

Pharmacy Quality Scheme (PQS) – Valproate audit quality criterion

Read the supporting information in the [NHS England & NHS Improvement \(NHSE&I\) PQS guidance](#) on pages 43-45

Refresh your understanding of the actions required of pharmacists in the [MHRA Drug Safety Update 2018](#)

Decide if you want to use the NHSE&I paper data collection table or PharmOutcomes for recording your patient information and, if using PharmOutcomes, whether you will add this information directly onto PharmOutcomes or whether you will record the information on paper and then add to PharmOutcomes at a later date

NHSE&I data collection table – Print out the data collection table which is available as Annex 10 in the [NHSE&I PQS guidance](#) (a standalone version of this table is available at psnc.org.uk/pqsvaproate)

PharmOutcomes – If you are going to record this on paper first and then transfer onto **PharmOutcomes**, print out copies of the patient data collection form at psnc.org.uk/pqsvaproate

Select a date when you are going to start your audit period (data must be collected for three consecutive months). Ensure you have stock of Patient Guides, Patient Cards, warning labels, etc. If you do not, copies can be ordered from the Sanofi medical information department on 0845 372 7101 or email

UK-Medicalinformation@sanofi.com

Start the audit. The audit should only include each patient once during the audit period. For all patients of childbearing potential that do not attend the pharmacy to collect their medicine, attempts should be made to contact the patient for this discussion to occur, e.g. by phone (if the records show that this has not previously happened). A copy of the Patient Guide (if the patient does not have one) and Patient Card should also be provided to the patient. A Patient Guide should only be provided if the patient has not received one previously or the patient no longer has a copy. Where such attempts have failed, this must be recorded on the PMR or other appropriate patient record.

Pharmacists must check the records of girls and women of childbearing potential for whom a prescription is dispensed for valproate, to ensure they have been advised on the risks of taking valproate in line with all the requirements as detailed in the [MHRA Drug Safety Update 2018](#):

- whether a Patient Card has been provided to the patient. This should happen every time valproate is dispensed – the patient card is included with each original pack of sodium valproate;
- that the patient was aware of the risks in pregnancy and the need for use of highly effective contraception;
- that the patient was aware of the need for annual specialist review;
- whether a Patient Guide has been provided to the patient; and
- if the child or woman of childbearing potential reports that she is not using highly effective contraception, that the patient has been referred to their GP or specialist (including if the pharmacist contacted the GP).

If using the **NHSE&I paper data collection table**, a template paper referral form (if required) is available at psnc.org.uk/pqsvaproate. This can be sent to the GP practice by post or hand delivery or secure email. The forms should not be faxed.

If using the **NHSE&I paper data collection table**, remember to record the other required information as detailed in the NHSE&I PQS guidance on the patient's PMR or appropriate patient record.

If using **PharmOutcomes**, an automatic referral (if required) can be sent to the patient's GP practice when the patient's data is added to the system.

PharmOutcomes – By creating a PharmOutcomes record you have created an appropriate patient record. You may also choose to record the detail of the above intervention, the provision of the Patient Guide and Patient Card on the PMR.

Once the audit is complete, keep your data collection table in a safe location, if using the **NHSE&I data collection table**, as you will need to report this information when you complete your PQS declaration on NHSBSA's Manage Your Service (MYS). This information also needs to be kept at the pharmacy and be available for at least two years for assurance purposes. If using **PharmOutcomes**, you can print out a report containing the required information.

If during the pharmacy's selected consecutive three-month audit period, no prescriptions are received for patients of childbearing potential taking valproate, then the pharmacy will be required to declare this on the day of declaration including the start and end date of their audit. NHSBSA has individual dispensing item data for each pharmacy and NHSE&I may review this data as part of a post-payment verification process.