
Organisation for Anti-Convulsant Syndromes (Ireland)

OACS (Ireland)

Annual Report 2020



Chairs opening remarks

2020 was another important year for OACs Ireland as we obtained a commitment from the Minister for Health in November 2020 to hold and independent Inquiry into the historical use and licensing of sodium valproate (Epilim). At our meeting the Minister stated that such an Inquiry should be speedy and fair. We very much welcomed this development as it should address many of the questions and issues raised over the years by our members.

However as this report is written there has been little or no progress and we are none the wiser about the format, timing or terms of reference of such an Inquiry. We hope we can constructively engage with the Minister and the Department of Health during the remainder of 2021.

During 2018 and 2019 we gave evidence to the UK Independent Medicines and Medical Devices Safety Review chaired by Baroness Cumberlege. In July 2020 the Report of the Review was published. Entitled 'First Do No Harm' the report examined testimony from hundreds of affected patients and drew important conclusions in relation to one of the medicines examined, Sodium Valproate.

Many of the conclusions and recommendations are likely to apply to the Irish context.

We continued our positive engagement with the Health Service Executive (HSE) through the office of the Chief Clinical Officer, Dr Colm Henry. Our engagement has been primarily about ensuring proper diagnoses of Foetal Valproate Syndrome/ Foetal Valproate Spectrum Disorder and the necessary health and social care services required by our members. Much progress has been made and members are beginning to receive proper diagnoses of Foetal Valproate Syndrome and as a result the HSE is prioritising services required by our members.

I wish to thank the members of the OACS Executive for their work during this year. Covid 19 set us all difficulties which had to be overcome, not least in our communications. I also want to especially thank Peter Murphy and Patrick Mc Geoghegan from Epilepsy Ireland for their unwavering support as partners in achieving improved services for those affected by sodium valproate use and seeking assurances from the Minister for Health regarding an independent Inquiry.

Our Organisation

Due to the Covid pandemic all of our meetings, except the January 2020 Executive Committee, were held on line by Zoom. 7 meetings of the Executive Committee were held and the Annual General Meeting (postponed twice due to Covid) took place on 22 September 2020. A Business plan for 2020 was approved and our website and Twitter presence expanded. One member of the Executive took overall responsibility for social media. We have 934 followers on Twitter and 130 members on our private Facebook page.

We have continued to grow our members and by the end of 2020 had 131 members. However, some families prefer to be contact by email.

We have consistently briefed members of the media in relation to our progress with seeking an Inquiry and improved services and some of our members have broadcast on national and local radio about the effects and implications for their families of using sodium valproate in pregnancy.

OACS has limited funds through gathering members subscriptions and private donations. However, we have valued the support of the Hospitals Saturday Fund in granting us funding to enable us to continue our work. Without this financial support we would not have been able to engage in the work we have done to date. We were also successful in being grant aided in late 2020 by the Community Foundation for Ireland to purchase necessary IT equipment to enable us to be more effective in our administration and communications. We will continue to seek appropriate funding for the work of OACS.

OACS is now a registered charity with the Charities Regulator and is aware of its responsibilities to maintain proper governance. One member of the Executive takes responsibility for issues and communications with the Regulator.

Similarly, one Executive Committee member has responsibility for advising on matters relating to General Data Protection Regulations (GDPR) and has undergone training in this regard. OACS Ireland is aware of the importance of data protection and the potential reputational damage of breaches of GDPR.

Voluntary sector partners

During 2020 OACS continued to build on a solid relationship with our colleagues in Epilepsy Ireland. Members of the OACS Executive have met with Epilepsy Ireland to ensure that the historical use and licensing of sodium valproate

remains at the forefront of our work towards an independent Inquiry. Together with Epilepsy Ireland we extended our work through local and national media including social media formats such as Facebook and Twitter. We sought the assistance of public representatives, journalists and of course our own members and their families. One of our members had an article printed in her local newspaper. Epilepsy Ireland have assisted us with media communications for which we are extremely grateful.

With the publication in the UK of the IMMDS Review 'First Do No Harm' both charities watched the outcome with interest and acted immediately by writing to the Minister for Health seeking a meeting. We were granted a meeting in November 2020 at which the Minister announced an Inquiry into the historical use and licensing of sodium valproate (Epilim) in Ireland. We were requested by the Department of Health in December 2020 to submit draft terms of reference and we worked with Epilepsy Ireland on a set of core principles which were submitted in January 2021. The Minister for Health stated he favoured a speedy and fair inquiry. Little has happened since then and we continue to press him and his department for a commencement date for the Inquiry.

Statutory sector partners

Our two main statutory sector partners in 2020 were the Health Service Executive (HSE) and the Health Products Regulatory Authority (HPRA).

We held a number of meetings with the HSE by videoconference to address the service issues encountered by our members. The HSE had funding approved for an additional consultant geneticist in Crumlin Children's Hospital to carry out assessments for FVS/FVSD. Unfortunately, the post could not be filled which was a frustration for all concerned. A temporary arrangement with an existing

geneticist was put in place but this proved unsatisfactory for many families who felt that insufficient time had been given to understand their situation. A consultant geneticist was recruited from the UK to provide sessional work during early 2021 in order to clear the backlog of those seeking clinical assessments and second opinions and this will be completed in the coming months. The report of the HSE Valproate Community Services Group was finalised and this provided the beginning of a planned service response and pathway for families with a diagnosis of FVS/FVSD. We continued to press for appropriate access to services for our members. However some of the issues raised by our members e.g. lifelong medical card, are outside of the HSE's remit and require a government policy decision. We continue to raise these issues with the Minister for Health.

OACS Ireland continued its engagement with the HPRA and in particular our concerns in relation to the 3rd generation of those being affected by Epilim. The HPRA has indicated that they fully appreciate the concerns of our members in relation to this important topic and have informed us that there is ongoing monitoring of this issue at European Union level via the European Medicines Agency safety committee. Further investigation and studies are required and the HPRA have committed to keeping OACS Ireland informed of the results of any further activity in this area.

Work with Public Representatives

Following the report of the Oireachtas Joint Committee on Health, entitled 'Report on Foetal Anti-Convulsant Syndrome' in 2018 OACS Ireland has continued to inform public representatives of the implementation of the recommendations from a user perspective. We have had supportive

engagements with many public representatives. Prior to the Covid pandemic we met with representatives and have received support in relation to our requests to both the HSE and Department of Health.

International partners

OACS Ireland continues to work with our UK and French patient organisations representing families affected by sodium valproate use. The publication of 'First Do No Harm' the report of the IMMDS review in July 2020 was a considerable step forward in raising the issues around sodium valproate with the UK government and the three national assemblies. 'First Do No Harm' made a number of recommendations regarding sodium valproate, including

- The Government to issue a fulsome apology to the families affected
- The appointment of a Patient Safety Commissioner
- Establishment of a Redress Agency to compensate those families affected
- Set up a scheme to meet the cost of care and support for families affected
- Set up a national database of those families affected

In Scotland the Secretary for Health indicated that they will implement all of the recommendations that it has the power to implement. They also indicated that they will add their voice to others in seeking to persuade the UK government and other devolved governments to also implement the recommendations.

In Wales the Health Minister apologised for the harm caused to women in Wales for a "system wide failure of the healthcare services".

In France on the month November 2020, it was report that the National Medicines Safety Agency (ANSM) has just been indicted for "injuries and involuntary manslaughter by negligence" following the marketing of Dépakine.

For families, it is a step forward, while their life rhymes with guilt. The National Agency for the Safety of Medicines and Health Products (ANSM) announced, Monday, November 9, to have been indicted for “injuries and involuntary manslaughter by negligence”, in the context of the marketing of Depakine, an antiepileptic. This product, prescribed to pregnant women, could cause malformations on the foetus. The molecule is marketed by the Sanofi laboratory, itself indicted last August. Dépakine is marketed in Ireland as Epilim.

Finance

OACS Ireland continues to receive subscriptions from its members and from generous individual donations. Our main source of funding in 2020 came from the Hospitals Saturday Fund. We also applied for, and were successful in receiving, a grant from the Community Fund in December 2020 to purchase necessary IT equipment. We are grateful to all our donors for their generosity and support.

At the beginning of 2020 our opening balance in our bank account was 5103.63 euro.

At the end of 2020 our closing balance was 4119.25 euro although all of the allocation from the Community Fund remained unspent and will roll over into 2021.

Although use of our funding was restricted due to the inability to organise face to face meetings the organisation still had ongoing costs such as insurance, training, stationery and printing, and website updates.

Executive Committee members 2020

Karen Keely (Chair)

Geoff Day (Vice Chair)

Theresa Byrne (Secretary)

Christina O'Callaghan (Treasurer)

Mike Glynn

Jimmy Dunne

Beverley Dunne

Danielle Delaney – until OACS AGM in September

Valerie Brennan

Nicki Memery