衞生署藥物辦公室
藥物註冊及進出口管制部

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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

12 February 2018

Dear Healthcare Professionals,

Women taking Esmya for uterine fibroids to have regular liver tests while EMA review is ongoing. No new patients should start treatment for the time being.

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the EMA Pharmacovigilance Risk Assessment Committee (PRAC) is currently reviewing the benefits and risks with Esmya (ulipristal acetate), following reports of serious liver injury, including liver failure leading to transplantation.

As a temporary measure while the review is ongoing, the PRAC has recommended regular liver monitoring for women taking Esmya for uterine fibroids. All women taking Esmya should have a liver function test at least once a month during treatment. If the test is abnormal (liver enzyme levels more than 2 times the upper limit of normal), the healthcare professional should stop treatment and closely monitor the patient. Liver tests should be repeated 2 to 4 weeks after stopping treatment.

The PRAC is also recommending that no new patients should be started on Esmya and no patients who have completed a course of treatment should start another one for the time being.

A link between Esmya and cases of serious liver injury is under review. These recommendations are temporary measures to protect patients' health, pending the conclusion of the review of Esmya which started in Dec 2017.

Please refer to the following website in EMA for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Esmya/human_referral_prac_000070.jsp&mid=WC0b01ac05805c516f

In Hong Kong, Esmya Tablets 5mg (HK-62553) is a pharmaceutical product registered by Orient Europharma Co. Ltd., and is a prescription-only medicine. Related news was previously issued by EMA, and was posted on the Drug Office website on 2 Dec 2017. So far, DH has not received any case of adverse drug reaction related to Esmya. As the review of Esmya is ongoing, DH will remain vigilant on the conclusion of the review and safety update of the drug issued by other overseas drug regulatory authorities. 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)