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

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貴處檔號

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衞生署藥物辦公室

24th April 2026

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Sodium-Glucose Cotransporter-2 Inhibitors

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the Committee) under the Pharmacy and Poisons Board has recently reviewed and considered the latest warnings regarding the risks of prolonged or incident diabetic ketoacidosis (DKA) for sodium-glucose cotransporter-2 (SGLT2) inhibitors despite stopping treatment in adult patients with type 2 diabetes issued by Health Canada, as well as the related safety labelling information as approved by the drug regulatory authority of the United States, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing SGLT2 inhibitors (including **canagliflozin, dapagliflozin, empagliflozin, ertugliflozin, etc.**) shall include the following new safety information (or equivalent [Note 1]) as appropriate:

*"**Posology and method of administration***

Temporary Interruption for Surgery

Withhold <Product name / Generic name> for at least 3 days, if possible, prior to major surgery or procedures associated with prolonged fasting. Resume <Product name / Generic name> when the patient is clinically stable and has resumed oral intake.

Note 1 Related safety information with other wording in accordance with reputable references and/or approved package inserts from drug regulatory authorities of reference countries may also be accepted on a case-by-case basis.

Special warnings and precautions for use

Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis

In patients with type 1 diabetes mellitus, <Product name / Generic name> significantly increases the risk of diabetic ketoacidosis, a life-threatening event, beyond the background rate. In placebo-controlled trials of patients with type 1 diabetes mellitus, the risk of ketoacidosis was markedly increased in patients who received sodium-glucose cotransporter 2 (SGLT2) inhibitors compared to patients who received placebo. <Product name / Generic name> is not indicated for glycemic control in patients with type 1 diabetes mellitus.

Type 2 diabetes mellitus and pancreatic disorders (e.g., history of pancreatitis or pancreatic surgery) are also risk factors for ketoacidosis. There have been postmarketing reports of fatal events of ketoacidosis in patients with type 2 diabetes mellitus using SGLT2 inhibitors, including <Product name / Generic name>.

Precipitating conditions for diabetic ketoacidosis or other ketoacidosis include under-insulinization due to insulin dose reduction or missed insulin doses, acute febrile illness, reduced caloric intake, ketogenic diet, surgery, volume depletion, and alcohol abuse.

Signs and symptoms are consistent with dehydration and severe metabolic acidosis and include nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. Blood glucose levels at presentation may be below those typically expected for diabetic ketoacidosis (e.g., less than 250 mg/dL). Ketoacidosis and glucosuria may persist longer than typically expected. Urinary glucose excretion persists for 3 days after discontinuing <Product name / Generic name>; however, there have been postmarketing reports of ketoacidosis and/or glucosuria lasting greater than 6 days and some up to 2 weeks after discontinuation of SGLT2 inhibitors.

Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis if indicated by the clinical situation. Assess for ketoacidosis regardless of presenting blood glucose levels in patients who present with signs and symptoms consistent with severe metabolic acidosis. If ketoacidosis is suspected, discontinue <Product name / Generic name>, promptly evaluate, and treat ketoacidosis, if confirmed. Monitor patients for resolution of ketoacidosis before restarting <Product name / Generic name>.

Withhold <Product name / Generic name>, if possible, in temporary clinical situations that could predispose patients to ketoacidosis. Resume <Product name / Generic name> when the patient is clinically stable and has resumed oral intake.

Educate all patients on the signs and symptoms of ketoacidosis and instruct patients to discontinue <Product name / Generic name> and seek medical attention immediately if signs and symptoms occur."

The above new safety information already incorporates the previously endorsed safety information related to DKA in patients with type 1 diabetes mellitus and other ketoacidosis.

You are required to ensure the sales pack labels and/or package inserts of the concerned products registered by your company contain the above safety information to comply with the new requirements.

In addition, please be reminded that the sales pack labels and/or package inserts of the registered pharmaceutical products containing SGLT2 inhibitors should contain the safety information previously endorsed by the Committee. For the list of previously endorsed safety information, please refer to the new "Search for Additional Safety Information" function in the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp.

Please review whether the concerned products registered by your company contain all required safety information on their sales pack labels and/or package inserts. If updates are required, please submit an application for the change of the registered particular(s) to the Drug Office via the abovementioned online PRS 2.0 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 being renewed by the Committee upon certificate expiry.

For further enquiries on the registration matters of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

c.c. 7-15/3, Product Files