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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

30 July 2013

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

Dear Dr. LI,

Mefloquine Hydrochloride – Label Changes due to Risk of Serious Psychiatric and Neurologic Side Effects

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement with respect to the strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine hydrochloride.

A boxed warning, the most serious kind of warning about these potential problems, has been added to the US drug label. The boxed warning states that, "Mefloquine may cause neuropsychiatric adverse reactions that can persist after mefloquine has been discontinued. Mefloquine should not be prescribed for prophylaxis in patients with major psychiatric disorders. During prophylactic use, if psychiatric or neurologic symptoms occur, the drug should be discontinued and an alternative medication should be substituted". The patient Medication Guide dispensed with each prescription and wallet card are also revised to include this information.

The neurologic side effects can include dizziness, loss of balance, or ringing in the ears. The psychiatric side effects can include feeling anxious, mistrustful, depressed, or having hallucinations. Neurologic side effects can occur at any time during drug use, and can last for months to years after the drug is stopped or can be permanent.

Healthcare professionals are advised to be alert for the development of these side effects in patients using the drug. If a patient develops neurologic or psychiatric symptoms, mefloquine should be stopped, and an alternate medicine should be used.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm362887.htm

In Hong Kong, there are two registered pharmaceutical products containing mefloquine. They are prescription-only medicines and indicated for prophylaxis and treatment of malaria. In view of FDA's latest recommendation, the matter will be discussed in the meeting of 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)