ANZSPM

13 March 2015

Ms Sophie Dunstone
Committee Secretary
The Senate Legal and Constitutional Affairs Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

By email to legcon.sen@aph.gov.au

Inquiry into the Regulator of Medicinal Cannabis Bill 2014

Dear Ms Dunstone,

ANZSPM (The Australian and New Zealand Society of Palliative Medicine Inc.) is a specialty medical society that facilitates professional development and support for its members and promotes the practice of palliative medicine. Our members are medical practitioners who provide care for people with a life threatening illness.

We are grateful for this opportunity to address the current Senate Inquiry into Palliative Care in Australia, and our submission, which has been approved by our President, Associate Professor Mark Boughey, and the ANZSPM Council, is attached.

Any inquiries in relation to this submission can be directed to Ms Marita Linkson,

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Executive Officer

ANZSPM

The Australian and New Zealand Society of Palliative Medicine Incorporated

ABN 54 931 717 498

Submission to

THE SENATE LEGAL AND CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE INQUIRY INTO THE

Regulator of Medicinal Cannabis Bill 2014

Authorised by Assoc. Prof. Mark Boughey, ANZSPM and the ANZSPM Council

March 2015

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About ANZSPM

The Australian and New Zealand Society of Palliative Medicine (ANZSPM) is a not-for-profit specialty medical society for medical practitioners who provide care for people with a life threatening illness.

ANZSPM facilitates professional development and support for its members, promotes the practice of Palliative Medicine and advocates for those who work in the field of palliative medicine.

ANZSPM is managed by a Council of members, which includes representation from New Zealand and also from the Australasian Chapter of Palliative Medicine. ANZSPM's day to day operations are managed by a part-time Executive Officer.

Our members are medical practitioners involved in caring for people with a life threatening illness – palliative medicine specialists, palliative medicine trainees, and other medical practitioners with an interest in palliative medicine.

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Executive Summary

Current research into cannabinoids is promising future delivery of enhanced symptom control and associated benefit to palliative care patients. Support is growing for access to Medicinal Cannabis for control of problematic symptoms such as nausea, seizures and pain. ANZSPM supports such research and the Regulator of Medicinal Cannabis Bill 2014 may assist in ensuring Australians are included in such studies.

ANZSPM believes it is important that the wider implications of the Bill are fully considered, with patient safety paramount. ANZSPM supports an evidence based approach to the use of medicinal cannabis as a pharmaceutical grade refined product with control mechanisms congruent with that of other medicinal drugs, administered via the Therapeutic Goods Association.

ANZSPM makes the following recommendations:

Recommendation 1. With patient safety paramount, Medicinal Cannabis use should be evidence-based and as a prescribed medication, regulators should establish the use of pharmaceutical quality products only, which are managed in the same way as other prescribed medications, via the existing mechanisms established by the Therapeutic Goods Act 1989.

Recommendation 2. That there is legislation to support research into the use of medicinal cannabis in controlled situations, such as Medicinal Cannabis trials, to allow palliative medicine practitioners to assess the medications for terminally ill patients and be better placed to provide guidance on future use of these drugs.

Recommendation 3. That the Inquiry Committee recognises that the full implications of the Bill will not be known for some time after implementation and that broader issues around licensing, use and access controls for medicinal cannabis need to be considered in any legislative change.

Recommendation 4. That if this Bill is passed, that ANZSPM is consulted to assist in developing guidelines for the use of medicinal cannabis.

Introduction

The Australian and New Zealand Society of Palliative Medicine Incorporated (ANZSPM), represents doctors working in Palliative Medicine in Australia and New Zealand.

Palliative Medicine doctors care for patients with life-limiting illnesses, and their families. The central expertise of doctors working in Palliative Medicine is the control of difficult symptoms such as pain, nausea and shortness of breath. But the practice of medicine from its antecedence in antiquity has been always more than the physical. It includes the need to listen to the spirit of a patient facing an illness, and attend to the multiple fears, concerns and regrets that proximity to mortality entails.

Improving patient outcomes with new therapeutic options is always exciting, but political imperative must not override good medical practice. This Bill has drivers that may risk sensible investigation of the therapeutic benefits of cannabinoids.

ANZSPM recognises that cannabis has been used in many societies, world-wide, over the centuries for medicinal, religious and recreational purposes. Current community support in Australia for access to medicinal marijuana for intractable symptoms has resulted from both easing of restrictions of use on both medical and recreational grounds in some countries (e.g. USA) and anecdotal evidence of benefits presented in the media, such as in the case of resistant paediatric seizures (1,2).

ANZSPM believes there would be a number of implications for the practice of palliative care that need to be considered.

Implications for Palliative Care

Though many ANZSPM members have cared for terminally ill patients who may have used cannabis both prior and during the final months of life, ANZSPM believes there are several areas of concern in regards to this Bill.

1. Controlling Medicinal Cannabis differently from all other prescribed medications within Australia could set a poor precedent

(i) The Bill unnecessarily establishes an additional method of medicinal drug regulation

The Regulator of Medical Cannabis Bill is quite complex and it will take some time to establish the Regulator and Board, and become operational. The Bill establishes the Regulator of Medicinal Cannabis to perform the functions of an agency, in accordance with the Convention (3), to approve the medicinal cannabis products to include on the register and control the production, use and import/export of these drugs. Drugs included on this register are not subject to the current process required for other medicinal products in Australia under the Therapeutic Goods Act 1989.

Inclusion on the Medicinal Cannabis Register does not, however, preclude application to the Therapeutic Goods Association (TGA) for inclusion on their

register, and possible PBS subsidisation. It does mean that there will be a separate subset of medications (cannabinoids) that are handled completely differently from all other prescribed medications within Australia. This is of concern, and could set a poor precedent.

2. Pharmaceutical data is necessary to support evidence-based medicine; variations in raw products impact on determination of best therapeutic outcomes

(i) Issues controlling the standard of less processed or 'raw' Medicinal Cannabis preparations will impact therapeutic outcomes

This Act is all encompassing and separates Medicinal Cannabis from the controls that are applied to all other medicinal products. The focus of the Bill is not to improve access to synthetic cannabinoid products currently in use overseas, though this will be enhanced, but instead is to provide regulation of access to less processed products directly derived from the cannabis plant. This raw cannabinoid product is impure with regards psychoactive ingredients, and has various THC/CBD (Tetrahyrocannabinol/Cannabididiol) levels depending on the species and production.

The Regulator's control of the standard of Medicinal Cannabis preparations, including the quality and quantity of the cannabis available, may have significant impact on determining best therapeutic outcomes. As there are many strains of cannabis with differing psychotropic capacity, determining what would be appropriate for a patient may be problematic, unless access to pharmaceutical data relating to particular plant is known.

As data about the most effective dose and dosage regime for a particular symptom is not known, it would be difficult for both the Regulator and prescriber to be confident of whether the preparation standard(s) determined are appropriate to provide the intended therapeutic outcome. Prescribing cannabis may be "try it and see" initially, with anecdotal evidence of efficacy on a given dose guiding future therapy, unless controlled trials can be instituted.

(ii) Patient safety is of paramount concern

The greatest issue is the safety aspect of the proposed drug. The side effect profile, level of impurities with other active ingredients, potential drug interactions and lack of rigorous scientific data supporting the use of cannabis in the therapeutic setting is very concerning.

Recommendation 1. *With patient safety paramount, Medicinal Cannabis use should be evidence-based and as a prescribed medication, regulators should establish the use of pharmaceutical quality products only, which are managed in the same way as other prescribed medications, via the existing mechanisms established by the Therapeutic Goods Act 1989.*

(iii) Research based practice of care is encouraged; research will support guidance on future use of medicinal cannabis

Access to new therapeutic goods normally only occurs after significant research has taken place proving effectiveness and safety. Palliative Medicine is actively encouraging research based practice of care, and outcomes of trials of medicinal cannabis will not be available for some time to come.

What are the future implications, if these raw products are found to be completely inappropriate in the palliative setting from a patient care and safety aspect? What is the cost to our professional standing?

If interested Palliative Care Clinicians could carry out the research at controlled sites on willing patients, before other medical practitioners can access the medications for terminally ill patients under their care, our industry could be in a better position to provide guidance on future use of these drugs.

Certainly, the research into the potential benefits of cannabinoids in controlling difficult symptoms is of great interest, and Australia is in a good position to assist in exploring the therapeutic gains that the newer cannabinoid products may be able to deliver in patient care. If this Bill facilitates this outcome it will be beneficial, but concern that the research effort may be hijacked by financial /business imperatives of producers and importers/exporters are real.

Recommendation 2. *That there is legislation to support research into the use of medicinal cannabis in controlled situations, such as Medicinal Cannabis trials, to allow palliative medicine practitioners to assess the medications for terminally ill patients and be better placed to provide guidance on future use of these drugs.*

3. The Bill establishes a Regulator but because it does not cover all the rules for the operation for each of its responsible domains, it will be some time before the full implications of the Bill will be known

In this Bill, the Regulator is responsible for determining the standards of the actual product itself. This includes the variety of plant sourced, quality of product produced, dosage form and schedule, packaging and labelling – almost all activities currently performed by the TGA.

The Regulator has powers to monitor compliance with the Act, or rules pertaining to the Act, and investigate any breaches. The Regulator also has the power to search and seize any items from licensees under investigation, as set out in the Regulatory Powers (Standard Provisions) Act 2014. The Regulator would then refer proven breaches to the Police for further action.

However, though the Bill establishes the Regulator, it does not cover all the rules for the operation for each of its responsible domains. Not surprisingly, the Regulator

will be responsible for developing these rules once the Act has passed. Therefore the full implications of this Bill will not be known for some time yet.

Some of the broader issues include:

(i) Pressure on medical practitioners to become registered and prescribe

As directed by the Bill, a medical practitioner has to apply to be included on the Register to facilitate access for the patient. This process may result in increased pressure from patients and carers, on members of our profession (especially), to become registered. As many of our patients are on multiple medications, where the additive effects of cannabis could be very detrimental many clinicians may be disinclined to prescribe or feel quite pressured by family who are not cognisant of the possible problems associated with the use of this drug.

(ii) Pressure on medical services to ensure ongoing availability of a licensed practitioner to provide ongoing supply to patients

Issues of ongoing supply may be problematic. Should one clinician within a palliative care service decide to support the use of cannabis and apply for a licence, there would need to be consideration by the greater team as to issues of responsibility for ongoing care and support, particularly at times of recreational leave for the licensee, etc. This adds another level of complexity to patient care when one clinician holds the licence but is not available to care for the client.

(iii) Increased education of clinicians to ensure patient safety

Expanded teaching of health professionals who will be dealing with patients that have access to the drug will need to be considered. Patients are not isolated to one health professional (the licencee), and general education will be required to enable pharmacists, nursing staff and medical practitioners who have clinical responsibilities of patients using the medicinal cannabis, to ensure ongoing safety and good clinical practice. This will be important particularly for Palliative Care and Mental Health Specialists where many of the drugs used for symptom control have additive properties to the effects of cannabis

(iv) Drug diversion

Drug diversion occurs with many prescribed medications, such as opioids, benzodiazepines and amphetamines. It is easy to foresee that this drug too will be diverted for recreational use also.

Ongoing access whilst admitted to a hospital, public or private, will need to be determined, particularly if the drug requires inhalation to be effective. Will special dispensation be required to enable patients to self-dose whilst in hospital or will this drug too be required to be kept in the safe by nursing staff and dispensed as directed by treating teams? What are the implications for the treating team in regard to prescribing this drug whilst a patient is in hospital, when they themselves do not hold the licence, particularly should a breach occur?

(v) Protections for prescribing practitioners

The medico-legal ramifications with being responsible for the outcomes associated with the use of this drug, particularly if there are breaches of the rules such as drug diversion, may also be of great concern to many ANZSPM members.

The Regulator would be yet another body which doctors, who apply for a licence, will be answerable to, with possible serious legal ramifications if breaches occur.

It is not known how Medical Indemnity Societies will support clinical members if there are legal implications arising, especially as the use of these drugs is not supported by good practice guidelines within a medical setting. Would patients signing consent forms that outline the experimental nature of this drug and the high risk of adverse reactions be sufficient?

Recommendation 3. *That the Inquiry Committee recognises that the full implications of the Bill will not be known for some time after implementation and that broader issues around licensing, use, and access controls for medicinal cannabis need to be considered in any legislative change.*

4. Resources to guide practice

(i) The need to establish guidelines for the clinical use of medicinal cannabis

If the Bill is passed, health professionals will need guidance on the use of medicinal cannabis in practice. Such guidelines would consider assessment criteria for prescribing, monitoring patient response, monitoring any potential misuse and for identifying possible drug interactions. Guidelines might also cover the relevant licensing arrangements.

ANZSPM would seek to be consulted in the development of any such guidelines.

Recommendation 4. *That if this Bill is passed, that ANZSPM is consulted to assist in developing guidelines for the use of medicinal cannabis.*

References

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