NCETA
Australia's National Research Centre on AOD Workforce Development

THE NATIONAL CENTRE FOR EDUCATION AND TRAINING ON ADDICTION

Level 3B,
Mark Oliphant Building
Laffer Drive, Science Park
Bedford Park, SA 5042

Tel +61 8 8201 7535
Fax +61 8 8201 7550

nceta@flinders.edu.au
www.nceta.flinders.edu.au

20 March 2015

Ms Sophie Dunstone
Committee Secretary
The Senate
Legal and Constitutional Affairs Legislation Committee
PO Box 6100,
PARLIAMENT HOUSE CANBERRA ACT 2600

Dear Ms Dunstone

Re: Inquiry into the Regulator of Medicinal Cannabis Bill 2014

Thank you for inviting the National Centre for Education and Training on Addiction (NCETA) to make a submission to the Committee's Inquiry into *Regulator of Medicinal Cannabis Bill 2014.* NCETA is an internationally recognised research centre that works as a catalyst for change in the alcohol and other drugs (AOD) field. The Centre's mission is to build the capacity of health and human services and related sectors to respond to AOD-related issues and problems. NCETA is one of three national centres of excellence focusing on AOD issues in Australia.

This submission is supportive of the Bill for two reasons. First, there is emerging evidence that cannabis may have a role in the treatment of a range of conditions, including chronic non-cancer pain;[1]**There are no sources in the current document.** chemotherapy-induced nausea and vomiting;[2] and a range of neurological conditions.[3] Second, by enhancing access to cannabis for research purposes the proposed regulatory arrangements will assist researchers address a number of knowledge gaps concerning the potential role of medicinal cannabis.

There are, however a number of cautions and caveats.

The need for rigour in regulation and decision-making

The Bill aims to create a parallel regulatory structure to sit alongside the *Therapeutic Goods Act 1989.* It will be critical to ensure that an appropriate level of rigour is maintained in the Regulator's decisions concerning the ways in which medicinal cannabis is made available and used. Given that pharmaceutical companies will also be able to apply to the Therapeutic Goods Administration to sell medicinal cannabis products under the TGA's legislation, it will be important to ensure the new approval mechanisms established under the Bill are both complementary to, and as rigorous as, those that currently apply to the TGA. Any short cuts to obtaining regulatory approval should be avoided at all costs.

The complexity of cannabis

Cannabis is a complex product consisting of a more than 100 cannabinoids, terpenoids, and flavonoids that produce individual, interactive and entourage effects.[4] Potency can vary widely.[5] Although delta-9-tetrahydrocannabinol is believed to be the principal psychoactive constituent of cannabis, other substances present may have important, additional effects.[4] Further, the active

ingredients of cannabis are likely to vary according to its state (green cannabis leaf, dried cannabis, oil etc.), condition and method of ingestion. Consequently there is scope for the composition, purity and concentration of the active constituents of cannabis to vary greatly. This, in turn, makes it likely that different strains, forms and potency of cannabis will be more beneficial for certain conditions than others. It will therefore be critically important for the Regulator to have access to highly sophisticated methods for differentiating and regulating cannabis strains, potency and forms.

The role of the Regulator in quality and probity control

The Regulator of Cannabis will have an important role to play in the quality control of medicinal cannabis. This is to avoid problems associated with contamination with pesticides, herbicides, or fungi, the latter being especially dangerous to immunocompromised individuals such as patients with HIV/AIDS or cancer.[4]

The Regulator will also have an important role in ensuring that only fit and proper individuals are involved in the production, distribution and dispensing of medicinal cannabis. This will involve ensuring that appropriate probity checks are undertaken to ensure that those involved in the industry have no significant relevant criminal history or links to organised crime.

Regulatory scheduling

Currently, cannabis products are listed under Schedule 9 (prohibited substances) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The exception to this is Sativex which is included in Schedule 8 and subject to specific controls. The scheduling implications of medicinal cannabis requires attention. For example, will medicinal cannabis be placed in Schedule 8 while illicit cannabis remains in Schedule 9 of the SUSMP?

Cooperation between the Commonwealth and States and Territories

As outlined in Part 1 Clause 7 of the *Regulator of Cannabis Bill 2014* the currently proposed medicinal cannabis system is to be implemented cooperatively between the Commonwealth and States and Territories. This will likely require States and Territories to amend legislation and undertake activities on behalf of the Commonwealth. These cooperative arrangements will be complex and will vary between jurisdictions due to differences in jurisdictional:

- Law enforcement approaches to illicit cannabis
- Regulatory structures and approaches in place for Schedule 8 drugs.

It will be important not to underestimate the complexities of these legislative and regulative arrangements in establishing the Regulator.

Adequate resourcing

It will be necessary to financially compensate States and Territories for activities related to the medicinal cannabis system. The Regulator's activities and those to be undertaken by States and Territories will need to be fully costed and appropriately resourced. Given that the Bill contains no appropriation, funds will need to be allocated by the Parliament for this purpose. Failure to ensure full and sufficient funding to the Regulator will result in regulatory gaps and inconsistency in approaches as are currently seen the regulation of Schedule 8 drugs across jurisdictions.
Prescriber guidelines and education

If medical practitioners are to have a role in prescribing cannabis it will be crucial that they have access to evidence informed guidelines about its appropriate medicinal uses. Such guidelines will need to be developed in consultation with relevant medical colleges and experts and supported by an extensive educational program to support practitioners in their prescribing decisions.

Community education

The introduction of arrangements such as those outlined in the Bill will also require an extensive community education process. In particular, the introduction of medical cannabis should not come at the expense of cannabis coming to be regarded as a harmless, natural product. The adverse effects of cannabis use have been well documented and include:

- A dependence syndrome
- Increased risk of motor vehicle crashes
- Impaired respiratory function
- Cardiovascular disease
- Adverse effects of regular use on adolescent psychosocial development and mental health.[6]

Any move to enhance the medicinal use of cannabis should not leave the broader community with the impression that cannabis use (particularly smoking) is a health promoting activity or not associated with a range of potential significant risks.

Avoiding diversion for misuse

A range of (prescribed) Schedule 4 and Schedule 8 medicines are currently being diverted for misuse including benzodiazepines, opioids and anti-psychotics.[7] This is occurring via:

- Stealing, forging or altering prescriptions
- Burglaries of surgeries and pharmacies and private homes
- Medication shopping (presenting to multiple prescribers and obtaining prescriptions for imaginary or exaggerated symptoms)
- Prescribing drugs in larger quantities than are needed for managing a patient's condition, providing an opportunity for the patient to sell the excess to others
- Health workers self-prescribing or otherwise misappropriating the drugs through their work.

Since cannabis is currently the most widely used illicit drug in Australia[8] it will be important to ensure that measures are in place to minimise diversion. One option to avert this possibility would be the inclusion of cannabis prescriptions in the national Electronic Recording and Reporting of Controlled Drugs (ERRCD) system currently being established. The ERRCD is being established to enhance the quality use, and minimise the diversion, of Schedule 8 drugs.

Evaluating the impact

It will also be important to evaluate the population health effects of the new scheme. From this perspective, it will be important to ensure that any benefits accruing to medical users of cannabis do not occur at the expense of increases in non-medical cannabis use and related risks and harms.[9]

In closing, I wish the Committee well with its deliberations.

Please do not hesitate to contact me if the Committee requires further information or detail.

Yours sincerely

Professor Ann Roche
Director
National Centre for Education and Training on Addiction (NCETA)
Flinders University

References

1. Lynch, M., Campbell, F. Cannabinoids for treatment of chronic non-cancer pain; A systematic review of randomized trials. *British Journal of Clinical Pharmacology.* 2011;72(5):735-44.
2. Parker, L., Rock, E., Limebeer, C. Regulation of nausea and vomiting by cannabinoids. *British Journal of Pharmacology.* 2011;163(7):1411-22.
3. Koppel, B., Brust, J., Fife, T., Bronstein, J., Youssof, S., Gronseth, G., et al. Systematic review: Efficacy and safety of medical marijuana in selected neurologic disorders. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2014;82(17):1556-63.
4. Wilkinson, S., D'Souza, D. Problems with the medicalization of marijuana. *Journal of the American Medical Association.* 2014;311(23):2377-8.
5. McLaren, J., Swift, W., Dillon, P., Allsop, S. Cannabis potency and contamination: A review of the literature. *Addiction.* 2008;103(7):1100-9.
6. Hall, W., Degenhardt, L. Adverse health effects of non-medical cannabis use. *The Lancet.* //;374(9698):1383-91.
7. Nicholas, R., Lee, N., Roche A. *Pharmaceutical Drug Misuse Problems in Australia: Complex Issues, Balanced Responses.* Adelaide: Flinders University; 2011.
8. Australian Institute of Health and Welfare*. National Drug Strategy Household Survey Detailed Report 2013.* Canberra: Australian Institute of Health and Welfare; 2014.
9. Fischer B, Murphy Y, Kurdyak P, Goldner E, Rehm J. Medical marijuana programs — Why might they matter for public health and why should we better understand their impacts? *Preventive Medicine Reports.* 2015 //;2(0):53-6.