



13th February 2023.

Strictly Private & Confidential.

Addressee only.

Mr. Stephen Donnelly,
Minister of Health,
Department of Health,
Block 1,
Miesian Plaza,
50-58, Lower Baggott Street,
Dublin 2.

Via E-mail only: ministers.office@healthgov.ie
stephen.donnelly@oireachtas.ie

Re: Sodium Valproate (EPILIM) Inquiry.

Dear Minister,

We trust this finds you well. We are contacting you to ascertain a precise indication for the establishment of the inquiry into the historical licensing and prescribing of Sodium Valproate in Ireland together with immediate clarification on a number of matters relating to the inquiry which remain outstanding. You as Minister for Health committed to holding this inquiry in 2020. You will be aware from our meeting in August last year that families affected by Sodium Valproate are eagerly awaiting the establishment of this inquiry.

Accepting the terms of reference on offer from the Department last year, was a very difficult decision for our families in OACS Ireland, as we continue to have significant reservations about the framework of the Terms of Reference including how it can examine adequately the historical licensing aspect which is very important to our members, which we outlined to you at our last meeting. However, we were left in no doubt by your team at the Department of Health, following this meeting, that the Terms of Reference on offer from the Department of Health at that time was the only version the Department would allow for the inquiry, if the inquiry was to proceed, and on that basis our members agreed to proceed, albeit very reluctantly.

Minister, it is also because of your own personal assurances for a 'fair and fast inquiry', that our members placed their faith in you to see this Inquiry through to the end. However, since informing the Department of our decision in early November 2022, we have been met with a wall of silence by your officials, and no further progress appears to have been made to establish the inquiry.

Our decision to proceed last year was based on the promises which you Minister, and your officials within the department gave us i.e. that the last version of the Terms of Reference could deliver an inquiry which will finally provide answers that families harmed by valproate so desperately deserve. We were assured that the agreed Terms of Reference would be put to cabinet by the end of December 2022, we note this did not happen.

Your own press release of November 2020 stated: "Parents and children impacted by sodium valproate have been fighting for many years for an inquiry into the licensing and use of this drug. I

have asked officials in my Department to begin work on this as a priority, and have emphasised the need for a fair and fast inquiry.”

We are now entering the third year since your initial commitment to establish this ‘fair and fast’ inquiry. Ireland seems to favor the protracted route when it comes to protecting our vulnerable citizens, especially those who do not have a voice or investigating issues of the past; issues which if properly investigated i.e. the purpose of this inquiry, would help to protect future generations of women with Epilepsy, Bi-Polar and other conditions treated by Valproate and indeed, to also help to support those who have been affected adversely by exposure to Sodium Valproate.

Minister – the repeated but empty commitments and ‘holding’ replies from your Department have all become sterile and meaningless. Our members have been beyond patient with this process. A sincere, definitive timeline is now called for from you in order that your commitment in November 2020 for ‘fair and fast’ inquiry into the historical licensing and use of Sodium Valproate may come to fruition once and for all. The continuing delay in establishing the inquiry is unacceptable for our families. We ask you to intervene to progress the inquiry to cabinet as a matter of urgency and therefore deliver on your past commitments to our members.

We look forward to hearing from you.

Yours sincerely,

Karen Keely
Chairperson

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