



**MULTIPLE SCLEROSIS AUSTRALIA  
MULTIPLE SCLEROSIS RESEARCH AUSTRALIA**

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**Submission to the Senate Legal and  
Constitutional Affairs Legislation  
Committee Inquiry into the Regulator  
of Medicinal Cannabis Bill 2014**

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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 focus on our 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 biology driving MS and how to stop MS from triggering the disease, causing further damage and how to repair existing damage that can reverse disability. We currently fund over 50 investigator-led projects and 8 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 Senate Legal and Constitutional Affairs Legislation Committee Inquiry into the Regulator of Medicinal Cannabis Bill 2014.

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

## Background

The stated intentions of this Bill that are of particular interest to MS Research Australia and MSA are:

- to create a scheme whereby authorised patients, their carer or their medical practitioner can access specific medicinal cannabis products for medical use.
- to operate in conjunction with medical practitioners, who can apply to the Regulator on behalf of a patient or carer.
- to ensure that medicinal cannabis is manufactured, supplied and used in a safe, consistent and controlled way (by ensuring that the licensing scheme requires that standards and regulations are complied with and that the product, and those authorised to use it, will have to meet certain standards and strict criteria).
- to allow authorised persons to develop, evaluate, test and improve cannabis products for medicinal purposes. The Regulator will also be responsible for issuing licences and prescribing a scheme for research and experiments with medicinal cannabis.

## MSA and MS Research Australia response to the proposed legislation

There are currently 23,000 people living with MS across the country with an additional 1000 diagnoses every year. 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, MS Australia 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. 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 for managing symptoms of chronic illnesses such as MS. As part of any debate on this issue, we would 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 effectiveness in managing a range of symptoms for people living with chronic conditions like MS.

The cannabis-derived treatment called Sativex (nabiximols) has been approved by the Australian Therapeutic Goods Administration for reducing spasticity in people with MS. Sativex is a mouth spray with proven benefits for muscle spasticity and motor control, and MS Australia and MS Research Australia would welcome Sativex being made available in Australia if regulations regarding access to cannabis-derived products were to change.

In July 2013 both MSA and MS Research Australia each wrote to the PBAC secretariat in support of the inclusion of Sativex on the Pharmaceutical Benefits Scheme (PBS), although this application was not approved by the PBAC. As the national peak bodies for people with MS in Australia we are passionate about the provision of affordable and accessible treatments that can improve the lives of people with MS, and 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.

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 note however 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 as yet, be other MS symptoms that could be investigated in clinical trials.

## **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, and will continue to monitor the debate regarding cannabis use for medical purposes and their potential impact on people affected by MS.

As stated earlier, our policy 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. MS Australia and MS Research Australia would welcome products such as Sativex being made available for people with MS in Australia, if regulations regarding access to clinically proven cannabis-derived products were to change.

The CEO or a representative of MS Australia or MS Research Australia would be happy to appear at a public hearing on this issue, if that would be helpful to this Inquiry Committee.