

衛生署藥物辦公室
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Possible Increased Risk of Pancreatitis and Pre-cancerous Findings of the Pancreas reported with Incretin Mimetic Drugs

Your attention is drawn to the US Food and Drug Administration (FDA) announcement on 14 March 2013 with respect to the unpublished new findings that suggested an increased risk of pancreatitis and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with incretin mimetic drugs. Incretin mimetic drugs include exenatide, liraglutide, sitagliptin, saxagliptin, alogliptin, linagliptin and vildagliptin.

These findings were based on examination of a small number of pancreatic tissue specimens taken from patients after they died from unspecified causes. FDA had asked the researchers to provide the methodology used to collect and study these specimens and to provide the tissue samples so the Agency could further investigate potential pancreatic toxicity associated with the incretin mimetic drugs.

FDA stated that the Warnings and Precautions section of drug labels and patient Medication Guides for these drugs contain warnings about the risk of acute pancreatitis. FDA had not yet reached any new conclusions about safety risks with these drugs and whether these drugs may cause or contribute to the development of pancreatic cancer. FDA will communicate its final conclusions and recommendations when its review is complete or when there is additional information to be reported. Healthcare professionals should continue to follow the prescribing recommendations in the drug labels at this time.

Please refer to FDA's website for details:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm343805.htm>

In Hong Kong, there are 15 registered pharmaceutical products belong to the class of incretin mimetic drugs with ingredients exenatide, liraglutide, sitagliptin, saxagliptin, linagliptin and vildagliptin. All of the products are prescription-only medicines. No pharmaceutical products containing alogliptin is registered. The registered package inserts of the registered products have included safety warnings about the risk of acute pancreatitis. The potential risk of developing pancreatic cancer is still under FDA's evaluation, thus the Department of Health will keep vigilance against any safety updates of the drugs released by FDA and other regulatory authorities, and bring up the matter to the Registration Committee of the Pharmacy and Poisons Board for consideration when necessary.

Please encourage your members to 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)

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