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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI

President

Hong Kong Academy of Medicine

(Fax Number: 2505 5577)

Dear Dr. LI,



DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND  
IMPORT/EXPORT CONTROL DIVISION  
3/F., Public Health Laboratory Centre,  
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

3 April 2013

**The United Kingdom: Novartis Pharmaceuticals UK Ltd is recalling all unexpired  
Miacalcic 200 IU Nasal Spray Solution**

Your attention is drawn to the announcement of the Medicines and Healthcare Products Regulatory Agency (MHRA) that all unexpired stock of the captioned product was being recalled irrespective of batch number and expiry date. The product is being withdrawn throughout the European Union after a study has shown an increased risk of malignancies with the long term use of calcitonin.

The announcement in the UK follows a review completed by the European Medicines Agency (EMA) concluding that there was evidence of a small increased risk of cancer with long-term use of calcitonin-containing medicines. EMA's Committee for Medicinal Products for Human Use (CHMP) recommended that they should only be authorised for the treatment of Paget's disease for patients who cannot be treated with alternative treatments, prevention of acute bone loss due to sudden immobilisation such as in patients with recent osteoporotic fractures, and the treatment of hypercalcaemia caused by cancer. However, the CHMP recommended that even for these uses, calcitonin treatment should be given for the shortest possible time using the smallest effective dose.

The CHMP concluded that the benefits of calcitonin did not outweigh the risks in the treatment of osteoporosis. Therefore, calcitonin should no longer be used for this indication. For details, please refer to MHRA's website:

<http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON257641>

In Hong Kong, there are 4 registered pharmaceutical products containing calcitonin and are prescription-only medicines. Miacalcic Nasal Spray 200iu (HK-43614) and Apo-Calcitonin Nasal Spray 200iu/spray (HK-58746) are nasal sprays, while Miacalcic Inj 100iu/ml (HK-27880) and Miacalcic Inj 50iu/ml (HK-28413) are injectable products. The nasal spray products are indicated for neurodystrophic disorders, bone pain associated with osteolysis or osteopenia and Paget's disease of bone, whereas injectable products have additional indications for hypercalcaemia and as adjuvant therapy for acute pancreatitis. All the four products are NOT indicated for the treatment of osteoporosis. The package inserts highlight that the treatment with calcitonin should be limited to the shortest possible time using the smallest effective dose. DH has not received any ADR related to calcitonin-containing product so far. A letter to inform healthcare professionals related to the safety concern was issued on 23 July 2012. The matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

*We are committed to providing quality client-oriented service*

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 23192920, fax: 21869845 or email: [adr@dh.gov.hk](mailto:adr@dh.gov.hk)). For details, please refer to the website at Drug Office under 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,



(H F LEE)

for Assistant Director (Drug)