



SUBMISSION TO SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE
INQUIRY INTO THE CRIMINAL CODE AND OTHER LEGISLATION AMENDMENT
(REMOVING COMMONWEALTH RESTRICTIONS ON CANNABIS) BILL 2018

JUNE 2018

EXECUTIVE SUMMARY

Painaustralia welcomes the opportunity to provide a submission to this Inquiry.

While we acknowledge the widespread use of cannabis products and degree of community support for greater access to them for a range of reasons, the focus of our submission is the role of cannabis to manage chronic pain.

The majority of people who seek medicinal cannabis do so for pain management, and there is growing interest and expectation around the use of these products to treat a range of conditions.¹

This may be due to increased awareness and availability of medicinal cannabis, the recent establishment of a regulatory framework for these products, and interest in seeking out alternatives to opioids and other pain medications.

It also highlights the significant gaps in access to and understanding of best practice pain management amid a rising pain burden. While one in five Australians live with chronic pain,² many people cannot access pain services due to cost or location or are simply unaware of the role these treatment options can provide in improving their quality of life and functionality. To date, chronic pain has been a neglected and misunderstood health issue. Often a cause for chronic pain cannot be identified, leading to a frustrating and lengthy remedial journey.

Chronic pain is not just uncomfortable. It permeates the lives of those who live with it, causing social and financial exclusion, deeply affecting people's capacity to work, their mental health and wellbeing and quality of life. It is the leading cause of early retirement³ (40%) and neck and lower back pain is the leading global cause of years lived with disability.⁴ Without access to best practice pain management, alternatives are being sought by and sold to a vulnerable population group.

Despite the legalisation and decriminalisation of cannabis in some jurisdictions in Australia and overseas, there is still limited availability of well-designed clinical studies to support quality evidence for the use of medicinal cannabis for chronic non-cancer pain (CNCP), and much public opinion on its use is influenced by anecdotes.⁵

While Painaustralia supports current efforts to enable quicker access to medicinal cannabis where it has been correctly prescribed, we are concerned the removal of the Commonwealth from the regulation of cannabis for medicinal purposes could have a range of unintended consequences.

The effective regulation of therapeutic goods, the development of a sound evidence base and a communication strategy about the appropriate use of medicinal cannabis are all critical enablers to ensure safe and effective use. Each of these enablers require further reform and investment and the continued role of the Commonwealth is essential, as we have much to learn about the role medicinal cannabis can play in addressing pain.

ABOUT PAINAUSTRALIA

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Members include pain and other specialists, health practitioners, health groups, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue.

RECOMMENDATIONS

That the Committee:

- note the specific issues for the millions of Australians living with chronic pain and reasons pain management is the key reason people are seeking medicinal cannabis products, including the rising pain burden and the significant gaps in access and awareness of best practice pain management services;
- note the clinical and scientific evidence base to guide the safe and effective use of medicinal cannabis in chronic non-cancer pain is inadequate and recommend investment and support for the expansion of this evidence base;
- recommend the vital role of the Commonwealth is upheld in regulating the safe and effective use of cannabis products for medicinal purposes, the development of a robust evidence base and ensuring greater awareness of prescribing and use of these products among consumers and health practitioners; and
- prioritise and recommend efforts to increase consumer awareness of cannabis products and their role in pain management are redoubled by all levels of government and the medical community.

Australia's pain burden and access to best practice pain management

One in five Australians live with chronic pain,⁶ rising to one in three Australians aged over 65. Chronic pain usually lasts longer than three months and is caused by chronic conditions such as migraine, osteoporosis, arthritis and other musculoskeletal conditions, conditions related to nerve pain, pelvic pain, facial pain and persistent post-surgical pain.⁷

Neuropathic or nerve pain is difficult to treat and can be debilitating. It can be caused by damage, injury or dysfunction of nerves due to trauma, surgery, disease or chemotherapy. Neuropathic pain can be the primary symptom of a stand-alone condition, such as multiple sclerosis or complex regional pain syndrome and can be associated with other conditions or forms of pain. We know more about the role of cannabis products in treating neuropathic pain than other forms of pain.

Chronic pain is not just uncomfortable. It permeates the lives of those who live with it, causing social and financial exclusion, deeply affecting people's capacity to work, their mental health and wellbeing and quality of life. It is the leading cause of early retirement (40%)⁸ and neck and lower back pain is the leading global cause of years lived with disability.⁹

Often no cause can be identified leading to a frustrating remedial journey that can include surgery, scans and x-rays that can have little benefit and cause harm^{10, 11} and reliance on pain medications including opioids despite a lack of evidence that long term opioid therapy is effective to address chronic pain and restore function.¹²

Without access or knowledge of best practice pain management, people in pain are seeking and are vulnerable to be sold alternative treatment options. Chronic pain has not received the same priority in policy and public awareness as other health conditions and remains misunderstood and neglected, despite its significant prevalence.

Increasing understanding that a traditional biomedical approach cannot adequately address all pain-related problems is critical. Expert consensus and a growing body of research in Australia and worldwide says that best-practice pain management that most effectively improves function and mood requires coordinated interdisciplinary assessment and management involving assessing, at a minimum, physical, psychological, and environmental risk factors in each patient.¹³

It also known as a 'bio-psycho-social' approach because it aims to address all the factors that influence the pain experience.¹⁴ Where available, the approach embraces a combination of medical, physical and psychological therapies and can be provided under one roof or separately, but integration of treatments is key to achieving health outcomes.

This approach is a key feature of Australia's own National Pain Strategy, developed in 2010 by over 200 delegates including pain specialists, health practitioners, researchers and consumers. The Strategy provides a blueprint for the treatment and management of acute, chronic and cancer pain and identifies key priorities to support greater access to pain services.

Since then, commitments have been made by various jurisdictions to improve understanding of pain in the community and health sector and addressing gaps in access to pain services.

Recently, the Australian Government committed to fund the development of a National Action Plan on chronic pain management. This is a most welcome announcement and we anticipate it will build on National Pain Strategy and provide a roadmap towards better outcomes for people living with chronic pain.

However, the implementation of a national approach through the Council of Australian Governments (COAG) would recognise that all governments have a role to play in reducing the pain burden and bring forward strategies that focus on prevention, early intervention, treatment and research.

As mentioned above, most people cannot access best practice pain services due to cost or location. Most public and private pain clinics that offer interdisciplinary care in one physical location are predominately located in the major capital cities.¹⁵ Pain specialists who serve both as a consultant to other physicians and often as the principal treating physician are concentrated in the major cities of New South Wales (NSW), Victoria and Queensland, as are the Level 1 Pain teaching clinics. There are no pain specialists in the Northern Territory (NT). There are only seven paediatric pain clinics in Australia, with three in NSW and none in Tasmania, the Australian Capital Territory or the NT.

Pain specialists provide holistic care that includes prescribing medication, coordinating rehabilitative services, performing pain relieving procedures, counselling patients and families, directing a multidisciplinary team that often includes psychological and psychiatric services, cooperating with other healthcare professionals and liaising with public and private agencies.¹⁶ There are only 316 active fellows of the Faculty of Pain Medicine (FPM) in Australia.

This makes it difficult for General Practitioners to refer patients to an interdisciplinary clinic or specialist. Meanwhile the Medicare Benefit Schedule (MBS) does not adequately underpin the provision of multidisciplinary care and allow greater collaboration and continuity of care between general practice, specialists and allied health providers for complex conditions, like chronic pain.

Without adequate pain management, there is a greater reliance on pain medications to treat chronic pain despite limited evidence of their efficacy for that purpose or safety.¹⁷ This includes a 30 per cent increase in opioid prescribing between 2009 and 2014¹⁸ and opioid overdoses including accidental overdoses at record levels in Australia¹⁹ and this is being acutely felt in regional communities where there are very limited pain services.²⁰

Given the significant gap in pain services, people living with chronic pain will continue to rely on medications, and there is growing community expectation medicinal cannabis offers a pharmacological solution despite low levels of clinical evidence for this use. While we acknowledge medications do have a role, they may also divert consumers from seeking out best practice services that have the best hope of restoring function and quality of life.

Recommendation:

That the Committee note the specific issues for the millions of Australians living with chronic pain and reasons pain management is the key reason people are seeking medicinal cannabis products, including the rising pain burden and the significant gaps in access and awareness of best practice pain management services.

Evidence-base for use of medicinal cannabis for chronic pain

Despite the legalisation and decriminalisation of cannabis in some places here and overseas, there have only been a limited number of well-designed clinical studies on medicinal cannabis²¹ and its role in treating chronic pain. There is little evidence about the suitable doses of individual cannabis products. This makes it difficult for practitioners to prescribe, despite community expectations that these products will be made available to treat CNCP.

The Federal Department of Health coordinated a set of clinical guidance documents in late 2017 for prescribers treating a range of conditions, including CNCP.²² The guidance was developed following a review of clinical use of medicinal cannabis in medical journals since 1980. It included randomised controlled trials as well as observational studies. Recent reviews of the evidence for chronic pain have revealed significant issues including lack of clarity around pain conditions, different cannabinoids and their effects on CNCP and limited information about adverse effects. The reviews reveal in some ways the complexity of chronic pain, such as reporting of pain outcomes.

The guidance covers eight cannabinoid products, including products available as registered or unregistered medications in liquid or capsule forms and administered orally or as sprays, as well as cannabis sativa, the plant-based herbal leaf that is smoked, vaporised or eaten.

The review concluded the following:

- There is a need for larger trials of sufficient quality, size and duration to examine the safety and efficacy of medicinal cannabis use in CNCP.
- There is some evidence that the delta-9 tetrahydrocannabinol (THC) extract of cannabis can reduce both MS -related neuropathic pain and other forms of neuropathic pain, but this is limited.
- There is insufficient evidence for the treatment of pain associated with arthritis and fibromyalgia and there is no scientific data to support use of medicinal cannabis products for chronic nociceptive or musculoskeletal pain.
- While some individuals with pain have reported that their use of opioids has been reduced when they use medicinal cannabis, clinical studies in this area are still ongoing.

In terms of prescribing, the guidance advises:

- That the use of medications, including medicinal cannabis, is not the core component of therapy for CNCP, favouring a comprehensive bio-social-physical assessment.
- Practitioners should distinguish between the setting of palliative care and CNCP, as in the latter setting, commencement of a medicinal cannabis product may expose the patient to life-long use of the medical cannabis product. There are no robust data regarding the consequences of such use.
- It is suggested that an initial treatment plan indicate that the medicinal cannabis product be used for a one-month trial to determine the effectiveness of the medication for the patient's condition/symptoms
- Pharmaceutical grade cannabinoids should be ceased where the desired effect is not apparent after 4–12 weeks; and psychoactive or other side-effects are prohibitive (particularly for THC preparations).
- There is little information available on dose-response.

The Faculty Pain Medicine/Australian and New Zealand College of Anaesthetists (FPM/ANCZA) statement on the use of medicinal cannabis for management of patients with CNCP concurs with this guidance, noting:

- FPM does not endorse the use of cannabinoids for CNCP until such a time a clear therapeutic role is identified in the scientific literature.
- Concerns with the adverse event profile in cannabis users, especially in young people including impaired respiratory function, psychotic symptoms and disorders and cognitive impairment.
- Substances intended for therapeutic purposes need to be fully characterised chemically, pharmacologically and toxicologically.
- Trials of cannabinoids are necessary and should be conducted on a coordinated national basis by highly credentialed persons and within strict parameters.²³

Recommendation:

That the Committee note the clinical and scientific evidence base to guide the safe and effective use of medicinal cannabis in chronic non-cancer pain is inadequate and recommend investment and support for the expansion of this evidence base.

Role of the Commonwealth in regulation, research and awareness

Given the high level of expectation of medicinal cannabis, it is critical the policy environment ensures the safe and effective use of these products, and only as part of a best practice pain management response that can give people the best chance to improve quality of life and restore function.²⁴

This policy environment includes:

- an effective regulatory framework that safeguards and enhances the health of Australians;
- the development of a robust evidence-base, coordinated on a national basis and with strict parameters; and
- significant efforts to inform consumers and practitioners about the safe and effective use of cannabis products, as well as empowering consumers to understand and seek out best practice pain management.

Currently, the Commonwealth is undertaking these three enabling roles with varying degrees of effectiveness and investment. Painaustralia argues that significantly more needs to be done, particularly regarding building the evidence-base and better informing consumers about the role, safety and efficacy of these products as well as best practice pain management.

The removal of the Commonwealth from the regulation of these products would leave a chasm in providing a strategic framework to understand what role they can play in pain management.

Despite the lack of an evidence-base, medicinal cannabis may be considered an option of last resort where a range of other therapies have been exhausted and offer relief in certain patients. Painaustralia supports commitments made at the April meeting of the COAG Health Council to streamline the application and approval process for unregistered medicinal cannabis and progress the development of a single national online application pathway.²⁵

While Painaustralia supports current efforts to enable quicker access to medicinal cannabis where it has been prescribed, we are concerned the removal of the Commonwealth from the regulation of medicinal cannabis could have a range of unintended consequences. At worst, this could see millions of Australians living with chronic pain offered 'false hope' of a treatment option that does not work and that diverts them from seeking and accessing best practice pain management that offers their best chance for a good quality of life and return to function.

Recommendations:

That the Committee:

- **recommend the vital role of the Commonwealth is upheld in regulating the safe and effective use of cannabis products for medicinal purposes, the development of a robust evidence base and ensuring greater awareness of prescribing and use of these products among consumers and health practitioners; and**
- **prioritise and recommend efforts to increase consumer awareness of cannabis products and their role in pain management are redoubled.**

CONCLUSION

Painaustralia is aware there is widespread community and political support for the greater availability of cannabis products to restore quality of life and function for those living with chronic pain.

Proponents for the deregulation of cannabis products argue it will offer a range of social and economic benefits to Australia. Based on the current limited clinical and scientific evidence we have, the solution to chronic pain is unlikely to be one of these benefits.

At this stage, we do not know enough about how these products will do this and this Inquiry highlights the need for a much deeper and more conclusive scientific and clinical evidence base to guide its future therapeutic use for chronic pain.

The removal of the Commonwealth, which is currently leading the regulatory and policy framework for the use of medicinal cannabis, could have a range of unintended consequences for the millions of Australians that live with chronic pain.

Importantly, this inquiry shines a light on pain as one of Australia's more significant yet neglected health challenges, the substantial gap in access to pain services and the need for holistic strategies to meet this burgeoning social and economic issue and we urge the continued consideration of these issues in the Parliament and by governments.

We commend this submission to the Inquiry.

REFERENCES

- 1 <https://www.tga.gov.au/sites/default/files/guidance-use-medicinal-cannabis-australia-overview.pdf>
- 2 <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4841.0Chapter12011>
- 3 <http://painaustralia.staging3.webforcefive.com.au/static/uploads/files/painaust-factsheet2-wfdahrmggvwp.pdf>
- 4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/>
- 5 <http://fpm.anzca.edu.au/documents/pm10-april-2015.pdf>
- 6 <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4841.0Chapter12011>
- 7 <http://www.painaustralia.org.au/about-pain/what-is-chronic-pain>
- 8 <http://painaustralia.staging3.webforcefive.com.au/static/uploads/files/painaust-factsheet2-wfdahrmggvwp.pdf>
- 9 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/>
- 10 <https://theconversation.com/spinal-fusion-surgery-for-lower-back-pain-its-costly-and-theres-little-evidence-itll-work-91829>
- 11 <http://www.abc.net.au/news/health/2018-06-11/treating-lower-back-pain-without-drugs-and-surgery/9850798>
- 12 <https://www.nps.org.au/medical-info/consumer-info/chronic-pain-explained?c=opioid-medicines-for-chronic-pain-804d9703>
- 13 https://s3.amazonaws.com/rdcmsiasp/files/production/public/Content/ContentFolders/Publications2/PainClinicalUpdates/Archives/PCU_20-7_web.pdf
- 14 <http://www.painaustralia.org.au/getting-help/right-care/multidisciplinary-pain-management>
- 15 <http://www.painaustralia.org.au/getting-help/pain-services-programs/pain-services>
- 16 <http://fpm.anzca.edu.au/about-fpm/about-pain-medicine>
- 17 <http://fpm.anzca.edu.au/documents/pm1-2010.pdf>
- 18 <https://www.tga.gov.au/sites/default/files/consultation-prescription-strong-schedule-8-opioid-use-misuse-in-australia-options-for-regulatory-response.pdf>
- 19 <http://www.abc.net.au/news/2018-05-13/australia-on-brink-of-prescription-painkiller-epidemic/9753506>
- 20 https://www.safetyandquality.gov.au/wp-content/uploads/2015/11/SAQ201_01_FrontSection_v10_FILM_TAGGED-3-Key-findings-and-recommendations.pdf
- 21 <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>
- 22 <https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-treatment-chronic-non-cancer-pain-australia>
- 23 <http://fpm.anzca.edu.au/documents/pm10-april-2015.pdf>
- 24 <http://fpm.anzca.edu.au/documents/pm10-april-2015.pdf>
- 25 https://www.coaghealthcouncil.gov.au/Portals/0/CHC%20Communique%20130418_corrected_1.pdf

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