衞生署藥物辦公室
藥物註冊及進出口管制部
香港九龍南昌街 382 號公共衞生檢測中心三樓
2319 8458

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

電話號碼 Tel. No.:
詢問處 Enquiries (852) 2319 8456
傳真號碼 Faxline No. (852) 2803 4962
本署檔號 OUR REF.: DH DO PRIE/7-30/15

3 July 2012

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

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

Dear Dr. LIANG,

New information regarding QT prolongation with ondansetron (Zofran)

Your attention is drawn to the new information released by the US Food and Drug Administration (FDA) that preliminary results from a recently completed clinical study suggest that a 32 mg single intravenous dose of ondansetron (Zofran, ondansetron hydrochloride, and generics) may affect the electrical activity of the heart (QT interval prolongation), which could pre-dispose patients to develop an abnormal and potentially fatal heart rhythm known as Torsades de Pointes. GlaxoSmithKline, the manufacturer of Zofran, has announced changes to the Zofran drug label to remove the 32 mg single intravenous dose. The FDA's recommendations are as follow:

- The use of a single 32 mg intravenous dose of ondansetron should be avoided. New information indicates that QT prolongation occurs in a dose-dependent manner, and specifically at a single intravenous dose of 32 mg.
- Patients who may be at particular risk for QT prolongation with ondansetron are those with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, or patients taking concomitant medications that prolong the QT interval.
- Electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia) should be corrected prior to the infusion of ondansetron.
- The lower dose intravenous regimen of 0.15 mg/kg every 4 hours for three doses may be used in adults with chemotherapy-induced nausea and vomiting. However, no single intravenous dose of ondansetron should exceed 16 mg due to the risk of QT prolongation.
- The new information does not change any of the recommended oral dosing regimens for ondansetron, including the single oral dose of 24 mg for chemotherapy induced nausea and vomiting.

Please refer to the following website in FDA for details:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm310219.htm

In Hong Kong, there are 24 registered pharmaceutical products containing ondansetron and are prescription-only medicines. Seven of them are injection products. The safety news on risk of abnormal heart rhythms of ondansetron has been released by FDA and posted on the website of Drug Office on 16 September 2011. The issue was discussed by the Registration Committee (the Committee) of the Pharmacy and Poisons Board on 28 February 2012 and the Committee decided that the drug product label should include safety information on risk of QT prolongation and Torsades de Pointes associated with the drug. In view of the FDA's new recommendation, the issue will be further discussed in the meeting of the Committee.

Please remind 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. Christine CHEUNG)
for AD(D)