LAW INSTITUTE VICTORIA

# Medicinal Cannabis

## SUBMISSION TO THE VICTORIAN LAW REFORM COMMISSION

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# INTRODUCTION

The Law Institute of Victoria (LIV) is pleased to make this submission to the Victorian Law Reform Commission (the Commission) in relation to the regulation of medicinal cannabis in Victoria. This submission has been prepared based on comments provided by the LIV's Health Law Committee of the Administrative Law and Human Rights Section. In this submission the LIV responds to select questions in the Commission's Medicinal Cannabis Issues Paper March 2015 (Issues Paper).

## General Comments

The LIV acknowledges that the Victorian Government has committed to enabling the lawful use of cannabis for medicinal purposes in exceptional circumstances and that the Commission has been asked to specifically report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) to allow people to be treated with medicinal cannabis in exceptional circumstances. The fundamental question being considered by the Commission is how to implement this policy, not whether the policy should be implemented. It is in this discourse that the LIV seeks to address in particular the regulatory issues raised.

Medicinal cannabis products regulated in Victoria need to be available in therapeutically appropriate forms that can be maintained for quality and consistency and produced specific to a defined therapeutic purpose. To ensure the quality and the consistency of the products, regulation needs to address the entire process of importation and/or cultivation, manufacturing and distribution, and not just use and possession. The Commission needs to consider the Commonwealth and international regulations applicable to the manufacture and distribution of medicinal cannabis, whilst ensuring safe and therapeutically appropriate products are made available for the (potentially vulnerable) users.

A difficulty in establishing a regulatory system around the cultivation and manufacture of medicinal cannabis is that an Australian medicinal cannabis product does not exist in an established and approved medicinal form.

When the Victorian Government established the regulations for the opiate industry, it was for an established and regulated pharmaceutical product approved under the *Therapeutic Goods Act 1989* (Cth) (TGA) that had a large international demand. It is unclear whether the development of medicinal cannabis within Victoria will be commercially viable and whether pharmaceutical companies and medical practitioners would be prepared to participate in the process where clinical evidence of the efficacy is not available and the potential demand is limited to exceptional circumstances. Whilst amendments to the *Drugs, Poisons and Controlled Substances Act* 1981 (Vic) may be an option for a regulated scheme for medicinal cannabis that could replicate the regulatory framework set up for the opiate (alkaloid poppy) industry, the lack of an approved and federally regulated product would create legal difficulties not present in the opiate industry example.

# SELECT QUESTIONS FROM THE ISSUES PAPER

## (3) What special considerations, if any, justify access to medicinal cannabis for:

***(a) patients who are under 18 years of age***

***(b) patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal cannabis?***

At common law, all competent adults can consent to and refuse medical treatment. If consent is not established, there may be legal consequences for health professionals. Generally, the more complex the healthcare or more serious the consequences, the stronger the need for evidence of the patient's capacity or incapacity to consent to the specific healthcare (or that of their authorised decision maker - e.g. guardian). 'Informed consent' refers to consent to medical treatment and the requirement to warn of material risk prior to treatment. As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment. Failure to do so may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent.[1]

With the example of a medicinal cannabis product that is not regulated under the Commonwealth TGA, medical practitioners would arguably need to provide an appropriate disclaimer as to the limited therapeutic research and the limited evidence of efficacy. The patient would need to assume the risk. This is more complicated in the situation of minors and people who lack capacity to give informed consent and their ability to assume that risk.

Determining the competence of a minor to consent can be very complex. A minor is capable of giving informed consent when he or she achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed and any possible consequences.[2] In these situations, a medical practitioner must ensure informed decision making, confirming the decision maker is aware of the benefits, the risks and any alternative treatments.

As the efficacy of the medicinal cannabis (without an established therapeutic product in an appropriate registered form) is still unclear (on a clinically trialed basis), this may cast doubt that express consent from a decision maker was adequately informed. With potential side effects including psychiatric disorders and dependence, medical practitioners need to be able to provide a proper analysis of risk / benefit ratio for patients. Therefore it is important that any product provided to a minor or a patient who lacks capacity be regulated for quality and therapeutic value in a measurable form with established efficacy and safety standards and guidelines.

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[1] *Rogers v Whitaker* (1992) 175 CLR 479.

[2] This test comes from the English case of *Gillick v West Norfolk AHA (1986)1 AC 150* which has been applied for many years when providing health services to minors.

## (5) Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal cannabis? If so , what should that be?

Whilst this is essentially a medical question, the LIV would recommend that the regulatory framework provide adequate flexibility for special applications. The Secretary of the Department of Health and Human Services (DHHS) may retain powers to extend the operation of the scheme on compassionate grounds that may reflect the development of medical research.

The regulation, however, should not be too broad in scope leading to the greater potential for misuse.

The legislation should provide some flexibility within the limitations to be prescribed in the regulations. There may be a possibility for the Secretary of DHHS to 'gazette' certain treatments for certain conditions. Currently, the special access scheme runs parallel to the Commonwealth TGA approval process, which provides medical practitioners a degree of flexibility to respond to development of medical research without undermining the Commonwealth TGA process.

## (6) If Victoria acted through a state agency, in what circumstances would it be legally entitled to establish a medicinal cannabis scheme which manufactured cannabis products without breaching the terms of the *Therapeutic Drugs Act 1989* (Cth) or the *Narcotic Drugs Act 1967* (Cth)?

A comprehensive medicinal cannabis scheme in Victorian would need to rely on collaboration with the Commonwealth Government. The regulation on importation, manufacture and distribution of pharmaceutical drugs sits predominately with the Commonwealth. A stand-alone Victorian scheme without Commonwealth amendments would be difficult.

The *Tasmanian Dam*[3] case has long established that, if the Commonwealth is a party to an international convention, it will retain the power to intervene in state legislation relevant to the international convention. As the manufacture of medicinal cannabis falls within Commonwealth obligations to three international conventions,[4] it is unclear how Victoria could protect itself from potential interference from the Commonwealth without some form of collaboration. Whilst the Commission has highlighted the High Court's

[3] *Commonwealth v Tasmania* (1983) 158 CLR 1.

[4] *Single Convention on Narcotic Drugs 1961,* opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964); *Convention on Psychotropic Substances 1971,* opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976)*; Convention Against illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988,* opened for signature 20 December 1988, 1582 UNTS 165 (entered into force 11 November 1990).

decision in *Bropho v Western Australia*[5] for a Victorian 'stand alone' system on the presumption that the statute does not bind the Crown, this matter did not involve Commonwealth obligations to international conventions and would continue to leave the State of Victoria exposed to the implications raised in the *Tasmanian Dam* case.

Further, section 51(xx) of the Australian Constitution provides that the Commonwealth Government has powers to make laws regarding foreign, trading and financial corporations, including state owned corporations. Even if the Victorian Government legislated out of the Commonwealth TGA any incorporated association or statutory corporation established to cultivate, manufacture and supply medicinal cannabis would arguably be engaging in significant trade. It is unclear whether an unincorporated and/or state public sector entity would be exempt from being considered a constitutional corporation, and therefore still subject to the corporations power.[6] This would also extend to the supply of medicinal cannabis.

As there are currently several states agitating for public access to medicinal cannabis, the states could negotiate with the Commonwealth Government over several options to assist, including facilitating importation. The states could make an application to the Secretary of the Commonwealth Department of Health to exercise its discretion to provide for a special access scheme and provide excluded goods declaration.

A special access scheme for the importation of already regulated therapeutic products would reduce many of the concerns between State and Commonwealth legislation. This would also eliminate the regulatory issues in cultivation and manufacturing of medicinal cannabis. The states would then be in a position to regulate the supply and distribution for exceptional circumstances in consultation with the medical profession. Where there are commercially produced and regulated products available overseas (from established medicinal cannabis suppliers, such as Dutch corporation Bedrocan that are already regulated for consistency and quality), a Special Access Scheme for the importation may be the best initial option, while the local market and its regulatory framework is being established.

## (8) Would the creation of a defence to prosecution for authorised patients and carers in possession of small amounts of dried cannabis or cannabis products be an adequate way of providing for people to be treated with medicinal cannabis in exceptional circumstances?

The LIV believes that the use of medicinal cannabis should be a medical concern not a criminal justice issue. However providing a defence to prosecution for possession (and presumably also administration and use) for medicinal purposes would not address the broader issues of cultivation, manufacture and supply.

[5] Bropho v Western Australia (1990) 171 CLR 1, 23.
[6] *Commonwealth v Tasmania* (1983) 158 CLR 1.

Offences relating to cultivation and supply are classified as serious indictable offences.[7] Supply of a drug to a minor holds a maximum penalty of 15 years imprisonment, as well as associated offences of conspiracy to traffic, cultivate or possess which could involve a range of health professionals, resulting in reluctance by those health professionals to take the risk of administering cannabis for medicinal purposes.

Recent amendments to the *Sentencing Act 1991* (Vic) mean that Court discretion for suspended sentences are not available for 'serious' or 'significant' offences, which would include cultivation and trafficking. Consequently, whilst an end user/patient/carer may have a defence against prosecution, the police may not have discretion to not investigate and prosecute an indictable offence, such as the cultivation and supply.

An unregulated scheme would also result in a supply of cannabis that would have no measure or control of the quality, consistency and therapeutic value of any product. A 'home grown' scheme would not adequately address a range of issues including:

- Consistency of therapeutic quality
- Liability issue for Doctors
- Risk of associated criminal activity like burglary
- Dangers of home hot houses
- Difficulties for police regulation and enforcement, e.g. detecting/preventing smoking in the home as a means of administration.

The defence would not adequately address the legislative objective of coherence. The LIV maintains that any schemes that would self-regulate the end user as a grower should be avoided, as it would undermine the regulatory system around cultivation and supply of drugs and weaken public confidence in the regulatory system.

## (9) What mechanism should Victoria use to regulate the cultivation of medicinal cannabis?

Victoria may be able to establish a state run legal entity (e.g. agency) that outsources to private operators under licence. However, this may be difficult to achieve without addressing Commonwealth legislation that may restrict such activities as outlined above.

Ideally, the number of such operators would be strictly limited to minimise the regulatory burden and ensure regulatory control, compliance and clinical standards are maintained.

[7] *Drugs, Poisons and Controlled Substances Act* 1981, s 72 B(b).

## (10) What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?

This question would appear to assume the medicinal cannabis is locally grown and produced instead of imported. (Please refer to our previous recommendation and below under (11) with regard to importation as the suggested preferred option in the first instance.)

As an alternative to distribution via authorised pharmacies, a newly established Victorian agency could act as a "clearing house" on behalf of authorised patients whose medical practitioner could prescribe and place the orders with the agency online. The medicinal cannabis could then be distributed to authorised pharmacies or the prescribing medical practitioners from whom it is then directly collected by the authorised patient /carer. This option could overcome the dilemma of the drug not being under the TGA scheme and not being subject to the normal prescription requirements /standard forms and documentation for TGA approved drugs.

In any event, it is recommended that Victoria adopts a scheme that allows the State to maintain stringent control with adequate audit at the distribution end. A regulated scheme should balance supply and demand to limit the risk of diversion.

## (11) How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?

Whilst Victoria could regulate the sale and distribution of a therapeutic medicinal product, it is the Commonwealth jurisdiction that regulates the cultivation and manufacture into an end therapeutic product to ensure the quality, safety and efficacy of medicines. As outlined above, to regulate a scheme without Commonwealth involvement would be very difficult.

As outlined previously, a relatively simple approach would be to import already established medicinal products such as those available in The Netherlands (Bedrobinol, Bedrocan, Bediol, and Bedica) which are already regulated for measurable quality and consistency. If the Commonwealth provided an exemption for the importations, the State Government could regulate the sale and distribution.[8]

[8] Currently the medicinal cannabis product Sativex / Nabiximols (an extract from cloned cannabis plants that has a defined dose with moderated psychotropic effects) has been approved by the Cth TGA, however it is still registered as a schedule 8 poison under the standard for Uniform Scheduling of Medicines and Poisons and has regulations over its storage and distribution. We understand the pharmaceutical company responsible for its distribution has not sought to distribute it within Australia at this point.

## (16) In what form(s) should medicinal cannabis be permitted to be supplied and used?

Medicinal cannabis should not be permitted where smoking is the method of delivery, as this poses secondary health risks and undermines other public health campaigns.

The most appropriate forms should be regulated to include those that:

- are the most medically effective in alleviating the condition/symptoms for which they are prescribed;
- allow prescribing health practitioners to properly exercise their professional judgment with respect to quantity, quality and efficacy of the product;
- are financially accessible to the end user (i.e. not cost prohibitive); and
- do not pose an unacceptable health risk to the end user or others.

Access to the regulated scheme in Victoria should be restricted to permanent Victorian residents and the drug may only be used when within Victorian borders. This would prevent issues with medical “tourism” and the conflict with criminal sanctions in other jurisdictions.

## (17) In what ways could Victoria’s medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?

The State Government has already announced participation in medicinal cannabis trials to explore the safety and benefits for a defined group. This will assist with the current shortage of pharmaceutical evidence; and help define the extent of potential uses and the potential market for commercial suppliers.