STATUTORY INSTRUMENTS.

S.I. No. 352 of 2025

DATA PROTECTION ACT 2018 (SECTION 60(6)) (INQUIRY INTO THE LICENSING AND USE OF SODIUM VALPROATE IN WOMEN OF CHILD-BEARING POTENTIAL IN THE STATE) REGULATIONS 2025

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I, JENNIFER CARROLL MACNEILL, Minister for Health, in exercise of the powers conferred on me by section 60(6) of the Data Protection Act 2018 (No. 7 of 2018), and having duly complied with subsections (9)(b) and (10) of section 60 of that Act, hereby make the following regulations, with respect to which, pursuant to section 6 of that Act, a draft has been laid before each House of the Oireachtas and a resolution approving the draft has been passed by each such House:

Citation

1. These Regulations may be cited as the Data Protection Act 2018 (Section 60(6)) (Inquiry into the Licensing and Use of Sodium Valproate in Women of Child-Bearing Potential in the State) Regulations 2025.

Definitions

2. 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 function" has the meaning assigned to it by Regulation 3;

"relevant objective" has the meaning assigned to it by Regulation 4;

"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.

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

Relevant function

3. In these Regulations, "relevant function" means a function performed by a relevant person that relates directly or indirectly to –

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

(b) reporting or making recommendations to the Minister in accordance with the terms of reference.

Relevant objective

4. In these Regulations, "relevant objective" means an objective –

(a) referred to in paragraph (b) and (o) of section 60(7) of the Act of 2018, and

(b) pursued by a relevant person in exercising a relevant function.

Scope: categories of personal data

5. These Regulations apply to personal data (including special categories of personal data) processed by a relevant person and in respect of which the Minister and inquiry chair are joint controllers.

Scope: purpose of processing

6. These Regulations apply to the processing of personal data to which these Regulations apply, by a relevant person, that is necessary for the achievement of a relevant objective.

Restriction

7. (1) The rights and obligations provided for in Articles 12 to 22, Article 34 and Article 5 (in so far as any of its provisions correspond to the rights and obligations in Articles 12 to 22), of the Data Protection Regulation, in respect of processing to which these Regulations apply, are restricted to the extent that such a restriction is –

(a) necessary, and only for so long as is so necessary, to safeguard a relevant objective, and

(b) proportionate to the need to safeguard that relevant objective,

including where the exercise of the right or compliance with the obligation, as the case may be, would –

(i) obstruct or otherwise prejudice, in whole or in part, the performance by the inquiry of a relevant function,

(ii) prevent the inquiry chair processing personal data to which these Regulations apply for a period of time, in a case in which any delay to the processing may prejudice the achievement of the relevant objective.

(2) Matters which are relevant, for the purposes of paragraph (1), in determining whether a restriction of a right or obligation is necessary to safeguard a relevant objective, and proportionate to the need to safeguard the relevant objective, include –

(a) whether or not the exercise of the right or compliance with the obligation would obstruct or otherwise prejudice the achievement by the inquiry chair of the relevant objective,

(b) the need to respect the essence of the right to data protection of the data subject, and

(c) the risks to the rights and freedoms of a data subject that may result from such a restriction.

Information to be provided where a right or obligation is restricted

8. (1) Subject to paragraph (3), where a right or obligation referred to in Regulation 7(1) is restricted in accordance with that Regulation, the inquiry chair shall notify the data subject concerned of the restriction, in writing and in a timely manner.

(2) A notification under paragraph (1) shall inform the data subject concerned of the following:

(a) the right or obligation referred to in Regulation 7(1) affected by the restriction;

(b) whether the right or obligation concerned has been restricted in whole or in part;

(c) the reasons for the restriction, unless informing the data subject concerned of the reasons may, in the opinion of the inquiry chair, obstruct or otherwise prejudice the achievement of the relevant objective;

(d) that the data subject concerned may lodge a complaint with the Data Protection Commission pursuant to Article 77(1) of the Data Protection Regulation;

(e) that the right referred to in subparagraph (d) is without prejudice to any other rights or remedies which the data subject concerned may have.

(3) Where the inquiry chair is of the opinion that notifying the data subject under paragraph (1) may be prejudicial to the achievement of a relevant objective, the inquiry chair may elect not to notify the data subject.

(4) Where requested to do so by a data subject notified in accordance with paragraph (1), the inquiry chair shall provide information on the policies and procedures referred to in Regulation 10(1) to the data subject.

Communication with data subject

9. The inquiry chair shall ensure that all information provided to a data subject under or in relation to these Regulations is provided in a concise, intelligible and easily accessible form using clear and plain language.

Safeguards

10. (1) The inquiry chair shall prepare and implement policies and procedures to provide for the matters referred to in Article 23(2)(d) and (f) of the Data Protection Regulation.

(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 a relevant person;

(b) the use of controls to ensure that personal data is only disclosed to a relevant person, or to a person otherwise entitled or permitted by law to receive that personal data;

(c) processes to ensure the accuracy of the personal data, that it is kept up to date and accurate, and that an accurate record of the data provided to the inquiry chair is kept;

(d) the determination of appropriate storage periods for personal data or classes of personal data taking into account the nature, scope and purpose of the processing of the category of data;

(e) the treatment of personal data or classes of personal data at the expiry of the storage periods referred to in subparagraph (d);

(f) data minimisation, including the use of anonymisation and pseudonymisation.

(3) The policies and procedures referred to in paragraph (1) shall be reviewed by the inquiry chair on a regular basis and updated where the inquiry chair considers it appropriate to do so.

Interaction with other law

11. The restriction referred to in paragraph (1) of Regulation 7 is in addition to and not in substitution for any restriction of the rights and obligations referred to in that paragraph under any other enactment or law of the European Union.

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.

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.

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[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.

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 instrument.*)

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 restricting of certain rights outlined in the General Data Protection Regulation 2016 for reasons of substantial public interest.

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