

# Appendix A: Audit data collection sheet

## Summary of actions for pharmacists

1. Ensure the [Patient card](#) is provided every time valproate is dispensed (or where incorporated into packaging, this is highlighted to the patient).
2. Remind patients of the [risks in pregnancy and the need for highly effective contraception](#).
3. Remind patients of the need for an annual review by a specialist and refer/signpost to the GP practice or specialist where appropriate.
4. Ensure the patient has received the [Patient guide](#) and note this in the PMR or appropriate record where appropriate.
5. Dispense valproate in the original package. In situations where repackaging cannot be avoided, always provide a copy of the package leaflet, and add a label with the warning to the outer box.
6. If a patient of childbearing potential reports that they are not taking highly effective contraception, refer them to their GP practice or specialist, where appropriate (including by contacting the GP practice if necessary).

## For further information:

- [MHRA Drug Safety Update – Valproate \(2018\)](#)
- [Valproate Pregnancy Prevention Programme](#)
- [Pregnancy Risks and the need for highly effective contraception](#)

Patients who are of childbearing age and have been dispensed a prescription for valproate: Start date:

End date:

		Patients' initials:						Sheet Totals						
		Y = Yes	N = No	DK = Don't know	Y/N/DK	Y/N/DK	Y/N/DK	Y/N/DK	Y/N/DK	Y/N/DK	Total Y	Total N	Total DK	
		*If the patient's representative does not know the answer record as don't know.												
1.	Has the patient/representative agreed to discuss their valproate medicine with the pharmacist? Y or N – if no, please answer Q4/4a only													
2.	Has the patient/representative been provided with advice and information in line with the MHRA Drug Safety Update on valproate 2018 concerning the potential impact on an unborn child? * Y / N or DK													
3.	Does the patient already have a copy of the Patient Guide? * Y / N or DK <b>If yes, move to Q3b.</b>													
3a.	If not, has the patient/representative now been provided with a copy of the Patient Guide by the pharmacist? Y or N <b>If no, move to Q4.</b>													
3b.	Is it recorded, or now recorded, on the PMR or other appropriate record that the patient has a copy of the Patient Guide? Y or N													
4.	Has the patient/representative been provided with a Patient Card by the pharmacist (this should be provided each time valproate is dispensed and can include patient cards incorporated into medication packaging where this is highlighted to the patient)? Y or N <b>If no, move to Q5.</b>													
4a.	Is it recorded on the PMR or other appropriate record that the Patient Card has been supplied? Y or N													
5.	Has the patient seen their specialist to discuss their use of valproate in the past 12 months? * Y / N or DK <b>If yes, move to Q5b.</b>													
5a.	If not, was the patient referred/signposted back to their GP practice or specialist for an annual review? Y or N													
5b.	Has this conversation been recorded on the PMR or other appropriate record? Y or N													
6.	Does the patient have highly effective contraception in line with the pregnancy prevention programme? * Y / N or DK <b>If yes, move to Q6b.</b>													
6a.	Was the patient referred/signposted back to their GP practice or specialist to discuss contraception? (Only if appropriate**) Y or N													
6b.	Has this conversation been recorded on the PMR or other appropriate record? Y or N													

\* If the patient's representative does not know the answer record as don't know.

\*\* Record as 'not applicable' (N/A) if it is not appropriate for the patient to be referred back to their GP practice or specialist if for example the patient has had a hysterectomy, is post-menopausal or for any other compelling reason to indicate there is no risk of pregnancy.