



Medicinal Cannabis Tasmania Pty Ltd
Application for authorisation to cultivate, supply &
possess cannabis plants for the purposes of scientific
research, analysis & study – 15 August 2014

Medcann Tas
Po Box 175
Burnie, Tasmania

Medicinal Cannabis Tasmania (Medcann Tas)



A report into the use of natural botanical medicinal cannabis
flower and extracted cannabinoids for medical purposes

Tasmanian Legislative Council

15 August 2014

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Terms of Reference

1. The efficacy and safety of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes;
2. If, and how, natural botanical medicinal cannabis flower and extracted cannabinoids could and/or should be supplied for medical use;
3. The legal implications and barriers to the medicinal use of natural botanical medicinal cannabis flower and extracted cannabinoids in Tasmania;
4. The legal implications and barriers to the growing and commercialisation of cannabis flower and extracted cannabinoids in Tasmania to ensure:
 - (a) a scientific-based approach;
 - (b) quality control;
 - (c) consistency;
 - (d) reliability; and
 - (e) ongoing research and development of cannabis-based medicines.
5. The potential impact on agricultural or other sectors within Tasmania; and
6. Any other matters incidental thereto.



Table of Contents

Executive summary	3
Cannabis – the facts	4
World Legalization	4
Legal Opioids	5
The efficacy and safety	6
Cannabis the plant	9
Cannabinoids	9
History of the medical use	11
How cannabis is administered	13
Legal Implications	15
Regulatory Framework	17
Potential impact to established agriculture	19
Conclusion	21



Executive Summary

"About 20 countries now allow medicinal cannabis. Why not Australia?"
Dr Alex Wodak AM President, Australian Drug Law Reform Foundation

"It seems unreal that we can have opiate based medication available to patients when they need it but they can't use cannabis-based medication"
Laura Giddings

"The rules are much, much stricter for farmers than they are even for opium poppies we've been trying to establish our hemp fibre industry for many years and not successfully, that's because of this burden of regulation." Jan Davis – Farmers and Graziers Association

People with advanced cancer and parents of children with rare and intractable forms of childhood epilepsy have recently begun to brave the media to discuss how medicinal cannabis had helped them and their families. They have testified that the symptoms of these diseases and the side effects of the treatments have been much worse than any side effects of medicinal cannabis.

The question should not be whether medicinal cannabis is usually more effective than conventional medications but whether patients should be able to benefit from cannabis if the conventional medications have been tried and failed.

More than two-thirds of Australians support the use of medicinal cannabis because they see this as a compassionate approach to suffering patients. Almost three-quarters of Australians believe we should be doing more research on medicinal cannabis.

The primary realisation for the Legislative Council is that Cannabis is widely available in Tasmania and has been for many years. The current legislation and laws prohibiting cannabis use for terminally patients are prolonging and adding to the suffering for many patients, forcing others to seek supply through illegal means, and restricting availability to those that the products could assist.

If Tasmania can legalize Medicinal Cannabis before other states do, the potential for the state economically could be the panacea for the state.



Cannabis the Facts

Cannabis is the most widely used illicit drug in Australia. According to the 2010 National Drug Strategy Household Survey, **35.4% of the Australian population reported using cannabis at some time in their lives**, with 10.3% having used it in the last 12 months. More than 700,000 Australians used cannabis in the previous week. 46.9% of 20-29 year olds reported ever using the drug. With restrictions, growing plants for personal use has been decriminalised in the Australian Capital Territory, South Australia and the Northern Territory.

Cannabis exists in Tasmania, it is used regularly, it is a cash crop for many and the sale and distribution has an effect on the State's economy.

World Legalization

23 states of the US have approved medicinal Cannabis. The first state to approve medicinal cannabis was California in 1996, but the trend has continued, with Maryland and Minnesota approving Cannabis for medical use as recently as 2014. To date, no reports indicate anyone has died from overdosing with Cannabis. Canada allows use when authorized by a physician.

Medicinal cannabis is currently legal or decriminalized in the Czech Republic, Germany, Finland, the Netherlands, Portugal and Spain. Possession of (small amounts of) cannabis is generally tolerated or not penalized in Belgium, Croatia, Estonia, Italy, and Switzerland.

Many South and Central American Countries are working toward complete legalisation of cannabis as a means to reduce crime and alleviate suffering for terminally ill patients.



Legal Opioids

3 Australians die each day from prescription opioids

We (Tasmania) allow the growing of poppies that are used to produce opioids. Opioids are listed as the primary cause of death for countless individuals worldwide, but we restrict the growing and distribution and use of cannabis for medicinal purposes that is rarely, if ever, the primary cause of death.

According to the United States **Center for Disease Control and Prevention**, they reported overdose deaths from prescribed drugs kills “113 people a day in the United States, while “6,748 are treated” for severe abuse of prescribed drugs. The overdose death numbers do not include deaths from complicated drug side effects. According to Fox News, the FDA deaths from prescribed drugs “between January 1998 and December 2005, a total of 467,809 serious complications were found, and reported deaths from those complications tripled from 5,519 to 15,107.”

The United Nations report on **Illegal Drug Use Worldwide** provides the following data:

1. Opioid overdose was the main cause of the estimated 99,000- 253,000 deaths worldwide related to illicit drug use in 2010.
2. In 2011, of the 41,340 drug overdose deaths in the United States, 22,810 (55%) were related to pharmaceuticals.
3. Of the 22,810 deaths relating to pharmaceutical overdose in 2011, 16,917 (74%) involved opioid analgesics (also called opioid pain relievers or prescription painkillers), and 6,872 (30%) involved benzodiazepines.
4. In 2011, about 1.4 million ED (Emergency Department) visits involved the nonmedical use of pharmaceuticals. Among those ED visits, 501,207 visits were related to anti-anxiety and insomnia medications, and *420,040 visits were related to opioid analgesics.*

To date, the numbers indicate that medical Cannabis possesses less of a public health threat than prescription drugs, prescribed by licensed medical doctors.



The efficacy and safety of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes:

It must be noted that the majority of information regarding medicinal cannabis comes from the United States and Europe, where studies and trials have been conducted

Safety

Cannabis and its psychoactive cannabinoid, THC, have an excellent safety profile. The United States Drug Awareness Warning Network Annual Report, published by the Substance Abuse and Mental Health Services Administration (SAMHSA), contains a statistical compilation of all drug deaths which occur in the United States. According to this report, there has never been a death recorded from the use of cannabis. Pharmacology expert and author Dr. Iverson explains the enormous doses that have been tested:

Laboratory animals (rats, mice, dogs and monkeys) can tolerate doses of up to 1000mg/kg. This would be equivalent to a 70-kg person swallowing 70g of the drug-about 5,000 times more than is required to produce a high. Despite widespread illicit use of cannabis, there are very few if any instances of people dying from an overdose.

Cannabis has an extraordinarily high estimated lethal dose, equivalent to smoking approximately 1,500 pounds in 15 minutes, a physical impossibility. Scientists have had to estimate the LD50, or Lethal Dose for 50% of the human population, because it has never been demonstrated. This puts cannabis in a class of its own, since even relatively safe medications such as aspirin have a lethal dose.

Dr. Grinspoon (Associate Professor Emeritus of Psychiatry at Harvard Medical School. Grinspoon was senior psychiatrist at the Massachusetts Mental Health Center in Boston for 40 years) had this to say in a 1995 article in the Journal of the American Medical Association: *“One of marihuana's greatest advantages as a medicine is its remarkable safety. It has little effect on major physiological functions. There is no known case of a lethal overdose; on the basis of animal models, the ratio of lethal to effective dose is estimated as 40,000 to 1. By comparison, the ratio is*



between 3 and 50 to 1 for secobarbital and between 4 and 10 to 1 for ethanol. Marijuana is also far less addictive and far less subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics.”

As Dr. Grinspoon observes, “The greatest danger in medical use of marijuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution.”

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The legalization of cannabis for medical reasons is viewed favourably by a large majority of Australian and in particular Tasmanians, including members of the medical community and Parliament. The proven benefits of Cannabis are:

- Cannabis is effective at relieving nausea and vomiting, especially caused by chemotherapy used to treat cancer.
- Cannabis can relieve spasticity of the muscles that is sometimes associated with multiple sclerosis and paralysis.
- Cannabis can help treat appetite loss associated with HIV/AIDS and certain types of cancers.
- Cannabis can relieve certain types of pain.
- Cannabis is safe, safer in fact than most other prescribed medications to treat the same symptoms.
- Studies show that smoking Cannabis alone (without the concurrent use of tobacco) does not increase the risk of lung diseases.
- Cannabis has been used for centuries as a medicinal agent with good effect.



Cannabis – the plant

The history of cannabis plant dates back thousands of years. The first written account of cannabis cultivation (ostensibly used as medical cannabis) is found in Chinese records dating from the 28th century B.C.E. And a nearly 3,000-year-old Egyptian mummy contained traces of THC, the main psychoactive chemical in cannabis, as well as other drugs [source: Parsche and Nerlich].

Cannabis sativa is perhaps the world's most recognizable plant. Pictures of the ubiquitous, green cannabis leaf show up in the news media, textbooks and drug-prevention literature. Its shape is made into jewellery, plastered on bumper stickers and clothing, and spray-painted on walls. The leaves are arranged palmately, radiating from a common center, like the fingers of a hand spreading apart. Although most people know what the cannabis plant looks like, they may know very little about its horticulture.

Believed to be a native plant of India, *Cannabis sativa* possibly originated in a region just north of the Himalayas. It's an herbaceous annual that can grow to a height of 8-12 feet (4 to 5.4 meters), with reports as high as 20 and 25 feet (the indica variety tends to be squatter). The plant has flowers that bloom from late summer to mid-fall, when grown outdoors.

Cannabinoids

Cannabis plants contain hundreds of chemicals, 109 of which fit into a category called **cannabinoids** [source: Mehmedic et al.]. THC, of course, is one of these cannabinoids, and it's the chemical most often associated with the effects that cannabis has on the brain. The concentration of THC and other cannabinoids varies depending on growing conditions, plant genetics and processing after harvest.

There are approximately 500 natural components found within the *Cannabis sativa* plant, of which up to 80 have been classified as 'cannabinoids'; chemicals unique to the plant. The most well-known and researched of these, delta-9-tetrahydrocannabinol, is the substance primarily responsible for the psychoactive effects of cannabis.



The effects of THC are believed to be moderated by the influence of the other components of the plant, most particularly the cannabinoids.

The cannabinoids are separated into subclasses. These are as follows:

- cannabigerols (CBG)
- cannabichromenes (CBC)
- cannabidiols (CBD)
- tetrahydrocannabinols (THC)
- cannabinol (CBN) and cannabinodiol (CBDL)
- other cannabinoids (such as cannabicyclol (CBL), cannabielsoin (CBE), cannabitriol (CBT) and other miscellaneous types)

Like opiates (substances derived from the opium poppy such as heroin), cannabinoids affect the user by interacting with specific receptors, located within different parts of the central nervous system. Two kinds of cannabinoid receptors have been found to date and are termed CB1 and CB2. A substance that occurs naturally within the brain and binds to CB1 receptors was discovered in 1992 and termed 'anandamide'. Additional naturally occurring substances that bind to CB1 have since been discovered, and these, together with the receptors are termed the 'endogenous cannabinoid system'.

The actual effects that the cannabinoids have reflect the areas of the brain they interact with. Interactions tend to occur in our limbic system (the part of the brain that affects memory, cognition and psychomotor performance) and mesolimbic pathway (activity in this region is associated with feelings of reward) and are also widely distributed in areas of pain perception.



History of Medical Use

A native of Central Asia, cannabis may have been cultivated as much as 10,000 years ago. It was certainly cultivated in China by 4000 B.C. and in Turkestan by 3000 B.C. It has long been used as a medicine in India, China, the Middle East, Southeast Asia, South Africa, and South America. The first evidence of the medicinal use of cannabis is in an herbal published during the reign of the Chinese Emperor Chen Nung 5000 years ago. It was recommended for malaria, constipation, rheumatic pains, "absentmindedness" and "female disorders."

Another Chinese herbalist recommended a mixture of hemp, resin, and wine as an analgesic during surgery. In India cannabis has been recommended to quicken the mind, lower fevers, induce sleep, cure dysentery, stimulate appetite, improve digestion, relieve headaches, and cure venereal disease.

In Africa it was used for dysentery, malaria, and other fevers. Today certain tribes treat snakebite with hemp or smoke it before childbirth. Hemp was also noted as a remedy by Galen and other physicians of the classical and Hellenistic eras, and it was highly valued in medieval Europe. The English clergyman Robert Burton, in his famous work *The Anatomy of Melancholy*, published in 1621, suggested the use of cannabis in the treatment of depression. The *New English Dispensatory* of 1764 recommended applying hemp roots to the skin for inflammation, a remedy that was already popular in Eastern Europe.

In the West cannabis did not come into its own as a medicine until the mid-nineteenth century. During its heyday, from 1840 to 1900, more than 100 papers were published in the Western medical literature recommending it for various illnesses and discomforts. It could almost be said that physicians of a century ago knew more about cannabis than contemporary physicians do; certainly they were more interested in exploring its therapeutic potential. The medical use of cannabis was in decline by 1890.



The potency of cannabis preparations was too variable, and individual responses to orally ingested cannabis seemed erratic and unpredictable. Another reason for the neglect of research on the analgesic properties of cannabis was the greatly **increased use of opiates after the invention of the hypodermic syringe in the 1850s, which allowed soluble drugs to be injected for fast relief of pain.** Toward the end of the 19th century, the development of such synthetic drugs as aspirin, chloral hydrate, and barbiturates, which are chemically more stable than Cannabis indica and therefore more reliable, hastened the decline of cannabis as a medicine.

The new drugs had striking disadvantages. More than a thousand people die from aspirin-induced bleeding each year in the United States, and barbiturates are, of course, far more dangerous. One might have expected physicians looking for better analgesics and hypnotics to turn to cannabinoid substances, especially after 1940, when it became possible to study congeners (chemical relatives) of tetrahydrocannabinol that might have more stable and specific effects.



How is Cannabis Administered

Cannabis may be taken by mouth or may be inhaled. When taken by mouth (in baked products or as an herbal tea), the main psychoactive ingredient in *Cannabis* (delta-9-THC) is processed by the liver, making an additional psychoactive chemical.

When *Cannabis* is smoked and inhaled, cannabinoids quickly enter the bloodstream. The additional psychoactive chemical is produced in smaller amounts than when taken by mouth.

A growing number of clinical trials are studying a medicine made from a whole-plant extract of *Cannabis* that contains specific amounts of cannabinoids. This medicine is sprayed under the tongue.

The active compounds in cannabis are available in several forms and can be administered in a variety of ways. Each delivery method has benefits and disadvantages.

Smoking

- (+) Delivers all of the plant's active compounds.
- (+) Easy to regulate dose (patients smoke until symptoms are eased, but are not intoxicated).
- (-) No standardization. Amounts of active ingredients may vary.
- (-) Burning cannabis produces toxins which can cause emphysema and lung cancer.
- (-) Illegal

Eating (as an added ingredient to baked dishes)

- (+) Delivers all of the plant's active compounds
- (+) Easy to regulate (patients consume small amounts until symptoms are eased, but are not intoxicated).
- (+) No toxins that can affect the lungs
- (-) No standardization. Amounts of active ingredients may vary.
- (-) Illegal

Marinol - Synthetic THC in pill form

- (+) Legal in the US.
- (+) Delivers some of the benefits of the whole plant.



- (–) Difficult to control dose.
- (–) Contains only one of the plant's active compounds (THC).
- (–) Patients report fewer of the positive effects and more negative side effects.

Vaporizer

- (+) Converts the active compounds to inhalable form without releasing toxins.
- (+) Delivers all of the plant's active compounds.
- (+) Easy to control dose.
- (–) No standardization. Amounts of active ingredients may vary.
- (–) Illegal in most states.

Sativex (nabiximols) - Extract from plants delivered as a spray

- (+) Contains all of the plant's active compounds.
- (+) Concentrations of active ingredients are standardized.
- (+) Relatively easy to regulate dose.
- (+) Legally approved for the medical treatment of Multiple Sclerosis.
- (–) Legal in a limited number of countries.

Cannabis contains approximately 109 active compounds with different properties, collectively called cannabinoids. Scientists are studying cannabinoids to understand their individual and combined effects and their potential benefits.



Legal Implications

It is illegal to use, possess, grow or sell cannabis in Australia, but the penalties for cannabis offences are different in each state and territory. In some states, if someone is caught with a ‘small amount’ of cannabis they may be given a \$50 fine, while in other states they may be charged with a criminal offence and receive a much larger fine, or even be sentenced to jail.

The definition of a ‘small amount’ of cannabis also differs between states and territories. In response to increases in hydroponic cannabis cultivation (cannabis grown in nutrient rich solutions usually under artificial light), the Australian Drug Misuse and Trafficking Act (1985) was amended in 2006. The amendment reduced the amount of indoor cultivated cannabis needed to qualify for a ‘commercial quantity’ and ‘large commercial quantity’.

In Victoria, Tasmania, Queensland, New South Wales and Western Australia; non-industrial cannabis is criminalized, although prison sentences for small amounts are rare. More commonly in these regions, first or second-time offenders caught with small amounts will be offered treatment and can avoid any criminal sentence or a criminal record. Repeat offenders caught with small amounts are likely to be fined and forced into treatment rather than sent to jail, though they may still obtain a criminal record.

South Australia has officially decriminalized personal use of non-industrial cannabis, although this is a poorly defined law. Northern Territory and the Australian Capital Territory have also decriminalized small amounts of non-industrial cannabis, and small amounts of non-hydroponically grown plants. In all regions, offenders caught with large amounts are considered to be trafficking and are much more likely to have a jail sentence handed down.

There is no current law allowing the medical use of cannabis in Australia, and the federal law regarding drug use places Cannabis in Schedule 9 (the most restrictive category, which also includes heroin), meaning it has no



legal medical use and cannot be prescribed by a doctor. Drugs in the other schedules are considered to have medical uses (for instance cocaine, morphine and amphetamine) and can be prescribed. Cannabis users who claim to use the plant for medical purposes are treated the same as anyone else using non-industrial cannabis.

A media report on 16 May 2014 stated that a New South Wales parliamentary committee has recommended the use of medically-prescribed cannabis for terminally ill patients and has supported the legalisation of cannabis-based pharmaceuticals on such grounds.

As part of the recommendation, the committee has called upon the cooperation of the federal Australian government for a scheme that would allow patients to possess up to 15 grams of cannabis. Also, both the patients and their carers would be required to obtain a certificate from a specialist, registration with the Department of Health and a photo Identification card.

Tasmania

Someone found in the possession of up to 50 grams of cannabis can be given a caution up to three times in ten years. For the first caution, information and referral is provided. A brief intervention is given with the second caution. On the third and final caution, the offender must be assessed for drug dependence and attend either a brief intervention or treatment program.



Regulatory framework

International

As would be true of the opium poppy industry, growing cannabis would need to be highly regulated under international and domestic law. As a signatory to the United Nations' Single Convention on Narcotic Drugs 1961 (the Convention), as amended by the Protocol Amending the Single Convention 1972; Australia would be required to carefully control and supervise all stages of the growing and production of cannabis as well as the import and export of narcotic material. Implementation of the Convention is overseen by the International Narcotics Control Board (INCB), which determines annual quotas for the growing of narcotic plants based on estimates of worldwide and initially Tasmanian production needs.

Commonwealth and State

International obligations, would be based on quotas determined by the INCB, are implemented through Commonwealth and state legislative frameworks which regulate the importation, possession, cultivation and processing of cannabis. Commonwealth and state legislative frameworks, we suspect, would impose separate importation and licensing requirements. While these processes operate concurrently, consultation processes between Commonwealth and state government agencies support a coordinated approach to importation and licence applications. In 1972 a joint decision of Commonwealth and state governments restricted the growing of opium poppies to Tasmania for security reasons could be applied.

Cultivation, possession or selling of cannabis are all criminal offences under Tasmania's Misuse of Drugs Act 2001. The activities would need to be licensed under Tasmania's Poisons Act 1971.

A separate licencing requirements must be met under the Poisons Act before the possession, cultivation, manufacture or supply of narcotic substances is permitted under Tasmanian law. Biosecurity, public health and security clearances also apply under licensing processes. We would suggest a Cannabis Advisory and Control Board (CACB) be established



under the Poisons Act to oversee and manage the cannabis industry in Tasmania, including providing advice to the Minister on any matter relating to the cannabis industry. The Board's role would be advisory only and the final determination on licence applications is made by the Minister, and may include broad public interest considerations.



The potential impact on agricultural or other sectors within Tasmania;

Cannabis remains the largest cash crop in America despite law enforcement spending an estimated \$20 billion annually to pursue efforts to outlaw the plant. Recent studies have shown that marijuana exceeds the combined value of corn (\$23.3 billion), wheat (\$7.5 billion) and artichokes (\$53.7 million).

In 2006, it was reported in a study by Jon Gettman, a marijuana policy researcher, that in contrast to government figures for legal crops such as corn and wheat and using the study's projections for the U.S production at that time, cannabis was cited as "the top cash crop in 12 states and among the top three cash crops in 30 other states". ***42 out of 50 states list cannabis as one of their top cash crops!***

The problem in assessing the value of a cannabis crop to the state is being experienced in the US. As growing cannabis under federal law in the US remains illegal; states cannot legally regulate its growth as they do other crops. Research indicates that a kilo of cannabis is valued at approximately \$8000 in Australia. A "good plant" can yield up to a kilo of cannabis flower, generally the yield would be just under ½ of a kilo. Subsequently, the illegal trade in cannabis flourishes.

With the knowledge that cannabis is already grown and sold profitably in Tasmania, the effect it would have on current agriculture would be minimal. If cannabis became a "legal" crop for medicinal purposes, the opportunities to export Tasmanian grown cannabis could be substantial. Cannabis, to be grown successfully, requires a considerable amount of water, with this Tasmania has a distinct advantage. The locations Medcann Tas has designated for growing all have their own water source.

Supply

For trials, if deemed necessary, Medcann Tas, is in a position to grow a summer crop immediately ***without the fear of theft.*** We have secure premises available for growth. Medcann Tas can source seeds from the



US or locally and liaise with US partners to access seeds that have proven medicinal value.

Medcann Tas can supply, with approval, a minimum of 50 kilos of cannabis flower for research purposes. The plants can be grown in an enclosed/locked facility. In addition, Medcann Tas has secured partnerships/agreements to grow with farmers in remote areas.

Conclusion/Facts:

1. Cannabis is readily available in Tasmania.
2. Laws to restrict recreational and medicinal use of cannabis are ineffective, costly and pointless. Whilst we all applaud the seizure of large amounts of cannabis, it has no real effect on supply.
3. Trials are not required; there is an abundance of research that has been conducted on the benefits of medicinal cannabis. Trials will only delay implementation and suffering for some.
4. Medicinal Cannabis is legal or becoming legal through-out the western world and is available on request in many third world countries
5. Cannabis is generally not addictive nor does it cause death as does opiates. Research indicates that it is virtually impossible to overdose on cannabis
6. Cannabis can be grown in enclosed settings reducing the threat of theft (more than 3000 poppy plants are stolen every year resulting in 3 deaths in the last 3 years)

MedCann Tas, has the facilities, the knowledge, the expertise to grow cannabis for trials. MedCann Tas believes that Medicinal Cannabis will flourish worldwide and in Australia within a short period of time.

Does Tasmania want to lead or follow, initiate or copy, accept or deny, assist or condemn? The Tasmanian Government has an opportunity to help the sick and suffering with proven natural medicines and to introduce a new multifaceted industry to the state.



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Medcann Tas
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The irony of the proposal is that Tasmania allows the growing, sale and distribution of opiates which are known killers and restrict the medicinal use of a natural plant that has been tried by more than 35% of Australians and has been in use for over 4000 years.