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# Community Pharmacy Quality Scheme 2019/20 Valproate Audit Report

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# Summary

The 2019/20 Pharmacy Quality Scheme (PQS) Valproate Audit, carried out in community pharmacies across England, indicates that the Medicines and Healthcare Regulatory Agency (MHRA) safety requirements for use of valproate in women and girls of childbearing age and trans men who are biologically able to be pregnant are still not being fully met.

Almost one in five had not seen their GP or specialist in the last 12 months to discuss valproate use and the need for appropriate contraception. Most patients confirmed that they did have highly effective contraception, but pharmacists were not referring/signposting a sizeable minority who appeared not to have appropriate contraception back to the prescriber.

Pharmacists are required to issue a patient card every time valproate is dispensed to all people aged 12-55 who are biologically able to be pregnant and to dispense valproate in the original package wherever possible. 11.1% of patients did not receive a patient card, which warrants further investigation.

All pharmacies should adhere to these requirements and document all information provided to and referrals for this patient cohort.

## Recommendations

### For community pharmacists

- Ensure a system is in place in the pharmacy to flag people of childbearing age who are biologically able to be pregnant who are prescribed valproate so that the MHRA safety requirements are always complied with.
- Issue the patient card each time valproate is dispensed to people of childbearing age who are biologically able to be pregnant. Ensure that where the card is incorporated into the packaging, this is pointed out to the patient.
- Pharmacy labels must not cover the card or warnings about use in pregnancy. Dispense valproate with a copy of the patient information leaflet and, if repackaged, with a warning on the new container.

- Refer **all** people aged 12-55 who are biologically able to be pregnant and have not had their valproate medication reviewed within the last 12 months to their GP or specialist, as well as to local contraception services as appropriate.
- For patients not referred to their GP or specialist, the pharmacist should be able to confirm the patient is fully informed, understands the risks of not using highly effective contraception and knows who to contact if their circumstances change. These details should be recorded in their patient medication record (PMR).
- Record the information provided and referrals in the pharmacy medication records.
- Community pharmacies should ensure **all** patients have access to information and advice so they can fully understand the risks of valproate to the unborn child. Not all patients have equal awareness, understanding and access to primary care. Community pharmacy is in the ideal position to tackle health inequalities which exist for some population groups, e.g. those with disabilities, patients in secure environments and the homeless. The same provision of care should be in place for such population groups and pharmacy teams should be mindful of communication preferences for patients with disabilities or when English is not their first language.
- Community pharmacy teams should continue to raise awareness with patients that they should have an adequate valproate pregnancy prevention programme (PPP) in place in line with [General Pharmaceutical Council guidance](#).

## For the NHS

- A digital system including the risk acknowledgment form for girls, women and trans men prescribed valproate, as recommended by the [Independent Medicines and Medical Devices Safety \(IMMDS\) review](#), should be made accessible to pharmacists at the point of dispensing. As an interim measure, the annual review date for valproate should always be included on prescriptions and/or should be accessible via the summary care record.
- Consideration should be given to system collaboration and aligning audit across primary care (with data collection from pharmacies and GP practices) and secondary care to provide a clearer picture of the service people who are prescribed valproate receive.

- There should be clear local integration of pharmacy and contraception services in shared care arrangements/pathways for people who are prescribed valproate to improve safety.

## About this report

### Audience

- NHS leaders responsible for patient safety, medicines optimisation and primary care contracts.
- Pharmaceutical Services Negotiating Committee (PSNC) and other national pharmacy bodies.
- Community pharmacists, primary care pharmacists and all others responsible for prescribing, dispensing or reviewing valproate.
- Wider valproate safety stakeholders, including the [NHS England Valproate Safety Implementation Group](#)<sup>1</sup>, [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#)<sup>2</sup> and [Care Quality Commission \(CQC\)](#)<sup>3</sup>.

### Purpose

To report the findings of a national community pharmacy audit of patients who could get pregnant and are prescribed valproate, undertaken as part of the Community Pharmacy Quality Scheme (PQS) 2019/20.

### Background

Valproate (sodium valproate, valproic acid and valproate semi-sodium) is a treatment for epilepsy and bipolar disorder, available in the UK since 1974. As with some other anti-epileptic medicines, it is known to be teratogenic – that is, it can cause physical or functional defects in the human embryo or foetus when taken during pregnancy.

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<sup>1</sup> <https://www.england.nhs.uk/patient-safety/sodium-valproate/>

<sup>2</sup> <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

<sup>3</sup> <https://www.cqc.org.uk/>

Evidence for the scale of harm when taken during pregnancy has increased in recent years and the MHRA now states that:

“If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects”.

The MHRA advises that valproate must not be used in anyone of childbearing potential unless a Pregnancy Prevention Plan (PPP) is in place. Specific actions for pharmacists to support the PPP include:

- remind patients of the risks in pregnancy and the need for highly effective contraception
- ensure patients have been given the patient guide
- remind patients of the need for annual specialist review
- if a person of childbearing potential is not aware of the need for contraception and has not been seen by their GP/specialist in the past year, dispense the medicine but also refer them to their GP.

This medicines safety audit was designed to determine whether pharmacists were undertaking the required actions and whether pharmacists or patients need further support to improve safety.

In 2019/20, the GP contract also had a quality improvement module on prescribing safety, which includes valproate use in female patients and facilitating collaborative work to reduce valproate harms in primary care.

## Audit method

**Audit population and timeframe:** All female patients of childbearing age dispensed valproate once in three consecutive months in 2019/20.

The audit tool was based on the pharmacist actions required by the MHRA. The PQS Valproate Audit Guidance (Appendix 1) and a data collection table (Appendix 2) were provided to pharmacy contractors through the PQS Guidance. Each pharmacy submitted pooled patient data to NHS Business Service Authority (NHSBSA) by the closing date: 28 February 2020.

# Results

10,293 community pharmacies – almost 90% of the 11,956 in England in 2019/20 – conducted the audit, of which 67.8% dispensed valproate to between one and five female patients of childbearing age during the three-month audit period, and 28.0% did not dispense valproate to any eligible patients. Prior to analysis, anomalous data was discarded (that for sites reporting more than 100 patients or inconsistent patient numbers).

The responses for the 12,068 (94.3%) patients/patient representatives who agreed to take part in the audit are summarised in Appendix 3; 724 (5.7%) patients did not agree to take part.

Of the 12,068 patients/patient representatives who participated in the audit:

- 94.4% (11,393) were provided with advice and information in line with the MHRA Drug Safety Update 2018 and including the potential impact on an unborn child but for 5.6% (675 people) were not.
- 10.6% (1,281) did not have the patient guide and 11.1% (1,345) did not have the patient card.
- 73.3% (8,842) reported discussing their valproate medication and the need for appropriate contraception with a GP or specialist in the last 12 months, but 17.6% (2,128) had not and 9.1% (1,097) were unsure.

In addition, 63.8% (7,693) reported having highly effective contraception but 36.2% (4,374) did not. Of the latter, 26.5% (1,159) were referred to the GP by the pharmacist about this issue.

Referrals to the GP and/or provision of the patient guide or patient card were recorded in pharmacy medication records for 63.6% (7,680).

# Discussion

This audit included almost 90% of community pharmacies in England, and so provides valuable insight into the provision of safety information about valproate to patients biologically able to be pregnant, prescribed this medicine across England. Also, data from the [NHSBSA Valproate Safety Dashboard](#) shows that about 30,000 female patients aged 13–54 were prescribed valproate in the three months from October to December 2019, and 12,068 of these participated in the audit (c40%).

In 2016, a [UK audit](#) of 55 mental health providers found that only half of women of childbearing age prescribed valproate for bipolar disorder had documented evidence that they had been given information on the risks to an unborn child and the need for adequate contraception. In contrast, this audit found that 94.4% of patients had received relevant safety warnings, including the potential impact on an unborn child, which is in line with the [Epilepsy Action](#) UK survey, conducted in the same period as this audit: it reported that of 514 women surveyed who were taking valproate, 11% were unaware that taking valproate in pregnancy can cause birth defects. However, it is of significant concern that a small number of patients still reported that they have not been given this important safety information.

Pharmacies are required to provide a [patient card](#) every time valproate is dispensed, but in this audit 11.1% of patients did not receive one; this warrants further investigation. Some valproate manufacturers now include the card as integral part of the packaging which may have affected how the audit question about provision of the card was interpreted. It seems likely this practice may be relevant to the Epilepsy Action [survey finding](#) that over half of respondents reported that they had never received the patient card from their pharmacist.

Women of childbearing age treated with valproate must be reviewed at least annually by the specialist or GP prescribing this medicine. The NHS [2017 Patient Safety Alert](#) on valproate required NHS trusts and GP practices to have systems in place that systematically identify all girls and women of childbearing age to ensure consistent use of the relevant resources to support fully informed decision-making. However, 17.7% of participants in this audit reported that they had not had a review with their specialist or GP in the last 12 months to discuss valproate and the need for appropriate contraception; Epilepsy Action found that 45% had not.



The valproate PPP requires women taking valproate who can get pregnant to use highly effective contraception, such as long-acting reversible contraceptives, intrauterine devices, implants or sterilisation. In this audit, about one-third of women (4,374) reported not using highly effective contraception and pharmacies referred 26.5% of this group to their GP or prescriber for this reason. Patients will have a variety of reasons for not using highly effective contraception, including not being sexually active and patient choice.

It is not clear why 5.6% (675 people) were not being provided with advice and information in line with the MHRA Drug Safety Update 2018 and the potential impact on an unborn child or why 11.1% (1,345) did not have the patient card, although this may have been related to the design of the data collection tool where the question design needed to be clearer. Potential reasons include the individual not wanting to discuss this with the pharmacist or medicines being collected on behalf of the patient (although this information should still be communicated).

Since this audit took place the [IMMDS review report](#) 'First Do No Harm' has been published. This focused on how the health system responds to reports from patients about harmful side effects from medicines and medical devices. A specific recommendation about valproate is that:

“An online system for the pregnancy prevention programme is considered, which includes confirmation that the Risk Acknowledgement Form has been signed within the previous year. This could be accessed by pharmacists at the point of dispensing.”

Implementation of such a system would enable pharmacists to rapidly identify patients who may require a review, while not overburdening women who are already aware of the risks in pregnancy and have made an informed choice about the treatment that best meets their needs. The small patient numbers at each pharmacy would make keeping such records a manageable task and could be usefully employed alongside access to the Risk Acknowledgement Form and Summary Care Record to ensure all women are appropriately informed about valproate.

In 2021, NHS England and NHS Improvement sent a [letter](#) to women and girls aged 12-55 who are currently prescribed sodium valproate, containing important reminders of safety considerations, including around contraception, pregnancy and regular prescribing reviews

# Conclusion

The audit indicates that safety requirements for use of valproate in patients who could get pregnant are still not being fully met. Almost 1 in 5 had not seen their GP or specialist in the last 12 months to discuss valproate use and the need for appropriate contraception. The majority of patients confirmed that they did have highly effective contraception, but there appeared to be a sizable minority without appropriate contraception that were not referred/signposted back to the prescriber by the pharmacy. Pharmacists are required to issue a Patient Card every time valproate is dispensed to a patient of child-bearing potential and to dispense valproate in the original package wherever possible. Recommendations for community pharmacists and the NHS can be found in the Summary of this report. All pharmacies should adhere to these Recommendations and document all information provision and referrals for this patient cohort.

# Appendix 1: NHS England and NHS Improvement Pharmacy Quality Scheme guidance 2019/20 – Valproate audit

## Aim

The aim of this audit is to reduce the potential of harm being caused by taking valproate during pregnancy.

## Rationale

As part of the [MHRA Drug Safety Update 2018](#) all pharmacies were sent a pack of information (the MHRA guide for healthcare professionals) advising them of the need to identify any girl or woman of childbearing potential currently being prescribed valproate and detailed a series of actions for healthcare professionals, including pharmacists, to undertake. The MHRA defines a girl or woman of childbearing potential as a pre-menopausal woman who is capable of becoming pregnant.

Valproate use in pregnancy is associated with an increased risk of children being born with congenital abnormalities and developmental delay. Valproate is contraindicated in women of childbearing potential unless the conditions of the valproate pregnancy prevention programme (PPP) are fulfilled. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant while taking valproate.

It is expected that pharmacy contractors will have undertaken the actions described in the [MHRA Drug Safety Update 2018](#). To refresh your understanding of this guidance we recommend that you read this in full before starting the audit.

The valproate safety audit is an audit of the provision of advice on pregnancy prevention for girls and women of childbearing potential taking valproate. This audit is to be completed during a consecutive three-month period determined by the pharmacy.

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.

Pharmacists should check whether the records include that the patient was advised in line with the MHRA Drug Safety Update 2018, namely:

- 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
- if the child or woman of childbearing potential reports that she is not using highly effective contraception, that the patient has been referred to the GP or specialist (including if the pharmacist contacted the GP).

If there is a record of this, this should be logged on the valproate audit data collection table (see Appendix 2). If there is not, the above should be discussed with patients for whom a prescription for valproate is received and then be logged on the valproate audit data collection table during the consecutive three-month audit period selected by the pharmacy.

For all patients of childbearing potential who do not attend the pharmacy to collect their valproate, attempts should be made for this discussion to occur (if the records show that this has not previously happened) and a copy of the patient guide (only if they have not previously received this or no longer have it in their possession) and patient card provided to them.

The advice should only be given to a patient representative if this is appropriate; it may be appropriate to follow-up directly with the patient. It is important women do not stop taking valproate without first discussing this with their prescriber.

The audit should only include each patient once during the audit period. For example, if a patient has their valproate dispensed on three occasions during the consecutive

three-month audit period, the information should only be recorded once as part of the audit.

The details of the discussion should be recorded on the patient medication record (PMR) or appropriate patient record.

## Reporting

Contractors are required to report the following data to NHS England on the Manage Your Service (MYS) application on the day of declaration for this quality criterion as part of this domain:

- The start and end date for the audit to enable confirmation of patient numbers against dispensing data as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed a prescription for valproate who are of childbearing potential, avoiding repetition of patients.
- Total number of patients (or patient representatives if appropriate) who have:
  - agreed to discuss their valproate with the pharmacist
  - declined to discuss their valproate with the pharmacist.
- Total number of patients who:
  - have been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child
  - have not been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child.
- Total number of patient representatives (only if appropriate) who:
  - have been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child
  - have not been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child.
- Total number of patients (or patient representative, where appropriate) who:
  - do have a copy of the patient guide
  - do not have a copy of the patient guide and have been provided with one.
- Total number of patients (or patient representatives) who:
  - have been provided with a patient card

- have not been provided with a patient card.
- Total number of patients who:
  - have seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months
  - have not seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months
  - did not know if they have seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months.
- Total number of patients who have reported that they:
  - are using highly effective contraception in line with the PPP
  - are not using highly effective contraception in line with the PPP.
- Total number of patients referred to their prescriber, as the patient has reported they are not using highly effective contraception in line with the PPP.
- Total number of patients for whom the detail of the above intervention, the provision of the patient guide and patient card were recorded on the PMR or appropriate form/patient record.

To support this audit, a valproate audit data collection table is provided. This table includes an option to record patient initials to help the pharmacy avoid duplication of patients during the audit period. No patient identifiable data should be submitted as part of this audit. All audit records should be kept at the pharmacy and be available for at least two years for assurance purposes.



# Appendix 3: PQS Valproate Audit Data Tables

Number of community pharmacies undertaking the audit = 10,293  
(Number of community pharmacies in England 2018/19 = 11,539<sup>4</sup>)

Number of eligible patients per pharmacy:

Number of patients	Number of pharmacies	Percentage
None	2,877	28.0%
1–5	6,969	67.8%
6–10	365	3.5%
11–100	72	0.7%
<b>Total</b>	<b>10,283*</b>	

\* 10 pharmacies reporting >100 patients excluded.

## Audit responses

Valproate audit questions	Number of patients*	Percentage (n = total response for each question)
3. How many patients of childbearing potential were dispensed valproate during the audit?	12,792	
4. How many patients (or their representative) agreed to discuss their valproate with a member of staff?	Yes: 12,068 No: 724	94.3% 5.7%
5. How many patients have been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child?	Yes: 11,393 No: 675	94.4% 5.6%

<sup>4</sup> <https://digital.nhs.uk/data-and-information/publications/statistical/general-pharmaceutical-services/in-2008-09---2018-19-ns>



Valproate audit questions	Number of patients*	Percentage (n = total response for each question)
6. How many patients (or representatives) were provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child?	Yes: 10,135 No: 1,933	84.0% 16.0%
7. How many patients (or representatives) have a patient guide?	Yes: 10,787 No: 1,281	89.4% 10.6%
8. How many patients (or representatives) have a patient card?	Yes: 10,723 No: 1,345	88.9% 11.1%
9. How many patients have seen their GP or specialist in the past 12 months to discuss the use of valproate and the need for appropriate contraception?	Yes: 8,842 No: 2,128 Don't know: 1,097	73.3% 17.6% 9.1%
10. How many patients have reported they are using highly effective contraception in line with the pregnancy prevention programme?	Yes: 7,693 No: 4,374	63.8% 36.2%
11. How many of those patients reporting they were not using effective contraception were referred to their GP or prescriber as a result?	1,159	26.5% (n = 4,374)
12. How many patients had any referral to their prescriber, or the provision of the patient guide or patient card recorded on their PMR or appropriate record?	7,680	63.6%

\* Pharmacies with inconsistent patient numbers excluded.

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