EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency update on Diane 35 and generics used in the treatment of acne

The French medicines agency announced today its plan to suspend the marketing authorisation for Diane 35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms) and its generics for acne treatment in France.

These medicines are widely used across Europe. They have been authorised at the level of individual Member States for many years. In France, they are only authorised for the treatment of acne, but in a number of other Member States they are also authorised for the treatment of acne in women who wish to receive oral contraception, as well as for the treatment of other skin conditions.

The announcement in France follows a review by the French medicines agency (ANSM) of known data. ANSM considered that Diane 35 and its generics carry a risk of thromboembolism which has been well known for many years, while their effectiveness in treating acne was only moderate and alternative treatments for acne are available. In addition, it noted that they are widely used off-label as a contraceptive.

Although Member States can take unilateral action to suspend the marketing authorisation of a medicine, European legislation requires that there is a coordinated European approach in these instances. France has already indicated that it will ask the European Medicines Agency to carry out a European-wide review of Diane 35 and its generics. Once the notification has been received, the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) will evaluate all evidence on the benefits and risks of these medicines and give a recommendation on whether their marketing authorisations should be varied, suspended or revoked, in the interest of all patients in the EU.

Pending the outcome of the PRAC review, women who are currently taking Diane 35 or one of its generics are advised not to stop the medicine. If a woman has concerns, she can discuss this with her doctor.

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Notes

1. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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