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Start of review of Diane 35 and other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms

The European Medicines Agency (EMA) has started a review of Diane 35 and other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms, following the decision by the French medicines regulatory agency (ANSM) to suspend Diane 35 and its generics in France within three months.

Diane 35 and other medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms are widely used across Europe and have been authorised for many years. Authorised uses differ between the Member States. In some countries including France, they are only authorised for the treatment of acne in women. In other Member States these medicines are also authorised as a contraceptive for use in women with acne and other hormone related conditions who wish to receive oral contraception.

The French decision follows a review by ANSM of reports of venous and arterial thromboembolism (VTE and ATE, the formation of blood clots in the veins or arteries) in association with Diane 35 and its generics since their marketing authorisation. Although the risk of VTE with these medicines has been known for many years, ANSM considered this risk to outweigh its moderate benefits in treating acne for which alternative treatments are available. In addition, it noted that in France these medicines are widely used off-label as a contraceptive.

The EMA will now review all available data on the risk of VTE and ATE with medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms, and will issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Full details are available under the 'data submission' tab.



More about the medicine

Medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms have been approved in all EU Member States except Cyprus via national procedures. They are available on prescription under various trade names. In France, Diane 35 has been authorised since 1987. It works by blocking the effects of a class of hormones called androgens. Authorised uses differ between Member States and include acne and other conditions caused by androgens such as hirsutism (excessive growth of hair on the face) and alopecia (loss of hair). They are also authorised in some Member States for use in women with these conditions who wish to receive oral contraception.

More about the procedure

The review of medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms has been initiated at the request of France, under Article 107i 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 these medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States. A CMDh position is expected in May 2013.