East London
NHS Foundation Trust

EXTERNAL MEMO

To:	ELFT Prescribers
Cc:	GPs, ELFT lead pharmacists, CCG lead pharmacists
From:	Dr Paul Gilluley- Chief Medical Officer
Email:	paul.gilluley@nhs.net
Subject:	Completion of Valproate Risk Assessment Forms
Date:	13/05/22

Background:

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.

Valproate must not be used in any woman or girl able to have children unless there is a pregnancy prevention programme (PPP) in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.
Reminder of the key facts about risks of valproate and pregnancy:

- 1 in 10 babies (10%) exposed to valproate in pregnancy are born with a congenital malformation – for the general population, the risk is about 2–3%
- Folic acid supplementation may decrease the general risk of neural tube defects but there is evidence that it does not reduce the risk of birth defects associated with valproate exposure
- There is no safe dose of valproate that can be used in pregnancy – in a comparative study, all doses of valproate increased the risk of major congenital malformations.
- Around 3 to 4 in 10 children (30–40%) exposed to valproate in pregnancy have delays in their development such as talking and walking later, lower intellectual abilities, poor language skills (speaking and understanding), and memory problems.
- IQ in school-aged children (age 6 years old) with a history of valproate exposure in pregnancy was recorded to be on average 7–10 points lower than children exposed to other antiepileptic drugs
- Children with a history of valproate exposure in pregnancy have a 3-fold risk of autistic spectrum disorder and 5-fold risk of childhood autism compared with general population
- Children exposed to valproate in pregnancy may be at increased risk of attention deficit/hyperactivity disorder (ADHD)

Healthcare professionals who seek to prescribe valproate to their female patients must make sure they are enrolled in the PPP. This includes the completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist, at least annually.

The Annual Risk Acknowledgement Form has been updated following feedback from healthcare professionals and stakeholders and should be used for all future reviews of female patients on valproate.

The form can now be used to record when the specialist considers the patient not to be at risk of pregnancy, either permanently or until the date of the next annual review. Patients or their responsible person must countersign this section to confirm details given are correct.

Please note that there is expectation from our GP collegues for secondary care clinicians to support with timely completion of annual risk assessment upon request and would greatly appreciate your support with this.

Further Information
https://www.gov.uk/drug-safety-update/antiepileptic-drugs-in-pregnancy-updated-advice-following-comprehensive-safety-review#national-review-of-safety-data

https://www.gov.uk/guidance/valproate-use-by-women-and-girls