



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How patients and healthcare professionals can be involved in public hearings

Eleventh Stakeholders forum on pharmacovigilance legislation

Presented by Juan Garcia Burgos on 21 September 2017
Head of Public Engagement Department

An agency of the European Union



Public hearings

The image features a blurred background of a public hearing or town hall meeting, with rows of people seated in an auditorium. A large, dark, mesh-covered microphone is positioned in the foreground, slightly to the right of the center. A large, thin white circle is superimposed over the image, framing the text and the microphone. A smaller, thin white circle is centered on the microphone's mesh head.

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



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

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

At the start of each referral, PRAC **consider need to hold a public hearing** (can also decide later), based on:

1

Feasibility in light of urgency of matter

2

Nature and extent of safety concern

3

Therapeutic effect of medicine and availability of alternatives

4

Potential impact of regulatory actions

5

Level of public interest



CONDUCTED IN ENGLISH

If speakers unable to present in English,
EMA can provide translation

A microphone is positioned in the center-right of the frame, its silver mesh grille clearly visible. The background is a blurred indoor setting, likely a public hearing room, with rows of wooden tables and chairs. People are seated at the tables, but they are out of focus. The lighting is warm and ambient. A large, thin white circle is superimposed over the image, centered on the microphone and the text.

Valproate Public Hearing

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

PRAC decision to hold public hearing



EUROPEAN MEDICINES AGENCY

Valproate and related substances

Summary

Key facts

Public hearing

All documents



New review of valproate use in pregnancy and women of childbearing age

EMA to consider if risks of these medicines require further restrictions of use

The European Medicines Agency (EMA) has started a review looking at the use of valproate-containing medicines in the treatment of women and girls who are pregnant or of childbearing age. These medicines are approved nationally in the EU to treat epilepsy, bipolar disorder and in some countries, migraine, and have been previously reviewed by the Agency.

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action should be recommended to minimise the risks in women who are pregnant or of childbearing age.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will examine the available evidence and will consult with relevant stakeholder groups. This will include holding a public hearing about their concerns. While the review is ongoing, patients prescribed valproate who have any concerns about their medication should discuss them with their healthcare professionals.

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A professional microphone with a silver mesh grille is positioned in the center of the frame. The background is a blurred indoor setting, likely a public hearing room, with rows of wooden desks and people seated in the distance. A large, thin white circle is superimposed over the image, centered on the microphone. The text "Organisation of a public hearing" is written in a bold, white, sans-serif font across the middle of the image, partially overlapping the microphone and the background.

Organisation of a public hearing



1

ANNOUNCEMENT

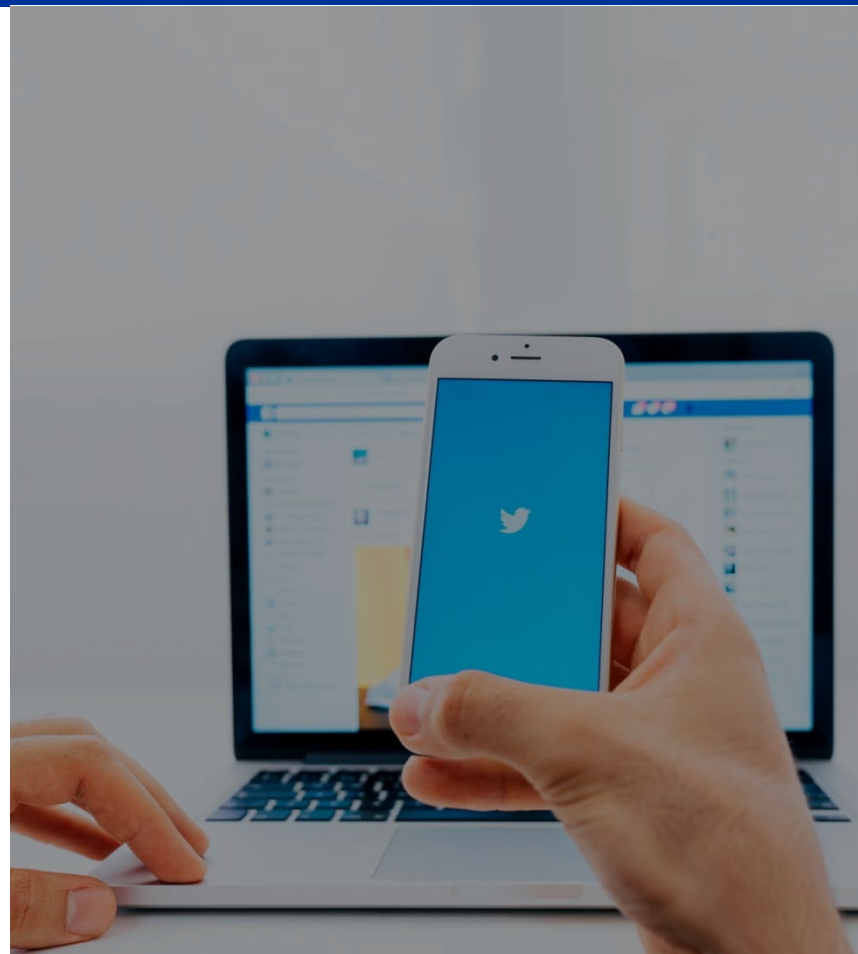
Date & time

Summary of issues & specific questions

Application form

Guidance & video

Announcement on EMA website & twitter



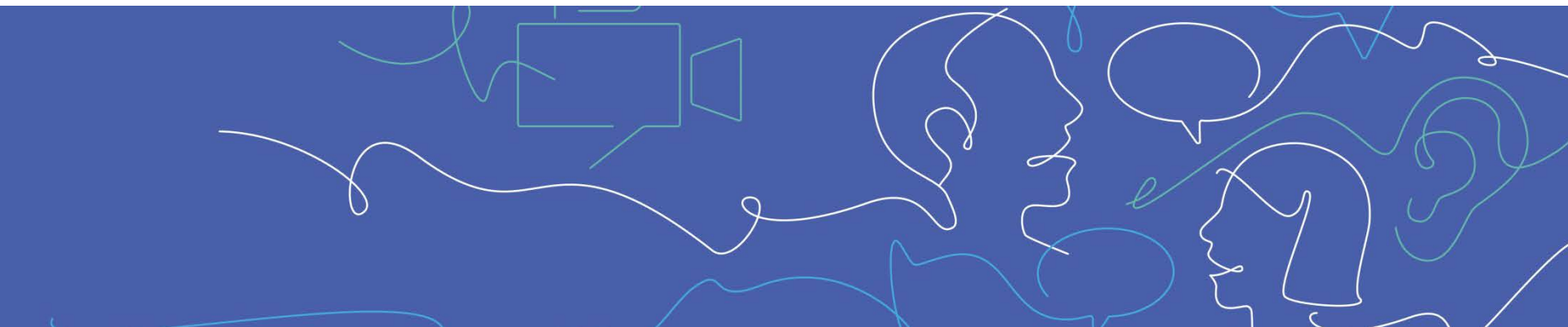


EUROPEAN MEDICINES AGENCY

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 substances¹ (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, Dilepsine, Depakin, Depakine, Depakote, Depamau, Depamide, Depakine, Diplexil, Dipromal, Epilim, Epionta, Epival, Ergenyl, Epso-Valept, Hexaquin, Kentim, Lepitan, Micropakine L-P, Orfil, Peltin, Valept, Valhel PR, Valpak, Valpro and Valprotek.



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

1



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, please indicate how you would require:

Will a carer accompany you?

☐ No

☐ Yes, name of carer:

Note that your carer needs to fill in a separate application form

If you are a carer, please provide the name of the person you are caring for:

The information you provide under the sections above will be used for the management of the meeting and for providing the hearing with the names of the attendees.

Speaker Applications

The questions below apply only to those requesting to speak.

Public Hearings will be conducted in English. However, if you require interpretation, please indicate below:

2



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 publichearings@ema.europa.eu

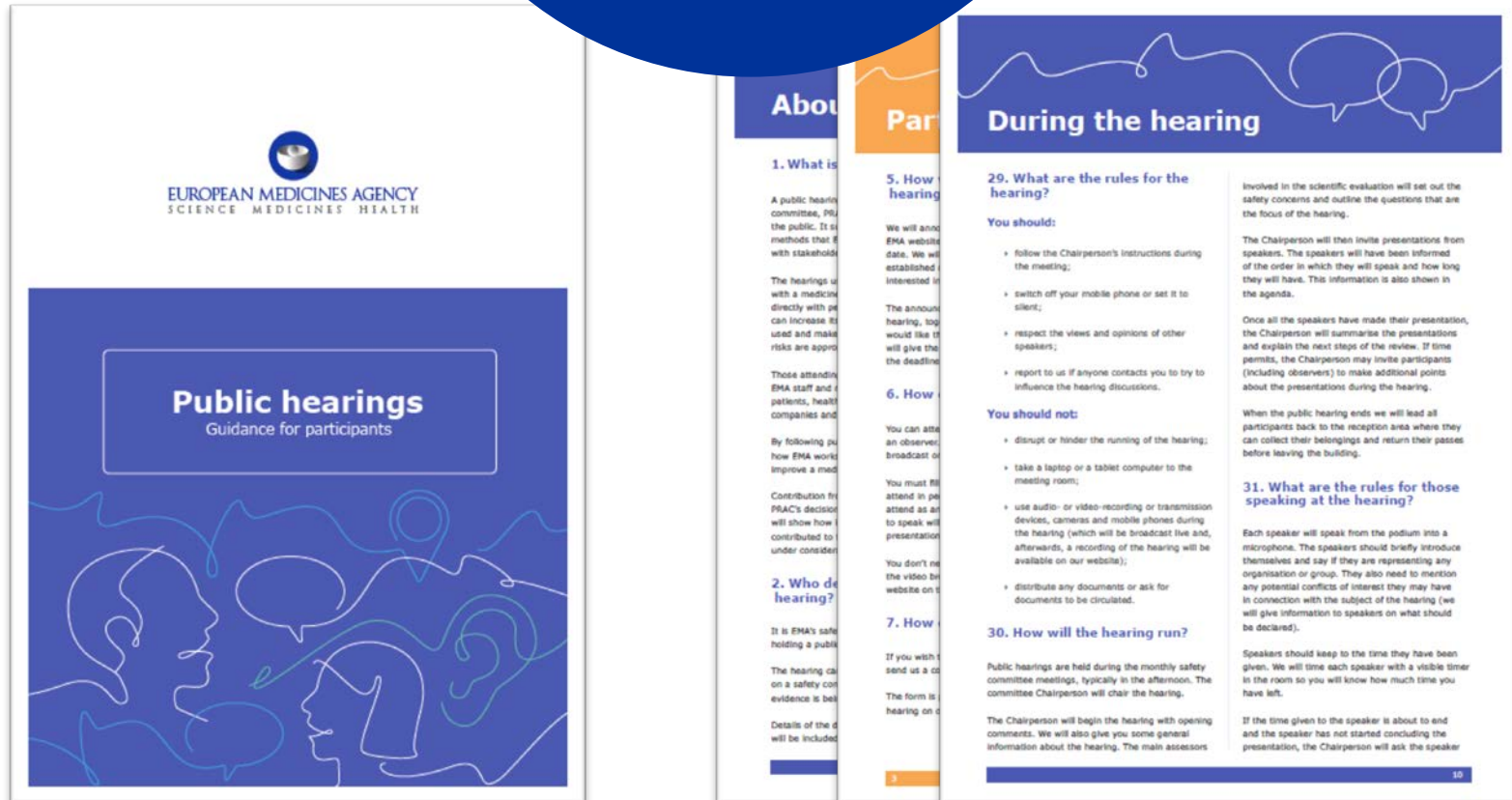
You should hear from us about your application within 2 weeks after the registration has closed.

3

Guidance for participants



EUROPEAN MEDICINES AGENCY



Video



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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

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)



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- Medicines for use outside the EU

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- Combined hormonal contraceptives
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- Shortages catalogue
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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.

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



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

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

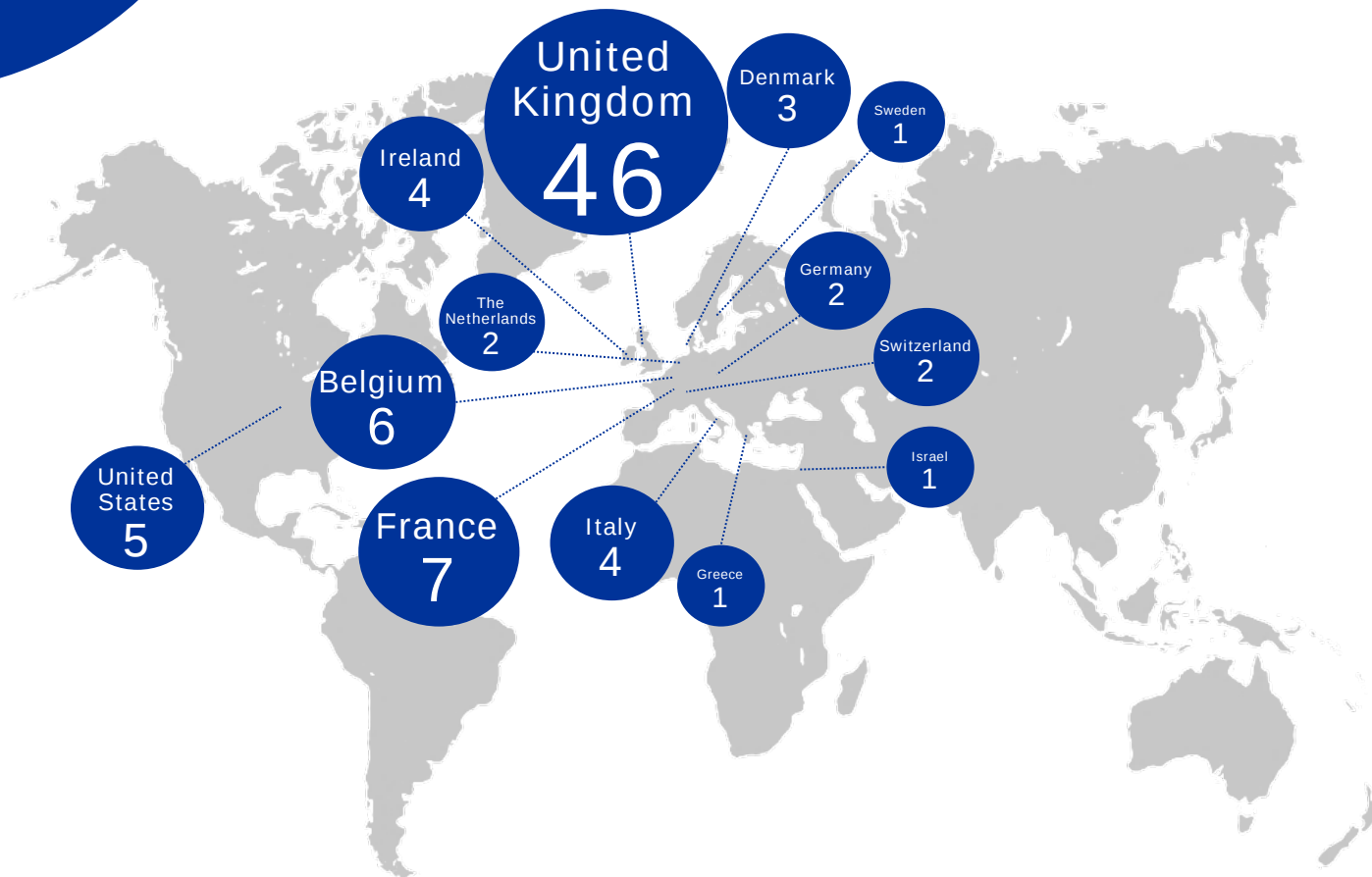
Discipline

Geographical
distribution



Participants

84





Speakers

32

speaker requests

25

contributions selected, grouped in

16

speaker slots

(families)

als

Pharmaceutical companies

Ireland
2

Belgium
2

France
2

Italy
1

United Kingdom
8/17

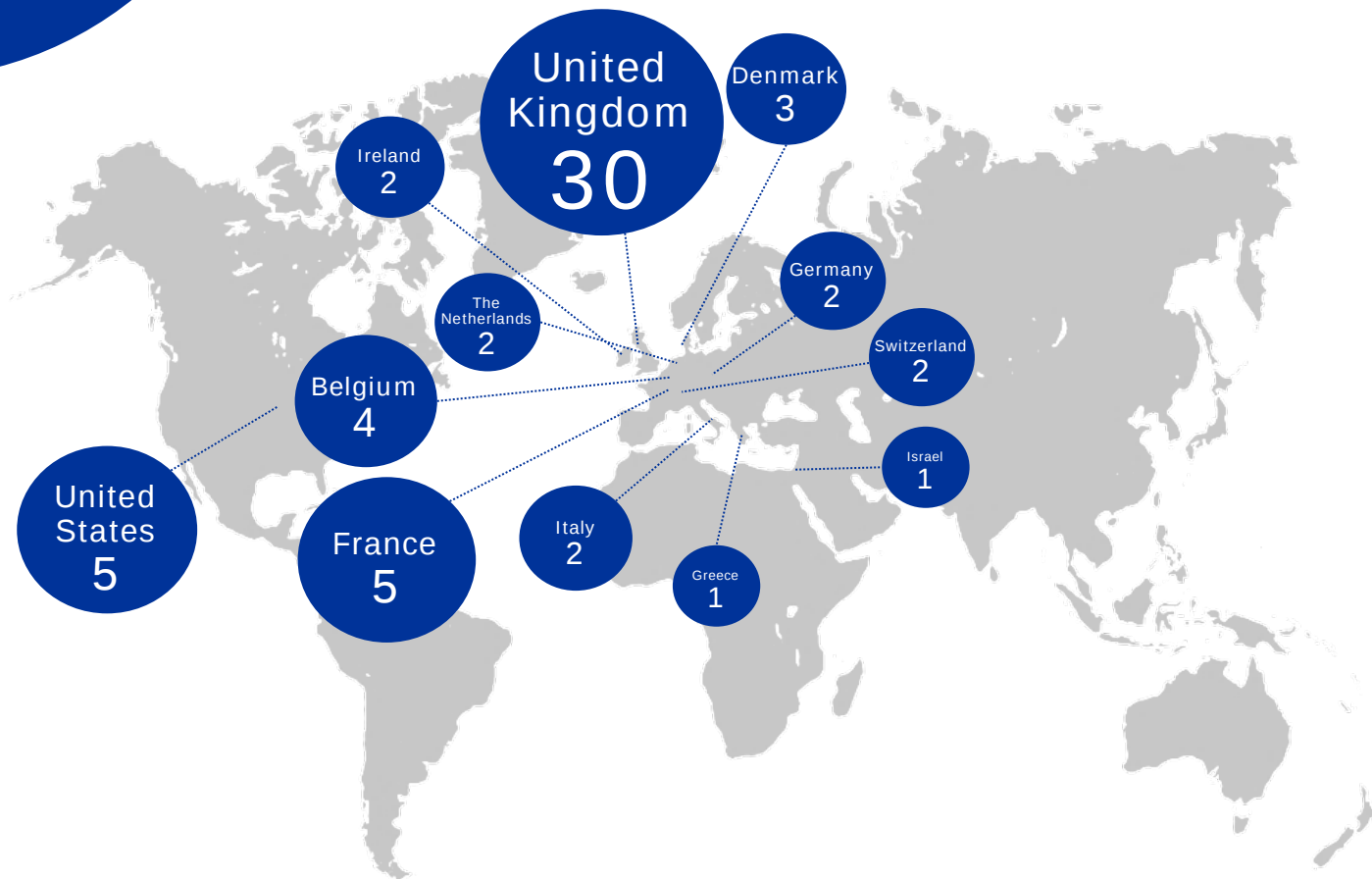
Sweden
1





Observers

59





3

CONDUCT

Chaired by PRAC chair

Rapporteurs overview

Speakers interventions

Summary & wrap-up

Broadcast live & recorded





Agenda

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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