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Press Office

Press release

European Medicines Agency starts safety review of Diane 35 and its generics

Pharmacovigilance Risk Assessment Committee to give EU-wide recommendation

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) formally started a safety review of Diane 35 (cyproterone acetate 2 mg, ethinylestradiol 35µg), associated names and its generics at its 4-7 February 2013 meeting.

The Europe-wide review has been initiated at the request of the French medicines regulatory agency (ANSM), following the announcement of its plan to suspend the marketing authorisations for Diane 35 and its generics for acne treatment in France over the next three months. This was the result of an analysis of known data, including reports of venous and arterial thromboembolism (VTE and ATE, the formation of blood clots in the veins or arteries) recorded in the French national pharmacovigilance database in association with Diane 35 and its generics over a period of more than 20 years.

These medicines have been authorised at the level of individual Member States for many years. They are widely used across Europe. However, their authorised uses differ between Member States. In many countries they are authorised as a contraceptive in women with hormone-related conditions such as acne, hirsutism (excessive growth of hair on the face) and alopecia (loss of hair). In France, they are only authorised for the treatment of acne, but ANSM has noted wide-spread off-label use as a contraceptive.

The risk of venous thromboembolism with these medicines is low but well known, and warnings are included in their product information to alert patients and prescribers to the risks. European legislation requires that there is a coordinated European approach when a Member State takes regulatory action in relation to a medicine that is authorised in more than one country. Therefore, the PRAC will evaluate all available evidence on the benefits and risks of these medicines and give a recommendation on whether their marketing authorisations should remain as they are, be varied, suspended or revoked, in the interest of all patients in the European Union. It is expected that the PRAC will adopt a recommendation at its 13-16 May 2013 meeting.

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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 them with her doctor.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information about Diane 35 and its generics, including where in the European Union these medicines are authorised, is available on the Agency's website.
3. The PRAC also formally started a review of combined contraceptives containing chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin and norgestimate, often referred to as third and fourth generation contraceptives. More information on this referral procedure is available on the Agency's website.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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