Submission to Regulator of Medicinal Cannabis Bill 2014

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PalliativeCare
AUSTRALIA

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Introduction

Palliative Care Australia (PCA) is the national peak body established by the collective membership of eight state and territory palliative care organisations and the Australian and New Zealand Society of Palliative Medicine. Together PCA members network to foster, influence and promote local and national endeavours to realise the vision of quality care at the end-of-life for all.

PCA, the member organisations and the individuals endorsing this submission support the intent of the *Regulator of Medicinal Cannabis Bill 2014* (the Bill). Elements of the Bill set in place appropriate mechanisms to establish a scheme that enables safe access to medical cannabis for people who require it. These include:

- A register of regulated medicinal cannabis products that meets appropriate standards that is modelled on the Australian Register of Therapeutic Goods.
- That criminal sanctions may apply where medicinal cannabis is misused, where there is a contravention of the Bill or a contravention of conditions of a licence under the Bill.
- A licensing scheme which allows for and encourages research and development.
- The establishment of standards to specify the quality and quantity of medicinal cannabis and compliance with these characteristics.
- That the membership of the Regulator includes people with qualifications in palliative care, medicine and pharmacology.

These and other aspects of the Bill are important given cannabis is currently an illegal substance, and there are concerns with its use for non-medical purposes, particularly in relation to the psychoactive properties of cannabis.

Adopting the use of cannabis for medicinal purposes requires a strong regulatory and approvals process that involves research and building the medicinal cannabis evidence base. The regulation of medicines, including medical use of cannabis, should be a matter for technical experts determined on the basis of health, science and clinical evidence and not a political decision.

PCA, the member organisations and individuals endorsing this submission call for:

- Further research and evidence on the use and benefits of medicinal cannabis and derivatives.
- The Bill to provide details on key prescribing issues including adverse effects and the provision of product information.
- The Bill to provide details on the evidence that will be required by the Regulator for approved products.
- The Regulator to ensure prescribers in Australia become familiar with the evidence-based indications for using cannabis and the therapeutic regime appropriate to particular individuals and their symptoms.
- The Regulator considers in the first instance that only purified oral preparations of known potency are made available.
- Palliative care expertise to remain in the suggested composition of the Board of the Regulator.

- A role for the Regulator to register medications used in different states and territories to enable these medications to be transported or used across jurisdictions.
- The Regulator to consider guidelines for the use of medical cannabis that have been developed by medical bodies, including countries where mechanisms for the use of medical cannabis have been introduced.
- The Bill to clarify whether a person with previous convictions for cultivating or supplying cannabis can hold a licence to cultivate or manufacture medicinal cannabis under the Bill.

The use of medicinal cannabis in palliative care

The World Health Organization (WHO) defines palliative care as:[1]

> …an approach that improves the quality of life of patients and their families facing the problems associated with life threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

Palliative care:

- Provides relief from pain and other distressing symptoms.
- Affirms life and regards dying as a normal process.
- Intends neither to hasten nor postpone death.
- Is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy.
- Includes those investigations needed to better understand and manage distressing clinical complications.

PCA and its member organisations believe all people have the right to safe, compassionate and appropriate care as they approach the end of their lives. This principle should be applied to all end of life care. Pain and other distressing symptoms can have a debilitating effect on all aspects of a person's life – psychological, social, emotional and spiritual. Having safe medications available to all Australians is essential to providing quality end of life care.

A central issue is that pharmaceuticals based on cannabis are not licensed in Australia. PCA believes it is necessary for medicinal cannabis, if found to be safe and effective, to go through an approval process, as is established with the Regulator. The Bill proposes that the Regulator will be responsible for issuing licences and prescribing a scheme for research and experiments with medicinal cannabis. This is an important aspect of the proposed Regulator, as research into new therapies which can relieve pain and other symptoms and prevent unnecessary suffering at the end of life is a vital requirement.

[1] World Health Organisation, WHO definition of Palliative Care, 2008. http://www.who.int/cancer/palliative/definition/en/, Accessed 17 February 2015

Need for a strong evidence base

At present there is not comprehensive evidence to address questions such as who may benefit from medicinal cannabis and derivatives; if there are ongoing and long-term benefits from continued use; and what are the nature and impact of any adverse effects. With other medications, these are issues that would be addressed through post-trial and use information. Therefore the same processes should apply to the supply and use of medicinal cannabis to provide this evidence.

Medicinal cannabis is not the only measure available to provide comfort for people with a terminal illness. While there are many accounts in the medical and non-medical literature of the value of cannabis in symptom relief, there are also clinical trials that have found no superior benefit of cannabis over other available medications for symptoms such as nausea, pain or weight loss. PCA supports the availability of medicinal cannabis where it is a viable option for individual patients who have failed to receive adequate assistance from other therapies or where it is determined by treating medical professionals that medicinal cannabis is the most suitable evidence based therapy.

Building the clinical evidence base to demonstrate whether medicinal cannabis assists in alleviating pain and other distressing symptoms and improves the quality of life of people who are living with a chronic illness, in the terminal phase of a condition or approaching the end of life, would assist in addressing concerns related to its use for consumers, carers and health professionals. The Bill incorporates provisions for the Regulator to maintain a register of regulated products which meet 'appropriate standards and that all designated requirements are met'. Also, that the Bill will operate with medical practitioners who can apply to the Regulator on behalf of a patient or carer for whom they intend to prescribe medicinal cannabis. The Bill does not provide detail on key issues for prescribing which the Regulator will need to address in developing standards. These include:

- The adverse effects of medicinal cannabis and products, particularly for raw medications or cannabis.
- Protections for doctors if a patient has adverse effects from medicinal cannabis when prescribed according to the Regulator.
- The provision of product information for registered medicinal cannabis including prescribing information, adverse effects, trial evidence and any such information that would typically be provided with a medication.

When products are approved by the TGA a body of evidence is required, and this will need to be addressed for the Regulator through the Bill. There are currently no details about the Regulator providing this sort of information, how it will be considered in registering products and if suppliers will need to supply this evidence.

Prescribers in Australia have little experience with the use of medicinal cannabis, and it will be the function of the Regulator to ensure that they become familiar with the evidence-based indications for using cannabis and the therapeutic regime appropriate to particular individuals and their symptoms. PCA and its member organisations would be willing to offer its support of educational programmes to address this at the appropriate time.

Cannabis is taken in a variety of ways – by smoking, inhalation or ingestion - and the actual potency of the therapeutic agent is usually unclear. Although it is possible to envisage preparations of dried cannabis leaf being authorised for prescription by medical practitioners, it may be preferable that in the first instance, only purified oral preparations of known potency be made available by the Regulator. Condoning the use of inhaled cannabis through smoking would also be a retrograde step in terms of efforts to reduce and prevent smoking. This could help make clear a distinction between legally-prescribed therapies and illegal use.

The potential role of medicinal cannabis in palliative care could be significant and the inclusion of palliative care in the suggested composition of the Board of the Regulator in the draft Bill is important given that:

- Palliative care practitioners possess understanding and expertise relevant to the use of medicinal cannabis.
- The population served by and those who would benefit from palliative care is appropriate for having access to medicinal cannabis, through being vulnerable to symptoms for which medicinal cannabis has been shown to have medicinal value.

Strong medical representation on the Board will be important to ensure that issues such as who medicinal cannabis can be used by, impacts of long term use and the level of use will be addressed properly.

Medicinal cannabis clinical trials

Along with the Bill, there is a proposed medicinal cannabis trial being led by New South Wales and supported by the Commonwealth and other states and territories, and the Victorian Law Reform Commission review into the use of medicinal cannabis. Strong regulation and clinical evidence towards the use of medicinal cannabis is important, as would be the case for the use and approval of any medication.

With any of the trial processes or the implementation of this Bill, it is important the introduction of medicinal cannabis follows proper process. This would include formally building medicinal cannabis into a person's treatment plan in consultation with their treating medical professional, to take into account other medicines a person may be taking, possible inter-drug reactions and whether it is appropriate for the individual.

Sativex, the cannabis derived mouth spray, is currently undergoing phase three clinical trials in cancer patients with pain that is not completely relieved by pain medications including opioids like morphine. This trial is being conducted in Australia and a number of countries around the world, involving 300 patient participants. Phase-one and phase-two trials of Sativex in more than 400 cancer patients found preliminary data to suggest Sativex may be useful in difficult cancer pain with few side effects. At the current time, this trial is ongoing.[2]

The Bill states that the system established through the legislation is to be implemented cooperatively between the commonwealth and the states and territories, and that states and

[2] Personal communication 18 March 2015

territories are likely to change laws relating to cannabis if they wish to participate. There would be a role for the Regulator to register medications used in different states and territories to enable these medications to be transported or used across jurisdictions. This would address the situation of a doctor being able to prescribe medicinal cannabis for a trial in NSW, for example, which would not be permitted or seen as legal in another state.

Guidelines for the use of cannabis for medical purposes

Some medical bodies have developed guidelines for the use of medical cannabis, including countries where mechanisms for the use of medical cannabis have been introduced. These may be worth considering in the development of processes for the Regulator.

In Canada, the Health Canada *Marihuana for Medical Purposes Regulations* came into effect on 1 April 2014. This permits a physician to sign a medical document authorising a person's access to and the dispensing of a specified quantity of dried cannabis which a person purchases from a licenced producer. The College of Family Physicians of Canada developed the *Authorizing Dried Cannabis for Chronic Pain or Anxiety* to provide preliminary guidance based on what is currently known about the use of cannabis for certain medical purposes.[3]

The Canadian document provides a series of recommendations graded as level I (based on well-conducted controlled trials), level II (well-conducted observational studies), or level III (expert opinion). The recommendations provide guidance on patients for whom dried cannabis is not appropriate and patients where cannabis should be authorised with caution. Other areas covered include:

- Assessing and monitoring potential misuse.
- Conducting appropriate assessments for pain, anxiety and mood disorders, and substance use disorders.
- That a physician should regularly monitor the patient's response to treatment considering the patient's function and quality of life in addition to pain relief and should discontinue authorisation if the therapy is not clearly effective or is causing the patient harm.
- Physicians should specify the percentage of tetrahydrocannabinol (THC) on the medical document for all authorisations for dried cannabis, just as they would specify dosing when prescribing any other analgesic.[4]

This guidance is worthy of consideration for this Bill and in states and territories where trials and inquiries are proposed.

The current procedures for the supply of certain medications found to be of value in the management of terminal illness are a potential model for the way in which the Regulator may

[3] College of Family Physicians Canada, (2014) Authorizing Dried Cannabis for Chronic Pain or Anxiety, Preliminary Guidance
http://www.cfpc.ca/uploadedFiles/Resources/_PDFs/Authorizing%20Dried%20Cannabis%20for%20Chronic%20Pain%20or%20Anxiety.pdf
[4] Ibid

license practitioners to prescribe or dispense medicinal cannabis and authorise its use by selected patients. The existing authority system allows for:

- A patient to be authorised by an attending practitioner as requiring palliative care.
- Particular listed preparations to be prescribed by recognised specialists in palliative care.
- A monitoring of prescribing by individual practitioners.

Monitoring and investigative powers of the Regulator

PCA and the member organisations and the individuals endorsing this submission recognise that the Bill incorporates powers of entry, search and inspection of persons involved in the supply, prescription and use of medicinal cannabis, and accepts that prescribers and users of medicinal cannabis must accept such provisions.

Criminal sanctions apply in the Bill to anyone who misuses medicinal cannabis or contravenes the Bill or conditions of a licence under the Bill. There also needs to be clarity around whether a person with previous convictions around cultivating or supplying cannabis can hold a licence to cultivate or manufacture medicinal cannabis under this Bill.

The role of medicinal cannabis

In conclusion, PCA and the member organisations and individuals endorsing this submission believe there is a place for medicinal cannabis in medical treatments and palliative care for specific symptoms. There are patients and doctors who strongly stand by its use, however what is needed, as is the case for any medications, is a strong evidence base and not only anecdotal stories. Existing evidence and results are not conclusive and some results are conflicting. Well-designed clinical trials and comprehensive information would allow doctors to prescribe medicinal cannabis with confidence.

All people have the right to safe, compassionate and appropriate care as they approach the end of their lives, and this should be the principle applied when considering any medications that help people to achieve this. Adopting the use of cannabis for medicinal purposes requires a strong regulatory and approvals process that involves research and evidence, which would allow doctors to prescribe and patients to use medicinal cannabis with confidence.

The Bill which establishes a Regulator to register approved medicinal cannabis products; standards for products; a licencing scheme for cultivating or supplying medicinal cannabis; authorisation processes for access and use by doctors, patients and carers; and establishes rules for research, marks a point of progression for the evidence-based use of medicinal cannabis in Australia.

Key issues for consideration from this submission are:

- The need for further research and evidence on the use and benefits of medicinal cannabis and derivatives.
- The Bill needs to provide detail on key prescribing issues including side-effects and the provision of product information.
- The Bill needs to provide details on the evidence that will be required by the Regulator for approved products.

- It will be the function of the Regulator to ensure prescribers in Australia become familiar with the evidence-based indications for using cannabis and the therapeutic regime appropriate to particular individuals and their symptoms.
- It may be preferable in the first instance that only purified oral preparations of known potency are made available by the Regulator.
- The importance of including palliative care expertise in the suggested composition of the Board of the Regulator.
- A role for the Regulator to register medications used in different states and territories to enable these medications to be transported or used across jurisdictions.
- The Regulator consider guidelines for the use of medical cannabis that have been developed by medical bodies, including countries where mechanisms for the use of medical cannabis have been introduced.
- A recognition of the Bill's powers of entry, search and inspection of persons involved in the supply, prescription and use of medicinal cannabis, and that criminal sanctions apply to anyone who misuses medicinal cannabis or contravenes the Bill or conditions of a licence under the Bill.
- The need for the Bill to clarify whether a person with previous convictions for cultivating or supplying cannabis can hold a licence to cultivate or manufacture medicinal cannabis under the Bill.