

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

**MINUTES OF A MEETING HELD ON THURSDAY 23rd NOVEMBER 2000 AT 10.00 a.m.
IN THE CONFERENCE ROOM ON THE 19th FLOOR AT MARKET TOWERS**

Committee Members:

Present

Professor A M Breckenridge (Chairman)
Professor J C Petrie (Co-Vice Chairman)
Professor I V D Weller (Co-Vice Chairman)
Ms H Barnett
Professor J Caldwell
Dr R T Calvert
Professor J H Darbyshire
Professor H J Dargie
Professor G W Duff
Dr B K Evans
Professor E C Gordon-Smith
Professor M J Kendall
Professor J M Midgley
Dr H Scarffe
Professor T Stephenson
Dr R J Taylor
Dr F Williams
Professor K Woodhouse

Apologies

Professor S Eykyn
Dr A V P Mackay
Professor K Park

Guest Member

Miss G Lachelin

[Redacted]

Professional Staff of MCA

Principal Assessors

[Redacted]

Licensing Division

[Redacted]

Post-Licensing Division

[Redacted]

Others

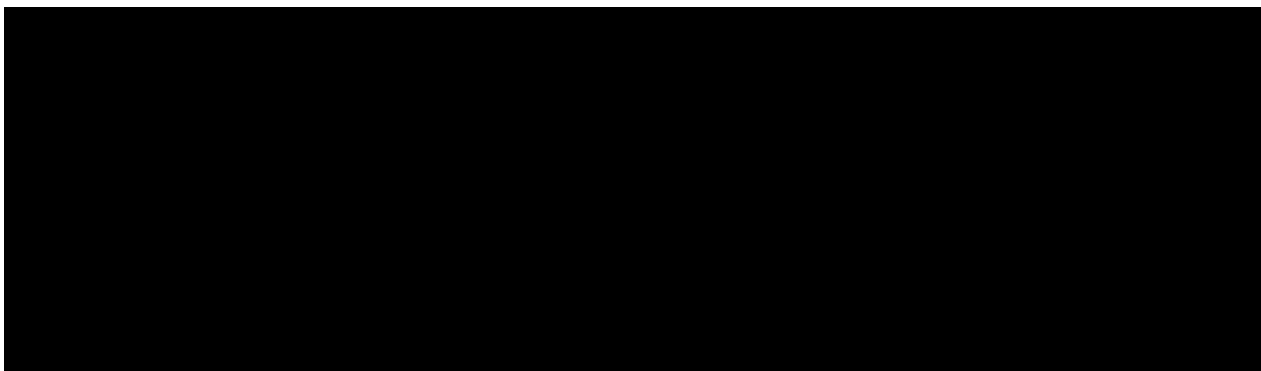
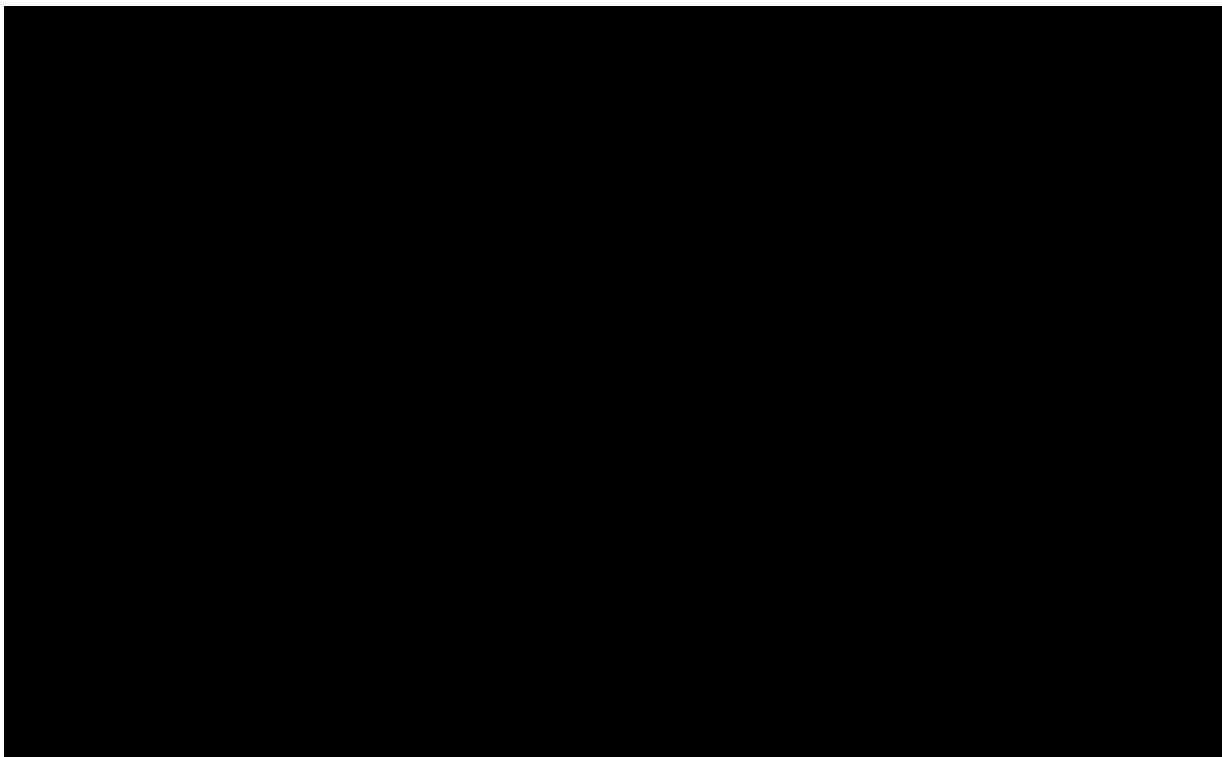
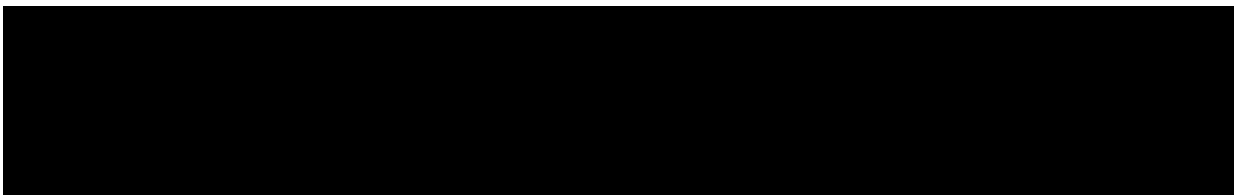
[Redacted]

Training

[Redacted]

1. **Announcements and Apologies**

- 1.1 The Chairman reminded the Committee that the papers and proceedings were confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.
- 1.2 The Chairman informed that Committee that apologies have been received from Dr Mackay and Professors Eykyn and Park for the day.
- 1.3 The Chairman welcomed Ms Gillian Lachelin attending as a member for the day.





Papers



6. Sodium Valproate And Developmental Delay – For Advice

- 6.1 Professor Darbyshire declared a non-personal non-specific interest, but this did not debar her from taking part in the proceedings.
- 6.2 The Committee noted **Tabled Paper II**.
- 6.3 The Committee noted the findings of the paper. It was noted that the study had methodological weaknesses and did not provide strong evidence of a causal link between sodium valporate exposure in utero and subsequent developmental delay. A particularly important confounder was identified as the fact that women with different epilepsy types will be treated with different antiepileptic drugs. In addition, the handling of siblings within the study could have had a major effect on the results. It was noted that the

