衞生署藥物辦公室
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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

12 February 2014

(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Saxagliptin - FDA to Review Heart Failure Risk

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement on reviewing heart failure risk with diabetes drug saxagliptin.

FDA had requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of the drug and heart failure. FDA's request resulted from a study published in the New England Journal of Medicine (NEJM), which reported an increased rate of hospitalization for heart failure, when the heart does not pump blood well enough, with use of saxagliptin compared to an inactive treatment. The study did not find increased rates of death or other major cardiovascular risks, including heart attack or stroke, in patients who received saxagliptin. The manufacturer is expected to submit the trial data to FDA by early March 2014, after which FDA will conduct a thorough analysis and report findings publicly.

At this time, FDA considered information from the NEJM study to be preliminary. Analysis of the saxagliptin clinical trial data is part of a broader evaluation of all type 2 diabetes drug therapies and cardiovascular risk. Healthcare professionals are advised to continue to follow the prescribing recommendations in the drug labels.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm385471.htm

In Hong Kong, there are five registered pharmaceutical products containing saxagliptin. They are all prescription only medicines indicated along with diet and exercise to improve glycemic control in adults with type 2 diabetes and registered by Bristol-Myers Squibb Pharma (HK) Ltd. The Department of Health (DH) has not received any adverse reaction report in connection with the drug. In view of FDA's announcement, DH has contacted the company for requesting the trial data and the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. DH will keep vigilant on any safety updates of the drug and actions taken by overseas regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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,

(Mr. Grant NG)
for Assistant Director (Drug)

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority