



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
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Circular 006 / 18

6th March 2018

Dear Pharmacist,

Please find enclosed a letter from Dr David Hanlon, National Clinical Advisor and Group Lead Primary Care in respect of an important patient safety matter.

Your cooperation with this important HSE initiative is appreciated.

Yours faithfully,

A handwritten signature in black ink, reading 'Anne Marie Hoey'.

Anne Marie Hoey
Primary Care Reimbursement & Eligibility



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Valproate and risk of abnormal pregnancy outcomes

Dear Colleague,

Is any female under your care currently on a valproate containing medication (most common brand is Epilim®)? Other valproate brands include Depakote® and Episenta®. Valproate products are licensed to treat epilepsy and bipolar disorder in Ireland and have been used off-label for migraine and chronic pain.

I am writing to give you initial notice of upcoming changes to HPRA arrangements for the prescribing of valproate and management of patients taking this medicine.

A recent review by the European Medicines Agency (EMA) has highlighted the high level of harm which can be caused by this medicine when taken during pregnancy. As a result, the HPRA will be shortly introduce increased restrictions on the use of valproate medicines and new measures, including a pregnancy prevention programme, to require appropriate counselling and information for patients taking this medicine.

The new measures and restrictions on use are currently being finalised and will be communicated to you shortly.

There are a significant number of patients who are potentially at risk and some may be under your care. While in many cases this medication will have been initiated by another doctor, many of these patients will be in contact with their general practitioner.

I am asking for your assistance to ensure that female patients of child-bearing potential currently or recently under your care and taking valproate are made aware of the risks. I recognise and appreciate that this is adding to the daily workload, but HSE pharmacy reported dispensing records do not provide a comprehensive patient-level list of those taking this medicine. The patient safety implications of valproate are so significant that we are taking a number of unusual steps and I am asking you to:

- Identify from your practice management system any female of child-bearing potential who has received valproate recently
- Contact any identified patients directly in the next few days
- Review with them their risks and need for effective contraception, using the patient information booklet, healthcare professional information and checklist for prescribers and patients on www.hse.ie/valproate
- Take further action if necessary, e.g. if treatment needs to be switched or if the woman is currently pregnant. Facilities for a rapid review by a specialist (neurologist or psychiatrist as appropriate) may be required and the HSE is making contact with relevant services to inform them of the issue.

The HSE and other relevant agencies will be communicating widely about this in the coming weeks, therefore we ask that you urgently commence these reviews to ensure your patients receive the appropriate information.

As updated information and advisories become available, they will be posted on the HSE website at www.hse.ie/valproate, which currently contains a number of helpful documents.

Yours sincerely,


Dr David Hanlon MICGP