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Media and Public Relations

Press release

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.

Hearing directly from EU citizens who have experience with valproate, whether they are patients, affected families, doctors or researchers, will enrich the available scientific evidence.

During the public hearing, people can make their voice heard by sharing their experience directly with the members of the PRAC. Their contributions will be taken into account in the committee's safety review and will help the PRAC to better understand public awareness of the risks and develop measures to reduce these risks. To ensure that the public interventions are as useful as possible, the PRAC has put together a list of three questions to be answered by the speakers.

Those interested in participating in the public hearing, either as speaker or as observer, should submit an **application form** to EMA, no later than **25 August 2017**.

EMA will review the applications and select speakers based on their experience with valproate-containing medicines and the way they plan to address the questions (a short description needs to be provided in the application form). The selection will also seek to reflect an appropriate representation of all groups of stakeholders, with a focus on patients and practitioners.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

EMA will try to accommodate as many people as possible. For those who cannot attend in person, the hearing will be **broadcast** live on EMA's website.

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 selects speakers.

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

Notes

1. This press release, together with the application form, the list of questions for speakers, an explanatory video and the guidance for public participants, is available on the Agency's website.
2. 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.
3. 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.
4. The public hearing follows the adoption of rules of procedure on the organisation and conduct of public hearings and a simulation training in 2016.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News