

## **EU drug agency to review safety of new-generation Pill (Update)**

January 28 2013

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The European Medicines Agency (EMA) on Monday said it would review safety data for third- and fourth-generation birth control pills, responding to French concern that these contraceptives may cause dangerous blood clots.

The agency, describing oral contraceptives as carrying only "a very rare risk" of clots, said a watchdog panel would assess whether European guidelines for using later versions of the Pill should be changed.

On January 11, France announced it would ask the EMA to modify prescription recommendations for the third- and fourth-generation pills.

It pointed to evidence that their use led to higher risk of blood clots compared with older versions of the Pill, although the risk in absolute terms is small.

France wants guidelines changed so that doctors no longer prescribe later-generation pills as a first option.

EMA said its Pharmacovigilance Risk Assessment Committee (PRAC) would be carrying out the review, the first time a member-state has asked for such an assessment for a contraceptive pill.

"Combined oral contraceptives are kept under close monitoring by national pharmacovigilance systems," EMA said in a press release.

"There is no reason for any woman to stop taking her contraceptive. If a woman has concerns, she can discuss this with her doctor."

The third-generation Pill was introduced in the 1990s, and the 4th generation in the last decade.

They contain synthetic versions of the female hormone progestogen, which the makers say avoid some of the side-effects of older formulations.

A Danish study published in the British Medical Journal (BMJ) in 2011 found women who took one of the newer types of Pill ran twice the risk of developing blood clots in the veins than those who used older-generation drugs.

Compared with non-users of the Pill, the risk of a clot was between three and six times higher.

Clots formed in the veins can break up and be transported to the heart or lungs and may be fatal.

In absolute terms, though, the risk is small, experts stress.

EMA said that birth-control pills in general "carry a very rare risk" of these clots. It said there were between 20 and 40 cases per 100,000 women in one year of use; third- and fourth-generation pills carried a relatively higher risk. Risks were described in leaflets to patients and doctors.

About 2.5 million women in France take the 3rd- and 4th-generation Pill, about half of all oral contraceptive users.

The storm in France was triggered partly by the case of a 25-year-old

woman, Marion Larat, who was left badly handicapped by a stroke that, in a lawsuit, she attributed to a later-generation pill made by German firm Bayer.

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