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SCIENCE MEDICINES HEALTH

Update on public hearing

PCWP/HCPWP joint meeting

Presented by Juan Garcia Burgos on 20 September 2017
Head of Public Engagement Department


Valproate Public Hearing

A public hearing provides

- An opportunity for the **public to be heard** by the PRAC leading to a more rounded understanding by PRAC of the issue
- An opportunity for **stakeholders groups** to listen and to be heard by others
- An opportunity to show a **listening and engaged** regulatory system

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

1

ANNOUNCEMENT

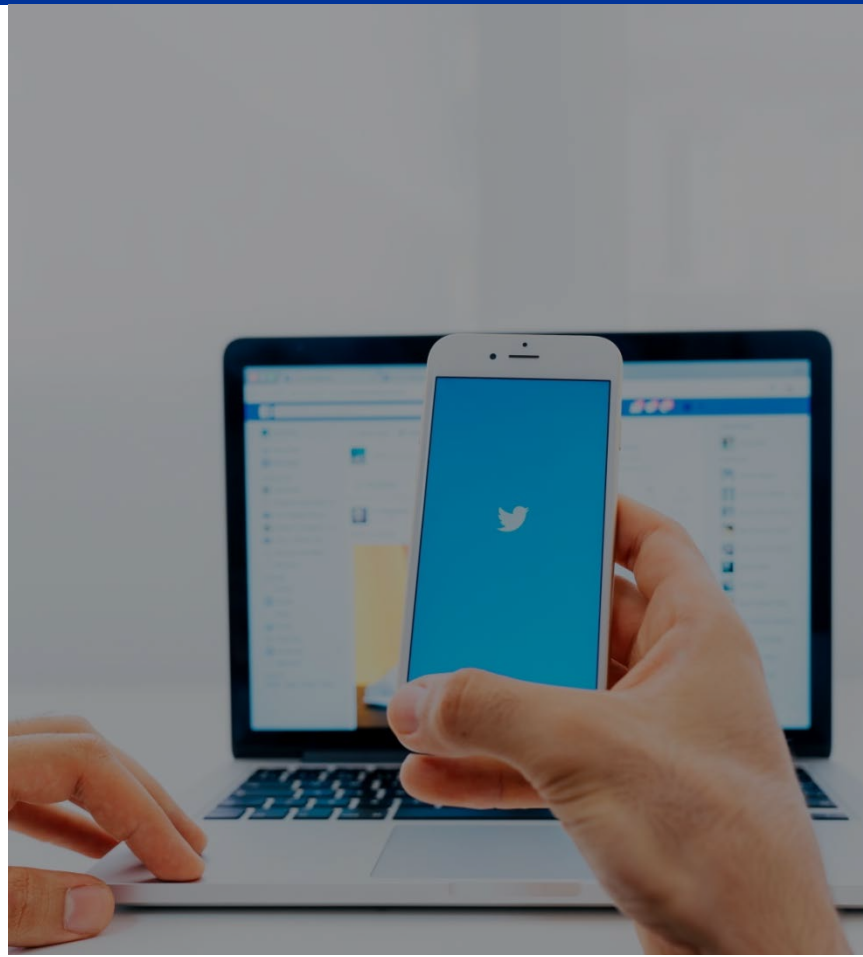
Date & time

Summary of issues & specific questions

Application form

Guidance & video

Announcement on EMA website & twitter



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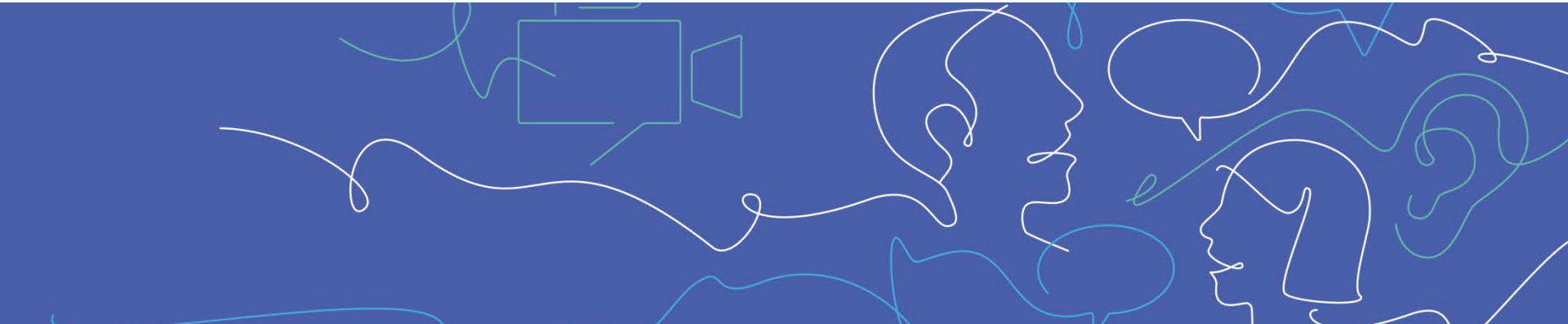
1st EMA Public Hearing: Valproate

To be held during the October PRAC meeting

Tuesday, 26 September 2017



Susac & LoQ adopted by PRAC

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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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

EMA/432817/2017

Question 1

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

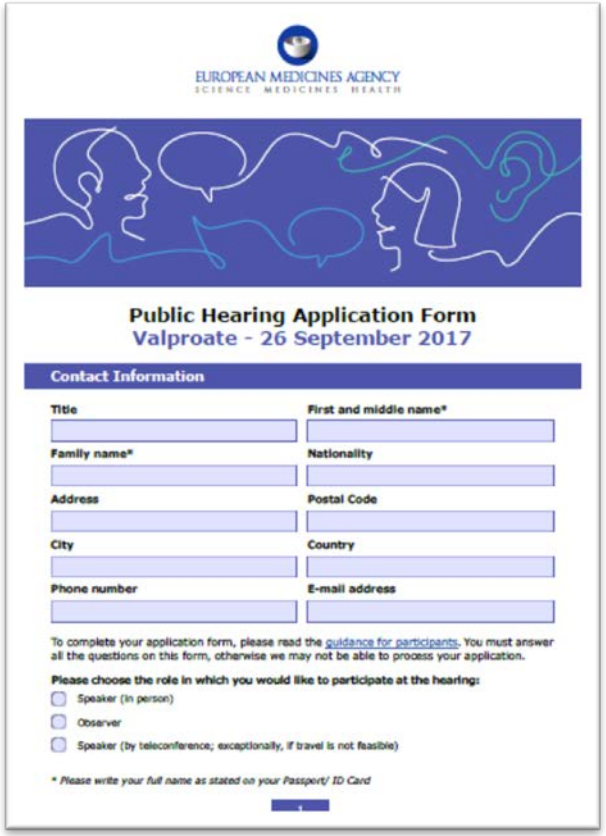
Question 2

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

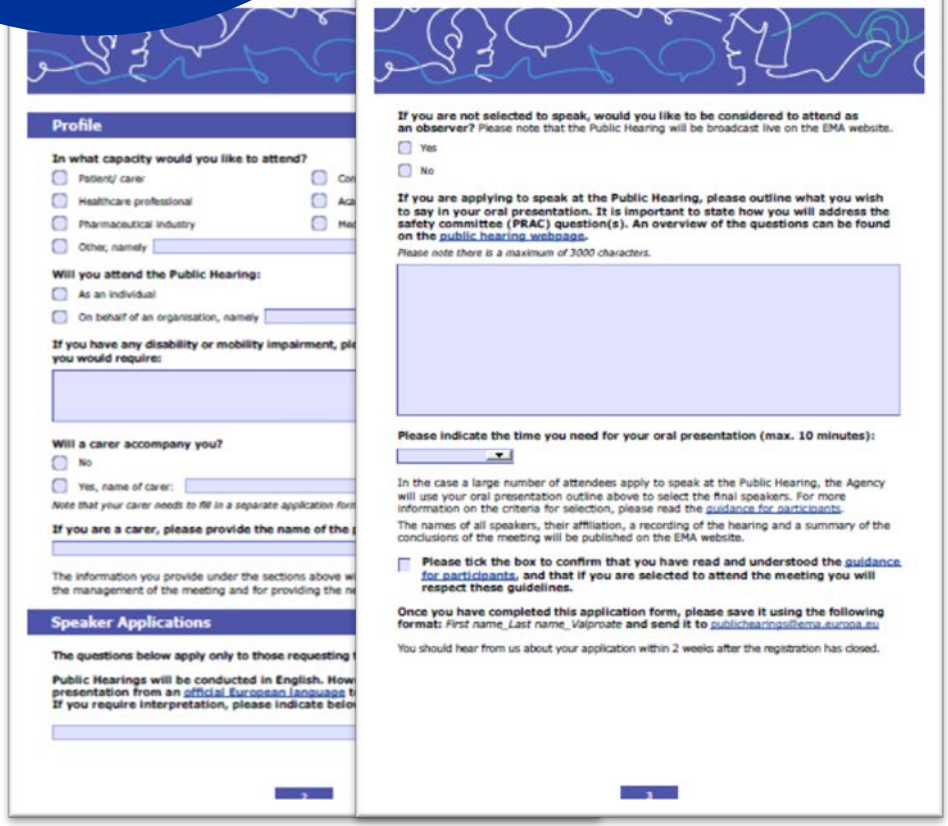
Title | First and middle name*
Family name* | Nationality
Address | Postal Code
City | Country
Phone number | E-mail address

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.

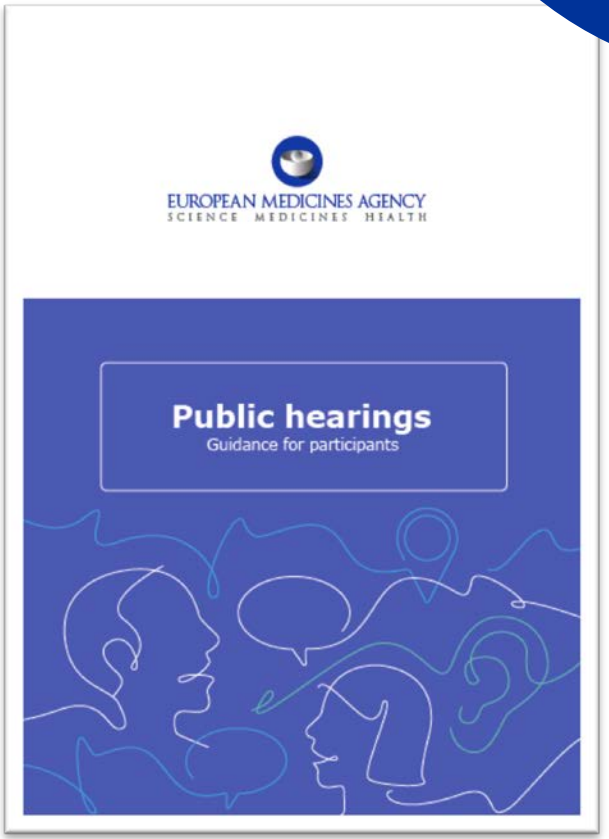
The names of all speakers, their affiliation, a recording of the hearing and a summary of the conclusions of the meeting will be published on the EMA website.

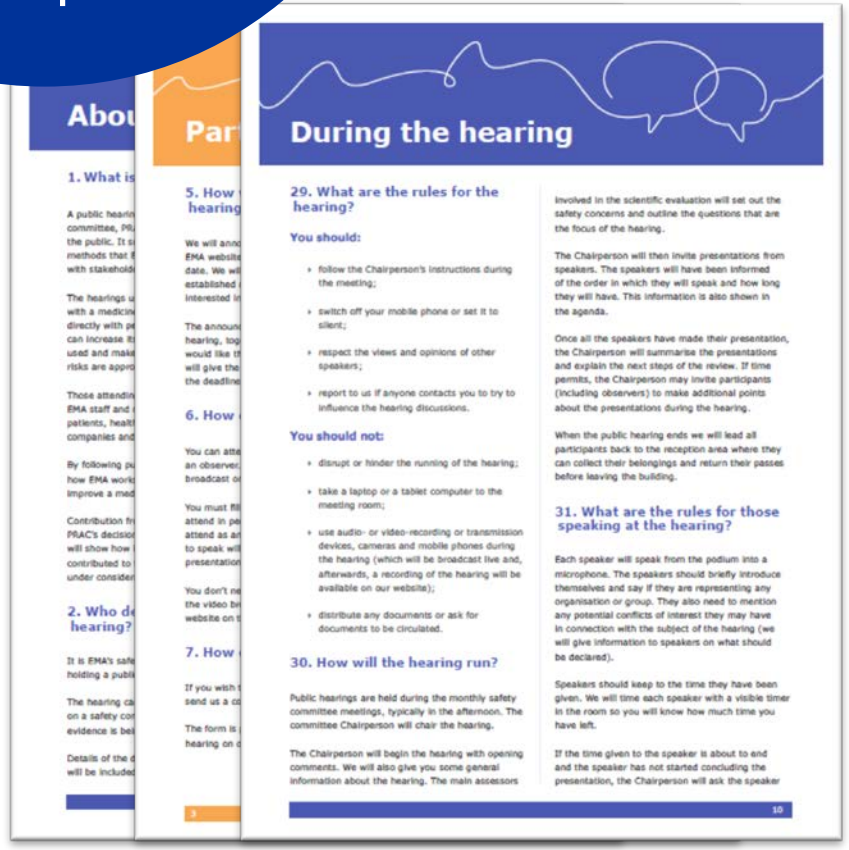
Please tick the box to confirm that you have read and understood the guidance for participants, and that if you are selected to attend the meeting you will respect these guidelines.

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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An agency of the European Union
0:05 / 2:57

Announcement website & twitter

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EMA seeks views of public during its safety review of valproate

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Press release

11/07/2017

EMA seeks views of public during its safety review of valproate

Registration opens for first public hearing

The European Medicines Agency (EMA) is inviting citizens to share their experience with valproate – a medicine that treats epilepsy, bipolar disorder and migraine – at its very first public hearing on **26 September 2017** at the Agency's offices in London.

The public hearing is part of a review by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) that looks at the safety of using valproate-containing medicines in women and girls who are pregnant or of childbearing age. There is a risk of malformations and neurodevelopmental problems in babies who are exposed to valproate in the womb, and the review follows concerns that EU-wide risk minimisation measures currently in place do not seem to be sufficiently effective.

"Patients are experts in their condition and we need to listen directly to what they have to say so their experience can be reflected in our scientific evaluation. This adds to our already existing initiatives to include patients in our work, such as our Patients' and Consumers' Working Party," says Guido Rasi, Executive Director of the European Medicines Agency.

Related content

- Public hearings
- Valproate and related substances
- Pharmacovigilance Risk Assessment Committee (PRAC)

Related documents

- Summary of safety concerns and list of questions for the public hearing on Valproate (11/07/2017)
- Public Hearing - Guidance for participants (11/07/2017)
- Public hearing application form (11/07/2017)

Video: public hearings at EMA

Dissemination

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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)

EMA website

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Valproate and related substances

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Summary | Key facts | Public hearing | All documents

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will hold a public hearing on this topic on **26 September 2017** at the Agency's premises in London. The hearing will be **broadcast live** on 26 September 2017 on EMA's website.

To view the broadcast please ensure you meet the YouTube requirements.

To view the video in the highest quality, click on the 'Settings' symbol in the right-hand corner of the video player on the YouTube page and select '720p' or a higher resolution.

At the public hearing, the PRAC will seek input on a **list of specific questions**. These are set out in the document below, together with a summary of the safety concerns with this medicine:

- Summary of safety concerns and list of questions for the public hearing on valproate

The application deadline to take part in the public hearing was 25 August 2017. EMA will write to all applicants within two weeks after the deadline to confirm whether they can attend.

Current status: Under evaluation

Live broadcast

- 26 September 2017
  12:45-18:00 UK time

The PRAC will hold a public hearing on this topic on 26 September 2017.

To watch the broadcast click on 'Public hearing' tab.

News

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 July 2017 (07/07/2017)
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 June 2017 (09/06/2017)
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 March 2017 (10/03/2017)

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Public hearings

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Public hearings are a new tool allowing the European Medicines Agency (EMA) to engage with European Union (EU) citizens in the supervision of medicines and listen to their views and experiences.

The EU's pharmacovigilance legislation enables the Pharmacovigilance Risk Assessment Committee (PRAC) to hold public hearings during certain **safety reviews of medicines**. They support the committee's decision-making by providing perspectives, knowledge and insights into the way medicines are used.

Public hearing on valproate-containing medicines (updated)

EMA will hold a public hearing on valproate and related substances on **26 September 2017** at the Agency's premises in London.

The hearing will be **broadcast live** on EMA's website from 12:45 to 18:00 UK time on 26 September. To watch the live broadcast, see: PRAC: 25-28 September 2017.

For more information, including the summary of safety concerns and list of specific questions for this public hearing, see Valproate and related substances.

Key objectives and benefits

Public hearings are expected to **give EU citizens a voice** in the evaluation of the safety of medicines and empower them to express their views on issues related to the safety of certain medicines and the management of risks.

Increase transparency by opening up the scientific evaluation process

Empower EU citizens by giving them a voice in the evaluation of the safety of medicines

Related content

- Pharmacovigilance Risk Assessment Committee (PRAC)
- Pharmacovigilance
- Implementation of the pharmacovigilance legislation
- Referral procedures
- Listening to the public's views on the safety of medicines (14/4/2016)

Related EU legislation

- Regulation (EC) 726/2004
- Directive 2001/83/EC

Video: public hearings at EMA

Guidance for participants

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

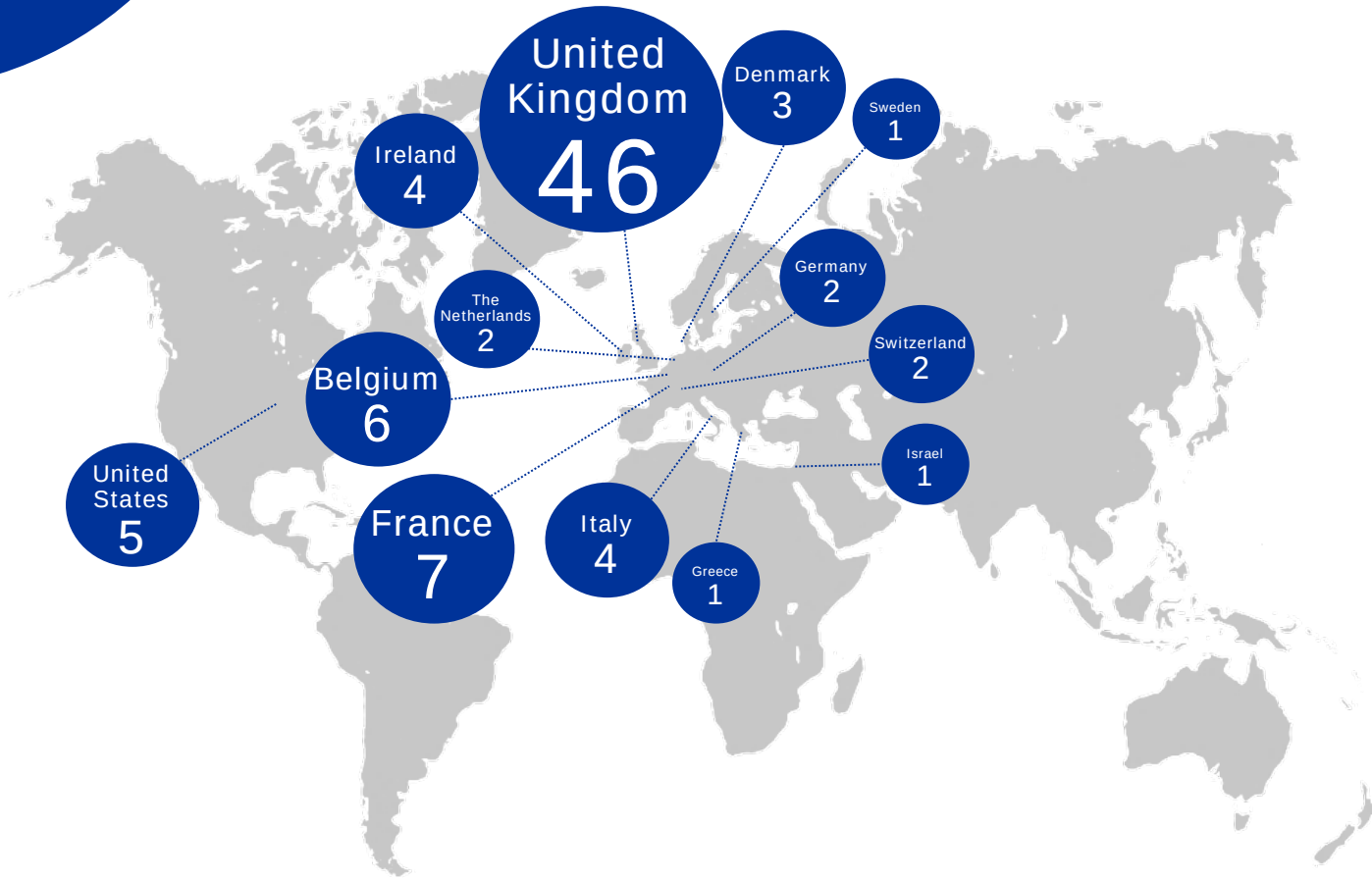
Criteria for selection

- Very focused contributions
- 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)

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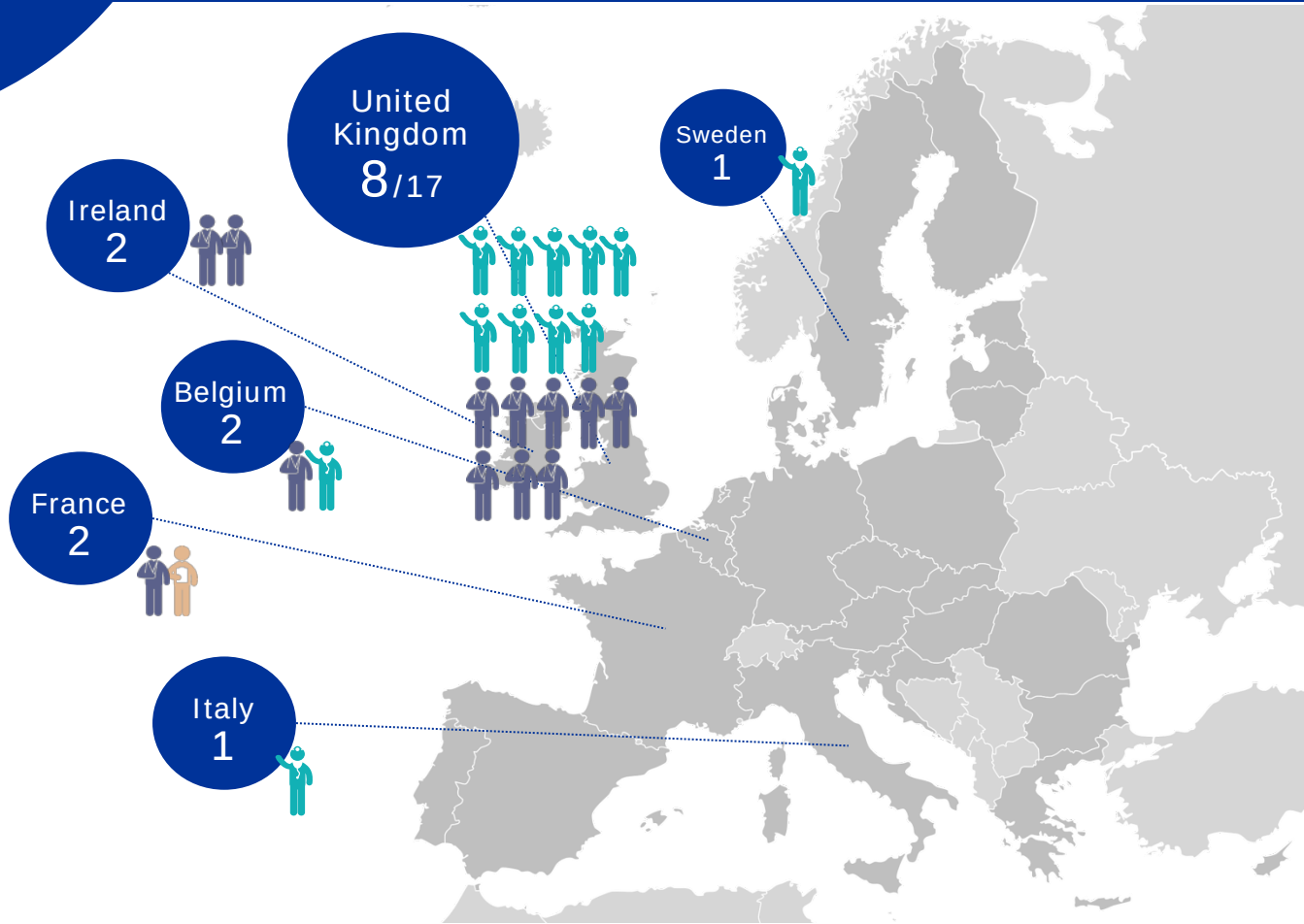
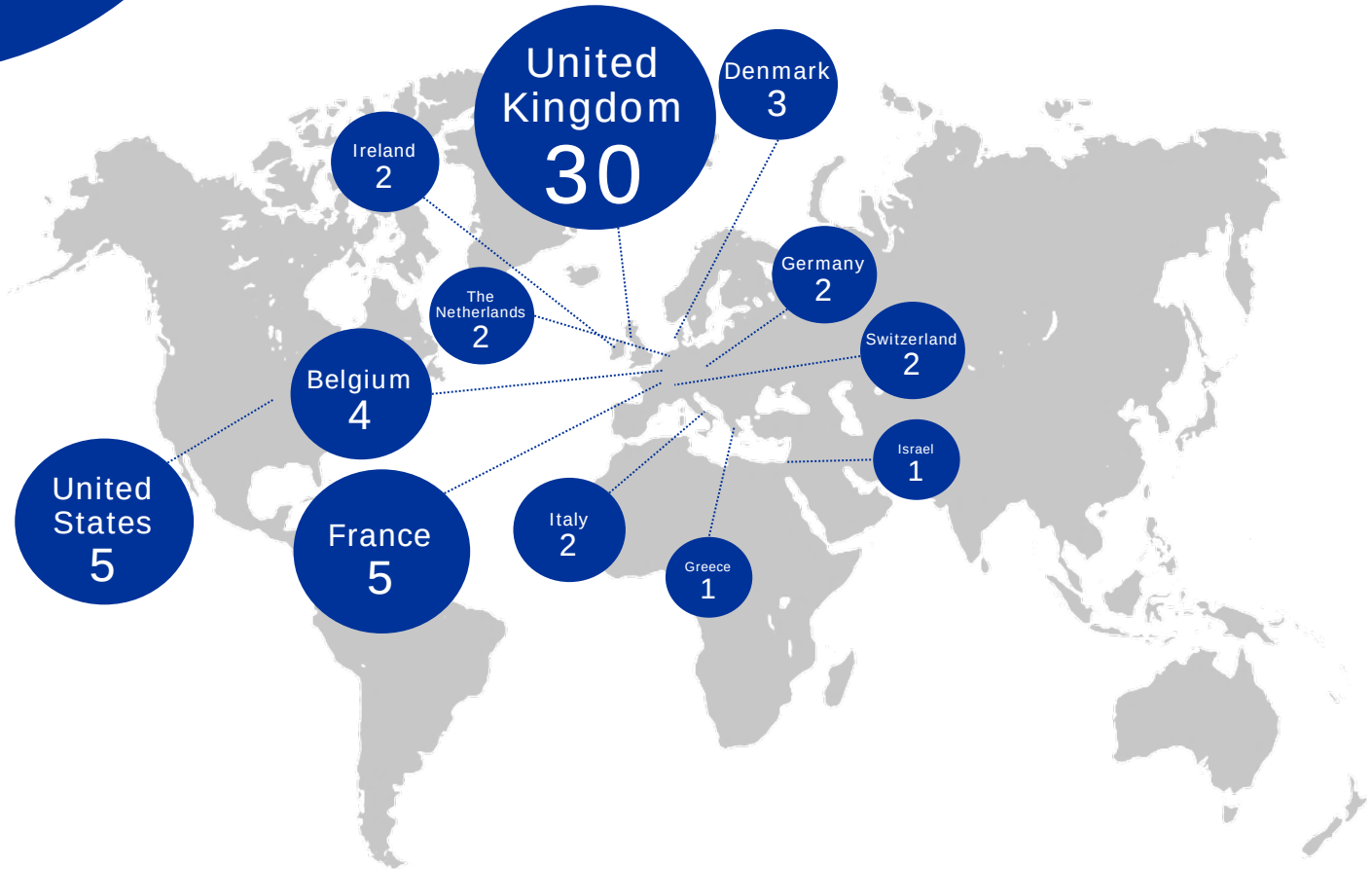
Pharmaceutical companies



Observers

59



3

CONDUCT

Chaired by PRAC chair

Rapporteurs overview

Speakers interventions

Summary & wrap-up

Broadcast live & recorded

Agenda

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Hearing duration: from 12:45 to 18:00

Welcome & Introduction	Referral overview, public hearing rules and background information on Valproate procedure	Speakers interventions (7 min per intervention): - Patients, carers & families *Coffee break*	Speakers interventions (7 min per intervention): - Pharmaceutical companies - Healthcare professionals & Academia	Wrap-up, summary of interventions & next steps

4

AFTER THE HEARING

Broadcast available online

Public summary to be published

Outcome to be integrated into the assessment report

Acknowledgement of the value of the contributions made by the public

Conclusion

- A milestone in EU medicines regulation
- A major step towards openness and transparency
- Need to make it valuable:
  - For the assessment
  - For the public
- Measure impact – ‘lessons learned’ exercise in 2017

Any questions?

Further information

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