

## SAFE USE OF VALPROATE

### March 2024 Update.

North East London system valproate implementation group had been convened to co-ordinate the implementation of the new regulatory measures as described in the MHRA [NPSA alert](#).by all prescribers.

The 2 new regulatory measures are:

- A. **All initiations, in women and men, under 55 years** must be agreed **by two independent specialists with documented evidence** that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
  
- B. **At their next annual specialist review, women of childbearing potential and girls** should be **reviewed using a revised valproate Annual Risk Acknowledgement Form (ARAF)**, to include a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

The group is now in the process for developing a referral pathway for patients identified as requiring an ARAF.

#### **Action for practices:**

- Continue to prescribe valproates for existing patients and provide advice and reassurance when needed unless you are asked to stop prescribing by a specialist.
- Make every contact count (MECC)
  - Use the opportunity to provide patients of childbearing potential with information
  - Ensure existing patients of childbearing potential continue to use a highly effective form of contraception. General patient-friendly information on contraception methods can be found on page 6 of the [bipolar-disorder](#). decision tool and NICE has also produced professional guidance on highly effective contraception <https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/>
- Prescribe appropriate quantities so that pharmacists can dispense a manufacturer's original full pack which will include all the necessary safety information for the patient
  - Where it is not in a patient's best interests to prescribe a full original pack, please document the reason in the patient record
- **A data set of patients in primary care who are not recorded as under the care of a local specialist will be shared with all practices. This will be accompanied with a referral pathway into specialist care that is currently under development.**