衞生署藥物辦公室
藥物註冊及進出口管制科

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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Some metformin medicines found to contain N-nitrosodimethylamine (NDMA)

Your attention is drawn to the recent announcements made by the Health Sciences Authority (HSA) of Singapore, the United States Food and Drug Administration (FDA) and Health Canada regarding an impurity N-nitrosodimethylamine (NDMA) detected in some metformin medicines.

NDMA is a type of nitrosamine impurity that can be found in food or the environment. They are commonly found in low levels in processed food (pickled vegetables, salted fish, processed meat products such as bacon and sausages) and in air pollution. NDMA is not expected to cause harm when ingested at low levels. Acceptable levels of nitrosamines are set in nanograms (ng), i.e., one billionth of a gram. A person taking a drug that contains NDMA at or below the acceptable level every day for 70 years is not expected to have an increased risk of cancer.

In Singapore, the HSA is recalling, as a precautionary measure, three metformin medicines found to contain trace amounts of NDMA, which are above the internationally acceptable level. The FDA and Health Canada announced that there are no metformin recalls affecting the US and Canadian market at this time. The matter is being investigated and evaluated by these regulatory agencies and any possible risk to patients identified will be announced in due course.

Metformin is a prescription drug used to control high blood sugar in patients with type 2 diabetes. Patients should continue taking metformin to keep their diabetes under control. It could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professional. The FDA recommends prescribers continue to use metformin when clinically appropriate, as the FDA investigation is still ongoing, and there are no alternative medications that treat this condition in the same way.

Currently in Hong Kong, there are 125 registered pharmaceutical products containing metformin. All products are prescription-only medicines.

So far, the Department of Health (DH) has received 17 cases of adverse drug reaction related to metformin. None of them is concluded to be related to the presence of NDMA. The DH has contacted the certificate holders of all registered metformin products for follow up on the local impact of the issue. The DH has also contacted the HSA for further information regarding the detection of NDMA in metformin products, and continues to remain vigilant on the update findings and investigation result announced by various overseas drug regulatory authorities for consideration of any action deemed necessary. The DH is currently collecting samples of metformin-containing products in the local market for analysis. You are advised to take note of the latest development.

The announcements by the HSA, FDA and Health Canada can be found in the following websites for details.

HSA:
https://www.hsa.gov.sg/announcements/news/hsa-recalls-three-out-of-46-metformin-medicines

FDA:
https://www.fda.gov/news-events/press-announcements/statement-janet-woodcock-md-director-fdas-center-drug-evaluation-and-research-impurities-found

Health Canada:
https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/71831a-eng.php

Healthcare professionals are advised to keep abreast of the latest development and announcements regarding the NDMA found in metformin products. You may need to give health advice to your patients when consuming metformin product and consider prescribing or providing alternative treatments if necessary. For the full list of registered metformin products, please access at Drug Office's website (http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/search_drug_database.html).

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,

(Joseph LEE)
for Assistant Director (Drug)