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**
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圖文傳真

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香港九龍南昌街382號
公共衛生檢測中心三樓

13th September 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Finasteride

On 7th September 2017, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings for finasteride imposed by the drug regulatory authorities of the United Kingdom, European Union and Canada, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing finasteride should include the following new warnings:

For finasteride 1mg

Precautions:
Mood alterations and depression
Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice.

For finasteride 5mg

Precautions:
Mood alterations and depression
Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.

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 by the Committee.

If you have any enquiries on the above issue, please contact Mr. Arthur Lee at 2319 8453.

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

CC/ART