

**Participant Information Sheet**

**Gathering Views – Sodium Valproate Experience**

**Gathering the views of people with experience of taking Sodium Valproate**

We are inviting people who are taking Valproate, or have stopped taking Valproate since August 2023, to share their experiences with us.

**We are** looking to talk to you, or your carer, if you are:

* currently taking Valproate or have stopped taking Valproate since August 2023. Examples of medicines that include Valproate are Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell. If you are in doubt whether a medication contains Valproate, you can search for it here: [Home - electronic medicines compendium (emc)](https://www.medicines.org.uk/emc/).
* Resident or were resident within Scotland within the above period
* a woman or man able to become pregnant or get someone pregnant if not on contraception
* between 12 - 55 years old

or

* a carer of people with the above characteristics.

**We are not** looking to talk to you, or your carer, if you are unable to become pregnant or get someone pregnant due to having been through menopause or having had a hysterectomy, a vasectomy or similar procedure. This is because there are differences in the prescription processes that our interviews will be focusing on.

**How you can take part**

If you want to participate in this work, please get in touch with us and complete the consent form at the end of this document. Please read this information sheet carefully and get in touch with us if you have any questions.

**Please get in touch with us via email at** **his.engagementevidence@nhs.scot** **or by speaking with one of our members of staff.**

**Engagement for this piece of work will be taking place from November 2024 until June 2025, and the report is anticipated to be published in August 2025, though this is subject to change.**

For this work we will be doing individual interviews that should last between 30 minutes to an hour. Interviews can be done online, via telephone or in person. Please let us know how you prefer to have this interview.

In the interview we’ll be asking you questions about your experience of taking Valproate, such as:

* when you started taking Valproate, how that worked and what information you got at the time
* your thoughts about this information and how it could be improved
* your thoughts on the prescription and annual process
* how your experience of taking Valproate could be improved
* what matters most to you about your experience with Valproate, and
* your thoughts about taking Valproate in future.

Taking part in this work will not influence your care in any way. We are focussing only on understanding your experience of this medication. Your participation is voluntary. During the interview we will take notes to ensure we capture what you’ve said accurately. We may also ask you if we can record the interview to help us take notes. You are free to withdraw your comments or views at any time without giving a reason. If your comments or views have already been shared online or on social media, or included in wider pieces of work, for example in a published report, it may not be possible to remove them and stop their use completely. However, we will delete the images or recordings from our database and will go to all reasonable efforts to stop using them in future.

**Equality monitoring information**: As part of this work, we will also be collecting equality monitoring information, such as information regarding sex, sexual orientation, disability, age, religion and ethnic group. Providing this information is optional but important. This information is anonymous and will not be linked to your feedback. It helps us ensure we gather feedback from people from a range of backgrounds and contexts. When thinking of people’s experiences of taking Valproate, it is important for us to hear from people with different characteristics and from different backgrounds, to help us understand their needs and potential barriers, taking into consideration health inequalities.

**Please complete the equality monitoring form online at this link:** [**https://www.smartsurvey.co.uk/s/EQMGVValproate/**](https://www.smartsurvey.co.uk/s/EQMGVValproate/) or if you prefer you can ask our staff to help you with this. Participants under the age of 18 should not complete an equality monitoring form. If you are participating as a carer, please complete the form with information regarding the person you are caring for.

We are committed to inclusive communication. Please let us know if you need further support to participate. This could be, for example, having a BSL interpreter during the interview or having someone else there to support you.

You can also let our staff know if you would like to receive a digital copy of the report from this work once it is published. They may also ask you whether you are happy for us to get in touch with you in the following months to ask you how you found your experience of participating in this work.

**About this work**

We have been asked by the Area Drug and Therapeutics Committee Collaborative (ADTCC) to carry out a Gathering Views exercise by asking patients about their lived experience of taking Valproate. The ADTCC are part of Scottish Government. They give professional and clinical advice and leadership to NHS boards and consider national and local guidance, which supports the safe, effective, and patient-centred use of medicines.

Valproate is a medication used to treat epilepsy, bipolar disorder, migraine and other off label conditions. While it can be a highly effective treatment, it poses a significant risk to babies born to women taking it during pregnancy, and there is evidence that there may also be risk associated with men taking Valproate when getting someone pregnant. In March 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) strengthened its regulatory position, prohibiting its use in pregnant women, girls, and persons of childbearing potential unless a risk acknowledgement form is in place and they are enrolled in a pregnancy prevention programme. All Scottish Health Boards are putting an action plan in place in response to a National Patient Safety Alert issued by the MHRA (Medicines and Healthcare Products Regulatory Agency) in November 2023, which called on organisations to adopt new regulatory measures for Valproate, Valproic Acid, and Valproate Semisodium. The alert can be found here [NatPSA/2023/013/MHRA](https://assets.publishing.service.gov.uk/media/6565ddf162180b0012ce82fd/NatPSA-2023-013-MHRA.pdf)

Patient views and lived experience will inform NHS Boards' plans for the safe use of Valproate, and help to consider any specific needs relating to diversity and health inequalities. This will ensure the person-centred, safe, and effective implementation of new measures, including for marginalised groups most at risk from inappropriate prescribing of Valproate.

**Further information and support around taking Valproate**

Our staff will not provide medical advice. This information and anything discussed during our engagement with you is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of a qualified health care provider.

If you are concerned about the safety of a medication, either you or your GP can report your side effects to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card Scheme. You can do this by:

* picking up a Yellow Card from your GP surgery or local pharmacy
* filling in a Yellow Card online <https://yellowcard.mhra.gov.uk/>, or
* calling the Yellow Card freephone hotline: 0800 731 6789.

Reporting side effects to the MHRA can help them identify any new side effects or safety issues they might not have known about.

If you have questions about your care or about Valproate, or concerns about your wider care, please contact your GP or other healthcare professional. If you wish to complain formally, then you can contact your local health board, as explained here: [NHS Inform – making a complaint about your NHS Care or Treatment](https://www.nhsinform.scot/care-support-and-rights/health-rights/feedback-and-complaints/making-a-complaint-about-your-nhs-care-or-treatment/).

If you would like to provide further feedback about your experience with Valproate, or if you don’t fulfil the criteria to participate in this work, please speak to your GP or medical team.

For further information on Valproate, please refer to the Medicines and Healthcare Products Regulatory Agency Patient Guide here [https://mhra-gov.filecamp.com/s/i/Zw7qR7wEy1YKeIEf](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhra-gov.filecamp.com%2Fs%2Fi%2FZw7qR7wEy1YKeIEf&data=05%7C02%7Csarah.tindall%40nhs.scot%7Cf5f6da6190de46ad097f08dcde15c97e%7C10efe0bda0304bca809cb5e6745e499a%7C0%7C0%7C638629432366822256%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=PhRnJXmMqxpsw9XFYsFSvegYUNlc2dk6JFR%2BE6U0Alg%3D&reserved=0)

**How we will use your information**

Your responses will be anonymised and only used for the purpose of this work. We may use quotes, but they will be made anonymous and will not include any identifying information. Anonymised quotes, summaries or analysis of your views may be used in the following ways:

* published reports
* presentation materials for education or improvement workshops, conferences or events
* information or promotion leaflets
* Healthcare Improvement Scotland’s websites or social media, or the websites or social media of partners mentioned in this document, and
* we may also use your contact details to get in touch with you after the work is completed, to find out about how the interview went and how we can improve.

To support our work, we will hold information relating to you, such as:

* personal details, which may include contact details, or health condition or diagnosis
* written notes of the comments and views you have given us, and
* audio or video recording of the interview to support note-taking.

We will hold records of our engagement with you only for as long as necessary following the conclusion of the project. All information will be held in accordance with the General Data Protection Regulation and the Data Protection Act 2018.

For our full privacy policy, please go to [www.hisengage.scot/privacy](http://www.hisengage.scot/privacy). For more information about how we process your personal data, or if you have a concern, contact our Data Protection Officer at his.ig@nhs.scot. Alternatively, you have the right to complain to the ICO, and you can find more information about this here: <https://ico.org.uk/concerns/>.

The Data Controller for this information is Healthcare Improvement Scotland (HIS). Under data protection laws you have the right to be informed of what your information will be used for; access to the information held about you; to rectification if there are any errors in the information held; of erasure; and to withdraw consent.



**Participant Consent Form**

**Gathering Views – Sodium Valproate experience**

By ticking the options below you are giving your consent to take part in a Gathering Views interview.

If you wish to proceed, please confirm the following, verbally or in writing:

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| --- | --- | --- |
| 1 | I have read and understood the information sheet. | [ ]  |
| 2 | I have been able to ask questions about this work and am happy with the answers I got. | [ ]  |
| 3 | I understand that I can choose whether or not I will take part in this interview and that I can choose not to answer any question or stop taking part at any time, without having to give a reason. | [ ]  |
| 4 | I agree for what I say to be used in reports and publications about this work, but that my name will not be used. I give permission for Healthcare Improvement Scotland to hold relevant personal data about me and I understand that my comments are anonymous. | [ ]  |
| 5 | I agree to take part in this work. | [ ]  |
| 6 | **For parent or legal guardian of children under 16 only:** I confirm that I have parental responsibility for this child. I consent to my child taking part and have read and understood the information provided. | [ ]  |
|  | If you are over 18, please also complete the equality monitoring form online at this link: <https://www.smartsurvey.co.uk/s/EQMGVValproate/> |  |

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| --- | --- |
| Name |  |
| Signature |  |
| Date |  |
| **Name and signature of parent/legal Guardian** |  |