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(IN REPLY PLEASE QUOTE THIS FILE REF.)

11 July 2022

Dear Healthcare Professionals,

Medicines containing nomegestrol or chlormadinone:
PRAC recommends new measures to minimise risk of meningioma

Your attention is drawn to the European Medicines Agency's (EMA) announcement that its Pharmacovigilance Risk Assessment Committee (PRAC) has recommended new measures to minimise the risk of meningioma with medicines containing nomegestrol or chlormadinone, which are used for gynaecological and menstrual disorders, hormone replacement therapy and, at lower doses, as hormonal contraceptives (birth control). Meningioma is a tumour of the membranes covering the brain and spinal cord. It is usually benign and is not considered to be a cancer, but due to their location in and around the brain and spinal cord, meningiomas can in rare cases cause serious problems.

The PRAC has recommended that medicines containing high-dose chlormadinone (5 – 10 mg) or high-dose nomegestrol (3.75 – 5 mg) should be used at the lowest effective dose and for the shortest duration possible, and only when other interventions are not appropriate. In addition, low- and high-dose nomegestrol or chlormadinone medicines must not be used by patients who have, or have had, meningioma.

As well as restricting the use of the high-dose medicines, the PRAC has recommended that patients should be monitored for symptoms of meningioma, which can include change in vision, hearing loss or ringing in the ears, loss of smell, headaches, memory loss, seizures and weakness in arms or legs. If a patient is diagnosed with meningioma, treatment with these medicines must be permanently stopped.

The product information for the high-dose medicines will also be updated to include meningioma as a rare side effect.

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The recommendations follow a review of available data, including post-marketing safety data and results from two recent epidemiological studies. These data showed that the risk of meningioma increases with increasing dose and duration of treatment.

The PRAC recommendations will be sent to the Committee for Medicinal Products for Human Use (CHMP) for the adoption of EMA's final opinion.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/medicines-containing-nomegestrol-chlormadinone-prac-recommends-new-measures-minimise-risk-meningioma

In Hong Kong, there is no registered pharmaceutical product containing nomegestrol. There is one registered pharmaceutical product (HK-65918) containing chlormadinone in combination with ethinyloestradiol in tablet dose form. The product is a prescription-only medicine. So far, the Department of Health (DH) has not received cases of adverse drug reaction related to chlormadinone. Related news was previously issued by EMA, and was posted on the Drug Office website on 2 Oct 2021. As the above PRAC's recommendation will be sent to CHMP for further endorsement, DH will remain vigilant on the development of the issue and safety update of the drug issued by other overseas drug regulatory authorities.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. 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 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,

(Terence MAN)
for Assistant Director (Drug)