

Submission to the Health Select Committee on the Misuse of Drugs (Medicinal Cannabis and other matters) Amendment Bill

March, 2018

*To serve the community by fostering safety
and high quality patient care in anaesthesia,
perioperative medicine and pain medicine.*



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1. Executive Summary

The Misuse of Drugs (Medicinal Cannabis) Amendment Bill was introduced to the New Zealand Parliament on 20 December 2017. It passed its first reading on 30 January 2018 and is now being considered by the Health Select Committee. The Bill introduces an exception and statutory defence for terminally ill people to possess and use illicit cannabis and to possess a cannabis utensil. It also enables the setting of standards that products manufactured, imported and supplied under licence must meet, and it amends Schedule 2 of the Act so that cannabidiol products are no longer classed as controlled drugs.

The issue of medicinal cannabis is particularly relevant to anaesthetists and specialist pain medicine physicians who are working with patients suffering acute and chronic pain daily. The Australian and New Zealand College of Anaesthetists (ANZCA) and the Faculty of Pain Medicine (FPM) have been involved in the Australian medicinal cannabis debate at state and federal government level for some time. In that jurisdiction, despite moves to make medicinal cannabis more available, no concrete evidence exists to support opinion regarding its efficacy in the management of chronic non-cancer pain.

Key points from ANZCA's and FPM's position on medicinal cannabis, with particular reference to its use in the management of patients with chronic non-cancer pain, are as follows:

- ANZCA and FPM do not take a stance on the issue of decriminalisation of personal use of cannabis preparations.
- There is little evidence for the efficacy of cannabinoids in chronic non-cancer pain situations.
- ANZCA and FPM do not recognise a need for greater availability of medicines in general and in particular do not endorse the use of cannabinoids in chronic non-cancer pain until such time as a clear evidence-based therapeutic role for them is identified in properly conducted and reported research studies.
- Substances intended for therapeutic purposes should be fully characterised chemically, pharmacologically and toxicologically.
- ANZCA and FPM are concerned about the adverse effect profile in cannabis users, including impaired respiratory function, psychotic symptoms and disorders, and cognitive impairment, particularly in the developing (including adolescent and young adult) brain.

Further information is available in *PM10 Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain*, here:

<http://fpm.anzca.edu.au/resources/professional-documents>

Overall, ANZCA and FPM consider that calls for the availability of cannabis-based products to treat chronic pain demonstrate that there is significant unmet need for pain management-related healthcare in the community. There is a lack of access to multidisciplinary pain medicine clinics that can work with patients to manage the multi-faceted biological, psychological, and socio-environmental contributors to chronic pain. New Zealand would benefit from a national pain plan to encourage education of the health workforce and community, and facilitate multidisciplinary care and active self-management at all levels of the healthcare system. Any research investigating the use of cannabinoids, and any legislation governing access to cannabis and cannabis-based products, needs to be considered in this broader context.

With respect to the broader unmet need for access to quality chronic pain management services, the debate around access to cannabis is highlighting a more pressing issue. In the view of ANZCA and FPM it needs to be clearly understood that cannabis access for the purposes of managing chronic non-cancer pain would represent no meaningful advance in pain management for the New Zealand community.

Feedback on specific clauses of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill are provided in section four, below.

2. About ANZCA

The Australian and New Zealand College of Anaesthetists (ANZCA) is the professional organisation for specialist anaesthetists (fellows) and specialist anaesthetists in training (trainees) in New Zealand and Australia.

ANZCA was formed in 1992 following 40 years as a faculty of anaesthetists of the Royal Australasian College of Surgeons. ANZCA is now a world-renowned institution in anaesthesia and pain medicine that has taken a leading role in many areas of anaesthesia, pain medicine and intensive care medicine. These include:

- Being recognised as a world leader in the treatment of pain by establishing the specialty of pain medicine through its Faculty of Pain Medicine (FPM).
- Setting high professional standards for patient safety through professional documents and other advocacy activities.
- Answering key questions in medical research by recruiting more than 30,000 patients to help with \$A25 million worth of studies for the ANZCA Clinical Trials Network and other research through the ANZCA Research Foundation, which in 2018 alone is funding research worth \$1.7 million.
- Training highly skilled future fellows in anaesthesia and pain medicine.
- Hosting more than 30 medical education events annually including the College's flagship event, the ANZCA Annual Scientific Meeting.
- Supporting anaesthesia in developing nations such as Papua New Guinea with clinical and educational visits, and the seeding of the Essential Pain Management program now being taught in 53 countries.
- Establishing intensive care medicine as a specialty by instituting training and accreditation programs through a joint Faculty of Intensive Care, and then by helping found the College of Intensive Care Medicine of Australia and New Zealand.

ANZCA, including FPM, is committed to high standards of clinical practice in the fields of anaesthesia, perioperative medicine and pain medicine. As the education and training body responsible for the postgraduate training programs of anaesthesia and pain medicine for Australia, New Zealand and parts of Asia, the College believes in ongoing continuous improvement and strives to ensure that its programs represent best practice and contribute to a high quality health system.

ANZCA's mission is to serve the community by fostering safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine.

ANZCA fellows and trainees

At December 31, 2017 there were 721 active and 86 retired fellows, and 244 trainees in New Zealand, and 5302 fellows (of whom 667 are retired) and 1268 trainees in Australia.

3. About FPM

The Faculty of Pain Medicine (FPM) is the professional organisation for specialist pain medicine physicians (fellows) and specialist pain medicine physicians in training (trainees).

The Faculty is responsible for the training, examination and specialist accreditation of specialist pain medicine physicians and for the standards of clinical practice for pain medicine in New Zealand and Australia. Formed in 1998, the Faculty is the first multidisciplinary medical academy in the world to be devoted to education and training in pain medicine. Although part of ANZCA, the Faculty's fellowship and representation remains multidisciplinary at all levels. It arose out of collaboration between five participating bodies – ANZCA, the Royal Australasian College of Physicians (RACP), the Royal Australasian College of Surgeons (RACS), the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and the Australasian Faculty of Rehabilitation Medicine (AFRM) of the RACP.

In 2005, the discipline was recognised in Australia as a medical specialty in its own right, and in New Zealand, the Medical Council accredited pain medicine as a scope of practice in 2012. This recognises the importance of the problem of unrelieved pain in the community and the need for a comprehensive medical response through education, training and practice.

The field of pain medicine recognises that the management of severe pain problems requires the skills of more than one medical craft group. Such problems include:

- Acute pain (post-operative, post-trauma, acute episodes of pain in "medical conditions").
- Cancer pain (pain directly due to tumour invasion or compression, pain related to diagnostic or therapeutic procedures, pain due to cancer treatment).
- Persistent (chronic) pain (including over 200 conditions described in the International Association for the Study of Pain (IASP) *Taxonomy of Chronic Pain 2nd Edition*, such as phantom limb pain, post-herpetic neuralgia, mechanical low back pain). In New Zealand, chronic pain affects more than one in five adults (21%).

In New Zealand and Australia, a career in pain medicine is generally obtained by qualifying as a Fellow of the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FFPMANZCA). Pain specialist training is also open to vocationally registered general practitioners and other specialists.

Fellows of FPM have a wide knowledge of the clinical, socio-psycho-biomedical and humanitarian aspects of pain and are well placed to follow a developing and challenging career path.

In 2016, world recognition for the Faculty was achieved through the awarding of the 2017 American Academy of Pain Medicine's (AAPM) Robert G. Addison, MD Award given in recognition of outstanding efforts to foster international co-operation and collaboration on behalf of the specialty of pain medicine. The European Pain Federation of the International Association for the Study of Pain, consisting of pain chapters from 37 countries, is now also using FPM's revised curriculum as the basis for its diploma.

FPM fellows and trainees

At December 31, 2017 there were 34 active (one retired) FPM fellows and nine FPM trainees in New Zealand. In Australia there are 340 FPM fellows (of whom 24 are retired) and 64 FPM trainees.

4. ANZCA response to the Misuse of Drugs (Medicinal Cannabis) Amendment Bill

The Misuse of Drugs (Medicinal Cannabis) Amendment Bill was introduced to the New Zealand Parliament on 20 December 2017. It passed its first reading on 30 January 2018 and is now being considered by the Health Select Committee. The Bill introduces an exception and statutory defence for terminally ill people to possess and use illicit cannabis, and to possess a cannabis utensil. It also enables the setting of standards that products manufactured, imported and supplied under licence must meet, and amends Schedule 2 of the Act so that cannabidiol products are no longer classed as controlled drugs.

The Health Select Committee has invited public submissions to the Misuse of Drugs (Medicinal Cannabis) Amendment Bill and ANZCA and FPM have prepared a response which outlines its general position on medicinal cannabis products for use in chronic pain, as well as addresses key issues raised by specific sections and clauses of the proposed Bill. For each of these issues, the relevant section of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill is presented below followed by ANZCA's/FPM's comments.

The issue of medicinal cannabis is relevant to anaesthetists and specialist pain medicine physicians, who are working with patients suffering acute and chronic pain daily.

4.1 ANZCA and FPM position on medicinal cannabis for use in chronic non-cancer pain

ANZCA and FPM do not take a stance on the issue of decriminalisation of personal use of cannabis preparations. However, ANZCA and FPM do have a position on medicinal cannabis with reference to its use in treating patients with chronic non-cancer pain. Chronic pain causes a significant burden of disease in New Zealand, affecting more than one in five adults (21%).

Public interest in making medicinal cannabis available for patients with chronic pain clearly signals the unmet need which exists in New Zealand, in terms of accessing appropriate services and treatments for managing persistent pain. The New Zealand public would benefit from a national pain management plan that encourages education of the health workforce and community in the management of chronic pain, supports the training of pain medicine specialists, and facilitates multidisciplinary care and active self-management at all levels of the healthcare system.

Scientific evidence shows that, at best, there is marginal clinical benefit for cannabis-based products in the management of chronic pain. Calls for the liberalisation of the availability of cannabis-based products are based more on anecdote than on sound clinical science and practice. ANZCA and FPM do not endorse the use of cannabis-based products in chronic non-cancer pain until such time as a clear evidence-based therapeutic role for such agents is identified in the scientific literature. Furthermore, ANZCA and FPM do not consider there is a need for greater availability of medicines in general for the treatment of chronic pain.

Chronic pain is a multi-faceted biological, psychological and socio-environmental experience, with the most complex cases requiring treatment from multidisciplinary teams including specialist pain medicine physicians, psychiatrists, physiotherapists, occupational therapists, nursing, and other health practitioner groups. Unimodal treatments, such as medication alone, are only a small component of treatment options. It is the exception to find a simple pharmacological solution to persistent pain and it is unreasonable to raise that expectation in the community. A necessary component of quality pain management is explaining to patients that medicines alone are not a panacea with respect to persistent pain therapy. This can be challenging, but is necessary, and runs in parallel to mitigating the frequent harm associated with poorly managed pharmacological interventions. Mitigation of significant health harms associated with what is often referred to as the "opioid epidemic" is closely related to this aspect of good pain management.

At this time, ANZCA and FPM consider medicinal cannabinoids should only be considered for patients with chronic non-cancer pain in the setting of a research programme. FPM intends to collaborate with professional organisations and consumer groups to develop a research strategy to further investigate the role of cannabinoids in chronic non-cancer pain.

ANZCA and FPM have been involved in the medicinal cannabis debate at state and federal government level for some time in Australia. Despite moves there to make medicinal cannabis more available, there still has been no concrete evidence on its efficacy for chronic non-cancer pain. This has strengthened the College's and the Faculty's position that quality pain management delivered via multidisciplinary teams is crucial to a more efficient health system that deals with the chronic pain burden in New Zealand.

ANZCA and FPM note that the Therapeutic Goods Administration (TGA) in Australia has comprehensively reviewed the use of medicinal cannabis for a number of conditions, and notes that medicinal cannabis is not considered a first-line therapy for any indication. Recommendations from its guidance for use of medicinal cannabis in the treatment of chronic non-cancer pain include that:

- The use of medications, including medicinal cannabis, is not the core component of therapy for chronic non-cancer pain.
- There is a need for larger trials of sufficient quality, size and duration to examine the safety and efficacy of medicinal cannabis for use in chronic non-cancer pain.

Further information from the TGA is available here: <https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-treatment-chronic-non-cancer-pain-australia>

4.2 Possession and use of controlled drugs

Part 5:	Section 7 amended (Possession and use of controlled drugs)
(1)	In section 7(2), replace "subsection (3)" with "subsections (2A) and (3)".
(2)	After section 7(2), insert: (2A) A person who contravenes subsection (1)(a) does not commit an offence if the person— (a) procures, possesses, consumes, smokes, or otherwise uses any plant or plant material of the genus <i>Cannabis</i> , any cannabis preparation, or any cannabis fruit or seed; but (b) has a certificate from a medical practitioner or nurse practitioner certifying that the person has a terminal illness.
(3)	After section 7(3), insert: (3A) In any proceedings for an offence against subsection (1)(a) in respect of possessing or using any plant or plant material of the genus <i>Cannabis</i> , any cannabis preparation, or any cannabis fruit or seed, the defendant may provide evidence that, at the time of the possession or use, the defendant had been diagnosed by a medical practitioner or nurse practitioner as having a terminal illness.
(4)	In section 7(4), replace "subsection (3)" with "subsections (3) or (3A) ".
(5)	After section 7(4), insert:

ANZCA comment:

ANZCA and FPM support that the exception and statutory defence for possession and use of illicit cannabis only applies to those with a terminal illness (defined in the legislation as an illness from which a person is reasonably expected to die within 12 months), and is not extended to those who suffer from chronic non-cancer pain. At this time, ANZCA's and FPM's position is that cannabis is not appropriate for the treatment of chronic pain. This is due to a lack of evidence for efficacy, and the adverse event profile in cannabis users, including (but not limited to) impaired respiratory function, psychotic symptoms and disorders, and cognitive impairment, particularly in the developing brain. Patients who experience chronic pain are at high

risk of comorbidities such as mental health issues and addiction, and are potentially more vulnerable to adverse effects. Extending the exception and statutory defence to those in chronic pain would exacerbate this risk and the burden of disease, without alleviating chronic pain.

ANZCA and FPM also support that this section of the Bill limits the role of the medical practitioner to diagnosing and certifying a terminal illness. It would be inappropriate to require medical practitioners to function in an authorising capacity for the use of plant (leaf) cannabis, whether this was legal or illicit.

4.3 Miscellaneous offences

Part 6: Section 13 amended (Miscellaneous offences)

After section 13(1), insert:

(1A) However, in any proceedings for an offence against subsection (1)(a) of possessing a pipe or other utensil (not being a needle or syringe) for the purpose of possessing or using any plant or plant material of the genus *Cannabis*, any cannabis preparation, or any cannabis fruit or seed, the defendant may provide evidence that, at the time of possessing the pipe or other utensil, the defendant had been diagnosed by a medical practitioner or nurse practitioner as having a terminal illness.

ANZCA comment:

As discussed above, ANZCA and FPM consider it appropriate that this section is only extended to those diagnosed by a medical practitioner or nurse practitioner as having a terminal illness.

4.4 Licences

Part 7: Section 14 amended (Licences)

After section 14(1), insert:

(1A) Without limiting subsection (1), the Governor-General may, by Order in Council on the recommendation of the Minister, make regulations to prescribe the minimum quality standard that must be met by a product or class of product—

- (a) that contains a controlled drug; and
- (b) that may be manufactured, imported, or supplied under a licence granted under this Act.

ANZCA comment:

ANZCA and FPM support the legislative (rather than voluntary) approach to ensuring medicinal cannabis products meet a minimum quality standard, and consider all cannabis-based products should be regulated in a manner consistent with other medicines, in the interests of ensuring safety and quality for patients.

ANZCA and FPM note that the definition of products that minimum standards can be set for includes products “that contains a controlled drug” and “may be manufactured, imported or supplied under a licence granted under this Act”. However, the amendment bill also proposes to deschedule cannabidiol products so that they are no longer controlled drugs. Will cannabidiol products be exempt from this clause, once cannabidiol products are descheduled and are no longer controlled drugs? ANZCA and FPM consider that regulations to prescribe minimum quality standards for cannabidiol containing products must still be

required even if cannabidiol products are descheduled. ANZCA and FPM also note that PHARMAC has previously declined to fund cannabidiol due to lack of evidence of its efficacy.

4.5 Review of certain provisions

Part 35E:	Review and report on operation of section 7(2A) and (3A)
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- (1) The Minister must, not later than 2 years after the commencement of this section, require the Ministry of Health—
- (a) to commence a review of the operation of section 7(2A) and (3A) since the commencement of those subsections; and
 - (b) to prepare a report on the review for the Minister.
- (2) The review and report required under subsection (1) must be completed within 12 months of the review commencing.
- (3) As soon as practicable after receiving the report, the Minister must present a copy of it to the House of Representatives.
- (4) The report on the review must include recommendations to the Minister on—
- (a) the implementation of the exception and defence provided by section 7(2A) and (3A) for persons who are terminally ill; and
 - (b) whether any amendments to those provisions are necessary or desirable.

ANZCA comment:

ANZCA and the FPM support the proposed review and reporting requirements on the operation of section 7(2A) and (3A).

4.6 Revocations

Part 9:	Schedule 2 amended
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- (1) In Schedule 2, Part 1, clause 1,—
- (a) in the item relating to **Cannabis** preparations, after “material”, insert “, other than a CBD product”;
 - (b) in the item relating to **Tetrahydrocannabinols**, after “controlled drug”, insert “or a CBD product”.
- (2) In Schedule 2, Part 1, clause 2, after “clause 1”, insert “, other than cannabidiol (an isomer of tetrahydrocannabinol) and any other isomers of tetrahydrocannabinols when in a CBD product,”.

ANZCA comment:

ANZCA and the FPM consider it appropriate to amend Schedule 2 of the Act so that cannabidiol and cannabidiol products are no longer classed as controlled drugs. This is consistent with the position of the World Health Organisation Expert Committee on Drug Dependence, which last year stated that as “cannabidiol does not appear to have abuse potential or cause harm... current information...does not justify scheduling of the substance.”

More information is available here: <http://www.who.int/features/qa/cannabidiol/en/>

As discussed above, however, cannabidiol products should still be required to meet minimum quality standards under regulations.

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