衞生署藥物辦公室
藥物註冊及進出口管制部

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BY FAX

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

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

Dear Dr. LIANG,

Health Canada: Xgeva (denosumab) - Risk of severe symptomatic hypocalcemia, including fatal cases

Your attention is drawn to that Health Canada is informing healthcare professionals of new important safety information related to hypocalcemia associated with Xgeva treatment.

Post-marketing cases of severe symptomatic hypocalcemia have occurred at an estimated rate of 1 - 2%, including some cases which were fatal. Signs and symptoms of these cases included altered mental status, tetany, seizures and QTc prolongation. During clinical trials, severe hypocalcemia (corrected serum calcium < 7 mg/dL or < 1.75 mmol/L) occurred in 3.1% of patients receiving treatment with Xgeva. Health Canada advised the risk of severe symptomatic hypocalcemia among patients receiving Xgeva may be minimized by the following:

- Correcting pre-existing hypocalcemia prior to initiating Xgeva therapy.
- Supplementing patients with calcium and vitamin D, unless hypercalcemia is present.
- Monitoring calcium levels as necessary while patients are receiving Xgeva.
- Identifying risk factors for hypocalcemia in patients receiving Xgeva. Patients with severe renal impairment (creatinine clearance < 30 mL/min) or receiving dialysis are at a greater risk of developing hypocalcemia in the absence of calcium supplementation.
- If hypocalcemia occurs while receiving Xgeva, additional short-term calcium supplementation may be necessary.

Health Canada reminded if severe symptomatic hypocalcemia occurs, the benefit of continuing the treatment in these patients should be reassessed. Please refer to Health Canada's website for details: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2012/xgeva_hpc-cps-eng.php

In Hong Kong, Xgeva (denosumab) is registered by GlaxoSmithKline Limited and it is prescription-only medicine. Xgeva is indicated for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours. And Xgeva is not indicated for the prevention of skeletal-related events in patients with multiple myeloma. In view of the Health Canada's recommendation, the matter will be discussed in the meeting of 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: 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. Lilly HO)
for AD(D)