



To: [REDACTED] and [REDACTED]

Department of Health. 50-58, Block 1, Miesian Plaza, Baggot St, D2

Date: 15th May 2023

Dear [REDACTED]

Although, in recent times, we have been having meetings with you/the Department of Health regarding some updates about the intended inquiry, the following issues remain outstanding:

Draft Terms of Reference:

- A. We are unclear from our recent discussions as to whether further changes or amendments have been made to the draft Terms of Reference by the DoH since the version we reluctantly agreed to November 2022. Please confirm whether any such changes, additions or amendments have been made to the November 2022 version?

If such changes have been made, then the Department of Health needs to provide, immediately, the draft Terms of Reference complete with **all** suggested changes made by various State parties, since the 24th November 2022 version, to OACS Ireland for consideration. Each of the proposed amendments made (if that is the case) must be clearly identifiable to OACS Ireland. Furthermore, OACS Ireland requests copies of all correspondence from each government Department (where applicable) regarding any proposed changes to be made to the Terms of Reference since November 2022.

DPA issues:

- B. You stated during the meeting of 10th May 2023 that the Data Protection issues have now been resolved. We require a draft consent form on the data protection issue for consideration by us and our members on how the personal data of those participating in the inquiry will be processed, stored, by your department and the Inquiry etc in compliance with the Data Protection Act 2018.

Key documents in the possession of relevant state bodies and other stakeholders:

- C. This inquiry should involve the investigation and assessment of considerable regulatory and historical licensing data, safety reports, minutes of meetings etc. As the proposed Inquiry is non statutory, we require to know now what processes/arrangements have been put in place by your Department to ensure the Inquiry has access to all relevant and necessary documents/data from State Bodies, Government Departments and other stakeholders to the Inquiry that come within its remit for the Inquiry.



In so far as non-State Bodies are concerned and in particular, drug companies, how is it proposed to gain access to all relevant documents?

E Portal:

- D. During this time OACS Ireland would like access to the documents/comments etc uploaded to the E Portal and any amendments /observations made by other government Departments at the end of this ten-day period.

Inquiry Resources:

- E. You informed us that a budget has been discussed and agreed with the Dept of Public Expenditure and Reform, but we have been given no detail about the headings against which this was calculated, or the total sum identified. Please indicate the process and costings to secure the following-
- Chairperson
 - The Panel to assist the Chair.
 - All relevant stakeholders participating before the inquiry.
 - Please confirm costs of stenographer to include provision of daily transcripts to all stakeholders will be paid for by the State.
 - Please also confirm what other headings the DoH intend the budget to cover and the estimated budget allocation for same.

Inquiry format:

- F. Please confirm:
- OACS members who choose to give evidence before the inquiry can do so in public.
 - Media reporting of the evidence before the inquiry will be allowed.
 - What arrangements will be in place for OACS members who choose to give evidence to the inquiry anonymously?
 - A stenographer will be present to record the evidence before the inquiry and that transcripts will be furnished to OACS Ireland legal team each day following the conclusion of evidence.

Chair and panel:

- G. Please confirm: -
- How do you propose to select the Chairperson for the Inquiry into Sodium Valproate? OACS Ireland wants to have input into the selection of the Chairperson.
 - The Panel/Experts who will assist the Chair, who are they? Who is selecting them? Is it the Department of Health? OACS Ireland would like input here also.
 - Will the Chair decide who are the core participants to the inquiry?



- Upon selection of Chairperson and subsequent establishment of the Inquiry, please confirm that OACS Ireland and families can meet the Chair as soon as possible to outline our views as primary stakeholder to the Inquiry.

State Stakeholders and other participants to the Inquiry:

- H. In relation to each Stakeholder listed as per Appendix 1, last draft ToR:-
- Have all the stakeholders been contacted by the DoH re participating in the inquiry?
 - Who is participating in the Inquiry?
 - Who has indicated a willingness/unwillingness to participate in the inquiry?
 - Have those stakeholders confirmed they will give evidence before the inquiry and have they confirmed they will furnish to the inquiry whatever documents that are in their possession that are relevant and necessary to the inquiry?

Legal costs for OACS:

- I. It is imperative that OACS is reassured that measures will be taken to address the imbalance of power between OACS and the access to legal support that the State bodies/government departments and other participants to the inquiry already have access to.

Please confirm that the legal costs and administrative supports for OACS Ireland will be covered in full by the State whilst participating in this Inquiry? OACS Ireland now need to select our legal team and we require clarity on the position of legal costs for OACS Ireland's participation in the Inquiry now. We cannot approach a legal team without knowing the position in relation to costs.

OACS Ireland will require to call experts in the field of Fetal Valproate Spectrum Disorder/Fetal Valproate Syndrome (FVSD/FVS). Will the Department confirm the costs of OACS witnesses before the Inquiry will be paid in full?

OACS Ireland will be attending the Inquiry for a considerable amount of time. Please confirm that all appropriate costs are covered for those participating in the inquiry on behalf of OACS. E.g., travel, accommodation, loss of earnings, administrative costs, office space, utilities and ancillary costs re OACS's participating in the inquiry.

Legal and other support for OACS members:

- I. Confirm that the legal costs for the individual families of OACS Ireland participating in this Inquiry will be covered in full by the State. If a family wishes to seek representation from a specific solicitor (separate to the OACS legal team) will the Inquiry cover these costs?



We have already raised the issues above with you at various times, in order to clarify same for our members, but have been unable to do so to date. In the absence of minutes of meetings being taken by the Department (you informed us previously you were not keeping minutes of our meetings), we now need to formally set out what requires clarification.

These outstanding matters need to be addressed and resolved to the satisfaction of our members, prior to our participation in the forthcoming inquiry.

Yours sincerely,

OACS Ireland