Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 July 2019

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[**PRAC**](https://www.ema.europa.eu/en/glossary/prac)**starts review of meningioma risk with cyproterone medicines**

EMA’s safety committee ([PRAC](https://www.ema.europa.eu/en/glossary/prac)) has started a review of medicines containing cyproterone, which are used for treating a range of conditions, including excessive hair growth, prostate cancer and acne, as well as in hormone replacement therapy.

The review will look into the risk of meningioma, a rare, usually non-malignant tumour of the membranes covering the brain and spinal cord, which can cause serious problems due to its location in the body.

A recent study in France suggested that the risk of meningioma, although very low, may be increased in people taking high doses of cyproterone for a long period.

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) will now examine the available evidence and make recommendations on the use of cyproterone-containing medicines across the EU.

More information is available below.

[**PRAC**](https://www.ema.europa.eu/en/glossary/prac)**recommends new measures to avoid dosing errors with methotrexate**

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) is recommending new measures to avoid dosing errors that have led to some patients incorrectly taking methotrexate-containing medicines daily instead of weekly.

Methotrexate is used to treat both inflammatory diseases and cancer. When used as an anti-inflammatory in the treatment of diseases such as arthritis and psoriasis, it is taken once a week. For the treatment of some types of cancer, a much higher dosage is needed and the medicine is taken more frequently. Mistakes in prescribing or dispensing methotrexate as well as misunderstandings of the dosing schedule have led to patients taking the medicine daily instead of weekly for inflammatory diseases, with serious consequences, including fatalities.

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) examined the available evidence and recommended additional measures to reduce dosing errors. These include restricting who can prescribe these medicines, making warnings on the packaging more prominent and providing educational materials for patients and healthcare professionals. In addition, to help patients follow the once-weekly dosing, methotrexate tablets for weekly use will be provided in blister packs and not in bottles or tubes.

More information is available below.