DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Chau Street, Kowloon, Hong Kong

BY FAX

15 December 2011

Dear Dr. LIANG,

FDA Drug Safety Communication: Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressants - use during pregnancy and potential risk of persistent pulmonary hypertension of the newborn

Your attention is drawn to that the U.S. Food and Drug Administration (FDA) is informing healthcare professionals on the use of selective serotonin reuptake inhibitor (SSRI) antidepressants by women during pregnancy and the potential risk of a rare heart and lung condition known as Persistent Pulmonary Hypertension of the Newborn (PPHN). The initial Public Health Advisory in July 2006 on this potential risk was based on a single published study. Since then, there have been conflicting findings from new studies evaluating this potential risk, making it unclear whether use of SSRIs during pregnancy can cause PPHN.

FDA has reviewed the additional new study results and has concluded that, given the conflicting results from different studies, it is premature to reach any conclusion about a possible link between SSRI use in pregnancy and PPHN. FDA will update the SSRI drug labels to reflect the new data and the conflicting results.

FDA advises healthcare professionals not to alter their current clinical practice of treating depression during pregnancy. For details, please refer to FDA’s website:


In Hong Kong, there are 108 selective serotonin reuptake inhibitor (SSRI) antidepressants registered and all are prescription-only medicines. In view of the FDA’s recommendation, the issue will be discussed in the 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 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.drugoffice.gov.hk at Drug Office under “Reporting an Adverse Drug Reaction”.

Yours sincerely,

(Ms Pamela LI)
for AD(D)

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