Medicines & Healthcare products Regulatory Agency

MHRA

Ms Joanna Wood
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Independent Medicines and Medical Devices Safety Review
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Dear Ms Wood

Thank you for your letter of 24 May providing the opportunity to respond to the transcript of the oral hearing with the All-Party Parliamentary Group for Valproate and Other Anti-Epileptic Drugs.

The safety of all antiepileptics is continually monitored and any new evidence to emerge from spontaneous reporting, observational studies or registries is reviewed to see if it has an impact on the balance of risks and benefits of these medicines.

Keppra (levetiracetam) was subject to an European-wide review of the data from the North American Antiepileptic Drugs Pregnancy Registry (NAAPR), European Registry of AEDs and Pregnancy (EURAP), and UCB AED Pregnancy Registry, which finished in 2018 and led to the following text being added to the Summary of Product Characteristics:

'Pregnancy

A large amount of post-marketing data on pregnant women exposed to levetiracetam monotherapy (more than 1800, among which more than 1500 exposures occurred during the 1st trimester) do not suggest an increase in the risk for major congenital malformations. Only limited evidence is available on the neurodevelopment of children exposed to Keppra monotherapy in utero. However, current epidemiological studies (on about 100 children) do not suggest an increased risk of neurodevelopmental disorders or delays.

Levetiracetam can be used during pregnancy, if after careful assessment it is considered clinically needed. In such case, the lowest effective dose is recommended.'

We addressed the issue of topiramate in our response to the transcript of Dr Morrow's oral evidence (attached for convenience). As mentioned in that response we will be consulting the Commission on Human Medicines on an overall review of the available evidence on the risks of all antiepileptics in pregnancy.

Yours sincerely

Dr June Raine
Director – Vigilance and Risk Management of Medicines

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