

Draft Clinical Guidance on Cannabis for Medicinal Use – Summary of Response from Multiple Sclerosis Ireland

Background

Muscle spasms or stiffness are common symptoms of MS, affecting at least 20% of people with MS at some time (NICE, 2003). MS Ireland advocates for people with MS in Ireland to be able to access the medicines they need to treat their condition and impact debilitating symptoms.

There has been considerable interest in the use of cannabis-based medicinal products to treat spasticity in the MS community in Ireland in recent years. Sativex, a cannabis-based oral spray, received a license in Ireland to treat spasticity associated with MS in 2014 but is currently not being reimbursed by the HSE and is therefore unavailable as a treatment option.

MS Ireland has conducted considerable advocacy work on Sativex, including a detailed submission made to the HSE Corporate Pharmaceutical Unit in February 2017. The submission included testimonials from people with MS who experience spasticity, and the impact it has on their quality of life. MS Ireland has also called on the pharmaceutical company that markets Sativex to re-engage with the HSE on price negotiations.

MS Ireland has drawn a clear distinction between products such as Sativex, which have undergone rigorous efficacy and safety testing to achieve regulatory approval, and non-pharmaceutical products that are not licenced for medicinal use (such as cannabis oils, for example). 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 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.

In February 2017, the Health Products Regulatory Authority (HPRA) released a report which recommended the establishment of an access programme for medicinal cannabis products for certain named conditions including spasticity associated with MS. MS Ireland cautiously welcomed the HPRA report, whilst still expressing concern that the efficacy, safety and quality of non-pharmaceutical products cannot be guaranteed. MS Ireland nonetheless recognises that many people with MS will welcome the opportunity to be able to legally access such products through the access programme.

MS Ireland was invited to provide feedback on the draft clinical guidelines for the cannabis access programme. A summary of our response is below.

Comments on draft clinical guidance

- MS Ireland believes that medicinal products that have a strong scientific evidence base to support their use should always be prescribed in preference to those that do not. The HPRA report supports this view. However Sativex, the only authorised cannabis medicine to treat spasticity in MS remains unavailable in Ireland as the HSE and the pharmaceutical company have failed to agree a price.

MS Ireland believes that it would be a serious missed opportunity if the establishment of the cannabis access programme was not used as an opportunity to re-open negotiations between the HSE and the pharmaceutical company, so that a price for Sativex can be agreed and it can be made available. Otherwise, it will be impossible for clinicians to meet the guidelines because they cannot prescribe the authorised product and will therefore have no option but to prescribe unauthorised products in the first instance.

- The HPRA report says that people with MS who are affected by spasticity “resistant to all standard therapies” may be considered for medicinal cannabis products. MS Ireland believes many people with MS will want to try cannabis based products before trying other therapies. Therefore there needs to be some guidance for clinicians on what other therapies should be tried first and for how long before prescribing a cannabis product.

- The HPRA report recommends establishing a register so that usage, effectiveness and safety of the cannabis products can be monitored. In order for data from such a register to be meaningful, it is important that clinicians agree on a set of measurement tools to be used to capture the effectiveness of the products in treating symptoms and improving quality of life.

MS Ireland would not suggest that these measures should be used as a determinant of access to the medications, but rather that if, as recommended by the HPRA report, there is to be long-term monitoring of the safety and efficacy of non-pharmaceutical medicinal cannabis products then agreed measures should be used in order to capture meaningful data.

It should also be noted that (although outside the remit of this consultation), if the ongoing monitoring of these products is to be done effectively, additional resources may be required for neurology centres in order to administer appropriate tests.

- If, as appears to be the case, there have been no studies done on possible interactions between disease modifying treatments (DMTs) for multiple sclerosis and cannabis products, this should be made very clear when the prescriber is discussing cannabis products as a potential treatment option with the person with MS, so that they are making a fully informed decision. This is particularly important as DMTs for multiple sclerosis interact with the immune system and central nervous system, and it is believed that cannabinoids may also do so (Cabral & Staab, 2005; Molina-Holgado, Guaza, Borell & Molina-Holgado, 1999).

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Further reading:

- HPRA report – ‘Cannabis for Medical Use – A Scientific Review’: <http://bit.ly/2w9v4CN>
- MS Ireland’s submission to the HSE Corporate Pharmaceutical Unit on Sativex: <http://bit.ly/2uZg1Nr>
- MS Ireland’s Briefing Document and Position Paper on Cannabis-Based Medicinal Products: <http://bit.ly/2vAX2h>

References:

Cabral, G. A & Staab, A. (2005). Effects on the immune system. In Pertwee, R. G. (Ed.), *Cannabinoids: Handbook of Experimental Pharmacology*, Vol. 168, pp 385-423.: Springer.

Molina-Holgado, E., Guaza, C., Borell, J & Molina-Holgado, F. (1999). Effects of cannabinoids on the immune system and central nervous system. *Biodrugs*, 12(5), 317-326.

National Institute for Clinical Excellence (2003) NICE Clinical Guidelines 8. Multiple Sclerosis: management of multiple sclerosis in primary and secondary care. London: Nice.