

## **Cannabis-based Medicinal Products - Briefing Document and Position Paper**

### **Background**

#### **Use of cannabis for medicinal purposes**

Cannabis, or the *cannabis sativa* plant, contains many different components including delta-9-tetrahydrocannabinol (THC), which is the primary active substance associated with the psychoactive effects of the plant. In addition to THC, cannabis contains numerous other active ingredients which have been observed to have a range of effects on the human body including pain relief and anti-inflammatory properties. For this reason, cannabis and its components have long attracted the attention of researchers interested in its potential benefits for the treatment of various conditions including multiple sclerosis.

#### **The legal situation in Ireland**

In Ireland, cannabis is currently a Schedule 1 drug controlled under the Misuse of Drugs legislation which makes it an offence to be in possession of cannabis or many of its extracts, including THC. This includes medicinal products that contain these components.

#### **Sativex**

Sativex is a prescription medicine that treats spasticity symptoms associated with MS for people who have not responded to other medicines. Sativex has been proven to reduce the frequency of spasms, improve sleep quality and mobility in performing daily activities, such as getting out of bed and getting dressed or washed and improving ability to walk.

A phase III clinical trial investigating the effects of Sativex in over 500 people showed that 48% of participants had 20% or more improvement in their spasticity. Amongst those who responded, about three quarters had an improvement of greater than 30% in their spasticity score within four weeks when compared with those taking a placebo (Novotna et al, 2011). Combined analysis of three clinical trials confirmed the effectiveness of Sativex (Wade et al, 2010). Some studies have also shown Sativex to be effective for the treatment of neuropathic pain (Barnes, 2006).

Sativex contains the cannabinoid THC and as such legislative change was required before it could be granted a license in Ireland. In July 2014 the existing legislation concerning the misuse of drugs was amended so that Sativex could be prescribed by physicians. In the same month the Health Products Regulatory Authority (HPRA) issued a licence for Sativex for the relief of moderate to severe spasticity for people with MS who do not respond to existing medications. This means that Sativex is authorised in Ireland and therefore a prescriber can legally prescribe it, a wholesaler can obtain it and a pharmacy dispense it.

However, in October 2014 the National Centre for Pharmacoeconomics (NCPE) issued a summary report recommending that the HSE did not reimburse Sativex at the submitted price. Further negotiations have taken place since then between the pharmaceutical company that markets Sativex and the HSE Corporate Pharmaceutical Unit, who have the ultimate responsibility for deciding whether or not the HSE will reimburse a product once the NCPE have made their recommendation.

The drug is also not available to purchase privately due to supply chain logistics involving how Sativex needs to be transported and stored. Sativex therefore remains unavailable to people with MS in Ireland at present.

### **MS Ireland's position on cannabis-based medicinal products**

MS Ireland continues to advocate for people with MS in Ireland to be able to access the medicines they need to treat their condition and impact debilitating symptoms. Sativex, a safe and thoroughly tested product (Barnes, 2006; Wade et al, 2010; Collin et al 2010; Novotna et al, 2011), should be made available to those with MS who it is indicated for. MS Ireland continues to lobby and advocate on this issue. MS Ireland calls on the Government, the HSE Corporate Pharmaceutical Unit and the pharmaceutical company that markets Sativex to enter into further negotiations regarding pricing.

MS Ireland also welcomes further scientific research into the potential benefits of cannabis and its components in treating and managing MS. Should further evidence emerge through research of other safe and effective ways for cannabis and its components to be used in medicinal products to treat and manage MS, existing legislation should not be a barrier to such products being made available to people with MS in Ireland who would benefit from them.

A clear distinction needs to be drawn between a product such as Sativex that has undergone rigorous efficacy and safety testing to achieve regulatory approval and non-pharmaceutical products that are not licenced for medicinal use. There are serious concerns about the safety and risks associated with unregulated, unstandardised non-pharmaceutical products containing cannabis extracts, in particular those that contain tetrahydrocannabinol (THC), the main psychoactive element in cannabis. MS Ireland strongly believes that thorough scientific research is the only way to demonstrate the effectiveness and safety of any potential therapy or treatment for MS.

MS Ireland advises that all treatments should be undertaken only following consultation with medical professionals.

## **References and further reading**

Barnes, M. P. (2006). Sativex<sup>®</sup>: Clinical efficacy and tolerability in the treatment of symptoms of multiple sclerosis and neuropathic pain. *Expert Opinion on Pharmacotherapy*, 7(5), 607–615. doi:10.1517/14656566.7.5.607

Collin, C., Ehler, E., Waberzinek, G., Alsindi, Z., Davies, P., Powell, K., ... Ambler, Z. (2010). A double-blind, randomized, placebo-controlled, parallel-group study of Sativex, in subjects with symptoms of spasticity due to multiple sclerosis. *Neurological Research*, 32(5), 451–459. doi:10.1179/016164109x12590518685660

Novotna A, Mares J, Ratcliffe S, et al; the Sativex Spasticity Study Group. A randomized, double-blind, placebo-controlled, parallel-group, enriched-design study of nabiximols\* (Sativex<sup>®</sup>), as add-on therapy, in subjects with refractory spasticity caused by multiple sclerosis. *European Journal of Neurology* 2011;18(9):1122-1131

Wade, D. T., Collin, C., Stott, C., & Duncombe, P. (2010). Meta-analysis of the efficacy and safety of Sativex (nabiximols), on spasticity in people with multiple sclerosis. *Multiple Sclerosis*, 16(6), 707–714. doi:10.1177/1352458510367462

Adapted from ‘CBD and cannabis in the treatment of epilepsy’ by Epilepsy Ireland, with kind permission. This document is available at:

[www.epilepsy.ie/index.cfm/spKey/news.epilepsy/spld/A3FD0003-CB64-43A9-BC9724D804178E6F.html](http://www.epilepsy.ie/index.cfm/spKey/news.epilepsy/spld/A3FD0003-CB64-43A9-BC9724D804178E6F.html)

Information for this document has also been taken and adapted from the following websites:

<https://www.mstrust.org.uk/a-z/sativex-nabiximols>

[www.livinglikeyou.com/en/stories/detail/clearing-the-smoke-on-ms-and-cannabinoids-yes-marijuana](http://www.livinglikeyou.com/en/stories/detail/clearing-the-smoke-on-ms-and-cannabinoids-yes-marijuana)

[www.ms-society.ie/uploads/File/Living%20with%20MS/Treating%20and%20Managing%20MS/Sativex%20Information%20Sheet%20May%202014.pdf](http://www.ms-society.ie/uploads/File/Living%20with%20MS/Treating%20and%20Managing%20MS/Sativex%20Information%20Sheet%20May%202014.pdf)

Further information on how medications are made available in Ireland is available here:

[www.ms-society.ie/uploads/File/Living%20with%20MS/Our%20publications/MS%20Ireland%20-%20Process%20for%20Licensing%20and%20Reimbursement%20of%20New%20Medications.pdf](http://www.ms-society.ie/uploads/File/Living%20with%20MS/Our%20publications/MS%20Ireland%20-%20Process%20for%20Licensing%20and%20Reimbursement%20of%20New%20Medications.pdf)

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