衞生署
藥物註冊組
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BY FAX

22 July 2011

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

Dear Dr. LIANG,

FDA reviews the increased risk of death and serious cardiovascular adverse events of Multaq (dronedarone)

FDA notified healthcare professionals that it is reviewing data from a clinical trial (the PALLAS study) that evaluated the effects of the antiarrhythmic drug Multaq (dronedarone) in patients with permanent atrial fibrillation.

The study was stopped early after the data monitoring committee found a two-fold increase in death, as well as two-fold increases in stroke and hospitalization for heart failure in patients receiving Multaq compared to patients taking a placebo. FDA is evaluating whether and how the preliminary results of the PALLAS study apply to patients taking Multaq for paroxysmal or persistent atrial fibrillation or atrial flutter. The PALLAS study results are considered preliminary at this time because the data have not undergone quality assurance procedures and have not been completely adjudicated. FDA will update the public when more information is available.

FDA recommended that patients taking Multaq should talk to their healthcare professional about whether they should continue to take Multaq for non-permanent atrial fibrillation. Patients should not stop taking Multaq without talking to a healthcare professional. Healthcare professionals should not prescribe Multaq to patients with permanent atrial fibrillation. For details, please refer to FDA's website:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm264204.htm

In Hong Kong, Multaq (dronedarone) is registered by Sanofi-Aventis HK Ltd., and is a prescription medicine. Department of Health will keep vigilance against any updated safety information in relation to the drug. Meanwhile, you are reminded to follow the recommendations in the product information with respect to the indication, contraindications and warnings, and exercise special care in prescribing and supplying Multaq (dronedarone).

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax: 2147-0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Pharmaceutical Service under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Ms Pamela LI)
for Chief Pharmacist