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(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

7 May 2013

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Valproate Anti-Seizure Products: Contraindicated for Pregnant Women for Prevention of Migraine Headaches

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement with respect to anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium, are contraindicated for pregnant women for the prevention of migraine headaches.

The final results of the Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) study showing that children exposed to valproate products while their mothers were pregnant had decreased IQs at age 6 compared to children exposed to other anti-epileptic drugs. The difference in average IQ between the children who had been exposed to valproate and the children who had been exposed to other antiepileptic drugs varied between 8 and 11 points depending on the drug to which valproate was compared. The valproate's pregnancy category for migraine use will be changed from "D" (the potential benefit of the drug in pregnant women may be acceptable despite its potential risks) to "X" (the risk of use in pregnant women clearly outweighs any possible benefit of the drug).

With regard to valproate use in pregnant women with epilepsy or bipolar disorder, valproate products should only be prescribed if other medications are not effective in treating the condition or are otherwise unacceptable. Valproate products will remain in pregnancy category D for treating epilepsy and manic episodes associated with bipolar disorder.

With regard to women of childbearing age who are not pregnant, valproate should not be taken for any condition unless the drug is essential to the management of the woman's medical condition. All non-pregnant women of childbearing age taking valproate products should use effective birth control.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350868.htm

In Hong Kong, there are 13 registered pharmaceutical products containing valproate and valproic acid. All of the products are prescription-only medicines. They are indicated for the treatment of epilepsy, manic episodes, bipolar disorder or prevention of migraine. There is no registered pharmaceutical product containing divalproex. So far, the Department of Health has not received any related adverse reports in connection with the drugs. In view of FDA's latest recommendation, the matter will be discussed in the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)

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