This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Direct Healthcare Professional Communication

December 6, 2020

Sodium Valproate, Epival® Pregnancy Prevention Programme. This letter is for **specialists and specialist nurses** managing patients treated with valproate medicines and **general practitioners and other Healthcare Professionals** who provide care to these patients.

Dear Healthcare Professional,

United Pharmaceuticals, marketing authorization holder of medicines containing Valproate, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you the following:

Summary

- Valproate should not be used in girls and women of childbearing potential unless other treatments are ineffective or not tolerated, as judged by an experienced specialist.
- Children exposed to valproate in utero are at high risk of serious developmental disorders (in 30 – 40% of cases) and of congenital malformations (in approximately 10% of cases).
- Important contraindications apply:
  - **In epilepsy:**
    - valproate is contraindicated in girls and women of childbearing potential, unless the conditions of the valproate pregnancy prevention programme (**"prevent"**), described in the documents enclosed, are met.
    - valproate is contraindicated in pregnancy unless there is no suitable alternative treatment.
- In girls and women of childbearing potential currently using valproate, management will need to be re-evaluated to ensure that the conditions of the valproate pregnancy prevention programme (**"prevent"**), described in the documents enclosed, are met.

- **As a reminder:**

Please find enclosed the Valproate educational materials, part of the **"prevent" valproate Pregnancy Prevention Programme**. These materials provide information on the risks of valproate and the conditions for use. This is a routine redistribution and changes made to the materials are only to clarify the existing regulatory situation and not due to new advice.

- 1 copy of an **updated version** of the *Guide for Healthcare Professionals* including prescribers, pharmacists, and other healthcare providers involved in the care of girls and women of childbearing potential using valproate medicines. **This contains full detail of the valproate pregnancy prevention programme (**"prevent"**).**
- 1 copy of the **updated version** of the *Valproate Annual Risk Acknowledgement Form* for the prescriber to document that the patient has understood the risks in every annual visit. **This should be signed by the patient, then scanned and saved in her Patient Medical Record.**
  A copy should be given to the patient and one copy sent to her GP.
- 3 copies of the *Patient Guide* for the prescriber to **provide a copy to ALL girls and women of childbearing potential** who start treatment on valproate or who are continuing treatment with valproate. Note the advice in this Guide has not changed since the previous version so the patient does not need to replace her current version if she still has it.
  A Patient Card is also available via the pharmacist to provide to all female patients when dispensing the product.

Call for reporting

Report suspected adverse drug reactions associated with Epival® (Sodium Valproate) by contacting:

Local representative / Cigalah Group

Sharafiyyah District - Al Yousfia Building

P.O. Box 19435 - Ali Bin Abi Taleb Street, Jeddah, 21435 Saudi Arabia

Tel: +966-12-6148259 - Mob: +966-539455825 - Fax: +966-12-6148458

Email: drug-safety@cigalah.com.sa - moghamdi@cigalah.com.sa

The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)

SFDA call center: 19999

Toll free phone: 8002490000 - Fax: +966-11-2057662

E-mail: npc.drug@sfda.gov.sa - Website: http://ade.sfda.gov.sa/

Yours faithfully,

Rania Malhas

Pharmacovigilance section head