THE AUSTRALIAN PAIN SOCIETY

SUBMISSION TO THE AUSTRALIAN GOVERNMENT SENATE INQUIRY INTO IMPROVING ACCESS TO MEDICINAL CANNABIS BILL 2023

MAY 2023

Submission method	Contact
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1.3. State/Territory: National organisation, office based in NSW

1.4. Remote, rural or regional: Included in our national reach

1.5. Date of Submission: 02 March 2023

1.6. Submission category:

Organisation – The Australian Pain Society (APS)
Peak body – Health Professionals

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2. Introduction

The Australian Pain Society (APS) is the only multidisciplinary organisation in Australia whose purpose is to advance pain management through education, research, and advocacy for transformational improvements in clinical care so that all people will optimal management throughout life.

At its 2010 Montreal meeting, the International Association for the Study of Pain declared that '*access to pain management is a fundamental human right*'. Specifically, that all people have the right to:

- Access to pain management without discrimination
- Acknowledgment of their pain and to be informed about how that pain can be assessed and managed
- Access to appropriate pain assessment and treatment by adequately trained health care professionals

As the Australian Chapter of the International Association for the Study of Pain, the APS is committed to supporting this declaration; now known as the *Declaration of Montreal*.

We appreciate the opportunity to provide this submission to the Senate Community Affairs Committee in response to the Inquiry into Improving Access to Medicinal Cannabis Bill 2023.

2.1. Background

The Bill proposes an amendment to the Therapeutic Goods (Poisons Standard - February 2023) to:

a) Re-schedule medicinal cannabis to Schedule 4 and allow any medical practitioner to prescribe medicinal cannabis,
b) Adopt a definition for cannabis that allows a higher level of tetrahydrocannabinol (THC), up from 0.1% to 1% to align Commonwealth law with state law,
c) Re-schedule whole plant cannabis products with a limit of 1% THC and 10% cannabidiol (CBD) to Schedule 3 so that it can be sold over the counter at a pharmacy or veterinarian to persons over 18 years old, and
d) Retain the listing for hemp as a food product with existing limits unchanged.

We understand that the stated purpose of the proposed Bill is to improve access to medicinal cannabis, suggesting that the current Special Access Scheme pathway continues to limit adequate provision of medicinal cannabis in a way that is cost effective, and suggests that re-scheduling cannabis to Schedule 4 of the Poisons Standard will allow for its inclusion on the Pharmaceutical Benefits Scheme (PBS) as a separate process.

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The Bill is proposing these changes because it believes that retaining some of the restrictions of the current legislation is also necessary to meet Australian obligations under International Conventions, in particular the right to health, work, privacy and reputation.

3. Our submission

We are supportive of evidence-based pharmacological options which can improve the lives of those living with chronic pain. The current evidence for the management of chronic pain supports a multidisciplinary approach to pain management whereby pharmacological options remain one of many tools that the patient may have available to them for the management of their pain condition.

Whilst adequate access to evidence-based pharmacological options is favoured, medicinal cannabis does not have sufficient scientific evidence at present and should be judiciously considered only after all other options have failed to manage the condition or symptoms. Thus, the re-scheduling of medicinal cannabis to Schedule 4 for any medical practitioner to prescribe would put undue pressure on medical practitioners to consider prescribing low evidence based medicinal cannabis for which limited information and no recognised prescriber training is available concerning clear indication for use, dosage to treat and dosage to minimise side effects.

The Bill further proposes that the cannabis plant works best when presented as a whole plant, with all 520 known compounds in the plant presented together, each working with others in an entourage effect. It then suggests that these whole plant products be down-scheduled to Schedule 3. An entourage effect is a synergistic response of the complex biological interactions of medicinal cannabis, and down-scheduling to Schedule 3, without the close supervision of an authorised medical practitioner as the prescriber, would increase the risk of potential drug-interaction or augmented side effects due to the 520 known compounds in the plant, even if the due diligence of the pharmacist was done at the point of sale. The availability of such products over the counter would make it challenging or impossible to closely supervise and monitor the patient.

Whilst appropriate dosing of CBD and/or THC to treat chronic pain and its comorbidities is under investigation but remains unclear to date, there is no current peer-reviewed evidence as to the indications for the use of whole plant cannabis products with a limit of 1% THC and 10% cannabidiol (CBD), if rescheduled to Schedule 3. To date, low concentrations of CBD and/or THC have been suggested for wellness, however evidence for this remains low and there are no definite measurable health benefits known at these concentrations. Most certainly, such concentrations of THC and CBD as these proposed would not suffice for chronic pain however, with the current Special Access Scheme (SAS) A and B data showing that the highest application for medicinal cannabis remains the chronic pain community, this should indicate to us that it is likely that those living with chronic pain may access over-the-counter concentrations and likely achieve no therapeutic effect due to subtherapeutic doses.

Medicinal cannabis remains an unapproved medicine by the ARTG. Rescheduling an unapproved medicine, from Schedule 8 to Schedule 4, would still require medical practitioners to access medicinal cannabis for their patients as an authorised prescriber or via the special access scheme approval pathway and would not result in the outcome claimed by the proposed Bill of permitting greater patient access to medicinal cannabis by implementing the down-scheduling proposal.

Medicinal cannabis has both acute and long-term adverse effects however it is recognised that cannabis is not associated with fatal overdoses. However, a major issue with acute dosing of medicinal cannabis products that contain THC is intoxication. Higher doses of THC are associated with acute adverse effects such as euphoria, anxiety and disorientation, subtle cognitive deficits such as impaired attention and short-term memory impairment may be experienced. THC-containing cannabis may impair driving performance. THC in medicinal cannabis may also cause enhanced appetite, dry mouth and dizziness as common side effects and cannabis may also cause nausea and vomiting. Whilst cannabidiol (CBD) in medicinal cannabis is not intoxicating one of the major concerns is its potential for drug interactions when used with other medicines as it inhibits enzymes in the liver required for drug metabolism. For this reason, it is important that medical practitioners should monitor the prescribing and supply of medicinal cannabis.

There is a need for more safety and pharmacovigilance studies with medicinal cannabis products. Most evidence on the potential long-term adverse effects of cannabis derives from its recreational use, which may not readily apply to medicinal cannabis use. Overall, cannabis has mild-to-moderate addictive liability. The issue of cannabis dependence in those using it purely for medicinal purposes has yet to be adequately studied. Overall, whilst medicinal cannabis is generally well tolerated when use with well monitored confines, the science related to its potential adverse effects is in its infancy.

The Australian Pain Society appreciates the intent of this Bill, however, there remains insufficient evidence for therapeutic support in the area of pain management and uncertainty as to how the rescheduling would allow for better access. At this time, we are not supportive of this Bill.

4. The evidence for the use of medicinal cannabis in chronic pain

Current Therapeutic Goods Administration (TGA) medicinal cannabis Special Access Scheme Category A and B data indicate that more than 90% of the applications for medicinal cannabis are for chronic pain of various types.

Special Access Scheme Category A data - https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data/medicinal-cannabis-special-access-scheme-category-data

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Special Access Scheme Category B data - https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data/medicinal-cannabis-special-access-scheme-category-b-data

The Faculty of Pain Medicine, in its *Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain, 2021*: https://www.anzca.edu.au/getattachment/d1eb1074-ef9c-41e6-a1af-31d82b70bcfa/PS10(PM)-Statement-on-Medicinal-Cannabis states that the scientific evidence for the efficacy of cannabinoids in the management of people with chronic non-cancer pain remains insufficient to justify endorsement of their clinical use. It remains very concerned about the adverse event profile in cannabis users, especially in young people, including impaired respiratory function, psychotic symptoms and disorders and cognitive impairment. It recognises that pragmatic trials of efficacy of cannabinoids in individual cases will continue, and that patients within these trials will be closely monitored.

The TGA has continued to advise that there is limited evidence for the effectiveness of medicinal cannabis in various medical conditions. There is also little known about the most suitable doses of individual cannabis products in varying patient populations and conditions. Thus, except for one product (Nabiximols), medicinal cannabis products are not registered on the Australian Register of Therapeutic Goods (ARTG) and, as in most other countries, remain as unapproved medicines.

Whilst the responsibility for its use lies with the authorised prescriber, there is also limited information available to help doctors determine the most appropriate and safe doses for their patients, while minimising potential side effects. Currently, there are relatively few studies comparing the effects of medicinal cannabis products against currently approved treatment for various conditions and symptoms, including that of chronic pain. Most studies reported in the medical literature have used either purified pharmaceutical substances or cannabis administered via smoking. There are currently no formal accredited and standardised training courses for the prescription of medicinal cannabis which are recognised by the training colleges for medical practitioners such as the Royal Australian College of General Practitioners (RACGP) or Australian College of Rural and Remote Medicine (ACRRM).

There is some evidence that cannabinoids can reduce pain in both multiple sclerosis related neuropathic pain and non-multiple sclerosis related neuropathic pain but, for many people, this reduction in pain may be only modest and the risk of harm remains great. There is insufficient evidence to allow any conclusions to be drawn about the use of cannabinoids in the treatment of pain associated with arthritis and fibromyalgia, due to very small studies. Overall, the quality of life or physical functioning of these patients have not been shown to be improved with medicinal cannabis, although there is some evidence that sleep can be improved. Clinical studies are ongoing to investigate if the use of medicinal cannabis products can result in the reduction in use of strong

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opioids, with particular attention to opioid-related deaths and incapacity from opioid overdoses, however no data from these studies is available as yet.

5. Publication authority

We agree to our submission being made public under our name: The Australian Pain Society

Supporting documentation:

- Special Access Scheme Category A data - https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data/medicinal-cannabis-special-access-scheme-category-data
- Special Access Scheme Category B data - https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data/medicinal-cannabis-special-access-scheme-category-b-data
- Faculty of Pain Medicine *Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain, 2021*: https://www.anzca.edu.au/getattachment/d1eb1074-ef9c-41e6-a1af-31d82b70bcfa/PS10(PM)-Statement-on-Medicinal-Cannabis