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DEPARTMENT OF HEALTH  
 DRUG OFFICE  
 DRUG REGISTRATION AND  
 IMPORT/EXPORT CONTROL DIVISION  
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 382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

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(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,

Bupropion Safety update – possible increased risk of some congenital cardiovascular malformations

Your attention is drawn to Singapore Health Sciences Authority's (HSA) announcement with respect to the possible increased risk of congenital cardiovascular malformations associated with bupropion (Wellbutrin SR tablet 150 mg).

Results from an epidemiology study investigating the risk of congenital cardiovascular malformations following bupropion exposure during the first trimester of pregnancy as well as findings from other studies suggested a potential increased risk of some congenital cardiovascular malformations such as ventricular septal and left outflow tract heart defects.

Healthcare professionals are encouraged to consider this new information and to weigh the option of alternative treatments in women who are pregnant or are planning to become pregnant.

Please refer to HSA's website for details:

[http://www.hsa.gov.sg/publish/hsaportal/en/health\\_products\\_regulation/safety\\_information/DHC\\_PL.print.html?Status=1](http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/DHC_PL.print.html?Status=1)

In Hong Kong, there are five registered pharmaceutical products containing bupropion including Wellbutrin SR sustained-release tab 150 mg (HK-52125). They are prescription-only medicines and are indicated for treatment of major depressive disorder or treatment of smoking cessation. In view of HSA's announcement, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

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](mailto: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)