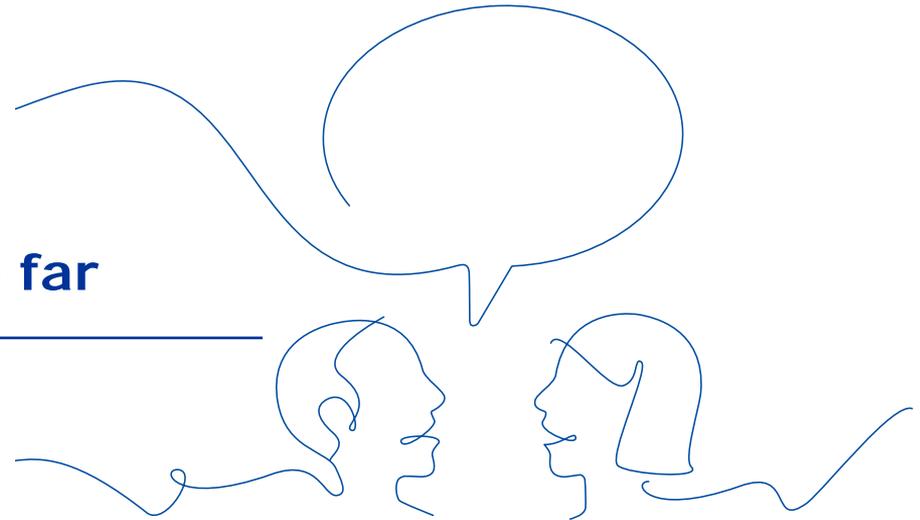




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Hearings; experience so far

Valproate / Quinolones



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Public Engagement Department, Stakeholders & Communication Division





- The PRAC can convene public hearings during safety referral procedures falling under **Article 20** of Regulation (EC) 726/2004 or **Articles 31 and 107i** of Directive 2001/83/EC
- A public hearing is a **way for PRAC to gain input and insights** from the public, supplementing other methods that EMA already uses for engaging with stakeholders
- **Anyone can apply to attend** a public hearing; as observer or speaker
- **Broadcast live**
- Half day meeting

1st Public hearing Valproate

26 September 2017

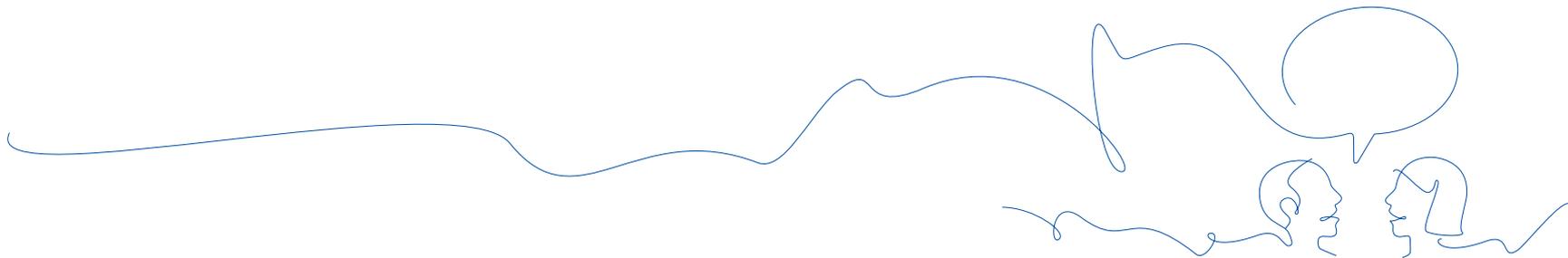
Getting input from the public on measures to reduce the risks of valproate medicines in pregnancy.

89 Applications received; 32 speakers / 57 observers
25 speaker selected within 16 speaker slots, 5 EU countries represented



Impact on the assessment and added value

- **Consultations** with patients and health professionals at **core of valproate safety review**
- Hearing helped to **identify the real problems** in clinical practice and for patients using Valproate
- Provided **valuable insights and information** which otherwise would have not been provided
- Contribution **shaped** subsequent **assessment** and identified the **questions for the stakeholder meeting** and **written consultation**





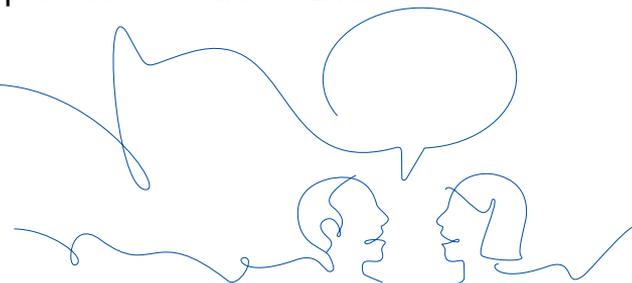
Impact on the assessment and added value

Public hearing identified **important themes** and **information**:

- Lack of communication of the risks to women being treated
- The need for a visual warning on the outer packaging
- The need for regular reviews for all women treated

Input used for recommending **new measures**:

- Further restrictions on the use of valproate in women
- New pregnancy prevention programme
- New risk acknowledgement form / guide for prescribers / patient booklet / DHPC
- Visual warning on the outer packaging



Participant Feedback

Direct feedback gathered via survey from those involved

43/65 (66%) Public participants responded
35/37 (95%) PRAC members responded



Overall feedback from all parties shows first hearing was **successful**

95%

of participants felt that the hearing
'was well conducted'

88%

of participants said they felt the public hearing
***'would make a difference to the Committee
recommendations'***

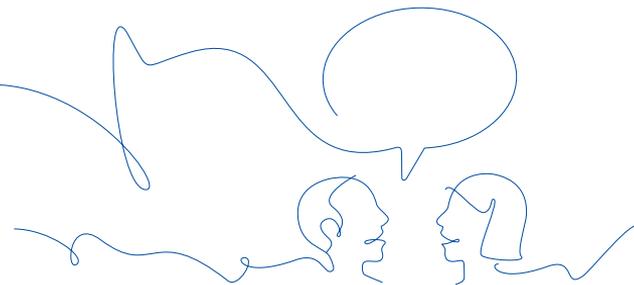
79%

of PRAC members said it would
***'make a difference to the assessment of
Valproate'***



Recommendations moving forward

- Similar **approach** and **structure** recommended
- **Individual assistance** - critical element for a successful public hearing
- **Guidance (documents/video)** vital for participants
- **Grouping** of similar interventions to maximise participation of speakers
- **Short and clear introductions**; allocate **majority of time to speakers** (7 mins each ideal)
- Questions for **clarification** from PRAC after each intervention
- Allowing **spontaneous public interventions** at the end





Limitations

Representation of participants;

UK / epilepsy focused

Need to **improve outreach** via the networks

(Dependent on the **level of interest and availability** of individuals /organisations)



Public hearing

Quinolone and Fluoroquinolone medicines

13 June 2018

Getting input from the public to better understand and manage serious and persistent side effects with these antibiotics

120 Applications (55 speakers / 65 observers)

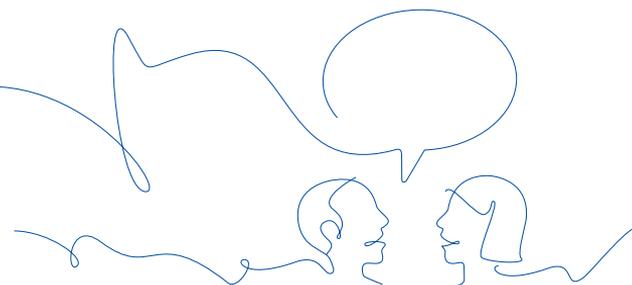
23 speakers selected, within 21 speaker slots, from 11 EU MS



Quinolone/fluoroquinolone Public hearing; outcome

Important information/themes raised:

- Symptoms life-changing and wide ranging
- Patients not given enough information about risks
- Healthcare professionals generally unaware of range and severity of possible symptoms (except Achilles tendon disorders)
 - Input shaped questions for subsequent expert meetings





Added value for ongoing assessment

Proposals gathered during the hearing:

- Restrict use
- Improve education for healthcare professionals
- Improve communication on toxicity; more information in the product information
- Improve management of side effects
- Encourage further research on cause of side effects
- Consider how certain foods affect patients' symptoms



Feedback

Direct feedback gathered via survey from those involved



Qualitative feedback (from both hearings)

"It was a **very good experience** in every way. Left us **feeling very confident** that **something will be done** to prevent anyone else suffering from these life changing permanent side effects. "

"I was very impressed by the **organisation** surrounding the meeting. The **conduct** of the meeting was **excellent**, and the **Committee members were engaged, sympathetic and understanding.**"

"**Very impressed by the openness** - despite the complexity of the subject - of the PRAC and willingness to hear on this topic."

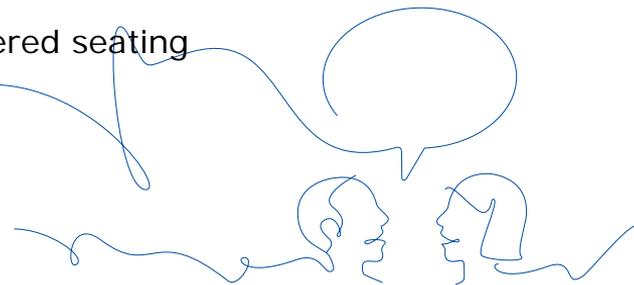
"It's important to take into account that **single personal experiences** can help to show up relevant issues but should be rightly weighed in the overall assessment from statistical point of view."

Overall conclusions

Public hearings **add value** to, and **improve quality** of, assessments;

- lead to better safety recommendations; in line with real needs of patients and healthcare professionals as identified during hearings
- allows different stakeholders to listen to and learn from each other
- increases overall transparency and understanding of regulatory procedures in Europe
- Organisational aspects – successful – learning through experience
- Resource intensive tool - decision to hold a hearing needs to be well balanced

Explore options for improved room set up in new EMA building, e.g. tiered seating





Any questions?

Further information

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