



**MULTIPLE SCLEROSIS RESEARCH AUSTRALIA
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**Joint submission to the Senate
Community Affairs References
Committee inquiry into the current
barriers to patient access to
medicinal cannabis in Australia**

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**Deidre Mackechnie, Chief Executive Officer, MS Australia
Dr Matthew Miles, Chief Executive Officer, MS Research Australia**

MS Research Australia
PO Box 625
North Sydney NSW 2059
1300 356 467

www.msra.org.au

MS Research Australia ABN 34 008 581 431

MS Australia
Level 19 Northpoint Building,
100 Miller St
NORTH SYDNEY NSW 2060
T: 02 8413 7977
F: 02 8413 7988

www.msaustralia.org.au

Multiple Sclerosis Australia ABN 51 008 515 508

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 MS, 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 causes, prevention, improving treatments, 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 positive change to the lives of people living with MS.
- **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:**
Who, as MS specialists, are 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, which addresses their changing needs.
- **International Collaboration:**
Representing the MS cause and promoting collaboration with our domestic and international partners.

MSA's member organisations are:

- MSWA (providing services and support in Western Australia)
- MS SA/NT (providing services and support in South Australia and the Northern Territory)
- MS QLD (providing services and support in Queensland)
- MSL (Multiple Sclerosis Limited providing services and support in Victoria, NSW, ACT and Tasmania)

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 are pleased to provide a submission to the Senate Community Affairs References Committee inquiry into the current barriers to patient access to medicinal cannabis in Australia.

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

Effectiveness of medicinal cannabis to treat MS – what the research shows

There are currently 25,600 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.

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 medicinal cannabis was a factor that can help improve their MS symptoms¹.

MS Research Australia has a web-page dedicated to providing the latest research information about medicinal cannabis and details about the effectiveness of medicinal cannabis in treating MS symptoms, its side-effects and how to access medicinal cannabis in Australia. Please visit: <https://msra.org.au/medicinal-cannabis-ms/>

The following extracts from the MS Research Australia web-page give a snapshot of the current research evidence regarding medicinal cannabis:

- Research has shown that medicinal cannabis can be useful to treat some of the **symptoms** of MS in some people. There is limited evidence that medicinal cannabis can have an effect on the disease course itself, by reducing the number of relapses, or slowing the progression of the disease and accumulation of disability.
- Human trials using medicinal cannabis to treat muscle **spasticity** have produced positive results overall, where it reduced frequency of spasms and pain associated with spasms, suggesting that medicinal cannabis can be effective for the treatment of spasticity.
- The scientific evidence that medicinal cannabis reduces **pain** in people with MS is varied and there is currently less certainty about its benefits than there is for spasticity in MS.
- In several studies, medicinal cannabis was found to improve a range of **urinary issues**, including the volume and number of urinary incontinence episodes during the day and

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.

night and the number of voids per day. Participants also felt that their bladder symptoms improved.

- Improvements in **sleep disturbances** due to a reduction in spasticity or neuropathic pain have been seen in some studies.
- Trials have noted an improvement in **sleep quality** and reduced sleep disturbance in people taking medicinal cannabis, but these changes were only small.

Our overall position

Both MS Australia and MS Research Australia are committed to supporting the provision of proven therapies for improving the lives of people with MS. Our position on these issues is guided by a scientific, evidence-based approach and we advocate for a regulatory framework that will enable access to 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.

In saying this, we also understand the frustration currently being experienced by many people in the MS community in Australia, their families, carers and friends, who, anecdotally, feel they are receiving great benefit from the use of cannabis and are seeking changes to the regulatory framework to make medicinal cannabis products more easily accessible, affordable and better understood.

This submission

MS Australia posted information about this inquiry on its social media channels and sought feedback from the MS community. Examples of the comments we received (verbatim, but de-identified) are included below, in italics, under the relevant term of reference. These individual comments do not necessarily reflect the organisational views of MS Research Australia and MS Australia, but are provided to give the reader a sense of the strongly held views of people living with MS. Every single response we received was in favour of improving patient access to medicinal cannabis.

There is clearly a great deal of interest from the broader community in cannabis to treat a range of conditions and symptoms. Some of the consumer comments indicate a lack of understanding of medicinal cannabis compared to other forms of cannabis that community members are accessing. It may be necessary for government agencies (e.g. the Department of Health) to make this distinction clear through a community education campaign, particularly as products are developed and registered in Australia and as the range of products available from overseas increases.

Terms of Reference

The current barriers to patient access to medicinal cannabis in Australia, including:

(a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials;

Consumer comments:

- *The special access scheme is a failure on so many levels. Consult fees; script fees; doctors ignorance & reluctance to prescribe; AMA position; driving - presence of THC does not check for driver impairment; some different legislation across the country (eg new growth & possession ability in ACT!), "a lack of evidence & need for more trials" that's not true, plenty of worldwide studies; stigma around use; cannabis is a natural product turned into something marketable by Pharma. People should have choice & majority support full legalisation. Not to mention jobs and growth!*
- *We are very backwards in our forward thinking in this country don't you think. it should of been legalized/ 40-50years ago don't you think*
- *The reluctance to use medicinal cannabis seems strange as morphine has been used for ages.*

(b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;

Sativex (a mouth spray based on the cannabis derived ingredient nabiximols containing both THC and CBD compounds) was the first medicinal cannabis product approved in Australia by the Therapeutic Goods Administration (TGA) in 2012 for the treatment of muscle spasticity in people with MS. Muscle spasticity is a significant problem for many people living with MS, affecting up to 90% 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.

It was not possible to access Sativex in Australia until there were changes to the regulations. Since 6 November 2017, Sativex became accessible through specific access schemes depending on the state or territory. It can be prescribed for the treatment of moderate to severe muscle spasticity in people with MS who have not responded adequately to other anti-spasticity medications.

Emerge Health Pty Ltd, the supplier of Sativex in Australia, has made a submission to the March 2020 meeting of the Pharmaceutical Benefits Advisory Committee (PBAC) to seek reimbursement of this medication on the Pharmaceutical Benefits Scheme (PBS). Both MS Research Australia and MSA support the listing of this medication on the PBS. We support affordable access to any proven treatment that has been deemed safe by the Therapeutic Goods Administration and helps to minimise the impact of the disease, allowing people with MS to live more fulfilling lives.

(c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;

The variation in the process between states is frustrating and confusing for both people living with MS and clinicians. MS Australia and MS Research Australia have sought to explain the regulatory framework through our websites and through links to the relevant authorities.

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;

Consumer comment:

- *I just came back from a US holiday of which I spent a lot in California. The freedom to get products over there easily and readily was so refreshing and progressive compared to the backward archaic measures implemented here. If we can prove on medical grounds we can have a better life quality of life with it and can readily prove our condition these barriers should not stand in the way as they do now. It is simply too hard and unaffordable to acquire it through legal channels forcing folks into illegal avenues which is just unnecessary.*

(e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;

(f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;

(g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;

Consumer comments:

- *I went to my GP and asked about getting it and was rudely told by him that in no way would they prescribe it at their clinic, if my Neurologist did it would probably help me & if I could get a DR to prescribe it take it, what I couldn't understand is why he didn't prescribe it for me I have MS & Fibromyalgia & osteoarthritis*
- *Better education for Drs about the products and the benefits. They won't prescribe something they don't understand and aren't comfortable with.*
- *I went to my local GP and he had no idea this was even an option? Is there any information available regarding trials etc and where we can get it?*

MSA and MS Research Australia are aware that a number of clinics have sprung up around Australia offering “streamlined access” for patients to medicinal cannabis products. Most of these clinics offer patients consultations with doctors on-line or over the phone, for a fee. We have been informed anecdotally that these clinics are providing services to people living with MS, but we have no way of gauging how many people with MS are being treated nor which medicinal cannabis products are being accessed.

Some examples of these clinics are:

Cannabis Doctors Australia, <https://cannabisdoctorsaustralia.com.au/>

Medical Cannabis Services, <https://medicalcannabisservices.com.au/>

Cannabis Access Clinics, <https://cannabisaccessclinics.com.au/>

(h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;

Consumer comment:

- *I work as a pharmacist and the biggest issue is stock turn around. By the time a TGA approval is made, the prescription dispensed, stock ordered etc. there is generally about 2-3 weeks from the initial consult with the doctor. It seems that the vapes seem to be more cost effective than the oils but still looking at \$300+/month. SAS approval needs to occur to make it viable as a treatment for MS. My mum is on several opioids and adjuvant analgesics currently for pain stemming from her MS but doesn't have the energy to go through the approval process.*

(i) the current status of the domestic regulated medicinal cannabis industry;

Consumer comments:

- *I don't understand why the government has to make it so hard for people with genuine chronic illnesses to be able to have medicinal cannabis if it is going to help us. It would reduce the need for other pain killers and their terrible side effects.*
- *It's not taken seriously as a treatment option and it should be*
- *It is currently a joke. I have had trials with off-market approaches with gr8 success.*

(j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;

Consumer comments:

- *I am way less drowsy on MC.*
- *I'm so sick of taking opioids and such. It's gross and makes me really sick and weed works way better especially for spasticity which I get very badly. It helps with so many things.*
- *I agree with everything that has been said, it is a huge benefit but not knowing how to access it, what is available or be able to pay for it consistently puts it in a very difficult place*

(k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;

(l) the significant financial barriers to accessing medicinal cannabis treatment;

Consumer comments:

- *I am lucky enough to be able to work full time so can afford medicinal cannabis. I am off all opioids, which I admit I was addicted to, and take medicinal cannabis morning and night and have no pain. It needs to be more accessible and affordable for people.*
- *The cost of it is just unobtainable for the average working person let alone on a disability pension. I did manage to obtain a couple of bottles because I didn't have to pay for it. It stopped 90% of my muscle spasms and let me think that life could be bearable again only to run out and not be able to get hold of any more either because I couldn't get a script or afford to buy it.*
- *Very expensive. I can't breathe due to my MS let alone sit and argue the point!*
- *It's far too expensive 😊 normal people like me who is getting a pension cannot afford it, it's so ridiculous that the people that are supposed to be helped can't get it 😊😊😊*
- *It's too expensive, I have try some taken just at night and it's amazing I can get out of bed in the morning, sleep better don't feel fatigue thought the day no pain, my mood different. Taking the oil I forget I have MS plus it's all natural way better than all the other things I take for pain and to help me sleep.
I just wish it was a lot cheaper*
- *It's too expensive. For 50ml it was \$300. To see any difference I would have needed a lot more per month, but unfortunately, can't afford \$1000 or more.*
- *That's [the price] ridiculous. I was going to look into it, but not now you've told us that.*
- *Much cheaper on black market. We're blown away with price.*
- *That is far too much I got my prescription a few months ago 100mls for \$299 and I still have some left*
- *It's way too expensive. I can't afford the current cost*

- *The cost makes it unobtainable and even if you could afford it there is a huge stuff around to get it*
- *Financially it is a struggle as I have changed medication (6yrs on fentanyl patches @ \$6/month & now on medicinal cannabis oil (seizures from post herpetic neuralgia greatly improved and also getting better quality of sleep) but it's \$350/month & still need another option for breakthrough pain.*
- *Drop the barriers and stop sweeping it under the carpet.*
- *Legalise it, let them grow their own, List it on the PBS*

(m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that; and

Consumer comments:

- *It's good to see MS Australia listening to its members and getting behind this important inquiry. Medical Cannabis does give relief where there was none and cost/ uneducated doctors shouldn't be barriers.*
- *I was told I did not qualify for medicinal cannabis as my pain was not bad enough but to keep taking pain tablets. A friend of mine gave me a joint and I only smoked a small amount of it. I had a pain free night and slept really well. I never get a good night's sleep and it impacts my quality of life as I have extreme fatigue. I have been told to use xx. So I am being forced to use pharmaceuticals when there is an alternative. If I knew a drug dealer I would break the law to get cannabis as that one night of being pain free and sleeping was heaven*

(n) any related matters.

Case study - My MS and Cannabis – by Dave (a consumer with MS, not his real name)

I have had Relapsing Remitting MS (RRMS) for over 15 years. I struggle with walking, still work full time and have muscle spasms and spasticity. I get 'mexican waves' where my hamstrings and quads tighten...down to my calves...my toes curl – then back up and back down.

I use a CBD Vape – Medipen – legal in UK for the past 5 years...when I have 4-5 puffs on it the waves stop within 3-4 minutes. I believe THC content is <.2% - the legal limit in UK – as opposed to the ridiculous level of .005% in Australia – the Australian requirement for CBD content to be below .0075% makes it almost the same as using nothing. The limits are almost set up to ensure CBD/THC doesn't pose a threat to harmful opioid based medicine and is impinging on my right to medical treatment that works and poses no risk to my life.

I also use 'green-market' tincture - bought on a donation only basis – when I had the flu – and a temperature left me unable to bend my legs, I couldn't roll over in bed let alone get out. One old fashioned eye-dropper of it and I could bend my knees to my chest under 10 minutes of dosage and get out of bed using a walker. Without that I would not have been able to even use a bed-pan.

I also make an alcohol-based tincture from dried leaf trim – that I had given to me after asking around. Results I get from 20ml is quite amazing. And yet it is illegal.

I also vape dried flower - I have had occasions when I have gone to friends for dinner – I have struggled to walk with a walker...then I have a vape – and I walk with one walking stick – sometimes 2. I couldn't drive a car or go to work – but the pain and spasticity eases right off and I walk with aids. When I use this each night before going to bed- I am able to walk to the end of my street and back each day, using sticks – approx. 600m – when my walking is usually max about 100m.

The only other thing I have had success with for spasticity is Baclofen – which left me unable to get out of bed until 10am – after taking it at 8pm – and then my legs were so 'soft' I had trouble standing.

I have spoken with 3 GPs – all of whom have been willing to write a script but don't know what for and said the process is all too hard. The fact is GPs and the medical profession are unaware of the benefits and the process for writing a script and with good reason - they are too busy.

If it were left to medical dispensaries as in the USA and Canada – the experts and the market would quickly establish what benefitted what and for whom. No-one would be in any danger and the market would have access to many different strains and ratios and products.

We need medical dispensaries for cannabis and we need them now- it is harmless (other than to Pharma profits) and the market will enable the good to thrive.

Please show some concern and compassion.

Conclusion

In recent years, MS Research Australia and MSA have made numerous submissions to various government enquiries regarding the regulation of medicinal cannabis in Australia (these are listed below).

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.

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 any adverse effects and side-effects of cannabis use.

Previous submissions:

- Submission on the Public Health (Medicinal Cannabis Affordability) Bill 2017 – Queensland Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (April 2017)
- Submission to the Therapeutic Goods Administration Proposed amendments to the Poisons Standard - ACMS and ACCS meeting, March 2016 (February 2016)
- Submission to the ACT Legislative Assembly Health, Ageing, Community and Social Services Inquiry into the exposure draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and related discussion paper (February 2015)
- Submission to the Senate Legal and Constitutional Affairs Legislation Committee Inquiry into the Regulator of Medicinal Cannabis Bill 2014 (March 2015)
- Submission to the Victorian Law Reform Commission's Medicinal Cannabis Issues Paper (April 2015)
- Submission to the Inquiry into the Public Health (Medicinal Cannabis) Bill 2016 – Queensland Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (July 2016)

All of these submissions are available from MS Australia's 'submissions' web-page, please visit: <https://www.msaustralia.org.au/about-msa/submissions>

KEY FACTS ABOUT MS:

- Multiple sclerosis (MS) is a neurological condition affecting the central nervous system (brain and spinal cord) that affects more than 25,600 people throughout Australia
- It is the most common chronic neurological condition diagnosed in young adults.
- MS is most commonly diagnosed between the ages of 20 and 40
- 75% of people diagnosed are women.
- MS varies significantly from person to person. For some people, it is a disease that comes and goes in severity with periods of unpredictable relapse and remission. For others it means a progressive decline over time. For all, it is life changing.
- Symptoms vary between people and can come and go; they can include severe pain, walking difficulties, debilitating fatigue, partial blindness and thinking and memory problems.
- There is no single known cause of MS; we do know that MS is caused by an autoimmune process that is directed at the insulation of nerve fibres, known as myelin, in the brain, spinal cord and optic nerve. The triggers for MS are a combination of genetics and environmental factors and the specific combination is likely to be different for everyone.