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本署檔號 OUR REF.: DH PS PRIE/7-30/15
(來函請註明此檔案號碼)
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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

20 May 2013

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

Dear Dr. LI,

The Risk of Potentially Fatal Cardiac Arrhythmias with Azithromycin

Your attention is drawn to the announcement of Health Canada on 14 May 2013 with respect to the revised Product Monographs for Zithromax and Zmax SR (azithromycin) regarding the risk of potentially fatal cardiac arrhythmias. A small absolute increase in the risk of cardiovascular deaths was observed in patients taking azithromycin as compared to those who took no antibiotics and those who took amoxicillin in a recent study. This risk mainly affected patients who were at a higher baseline risk for cardiovascular events.

Pfizer completed a review of all relevant available data, and updated the Precautions section of the Zithromax and Zmax SR product monographs to include the following additional instructions:

- There have been rare reports of QT prolongation and *torsades de pointes* in patients receiving therapeutic doses of azithromycin.
- Caution is required when treating patients with congenital or documented QT prolongation; with electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesemia or with clinically relevant bradycardia, cardiac arrhythmia or cardiac insufficiency.
- Caution is also required when treating patients currently receiving treatment with other active substances known to prolong QT interval such as antiarrhythmics of classes IA and III, antipsychotic agents, antidepressants and fluoroquinolones.
- Elderly patients may be more susceptible to drug-associated effects on the QT interval.

Prolonged cardiac repolarization and QT interval have been seen in treatment with macrolides including azithromycin. Healthcare practitioners should consider the risk of fatal cardiac arrhythmias with azithromycin when prescribing antibacterial treatment for patients who are already at risk for cardiovascular events.

Please refer to the following website in Health Canada for details:
http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/29199a-eng.php

In Hong Kong, there are 62 registered pharmaceutical products containing azithromycin and are prescription-only medicines. Related news has been released by FDA and HSA, and was posted on the website of Drug Office on 18 May 2012, 13 March 2013 and 6 May 2013. So far, the Department of Health (DH) has not received any related adverse reports in connection with the drug. The matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The DH will keep vigilant on any updated news of this product.

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 "Reporting an Adverse Drug Reaction": 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)