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
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

7 Nov 2019

Chairman
The Hong Kong Association of Medical Laboratories Limited

Dear Sirs,

The FDA warns that biotin may interfere with lab tests

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement that it is updating its 2017 safety communication to remind the public, health care providers, lab personnel, and lab test developers that biotin, often found in dietary supplements, can significantly interfere with certain lab tests and cause incorrect results that may go undetected. The FDA wants to make the public and health care providers aware about biotin interference with lab tests so that patients, physicians, and laboratories can work together to help prevent adverse events.

As noted in the original safety communication, while biotin in patient samples can cause falsely high or falsely low results, depending on the type of test, the FDA is particularly concerned about biotin interference causing a falsely low result for troponin, a clinically important biomarker to aid in the diagnosis of heart attacks, which may lead to a missed diagnosis and potentially serious clinical implications. The FDA continues to receive adverse events reports indicating biotin interference caused falsely low troponin results.

Since the FDA's safety communication on this topic in 2017, some lab test developers have been successful at mitigating the biotin interference of their assays, but others have not yet addressed it. The FDA remains concerned about troponin laboratory tests that have not addressed the risk of biotin interference. The FDA has posted a webpage on "Biotin Interference with Troponin Lab Tests - Assays Subject to Biotin Interference" to notify the public about troponin assays where the risk of biotin interference has not yet been addressed.

Please refer to the following website in FDA for details:
https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication

In Hong Kong, there are 113 registered pharmaceutical products containing biotin. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to biotin.

Related news was previously issued by FDA and Singapore Health Sciences Authority, and was posted on the Drug Office website on 29 Nov 2017, 28 May 2019 and 12 Sep 2019. Letters to inform local healthcare professionals were issued by the DH on 29 Nov 2017.

Laboratories and laboratory personnel are advised to take note of this announcement and to work together with patients and physicians to prevent adverse events.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)

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Secretary
COC, Pathology
Hospital Authority

Dear Ms. CHUNG,

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(Joseph LEE)
for Assistant Director (Drug)