painaustralia
working to prevent and manage pain

16 March 2015

Committee Secretary
Senate Legal and Constitutional Affairs Legislative Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Via email: legcon.sen@aph.gov.au

Dear Sir / Madam

Submission to the Senate Legal and Constitutional Affairs Legislation Committee regarding the Regulator of Medicinal Cannabis Bill 2014

Thank you for the invitation for Painaustralia to make this submission to the Senate Legal and Constitutional Affairs Legislation Committee regarding the **Regulator of Medicinal Cannabis Bill 2014.**

Painaustralia was formed in 2011 as a not-for-profit body to work with state and federal health authorities, health care professional and consumer bodies, funders, educational and research institutions and other stakeholders to facilitate implementation of the National Pain Strategy 2010. Painaustralia works collaboratively with members and partners, including more than 150 organisations that contributed to the National Pain Strategy. Founding partners, the Australian Pain Society (APS) and the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists (FPM, ANZCA), provide much of Painaustralia's core funding, along with the Pain Management Research Institute (University of Sydney, Royal North Shore Hospital).

FPM is the professional body responsible for the education, training and continuing professional development of specialist pain medicine physicians in Australia and New Zealand. As such the Faculty not only has a role in establishing standards of clinical care in the context of the discipline of Pain Medicine but also is involved in the broader societal aspects of drugs and devices that may be used to treat people experiencing pain. As such the Faculty continues to be engaged with the Pharmaceutical Benefits Advisory Committee of the Department of Health and Ageing, especially with respect to the controversial issue of opioid pharmacotherapy for chronic pain.

Painaustralia recognises that the legal and regulated use of medicinal cannabinoids is being urged for a number of diverse medical conditions. Consistent with its charter, Painaustralia's focus is to support ways and means to ease the burden of pain in the population. This burden

painaustralia
working to prevent and manage pain

has two main components: the situation of palliative care and of unrelieved pain due to cancer; and the much larger problem, in terms of patient numbers and cost to the community as a whole, of chronic non-cancer pain (CNCP).

Painaustralia is supportive of clinically sound and appropriately regulated use of medicinal cannabinoids in situations of palliative care.

However the use of medicinal cannabinoids in CNCP poses a very different and difficult set of considerations. This is the focus of this submission, which is informed largely by the stance of the FPM. Painaustralia acknowledges there may be some divergence from this opinion by other members of our organisation.

Summary

This submission by Painaustralia calls for:

- "Medicinal cannabis" to be specifically defined in the Bill
- The need to ensure, so far as is possible, that the processes set up by this Bill do not lead to inappropriate prescription and unsanctioned use of cannabinoid products, as has happened with opioids.
- Adherence to the principle that substances intended for therapeutic purposes be fully characterised chemically, pharmacologically and toxicologically
- Caution in facilitating the use of cannabinoids for people with chronic non-cancer pain until such time as a clear role for them is identified in the scientific literature.
- Facilitation of pragmatic trials of medicinal cannabinoids in chronic non-cancer pain under strict conditions.

1. Overview

As is stated in the Explanatory Memorandum that accompanies the Bill, the intent is to regulate medicinal cannabis as set out in the *Single Convention on Narcotic Drugs 1961* which essentially requires cannabis and cannabinoids to be treated in the same way as opium, opiates and opioids.

Indeed it is the evolution of the opioid issue, with its unintended consequences, that influences greatly the Faculty's attitude to the question of "medicinal cannabis" when applied to the matter of treating pain in general and CNCP in particular.

Painaustralia is very much aware that two questions currently pre-occupying the practice of pain medicine are the lack of data on the long term effectiveness of opioids in the management of chronic non-cancer pain (CNCP), and the rise in problematic use and harms of opioids, including overdose and dependence, arising out of the marked increases in opioid prescribing in recent years.

painaustralia
working to prevent and manage pain

Painaustralia believes that this situation reflects three main factors:

- inadequate knowledge and skill of medical and other health practitioners in the assessment and management of patients with CNCP, especially in the community (an issue of education and training);
- poor application and lack of funding for existing evidence-based strategies; and
- the challenges inherent in performing clinical trials to determine the long-term efficacy of *any* drug in the complex multifactorial predicament of CNCP.

Clearly these factors are related: inadequate education regarding the nature of CNCP leads to excessive and inappropriate reliance by medical practitioners on drug therapy in a situation where long-term outcomes are difficult to determine.

A further factor has been the propensity for misuse of opioids, either in unsanctioned ways by those for whom they have been prescribed, or by leakage into the illicit drug market where they are used for other than therapeutic purposes.

Painaustralia and the Faculty cannot overemphasise their concern that society at large, regulatory authorities in particular and the medical profession as a whole do not go down the same path that has led to the current problems with opioids. Despite both opioids and cannabinoids falling under the auspices of the *Single Convention on Narcotic Drugs 1961*, there is one major difference between them, namely that cannabis is readily obtainable in contemporary society whereas opium is not.

Specialist pain medicine physicians are aware that many patients use cannabis – and this is considered to be *unhelpful* in therapeutic programs that are intended to promote self-management of CNCP.

2. Technical issues

Before articulating some principles that should underpin legislation concerning the medicinal use of cannabinoids, two observations need to be made.

i. "Medicinal cannabis" in fact is not defined in the Bill. Given that "medicinal" means "pertaining to or having the properties of a medicine [itself defined as 'any substance or substances used in treating *disease'* (emphasis added)]", or as "curative" or "remedial", it is important that the substances under consideration be shown to have those properties.

   Painaustralia believes that in this context "medicinal" should refer to cannabinoid preparations of sufficient and consistent quality to be capable of being tested for

painaustralia
working to prevent and manage pain

efficacy and safety, and calls for a *specific definition of medicinal cannabis* to be incorporated into the Bill.

It is not clear that Clause 13(2)(b) – "the regulator is satisfied that the cannabis product is suitable for medicinal use" – satisfies this requirement.

Painaustralia is also concerned about the use of terms such as "medical cannabis" and "medical marijuana", given that only substances that are fully characterised in terms of their chemistry, pharmacology and toxicology should be considered as potential medicines.

ii. It is noted that the Bill "…is designed to be a parallel [to the TGA] system for authorising the cultivation and production of cannabis for medicinal use and research". Are we to assume that is because of the 1961 Convention, in which respect we would ask why there is not a similar parallel process for opioids?

However it is also stated that:
This Bill provides for a system of regulating medicinal cannabis that is entirely separate from the TGA. A number of provisions of the Bill make it clear that the TGA does not apply to things done in accordance with licences or authorisations issued by the new Regulator of Medicinal Cannabis. However, this would not prevent pharmaceutical companies applying to the Therapeutic Goods Administration to sell medicinal cannabis instead of using the scheme established by this Bill. They will effectively have a choice about which system to use (although the cultivation of medicinal cannabis will only be covered by this Bill).

This raises the question of why is it considered necessary or desirable for pharmaceutical companies seeking to develop cannabinoid products to be able to choose between the Regulator of Medicinal Cannabis and the Therapeutic Goods Administration.

3. Faculty of Pain Medicine position on medicinal cannabinoids in chronic non-cancer pain

The Faculty has examined the issue of the use of medicinal cannabis in the management of patients with chronic non-cancer pain (CNCP). This group of patients, which constitutes the largest in terms of "burden of disease" in the context of pain, is quite heterogeneous in cause and complexity, and consequently in approaches to management.

The Faculty has articulated the following statements of principle, with the request that legislators take them into consideration in the context of this Bill. It is emphasised that these

painaustralia
working to prevent and manage pain

statements apply to *this group of patients only* and cannot be extrapolated to the care of patients in palliative care.

- FPM considers that calls for the liberalisation of the availability of cannabinoids as medicines are based more on anecdote than on sound clinical science and practice.
- The conceptual framework that informs the assessment of people with CNCP emphasises active engagement of patients in multimodal pain management programs, and recognises the adverse effects on this that may be associated with polypharmacy in general and with cannabinoids in particular.
- FPM does not recognise a need for greater availability of medicines in general and in particular does not endorse the use of cannabinoids in CNCP until such time as a clear therapeutic role for them is identified in the scientific literature.
- With the possible exception of pain and spasticity in multiple sclerosis, there is little evidence for the effectiveness of cannabinoids in CNCP, whether or not the pain is "neuropathic".
- FPM recognises the difficulties inherent in performing trials of any medication in this group of patients. Nonetheless FPM believes that trials of cannabinoids are necessary and should be conducted on a coordinated national basis, by highly credentialed persons and within strict parameters.

Thank you for the opportunity to comment on this Bill. For further information please see the contacts below.

Ms. Lesley Brydon
Chief Executive Officer

Contact persons:

Ms. Lesley Brydon
Chief Executive Officer
Painaustralia

Professor Milton Cohen
Director of Professional Affairs, Faculty of Pain Medicine
Painaustralia Board member