STATUTORY INSTRUMENTS.

S.I. No. 350 of 2025

DATA PROTECTION ACT 2018 (SECTION 38(4)(B)) (INQUIRY INTO THE LICENSING AND USE OF SODIUM VALPROATE IN WOMEN OF CHILD-BEARING POTENTIAL IN THE STATE) REGULATIONS 2025

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DATA PROTECTION ACT 2018 (SECTION 38(4)(B)) (INQUIRY INTO THE LICENSING AND USE OF SODIUM VALPROATE IN WOMEN OF CHILD-BEARING POTENTIAL IN THE STATE) REGULATIONS 2025

I, JENNIFER CARROLL MACNEILL, Minister for Health, in exercise of the powers conferred on me by subsection (4)(b) of section 38 of the Data Protection Act 2018 (No. 7 of 2018) and having duly complied with subsections (4) and (5) of section 38 of that Act, hereby make the following regulations:

Citation

1. These Regulations may be cited as the Data Protection Act 2018 (Section 38(4)(b)) (Inquiry into the Licensing and Use of Sodium Valproate in Women of Child-Bearing Potential in the State) Regulations 2025.

Revocation

2. The Data Protection Act 2018 (Control of Data for the Inquiry into the Historical Licensing and Use of Sodium Valproate) Regulations 2024 (S.I. No. 752 of 2024) are revoked.

Definitions

3. In these Regulations –

"Act of 2018" means the Data Protection Act 2018 (No. 7 of 2018);

"inquiry" means the inquiry into the licensing and use of sodium valproate in women of child-bearing potential in the State, approved by decision of the Government on 11 July 2023;

"inquiry chair" means the person appointed by the Minister to conduct the inquiry and provide a final report to the Minister;

"Minister" means the Minister for Health;

"relevant person" means –

(a) the inquiry chair,

(b) counsel for the inquiry,

(c) a legal advisor to the inquiry chair,

(d) a member of staff of the inquiry,

(e) a clinical psychologist providing services to the inquiry chair in connection with the inquiry,

(f) the Minister, and

(g) any other person acting for, appointed by or working under the direction of the inquiry chair or the Minister in connection with the inquiry;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 25th July, 2025.

"relevant task", in relation to the inquiry, means a task carried out by a relevant person in connection with the terms of reference;

"terms of reference" means the terms of reference of the inquiry, which terms are set out in the Schedule.

Application of Regulations

3. These Regulations apply to personal data –

(a) processed by the inquiry, and

(b) in respect of which the inquiry chair and the Minister are joint controllers.

Processing – public interest

4. Subject to the General Data Protection Regulation and the Act of 2018, the processing by a relevant person of personal data to which these Regulations apply, and which is necessary and proportionate for the performance of a relevant task carried out in the public interest by a relevant person, is hereby specified.

Circumstances in which personal data may be processed

5. Without prejudice to the generality of Regulation 4, the circumstances in which personal data to which these Regulations apply may be processed shall include the performance by a relevant person of such relevant tasks as the inquiry chair considers necessary and proportionate to enable the inquiry to –

(a) inquire into the matters set out in the terms of reference, or

(b) report or make recommendations to the Minister in accordance with the terms of reference.

Persons to whom personal data may be disclosed

6. Personal data to which these Regulations apply may be disclosed to a relevant person in accordance with such policies and procedures as may be provided for under Regulation 7.

Conditions of processing

7. (1) The inquiry chair shall prepare and implement policies and procedures to provide for the processing of personal data under these Regulations.

(2) Without prejudice to the generality of paragraph (1), the policies and procedures referred to in that paragraph shall provide for the following:

(a) the use of secure storage, passwords, encryption and other methods to ensure personal data can only be accessed by the inquiry chair or by a relevant person authorised by the inquiry chair to access that data;

(b) the use of controls to ensure that personal data are only disclosed to –

(i) a relevant person, or

(ii) a person entitled or permitted by law to receive that personal data;

(c) the determination of appropriate storage periods for personal data or classes of personal data;

(d) the treatment, including erasure where relevant, of personal data or classes of personal data at the expiry of the storage periods referred to in subparagraph (c);

(e) data minimisation, including the use of anonymisation and pseudonymisation where appropriate.

(3) The inquiry chair shall –

(a) review the policies and procedures referred to in paragraph (1) on a regular basis, and

(b) update those policies and procedures as the inquiry chair considers appropriate.

Schedule
Inquiry into the licensing and use of sodium valproate in women of child-bearing potential in the State

Terms of Reference

Purpose and focus of the Inquiry

The purpose of the inquiry is as follows:

- To provide a voice to persons with a diagnosis of foetal valproate spectrum disorder (FVSD[1]), or progressing through the diagnostic pathway, their mothers and other family members.
- To document the regulation of sodium valproate in the State from initial licensing until the present day and the corresponding practices and controls in place relating to the prescribing and dispensing of this product to women of child-bearing potential throughout this time.
- To develop a timeline of significant developments in the scientific knowledge relating to the teratogenicity of sodium valproate.
- To assess the Irish health system's current capacity to respond, disseminate and implement measures that address safety issues relating to use of sodium valproate in women of child-bearing potential, and to provide recommendations regarding same, with consideration of relevance to other anti-seizure medications (ASMs).
- To assess the adequacy of services and supports currently provided to those diagnosed with FVSD and their caregivers, and to provide recommendations regarding same if identified.

[1] International Classification of Diseases, Version 11, as adopted by the WHO Assembly in March 2019, defines Fetal Valproate Spectrum Disorder (code LD2F.03) as: Fetal valproate spectrum disorder (FVSD) and Fetal valproate syndrome (FVS) describe the range of signs and symptoms which occur as a consequence of exposure to sodium valproate or valproic acid in the womb. A wide range of physical anomalies occur at increased frequency, including spina bifida, major and minor limb abnormalities, oral clefting, cardiac defects, hypospadias, and joint laxity. A characteristic pattern of facial dysmorphism is frequently present, especially notable in early childhood. Neurodevelopmental problems including reduced IQ, poorer language and motor development, increased rates of autistic spectrum disorder and attention deficit hyperactivity disorder are observed in up to 40% of those exposed. Vision problems such as myopia and astigmatism are also common. Risks are dose dependent and the impact on the brain may be seen at lower doses than those required for physical development alterations.

Review Phase

- Establish a timeline on the licensing and use of sodium valproate in women of child-bearing potential and the emergence of evidence regarding its teratogenicity since it was first licensed in the State until the present day by review of the following:
    1. Documentation on the licensing and regulation of sodium valproate for use in women of child-bearing potential in the State and associated safety reports.
    2. Reports and studies that have been conducted regarding the use and impact in the State of sodium valproate in women of child-bearing potential.
    3. Any formal notifications alerting of safety concerns relating to the use of this medicine in women of child-bearing potential.
    4. Any guidance documents issued within the State for the use of this medicine in women of child-bearing potential.
    5. Work completed by the EMA to reduce valproate exposure in pregnancy, particularly reports and recommendations issued in 2014 and 2018 and implementation of same in the State.
    6. Government commissioned reports published in the U.K. and other European jurisdictions concerning the use of sodium valproate in women of child-bearing potential.
- Issue and review questionnaires to stakeholders to support this collation of information relating to sodium valproate. A list of suggested stakeholders is given in Appendix 1.

Oral statements

- Following assessment of written submissions and documents, invite individuals diagnosed with FVSD, their mothers and other family members who wish to engage with the inquiry to provide oral statements.
- Document the impact and experience of sodium valproate on the lives of those affected - both the women prescribed valproate in pregnancy and those with a diagnosis of FVSD and their families.
- At the Chair's discretion, other stakeholders may also be invited to attend oral sessions, in separate sittings to patients and their families.

Assessment of current systems and recommendation for improvements if identified

- Based on the documented experiences of women given during oral sessions and through written submissions, make recommendations as to how communication and discussion of risks may be improved for any woman prescribed sodium valproate.
- Review current systems in place to ensure clear communication of risks to, and obtainment of informed consent from, women of child-bearing age who are prescribed sodium valproate. Make recommendations for improvement if identified.
- Review the controls in place regarding the prescribing and dispensing of sodium valproate to women of child-bearing age in the State including the adequacy of same to support implementation of the approved pregnancy prevention programme. Assess their adequacy and make recommendations as to how these controls can be improved if identified.
- Consider the relevance of recommendations made to the use of other ASMs in women of child-bearing potential.
- Being cognisant of the systems already in place for the dissemination of medicines safety information, make recommendations as to how these systems may be improved where risks are identified for use of ASMs during pregnancy.
- Consider the adequacy of services and supports currently provided to FVSD patients and their families, considering both statements submitted and information gathered by the inquiry.
- Make any other recommendations considered appropriate by the Chair to support those with a diagnosis of FVSD.

Deliverables and Associated Schedule

- Interim report to be provided to Minister within 6 months of the commencement date of the inquiry, with update to those who have participated in the inquiry as relevant.
- Interim report will outline any assessments and recommendations made to that point, highlighting issues for immediate action that may become apparent during the conduct of the review.
- At this time, agree a date for provision of the final report to the Minister for Health, ideally within 12 months but not later than 18 months after the commencement of the inquiry. No further extension beyond 3 months will be given beyond this agreed date.

Subject to legal advice, stakeholders, including individuals and families who provided oral statements will be provided with a **confidential** copy of the final report by the Minister in advance of publication.

Suggested list of Stakeholders

The Chair may invite submissions from a range of stakeholders, including but not limited to:

Stakeholder	***Individual bodies** (if **applicable)***
Individuals and families with a diagnosis of FVSD	• HSE • OACS • Epilepsy Ireland
Organisation for Anticonvulsant Syndrome (OACS) Ireland	*n/a*
Health Products Regulatory Authority (HPRA)	*n/a*
The Health Service Executive (HSE)	*n/a*
The Department of Health	*n/a*
Sanofi	*n/a*
Prescribers of sodium valproate	• Irish Medical Organisation • Medical Council • Irish College of General Practitioners • HSE Clinical Leads for Epilepsy and Neurology • College of Psychiatrists of Ireland
The Pharmaceutical Society of Ireland	*n/a*
Epilepsy Ireland	*n/a*
Disability Federation of Ireland	*n/a*

Form and structure of inquiry proposed

The proposed non-statutory inquiry will be structured according to three separate strands. The first strand will create a timeline for the use of sodium valproate in the State in women of child-bearing potential including information on regulation, prescribing, dispensing and safety information issued.

The second strand of the inquiry will enable oral statements to be given by individuals diagnosed with FVSD, their mothers and other family members who may wish to participate in this inquiry. This will provide mothers, patients and

their families with an opportunity to tell their story. These statements will be considered in the third phase by the Chair in developing recommendations on supports for patients.

Other stakeholders may also be invited to provide statements in separate sessions. All sessions will be held in private.

The third strand will involve the following:

- An assessment of the current systems in place to respond, disseminate and implement measures that address safety issues relating to use of sodium valproate in women of child-bearing potential and to provide recommendations for improvement of systems if identified.
- Development of other recommendations based on the Chair's assessment of:
    1. relevance of findings regarding current control systems for sodium valproate for other ASMs that may be used in women of child-bearing potential, particularly if new evidence emerges.
    2. services and supports for those diagnosed with FVSD

  as informed by information collated during the inquiry.

The scheduling of work across and within these strands will be at the discretion of the Chair of the inquiry. The Chair will be required to highlight any issues encountered in obtaining necessary documentation to the Minister, should they arise during the inquiry. A record of this will be included in the reports prepared by the Chair.

Data Protection and Records Management

The inquiry should operate to the highest and most appropriate standards of data protection and records management. The Chair will act as data processor, and, with the Minister for Health, as joint data controller. The Minister may make regulations to enable the inquiry to process personal data and special categories of data. A Data Protection Impact Assessment will be put in place. Records created in the course of the conduct of the inquiry will be available to the Minister for Health. However, at the cessation of the inquiry, decisions will be made regarding the disposal or retention of records, balancing data subject rights with the Minister's obligations under the National Archives Act 1986 and Regulations 1988.

Supporting Patient & Family Participation

Regarding patients and families who choose to engage with the inquiry, it is acknowledged that this will be a difficult experience for many. It is considered by the Minister for Health that the participants, for reasons of their health and wellbeing, or due to their care commitments, or due to practical matters arising from their circumstances, may encounter barriers to participation.

The Minister for Health will ask the Chair to examine the provision of appropriate supports to enable participation. Counselling supports, a modest ex-

gratia payment, or reasonable support to access other professional advice, could be considered by the Chair. While supports should be specific to the needs of the cohort of individuals participating in this inquiry, the Minister will ask the Chair to consider the supports provided to participants in the Scally Inquiry, and whether a similar process could apply in this context.

Any such supports will be put in place on a one-off basis, and are specific to this non-statutory inquiry, it is not intended to set a precedent. However, in keeping with the independence of their role, the Chair will make all final decisions as to how best to establish and encourage participation with the inquiry. Further information on any supports being provided would be issued to participants upon application to the inquiry.

As part of the establishment of the inquiry, the Chair will develop a strategic awareness campaign with the aim of achieving a high level of participation in the inquiry.

Appointment of a Chair

The Chair will be appointed by the Minister. The Chair will not have any conflicts of interest which could be seen as undermining the independence or integrity of the inquiry. The Chair must be an appropriate person who is competent to carry out and manage the process of the inquiry in a timely manner, while giving due regard to the primacy of a person-centred, fair and independent process, and giving weight to all stakeholders and participants. The Chair must have familiarity with the Health and Social Care services in the State. The Chair may require, and must consider, independent and expert advice in relation to some elements of the inquiry. The Chair must be able to evidence experience appropriate to the conduct of a non-statutory inquiry.

Role of the Chair

- The Chair shall conduct the inquiry independently in accordance with the Terms of Reference as set out above, and will:
    - With initial support from Department of Health, establish and operationalise the inquiry
    - With Department of Health support, and in consultation with patient groups, the Chair will provide appropriate supports to facilitate the participation of patients and their families with this inquiry. In keeping with the independence of the role, the Chair will make all final decisions as to how best to establish and encourage participation with the inquiry
    - Develop a strategic awareness campaign to promote participation in the inquiry
    - Conduct the review phase
    - Gather and assess statements from affected families
    - Gather and assess information and statements from other identified stakeholders

- Assess current systems and supports and make recommendations if identified
- Produce the interim and final reports

- The Chair will identify and set out such support and advice as they deem necessary for the conduct of the inquiry, to be finalised by agreement with the Minister for Health
- Within the bounds of the Terms of Reference, the Chair will gather such information as they require in order to conduct an independent, fair and rigorous process
- In order to gather information relevant to the inquiry, the Chair shall act as a joint Data Controller with the Minister for Health, subject to an agreement to be put in place
- The Chair will adhere to the legal basis for processing personal data and special categories of data as set out in the Data Protection Impact Assessment for the inquiry
- The Chair will ensure that records formed as part of the conduct of the inquiry are managed appropriately, with arrangements made for retention or destruction of records as appropriate

Implementation of Recommendations

The Department is committed to considering all recommendations made in the final report. After the final report is submitted to the Minister, a working group consisting of relevant stakeholders will be established within 3 months to provide quarterly progress reports on the implementation of accepted recommendations of the inquiry.

L.S.

GIVEN under my Official Seal,
21 July, 2025.

JENNIFER CARROLL MACNEILL,
Minister for Health.

EXPLANATORY NOTE

(*This note is not part of the Instrument and does not purport to be a legal interpretation.*)

The purpose of these Regulations is to enable the commencement of the non-statutory inquiry into the licensing and use of sodium valproate in women of child-bearing potential in the State by providing a legislative base for the controlling and processing of personal data by the joint data controllers as required to fulfil the aims of the inquiry.

These Regulations revoke the Data Protection Act 2018 (Control of Data for the Inquiry into the Historical Licensing and Use of Sodium Valproate) Regulations 2024 (S.I. No. 752 of 2024).

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