

European experts advise against epilepsy drug in pregnancy

9 February 2018



France's medicines regulator, known by the acronym ANSM, asked the London-based European Medicines Agency (EMA) to conduct a risk review of an epilepsy drug when used during pregnancy

An expert committee of Europe's medicines watchdog recommended Friday that a drug used to treat epilepsy and linked to malformations in children not be used in pregnancy.

The compound, valproate, is also used for migraine and [bipolar disorder](#), and doctors already advised against prescribing the [medicine](#) for pregnant women in France.

France's medicines regulator, known by the acronym ANSM, asked the London-based European Medicines Agency (EMA) to conduct a risk review.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) said in a statement Friday it was recommending that valproate not be used by [pregnant women](#) for any of the three medical conditions.

For women suffering from epilepsy, however, it

may be impossible for some to stop after becoming pregnant, it said. These may have to continue treatment, though with "appropriate specialist care".

The experts also advised against prescribing the drug for [women](#) "from the time they become able to have children", unless using contraception.

Valproate medicines are licenced under different names by national drugs authorities.

The committee recommendations will now go to another body of the EMA, which deals with concerns over drugs that are not centrally authorised in the EU.

Last April, a preliminary study showed that valproate caused "severe malformations" in as many as 4,100 children in France since the drug was first marketed in the country in 1967.

Women who took the [drug](#) during pregnancy to treat epilepsy were four times more likely to give birth to babies with [congenital malformations](#), said a report of the French National Agency for the Safety of Medicines (ANSM) and the national health insurance administration.

Birth defects included spina bifida—a condition in which the spinal cord does not form properly and can protrude through the skin—as well as defects of the heart and genital organs.

The risk of autism and developmental problems was also found to be higher.

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