



8th July 2020

Dear Minister Donnelly,

We trust this finds you well in these unprecedented times for the country. We would like to congratulate you on your appointment as Minister for Health and we wish you every success for the years to come.

We are writing to you regarding the issue of sodium valproate and the need for an independent inquiry in Ireland. As you know, children exposed to the drug in the womb are at a high risk of serious developmental disorders and congenital malformations. A 2019 HSE Rapid Assessment Report estimates that up to 1,250 children in Ireland have been affected by in-utero exposure to valproate between 1975 and 2015.

We welcomed your commitment prior to the general election – and that of your coalition partners in the Green Party - on the need for an independent inquiry to examine the historical licencing and use of valproate in Ireland and into its ongoing effects.

We are now requesting that this inquiry is now established as a matter of urgency.

Today, the UK's Independent Medicines and Medical Devices Safety (IMMDS) non-statutory inquiry issued their final report and recommended that the British Government issue a full apology on behalf of the healthcare system to all those impacted by valproate. The recommendation follows a two-year independent investigation which collected thousands of documents and hundreds of hours of testimony in concluding that *"as data emerged on the risks of the use of sodium valproate over the decades, it took too long for action to be taken by the healthcare system to ensure that risks were minimised"*.

Your colleague and predecessor Minister Harris noted in previous Dáil responses that he was monitoring the UK review closely before deciding on the next step for families impacted here in Ireland. You will also be aware that in 2018, the Oireachtas Committee on Health made 12 recommendations on the State's response including that an independent inquiry be established to investigate the historical use of the drug.

Hundreds of families in Ireland, some of whom you have met already, are living every day with the ramifications of being prescribed this drug in pregnancy. They are caring for their children, many of whom are now adults, with serious irrevocable disabilities and the most complex of needs. They have questions as to how their situations were allowed to happen, despite growing evidence since the 1960s about the risks of the drug in pregnancy. They want to know why it took until 2014 for regulatory action and they want to know why they continued to receive sodium valproate, often without any discussion of the risks, throughout a period when the adverse effects were well documented.

They cannot wait any longer to see these and other historical issues investigated. In light of today's UK report findings, they too deserve answers and it is clear that the only pathway for them getting these answers is via an independent inquiry. On behalf of all families affected by sodium valproate, we hope and expect that that your commitment to an inquiry will now be honoured.

In addition to the above, we have serious concerns about the effectiveness of the State's response to implementing measures aimed at reducing the risk of children being born with valproate-related disabilities in future.

Since 2018, a range of welcome measures have been put in place by the HPRA and the HSE. For example, valproate must be initiated by a specialist and must not be used in girls and women who may be able to have children unless the terms of a pregnancy prevention programme (PPP) are followed. The HSE established a Valproate Response Project, which among other work during its term, issued direct correspondence to patients and their GPs.

Despite these and other steps, data collected this year by Epilepsy Ireland from service users prescribed valproate since 2018, has found that three in 10 women have never had a discussion with a health care professional about the risks of valproate in pregnancy and only one in four women had ever heard of the (mandatory) Pregnancy Prevention Programme. Most worryingly, one in six respondents were unaware that valproate increased the risk of birth defects while one-third were unaware of the risks of neurodevelopmental disabilities.

These are extremely concerning findings. They point to a devastating situation where children are potentially being born in Ireland in 2020 that have been exposed to valproate in-utero without their parents having any prior knowledge of the risks. Further action is required to ensure that no more children are born in Ireland with preventable valproate-related disabilities.

Alongside the establishment of an inquiry, we are also seeking that you establish a Valproate Stakeholder Group consisting of representatives from the HPRA, HSE, Department of Health, PSI, healthcare professional bodies, patient groups and other relevant stakeholders in order to collaboratively tackle and resolve issues of risk minimisation once and for all.

Capacity within the HSE's epilepsy service must also be increased to enable the mandatory annual consultations and risk acknowledgements to take place. For example, four out of six epilepsy specialist nursing posts, approved in 2018 for this specific purpose remain vacant today.

Finally, access to a range of community supports and services is of critical importance to families affected by foetal valproate syndrome. The HSE Valproate Response Team worked with OACS Ireland in 2018 and early 2019 to develop a community support package and a summary of the HSE Valproate Response Team's proposal was included in their final report in March 2019. It stated that the "proposal and the funding required is currently under consideration by the HSE Community Operations". To date, none of the measures proposed in the Community Operations sub-group proposal have been actioned or resourced and families today are no better supported than they were two years ago.

Minister, while some good work has taken place since 2018, too many aspects remain incomplete or have not been as effective as originally intended.

In conclusion, we are seeking an urgent meeting with you to discuss:

- 1) The establishment of an independent inquiry
- 2) The establishment of a Ministerial-appointed valproate stakeholder group
- 3) The need to activate measures proposed by HSE in 2019 to support families affected by foetal valproate syndrome.

Thank you for your time and attention to this matter. We look forward to your response and to discussing these matters with you shortly.

Yours sincerely,

Peter Murphy  
CEO, Epilepsy Ireland

Karen Keely  
Chair, OACS Ireland