EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# EMA's 1st public hearing (Valproate)

PCWP meeting with all eligible patient/consumer organisations

Presented by Nathalie Bere
Public Engagement Department

An agency of the European Union

# Public hearings

# Key principles

## PRAC can hold public hearings

In the **context of safety referral procedures** (Article 20 of Regulation (EC) 726/2004, Article 31 or 107i of Directive 2001/83/EC)

## Public is invited to express its views

Guided by a **pre-defined set of questions**

## Any member of the public can apply to attend as a speaker or an observer

If the number of requests is greater than can reasonably be accommodated only the most appropriate applications will be **selected based on PRAC questions** and focus of the hearing

Public hearings complement EMA's existing **channels for engaging with patients and healthcare professionals** in the assessment of medicines, such as written consultations and participation in EMA expert meetings during safety reviews

# Aims of a public hearing

## Increase transparency

By opening up the scientific evaluation

## Empower citizens

By giving them a voice in the evaluation of medicines

## Engagement

Helps them to understand how regulators work

## Adds value

Help us in ensuring safety of medicines

TRUST

# Key characteristics

PRAC **considers need to hold a public hearing** based on:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| Feasibility in light of urgency of matter | Nature and extent of safety concern | Therapeutic effect of medicine and availability of alternatives | Potential impact of regulatory actions | Level of public interest |

# CONDUCTED IN ENGLISH

If speakers unable to present in English,

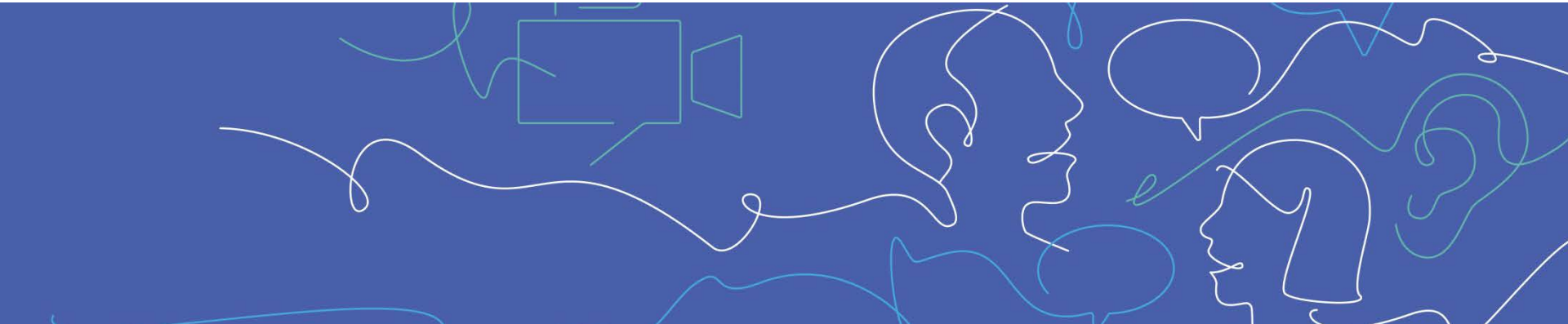
EMA can provide translation


Valproate Public Hearing

EUROPEAN MEDICINES AGENCY

# 1st EMA Public Hearing: Valproate

## Tuesday, 26 September 2017



# PRAC decision to hold public hearing

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## Based on pre-defined criteria:

- A public hearing is possible within the assessment timelines
- A known high risk of neurodevelopmental disorders in children exposed in utero (30-40%) and ongoing regulatory efforts to reduce this risk
- Outcome expected to result in changes to existing RMMs
- Input from patients/carers and healthcare professionals will add value to the PRAC assessment
- High level of public interest; seen in previous PhV referral, continued media reporting and patient organisations expressing concerns

# Organisation of the public hearing

# 1

# ANNOUNCEMENT

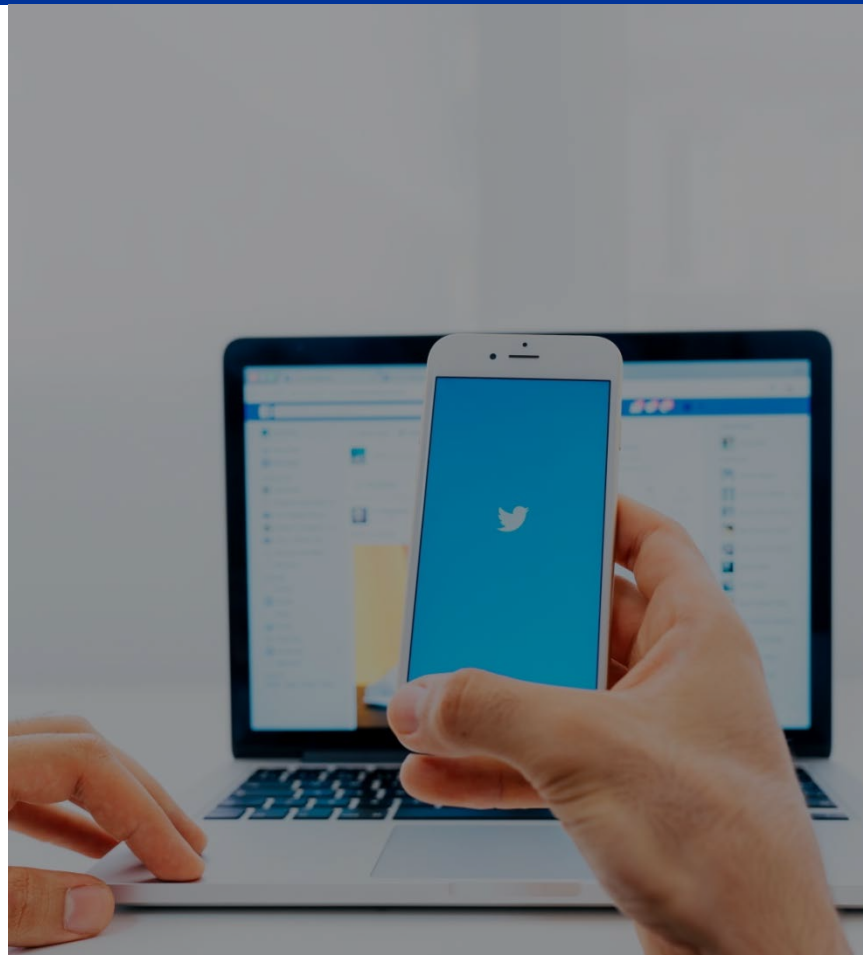
Date & time

Summary of issues & specific questions

Application form

Guidance & video

Announcement on EMA website & twitter



# Susac & LoQ adopted by PRAC

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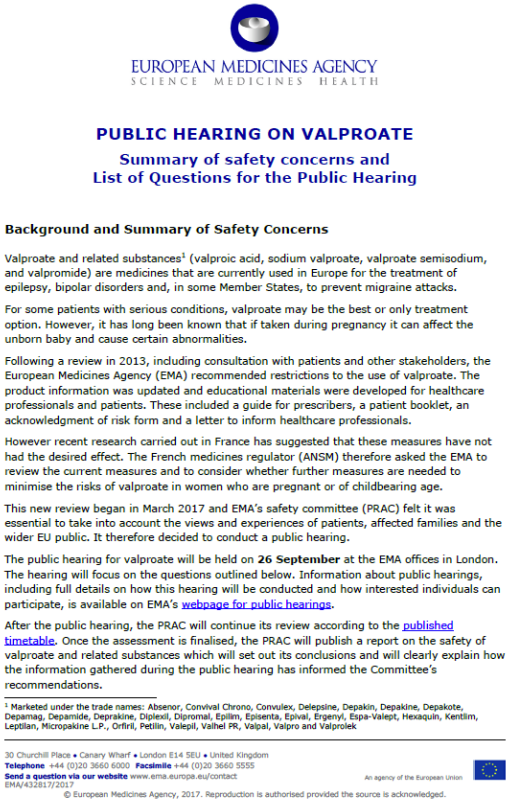

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**PUBLIC HEARING ON VALPROATE**

**Summary of safety concerns and List of Questions for the Public Hearing**

**Background and Summary of Safety Concerns**

Valproate and related substances[1] (valproic acid, sodium valproate, valproate semisodium, and valpromide) are medicines that are currently used in Europe for the treatment of epilepsy, bipolar disorders and, in some Member States, to prevent migraine attacks.

For some patients with serious conditions, valproate may be the best or only treatment option. However, it has long been known that if taken during pregnancy it can affect the unborn baby and cause certain abnormalities.

Following a review in 2013, including consultation with patients and other stakeholders, the European Medicines Agency (EMA) recommended restrictions to the use of valproate. The product information was updated and educational materials were developed for healthcare professionals and patients. These included a guide for prescribers, a patient booklet, an acknowledgment of risk form and a letter to inform healthcare professionals.

However recent research carried out in France has suggested that these measures have not had the desired effect. The French medicines regulator (ANSM) therefore asked the EMA to review the current measures and to consider whether further measures are needed to minimise the risks of valproate in women who are pregnant or of childbearing age.

This new review began in March 2017 and EMA's safety committee (PRAC) felt it was essential to take into account the views and experiences of patients, affected families and the wider EU public. It therefore decided to conduct a public hearing.

The public hearing for valproate will be held on **26 September** at the EMA offices in London. The hearing will focus on the questions outlined below. Information about public hearings, including full details on how this hearing will be conducted and how interested individuals can participate, is available on EMA's webpage for public hearings.

After the public hearing, the PRAC will continue its review according to the published timetable. Once the assessment is finalised, the PRAC will publish a report on the safety of valproate and related substances which will set out its conclusions and will clearly explain how the information gathered during the public hearing has informed the Committee's recommendations.

[1] Marketed under the trade names: Absenor, Convival Chrono, Convulex, Delepsine, Depakin, Depakine, Depakote, Depamag, Depamide, Deprakine, Diplexil, Dipromal, Epilim, Episenta, Epival, Ergenyl, Espa-Valept, Hexaquin, Kentilm, Leptilan, Micropakine L.P., Orliril, Petilin, Valepil, Valhel PR, Valpal, Valpro and Valprolek

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**Send a question via our website** www.ema.europa.eu/contact

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EMA/432817/2017

## Question 1

What is your view of the risks of taking valproate during pregnancy, including its potential effect on the child?

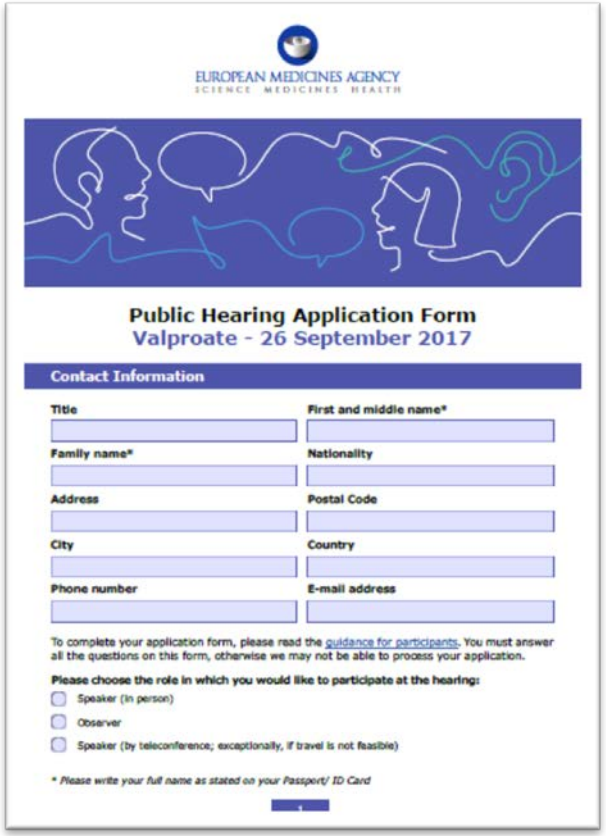
## Question 2

What are your views on the measures currently in place to reduce the risks of using valproate during pregnancy?

## Question 3

What other measures should be taken to reduce the risks of using valproate during pregnancy?

# Application form



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**Public Hearing Application Form**
**Valproate - 26 September 2017**

**Contact Information**

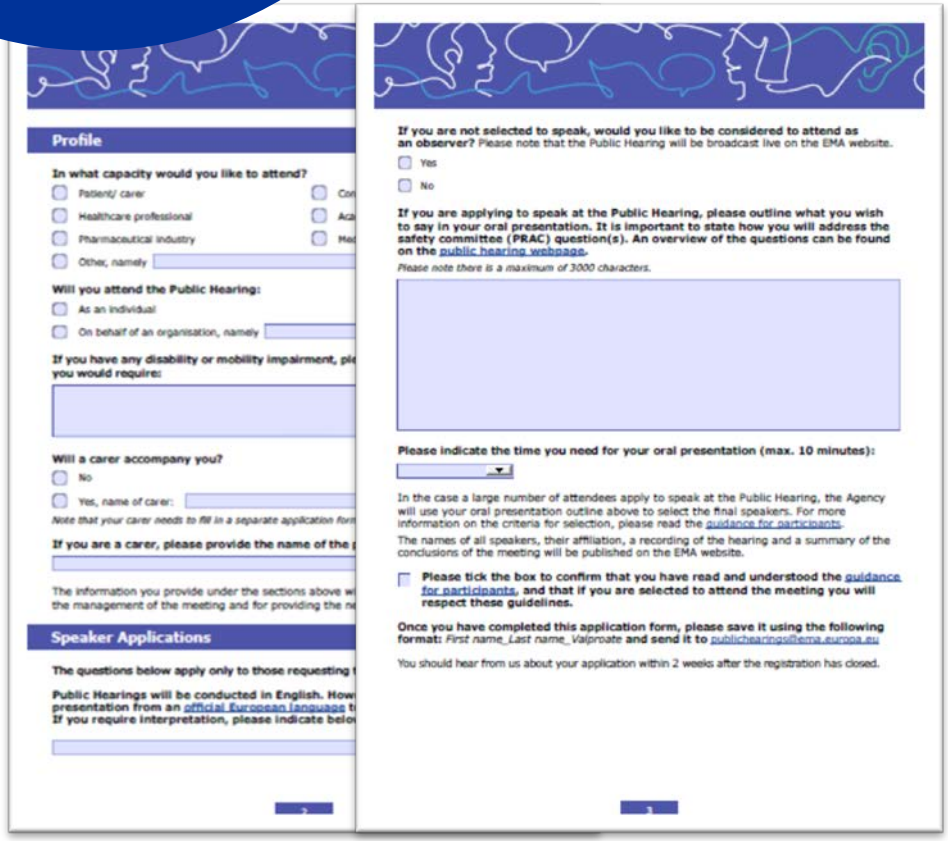
Title | First and middle name*
Family name* | Nationality
Address | Postal Code
City | Country
Phone number | E-mail address

To complete your application form, please read the guidance for participants. You must answer all the questions on this form, otherwise we may not be able to process your application.

**Please choose the role in which you would like to participate at the hearing:**

- Speaker (in person)
- Observer
- Speaker (by teleconference; exceptionally, if travel is not feasible)

** Please write your full name as stated on your Passport/ ID Card*



**Profile**

**In what capacity would you like to attend?**

- Patient/ carer
- Healthcare professional
- Pharmaceutical industry
- Other, namely

**Will you attend the Public Hearing:**

- As an individual
- On behalf of an organisation, namely

**If you have any disability or mobility impairment, pl… you would require:**

**Will a carer accompany you?**

- No
- Yes, name of carer:

*Note that your carer needs to fill in a separate application for…*

**If you are a carer, please provide the name of the …**

The information you provide under the sections above w… the management of the meeting and for providing the n…

**Speaker Applications**

**The questions below apply only to those requesting …**

**Public Hearings will be conducted in English. How… presentation from an official European language t… If you require interpretation, please indicate belo…**

**If you are not selected to speak, would you like to be considered to attend as an observer?** Please note that the Public Hearing will be broadcast live on the EMA website.

- Yes
- No

**If you are applying to speak at the Public Hearing, please outline what you wish to say in your oral presentation. It is important to state how you will address the safety committee (PRAC) question(s). An overview of the questions can be found on the public hearing webpage.**

*Please note there is a maximum of 3000 characters.*

**Please indicate the time you need for your oral presentation (max. 10 minutes):**

In the case a large number of attendees apply to speak at the Public Hearing, the Agency will use your oral presentation outline above to select the final speakers. For more information on the criteria for selection, please read the guidance for participants.

The names of all speakers, their affiliation, a recording of the hearing and a summary of the conclusions of the meeting will be published on the EMA website.

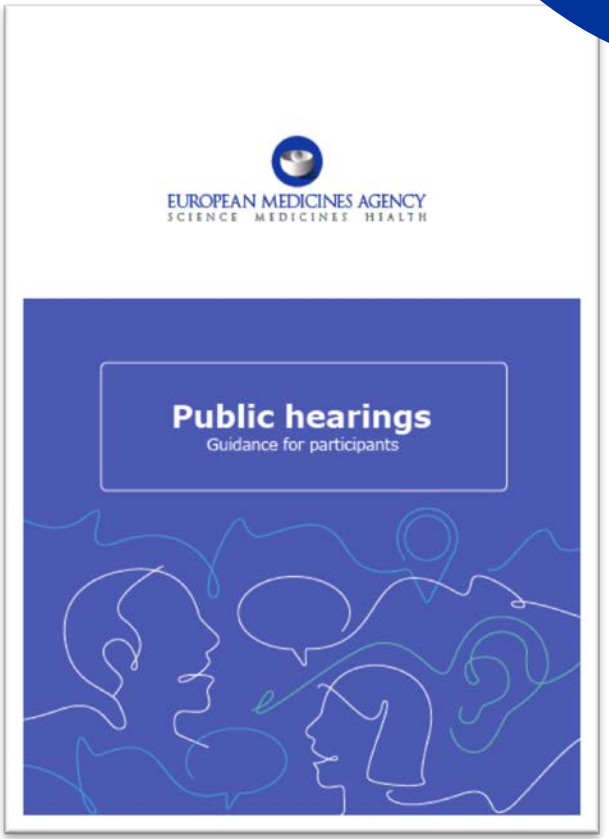
**Please tick the box to confirm that you have read and understood the guidance for participants, and that if you are selected to attend the meeting you will respect these guidelines.**

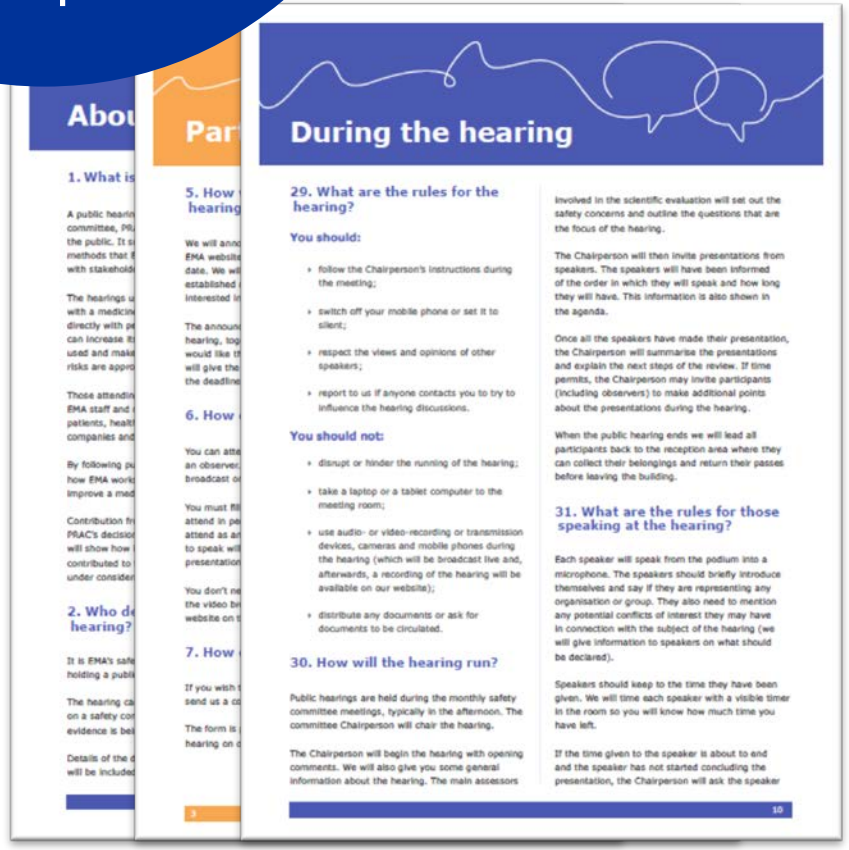
**Once you have completed this application form, please save it using the following format:** *First name_Last name_Valproate* **and send it to** publichearingsoffice.europa.eu

You should hear from us about your application within 2 weeks after the registration has closed.

# Guidance for participants





# Video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0:05 / 2:57

# Dissemination

## Wide dissemination to stakeholder groups:

- Relevant patient, healthcare professional organisations and academia
- Affected families and individuals previously in contact with the EMA
- Organisations identified through the NUI
- Twitter and media outreach
- Early Notification System (ENS)

# 2

# PREPARATION

Review applications

Draw up list of speakers/observers according to group & relevance

Allocate time slots

# Preparation

## Applications review:

- Decide on speakers and observers
- Ensure appropriate representation across all groups

## Numbers attending:

- Ideally between 12-16 speakers
- 100 observers maximum
- Depends on level of interest and relevant applications

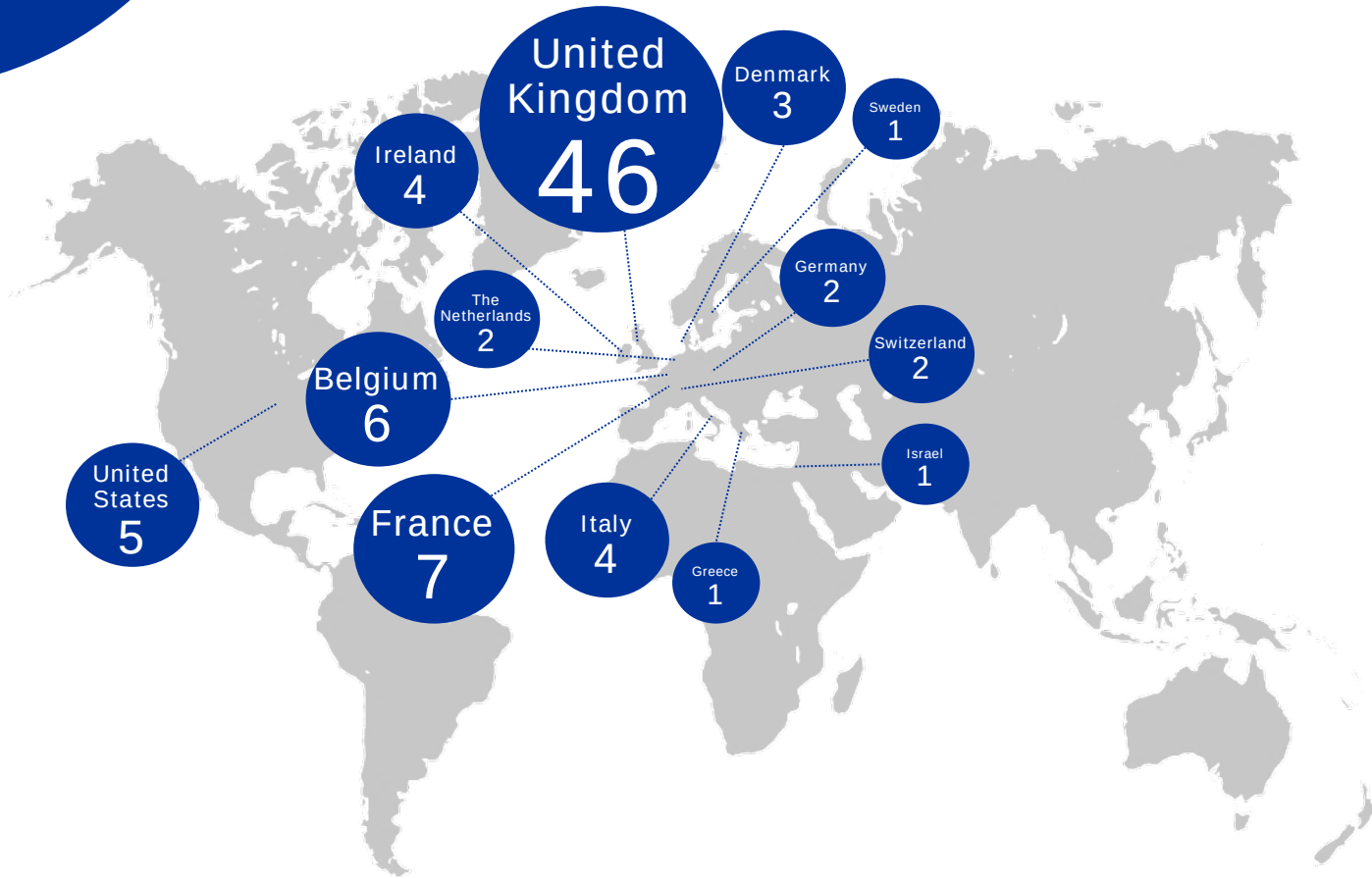
# Criteria for selection

- Selection based on the relevance to the PRAC questions
- Balanced representation based on:

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| Content | Affiliation | Discipline | Geographical distribution |

# Participants

84



# Speakers

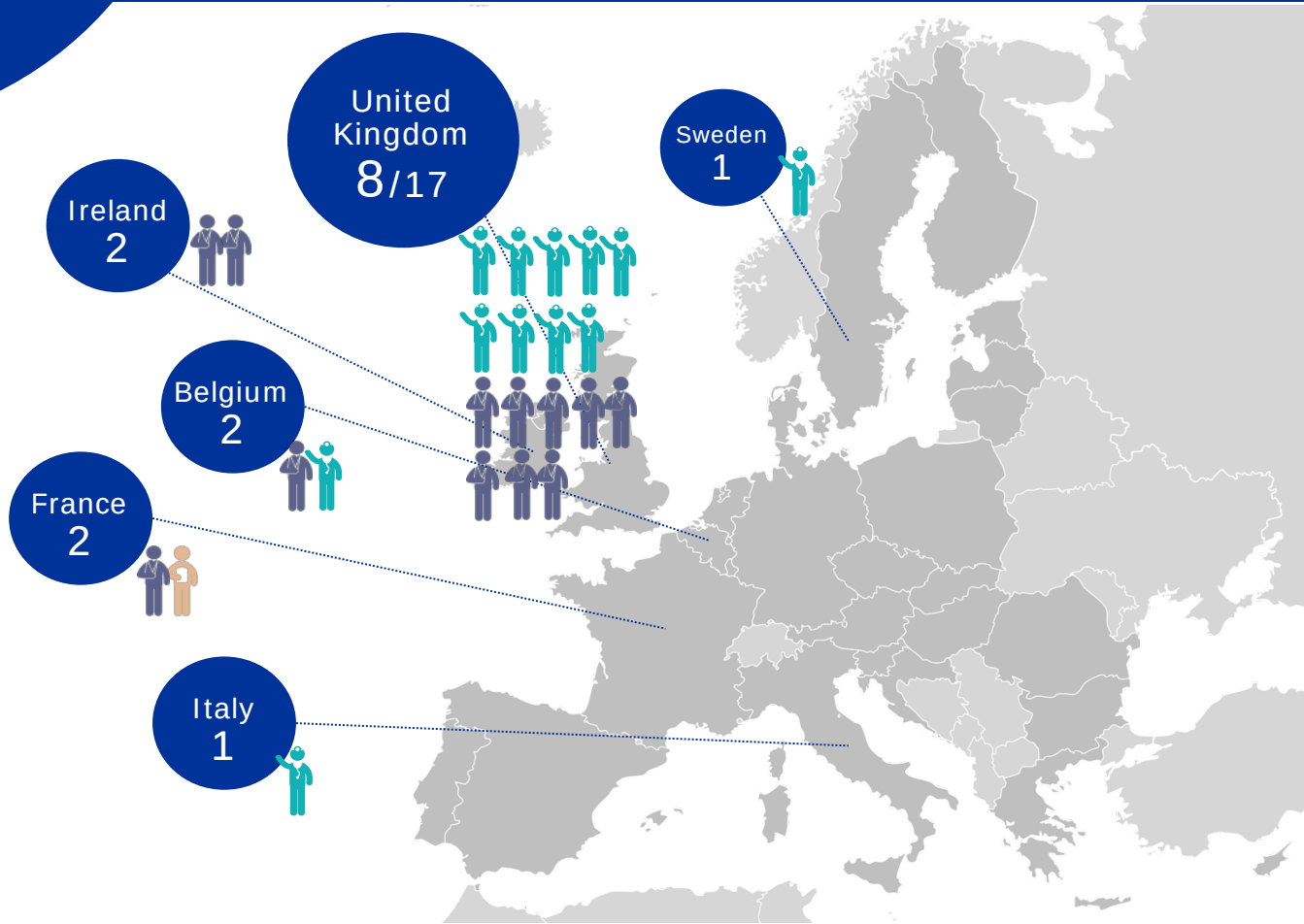
**32** speaker requests

**25** contributions selected, grouped in **16** **speaker slots**

amilies)

als

Pharmaceutical companies



# Observers

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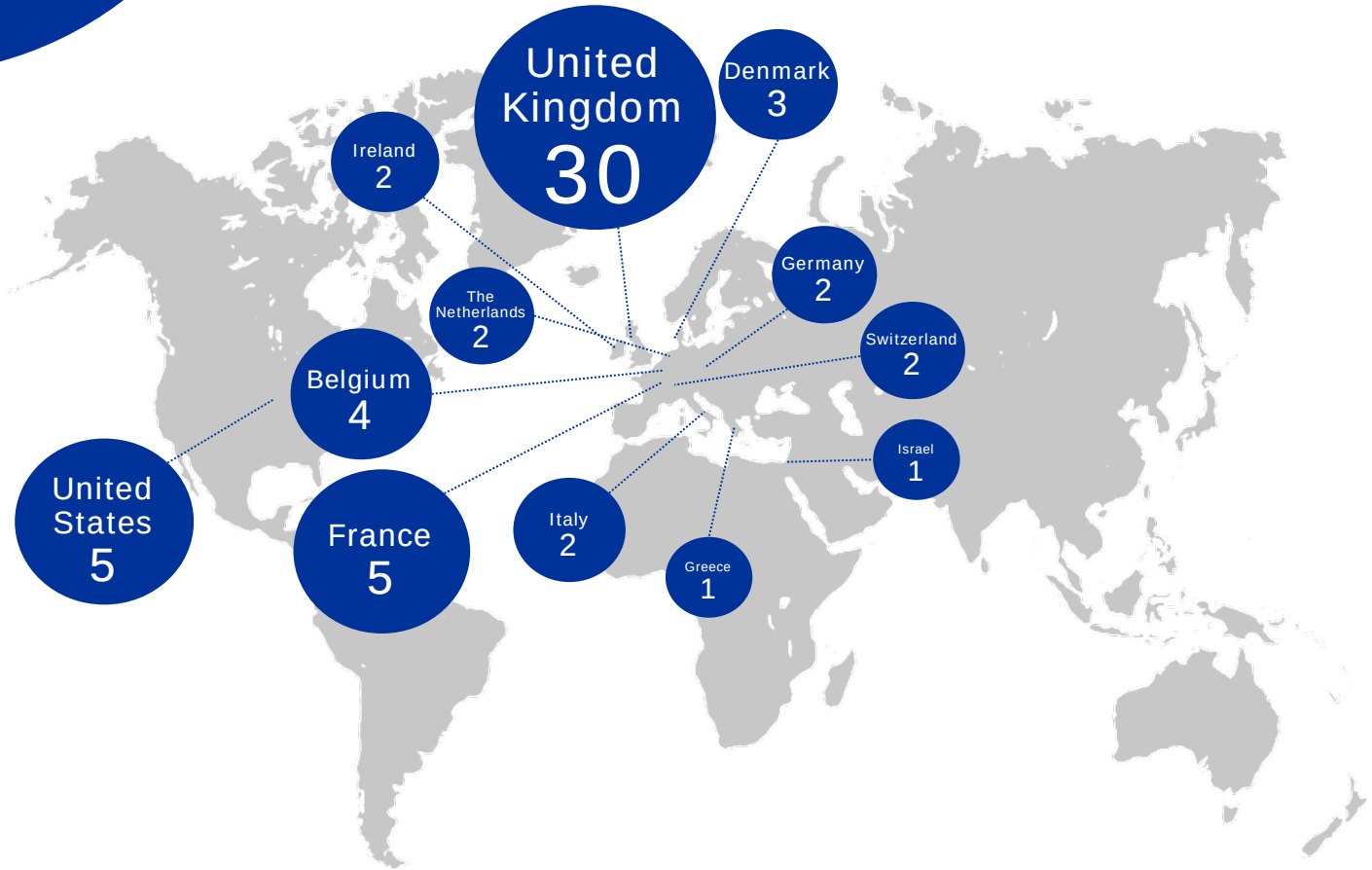

# 3

# CONDUCT

Chaired by PRAC chair

Broadcast live & recorded

# Agenda

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**Hearing duration: from 12:45 to 18:00**

| | | | | |
|---|---|---|---|---|
| Welcome & Introduction | Referral overview and background information on Valproate procedure | Speakers interventions (7 min each):<br>- Patients, carers & families<br>*Coffee break* | Speakers interventions (7 min each):<br>- Pharmaceutical companies<br>- Healthcare professionals & Academia | Wrap-up, summary of interventions & next steps |

# 4

# AFTER THE HEARING

Broadcast and Public summary published

Outcome will be integrated into the assessment report

Acknowledgement of the value of the contributions made by the public

# Conclusions

- A milestone in EU medicines regulation
- ‘Lessons learned’ exercise to be carried out

Initial feedback very positive :

- Well conducted with optimal timing
- Relevant and valuable contributions
- Better understanding of issues and options
- Lessons learnt report to be presented and published


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# Any questions?

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