.

The Secretariat were asked to consider the points made at the meeting and the working arrangements of the Committee generally, in the light of the Opren case, and to report back to the Committee.

4. CONSIDERATION OF APPLICATIONS

The Committee considered the applications listed, and their advice is given in Annex A.

4.1. Mobiflex Tablets 10 mg and 20 mg: PL 0031/0199-200: Roche Products

The Committee asked the Secretariat to consider whether there should be a standard requirement, in relation to applications to license NSAIDs, that phototoxicity testing should be carried out. It was agreed that a paper should be prepared for consideration by ARGOS, SEAR and CSM.

4.2. Alfentanil Injection: CT 0242/0126: Janssen Pharmaceuticals

4.2.1. Professor Grahame-Smith declared a specific interest and took no part in the consideration of this application.

4.2.2. Professor Rawlins declared a non-specific interest.

4.3. Nubain: PL 4534/0003: Du Pont

Professor Dundee declared a non-specific interest.

5. WRITTEN REPRESENTATIONS

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

5.1.1. Fluoxetine Capsules: PL 0006/0195-8: Lilly Industries

Professor Elworthy declared a specific interest and took no part in the consideration of this written representation.

5.1.2. Azactam Injection: PL 0034/0250-6: E R Squibb and Sons

Professor Asscher declared a specific interest and took no part in the consideration of this written representation.

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

6. HEARING

6.1. The Committee held a Hearing on the following product:

Buspar Tablets: PL 0125/0162-3: Bristol Myers

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

7. CNS REACTIONS TO XYLOMETAZOLINE AND OXYMETAZOLINE IN YOUNG CHILDREN

This paper was deferred for consideration at a later meeting.

8. SCREENING FOR HTLV III

8.1. The Committee considered this paper together with tabled paper 3, a letter from Dr Schild of NIBSC.

8.2. The Committee endorsed the recommendation of the Biologicals Sub-Committee that the following remark should be passed to the Licensing Authority:

'The Committee are anxious that individual donations for all blood products should be screened for HTLV III from the earliest possible date. Manufacturers should be requested to confirm that donations are being screened and to provide information about the nature of the screening tests used.'

8.3. In discussion, it was also suggested that the Licensing Authority should consider the question of unlicensed blood products prepared in the UK under Crown privilege.

9. DRAFT 'CURRENT PROBLEMS' ARTICLE:

The Data Protection Act and Yellow Card Reports

Subject to some amendments, the article was approved for publication.

10. OPREN (tabled paper 1)

The Committee considered this paper and, after discussion, agreed with the proposal that the Secretary (or Assistant Secretary) should be empowered, on behalf of the CSM, to issue instructions to the Treasury Solicitor on the basis set out in the paper.

11. CSM UPDATES

Dr Mann reported that articles for publication in the 'CSM Update' series had been agreed up to February 1986.

12. DISCLOSURE OF INTERESTS (tabled paper 2)

The Committee noted this paper. Mr Hagger thanked members of the Committee, and its Sub-Committees, for submitting their views and informed them that a redrafted paper would be presented to the Committee in due course.

13. SECRETARY/MEDICAL ASSESSOR'S ORAL REPORT

Dr Isaacs informed members that Dr Wood was moving to work on the Adverse Reactions section. He thanked her for her work on Hearings and Written Representations, which would now be taken over by other members of the Secretariat.

14. ANY OTHER BUSINESS

Members were informed that the January meeting would be a one-day meeting.

15. DATE AND TIME OF NEXT MEETING

Thursday 19th December 1985 at 10.30 am.