



Stephen Donnelly
Minister for Health
Department of Health
Hawkins House
Hawkins Street
Dublin 2

Irish Epilepsy League (IEL)
249 Crumlin Road
Crumlin
Dublin 12
D12 RW92

Re: Concerns about Medical Cannabis Access Programme (MCAP)

03/04/2021

Dear Minister,

We write as representatives of the Irish chapter of the ILAE ('Irish Epilepsy League'), Epilepsy Ireland and The National Clinical Programme for Epilepsy. Established in 2010, the National Clinical Programme for Epilepsy is part of the Clinical Care Programme for Neurology. The Irish Epilepsy League is the Irish branch of the International League Against Epilepsy, an international medical and scientific organisation involved in epilepsy related education, research and advocacy. Epilepsy Ireland is the foremost patient support organisation for epilepsy in Ireland.

As a group of organisations focussed on the care of people living with epilepsy in Ireland, we welcome advances in the care of children and adults with epilepsy. We are very sympathetic to the needs of people with severe, treatment-resistant epilepsy. We value well-controlled research studies that lead to a better understanding of epilepsy and the development of safe and effective treatments. Broadly speaking, two compounds derived from cannabis have been studied as potential treatments for severe epilepsy- CBD (cannabidiol) and THC (tetrahydrocannabinol). The evidence supporting use of purified (>98%) CBD in epilepsy is far more encouraging than the published evidence supporting use of THC both in terms of efficacy and safety. Purified CBD has been shown in clinical trials to be effective for some patients with specific diseases associated with severe epilepsy such as Dravet syndrome, Tuberous Sclerosis and Lennox-Gastaut syndrome. In addition, CBD is proving to be relatively safe for patients, albeit under clinical supervision (as CBD can interact with conventional anti-seizure medications, and has some risk of side-effects). On the other hand, not only is there a lack of evidence to support the use of THC in epilepsy, but there are significant concerns regarding its psychiatric and cognitive effects, particularly when used in children.

We welcome the establishment of the Medicinal Cannabis Access Programme (MCAP) in providing a safer, more controlled environment for people with severe, treatment-resistant epilepsy to access cannabis-based products, that may for some, result in fewer seizures and an improved quality of life. In



particular, we welcome the Department's evidence-based clinical guidelines that underpin the scheme. We had hoped that the Medical Cannabis Access Programme (MCAP) would provide a means for accessing a purified CBD product for people with severe epilepsy pending marketing authorisation of 'Epidyolex' in Ireland. Epidyolex was approved by the EMA in September 2019 although in Ireland, the NCPE have recently recommended that the drug is not reimbursed unless the cost-effectiveness can be improved.

However, we are concerned about a number of aspects of the forthcoming MCAP:

- (i) As we understand it, no purified CBD product, meeting the criteria detailed in the Department's 'Clinical Guidance on Cannabis for Medical Use', has yet been accepted by the HPRA for use in the MCAP. Patients who could benefit from CBD therapy will still not have access to this proven therapy.
- (ii) A number of high potency THC-containing products have been accepted.
- (iii) Most neurologists in Ireland will be reluctant to prescribe THC-containing products for epilepsy given the weak evidence base and potential for the aforementioned neuropsychiatric side effects.
- (iv) There is significant misunderstanding among the public and among patients regarding the role of cannabis-based products and about what the MCAP can offer people living with Epilepsy. This runs the risk of heightening the expectations of patients and families. This is in contrast to the available data and the significant concerns among Neurologists who will be tasked with supervising the administration of MCAP-supported products.
- (v) There is under-appreciation of the risks associated with THC-containing compounds.
- (vi) Because there is widespread concern about the MCAP among Neurologists in Ireland (because inappropriate and potentially harmful products will be available through the programme), the programme runs the risk of not being utilised.
- (vii) Finally we are concerned that the MCAP will prove to be a missed opportunity to help people living with epilepsy in Ireland. If the MCAP only supports THC-containing products, many patients that might benefit from CBD will not receive this evidence-based treatment. This is especially pertinent given that the only authorised CBD medicine, Epidyolex remains inaccessible to patients under the Long-Term Illness Scheme or GMS.

On behalf of the IEL, Epilepsy Ireland and National Clinical Programme for Epilepsy, we hope you will consider the issues outlined above and, in particular, we advise that the MCAP not be launched without inclusion of a purified CBD product. We would welcome a meeting to discuss the issues at hand. We hope that you will consider our position as advocates for patients and families who live with severe epilepsy.



Yours faithfully,

A handwritten signature in black ink that reads 'Daniel Costello'.

Daniel Costello
Consultant Neurologist, Cork University Hospital
President, Irish Epilepsy League (IEL)

A handwritten signature in black ink that reads 'Peter Murphy'.

Peter Murphy
CEO, Epilepsy Ireland

A handwritten signature in purple ink that reads 'Ronan Kilbride'.

Ronan Kilbride
Consultant Neurologist & Neurophysiologist, Beaumont Hospital
Clinical Lead, National Clinical Programme for Epilepsy

A handwritten signature in black ink that reads 'Norman Delanty'.

Norman Delanty
Consultant Neurologist, Beaumont Hospital

A handwritten signature in black ink that reads 'Colin Doherty'.

Colin Doherty
Consultant Neurologist, St James's Hospital

A handwritten signature in black ink that reads 'Kathleen Gorman'.

Kathleen Gorman
Consultant Paediatric Neurologist, Children's Hospital Ireland (CHI) at Temple Street



Bryan Lynch

Bryan Lynch

Consultant Paediatric Neurologist, Children's Hospital Ireland (CHI) at Temple Street

Olivia O'Mahony

Olivia O'Mahony

Consultant Paediatric Neurologist, Cork University Hospital

Amre Shahwan

Amre Shahwan

Consultant Paediatric Neurophysiologist & Epileptologist, Children's Hospital Ireland (CHI) at Temple Street

Peter Widdess-Walsh

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Consultant Neurologist, Beaumont Hospital