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EMA starts review of meningioma risk with nomegestrol- and chlormadinone-containing medicines

EMA has started a review of medicines containing the active substance nomegestrol or chlormadinone. These medicines can be used, alone or in combination with other active substances, to treat gynaecological disorders such as amenorrhea (absence of menstrual periods) and other menstrual disorders, uterine bleeding, endometriosis (a condition in which tissue similar to the lining of the womb grows elsewhere in the body), breast tenderness, and as hormone replacement therapy or contraceptives (birth control).

The review was requested by the French medicines agency (ANSM) following new data from two epidemiological studies carried out in France in women taking these medicines to investigate the risk of meningioma, a tumour of the membranes covering the brain and spinal cord. This tumour is usually non-malignant 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.

Cases of meningioma have been reported in women taking medicines containing nomegestrol or chlormadinone, and warnings are already included in the prescribing information for some of the medicines. However, the information for prescribers and patients may differ across EU Member States.

Data from the two studies suggest that the risk of meningioma increases with dose and duration of treatment and may be greater in women taking nomegestrol or chlormadinone for several years. The studies also showed that after women had stopped taking nomegestrol or chlormadinone for one year or more, the risk of developing these tumours was reduced and comparable to the risk in people who never used these medicines.

In light of these new data, EMA's safety committee (PRAC) will now examine the available evidence and make recommendations as to whether the marketing authorisations for nomegestrol- and chlormadinone-containing medicines should be amended across the EU.

More about the medicines

Medicines containing nomegestrol acetate or chlormadinone acetate currently being reviewed are available as tablets to be taken by mouth. They are available on their own or in combination with

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oestrogens, and are marketed under several trade names including Belara, Lutenyl, Luteran, Naemis, Zoely and several generic medicines.

With the exception of Zoely (nomegestrol acetate/estradiol), which is centrally authorised, all other medicines concerned by this procedure have been authorised via national procedures.

More about the procedure

The review of nomegestrol- and chlormadinone-containing products 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. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.