



**ANCD**

AUSTRALIAN NATIONAL COUNCIL ON DRUGS

# **Medicinal use of cannabis:**

## **Background and Information Paper**

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## Introduction

The use of any medication should be based on the clinical evidence of safety and efficacy. To know whether cannabis should be used medicinally, we need to know whether cannabis is a safe and effective treatment for particular conditions, whether it is associated with significant adverse effects, and how it compares to other treatments for those specified conditions. There are a number of different pharmaceutical cannabis products as well as crude cannabis which can also be administered in a range of ways. However, at present, the evidence on the medicinal uses of most cannabis products is incomplete.

In addition to the question of therapeutic effectiveness, using cannabis for medicinal purposes raises legal, regulatory, and other practical issues. If the evidence does support medicinal use of cannabis, enabling patient access raises complex issues of supply and its organisation within the usual processes of the healthcare system, as well as issues of legally distinguishing medicinal from non-medicinal usage.

While these questions and issues continue to raise debate, in Australia there are currently people using illicit cannabis for medicinal purposes. Potentially this means possibly seriously ill patients are being exposed to the risks associated with engaging with an illicit market, including arrest and prosecution, and the resultant stress and worry. Some argue that patients are being blocked from accessing a product which could be beneficial, by the legal status which is actually aimed at prohibiting non-medicinal, rather than medicinal use. They believe this is itself problematic.

Yet, despite continued media and government attention over the last few decades, the current state of the evidence, combined with the legal and regulatory difficulties, continue to prohibit any progress in addressing this issue.

To achieve this, there is a need to disentangle medical and scientific questions from legal and ideological ones in considering whether and how medicinal cannabis should be used in Australia. This is difficult to achieve, since the range of acts and regulations that control non-medicinal uses of cannabis will necessarily impact on medicinal use. In this background paper we seek to begin disentangling these issues. Whilst the background paper includes a discussion of laws aimed at the control of non-medicinal cannabis use, the ANCD takes no view on issues of legalisation or decriminalisation of cannabis for non-medicinal purposes.

The paper provides an overview of what is known about medicinal cannabis use in Australia, the current state of the scientific and medical evidence for its use, and problems with the current situation in Australia. We then explore some current responses. Given the complexities of this issue we are not yet seeking to provide specific guidance on how to resolve the problems, but rather to identify areas that require further action or investigation.

## Background

Cannabis is believed to have been used for medical purposes for thousands of years. The earliest well-documented evidence of use has been dated to 4,000 BCE in China, and textual evidence indicates it was used medicinally in various locations (including Greece, China, India, Egypt and the Middle East) up to 4,000 years ago. Cannabis has been used to treat many conditions, including pain, anxiety, gout, burns, dandruff, jaundice, depression, insomnia, appetite loss, and asthma, amongst others ([Russo 2004](#)).

In the twentieth century, medicinal use of cannabis decreased, partly due to the increasing availability and use of opiates and synthetic drugs ([Grinspoon and Bakalar 1995](#)). Concerns over non-medicinal drug use led to a number of international agreements, which were based on the principle that drugs should only be used for medical or scientific purposes, and introduced controls on cannabis as well as other drugs. In Australia, restrictions were placed on the use, sale and possession of cannabis. Its importation was banned in 1926 by the Commonwealth, and State and Territory legislation was introduced from the 1920s ([Griffith and Jenkin 1994](#)).

Australia has ratified a number of international instruments to which it has obligations, including the *Single Convention on Narcotic Drugs 1961*, the *United Nations Convention on Psychotropic Substances 1972*, and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*. These do not prevent signatories from making cannabis (and other drugs) available for medical and scientific purposes ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)). But they do have implications for how medicinal cannabis could be supplied and who may cultivate it, and have had an impact on domestic drug laws prohibiting cultivation, supply, possession, and use.

Federally, cannabis and tetrahydrocannabinols are currently listed under schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Schedule 9 contains prohibited substances, such that this listing means the use of cannabis and tetrahydrocannabinols “should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities” ([Commonwealth of Australia 2013](#)). This general restriction does not present a barrier to the medicinal use of pharmaceutical products containing cannabinoids if they obtain registration via the Therapeutic Goods Administration and are rescheduled.<sup>1</sup> In November 2012, Sativex, an

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<sup>1</sup> Nabilone and dronabinol (synthetic cannabinoids usually used to treat pain and wasting associated with HIV or chemotherapy) are included in schedule 8, which lists controlled drugs (that is, “substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence”). These cannabinoid medications have never been marketed in Australia and are therefore unregistered. Because of this, they were included on schedule 8 to enable particular patients to access them through the Special Access Scheme (SAS), a program which allows therapeutic goods that are not registered in Australia to be supplied to individual patients. Without specific listing in schedule 8, they were captured under the schedule 9 listing of cannabis and tetrahydrocannabinols, which had the effect of preventing SAS access. For similar reasons, nabiximols (Sativex) was included in schedule 8 in 2010. Following the registration of Sativex in 2012, nabiximols remains on schedule 8, though other parts of the SUSMP were amended to reflect this change (specifically, nabiximols was moved from

oromucosal spray containing cannabinoids, was included in the Australian Register of Therapeutic Goods for the treatment of muscle spasticity related to multiple sclerosis ([Commonwealth of Australia 2012](#)).

Over the last few decades, there have been repeated calls for access to medicinal cannabis in Australia, stimulated partly by case reports detailing successful treatment of individual patients, as well as medicinal cannabis programs in several countries. Canada's medicinal cannabis program, introduced in 2001, has used a government-licensed grower and distributed medicinal cannabis centrally, through Health Canada, to those with medical evidence of need. Patients (or their designated carers) have also been able to obtain licenses to grow their own supply. Canada is altering its system during 2014 so that patients will buy supplies from licensed producers ([Health Canada 2013](#)). In the Netherlands, medicinal cannabis for patients with serious illnesses was made available on prescription in 2003. Licenses to grow medicinal cannabis are granted by the Office for Medical Cannabis, and growers are required to destroy any crops that are not bought by the Office. Several plant strains with standardised concentrations of particular cannabinoids have been developed (Bedrocan, Bedrobinol, Bedica and Bediol) ([Mather et al. 2013](#)). Dried herb or a standardised, granulated product is distributed by pharmacies and can be administered in a tea or through a vaporiser ([NSW Government 2013](#)). In the USA, over 20 states and the district of Columbia have legalised or decriminalised medicinal cannabis, although it remains illegal at the federal level. States have utilised a range of different schemes for exemptions from prosecution and for supply ([NSW Government 2013](#)). In Israel, patients may receive licenses to grow their own supply, and cannabis produced by other licensed growers is distributed centrally. The Czech Republic is also implementing a medicinal cannabis program, and some European countries import products from the Dutch program ([Hazekamp et al. 2013](#)).

In Australia, the medical potential of cannabis was acknowledged in several Government reports during the 1990s, including some released by the National Drug Strategy Committee ([1994](#)) and the Ministerial Council on Drug Strategy ([1998](#)). A NSW Working Party on the Use of Cannabis for Medical Purposes investigated the issues during 1999-2001. Its final report recommended:

- more medical research into cannabis products;
- a compassionate medicinal cannabis scheme for appropriate patients, and;
- a trial of exemption from prosecution for growing, possessing, or using cannabis for medical purposes in NSW ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)).

This trial was planned in the early 2000s ([Johns 2004](#)) but did not proceed.

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appendix D, paragraph 3 to appendix D, paragraph 1. This was to reflect its registered status, while maintaining the requirement for prescription from a medical practitioner with a schedule 8 permit, generally a specialist practitioner) (Therapeutic Goods Administration 2003, Therapeutic Goods Administration 2010, Therapeutic Goods Administration 2013).

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In 2013, the NSW Parliament released the report of its General Purpose Standing Committee No 4 on a subsequent inquiry into the medicinal use of cannabis. Among its recommendations were to:

- express the in-principle support of the NSW government for the expanded use of medicinal cannabis for appropriate patient groups, further clinical trials, and ensuring the affordability of pharmaceutical cannabinoids (recommendation 1).
- enable medicinal use to be a complete defence against charges of using or possessing up to 15g of cannabis; establish a register of authorised medicinal users; further consider supply issues; and provide education for patients and doctors (recommendations 2-5). ([General Purpose Standing Committee No 4 2013](#))

The NSW Government has indicated it does not support these recommendations, except for recommendation 1 ([NSW Government 2013](#)).

## Medicinal use of cannabis in Australia

Despite its illicit status, some patients do use cannabis to treat a range of conditions. Very little is known about the population of people who use cannabis medicinally in Australia, or the prevalence of use. In 2001, Hall and colleagues estimated the maximum number of people in NSW who might have benefited from medicinal cannabis for cancer- or HIV-related wasting, nausea associated with chemotherapy, muscle spasticity, or chronic pain to be 18,900 ([Hall et al. 2001](#)). However, it is not known how many people might use medicinal cannabis were it available.

International studies have reported use rates of medicinal cannabis as follows (though it should be noted that we do not know how Australia may compare):

- Surveys of patients with HIV in various US states have reported rates of cannabis use of between 15 and 46 per cent ([Ogborne et al. 2000](#), [Ware et al. 2005](#)).
- Surveys of patients with HIV in Canada reported use rates of between 15 and 35 per cent ([Ware et al. 2005](#), [Walsh et al. 2013](#)).
- A survey of chronically ill patients in Canada found that 32 per cent reported medicinal use of cannabis ([Ware et al. 2005](#))
- A survey of multiple sclerosis patients in Canada reported that 16 per cent had used cannabis medicinally ([Page et al. 2003](#)).
- A survey of chronic non-cancer pain patients in Canada found that 15 per cent of patients had used, and 10 per cent currently used, cannabis for pain relief ([Ware et al. 2003](#)).

- A study of pharmacy dispensing records in the Netherlands estimated that 5-8 people per 100,000 used medicinal cannabis ([Hazekamp and Heerdink 2013](#)).
- A province-wide survey of people aged 18 and over in Ontario, Canada, found that 2% reported using cannabis medicinally in the past year ([Ogborne et al. 2000](#)).

To date one small survey of 128 people who used cannabis medicinally has been undertaken in Australia ([Swift et al. 2005](#)).<sup>2</sup> Its results are largely consistent with similar surveys undertaken overseas (though some international research notes patients using cannabis for further conditions or symptoms than those listed below). The conditions or symptoms for which it was used by these 128 people are presented in table 1. Most respondents used cannabis for multiple conditions or symptoms.

<b>Table 1: Conditions/symptoms treated with cannabis</b>	
<b>Condition/symptom</b>	<b>%</b>
Depression	56
Chronic pain	57
Arthritis	35
Migraine	17
Weight loss	26
Persistent nausea	27
Spinal cord injury	13
Spasms (spasticity)	16
Fibromyalgia	13
Wasting	11
ME (chronic fatigue)	13
Neuralgia/neuropathy	12
HIV/AIDS	8
Multiple sclerosis	7
Cancer	4
Other neurological disorder	6
Glaucoma	2
PTSD	<1
Irritable bowel syndrome	<1
Source: Swift et al (2005)	

The survey found that use was typically long-term and regular. Many respondents had previously or were continuing to use cannabis non-medicinally, and some had discovered its therapeutic effects from their non-medicinal use. Others had tried cannabis at the suggestion of friends or doctors. Most respondents had tried various routes of administration, but reported typically smoking the cannabis. Although many reported

<sup>2</sup> The authors note two other unpublished surveys undertaken which were not available.

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concerns with smoking, particularly with its respiratory effects, smoking was preferred due its quick effect, allowing self-titration of dose, as well as cost considerations.

There was a high level of satisfaction among the sample with the effects of cannabis in relation to the condition or symptom for which it was being used. About two-thirds (62%) of respondents reported reducing or ceasing use of other medication after starting to use cannabis. This finding is consistent with international surveys, which also reveal high rates of patient satisfaction ([Ogborne et al. 2000](#), [Grotenhermen and Schnelle 2003](#), [Ware et al. 2005](#), [Reiman 2007](#), [Aggarwal et al. 2013](#), [Walsh et al. 2013](#)). Many of these surveys may be skewed towards patients who have chosen to continue using medicinal cannabis, and of course these self-reported patient perceptions provide no evidence of efficacy. However, these surveys have been considered evidence of good toleration of medical cannabis among many patients.

## Scientific and medical evidence

The evidence base for medicinal uses of cannabis is progressing, but is still very much incomplete. The majority of the currently available evidence concerns pharmaceutical preparations rather than crude cannabis. A brief overview for information purposes follows.

There are over 60 cannabinoids present in cannabis plants ([Ben Amar 2006](#)). The most-studied at present include delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). CBD does not appear to have any of the psychoactive effects associated with THC, and may modulate some of the effects of THC ([Mather et al. 2013](#)).

In addition, there are cannabis derivatives and synthetic cannabinoids. These include dronabinol (synthetic THC) and nabilone (a synthetic analogue of THC). Medical cannabis products that have been developed include:

- Marinol (dronabinol), oral tablets/capsules
- Cesamet (nabilone), oral capsules
- Sativex, a mouth spray containing THC and CBD (as well as some other cannabinoids as residue of the manufacturing process) ([Hazekamp and Grotenhermen 2010](#))

Pharmaceutical products which contain cannabinoids have received marketing approval in various countries. Marinol and Cesamet have been available since the 1980s in several countries, for nausea and vomiting associated with cancer chemotherapy; dronabinol is also registered for wasting or cachexia (appetite loss) associated with HIV ([Hazekamp et al. 2013](#)). Sativex has been approved in 24 countries at time of writing for muscle spasticity associated with multiple sclerosis ([GW Pharmaceuticals 2014](#)). Several other products are currently under investigation in clinical or early phase trials.

Clinical trials have investigated medicinal cannabis products for a range of indications. These include pain associated with various conditions, such as cancer, HIV, multiple sclerosis, arthritis, and others. Systematic reviews of the evidence suggest that a number of the

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cannabis pharmaceuticals have some efficacy for treatment of pain, particularly chronic and neuropathic pain ([Ben Amar 2006](#), [Hazekamp and Grotenhermen 2010](#), [Borgelt et al. 2013](#)).

Trials of oral THC (i.e., nabilone and dronabinol) have shown it has efficacy for appetite stimulation and weight gain among patients with HIV, advanced cancer, and anorexia. Several studies have confirmed its efficacy as an anti-emetic (reducing vomiting) for patients undergoing chemotherapy ([Ben Amar 2006](#)).

Combinations of THC and CBD (including Sativex) have shown efficacy in the treatment of spasticity associated with multiple sclerosis. This may be partly related to its analgesic effects, but also to its anti-inflammatory and other properties ([Hazekamp and Grotenhermen 2010](#)).

Cannabinoids are also thought to have some neuroprotective effects, and have been investigated for the treatment of glaucoma, with evidence as yet unclear ([Ben Amar 2006](#), [Hazekamp and Grotenhermen 2010](#)).

Studies have also been undertaken on the use of various cannabis products in treating obsessive-compulsive disorder, schizophrenia, Tourette's syndrome, spinal cord injuries, and epilepsy ([Ben Amar 2006](#), [Hazekamp and Grotenhermen 2010](#)). Cannabinoids are thought to have possible antipsychotic, anticonvulsant, and anti-tumor effects. Much of this research is still quite preliminary or has not yet yielded clear results.

There are few controlled studies available on the medicinal use of crude or smoked cannabis, though it has been investigated for treatment of pain ([Borgelt et al. 2013](#)).

There is a need for more research on all of these matters, and a number of complexities and limitations should be noted. The effects of cannabinoids can differ significantly with different dosages. For example, in some studies where cannabis products have shown efficacy for treating pain, they also appeared to increase pain at higher doses ([Ben Amar 2006](#)). Some of the different cannabinoids appear to modulate the effects of others, and to interact with other medications (including other analgesics), in ways that are not yet well understood. Some of the effects of cannabinoids appear to increase linearly with dosage, while others reach a threshold ([Hazekamp and Grotenhermen 2010](#)). Cannabinoids appear to have highly variable effects on different individuals, which may relate to individual tolerance, as well as to differences in absorption. The hormone levels of individual patients may alter the effects of THC, and significant differences in effect by gender have been observed in some studies ([Hazekamp and Grotenhermen 2010](#)). There is also incomplete evidence surrounding the different effects of cannabinoids used via different routes of administration.

We also lack clarity on how cannabinoids compare to other possible treatments in many cases. For instance, though oral THC has efficacy as an anti-emetic, it is not clear whether it is more efficacious than other products, particularly as the comparative research was undertaken several decades ago. Similarly, there is a need for more research on how cannabinoid analgesics compare to other analgesics, and their suitability for different patients. Cannabinoids may also be useful as a second-line treatment for some groups of



patients who do not respond to or cannot tolerate treatments with greater demonstrated efficacy.

Cannabis products can have adverse effects, including in some cases psychotropic effects. Other adverse effects reported in clinical trials include dizziness, sedation/drowsiness, confusion, vertigo, and dry mouth ([Ben Amar 2006](#)). The acceptability of these effects needs to be evaluated in light of the side-effects of alternative medications for particular indications, as well as severity. Investigation of the neurological basis of the effects of different cannabinoids and the brain's endocannabinoid system is ongoing, so that our understanding of the causal mechanisms involved is currently incomplete.

There are also well-known adverse effects related to crude cannabis use. Acute effects can include anxiety and panic; impaired attention, memory or psychomotor skills; increased accident risk; and increased risk of psychosis among some vulnerable users. Chronic effects include respiratory diseases including chronic bronchitis and cancer; dependence; impairments of memory or learning abilities; and effects on motivation ([NCPIC n.d.](#), [Hall and Solowij 1998](#)).

## The Australian situation

Although we lack data on the prevalence and nature of medicinal use of cannabis in Australia, it appears that people are accessing or growing cannabis illicitly for medicinal use. This has a number of problematic consequences. By either engaging with the illicit market or illicitly growing their own supply, these patients are exposed to a number of risks. There are risks of arrest and criminal penalties, and risks to using an unregulated product of variable chemical constitution and quality without medical supervision. In addition, since many smoke the product, there are health risks such as respiratory damage. All these factors may cause additional distress for patients, many of whom may already be very ill.

The Australian survey of people who used medicinal cannabis ([Swift et al. 2005](#)) reports that 27 per cent of respondents stated they had been arrested, cautioned or convicted for their medicinal cannabis use. Seventy-six per cent reported concern about the illegal status of cannabis and 60 per cent reported a fear of being arrested. Most respondents also reported issues with variability in the quality or effectiveness of their cannabis supply ([Swift et al. 2005](#)).<sup>3</sup>

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<sup>3</sup> International surveys of patients using medicinal cannabis provide similar results, with some proportion of patients coming into contact with law enforcement and experiencing law enforcement activities that are aimed at controlling non-medicinal cannabis use (Ogborne et al. 2000, Aggarwal et al. 2013). These included searches, arrests, prosecutions and incarceration; as well as job loss, and threats of child removal and home eviction. Patients also reported damage to personal and family relationships and increases in depression, which may have been related to the illicit status cannabis use. In the USA (where the situation is further complicated by the inconsistent jurisdictional and federal laws) one study reported increased psychological distress among medicinal cannabis patients, even when psychological distress resulting from chronic illness itself was controlled for (Aggarwal et al. 2013).

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Whilst this evidence is now nearly a decade old, these issues could be expected to continue for people using cannabis medicinally, given that legal and regulatory arrangements have not changed. There were 61,011 cannabis-related arrests in 2011-12, and 86% of these were consumer arrests; the number continues to increase over time ([Australian Crime Commission 2013](#)). The recent registration of Sativex will not affect those using for many of the conditions in Table 1.

In the most recent National Drug Strategy Household Survey, 69 per cent of respondents supported legislative change to permit the medicinal use of cannabis, and 74 per cent supported clinical trials to investigate the medicinal uses of cannabis ([Australian Institute of Health and Welfare 2011](#)). This strong public support perhaps reflects the existence of much anecdotal evidence of its efficacy, as well as the belief that its use is primarily by terminally ill patients who lack other treatment options. Despite the incomplete evidence about efficacy, and lack of data on usage patterns, it is important to recognise that in a context where use is prohibited, these beliefs can have negative effects of their own. Patients who believe that a product exists that could help them, but that it is beyond their legitimate reach due to laws targeting non-medicinal use, may be caused particular distress at the lack of compassion this apparently signals. Some have argued that restricting the medicinal use of cannabis is morally problematic, on the basis that it conflicts with a general moral obligation to avoid inflicting unnecessary suffering ([e.g., Lucas 2009](#)). Frustration at a system which results in this situation may lead to decreased respect for the law.

The illicit status of medicinal cannabis also impacts on our knowledge about its use, making it difficult to gather data on the extent of its use, and use patterns among chronically or terminally ill patients. This in turn hinders the correction of misinformation or information that lacks a good evidence-base.

The ANCD does not endorse the use of medicines that have not been thoroughly evaluated for safety and efficacy. However, we also recognise that a situation where some patients use illicit cannabis medicinally is problematic and may cause significant problems and distress for people coping with illness, and their families. We further recognise that this situation has not been resolved, despite several inquiries and calls to institute different systems, over several decades. Attempts to address this matter continue to be hindered by gaps in the evidence base and the difficulties of negotiating the legal and regulatory complexities.

In the following sections, we discuss issues and challenges surrounding the various routes that may be taken to address them.

## Pharmaceutical cannabis

Any medical product needs to conform to Australia's laws and regulations governing therapeutic goods. Pharmaceutical cannabis products that can be assessed through the usual procedures for therapeutic goods may thus provide the best way to obtain the benefits of cannabinoids for treatment. The recent approval of Sativex demonstrates that

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this is feasible. This would mean that products are required to present evidence of safety and efficacy for assessment by the TGA, ensuring that available treatments have a sound evidence base. Products would be subject to the same quality control procedures as other medicines, and use could occur under medical supervision.

Approval of pharmaceutical cannabis products will, however, take a significant length of time, including product development and testing (for the many and varied conditions for which it has potential uses) as well as approval processes themselves. Relying on the introduction of pharmaceutical products to resolve the above problems is also problematic because it depends on registration being sought by pharmaceutical companies. Even where the evidence exists this may not occur, since Australia's comparatively small market may not offer a sufficient incentive to manufacturers.

In addition, pharmaceutical products will be much more costly than crude cannabis. Sativex was reported in 2013 to cost around \$500 per month or \$6,000 per year ([General Purpose Standing Committee No 4 2013](#)). In contrast, the survey undertaken by Swift and colleagues (2005) reported a median weekly spend of \$50 per week, or \$2,600 per year, on crude cannabis. It is likely that some patients would continue using crude cannabis as a result, unless pharmaceutical products were included on the Pharmaceutical Benefits Scheme.

Further, as the patient surveys reveal, many prefer smoked crude cannabis to other routes of administration due to its more rapid onset, which enables patients more easily to titrate their dose. As currently developed pharmaceutical preparations have a slower onset ([Hazekamp et al. 2013](#)), it is possible that some patients would continue use of crude cannabis for this reason. Oromucosal sprays recently developed or under development have been reported to have an absorption rate similar those of oral capsules ([Mather et al. 2013](#)), though patients indicate it may be more rapid, with corresponding increases in patient satisfaction ([Hazekamp et al. 2013](#)).

## Crude cannabis

Arguments for enabling crude cannabis to be used medicinally can thus be made on the basis of the relative ease of manufacture, lower costs, and potential relative immediacy. However, as well as the legal and regulatory complexities this would involve, and the few clinical trials that have as yet been undertaken on crude cannabis, crude cannabis raises concerns about health risks associated with the route of administration.

Although medicinal cannabis is available in a number of countries, this availability has occurred through other methods to those that are standard for approval and supply of medicines. At present, Australian laws relating to the cultivation, possession and use of cannabis would preclude any registration of crude cannabis via the TGA. Even if legal amendments that would enable legal supply and use of crude cannabis for medical purposes were made, it is unlikely that crude cannabis could become available through the standard routes for medical products in Australia. Plants cannot be patented, so it is unlikely that any application would be made to register cannabis plant products ([Working Party on the Use of](#)

[Cannabis for Medical Purposes 2000](#)).<sup>4</sup> Even if such an application were made, there does not appear to currently be an evidence base available that would be sufficient to establish the efficacy of crude cannabis for a particular indication. In addition, plant matter may vary in concentration and so fail to meet quality control criteria, and any product that could be smoked is unlikely to meet safety criteria ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)).<sup>5</sup>

Some research on alternative routes of administration has been undertaken, though for the most part these other administration routes have a slower rate of absorption and so make dosing more difficult. The standardised, granulated plant matter supplied in the Netherlands is designed to be administered only as a tea or via a vaporiser. Some recent research into the use of vaporisers suggests comparable rapidity of onset to smoking, with fewer effects on the respiratory system ([Fischedick et al. 2010](#), [Van Dam and Earleywine 2010](#)). This research is still in the early stages. Some have argued that smoking of cannabis may be acceptable in cases where a patient is terminally ill, since this would mean the long-term health effects of smoking are irrelevant ([General Purpose Standing Committee No 4 2013](#)) (although it is not clear how this might be responded to in regulatory terms).

Some have voiced concerns that sanctioning of medicinal cannabis could lead to increases in non-medicinal use, and undermine attempts to reduce non-medicinal demand, or that medicinal cannabis could be diverted to the illicit market ([General Purpose Standing Committee No 4 2013](#)). Current evidence suggests that the introduction of medicinal cannabis programs has no effect on non-medicinal use, though there is a need for further research and systematic appraisal of these programs ([Gorman and Huber 2007](#), [Wall et al. 2011](#), [Cerdeira et al. 2012](#), [Harper et al. 2012](#), [Lynne-Landsman et al. 2013](#)).

Another concern is that, should any crude formulation of cannabis become available, this might alter patient and clinician choices in undesirable ways, such as choosing to use cannabis over other available analgesics, for which there may actually be better evidence. Like other medicines, cannabis may come to be used beyond those uses for which there is evidence of efficacy ('off-label' use), and there is the possibility of pressure being placed on medical practitioners to ensure supply. Concerns have been expressed over apparent expansions of the use of medicinal cannabis in some US states, either to indications where treatment with cannabis is not supported by any evidence or unlikely to be of benefit, or as a result of laxity in supply processes ([Nussbaum et al. 2011](#)). A converse situation occurred in Canada after the introduction of its medicinal cannabis program, with clinicians reticent to engage with the program leading to poor patient uptake and continued use via the illicit market ([Lucas 2009](#), and see [Nussbaum et al. 2011](#)).

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<sup>4</sup> In the USA, one not-for-profit company and one for-profit company are reportedly pursuing marketing approval from the US regulator (the Food and Drugs Administration). If they are successful this would impact on the likelihood of this occurring elsewhere.

<sup>5</sup> Cannabis smoke has been linked to cardiovascular disease, respiratory illnesses, and cancer, as well as negative effects on the immune and reproductive systems. There are concerns about the effects of cannabis use on mental health and cognitive function, as well as the potential to lead to dependence (Copeland et al. 2004).

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Arguments for the availability of crude cannabis for medicinal purposes are therefore currently hindered by the lack of sufficient, rigorously conducted medical research. Further research is needed in order for this route to offer an alternate system. Research into the safety and efficacy of non-smokeable forms of cannabis would be particularly warranted.

## Supply

As noted above, Australia's obligations to international instruments do not prohibit the medicinal use of cannabis, but do have an impact on how it could be supplied. The 1961 Convention introduced a system of international controls on the cultivation of opium poppies and cannabis plants. Australia would need to establish or assign a current government agency for the regulation of any cannabis cultivation undertaken for medical or scientific purposes. Licenses would need to be granted to appropriate parties. As cannabis plants are not approved for sale in Australia, without legislative changes any cannabis cultivated could only be used for scientific purposes, and not for supply outside of a scientific or clinical trial ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)).

To import cannabis for medicinal purposes, Australia would need to specify in advance to the International Narcotics Control Board the amount to be imported each year, and provide importers with licenses and permits. Import is likely to be more expensive than cultivation in Australia. State or Territory laws in the jurisdiction of import may also need to be amended ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)).

The 1988 Convention requires Australia to prevent illicit cultivation of cannabis plants, but licensed and permitted provision for medicinal use would not contravene the Convention. Exemptions from prosecution for patients growing their own cannabis for medicinal purposes are thus possible without contravening international conventions ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)). This would require formulation of a legislative framework.

## Law enforcement options

The above issues mean that any provision of crude cannabis for medical purposes is unlikely to occur for some time. Given the difficulties with making either pharmaceutical products or crude cannabis available in a timely manner, some have considered options for addressing the problems of the current situation in the interim. Several ways to avoid the punitive pursuit of those who use cannabis medicinally are suggested in available literature and by international examples.

First, some international medicinal cannabis programs rely on registration schemes; that is, patients with relevant conditions are placed on a registry which exempts them from prosecution for cultivating, possessing or using small amounts of cannabis.<sup>6</sup> These patients

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<sup>6</sup> For discussion of several variations of such schemes see General Purpose Standing Committee No 4 (2013).

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may then grow their own cannabis, or obtain it from central providers, sellers, or compassion clubs, and be confident of legal protection. Such schemes may bring with them difficulties from a law enforcement perspective (in addition to those of supply). They result in there being two classes of people to whom different laws apply; and leave open that some patients who are unable to grow their own plants will still access the illicit market. Such a system has also led to privacy concerns in Canada, as patient information may be disclosed to law enforcement agencies ([Lucas 2009](#)). International programs have experienced difficulties with registration schemes being extended to many more patients than are likely to benefit medically. In addition, there would be a need to restrict access to those patients with indications for which treatment with cannabis is medically indicated; but we currently lack a thorough evidence base to identify the relevant conditions. Such schemes can be considered problematic if they amount to a de facto sanctioning of cannabis as a medicine, beyond what is mandated by the evidence base.

A second option noted in some of the literature is a non-enforcement agreement, where law enforcement officials agree not to pursue arrests or prosecutions of people who can show medical evidence of a relevant condition for which they are using cannabis, though such use would remain formally illegal ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)). Again, this would raise a number of difficulties. Such agreements can be practically difficult to institute, and may come to be applied too broadly in some cases (e.g. to non-medicinal uses) and too narrowly in others. Indeed, the line between medicinal and non-medicinal use is not always clear. Thus this option may lead to inconsistent treatment of people who are in similar situations. And again, this solution is problematic given that it is not clear which, if any, conditions could be treated with crude cannabis. It could also be regarded as sanctioning the medicinal use of cannabis beyond that which is justified by the evidence.

A third option, suggested primarily by legal cases in the USA and discussed in some Australian literature, is the use of legislative amendments to ensure that 'medical necessity' is a clear and recognised defence against charges of possessing, using, or cultivating small amount of cannabis in all jurisdictions ([Working Party on the Use of Cannabis for Medical Purposes 2000](#)). This would not resolve all of the problems of the current situation which have been noted: such patients might still be prosecuted, and would still be exposed to some of the other risks attendant with accessing an illicit product. Nonetheless this might be considered as an interim step while further research is undertaken and the above options are further examined.

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