



**MULTIPLE SCLEROSIS AUSTRALIA
MULTIPLE SCLEROSIS RESEARCH AUSTRALIA**

**Submission to the Therapeutic
Goods Administration Proposed
amendments to the Poisons
Standard - ACMS and ACCS
meeting, March 2016**

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About Multiple Sclerosis Australia

MS Australia (MSA) is the national peak body for people living with multiple sclerosis (MS) in Australia. Our role is to work on behalf of all state and territory based member organisations to provide a voice for people living with multiple sclerosis across the country to support the development of:

- Research
- Advocacy and Awareness
- Communication and Information
- Services provided by our member organisations
- International Collaboration

MSA advocates across all stakeholders, governments and communities, on behalf of our members, to represent people who are diagnosed with the disease, their carers and the broader MS community.

Our Vision

Is consistent with the vision of the Multiple Sclerosis International Federation – **'A world without MS'**

Our Mission

MSA will support our members and work towards meeting the needs of people with MS, their families and carers. We will facilitate a national comprehensive representation of the Member organisations through advocacy and communication.

Our Purpose

On behalf of our members and people with MS, our purpose is to develop:

- **Research:**
Supporting ongoing research to pursue further knowledge in targeting prevention, improving treatment, enhancing quality of life and ultimately, to find a cure.
- **Advocacy and Awareness:**
Although MS impacts people differently, there are common, fundamental issues for people affected by the disease. We are steadfastly committed to giving these people a voice and remain willing and able to work with government and the Australian society to champion issues in a dynamic policy environment to bring about change to the lives of people living with this disease.
- **Communication and Information:**
Utilising traditional, contemporary and innovative channels to source information and share it with people with MS, our member organisations and our key stakeholders.
- **Support for our member organisations:**
As MS specialists providing and facilitating high quality services that span the life-time needs of people affected by MS and other degenerative neurological conditions, their families and carers – from the point of early symptoms and pre-diagnosis, that addresses their changing needs.
- **International Collaboration:**
Representing the MS cause and promoting collaboration with our domestic and international partners.

About Multiple Sclerosis Research Australia

MS Research Australia is the largest not-for-profit organisation dedicated to funding and coordinating MS research in Australia.

Our Mission is to accelerate Australian MS research toward the prevention, better treatments and a cure for MS.

As a member of the MS Australia network, MS Research Australia achieves our mission by working in partnership with relevant medical research institutes and scientists around Australia, encouraging collaborations and focusing on Australian strengths in this research. MS Research Australia is ultimately working towards *freedom from MS*.

Our research strategy aims to accelerate research activity in areas where Australian scientists can have the greatest impact in worldwide MS research. We work in close partnership with and encourage collaboration between a number of Australia's top medical research centres.

MS Research Australia is guided by an informed scientific agenda to accelerate advances and focus on funding research that will increase our understanding of the triggers for MS, the biology driving MS and how we may prevent the ongoing damage caused by MS and repair existing damage that can reverse disability. We also encourage research that will lead to improvements in symptom management, rehabilitation and support services to help people with MS maintain quality of life. We currently fund over 50 investigator-led projects and 7 national collaborative platform projects to advance our understanding of MS.

Together with a robust governance structure, MS Research Australia believes this approach will result in further significant breakthroughs in the knowledge and effective treatment of MS and major steps toward understanding the cause and developing the cure.

Introduction

MS Australia (MSA) and MS Research Australia welcome the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) proposed amendments to the Poisons Standard - ACMS and ACCS meeting, March 2016.

The focus of the comments, suggestions and recommendations provided in this submission are specifically on key areas that will impact on people affected by MS.

MS Australia and MS Research Australia response to the proposed amendments

There are currently 23,000 people living with MS across the country and this number is increasing. MS can be a particularly debilitating disease with an unpredictable disease course that affects people in different ways. For some it is a disease with periods of unpredictable relapse and remission. For others it is a progressive decline over time. For all, it is life changing.

As such, MSA and MS Research Australia together support any proven treatment that has been deemed safe by the Therapeutic Goods Administration and that helps to minimise the impact of the disease and allow people with MS to live more fulfilling lives.

The availability of medicinal cannabis-based products is a complex issue giving rise to an interesting debate that is currently occurring in a number of states across the country.

There are risks to consider with the availability of medicinal cannabis products. All medicinal products derived from cannabis require strict regulation and standardised doses of active ingredients, to ensure products are safe and effective, and can produce reliable effects with a controlled risk of adverse events.

Robust and reliable evidence is needed to determine the possible benefits and risks of cannabis-based products for managing symptoms of chronic illnesses such as MS. As part of any debate on this issue, MSA and MS Research Australia encourage the promotion of randomised controlled clinical trials to be conducted to determine the components, dosage and frequency of either cannabis or cannabis-based products and their efficacy and safety for managing a range of symptoms for people living with chronic conditions like MS.

A 2004 international survey of over 2,500 people with MS conducted by Australian researchers, indicated that around 10% of people with MS believed that cannabis was a factor that can help improve their MS symptoms.¹

The most significant cannabis-derived product to have been studied for potential benefits in people with MS to date is the Sativex (nabiximols). Its principal active cannabinoid components are the cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). Sativex is a mouth spray with proven benefits for muscle spasticity and motor control. Despite a licensing approval from the TGA for reducing spasticity in people with MS, Sativex has not been made available to people with MS in Australia due to the limitations of scheduling of cannabis-derived products.

As such, MSA and MS Research Australia would strongly support the inclusion of botanically derived extracts (or derivatives) of cannabis, and tetrahydrocannabinols (THC) where they are botanically derived from cannabis, as Schedule 8 entries, such that Sativex can be made available in Australia under the current TGA approval for reducing spasticity in people with MS.

As the national peak bodies for people with MS in Australia we are passionate about affordable access to proven treatments that can improve the lives of people with MS. We are guided by the most up-to-date research and evidence-based recommendations to support the application of potential new therapies for MS symptom management. As such, MSA and MS Research Australia previously wrote to the PBAC secretariat in support of an application for inclusion of Sativex on the Pharmaceutical Benefits Scheme (PBS), although this application was not approved by the PBAC.

¹ Simmons RD, Ponsonby AL, van der Mei IA, Sheridan P, *What affects your MS? Responses to an anonymous, Internet-based epidemiological survey*, *Mult Scler*. 2004 Apr;10(2):202-11.

Muscle spasticity is a significant problem for many people living with MS, affecting over 80% during the course of the disease and negatively impacting mobility and personal independence. Spasticity can cause pain, sleep disturbance and reduced mobility. These symptoms can significantly limit a person's quality of life as they have less energy, ability to complete everyday tasks and social activity. It can also lead to an increased reliance on carers and the health system if symptoms progress to a stage where mobility is significantly hampered or hospitalisation is required.

To date, available medications to treat spasticity for people with MS are not always effective and can have intolerable side effects. Sativex represents a potential new choice of symptom modifying therapy for people with MS who experience spasticity. To date, clinical trials of Sativex have indicated that it can reduce spasticity, pain and spasms and improve the quality of sleep.

Being able to better manage and limit the impact of spasticity would help give people with MS greater coordination and ability to complete everyday tasks which at times can be vital to maintaining self-esteem and a connection with family, friends and loved ones. It can also mean less time in hospital, meaning less strain on valuable medical and disability resources, which helps to reduce the economic impact of MS on society.

It is important to acknowledge that Sativex does have side effects that will vary with each case. These can include dizziness, tiredness, depression, memory loss and nausea.

It is also worth noting that Sativex is not a treatment to 'cure' MS, and while this treatment has clinical trial data and approval for spasticity, there may be other MS symptoms that may benefit from cannabis-based products which could be investigated in clinical trials.

MS Australia and MS Research Australia understand and acknowledge that people affected by MS will wish to investigate all options available to them to maintain their quality of life, whilst wanting the evidence-based reassurance that medications are safe, effective and affordable.

To this end, to facilitate safe and appropriate access to cannabis-based medications, we would be supportive of the additional option suggested, that access to be restricted to state/territory authorised medical practitioners. We would also welcome a regulatory framework that facilitates clinical trials for any new, unapproved cannabis-derived products to ensure that they can be tested for efficacy and safety within in a safe and supportive medical environment for patients.

Conclusion

Both MS Australia and MS Research Australia are committed to supporting the provision of proven therapies for improving the lives of people with MS.

As stated earlier, our position on these issues is guided by a scientific, evidence-based approach and we would advocate for a regulatory framework that will facilitate further clinical trials to determine the components, dosage and frequency of cannabis-based products and their effectiveness in managing a range of symptoms for people living with chronic conditions like MS.

We advocate for access, via authorised medication professionals, to approved, proven standardised formulations that have been clinically shown to be beneficial for specific medical needs (such as spasticity in MS where other medications are not effective or are contraindicated), while providing regulation that facilitates further research.

A regulatory framework that also ensures that the licensed manufacture of cannabis-based products results in quality-controlled products, with consistent components and concentrations would also facilitate the conduct of clinical trials. This would enable accurate data to be gathered on the safety and benefits of cannabis-based medications and allow accurate determination of which components of cannabis are most effective for specific symptoms and circumstances. This could lead to optimisation of medicinal effects and reduction of adverse effects and side-effects of cannabis use.

MS Australia and MS Research Australia would welcome licensed products such as Sativex being made available for people with MS in Australia, through the inclusion of botanically derived extracts (or derivatives) of cannabis, and tetrahydrocannabinols (THC) where they are botanically derived from cannabis, as Schedule 8 entries.