ACT Government

ACT GOVERNMENT SUBMISSION

to the Senate Legal and Constitutional Affairs Legislation Committee Inquiry into the Regulator of Medicinal Cannabis Bill 2014.

INTRODUCTION

The tabling of the *Regulator of Medicinal Cannabis Bill 2014* (the Regulator Bill) in the Senate on 27 November 2014 has generated significant public interest and debate, both locally and at a national level. In the ACT, the Legislative Assembly Standing Committee on Health, Ageing, Community and Social Services is currently conducting an Inquiry into the exposure draft of the *Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014* and related discussion paper, and the ACT Government will consider the Committee's Report when it is handed down in June 2015.

The ACT Government believes that a national approach to the regulation of the medicinal use of cannabis is required, and supports the compassionate intent behind the Regulator Bill.

The ACT Government notes that the Regulator Bill establishes the Regulator of Medicinal Cannabis (the Regulator). The Regulator will be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis. It is also noted that the Regulator will have powers to monitor compliance with the Bill and investigate breaches.

DISCUSSION

CLINICAL NEED

Clinicians from a variety of specialties have been consulted in relation to the medicinal use of cannabis. These specialties include:

- Pain;
- General Practice;
- Neurology;
- Sexual Health;
- Oncology;
- Anaesthetics; and
- Addiction medicine.

These specialties were consulted with a view to assessing the potential clinical need for medicinal cannabis. Consideration should also be given to the possible impact on clinical practice which may arise from increased presentations by patients who abuse cannabis in areas such as Emergency Medicine, rehabilitation and mental health services.

Although aware that some patients are already using cannabis (either recreationally or medicinally), clinicians feel that there is very limited clinical need and perceived demand for access to medicinal cannabis.

There are serious concerns about the use of cannabis by a child and the possible impact on a child's brain (including in-utero), development and learning, and passive exposure or access to cannabis prescribed to a child's parent or carer. In addition, the issue of access and use by a parent or carer of a child's cannabis has not been addressed.

REGISTER OF REGULATED MEDICINAL CANNABIS PRODUCTS

There is a general reluctance among clinicians to recommend cannabis use. This is primarily due to the lack of a quality controlled supply, dosing standards and the absence of approval from the Therapeutic Goods Administration (TGA), with the exception of the cannabis extract Sativex®.

Concerns related to the lack of TGA approval may be mitigated by the inclusion of products on the register of regulated medicinal cannabis products. However, the process by which cannabis products may be considered by the Regulator as "suitable for medicinal use" is unclear. The ACT Government believes that consultation with clinicians prior to the development of any rules or standards is essential.

In the event that the register of regulated medicinal cannabis products is established, consideration should be given to undertaking a comprehensive educational campaign for both clinicians and the public at large. In addition, jurisdictional law enforcement agencies should be afforded access to the register in accordance with relevant privacy legislation and guidelines.

INTERSECTION WITH ACT LAWS

It is noted that the medicinal cannabis system set up by the Regulator Bill is to be implemented cooperatively between the Commonwealth and participating States and Territories. If the ACT agreed to enter into an arrangement with the Commonwealth to participate in the system, it is noted that the ACT would need to amend its laws relating to the unlawful possession and administration of cannabis.

LIMITED DETAIL

The ACT Government is concerned that the Regulator Bill does not consider the impacts on law enforcement. Law enforcement agencies will be responsible for dealing with instances involving the diversion of authorised medicinal cannabis products to the illicit market, and to enforce other associated ACT legislation (for example, the *Road Transport (Alcohol and Drugs) Act 1977*) .

While the Regulator Bill proposes to give the Regulator powers to monitor compliance with the Act and the rules (including powers to investigate breaches), there is no way to assess the possible impact on other law enforcement agencies.

The absence of draft or indicative principles or processes for the development of the rules creates uncertainty about the efficacy of the scheme to prevent or minimise diversion and threats to public health and safety. International experience suggests that careful consideration of the detail regarding supply regimes and the specific conditions and symptoms for which treatment with medicinal cannabis is authorised is crucial to ensuring that public health and safety are protected.

Consideration could be given to including principles in the Regulator Bill to serve as a guide for the development of the rules which should be made by the Executive, and not the Regulator. The rules should also be subject to parliamentary scrutiny to ensure they accord with principles set out under the Act.

SUPPLY AND DISTRIBUTION

The Regulator Bill does not consider issues associated with supply and distribution models. The resourcing requirements associated with ensuring appropriate oversight and distribution of medicinal cannabis products would likely be significant. Extensive consultation with representatives from the relevant professional organisations (for example, pharmacists) is essential.

CONCLUSION

In principle, if a decision is taken to implement a national regulatory framework for medicinal cannabis, the ACT Government supports the development of rules that will ensure the tightly regulated supply, distribution and use of medicinal cannabis products based upon agreed national standards.

While the responsibilities and powers of the Regulator are outlined clearly in the Regulator Bill, the manner in which these responsibilities are to be carried out – particularly with regard to the role of participating States and Territories – is unclear at this stage. The Explanatory Memorandum makes reference to this issue, and the ACT Government acknowledges the Regulator will require flexibility and that it is entirely appropriate for many operational details to be outlined in the rules. However, the ACT Government believes that careful consideration of the following issues is essential to any scheme proposing to regulate the medicinal use of cannabis:

a) Medical Perspective – including clinical need, effectiveness, toxicity and educational requirements;
b) Law Enforcement Perspective – including impact on crime, driving and enforcement issues associated with licence holders;
c) Regulatory Issues – including alignment and conflict between jurisdictional and national laws;
d) Public Health Perspective – including impacts on public health;
e) National & Cross Jurisdictional Issues – including clinical trials and transport between jurisdictions; and
f) International Experience – lessons to be learnt from frameworks in place overseas.

Should the Regulator Bill be enacted, the ACT Government would be eager to participate in the development of the rules, with a view to ensuring that these issues and perspectives are satisfactorily addressed and incorporated.