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

**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

16 August 2012

Dear Healthcare Professionals,

FDA: Codeine use in certain children after tonsillectomy and/or adenoidectomy may lead to rare, but life-threatening adverse events or death

Your attention is drawn to that the U.S. Food and Drug Administration (FDA) is reviewing reports of children who developed serious adverse effects or died after taking codeine for pain relief after tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome.

Recently, three pediatric deaths and one non-fatal but life-threatening case of respiratory depression were documented in the medical literature. These children (ages two to five) had evidence of an inherited (genetic) ability to convert codeine into life-threatening or fatal amounts of morphine in the body. All children had received doses of codeine that were within the typical dose range.

When codeine is ingested, it is converted to morphine in the liver by an enzyme called cytochrome P450 2D6 (CYP2D6). Some children have DNA variations that make this enzyme more active, causing codeine to be converted to morphine faster and more completely than in other people. Therefore they are more likely to have higher than normal amounts of morphine in their blood after taking codeine. High levels of morphine can result in breathing difficulty, which may be fatal. Taking codeine after tonsillectomy and/or adenoidectomy may increase the risk for breathing problems and death in those children.

FDA advised that healthcare professionals should be aware of the risks of using codeine in children, particularly in those who have undergone tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome. For those children, doctors may consider prescribing alternative analgesics. If it is necessary to prescribe codeine-containing drugs, the lowest effective dose for the shortest period of time should be used on an as-needed basis. Besides, doctors should counsel parents or caregivers on how to recognize the signs of morphine toxicity and advise them to seek medical attention immediately if their child is exhibiting these signs.

Please refer to FDA's website for details:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm315627.htm

In Hong Kong, there are about 362 registered pharmaceutical products containing codeine which is usually used to relieve pain and cough. Most of the registered products are cough and cold syrup. 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: 2147 0457 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. Christine CHEUNG)
for AD(D)