衞生署藥物辦公室
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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Medication-assisted treatment with methadone and buprenorphine: Neonatal opioid withdrawal syndrome

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding FDA is requiring safety labeling changes for methadone and buprenorphine products when used by pregnant women for medication-assisted treatment (MAT) of opioid use disorder to ensure providers have complete information about the benefits and risks of these products.

National guidelines from the American College of Obstetricians and Gynecologists (ACOG) and the Substance Abuse and Mental Health Services Administration (SAMHSA), and international guidelines from the World Health Organization, recommend that pregnant women with opioid addiction be treated with methadone or buprenorphine. According to these guidelines, the rationale for MAT during pregnancy is to prevent complications of opioid abuse, addiction and withdrawal, and encourage prenatal care and drug treatment.

However, MAT can also present challenges due to the risk of the developing fetus being exposed to opioids, which can lead to neonatal opioid withdrawal syndrome (NOWS). NOWS can be effectively managed, but may be life-threatening if not recognized and treated.

Since NOWS can result from in utero exposure to opioids – whether medically authorized or illicit – the risk of NOWS from MAT must be balanced against the risk of untreated opioid addiction during pregnancy; an independent advisory committee and numerous reproductive health experts agree this balance is important. If left untreated, illicit opioid use is associated with poor pregnancy outcomes such as low birth weight, preterm birth, or fetal death.

The FDA's action requiring safety labeling changes is among a number of steps the agency has taken recently to inform prescribers about the appropriate use of opioid medications. Labels for buprenorphine products that are used to treat pain are already required to provide information to prescribers about the risks associated with NOWS in a boxed warning, which is the FDA's strongest warning. These new safety labeling change requirements for methadone and buprenorphine products that are used for MAT include a statement in the Warnings and Precautions section about the risk of NOWS, as well as related modifications to the Pregnancy, Dependence, and Patient Counseling Information sections. (A boxed warning for NOWS is not being required for the MAT-only methadone and buprenorphine products.)

Please refer to the FDA's website for details:

http://www.fda.gov/Drugs/DrugSafety/ucm503630.htm

In Hong Kong, there are five registered pharmaceutical products containing methadone, and eight products containing buprenorphine. All products are prescription only medicines. So far, the Department of Health (DH) has not received any adverse drug reaction case related to methadone or buprenorphine. In view of the above FDA announcement, the matter will be 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,

(Grant NG)
for Assistant Director (Drug)