

## [News story: New measures to avoid valproate exposure in pregnancy](#)

Dr June Raine, Director of MHRA's Vigilance and Risk Management of Medicines Division said:

We welcome the [CMDH endorsement](#) of the strengthened regulatory position on valproate medicines which we have been championing through the Europe-wide review.

Valproate (Epilim, Depakote and other generic brands) is associated with a significant risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy. If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects.

Valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.

These new regulatory measures also include a ban on the use of valproate for migraine or bipolar disorder during pregnancy, and a ban on the use of valproate to treat epilepsy during pregnancy unless there is no other effective treatment available.

Patient safety is our highest priority. We are committed to making sure women and girls are aware of the very real risks of taking valproate during pregnancy. However, we also know it is important women don't stop taking valproate without first discussing it with their doctor.

This regulatory position has been developed through close collaboration with professional bodies, health system organisations, and patient and campaign groups.

I would like to particularly thank the families of the Valproate Stakeholder Network who have shared their experiences and expertise with us. Their support will help keep future generations of children safe.