26 September 2017
EMA/630591/2017
Media and Public Relations

Press release

EMA's first public hearing: giving EU citizens a voice to help reduce the risk of valproate

Live broadcast on 26 September from 12:45 to 18:00 UK time

European citizens representing patients, carers, healthcare professionals and academia will share today their experience with valproate – a medicine that treats epilepsy, bipolar disorder and migraine – at the first public hearing ever held by the European Medicines Agency (EMA) at its offices in London.

The public hearing is part of a review of the safety of using valproate-containing medicines in women and girls who are pregnant or of childbearing age by EMA's Pharmacovigilance Risk Assessment Committee (PRAC). 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.

During the public hearing, speakers from six EU Member States will share their experience directly with the members of the PRAC. There are a total of 25 speaker contributions, grouped into 16 speaker slots, as highlighted in the agenda of the event. An additional number of individuals will attend the hearing as observers, making a total of 84 participants. To ensure that as many people as possible have a chance to share their experience with the PRAC, the speakers were allocated maximum seven minutes to address three specific questions where the Committee needs their input:

- What are their views of the risks of taking valproate during pregnancy, including its potential effect on the child?
- What are their views on the measures currently in place to reduce the risks of using valproate during pregnancy?
- What other measures should be taken to reduce the risks of using valproate during pregnancy?

The input received during the hearing on these three questions will be incorporated into the on-going assessment on valproate and will be used to finalise it.

Giving EU citizens a voice in the evaluation of medicines will enrich the available scientific evidence and add value to the PRAC assessment.

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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's expert meetings during safety reviews.

The hearing will be broadcast live on EMA's website (the 'Public hearing' tab) from 12:45 to 18:00 UK time on 26 September 2017.

Practical information on EMA's public hearings is available in a video and the Guidance for public participants, which explains what to expect from a public hearing, how to register and how EMA selected the speakers.

The agenda of the public hearing and the list of participants are now available.

If additional information is needed, interested citizens can send an email to publichearings@ema.europa.eu.

Notes

- The review of valproate was initiated on 9 March 2017 at the request of the French medicines regulator ANSM, under Article 31 of Directive 2001/83/EC.
- The review will be carried out by the Pharmacovigilance Risk Assessment Committee(PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make recommendations. The PRAC recommendations will then be sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.
- The public hearing follows the adoption of rules of procedure on the organisation and conduct of public hearings and a simulation training in 2016.

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