

PHARMACY AND POISONS BOARD

HONG KONG

香港藥劑業及毒藥管理局

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香港九龍南昌街382號
公共衛生檢測中心三樓

25th February 2016

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Safety Warnings for Proton Pump Inhibitors

On 18th February 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 proton pump inhibitors (PPIs) with regard to the risk of subacute cutaneous lupus erythematosus, and decided that the sales pack labels and/or package inserts of pharmaceutical products containing PPIs, including omeprazole, esomeprazole, rabeprazole, pantoprazole, lansoprazole and dexlansoprazole, should include the following new safety warnings:

Special warnings and precautions:

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping [BRAND NAME]. SCLE after previous treatment with a proton pump inhibitor may increase

the risk of SCLE with other proton pump inhibitors.

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

SM/CC