衞生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
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(來函請緊明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

11 January 2013

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

Dear Dr. LIANG,

Zolpidem containing products: FDA requires lower recommended doses

Your attention is drawn to the US Food and Drug Administration's (FDA) recommendation on 10 January 2013 with respect to lowering the current dose of zolpidem. It is because new data showed that zolpidem blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving.

The data showed that the risk for next-morning impairment is highest for patients taking the extended-release forms of zolpidem. Besides, women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men.

FDA advised that the recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products and from 12.5 mg to 6.25 mg for extended-release products; and the labelling should recommend that healthcare professionals consider prescribing the lower doses (5 mg for immediate-release products and 6.25 mg for extended-release products) for men.

FDA urged healthcare professionals to caution all patients who use zolpidem about the risks of next-morning impairment for activities that require complete mental alertness, including driving, and to inform patients that impairment from sleep drugs can be present despite feeling fully awake. Moreover, for zolpidem and other insomnia drugs, doctors are advised to prescribe the lowest dose that treats the patient's insomnia.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm

In Hong Kong, there are 14 registered pharmaceutical products containing zolpidem which include immediate-release 5 mg or 10 mg tablet and modified-release 6.25 mg or 12.5 mg tablet. They are prescription-only medicines and indicated for the treatment of insomnia. Zolpidem is also controlled as psychotropic substances internationally including Hong Kong. According to the FDA's recommendations, the matter will be discussed in the meeting of the 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: 2186 9845 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)

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