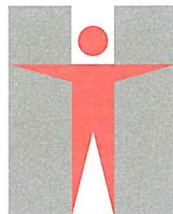


衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓



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

2319 8458

電話號碼 Tel. No.:

詢問處 Enquiries (852) 2319 8458

傳真號碼 Faxline No. (852) 2803 4962

本署檔號 OUR REF.: DH DO PRIE/7-30/15

18 September 2019

(來函請敘明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Potential contamination of Ranitidine with N-nitrosodimethylamine

Your attention is drawn to the recent announcements made by the European Medicines Agency (EMA), the United States Food & Drug Administration (US FDA), Health Canada, the Health Sciences Authority (HSA) of Singapore and the Therapeutic Goods Administration (TGA) of Australia regarding an impurity N-nitrosodimethylamine (NDMA) detected in the raw material and finished products of Ranitidine.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Acceptable levels of nitrosamines are set in nanograms (ng), i.e., one billionth of a gram, and is based on what is considered as reasonably safe if a patient continues to take the affected medicine every day for a lifetime of 70 years. There is no immediate health risk associated with this medication as the risks are associated with long-term use. In some regions, the supplies of some Ranitidine products have been stopped or suspended.

The cause of the contamination and the possible risk to patients are being investigated and evaluated by various regulatory agencies and any measures to address the issue will be announced in due course.

Currently, there are 67 registered pharmaceutical products containing ranitidine in Hong Kong. These products in the forms of oral preparations and injections are controlled as over-the-counter medicines and prescription-only medicines respectively. So far, DH has not received any case of adverse drug reaction related to ranitidine. The DH has been contacting the certificate holder of all registered ranitidine products for follow up on the local impact of the issue. The DH keeps vigilant on the development of the issue and any safety update of the drug issued by overseas drug regulatory authorities for consideration of any action deemed necessary. You are advised to take note of the

latest development.

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

EMA:

<https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma>

US FDA:

<https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine>

Health Canada:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70989a-eng.php>

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/71029a-eng.php>

HSA:

https://www.hsa.gov.sg/content/hsa/en/News_Events/HSA_Updates/2019/HSA-stops-supply8brandsRanitidine.html

TGA: <https://www.tga.gov.au/alert/ranitidine>

Healthcare professionals are advised to keep abreast of the latest development and announcements regarding the NDMA found in ranitidine products. You may need to give health advice to your patients when consuming ranitidine product and consider prescribing or providing alternative treatment if necessary. There are other registered alternatives in Hong Kong that are authorized for the same or similar uses as Ranitidine. For the full list of registered Ranitidine 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)