



Organisation for Anticonvulsant Syndromes (Ireland)

OACS Ireland

Annual Report 2021

Chairs Opening Remarks

2021 was another important year as we sought to progress the Inquiry into the historical licensing and use of sodium valproate (Epilim) in Ireland which was promised by the Minister for Health in November 2020. At the time we very much welcomed his commitment. We responded quickly to a request by his officials in the Department of Health to provide our initial thoughts on Terms of Reference. However, it took until the late summer of the year before we received a response to engage in negotiations with the department. Nevertheless, with our partners, Epilepsy Ireland, we made good progress in agreeing potential terms of reference with departmental officials. However, as we write we still have not received terms of reference which we find acceptable and as such the Ministers commitment to a 'speedy and fair' inquiry remains to be achieved. Our second major action during the year was to progress effective diagnosis and services for those affected by sodium valproate. We held many meetings with the Chief Clinical Officer in the HSE and some progress was made. We secured a commitment to offer speedy diagnosis for those affected by sodium valproate including those who sought second opinions. Whilst the Children's Hospital Crumlin (CHI) were unable to secure a permanent new geneticist they were able to arrange for a geneticist to make see patients and provide diagnosis on a contract basis from the UK. This process has worked well and as we write most families have been assessed and received a diagnosis. Following diagnosis, a process to secure appropriate community services was agreed. However, as we write many of the patients have still to receive the services they so desperately need.

OACS will continue to lobby and represent our members to get the inquiry promised and the services they require.

I want to particularly thank the Hospitals Saturday Fund for their continued financial support to OACS, without which we would not be able to operate.

Finally, I wish to thank all the OACS members who supported the organisation and made their own efforts to progress our aims by contacting their local public representatives. The OACS Executive Committee also worked hard to make progress on our key issues as did our colleagues in Epilepsy Ireland who continued their valued support. My thanks go, to you all.

Our Organisation

As the Covid pandemic continued during 2021 our organisational arrangements continued through the use of remote meetings. We held our regular Executive Committee meetings remotely and our Annual General Meeting in September. Our website <https://oacsireland.com> was continually updated. We also have an active Facebook page (135 followers) for our members and regularly use Twitter (994 followers) and Instagram (128 followers) to engage with the wider population.

At the end of 2021 we had over 100 members who we regularly brief directly through e mail on issues of interest. OACS Executive members regularly engage with the media and some of our members have appeared on local radio to discuss their own situations.

Voluntary sector partners

Our partnership with Epilepsy Ireland remained solid as we continued to work together to agree our approach to lobbying Government for the promised Inquiry into the historical licensing of sodium valproate. Where necessary we have produced joint media statements and made joint submissions to Government and statutory bodies.

Statutory sector partners

We continued to engage with the Health Service Executive (HSE) through the offices of the Chief Clinical Officer, children's Hospital Ireland (CHI) and Community Health Offices (CHOs). 2021 saw the assessment of many families who had sought a formal diagnosis of Fetal Valproate Spectrum Disorder (FVSD). CHI were able to facilitate first and second opinion assessments of those affected by taking sodium valproate by engaging a specialist geneticist from the UK. Dr Saagar made many visits to Ireland to meet families and make clinical assessments. Families reported being very pleased with the way in which these assessments were conducted.

Following assessments families received letters stating the outcome of tests and services required. These assessments are then passed on to CHOs. Unfortunately, the response from the 9 CHOs has been patchy, some providing appropriate and timely services and others not providing any service or placing families on long waiting lists. This is not our understanding of what has been agreed with the

HSE. We continued to meet the HSE to ensure a more uniform and agreed approach to service provision.

Our Chair continued to engage with the Health Products Regulatory Authority (HPRA) on many of the issues regarding labelling and information relating to sodium valproate. She is a member of the HPRA Patient Forum, which is a platform for dialogue and exchange on topics relevant to patients regarding the regulation of medicines and medical devices. It was established to give patients a voice in the regulatory process, especially in the areas of patient safety, licensing, and use, and on how the HPRA communicates with wider society. The HPRA informed us that they are working on articles for a number of other anti-epileptic medicines following recent product information updates concerning pregnancy. A special edition drug safety newsletter on sodium valproate has also been prepared

[https://www.hpra.ie/homepage/medicines/special-topics/valproate-\(epilim\)](https://www.hpra.ie/homepage/medicines/special-topics/valproate-(epilim)) .

OACS participated in the annual Med Safety Week, a global media campaign supported on social media about Covid 19 vaccine and potential adverse drug reactions. We continued to engage with officials in the Department of Health to agree the terms of reference for the promised inquiry into historical licensing of sodium valproate. In the early months of 2021, there was no progress or indeed any contact from the Department of Health (DoH). In the latter part of the year, we had positive contact and made significant progress in agreeing key aspects of the inquiry. However, the DoH remained firm that a statutory inquiry would not take place and only a non-statutory inquiry or review was on offer. OACS has maintained our position of seeking a statutory inquiry, but this remains a significant point of disagreement. All parties have stated that they want the inquiry to be established as quickly as possible.

However, at the time of writing we do not have agreement on the final terms of reference.

Work with Public Representatives

We continued to work with public representatives of all political parties to brief them on progress with the Inquiry and services for our members. 17 parliamentary questions were asked by public representatives, of which 9 related to the progress of the promised inquiry and 4 related to services required by families. Our approach is to meet any public representative who express an interest in the issue of sodium valproate. Also, many of our members have contacted their local public representatives raising concerns about their own individual situations.

International Partners

We continued to work with patient groups in other countries that have sought to address the issues around sodium valproate. In particular we supported the UK groups that are campaigning for implementation of the recommendations of the Cumberlege Review entitled 'First Do No Harm'. Although published for more than a year few of the recommendations have been implemented in the UK. This

remains a cause for concern there and does not bode well here if the Irish government intends to follow the UK process.

Our Finances

OACS Ireland managed its finances well on a small budget for 2021. Income for the year was €3768 and increase of almost €1600. The bulk of the income came from a Hospitals Saturday Fund grant of €3000. However, €756 came from donations and membership fees, compared to €170 in previous years.

Expenditure was down by almost €700 compared to 2020 and much of this was due to holding meetings on Zoom rather than in person. Overall expenditure came to €2472 of which almost €1600 was spent on equipment including a laptop. This was essential to increase OACS ability to communicate with its members, the statutory bodies and the public/media.

OACS opening funds on 1 January 2021 were €4120 but through our prudent management of funds this had increased to €5413 at 31 December 2021.

Our Executive Committee 2021

Karen Keely (Chair)

Geoff Day (Vice Chair)

Theresa Byrne (Secretary)

Christina O'Callaghan (Treasurer until September 2021)

Mike Glynn (Treasurer from September 2021)

Jimmy Dunne

Beverley Dunne

Valerie Brennan

Nicki Memery

