Submission

Senate Legal and Constitutional Affairs Legislation Committee

Regulator of Medicinal Cannabis Bill 2014

March 12, 2015

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

Re: Inquiry into the Regulator of Medicinal Cannabis Bill 2014

Dear Ms. Dunstone:

Thank you for accepting this submission from the Cannabis Policy Project (CPP).

The CPP is a new organization formed with the goal of providing coherent and sound legislative, regulatory and policy advice to both the Federal and State governments of Australia. The CPP is comprised of concerned professionals and patients along with an international expert from Canada.

Our submission provides an analysis of the Bill and eight recommendations on how to improve it from its present form. The analysis and recommendations are based on the current medicinal cannabis situations in Australia and the experiences of other jurisdictions – most notably Canada, Israel, The Netherlands and The United States.

Thank You,

Craig Ellis
Executive Director
Cannabis Policy Project

Ivan Ross Vrána
Board Member
Cannabis Policy Project

Introduction:

We welcome the introduction of the Bill and regard it as a very important step towards introducing a medicinal cannabis program in Australia.

However, in its current form we feel that it risks repeating some of the significant issues that have arisen overseas as well as creating a system that will fall short of its promise to meet the needs of patients who need to access medical cannabis. As such it also runs the risk of failing to arrest the massive black market for cannabis that exists in Australia.

For the purposes of this submission we define medical cannabis as being produced under strict guidelines that include the following:

- pharmaceutical grade good production practices and procedures;
- protecting the health and safety of the community;
- ensuring the security of the facility and all personnel; and
- implementation of record keeping systems that allows for inventory control, auditability and traceability.

Analysis:

Definition of the Responsible Minister

The proposed Bill does not identify the Ministry under which it will operate. One could assume it will be the Health Minister though this is not clear in the proposed Bill. This is a very important consideration given both local (e.g. the Tasmanian poppy industry) and international experience tends to focus more on security and law enforcement issues than on the production of a product used for health purposes. Since cannabis is being used as a medicine, guidance as to its use and production must come from the Minister of Health.

Transparency and Good Governance

It is of considerable concern that the Bill gives the Regulator numerous unchecked powers. For example Section 13(2)(b) gives the regulator the option to place a very narrow definition on the suitability of a cannabis product. It is conceivable that as it currently reads the regulator could refuse all products. Similarly, we would argue Section 14 confers excessive powers to the regulator.

Sections of the Bill such as these require amendment so that the spirit of the legislation can be maintained. In order to enhance transparency and good governance we would argue that it is necessary for the Regulator, through the Minister of Health, report annually to Parliament.

To maintain public confidence in the Regulator the Chair should be an independent Director and not the Chief Executive Officer. There needs to be a clear separation of

roles and responsibilities between these two positions so the standards of good governance within a public administrative body are maintained.

Medicinal Cannabis Products and Eligible Patients

The Bill is silent on what conditions will be allowed to be treated with medicinal cannabis. The scheme being established under the proposed Bill should require the Regulator to make rules stipulating how medical conditions are determined for inclusion on the list while creating a mechanism that allows input from medical experts, patients and the Board.

Medicinal Cannabis Products and Medical Practitioners

By making medical practitioners the "gatekeepers" of the system, the Bill merely establishes a regime which has faltered in all other jurisdictions such as Canada and the United States.

If the scheme codifies the conditions under which medical cannabis can be made available to patients a provision should be added to the Bill that stipulates a document, instead of a prescription, attesting to the patient's medical condition should be sufficient to access medicinal cannabis. This would in practice be similar to the system recently put in place in New South Wales which does not require a Physician to prescribe cannabis but merely to attest to the existence of a medical condition that negatively affects the health of a patient.

It is the view of the CPP such a system will lead to enormous savings within the health care system and avoid putting an undue burden on both Physicians and patients. In this way the proposed Regulator and health care practitioners are partners within this new field of health care.

Fees – Cost Recovery

In Section 63 of the Bill the Regulator has the scope to allow for fees to be charged. We would suggest this section be enhanced so these rules, once developed only pertain to those seeking authorization from the Regulator to produce medicinal cannabis. While not wanting to place an unnecessary burden on a new industry, the CPP would support the development of such rules as long as they follow the parameters set out in the Government's Cost Recovery Policy which requires a Cost Recovery Impact Statement.

The benefits of such a system would ensure complete transparency in the Regulator's approval methods (for those seeking to produce medicinal cannabis), establish firm timelines and a staff explicitly dedicated to managing the process while working directly with those seeking approvals. Such a regime could be similar to the obligations applied to the Therapeutic Goods Administration when its charges fees for the approval of a new pharmaceutical product.

Method of Distribution

The Bill is completely silent on the method of distribution. International experience would suggest that a method must be specified in the Bill and that accessibility must be a straight forward process if a regulated supply is to be maintained and the black market is to be eradicated.

In Canada, the only legal method for distribution specified in the governing regulations is via mail order. However, this narrow method of distribution has made the product difficult to access on a regular basis. The unattended consequence is that demand has been filled by dispensaries (particularly in Vancouver) operating across Canada that are illegal. Licensed producers regulated by Health Canada would lose their license if they sold to these organization and as such the black market is still a reality – something the new regime instituted in Canada was supposed to address and limit.

Furthermore, it is conceivable that medically approved cannabis products will range from pre-packaged oral treatments through to raw cannabis with various cannabinoid profiles at various weights and strengths.

It is the view of the CPP that pharmacies and pharmacists are neither equipped nor trained to deal with this new range of medicines. It is our contention that a regulated medicinal cannabis regime can only be delivered through a properly regulated dispensary system.

We understand that a dispensary model may conjure up the images of quasi-recreational usage as per California. However, if the Bill does not address this issue it is very conceivable that an unregulated system supplied by the black market will continue to fill the void.

It is our view that only through approved and regulated dispensaries that patients will be able to access expert advice and a full range of cannabis products. A State regulated dispensary system should be specified in the Bill.

Recommendations:

The following are the CPP's recommendations as to how the Bill can be improved:

Recommendation 1

Part 3, Division 2, Section 31 be altered to clearly state the Regulator comes under the Ministry of Health and that it report directly and annually to Parliament.

Recommendation 2

Create a new section in Part 3, Division 2 that states: "*The Regulator produce an Annual Report submitted to Parliament and the Minister of Health submit a copy of the report to each House of the Parliament within 15 sitting days of that House after its receipt by the Minister. The Annual Report will detail:*

- *statistical highlights;*
- *number of products approved;*
- *number of licenses approved;*
- *number of products recalled;*
- *conditions approved for treatment with medicinal cannabis;*
- *list of approved medicinal cannabis products;*
- *timeliness of decisions;*
- *matters dealt with during the year;*
- *governance report;*
- *budget; and*
- *any Board decisions pending.*"

Recommendation 3

That the language in Part 3, Division 5, Section 49(2) is deleted ("*The Chair is the Chief Executive Officer*") and replaced with: "*The Chief Executive Officer is separate from the Chair of the Regulator and the position is to be appointed as per the rules of the Australian Public Service Commission and is answerable to the Board and Minister of Health.*"

To maintain public confidence in the Regulator the Board should be independent from the Chief Executive Officer and staff of the Regulator.

Recommendation 4

Part 2, Division 2, Section 13(2)(b) be altered to read: "*The Regulator is satisfied that a cannabis product is suitable for medicinal use for which it will not be unreasonably withheld and as part of this decision making process experiences in other Australian States and international jurisdictions be taken into account. Other international jurisdictions should include but are not limited to:*

- *Canada;*
- *Israel*
- *The Netherlands; and*
- *The United States.*"

The CPP has suggested the four countries above given they have been creating legislation, regulations and policies for over 15 years within the field of medicinal cannabis.

Recommendation 5
Part 2, Division 2, Section 14 be amended to include language which stipulates: "*Reasons for any such removal or variation are to be published on the Regulator's website and documented in its Annual Report.*"

Recommendation 6
Part 2, Division 4, Section 19(1)(d) be amended to read: "*Medical practitioners, or classes of medical practitioners attest to the patient's medical condition that negatively affects the health of a patient.*"

Recommendation 7
Part 3, Division 6, Section 63(4) be expanded to include the following language: "*The Rules may prescribe the way in which a fee is to be worked out within parameters set out in the Government's Cost Recovery Policy which requires a Cost Recovery Impact Statement and if instituted will only apply to those seeking to produce medicinal cannabis.*"

Recommendation 8
That a new Part of the Bill be added which clearly outlines a legal and regulated distribution method for medicinal cannabis. The CPP would recommend the Bill state that distribution is based on a dispensary system which is to be developed by the Regulator in consultation with the States and local municipalities while allowing for the actual regulation to be undertaken by those respective jurisdictions.

About the Authors:

Mr. Craig Ellis has over 25 years of private and public company experience. His work has frequently involved him working closely with government and government agencies in developing and improving industry regulations. He has a particular interest in progressive social issues including drug law reform.

Mr. Ivan Ross Vrána is the Principal behind Aslan Ross Consulting – located in Ottawa, Canada. Prior to founding the company in 2012, Mr. Vrána worked for Health Canada for over 15 years. His last position within the Department saw him lead the team that was directly responsible for developing the policy proposal which was adopted by Cabinet that resulted in Canada's *Marihuana for Medical Purposes Regulations*.