



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2024

EMA multi-stakeholder workshop on the guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

29 Jan 2024 (09:00 – 16:45 CET)
European Medicines Agency, Amsterdam
Virtual meeting (Webex)

Item	
09:00-09:10	Welcome and Opening Pavel Balabanov (Head of Office of Neurological and Psychiatric Disorders, EMA) André Elferink (CNS Working Party Chair, MEB)
09:10-11:00	Session 1: Clinical development in epilepsy syndromes <i>Chair: Mario Miguel Rosa (CNS Working party, Infarmed)</i> Speakers: Sylvie Benchetrit (PDCO Vice Chair, ANSM) Loes den Otter (Clinical assessor, MEB) Stephane Auvin (ILAE) Julian Isla (Patient representative, member of COMP) Robert Roebling (EFPIA/UCB)
11:00-11:15	Coffee break
11:15-13:00	Session 2: Clinical development in paediatric population and extrapolation between age groups <i>Chair: Sylvie Benchetrit (PDCO Vice Chair, ANSM)</i> Flora Musuamba Tshinanu (MSWP Vice Chair, AFMPS-FAGG) Speakers: Loes den Otter (Clinical assessor, MEB) Stephane Auvin (ILAE), Jan-Peer Elshoff (EFPIA/UCB)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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13:00-14:00	Lunch break
14:00-15:15	Session 3: Evidence needed to support extrapolation to monotherapy <i>Chair: André Elferink (CNS Working Party Chair, MEB)</i> Speakers: Mario Miguel Rosa (CNS Working party, Infarmed) Jacqueline French (ILAE), Flora Musuamba Tshinanu (MSWP Vice Chair, AFMPS-FAGG)
15:15-15:30	Coffee break
15:30-16:30	Overall Q&A session <i>Chair: André Elferink (CNS Working Party Chair, MEB)</i> All speakers and participants
16:30-16:45	Closing remarks André Elferink (CNS Working Party Chair, MEB) Pavel Balabanov (Head of Office of Neurological and Psychiatric Disorders, EMA)

List of speakers

- André Elferink (CNS Working Party Chair, MEB, NL)
- Pavel Balabanov (Head of Office of Neurological and Psychiatric Disorders, EMA, NL)
- Mario Miguel Rosa (CNS Working party, Infarmed, PT)
- Sylvie Benchetrit (PDCO Vice Chair, ANSM, FR)
- Flora Musuamba Tshinanu (MSWP Vice Chair, AFMPS-FAGG, BE)
- Loes den Otter (Clinical assessor, MEB, NL)
- Stephane Auvin (ILAE, Regulatory Affairs Task Force, FR)
- Jacqueline French (ILEA Regulatory Affairs Task Force, US)
- Jan-Peer Elshoff (EFPIA/UCB, DE)
- Robert Roebling (EFPIA/UCB, DE)
- Julian Isla (patient representative, member of COMP, SP)