Australian Government

Department of Health

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

Dear Committee Secretary

I am writing in regards to the Legal and Constitutional Affairs Legislation Committee's inquiry of the Regulator of Medicinal Cannabis Bill 2014 (the RMC Bill).

Cannabis, being a narcotic drug is tightly controlled in Australia. The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis derived products are regulated by a number of Commonwealth, State and Territory laws. At the Commonwealth level, these laws include the *Therapeutic Goods Act (1989)*, *Criminal Code Act 1995, Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 199*0, the *Customs Act 1901* and the *Narcotic Drugs Act 1967*(the ND Act*)*. Australia also has a number of obligations that it must fulfil with respect to the controls on a licit market in cannabis, cannabis resins and its extracts under the *United Nations' Single Convention on Narcotic Drugs (1961).*

There is already in place a system for regulating access to medicinal "narcotic" drugs which relies on a combination of Commonwealth, State and Territory laws. The Department of Health is the lead Commonwealth agency in relation to narcotic drugs policy, in the implementation of Australia's obligations under international narcotic drugs treaties to which it is a party and is responsible for the national drug strategy. The Department of Health administers legislation and specified provisions in relation to narcotic drugs, therapeutic goods and the issuing of licence and permission with regard to drugs and therapeutic goods. These subject matters are implemented in the ND Act (sections 9, 10, 11, 13, 19, 23 and 24(1)), the *Therapeutic Goods Act 1989*, and parts of the Customs (Prohibited Imports) Regulations (the Customs (PI) Regs) and Customs (Prohibited Exports) Regulations (the Customs (PE) Regs). Other parts of the ND Act are administered by the Attorney-General's Department.

The current regulatory system on narcotic drugs involves a significant number of Commonwealth agencies such as Australian Customs and Border Protection, the Department of Health, Attorney-General's Department, the Australian Federal Police and Department of Foreign Affairs and Trade. The complexity and interrelationships of the matters administered by these different agencies would need to be taken into consideration in the effective implementation of proposed regulatory frameworks applying to cannabis and cannabis products. The RMC Bill proposes to set up a regulatory system in relation to the provision of cannabis for medicinal use that would cut across and replicate existing Commonwealth, State and Territory legal regimes.

The RMC Bill as currently drafted leaves a number of important legal and practical issues unidentified and/or unresolved, leading to the risk of regulatory gaps, overlapping laws, lack of clarity about the exercise of jurisdiction by agencies and, in relation to activities intended to be regulated under the RMC Bill, possible inconsistency with other existing laws.

Therefore, on behalf of the Department of Health, I wish to provide you with the following observations about the potential interactions between the RMC Bill and Commonwealth laws and international obligations to the extent that they are within the Department's sphere of responsibility.

Therapeutic Goods Act 1989

The *Therapeutic Goods Act 1989* (the TG Act) requires that therapeutic goods that are intended to be supplied in Australia (whether produced in Australia or elsewhere), exported from Australia, and imported into Australia, be entered in the Australian Register of Therapeutic Goods (ARTG), unless the goods are exempt from that requirement, or are otherwise approved or authorised under other provisions of the TG Act. Therapeutic goods (include medicines) are goods that generally are presented, or for any other reason likely to be taken for therapeutic use.[1]

"Therapeutic use" under the TG Act include use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, and influencing, inhibiting, or modifying a physiological process in persons.[2] Therapeutic use can be equated to indications for a particular therapeutic good, such as use for the treatment of a particular cancer. In relation to a medicine, the TG Act defines a medicine as therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human, and any other therapeutic goods declared by the Secretary, Department of Health, not to be therapeutic devices.

The RMC Bill appears to operate in parallel with the TG Act on the basis of choice by a person to opt into the RMC Bill Scheme and opt out of the TG Act scheme. The implication of the opting in and opting out mechanism could be significant. This is particularly the case in relation to the application of the TG Act, as the definitions of "medicinal cannabis" and "medicinal use" are not clearly articulated in the RMC Bill and it is not clear how they would not be caught by the definition of "therapeutic goods" in the TG Act. The complexity of this opting in and opting out system can be confusing for the regulated persons, the regulator and other agencies such as the TGA. Without a clear definition, it is not clear to consumers, health professionals, the industry and the regulators which law applies and what their legal obligations and responsibilities would be. It would be difficult for the regulators to determine what their powers are and whether they have the right to take regulatory action in relation to a particular product or activity.

International obligations

Australia is a party to international agreements that aim to restrict production, manufacture, export, import, distribution, trade, and possession of narcotic drugs (including cannabis) exclusively to medical and scientific purposes.

Three key drug control conventions are relevant to the provision of cannabis for medicinal use:

- the *Single Convention on Narcotic Drugs (1961)* (the Single Convention), which specifies the obligations of signatory states for narcotic drugs listed in schedules annexed to the Convention; and
- the *Convention on Psychotropic Substances (1971),* and
- the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (1988), which aims to promote cooperation between parties to address various aspects of illicit traffic in narcotic drugs and psychotropic substances.

The Commonwealth is responsible for the implementation of international agreements that it enters into and generally has the power to make legislation to implement Australia's treaty obligations. Accordingly, the Commonwealth, is responsible for ensuring that any Commonwealth, State or Territory medicinal cannabis scheme is consistent with Australia's treaty obligations under the three drug control conventions cited above.

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1 The full definition is set out in section 3 of the *Therapeutic Goods Act 1989.*

2 Ibid.

It is the Department's view that there are aspects of the RMC Bill which may not adequately implement Australia's obligations under the drug control conventions, in particular the Single Convention. For example, clause 30 of the RMC Bill provides that the Regulator has the functions of the Agency referred to in Article 23 of the Single Convention. However, the RMC Bill does not specifically provide that the Regulator will be the sole agency that can authorise and licence cultivation of cannabis plants in Australia, nor that it is required to purchase and take physical possession of cannabis crops, as required by Article 23.

Article 23 also requires that the Agency must have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers, of medicinal cannabis or cannabis preparations. To ensure clarity of the functions of the Regulator and to ensure that Australia meets its international obligations, it would be preferable if the functions and powers of the proposed Regulator were drafted in a way that more clearly conforms with all the requirements of Articles 28 and 23, rather than simply referencing relevant articles of the Single Convention, and generally requiring that the scheme operate in accordance with the Single Convention.

Paragraph 3 of Article 29 and paragraph 2(a) of Article 30 of the Single Convention require Australia to prevent the accumulation, in the possession of drug manufacturers, traders, distributors, State enterprises or duly authorised persons, of quantities of drugs in excess of those required for the normal conduct of business having regard to the prevailing conditions. Given this obligation, the Department of Health is concerned by the potential existence of more than one agency under Commonwealth and State and Territory law that can grant authorisations and licences with regard to dealings in cannabis. This situation would make it difficult for Australia to prevent the accumulation of quantities of drugs in excess of those quantities permitted under the Single Convention.

Furthermore, under Article 21 of the Single Convention, Australia has obligations to limit the total quantities of cannabis manufactured and imported in any one year to the amount consumed, exported, manufactured into other products, and any stocks required or estimated for special purposes, minus any amounts seized and diverted for licit use.. Under Article 20, Australia is also required to provide the United Nations International Narcotics Board (INCB) by 30 June each year with statistical returns in relation to of production, manufacture, consumption, stocks and seizures of narcotic drugs. .

These requirements are not addressed in the RMC Bill and it is unclear from the RMC Bill whether the Regulator would be responsible for meeting these obligations.

***Customs (Prohibited Imports) Regulations 1956 and Customs (Prohibited Exports) Regulations 1958* (Customs Regulations)**

Under the *Customs (Prohibited Imports) Regulations 1956* (the Customs (PI) Regs), a person wishing to import a drug must apply in writing for both a licence and a permit from the Secretary of the Department of Health. Cannabis is included in Schedule 4 of the Customs (PI) Regs, which includes drugs in Schedules I and II of the Single Convention (as well as those with additional controls in Schedule IV). Permits for import of Schedule 4 drugs must specify the quantity of the drug planned for import in order to estimate the total amount of that drug authorised for import into Australia that year. The amount approved for import is reported annually by the Department of Health to the INCB.

Section 51A of the *Customs Act 1901* provides that: substances or plants that are determined to be "border controlled" drugs, plants or a border controlled precursor under the Commonwealth *Criminal Code* are also taken to be prohibited imports under the *Customs Act*. Section 50(3) of the *Customs Act* allows the Customs (PI) Regs to establish a system of licences and permissions in relation to the importation of prohibited goods.

Part 2, Division 7 of the RMC Bill seeks to establish an import and export licensing scheme for cannabis and cannabis products for medicinal or experimental purposes and excludes the operation of the ND Act and the TG Act to the extent that activities are done in accordance with an import licence

or an export licence under the RMC Bill. However, the RMC Bill does not refer to or link with the application of the *Customs Act 1901*, the Customs (PI) Regs and the Customs (PE) Regs which currently also deal with importation and exportation of cannabis and cannabis resin.

The Customs (PI) Regs and the Customs (PE) Regs already provide a comprehensive import and export licensing schemes that cover cannabis. The current provisions as they apply to narcotic drugs fully comply with Australia's obligations under the Single Convention. The RMC Bill authorises the making of rules to prescribe an export and import licensing scheme. It is not clear how both the RMC Bill scheme and the Customs legislation can operate to regulate the same activities in relation to cannabis.

Clause 26 requires the Regulator to maintain a register of import and export licences and to make that register available to the public. This information is not made publicly available under the Customs Regulations due to the commercial value of the information, confidentiality with regard to the companies involved and for security reasons.

The RMC Bill does not appear to override the prohibition on importation and exportation of cannabis products under the customs legislation without amendments to the current customs legislation. Further consideration on the best way to achieve consistency and avoid duplication between the RMC Bill and the customs legislation with respect to import and export licences is required to ensure compliance with the requirements of the Single Convention and clarity of the authority and jurisdiction of all agencies involved in the regulation of these activities including whether amendments are required at the primary legislation level.

It is the Department of Health's view that given the complexity and uncertainty which is likely to result from dual import and export systems, it is not clear that the existing system could be utilised to facilitate the collecting of data and statistics required under Australia's international obligations.

Narcotic Drugs Act 1967

The *Narcotic Drugs Act 1967* (ND Act) regulates the manufacture of all narcotic drugs under the requirements of the Single Convention through a similar licence and permit regime. The ND Act provides a mechanism to ensure the manufacture of all narcotics is in accordance with global licit demand, and to enable Australia to meet its set reporting obligations. A licence and permit to manufacture may be granted if a prospective manufacturer is able to provide the required information on the quantity of narcotic material to be manufactured and the premises on which it is being manufactured, to a delegate of the Minister for Health. The current manufacturing licensing and permit regime takes into consideration the State legislative framework in relation to the manufacture of narcotic drugs from opium poppy straws.

The RMC Bill purports to displace the operation of the ND Act in various provisions (clause 16, 19, 20, 24 and 3). However, it is not clear how this will operate. For example, with respect to medicinal licences the ND Act does not apply in relation to an activity engaged in, or a thing dealt with, in accordance with a medicinal licence. Where a person does not act in accordance with the conditions of their medicinal licence they commit an offence under clause 17 of the RMC Bill. However, where a person is non-compliant with licence conditions and the activity engaged is not accordance with the medicinal licence they will be, based on the current wording of the RMC Bill, subject to the ND Act again (refer to clauses 16(4) and 20(5) of the RMC Bill). The RMC Bill does not provide for the revocation of any licence or authorisation granted. A licensee may argue that the activity or thing covered by a licence is under the jurisdiction of the RMC Bill scheme despite a breach of condition.

There is a question about whether there will be several offence provisions from different legislative schemes potentially applying to the same activity. It is not clear what the intention is, whether the ND Act regime is not intended to apply at all, or is intended to apply only in limited circumstances, and, if so, when. Further consideration should be given to the interrelationship between the RMC Bill and the ND Act and whether there is value in dealing with the regulation of medicinal cannabis by

amendments to the ND Act rather than creating a completely separate and free-standing regime. Building on the existing legislative framework may assist in ensuring consistency, achieving clarity and avoiding duplication of regulation due to several applicable laws.

Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990

The *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* deals with trafficking narcotic drugs and psychotropic substances in accordance with the United Nations *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*. Section 6 defines the meaning of 'dealing in drugs' to include: cultivation of cannabis plant with the intention of producing narcotic drugs; the separation of cannabis or cannabis resin from the plant which they are obtained. The term 'narcotic drug' is defined in Schedule 2 and includes cannabis and cannabis oil. Under section 9 it is an offence for a person to have or be in the possession of equipment or materials that can be used in, or for dealing a drug that is referred to in subsection 6(1)(a),(b), or (c) and constitutes an offence against a law of the Commonwealth, or of a State or Territory. Further consideration needs to be given to whether amendments to this Act are required in relation to the production of cannabis for medicinal or experimental use sanctioned under the RMC Bill.

Other comments

In addition to the interaction the RMC Bill has on Commonwealth Law, it establishes separate statutory agency comprising members that form the 'Regulator' plus a CEO and staff. The establishment of a separate entity is not in keeping with the Government's policy on a smaller and more rational government. Details of this policy can be found in the Ministerial Paper of May2014: http://www.financeminister.gov.au/publications/docs/smaller-and-more-rational-government.pdf The RMC Bill also proposes that the CEO of the entity be the Chair of the regulator. It is not clear whether there may be any potential conflicts for a person to hold these dual statutory positions, whether the person would be entitled to remuneration for each role. Further consideration should be given to whether existing government agencies could support the work of the Chair and members of the regulator.

Involvement of participating States and Territories in the implementation of the regulatory framework, including the delegation of powers and duties by the Regulator to State and Territories officers and employees may result in significant difficulties in preventing diversion or national accumulation in stocks of cannabis.

Therefore, it is the view of the Department that further detailed consideration of the interrelationships of these laws is required to ensure that that any potential legislative framework applying to the medicinal and experimental use of cannabis in Australia is coherent, clear and workable.
If the Bill were to proceed, the Department of Health believes that it would require substantial revision and reconsideration to address the issues raised in this submission.

I hope you find this submission of assistance. Should you require further information please contact my office on

Yours sincerely

Martin Bowles
Secretary
Department of Health
20 March 2015