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# Review of meningioma risk with cyproterone medicines

EMA 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. The risk of meningioma with cyproterone daily doses of 10 mg or more has been known since 2008 and information was included in the prescribing information for these medicines along with a warning that cyproterone should not be used in people who have or have had a meningioma tumour. However, there was no information at the time on the magnitude of the risk and how the risk could change with different doses.

A recent study in France has now suggested that the risk of meningioma, although still very low, may be greater in those taking high doses of cyproterone for a long period. The study also showed that after patients had stopped cyproterone treatment for at least one year, the risk of developing these tumours was much reduced but remained slightly higher than usual.

Due to their location in and around the brain and spinal cord, meningiomas can cause serious problems. The French medicines authority has therefore asked EMA to investigate this risk, taking into account all the latest data.

EMA's safety committee (PRAC) will now examine the available evidence and make recommendations as to whether the marketing authorisations for cyproterone-containing medicines should be amended across the EU.

## More about the medicine

Cyproterone is an antiandrogen medicine, meaning that it blocks the action of androgens, a type of sex hormone found in both men and women, and it also acts in the same way as another sex hormone called progesterone. Medicines containing cyproterone are used to treat various androgen-dependent conditions such as hirsutism (excessive hair growth), alopecia (hair loss), early puberty, amenorrhoea (lack of menstrual period), acne and prostate cancer. They are also used in hormone replacement therapy. Cyproterone medicines contain either cyproterone alone or cyproterone at a lower dose in combination with an oestrogen (a third type of sex hormone).

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Cyproterone has been authorised in the EU via national procedures since the 1970s and is available on prescription under various trade names.

**More about the procedure**

The review of cyproterone-containing medicines has been initiated at the request of France, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As cyproterone-containing medicines are all authorised nationally, the PRAC recommendations will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.