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, Kentlim, Leptilan, Micropakine L.P., Orfiril, Petilin, Valepil, Valhel PR, Valpal, Valpro and Valprolek

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EMA/432817/2017

Questions for the public hearing on valproate

Based on your experience with valproate treatment during pregnancy:

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?