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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

EMA recommended the suspension of ulipristal acetate for uterine fibroids during ongoing review of liver injury risk

Your attention is drawn to the European Medicines Agency's (EMA) announcement that it has recommended women to stop taking 5-mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids while a safety review is ongoing. No new patients should start treatment with the medicines, which will be temporarily suspended throughout the European Union during the review.

EMA is starting its review at the request of the European Commission following a recent case of liver injury, which led to liver transplantation in a patient taking the medicine.

A 2018 EMA review concluded that there is a risk of rare but serious liver injury with ulipristal acetate medicines for the treatment of uterine fibroids, and measures were implemented to minimise the risk. However, as the new case of serious liver injury occurred in spite of adherence to these measures, EMA is starting a new review.

In Europe, cases of serious liver injury have been reported, including 5 that led to transplantation, out of over 900,000 patients who have been treated with ulipristal acetate for fibroids since its authorisation in 2012.

Ulipristal acetate is also authorised as a single-dose medicine for emergency contraception in Europe. This review does not affect the single-dose ulipristal acetate emergency contraceptive (ellaOne and other trade names) and there is no concern about liver injury with these medicines. Further information and updated recommendations will be provided once the review is concluded.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/medicines/human/referrals/ulipristal-acetate-5mg-medicinal-products

In Hong Kong, Esmya (ulipristal acetate) Tablets 5mg (HK-62553) is a pharmaceutical product registered by Orient Europharma Co. Ltd, and is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to Esmya (ulipristal acetate 5mg).

Related news was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 2 Dec 2017, with the latest update posted on 13 Sep 2019. Letters to inform local healthcare professionals of the risk of serious liver injury were issued by the Department of Health (DH) on 12 Feb 2018. On 12 Dec 2018, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the relevant warnings should be included in the package insert of the product.

In light of the above EMA's announcement, the DH will remain vigilant on the conclusion of the review and any safety updates issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and Adverse Drug Reaction 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)