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27<sup>th</sup> February 2017

Dear Mr Flanagan,

**Re: Sativex**

I am writing to you regarding Sativex, which is licensed to treat spasticity symptoms associated with Multiple Sclerosis (MS) for people with MS who have not responded to other medicines.

Since Sativex was issued a license in 2014, MS Ireland has been advocating for it to be reimbursed by the HSE so that people with MS who would benefit from this treatment can access it. We are aware that in October 2014 the NCPE issued a summary report not recommending reimbursement for Sativex, and that the last contact between the HSE and the pharmaceutical company Almirall took place on 29<sup>th</sup> April 2015.

MS Ireland is aware that Sativex is currently being reimbursed by public health systems in a number of countries including Wales, Germany, Italy, Spain, Norway, Denmark, Luxembourg, Belgium and Canada. In addition, it is reimbursed on a case by case basis in Switzerland and Sweden. We have written to the Minister for Health twice in the last year requesting that this issue is revisited as we are aware of many people with MS who have been informed by their neurologists that this medication would be of great benefit to them, but are unable to obtain it.

The option to make a Patient Group Submission was not available at the time Sativex was assessed by the NCPE. Therefore I would like to take this opportunity to submit some relevant information that would have been included in a Patient Group Submission had this option been available at the time. I am attaching some personal testimonials from people with MS who are affected by the lack of availability of Sativex and outlining what the advantages of Sativex would be compared to both pharmaceutical and non-pharmaceutical alternatives. I am also including a letter from Consultant Neurologist Dr Lisa Costelloe who is supporting our call for this medication to be reimbursed by the HSE, and some additional studies on the efficacy and cost-effectiveness of Sativex that have been published since the NCPE review.

MS Ireland also notes the report on medicinal cannabis released by the HPRA on 10<sup>th</sup> February 2017, recommending the establishment of a pilot scheme for accessing medicinal cannabis for people affected by three conditions, including spasticity associated with multiple sclerosis. The report notes that pharmaceutical standard products such as Sativex, which have been through vigorous testing processes, should be given prescribing priority over unstandardized, non-pharmaceutical products. It would therefore seem to be a matter of some urgency that the issue of Sativex is revisited before the establishment of the pilot programme recommended in the report.

MS Ireland Submission to the HSE Corporate Pharmaceutical Unit on Sativex

MS Ireland would like to request that Sativex is brought back to the HSE Drugs Group at the next opportunity. MS Ireland will also contact Almirall to request that they re-engage with the HSE on this issue.

Please contact my colleague Harriet Doig at [harrieted@ms-society.ie](mailto:harrieted@ms-society.ie) or on 086 413 4265 if you have any questions in relation to this submission.

Kind regards,

A handwritten signature in blue ink that reads "Ava Battles". The signature is fluid and cursive, with a long horizontal stroke extending to the right from the end of the name.

Ava Battles  
CEO

CC Minister Simon Harris TD, Minister for Health  
CC Anne Marie Hoey, Primary Care Reimbursement Service  
CC Dr Lorraine Nolan, Chief Executive, HPRA



### **Submission to the HSE Corporate Pharmaceutical Unit on Sativex**

There are over 9,000 people with Multiple Sclerosis (MS) in Ireland<sup>1</sup>. MS is the most common chronic disabling disease of the central nervous system, with the onset of disease typically arising between 20 to 40 years of age. Muscle spasms or stiffness are common symptoms, affecting at least 20% of people with MS at some time<sup>2</sup>.

MS Ireland consulted with people with MS affected by stiffness and spasticity about how these symptoms impact on their quality of life and how being able to access Sativex would benefit them. An anonymous survey was conducted in January 2017 via our social media channels. Respondents were also given the opportunity to answer the survey via email or over the telephone.

### **Survey results**

#### **Asked to describe how spasticity affects them, respondents replied:**

*"I'm only in my 20s and it already affects my walking. It stops me walking long distances and it causes me a lot of pain".*

*"Daily, especially morning & night time. Spasticity affects my ability to walk, and my work as I work on a computer, my left arm is affected".*

*"It affects my walking and my sleep it gives me a lot of pain".*

*"It's a constant tightening of my muscles that without medication, means fighting against it for every movement, walking, using my hands, even breathing".*

*"MS causes spasticity in my legs when I go to bed. This makes falling to sleep very difficult, as it causes pain. During the daytime, spasticity in my right hand makes using any tools e.g. knife and fork, scissors etc. almost impossible".*

*"I wake up totally stiff. Carers that come in find it very difficult to get me out of bed. I don't want to use a hoist. Sitting in wheelchair and legs will just shoot out in front of me – my legs get very stiff and whoever is with me finds it very difficult to get my legs out of spasm... Had major impact on my quality of life".*

*"I am in a lot of pain ,as you can imagine if any muscle goes into spasm it won't always get better without medication or physio".*

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<sup>1</sup> MS Ireland (2015) Societal Costs of Multiple Sclerosis in Ireland 2015. Dublin: UCD and MS Ireland

<sup>2</sup> National Institute for Clinical Excellence (2003) NICE Clinical Guidelines 8. Multiple Sclerosis: management of multiple sclerosis in primary and secondary care. London: Nice.

*"If I get over-tired, my legs just stop working. They jerk, spasm and head off in the wrong direction. They become stiff and like they belong to another body!"*

*"It totally limits my mobility. I can barely shuffle indoors while using furniture/walls for support. Outdoors I rely on a wheelchair".*

*"My legs spasm uncontrollably and as a wheelchair user it is very difficult".*

*"Hard to sit down for more than 20 minutes without spasms".*

*"It affects my balance and ability to walk upstairs and go out on my own".*

*"Difficulty in moving my legs".*

*"Find it very difficult to sleep at night. Legs all over the place".*

*"It affects my legs, and keeps me awake most nights".*

*"Spasticity effects my legs and arms. Creating falls due to muscles in my legs unable to move correctly at the right time, hence my balance is bad".*

**Asked to describe difficulties carrying out everyday activities or instances where they require assistance or support as a result of spasticity, respondents replied:**

*"Getting moving in the morning and dressing myself, can also affect my walking".*

*"Washing myself, stairs sometimes, trying to hold pot/cup".*

*"...it makes everything so much harder, more energy sapping, painful".*

*"Holding anything in hand while holding a cane . Leg problems while walking or seating".*

*"Affects in lots of ways, can't go out socially, can't get to the loo when I am out. If I go out I make sure I don't have to go to the loo so I can only go out for a short time. I have people that come in the morning and at night but need more assistance than this".*

*"I find it harder to walk".*

*"Sometimes I need someone to walk with me as I veer off, sometimes leaving the pavement altogether. I really struggle at times. Other times I can hardly get out of bed or off the sofa".*

*"Shopping is impossible alone now as I cannot walk. Hanging out laundry an impossibility as I cannot walk to clothes line and soon lose balance trying to stand and reach up. My unsteady gait means I am unable to carry any beverages. I can no longer use my feet so driving is not an option now".*

*"Sweeping and Hoovering".*

*"Normal tasks take twice as long".*

*"Need help getting in/out of car".*

*"Just walking to the shop can be impossible. The pain the spasticity causes means I end up using a wheelchair for a lot of longer trips. Sitting at the desk to work causes pain. I can no longer drive distances over 15mins. Everyday life starts to become isolating".*

*"Going shopping, getting around the house to clean and change beds etc".*

*"I can't walk safely without an aid or someone to 'hang' onto. Its effects daily activities from getting around the house to being able to go to work".*

*"I am unable to walk for more than a few feet. I am unable to do housework. Unable to do shopping for my household. I am unable to walk safely to pay for the petrol in my car. I have difficulty getting up and down the stairs or getting up steps I have difficulty standing cooking. For all of these I require assistance".*

*"Being so tired from not sleeping".*

**Asked to describe the impact of spasticity on personal and family relationships, respondents replied:**

*"My partner ends up having to do nearly everything around the house (cooking, cleaning, shopping, trips to the chemist) cause being on my feet too long causes pain. It's difficult to accept that he's essentially become my carer. I hate him having to watch me cry some nights with the pain as my legs spasm and there's nothing we can do. The pain is just horrendous".*

*"My family and friends consider my needs when going out at night etc. helping me with shopping on occasion, always dropping me at the door, so it does affect my social life, but once allowances are made, life goes on".*

*"It takes away independence, making you rely more on your family".*

*"It wears you down when you're dealing with pain and stiffness".*

*"Don't like going out in public, hard at family events, self-conscious".*

*"It brings sadness into your home because no one can help you and that frustrate family".*

*"People don't understand and they think you're not trying hard enough. Or they say "well, I'm tired too" or "it's your age". It makes me resentful and angry. I don't feel like I know them anymore or maybe they no longer know me".*

*"I feel I've been robbed of my confidence and feel "child-like" needing the physical assistance of family. My husband has become my carer and I feel our once intimate relationship is fast becoming one of Patient/Carer nature".*

*"Very depressing".*

*"I become more impatient".*

*"The constant involuntary tremors of my legs effect my mood hence can be difficult for everyone".*

*"It makes you feel dependant on other family members and depressed because you feel like you're a burden on them".*

*"If I go out of the house I need someone with me for safety reasons & for myself as I am scared to walk on my own".*

*"My personal and family relationships have become restricted to home unless there is someone to assist me as I walk. It is an ordeal for me to do things so I tend to avoid where possible going out".*

*"It wrecks your life".*

*"Had to move to separate bedroom from my husband (8 years now) as I kicked him a lot at night".*

**Asked to describe the impact of spasticity on their ability to work, respondents replied:**

*"Have to rest a lot".*

*"Spasticity in my leg and hand also prevents me from working, I worked as a restorative architectural artist which requires meticulous use of my limbs. Obviously, climbing ladders/scaffolding are no longer a possibility".*

*"Affects my ability to type, the fingers on my left hand tend to lock, I use my right while I work on my keyboard now whereas up to five years ago I had touch typing".*

*"Not able to work".*

*"I am unable to work".*

*"I can no longer drive to work yet I don't qualify for an adapted car. It means I now have to work from home which I'm lucky I'm allowed to do otherwise I'd be out of work. However it's so lonely and isolating and has a knock-on effect on your mental health. I also have to get up continuously while working to try and stretch to lessen the pain. I work with a hot water bottle on my leg to try and ease the pain. I've used the hot water bottle so much to distract from the pain that it's actually caused a burn on my leg".*

*"It's hard seeing the look on peoples' faces as they see me collide with a door or the wall or struggling to walk or stand up. It's half pity, half horror. I don't feel like a part of the team any more".*

*"I cannot drive now and walking is reduced to shuffling unsteadily. I have reduced my work hours/load and will continue to end of year when contract ends".*

*"Due to balance etc it makes you limited to job choices".*

*"I can't walk across the busy road by myself to get into the office without help".*

*"I am at present on Illness Benefit from work, due to no ability to being able to walk from pillar to post or write properly due to spasticity in my arms. I am unable to carry items that most people can due to my muscle stiffness affecting my balance and in muscle pain".*

*"Cannot work, no social welfare, living on breadline".*

*"I had to retire six years ago".*

**Asked to describe the impact of spasticity on their social life, respondents replied:**

*"...too tired".*

*"Don't socialise very much normally too sore".*

*"During the daytime, spasticity in my right hand makes using any tools e.g. knife and fork, scissors etc. almost impossible, particularly in a social situation. This can influence what I eat in the company of others thus inhibiting my social life".*

*"Affects in lots of ways, can't go out socially, can't get to the loo when I am out".*

*"I don't get out as much as I'd like because I know I'll be aching and exhausted by most evenings".*

*"Very limiting, non-existent. Which results in isolation".*

*"I find it hard to have a social life when in pain".*

*"It's hard to go out nowadays and I was such a party animal. Now I have to hope that on the day the outing is planned, that I will be able to walk at least normally. If at all. And I worry about being knocked and falling over".*

*"Getting out in a wheelchair isn't always easy or fun. It makes me self-conscious when I struggle to shuffle. I prefer to avoid crowds and new people or unfamiliar places/situations".*

*"Don't go outside home very often".*

*"Limits your time out".*

*"It affects my confidence in social situations and my social life isn't great".*

*"I have no social life anymore. Either friends come to see me or I don't get to go out. It's too difficult when you can't walk far and you're in pain".*

*"I don't like to go out too much especially on my own and makes me feel isolated and unable to go out with friends etc because I don't want to feel like I'm a burden on them and limit their enjoyment of wherever they want to go even night clubs etc".*

*"Socially I tend to stay indoors as I hate to impose on people too much. so in a sense I'm a bit of a hermit until I have someone to go with".*

*"My social life has become almost non-existent due to a reluctance of being able to walk into anywhere and then having to walk in/out of bathrooms is an ordeal".*

*"What social life".*

**Asked if they had ever been offered or prescribed any treatments or therapies (besides Sativex) to treat spasticity and associated symptom and if so, how effective they were, respondents replied:**

*"I was on Baclofen but the side effects - muscle weakness, meant the price to my mobility was too high to make any benefits worthwhile".*

*"I have been prescribed and taken Lyrica in the past but discontinued taking it as it didn't work very well for me and also left my brain "fuzzy" the following day".*

*"I suffer from severe painful spasms in my legs, unfortunately the medications I am prescribed to help with this have little effect, and this is an ongoing chronic problem".*

*"Yeah but they make you very sleepy so I didn't want to walk around like a zombie".*

*"Baclofen - moderately successful but I find it sedating, which is the last thing I need, already dealing with severe fatigue".*

*"Was prescribed other anti-spasm tablets but I found they weakened me".*

*"I have got steroid injections ,tablets and did not work".*

*"I take Baclofen for stiffness and to relax my muscles, not very effective at all, still have tremors".*

*"Baclofen which made a huge difference to my range of motion but again if I'm on my feet for any length over 15 mins it's like I haven't taken it and the spasticity and the pain slowly keep increasing".*

*"Only Ativan to relax my muscles, this helps but only temporarily".*

*"I was prescribed Baclofen, however it completely threw my balance off and walking was worse as some tightness holds me up!! I've tried muscle relaxants, however a similar problem. I found Difene great, makes my legs so much looser however my neuro tells me I can't take this long term so I'm left with nothing".*

*"Yes, the side effects were as bad as the symptoms being treated. More out of myself than in myself... totally tranquillising".*

*"OxyContin,a horrible drug, I am now addicted to it".*

**Asked if they have ever tried any other treatments (aside from those prescribed by a physician) to treat spasticity and associated symptoms and if so to describe them, respondents replied:**

*"I regularly use CBD cannabis oil that I source online. This makes a HUGE beneficial difference to the spasticity in my legs and my mobility".*

*"Yes CBD oil I get relief within half hour".*

*"Magnesium - didn't do anything. Physio - costly and ineffective, even the physio said she was treating me just to see me tighten up again".*

*"Cannabis helped a lot".*

*"Spending a fortune I haven't got on hemp oil. Would prefer Sativex".*

*"I've had a couple of spliffs! But I don't get on with that very much so haven't done it since".*

*"Low Dose Naltrexone- LDN Of no use at all".*

*"Physio - lots and lots of it and it costs a fortune but it helps to loosen up tightness but you have to keep repeating exercises throughout the day to try and get relief".*

*"Exercise, stretching, only get a short burst of looseness".*

*"Yes, cannabis".*

*"I have tried CBD, it helps with the pain and it helps sleeping".*

**Asked what they think would be different about Sativex compared to other treatments, respondents replied:**

*"...relax you more".*

*"I think it could be of great benefit to those of us with MS, relieving muscle stiffness and in some cases pain. If it was made available on the long-term illness card it would save me the expense of buying CBD oil".*

*"It won't make me drowsy and it doesn't affect the liver".*

*"I just want to be able to try it as an option. Baclofen is the only thing on offer and if I could take Sativex instead without being as sedated, that would really help improve my quality of life".*

*"Would like to have the choice".*

*"Sativex hopefully would relax the body and result in less spasticity as conventional meds don't seem to work for me".*

*"It would help control both the pain and the spasticity. The pain is the big one for me - I have a reduced quality of life because of it".*

*"From what I've read and heard about it, it has long lasting relaxation of muscles, mind and general painful symptoms of MS".*

*"I would be hoping it would have a similar effect to Difene" [but can be taken long term]*

*"I wouldn't be dealing with all the other side effects of the pharmaceutical drugs which for me created in addition a different set of problems!"*

*"Reviews on it are excellent and it would be less damaging to organs than most other drugs".*

**When asked what difference they believed Sativex would make to their daily lives, the respondents replied:**

*"...free my legs up".*

*"It would make a lot of difference, both to my work and my mobility in my daily life".*

*"A huge difference, taken regularly I believe it could give me a better quality of life".*

*"If it works then it would be nice to be freer of movement, less in pain. Less sedated".  
"Big difference to daily life and confidence".*

*"If it works it would help with muscle pain and walking".*

*"If it made walking easier, I'd be so happy. Life is so difficult at the moment".*

*"I want to try it to ease my pain and perhaps reduce my spasticity".*

*"Would make easier to get around".*

*"It would definitely help improve my social life, help me do my daily activities without the uncomfortable and pain of constantly shaking legs that make it hard in a wheelchair".*

*"I could get back out and start socialising without being in constant pain. I might get back to working the odd day in the office. It would let me be a part of society again".*

*"It would make enormous difference I think because it would ease pain and cramps down my spine and legs so that would make it so much easier to go about my daily business and give me a some sort of normal life without depending on others".*

*"I could walk. Unaided without the help of anyone. Independence".*

*"I think I should be able to walk better and have less falls without being overwhelmed by an awful lot of side effects".*

*"Sativex would help me get off OxyContin, a terrible drug, never in my life did I think I would become a opioid addict".*

*"Help me to sleep at night. That would be a huge relief".*

## **Summary**

It can be clearly seen from these responses that Sativex has enormous potential to improve the quality of life of people with MS who are affected by spasticity and stiffness. Respondents were consistent in articulating that spasticity causes them pain and discomfort and reduces their mobility and independence. This in turn has an impact on all areas of daily life including the ability to work, socialise and engage in family life. Some respondents also indicated that as Sativex is not available they are purchasing cannabis, CBD oil or hemp oil as alternatives. There are serious concerns about the safety and risks associated with unregulated, unstandardised non-pharmaceutical products such as these. These products are also expensive and in the case of CBD oil and cannabis, currently illegal, meaning that people with MS are resorting to breaking the law in order to relieve debilitating symptoms. MS Ireland believes that this is unacceptable when there is a licensed, proven, legal alternative in the form of Sativex.

The NCPÉ's report of 11<sup>th</sup> July 2014 estimates an overall budget impact for Sativex of €396,901 in year 1 rising to €797,014 in year 5, based on an eligible population of approximately 830. MS Ireland would argue that this is a relatively modest impact given the potential benefits in terms of increased quality of life for those who are affected by spasticity and stiffness who do not respond to other treatments. Some of this cost could also be offset against continual

participation in the workforce, which as the above evidence indicates can be severely impacted by spasticity, and use of other healthcare resources such as GP visits.

MS Ireland warmly welcomed the decision taken by the HSE in October 2015 to reimburse Fampyra (Fampridine), another symptomatic treatment for MS, on a responder basis. Since this decision was taken, MS Ireland has received highly positive feedback from people with MS for whom the availability of this medication has made a dramatic difference to their mobility, independence and quality of life.

The NCPE's report states that "A four week trial of Sativex is required to identify patients who receive an initial response". **MS Ireland would like to ask that consideration be given to all possible options in the case of Sativex, including that it be reimbursed on a responder basis in a similar way to Fampyra. An approach similar to this has been adopted in Switzerland and Sweden.**

MS Ireland also notes the report on medicinal cannabis released by the HPRA on 10<sup>th</sup> February 2017. This report names spasticity associated with multiple sclerosis as one of three conditions for which prescribing of medicinal cannabis can be considered where other treatment options have failed. The report also notes that the safety, efficacy and quality of non-pharmaceutical standard cannabis-based products cannot be guaranteed as they have not been subjected to the same level of rigorous testing as pharmaceutical products such as Sativex. The report further recommends that pharmaceutical products that have been thoroughly researched should be given preference in prescribing practice over non-pharmaceutical products. **Given this, it is a matter of urgency that Sativex be made available before the establishment of the pilot scheme recommended by the HPRA's report, as otherwise patients may be accessing untested, unproven products instead of a safe, thoroughly tested and licensed alternative.**

Harriet Doig, Information, Advocacy and Research Officer, can be contacted for any questions relating to this submission on 01 678 1600 or by email to [harrieted@ms-society.ie](mailto:harrieted@ms-society.ie).