

衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓

2319 8458

電話號碼 Tel. No.:

詢問處 Enquiries (852) 2319 8458

傳真號碼 Faxline No. (852) 2803 4962

本署檔號 OUR REF.: DH DO PRIE/7-30/15

(來函請敘明此檔案號碼)

(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

21 April 2017

Dear Healthcare Professionals,

Prescription codeine pain and cough medicines and tramadol pain medicines: FDA restricts use in children; recommends against use in breastfeeding women

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding restriction on use of codeine and tramadol medicines in children; and recommendation against use in breastfeeding women.

In the U.S., codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

As a result, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond the FDA's 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. FDA is now adding:

- FDA's strongest warning, called a Contraindication, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new Contraindication to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Health care professionals should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Consider recommending over-the-counter (OTC) or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection, not serious, and usually will get better on its own so treatment may not be necessary.

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*

Please refer to the following website in FDA for details:

<https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm>

In Hong Kong, there are 312 registered pharmaceutical products containing codeine, including 30 products classified as prescription-only medicines (i.e. containing codeine 0.2% or more) and the remaining products classified as pharmacy-only medicines. News on codeine safety was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 2012, with the latest update posted on 5 January 2017. The Department of Health (DH) had issued letters to inform local healthcare professionals on the risk of respiratory depression on 16 August 2012, and on the restrictions to patients older than 12 years old on 7 June 2013. DH had posted the previous FDA evaluation on potential risk of serious side effects in children using codeine cough-and-cold medicines on the Drug Office website on 2 July 2015. On 5 July 2013, the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee) decided that the sales packs and/or package inserts of pharmaceutical products containing codeine should be updated to include the latest safety warnings restricting the use of codeine to patients older than 12 years old.

Meanwhile, there are 50 registered pharmaceutical products containing tramadol, and they are prescription-only medicines. DH had also posted the previous FDA evaluation on the risk of tramadol in children aged 17 and younger on the Drug Office website on 22 September 2015.

So far, DH has received 1 case of adverse drug reaction (ADR) after receiving codeine, and 2 cases of ADRs after receiving tramadol, but none of them was related to respiratory depression in adult or infant.

In view of the latest conclusions with new contraindication and warning of codeine and tramadol in the above FDA announcement, the matter will be further discussed by the Registration 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 drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)