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

5th May 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Fluoroquinolones for Systemic Use

On 28th April 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 fluoroquinolones imposed by the drug regulatory agencies of overseas countries such as EU, Canada and Singapore, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing fluoroquinolones including ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, prulifloxacin and sparfloxacin for systemic use should include the following new warnings:

Vision disorders

If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.

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 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