

Morning-after pill may not work in heavier women

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The European Medicines Agency says it has started a review of emergency contraceptives to see if they work less well in heavier women.

In November, French drug maker HRA Pharma announced its morning-after pill Norlevo was less effective in <u>women</u> weighing more than 75 kilograms (165 pounds) and that it didn't work for women more than 80 kilograms (176 pounds). HRA Pharma changed its labels to warn patients after consulting with European regulators.

In a statement on Friday, the EMA said it would evaluate new data suggesting that a high body weight could compromise the effectiveness of the morning-after pill.

"This is an efficacy issue," said Monika Benstetter, an agency spokeswoman. "We need to find out what the association is with (body mass index) and if there is a cut-off threshold for when the medicine becomes less effective."

HRA Pharma's Norlevo contains levonorgestrel, the same active ingredient in other medicines including ellaOne, Levonnelle and Levodonna. One of the studies that prompted the label change on Norlevo found the risk of emergency contraception failing was higher in women with a body mass index higher than 25, considered to be overweight.



EMA's Benstetter said the agency needed to perform an assessment of all products in the same category as Norlevo to ensure labels across the European Union are consistent. She said there was no timeline on when the review would be completed.

In November, the U.S. Food and Drug Administration said it was also studying the issue.

The morning-after pill can be taken up to 72 hours after unprotected sex. It contains a higher dose of the hormone in regular <u>birth control pills</u> and works by preventing ovulation or fertilization of an egg. It has no effect if a woman is already pregnant.

Some doctors have previously advised that heavy women consider alternatives like a copper IUD, a birth control device that can be fitted on the uterus.

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