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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

16 August 2013

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

Dear Dr. LI,

Fluoroquinolones taken by mouth or by injection - Risk of Possibly Permanent Nerve Damage

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement with respect to the strengthened and updated warnings regarding the serious side effect of peripheral neuropathy associated with fluoroquinolones.

This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent. The risk of peripheral neuropathy occurs only with fluoroquinolones that are taken by mouth or by injection. The topical formulations of fluoroquinolones, applied to the ears or eyes, are not known to cause this risk.

Peripheral neuropathy is a nerve disorder occurring in the arms or legs. Symptoms include pain, burning, tingling, numbness, weakness, or a change in sensation to light touch, pain or temperature, or the sense of body position. Peripheral neuropathy is an identified risk of fluoroquinolones and was added to the Warnings or Warnings and Precautions sections of all the US labels for systemic (oral and injectable) fluoroquinolone drugs in 2004. The risk of peripheral neuropathy is also described in the Medication Guides for these products.

FDA has continued to receive reports of peripheral neuropathy even after the adverse reaction was added to the fluoroquinolone drug labels. The results of FDA's recent review of the Adverse Event Reporting System (AERS) database indicate that although the risk of peripheral neuropathy is described in the drug labels of each marketed systemic fluoroquinolone, the potential rapid onset and risk of permanence were not adequately described. FDA has required the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs be updated to better describe the serious side effect of peripheral neuropathy.

If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolone antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm365302.htm

In Hong Kong, there are 199 registered pharmaceutical products containing fluoroquinolones in oral or injectable forms. They are antibacterial drugs and are prescription-only medicines. The Department of Health has not received any adverse drug reaction report in relation to fluoroquinolones so far. 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,

(HF LEE)
for Assistant Director (Drug)

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aspire to be an internationally renowned public health authority