# Communication of the President of the Office of 18.08.2023 regarding the conduct by the EMA's PRAC Committee of a review of data on the potential risk of neurodevelopmental disorders (NDDs) in children of men taking valproate-containing medicines.

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EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is reviewing data on the potential risk of neurodevelopmental disorders (NDDs) in children conceived by fathers taking valproate medicines.

The review is focussing on data from a retrospective observational study conducted by companies as an obligation following a previous review of valproate use during pregnancy.

This retrospective observational study compared the risk of NDDs (including autism spectrum disorder) in children born to men taking valproate with the risk in children born to men taking lamotrigine or levetiracetam (other treatments for epilepsy). It was carried out using multiple registry databases in Denmark, Norway and Sweden.

Initial results of the study may indicate an increased risk of NDDs in children born to men taking valproate in the three months before conception. However, the PRAC has identified important limitations with the data from the study.

In particular, the PRAC had questions about the definition of NDDs used in the study and the specific type of epilepsy the patients had. The latter is important because valproate may be prescribed more often for some types of epilepsy which are associated with NDDs.

In addition, after submitting the study results, the companies informed the PRAC about errors in the Norwegian database; the impact of these errors is not yet known.

The PRAC has therefore requested companies to provide analyses of corrected data and additional information as soon as possible to address the limitations.

The PRAC will review the required data as they become available and make an EU-wide recommendation. While awaiting the outcome of the PRAC's evaluation, some Member States have implemented interim national recommendations.

Male patients being treated with valproate should not stop taking their medicine without talking to their doctor, as their epilepsy or bipolar disorder could become worse. Sudden discontinuation of treatment for epilepsy could trigger seizures. Patients who have any questions about their

treatment should speak to their healthcare professional.

Previous recommendations to avoid exposure to valproate medicines in women during pregnancy due to the risk of congenital malformations (birth defects) and neurodevelopmental disorders remain in place.

More information available on the website: https://www.ema.europa.eu/en/news/ema-review-data-paternal-exposure-valproate [1]

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President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products



**Links**
[1] https://www.ema.europa.eu/en/news/ema-review-data-paternal-exposure-valproate