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13 March 2015

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

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

Dear Ms Dunstone

Re: Inquiry into the Regulator of Medicinal Cannabis Bill 2014

The Bar Association of Queensland ("BAQ") is a professional organisation that represents over one thousand practising member barristers.

BAQ has been invited to provide a submission addressing the Regulator of Medicinal Cannabis Bill 2014 ("the Bill").

Summary of Submissions

1. The BAQ expresses its in principle support for the Bill.
2. The BAQ supports there being no provision in the Bill enabling the use of 'crude cannabis' by individual registered patients for medicinal purposes.
3. The BAQ submits that a cautious and evolutionary approach to the regulation of medicinal cannabis be taken.
4. It ought to be made clear that medicinal use of approved cannabis products by registered patients should be a complete defence against any criminal charges relating to the possession and/or use of approved cannabis products in participating States and Territories.

Introduction

There is a clear distinction between the medicinal use of regulated pharmaceutical products and the use of cannabis for recreational purposes. The recreational use of cannabis and cannabis related products is illegal in all states in Australia. It is not the intention of BAQ to support any change in the current law with respect to the recreational use of cannabis or cannabis related products.

At this time for any form of cannabis to be approved for medicinal use in Australia an application must be submitted to the Therapeutic Goods Administration ("TGA") with supporting documentation assessing the product's quality, safety and efficacy.

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The TGA then decides to approve or reject the application. If approved, the product is included in the Australian Register of Therapeutic Goods ("ARTG"). Currently the only cannabis related pharmaceutical product registered on the ARTG is *Sativex®*, an oral mucosal spray preparation. *Sativex®* is registered for symptom improvement in patients with moderate to severe spasticity related to multiple sclerosis. *Sativex®* is included in schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons and is subject to specific controls.

There is a diverse range of information available in relation to the current use of cannabis for medicinal purposes. There is no robust data available on the prevalence and nature of medicinal use of cannabis in Australia. However, there is no doubt that there are a number of Australian individuals using illicit cannabis for medicinal purposes. As a result seriously ill individuals are exposed to the risks associated with the illicit drug trade, such as arrest and criminal prosecution and sanction.

International Instruments

There are a number of international instruments, to which Australia is a signatory affecting the Bill. These include the *Single Convention of Narcotic Drugs* 1961, the *United Nations Convention of Psychotropic Substances* 1972, and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* 1988. All of these conventions permit a signatory to utilise an identified substance for medical and scientific purposes. These instruments provide that a government agency must be established to regulate cannabis cultivation for medical or scientific purposes. The Bill complies with that obligation. The BAQ is therefore satisfied that the Bill is consistent with those international agreements to which Australia is a signatory.

Other countries and Medicinal Cannabis

Medicinal cannabis is currently legal in many countries in the world. There are a number of legislative approaches to the use and access to medicinal cannabis in these places.

Canada introduced its medicinal cannabis program in 2001. It has a government licenced grower responsible for the central distribution of medicinal cannabis through *Health Canada*. In 2014 the system was amended to enable licensed producers to sell supplies directly to patients.

In the Netherlands medicinal cannabis has been available to patients on prescription since 2003. The Office for Medical Cannabis buys all crops produced under licence. Dried herb or a granulated product is distributed by pharmacies for administration in a tea formula or via a vaporiser.

In the United States over 20 states have legalised or decriminalised medicinal cannabis. There is a range of licensing regimes across these states.

Other countries with approved medicinal cannabis regimes include the United Kingdom, Israel, Austria, Germany, the Czech Republic and New Zealand.

The Bill

At this time it is unclear which States will participate in the national system proposed under the Bill. All Territories will be automatically included.

The Bill provides that the Regulator will have powers to approve cannabis products for inclusion in the register of regulated medicinal cannabis products. These products will be included in the regulated medicinal cannabis products register rather than the ARTG. It appears from the explanatory memorandum to the Bill that pharmaceutical companies will have a choice as to which regime they apply to for approval to sell medicinal cannabis products.

It is unclear if two separate applications may be submitted concurrently to these authorities (the TGA and the Bill Regulator). It is also unclear if an application is rejected by one Regulator that fact and reasons for that rejection are required to be disclosed to the other Regulator should the company make a subsequent application pursuant to the alternative scheme. This should be clarified

The Regulator has power to make rules for a medicinal cannabis licensing scheme which will regulate, inter alia, production, use, experimental use, transport, and import and export of medicinal cannabis. The Regulator is expected to prescribe an authorised patients and carers scheme. This scheme will provide authorisation for individual's use of regulated medicinal cannabis products, supply of the products to authorised patients and other incidental factors.

The Regulator is also empowered to monitor compliance with the Act and the rules and investigate any breaches.

No draft rules have been published therefore there is no BAQ submission in respect of the anticipated rules.

It is expected that the licensing application process will reflect the TGA process to a great extent. No additional comment arises from this.

Yours faithfully

Shane Doyle QC
President