

衛生署藥物辦公室
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

7 June 2013

Dear Healthcare Professionals,

Codeine – Recommends only be used in patients aged 12 and over

Your attention is drawn to Health Canada's announcement with respect to the recommendation on codeine only be used in patients aged 12 and over.

Health Canada has reviewed the safety of prescription pain and cough medications containing codeine and is no longer recommending their use in children less than 12 years of age. This recommendation is based on very rare cases of serious side effects and deaths in children that have been attributed to codeine, when given directly to a child, or to babies from breast milk. Non-prescription products containing codeine in Canada already indicate that they should not be administered to children.

Once ingested, codeine is converted by the body into morphine. Some people ("ultra-rapid metabolizers") convert codeine into morphine more rapidly and completely than do others. The use of codeine by these ultra-rapid metabolizers can potentially lead to unexpected morphine overdose. However, not all of the serious side effects have been linked to overdose. Other risk factors, including surgery to remove tonsils, may increase the risk of known codeine side effects such as the slowing of breathing.

Healthcare professionals are advised to seek alternatives to codeine for the management of mild to moderate pain or cough in children less than 12 years of age.

Please refer to Health Canada's website for details:

<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/33915a-eng.php>

In Hong Kong, there are 360 registered pharmaceutical products containing codeine, which is an ingredient used to relieve pain and cough. In April 2009, the Registration Committee of the Pharmacy and Poisons Board (the Committee) had decided that pharmaceutical products for the treatment of cough and cold should not be used for children under 6 years of age, and the label of cough and cold products should be revised accordingly. News regarding contraindication on use of codeine in children after tonsillectomy and/or adenoidectomy has been released by US FDA, and a letter to inform healthcare professionals was issued on 16 August 2012 by the Drug Office of the Department of Health. In view of Health Canada's latest recommendation, the matter will be discussed in the meeting of the Committee. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please 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 faithfully,

(Ms. Pamela LI)

for Assistant Director (Drug)

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