PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

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圖文傳真

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公共衞生檢測中心三樓

21st June 2019

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Fluoroquinolones for Systemic Use

On 20th June 2019, 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 fluoroquinolones for systemic use imposed by the drug regulatory authorities of the United States, Canada, European Union, United Kingdom, Australia and Singapore, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing fluoroquinolones for systemic use should be updated and replaced by the following new safety information as appropriate:

(I) Risk of disabling and persistent serious adverse reactions

"***Warnings and Precautions***

Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects

Fluoroquinolones, including [Product Name / Generic Name], have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions can occur within hours to weeks after starting [Product Name / Generic Name]. Patients of any age or without pre-existing risk factors have experienced these adverse reactions.

Discontinue [Product Name / Generic Name] immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including [Product Name / Generic Name], in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.

Because fluoroquinolones, including [Product Name / Generic Name], have been associated with serious adverse reactions, reserve [Product Name / Generic Name] for use in patients who have no alternative treatment options for the following indications:

- *Uncomplicated urinary tract infection*
- *Acute bacterial exacerbation of chronic bronchitis*
- *Acute bacterial sinusitis."*

(II) Risk of aortic aneurysm and dissection

*"**Special warnings and precautions for use***

Aortic aneurysm and dissection

Epidemiologic studies report an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population.

Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease, or in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g., Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, known atherosclerosis).

In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department."

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