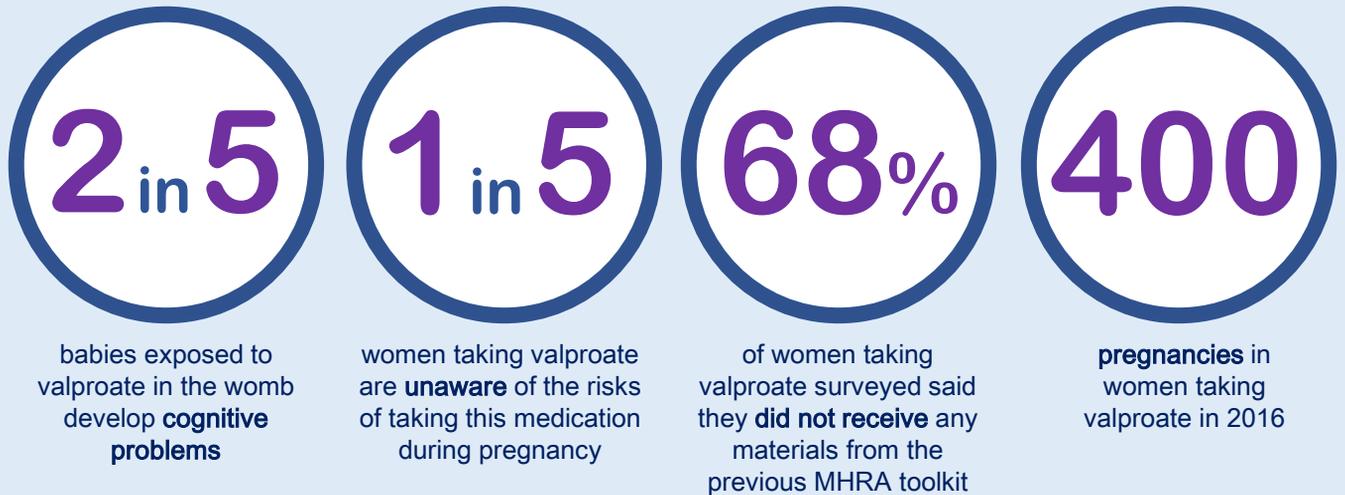


Safe supply of valproate medication

Efforts to raise awareness of the risks around valproate-containing medicines and pregnancy have not been successful to date, despite the fact that the most recent research shows **every baby is at risk** and the **scale of the issue, and the harm caused, is bigger than Thalidomide**.



Now imagine how you can help drastically change these odds, just by having a conversation. **27,000 girls and women** of childbearing potential in the UK currently receiving prescriptions for valproate need you to do just that. Pharmacy professionals, alongside government departments, regulatory bodies, professional bodies and pharmacy organisations, all have a collective responsibility to prevent more harm.

In April 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) changed the licence for valproate medicines (Epilim, Depakote and generic brands) so these must no longer be prescribed to women or girls of childbearing potential (age 12-49) unless they are on a **Pregnancy Prevention Programme (PPP)**. This brings valproate in line with other highly teratogenic medicines, such as isotretinoin and thalidomide.

The change in licencing is intended to drive behavioural change in healthcare professionals and ensure all patients are fully aware of the risks and the need to avoid becoming pregnant. All girls and women of childbearing potential who are prescribed valproate should have a discussion with their GP, who will arrange for them to have their treatment reviewed by a specialist and for a PPP to be put in place. Each PPP includes the completion of a signed risk acknowledgement form. You can find out more in the [updated MHRA toolkit](#).

Despite the risks, no girl or woman should stop taking valproate without first discussing it with their doctor. Therefore, pharmacists should **always** dispense the prescription (where clinically appropriate, in line with their usual procedures), counselling the patient and referring them to their GP if necessary. Patients in turn should ask questions and be encouraged to speak openly and frankly with their healthcare professionals.

In autumn 2018, the regulatory changes will be further supported by smaller pack sizes, to encourage monthly prescribing, and a warning image on valproate packaging and blister packs. However, **in the interim**, pharmacists should hand out a patient card and patient booklet when counselling every woman of childbearing potential (age 12-49) who presents in the pharmacy with a prescription for valproate.

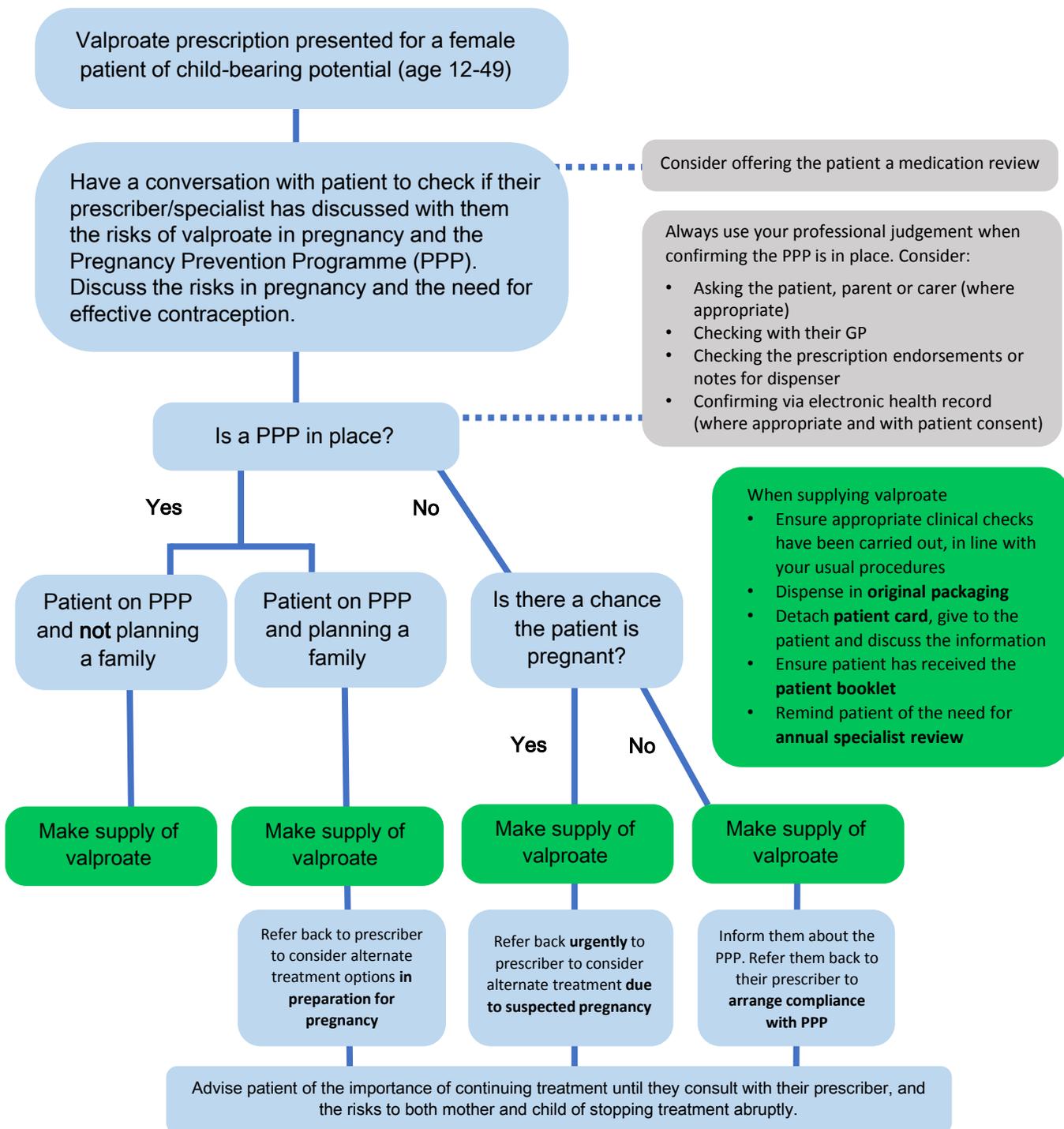
If you have not received the new 2018 patient cards, patient booklets and/or warning stickers from your wholesaler, contact Sanofi on 0845 372 7101 or email uk-medicalinformation@sanofi.com.

On the following pages you can find a [supply pathway](#) and [key considerations](#) for your interactions with patients. You should also read the booklet for healthcare professionals, which you'll receive from Sanofi via your wholesaler. You may also wish to consider using this to inform your Continuing Professional Development and revalidation.

Valproate supply pathway

to support girls and women of child-bearing potential

The below pathway can be used by pharmacists to support conversations with patients (their parent or carer) when supplying valproate medication. It should be considered for both newly prescribed valproate prescriptions and repeat supplies, as patient circumstances may change.



Online pharmacies and deliveries

All patients who have medicines delivered need to be provided with the same advice and care as patients who collected their medication face-to-face in a pharmacy. The pharmacy standard operating procedures should ensure this happens. See [GPhC](#) and [PSNI](#) guidance for more information.

Key considerations

Opportunities to discuss medication

It is important that **ALL** valproate prescriptions presented to a pharmacy for women and girls of child-bearing potential are identified, so that steps can be taken to manage the risks of valproate in pregnancy. Pharmacy teams can do this in many ways such as:

- Proactively setting PMR alerts for relevant patients, reminding team members to discuss risks
- Flagging up of prescriptions for valproate by having reminder stickers to counsel patients when handing out medication
- Offering patients a medication review, such as a Medicines Use Review (MUR). This presents an opportunity to also offer contraceptive advice if appropriate.

Sensitivity of conversation

Pharmacists should discuss child bearing potential and any intentions to start a family with patients (parents or carers) in a **sensitive manner**. Pharmacists should always exercise their professional judgement when having these conversations and may choose to use the consultation room if available.

Using the [supply pathway](#), check you have completed the following in each interaction:

- Remind patient of the risks of taking valproate in pregnancy and need for effective contraception
- Provide **patient card** and **patient booklet** if they have not already received one
- Refer** patients not complying with the PPP, planning a family, who may be pregnant, or who report not taking their medicine as prescribed to their prescriber
- Remind patient that they need to have an **annual review** with their specialist
- Highlight the **risks** for both mother and baby of **stopping the medication abruptly** without consulting their doctor if appropriate
- Medication should be dispensed in **whole packs whenever possible**. All packs should have a warning label either on the carton itself or via a sticker. If you have not received warning stickers from your wholesaler, contact Sanofi on 0845 372 7101.
- Ask if experiencing any **suspected adverse reactions, including adverse pregnancy outcomes** and report via **Yellow Card scheme** - valproate is subject to additional monitoring
- Make a record on Patient Medication Record (**PMR**) of conversations and advice offered

Communication / engagement with local GP surgery

Pharmacists should engage with their local GPs about how to best refer patients who are non-compliant with the PPP, planning a family, who may be pregnant, or who report not taking their medicine as prescribed to their prescriber. They may already have a referral system in place to help identify these patients and efforts to increase awareness and reduce harm should be in partnership.



Community Pharmacy
Patient Safety Group

