PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

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3rd March 2026

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Medroxyprogesterone Acetate

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the Committee) under the Pharmacy and Poisons Board has recently reviewed and considered the latest warnings regarding the risk of meningioma related to the use of medroxyprogesterone acetate issued by the European Medicines Agency, as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Canada, Singapore, the United Kingdom and the United States, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing medroxyprogesterone acetate shall include the following new safety information (or equivalent Note 1) as appropriate:

Note 1 Related safety information with other wording in accordance with reputable references and/or approved package inserts from drug regulatory authorities of reference countries may also be accepted on a case-by-case basis.

For pharmaceutical products containing:

(I) high-dose medroxyprogesterone acetate (injectables and ≥100 mg tablets) with non-oncological indication only:

*"**Contraindications***

Meningioma or history of meningioma.

Special warnings and precautions for use

Meningioma

Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients treated with medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice. If a patient is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precautionary measure.

In some cases, shrinkage of meningioma was observed after treatment discontinuation of depot medroxyprogesterone acetate.

Undesirable effects

Neoplasms benign, malignant and unspecified: Meningioma."

(II) high-dose medroxyprogesterone acetate (injectables and ≥100 mg tablets) with oncological indication only:

*"**Special warnings and precautions for use***

Meningioma

Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients should be monitored for signs and symptoms of meningiomas in accordance with clinical practice. If a patient is diagnosed with meningioma, the need for further treatment with medroxyprogesterone acetate should be carefully considered on a case-by-case basis taking into account individual benefits and risks. In some cases, shrinkage of meningioma was observed after treatment discontinuation of depot medroxyprogesterone acetate.

Undesirable effects

Neoplasms benign, malignant and unspecified: Meningioma."

(III) high-dose medroxyprogesterone acetate (injectables and ≥100 mg tablets) with both non-oncological and oncological indications:

*"**Contraindications***
Meningioma or history of meningioma (for non-oncological indications).

Special warnings and precautions for use
Meningioma
Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients treated with medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice.
In some cases, shrinkage of meningioma was observed after treatment discontinuation of depot medroxyprogesterone acetate. If a patient treated for a non-oncological indication is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precautionary measure.
If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with medroxyprogesterone acetate should be carefully considered on a case-by-case basis taking into account individual benefits and risks.

Undesirable effects
Neoplasms benign, malignant and unspecified: Meningioma."

(IV) medroxyprogesterone acetate that are not injectables and <100mg tablets:

*"**Special warnings and precautions for use***
Meningiomas have been reported following long term administration of progestogens, including medroxyprogesterone acetate. This medicine should be discontinued if a meningioma is diagnosed. Caution is advised when recommending medroxyprogesterone acetate to patients with a history of meningioma."

You are required to ensure the sales pack labels and/or package inserts of the concerned products registered by your company contain the above safety information to comply with the new requirements.

In addition, please be reminded that the sales pack labels and/or package inserts of the registered pharmaceutical products containing medroxyprogesterone acetate injections should contain the safety information previously endorsed by the Committee. For the list of previously endorsed safety information, please refer to the new "Search for Additional Safety Information" function in the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp.

Please review whether the concerned products registered by your company contain all required safety information on their sales pack labels and/or package inserts. If updates are required, please submit an application for the change of the registered particular(s) to the Drug Office via the abovementioned online PRS 2.0 for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not being renewed by the Committee upon certificate expiry.

For further enquiries on the registration matters of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

c.c. 7-15/3, Product Files