

Medicinal Cannabis in Australia: Science, Regulation & Industry

A White Paper Developed by The University of Sydney
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1. Executive Summary

This report sets out the key challenges, risks and opportunities associated with establishing a national medicinal cannabis scheme in Australia. The report is comprised of several sections, each intended to serve as a reference for future policy discussions in the Australian medicinal cannabis industry. Section 2 begins by discussing the medicinal and scientific aspects of the debate, specifically addressing the evidence supporting medicinal cannabis treatments for various conditions. Section 3 then examines how medicinal cannabis regulation has been approached internationally, in addition to exploring recent developments and expected challenges for Australia. Section 4 develops two methodological approaches for estimating the potential domestic demand for medicinal cannabis in Australia. Section 5 discusses how medicinal cannabis might be regulated in order to encourage industry competition, innovation and economic growth. Section 6 summarises the areas in which further future research is required. The report is based on the premise that for an Australian medicinal cannabis scheme to be successful it must not only deliver high quality and low cost outcomes to patients, but also be both politically and commercially sustainable.

The balance of this Executive Summary looks briefly at the main findings of each section in turn.

Section 2 explores the therapeutic and scientific qualities of cannabis, and provides an overview of the conditions for which medicinal cannabis is able to provide relief.

Section 2.1 frames the therapeutic value of medicinal cannabis through the personal accounts of people suffering from chronic diseases. These personal accounts elucidate the potential of medicinal cannabis to provide relief where

conventional treatments have not been sufficient. Although anecdotal, these accounts reinforce some of the reasons why medicinal cannabis should be legalised, and why concerns about patient safety, medical costs and quality controls are so often at the centre of these debates.

Section 2.2 explains how medicinal cannabis is currently used in Australia. It does so by relating the statistics surrounding cannabis use in Australia to the ever-growing interest among the Australian population towards the therapeutic properties of medicinal cannabis.

Section 2.3 discusses the science surrounding medicinal cannabis, showing how it differs from conventional treatments. The complexities of the cannabis plant are examined, along with the challenges of using it in conventional medicine and clinical research. Many of these difficulties are attributed to the fact that cannabis is not a single chemical compound, but is comprised of hundreds of compounds, each varying in their medicinal properties and side effects.

Section 2.4 draws from the global scientific community to collate some of the evidence supporting the use of medicinal cannabis for various medical conditions. This information has been tabulated by the strength of supporting evidence in order to establish the scope of medicinal cannabis treatments. These findings demonstrate a high level of support for treating conditions such as HIV/AIDS, Multiple Sclerosis, Arthritis, Cancer, Alzheimer's Disease, and nausea and vomiting relating to some cancer treatments.

Section 3 explores how medicinal cannabis schemes have operated internationally, and outlines how the challenges, risks and opportunities experienced overseas may be of relevance to Australia.

In order to clearly articulate how these complex schemes function, section 3.1 establishes a framework through which medicinal cannabis regulation can be analysed. The key components of regulation have been simplified to: governance, production, distribution, access, and consumption.

In section 3.2, this framework has been applied to the regulatory schemes of three countries in which cannabis has been legalised for medicinal purposes: Canada, Israel, and the Netherlands. These countries were selected for their contrasting approaches to regulation, and their corresponding challenges and opportunities which policy-makers must consider when designing such a scheme for Australia. Canada, which has the most recently established medicinal cannabis scheme of the three, has a sizeable medicinal cannabis industry, along with a political system that is relatively congruent to Australia. Conversely, Israel has one of the oldest and most established medicinal cannabis industries globally, and is widely considered to be the hub for innovation and research into medicinal cannabis. The Netherlands has a well-established and sophisticated medicinal cannabis industry, and is a leading exporter of medicinal cannabis products to several countries including Germany and the Czech Republic.

Section 3.3 summarises recent developments in medicinal cannabis in Australia. These include developments from both State and Federal Government along with private institutions reflecting historical momentum towards medicinal cannabis legalisation.

Section 3.4 concludes with a summary of the various challenges and risks associated with the implementation of medicinal cannabis schemes. These include regulatory challenges to the governance of medicinal cannabis using existing frameworks, importation, and product diversion. And patient concerns such as quality control, affordability, and education about medicinal cannabis treatments.

Section 4 develops two approaches to estimating the level of demand for medicinal cannabis in Australia.

The first assumes regulations that allow a relatively small number of patients to access highly refined, pharmaceutical cannabis products. An estimate is made of the number of people in Australia who might be eligible to use medicinal cannabis based on the conditions most likely to be approved. Then, based on the recommended dosage for each condition (using information available for pharmaceutical-grade cannabis products), an estimation is made for the total national demand for these pharmaceuticals in the form of their total active ingredients.

The second method assumes more broadly-prescribed cannabis in its medicinal-grade herbal form, or in its medicinal-grade product form. Using the case study countries of Israel, the Netherlands and Canada, the national per-annum consumption of medicinal-grade cannabis is estimated for each country. This is then adjusted for the size of the Australian population to arrive at a final forecast. This figure estimates how much medicinal cannabis would need to be produced if Australia had the same percentage of medicinal cannabis patients who consumed the same amount on average as each of the countries in question.



Section 5 discusses how medicinal cannabis should best be regulated in order to encourage industry competition, innovation and economic growth.

Section 5.1 examines how the regulation of an Australian medicinal cannabis industry will affect the cost, quality and safety of cannabis products, as well as the industry's capacity for innovation, responsiveness and scalability. This section posits that a well-regulated, competitive marketplace is necessary to ensure that high quality, low cost cannabis medicines are provided to patients. The importance of establishing effective regulation is emphasised, particularly regarding patient safety relating to pesticide use, product labelling and quality control. It argues that avoiding unnecessarily stringent regulation will help to ensure lower prices for patients. This section concludes by emphasising that regulation will need to facilitate the eventual upscaling of the medicinal cannabis industry, which may involve allowing for the export of cannabis-based products.

Section 5.2 highlights the need to support the medicinal cannabis industry through research, development and innovation. It examines how this can improve the lives of medicinal cannabis patients, provide Governments with more effective ways to monitor and assess the industry, and assist in building a positive public perception of the industry.

Section 6 explores the various aspects of the medicinal cannabis industry in which further research will be required.

2. Medicinal Cannabis

Section 2 explores the therapeutic and scientific qualities of cannabis, and provides an overview of the conditions for which medicinal cannabis is able to provide relief.

2.1. Why medicinal cannabis?

When discussing the political and regulatory aspects of medicinal cannabis, it can be all too easy to forget what makes this such a headline issue. Cannabis has the potential to provide relief to people living in some of the most difficult and painful circumstances we can experience as human beings. Even the possibility of attaining, or helping a loved one attain, a slight relief from these symptoms is enough to drive law-abiding people into the arms of the black market.

In August 2015, The Victorian Law Reform Commission (VLRC) issued a report on medicinal cannabis. As part of their research, the VLRC received hundreds of testimonials from Australians whose lives had changed after they began treatment with medicinal cannabis. Although anecdotal, these stories are crucial for appreciating not only where the pressure to legalise is coming from, but also why concerns about patient safety, medical costs and quality controls are so often at the centre of these debates.

2.1.1. Multiple Sclerosis

A woman with Multiple Sclerosis (MS) suffering from pins and needles, electric shocks, nerve pain that affected her ability to walk, severe throat spasms, loss of sensation to part of her face and extreme fatigue said,

“[As a result of taking cannabis oil] I no longer lose my hair, I no longer get the pins and needles or the electric shocks, I have recovered some of the feeling in my face but not all. If I take a small amount of cannabis oil every other day, I am able to do activities that include walking, without extreme pain. My MS has also not progressed”¹

2.1.2. Epilepsy

According to the World Health Organisation² epilepsy is one of the most common neurological diseases. Approximately 25,000 people are diagnosed with epilepsy each year in Australia.³ In some cases, these are children suffering from rare and extremely dangerous forms of epilepsy. Michelle Whitelaw from Brisbane wrote about her despair as a parent with sick children,

“Knowing that neither of my sons have any possibility of improving medically leaves a very doomed future ahead. From the minute your child is diagnosed, with any incurable life threatening medical diagnosis, you grieve. You grieve for normality and you want their suffering to stop. The dark days, when you feel suffocated and consumed, you live minute by minute. It’s not living ...”⁴

In December 2014, Michelle decided to treat her sons with medicinal cannabis. What she witnessed has been,

“Miraculous ... we have seen only three clinical seizures in over five months. That is a reduction of 75,000 seizures ... His pupils are no longer fixed nor dilated. He is eating/drinking without choking, attending school, able to write, speech is improving, walk steady, kick a ball and ride his bike, socialize, dress and toilet himself. All of these are FIRSTS. His personality is bubbly and he is so incredibly alive and well”⁵

2.1.3. Cancer

There are many powerful accounts of the advantages of pain relief for people suffering from terminal cancer. One such account is from a father whose son recently passed away,

“Chemotherapy and all the drugs he took failed to relieve his pain and suffering and this is why he turned to cannabis oil which I’m pleased to say helped him through this terrible body wasting and destruction ... my son was able to sleep, he was able to eat, an appetite that had left his body many months before returned with a vengeance he was not pain free but it was manageable at a level far, far lower than what doctors were able to give”⁶

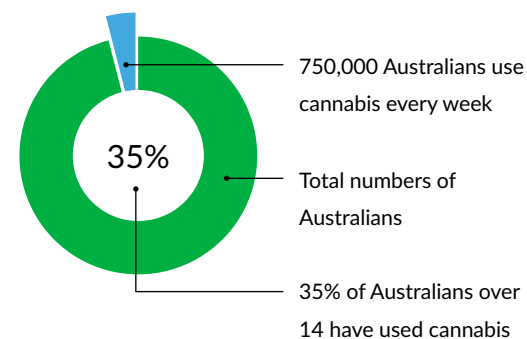
2.1.4. Chronic Pain

People suffering intense chronic pain have also reported great success from using medicinal cannabis. Lindsay Milton had a spinal injury 25 years ago and required surgery. After the surgery, the medication he was using for the pain were ineffective and he resorted to taking extra medication to offset the side effects of the painkillers. This is what he had to say after starting medicinal cannabis:

“Two days into using cannabis I knew things could only get better if what was happening with pain relief continued and it did. I started sleeping better, was getting five times the pain relief pharmaceuticals were giving me and I got my appetite back all with no side effects whatsoever”⁷

2.2. Current Australian use of medicinal cannabis

The Victorian law reform report estimates that 750,000 Australians use cannabis every week,⁸ and that 35% of Australians over the age of 14 have used it within their lifetime.⁹ It is difficult to accurately estimate the total user base of medicinal cannabis within this estimate,



but the Medicinal Cannabis Users Association of Australia (MCUA), an online advocacy and educational group, recently claimed that their membership was increasing by 150 people a week.¹⁰

Increasing discussion of the therapeutic properties of medicinal cannabis has created a surge of interest in Australia for its use as an alternative to conventional treatments for a range of health conditions. On top of this, recent surveys have shown that cannabis use by Australians over 50 has increased dramatically, even exceeding the use of cannabis by young Australians,¹¹ and this could be due to the fact that older people tend to suffer more from conditions such as cancer and chronic pain.



According to one submission to the VLRC 2015, more and more Australians are now seeking both knowledge and access to medicinal cannabis,¹² driven by ineffectiveness of or adverse effects from conventional treatments, financial difficulties relating to existing pharmaceutical treatments and diminished quality of life for patients.¹³

The increase in demand for medicinal cannabis has been accommodated by the black market or home cultivation.¹⁴ Many medicinal cannabis groups have reported difficulties in meeting demand for patients due to the legal barriers they have faced in every phase of their supply chain.¹⁵

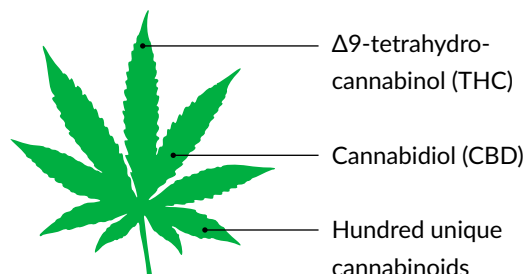
As many patients are incapable of growing cannabis due to a lack of skill in cultivating safe and high quality cannabis, or from being restricted from accessing the resources required for its cultivation, the only platform available to them is the black market. The main concerns expressed by patients forced into the black market include poor quality of medicinal cannabis; continuity of supply to meet therapeutic needs; unknown consistency of cannabinoid content; the possibility of prosecution; and unregulated, unnecessary high prices.¹⁶

The use of medicinal cannabis has also resulted in increased incarceration rates and associated state expenses. The Australian Crimes Commission (ACC) predicts seizures and arrests surrounding cannabis (whether for medicinal or recreational purposes) will continue to increase as long as the substance remains illegal for medicinal use.¹⁷

2.3. Cannabis in medical science

Cannabis has generated some unique challenges for established pharmaceutical processes. This is largely due to the 'single compound, single target'¹⁸ paradigm of modern medical science. This paradigm seeks to identify and extract or synthesise an individual chemical which is then tested in a clinical trial environment to measure the effect which that single chemical has on certain medical conditions. Although this process works very well most of the time, single chemical and single target pharmaceuticals may be less effective in treating complex conditions with multiple causes and effects, such as cancer.¹⁹

Cannabis is not a single chemical. It is a plant with many chemical components that vary in strength and medicinal efficacy depending on the plant's genetic origin, how it is grown, how it is prepared and how it is consumed.²⁰ Almost all of the chemicals found in cannabis which have – or are believed to have – medicinal benefits are unique to the plant. These are called 'cannabinoids'.²¹ Although scientists have identified more than a hundred unique cannabinoids so far, the most prevalent of these are Δ 9-tetrahydrocannabinol (THC) and cannabidiol (CBD).²²



THC was the first cannabinoid to be isolated and has been the main focus of research since its discovery in 1964.²³ In the 1990s, research into THC uncovered an "elaborate new biochemical system" in the human body which was named the "endocannabinoid system".²⁴ This system is made up of natural cannabinoid receptors which exist throughout the human body and brain. These receptors respond to cannabinoids and have been shown to affect,

"A large number of pathological conditions — cardiovascular, neurodegenerative, reproductive, gastrointestinal, liver, lung, skeletal, and even psychiatric and cancer diseases"²⁵

THC is the 'psychoactive' part of cannabis that produces the 'high' and so far has been used to treat severe nausea, severe pain and muscle spasticity.

CBD, in contrast, is not psychoactive, and so far has been used to treat severe epilepsy and several inflammatory disorders.²⁶ As THC is the only cannabinoid with the potential for recreational use, illicit cannabis plants have been selectively bred to express very high levels of THC without regard for the other cannabinoids. Medical science is now beginning to breed medical-specific plants with higher levels of CBD and other cannabinoids.²⁷

Because cannabis varies so widely, patients who use medicinal cannabis tend to prefer certain strains over others depending on their particular condition, and how their body reacts to the medicine.²⁸ This is something which many patients value quite highly. For example, in 2011 Canada only provided a single strain

of medicinal cannabis for patients. These patients complained that only having one strain of cannabis was ineffective for many. As a result the program went into review and in June 2013 the Marihuana for Medical Purposes Regulations (MMPR) came into force with the objective of providing “reasonable access to marihuana for medical purposes”.²⁹ Canada now deliberately provides patients with more choice³⁰ by not restricting medicinal cannabis producers (of which there are currently 27) in the variety of strains they can provide, and by allowing patients to select which provider they want to use.³¹

There are two main reasons why the traditional pharmaceutical model is not well suited to cannabis. The first is that there are hundreds of chemicals in cannabis, a vast majority of which almost nothing is known about. The research required to fully understand the plant has been hindered by political barriers, and medical science is only now beginning to catch up on several lost decades.

The second reason is that medicinal cannabis patients often find that whole-plant cannabis medicines are more effective than pharmaceutical cannabis medicines.³² There is reason to believe this may be caused by a ‘synergistic effect’ or ‘entourage effect’ from the various chemicals working together.³³ More research is needed, but this synergy has already been observed between THC and CBD in the treatment of pain.³⁴ This may mean that in some cases using whole-plant



cannabis can be more effective than using pharmaceutical cannabis products.³⁵ However, the single chemical, single target methodology of pharmaceutical science is heavily embedded in the institutions which manage pharmaceutical medicines. This is why whole-plant cannabis has had such difficulty being approved for use through existing regulatory bodies in Australia such as the Therapeutic Goods Administration.³⁶

2.4. Medicinal cannabis treatments

The table summarises the conditions which THC and CBD are known to be able to treat. This list is neither exhaustive nor definitive. It is here only to provide a snapshot of the current state of cannabis research.

2.4.1. Confirmed treatments

Condition	Treatment	Source of Treatment			
		CBD	THC	Both	Strength of evidence
AIDS/HIV	Pain reduction			Sativex	High ³⁷
	Appetite stimulation and weight gain		Dronabinol (Marinol) ³⁸		High ³⁹
Alzheimer's Disease	Inhibition of neurodegeneration		Injected (still in experimental phase)		High ⁴⁰
Arthritis	Joint destruction suppression	Oral or injected			High ⁴¹
Nausea and vomiting due to chemotherapy	Reduce nausea and vomiting		Oral: Nabilone & dronabinol (Marinol)	Sativex ⁴²	High ^{43 44}
Cancer	Pain reduction		Smoked	Nabiximols	High ^{45 46}
Diabetic peripheral neuropathy	Pain reduction		Aerosolized ⁴⁷ , Oral: Nabilone ⁴⁸		High ⁴⁹
Multiple Sclerosis	Improve spasticity		Oral: Dronabinol (Marinol) & Nabilone	Sativex	High ^{50 51 52 53 54}
Anxiety and depression	Improvement in mood scale		Dronabinol (marinol) & Nabilone ⁵⁵	Sativex	High ^{56 57}

2.4.2. Potential treatments

Condition	Treatment	Source of Treatment			Strength of evidence
		CBD	THC	Both	
Arthritis	Symptomatic relief of joint pain.	Oral			Moderate ⁵⁸
Chronic non-cancer pain	Pain reduction			Oral mucosal cannabis spray	Moderate ⁵⁹
Epilepsy	Reduction in seizure frequency			CBD-enriched cannabis oil	Moderate ⁶⁰
Glaucoma	Ocular therapeutic support			Orally, intravenously, or inhalation	Moderate ^{61 62}
Schizophrenia	Reduced psychotic symptoms	Oral			Low ^{63 64}
Tourette syndrome	Improvement in tic severity		Capsules: Dronabinol & Nabilone ⁶⁵	Sativex	Moderate ⁶⁶
Inflammatory bowel disease (including Crohn's disease)	Decrease Crohn's disease Activity Index (CDAI) scores		Smokeable		Low ⁶⁷
Sleep disorders	Improvement in insomnia		Nabilone ⁶⁸	Sativex	Moderate ⁶⁹

3. Regulation and Industry

Section 3 explores how medicinal cannabis schemes have operated internationally, and outlines how the challenges, risks and opportunities experienced overseas may apply to Australia.

3.1. Framing medicinal cannabis regulation

Medicinal cannabis regulations can be complex and confusing. This section provides a framework for understanding the key components of regulation and how widely they can vary. This framework will then be applied to some international examples. This will help identify the risks, opportunities and alternatives, which Australian policy makers should consider.

Medicinal cannabis regulation can be broken down into 5 components:

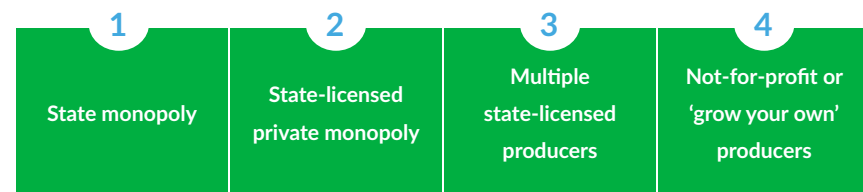
3.1.1. Governance

In order to legalise and regulate medicinal cannabis, certain powers and responsibilities are created to govern the industry. These powers tend to be invested in either an existing regulatory body or a new regulatory body which has been created specifically to manage medicinal cannabis.

Often some powers and responsibilities are given to a new regulatory body, and others given to existing bodies. For example, the regulation of cannabis cultivation licenses might go to the new body, while the scope of Customs and Law Enforcement might be expanded to accommodate other aspects of medicinal cannabis.

3.1.2. Production

Although some countries have only legalised medicinal cannabis imports, it is more common for countries to also legalise and regulate domestic production. There are four main ways in which legal medicinal cannabis tends to be produced:



Having a monopoly producer provides excellent oversight and control, but often results in higher costs to patients and less patient choice.⁷⁰ It also means that any problems with the monopoly producer can significantly disrupt the supply of medicinal cannabis. In cases such as the previous Canadian MMPR, which allowed Prairie Plant Systems a monopoly over medicinal cannabis prescriptions in Canada, patients complained of low quality, inadequate supply and inappropriate strains for their conditions, prompting the Canadian Government to revamp the entire MMPR in 2013.

Multiple state-licensed producers can provide greater patient choice and lower costs to patients, as long as the licensing system is balanced and not cumbersome.

Many countries have not-for-profit groups which act as collective producers or buyer's clubs, or allow patients to grow their own medicinal cannabis, but this makes it very difficult to regulate dosage or impose quality or standards controls.⁷¹

The forms which medicinal cannabis takes can be broken down into three categories:



Pharmaceutical



Medicinal-grade



Illicit

Pharmaceutical cannabis products are developed and patented by drug companies. They contain naturally derived or synthetic forms of cannabinoids which have undergone clinical trials and have been approved as a pharmaceutical medicine. Crucially, they only contain known amounts of individual cannabinoids, usually only one or two. This is desirable because it results in better-known and tested effects, and because dosages are easier to accurately determine and administer. However, if they are made available at all, they are extremely expensive.⁷²

Medicinal-grade cannabis products are quality-controlled forms of cannabis that have been subject to strict regulation in their cultivation, manufacture and testing. Medicinal-grade cannabis can be provided to patients in its raw herbal

form, or in a processed form such as an oil, balm, capsule or pill. Medicinal-grade cannabis is far cheaper, and many patients find it more effective than pharmaceutical grade cannabis.

Illicit cannabis includes those products that have not been subject to any form of regulation or quality control, such as cannabis acquired via the black market. Cannabis produced under a 'grow your own' scheme is similarly untested, and is usually of the same quality as illicit medicinal cannabis.

3.1.3. Distribution

Distribution can be direct or indirect. Where distribution occurs directly, patients receive their medicinal cannabis directly from the producer, either by picking up their medicine from the producer or having it distributed to them by courier or post. Indirect distribution is when patients visit a pharmacy or dispensary to access their medicine.

3.1.4. Access

The process by which patients access medicinal cannabis is contingent upon the distribution scheme in place. If distribution is done through dispensaries, patients are usually provided with a license or authorisation from their doctor. This allows them to purchase certain amounts of medicinal cannabis from the dispensary that is most convenient for them. If distribution is done through pharmacies, patients require a prescription which they take to a pharmacy just like any other.

Where there is tighter regulation over access to medicinal cannabis, medical practitioners will typically serve as gatekeepers, and are granted controlling authorisation through prescription.⁷³

The choice of doctors allowed to prescribe medicinal cannabis is also part of the access scheme. In some places, any doctor may issue a license/authorisation. In other places, this power may be limited to a small number of specific doctors, or to a specific 'class' of doctors determined by their specialisation.

Regulators are able to broaden or narrow the scope of their medicinal cannabis program substantially depending upon how they chose to distinguish patient eligibility. In some places, any patient may be able to access medicinal cannabis through their doctor. In other places, the kinds of patients which doctors are permitted to approve for medicinal cannabis use can be limited to a specific set of conditions, a specific set of symptoms, or some combination of conditions and symptoms.

3.1.5. Administration

The ways in which patients administer medicinal cannabis will depend upon the forms of medicinal cannabis that are available. Where only pharmaceutical cannabis products are available, the method of administration will be determined by the pharmaceutical manufacturer. There are no pharmaceutical cannabis products which can be smoked.

Medicinal-grade cannabis can be made available in a variety of forms. It can be provided in its raw herbal form which can then be smoked, but although this method is claimed to provide the fastest relief from symptoms, is not advised for health reasons.

Medicinal-grade herbal cannabis can also be vaporised. In this method, the cannabis is heated to a temperature at which the cannabinoids become vaporised and can be inhaled but the plant material does not combust, and no smoke is produced or inhaled.⁷⁴ Medicinal-grade cannabis can also be processed by the patient into food. And it can also be made available in forms which cannot be smoked, such as an oil, balm, capsule or pill.

3.2. International experience

3.2.1. Canada

3.2.1.a. Governance

Health Canada (HC) is the primary governing body for the Canadian medicinal cannabis industry.⁷⁵ It conducts regular inspections of licensed producers to verify their compliance with the standards set out by the Marijuana for Medical Purposes Regulation (MMPR) - a set of regulations for the production and distribution of medicinal cannabis - and penalises any party acting in contravention to it (through seizures and suspension of licenses).⁷⁶ As medicinal cannabis is sourced entirely from licensed producers, Health Canada is assigned to overlook all aspects of licensing and regulation for registered producers.⁷⁷ Any unauthorised activities associated with cannabis are considered to be criminal offences and are subject to the penalties set out in the Controlled Drugs and Substances Act (CDSA) (1996).⁷⁸

3.2.1.b. Production and distribution

Cannabis is labelled as a 'Schedule II substance' under Canada's federal drug control statute, the CDSA. This means that activities relating to production and possession for the purposes of trafficking are illegal, except for licensed producers with import permits granted by the Office of Medical Cannabis (OMC),⁷⁹ a department within HC. Eligible producers are prohibited from operating a store front. Annual production and consumption statistics are submitted to the International Narcotics Control Board; a quasi-judicial control arm for the United Nation's international drug conventions.⁸⁰

With the exception of Sativex and Cesamet, which have received Notices of Compliance authorising their sale as therapeutic products in Canada, at present no applicants have obtained approval under the FDA.⁸¹ Both of the preceding drugs are of pharmaceutical-grade quality, with Sativex® available as a THC/CBD active spray⁸² and Cesamet in pill form containing a synthetic cannabinoid similar to THC.⁸³

Although producers can decide on which plant strains to provide, they are required to test each batch of cannabis for the percentage of THC and CBD and label the medicine accordingly.⁸⁴ After further quality testing conducted by the OMC, the medicine is then distributed to the patient or the practitioner directly.

3.2.1.c. Eligibility

Under the new regulations, those who fall into one of three categories can apply for authorisation to possess cannabis for medical purposes:⁸⁵

- » **Category 1:** People with terminal illnesses that have a life span prognosis of less than 12 months.
- » **Category 2:** People who suffer from specific symptoms associated with serious medical conditions including: MS, epilepsy, spinal cord conditions, cancer, AID/HIV and severe arthritis.
- » **Category 3:** People suffering from symptoms associated with a serious medical condition, other than those described in category 1 and 2, where conventional treatments have failed to relieve symptoms.

Eligible patients may possess a maximum 30-day treatment supply of cannabis at any one time.⁸⁶ However, access is limited to dried cannabis and oil. Derivatives such as resins, extracts and edibles cannot be sold.⁸⁷

Under the MMPR, the choice of producer is at the patient's discretion; however, they are limited to a single supplier.⁸⁸ Products are clearly labelled with the patient's name to assist with proof of eligibility.⁸⁹

3.2.1.d. Taxation protocol

Under the Income Tax Act (1985), The Canada Revenue Agency - Canada's federal tax authority - allows registered patients to claim the cost of their prescribed cannabis as an allowable medical expense against their income tax.⁹⁰

3.2.2. Israel

3.2.2.a. Governance

In Israel, the medicinal cannabis industry is administered by the Medical Cannabis Unit (MCU) within the Ministry of Health. The MCU issues patients with permits to use cannabis for therapeutic purposes.⁹¹ It also provides various medicinal cannabis related research bodies with permits in order to support scientific research into medicinal cannabis and manages cannabis regulation through a variety of government departments such as Health, Customs, Police, and Agriculture.

In any arrangement regarding the use of medicinal cannabis, parties involved are required to comply with the laws imposed under the Dangerous Drugs Ordinance (1973), as well as the provisions of the Single Convention on Narcotic Drugs 1961.⁹²

3.2.2.b. Production and distribution

In order to cultivate and supply cannabis for medicinal purposes, domestic producers must be licensed by the Israeli Ministry of Health.⁹³ Growers are required to deliver their produce to a logistics centre operated by a company partly controlled by the government to ensure compliance.⁹⁴ The country's first and largest production centre is Tikun-Olam, which originally operated on a not-for-profit model; however, with increasing number of licensed patients over the years and high production costs, it has transitioned towards a for-profit model.⁹⁵ As a result, the government began requiring licensed growers to charge

patients a monthly fee of 360 Israeli New Shekels (approximately \$100 USD) for up to 100 grams per month.⁹⁶ In response to high demand internationally, Israel's cannabis producers have lobbied for the removal of restrictions surrounding exportation of domestically produced medicinal cannabis.⁹⁷

3.2.2.c. Eligibility

Israel uses a condition-based model for approval. In order to be eligible, patients are required to have undergone conventional treatments or must be experiencing severe symptoms from a terminal illness or undergoing extensive chemotherapy. Once a patient is authorised, they are then able to access medicinal-grade herbal cannabis products such as cannabis oil extracts, edibles and smokeable dried plant matter. The use of other derivatives is expressly prohibited in order to ensure product quality and the user's safety.⁹⁸

In order to access medicinal cannabis, patients must be authorised by government-approved specialist medical practitioners. Family practitioners (GPs) are not permitted to grant such authorisations.⁹⁹ If a specialist wishes to authorise an eligible patient, they must apply on the patient's behalf to the Medical Director of a psychiatric hospital, in whom the Ministry of Health has appointed the final authority to approve supply. Upon approval, the patient may then receive medicinal cannabis from a distribution centre.¹⁰⁰

Israel differs from other jurisdictions in terms of its health insurance. Patients are able to receive compensation for medicinal cannabis from most health insurance providers.¹⁰¹

3.2.3. The Netherlands

3.2.3.a. Governance

The Dutch government has established the Office of Medical Cannabis (OMC) as the primary organisation responsible for the production of cannabis for medicinal and research purposes.¹⁰² The OMC holds absolute control over all supply to licensed research facilities, pharmacies and practitioners, as well as all import and export activities relating to medicinal cannabis products.¹⁰³ The OMC sets the price of medicinal cannabis products based upon the costs of purchasing, analysing, packaging and distributing the product.¹⁰⁴ Applicants for licenses granted through the OMC are subjected to a review of financial reports and additional security screening to determine any ongoing or potential illegal activities. The adoption of such a framework implies that the Netherlands is acting in accordance with Article 28 of the Single Convention on Narcotic Drugs (1961).¹⁰⁵

The OMC is obliged to act in accordance with Dutch drug laws, which make a distinction between Category I drugs (hard drugs) and Category II drugs (soft drugs) and lists exemptions for establishments seeking to work with drugs for medicinal and scientific purposes.^{106 107}

Supporting regulatory bodies include the Health Care Inspectorate (IGZ), which is a government entity that enforces quality controls and preventative measures relating to medicinal products, and the Instituut voor Verantwoord Medicijngebruik (IVM), which is a separate entity that helps healthcare professionals to be informed on the use of specific medications.^{108 109}

3.2.3.b. Production and distribution

The OMC is responsible for delivering medicinal cannabis to pharmacies and overseeing the distribution from pharmacies to eligible patients who have received approval from their practitioners. This is because producers are restricted from selling to the market directly, in contrast to Canada's distribution system.¹¹⁰

At present, all medicinal cannabis is grown by a single, for-profit, state licensed company; Bedrocan BV, under contract with the OMC. The company delivers medicinal cannabis in the form of dried and manicured flowers from female plants (buds).¹¹¹ The company is ISO9001 certified and also adheres to the Code of Good Manufacturing Practice (GMP). Similarly, the company's production procedure is in compliance with the guidelines set out by the internationally recognized Good Agricultural Practice (GAP) standards.¹¹² The quality and safety of the final products are guaranteed through mandatory testing by certified laboratories.

Bedrocan is permitted to export its produce through the OMC. Countries including Finland, Germany and Italy have all imported from the Dutch (produced by Bedrocan). Patients from these regions obtained prescriptions from their doctors and provided them to a pharmacy, which then applied for import licences from their home jurisdiction to be approved by the Dutch government. However, with the high costs of importation, international use of Bedrocan has proven an expensive endeavour.¹¹³

3.2.3.c. Eligibility

Permission to use medicinal cannabis is at the doctor's discretion, however the standard of the prescription issued must comply with the conditions stated in the Dutch-Opium law.¹¹⁴ Smoking cannabis is actively discouraged due to health concerns, so once granted access, patients are recommended to use medicinal cannabis in the form of tea or inhalation after vaporisation.¹¹⁵ As medicinal cannabis is not included in the standard insurance package of health insurers, patients are unable to claim treatment expenses. However, some health insurance companies reimburse medicinal cannabis partly through a supplementary insurance scheme.¹¹⁶

3.2.3.d. Taxation protocol

Under European law, Bedrocan is not allowed to levy import duties, VAT, or excise taxes on cannabis, as it is a prohibited substance.¹¹⁷

3.3. The Australian case

Medicinal cannabis is a rapidly growing phenomenon internationally, but in Australia it has only been in the last few years that it has been seriously discussed. These discussions reflect the growing public support for medicinal cannabis, with a recent Roy Morgan poll reporting that 91% of Australian support the legalisation of medicinal cannabis.¹¹⁸ The following section outlines these recent developments for medicinal cannabis in Australia.

3.3.1. NSW Clinical Trials

In December 2014 the NSW Government announced it would invest \$9 million over a five-year period on clinical trials of cannabis products.¹¹⁹ The trials seek to investigate the use of cannabis and cannabinoid-based products in treating symptoms stemming from a range of conditions. The program comprises three trials, each focusing on particular conditions for which standard treatments have not been effective. The QLD, VIC and TAS Governments have partnered with NSW to participate in these trials.¹²⁰

The first set of trials, beginning in 2016, is for children with severe, drug-resistant epilepsy. This has been organised as a result of a partnership with Sydney Children's Hospital Network and GW Pharmaceuticals, who announced in October 2015 that they would be providing Epidiolex – a pharmaceutical grade cannabis product containing refined CBD extracted from medicinal-grade cannabis – to the NSW Government for these trials.¹²¹

The second and third set of trials will focus on adults with terminal illness, with a focus on improving quality of life through mitigating symptoms of chronic pain and chemotherapy-induced nausea and vomiting.¹²²

Also in December 2014 the Baird Government announced that it would issue guidelines to NSW police officers to not prosecute terminally ill patients found with less than 15 grams of cannabis.¹²³ While this effort can be viewed as providing psychological relief for terminally ill patients fearing prosecution for cannabis possession, it ultimately serves as an interim solution.

3.3.2. The Victorian Law Reform Commission Report

The Victorian Law Reform Commission's report on medicinal cannabis was published in August 2015 in response to increasingly vocal public support and political pressure to allow the use of medicinal cannabis for people in exceptional circumstances.

The report is one of the most comprehensive documents to date regarding the implementation of a medicinal cannabis scheme in Australia, and is the culmination of several months of public submissions stemming from the Commission's issue paper published in March 2015. The report reviews how Victorian legislation could be amended, and also considers how these changes would interact with existing Commonwealth and international laws and regulations. Specifically, the report explores how such a scheme would operate in terms of prescribing practices, eligibility criteria, the role of practitioners, and the form, manufacture, and distribution of medicinal cannabis products.

The Commission concluded that eligibility for medicinal cannabis treatment should be based on a patient's medical condition and its associated symptoms.¹²⁴ Such symptoms, the report suggests, should initially be limited to muscle spasticity, severe cases of pain, nausea, seizures resulting from conditions including cancer, HIV/AIDS, multiple sclerosis and epilepsy.¹²⁵ The report further recommended that the Minister for Health should create an independent advisory committee on medicinal cannabis to provide ongoing responsiveness to clinical literature regarding the conditions and symptoms on which eligibility would be determined.¹²⁶

Medical practitioners would play a key role if the Commission's recommendations are implemented by the Victorian Government: specialist medical practitioners would determine which patients receive treatment, and general practitioners would monitor treatment efficacy and side effects. The Secretary of the Department of Health and Human Services would be responsible for approving an Authority to Dispense Medicinal Cannabis, for which eligible specialist practitioners would be required to apply in order to authorise a patient's use of medicinal cannabis.¹²⁷

Under the Commission's recommendations, medicinal cannabis should be cultivated and manufactured domestically by licensed private entities. Such a scheme would be largely based on the existing regulatory arrangements for the alkaloid poppy industry. The Victorian Government would also be tasked with establishing a process for quality assurance and for the approval of new medicinal cannabis products. In compliance with the Single Convention on Narcotic Drugs 1961, the Secretary of the Department of Health and Human Services would then take possession of these medicinal cannabis products and arrange for distribution to pharmacies.¹²⁸

3.3.3. The Lambert Initiative

In June 2015, the University of Sydney was gifted \$33.7 million to establish the Lambert Initiative – a multi-year program that will extend the University's existing clinical and scientific cannabinoid-related expertise to ultimately produce cannabinoid-based medicines. The program will involve “medicinal chemistry, cellular and preclinical research, early human testing and clinical trials in patients”, and ultimately aims to “optimise and introduce safe and effective cannabinoid

therapeutics into mainstream medicine” for a range of diseases.¹²⁹ Additionally, the Lambert Initiative will work towards shaping the attitudes people have towards medicinal cannabis in Australia by training health professionals and working with media and consumer organisations to educate the general public.¹³⁰

3.3.4. Centre for Medicinal Cannabis Research and Innovation

Less than a week after the Lambert Initiative’s announcement, NSW Premier Mike Baird pledged \$12 million over four years to create the Centre for Medicinal Cannabis Research and Innovation. The Centre will involve local and international researchers with the aim of furthering existing knowledge of the therapeutic value of cannabis-based products, and monitoring the NSW-funded clinical trials. The Centre will support “evidence-based innovation” in the medicinal cannabis industry, and assist stakeholders to navigate regulatory processes in order to foster innovation.¹³¹

3.3.5. The Regulator of Medicinal Cannabis Bill 2014

On the 11th of August 2015, the Regulator of Medicinal Cannabis Bill 2014 was published by the Federal Senate. The Bill, first introduced by Senator Di Natale in November 2014, drew on hundreds of submissions from individuals and public and private groups. There was almost unanimous support for providing certain patients with access to cannabis based medicines, reflecting widespread public support calling for the legalisation of medicinal cannabis.¹³²

The Bill proposed the establishment of a new medicinal cannabis regulatory body, which would “be responsible for formulating rules for licensing the production,

manufacture, supply, use, experimental use and import and export of medicinal cannabis.”¹³³ The Bill outlined the specific domains in which the Regulator would be responsible for creating and implementing new legislation.¹³⁴

The push for a dedicated regulatory body for medicinal cannabis stemmed from the ongoing issues regarding the Therapeutics Goods Administration’s (TGA) approval process for cannabis-based medicines. The TGA is tasked with monitoring and assessing that therapeutic goods available in Australia are of an acceptable standard. However, due to the high barriers to entry and administrative difficulties, pharmaceutical companies currently hold a monopoly over approved cannabis-based drugs, which has made access to medicinal cannabis exceptionally difficult and expensive for patients and researchers. In 2014, the most promising of these drugs, Sativex®, was deemed unlikely to be subsidised by the Pharmaceutical Benefits Scheme (PBS) because its medical benefits did not “justify the manufacturer’s asking price”.¹³⁵ As of January 2016, the TGA has proposed amendments to the Poisons Standard which would allow medicinal-grade cannabis in both herbal and processed forms to be registered as Therapeutic Goods.¹³⁶ This would potentially allow for the production and prescription of medicinal cannabis products that have not been refined and tested to the same extent as pharmaceutical products. They would therefore be cheaper, wider in variety and more immediately available for patients. What this will mean for medicinal cannabis in Australia will require ongoing research.

The Regulator envisaged under the Bill would be charged with issuing licenses for production to private cultivators and manufacturers. It would also be required to maintain a register of approved medicinal cannabis products and manage the approval and revocation of these products. However, pharmaceutical companies

and medicinal cannabis companies would be able to apply to have their product licensed for production under either the Regulator or via the TGA if they chose.¹³⁷ The Regulator would be tasked with developing standards relating to products including the quality and varieties of cannabis and determine testing, packaging and labelling requirements.¹³⁸

The supply and use of medicinal cannabis would also come under the administration of the Regulator, which would develop standards for the distribution of medicinal cannabis, including licensing schemes for transport, import and export. The Regulator would develop an 'authorised patients and carers scheme' which would allow for regulated cannabis products to be used by medical practitioner-authorised patients, supplied by carers and prescribed by medical practitioners.¹³⁹ The Regulator would also manage a list of approved conditions for which cannabis can be prescribed, and continually review medical evidence to expand this list if needed. The membership of the Regulator would include representation from the fields of medicine, pharmacology, and palliative care, along with specialisations in botany, horticulture, law enforcement and patient advocacy.¹⁴⁰

Licensing experimental use of medicinal cannabis would also come under the administration of the Regulator. Experimental licences would be reserved for entities seeking to test and develop varieties of cannabis, methods of cultivation, testing and administration, and performing tests, trials and experiments relating to new product development.¹⁴¹ The Bill emphasised that this effort would "help position Australia as a global leader in the fast moving areas of cannabinoid

therapeutics".¹⁴² Finally, the Regulator would be responsible for monitoring the compliance of licensees and investigating breaches of the regulations that they establish.

3.3.6. The Narcotic Drugs Amendment Bill 2016

On the 10th February 2016, Federal Health Minister Susan Ley introduced the Narcotic Drugs Amendment Bill 2016 (the 2016 Bill) into the Lower House. The Bill is separate from, but in many ways similar to, the Regulator of Medicinal Cannabis Bill 2014 (the 2014 Bill). The 2016 Bill aims to "provide a legislative framework that will enable cannabis cultivation in Australia and provide Australian patients in need with access to medicinal cannabis for therapeutic purposes".¹⁴³

The 2016 Bill shares the objectives and concerns of the 2014 Bill, and details the proposed amendments to the various pieces of Commonwealth legislation required to enact the domestic production, processing, distribution and administration of medicinal cannabis products. The significant differences between these Bills are to do with the role of the Regulator and the TGA.

In the 2014 Bill, a new regulatory body with a wide range of powers was envisioned. Although this would be a challenging and potentially expensive operation, it was believed to be necessary in order to bypass the rigid classification and approval system of the TGA. In the 2016 Bill, it is instead proposed that,

“The Department of Health, through the newly established Office of Drug Control, will license those who cultivate, produce and manufacture cannabis and cannabis products for medical and scientific use, while the TGA would regulate the manufacture, registration and supply of medicinal cannabis products, in the same way that it does for all other therapeutic goods”¹⁴³

In this way, the Office of Drug Control would be responsible for regulating the operational side of the medicinal cannabis industry, while the TGA would be responsible for regulating the types and forms of approved medicinal cannabis products.

The 2016 Bill similarly proposes two license types; one for the production of medicinal cannabis for patient use, and the other for cannabis research purposes. Both licenses would need to stipulate in advance the type and volume of cannabis to be produced. Although cannabis produced for export would not initially be regulated by the 2016 Bill, this is mentioned as a potential option for future legislation.¹⁴⁴

The Minister has indicated that medicinal grade herbal cannabis will not be made available to patients. Instead, only processed, non-smokeable medicinal grade products will be distributed.¹⁴⁵ This is in-line with the 2016 Bill’s requirement for each licensed medicinal cannabis grower to have in place a contract with a medicinal cannabis product manufacturer.¹⁴⁶ The 2016 Bill quickly passed both houses of Parliament.

3.3.7. Draft Public Health (Medicinal Cannabis) Bill 2016

The passage of Federal legislation in February 2016 began the process of regulating the production and supply of medicinal cannabis in Australia. In order to provide medicinal cannabis to patients, each State and Territory will now have to enact their own legislation to fill the regulatory gap between the production of medicinal cannabis products and the administering of these products to patients.

At the Federal level, regulation will cover licensing for domestic cultivation and product manufacturing through the Office of Drug Control, and the approval of medicinal cannabis products through the TGA. At the State/Territory level, regulation will need to cover how medicinal cannabis treatments are approved,



prescribed and administered, as well amending criminal and civil offences related to cannabis possession, use and inhibited driving.

In March 2016, the Queensland State Government released a draft Bill for public comment and discussion which describes one of the ways in which this regulation might be tackled. The key elements of this Bill are patient eligibility, prescription approval and dispensing processes.

The draft Bill does not specify particular conditions or symptoms which would be eligible for treatment with medicinal cannabis. Under the proposed scheme, any doctor – GP or specialist – could apply to the Chief Executive of Queensland Health for permission to prescribe medicinal cannabis.¹⁴⁷ This application would include the reason for treatment and the proposed treatment program, as well as the proposed product and dosage level. The particular medicinal cannabis product requested must either already have been approved by the TGA, or have the capacity to be approved by the TGA. TGA approval would be required before any medicinal cannabis product is provided to patients.¹⁴⁸

The Chief Executive of Queensland Health would be informed by an expert panel but would not be beholden to their recommendations¹⁴⁹ and would have executive power in approving or rejecting an application. Rejected applications could be appealed, and if rejected a second time, would have the possibility of being reviewed by the Queensland Civil and Administrative Tribunal.¹⁵⁰ Ideally, approvals would be issued within 90 days of the application.

Once approved, a prescription valid for up to one year would be issued to the patient and they would be able to access their medicine from an approved

pharmacist. Pharmacists would similarly apply to the Chief Executive to be eligible to dispense medicinal cannabis.¹⁵¹

As this draft Bill is the first to respond to the new Federal legislation, it is possible that it will influence to some extent how other States and Territories approach their regulation. However it is important to remember this is just one of many different possible approaches available to policy makers.

One of the potential problems inherent in this system, and what will require close and ongoing scrutiny, is the extent to which the TGA approval process allows relatively easy access to the essential medicines that patients so urgently require.

3.4. Challenges and concerns

3.4.1. Regulation

One of the greatest challenges associated with medicinal cannabis in Australia has been getting cannabis-based medicines approved by the Therapeutic Goods Administration (TGA). As a part of the Department of Health, the TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods.¹⁵² In order for a therapeutic good to be lawfully supplied in Australia, it must be registered on the Australian Register of Therapeutic Goods (ARTG).¹⁵³ This process requires companies to provide clinical trial data, followed by an approval process that can take up to a year to complete and costs approximately \$250,000 per new chemical entity.¹⁵⁴ Because cannabis is not a single chemical but a mixture of various chemical compounds, it

has been difficult to get TGA approval for medicinal-grade cannabis products.¹⁵⁵ This is one possible reason why conventional pharmaceutical companies have shown little interest in investing in medicinal-grade cannabis products that are costly to develop and difficult to get approved.¹⁵⁶ As of January 2016, the TGA has proposed amendments to the Poisons Standard which would allow medicinal-grade cannabis in both herbal and processed forms to be registered as Therapeutic Goods¹⁵⁷. What this will mean for medicinal cannabis in Australia will require further research.

3.4.2. Importation

The importation of medicinal cannabis into Australia faces various challenges in terms of criminal law, customs regulations, and the TGA framework. At present, the TGA prohibits companies from importing unapproved medicines, and places restrictions on their administration and wholesale supply.¹⁵⁸ Moreover, the importation of medicinal cannabis would likely be very expensive, owing to the high costs and lengthy procedures currently in place under the TGA.¹⁵⁹ The financial burden is likely to fall on patients and researchers. Several academic groups have already raised this as an issue in undertaking research in medicinal cannabis, as they are forced to import from Europe or the USA at great expense.¹⁶⁰

3.4.3. Affordability

The price of legally obtaining medicinal cannabis remains a great concern for patients. In contrast to illicit market dealers, licit distributors bear significant operational costs, including taxation and administration fees.¹⁶¹ All of these costs are inevitably reflected in the sale price of licit medicinal cannabis. In Colorado, it is reported that the price of medicinal cannabis is approximately double that of 'high-quality cannabis' available from the illicit market in United States.¹⁶² If this pattern is followed in Australia, it may lead to lower income patients being forced to source cannabis from the illicit market if market mechanisms such as price ceilings and government subsidies are not put in place.

3.4.4. Quality control

Due to the herbal nature of cannabis, quality assurance remains a key challenge in ensuring its safety and efficacy for medicinal use. Unregulated medicinal cannabis products can carry various risks including heavy metals and unsafe levels of mould. Depending on the genetic makeup and growing conditions of the plant, the cannabinoid content of the cannabis plant can vary greatly:¹⁶³ University of Melbourne Professor David Pennington argues that cannabis in herbal form could never be permitted for medical prescription due to variation in its potency, actions, and effects on individuals.¹⁶⁴ Product standardisation and

quality assurance will be critical in ensuring the safety, consistency and reliability of medicinal cannabis treatment. In the Netherlands for example, where licensed producer Bedrocan produces several strains of medicinal cannabis, cultivation and manufacture is carefully controlled through careful plant breeding and standardised growing conditions.¹⁶⁵

3.4.5. Diversion

Product diversion occurs when there is leakage of medicinal cannabis from the licit market to the illicit market. The prospect of eligible patients sharing or selling their personal supply poses a challenge for law enforcement. A 2012 study in Colorado showed that among a sample of 164 adolescents, 74% had illicitly used other people's medicinal cannabis supply.¹⁶⁶ However, product diversion in the United States has been attributed to the absence of a prescription system, which Australia would be likely to employ for any medicinal cannabis scheme. Prescriptions would mitigate the risk 'doctor shopping' amongst patients, allow control for over-prescription, and minimise diversion to the illicit market through regulated distribution.¹⁶⁷

3.4.6. Education

The lack of education and resources for both doctors and patients is another issue in the legalising of medicinal cannabis. As there is only limited trial data and medicinal experience with cannabis at present, knowledge of the use of cannabis, its pharmacology and adverse effects is lacking.¹⁶⁸ As a result, medical practitioners may not be willing to prescribe medicinal cannabis because of insufficient knowledge about its usage and efficacy.¹⁶⁹ Furthermore, as patients may not be able to receive adequate education and advice about the suitable conditions, dosage and the potential side effects of medicinal cannabis, there remains the possibility of cannabis misuse.¹⁷⁰ However, as clinical literature in the field expands and matures, patients and doctors will likely grow more confident in dealing with medicinal cannabis.

4. Forecasting Australian demand

Demand for medicinal cannabis in Australia will depend on which conditions and symptoms are approved for medicinal cannabis treatment, recommended dosages, and the range and type of approved medicinal cannabis products.

This section includes two different demand estimates based on two possible regulatory outcomes.

The **first method** assumes regulations that allow a relatively small number of patients to access highly refined, pharmaceutical cannabis products. An estimate is made for how many people in Australia would be eligible to use medicinal cannabis based on the conditions most likely to be approved. Taking from the VLRC, these are¹⁷¹:

1

First method

1. Severe muscle spasms or severe pain resulting from Multiple Sclerosis
2. Severe pain arising from cancer, HIV or AIDS
3. Severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
4. Severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects that are intolerable for the patient

5. Severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.

Then, based on the recommended THC/CBD dosage for each condition (using information available for pharmaceutical-grade cannabis products), an estimate is made for the total national demand for these pharmaceuticals and their total THC and CBD content.

2

Second method

The **second method** assumes more broadly prescribed cannabis in its medicinal-grade herbal form, or in its medicinal-grade product form (oils, tinctures etc.). Using the case study countries of Israel, the Netherlands and Canada, the national per-annum consumption of medicinal-grade cannabis is estimated for each country.

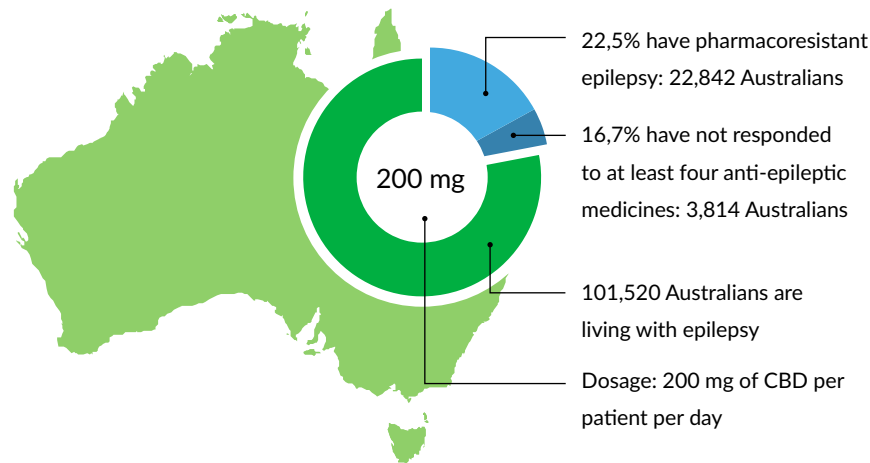
This is then adjusted against the Australian population to arrive at a final figure. This figure basically estimates how much medicinal cannabis would need to be produced if Australia had the same percentage of medicinal cannabis patients who consumed the same amount on average as the countries in question. An estimate is then made for the size of the space required to grow these amounts of medicinal cannabis.

4.1. First method: based on patient numbers

4.1.1. Epilepsy

4.1.1.a. Pharmacoresistant epilepsy

Epidemiological data on epilepsy in Australia is sparse. A 15 year longitudinal study from France showed that in the city of Beziers (population 59,407 in 1990, at the beginning of the study), the rate of epilepsy per 1,000 people aged 16 and older was 5.4 (0.0054 per capita).¹⁷² Of these, 22.5% were classified as having 'pharmacoresistant epilepsy': these were people who had at least one seizure per year and for whom two front-line anti-epileptic medicines had proved to be ineffective.¹⁷³ Of this group, 16.7% had tried four or more anti-epileptic medicines without relief.



If we take these rates and scale them up to the size of the Australian population aged 16 and older (approximately 23.5 million, minus approximately 20%)¹⁷⁴, that would mean 101,520 Australians are living with epilepsy.

If 22.5% of these people have pharmacoresistant epilepsy, that would mean 22,842 Australians. Taking 16.7% of this group would mean 3,814 Australians living with epilepsy which has not responded to at least four anti-epileptic medicines.

4.1.1.b. Severe childhood epilepsy

Although there is some evidence to suggest that CBD could be used for treating pharmacoresistant epilepsy, most medicinal cannabis research is particularly concerned with using CBD to treat severe pharmacoresistant childhood epilepsy, specifically Dravet (DS) and Lennox-Gastaut (LGS) syndromes.

LGS has a mortality rate of 3-7%.¹⁷⁵ For DS this rises to 16-18%.¹⁷⁶ When not fatal, these conditions usually cause severe brain damage, personality disorders, and have disastrous effects on the quality of life of the patient and their family. In a review of the LGS literature, Saleh and Stephen state that in 'developed' countries, LGS presents in 2 per 100,000 children 0-14 years old (0.00002% of 0-14 year olds).¹⁷⁷ The seminal research paper on the prevalence of DS comes from Hurst in 1990, who estimated its prevalence at 1 per 40,000 children 0-7 years old (0.000025% of 0-7 year olds).¹⁷⁸ However, there is a lack of recent data.

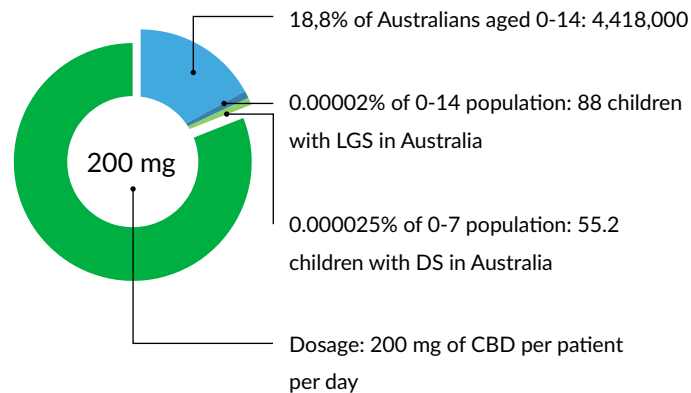
As of 2014, the percentage of Australians aged 0-14 was 18.8% of the population.¹⁷⁹ If the Australian population is 23.5 million, the number of Australians aged 0-14 would be 4,418,000.

If we assume that the number of Australians aged 0-7 is half the number of Australians aged 0-14, this gives us 2,209,000 Australians.

If we take 0.00002% of the 0-14 population (4,418,000), that gives us 88 children with LGS in Australia.

If we take 0.000025% of the 0-7 population (2,171,400), that gives us 55.2 children with DS in Australia.

Combining adult and child patients gives us a total number of 3,957.



4.1.1.c. Demand

There are currently no medicinal cannabis pharmaceuticals prescribed for epilepsy, although the use of illicit medicinal cannabis in the form of CBD-heavy oil to treat severe epilepsy is becoming more common. 200 mg of CBD per day has been the dose administered in at least two clinical/experimental trials to date.¹⁸⁰

Working on the assumption of 200 mg of CBD per patient, per day would mean 288,861,000 mg (288.8 kg) CBD per annum in total.

4.1.2. Cancer

4.1.2.a. Pain

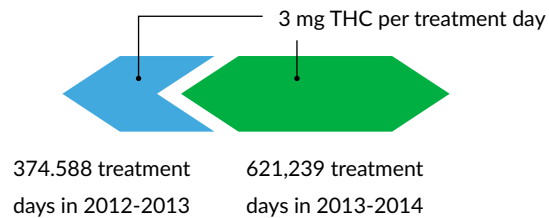
According to Pain Australia, there has yet to be a major study on the prevalence of severe pain in adult cancer patients.¹⁸¹ There are many different types of cancers with different rates of incidence, prevalence and severity, and the nature, extent and intensity of pain which cancer patients experience is also highly variable.¹⁸² As such, a forecast for the likely demand for medicinal cannabis by Australians living with severe cancer pain has not been attempted here.

4.1.2.b. Nausea

In 2013-2014, there were 621,239 treatment sessions (or 'events') for radiation oncology in Australian hospitals.¹⁸³ In 2012-2013, Australian patients underwent a total of 374,588 'treatment days' for chemotherapy.¹⁸⁴ Let us assume that

patients only undergo one radiation treatment session (or 'event') per day. Let us also assume that the aggregate number of 'treatment days' for chemotherapy is not the total time spent by patients undergoing chemotherapy aggregated into a measurement of days, but that it actually represents only one treatment session per day. Working under these assumptions gives us a total of 995,827 treatment days per annum.

Estimates vary on how many of these patients experience intractable nausea as a result of their treatments. However since it is likely that a vast majority would experience nausea of some kind, the entire data set has been chosen.



4.1.2.c. Demand

Let us assume Cesamet (containing 'nabilone', a synthetic form of THC) is prescribed at the same dosage level for radiation therapy as it is for chemotherapy (2-4 mg per treatment day)¹⁸⁵, and take the average of this amount to be 3 mg per treatment day.

If we multiply 3 mg by the number of treatment days, we get 2,987,481 mg (2.9 kg) of THC per annum.

4.1.3. HIV/AIDS

In September 2015, the Australian Federation of AIDS Organisations (AFAO) stated that 27,150 Australians were living with HIV/AIDS.¹⁸⁶

4.1.3.a. Wasting

Thankfully, advances in antiretroviral treatments mean that severe wasting related to HIV/AIDS in Australia now only occurs in a small number of people living with the virus.¹⁸⁷ Although those who experience severe wasting should certainly be provided access to medicinal cannabis, it is likely their demand for medicinal cannabis would not be statistically significant for the purposes of this section. Because of this, their estimated demand has not been forecast.

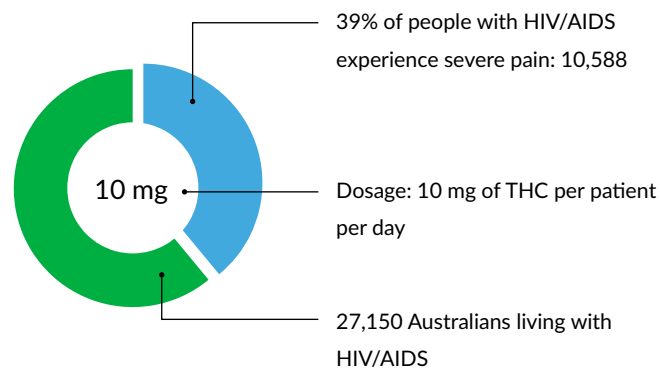
4.1.3.b. Pain

The prevalence and intensity of pain is notoriously difficult to determine. HIV/AIDS related pain in particular is often complex and multi-causal. Chronic pain currently presents in 39-85% of people living with HIV/AIDS.¹⁸⁸ Although this figure does not differentiate between degrees of pain severity, there is evidence that pain in HIV patients is significantly undertreated.¹⁸⁹ With no accurate data on the number of Australians living with severe pain relating to HIV/AIDS, let us work under the assumption that 39% of people living with HIV/AIDS experience severe pain. This is 10,588 people.

4.1.3.c. Demand

The pharmaceutical cannabis product Marinol (containing 'dranabinol', a synthetic form of THC) has been trialled on HIV/AIDS patients at a dosage level of between 2.5 and 20 mg/day¹⁹⁰ to treat severe wasting. Clinical trials have also been conducted using Marinol for pain relief. The recommended dosage for the treatment of wasting is 2.5-10 mg per day, while a clinical trials on pain relief administered 10-20 mg per day.¹⁹¹

Let us assume the average dosage per patient would be 10 mg per day. Per patient, per annum, this would mean 38,646,200 mg (38.6kg) THC.



4.1.4. MS

In 2009, the Survey of Disability, Ageing and Carers (SDAC) reported that 23,700 Australians were living with MS.¹⁹² A study of MS patients conducted in 2011 found that 84.3% of MS patients live with muscle spasticity.¹⁹³ Another study conducted in 2004 found that of those MS patients living with muscle spasticity, 53% exhibited moderate to severe spasticity.¹⁹⁴

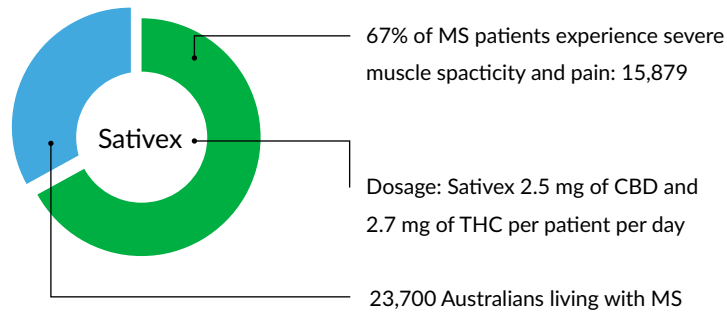
If we take 84.3% of 23,700, we get 19,979 MS patients living with muscle spasticity. Assuming that medicinal cannabis treatments would only be prescribed for those with moderate to severe symptoms (53% of 19,979) gives us an approximate patient figure of 10,588. This is 44.6% of MS patients.

4.1.4.a. Pain

According to MS Australia, chronic pain is experienced by 64-69% of MS patients.¹⁹⁵ Working under the assumption that those people experiencing moderate to severe muscle spasms would be included in the number of people experiencing chronic pain, and taking the mid-point of 67%, gives us 15,879.

4.1.4.b. Demand

Sativex, (containing concentrated THC and CBD extracted from herbal cannabis) has been prescribed for muscle spasticity and pain related to MS. Per dose, Sativex contains 2.5 mg of CBD and 2.7 mg of THC.



Patients are advised to take between 1 and 20 doses per day, and a normal daily intake is 8 doses.¹⁹⁶ Per patient, per day this makes 20 mg of CBD and 21.6 mg of THC.

The daily dosage amount for all patients is therefore 211,760 mg CBD and 228,700 mg of THC. Over the course of a year, this totals 115,916,700 mg (115.9 kg) CBD; and 125,190,036 mg (125.1 kg) THC.

4.1.5. Chronic pain

Chronic pain is believed to occur in up to 30% of the adult population.¹⁹⁷ What proportion of these people would qualify for medicinal cannabis treatment according to the guidelines established by the VLRC is unknown. Therefore, a forecast for the likely demand for medicinal cannabis by this group has not been attempted here.

4.1.6. Summary

Combining the aggregate amounts for these three conditions gives us a total annual demand of 166.6 kg THC and 404.7 kg CBD.

These very rough numbers represent the potential demand for a small number of conditions which could be treated with medicinal cannabis. They are also calculated in terms of pure THC and CBD extracted from the cannabis plant. The efficiency at which these pure cannabinoids could be extracted from herbal cannabis would vary greatly and be dependent on the quality and composition of the plants and the method of extraction and purification used. Working forward from these numbers to some kind of accurate demand forecast would require more data than is currently available.

Condition	HIV/AIDS	MS	Epilepsy	Condition	Cancer	
Patients	10,588	15,875	3,957	Dosage per treatment session	3 mg (THC)	
Dosage per day, per patient	10 mg THC	20 mg CBD	21.6 mg THC	300 mg CBD	Treatment sessions per annum	995,827
Demand per annum	38.6 kg THC	115.9 kg CBD	125.1 kg THC	288.8 kg CBD	Demand per annum	2.9 kg THC

4.2. Second method: based on case study countries

4.2.1. Israel

In 2010, Israel had only around 1,000 registered medicinal cannabis patients.¹⁹⁸ By September 2015, there were approximately 22,000 registered medicinal cannabis patients.¹⁹⁹ According to Tikun-Olam, the average daily consumption of their patients is 1.4 g of medicinal-grade herbal cannabis.²⁰⁰

If we take the number of patients (22,000) and multiply it by how much the average patient consumes in a day (1.4 g), we get 30.8 kg. This is the national, per-day amount. If we assume the per-day amount is consumed every day of the year, we get 11,242 kg as an annual figure for Israel.

Scaling this by the relative populations of Israel and Australia gives an annual figure of 31,450 kg for Australia.

4.2.2. Canada

In 2011, it was estimated that 12,000 Canadian patients used medicinal cannabis.²⁰¹ By March 2015, there were 18,512 registered patients who accessed medicinal cannabis from licensed producers. By September 2015, this had grown to 30,537.²⁰² According to Health Canada, the average daily consumption of medicinal cannabis is 1.1 g per patient.²⁰³

So using the same method as before, we get a national daily consumption of 33,590 g. Which per annum totals 12,260 kg.

Note: this estimate is far below the total amount which Canadian providers are currently licensed to produce (45,000 kg per annum). And far above the actual amount of cannabis produced by these licensed providers between April and September 2015 (3,244 kg).²⁰⁴

Scaling this by the relative populations of Canada and Australia gives an Australian demand of 8,208 kg per annum.

4.2.3. The Netherlands

In 2011, there were fewer than 10,000 medicinal cannabis patients in the Netherlands. By 2014 there were more than 15,000, growing to approximately 25,000 in 2015.²⁰⁵ In 2010 it was estimated that that average daily use of Dutch patients was 0.68 g.²⁰⁶

This would mean 17 kg per day, or 6,205 kg per annum.

Scaling this for population gives an estimated Australian demand of 8,679 kg per annum.

4.2.4. Summary

Based on these very rough numbers, if Australia were to emulate the medicinal cannabis regulations of the Netherlands or Canada, we would initially need to provide at least 8,000 kg of cannabis to patients per annum. Patient numbers in all of our case study countries have been growing and are likely to grow further. Any more accurate estimate would have to be on the basis of a specific proposed regulatory framework.

	Israel	The Netherlands	Canada
No. patients	22,000	25,000	30,537
Average daily consumption per patient	1.4 g	0.68 g	1.1 g
National daily consumption	31 kg	17 kg	33.5 kg
National annual consumption	11,242 kg	6,205 kg	12,260 kg
Population of country	8,400,000	16,800,000	35,100,000
Per capita, per annum consumption	1.33 g	0.369 g	0.349 g
Projected Australian demand	31,450 kg	8,679 kg	8,208 kg

4.3. Primary crop production

There are three main ways in which medicinal-grade cannabis can be grown. These are outdoors, in greenhouses, and indoors.

Indoor production is carried out using artificial lights and multiple harvests a year are possible.²⁰⁷ However, it is very expensive and uses large amounts of electricity for the lighting systems, climate control and ventilation.²⁰⁸ Indoor production is quite common, but only necessary in places where greenhouse or outdoor production is not possible or not permitted by regulation.

Outdoor production has the greatest output per land area per harvest, but produces less cannabis over the course of a year as fewer harvest are possible.²⁰⁹ It requires almost no energy costs and is the cheapest form of production.

Greenhouses are able to produce less cannabis per land area than indoor production, but since greenhouses are capable of producing two harvests per year, they can produce more per year than outdoor production. They are also slightly more expensive than outdoor production, but are also more easily secured and can be better protected against theft and wildlife. Greenhouses are also much cheaper than indoor production.²¹⁰

According to MGC Pharmaceuticals, a professional greenhouse is capable of growing 400-450 plants per square kilometre. These plants can produce around 300 kg of medicinal-grade herbal cannabis per harvest, and two harvest a year are possible. Per year, this means 600 kg of cannabis per 1,000 m² of greenhouse growing space. This works out to be 1.66 m² per 1 kg of cannabis.



Therefore, meeting the production levels in our various examples would require 13,000 to 51,000 m² of greenhouses.

These calculations not take into account the space that would be required for offices, security perimeters, irrigation systems, power sources or other on-site necessities. It also does not take into account the space and fixed infrastructure that would be required to dry, process and package medicinal-grade cannabis products.

The ratio of area to kg of cannabis produced would also fluctuate depending on technological advancements and economies of scale. If a single producer managed 51,000 m² of greenhouse space producing 31,000 kg of cannabis in a central location, this would likely require less space per kg than if that production output was shared by two producers, or twenty. Thankfully, Australia has an abundance of space with perfect growing conditions for both greenhouses and outdoor crops.

5. Policy Options and Recommendations

Section 5 discusses how the medicinal cannabis should best be regulated in order to encourage industry competition, innovation and economic growth.

5.1. Regulating competition

The medicinal cannabis industry in Australia will face some unique challenges. The commercial viability of the industry and its ability to provide high quality and affordable medicine to those in need will be strongly determined by Government regulation. Regulation will affect the cost, quality and safety of cannabis medicines as well as the capacity for the industry to be innovative, responsive and scalable. At their core, these factors relate to the balance which must be maintained between effective regulatory controls and the free functioning of markets. As argued by the VLRC,

“Any scheme would need to provide the necessary amount of regulation to achieve its objectives while not becoming so complex, burdensome and expensive that it deters those on whom its success depends”²¹¹

A well-regulated, competitive marketplace for eligible producers will help ensure that the necessary varieties of high quality cannabis medicines are provided to patients, while the harnessing market forces will maintain downward pressure on prices.

Many medicinal cannabis industries have suffered from a lack of effective regulation. Without specific, enforceable policies concerning such things as pesticide use, labelling and potency consistency, patient safety can be put at risk. Ensuring medicinal cannabis products are ¹ free of adulterants and ² contain a known, consistent and clearly labelled concentration of active ingredients is of the highest priority for the industry. This should be reflected in regulation. It also will be important to ensure that regulation is consistent across the Australian States and Territories such that the industry is able to operate efficiently and predictably throughout Australia.

Formulating clear and transparent standards which medicinal cannabis crops and products must meet would be a valuable first step. Requiring independent batch testing verification would also be necessary. Ideally, the industry should also be supported in the innovation of new, safer and more efficient methods of cannabis production, cannabinoid extraction and medicinal cannabis administration.

International experience has shown that the most efficient way to achieve the necessary variety of high quality, low cost medicinal cannabis products is not by having Government legislate every aspect of the industry. Instead, Government should provide a regulatory framework within which a dynamic industry can emerge and grow. Hindering market competition by placing unnecessarily stringent limits on the number of licenses available for producers would likely increase the cost of medicinal cannabis products. And without appropriate measures to ensure medicinal cannabis is produced responsibly and safely, patient welfare may be compromised. Getting this balance right will take time and existing medicinal cannabis firms can be of great assistance in this process. Many have navigated complex regulatory requirements in other jurisdictions. They

also possess a wealth of specialist knowledge in the areas of medical science, agronomy, manufacturing and distribution.

It is also crucial that medicinal cannabis regulation is capable of facilitating the eventual upscaling of the industry in Australia. As medical science continues to discover new uses for cannabinoids, demand for medicinal cannabis will grow. As Australia continues to lead the world in agriculture, medical devices and education, the potential for an export-oriented medicinal cannabis industry could be realised. Now is the time to urgently develop Australia's capacity to provide essential medicine not only to our own citizens, but also to the citizens of those countries which are unable to do so.

An area not yet considered in detail by policy makers is the potential for Australian exports. When Italy began importing medicinal-grade cannabis from the Netherlands in 2013, the limits placed on exports by the Dutch Government meant that Italian patients were having to pay on average €1,000 per month; ten times the price of the same amount of illicit street cannabis.²¹² The Australian medicinal cannabis firm AusCann previously announced that within three years of regulation being passed it could supply up to 10 tonnes of medicinal cannabis to the Canadian market.²¹³ If Canadian medicinal cannabis retails on average at \$7.5 CAD per gram^{214 215}, the retail value of 10 tonnes would exceed \$75,000,000 CAD. While concerns about domestic overproduction in Australia are legitimate, international demand for medicinal-grade cannabis is substantial and growing. There are many reasons to be optimistic about the direction of medicinal

cannabis policy in Australia. The Regulator of Medicinal Cannabis Bill 2014, the VLRC and the Narcotic Drugs Amendment Bill 2016 support a regulatory framework which avoids the creation of monopolies by issuing multiple licenses for cannabis agriculture and manufacturing.^{216 217} As well as allowing for the specialisation of cannabis firms in particular stages of the supply chain, both Bills propose a class of licenses explicitly for cannabis research and development.²¹⁸ This support for innovation will be of great benefit to patients, carers, the medical community, the medicinal cannabis industry and Australia.

It is likely that any initial regulation will need to be adjusted as patients' needs change and as scientific and industrial knowledge progresses. This means that crafting regulatory processes and institutions which can accommodate change is important. But frequent and significant regulatory changes can place a heavy burden on any industry. Having policy makers work collaboratively with patients, the medical community and medicinal cannabis producers can help reduce these burdens. This could be achieved through supporting the formation of an industry peak body, and by including industry representatives in the policy development process alongside patient, law enforcement and medical science groups.

5.2. Innovation, R&D and technology

Recently there has been a lot of discussion in Australia regarding 'innovation' and its importance for the Australian economy.²¹⁹ Innovation can often sound very abstract and it is sometimes difficult to find real and meaningful examples with which to illustrate its importance.

Medicinal cannabis industries around the world face some very complex challenges and opportunities which have motivated significant technological innovations. Even leaving aside the tremendous and ongoing medical discoveries, whole networks of ancillary industries are now inventing and producing a diverse range of creative products to help patients access medicinal cannabis, and to help Governments manage the industry. From more efficient agricultural production to sophisticated real-time inventory monitoring solutions; from new techniques in food production and infusion to spectrographic analysis; from new medical devices to big data price aggregation. And all in just the last few years.

Patient wellbeing is the essential objective of any successful medicinal cannabis industry, which means guaranteeing the safety, quality and affordability of medicinal cannabis. Supporting the industry in this endeavour will help to create new, more efficient, more affordable products for patients; better, safer, more accurate delivery mechanisms for patients; and a wider range and greater choice of high quality medicine.

A competitive domestic medicinal cannabis industry will also be able to provide our medical scientists with the raw materials they need to find the next

treatment, or the next cure, which remains hindered by the high financial and bureaucratic cost of obtaining medicinal-grade cannabis from overseas.²²⁰

Australia is well placed to become a world leader in the medicinal cannabis industry. This would be furthered by providing appropriate incentives to entrepreneurs and facilitating greater collaboration between researchers and industry, as reflected through such programs as the Biomedical Translation Fund in the Turnbull Government's Innovation Statement.²²¹ In other places around the world, the challenges and opportunities of medicinal cannabis are being addressed by some quite unconventional means. Cannabis-specific 'hackathons' have already been held in both Denver and Seattle, where technology enthusiasts gather and compete to develop new solutions aimed at everything from product diversion to agricultural education.^{222 223} The potential for the employment of new technological platforms such as smart phones for the collation of patient data is very exciting. Along with the recent developments in Australia's path towards electronic patient records, leveraging these new platforms could help capture anonymised data on patient use, dosage levels, and side effects to improve the efficacy of medicinal cannabis treatments.

Innovation can likewise address issues surrounding governance and oversight. Seed-to-sale inventory tracking technologies can help avoid illicit diversion, aid in inventory monitoring, and even provide the reporting data required to comply with the UN Single Convention. These assurances would also help demonstrate the integrity of the medicinal cannabis industry to the public and the law enforcement community.

6. Future Research

This paper has attempted to provide an introduction to medicinal cannabis in Australia and as such it has been unable to address some key issues in any great detail. In the coming months, MGC and the University of Sydney Community Placement Program will collaborate with groups such as BuddingTech and endeavour to close these gaps. In particular, future work in this area will include:



Quality & Safety Best Practices. What are the most effective, efficient and internationally recognised standards and procedures around medicinal cannabis production, product testing and labelling?



Cultivation & Agronomy. How can Australia lead the world in medicinal cannabis cultivation and new agricultural practices? Which strains of cannabis express certain cannabinoid profiles, and how can we create more effective medicinal cannabis plants?



Industry Growth & Export Markets. What industry structures, investment patterns and international relationships would support Australia's medicinal cannabis industry? And what kind of regulation and standards would need to be crafted to facilitate an Australian export market for medicinal cannabis?



Medicinal Cannabis Products. Which delivery mechanism work best for certain cannabinoids and conditions? What kinds of new products and medical devices might further improve patient wellbeing?



Medical Education. How can Australia become a world leader in medical cannabis education? Who requires education and what types of institutes need to be created in order to deliver this?



Extraction & Purification. What are the current techniques and technologies required to extract and purify cannabinoids from herbal cannabis? How can these be improved or innovated?



Banking & Financial. What are the best ways for the Australia to introduce banking and taxation regulations to the medical cannabis industry? Other countries face challenges with banking, taxation and dealing with larger financial institutions, how can Australia avoid these pitfalls?

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