

# Epilepsy drug behind up to 4,100 'severe birth defects' in France

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The epilepsy medication valproate is responsible for "severe malformations" in 2,150 to 4,100 children in France since the drug was first marketed in the country in 1967, according to a preliminary study by French health authorities.

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

"The study confirms the highly teratogenic"—that is, capable of causing birth defects — "nature of valproate," said Mahmoud Zureik, scientific director of ANSM and a co-author of the report.

"The figure of about 3,000 severe malformations is very high," he told AFP.

The types of birth defects attributed to the drug 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, and will be quantified in a follow-up report later this year.

An earlier estimate suggested that 30 to 40 percent of children exposed in the womb could suffer such disorders.

## **Risks known since 1980s**

From 1967 to 2016, between 64,100 and 100,000 pregnancies in France were exposed to valproate, resulting in 41,200 to 75,300 live births, according to the report.

The vast majority of the birth defects occurred for women under treatment for epilepsy.

But starting in the late 1970s, valproate—marketed around the world as Depakine, Depakote, Stavzor and other trade names—was also prescribed in France to treat bi-polar disorder.

Bi-polar women taking the drug were twice as likely to give birth to children with major birth defects, the study found.

The lower risk compared with women treated for epilepsy probably stems from the fact that—for pregnant bi-polar women—doctors stopped prescribing valproate early in the pregnancy, Zureik said.

"The risk of severe malformation is limited to the first two trimesters of pregnancy," said Alain Weill, a researcher at the French health insurance administration and a co-author of the report.

The risk of birth defects associated with valproate has been known since the 1980s, especially for spina bifida, which occurs 20 times more frequently in fetuses exposed to the medication.

But the drug can still be prescribed to pregnant women when all other forms of treatment for epilepsy fail. That ruling, however, was put in

place only in 2015.

Valproate is sold in France under the brand name Depakine by pharmaceutical giant Sanofi, but is also available in generic forms.

## **Inadequate warnings?**

Some French families of children with birth defects born to women who took the drug while pregnant—grouped under an umbrella association called APESAC—have sued the company, claiming that it did not adequately warn about the risks.

"The number of victims is potentially huge," said APESAC president Marine Martin, who says two of her children—a girl and a boy—suffered physical defects brought on by valproate.

"We need to take into account children with malformations and autism, as well as families that lost a baby due to treatment during pregnancy," she told AFP.

Her association estimates a total of 30,000 to 50,000 victims—children and families included.

Gerard Bapt, a deputy in France's national assembly and a board member of ANSM, welcomed the report.

"It now appears fundamental that valproate in all its forms should not be prescribed for women of child-bearing age," he said in a statement. Medically necessary exceptions, he added, should be rare and accompanied by "mandatory contraceptive use".

In a statement, Sanofi said it had been "totally transparent with health authorities."

"We are aware of the painful situation confronting the families of children showing difficulties that may have a link with the anti-epileptic treatment of their mother during pregnancy," the drugmaker said.

France was last hit by a major drug scandal in 2010, when it was revealed that the off-label use of a diabetes drug called Mediator for weight-loss could cause fatal heart problems.

The legal fallout from that episode is still unfolding.

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