

RESTRICTED - COMMERCIAL

CSM/2000/17th Meeting

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

**MINUTES OF A MEETING HELD ON THURSDAY 26TH OCTOBER 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 H Darbyshire
- Professor H J Dargie
- Dr M J Donaghy
- + Professor G W Duff (item 10 only)
- Dr B K Evans
- Professor E C Gordon-Smith
- * Professor M J Kendall
- ^ Professor M J S Langman
- * Dr A V P Mackay
- ^ Professor J M Midgley
- Professor K Park
- Dr H Scarffe
- Dr R J Taylor
- Dr P Wilkie
- Dr F Williams

Professional Staff of MCA

[Redacted]

Licensing Division

[Redacted]

Post-Licensing Division

[Redacted]

ES Division

[Redacted]

Others

[Redacted]

Training

[Redacted]

Apologies

- Dr R T Calvert
- Professor S Eykyn
- Professor J C Petrie (Co Vice Chairman)
- Professor I V D Weller (Co-Vice Chairman)

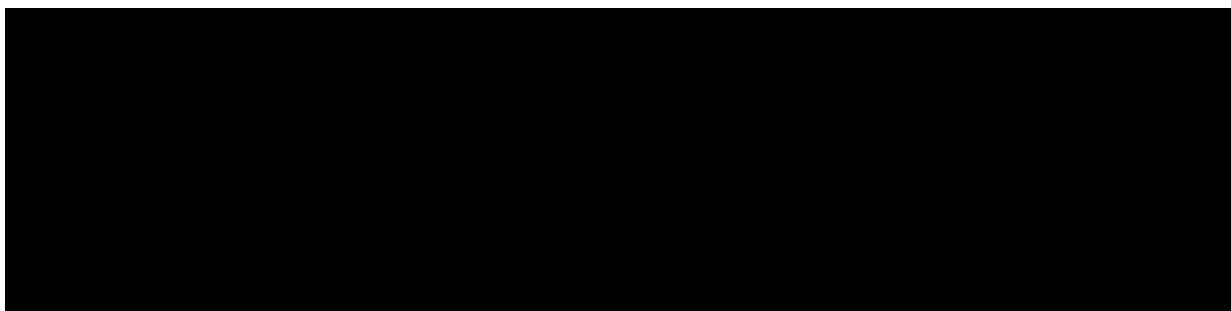
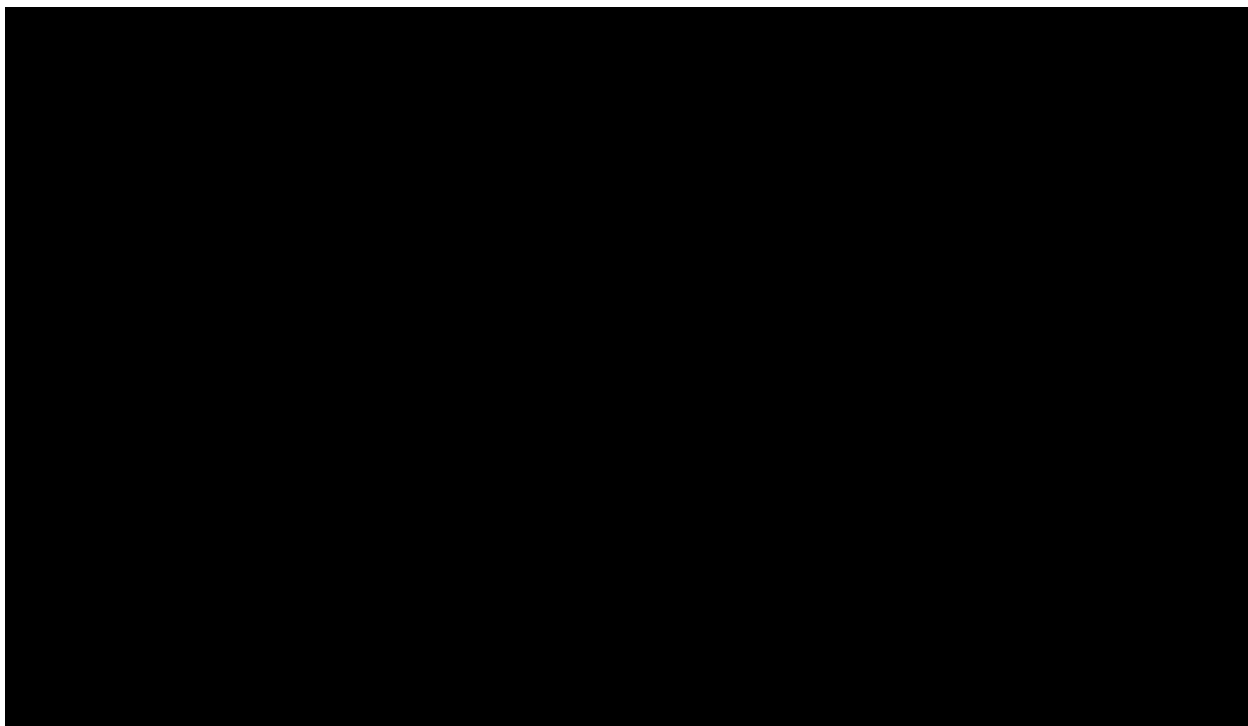
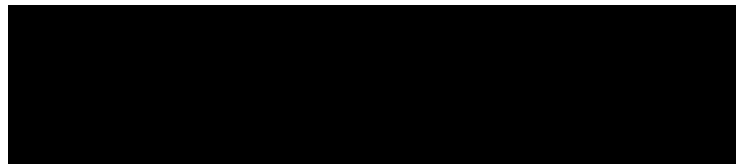
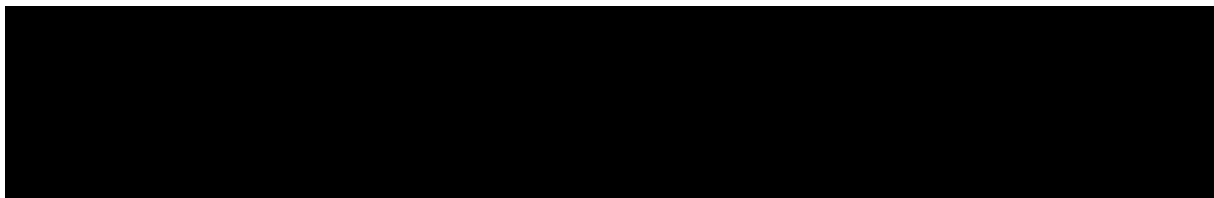
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- * Left after item 6.1
- + Arrived after lunch
- Left after item 9.1
- ^ Left after item 14

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 Apologies were received from Professors Eykyn, Petrie, Weller and Dr Calvert for the day.

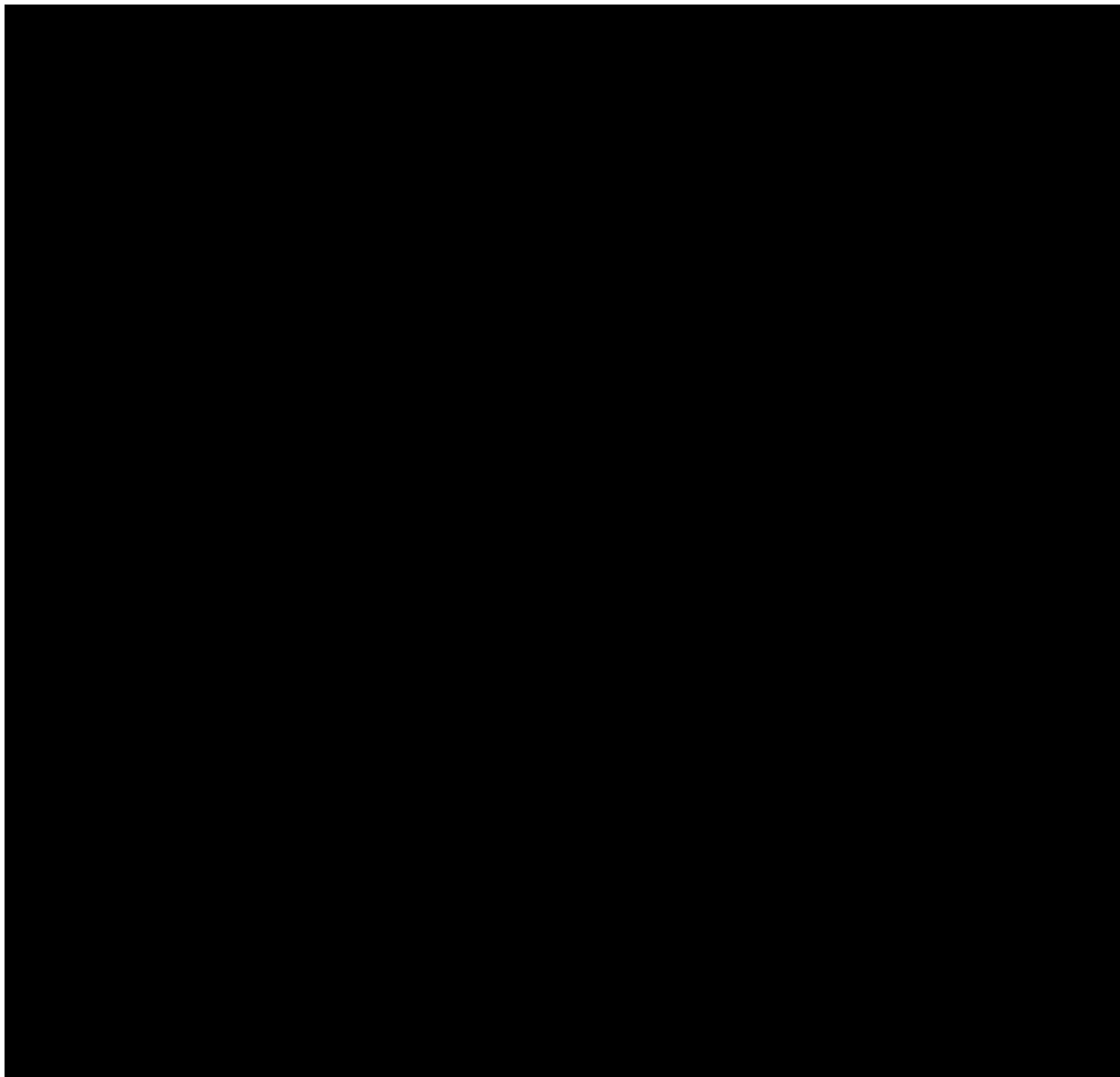


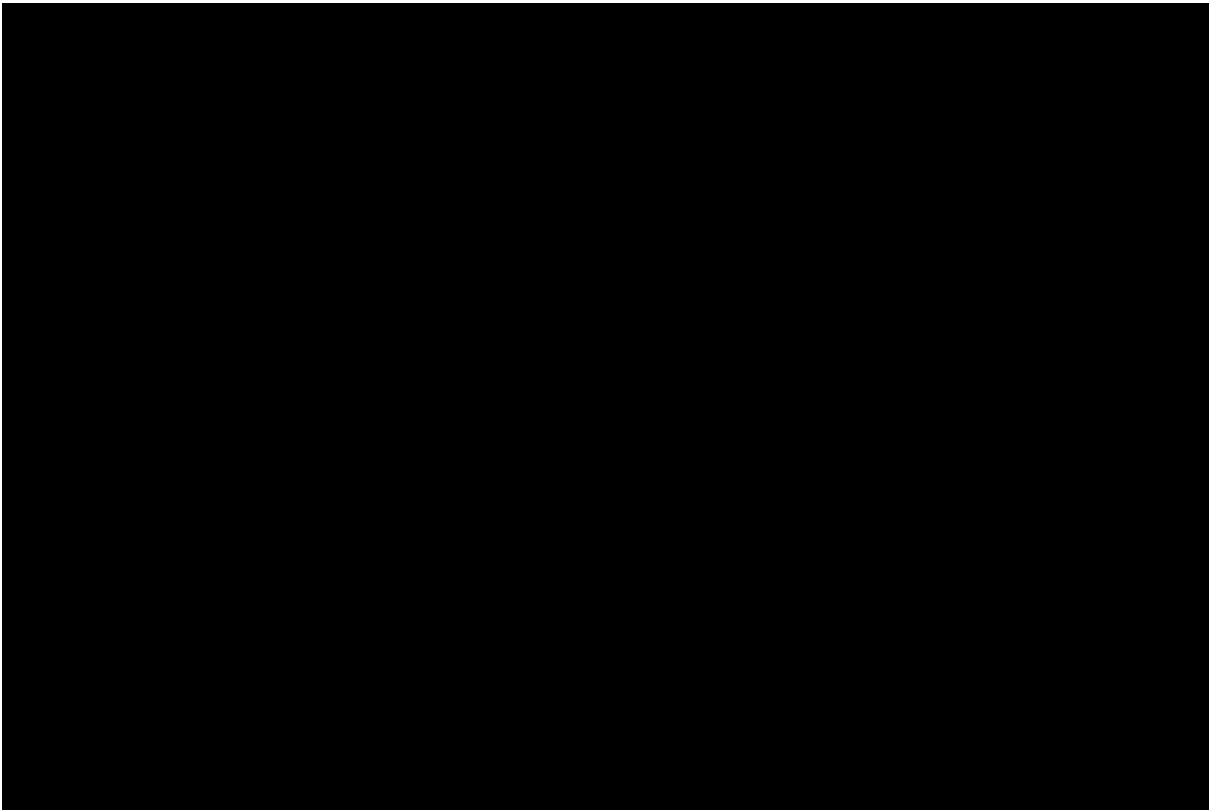
valproate weight gain should be strengthened and, that new warnings about PCOS were required.

11.2 The Committee was informed that since that time, the MAH, Sanofi Winthrop has strongly objected to the requested changes on the grounds that the data on PCOS are not robust and understanding of the syndrome is still evolving. In support of their objections the MAH has submitted neurology, statistical and reproductive endocrinology experts' review of the data.

11.3 The Committee considered the evidence before them and endorsed the recommendations of the Pharmacovigilance sub committee that:

- PCOS – Symptoms of PCOS should be mentioned only in Section 4.8 of the SPC.
- Weight gain – Strengthened warnings about weight gain should appear in Section 4.4 of the SPC with monitoring advice, and the existing warning in Section 4.8 should be reinforced and cross-referenced to Section 4.4.





16. **Any Other Business**

None.

17. **Date and Time of Next Meeting**

The next meeting will take place on **Wednesday 8th November 2000 at 10.00am**