MedicalXpress

Acne pill benefits outweigh blood clot risk, EU body says

May 30 2013

An EU medicines watchdog on Thursday endorsed the safety of acne drug Diane-35, also widely used as a contraceptive, despite protests from France, which has suspended its use.

The CMDh, which groups EU drug agencies, agreed with a ruling by the European Medicines Agency (EMA) two weeks ago that the benefits of Diane-35 outweighed the risks of developing blood clots.

The CMDh decision, by 26 votes to France's one, agreed with an EMA proposal that the drug should be prescribed solely for acne treatment, as also indicated by its German manufacturer, Bayer.

It should not be used in combination with hormonal contraceptives, as this would expose the user to double doses of the female hormone oestrogen and a higher risk of potentially deadly blood clots.

The CMDh is tasked with resolving disagreements between EU member states and assuring uniform drug safety measures.

The risk of developing blood clots from these kinds of medicines was "low and well-known", said an EMA statement announcing the CMDh's decision.

Diane-35 is authorised in over 100 countries and used by millions of women.

According to the package insert on Bayer's website, the pill should be used for hormonal skin conditions in cases where other treatments had not worked.

The leaflet seeks to discourage the drug's use for birth control alone —although Diane-35's hormone make-up means it acts as a contraceptive by blocking ovulation.

The insert does warn of a higher risk of blood clots in the blood vessels, which can break off and obstruct blood flow to key organs and cause heart attacks or strokes, even death.

In January, French health regulator ANSM suspended sales of the hormone tablet, which it linked to four deaths and more than 100 cases of blood clots in the past 25 years.

In France, Diane-35 had been authorised for acne treatment but had also sometimes been prescribed as a contraceptive—about 315,000 women in the country used it in 2012.

The CMDh's decision will now be sent to the European Commission for a legally binding decision to be applicable throughout the EU—including France.

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Citation: Acne pill benefits outweigh blood clot risk, EU body says (2013, May 30) retrieved 10 April 2024 from https://medicalxpress.com/news/2013-05-acne-pill-benefits-outweigh-blood_1.html

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