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(IN REPLY PLEASE QUOTE THIS FILE REF.)

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

Dear Healthcare Professionals,

Type 2 diabetes medicines containing saxagliptin and alogliptin: risk of heart failure

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin.

Saxagliptin and alogliptin are part of the class of dipeptidyl peptidase-4 (DPP-4) inhibitor drugs, which are used with diet and exercise to lower blood sugar in adults with type 2 diabetes.

A FDA safety review has found that type 2 diabetes medicines containing saxagliptin and alogliptin may increase the risk of heart failure, particularly in patients who already have heart or kidney disease. As a result of the review, FDA is adding new Warnings and Precautions to the drug labels about this safety issue.

FDA evaluated two large clinical trials conducted in patients with heart disease. These clinical trials were also discussed at the FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting in April 2015. Each trial showed that more patients who received saxagliptin- or alogliptin-containing medicines were hospitalized for heart failure compared to patients who received a placebo. Details of the results can be found at the FDA website.

Healthcare professionals are advised of the following:

- Risk factors of hospitalization for heart failure include a history of heart failure or renal impairment, and this safety risk was found in clinical trials among patients with these medical issues.
- Consider the risk and benefits of saxagliptin or alogliptin prior to initiating treatment in patients at a higher risk for heart failure.
- Observe patients receiving saxagliptin or alogliptin for signs and symptoms of heart failure.
- Consider discontinuing the drug and monitor diabetes control if heart failure develops. If blood sugar level is not well-controlled with a patient's current treatment, other diabetes medicines may be required.
- Encourage patients to read the Medication Guide they receive with their prescriptions.

Please refer to the FDA's website for details:
http://www.fda.gov/Drugs/DrugSafety/ucm486096.htm

In Hong Kong, there are five registered pharmaceutical products containing saxagliptin approved under the brand names of Onglyza and Kombiglyze XR, and seven registered products approved under the brand names of Oseni and Nesina. All these products are prescription only medicines. Related news on review of heart failure of saxagliptin was previously issued by the FDA, and was posted on the Drug Office website on 12 February 2014. Letters to inform local healthcare professionals were also issued on the same day. So far, the Department of Health (DH) has not received any adverse drug reaction case related to saxagliptin or alogliptin. In view of the conclusion of the FDA safety review, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)