

## **Managing females of child bearing potential (FCBP) prescribed valproate at the primary care/secondary care interface**

### **Introduction**

This document sets out the responsibilities Sussex Partnership NHS Foundation Trust's (the Trust) community teams and GP practices have to minimize the risks of any female of child bearing potential (FCBP) becoming pregnant while taking valproate. See references below for links to the latest MHRA guidance, the valproate annual risk acknowledgement (VARA) form and additional advice from the royal colleges.

There needs to be absolute clarity of the roles the Trust will play and that of GPs. This document lays out the different responsibilities.

### **Proposed responsibilities**

1. GPs will check that any FCBP being prescribed valproate has either:
  - an up to date VARA form or
  - a DNA letter from a Trust clinician explaining the FCBP failed to attend a planned appointment and another appointment has been made.
2. GPs will refer any FCBP without an up to date VARA form or DNA letter to their local relevant mental health team, explaining they have no up to date VARA form to support continuing prescribing.
3. The Trust will set up a database of all FCBP known to the service that will be used to record annual reviews and DNAs. This will also be used to generate the following year's appointment requests. This will be managed by the Pharmacy Team Administrator.
4. On receipt of a referral for a valproate review for a FCBP it will be forwarded to the local valproate clinic administrator who will double check whether the FCBP has been seen and a VARA form completed in the last 12 months.
  - If seen recently a copy of the VARA form will be sent to the GP and the date of the last review and the patient's details added to the valproate database if not already recorded.
  - If not seen within the last 12 months, a new appointment will be made.

5. The Trust will set up valproate review clinics in each locality, run by mental health specialists, usually a pharmacist, to check that the FCBP:
  - Wishes to remain on valproate after reading the valproate patient booklet
  - Is not planning to become pregnant in the next 12 months
  - Is either on highly effective contraception or there is an absence of risk of getting pregnant and this is expected to remain so for the next 12 months, e.g. husband has had a vasectomy
  - There are no other issues relating to the treatment, e.g. side-effects, concerns about efficacy.
  - Arrange for pregnancy test to be done with the GP if thought appropriate.
  
6. The Trust specialist will either:
  - Refer the FCBP urgently to see a consultant if there are concerns about the treatment's efficacy, side effects or the woman/girl is considering becoming pregnant or is at increased risk of becoming pregnant.
  - If remaining on valproate, both the specialist and the FCBP (or representative if she lacks capacity) will sign the VARA form.
  
7. Following the appointment the Trust specialist will:
  - Send a copy of the VARA form to the GP, along with any additional information if relevant or explain that the FCBP is being referred on to a consultant and the reason why.
  - Record the appointment on the Trust's valproate database.
  - If a highly effective contraception needs to be started and the woman has agreed to get this as soon as possible, the GP will be phoned explaining that the FCBP has agreed to get highly effective contraception.
  
8. If the FCBP has agreed to start highly effective contraception the GP should confirm this has been started before prescribing further valproate. If the highly effective contraception has not been started the GP:
  - Must confirm an appointment has been made to obtain highly effective contraception and if made prescribe the minimum quantity of valproate to cover the period until the appointment.
  - If the FCBP has yet to make an appointment but intends to do so, a reduced quantity of valproate should be prescribed until obtained.
  - If the FCBP has decided against obtaining highly effective contraception or keeps failing to obtain it despite agreeing to do so, an action plan needs to be made with the specialist about future engagement and treatment options.
  
9. If the FCBP fails to attend an appointment the specialist will:
  - Make a second appointment with the FCBP.
  - Write to the GP explaining the FCBP DNAed and a second appointment is being made.
  
10. If the FCBP fails to attend a second appointment the specialist must contact the FCBP's GP to discuss and agree a suitable action plan to get the FCBP's engagement.

11. Though the continued prescribing of valproate should usually be supported by an in-date valproate VARA form, GPs will be expected to continue prescribing until the FCBP has been reviewed. GPs may wish to restrict valproate prescriptions to weekly supplies as an inducement to get the FCBP's engagement.

12. In the unlikely event that a FCBP refuses to engage in the review process and insists on staying on valproate the following steps should be considered:

- Offering the FCBP the option of having the annual review done and VARA form completed in the GP practice.
- Allowing monthly or two monthly valproate prescriptions only if the FCBP (or legal representative) completes the Valproate Refusal to Attend Annual Reviews Form (appendix 1) with the GP. A copy should be given to the FCBP and a copy sent to the Trust specialist.
- All steps taken to encourage engagement with the specialist should be fully documented in the FCBP's notes, held by both the GP and the Trust.

## References

MHRA guidance:

<https://www.sussexpartnership.nhs.uk/node/5617/attachment>

Form:

<https://www.sussexpartnership.nhs.uk/node/5618/attachment>

Royal colleges' advice

<https://www.gov.uk/drug-safety-update/valproate-medicines-and-serious-harms-in-pregnancy-new-annual-risk-acknowledgement-form-and-clinical-guidance-from-professional-bodies-to-support-compliance-with-the-pregnancy-prevention-programme>

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## Valproate prescribing in females of child-bearing potential

### Patient refusal to attend annual reviews form

(This form is not suitable for patients that lack capacity)

*Initial each box if you agree with the statement.*

I confirm that I am refusing to attend annual reviews to discuss my continued use of valproate medication despite warnings about the risks associated with taking it.

I confirm that Dr .....has:

Given me written information on the risks of taking valproate, including to an unborn baby if I became pregnant.

Explained the benefits and possible side-effects, including the risks to an unborn baby, of taking valproate and I have understood the explanation.

Explained the need for me to use highly effective contraception (e.g. injectable contraception or the coil) while taking valproate if I ever have intercourse with a man (unless he has had a vasectomy) and I have understood the explanation.

Explained to me that if I wish to get pregnant I need to discuss this with my doctor before I stop using contraception or have sexual intercourse with a man or get artificially inseminated and I have understood the explanation.

Explained the consequences of suddenly stopping using this medication and I have understood the explanation.

I have had enough time to consider my decision and to ask questions.

I understand I can request to start having annual reviews at any time and these will be arranged as soon as possible.

I agree I will inform my doctor as soon as possible if I think I might be pregnant

I agree I will inform my doctor if I plan to become pregnant, before becoming pregnant and before stopping the valproate so other treatments can be agreed first.

I understand that signing this form does not affect my care and that I can change my mind at any time and attend annual reviews.

Signed: ..... (patient) ..... (printed name)

Date: .....

Signed: ..... (doctor) ..... (printed name)

Date: ..... ( title)

*\*Delete as appropriate*

Once completed the form should be scanned into the patient's notes, a copy sent to the local valproate review clinic and a copy given to the patient.

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