

PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

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21st April 2016

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Safety Warnings for Bisphosphonates

On 14th April 2016, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest overseas recommendations on the risk of osteonecrosis of the external auditory canal associated with the use of bisphosphonates, and decided that the sales pack labels and/or package inserts of pharmaceutical products containing bisphosphonates should include the following new safety warnings:

Special warnings and precautions for use

Osteonecrosis of the external auditory canal

Osteonecrosis of the external auditory canal has been reported with bisphosphonates, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and

chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections.

You are therefore required to review and revise, if necessary, the sales pack labels and/or package inserts of the concerned products registered by your company to ensure that the products comply with the above requirements. The revised sales pack labels and/or package inserts should be submitted to the Committee for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products by the Committee.

If you have any enquiries on the above issue, please contact the Drug Office duty officer at 2319 8458.

Yours sincerely,



(Clive CHAN)
Secretary,
Pharmacy and Poisons (Registration of
Pharmaceutical Products and Substances: Certification
of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files

KL/CC