CSM/Mins/83

GRO-C: Mr Burrage

GRO-C

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

CSM/83/7th Meeting

Minutes of the meeting held on Thursday 21st July 1983 and Friday 22nd July 1983

Present

Professor Sir Abraham Goldberg (Chairman)
Professor W I Cranston
Professor H K Weinbren
Professor D G Grahame-Smith*
Professor A E A Read
Professor J Dundee
Dr F Fish
Professor R Girdwood*
Professor B M Hibbard*
Professor F A Jenner
Dr M Richards
Professor M D Rawlins
Professor A M Breckenridge*
Dr J Smith
Professor P Elworthy*
Mr W Darling

(* Thursday only)

Dr G Jones (Medical Assessor)
Dr J Calderwood (Pharm Assessor)
Miss Z Spencer (Secretary)
Mr J Griffiths
Mr H Morgan
Mr T Kirkley
Dr A Nath
Dr S Grieve
Dr S Fawcett
Dr C Twomey
Mr A C Cartwright
Dr J C P Weber
Dr R Penn
Dr M Glen-Bott
Dr S Vellucci
Dr L Hill
Dr K Winship
Dr R D Mann
Dr C Speirs
Miss H Mallett
Dr M Glen-Bott

Also Present

Mr N M Hale
Dr J P Griffin
Mr P Allen
Mr P Morris
Mr A G Stewart
Dr A T B Moir

GRO-C

22 Sept. 1983

1. APOLOGIES AND ANNOUNCEMENTS

1.1 The Chairman repeated his usual reminder that the papers and proceedings were confidential and should not be disclosed.

1.2 Apologies were received from Professor Vessey, Dr Holt and Professor Hull for the 21 and 22 July and from Professor Grahame-Smith, Professor Girdwood, Professor Elworthy, Professor Hibbard and Professor Breckenridge for the 22 July.

1.3 The Chairman introduced and welcomed Dr Soliman and Dr El Lawy, from the Egyptian Health Authority, who attended the Committee on 22 July.

2. MINUTES OF THE MEETING HELD ON 16 JUNE 1983

The Chairman signed the minutes as a true record of the meeting.

3. MATTERS ARISING FROM THE MINUTES

The Chairman informed members that papers on Etomidate and Osmosin were before them at this meeting.

4. TABLED PAPER 3 RENEWAL OF PL 0001/0080: ANTURAN 200 mg (SULPHINPYRAZONE): CIBA GEIGY

4.1 The Committee considered a proposal by the Licensing Authority to renew the above product licence otherwise than in accordance with the application, i.e. only for the indication relating to gout.

4.2 The Committee considered that there was inadequate evidence of safety and efficacy for the indication of cardiac mortality following myocardial infarction. Since the product licence was granted the data had been reanalysed suggesting that the risk benefit ratio was not in favour of the drug. There was concern regarding the safety of Sulphinpyrazone in patients with recent myocardial infarction because of adverse effects on renal function.

4.3 The Committee agreed with the Licensing Authority proposal. Because the product licence would stay in force until the renewal application was determined, the Committee decided that it would determine its advice to the Licensing Authority in October and that the company should be offered the opportunity of appearing before the Committee at a hearing at the October meeting.

5. TABLED PAPER 4 SUMMARY OF MAIN POINTS FROM A CONSIDERATION OF AIDS AND LICENCE BLOOD PRODUCTS BY BIOLOGICALS SUB COMMITTEE 13 JULY 1983

5.1 Dr Smith spoke to this paper and reported to the Committee on the above discussion.

5.2 The Committee endorsed the recommendations of the Biologicals sub-committee.