



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Public Hearing: Valproate

Tuesday, 26 September 2017

Pharmacovigilance Risk Assessment Committee (PRAC)



# Agenda

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Chair: June Raine (PRAC chair)

**11:45** *Registration opens*

**12:30** *Participants escorted to meeting room 3M*

**12:45** **Welcome and introduction**

- ▶ **Guido Rasi** (EMA Executive Director)
- ▶ **Linda McAvan** (Member of European Parliament)
- ▶ **June Raine** (PRAC chair)

**13:00** **Public hearing rules and background information on Valproate's ongoing assessment**

- ▶ **Juan García Burgos** (EMA Head of Public Engagement)
- ▶ **Sabine Straus** (PRAC rapporteur)

**13:15** **Speakers interventions** (*7 minutes per intervention*)

**General public (patient representatives, carers, families)**

**Speaker 1:**

- ▶ **Catherine Cox**<sup>1</sup>, Fetal Anti-Convulsant Support Association, UK  
Janet Williams, Independent Fetal Anti-Convulsant Trust (In-FACT) & FACS Syndrome Association, UK

**Speaker 2:**

- ▶ **Marine Martin**, Association of Parents of Children with the syndrome anticonvulsant (APESAC), France

**Speaker 3:**

- ▶ **Karen Keely**, FACS Forum, Ireland

**Speaker 4:**

- ▶ **Clare Pelham**, Epilepsy Society, UK  
Philip Lee, Epilepsy Action, UK

**Speaker 5:**

- ▶ **Nathalie Raemdonck**, Belgian Association of Victims of Valproate Syndrome (ABVSV/ BVSVS), Belgium

**Speaker 6:**

- ▶ **Martin Brodie**, International Bureau for Epilepsy (IBE)

**Speaker 7:**

- ▶ **Josephine Tapper**, Patient, member of Bipolar UK

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<sup>1</sup> For grouped interventions, the name in **bold** is the speaker

**Speaker 8:**

- ▶ **Joanne Cozens**, Organisation for Anti-Convulsant Syndromes (OACS), UK  
Emma Friedmann, FACSAWARE.NET, UK
- ▶ **Branwen Mann**, Patient representing Anti-Convulsant Syndrome, OACS Youth Trustee

**15:15** Coffee break

**15:40** Speakers interventions (7 minutes per intervention)

**Pharmaceutical companies**

**Speaker 9:**

- ▶ **Eric Teo**, Sanofi

**Healthcare professionals and academia**

**Speaker 10:**

- ▶ **Jurate Svarcaite**, Pharmaceutical Group of the European Union (PGEU)

**Speaker 11:**

- ▶ **Helen Cross**, European Reference Network for Epilepsy (EpiCARE)  
Timothy Barrett, University of Birmingham, UK  
Daniel Hawcutt, Royal College of Paediatrics and Child Health (RCPCH), UK

**Speaker 12:**

- ▶ **Torbjörn Tomson**, International League Against Epilepsy (ILAE) (CEA)

**Speaker 13:**

- ▶ **Anthony Marson**, European Academy of Neurology (EAN)  
Philip Smith, Association of British Neurologists (ABN)  
Sanjay Sisodiya, Epilepsy Society, UK  
Dyfrig Hughes, Centre for Health Economics and Medicines Evaluation, Bangor University, UK

**Speaker 14:**

- ▶ **Paolo Martelletti**, European Headache Federation (EHF), Department of Clinical and Molecular Medicine, Sapienza University, Italy

**Speaker 15:**

- ▶ **Kim Morley**, Epilepsy specialist midwife/ nurse practitioner, UK

**Speaker 16:**

- ▶ **Angelika Wieck**, European Psychiatric Association (EPA)/ Greater Manchester Mental Health NHS Foundation Trust

**17:30** Wrap up, summary of interventions and next steps

- ▶ **June Raine** (PRAC chair)

**18:00** End of public hearing

# List of Speakers

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*Note: Some speakers have been grouped together*

## **General public (patient representatives, carers, families)**

<b>Catherine Cox</b>	Fetal Anti-Convulsant Support Association, UK
<b>Janet Williams</b>	Independent Fetal Anti-Convulsant Trust (In-FACT) & FACS Syndrome Association, UK
<b>Marine Martin</b>	Association of Parents of Children with the syndrome anticonvulsant (APESAC), France
<b>Karen Keely</b>	FACS Forum, Ireland
<b>Clare Pelham</b>	Epilepsy Society, UK
<b>Philip Lee</b>	Epilepsy Action, UK
<b>Nathalie Raemdonck</b>	Belgian Association of Victims of Valproate Syndrome (ABVSV/ BVSVS), Belgium
<b>Martin Brodie</b>	International Bureau for Epilepsy (IBE)
<b>Josephine Tapper</b>	Patient, member of Bipolar UK
<b>Joanne Cozens</b>	Organisation for Anti-Convulsant Syndromes (OACS), UK
<b>Emma Friedmann</b>	FACSAWARE.NET, UK
<b>Branwen Mann</b>	Patient representing Anti-Convulsant Syndrome, OACS Youth Trustee

## **Pharmaceutical companies**

<b>Eric Teo</b>	Sanofi
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## **Healthcare professionals and academia**

<b>Jurate Svarcaite</b>	Pharmaceutical Group of the European Union (PGEU)
<b>Helen Cross</b>	European Reference Network for Epilepsy (EpiCARE)
<b>Timothy Barrett</b>	University of Birmingham, UK
<b>Daniel Hawcutt</b>	Royal College of Paediatrics and Child Health (RCPCH), UK
<b>Torbjörn Tomson</b>	International League Against Epilepsy (ILAE) (CEA)
<b>Anthony Marson</b>	European Academy of Neurology (EAN)
<b>Philip Smith</b>	Association of British Neurologists (ABN), UK
<b>Sanjay Sisodiya</b>	Epilepsy Society, UK
<b>Dyfrig Hughes</b>	Centre for Health Economics and Medicines Evaluation, Bangor University, UK
<b>Paolo Martelletti</b>	European Headache Federation (EHF), Department of Clinical and Molecular Medicine, Sapienza University, Italy
<b>Kim Morley</b>	Epilepsy specialist midwife/ nurse practitioner, UK
<b>Angelika Wieck</b>	European Psychiatric Association (EPA)/ Greater Manchester Mental Health NHS Foundation Trust

# Speakers declaration of interests (where applicable)

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## **Epilepsy Society, UK**

In the past three years, Epilepsy Society has received the following grants / donations: £30,348 from Sanofi and £8,248 from Desitin Pharma Limited.

## **Epilepsy Action, UK**

In the past three years, Epilepsy Action has received the following grants / donations: £700 from Sanofi, £12,450 from Aventis Pharma Ltd (trading as Sanofi) and £11,500 from Desitin Pharma Limited.

## **Paolo Martelletti**

Part of an advisory Board and RCTs Principal Investigator for Fremanezumab (Teva).

# Venue

The European Medicines Agency can be reached:

► **By Underground**

The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

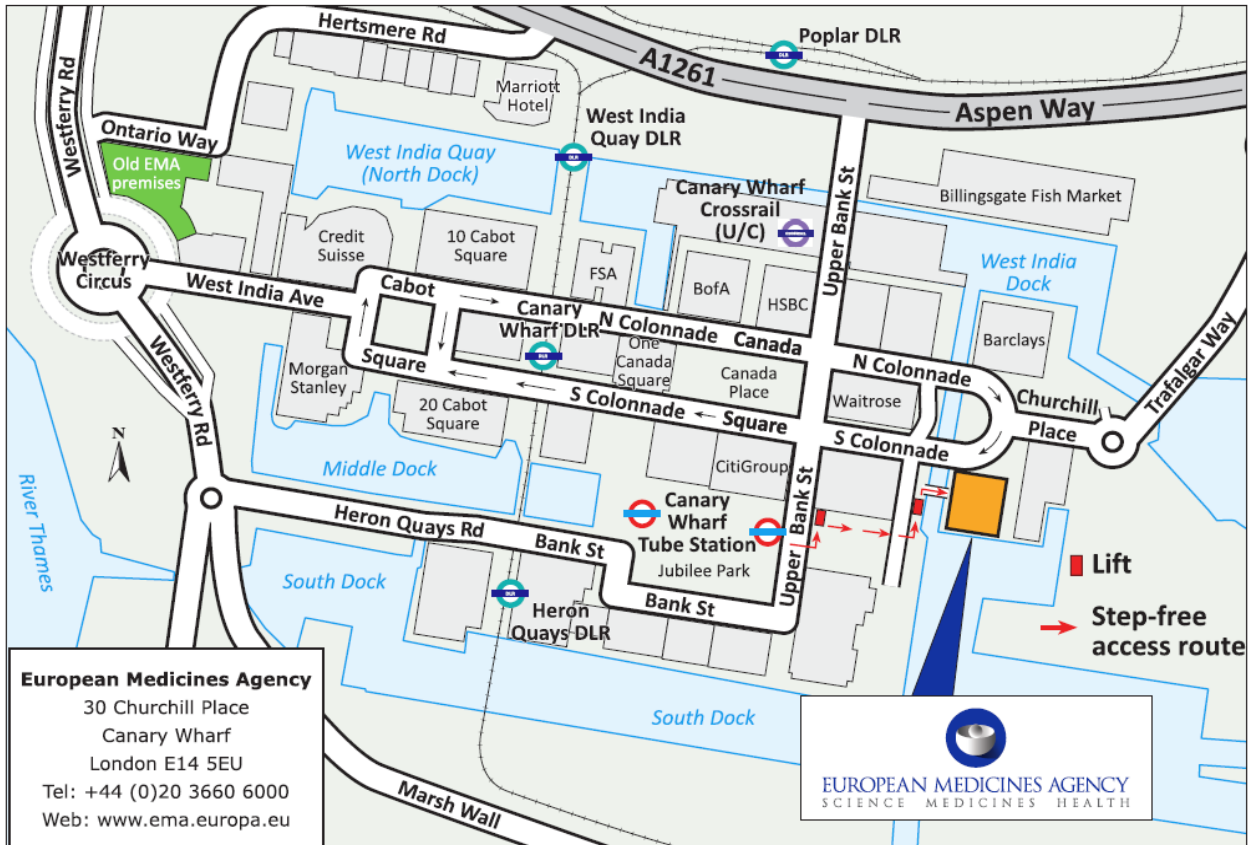
► **By Docklands Light Railway (DLR)**

The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

► **By car**

There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website:

<http://canarywharf.com/getting-here/parking/>



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