

Experts weigh risks of epilepsy drug in pregnancy, as EU considers safety recommendations

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As the European Commission considers whether to introduce a partial ban on use of the epilepsy drug valproate in pregnancy over risks to unborn babies, researchers in *The BMJ* discuss the arguments and the implications for patients and healthcare professionals.

Valproate is an effective treatment for epilepsy, bipolar disorder and migraine. For some [women](#) with epilepsy, it may be the only effective treatment option.

But the drug carries a 10% chance of causing physical abnormalities and a 30-40% risk of developmental problems such as autism and developmental delay in children born to mothers who take it. In the UK alone, around 20,000 children have been harmed since valproate was introduced in the 1970s.

Earlier this year, the European Medicines Agency recommended that valproate should not be used in pregnancy unless the woman has epilepsy that has not responded to alternative medications. It should not be prescribed to women of childbearing age unless they use contraception. But surveys show that many women with epilepsy are still unaware of the risks.

Responses from expert advisory groups and regulators have varied, from those advocating shared decision making and informed patient choice

about taking valproate in pregnancy, to restricted use when other treatments have failed, to prohibition of valproate in pregnancy coupled with a pregnancy prevention programme in all women taking it.

Consultant neurologists Heather Angus-Leppan and Rebecca Liu say, despite international consensus on the harmful effects of valproate during pregnancy, its use may be warranted in certain situations.

They explain that valproate may be the only effective treatment in certain patients and that untreated epilepsy also carries serious risks to both mother and unborn child.

Banning valproate "imposes less [effective treatment](#) for some female patients than for other people with a similar life threatening or serious condition, without their consent." they write, while mandating contraception for all women taking valproate "could be considered an infringement of patient autonomy and liberty."

They warn that the unknown number of women taking long term valproate who are not under specialist care are at particular risk, and publicity that generates fear and anxiety without guidance "may result in women stopping their treatment without support."

Further research into alternatives to valproate may help guide [treatment](#) in the future, they say. In the meantime, women need specialist information about the risks and benefits of valproate and its alternatives to help them make truly informed decisions, while regulatory guidance "should reflect the full range of risks and benefits of valproate and be based on both ethical and practical considerations for the individual, not just the population."

In a linked editorial, consultant perinatal psychiatrists Angelika Wieck and Sarah Jones explain that, if the European Commission accepts the

recommendations, all women of childbearing age who are being prescribed valproate will require regular review and must follow a pregnancy prevention programme.

Valproate packaging will also carry a visual warning of the pregnancy risks and [patients](#) will receive a warning card with each prescription. Patients who are already pregnant and taking valproate should be reviewed urgently by a specialist.

"It has taken half a century since [valproate](#) was first introduced to understand the full extent of harm to unborn children," they write. "Current regulatory systems are clearly inadequate at identifying and assessing the reproductive risks of medicines."

Although challenging to achieve, "we urgently need a regulatory system for the

standardised and timely collection of pregnancy outcome data for new and existing drugs that may harm offspring," they add. "Mandatory [pregnancy](#) registers, targeted data mining of other resources, and regular evaluation of all available evidence would be key elements to achieve this aim."

More information: Weighing the risks of valproate in women who could become pregnant www.bmj.com/content/361/bmj.k1596

Editorial: Dangers of valproate in pregnancy
www.bmj.com/content/361/bmj.k1609

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