衞生署藥物辦公室
藥物資訊及進出口管制科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

9 Sep 2024

Dear Healthcare Professionals,

EMA recommends measures to minimise the risk of meningioma with medicines containing medroxyprogesterone acetate

Your attention is drawn to the European Medicines Agency (EMA) announcement that the Pharmacovigilance Risk Assessment Committee (PRAC) recommends measures to minimise the risk of meningioma, a type of brain tumour, with medicines containing medroxyprogesterone acetate.

These medicines are used for gynaecological (including contraception and endometriosis) and oncological indications.

Meningiomas are tumours of the tissue layer surrounding the brain and spinal cord. Usually they are benign (non-cancerous) and grow slowly but, depending on the size or location, they can cause serious problems.

The committee's recommendations followed a review of data from epidemiological studies, case studies from the medical literature and cases reported in the pharmacovigilance database of the European Union. These data show an increased risk of meningioma in people taking high doses of medroxyprogesterone acetate (injectables and ≥100 mg tablets) for several years. Although the relative risk of meningioma is significantly increased with the use of high-dose medroxyprogesterone acetate, the absolute risk is very small.

PRAC recommended that, in patients who have a meningioma or have had one in the past, medicines containing high-dose medroxyprogesterone acetate must not be used, unless medroxyprogesterone acetate is needed for the treatment of an oncological indication.

PRAC also recommended that patients taking high doses of medroxyprogesterone should be monitored for symptoms of meningioma, which can include change in vision, hearing loss or ringing in ears, loss of smell, headaches, memory loss, seizures and weakness in arms and legs. If a patient

treated for a non-oncological indication is diagnosed with meningioma, treatment with high-dose medroxyprogesterone acetate must be stopped. If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with high-dose medroxyprogesterone should be carefully considered, on a case-by-case basis, taking into account individual benefits and risks.

The product information for medicines containing high-dose medroxyprogesterone acetate will be updated to include meningioma as a possible side effect of unknown frequency.

The PRAC has agreed a direct healthcare professional communication (DHPC) to inform healthcare professionals of the increased risk of developing meningioma with high doses of medroxyprogesterone acetate (all injectable and ≥100 mg oral formulations), primarily after prolonged use (several years). The DHPC will highlight that medicines containing high doses of medroxyprogesterone acetate, when used for contraception or non-oncological indications, are contraindicated in patients with meningioma or with a history of meningioma. If a meningioma is diagnosed in a patient treated with high doses medroxyprogesterone acetate, treatment must be stopped.

If a meningioma is diagnosed in an oncological patient treated with high doses medroxyprogesterone acetate, the need to continue the treatment should be carefully reconsidered, on a case-by-case basis taking into account individual benefits and risks.

Patients treated with high doses medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-2-5-september-2024

In Hong Kong, there are 10 registered pharmaceutical products containing medroxyprogesterone acetate and 6 of them contain high doses of medroxyprogesterone acetate (injectable and ≥100 mg oral formulations). All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reactions related to medroxyprogesterone acetate. In light of the above EMA's announcement the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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 Clinical Trials and 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,

(Terence MAN)
for Assistant Director (Drug)