

**Cannabidiol 2:  
Response to the Expert Advisory Committee  
on Drugs' Queries**

**Prepared by the Ministry of Health**

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## INTRODUCTION

The Expert Advisory Committee on Drugs (the Committee) considered the scheduling of the Class B1 controlled drug cannabidiol (CBD) at its meeting on 27 April 2016. The result of this consideration was some follow-up questions and a deferral of any decision to the 26 October 2016 meeting.

The Committee asked questions on the proposal to align with Australia by allowing CBD preparations containing 2% of other cannabinoids found in cannabis as prescription medicines.

The questions posed by the Committee at the meeting on 27 April 2016 were:

1. What was the process that led to the 0.35% threshold of tetrahydrocannabinol (THC) content allowed in hemp?
2. What was the process for the Australian Therapeutics Goods Administration (TGA) to reach the 2% threshold of other cannabinoids found in cannabis in CBD preparations?
3. What are the levels of THC found in the average cannabis circulating the New Zealand market?
4. What are the effects of consumption of products containing different levels of THC?

These questions will be responded to below.

## BACKGROUND INFORMATION

Please read this document in conjunction with the information provided for the 27 April 2016 meeting.

Throughout this document, THC is used to refer to  $\Delta^9$ -tetrahydrocannabinol which is one of a number of tetrahydrocannabinols (THCs) found in cannabis. THC is the major psychoactive component found in cannabis. This distinction is important to note as legislation often simply says tetrahydrocannabinol or THC but this is assumed to mean  $\Delta^9$ -THC.

### Recent International Decisions in Relation to Cannabis

#### United States of America

Cannabis (marihuana/marijuana) is currently a Schedule I controlled substance in the United States (US) Controlled Substances Act (CSA). CBD is included in the CSA definition of marihuana and is therefore also a Schedule I controlled substance. The US Drug Enforcement Administration (DEA) have recently reviewed the scheduling of cannabis in response to a petition to remove it from Schedule I. The DEA denied the petition and have decided not to reschedule cannabis because it did not have an accepted medical use in the US, there was a lack of accepted safety for its use even under medical supervision and it has a high potential for abuse.

Some references to the DEA Denial of Petition To Initiate Proceedings To Reschedule Marijuana will be made throughout this report as they have provided a thorough review of the literature information in their document published on the Federal Register (DEA 2016).

### **Australia and New Zealand**

Food Standards Australia New Zealand (FSANZ) recently consulted with the public on whether low-THC hemp seed food should be allowed. If this progressed it would allow foods with very low levels of THC (5 mg/kg or 0.0005%), CBD and other cannabinoids (as contaminants) to be sold in New Zealand. Currently FSANZ is not proposing to set an upper limit for CBD in low-THC hemp seed foods. In order for this to take effect, changes to the Misuse of Drugs Act 1975 (MoDA) and potentially the Medicines Act 1984 would be required.

## **1. What was the process that led to the 0.35 percent threshold of THC content allowed in hemp?**

The New Zealand Misuse of Drugs (Industrial Hemp) Regulations 2006 defines industrial hemp as:

- hemp in the form of—
  - (a) plants with a THC content that is—
    - (i) generally below 0.35%; and
    - (ii) is not above 0.5%; or
  - (b) seeds harvested from plants of that kind.

If the plants are above 0.35% THC then the Director-General must be informed and may require further tests to be done or the plants to be harvested. If the plants are above 0.5% THC the Director-General may require further tests to be done, the plants to be harvested and/or the plants to be destroyed.

Information regarding the decision to allow 0.35% of THC in industrial hemp was not able to be definitively identified prior to the completion of this report. It is likely that the 0.35% limit of THC in industrial hemp was based on Australian legislation in force at the time but it is not clear if psychoactive effects were taken into account when this was set.

At a federal level, cannabis is controlled in Australia under the Poisons Standard February 2016, which specifies cannabis as a Prohibited Substance, except processed hemp fibre containing 0.1% or less of THC and products manufactured from such fibre. THC's are also Prohibited Substances except in hemp seed oil, containing 50 mg/kg or less of THC's when labelled with a warning statement 'Not for internal use' or 'Not to be taken', or in products for purposes other than internal human use containing 50 mg/kg or less of THC's.

Industrial hemp cultivation is controlled in Australia at the State level. The THC limits for these are described below. More detailed information can be found in Appendix 1.

| State                        | THC levels allowed in hemp plants        | THC levels allowed in plants producing hemp seed |
|------------------------------|--|--|
| Western Australia            | 0.35%                                    | N/A  |
| Australian Capital Territory | 1%                                       | 0.5%   |
| New South Wales              | 1%                                       | 0.5%   |
| Queensland                   | 1%                                       | 0.5%   |
| Tasmania*                    | 1%                                       | 0.5%   |
| Victoria                     | 0.35%                                    | N/A  |
| Northern Territory           | no legislation allowing hemp cultivation |  |
| South Australia              | no legislation allowing hemp cultivation |  |

\*Tasmania had a limit of 0.35% THC in industrial hemp crops until recently. In 2013, the Parliament of Tasmania’s House of Assembly Standing Committee on Environment, Resources and Development published a report on the Inquiry into the Tasmanian Industrial Hemp Industry in which they reviewed the difference in THC between Tasmania (0.35%) and some other states who had a THC limit of 1%. The Chief Pharmacist of the Tasmanian Department of Health and Human Services noted that Tasmania was the first jurisdiction in Australia to licence the growing of industrial hemp in 1991. They followed the European standard for industrial hemp which was 0.3% and set it at 0.35% for a slightly higher ‘margin of safety’ as they had no way of knowing what THC levels to expect (Parliament of Tasmania 2013).

For the Australian Capital Territory, New South Wales, Queensland and Tasmania the differences in allowances for THC levels in hemp plants and in plants producing hemp seeds is explained as recognising that the leaves and flowering heads of plants grown using certified hemp seed may have more than 0.5% THC because of environmental conditions beyond a grower’s control.

In the US, for industrial hemp, no more than 0.3% THCs are allowed (including all isomers, acids, salts, and salts of isomers of THCs) (Department of Agriculture et al. 2016).

## 2. What was the process for the Australian Therapeutics Goods Administration (TGA) to reach the two percent threshold of other cannabinoids found in cannabis in CBD preparations?

The 2% threshold for cannabinoids found in cannabis to be allowed in CBD preparations was proposed to ensure the product Epidiolex® would meet the criteria of a prescription medicine rather than a prohibited substance in Australia.

[9(2)(ba)(i)]

[REDACTED] The proposal made by the Victoria and Western Australian Health departments indicated that Epidiolex® was a plant-derived 98% pure cannabidiol product.

[9(2)(ba)(i)]

[REDACTED] Epidiolex® is a liquid formulation of pure 100 mg/mL CBD with excipients. We have contacted them to confirm if the CBD extract used in the product is 100% pure CBD or if there are impurities. We are awaiting their response.

If Epidiolex® is 100 mg/mL CBD then CBD is only 10% (w/v) of the final product. If the CBD extract is assumed to have 2% of other cannabinoids found in cannabis then this would only be 0.2% (w/v) of other cannabinoids in the final product.

Dosages of Epidiolex® used in trials has generally been 20 mg/kg/day and another trial using 10 mg/kg/day as well is being conducted (GW Pharmaceuticals 2016a, 2016b). For a 60 kg person, 20/mg/kg/day would be 1200 mg/day which would be equivalent to 2.4 mg/day of other cannabinoids being administered. In the trials for Epidiolex® using 20 mg/kg/day dosages for the treatment of Lennox-Gastaut and Dravet syndromes, the common adverse reactions noted (experienced in >10% of Epidiolex® treated patients) did not include any euphoria-type reactions (GW Pharmaceuticals 2016a, 2016b).

The proposal also noted that the only product known that claims to have a higher CBD content than Epidiolex® is produced by Insys Therapeutics and is a synthetic form of CBD which claims more than 99% purity (Department of Health 2014). The product produced by Insys is not yet available on the market and is still undergoing clinical trials. Insys Therapeutics' recently completed its Phase 1/Phase 2 safety and pharmacokinetic study in paediatric epilepsy patients with treatment-resistant epilepsy. This study tested Insys' pharmaceutical CBD oral solution which they claim is 99.5% pure CBD in a triglyceride-based formulation with daily doses of 10 mg/kg, 20 mg/kg or 40 mg/kg (Insys Therapeutics 2016).

In the future it may be possible for higher concentration products to be developed and high doses of CBD products should also be considered. If a pure CBD product was available on the market, this could have 2% of other cannabinoids in it. This could result in therapeutic levels of THC, which is the responsibility of the healthcare practitioner to manage. The effects of the THC may also be mitigated by the CBD (see question 4 for more information).

It should also be noted that, [9(2)(ba)(i)] it is unlikely that the 2% for other cannabinoids would consist only of THC as the CBD and THC could not be easily separated from the other related compounds.

### 3. What are the levels of THC found in the average cannabis circulating the New Zealand market?

#### Background

Cannabis plants synthesise  $\Delta^9$ -tetrahydrocannabinolic acid (THCA) and cannabidiolic acid (CBDA), which are then converted to THC and CBD, respectively, by non-enzymatic decarboxylation which occurs with heat. Heating the cannabis plant material to 100°C, 150°C [6(b)(i)] has been shown to convert the THCA to THC completely ([6(b)(i)] Taschwer and Schmid 2015). However, THC will also degrade at these temperatures and has been shown to reduce in concentration once the maximum THC concentration is reached after three hours at 100°C and after one hour at 150°C. The same study found that when cannabis is stored at room temperature (25°C) for 12 months, THCA is converted to THC in small amounts; for example one sample increased from 1.22% THC to 3.23% THC with a corresponding percentage drop in THCA (Taschwer and Schmid 2015).

This is important to note as some testing methods will cause THCA to be converted to THC during the testing and so the THC level reported will actually be a mixture of the THCA and THC level in the plant combined. It is also likely that at the high temperatures used for detecting the THC + THCA levels with some methods, the reported concentration may be lower than they should due to degradation of the THC (Taschwer and Schmid 2015). The same idea can be applied to CBD; depending on the test used, the value reported may apply to CBD levels or the CBD and CBDA levels combined. [6(b)(i)]

[6(b)(i)] It has been found that THCA is not converted into THC in rats *in vivo* (Rock et al 2013).

#### THC levels in cannabis

In New Zealand and internationally there has been a trend of rising THC levels in cannabis. A summary of the articles reviewed in Appendix 2 is listed in the table below. The leaf and female flowering heads of the cannabis plant are generally used for smoking. The female flowering heads of the cannabis plant tend to have more THC in them when compared to the leaves.

| Country results measured in | Cannabis plant part   | Year      | Average THC  | Reference                     |
|-----------------------------|-----------------------|-----------|--------------|-------------------------------|
| New Zealand                 | Leaf                  | 1978-1996 | 1.0% to 1.6% | (Poulsen and Sutherland 2000) |
| New Zealand                 | Female flowering head | 1979-1996 | 3.3% to 3.6% | (Poulsen and                  |

|                               |                         |                       |  |                                      |
|-------------------------------|-------------------------|-----------------------|--|--------------------------------------|
|                               |                         |                       |  | Sutherland 2000)                     |
| New Zealand                   | Range of plant material | 2008-2009             | 10.9%  | (ESR: Forensic Internal Report 2011) |
| Not specified (International) | Leaf                    | 1997 (date published) | 0.5% to 4%   | WHO 1997 (review)                    |
| Not specified (International) | Female flowering head   | 1997 (date published) | 7% to 14%  | WHO 1997 (review)                    |
| USA                           | Range of plant material | 1983-1992             | ~3%  | (EISohly et al 2000)                 |
| USA                           | Range of plant material | 1993                  | 3.4%   | (Mehmedic et al 2010)                |
| USA                           | Range of plant material | 2008                  | 5.8%   | (Mehmedic et al 2010)                |
| USA                           | Female flowering head   | 1993                  | 5.8%   | (Mehmedic et al 2010)                |
| USA                           | Female flowering head   | 1999                  | 13.4%  | (Mehmedic et al 2010)                |
| USA                           | Female flowering head   | 2008                  | 11.5%  | (Mehmedic et al 2010)                |
| Australia                     | Female buds             | 2010-2011             | 16.6% (THC+THCA)                                       | (Swift et al 2013)                   |
| Austria                       | Not specified           | 2015 (date published) | 12.18% to 12.77% (following conversion of THCA to THC) | (Taschwer and Schmid 2015)           |
|                               |                         |                       |  |                                      |
| New Zealand                   | Oil (imported to NZ)    | 1975-1989             | 7% to 45%  | (Poulsen and Sutherland 2000)        |
| New Zealand                   | Oil (locally produced)  | 1983-1995             | 13%  | (Poulsen and Sutherland 2000)        |
| Not specified (International) | Oil                     | 1997 (date published) | 15% to 50%   | WHO 1997 (review)                    |



## Other cannabinoids found in cannabis

It is important to note the other cannabinoids that are also present in cannabis and likely to be part of the impurities found in a CBD preparation. Naturally occurring cannabinoids are sometimes referred to as phytocannabinoids to distinguish the naturally occurring from the synthetic cannabinoids.

[6(b)(i)]

| [6(b)(i)] | [6(b)(i)] | [6(b)(i)] |
|-----------|-----------|-----------|
| [6(b)(i)] | [6(b)(i)] | [6(b)(i)] |
| [6(b)(i)] | [6(b)(i)] | [6(b)(i)] |
| [6(b)(i)] | [6(b)(i)] | [6(b)(i)] |
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[6(b)(i)] cannabidiol (CBD) but there are clinical trials being performed using CBD, which indicates that intoxicating effects are unlikely ([6(b)(i)] [6(b)(i)] GW Pharmaceuticals 2015).

## 4. What are the effects of consumption of products containing different levels of THC?

### Difficulty in determining the relationship between THC concentration and its effects

It can be very difficult to determine the amount of THC that has been absorbed by a person who has taken it, this is because inconsistent amounts of THC are absorbed when smoking or ingesting cannabis. The difficulty in determining the amount of THC absorbed makes it difficult to determine the effects of specific levels of THC.

When cannabis is smoked, THC in the blood plasma can be detected within seconds and peak THC concentrations can be found in less than 10 minutes, reaching a peak after 15 to 40 minutes (Ohlsson et al 1980; Huestis et al 1992; Gonzalez 2007; Grotenhermen 2003). THC levels can vary depending on the experience of the cannabis user and how they smoke (depth and duration of inhalation, frequency of puffs, breath-hold etc.) (Hawks 1982; WHO 1997; Gonzalez 2007; Grotenhermen 2003).

A typical cannabis cigarette contains between 5 and 150 mg of THC in 0.5 to 1.0 g of cannabis, with a THC percentage in the range of 1% to 15% THC (WHO 1997). Only 20% to 70% of the THC found in the smoke of a cannabis cigarette is thought to reach the smoker as the rest is burnt, remains in the butt of the cigarette and/or is lost as sidestream smoke (Hawks 1982; WHO 1997; Grotenhermen 2003). This, plus incomplete absorption in the lungs of THC, results in only 8% to 24% (mean 18%) of the overall THC in a cannabis cigarette reaching the bloodstream (Ohlsson et al 1980; WHO 1997; Grotenhermen 2003). It takes only 2 to 3 mg of smoked THC to produce a brief high in an occasional cannabis user, which means that one cannabis cigarette would be enough for two to three people to achieve a brief high. However, heavy cannabis smokers may consume much higher doses of THC per day (WHO 1997).

When substances such as THC and CBD are taken orally, they must go through 'first-pass metabolism'. This means that drugs will be metabolised by the liver before they reach the brain or any other tissues, which will affect the amount of active substance that reaches the target receptors and reduce the overall bioavailability (Hawks 1982; Grotenhermen 2003; [6(b)(i)]). When cannabis is orally ingested (eaten or drunk) the peak plasma concentrations of THC are generally reached within 60 to 120 minutes but this can vary considerably between individuals with differences of up to six hours observed. The THC levels in plasma may also vary between individuals and peak several times when orally ingested (Ohlsson et al 1980; Gonzalez 2007; Grotenhermen 2003). The systemic availability has been reported as 4% to 12% of THC ingested (mean 6%) (Ohlsson et al 1980).

There is no simple relationship between blood levels of THC and THC metabolites and the degree of intoxication. THC and its metabolites can be detected in the body for weeks following cannabis use as they are highly fat soluble (Hall et al 2001; Grotenhermen 2003). In fact, THC can be found stored in body fat more than 28 days after cannabis use (Hall et al 2001). In studies it has been reported that the peak 'high' experienced after smoking cannabis lags behind the peak THC concentration in blood or plasma. This is likely due to rapid extraction of the lipophilic THC into fat and tissues (which includes the brain) (Ohlsson et al 1980; Huestis et al 1992). It is also less clear if regular users of cannabis would achieve intoxication from the same levels of THC as occasional users (Hall et al 2001).

Tests attempting to correlate THC concentrations with intoxication, psychomotor impairment or other behavioural changes, have found a wide variability in how individuals respond to THC (Huestis et al 1992; WHO 1997). Factors that affect an individual's response to THC include the mode of administration, physiological and pharmacological differences, differences in tasks used to measure behavioural changes, alcohol intake and drug experience (ie, regular cannabis smokers will react differently to occasional cannabis smokers) (WHO 1997).

### **Some effects of THC consumption**

Huestis et al (1992) tested six individuals with a history of cannabis use that ranged from 0.4 to 7.9 cannabis cigarettes smoked each week on average. The THC levels of the cannabis cigarettes used were 1.75% and 3.55% and individuals reported feeling a similar level of drug effect after each one, with the lower dose taking six minutes longer for the peak drug effect to be reported. A similar level of drug effect was felt despite the 3.55% THC cigarette resulting in a higher blood concentration of THC. However, between individuals, the drug effect reported to be felt varied considerably with the individual with the lowest THC blood levels (whose average cannabis use was 0.8 times per week) reporting the greatest increase in drug effect felt after smoking the 3.55% THC cigarette (Huestis et al 1992).

The THC metabolite 11-hydroxy-THC is 20% more potent and penetrates the brain more rapidly than THC. 11-hydroxy-THC is produced when THC is ingested orally and to a much lesser extent when smoked (Hawks 1982; Hall et al 2001; Grotenhermen 2003).

Some additional information on the effects of consumption of products containing different levels of THC can be found in the green highlighted sections provided from the DEA's Denial of Petition To Initiate Proceedings To Reschedule Marijuana (DEA 2016). These sections are:

- page 53695 (page 9 of pdf)
- page 53698-53699 (pages 12-13 in pdf)
- page 53723 (page 37 of pdf)

- page 53743 (page 57 of pdf)
- page 53749 (page 63 of pdf)
- page 53754 (page 58 of pdf)
- page 53758 (page 72 of pdf).

## CBD and THC

CBD has been shown to have low affinity for the CB1 and CB2 receptors but acts as an antagonist of CB1 and CB2 receptor agonists (Pertwee et al 2008; 6(b)(i)). It should also be noted that some studies which are reviewed reflect pure THC being tested, whereas when CBD is present in high enough concentrations it has been proposed to have inhibitory effects on THC activity. There is still relatively little robust evidence on the inhibitory effects of CBD on THC and more research is required in this area (Englund et al 2013; Morgan et al 2010a; Morgan et al 2010b). However, it is likely that if CBD is present in a product, it might work to reduce the psychoactive effects of THC and any other CB1 receptor agonists (the CB1 receptor being the one thought to be predominately associated with the psychoactive effects of THC and other psychoactive cannabinoids). Therefore this should be considered as well when determining what an acceptable limit for other cannabinoids in a CBD preparation would be.

Some additional information on the effects of consumption of products containing different levels of THC and CBD can be found in the yellow highlighted sections provided from the DEA's Denial of Petition To Initiate Proceedings To Reschedule Marijuana (DEA 2016). These sections are:

- pages 53694-53695 (pages 8-9 of pdf)
- page 53749 (page 63 of pdf).

(Note: both sections give the same information about the same studies)

## CONCLUSION

The limit of 0.35% THC in industrial hemp is thought to be based on the Australian limits originally set by Tasmania. However, it is unclear if any consideration was given to psychoactive effects of THC at this level. The Australian decision to allow 2% of cannabinoids found in cannabis in CBD preparations was proposed to ensure Epidiolex® would meet the criteria of a prescription medicine rather than a prohibited substance. The levels of THC in cannabis has been growing both in New Zealand and internationally, from around 3% THC in the 80s and 90s to around 10% to 15% in more recent studies. It is difficult to determine the effects of different levels of THC in cannabis as an individual's reaction to THC can vary widely due to a number of factors.

It is expected that in the current products available, THC levels would be unlikely to cause a psychoactive effect due to the low overall levels of THC (2% or less) and high levels of CBD mitigating the THC effects.

CBD is still a prescription medicine under the Medicines Act 1981, therefore any products containing CBD would need to be assessed prior to consent being given. This would mean that the cannabinoid content would be known and the effects of this would also have been tested in order to gain consent. The risks of any unapproved CBD-containing medicines would only apply to a limited number of patients and they would be closely supervised by their doctor. The cost of CBD-containing medicines would also mitigate any risks of diversion of consented or unconsented products.

## REFERENCES

[6(b)(i)]

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## APPENDIX 1: Control of Industrial Hemp Cultivation in Australia

Western Australia control industrial hemp cultivation in the Industrial Hemp Act 2004, which has the following definition for industrial hemp.

- Industrial hemp means cannabis, the leaves and flowering heads of which do not contain more than 0.35% of tetrahydrocannabinol.

The Australian Capital Territory controls industrial hemp cultivation in the Hemp Fibre Industry Facilitation Act 2004, which has the following definitions and explanations.

- Industrial hemp plant means a hemp plant with a THC concentration in its leaves and flowering heads of not more than 1%.
- Certified hemp seed means seed certified, in the way prescribed under the regulations, by any of the following as seed that will produce hemp plants with a THC concentration in their leaves and flowering heads of not more than 0.5%:
  - (a) a grower;
  - (b) a category 1 or category 2 researcher.
- While industrial hemp plants may have a THC concentration in their leaves and flowering heads of not more than 1%, certified hemp seed must be seed harvested from a plant with a THC concentration in its leaves and flowering heads of not more than 0.5%. The difference recognises that the leaves and flowering heads of plants grown using certified hemp seed may have more than 0.5% THC because of environmental conditions beyond a grower's control.

New South Wales control industrial hemp cultivation in the Hemp Industry Act 2008 and Hemp Industry Regulation 2016, which have the following definitions and conditions.

- Low-THC hemp means any plant of the genus Cannabis, by whatever name that plant may be called, that has a concentration of THC in its leaves and flowering heads of no more than 1%, and includes the seed of any such plant and any product (such as oil or fibre) derived from any such plant.
- A licensee may only use seed that is supplied on the basis that it will not produce hemp that has a concentration of THC (in its leaves and flowering heads) of more than 0.5%.

Queensland control industrial hemp cultivation in the Drugs Misuse Act 1986, which has the following definitions and explanations.

- Industrial cannabis plant means a cannabis plant with a THC concentration in its leaves and flowering heads of not more than 1%.
- Certified cannabis seed means seed certified, in the way prescribed under a regulation, by any of the following as seed that will produce cannabis plants

with a THC concentration in their leaves and flowering heads of not more than 0.5%—

- a) a grower;
  - b) a category 1 or category 2 researcher;
  - c) a person authorised under a regulation under section 48 to supply industrial cannabis seed.
- Note—Certified cannabis seed is seed certified to produce plants with a THC concentration in their leaves and flowering heads of not more than 0.5%. However, industrial cannabis plants may have a THC concentration in their leaves and flowering heads of not more than 1%. The difference recognises that the leaves and flowering heads of plants grown using certified cannabis seed may have more than 0.5% THC because of environmental conditions beyond a grower's control.

Tasmania currently control industrial hemp cultivation in the Industrial Hemp Act 2015, which has the following definitions.

- Industrial hemp means any plant of the genus *Cannabis* that –
  - (a) has been grown from certified hemp seed; and
  - (b) has a concentration of THC in the leaves and flowering heads of not more than 1% –and includes the seed of any such plant and any product derived from any such plant.
- Certified hemp seed means seed certified, in accordance with the regulations, as seed that will typically produce hemp plants with a concentration of THC in the leaves and flowering heads of not more than 0.5%.

Tasmania, however, had a limit of 0.35% THC in industrial hemp crops until recently. In 2013, the Parliament of Tasmania's House of Assembly Standing Committee on Environment, Resources and Development published a report on the Inquiry into the Tasmanian Industrial Hemp Industry in which they reviewed the difference in THC between Tasmania (0.35%) and some other states who had a THC limit of 1%. The Chief Pharmacist of the Tasmanian Department of Health and Human Services noted that Tasmania was the first jurisdiction in Australia to licence the growing of industrial hemp in 1991. They followed the European standard for industrial hemp which was 0.3% and set it at 0.35% for a slightly higher 'margin of safety' as they had no way of knowing what THC levels to expect (Parliament of Tasmania 2013).

Victoria control industrial hemp cultivation in the Drugs, Poisons and Controlled Substances Act 1981, which has the following definitions.

- Low-THC cannabis means cannabis, the leaves and flowering heads of which do not contain more than 0.35 per cent of tetrahydrocannabinol.
- The Act does not apply to certain processed products
  - (1) This Act does not apply to—
    - (a) a processed fibre product made from cannabis if the product—

- (i) does not contain more than 0.1 per cent of tetrahydrocannabinol; and
  - (ii) does not contain whole cannabis seeds; and
  - (iii) is in a form not suitable for ingestion, smoking or inhaling purposes; or
- (b) a processed product made from cannabis seeds if the product—
  - (i) does not contain more than 0.001 per cent of tetrahydrocannabinol; and
  - (ii) does not contain whole seeds.
- Application for authority to cultivate and process low-THC cannabis
  - (1) A person may apply to the Secretary for an authority authorising that person, for commercial or research purposes relating to non-therapeutic use—
    - (a) to possess, process, sell or supply cannabis seed which has been harvested from low-THC cannabis; or
    - (b) to cultivate and possess cannabis from seed which has been harvested from low-THC cannabis; or
    - (c) to possess, process, sell or supply cannabis which—
      - (i) is substantially free of leaves and flowering heads; and
      - (ii) does not contain tetrahydrocannabinol in excess of 0.1 per cent.

The Northern Territory and South Australia do not have any legislation allowing the cultivation of hemp.

## **APPENDIX 2: The THC Content of Cannabis**

### **The THC content of cannabis in New Zealand**

In the late 70s to early 80s, cannabis plant, resin and oil was illegally imported into New Zealand for use. Since the late 80s the rates of these imports have reduced due to locally grown cannabis and locally manufactured cannabis oil becoming more available.

Dried cannabis leaf seized between 1978 and 1996 that was analysed by the Institute of Environmental Science and Research Limited (ESR) had THC contents in the range of 0.2% to 4.2% with an average in the range of 1.0% to 1.6% (Poulsen and Sutherland 2000). Internationally, the THC content of cannabis leaf was typically in the range of 0.5% to 4% (WHO 1997).

The dried cannabis female flowering heads (seized in New Zealand between 1979 and 1996) tested by ESR had THC in the range of 0.7 to 9.7% with an average in the range of 3.3 to 3.6% (Poulsen and Sutherland 2000). Internationally, the THC content of the dried cannabis female flowering heads was thought to be in the range of 7% to 14% (WHO 1997). The ESR study also looked at a few hydroponically

grown cannabis samples analysed in 1994 with potencies in the range of 2.7% to 5.5%, two hydroponically grown cannabis samples analysed in 1995 with potencies of 6.6% and 6.7% and one hydroponically grown cannabis sample analysed in 1996 with a potency of 8.8% (Poulsen and Sutherland 2000).

In the ESR study it was reported that imported cannabis oil seized by the Police between 1975 and 1989 ranged in potency from 3.1% to 66% THC with yearly averages ranging between 7% and 45%<sup>1</sup> (Poulsen and Sutherland 2000). The locally produced cannabis oil seized by Police between 1983 and 1995 had potencies in the range of 0.1% to 67% THC with an average of 13% THC. The report noted that the New Zealand produced cannabis oil has a higher proportion of low potency cannabis oil when compared to imported cannabis oil (10% of NZ produced cannabis oil products had below 5% THC) but attributed this to some manufacturers increasing the bulk of their products with a molasses-like material (Poulsen and Sutherland 2000). Internationally, the THC content of cannabis oil varied between 15 and 50% (WHO 1997).

In another study, ESR analysed the THC content of 63 cannabis plant material samples received in 28 submissions made by the [9(2)(ba)(i)] between April 2008 and May 2009.

These samples had been grown either hydroponically, outdoors or in soil indoors. There were a range of samples from just the flower (mature and immature) to stalks with the flower or the flower and immature seed. They found the THC levels in these samples ranged from 4.0 to 18.15% with an average of 10.9%. In general, it appeared that the more mature or larger the flower component of the sample, the higher the THC content was (ESR: Forensic Internal Report 2011).

### The THC content of cannabis internationally

Swift et al (2013) measured the THC and THCA content of the female buds of cannabis confiscated between October 2010 and October 2011 during a cannabis cautioning programme in New South Wales, Australia. This showed a mean of 2.52% THC (median of 1.45% THC) and a mean of 14.08% THCA (median of 12.95% THCA) (Swift et al 2013). [6(b)(i)]

In the USA a Potency Monitoring programme is being carried out by the University of Mississippi for the National Institute on Drug Abuse. They have found that between 1993 and 2008 the potency of confiscated cannabis (including leaves, stems, seeds and buds – flowering tops of female plants with seeds) increased from a mean of 3.4% THC in 1993 to a mean of 5.8% THC in 2008 (Mehmedic et al 2010). Before this, between 1983 and 1992 the THC content of cannabis fluctuated around 3%

<sup>1</sup> The years 1975-1980 only had 10 seizures of imported cannabis oil and so were grouped with an average of 21%. The year 1987 was not included in this data.

(EISohly et al 2000). For the unfertilised female flowering heads (with no seeds) the THC content fluctuated a little but overall increased between 1993 and 2008. In 1993 the THC content of the unfertilised female flowering heads was 5.8%. This increased until a maximum mean of 13.4% THC was reached in 1999, after this the THC content dropped a little and then stabilised between 2002 and 2008 with a mean THC content of 11.5% in 2008. Over this time period, the number of unfertilised female flowering head samples increased and a corresponding decrease in the number of other cannabis plant samples could be seen (Mehmedic et al 2010).

In cannabis seized in Austria, where the THC and THCA levels were measured separately, the THC contents were detected in the range of 0.48% to 5.23% with THCA contents in the range of 5.03% to 21.56% detected. In conversion tests where the samples were held at 100°C, after three hours 12.18% THC was detected and no THCA remained. When samples were held at 150°C, after one hour 12.77% THC was detected and no THCA remained (Taschwer and Schmid 2015).

Some additional points on the THC content of cannabis internationally can be found in the blue highlighted sections provided from the DEA's Denial of Petition To Initiate Proceedings To Reschedule Marijuana (DEA 2016). These sections are:

- pages 53698-53699 (pages 12-13 of pdf)
- page 53745 (page 59 of pdf) point 7. Potency Monitoring Project plus Figure 1 on page 53746 (page 69 of pdf)
- page 53753 (page 67 of pdf).