



## Organisation for Anticonvulsant Syndromes Ireland

### (OACS Ireland) Annual Report 2019

#### Address from Karen Keely, Chair of OACS Ireland

2019 proved a landmark year for OACS Ireland. Our organisation has been in existence for just over a year but 2019 was a year of considerable progress. We were approved as a charity by the Charities Regulator which means we can now apply for and receive funding for our work. We are grateful to the Irish Hospitals Saturday Fund for their financial support to date. During 2019 we made significant progress working with the HPRa to improve the labelling on the anti-epileptic drug Epilim (sodium valproate). This will alert pharmacist, doctors and users of Epilim to its potential implications if taken prior to and during pregnancy. We worked closely with the HSE to put in place a care pathway for those affected by the use of Epilim. At our request the HSE commissioned an epidemiological report to establish the potential numbers of those affected. This report was published in early 2019 and is available on the OACS Ireland website: [HSE Report on prenatal exposure](#)

We also, started work on the **HSE Women's Health Program in 2019**. The aim of the medium to long term response to the valproate is to set up a Programme for Women's Health in Epilepsy within one of the Regional Epilepsy Centres, which will coordinate this national response. This means that, fulfilling the PRAC and HPRa requirements, all women taking valproate will have yearly follow-up, sign the valproate agreement form, be kept up to date with developments and signposted to other services including the diagnostic service for those potentially exposed during pregnancy.

This will include the development and enhancement of a mandatory National Epilepsy Pregnancy Register. The enhancement of the National Epilepsy EPR will support the implementation of the full requirements of PRAC/HPRa documentation, yearly and also develop a surveillance reporting structure. We continued to make representations to elected representatives and the government to ensure that those affected receive the best and most appropriate services. We have made some progress on this but there is more to do. We were disappointed that the Minister for Health has yet to respond to our call for and inquiry into the issues around sodium valproate and consider a compensation package for those affected. We will apply ourselves to this aspect in the coming months.

We have sought to publicise the work of OACS Ireland through social and print media and as a result have recruited more members to the organisation. We have an active private and Public Facebook pages , the link to our public Facebook page is as follows : [www.facebook.com/OACSireland](http://www.facebook.com/OACSireland) . Our

Twitter account [twitter.com/oacsireland](https://twitter.com/oacsireland) is to keep in touch with those interested in the work of OACS Ireland. Our activity has been international, working with colleagues in France, where much progress has been made and the French government has put in place a compensation scheme, and the United Kingdom where we gave evidence to the Cumberlege Review set up by the UK government to examine the sodium valproate issue.

Our organisation continues to get stronger with an active Executive Committee. I want to thank them all, those who left the Committee and new arrivals, for their contribution during 2019. I particularly want to thank Peter Murphy, CEO of Epilepsy Ireland and Joan O'Donnell late of Disability Federation of Ireland without whose commitment and support OACS Ireland would not exist and we would not have made the progress we have to date.

We will renew our efforts in 2020 to support our members and argue for the resources and services they require.

### Our organisation

OACS Ireland held its second Annual General Meeting on 23<sup>rd</sup> February in the Ashling Hotel at which its Executive Committee for the year was elected. The Executive Committee held 5 meetings during 2019. A Strategic Plan and a Business Plan were approved as well as the policies on conflict of interests and vulnerable people. We set up an Audit Committee to ensure our finances are in order and appropriately used. Considerable work was undertaken by Board members to establish our website <https://oacsireland.com/> and we continued to manage our closed Facebook page which currently has 127 contacts. While our new recently launched Facebook page OACS has received 200 hits this page was only launched recently. We have produced a leaflet for distribution about the work of OACS Ireland and advice on the issues around sodium valproate use.

As we have no premises for the organisation we decided to purchase a mailbox address as follows

OACS Ireland, c/o Carmichael House, 4 Brunswick St North, Arran Quay, Dublin D07 RHA8

Much effort was put into obtaining registration from the Charities Regulator and approval was received in October 2019. This will allow us to actively seek funding to continue the organisations work. Until now we have had to rely on membership contributions and a small grant from the Hospitals Saturday Fund through the Disability Federation of Ireland for which we are most grateful.

Our membership now stands at 161. We hope to expand this in the coming year.

### **Working with Statutory Bodies**

Following the European Medicines Agency (EMA) ruling in 2018 on the future use of sodium valproate we have continued to work with the Health Products Regulatory Authority (HPRA), the Health Service Executive (HSE) and the Pharmaceutical Society of Ireland (PSI) and the MHRA in UK.

The HPRA issued new guidance in 2018 to pharmacists and new packaging for sodium valproate with clear labelling and information for patients. OACS Ireland was actively involved in advising on content and throughout 2019 continued to monitor the implementation of the guidance. As a result of the 'Epilim in a bag' campaign, where the public were asked to report circumstances where they only received Epilim with no warning notice or advice from the pharmacist, a number of complaints were made to the PSI. These are currently being investigated.

The bulk of OACS work in 2019 was with the HSE. OACS members were involved in the HSE Valproate Project Group as well as the overall Valproate Steering Group. The Project Group. The project aimed to create a comprehensive action plan which will track and monitor actions to achieve the following objectives;

1. Ensure women of childbearing age who continue / commence taking Epilim (Sodium Valproate) are monitored, subject to annual specialist review & have access to specialist services when required.
2. Support the implementation of the HPRA guidance on the pregnancy prevention programme.
3. Ensure that people who may have been impacted by current or historic risks of Epilim exposure in the womb are provided with information and support.
4. Estimate the number of children / adults who may have been impacted by exposure to Epilim in the womb (Foetal Anticonvulsant Syndrome, FACS).
5. Develop a diagnostic pathway for children / adults who may have FACS.
6. Develop an assessment and intervention (or care) pathway for those children and adults diagnosed with FACS
7. Scope support needs for children/adults diagnosed with FACS, & make recommendations regarding Disability / Mental Health Services.
8. To establish a Programme for Women's Health in Epilepsy.

Some progress has been made with the HSE in developing a pathway of care for those affected by FACS, seeking new specialist roles to assess and support those affected and to argue for new resources to both diagnose the syndrome and to provide appropriate services. Whilst the cooperation between OACs Ireland and the HSE has been *somewhat* positive there remains concern about implementation of the 8 objectives above and the resources to employ new staff. In 2019 funding was made available for the recruitment of an *additional geneticist at Crumlin Children's Hospital but to date no new consultant has been recruited*. It remains a matter of concern to OACS Ireland that only an ad hoc arrangement to assess women and their children for genetic testing is in place. This resulted in a less than favourable experience by the women and children who were offered appointments. So much so that OACs Ireland has formally written to the HSE Chief Clinical Officer on the matter.

The HSE Valproate Response Project Report was completed by the HSE in October 2019 and a copy was forwarded to the Department of Health. By the end of 2019 the report had not been publicly published and the HSE and Department of Health had not publicly commented on its content.

A number of public representatives sought clarification on this during late 2019 by way of parliamentary questions (PQs). OACS Ireland is grateful to these public representatives who have assisted the organisation with its objectives to ensure that those affected by FACS receive appropriate advice, services and support.

### **Seeking support from the Minister for Health**

OACS Ireland has consistently argued that there should be an independent investigation into the use of valproate. This approach was backed by the Oireachtas Health Committee in its report of May 2018 on the matter. Also the Committee recommended that further examination should be given to compensating FACS patients. OACS Ireland supports this view as well and has written to the Minister for Health on the matter. We continue to seek a meeting with the Minister to discuss these requests.

Both the French and UK governments are aware of the need to address FACS amongst their populations. The French government has in place a compensation scheme for those affected and the UK government has ordered a review of FACS as part of the Cumberlege Review <http://www.immdsreview.org.uk/> The chair of OACS Ireland gave evidence to the Review in 2018 and in 2019.

### **Our public activities**

OACS Ireland attended and spoke at the 1st National Conference on The Consequences of Sodium Valproate in Trinity College Dublin on March 22nd, 2019. This event was organised by the Health Service Executive, Epilepsy Ireland, OACS Ireland, Trinity College Dublin and the FACS Forum.

The event was attended by patients & families affected by valproate exposure, healthcare professionals and policymakers and featured experts from the UK and Ireland in addition to the experiences of families affected and updates on the Irish response to the valproate problem to date.

**The conference addressed key issues:**

- The pharmacology of sodium valproate
- Sodium valproate: Who knew what and when?
- Reducing the risks associated with sodium valproate
- Diagnosing and managing foetal valproate syndrome
- Living with foetal valproate syndrome and the consequences of sodium valproate
- The Irish Health Service's response to the valproate problem

It was a well-supported packed day and hugely beneficial to our cause. You can find out more about the conference and its outcomes here: <https://bit.ly/31vYZqF>

OACS Ireland continued to speak about FACS to the media in order to achieve our stated objectives. Articles appeared on radio and many newspapers in 2018/2019 and now in 2020.

Working with other voluntary sector organisations

OACS Ireland continued its strong relationship with Epilepsy Ireland. This involved working together on HSE project teams and together in discussions with the HSE, HPRA, PSI and other voluntary organisations.

International work

OACS Ireland developed as part of the UK OACS charity. Since becoming independent OACS Ireland has continued to maintain close working relationship with its sister organisation in the UK. We have attended UK events and worked with other UK colleagues on presenting information to the Cumberlege Review. Our colleagues in France have taken the lead in working with the French government to put in place a compensation scheme and we receive regular reports on progress in this country. There is also a European network of anti-convulsant syndrome groups from (name other countries)

Financial report

OACS Ireland is funded by a combination of member subscriptions and a grant from the Hospitals Saturday Fund for which we are most grateful. Now that we have charity status it will be possible to apply to bodies such as Dormant Accounts, Lottery and others for funds to develop services outlined in our business plan.

At the end of 2019 the charity had income of €6707.87 and expenditure of €1865.91 giving a closing balance of €4841.96

## Appendix

Executive Committee members 2019:

Karen Keely (Chair)

Geoff Day (Vice Chair)

Deborah Mundow (Secretary until 22 June 2019)

Theresa Byrne (Appointed 22 June 2019 and Secretary from 14 September 2019)

Christina O'Callaghan (Treasurer)

Mike Glynn

Jimmy Dunne

Beverley Dunne

Denis Hurley (resigned 14 September 2019)

Elaine Hurley (resigned prior to AGM)

Danielle Delaney (appointed 22 June 2019)

Valerie Brennan (appointed 14 September 2019)