



**Submission to the Department of Health Consultation
on Draft Misuse of Drugs (Amendment) Regulations
2013 which will amend the Misuse of Drugs
Regulations, 1988**

Multiple Sclerosis Ireland, September 2013

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Summary

1) **Multiple Sclerosis Ireland**

MS Ireland is the only national organisation providing information, support and advocacy services to more than 8,000 people with multiple sclerosis (MS) in Ireland. The organisation is more than fifty years in existence and has been working with people with MS, their families and carers to ensure people with MS have the opportunities to live to the fullest of their capabilities. MS Ireland also collaborates with health professionals and the medical and scientific community on all aspects of the condition.

2) **Scope of MS Ireland submission to the Department of Health**

This submission refers to the proposed amendments to the Misuse of Drugs Regulations, 1988, to legalise cannabis-based medication for the management of symptoms of multiple sclerosis. Due to the chemical composition of the treatments, to make cannabis-based medication available to people with MS means substantive changes to two statutory areas: **law and health policy** (as outlined in 3.2 below).

3) **Context**

Ireland has one of the highest rates of MS in the world¹. MS is a progressive neurological condition of the central nervous system, affecting more than 8,000 Irish people. The presence, severity and duration of symptoms differ from person to person, as does the progression of the condition. Spasticity (and the pain associated) is one symptom of MS; a number of treatments and interventions are available to help alleviate its impact. MS Ireland believes people with MS should have access to all and any appropriate and licensed treatments that would improve or assist in the management of their condition².

¹ European MS Platform, MS Barometer 2011

http://www.emsp.org/attachments/article/160/MS_Barometer_2011.pdf

² Canadian Medical Association Journal May 2012,

<http://www.cmaj.ca/content/early/2012/05/14/cmaj.110837>

Commentary

3.1

MS Ireland welcomes the proposals to make Amendments to the Misuse of Drugs Regulations, 1988, viewing the changes as a progressive step towards introduction of another effective treatment of symptoms of multiple sclerosis (MS).

- MS Ireland believes people with MS should have access to all and any appropriate and licensed treatments that would improve or assist in the management of their condition. These treatments allow individuals to carry out daily tasks to the best of their abilities while managing the symptoms the condition (as outlined in 4.1 below).
- **Anecdotal evidence** suggests people with MS are currently using cannabis to treat their symptoms. They are forced to purchase this illegally with the result that they have being brought before the Irish Courts on criminal charges and have subsequently been prosecuted. A recent report into the use of medicinal cannabis suggests 66% of people surveyed would agree with cannabis being permitted for medical use³.
- People living with MS, their carers and providers of care and support, have all been detrimentally affected by **cuts in health services** in particular and overall reductions to statutory services in general. These reductions have limited the ability of the Irish healthcare infrastructure to meet the aims of the proposed patient-centered and healthcare based on patient need as proposed in **Future Health**⁴.

³ National Advisory Committee on Drugs and Alcohol (NACDA) 2010/2011 Drug Prevalence Survey
http://www.nacd.ie/images/stories/docs/publicationa/Drug_Prev_SurveyCannabis_Results_B3.pdf

⁴ Future Health: A Strategic Framework for Reform of the Health Service 2012-2015
http://www.dohc.ie/publications/Future_Health.html

- **Pharmoeconomics:** A report by the MS International Federation (MSIF) estimates the total average lifetime-cost to the person affected and to society as a whole is €890,000⁵. Managing symptoms is vital to allow individuals to conduct daily tasks and to maintain a person's contribution to society. Participation in the workforce eases the economic burden of the condition for the individual and society as a whole (see next point, Employment).
- **Employment:** People with MS typically want to stay in employment, progress in their chosen careers and maintain their current healthy state for as long as possible. Work offers opportunities, provides income and security, a sense of purpose, social connectivity and assists in retaining personal dignity⁶. Access to this medication could assist with a person retaining and/or regaining these abilities⁷.

3.2

The proposed changes to the Legislation involve different aspects of policy:

Law and Health. Some comments on the issues follow:

Law

- MS Ireland understands the need to prevent the abuse of controlled substances. However, the organisation is hopeful the changes to the Misuse of Drugs Act, 1988, will reflect the ongoing research into the benefits of medicinal cannabis and cannabis-based medication extract for the symptoms of MS. It is through a reasoned, demystifying approach to cannabis-based medication that the **best interests of people with MS** can be met.

⁵ Global Economic Impact of Multiple Sclerosis

http://www.msif.org/includes/documents/cm_docs/2011/g/global_economic_impact_of_ms.pdf?f=1

⁶ Ready to Work? Meeting the Employment and Career Aspirations of People with MS

http://www.theworkfoundation.com/DownloadPublication/Report/289_289_MS3.pdf

⁷ Cannabis, Pain and Sleep,

http://www.researchgate.net/publication/6126756_Cannabis_pain_and_sleep_lessons_from_the_therapeutic_clinical_trials_of_Sativex_a_cannabis-based_medicine/file/9c9605162c845600b8.pdf

- Given the time it has taken for such legislative changes there is concern that the limiting of the legislation to a *specific commercial* product (Sativex) may cause difficulties in the future. Given the years of advocacy on this issue as well as ongoing research into this area it is important to allow for additional innovative products to be introduced.
- Currently people with MS who use cannabis to control their symptoms are purchasing it illegally.
- One of the issues that may impact the proposed amendments is the expected Private Members Bill being brought to the Houses of the Oireachtas on October 29th 2013 by Deputy Luke Flanagan.

Health

- There is widely available data on the efficacy of cannabis to treat spasticity, sleep disorders, pain and other symptoms associated with MS⁸. Anecdotal evidence suggests cannabis is an effective treatment for MS related symptoms including bowel and bladder disorders, spasticity and sleep disorders (as outlined in 4.2 below).

Recommendations

MS Ireland welcomes and supports the amendments to the legislation.

However, the following concerns have been identified:

1. The proposed changes to the Misuse of Drugs Act, Amendment of Schedule 1 to the Principal Regulations should allow for other current medicinal preparations containing cannabis extract as well as the current liquid preparations proposed containing cannabis extract as are currently authorized by the Irish Medicines Board (Pg. 9/17, 16.a.1 and 16.a.ii). If not limited to one product, the amendment would circumvent potential delays for products subsequently authorized by the Irish Medicines Board.

⁸ Neurology, 2004 http://www.direct-ms.org/pdf/DrugsMS/Patterns_of_cannabis.pdf

2. Anecdotal evidence from other jurisdictions suggests that Sativex is a costly treatment. Given the recent reductions in funding for health services and the persistent difficulties in funding MS therapies MS Ireland is concerned at how accessible Sativex will be once the legislative issues are resolved. Changing legislation to allow for the introduction of cannabis-based medications such as Sativex is redundant if it cannot be funded adequately for the person with MS. Under Article 4 of the UN Convention of the Rights of Persons with Disabilities, States Parties will adopt legislative measures for people with disabilities⁹.
3. The situation for international travellers with MS who use cannabis-based medication and travel to Ireland is something MS Ireland would like clarified. Medicinal cannabis and cannabis-based medication is prescribed to people with MS in other EU jurisdictions. Protection of these individuals should also be addressed in these proposed amendments (Consultation Draft 4, Amendment of Article 3 of the Principal Regulation) in accordance with the UN Convention on the Rights of Persons with Disabilities.

4. Information on Multiple Sclerosis

MS is a chronic, progressive, demyelinating condition that affects the Central Nervous System (CNS). It is an unpredictable condition that profoundly affects the quality of life of the person diagnosed; there is **no cure**. It is not yet known why an individual's immune system attacks the myelin, the fatty substance that protects the nerves in the Central Nervous System. The damaged myelin, that is transformed to scar tissue known as *sclerosis* gives the condition its name.

⁹ UN Convention on the Rights of Persons with Disabilities, Article 4
<http://www.un.org/disabilities/convention/conventionfull.shtml>

- MS is usually diagnosed between the ages of 20-40 and is the most common cause of disability affecting young adults¹⁰. It affects both the quality of life and life expectancy of the person.
- Symptoms include: blurred vision, bladder and bowel problems, cognitive issues, depression, extreme fatigue, insomnia, loss of function and movement, neuropathic pain, numbness in legs and hands, spasticity, speech problems and other issues.

4.1 Management of MS

There are many different approaches to treating MS including disease-modifying therapies that may delay the progression of the condition and reduce the number of relapses¹¹. Lifestyle changes such as improved exercise and dietary programmes are also important aspects of managing life with the condition. Many people with MS use a variety of complementary therapies to ease their symptoms. For people with spasticity and sleep disorders, prescribed medication can have detrimental side-effects that exacerbate symptoms of MS (depression and fatigue). Some of these individuals use illegally purchased cannabis to ease their symptoms (as outlined in 5 below).

4.2 Spasticity

Spasticity is caused by imbalanced nerve signals due to the damage to the brain and spinal cord. The involuntary muscle tightening is often crippling, seriously debilitating and painful and reduces an individual's ability to carry out everyday tasks such as dressing, walking, working, socializing and intimate relationships. It can also have a detrimental impact on personal dignity.

- In 2010 an Irish study carried out by the University of Limerick as part of MS Ireland's ***Getting the Balance Right*** exercise and research

¹⁰ EMSP MS Fact Sheet <http://www.emsp.org/multiple-sclerosis/ms-fact-sheet>

¹¹ Some of the current treatments prescribed for people with MS, have been linked to Progressive multifocal leukoencephalopathy, PML. This is a rare and usually fatal viral disease that damages white matter in the brain and is caused when the human immune system is suppressed <http://www.nejm.org/doi/full/10.1056/nejmoa051782#t=article>.

programme, 68% of people with MS reported some degree of spasticity. The research also showed that 15% of participants cited spasticity as one of their three main symptoms of MS and 42% of participants took some form of spasticity medication.

- Other than the immediate effect, spasticity can also cause a number of medical problems including skin breakdown and contractures (where a limb becomes fixed in one position). It can also be challenging for carers as managing its impact can be painful and difficult.
- Some of the medications prescribed to treat spasticity have side-effects that exacerbate *other* MS symptoms including depression and fatigue. Physical movement including physiotherapy, different exercises and physical therapy techniques can be used to help with stretching, flexibility and overall mobility. However, while this activity does somewhat ease the person's spasticity, it is the combination of treatments that benefit the person.
- Ensuring good Quality of Life (QoL) through symptom management is fundamental to the treatment of MS. The fluctuating, progressive nature of the condition means the individual has to make substantive changes to allow them live as well as possible. The management and control of symptoms such as spasticity is fundamental to meeting a person's psychological and physical needs.

5. Personal Testimonies

The following extracts are from personal experiences of people who use cannabis as a means to ease their symptoms and regain function as well as someone considering using cannabis-extract for their symptoms. Names have been changed.

Brian, Cork

“Since diagnoses life has changed. My limp has never fully gone away, I can walk only about 2km at most before my legs completely stiffen up and I have to sit down. The muscles in my right leg are very stiff all the time (for which I get physiotherapy every now and then which helps loosen the muscles). I have stabbing-type pains on both legs, which are not too bad most of the time; they do get worse in the evening. I had optic neuritis in June 2010, which has not fully gone away, and I now have partial vision in my left eye.

I have pins and needles in both arms and legs at all times; this is very, very annoying. The pins and needles don't prevent me doing any thing but this symptom is an irritating, constant reminder there is something wrong with my body. As well as the pins and needles, I experience an electric-type sensation down my spine and out through my arms and legs. This feeling of electricity is not constant but occurs at least 3 - 6 times per week and lasts for hours.

At night my legs spasms, twitch and move by themselves; this impacts my sleep. This happens during the day as well but it is not that noticeable as I walk a bit at work and it is only noticeable when I stand up after sitting at my desk.

As for cannabis, this is the only drug that gets rid of 90% of the symptoms for a short period of time. The only symptom it does not ease is the optic neuritis. Cannabis loosens up all the stiff leg muscles, gets rid of all the pins and needles in my arms and legs, and removes the electric type feeling in my arms and legs.

I like to remain as active as possible and the use of cannabis helps me do this. I find when I use cannabis I can walk 3 to 5 km, do any physical activities I need to do such as gardening and get on with my life.

I like to tell people who ask me why I use cannabis that it makes me feel *normal*. If only for an hour or so I feel normal for that hour. I don't feel like my body is electric and twitching.”

Sarah, 45

“When I was initially diagnosed with MS, I used up to four tablespoonfuls daily of hemp oil and the feeling of well-being plus some lessening of pain kept me going. I am aware that this part of the cannabis plant is quite different and legal compared to cannabis per se. I am aware that a number of cannabis medications have been available in Canada, England, Spain and other EU countries.

I would be tempted to move to one of these countries if my symptoms of pain increase to point where current medications become limited or limit my Quality of Life. Cannabis-based medication is a simpler solutions to these symptoms. I have great interest in the legalisation of Sativex or any other quality-controlled cannabis-based solution.

Currently am on a lot of medication and, regardless of information received and researched, who knows what long-term organic brain damage is being done by taking any/all the current MS medical interventions? I am well aware that some people believe cannabis has reputation of exacerbating pre-existing schizophrenia and other mental illnesses in a few individuals. However, many medications on the market for MS have serious warnings of short and long-term use.

I would be pleased to try quality-controlled cannabis-based medications if further solutions for pain-control and improved health and wellbeing.”

End

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