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

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Canagliflozin: New information on bone fracture risk and decreased bone mineral density

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement regarding new information on bone fracture risk and decreased bone mineral density in patients taking canagliflozin.

FDA has strengthened the warning for the type 2 diabetes medicine canagliflozin (Invokana, Invokamet) related to the increased risk of bone fractures by adding a new WARNING AND PRECAUTION and revised the ADVERSE REACTIONS section of the products' drug labels.

Canagliflozin is a prescription medicine in the US, and is used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors.

FDA is continuing to evaluate the risk of bone fractures with other drugs in the SGLT2 inhibitor class, including dapagliflozin (Farxiga, Xigduo XR) and empagliflozin (Jardiance, Glyxambi, Synjardy), to determine if additional label changes or studies are needed.

Health Care Professionals are advised of the following:

- Bone fractures have been seen in patients taking the type 2 diabetes medicine canagliflozin.
- Fractures can occur as early as 12 weeks after starting canagliflozin.
- Canagliflozin has also been linked to decreases in bone mineral density at the hip and lower spine.
- Consider factors that contribute to fracture risk prior to initiating canagliflozin.
- Counsel patients about factors that may contribute to bone fracture risk.

Please refer to the FDA's website for details:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm461876.htm

In Hong Kong, there are two registered pharmaceutical products containing canagliflozin, namely Invokana Tablets 100mg (HK-63499) and Invokana Tablets 300mg (HK-63500) which are registered by Johnson & Johnson (Hong Kong) Ltd, and two registered pharmaceutical products containing dapagliflozin, namely Forxiga Tablet 5mg (HK-63301) and Forxiga Tablet 10mg (HK-63302) which are registered by Astrazeneca Hong Kong Ltd. All products are prescription-only medicines. There is no registered pharmaceutical product containing empagliflozin.

So far, the Department of Health (DH) has not received any adverse drug reaction (ADR) case on Invokana. DH has received one ADR case on Forxiga, and it is not related to bone fracture and/ or decreased bone mineral density. In view of the US FDA's announcement on strengthened warning for canagliflozin-containing medicines, the matter will be discussed in the meeting of 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)