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 potential risk of esophageal cancer of oral bisphosphonates drugs

The U.S. Food and Drug Administration (FDA) is continuing to review data from published studies to evaluate whether use of oral osteoporosis drugs bisphosphonates is associated with an increased risk of esophageal cancer.

There have been conflicting findings from studies evaluating this risk. The largest studies that FDA has reviewed, thus far, are two epidemiologic studies using one patient database (the U.K. General Practice Research Database). One study found no increase in the risk of esophageal cancer. The second study found a doubling of the risk of esophageal cancer among patients who had 10 or more prescriptions of the drugs, or who had taken the drugs over 3 years. Other external researchers investigating this issue, using different patient databases, have reported no increase in risk, or a reduced risk.

At this time, FDA believes that the benefits of oral bisphosphonate drugs in reducing the risk of serious fractures in people with osteoporosis continue to outweigh their potential risks. FDA's review is ongoing and the Agency has not concluded that patients taking oral bisphosphonate drugs have an increased risk of esophageal cancer. It is also important to note that esophageal cancer is rare, especially in women. For details, please refer to FDA's website:

http://www.fda.gov/Drugs/DrugSafety/ucm263320.htm

In Hong Kong, bisphosphonates products approved for osteoporosis includes alendronate, ibandronate, risedronate and zoledronate, and are prescription drugs. Department of Health will keep vigilance against any updated safety information in relation to the drug.

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