



10th March, 2015

Inquiry into the Regulator of Medicinal Cannabis Bill
Legal and Constitutional Affairs Legislation Committee
The Senate
Parliament House
Canberra, ACT, 2600

Re: Submission to the Inquiry into the Regulator of Medicinal Cannabis Bill 2014

Thank-you for the opportunity to provide comment on the proposed Bill. We read the proposed Bill with interest. Access to cannabis (whether medicinal-grade herbal cannabis or pharmaceutical preparations) is a complex health and social issue.

As drug policy scholars we have considered the various issues associated with the provision of cannabis for medicinal use. The attached paper outlines some of the issues, which we hope will be informative to the Committee.

We note that the proposed Bill is broad in its intent, and thus would conform to the broader definition of medicinal cannabis in the attached paper, rather than the narrow definition (prescribed by a trained medical professional, for known medical conditions, for which there is demonstrated evidence of efficacy).

Yours sincerely

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Medicinal cannabis in Australia – Framing the regulatory options

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March, 2015

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Citation: Belackova, V., Ritter, A., Shanahan, M., Chalmers, J., Hughes, C. Barratt, M. & Lancaster, K. (2015). Medicinal cannabis in Australia – Framing the regulatory options. Sydney: Drug Policy Modelling Program.



Introduction

A wide societal, expert and policy debate has recently emerged around the use of cannabis for medical purposes ('medicinal' or 'therapeutic' cannabis) in Australia. Cannabis is the most widely used illicit psychoactive substance [1] and has been subject to ongoing debate about its legalisation [2]. The cannabis plant and/or constituents of the cannabis plant also have medicinal properties for treating specific health conditions [3]. Due to the way in which cannabis, as an illicit drug, has historically been understood politically, socially and legally, designing schemes that regulate access to medicinal cannabis for patients (but not access for other purposes) thus represents a complex and controversial policy challenge.

The Australian public are in favour of the use of cannabis as a medicine. According to the National Drug Strategy Household Survey, almost three quarters of Australians support "a clinical trial for people to use marijuana to treat medical conditions" (73.5 % in 2004, 73.6 % in 2007, 74.0 % in 2010 and 75 % in 2013) [4]. And more than two thirds of the Australian population support a permanent legislative provision in the form of a "change in legislation permitting the use of marijuana for medical purposes" (67.5 % in 2004, 68.6 % in 2007, 68.8 % in 2010 and 69.0 % in 2013) [4].

There have also been strong indications of political support. For example, in September 2014, the Premier of New South Wales announced clinical trials of medicinal cannabis (in children with severe epilepsy, for terminal illness and as a treatment for nausea in cancer patients). In addition, NSW Police guidelines have been amended to allow police to not charge terminally ill adults or their carers who use cannabis to alleviate symptoms (the NSW Terminal Illness Cannabis Scheme [5]). The Prime Minister Tony Abbott noted that "something that has been found to be safe in a reliable jurisdiction shouldn't need to be tested again here", suggesting that medicinal cannabis should be made accessible in Australia without the need for further trials [6]. The Victorian Law Reform Commission is

[1] UNODC (2013). World Drug Report 2013. New York: United Nations; 2013

[2] For a comprehensive report on cannabis legalisation, see Caulkins, J.P., Kilmer, B., Kleiman, M. MacCoun, R. Midgette, G. Ogelsby, P., Pacula, R. & Reuter, P. (2015) Considering Marijuana Legalization Insights for Vermont and Other Jurisdictions. Available at: http://www.rand.org/pubs/research_reports/RR864.html. In this report, Caulkins and colleagues consider a number of options for the adult recreational market. The twelve alternatives are (from most restrictive to least restrictive): prohibit and increase sanctions; prohibit but decrease sanctions; allow adults to grow their own; communal own-grow and distribution; retail sales only; government operates the supply chain; public authority (near monopoly); non-profit organisations; for-benefit companies; very few monitored licensees; standard commercial model; and repeal-only of state prohibition. They argue that the two most commonly discussed options (prohibit but decrease sanctions; and standard commercial model) belie the range of middle-ground options.

[3] Two relevant references are: a). NCPIC. (2014). The use of cannabis for medical purposes. Sydney: National Cannabis Prevention and Information Centre. b). Farrell M, Buchbinder R, Hall W. (2014). Should doctors prescribe cannabinoids? British Medical Journal, 348, g2737.

[4] AIHW. (2014) National Drug Strategy Household Survey Detailed Report 2013. Canberra: Australian Institute of Health and Welfare

[5] NSW Government (2015) Terminal Illness Cannabis Scheme: Fact sheet for adults with a terminal illness and their carers. Available from: <http://www.nsw.gov.au/tics>.

[6] Knott M. Tony Abbott backs legalisation of medical cannabis. Sydney Morning Herald. 2014 September 17. Available from: <http://www.smh.com.au/federal-politics/political-news/tony-abbott-backs-legalisation-of-medical-cannabis-20140917-10i6eb.html>

currently exploring regulatory options for medicinal cannabis access [7] after the Labor Premier referred the matter to them. The ACT Legislative Assembly is currently conducting an Inquiry into medicinal cannabis [8]. In February, 2015, the federal Senate referred the proposed “Regulator of Medicinal Cannabis Bill 2014” to the Legal and Constitutional Affairs Legislation Committee. The Bill proposes the establishment of an Australian regulator, responsible for formulating rules for licensing the production, manufacture, supply, use, and import and export of medicinal cannabis [9]. These very recent activities have built from earlier work [10]. Support has not been universal [11, 12], and there remains considerable uncertainty about the effects of long-term cannabis use: “If medical use is likely to be long term, patients should be warned that the adverse effects of long term use are unclear” [13].

There are a number of issues in this debate, including the level of evidence for cannabis based treatments and for its symptom alleviation in different diagnoses; access to and supply mechanisms for medicinal cannabis; the type of cannabis preparation (use of herbal product versus pharmaceutical preparations); and the extent of differentiation between medicinal cannabis and recreational cannabis and the associated markets.

The aim of this paper is to explore and provide a framework for discussion around the regulatory issues, notably access and supply of medicinal cannabis. In considering the regulatory options and models, this paper does not cover the clinical efficacy of medicinal cannabis for use in different medical conditions, leaving that discussion for the relevant medical specialists. A summary of current research on efficacy and effectiveness of medicinal cannabis treatments can be found elsewhere in the literature. [14]

[7] For details see: <https://www.viclabor.com.au/news/labor-medical-cannabis-should-be-legal/> They are due to report end August 2015

[8] For details, see: http://www.parliament.act.gov.au/in-committees/standing_committees/Health,-Ageing,-Community-and-Social-Services/inquiry-into-exposure-draft-of-the-drugs-of-dependence-cannabis-use-for-medical-purposes-amendment-bill-2014-and-related-discussion-paper?inquiry=624651

[9] The Committee is due to report by April 2015.

[10] Previous work in this area: a). NSW Parliament. Report of the Working Party on the Use of Cannabis for Medical Purposes: Working party on the use of cannabis for medical purposes; Sydney. NSW Parliament. 2000. b). NSW Parliament Legislative Council General Purpose Standing Committee No. 4. The use of cannabis for medical purposes. Sydney, NSW: New South Wales Parliament, Legislative Council; 2013

[11] For example Drug Free Australia has issued a position paper that disputes the use of medicinal cannabis on the grounds of its adverse effects, risk of proliferation into recreational settings, availability of other comparable medication and “moral hazard” related to promoting medicinal effects of cannabis outside of evidence-based medicine. Drug Free Australia’s position on Medicinal Marijuana / Cannabis. 2014. Available at: www.drugfree.org.au.

[12] Several representatives of the Australian Pain Society have concluded that there is a need for more efficacy data, and that the safety and tolerability profile of medicinal cannabis is unknown. They argue that medicinal cannabis should only be considered where the standard therapy has failed; and, congruent with current evidence, only for neuropathic pain (Ware MA, Desroches J. (2014) Medical Cannabis and Pain. Pain Clinical Updates, XXII,3).

[13] Farrell M, Buchbinder R, Hall W. (2014). Should doctors prescribe cannabinoids? British Medical Journal, 348, g2737.

[14] NCPIC. (2014). The use of cannabis for medical purposes. Sydney: National Cannabis Prevention and Information Centre

By examining international regulatory systems, this paper aims to help Australian decision makers distinguish between the different models and identify some of their advantages and limitations. Any discussion of medicinal cannabis should be underpinned by the *International Convention on Economic, Social and Cultural Rights* that states that everyone has the right to the highest attainable standard of physical and mental health [¹⁵], and to the *Australian Charter of Healthcare Rights* that stipulates the right to receive safe and high quality care provided in an effective continuum [¹⁶].

In discussing medicinal cannabis, there is clear overlap with the wider debate about cannabis prohibition. This paper is not designed to close off discussion of cannabis legalisation more broadly but here we focus solely on medicinal cannabis, and we situate this paper's discussion within the framework of existing Australian laws. The regulatory model for medicinal cannabis thus needs to be developed with consideration of the international system of drug control and the international treaties [¹⁷] of which Australia is a signatory.

The debate and policy considerations for regulation of medicinal cannabis are distinguishable from those concerned with regulation of recreational cannabis use. The last few years have seen increased discussion and policy changes in the regulation of cannabis for non-medical purposes e.g. the legalisation of cannabis in Washington State, Colorado, Alaska and Uruguay. Such initiatives may exist in parallel to those of regulation of medical cannabis. However, the issues, challenges and regulatory models for medicinal cannabis differ significantly from those for recreational cannabis. [¹⁸]

Medicinal cannabis

There are over one hundred cannabinoids in the cannabis plant. To date, the main active constituents of the cannabis plant that have proven medicinal properties are THC (delta-9-tetrahydrocannabinol) and CBD (cannabinol). Although there is some evidence of synergistic [¹⁹]

Farrell M, Buchbinder R, Hall W. (2014). Should doctors prescribe cannabinoids? *British Medical Journal*, 348, g2737.

[¹⁵] International Convention on Economic, Social and Cultural Rights. (1976).

[¹⁶] ACSQH. (2008). *Australian Charter of Healthcare Rights*. Sydney: Australian Commission on Safety and Quality in Health Care

[¹⁷] There are three treaties:

1961 Single Convention on Narcotic Drugs

1971 United Nations Convention on Psychotropic Substances

1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

[¹⁸] For example the regulation of recreational cannabis use in Washington State and Colorado were informed by lessons from regulation of medical cannabis but demanded additional considerations as well. For discussion of complexities and challenges involved see: a). Pacula, R. L., Kilmer, B., Wagenaar, A. C., Chaloupka, F. J., & Caulkins, J. P. (2014). Developing public health regulations for marijuana: Lessons from alcohol and tobacco. *American Journal of Public Health*, 104(6), 1021-1028. b). Caulkins, J. P., Kilmer, B., Kleiman, M. A. R., MacCoun, R. J., Midgette, G., Oglesby, P. Pacula, R. L., & Reuter, P H. (2015). *Options and Issues Regarding Marijuana Legalization*. PE-149-RC. Santa Monica: RAND.

[¹⁹] Also known as the "entourage effect".

treatment effects from the combination of all the cannabinoids within cannabis [²⁰], their indication for specific diagnoses remains scientifically un-tested.

There are three main forms of cannabis that can be used medicinally. First, a medical grade product with standardised content of the active constituents, presented as a medication (standardised packaging, dosing and so on). This is effectively the same as for any pharmaceutical preparation that adheres to the requirements of the Therapeutic Goods Administration (TGA), the agency that oversees the registration of medications in Australia. Several pharmaceutical preparations of cannabinoids have been introduced onto the market. These are either nabiximols - preparations that isolate pure THC and CBD from the cannabis plant (e.g. Sativex), or that contain synthetically derived THC (e.g. dronabinol). Most clinical trials, which represent the highest standard for assessing the efficacy of medication in humans, have been conducted with these pharmaceutical preparations, rather than with herbal cannabis. To date, cannabinoids other than CBD and THC have not been isolated into pharmaceutical preparations, and thus the synergistic effect has only been observed when herbal cannabis or its compounded extracts are used medically.

The second form of cannabis for medicinal use is herbal cannabis that is produced and processed in controlled and standardised conditions, and is 'medical-grade herbal cannabis'. This means that its cultivation has to be standardised to produce stable levels of cannabinoids (THC and CBD), and the product has to be free of any harmful adulterants. The Dutch licensed grower 'Bedrocan' [²¹] provides an example of this type of process.

Herbal cannabis that is available through the illegal market which has an unknown and potentially unstable content of THC, CBD, and of other active constituents is a third option. It may have adulterants and moulds as a result of improper air circulation and drying, heavy metals taken up from the soil and air, and pesticides or other chemical residues from pest protection and fertilisation [21]. While it is possible for non-regulated growers to produce stable cannabis free from adulterants, the reliance on unregulated suppliers for the manufacturer of medical products poses substantial risks for patients who cannot be guaranteed product stability and purity. [²²]

The potential modes of administration of medicinal cannabis include oral administration of pills (for the pharmaceutical preparations), use of oromucosal spray, a tincture or ointment or vaporisation of

[²⁰] References: a).Russo EB. Taming THC: potential cannabis synergy and psycocannabinoid-terpenoid entourage effects. *British Journal of Pharmacology*. 2011(163):1344–64. b). McPartland JM, Russo EB. Cannabis and Cannabis Extracts. *Journal of Cannabis Therapeutics*. 2001;1(3-4):103-32. c). Russo EB, Partland JM. Cannabis is more than simply delta-9-tetrahydrocannabinol. *Psychopharmacology*. 2002;165(4):431-2.

[²¹] Hazekamp A. (2006) An evaluation of the quality of medicinal grade cannabis in the Netherlands. *Cannabinoids*. 1(1):1-9.

[²²] There is a fourth form of cannabis – hemp, which zero THC content. Hemp does not have psychoactive properties, neither does it have medicinal properties referred to above (unless a specific strain with significant CBD content is used). Hemp is nevertheless an important source of fibre and hemp seeds have been demonstrated to contain several important nutrients. References include: a). Girgih A, T., Alashi A, He R, Malomo S, Aluko R, E. Preventive and treatment effects of a hemp seed (*Cannabis sativa* L.) meal protein hydrolysate against high blood pressure in spontaneously hypertensive rats. *European Journal of Nutrition*. 2013;53(5):1237-46. b). Leizer C, Ribnicky D, Poulev A, Dushenkov S, Raskin I. The Composition of Hemp Seed Oil and Its Potential as an Important Source of Nutrition. *Journal of Nutraceuticals, Functional and Medicinal Foods*. 2000;2(4):35-53. c). Callaway JC. Hempseed as a nutritional resource: An overview. *Euphytica*. 2004;140(1-2):65-72.

Despite it being non-psychoactive and nutritious, Australia is one of only a handful of countries that continues to ban hemp in food products.

the herbal product [23]. As a medicinal product, smoking cannabis (joints or bongs) is not recommended given the well-known attendant harms associated with smoking. [24]

To summarise, both the cannabis plant and related pharmaceutical preparations have been used in medicine and fall under the term “medicinal cannabis”. While the benefit of herbal cannabis may lie in the synergistic effect of its compounds, particular pharmaceutical preparations have attained a higher level of scientific evidence. [25]

Clarifying the boundary to medicinal cannabis

While the active ingredients (THC, CBD or synergistic effects of multiple cannabinoids), or the form (pharmaceutical preparation, medical-grade herbal cannabis, or herbal product) can describe medicinal cannabis and its varieties, there remains an important challenge in specifically defining what is meant by the medical use of cannabis. A continuum exists, ranging from the way in which cannabis is perceived by the person consuming it to be beneficial to his or her health (the broadest definition), to a very narrow definition that conforms to medical terminology: that is, a medication which is recommended or prescribed by a doctor for a set of conditions where it has proven to be an effective treatment [26]. In the case of the narrowest definition, medicinal cannabis is that which is: (i) prescribed by a trained medical professional [27]; (ii) for a known medical condition; (iii) for which there is research demonstrating its efficacy as a treatment. This can mean that while many recreational cannabis users perceive health benefits from their cannabis use, a narrow definition would only consider it a medical use where scientific evidence of health improvement exists.

The choice of definition is important: for the narrow definition of medical use, medical regulation and prescription regimes are essential; while in the broad definition, these are not an essential element of the regulatory regime. Thus the way in which regulators define medicinal cannabis will bear on its regulatory form.

Where the narrow definition is employed, there is an apparent clear distinction between cannabis used medicinally and cannabis used recreationally. This may be advantageous in relation to establishing a boundary around medicinal cannabis use, securing patients’ rights to access the most appropriate treatment, and reducing the risks of leakage from the medicinal market to the recreational market. It sets clear operating procedures regarding access to and availability of this

[23] Edible forms of cannabis are also now proliferating in the legal adult recreational market.

[24] Publications demonstrating the harms associated with smoking cannabis:

Gordon AJ, Conley JW, Gordon JM. (2013). Medical Consequences of Marijuana Use: A Review of Current Literature. *Curr Psychiatry Rep*,15:419-30.

Zhang LR, Morgenstern H, Greenland S, Chang S-C, Lazarus P, Teare MD, et al. (2015) Cannabis smoking and lung cancer risk: Pooled analysis in the International Lung Cancer Consortium. *International Journal of Cancer*,136(4):893-904.

Hall W, Solowij N. (1998) Adverse effects of cannabis. *The Lancet*, 352(9140):1611-6.

[25] This situation is unsurprising because funding for clinical trials largely comes from pharmaceutical companies, who can only make a profit from a medicine if it is a pharmaceutical preparation not a plant.

[26] Under current evidence these conditions are mainly nausea, anorexia, spasticity and neuropathic pain. In vitro studies demonstrate a potential for treatment in some types of cancer, but any conclusions in this area are preliminary and further research is needed.

[27] A slightly less narrow definition would not involve prescription by a doctor per se, but recommendation by a doctor in the absence of prescription.

particular type of medicine to certain patient groups. Maintaining a clear distinction between medicinal and recreational cannabis use requires attention to preventing the sale or exchange of medicinal cannabis on the black market (referred to as ‘diversion’) [²⁸].

However, the strict definition ignores grey areas, including the blurred boundaries between medical and recreational use in practice [²⁹], and complexities in whether or not all medical use will be recognised. The strict definition may lead to the creation of ‘deserving’ (medicinal) cannabis patients and ‘undeserving’ (recreational) cannabis users. [³⁰] This is problematic because of the way policy then creates categories of people, and sets ‘deserving’ and ‘undeserving’ groups in opposition to each other.

The choice of the definitional boundary around the medical use of cannabis also speaks to the form of cannabis: pharmaceutical, medical-grade herbal or herbal. Highly regulated medicinal cannabis regimes (prescription systems) might be better suited for pharmaceutical preparations than for deploying herbal cannabis of medicinal grade. And such regimes would be less susceptible to diversion [³¹]. However, some medicinal cannabis patients may prefer the synergistic effects from the presence of a variety of cannabinoids in the cannabis plant or find pharmaceutical products too costly. As a result, eligible patients might prefer to source cannabis for their medicinal use on the illegal market or via their own self-supply. A policy and regulatory challenge is balancing the extent of access and availability of medicinal cannabis (both pharmaceutical and medical-grade herbal) against the risk of diversion into recreational markets.

Thus a key issue in the medicinal cannabis debate is the extent to which a policy and regulatory framework for medicinal cannabis should seek to distinguish clearly between medicinal cannabis use and recreational cannabis use: that distinction is achieved with a highly medicalised and regulated model (i.e. prescription of medicinal cannabis to a limited set of clinically-approved conditions) but with the attendant risks noted above.

It is in light of these issues, that we discuss regulatory options. In the first instance, we summarise the international experience.

[²⁸] Indeed, much of the design of medicinal cannabis regulation has been primarily concerned with reducing the risks of diversion of cannabis from the ‘legitimate’ medicinal market to the ‘illegitimate’ recreational market. In light of the considerable grey areas it may be preferable to use the term ‘net widening’ rather than diversion. Net widening comes from criminal justice and refers to policies or programs which result in a greater number of people being subject to the criminal justice system. In a sense the concern with medicinal cannabis is the same – a policy/program that results in a greater number of people using cannabis than would in the absence of that policy/program.

[²⁹] For example, a person may consume cannabis believing that it will reduce some physical symptoms, in the absence of a diagnosis, prescription by a doctor, or known efficacy for that condition. This could be said to conform to medicinal cannabis use in practice. Similarly, a person using cannabis recreationally may also benefit from its therapeutic effects (such as relaxation).

[³⁰] The work of Schneider outlines the ways in which two classes of citizens can be created: a). Schneider A, Ingram H. Social Construction of Target Populations: Implications for Policits and Policy. *American Political Science Review*. 1993;87(2):334-47. b). Schneider A, Ingram H. *Deserving and entitled: Social constructions and public policy*. Albany: State University of New York Press; 2005.

[³¹] Although the fact that a medication is registered and regulated in no way guarantees that it is not diverted and used for other purposes. Buprenorphine diversion, for example, is well-documented (ref: Lavonas,E.J. et al., (2014). Abuse and diversion of buprenorphine sublingual tablets and film, *Journal of Substance Abuse Treatment*, 47(1),27-34).

International models

Several countries provide access to medicinal cannabis. The legislative basis for the availability of medicinal cannabis ranges from simple removal of criminal sanctions for patients whose medical doctor has recommended the use of cannabis, to state-level provisions of medicinal-grade herbal cannabis or pharmaceutical preparations obtained by the patient from a pharmacy with a doctor's prescription. Australian regulators currently have the opportunity to examine and learn from overseas models of medicinal cannabis regulation, which are briefly summarised here, and in Appendix 1.

In relation to the medication forms, nabiximols (extracts from cannabis plant, e.g. Sativex) have been registered in six countries to date (Austria, Canada, New Zealand, UK, Australia and the Czech Republic). Synthetic pharmaceutical preparations are registered medications in eight countries at present (Austria, Canada, Germany, France, Spain, Switzerland, UK, US).

Currently, eight countries have made medicinal grade herbal cannabis available. The US (fifteen of its states and the District of Columbia) [³²], Israel and Canada provide medicinal grade herbal cannabis through a system of dispensaries [³³]. In the Netherlands, herbal cannabis of medicinal grade (grown by Bedrocan) is available in pharmacies (the dried herbal material has the status of a source substance for compounded medication which can be then prepared by pharmacists). Bedrocan exports to several European countries including Finland and Denmark (individual imports) and the Czech Republic (pharmacies). The Czech Republic government is currently also contracting domestic cannabis cultivators to supply medicinal grade herbal cannabis. Recently, Uruguay has legislated for herbal cannabis in pharmacies.

In some US states (Alaska, Hawaii, Maryland), medicinal cannabis patients are exempted from criminal prosecution, but there is no official supply of cannabis available to them. Indeed, there is substantial variation in the ways in which different US states regulate medicinal cannabis. [³⁴]

The above variety of approaches (registered pharmaceutical products, medicinal grade herbal cannabis, patient exemption from prosecution) offer different advantages and limitations in terms of treatment availability, product quality and its adherence to medicinal product standards, as well as in their overlap with the recreational market, and adherence to the international treaties (1961 Single Convention on Narcotic Drugs; see Appendix 2). They also differ in the range of supply options.

The research evaluating the impact of medical cannabis comes from the US where most studies have compared states with medicinal cannabis to those without medicinal cannabis, without regard to the substantial between-state variation in medicinal cannabis regulations. There have been a number of different outcomes examined, all taking a public health perspective on examining the impact of medicinal cannabis legislation. The studies thus far have examined the relationship between the presence of medicinal cannabis programs and rates of recreational cannabis use amongst young

[³²] In the U. S., apart from the state-level medicinal cannabis provisions, a limited federal trial using herbal cannabis is currently underway (Aggarwal SK, Carter GT, Sullivan MD, ZumBrunnen C, Morrill R, Mayer JD. (2009) Medicinal use of cannabis in the United States: Historical perspectives, current trends, and future directions. *Journal of Opioid Management*, 5(3).

[³³] Dispensaries refer to specially designated "stores" for medicinal cannabis dispensing to authorised individuals.

[³⁴] For an overview, see: Pacula, R. L., Boustead, A. E., & Hunt, P. (2014). Words Can Be Deceiving: A Review of Variation Among Legally Effective Medical Marijuana Laws in the United States. *Journal of Drug Policy Analysis*, 7(1), 1-19.

people, cannabis potency, cannabis arrests, cannabis treatment admissions, alcohol consumption and fatal opioid overdose. While studies have differed in their main findings, it is fair to say that across the relatively small body of work, there appears to be few significant adverse outcomes from the policies. [³⁵]

In light of international models and existing research, we consider possible models for Australia, as detailed in the next section.

Regulatory options

The two key features of a medicinal cannabis system are:

- A. Patient authorisation
- B. Supply sources.

Table 1 provides a conceptual summary of the different regulatory options for (A) patient authorisation for medicinal cannabis, and (B) for the cannabis supply source. These are necessarily somewhat simplified and there are potential variants within each of the patient authorisation (A) options and the cannabis supply (B) options – but nevertheless the table provides a succinct overview of the key regulatory and policy options.

The options for patient authorisation and for cannabis supply are not necessarily mutually exclusive (except for columns B1 and B2). The optimal combination will depend on the policy goals. If the goal is to maximise access for as many patients as possible across a wide range of illnesses, with less concern about net-widening [³⁶], then options A1 and B1 will be appropriate. If the goal is to tightly limit medicinal cannabis to a small group of people with specific illnesses, and to minimise any diversion of cannabis to the recreational market, then A3 and B5 will be appropriate.

[³⁵] The published peer reviewed studies are:

- Pacula RL, Powell D, Heaton P, Sevigny EL. (2014) Assessing the Effects of Medical Marijuana Laws on Marijuana Use: The Devil is in the Details. *Journal of Policy Analysis and Management*, 34(1),7-31
- Sevigny, E. L., Pacula, R. L., & Heaton, P. (2014). The effects of medical marijuana laws on potency. *International Journal of Drug Policy*, 25(2), 308-319.
- Bachhuber, M. A., Saloner, B., Cunningham, C. O., & Barry, C. L. (2014). Medical cannabis laws and opioid analgesic overdose mortality in the united states, 1999-2010. *JAMA Internal Medicine*, 174(10), 1668-1673.
- Pacula, R. L., & Sevigny, E. L. (2014). Marijuana Liberalizations Policies: Why We Can't Learn Much from Policy Still in Motion. *Journal of policy analysis and management : [the journal of the Association for Public Policy Analysis and Management]*, 33(1), 212-221.
- Salomonsen-Sautel, S., Min, S.-J., Sakai, J. T., Thurstone, C., & Hopfer, C. (2014). Trends in fatal motor vehicle crashes before and after marijuana commercialization in Colorado. *Drug and Alcohol Dependence*, 140(0), 137-144.
- Lynne-Landsman, S. D., Livingston, M. D., & Wagenaar, A. C. (2013). Effects of State Medical Marijuana Laws on Adolescent Marijuana Use. *American Journal of Public Health*, 103(8), 1500-1506.
- Anderson, D. M., Hansen, B., & Rees, D. I. (2013). Medical Marijuana Laws, Traffic Fatalities, and Alcohol Consumption. *Journal of Law and Economics*, 56(2), 333-369.
- Harper, S., Strumpf, E. C., & Kaufman, J. S. (2012). Do Medical Marijuana Laws Increase Marijuana Use? Replication Study and Extension. *Annals of Epidemiology*, 22(3), 207-212.

[³⁶] Usually referred to as 'diversion'.

Table 1: Patient authorisation (A) and medicinal cannabis supply (B) options

A: PATIENT AUTHORISATION	B: SOURCES OF CANNABIS SUPPLY				
	I. HERBAL CANNABIS				II. PHARMACEUTICAL PREPARATIONS
	B1: No legitimate supply of cannabis, sourced from illegal market (not medicinal grade)	B2: Patients / caregivers can cultivate cannabis (not medicinal grade)	B3: Authorised imported herbal cannabis (medicinal grade)	B4: Herbal cannabis (medicinal grade) grown domestically by licensed producers	B5: Pharmaceutical preparations (medicinal grade)
A1: Specific exemptions from criminal law based on patient diagnoses	X	X	-	-	-
A2: Specific exemptions from criminal law based on doctor's recommendation for medicinal cannabis use (dispensaries)	X	X	X	X	-
A3: Authorisation of patients via prescription system (pharmacies)	-	-	X	X	X

X: The crosses represent the potential match between patient authorisation mechanism and cannabis supply options. Note: The clinical trial option is not represented in the above table as this is not a regulatory option per se.

A1: Specific exemptions from criminal prosecution for personal use and possession of cannabis for individual patients based on patient diagnosis

Under the framework of the U.N. treaties, it is possible to exempt the possession of cannabis (and other drugs) for personal use from the national criminal law. Such an exemption can be applied to medicinal cannabis patients (and/or their caregivers), conditional on a process of certification of these persons for their diagnoses.

Unless steps are taken to create an official source of medicinal cannabis supply, patients and/or caregivers either source the product from the illegal market (B1), or are authorised to cultivate their own (B2). In either of these cases, it is most likely that the cannabis produced will not be medical grade. In this option the doctor approves a treatment with no known dose, script and perhaps no ongoing role in monitoring the patient's response to the medication. Some doctors may not be willing to participate in such an unregulated arrangement.

If caregivers are exempted and allowed to cultivate cannabis for medical purposes (B2), this is not in line with the intent of the U.N. provisions for medicinal cannabis cultivation.

A2: Specific exemptions from criminal law based on doctor's recommendation for medicinal cannabis use (dispensaries)

An alternative to the exemptions based on patient diagnoses (A1) is a recommendation by a doctor that the patient is eligible to use medicinal cannabis. Internationally, these recommendations have commonly been used as an authorisation for access to medicinal cannabis through a dispensary [³⁷].

The advantage of a dispensary system (under B3 or B4) is the multiple varieties of cannabis and various application forms [³⁸] which allow the patient to benefit from different combinations of cannabinoids and their synergistic effects. Such varieties are, in general, not available on the illegal market (B1), and would be difficult to achieve by personal / designated cultivator (B2), or by the current level of pharmaceutical development (B5). Another advantage is that the doctor's recommendation can be driven by the patient's symptoms, and thus not limited to a specific diagnosis, facilitating wide access for a variety of conditions, doctor permitting. The concomitant disadvantage is that the range of conditions for which a medical recommendation can be made is theoretically limitless, which does not conform to the more usual medical approach of relying on an evidentiary basis to medical recommendations.

In the situation where recommendations are used (instead of a more standard prescription system: the A3 option), the doctor might be less willing to follow up on the patient's medication. There are no inherent controls in this option on "doctor shopping". Another disadvantage of this option is that it relies on the establishment of specialist shopfronts – dispensaries – which themselves require regulation.

Up to now, dispensaries have been used as an intermediary between domestic cultivators and patients. According to the U.N. treaty (see Appendix 2) domestic medicinal cannabis cultivation shall be controlled by an agency that takes possession of all medicinal cannabis cultivated in the country, in order to prevent overlap with the illegal market. This would require that the agency operates between the cultivators and the dispensaries / patients. Unless this is achieved, overlap with the illegal market might be difficult to prevent, and adherence to the U.N. treaty will be weak.

A3: Authorisation of patients via prescription system (pharmacies)

Under a prescription regime, medicinal cannabis patients can lawfully possess the amount of pharmaceutical preparations / herbal cannabis prescribed to them, as with any other prescribed substance (e.g. opioids). No specific exemptions from the criminal law to protect patients are needed in this case. Whether medicinal cannabis can be prescribed to patients depends on scheduling of medicinal cannabis in the national / state law. The doctor can either prescribe a pharmaceutical preparation, or an active compound that is present in the cannabis plant (THC, CBD, or combination of both).

[³⁷] Rather than a pharmacy per se. The international models of medicinal cannabis dispensaries are specially designated stores for the purpose of providing medicinal cannabis alone.

[³⁸] Papers which describe the dispensary system include: a). Capler R, Lucas P. Guidelines for the Community-Based Distribution of Medical Cannabis in Canada. Vancouver: Compassion Club Society; May 2006 . b). Lucas PG. Regulating compassion: an overview of Canada's federal medical cannabis policy and practice. Harm Reduction Journal. 2008;5(5). c). Reiman A. The Fallacy of a One Size Fits All Cannabis Policy. Humboldt Journal of Social Relations. 2013(35):104-22.

Prescribed pharmaceutical preparations (B5), as well as herbal cannabis of medicinal grade (B3, B4) can be then obtained from pharmacies, like any other medication. Although diversion can occur, prescription systems, in general, have mechanisms that limit the diagnoses for which a drug can be prescribed, that reduce the risks of “doctor shopping”, control for over-prescription, and minimise leakage to the illegal market. Given it is a prescription-based system, a disadvantage is the potential cost to patients, including the medical assessment and diagnosis that would be required prior to prescription, as well as pharmacy dispensing fees. However whether pharmaceutical cannabis is more costly to the patient than supply from the illegal market is unknowable at present, and will depend on a number of factors including whether the pharmaceutical product is registered on the Pharmaceutical Benefits Scheme (PBS), and whether medicinal grade herbal cannabis is supplied under government monopoly.

B3: Authorised imported herbal cannabis (medicinal grade)

Currently, there is medicinal grade herbal cannabis available on the international market. With appropriate scheduling, it could be imported into Australia and made available in pharmacies or in dispensaries. Such herbal cannabis has been marketed as a source substance for compounding medication (thus, not subjected to TGA registration procedures that apply to pharmaceutical preparations). It is up to the (compounding) pharmacist to decide on the form that is most appropriate for the patient (i.e. tincture, herbal product for vaporisation). The patient, after consultation with the compounding pharmacist, can benefit from further adjustments in the form as well as the cannabis variety that is most suitable for his/her condition. This might reduce patients’ incentive to seek a more suitable cannabis variety on the illicit market. However, one limitation of such a process is the availability and willingness of compounding pharmacist to participate in such a program.

B4: Herbal cannabis (medicinal grade) grown domestically

Medicinal grade herbal cannabis can be produced domestically (B4) and subjected to a prescription regime (A3) or doctors’ recommendation (A2). According to the U.N. treaties, domestic medicinal cannabis cultivation must be controlled by an agency that takes possession of all medicinal cannabis cultivated in the country. In this case, the agency buys the entire crop from cultivators, and assures its distribution into pharmacies (aimed at ensuring no overlap with the illegal market). The benefits of domestic cultivation might be the creation of a sustainable industry (job creation and economic growth), potential for export, and the potential for further research into the properties of various cannabinoids present in the cannabis plant and their synergistic effects.

B5: Pharmaceutical preparations

For pharmaceutical preparations such as nabiximols or synthetic cannabinoid pharmaceutical products (B5), standard registration with the Therapeutic Goods Administration is required. This might be a costly and time-consuming process but it adheres to the usual processes for the registration of medicines in Australia. An evidence-base in the form of clinical trials is required for each product that is registered through the TGA. At the same time, research into cannabinoids treatment efficacy is substantially limited by the classification of cannabis in national and international law. Additionally, single-compound pharmaceutical preparations are unable to produce synergistic effects of multiple cannabinoids present in herbal cannabis, and further pharmaceutical development is likely to take many years.

Conclusions

The debate on medicinal cannabis and its use is controversial in the sense that it represents a collision of terms, concepts, legal boundaries and values. The aim of this paper has been to frame the debate, especially with respect to the different regulatory options for medicinal cannabis that have been used internationally.

DPMP believes that any medicinal cannabis debate in Australia should be informed by the experience of different regulatory regimes abroad. There are a wide variety of options to consider. Several models involve a higher level of control against net-widening and diversion; some allow for a greater adherence with standard medical practice; and others are more open to fast introduction of innovative, yet emerging treatment options. A key issue is the extent to which only pharmaceutical cannabis products versus herbal products under suitable regulatory control should be introduced.

There are two key features to a regulatory framework for medicinal cannabis: patient authorisations and supply sources. Within patient authorisations, policy makers need to determine the extent to which authorisation is strictly limited versus more broadly defined (with the parallel prescription versus recommendation options). The supply options requires decisions about the extent to which the key goal is ensuring that high quality and a range of product types (pharmaceutical, medical grade herbal, herbal) are available to patients versus minimising the risk of diversion into the recreational market.

The tightness of the model will depend on the extent to which it is desirable to draw clear distinctions between medicinal and recreational use, with the attendant risk of creating a false dichotomy and valorising medicinal use at the expense of marginalising recreational use and non-recognised medical use.

APPENDIX 1: Medicinal cannabis across the globe – overview of currently deployed modes of patient access and supply of medicinal cannabis.^[39]

Source of medicinal cannabis within the country	Official medicinal cannabis dispersion to patients	Where applied	PROs	CONs	Adherence to international treaties
1) No official source of medicinal cannabis (patients exempted from criminal procedures upon doctor’s recommendation / certification (i.e. patient registry / cards)	State-level tolerance to patient’s own cannabis cultivation under medical certification that expands to caregivers	U.S. - selected states (Alaska, Hawaii, Maryland), Canada	– patients and caregivers not criminalised for medicinal cannabis use, own cultivation and cultivation / administration by a 3 rd person	– not medicinal grade cannabis – treatment follow-up with the doctor not required – no control on cannabis diversion to the recreational market	It is rightful not to proceed with use and personal possession of cannabis under the criminal law.
2) Supply of medicinal cannabis tolerated upon doctor’s recommendation	Specific state or county level laws for medicinal cannabis dispensaries	U.S. - selected states (Arizona, California, Colorado, Delaware, District of Colombia, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington), Canada	– quality competition between producers – patients (caregivers) and suppliers not criminalised for medicinal cannabis use, own cultivation	– medicinal quality control dependent on state-level regulations – treatment follow-up with the doctor not required – low control over dispensaries and conflation with recreational users’ market (prescription regime lacking due to federal laws)	Non-adherence to 1961 U.N. treaty on medicinal cannabis - the U.S. federal scheduling doesn’t recognise cannabis as a medicinal drug, and therefore dispensing is not controlled by a prescription regime. It is, however, rightful not to proceed with use and personal possession of cannabis under the criminal law, and such provision has been applied to cultivation for own use.

^[39] Several examples of non-medicinal provisions of cannabis to patients exist, among them the most significant one that has captured the attention of the international policy audience is tolerance of cannabis cultivation under user-related provisions of the criminal law that has resulted in *cannabis social clubs* (these can be found in Spain, Belgium and Uruguay). The advantage of the cannabis social clubs is that the quality of medicinal cannabis is assured by the users – ie social club members. However, it is not included within the table as it is not circumscribed as medicinal cannabis per se.

<p>3) Medicinal cannabis trial</p>	<p>Certified small-scale provisions of federally-cultivated marijuana</p>	<p>U.S. National Institute of Drug Addiction (NIDA)–selected states (Therapeutic Research Program)</p>	<ul style="list-style-type: none"> – control over the number and conditions of patients – medicinal grade product – low chances for diversion into recreational market on the wholesale level due to single production point – low chances for diversion into recreational market due to restricted no. of patients 	<ul style="list-style-type: none"> – limited patients’ access – monopoly-originated product, patients complaints about quality 	<p>In adherence with 1961 Single convention on medicinal provisions of controlled substances.</p>
<p>4) Outsourcing herbal cannabis / pharmaceutical preparations from abroad</p>	<p>Herbal cannabis: Individual imports based on prescription and further administrative approvals (herbal cannabis from the Netherlands, Sativex from the UK)</p>	<p>Finland, Denmark</p>	<ul style="list-style-type: none"> – no specific regulatory system needed, administratively managed by the substance control act authority – medicinal grade herbal product – treatment follow-up with the doctor required as with any other medication – low chances for diversion into recreational market given the restricted no. of patients and lack of domestic production 	<ul style="list-style-type: none"> – individual imports are costly and a heavy administrative burden is imposed on the patient 	<p>In adherence with 1961 Single convention on medicinal provisions of controlled substances.</p>
	<p>Pharmaceutical preparations: Prescription and pharmacy dispersion of synthetic cannabinoids</p>	<p>Dronabinol or marinol available in Austria, Canada, Germany, France, Spain, Switzerland, UK, U.S., Sativex</p>	<ul style="list-style-type: none"> – existing medicine regulatory system used – treatment follow-up with the doctor required as with any other medication – medicinal-grade product – low chances for 	<ul style="list-style-type: none"> – narrow range of available cannabis medication (lack of herbal products) 	<p>In adherence with 1961 Single convention on medicinal provisions of controlled substances.</p>

		available in Austria, Canada, New Zealand, UK, Australia and the Czech Republic	diversion into recreational market (herbal cannabis not available)		
5) Licensing of growers by an agency	agency that doesn't take possession of all domestically grown cannabis; herbal cannabis dispensed via an auxiliary system on doctor's recommendation	Israel, Canada	<ul style="list-style-type: none"> - quality competition between producers (e.g. Canada has recently transferred from state-owned production to licensing system due to concerns of product quality under monopoly production) - low chances for diversion into recreational market on wholesale level given the control via agency 	<ul style="list-style-type: none"> - costs of setting up an agency or of assigning its tasks to one of the existing agencies within the country - medicinal quality not guaranteed by the system - treatment follow-up with the doctor not required - chances for diversion into recreational market on consumer level given lack of control via prescription 	Partially in adherence with 1961 Single convention on medicinal provisions of controlled substances; control under prescription system is required by the treaty. The possession of cannabis by the agency is rather symbolic.
	agency that takes possession of all domestically grown cannabis ; herbal cannabis dispensed in pharmacies upon doctor's prescription	The Czech Republic, The Netherlands, Uruguay, The United Kingdom (herbal production for Sativex)	<ul style="list-style-type: none"> - quality competition between producers (e.g. Canada has recently transferred from state-owned production to licensing system due to concerns of product quality under monopoly production) - full adherence to medical and prescription system (herbal cannabis classified as a source substance to compounding pharmacists) - treatment follow-up with the doctor required as with any other medication - low chances of diversion into recreational market on wholesale level given the control via agency and on 	<ul style="list-style-type: none"> - costs of setting up an agency or of assigning its tasks to one of the existing agencies within the country 	In adherence with 1961 Single convention on medicinal provisions of controlled substances.

consumer level given the
control via prescription

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APPENDIX 2: Adherence of the current medicinal cannabis regulatory models to U. N. 1961 Single Convention on Narcotic Drugs

THC (one active ingredient in cannabis and used to achieve both medicinal and recreational effects) is an internationally controlled substance through the three United Nations conventions of which the 1961 Single Convention on Narcotic Drugs sets up the boundaries for medicinal drug provision. The Single Convention also stipulates that cannabis can be permitted for the purpose of clinical trials, if under direct supervision and control of a central authority.

As Appendix 1 shows, the countries that provide access to medicinal cannabis differ in their adherence to the treaty. The two crucial U.N. requirements – control of supply by prescription (Article 30 of the Single Convention) and control of production via an agency (Article 23 of the Single Convention) – are discussed below with reference to the different models.

U.N. 1961 Single Convention on prescription and medicinal grade standards

The 1961 Single Convention on Narcotic Drugs requires that if cannabis is used as a medicine in individual countries, this should be subjected to a similar regime as the provision of opiates in medicine. This requires that medicinal cannabis (as a Schedule I substance of this treaty) is supplied and dispensed upon medical prescription (Article 30). The fact that medicinal cannabis goes through the standard medical prescription system also guarantees its quality standards.

This condition has not been adhered to in those US states with medicinal cannabis laws - a medical prescription would contravene the US federal scheduling that sees no medicinal value in the substance. Instead of prescription and a subsequent pharmacy distribution, a doctor's recommendation and an auxiliary system of dispensaries or producer-patient arrangements have been used. (This is also the case in Israel and Canada).

U.N. 1961 Single Convention on production and its control

Secondly, the U.N. Single Convention requires that if cannabis is to be produced within a country for medicinal purposes, its production shall be controlled by an agency that licenses producers and that takes possession of all the crops produced within the country for such purpose (Article 23). This currently does not occur in the case of the US state-level medicinal cannabis laws where no agency has been set up, and dispensaries provide medicinal cannabis directly to the patients. In other places like Israel and Canada, the agency does not take possession of the cannabis produced by their licensed growers, despite a strong regulatory system imposed on its licensed growers.

Models with full adherence to the 1961 Single Treaty

With respect to medicinal cannabis prescription and domestic production, several states have fully adhered to the U.N. 1961 Single Convention on Narcotic Drugs.

This would generally require that cannabis, or its active compounds, are scheduled as a substance with medicinal properties in the national law. As such, prescription and import of registered pharmaceutical preparations has been possible in Germany and in Switzerland. In other states, herbal medicinal cannabis has been imported upon individual requests from the Dutch Office for Medicinal Cannabis (namely to Finland and to Denmark). Individual imports require specific approval by the institution that implements a substance control act in each country.

The Office for Medicinal Cannabis (OMC) in the Netherlands is an example of adherence to the Single Convention with domestic cannabis cultivation for medicinal purposes. The OMC has contracted Bedrocan, a grower who produces standardised medicinal grade cannabis (thus with a stable THC and CBD levels, and clear of pesticides, fungi and other adulterants) upon OMC's order. The product

is then dispensed to the patients upon doctor's prescription and health department approval through pharmacies. Herbal cannabis produced by Bedrocan has a status as a source substance for compound medication prepared by the pharmacists, and thus, it was not required to go through the standard registration process. A similar model has been recently approved in the Czech Republic, except that the licensing system will be open to up to 10 growers in order to maintain competition among them, and is to be pursued in Uruguay, along with other market options.

Patients access in non-medical settings beyond the scope of the U.N. Single Convention and its medicinal cannabis provision

Recently, the emergence of cannabis social clubs in Spain and other places with favourable national laws has caught the attention of international drug policy makers. The model sets up a cannabis cultivation collective that supplies herbal cannabis to its members, primarily recreational users. The collective is also open to medical patients to join as members. This model is not in line with the U.N. treaties.