



Organisation Anticonvulsant Syndrome Ireland

OACS Ireland Annual Report 2023

Chairs opening remarks

2023 was a hugely significant year for OACS and its members. After many years of campaigning and lobbying the Minister for Health, Stephen Donnelly TD, agreed the terms of reference for an independent inquiry into the historical use of Epilim. These were finally approved by Cabinet in July 2023. On behalf of its members OACS wishes to thank the Minister for his ongoing support in recognising the need for an Inquiry and taking it to this stage. As I write a Chair of the Inquiry has been appointed and we hope now that this can move forward quickly and meet the deadlines set by the terms of reference.

We continued to advocate and support our members in obtaining the best possible services for our members. This required continued contact with members of the HSE to resolve the many queries and concerns about the level and adequacy of services. While generally our engagement has been good some of our members still do not have the services they require. This is not acceptable. We continue to communicate regularly with our members who in turn have supported us during the last few years.

We continue to work with our partners in Epilepsy Ireland who have given us great support and advice during the year. We made some changes during the year relating to each organisations responsibilities but we continue to regularly update each other on our respective relevant areas of work.

Finally, I want to thank the OACS Executive Committee who have assisted the officers of OACS in their work. I want particularly to thank Geoff Day, Vice Chair and Theresa Byrne OACS secretary who has supported me during some very difficult times throughout this process. Last year I stressed the need for members to come forward to sit on the Executive Committee. Our constitution requires some Executive members, myself included, to come off the Committee in 2025 having completed our defined period in office. If any member would be interested in joining the Executive Committee, please do contact me on oacsireland@gmail.com to discuss what you can contribute.

Karen Keely
Chair OACS Ireland

Independent Inquiry

After two and a half years negotiating with the Department of Health, we finally signed off on terms of reference for an independent inquiry into the historical use of Epilim. This has been an arduous process with an outcome which we did not fully agree with. However when we were presented with the final terms of reference as an all or nothing option we agreed with our members support, to proceed. In July 2023 Minister Stephen Donnelly obtained Cabinet approval for the non statutory inquiry and the recruitment process for a suitable chair began. The Department of Health decided to seek interest from a selected list of individuals. However it was clear by the year end that this process would not produce a suitable chair and a formal public recruitment process began. OACS had no part in either process although we were kept informed by the Department of Health.

We of course have been disappointed by the slowness of the process but recognise that it is important that we have the right person to undertake the comprehensive in depth independent review required.

Our organisation

At the end of 2023 we had over 100 members. Our Executive Committee continued to meet regularly during 2023 either remotely or face to face. We held our Annual General Meeting on 18 November 2023 which was attended by some 20 members.

We continued to engage with social media through Facebook, Twitter (nowX) and Instagram that some of our members engage with.

Our voluntary partners

We continued our strong partnership with Epilepsy Ireland which included advice on the terms of reference and on media input. During the year we adjusted our respective responsibilities with OACS taking a primary role in pursuing the progress of the Inquiry. We remained committed to communicating progress to each other and this continues to date.

Statutory partners

Health Services Executive

We continue to engage with the HSE at corporate and local level to ensure that our members receive the services they require. Unfortunately at times this has been a difficult process and we have encountered some resistance to our requests. These have been taken to corporate level through the Chief Clinical Officer. One such example of this was the lack of appropriate staff member contact for our families in the Childrens Hospital Crumlin. Even with this contact point in place our members are still experiencing delays in getting appointments for initial assessment. We also requested progress on getting in place neuropsychology, paediatric staff to ensure an effective team for final diagnosis.

Health Products Regulatory Authority

The HPRA organises a Patient Forum which is a dialogue and exchange on topics of importance to patients. We actively participated in this forum during 2023 and whose aims are

- to provide a mechanism for exchange of information on issues of interest and facilitate engagement with patients in regulatory activities
- to listen to, and understand, patients and representative organisations views and consult them in the development of relevant policies plans and activities
- to incorporate the values and perspectives of patients into HPRA activities wherever possible and into the wider EU network
- to help optimise dialogue, communication and information exchange on health products and regulatory activities between the HPRA, patients and the public and vice versa.
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We took part in the HPRA's eighth annual MedSafetyWeek in November which aims to highlight the importance of reporting suspected side effects and safety issues arising resulting from a persons medication.

The European Medicines Agency (EMA) issued an update on its ongoing review of data on the potential risk of neurodevelopmental disorders in children conceived by fathers taking Epilim. In May 2023 the results of a study of registry databases from a number of countries indicated that there may be an increased risk of neurodevelopmental disorders in children whose fathers took Epilim in the 3 months before conception. The EMA acted following pressure from patient groups and advocates, including OACS, throughout Europe. The HPRA followed up the EMA advice by issuing a letter to healthcare professionals about the results of this research and implications for practice.

Following a review of three recent studies, the EMA Risk Assessment Committee has recommended that a Pregnancy Prevention Programme be introduced around the use of another anti seizure medication called Topamax. The early

evidence indicates that women exposed to Topamax may have a higher risk of neurodevelopmental disorders.

Other activities

We were delighted to welcome a key paper written by M. Bluett-Duncan and R Bromley with other health care professionals along with input from patient groups in Ireland, UK and New Zealand and published in the medical journal of Neurotoxicology and Teratology. It is the largest study of the neurodevelopmental phenotype of Fetal Valproate Spectrum Disorder. Some OACS families took part in the study for which we are very grateful.

OACS chairperson was invited to speak at the 34th Annual ENTIS conference held in the Royal College of Surgeons on 31st August 2023. ENTIS is the global network of Teratology Information Services and has the primary aim of preventing birth defects and developmental disorders which arise as a consequence of perinatal exposures. Karen spoke on the subject of secession antiseizure medicines in pregnancy from the patient's perspective.

OACS finances

The OACS Accounts for 2023 are attached at appendix 2. The Opening Bank Balance on 1st Jan 2023 was 4,126 and the ending Balance on 31st Dec 2023 was 2,198. A net spend of €1,928. This represented an increase of spend of €640 over 2022 but this was due to the cost of the AGM in 2023 of €920. Spending in 2024 is also going to be much higher due to purchases of a computer and printer but things should settle down in 2025. Cash in bank at present (30th June 2024) is 2,089 and if this is handled prudently should see OACS to the end of 2025. We will continue to apply for grants as appropriate.

OACS will not be able to sustain the costs of appearing before the independent Inquiry into historical use of Epilim in 2024 without financial support.

Appendices

Address: Organisation Anticonvulsant Syndromes Ireland (OACS Ireland). Charity Number (RCN) 20204646. 4 North Brunswick Street Dublin 7 D07RHA8. Postal Box 4. Website: <https://oacsireland.com/> Twitter: @oacsireland Email: info.oacsireland@gmail.com

Appendix 1.

OACS Executive Committee 2023

Karen Keely (Chair)

Geoff Day (Vice Chair)

Theresa Byrne (Secretary)

Mike Glynn (Treasurer)

Christina O'Callaghan

Beverley Dunne

Valerie Brennan

Joanne Cozens

Debbie Reynolds

Margaret Lennon

Appendix 2

OACS Ireland accounts 2023

	2023	2022
Opening bank balance 01/01/23	4126	5414
Membership subscriptions	140	10
Grants	0	0
Donations	340	300
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Total Income	480	310
Carmichael House office services	306	180
Garda vetting	31	0

Meeting expenses	10	117
Zoom subscription	172	172
Bank fees and Govt duty	20	25
Insurance	290	290
Computer software/applications	188	108
Mobile phone charges	132	121
Stationary and office supplies	339	585
AGM expenses	920	0
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Total expenses	<u>2408</u>	<u>1598</u>
Net income/(Expend)	<u>-1928</u>	<u>-1288</u>
Closing bank balance 31/12/2023	<u>2198</u>	<u>4126</u>

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