衛生署

藥物註冊組

香港九龍南邑街 382 號公共衛生檢測中心三極



DEPARTMENT OF HEALTH PHARMACEUTICALS REGISTRATION SECTION

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

BY FAX

21 July 2011

2319 8458

電話號與 Tel. No.: 询問處 Enquiries

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(852)2319 8458

傳真號碼 Faxilne No.

(852)2803 4962

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(來國讀敘明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REE)

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

Dear Dr. LIANG,

FDA reminder for parents: do not give infants cough and cold products designed for older children

In 2008 in the United States, manufacturers voluntarily removed over-the-counter (OTC) infant (less than 2 years of age) cough and cold products from the market and re-labeled other cough and cold products to state: "do not use in children under 4 years of age". However, there are concerns that many parents may be giving cough and cold products that designed for older children to their infants. FDA therefore reminds all caregivers never to give a child under two years of age any kind of cough and cold product containing decongestants or antihistamines, without seeking the advice of a healthcare provider. These cough and cold products include those that contain the decongestants ephedrine, pseudoephedrine, or phenylephrine, and the antihistamines diphenhydramine, brompheniramine, or chlorpheniramine.

Cough and cold products for children under two years old were voluntarily removed from the market because of safety concerns as there were many reports of harm, and even death, to children who used these products. These reports of harm occurred when the child received too much medication such as in cases as accidental ingestion, unintentional overdose, or after a medication dosing error. In those reports of harm that lead to a child's death, most of those children were under two years of age. For detail, please refer to FDA's website:

http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm263948.htm

In Hong Kong, the safety issue had been discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board in April 2009. The Committee decided that pharmaceutical products for the treatment of cough and cold should no longer be indicated for the use of children under 6 years of age.

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".

Yours sincerely,

(Ms Pamela LI)
for Chief Pharmacist