衞生署藥物辦公室
藥物註冊及進出口管制部

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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

BY FAX

12 July 2012

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

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

Health Canada: Sanofi Toronto Facility Update Regarding ImmuCyst

Your attention is drawn to that Health Canada has completed a thorough health risk assessment of the bladder cancer treatment ImmuCyst produced at Sanofi Pasteur's manufacturing plant in Toronto, which detected mould in the sterile manufacturing areas during a Health Canada inspection.

Health Canada's review has concluded that ImmuCyst should remain available to bladder cancer patients, provided the drug continues to meet quality assurance standards.

Health Canada has also requested Sanofi to advise Canadian health care practitioners of the situation as soon as possible. It was anticipated that the global supply of ImmuCyst might be affected in view of the manufacturing problems at the Toronto plant. Health Canada is working with Sanofi to expedite its correction to the manufacturing problems and will consult its international regulatory counterparts, including the U.S. Food and Drug Administration to lessen the global impact.

Please refer to Health Canada's website for details:

http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2012/2012_111-eng.php

In Hong Kong, Immucyst BCG Immunotherapeutic (HK-37556), containing BCG, is registered by Sanofi-Aventis Hong Kong Limited and is a prescription-only medicine. It is indicated for intravesical use in the prophylaxis and treatment of carcinoma *in situ* (CIS) of the urinary bladder. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment, especially when alternatives are not readily available to meet immediate patient need. Department of Health will keep in vigilance on the issue.

Department of Health also noted that the same manufacturing plant in Toronto produces another BCG vaccine, which was recalled in Canada in June 2012. However, the recalled product is not registered in Hong Kong.

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: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.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. Lilly HO)
for AD(D)