

# An overview of medicinal cannabis

Current state of play in 2016

# Introduction

This paper provides an overview of the current state of play with respect to issues related to medicinal cannabis. It defines medicinal cannabis and explores the potential health benefits of medicinal cannabis.

The paper includes information on the medicinal cannabis market including key industries and products.

This paper outlines some of the legislative constraints relating to the cultivation, production, importation and exportation of medicinal cannabis. These legal constraints arise out of restrictions placed on cannabis under the international Single Convention on Narcotic Drugs 1961 of which Australia is a signatory.

Any opportunity to progress the cultivation and supply of medicinal cannabis, and potential exportation, as a viable industry in Queensland would require changes to both commonwealth and state laws.

It concludes with information on what Australian jurisdictions are doing with respect to supporting clinical trials and undertaking regulatory reforms to improve access to medicinal cannabis.

1. Tod H Mikuriya (ed) *"Marijuana: Medical Papers"*, 1839–1972 (Symposium Publishing, 2007)  
Robert C Clarke and Mark D Merlin, *"Cannabis: Evolution and Ethnobotany"* (University of California Press, 2013) ch8.

2. Ethan Russo, 'Cannabis in India: Ancient Lore and Modern Medicine' in Raphael Mechoulam (ed) *"Cannabinoids as Therapeutics"* (Springer, 2005) 1–22



## What is medicinal cannabis?

The use of cannabis for medical purposes spans several thousand years and many cultures<sup>1</sup>. Evidence from ancient China and Persia shows cannabis was used as a herbal remedy for a wide range of medical applications.<sup>2</sup>

More recently cannabis use has been prohibited or restricted however it appears a cultural shift is gaining momentum across the world.

With more research and increased scientific knowledge, it is becoming clear that the use of medicinal cannabis is poised to have a genuine role in the treatment of a range of medical conditions.

Not surprisingly, there are a multitude of perceptions within the community about what medicinal cannabis means.

The term 'medicinal cannabis' used in this paper refers specifically to a product that is used for therapeutic purposes.

The term 'medicinal cannabis' does not include the recreational use of cannabis products.

Cannabis is used throughout this paper denoting the scientific name of the plant's genus: *Cannabis*.

# Active ingredients in cannabis

The cannabis plant contains a unique group of chemicals called cannabinoids which affect the human body in a variety of ways.

Although there are more than 100 cannabinoids, the best known are delta-9- tetrahydrocannabinol (THC) and cannabidiol (CBD) as they are generally the focus of medical use.<sup>3</sup>

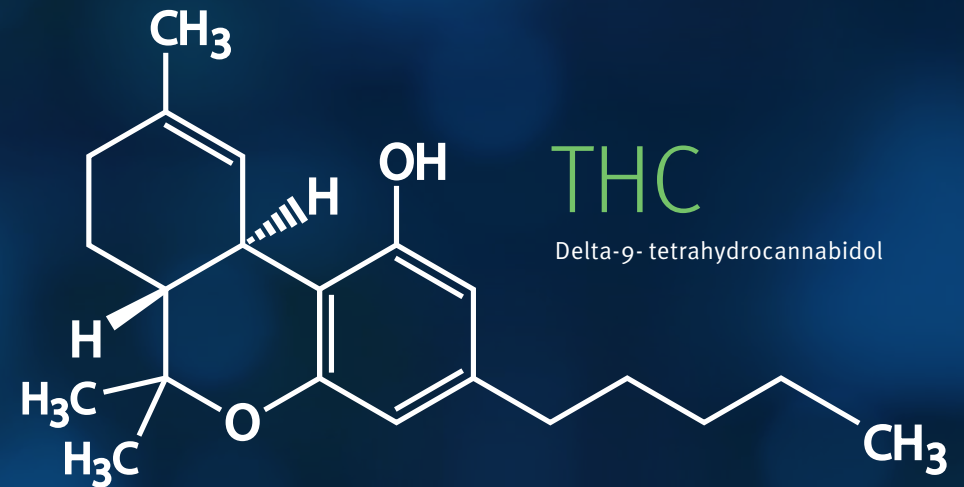
THC is the compound that is responsible for the psychotropic effect of cannabis, and because of this is often referred to as the active constituent of cannabis.

CBD compounds have different biological effects with virtually no psychotropic potential.

It is becoming increasingly clear that further research into the lesser known cannabinoids may uncover potential for therapeutic use for certain medical conditions. Other cannabinoids which are under investigation include cannabigerol (CBG) and tetrahydrocannabivarin (THCV).<sup>4</sup>

3. Laurence E Mather, Evert R Rauwendaal, Vivienne L Moxham-Hall, Alex D Wodak, '(Re)introducing Medicinal Cannabis' (2013) 199 Medical Journal of Australia page 759

4. Victorian Law Reform Commission (2015) "Medicinal Cannabis Issue Paper March 2015" Victoria Law Reform Commission, 2015, 10–11



# Evidence of health benefits of medicinal cannabis

As more research is conducted and scientific knowledge increases, there is growing evidence that medicinal cannabis offers a valuable medical option for treating a range of symptoms. Moreover, research into the use of medicinal cannabis is strongly supported in Australia.<sup>5</sup>

*“A civilised and compassionate country that supports evidence-based medicine and policy should acknowledge that medicinal cannabis is acceptably effective and safe, and probably also cost-effective, especially when the costs of resource use and improvement to the lives and functionality of patients and carers are considered.”<sup>6</sup>*

5. Australian Institute of Health and Welfare, 2010 National Drug Strategy Household Survey report. Canberra: AIHW, 2011. (AIHW Cat. No. PHE 145; Drug Statistics Series No. 25.), accessed November 2015. [www.aihw.gov.au/publication-detail?id=32212254712](http://www.aihw.gov.au/publication-detail?id=32212254712)

6. Laurence E Mather, Evert R Rauwendaal, Vivienne L Moxham-Hall, Alex D Wodak, '(Re)introducing Medicinal Cannabis' (2013) 199 Medical Journal of Australia page 757



Medicinal cannabis is best used for symptomatic relief rather than as a curative treatment.

Current evidence indicates claims can be made that cannabis is viewed favourably for treating:

- Muscular spasms and other symptoms of multiple sclerosis
- Arthritis (including for example osteoarthritis, rheumatoid arthritis, ankylosing spondylitis)
- Chemotherapy-induced nausea and vomiting
- Epilepsy with severe seizures
- HIV/AIDS-related symptoms
- Chronic pain.<sup>7</sup>

7. Victorian Law Reform Commission (2015) “Medicinal Cannabis Issue Paper March 2015” Victoria Law Reform Commission, 2015, 29–30

# Medicinal cannabis market

With global opportunities for the legal use of medicinal cannabis slowly increasing, there has also been some growth in the economic market.



## USA

In 2014 the legal medicinal cannabis market was one of US's fastest growing industries. The US legal cannabis market grew from \$1.5 billion in 2013 to \$2.7 billion in 2014.<sup>8</sup> Some estimates suggest that the US market will be worth \$25 billion by 2020.<sup>9</sup>

Largest markets in Europe:



## Europe

With respect to Europe, medicinal cannabis is currently imported in small quantities from the Netherlands and used by patients in 10 European countries. The largest markets are France, Italy, Netherlands and Romania.



## Canada

The Canadian market for medicinal cannabis was estimated at \$144 million in 2014 with an expected annual growth of 23 per cent until 2024 when the government estimates the market will be worth about \$1.4 billion.<sup>10</sup>

All evidence suggests that the global market will be worth billions of dollars once the industry is fully established.

The full potential of this market will however be subject to cannabinoid drugs having completed the various testing phases and being on the market shelf.

Australia has yet to enter the medicinal cannabis market because of the challenging legal environment that impacts on growing, exporting and importing this product.

8. Janet Burns, 'After "Year of Pot," Cannabis Industry is worth serious cash', Alternet, 11 July 2015, accessed November 2015. [www.alternet.org/drugs/after-year-pot-cannabis-industry-worth-serious-cash](http://www.alternet.org/drugs/after-year-pot-cannabis-industry-worth-serious-cash)

9. Matthew A. Karnes, The Greenwave Report (2nd edition) 'State of the emerging marijuana industry current trends and projections – Executive Summary' GreenWave Advisors, November 2015, accessed November 2015. [www.greenwaveadvisors.com/wp-content/uploads/EXECSUMMARYWITHCOVER.pdf](http://www.greenwaveadvisors.com/wp-content/uploads/EXECSUMMARYWITHCOVER.pdf)

10. MMJPhytotech, 'Medicinal Cannabis Industry,' accessed November 2015. [www.mmjphytotech.com.au/medical-cannabis-industry/industry-overview/](http://www.mmjphytotech.com.au/medical-cannabis-industry/industry-overview/)



# The pharmaceutical cannabis industry

There are a number of key companies currently dominating the pharmaceutical industry with respect to medicinal cannabis products.

The market leader and seller of medicinal cannabis products is the British company GW Pharmaceuticals.

Their main product is Sativex, which is a mouth spray used in the treatment of neuropathic pain and spasticity for patients with multiple sclerosis.

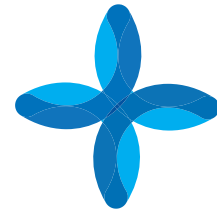
In addition, GW Pharmaceuticals has a number of other pharmaceutical products in development. These include Epidiolex and products containing cannabidiol (CBDV), which will be used in clinical trials for treatment resistant epilepsy, supported by the NSW and Queensland governments in 2016.

Another important company is Insys Therapeutics, which is an American-based company. Their largest-selling drug, Subsys, is prescribed for the treatment of advanced pain associated with cancer.

Subsys is a synthetic version of cannabidiol (CBD) as compared to other cannabis biotech companies that look at the organic versions of the drug. Subsys has accounted for almost 100 per cent of the company's 2014 year-to-date revenue.<sup>11</sup>

Arena is a potential player in the medicinal cannabis market. Arena has recently received a patent for a compound that is being tested for its ability to treat chronic pain and fibrotic disease.<sup>12</sup>

PharmaCyte Biotech is another US-based biotechnology company that is preparing to commercialize a cannabis-based treatment that slows the progression of some cancers and reduces the side effects usually associated with cancer treatments.<sup>13</sup>



## Export of medicinal cannabis

There are significant international constraints on exporting medicinal cannabis under the Single Convention on Narcotic Drugs 1961, which limits trade in cannabis because it is an identified narcotic drug. This means that it is illegal to trade except for medical or scientific research purposes.

Consequently there is not a significant export trade in this product.

There are some countries currently engaging in limited export activity.

For example, the Netherlands have a small controlled export to other countries in the EU which is regulated by the Office of Medicinal Cannabis.<sup>14</sup>

Specifically, in 2006–2013, the Netherlands' government-owned company Bedrocan exported more than 100 kg of medicinal cannabis mostly to Italy, Finland and Germany.<sup>15</sup> Bedrocan has an annual turnover of two million euro per annum.<sup>15</sup>

Under US Federal law, cannabis cannot be exported but Canada does permit exporting for scientific research.

Israel has an established domestic market, strong scientific research and is currently exploring opportunities to export to the US and Canada.<sup>16</sup>

11. Ryan Barnes, 'What the largest Cannabis Stocks can tell us,' Marijuana Investor News, 28 January 2015, accessed November 2015. [www.mjnews.com/5-largest-cannabis-stocks-can-tell-us/](http://www.mjnews.com/5-largest-cannabis-stocks-can-tell-us/)

12. Ryan Barnes, 'Are Cannabis stocks riding a market wave?' Marijuana Investor News, 29 April 2015, accessed November 2015. [www.mjnews.com/cannabis-stocks-riding-market-wave/](http://www.mjnews.com/cannabis-stocks-riding-market-wave/)

13. Bloomberg Business Week, 'For These 55 Marijuana Companies, Every Day is 4/20', accessed November 2015. [www.bloomberg.com/graphics/2015-weed-index/](http://www.bloomberg.com/graphics/2015-weed-index/)

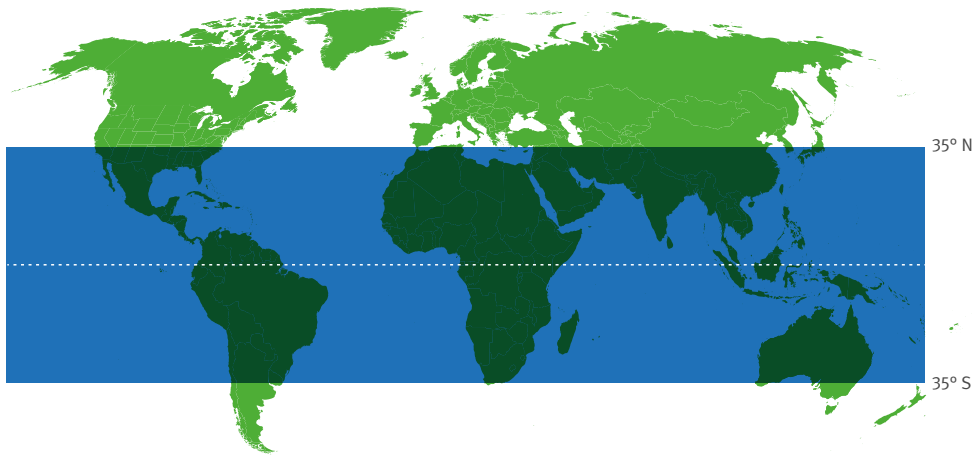
14. Bedrocan®, Netherlands, accessed November 2015. [www.bedrocan.nl/](http://www.bedrocan.nl/)

15. Eva Schrama Sjors van Beek, 'Dutch government is exporting more and more medical marijuana,' Sargasso, 15 February 2015, accessed November 2015. <http://sargasso.nl/nederlandse-overheid-exporteert-steeds-meer-mediwiet/>

16. Debra Borchardt, 'Israel, Canada want a piece of New York's Medical Marijuana' Forbes, 18 January 2015, accessed November 2015. [www.forbes.com/sites/debraborchardt/2015/06/18/israel-canada-want-a-piece-of-new-yorks-medical-marijuana/](http://www.forbes.com/sites/debraborchardt/2015/06/18/israel-canada-want-a-piece-of-new-yorks-medical-marijuana/)

# Implications for Australia

The ideal growing regions for cannabis are within 35° of the equator—Australia has ideal growing conditions.



Australia has proven experience in growing medicinal products.

For example, Tasmania is licensed to grow poppies for the commercial production of alkaloid-based pharmaceuticals and is the largest producer of lawfully manufactured narcotic material in the world.

Tasmania's poppy industry is now worth about \$290 million with around 23,000 hectares of crop grown by 850 farmers.<sup>17</sup>



17. The Department of State Growth, Tasmania, 2015, Sector Summary Food and Agriculture: Poppy, accessed November 2015, [www.stategrowth.tas.gov.au/\\_data/assets/pdf\\_file/0008/89549/Poppy.pdf](http://www.stategrowth.tas.gov.au/_data/assets/pdf_file/0008/89549/Poppy.pdf)

18. Data sourced from Queensland Department of Agriculture and Fisheries, December 2015

# Implications for Queensland

With the use of medicinal cannabis increasing worldwide, the medicinal cannabis market could represent new opportunities for the Queensland agriculture industry. Queensland's experience in growing industrial hemp may provide valuable lessons in the future.

## Queensland's industrial hemp industry

Queensland has an existing industrial hemp industry that is tightly regulated through a licencing scheme to ensure the plant is only grown to obtain the fibre. To support a sustainable industry through improved plant strains, research of the plant can be conducted under relevant research licences, which again limits

research activities to industrial uses of hemp.

Currently there are eight licenced growers in Queensland with more than 64 hectares of crop under cultivation for purposes of harvesting seeds. Additionally there are three category 1 licences issued and one category 2 issued for research purposes.<sup>18</sup>



## Licences and categories

Category 1 licence is for class A and B research.

Category 2 licence is for class B research.

Class A research cannabis plants have a THC concentration in the leaves and flowering heads of three per cent or more.

Class B research cannabis plants have a THC concentration in the leaves and flowering heads of more than one per cent but less than three per cent.



# Legislative constraints for the medicinal cannabis industry at the moment

The Commonwealth *Therapeutic Goods Act 1989* sets out requirements for supplying, importing, exporting, manufacturing and advertising therapeutic goods. Importantly, the Act establishes standards for the quality of therapeutic goods and the Therapeutic Goods Administration (TGA), a division of the Commonwealth Department of Health has responsibility for evaluating and categorising therapeutic goods.

## Commonwealth reforms

The Commonwealth *Narcotic Drugs Act 1967* establishes a national licensing scheme for the manufacture of narcotic drugs. In February 2016 the Commonwealth Government amended the *Narcotic Drugs Act 1967* to establish a licencing and permit scheme for the lawful cultivation and manufacture of medicinal cannabis products.

When licenced, state and territory entities will be able to cultivate cannabis for use in clinical trials and by specific patients where appropriate state and territory legislation is in place. Commonwealth, state and territory laws will ensure Australia meets all of its international obligations under the Single Convent on Narcotic Drugs.



### New South Wales Clinical trials approach

The NSW Government has established the Centre for Medicinal Cannabis Research and Innovation to monitor key clinical trials and to undertake broader research of cannabis products for therapeutic purposes.

With respect to the clinical trials, NSW is currently leading trials with:

- children with severe drug-resistance epilepsy
- adults with chemotherapy-induced nausea and vomiting
- adults with terminal illness (focusing on relief for pain, nausea and vomiting).

The trial will commence in 2016 using a medicinal cannabis product for treating children with severe drug resistant epilepsy.



### Victoria Regulating for exceptional circumstances

In October 2015, the Victorian Government committed to making legislative changes to establish a medicinal cannabis model that covers cultivation, manufacture and supply of medicinal cannabis products for patients in exceptional circumstances.

This model will determine patient eligibility and provide clinical oversight with advice from specialists, general practitioners, nurses and pharmacists.

To enable an ongoing and reliable supply of medicinal cannabis, the Victorian Government will oversee a cultivation trial at a Victorian research facility.







## Queensland Using medicinal cannabis under an integrated treatment plan

In Queensland, medicines, poisons and therapeutic goods are regulated under the *Health Act 1937* and the Health (Drugs and Poisons) Regulation 1996.

In 2015, the Queensland Government amended the Health (Drugs and Poisons) Regulation 1996 to allow for the use of medicinal cannabis in clinical trials.

The Queensland Government has also released a draft of the Public Health (Medicinal Cannabis) Bill 2015 for community and industry consultation. The Bill will facilitate the use of medicinal cannabis under clinical and medical supervision as part of a patient's integrated treatment plan.

Members of the community may participate in the consultation and provide feedback on the Bill through the Queensland Government's Get involved website. Comment will also be sought from health industry stakeholders, particularly medical professionals and healthcare workers.

The Queensland Government will continue to work with the Commonwealth Government to ensure a coordinated approach to any national licensing scheme.

## Conclusion

The issues involved in addressing legislative constraints relating to opportunities for cannabis cultivation, production, importation and exportation are complex.

While there is evidence of the possible therapeutic value of medicinal cannabis, future reforms will need to be mindful of these legal complexities. However it is likely that clinical trials and current reforms will continue to shape the future use of medicinal cannabis in Australia.