EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 November 2014
EMA/180375/2014
Scientific and Regulatory Management Department

Workshop on Alzheimer's disease

Final programme

24-25 November 2014
European Medicines Agency, London, United Kingdom

Room 3A

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Objective of the workshop

With this workshop, the EMA is providing an opportunity for different stakeholder groups to come together and discuss the key scientific issues in the field.

The main goal of the workshop is to make sure that, while revising its guideline, the EMA can take the most up-to-date scientific developments in understanding and treatment of Alzheimer's Disease into consideration, as well as the positions of experts in the field on the main topics covered in the Discussion paper.

The workshop will bring together representatives from the pharmaceutical industry, academic experts, patients and regulators.

Programme overview

Sessions

Session 1 The latest advances in the understanding of the pathophysiology of Alzheimer's Disease and the discovery of disease-modifying treatment targets

Session 2 The changing diagnostic criteria for Alzheimer's Disease, including early and asymptomatic disease stages, and their impact on the clinical trial design

Session 3 The scientific and regulatory approaches to facilitating disease-modifying drug development and registration in a global environment

Session 4 The choice of outcome parameters and need for distinct assessment tools with regard to the different disease stages in Alzheimer's Disease

Session 5 The potential use of biomarkers and their temporal relationship with the different phases of Alzheimer's Disease in different stages of drug development

Session 6 The place for treatments of associated neuropsychiatric and other symptoms

List of panellists/speakers

Dr Eric Bastings, FDA

Dr Thomas Blaettler, Roche/European Federation of Pharmaceutical Industries and Associations (EFPIA)

Pr Olivier Blin, Assistance Publique-Hôpitaux de Marseille

Pr Karl Broich, Chair of the Central Nervous System Working party (CNSWP)

Mr David Brown, Scientific Advice Working Party (SAWP)

Dr Martha Brumfield, CAMD Critical Path Institute

Dr Florence Butlen-Ducuing, CNS Office, EMA

Pr Bruno Dubois, Hôpital La Salpêtrière, Paris

Dr Billy Dunn, FDA

Dr Jean Georges, Alzheimer Europe

Dr Manuel Haas, Head of CNS Office, EMA

Dr Marion Haberkamp, CNSWP and SAWP

Mr Robert Hemmings, Committee for Medicinal Products for Human Use (CHMP), Chair of the SAWP

Dr Jens Heisterberg, CNSWP and CHMP

Dr Iva Holmerova, Czech Alzheimer's Society

Dr Maria Isaac, Scientific Advice Office, EMA

Pr Frank Jessen, Dept. of Psychiatry, University of Bonn

Dr Akifumi Kamata, PMDA Japan

Dr Veronika Logovinsky, Eisai Ltd./EFPIA

Ms Raj Long, UK Government Dementia Integrated Development, and World Dementia Council

Dr Johan Luthman, Eisai Ltd./EFPIA

Dr Valentina Mantua, CNSWP and SAWP

Ms Mary-Frances Morris, Alzheimer Scotland

Pr Takashi Moritoyo, PMDA Japan

Pr Luca Pani, SAWP, CNSWP, CHMP

Dr Elektra Papadopoulos, FDA

Ms Helga Rohra, Alzheimer Europe

Dr Gary Romano, Janssen/ EFPIA

Dr Tomas Salmonson, Chair of the CHMP

Dr Charles Scerri, Malta Dementia Society

Dr Rachel Schindler, Pfizer/EFPIA

Pr Reinhold Schmidt, European Academy of Neurology (EAN)

Dr Eric Siemers, Eli Lilly/ EFPIA

Programme details

Monday, 24 November 2014

09:00–09:30	**Registration**
	Register at the reception on the ground floor and receive your badge. Then join delegates in room 3A.
	Welcome and opening
09:30-09:45	***European Medicines Agency***
09:45-10:00	***Patients association*** **Helga Rohra**
Session 1:	**The latest advances in the understanding of the pathophysiology of Alzheimer's Disease and the discovery of disease-modifying treatment targets**
	Chaired by: **Robert Hemmings**
10:00–10:15	***Academia*** **Frank Jessen**
10:15–10:30	***EFPIA / Industry*** **Gary Romano**
10:30–10:50	***Questions and discussion***
10:50–11:20	**Coffee break**
Session 2:	**The changing diagnostic criteria for Alzheimer's Disease, including early and asymptomatic disease stages, and their impact on the clinical trial design**
	Chaired by: **Luca Pani**
11:20–11:35	***Academia*** **Bruno Dubois**
11:35–11:50	***EFPIA / Industry*** **Eric Siemers**
11:50–12:05	***EU Regulatory*** **Marion Haberkamp**
12:05–12:25	***Questions and discussion***

12:25–13:25 **Lunch**

Session 3: The scientific and regulatory approaches to facilitating disease-modifying drug development and registration in a global environment

Chaired by: **Tomas Salmonson**

13:25-13:40 ***FDA - CDER (by Teleconference)***
Billy Dunn, Eric Bastings

13:40-13:55 ***PMDA***
Takashi Moritoyo

13:55-14:10 ***EU Regulatory***
David Brown

14:10-14:25 ***Questions and discussion***

14:25-14:40 ***Patient Association***
Jean Georges

14:40-14:55 ***EFPIA / Industry***
Thomas Blaettler

14:55-15:10 ***UK Government Dementia Integrated Development, and World Dementia Council***
Raj Long

15:10-15:25 ***Questions and discussion***

15:25-15:45 **Coffee break**

Session 4: The choice of outcome parameters and need for distinct assessment tools with regard to the different disease stages in Alzheimer 's disease

Chaired by: **Karl Broich**

15:45-16:00 ***FDA SEALD (by Teleconference)***
Elektra Papadopoulos

16:00-16:15 ***Patient Association***
Iva Holmerova

16:15-16:30 ***CAMD - Critical Path Institute***
Martha Brumfield

16:30-16:45 ***EFPIA / Industry***
Veronika Logovinsky

16:45-17:00	***EU Regulatory*** **Jens Heisterberg**
17:00-17:20	***Questions and discussion***
	Closing remarks **Luca Pani**

Tuesday, 25 November 2014

Session 5: The potential use of biomarkers and their temporal relationship with the different phases of Alzheimer's Disease in different stages of drug development

Chaired by: **Karl Broich**

09:00-09:15	***Academia*** **Olivier Blin**
09:15-09:30	***EFPIA / Industry*** **Johan Luthman**
09:30-09:45	***EU Regulatory*** **Valentina Mantua**
09:45-10:05	***Questions and discussion***

Session 6: The place for treatments of associated neuropsychiatric and other symptoms

Chaired by: **Robert Hemmings**

10:05–10:20	***PMDA*** **Akifumi Kamata**
10:20–10:35	***Patient Association*** **Mary-Frances Morris**
10:35-10:50	**Health care professionals** **Reinhold Schmidt**
10:50–11:05	***EFPIA / Industry*** **Rachel Schindler**
11:05–11:20	***EU Regulatory*** **Luca Pani**
11:20–11:40	***Questions and discussion***
	Closing remarks **Karl Broich**