

**Submission
No 95**

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

Organisation: Alcohol and other Drugs Council of Australia (ADCA)

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Inquiry into the use of cannabis for medical purposes
by the
New South Wales Legislative Assembly General Purpose Standing Committee

21 February 2013

The Alcohol and other Drugs Council of Australia (ADCA) welcomes the opportunity to respond to the New South Wales Legislative Council inquiry into the use of cannabis for medicinal purposes. ADCA is the national non-government peak body representing the interests of the Australian alcohol and other drugs (AOD) sector. It works with government, non-government organisations, business and the community to promote evidence-based, socially just approaches aimed at preventing or reducing the health, economic and social harm of alcohol and other drugs to individuals and the broader Australian community.

This submission – and its recommendations – is supported by the Public Health Association of Australia (PHAA). The PHAA is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

An overview

Cannabis has been used as a medicine for thousands of years, with instances of its use over centuries recorded in Asian, sub-continental and – more recently – European pharmacopeia.

Medicinal cannabis is said to have been very common in Australia in the nineteenth and early twentieth century, although evidence to this end is poorly documented. Pharmacists are known to have made a tincture of cannabis, often combined with opium, chloroform and morphine. Cannabis cigarettes to treat asthma were popular until after World War II.

In his Southern Cross University PhD thesis *Legalisation of medicinal cannabis in New South Wales* (2010) Graham Irvine observes that although ‘there had been attempts by state parliamentarians to ban or restrict the legal use of cannabis as medicine going back to the 1900s, medicinal cannabis remained legal in New South Wales until the passage of the Police Offences Amendment (Drugs) Act 1954 (NSW), which in turn was repealed and replaced by the Poisons Act 1966 (NSW). This 1966 Act introduced even harsher penalties for the use of cannabis in any form, whether for medicinal purposes or otherwise’ⁱ.

Notwithstanding, tincture of cannabis was listed in the Australian pharmacopeia until 1977. By then, the global “war on drugs” was in full swing and cannabis was high on the hit list of police and drug control agencies, despite being nothing more than a blip on the radar of the burden of illness.

With the war on drugs now increasingly called into question, attitudes to cannabis use – both recreational and medicinal – are more liberal. Most recently, 69 per cent of respondents to the Commonwealth Department of Health and Ageing’s 2010 National Drug Strategy Household Survey supported changing legislation to permit the use of cannabis for medical purposes, while 74 per cent supported a clinical trial for people to use the drug to treat medical conditions.

New South Wales has considered the legalisation of cannabis on compassionate grounds on several occasions. In 1999, the then Premier Bob Carr announced that the Government would investigate the use of cannabis for medicinal purposes, with a working party to examine the feasibility of making it available for therapeutic purposes.

The working party recommended in August 2000 that NSW introduce a compassionate regime to assist those suffering from the range of illnesses identified in their report to gain the benefits associated with the use of cannabis without facing criminal sanctions, pending the development of safer and more efficient methods to deliver cannabinoids.

In 2003, the New South Wales Government said it would introduce legislation to allow a four-year trial of the medical use of cannabis, with Premier Carr saying the case for the decriminalisation of cannabis was stronger than ever, but only for people who could not be assisted by conventional treatment. It was proposed that people suffering from cancer, HIV, spinal injuries and other conditions would be eligible for registration with a new Office of Medical Cannabis.

Unfortunately, the proposal failed to generate sufficient impetus and to all intents and purposes, vanished, which raises the question whether federal and state governments have the political will to entertain trials of medicinal cannabis.

As signatories to the 1988 United Nations Treaty, Australia is required to make it a criminal offence to cultivate, supply or possess cannabis. The exception is for 'scientific or medical purposes' under the earlier 1961 treaty.

Global use of medicinal cannabis

The cannabis plant has been used for medicinal purposes for thousands of years. However, cannabis use began to decline in the early 20th century as advances were made in modern medicine. Nearly a century later, investigation of the therapeutic potential of cannabis is re-emerging, perhaps because of increasing botanical drug development and the discovery of the human endocannabinoid system.

Cannabis was first listed in the official United States pharmacopeia in 1850, where it remained until 1941; in the United Kingdom it was listed until 1954. The structure of the main active ingredient of cannabis plants – delta-9 tetrahydrocannabinol (THC) – was discovered in the 60s. More than 20 years later, researchers found the first cannabinoid receptor, followed by the discovery that humans create cannabinoid-like chemicals within their own bodies, known as endocannabinoidsⁱⁱ.

Plant based cannabis medicines have been officially approved for use in more than a dozen countries including the UK, Denmark, the Czech Republic, Austria, Sweden, Germany, Spain, Canada, Italy, Israel and New Zealand. Medicinal cannabis is available in the USA in eighteen states and Washington DC (covering more than 40% of the national population).

In the Netherlands, medical cannabis has been available on prescription since 2003. The cannabis is grown under strictly controlled conditions to ensure quality standards. Netherlands health authorities have produced short information packages on its use^{iii iv}. The Dutch Government recommends that medicinal cannabis is prepared as a tea or inhaled through a vaporiser to avoid exposure to smoke. Its literature points out that the cannabis sold in coffee shops hardly ever meets the quality standards of medicinal cannabis, which is cultivated under controlled conditions by licensed growers.

Like Holland, Canada has a licensed producer of medical cannabis^v.

The UK has approved the use of the cannabinoid nabiximols, marketed as Sativex, in the treatment of MS spasticity, with the recommendation that individual users discuss its suitability with their physician^{vi}. The manufacturer GW is also trialling it for the relief of cancer pain.

Specific arrangements for use or supply differ in the US where state medical marijuana laws allow physicians to recommend cannabis and in some instances permit patients to cultivate cannabis plants. Referenda were conducted in several American states as early as 1996 to legalise medical cannabis – largely with positive results. In a 2011 study of over 1,700 patients receiving medicinal cannabis in California, physicians most commonly recommended its use for pain, insomnia and anxiety^{vii}.

Despite this, the US Federal Administration continues to treat cannabis as a prohibited substance, and has warned state legislatures that by approving cannabis use they are breaking

federal laws. The US Justice Department has written to several states highlighting this anomaly^{viii}. Worth noting is the letter from the Colorado Attorney General John Suthers to the state governor John Hickenlooper which notes “explosive growth” in the number of people claiming to use cannabis for medical purposes – approximately 123,000 registered users – since the state enacted a medical cannabis regulatory scheme in 2000. Suthers says that the US Justice Department will vigorously enforce federal laws relating to marijuana – even if it is permitted under state law. The issue emerged again last November when the state voted to legalise cannabis for recreational, non-medical use^{ix}.

The American Medical Association’s Council of Scientific Affairs recently amended its stance, urging a change to federal laws to allow unfettered research into the use of medicinal cannabis^x.

Evidence that supports the use of medical marijuana

Doctors were prescribing cannabinoids even before they knew exactly how they worked. Researchers discovered two receptors in the human body on which cannabinoids act. They are called cannabinoid receptor 1 (CB1) and cannabinoid receptor 2 (CB2). CB1 is a receptor present mainly in our central nervous system that plays a role in nausea, vomiting, and anxiety; it is affected by cannabis and THC. CB2 is found in other body tissues and plays a role in our immune system.

Cannabinoids are believed to be anti-inflammatory, mainly through activation of the CB2 receptor and have been used mainly to alleviate symptoms of multiple sclerosis. There is also experimental evidence to suggest that they may be immunomodulatory, that is, they may alter the immune response by augmenting or reducing the ability of the immune system to produce antibodies or sensitized cells that recognize and react with the antigen that initiated their production. Some immunomodulators are naturally present in the body, and some are available in pharmacologic preparations.

In the quest for a better evidence base on which to evaluate the positives and negatives of cannabinoids, several major reviews have been published.

Canadian researcher Mohamed Ben Amar reviewed 72 controlled studies carried out between 1975 and 2005, evaluating the therapeutic effects of cannabinoids, detailing where the project was held, the number of patients assessed, the type of study and comparisons done, the products and the dosages used, their efficacy and their adverse effects. Amar observed that cannabinoids present therapeutic potential as antiemetics, appetite stimulants in debilitating diseases like cancer and AIDS, analgesics, and in the treatment of multiple sclerosis, spinal cord injuries, Tourette’s syndrome, epilepsy and glaucoma^{xi}.

A subsequent review by researchers from Leiden University in the Netherlands trod similar ground for the period 2005-09^{xii}.

These reviews demonstrate that the evidence base for the use of medicinal cannabis for certain specified conditions is strong. However, the therapeutic use of cannabis and cannabis-based medicines raises safety concerns for patients, clinicians, policy-makers, insurers, researchers and regulators. Although the efficacy of cannabinoids is increasingly demonstrated in randomised controlled trials, most safety information comes from studies of recreational use.

As such Australia, where the prevalence of recreational cannabis use is among the highest in the world^{xiii}, may be an ideal proving ground. Despite high levels of use, recreational cannabis accounts for only 0.2 per cent of the burden of illness in Australia – well below that of other drugs^{xiv}; all illicit drugs exceed marijuana by a factor of ten, alcohol is 11 times greater and tobacco 39 times. In long term studies of large populations, the effect of cannabis on life expectancy is minimal in males and unable to be measured in females.

Concerns over the severe mental health effects of cannabis apply to a small minority using prodigious quantities of cannabis, usually on a daily basis^{xv}.

Evidence against

Harm from cannabis used in its most common form – as cigarettes – would appear to lie in the way it is ingested. Cannabis smokers usually inhale deeply and hold the intake to generate the maximum effect before exhaling. As such, smoking cannabis is regarded as medically unacceptable. The British Lung Foundation commissioned research into its health effects in 2002,^{xvi} warning strongly against cannabis smoking on the basis of the damage it caused to lungs. Since then, the foundation has continued to publish related research findings.

As mentioned previously, The Dutch Government recommends the preparation of medicinal cannabis either in a tea or inhaled through a vaporiser to avoid exposure to smoke.

In 2008, researchers at Montreal University reviewed safety studies of medical cannabinoids published over the past 40 years to create an evidence base for cannabis-related adverse events and to facilitate future cannabis research initiatives. They found that short-term use of existing medical cannabinoids appeared to increase the risk of non-serious adverse events, while the risks associated with long-term use were poorly characterised in the material they studied. The research team observed that high-quality trials of long-term exposure would be needed to further characterise safety issues related to the use of medical cannabinoids^{xvii}.

In August 2000, the NSW Working Party on the Use of Cannabis for Medical Purposes highlighted the adverse effects of cannabis on motor skills and the mental health of vulnerable individuals. The report said “these health risks should not rule out the use of cannabis for medical reasons, but they must be taken seriously, particularly if long-term cannabis use is being considered for the treatment of a chronic condition”^{xviii}.

Some submissions to the working party noted that smoking cannabis posed health risks, while others surmised that smoking allowed better dose titration than, for example, eating. Many submissions recommended the development of alternative products or ways of taking cannabis for medical purposes.

The Mental Health Council of Australia 2006 report *Where There's Smoke*, explored the relationship between cannabis and mental health. The report revealed that the average age for first time users in the 12-19 year cohort stood at 14.9 years. The MHCA's mental health working group expressed particular concern because of the physiological changes that occur in brain development at that stage of life^{xix}. ADCA notes that this is not the target group at the centre of this inquiry, and that this age group with short life expectancy should not be denied the right to use cannabis.

Safer ways to use cannabis - quality assurance

Modern horticultural techniques ensure that cannabis plants cultivated for medicine can be grown and harvested in controlled, contaminant free conditions to produce consistently high quality pharmaceutical products (sometimes called ‘phytopharmaceuticals’ or botanical drug substances).

There is a thriving government authorised industry of licensed cannabis growers in several countries including, as mentioned previously, Canada and the Netherlands.

Doctors and medical societies in countries like Israel and Canada can now prescribe medical cannabis (including low THC formulations for children).

Extensive literature exploring cannabis use in treatment is available to the medical profession^{xx}.

Synthetic cannabis

While not strictly within the terms of reference of this inquiry, the growth in the availability of “synthetic” cannabis warrants mention.

While the term suggests a product manufactured possibly under controlled conditions, nothing could be further from the truth. Synthetic cannabis consists of a range of manufactured cannabinoids typically sprayed onto herbal products, many of which are listed as inactive on the product packaging.

Synthetic cannabinoids are designed to affect the body in a manner similar to cannabis without being derived from the cannabis plant. Because they can be purchased with no age restrictions, their popularity among young people has grown. They are known by a variety of names, such as “Kronic”, “Spice” or “K2,” and sometimes are referred to as “synthetic marijuana” or “fake marijuana” because they are marketed with claims that their effects mimic those of cannabis. A comprehensive national ban was imposed on these products in the USA last year but distributors continued to market them as “legal” and “not for human consumption”, allowing their purchase online and in legal retail outlets.

They have been associated with agitation, anxiety, nausea, vomiting, tachycardia, elevated blood pressure, tremor, seizures, hallucinations, paranoid behaviour, and non-responsiveness. Because they contain different ingredients, it is difficult to identify which synthetic cannabinoids cause which physical effects.

The US Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Abuse Warning Network (DAWN) estimates that of 120 million visits to emergency departments in 2009 at least 4.5 million were drug related. DAWN attributed nearly 11,500 presentations to hospital emergency in 2010 to synthetic cannabinoids – three quarters of them people aged between 12 and 29, and 78 per cent of them male^{xxi}.

Synthetic cannabis products have been available – often under different names – in Australia for some time. The Department of Health and Ageing last year amended the Poisons Standard to proscribe a number of synthetic substances.^{xxii} Like the US, Australia faces the difficulty of policing online sites like Silk Road, through which people can order drugs. Proscription of such products is fraught with difficulties due to their uncertain composition and the ability of manufacturers to sidestep proscription by altering the proportion of and substituting ingredients.

The National Cannabis Prevention and Information Centre’s Bulletin from March 2012 summarised the legal position in each state and territory relating to synthetic cannabis^{xxiii}.

Considerations and recommendations

Given that Australia is a signatory to the 1961 United Nations Treaty that specifically permits the use of cannabis for scientific or medical purposes, ADCA supports the concept of a medicinal cannabis regime with appropriate government controls over quality and supply. To avoid a situation similar to that in the USA, the Australian Government would have to unambiguously support the states and territories should they choose to trial medicinal cannabis.

Acknowledging the lack of detailed knowledge about this issue in many jurisdictions, information for the community is very important. Incremental changes should be made from trialling through to appraisal and approval of medicines, and each step evaluated to determine benefit and minimal adverse consequences – and to promote the findings. Positive results should prompt consideration of further liberalisation. Experts should be invited to recommend which conditions warrant the highest priority for the use of medicinal cannabis, with the situation reviewed and recommendations made to government at least annually.

ADCA Submission to the NSW Legislative Council General Purpose Standing Committee
Inquiry into the use of cannabis for medical purposes

ADCA supports ongoing research into medicinal cannabis to determine efficacy and safety as they relate to a range of conditions/ illnesses. It also supports the use of medicinal cannabis in the existing legal framework – particularly in palliative cases for patients with poor life expectancy.

ADCA recommends:

- that in the current climate, medicinal cannabis be treated as a second or third line drug for people with intolerably severe symptoms and where more conventional medicines have either proven ineffective or result in unacceptable side effects.
- that given the associated risks, *smoking* cannabis as a medical treatment, as opposed to other forms of ingestion, should be entertained only where patients have a short life expectancy.
- that use of medicinal cannabis be consistent with best medical practice of using the lowest dose over the shortest duration to achieve desired results
- ongoing research to optimise dose and route of administration, quantify therapeutic and adverse effects, and examine interactions and,
- acknowledgment that efficacy may be greater for the whole plant than for extracts, which has significant implications for regulation of cannabis as a medicine.

ADCA thanks the NSW Legislative Assembly Social Policy Committee for the opportunity to provide comment to the inquiry. Should you wish to discuss any issues we raise in this submission please contact [redacted] in our office in the first instance or [redacted].

I welcome the opportunity to discuss this submission further.

Yours sincerely

David Templeman
Chief Executive Officer

21 February 2013

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- ⁱ <http://epubs.scu.edu.au/cgi/viewcontent.cgi?article=1191&context=theses>)
- ⁱⁱ <http://scienceblog.cancerresearchuk.org/2012/07/25/cannabis-cannabinoids-and-cancer-the-evidence-so-far/>
- ⁱⁱⁱ http://www.youtube.com/watch?v=hE60il2pl_k&feature=youtu.be
- ^{iv} http://www.cannabisbureau.nl/en/doc/pdf/5089-A5-BMC-Pat-ENG-web_25097.pdf
- ^v <http://www.prairieplant.com/cannimed-medicinal-marijuana.html>
- ^{vi} <http://www.gwpharm.com/Sativex.aspx>
- ^{vii} <http://www.ncbi.nlm.nih.gov/pubmed/21858958>
- ^{viii} <http://medicalmarijuana.procon.org/sourcefiles/DOJ-Threat-Letters.pdf>
- ^{ix} <http://www.smh.com.au/world/us-election/washington-colorado-allow-marijuanas-recreational-use-20121107-28yuu.html>
- ^x <http://www.ama-assn.org/ama1/pub/upload/mm/443/csaph-report3-i09.pdf>
- ^{xi} Ben Amar, M 2006, 'Cannabinoids in medicine: a review of their therapeutic potential', *Journal of Ethnopharmacology*, vol. 105, no. 1-2, pp. 1-25.
- ^{xii} Hazekamp, A., & Grotenhermen, F. (2010). Review on clinical studies with cannabis and cannabinoids 2005-2009. *Cannabinoids*, 5, 1-21.
- ^{xiii} UNODC, *World Drug Report 2012* (United Nations publication, Sales No. E.12.XI.1)
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- ^{xv} Johns A Psychiatric effects of cannabis *BJP February 2001 178:116-122; doi:10.1192/bjp.178.2.116*
<http://bjp.rcpsych.org/content/178/2/116.full>
- ^{xvi} <http://www.blf.org.uk/Page/Special-Reports>
- ^{xvii} <http://www.cmaj.ca/content/178/13/1669.full>
- ^{xviii} <http://ndarc.med.unsw.edu.au/resource/report-working-party-use-cannabis-medical-purposes-vol-1>
- ^{xix} <http://mhca.org.au/index.php/component/rsfiles/download?path=Publications/Where%20There%27s%20Smoke%20Cannabis%20and%20Mental%20health.pdf>
- ^{xx} <http://medicalmarijuana.ca/for-doctors/marijuana-literature>
- ^{xxi} SAMHSA 2012, *Drug-Related Emergency Department Visits Involving Synthetic Cannabinoids*, The DAWN Report, Dec 4, 2012
<http://www.samhsa.gov/data/2k12/DAWN105/SR105-synthetic-marijuana.htm>
- ^{xxii} <http://www.tga.gov.au/pdf/scheduling/scheduling-decisions-1202-final.pdf>
- ^{xxiii} <http://ncpic.org.au/ncpic/publications/bulletins/article/synthetic-cannabinoids-the-australian-experience>