

EU drug agency rejects French request on birth pills

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The European Medicines Agency (EMA) on Friday rejected a French request to tighten prescription guidelines on types of birth-control pills linked with a relatively higher risk of blood clots.

A panel reviewed the evidence and concluded that the "benefits of all combined hormonal contraceptives (CHCs) continue to outweigh risks," the EU watchdog said, using the medical term for contraceptive [pills](#).

"There is no reason for women who have been using CHCs without any problem to stop taking them on the basis of this review."

In January, France asked the EMA to modify prescription guidelines for so-called third- and fourth-generation of the pill, which were introduced in the 1990s and in the last decade respectively.

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

A Danish study in 2011 found that women who used later generations of the pill ran twice the risk of developing [blood clots](#), known as venous thromboembolism (VTE), compared to those who used older-generation drugs.

Compared with non-users of the Pill, the risk of a clot was three to six times higher. A VTE can be dangerous as clots formed in the veins can break up and be transported to the heart or lungs.

In absolute terms, though, the risk is low, experts have said.

In its review, the EMA's Pharmacovigilance Risk Assessment Committee found that the risk of VTEs with all contraceptives "is small," the agency said.

"There are small differences between the CHCs depending on the type of progestogen they contain," it added.

The EMA said it recommended updating the product information leaflet for [birth control pills](#) "to help women make informed decisions about their choice of contraception."

It also recalled advice to doctors to make regular assessments about the risk of blood clots to any patient who is taking contraceptive pills.

Risk factors include smoking, migraines, being overweight and increasing signs of ageing, the agency noted.

France had wanted the EMA to recommend that doctors no longer prescribe later-generation pills as a first option.

The health ministry also dropped the two later generations of the pill from the list of medications that are reimbursed under France's national health insurance programme.

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