EXECUTIVE SUMMARY

Painaustralia is pleased to provide a submission to the Victorian Legal and Social Issues Committee’s Inquiry on the use of Cannabis in Victoria.

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.

Our submission responds to term of reference (e) and assesses the health, mental health, and social impacts of cannabis use on people who use cannabis, their families and carers. Painaustralia recommends that the Inquiry:

- consider the current gap in pain management options for the over 857,000 people living with chronic pain in Victoria.
- consider the broader implications of enabling access to medicinal cannabis for pain management
- consider the potential for harm presented by cannabis, particularly for individuals with complex comorbidities
- consider the broader health and mental health implications of cannabis consumption.
- accompany any harm minimisation strategy with a targeted education and awareness campaign around quality use of Cannabidiol (CBD) and other medicinal cannabis products. Such a campaign should include an emphasis on:
  o quality use of CBD and other cannabis products
  o supporting informed decision making
  o highlight the potential for adverse events through interactions with other drugs

![Top 4 illicit drugs used in the last year](source: National Drug Strategy Household Survey 2019)
THE ISSUE

Pain causes many people to turn to cannabis and is, in fact, the top reason that people cite for seeking cannabis from dispensaries\(^1\). There is growing interest and expectation around the use of these products to treat a range of conditions.\(^2\)

This may be due to increased awareness and availability of medicinal cannabis, significant industry promotion, the recent establishment of a regulatory framework for these products, and interest in seeking out alternatives to opioids and other pain medications. The 2019 National Drug Strategy Household Survey Report by the Australian Institute of Health and Welfare shows that cannabis remains the most commonly used illicit drug.

Painaustralia’s acknowledges the widespread use of cannabis products and degree of community and political support for greater access to medicinal cannabis for a range of reasons. This situation highlights the significant gaps in access to, and understanding of, best practice pain management amid a rising pain burden.

BACKGROUND

The growing prevalence and cost of pain

Painaustralia’s report, The Cost of Pain in Australia by Deloitte Access Economics, provides the most comprehensive analysis of the financial impact of chronic pain in Australia. It shows that chronic pain affects more than 3.37 million Australians. Chronic pain, also called persistent pain, is pain that continues for more than three months after surgery, an injury, as a result of disease, or from another cause. In Victoria in 2020, over 857,500 people live with chronic pain.

For those who experience chronic pain, the pain can be debilitating and have an adverse effect on work, sleep, and relationships. Individuals with chronic pain may also commonly experience comorbidities such as depression, sleep disturbance and fatigue.

These comorbidities often contribute to worse health, societal and financial outcomes – for example, major depression in people with chronic pain is associated with reduced functioning, poorer treatment response, and increased health care costs. Nearly half of all people in pain also live with depression and anxiety. Painaustralia’s report finds that the reported comorbidity for chronic pain and depression or anxiety is estimated at 44.6% of patients, which is within the range of estimated values from the international literature.\(^3\)

The consequences of these gaps are immense. The price paid by people with chronic pain is continued physical and psychological ill health, social exclusion and financial disadvantage. Opioids continue to be over-prescribed for pain, with unacceptable consequences including dependency and opioid-related deaths.

Society as a whole pays the price too. The total financial costs associated with chronic pain were estimated to be $73.2 billion in 2018, which equates to $22,588 per person with chronic pain.\(^4\) In Victoria, this cost was over $35 billion in 2018.

More than 68% of people living with chronic pain are of working age. Without action, the prevalence of chronic pain will increase to 5.23 million Australians (16.9%) by 2050.

In 2018, the staggering cost of chronic pain to taxpayers (including quality of life) was $139 billion. This was on top of the fact that last year alone, Australians paid $2.7 billion in out of pocket expenses to manage their pain, with costs to the health system in excess of $12 billion.
In 2020 3.37 million Australians lived with chronic pain. This is set to rise to 5.23 million by 2050.

44.6% of people with chronic pain also live with depression and anxiety.

20% of all GP presentations in Australia involve chronic pain.

Medications are used in close to 70% of GP consultations for chronic pain management.

Referrals to pain specialists occur in less than 15% of GP consultations where pain is managed.

**FINANCIAL COST**

$139.3 billion

$12.2 billion health system cost

$48.3 billion lost productivity

$12.7 billion other financial cost

$66.1 billion reduction in quality of life

*Deloitte Access Economics (2019), The Cost of Pain in Australia*
The impact of inaction

Despite the burgeoning cost and impact of pain, our current clinical pathways are failing consumers. An epidemic of pain in Australia has seen problematic increases in the level of harm and deaths due to opioid misuse. With over three million people prescribed 15.4 million opioid scripts in 2016–17 it is unsurprising that opioids now account for 62% of drug-induced deaths, with pharmaceutical opioids now more likely than heroin to be involved in opioid deaths and hospitalisations. In 2016–17 there were 5,112 emergency department presentations and 9,636 hospitalisations due to opioid poisoning, with three deaths per day attributed to opioid harm, higher than the road toll.

Currently the MBS does not support a best-practice treatment model, leading to unnecessary use of hospital-based services and more significantly, an over-reliance on medication including opioids, which is associated with significant harm. Nearly 70% of pain management consultations end with a GP prescribing pain medication. Another 13% will end in imaging, but less than 15% can hope to be referred to an allied health professional.

This unfortunately means that for the 3.37 million people living with chronic pain, access to best practice care is problematic at best, and fatal at worst. Understandably the physical, mental and emotional toll of chronic pain impacts every facet of patients’ lives. The lack of pain specialist care and GPs with limited options to deal with chronic pain means that millions of Australians are falling through the cracks of the country’s health system.

**Recommendation 1:**

Painaustralia recommends that the Inquiry consider the current gap in pain management options for the over 857,000 people living with chronic pain in Victoria.
CANNABIS AND CHRONIC PAIN

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

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 pain and much public opinion on its use is influenced by anecdotes.

Painaustralia supports current efforts to enable quicker access to medicinal cannabis where it has been correctly prescribed, and we have supported commitments made at the meeting of the Council of Australian Governments (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.

However, we are concerned that the accelerated push to legalise cannabis and embrace medicinal cannabis for chronic pain across jurisdictions, may have some unintended consequences. At worst, this could see millions of Australians living with chronic pain offered ‘false hope’ of a treatment option that has limited benefit and diverts them from seeking and accessing best practice pain management offering them the best chance for a good quality of life and return to function.

The biopsychosocial framework that informs the assessment and management of people with chronic pain requires active engagement of patients in a multimodal management program, and this approach recognises the adverse effects that may be associated with polypharmacy in general and with cannabinoids in particular.

Recommendation 2:

Painaustralia recommends that the Inquiry consider the broader implications of enabling access to medicinal cannabis for pain management.

EVIDENCE-BASE FOR USE OF CANNABIS FOR CHRONIC PAIN

When it comes to chronic pain, there is a need to expand availability of safe and effective treatments as current treatments are not adequate. Studies to date have not systematically addressed this question in a large population of people taking opioids for chronic pain.

There is little evidence about suitable doses of individual cannabis products like CBD, such as randomised controlled trials or systematic reviews, that enable definitive statements on effectiveness of medicinal cannabis for pain management. This lack of evidence makes it difficult for practitioners to prescribe, despite community expectations that these products will be made available to treat chronic pain.

“Synergy with THC appears to be required for neuropathic pain management; international approaches/consensus statement will suggest CBD first, titrate up to 40 mg before considering addition of THC”

Painaustralia Clinical Advisor

The strongest scientific evidence is for its effectiveness in treating childhood epilepsy syndromes, such as Dravet syndrome and Lennox-Gastaut syndrome (LGS), which typically do not respond to antiseizure medications. Painaustralia notes that these indications are the only ones that the Pharmaceutical Benefits Advisory Committee (PBAC) is considering for potential listing of CBD on the Pharmaceutical Benefits Scheme.

Recent NICE (National Institute for Health and Care Excellence) Guidelines also do not recommend offering CBD to manage chronic pain in adults unless as part of a clinical trial. The Guidelines note that the evidence did not show a reduction in opioid use in people with chronic pain prescribed medicinal cannabis.
As noted by the Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE) Prescribing Guidance Prescribing Cannabis Medicines for Non-Cancer Pain (CNCP), currently there is insufficient information to make a recommendation about the role of medicinal cannabis in the treatment of pain associated with arthritis and fibromyalgia. The best evidence of medicinal cannabis currently refers to neuropathic pain states, although it is constrained by similar methodological issues of limited sample size.\textsuperscript{11}

The Australian Pain Society (APS) notes that evidence regarding specific doses of CBD is lacking, but preliminary data suggests a low risk of adverse effects at a dose of 60mg/day.

Comparatively, consumer support for this product may increase efficacy via placebo effects, although this remains to be tested.

“In the absence of significant harm or drug interactions they should be exempted and included as a nutraceutical. People respond to a sugar pill and we need every tool in our arsenal to reduce pain.”

Input from Painaustralia’s Consumer Advisory Group

**Potential for harm**

The potential for drug-drug interactions of cannabis and its derivatives such as CBD and THC with other commonly used medications is high\textsuperscript{12,13,14}

The APS highlights that although there are mechanistic and animal studies suggesting that CBD inhibits inflammatory and neuropathic pain, there is a lack of human data to substantiate the claim that CBD improves pain control.

As noted in the TGA’s own \textit{Review on the safety of low dose cannabidiol} “At low doses, CBD appears to have an acceptable safety and tolerability profile, although it was evident that there is a high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs that are metabolised via cytochrome P450 (CYP) pathways. Currently there is insufficient evidence as to whether these would not occur with the use of low dose CBD.”

CBD is a strong inhibitor for Cytochrome P450 2D6 (CYP2D6) and Cytochrome P450 3A4 (CYP3A4) which are responsible for the metabolism for most pharmaceuticals.\textsuperscript{15} CBD therefore has the potential to increase the serum drug level for most opioids, sedatives, anticoagulants,\textsuperscript{16} antipsychotics, antidepressants, antiepileptics, cardiovascular agents, and cancer therapies.\textsuperscript{17}

Overarching research suggests that potential CBD-related risks include liver injury, adverse drug interaction (e.g. with warfarin) and sedation (esp. if used with alcohol or other sedative agents)\textsuperscript{18} As such, if access to CBD is enabled (even at low doses), this policy move must be supported by enhanced consumer information and decision-making support.

This presents as a major issue for the chronic pain community, who often have multiple complex comorbidities, most of which are managed through the use of multiple medications. **OTC access to CBD must therefore be supported by enhanced information about drug-drug interactions.** Importantly, as the health risks associated with CBD and other cannabis products come under increasing scrutiny, pharmacovigilance during its use in growing numbers of people may uncover other problems.
Table 1.1: Comorbidities associated with chronic pain, Australia 2018

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Percentage of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression or anxiety</td>
<td>44.6</td>
</tr>
<tr>
<td>Osteoarthritis and degenerative arthritis</td>
<td>29.3</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>25.1</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12.5</td>
</tr>
<tr>
<td>Heart disease</td>
<td>8.4</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>7.3</td>
</tr>
<tr>
<td>Ulcer or stomach disease</td>
<td>7.3</td>
</tr>
<tr>
<td>Lung disease</td>
<td>5.4</td>
</tr>
<tr>
<td>Stroke or neurological condition</td>
<td>5.3</td>
</tr>
<tr>
<td>Anaemia or other blood disease</td>
<td>4.7</td>
</tr>
<tr>
<td>Cancer</td>
<td>4.3</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>3.1</td>
</tr>
<tr>
<td>Other medical problems</td>
<td>31.1</td>
</tr>
</tbody>
</table>

Source: Adapted from Tardif et al (2018).

Consumers have however noted that they already manage the risk of multiple medications and interactions.

“Noting that it won’t be a silver bullet or suitable for all people experiencing chronic pain, I think it is important to also note that many traditional pain medications are “hit and miss” and work very differently for different people. Many people have to try a host of different treatments, many of which have bad side effects, before finding something that works effectively for pain management without life-impacting side effects. As such, I don’t think “it isn’t a miracle cure” is a good reason to not progress with making it more available as an option for those with chronic pain to try.”

Input from Painaustralia’s Consumer Advisory Group

Consumers also note that treatment accessibility is important, and downgrading CBD oil will hopefully make it more accessible to those who may benefit from it. This applies to those in regional areas who many not have a choice of doctors or specialists who are up to date with CBD as a treatment and may be unlikely to prescribe it, for those who struggle to find the time and the money to get prescriptions regularly, etc.

**Recommendation 3:**
Painaustralia recommends that the Inquiry consider the potential for harm presented by cannabis, particularly for individuals with complex comorbidities.
Overarching health concerns with use of Cannabis Products

The use of cannabis (particularly its principal psychoactive constituent, tetrahydrocannabinol or THC) is associated with health risks including lung disease (when smoked), cardiovascular disease, acute pancreatitis, and cannabinoid hyperemesis syndrome.\(^1\) Cannabis users are also at increased risk for occupational injuries, and cannabis-associated “drugged driving”—sometimes fatal—is increasing. Finally, the myth that cannabis is nonaddictive has been dispelled by studies of forced abrupt cessation of use indicating potential rebound hyperalgesia and craving.\(^2\)

The Federal Department of Health coordinated a set of clinical guidance documents in late 2017 for prescribers treating a range of conditions, including chronic pain.\(^2\) The reviews reveal in some ways the complexity of chronic pain, such as reporting of pain outcomes. In terms of prescribing, the guidance advises that the use of medications, including medicinal cannabis, is not the core component of therapy for chronic pain, favouring a comprehensive bio-social-physical assessment.

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 chronic pain concurs with this guidance.\(^2\)

The APS notes that points to consider include advising consumers to inform their doctors that they are taking CBD and to collaboratively develop a pain management plan (if they don’t already have one). Moreover, consumers should be advised of the evidentiary limitations regarding CBD for pain management including side effects, driving impacts and metabolic functioning.

As noted in the Royal Australian College of General Practice (RACGP)’s Medicinal Use of Cannabis position statement,\(^2\) there is a need for more public and medical education. This education should reflect the current state of knowledge and contextualise the use of medical cannabis as a last-resort medication for specific categories of illness that can only be prescribed in rare circumstances after stringent legislative criteria are satisfied.

Painaustralia supports the RACGP’s position statement and reiterates that medicinal cannabis should be used only as a last-resort medication for specific categories of illness and only where the evidence base exists.

Cannabis use and impact on mental health

Given the high cost associated with current access of medicinal cannabis products in Australia, it is important to consider the option to access both medicinal cannabis products with THC as well as unregulated cannabis products via the black market, which presents a cheaper and more affordable pathway to most consumers. The broader health implications of enabling access to cannabis should therefore be part of the consideration of down-scheduling.

It is also important to note that for those with psychotic disorders or at risk of developing them, medicinal cannabis may present higher risks. The comorbidity between mental and physical health problems is well documented, especially when illness becomes chronic. Nowhere do psychiatric and medical pathologies intertwine more prominently than in pain conditions.\(^2\) Chronic pain deeply affects the capacity to work, mental health and wellbeing as well as relationships. Distressingly, it can also end in suicide.

As one of the peak bodies representing mental health expertise in Australia, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) has particular insight into the significant psychiatric morbidity associated with cannabis use. They note that several studies linked cannabis use to increased risk for chronic psychosis as well as worse outcomes for people who already have psychosis.\(^2\)
Rates of mental health and suicide are higher among people living with pain. Major depression is the most common mental health condition associated with chronic pain, with among 30-40% of people with a diagnosed mental health condition also presenting for treatment for chronic pain. High rates of generalised anxiety disorder, post-traumatic stress disorder and substance misuse are often present for people living with chronic pain.

Almost a third of Australian adults with severe or very severe pain experience high levels of psychological distress; around three times the rate of those with mild pain and six times the rate of those with no pain. One in five Australian adults with severe or very severe pain suffer depression or other mood disorders.

Suicidal behaviour is also two to three times higher in people with chronic pain than the general population. While these figures are dramatic, chronic pain has not received the same priority in policy and public awareness as mental health (despite its significant prevalence among people with mental health conditions) and remains misunderstood and neglected.

It is paramount that treatments for pain management are based on rigorous evidence. The experience and expression of chronic pain varies between individuals, reflecting changing interactions between physical, psychological and environmental processes. The diagnosis of major depression in patients with chronic pain requires differentiation between the symptoms of pain and symptoms of physical illness, so specific clinical knowledge is helpful.

Emerging research has once again highlighted that that use of medical cannabis products, and their perceived efficacy, may be linked more to the mental health state of the individual as opposed to the severity of pain. These findings are particularly important in the context of enabling access to yet another pharmacological intervention such as CBD, as there is well established research that indicates that among individuals with chronic pain prescribed opioids, depression has been associated with increased opioid dosage.

**Increasing understanding that chronic pain is a disease of the person, and that a traditional biomedical approach cannot adequately address all pain-related problems is critical, and this needs to be a major consideration of any process that examines the access and consumption of cannabis products.**

**Recommendation 4:**

Painaustralia recommends that the Inquiry consider the broader health and mental health implications of cannabis consumption.

**Significance of informed decision making**

As highlighted throughout our submission, it is vital to note that medication alone is not helpful for the management of chronic pain and patients need to adopt other strategies. All medications, including cannabis and its by-products like CBD and THC, have side-effects and many can be harmful if used over the long-term. We need to monitor the impacts of changes to scheduling that considers societal costs of overuse of medications and a shift from lifestyle and holistic interventions to pharmaceutical interventions. In short, we need to weigh the costs versus the benefits.

“I believe it only provides a safeguard to the extent that people don’t exceed the recommended daily dosing. As most people are presently taking substantially more to attain analgesia, improved sleep etc, it’s difficult to assume that it will be used as directed.”

*Input from Painaustralia’s Consumer Advisory Group*

Many questions still remain around the effect of CBD on legal requirements around driving. The legal aspects relate to driving with THC in the system so trace amounts of THC may be found in CBD products (if plant derived), and given fat soluble/stored, can accumulate to detectable levels (and potentially impairment levels) with regular CBD use. There is a potential for false positive roadside tests and high sensitivity blood analysis being positive.
Consumers also expect all OTC drugs to be regulated for consistency. Consumers maybe unaware of small amounts of THC that remains in plant derived CBD concentrates, and the safety of high dose CBD.

Painaustralia therefore recommend that any harm minimisation approach for cannabis be accompanied by a targeted education and awareness campaign around quality use of CBD and other medicinal cannabis products, as well as an evaluation of the change.

A good example of a platform to support a campaign is the recent information portal for medicinal cannabis launched by NPS Medicinewise. The portal assists health professionals and consumers navigate evidence-based information about medicinal cannabis and helps explain the regulatory framework and process required to access medicinal cannabis for both consumers and health professionals. It also provides summaries on the latest evidence for medicinal cannabis.

**Recommendation 5:**

Painaustralia recommends that any harm minimisation approach to cannabis should be accompanied by a targeted education and awareness campaign to promote available resources and optimise the take up of these resources. The campaign should include an emphasis on:

- quality use of CBD and other cannabis products
  - supporting informed decision making
- highlight the potential for adverse events through interactions with other drugs

**CONCLUSION**

Despite the lack of a current evidence-base, cannabis may be considered an option of last resort for chronic pain management where a range of other therapies have been exhausted.

While Painaustralia supports current efforts to enable and expedite access to medicinal cannabis where it has been correctly prescribed, we remain concerned about the unintended consequences of inappropriate cannabis prescribing on a uniquely vulnerable cohort of consumers.

The development of a sound evidence base remains a critical enabler to ensure safe and effective use of current and emerging medicinal cannabis products such as CBD and THC in chronic pain and requires further research and investment as we still have much to learn about the role cannabis can play in addressing chronic pain conditions.

It is important that a comprehensive consumer information campaign be implemented to assist consumers to make informed decisions about the use of medicinal cannabis appropriate to their individual circumstances.
REFERENCES

11. Ware M. J Pain 2015; 16, p1221