

衛生署

藥物註冊組

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BY FAX

4 July 2011

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

**US FDA Drug Safety Communication: Risk of Impaired Cognitive Development in
Children Exposed In Utero (During Pregnancy)**

Your attention is drawn to the US Food and Drug Administration (FDA)'s announcement that children born to mothers who take the anti-seizure medication valproate sodium or related products (valproic acid and divalproex sodium) during pregnancy have an increased risk of lower cognitive test scores than children exposed to other anti-seizure medications during pregnancy. This conclusion is based on the results of epidemiologic studies that show that children born to mothers who took valproate sodium or related products throughout their pregnancy tend to score lower on cognitive tests (IQ and other tests) than children born to mothers who took other anti-seizure medications during pregnancy.

FDA advised that healthcare professionals should inform women of childbearing age of the increased risk for adverse effects on cognitive development with prenatal valproate exposure and should continue to counsel women of childbearing potential taking valproate about the increased risk of major malformations, including neural tube defects, when valproate is used during pregnancy. The benefits and risks of valproate when prescribing this drug to women of childbearing age should be weighed. For detail, please refer to FDA's website:

<http://www.fda.gov/Drugs/DrugSafety/ucm261543.htm>

In Hong Kong, there are 16 registered valproate products (valproic acid and divalproex sodium) and they are prescription-only medicines. In view of FDA's latest decision, the issue will be discussed in the coming meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: <http://www.psdh.gov.hk> at Pharmaceutical Service under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Ms Pamela LI)
for Chief Pharmacist