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(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

27 June 2012

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

Dear Dr. LIANG,

FDA: Cefepime and risk of seizure in patients not receiving dosage adjustments for kidney impairment

Please kindly note that the US Food and Drug Administration (FDA) reminded healthcare professionals about the need to adjust the dosage of the antibacterial drug cefepime in patients with renal impairment. There have been cases of a specific type of seizure called nonconvulsive status epilepticus associated with the use of cefepime, primarily in patients with renal impairment who did not receive appropriate dosage adjustments of cefepime.

Cases of nonconvulsive status epilepticus associated with cefepime are documented in the medical literature and have been identified in FDA's Adverse Event Reporting System (AERS) database. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment; however, some cases occurred in patients receiving dosage adjustment appropriate for their degree of renal impairment. In the majority of cases, the seizures were reversible and resolved after discontinuing cefepime and/or after hemodialysis.

FDA advised that to minimize the risk of seizures, healthcare professionals should adjust the dosage of cefepime in patients with creatinine clearance less than or equal to 60 mL/min. If seizures associated with cefepime therapy occur, consider discontinuing cefepime or making appropriate dosage adjustments in patients with renal impairment.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm309822.htm

In Hong Kong, there are four registered pharmaceutical products containing cefepime and are prescription-only medicines. Cefepime is a broad-spectrum cephalosporin antibiotic. In view of the FDA's recommendation, the matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

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: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.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. Lilly HO)
for AD(D)