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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

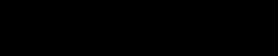
Professor K Park

Guest Member

Miss G Lachelin

Professional Staff of MCA

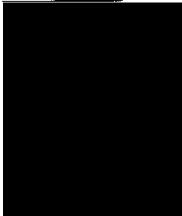
Principal Assessors



Licensing Division



Post-Licensing Division



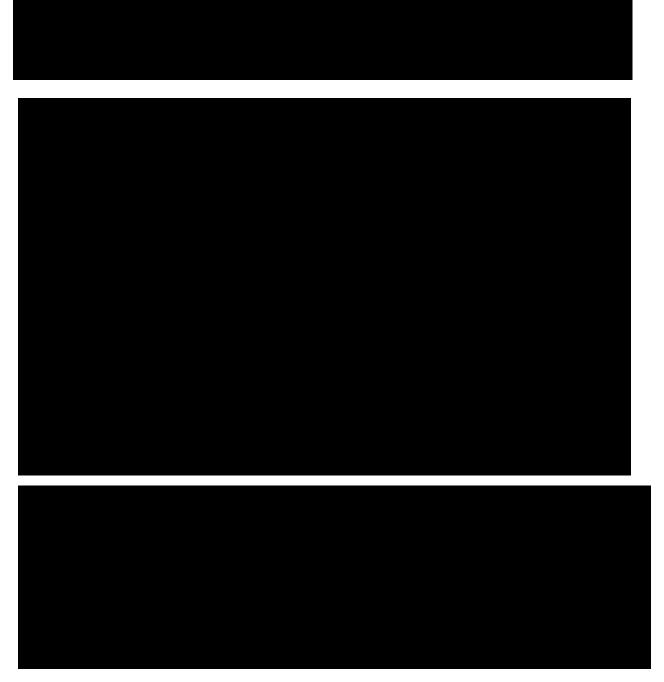
Others



Training

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

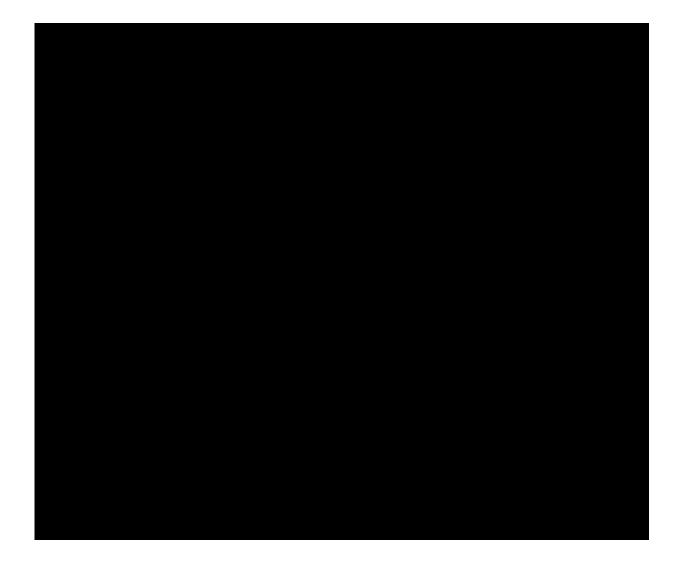


6. Sodium Valproate And Developmental Delay - For Advice

- 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

evidence from different studies was contradictory and overall there was no clear difference between the different anti-epilepsy drugs. The committee noted that further studies were in progress and therefore further data should be available in the future.

6.4 The Committee noted that there was evidence that the best practice guidelines for treatment of pregnant women with epilepsy were not widely followed. It was also noted that these guidelines did not address the issue of the possible association of polycystic ovarian syndrome with sodium valproate. The committee concluded that the evidence currently available did not clearly support a causal association between sodium valporate exposure utero and developmental delay, however, there was a signal of a safety issue which should be kept under close review. It was recommended that the existing warning that sodium valporate was for second line use only in women of child bearing potential should be more prominent in product information and that this issue should be referred to the Committee's paediatric medicines working group. When considered by the paediatric working group an assessment of efficacy in pregnancy should be provided in addition to the existing assessment report.





17. Any Other Business



18. Date and time of Next Meeting

The next meeting will take place on Wednesday 13th December 2000 at 10.00am

