Food and Drugs Authority

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Dear Healthcare Professional,

RESTRICTIONS TO PREVENT THE USE OF VALPROATE MEDICINES IN WOMEN AND GIRLS OF CHILDBEARING POTENTIAL

The Food and Drugs Authority (FDA) wishes to bring to your attention restrictions and measures to prevent valproate exposure during pregnancy because babies exposed in utero to valproate are at high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases).

Valproate has been registered for use in Ghana for the treatment of generalized, partial or other epileptic seizures.

Below is the summary of the restrictions:

- Valproate should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated.
- In pregnancy and in women of childbearing potential who have epilepsy valproate is **contraindicated** unless the conditions of the pregnancy prevention programme are fulfilled (see below).
- For women of childbearing potential currently using valproate the treatment may need to be re-evaluated to decide if the conditions of the pregnancy prevention programme are fulfilled.

Key elements of the Pregnancy Prevention Programme:

The prescriber must ensure that:

- individual circumstances is evaluated in each case, involving the patient in the discussion, to guarantee her engagement, discuss therapeutic options and ensure her understanding of the risks and the measures needed to minimise the risks.
- the potential for pregnancy is assessed for all female patients.
- the patient has understood and acknowledged the risks of congenital malformations and neurodevelopmental disorders, including the magnitude of these risks for children exposed to valproate in utero.
- the patient understands the need to undergo pregnancy testing prior to initiation of treatment and during treatment, as needed.
- the patient is counseled regarding contraception, and that the patient is capable of complying with the need to use effective contraception, without interruption during the entire duration of treatment with valproate.

- the patient understands the need for regular (at least annual) review of treatment by a specialist experienced in the management of epilepsy.
- the patient understands the need to consult her physician as soon as she is planning a pregnancy to ensure timely discussion and switching to alternative treatment prior to conception, and before contraception is discontinued.
- the patient understands the need to urgently consult her physician in case of pregnancy.
- the patient has acknowledged that she has understood the hazards and necessary precautions associated with valproate use.

These conditions also concern women who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

Valproate medicines (Valproate sodium) registered by the FDA are Epilim Tablets and Epilim Syrup.

The FDA will like to advice healthcare professionals to report adverse drug reactions to valproate containing products and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh or call Mobile no: 024431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER