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
公共衞生檢測中心三樓

21st June 2019

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Sodium/Glucose Co-transporter 2 (SGLT2) Inhibitors

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 sodium/glucose co-transporter 2 (SGLT2) inhibitors 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sales pack labels and / or package inserts of registered pharmaceutical products containing SGLT2 inhibitors should be updated and replaced by the following new safety information as appropriate:

*"**Adverse Reactions***

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)

Reports of necrotizing fasciitis of the perineum (Fournier's Gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical

intervention, have been identified in post-marketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors, including [Product Name / Generic Name]. Cases have been reported in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death.

Patients treated with [Product Name / Generic Name] presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue [Product Name / Generic Name], closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control."

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