

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

電話號碼 Tel. No.: 2319 8458

詢問處 Enquiries (852) 2319 8458

傳真號碼 Faxline No. (852) 2603 4962

本署檔號 OUR REF.: DH DO PRIE/7-30/15

BY FAX

7 March 2013

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

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Identification of the potential for crystallization in one batch of Cytarabine Injection 100mg/ml (1g/10ml)

Your attention is drawn to Medicines and Healthcare products Regulatory Agency's (MHRA) announcement on 6 March 2013 with respect to the potential for crystallisation in one batch (batch number: Z031966AA, expiry date: March 2014) of Cytarabine Injection 100mg/ml (1g/10ml) identified by the Hospira UK Limited.

The crystals have been determined to be the active ingredient Cytarabine. According to the Hospira UK Limited, the most probable cause for crystallisation is from particles of dried Cytarabine introduced during the filling process, which acted as a seed for crystal formation. The company has informed MHRA that no adverse events have been reported in connection with this crystallisation issue. Under the circumstances, healthcare professionals are asked to visually inspect vials for particulate matter prior to use. If crystals are found, the product should not be used.

Please refer to MHRA's website for details:

<http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON247079>

In Hong Kong, Cytarabine Inj 10% (Hospira) (HK-35149) is registered by Hospira Limited (Hospira) and is a prescription-only medicine. According to Hospira, the affected batch has been distributed to hospitals of the Hospital Authority, private hospitals and veterinary clinics since December 2012. Based on the information available, healthcare professionals are advised to visually examine the product before use. If crystals are found, the product should not be used. So far, the Department of Health (DH) has not received any adverse drug reaction report in relation to cytarabine injection. The DH will keep vigilant on the above issue.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)

for Assistant Director (Drug)

We are committed to providing quality client-oriented service