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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

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

Dear Healthcare Professionals,

Fluoroquinolones: restricting use for certain uncomplicated infections

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding restricting use of fluoroquinolone for certain uncomplicated infections.

FDA is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolone should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, FDA is requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. Currently available FDA-approved fluoroquinolone antibacterial drugs for systemic use include moxifloxacin, ciprofloxacin, gemifloxacin, levofloxacin and ofloxacin. FDA is continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

Health care professionals should stop systemic fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course

Please refer to the FDA's website for details:

http://www.fda.gov/Drugs/DrugSafety/ucm500143.htm

In Hong Kong, there are 248 registered pharmaceutical products which are fluoroquinolone antibacterial drugs, including 106 ciprofloxacin products, 66 levofloxacin products, 52 ofloxacin products, 9 moxifloxacin products, 11 norfloxacin products, 2 lomefloxacin products, 1 prulifloxacin product and 1 sparfloxacin product. All these products are prescription only medicines. So far, the Department of Health (DH) has received one adverse drug reaction case (ADR) in connection with levofloxacin, but it was not related to the serious side effects mentioned in the above announcement. No ADR case has been received for the other fluoroquinolone drugs. In view of the FDA announcement, the matter will be discussed by 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 report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)

We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority