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

Tel. No.: 2319 8468

電 話

Fax No.: 2803 4962

圖文傳真

C/O Drug Office

3/F., Public Health Laboratory Centre,

382 Nam Cheong Street, Kowloon, Hong Kong.

香港九龍南昌街382號

公共衛 生 檢 測中心三樓

17th December 2015

To: Certificate holders of

registered pharmaceutical products

Dear Sirs / Madams,

New Safety Warnings for Clopidogrel and Repaglinide

In order to ensure the safe use of clopidogrel and repaglinide, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) decided at the meeting on 4 December 2015 that the sales pack labels and/or package inserts of pharmaceutical products containing clopidogrel and repaglinide should include the following new safety warnings:

a. For products containing clopidogrel,

"The concomitant use of this product and repaglinide is contraindicated."

b. For products containing repaglinide,

"The concomitant use of this product and clopidogrel is contraindicated."

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