衞生署藥物辦公室
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(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

12 January 2018

Dear Healthcare Professionals,

FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement on safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older because the risks of these medicines outweigh their benefits in children younger than 18. FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the Boxed Warning, FDA's most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

FDA is taking this action after conducting an extensive review and convening a panel of outside experts. Both of these determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

Healthcare professionals should be aware that FDA is changing the age range for which prescription opioid cough and cold medicines are indicated. These products will no longer be indicated for use in children, and their use in this age group is not recommended. Healthcare professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include over-the-counter (OTC) products such as dextromethorphan, as well as prescription benzonatate products.

Other Boxed Warnings and Warnings and Precautions will also be added to the label for prescription cough and cold medicines containing codeine or hydrocodone, to be consistent with the safety issues described in the labels of prescription opioid pain medicines.

Please refer to the following website in FDA for details:

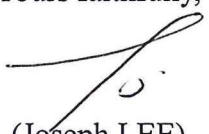
https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm

In Hong Kong, there are 309 registered pharmaceutical products containing codeine, which is an ingredient used to relieve cough. There is no registered pharmaceutical product containing hydrocodone. News on safe use of codeine preparation had been issued by various overseas drug regulatory authorities since 2012, with the latest update posted on the Drug Office website on 29 Nov 2017. In connection with the safety updates, the Department of Health (DH) had issued letters to inform local healthcare professionals on 16 Aug 2012, 7 Jun 2013 and 21 Apr 2017. So far, the DH has received one case of adverse drug reaction related to codeine for cough.

On 7 Dec 2017, the Registration Committee of the Pharmacy and Poisons Board decided that the sales pack labels and/or package inserts of products containing codeine should include contraindication for all children younger than 12 years of age and for post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy, and other safety warnings. In view of the above FDA's announcement, the matter regarding the updated age limit and safety information will be further discussed by the Registration Committee of the Pharmacy and Poisons Board. 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)