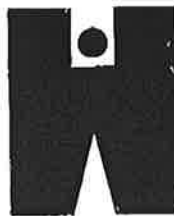


衛生署藥物辦公室  
藥物註冊及進出口管制部



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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,

**US FDA: DPP-4 inhibitors for type 2 diabetes may cause severe joint pain**

The United States Food and Drug Administration (FDA) is warning that the type 2 diabetes medicines sitagliptin, saxagliptin, linagliptin and alogliptin may cause joint pain that can be severe and disabling. A new Warning and Precaution about this risk has been added to the label of all medicines in this drug class, called dipeptidyl peptidase-4 (DPP-4) inhibitors.

In a search of its adverse event database and the medical literature, FDA identified cases of severe joint pain associated with the use of DPP-4 inhibitors. Patients started having symptoms from 1 day to years after they started taking a DPP-4 inhibitor. After the patients discontinued the DPP-4 inhibitor medicine, their symptoms were relieved, usually in less than a month. Some patients developed severe joint pain again when they restarted the same medicine or another DPP-4 inhibitor.

Patients should not stop taking their DPP-4 inhibitor medicine, but should contact their healthcare professional right away if they experience severe and persistent joint pain. Healthcare professionals should consider DPP-4 inhibitors as a possible cause of severe joint pain and discontinue the drug if appropriate.

Please refer to the following website in FDA for details:

<http://www.fda.gov/Drugs/DrugSafety/ucm459579.htm>

In Hong Kong, a total of 5 registered ingredients belongs to the DPP-4 inhibitor drug class including sitagliptin, saxagliptin, linagliptin, alogliptin and vildagliptin. There are 8 registered pharmaceutical products containing sitagliptin (HK-56092, HK-56093, HK-56094, HK-56186, HK-56187, HK-63246, HK-63249 and HK-63250), 5 products containing saxagliptin (HK-59907, HK-60783, HK-62251, HK-62252 and HK-62253), 4 products containing linagliptin (HK-61383, HK-61966, HK-61967 and HK-62327), 7 products containing alogliptin (HK-62859, HK-62860, HK-63195, HK-63196, HK-63496, HK-63497 and HK-63498) and 8 products containing vildagliptin (HK-57309, HK-59043, HK-59044, HK-59813, HK-61982, HK-61983, HK-61984 and HK-63165). All the products are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction (ADR) on linagliptin and two cases of ADR on vildagliptin. None of them are related to joint pain. In view of new safety warning issued, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. The DH will remain vigilant on any safety updates of the drugs.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto: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 sincerely,

(Grant NG)

for Assistant Director (Drug)

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