## 藥物註冊組

香港九龍兩昌街 382 號公共衛生檢測中心三樓



## DEPARTMENT OF HEALTH PHARMACEUTICALS REGISTRATION SECTION

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

電話號碼 Tel. No.:

2319 8458

納明城 Enquiries (852)2319 8458

傅真號码 Faxilne No.

(852)2803 4962

本器樹號 OUR REF:

DH PS PRIE/7-30/15

(來函請敍明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Dr. LIANG,

BY FAX

27 July 2011

## FDA - safety alerts on Methylene Blue injectable and Zyvox (linezolid)

FDA has received reports of serious central nervous system reactions when methylene blue injectable and Zyvox (linezolid) are given to patients taking psychiatric medications that work through the serotonin system of the brain.

Methylene blue injectable is used to treat methemoglobinemia. Zyvox (linezolid) is an antibacterial drug used to treat infections, including pneumonia and infections of the skin. Both are reversible monoamine oxidase inhibitors (MAOI).

Although the exact mechanism of the drug interactions are unknown, it is believed that when methylene blue injectable and Zyvox (linezolid) are given to patients taking serotonergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity symptoms such as twitching, sweating and diarrhea. In the United States, safety information about these potential drug interactions and important drug usage recommendations for emergency and non-emergency situations are being added to the drug labels for serotonergic psychiatric medications and Zyvox (linezolid). For details, please refer to the FDA's websites:

Methylene blue;

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm265476.h tm

Zyvox (linezolid):

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm265479.h tm

In Hong Kong, Methylene Blue Injection (HK-59020) is registered under Sino-Asia Pharmaceutical Supplies Ltd. As for Zyvox (linezolid), there are three registered dosage forms, respectively as tablet (HK-48055), injectable (HK-48056) and granule (HK-48057). They are prescription items, registered under Pfizer Corp. HK Ltd. In view of the FDA's actions, the matter will be discussed in the coming meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 8633, fax; 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.psdh.gov.hk at Pharmaceutical Service under "Reporting an Adverse Drug Reaction",