Dear Healthcare Professionals,

**XGEVA (denosumab) Solution for Injection 120mg/vial**

**Risk of Multiple Vertebral Fractures (MVF) following treatment discontinuation**

Your attention is drawn to the Singapore Health Sciences Authority’s (HSA) announcement that Amgen Singapore Manufacturing Pte Ltd would like to inform healthcare professionals of the risk of Multiple Vertebral Fractures (MVF), that may occur following discontinuation of treatment with XGEVA (denosumab), particularly in patients with risk factors such as osteoporosis or prior fractures. Cases of MVF, not due to bone metastases, have occurred rarely following discontinuation of XGEVA in patients participating in ongoing clinical trials. These fractures had occurred in post-menopausal women with malignancies who had previous fractures or who had known osteoporosis.

Healthcare professionals are advised to evaluate the individual patient’s risk for vertebral fractures, following treatment discontinuation with XGEVA. Patients should also be advised not to interrupt XGEVA treatment without their physician’s advice. The local package insert for XGEVA will be updated to include warnings regarding the risk of MVF.

Please refer to the following website in HSA for details:


In Hong Kong, Xgeva Solution For Injection 120mg (HK-61163) is a pharmaceutical product registered by Amgen Asia Holding Limited, and is a prescription only medicine. So far, the Department of Health (DH) has received 9 cases of adverse drug reaction related to denosumab, but none of them was related to MVF. In light of the above HSA’s announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority
Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)