**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**
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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**
**公共衞生檢測中心三樓**

12th December 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

**New Warnings for Isotretinoin**

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

*Adverse reactions*
*Sexual dysfunction including erectile dysfunction and decreased libido*

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. Paul Wong at 2209 9495.

Yours faithfully,

(TK 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