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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圖文傳真

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香港九龍南昌街382號
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6th December 2019

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Lovastatin Products

On 4th December 2019, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the safety aspects of concurrent consumption of red yeast rice with lovastatin drugs, precautions on pregnancy in using lovastatin, and regulatory controls of lovastatin-containing products by other drug regulatory authorities of the United States, European Union, Canada, Australia and Singapore. The Committee has decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing lovastatin should be updated and replaced by the following safety information as appropriate:

(i) "Concurrent consumption of red yeast rice

Consuming red yeast rice or its supplement together with lovastatin should be avoided as it may potentiate the side effects of lovastatin. Seek medical advice before use if you are taking lovastatin."

(ii) Precaution on pregnancy

Contraindications

Lovastatin is contraindicated during pregnancy and in nursing mothers.

Lovastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive. If the patient becomes pregnant while taking this drug, lovastatin should be discontinued immediately and the patient should be apprised of the potential hazard to the fetus."

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 new 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 or registration not renewed by the Committee.

If you have any enquiries on the above issue, please contact Mr. Paul WONG at 2209 9495.

Yours faithfully,

(T.K. YIM)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

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

TK/PW