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RACP Submission:

NZ Misuse of Drugs (Medicinal Cannabis) Amendment Bill Submission 2018

March 2018

Introduction

The Royal Australasian College of Physicians ("RACP") welcomes the opportunity to submit feedback on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill 2018 ("the Bill"). **Our submission should not be taken to mean that the RACP supports the intention of the Bill.**

The RACP works across more than 40 medical specialties to educate, innovate, and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

The purpose of our submission is to:

1. Provide feedback on the concerning aspects of the Bill,
2. Highlight the impact that the introduction of the scheme would have on physician practise in New Zealand, and
3. Highlight the impact on the person, carers, and other health professionals.

Key issues observed in this Bill are that:

- The RACP is concerned about the lack of a robust evidence base for the use of medicinal cannabis.
- The RACP is concerned about the lack of high quality research and well-designed and conducted clinical trials present for the use of medicinal cannabis.
- The RACP is concerned about the lack of a safe or reliably consistent supply for terminally ill people who would be covered under the defence if the Bill passes.
- The RACP is concerned about the lack of detail contained in the Bill in relation to the proposed "medicinal cannabis scheme".

The Bill

The Bill amends the Misuse of Drugs Act 1975 (the Act) by:

- Introducing an exception and a statutory defence for "terminally ill" people to possess and use illicit cannabis and to possess a cannabis utensil. "Terminally ill" in this context will mean an illness from which a person can reasonably be expected to die within 12 months; and
- Providing a regulation-making power to enable setting of standards that products manufactured, imported, and supplied under licence must meet; and
- Amending schedule 2 of the Act so that Cannabidiol (CBD) and CBD products are no longer classed as controlled drugs.

The first reading also introduced a proposed "medicinal cannabis scheme".

Terminology

Cannabis

In this submission, the term "cannabis" refers to any preparations of the cannabis plant of the type *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*. The types normally used for medical use are *Cannabis sativa* and *Cannabis indica*, with 'hybrid' plants also available[1].

Cannabinoids

Cannabinoids are a class of diverse chemical compounds that act on cannabinoid receptors in cells that modulate neurotransmitter release in the brain. Cannabinoids come from three sources, one of which is phytocannabinoids, which are cannabinoid compounds produced by plants *Cannabis sativa* or *Cannabis indica*.

[1] Victorian Law Reform Commission. Medicinal Cannabis Report. August 2015.

Cannabinoids are sometimes used therapeutically[2]. Leaves and flowers of cannabis contain over 400 distinct compounds and at least 100 different phytocannabinoid compounds. Two major constituents are tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is responsible for most psychoactive properties of cannabis. Cannabidiol has anxiolytic and anti-psychotic properties[3]. Cannabinoid extracts are also included under this definition, including the oro-mucosal spray nabiximols (or Sativex) that contains both THC and CBD[4].

Medicinal Cannabis

The term 'Medicinal' means 'relating to, having the properties of, a medicine; curative; remedial'[5]. In this submission the term 'medicinal cannabis' means when cannabis is used for a medicinal objective. This includes to achieve a curative or remedial effect[6]. Within this definition, medicinal purposes will include those that are 'therapeutic'[7].

Background

The use of cannabis is a contentious and divisive issue, particularly when placed in the context of medicinal use to relieve symptoms related to terminal illness. Arguments for and against its use in relation to illness are well-articulated in the medical literature and public discourse in New Zealand and internationally[8].

Despite the criminal liability associated with it, cannabis use is widespread in New Zealand. The reported annual use is 10.2%[9]. High degrees of use may indicate a degree of acceptance of use in New Zealand and may imply that there is a population who may wish to use it medically should it be available for such use. **However, it should be noted that the two issues of recreational and medicinal use are separate and should be treated as such.**

One pharmaceutical grade cannabis product is licensed for use in New Zealand. This product is marketed as 'Sativex' and is approved by Medsafe for an add-on treatment for patients with moderate to severe spasticity due to Multiple Sclerosis where response to anti-spasticity medication has not occurred. Ministerial approval may be made for non-approved authorisations including neuropathic and chronic pain[10].

RACP Position

The RACP acknowledges the people who have had a prognosis of terminal illness; and recognises the diverse range of views that people living with a terminal illness have on this issue.

The RACP is concerned about the lack of robust evidence base for medicinal cannabis. Patients deserve reliable, safe, and consistent products. This requires well designed randomised controlled trials with larger sample sizes that determine the medical benefits and the effects of cannabis for the conditions the use of the regulatory regimes applied to other medicines[11,12,13].

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[2] World Health Organization. The Health and Social Effects of Nonmedical Cannabis Use. Geneva 2016.
[3] Elsohly MA, Slade D. Chemical constituents of marijuana. Life Sci. 2005; 78(5):539–548.
[4] Sachs J, McGlade E, Yurgelun-Todd D. Safety and toxicology of cannabinoids. Therapeutics. 2015 Oct; 12(4): 735-746.
[5] Macquarie Dictionary. 6th ed. Australia: MacQuarie Library Pty.Ltd; 2013.
[6] Caulkins JP et al. Marijuana Legislation: What Everyone Needs to Know. Oxford University Press 2012.
[7] The etymological origin from the Greek of 'therapeutic' includes 'healing' and 'curing'.
[8] The New Zealand Law Commission and the New Zealand Drug Foundation have argued for increased access to medicinal cannabis. Australia, the Netherlands, Canada, Germany, Ireland, Israel, and the USA (at state and federal level) all have varying laws and regulations in relation to medicinal cannabis use ranging from legalisation to complete prohibition of possession or use of cannabis unless used in approved research settings.
[9] United Nations Office on Drugs and Crime. World Drug Report 2009. 2009.
[10] Newton-Howes G, McBride S. Medicinal cannabis: moving the debate forward. NZMJ. 2016 Nov.129;1445.
[11] Martin JH, Bonomo Y, Reynolds A. Compassion and evidence in prescribing cannabinoids: a perspective from the Royal Australasian College of Physicians. Med J Aust. 2018; 208(3): 107-109.
[12] RACP Submission on the Inquiry into Regulator of Medicinal Cannabis Bill 2014. 16 March 2015.
[13] RACP Submission to the Victorian Law Review Commission on Medicinal Cannabis. April 2015.

While medicinal cannabis shows potential for some patients, further research is needed to determine its efficacy. It should be subject to the same scrutiny as any other medicine. Further high-quality research and well conducted clinical trials are required to expand and recognise a range of conditions where careful use of therapeutic cannabinoids can improve outcomes as well as determine product safety and suitability.

RACP Comments on the Bill

Lack of quality cannabis research

There is a lack of a robust evidence base for the efficacy of cannabis and cannabinoid agents in alleviating symptoms or treating disease[14]. Many of the case studies cited for the efficacy of medicinal cannabis are of limited use because they are low in the evidentiary hierarchy. They rely on case studies, make claims arising from small patient cohorts, and lack controls and methodological rigour[15]. Some otherwise promising studies that have been conducted are of limited use because they were conducted on animals or cell lines, and not humans[16].

There is also a wide variety in the type of medicinal cannabis used in reported studies[17]. Few research trials have been conducted under close medical supervision using medicinal cannabis of a known constituency, with double-blind techniques or effective placebo-controls[18].

Further high-quality research and well designed and conducted clinical trials are required to expand and recognise a range of conditions where careful use of therapeutic cannabinoids can improve outcomes as well as determine product safety and suitability. Deficits need to be addressed in current or future research before cannabis is used for medicinal purposes. Clinical trials are currently underway in NSW in relation to epilepsy, palliative care, and chemotherapy induced nausea. Adult clinical trials are in the pilot phase, with the aim to include more patients in the definitive stage in 2018, depending on results. No published data has been released to date[19].

Patient safety will always be paramount and there is a need first to determine who will benefit most from cannabis, as opposed to those who will benefit more from other types of treatment. It is important that clinical trials, research, and consultation continue. If used then it is important that medicinal cannabis is administered in the safest way possible for the patient.

While medicinal cannabis shows some potential for certain patients, further research is required to determine its efficacy. It should be subject to the same scrutiny as any other medicine.

Patient Safety

Under the Bill terminally ill people will be using an unregulated supply of cannabis that has been obtained on the black market. The regulation clauses in the Bill only apply to CBD products. Users of medicinal cannabis will therefore still not be able to ensure the safety of the supply of the cannabis that they are using. Black market cannabis is often mixed with other substances that could be harmful to the person using it. The lack of regulation also means that the potential for significant batch to batch variation CBD concentration and potential product impurities. There is a clear lack of a safe or reliably consistent supply for terminally ill people.

There are also risks involved for the terminally ill person in self-administration. The terminally ill person will not have the knowledge or ability to safely determine the appropriate amount of cannabis for their illness.

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[14] KA Belendiuk, LL Baldini, M Bonn-Miller. Narrative review of the safety and efficacy of marijuana for the treatment of commonly state-approved medicinal and psychiatric disorders. Addiction science and Clinical Practice. 2015; 10(10): 6.
[15] Victorian Law Reform Commission. Medicinal Cannabis Report. August 2015. Melbourne.
[16] Ibid.
[17] Ibid.
[18] Ibid.
[19] NSW Government Centre for Medicinal Cannabis Research and Innovation [Website].

Associated risks/ adverse effects

The RACP recognises the range of health issues associated with short and long-term cannabis use. Recent use is associated with impairment of executive function including memory, and heavy use may be associated with deficits in decision making and concept formation that may not change when use is stopped. New Zealand surveys suggest that there is a 1.4% prevalence of abuse and dependence related to illicit use of cannabis[20].

Short term use of cannabis is associated with impaired short-term memory, impaired motor coordination, altered judgment, and paranoia and psychosis at high doses[21]. Vascular conditions are also associated with cannabis use, including myocardial infarction, stroke, and transient ischemic attack[22,23,24]. Long-term or heavy use of cannabis is associated with chronic bronchitis and an increased risk of chronic psychosis-related health disorders[25,26,27]. There is evidence of an association between cannabis use and acute and chronic mental illness and psychiatric conditions including depression, anxiety, psychosis, bipolar disorder, schizophrenia, and an amotivational state[28,29]. Cannabis may exacerbate pre-existing symptoms of psychosis and schizophrenia[30].

A number of studies have shown a relationship between cannabis use in adolescence and the risk of developing psychotic symptoms. Daily cannabis use in adolescence is associated with a range of negative outcomes including leaving school early, cognitive impairment, increased use of other drugs, depression, and suicidal ideation[31]. This is of particular importance in this case as the Bill does not have any age restrictions in relation to who can use the defence.

Smoking is one of the main ways that cannabis is used[32]. Hash (cannabis resin) can be mixed with tobacco and smoked as a cigarette or joint, or smoked in a pipe with tobacco. Hash oil may be applied to a cigarette or joint. Cannabis smoking could cause cancers in the aerodigestive tract (mouth, tongue, and oesophagus) and lungs[33]. Effects of regularly smoking cannabis are associated with symptoms of bronchitis and inflammation[34]. There is evidence that chronic cannabis use leads to an increased risk of chronic bronchitis,[35] increased risk of

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[20] Wells JE, Browne MA, Scott KM et al. Prevalence, interference with life and severity of 12 month DSM-IV disorders in Te Rau Hinengaro: the New Zealand Mental Health Survey. Australian and New Zealand Journal of Psychiatry. 2006 Oct;40(10):845-54.

[21] Gage SH, Hickman M, Zammit S. Association between cannabis and psychosis: epidemiologic evidence from a U.S national longitudinal study. JAMA psychiatry. 2016; 73:388-395.

[22] Hackam DG. Cannabis and stroke: systematic appraisal of case reports. Stroke. 2015; 46:852–856.

[23] Barber PA, Roberts S, Spriggs DA, et al. Adverse cardiovascular, cerebrovascular, and peripheral vascular effects of marijuana: what cardiologists need to know. Am J Cardiol. 2014;113:1086.

[24] Barber PA, Pridmore HM, Krishnamurthy V, Et al. Cannabis, ischemic stroke, and transient ischemic attack: a case-control study. Stroke. 2013; 44:2327-2329.

[25] Joshi M, Joshi A, Bartter T. Marijuana and lung diseases. Curr Opin Pulm Med. 2014; 20:173-179.

[26] Blanco C, Hasin DS, Wall MM, et al. Cannabis use and risk of psychiatric disorders: prospective evidence from a U.S. national longitudinal study. JAMA Psychiatry. 2016; 73: 388-395.

[27] De Graaf R, Randovanovic M, Van Laar M, et al. Early cannabis use and estimated risk of later onset of depression spells: Wpidemiologic evidence from the population-based World Health Organisation World Mental Health Survey Initiative. Am J Epidemiol. 2010; 172: 149-159.

[28] Volkow ND, Baler RD, Compton WM, Weiss SR. Adverse health effects of marijuana use. N Engl J Med. 2014;370:2219–2227.

[29] Reece AS. Chronic toxicology of cannabis. J Clin Toxicol. 2009;47:517–524.

[30] Van der Meer FJ, Velthorst E, J Meijer C, WJ Machielsen M, de Haan L. Cannabis use in patients at clinical high risk of psychosis: impact on prodromal symptoms and transition to psychosis. Curr Pharm Des. 2012;18:5036-5044.

[31] Hall W, Renstrom M, Poznyak V. eds. The Health and Social Effects of Nonmedical Cannabis Use: the State of Knowledge: Knowns and Unknowns. Geneva: World Health Organisation; 2016.

[32] Sachs J, McGlade E, Yurgelun-Todd D. Safety and Toxicology of Cannabinoids, Neurotherapeutics. 2015 Oct. 12(4) 735-746.

[33] Hall W, MacDonald C, Currow D. Cannabinoids and cancer: causation, remediation, and palliation. Lancet Oncol. 2005 Jan;6(1):35-42.

[34] Hall W, Derenhardt L. Adverse health effects of non-medical cannabis use. Lancet. 2009; 374(9698):1384-91.

[35] Tashkin DP. Effects of marijuana smoking on the lung. Ann Am Thorac Soc. 2013 Jun; 10(3): 239-47.

emphysema,[36] chronic respiratory inflammation,[37,38] and impaired respiratory function[39,40]. With no regulation, users of cannabis would not be able to get advice on dosage and safer methods of use, including as a vaporiser or in a tea[41].

All medicines come with some risk of toxicity and adverse side effects. A medicine may be toxic but justified due to being necessary to treat a condition. However, it is concerning that in the case of cannabis, the risks are not well enough studied or known for a safe assessment to be made as to its patient benefits[42]. There are few studies on the side effects of medicinal cannabis, including the non-smokable forms[43]. Most of what is known about the adverse effects of cannabis comes from studies of recreational users[44]. Risks should not be disregarded simply because a person is terminally ill or approaching the end of their life.

Relationship to smoke-free campaigns and legislation

The Bill allows the defence to be used for any use of cannabis in any form by a terminally ill person who has the required certificate. This will likely include loose-leaf cannabis through smoking as it is a popular method of using cannabis. The alignment of this Bill with smoke-free health campaigns or legislation and the dangerous effects of smoking should therefore be considered.

A goal of the Smoke-Free Environments Act 1990 is to restrict minors' access to smoking products. The alignment between that goal and this Bill will need to be addressed, especially if terminally ill children smoke cannabis in a communal setting around other children who could be exposed to second-hand smoke, for instance in a hospice or hospital.

Use by youth/minors

There appears to be no age limit to use the defence in the Bill. The RACP have concerns about the effect of cannabis use on children who have had a prognosis of terminal illness, and whose brains are still developing. Children may attempt to use cannabis in hospital or hospice settings, which would in turn affect other children or patients around them.

Defence only

The Bill offers a legal defence for cannabis use if the person has been diagnosed as terminally ill. This means that police may still confiscate a terminally ill person's medicinal cannabis. The terminally ill person may still be detained, charged, and prosecuted, depending on the circumstances and how the defence is applied by the courts. The person would have a defence in court, but they could still be subjected to police search and prosecution. Such a situation could be emotionally traumatic for the person and their whānau, particularly when they are going through an already emotionally difficult terminal illness.

No protection for third parties

There is no protection for third parties who may get the drug for the terminally ill person. Terminally ill people do not necessarily have the physical capacity to source and collect illegal cannabis themselves and some would likely need help from friends, whānau, or family members.

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[36] Reese AS. Chronic toxicology of cannabis. Clin Todicol (Phila). 2009 Jul; 47(6):517-24.
[37] Ibid.
[38] Kalant H. Adverse effects of cannabis on health: an update of the literature since 1996. Prog Neuropsychopharmacol Biol Psychiatry. 2004 Aug;28(5):849-63.
[39] Hall W, Derenhardt L. Adverse health effects of non-medical cannabis use. Lancet. 2009; 374(9698):1384-91.
[40] Hall W. The adverse health effects of cannabis use: What are they, and what are their implications for policy? Int J Drug Policy. 2009 Nov;20(6):458-66.
[41] Pledger MJ, Martin G, Cumming J. New Zealand health survey 2012/13: characteristics of medicinal cannabis users. 2016 April 22; 129 (1433).
[42] Victorian Law Reform Commission. Medicinal Cannabis Report. August 2015.
[43] Ibid.
[44] Volkow ND, Baler RD, Compton WM, et al. Adverse health effects of marijuana use. N Engl J Med. 2014;370:2219–2227.

Inconsistent qualifications for use of defence

The Bill uses inconsistent terminology. Sections 5 and 6 of the Bill both refer to the need for the defendant to have been diagnosed by a medical practitioner or nurse practitioner as having a terminal illness. Section 5 refers to the need for there to be a diagnosis and then refers to the need for a certificate from a medical practitioner or nurse practitioner certifying that the person has a terminal illness.

It is unclear whether, in order to use the defence, the defendant in all cases will need to hold a certificate certifying that they have a terminal illness, or whether in relation to cannabis utensil possession they do not need a certificate but for use of cannabis they will need one. More clarification is needed on this issue.

Lack of detail surrounding medicinal cannabis scheme

In their first reading of the Bill the Government proposed a medicinal cannabis "scheme" that will be reported on in March 2018. There has been insufficient detail provided as to what that scheme will involve and the Bill is disappointingly silent on the scheme. It is difficult to comment in detail on the Bill due to lack of clarification about what the medicinal cannabis scheme will entail.

Prognosis of Terminal Illness

12-month time span

Being confident of a 12-month time span on an individual basis is very difficult. Prognostication is generally a variable skill not only affected by patient factors but also level of clinician experience, duration of relationship with the person, and whether it is done by an individual or a multidisciplinary team. It is based on statistical data which will only apply on average. Therefore, if a certain group of patients have a 12-month expectation of life, a significant proportion will die before this time and a significant proportion afterwards. Studies are also heterogeneous[45].

Diseases differ in their course. For instance, in many cases cancer is a predictable cause of death, but different types of cancer run different courses. Some cancers often have an aggressive course with poor predicted survival, whilst other cancers have a slower course. Although most studies have been in the cancer population, there are studies in the non-cancer population where forecasting is even more inaccurate. The trajectory for diseases like dementia or Parkinson's disease may be extremely unpredictable. Therefore, being confident of a 12-month time span is difficult, and accurate forecasting almost impossible[46].

Nurse Practitioner's role

The RACP strongly recommends that nurse practitioners should not prognosticate in relation to terminal illness, as it is not part of training or expected curriculum. The role of the nurse practitioner in relation to the proposed defence needs to be clearly defined.

Access in prison, hospitals, or hospice / acute care settings

There are both legal and ethical considerations that would need to be addressed if cannabis were to be used in acute care setting such as hospitals, hospices, and prisons where terminally ill people may reside. Many such institutions have internal policies prohibiting drug use or smoking on facility grounds, regardless of the reason for the use. This would restrict access to cannabis for some people. Inpatient use of medicinal cannabis would also carry health or legal implications for nursing and medical staff members as well as fellow patients.

Fairness

Those who are not able to get a certification or diagnosis that they are terminally ill, but who still may benefit from using medicinal cannabis, cannot use the defence. This includes people living with a range of long term conditions, people undergoing chemotherapy, people living with chronic pain, and those living with traumatic brain injuries.

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[45] White N, Reid F, Harris A, Harries P, Stone P. A systematic review of predictions of survival in palliative care: How accurate are clinicians and who are the experts? PLoS one 2016; 11(8):e0161407.
[46] Ibid.

Use unspecified

There is no condition in the Bill that the cannabis possessed or used by the person is for a medical and/or therapeutic purpose, for instance appetite stimulation or pain management.

Diagnosis and prognosis

The Bill uses the term “diagnosis” of the terminal illness by the nurse practitioner or medical practitioner. The term “diagnosis” is typically used for the identification of a condition. The correct terminology is “prognosis” when used in relation to a prediction of the course and outcome of a condition. Members may wish to recommend that the terminology is changed.

Summary

- This submission is the view of the RACP. It recognises that opposing views are held within the medical profession and in the community on the issues of medicinal use of cannabis.
- The RACP is concerned about the lack of robust evidence base for medicinal cannabis and lack of a safe or reliably consistent supply for terminally ill people if they are allowed a defence under the Bill.
- The RACP are concerned about the safety of vulnerable patients if the use of unregulated black-market cannabis is allowed through the Bill.
- The RACP are concerned about the lack of detail contained in the Bill, in particular in relation to the medical cannabis scheme.
- The RACP supports the need for further high-quality research and well designed and conducted clinical trials. These are needed to recognise the range of conditions where careful use of therapeutic cannabinoids can improve outcomes, and to determine product safety and suitability.

The RACP thanks the Health Select Committee for the opportunity to provide feedback on this Bill. The RACP would like to present in person to the Health Select Committee. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Yours sincerely

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