



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# European Medicines Agency to review third- and fourth-generation combined oral contraceptives

## Review to determine whether changes to authorisation are necessary

The European Medicines Agency has been asked by France to review third- and fourth-generation combined oral contraceptives to determine whether there is a need to restrict the use of these medicines to women who cannot take other combined oral contraceptives.

France has made this request amid recent initiatives to reduce the use of third- and fourth-generation combined oral contraceptives by French women in favour of using second-generation oral contraceptives.

It is well established that combined contraceptives carry a very rare risk of venous thromboembolism (VTE or blood clots). The absolute risk is very small (between 20 and 40 cases per 100,000 women in one year of use), and the risk differs between different generations of combined contraceptives. There is a higher risk for third- and fourth-generation contraceptives compared with first- and second-generation contraceptives. Information about the risks of VTE is included in leaflets for patients and prescribers, and has been continuously updated.

The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) will be reviewing third- and fourth-generation combined oral contraceptives to give its opinion on whether the currently available product information provides the best information possible for patients and doctors to take appropriate healthcare decisions. This is the first time that Member States have requested the Agency to give an EU-wide recommendation for these medicines under the framework of the new pharmacovigilance legislation.

Combined oral contraceptives are kept under close monitoring by national pharmacovigilance systems. There is no reason for any woman to stop taking her contraceptive. If a woman has concerns, she can discuss this with her doctor.

More information about the review by the PRAC will be published following the next meeting of the Committee on 4 to 7 February 2013.



## Notes

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1. This press release, together with all related documents, and more information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

## Contact our press officers

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