



4th August 2021

Dear Minister,

We trust this finds you safe and well.

We are writing to you in relation to the Sodium Valproate Inquiry which you announced in November 2020.

As you know, the announcement was warmly welcomed by Epilepsy Ireland and OACS Ireland and was a huge relief to families who have been impacted by the drug.

When we met last November, we were particularly excited by your personal commitment to the issue and your desire to seek a speedy, yet thorough resolution.

Unfortunately, what we have experienced thus far has been the opposite of speedy and thorough. It has now been nine months since your announcement and eight months since we responded to the Department's request for input into the inquiry's draft terms of reference. The reality is that nothing of significance has happened to progress the establishment of the inquiry since then.

We have been unable to get any updates of note from the Department about the status of the inquiry, its terms of reference, its membership, or when it will be established.

We understand that these are by no means "normal" times and the challenges faced by the Department in responding to the many consequences of Covid-19 are significant and unique. However, we feel that we have been more than patient with the process (or lack thereof) and with frustrations growing among families affected, the time has now come to write to you once again seeking an urgent update on plans to establish the inquiry.

We are also concerned that there have been no attempts to establish a stakeholder group to work on continuing efforts to minimise the risks associated with valproate use in women. As we highlighted in November, the problems of Sodium Valproate are not purely historical and significant risks remain that children will continue to be born with valproate-related disabilities unless further action is taken.

This is backed up by recent data from an RCSI/ HPRAs study funded by the Health Research Board and also by new international data produced by the International Bureau for Epilepsy. This is in addition to an Epilepsy Ireland survey in 2020 which identified serious ongoing concerns about the implementation of existing safety measures and awareness of the risks involved with valproate prescribing in pregnancy.

We remain convinced that the only way we can successfully mitigate this ongoing risk is to combine the efforts of state bodies such as the HPRAs, HSE and PSI with representative groups like the ICGP, IPU and patient organizations to work collaboratively as a 'stakeholder group' to identify areas for improvement and work to resolve them.

Finally, supports must be put in place for families who are caring for children who have been exposed to Sodium Valproate. Children who have been exposed to valproate have significant, varying and developing care needs - needs which impact on the entire family

unit. In recognition of the significant challenges facing families impacted by valproate, the HSE Valproate Response Project made several recommendations in 2018 including:

- Appointment of a National FACS Assessment Team.
- A Full Pathway of Care for Referred Children/Adults to Community Services.
- A Package of Community Supports to help support families with the complex care needs of their children
- Establishment of Register for individuals impacted with FACS.

To date, a diagnostic service has been established at Crumlin Hospital but none of the above measures have been fully implemented or resourced.

As we have noted in our previous correspondence and discussions on this matter, families affected by Sodium Valproate in Ireland have waited long enough for the answers they deserve. Equally, there is no justification in 2021 for there to be serious concerns about the risk that children may still be born with valproate-related disabilities. Finally, families who have been impacted by valproate need support to help them with the complex needs of their children – many of whom are now adults.

These matters can be addressed by the establishment of an inquiry; the establishment of a stakeholder group; and by ensuring the agreed services are put in place.

We would be grateful for the opportunity to discuss these matters further in person and how we can continue to work together to achieve desired outcomes. We would appreciate if you could give this correspondence your urgent attention and we look forward to your reply.

Yours sincerely,
Peter Murphy,
CEO, Epilepsy Ireland

Karen Keely
Chairperson, OACS Ireland