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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

Dear Healthcare Professionals,

Safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement with respect to class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain.

FDA is invoking its authority to require safety labeling changes and postmarket studies to combat the crisis of misuse, abuse, addiction, overdose, and death from these potent drugs. The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death.

The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother's womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

Please refer to FDA's website for details:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm

In Hong Kong, there are 24 pharmaceutical products which belong to ER/LA opioid analgesics, including the ingredients hydromorphone, morphine, oxycodone, tramadol, buprenorphine and fentanyl. All are prescription-only medicines and are indicated for use as analgesics. In view of the FDA's recommendation, the matter will be discussed in the meeting of 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 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)