

# Tasmanian Government Response to the

# Legislative Council

# Government Administration Committee A

Report on Legalised Medicinal Cannabis



# Introduction

This paper constitutes the Tasmanian Government's Response to the recommendations contained in the Legislative Council Government Administration Committee A *Final Report on Legalised Medicinal Cannabis* (the Final Report).

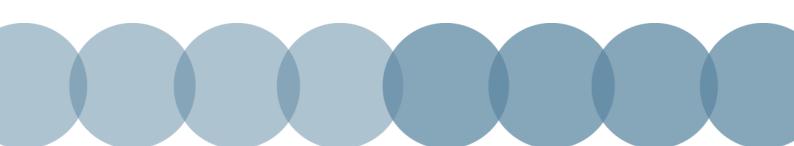
On 20 November 2014 the Committee released an Interim Report on Legalised Medicinal Cannabis (the Interim Report). The Government addressed the Interim Report by indicating that a response would be provided to the Committee's Final Report and recommendations.

The Committee intends for the Interim Report to be the primary and Final Report for the Committee, therefore the Government has addressed the Interim Report recommendations in this response. The final report also refers to two key developments which include the:

- Regulator of Medicinal Cannabis Bill 2014; and
- New South Wales Government Clinical Trials.

Whilst there are no direct recommendations in relation to these developments, the Government has addressed these key developments at the end of this Response.

The Committee is thanked for the valuable work it has undertaken in investigating the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.



#### Recommendation I

The Tasmanian Government introduces legislation to immediately provide protection to individuals who are currently using medicinal cannabis from criminal charges associated with possession and administration of medicinal cannabis on compassionate grounds.

#### **Discussion:**

The Tasmanian Government does not support a move to legislate for protection against criminal charges associated with possession and administration of medicinal cannabis outside sanctioned medical regulation. Cannabis remains the most commonly used illicit recreational drug in Tasmania and Australia and the social and health harms associated with its use are well documented. There is also evidence to suggest that in the United States of America cannabis use is higher in states where cannabis has been legalised for medical purposes. The introduction of legislation, in the absence of a regulated framework in relation to the use of cannabis for diagnosed medical conditions, effectively provides an avenue for any user of cannabis to claim it is being used for medical purposes.

Tasmania Police has stated on a number of occasions that it has not sought to actively pursue persons who make reasonable claims in relation to the use of cannabis for medical purposes. However, Tasmania Police is authorised and obligated to enforce the law in relation to the *Misuse of Drugs Act 2001*. As such, Tasmania Police is required to investigate circumstances where cannabis is reported or discovered, and to seize the drug. Decisions to prosecute are then made on a case-by-case basis.

#### Government position:

This recommendation is <u>not</u> supported.

#### **Recommendation 2**

The Tasmanian Government develops a legislative framework to enable the use of medicinal cannabis under medical supervision, including the preparation, cultivation and supply of medicinal cannabis.

#### **Discussion:**

Any Tasmanian legislative framework must be compliant with national and international legislation.



Cannabis is an illegal drug under both Commonwealth and state laws, and is the most widely misused substance in Tasmania and Australia. The cultivation, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis derived products are regulated by a number of Commonwealth and state laws. Australia also has international obligations that it must fulfil with respect to the United Nations Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971) and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). The current regulatory system on narcotic drugs also involves the work of a significant number of Commonwealth and state agencies. The complexity and interrelationships of these agencies and legislation needs to be taken into consideration in the implementation of any reform or new legislation that may relate to cannabis and cannabis derived products.

The Tasmanian Government is open to the potential use of medicinal cannabis in Tasmania, subject to a proper evidence-based approach, a robust and strong regulatory framework and appropriate approvals from national regulators. Prior to any Tasmanian legislative reform, it is important that there is appropriate assessment of whether cannabis or cannabinoids are a legitimate medical therapy. This assessment should occur in the first instance through the established national drug approval process managed by the Therapeutic Goods Administration (TGA).

The Tasmanian Government has a limited role in the regulation of therapeutic goods. Instead, the assessment of quality, safety and efficacy of medicines is primarily a function of the Australian Government, undertaken by the TGA. The Commonwealth *Therapeutic Goods Act 1989* requires that any product for which therapeutic claims are made must be included in the Australian Register of Therapeutic Goods before it can be supplied in, imported to or exported from Australia.

The Commonwealth *Therapeutic Goods Act1989* requires the registration of medicines where high level therapeutic claims are made. The Tasmanian *Therapeutic Goods Act 2001* adopts the Commonwealth legislation and ensures application of the legislation to all manufacturers and traders of medicines in Tasmania. The Tasmanian legislation makes no provision for exemption.

Pharmaceutical products, including cannabis derived products, should only be approved based on robust peer reviewed scientific evidence. Evidence can be generated through properly conducted clinical trials, and there should be no attempt to accelerate, or bypass this step which exists to protect the community. No form of cannabis can be approved for medicinal use unless an application is made to the TGA with supporting data to assess its quality, safety and efficacy. Unless medicinal cannabis is proven to meet these standards, the Australian Government cannot override these national safety controls and legalise the use of cannabis as a medicine.

The Tasmanian Government does not support any situation where any form of medicinal cannabis is accessed through the illicit drug market. This situation places registered patients and their carers at considerable risks, including unknown quality of the cannabis supplied and contact with illicit drug dealers.

Issues of public safety remain of significant interest to the Tasmanian Government. In relation to the use of cannabis, drug-driving is an issue of concern and despite the social functionality of persons using cannabis for medical reasons, Tasmania Police will not support medical use as a defence.

On 17 September 2014, the New South Wales (NSW) Government announced a clinical trial of the medicinal use of cannabis. The Tasmanian Government is investigating the opportunities for partnering with the NSW Government in the medicinal cannabis trials. These trials will assist to establish an evidence-base on the efficacy and safety of medicinal cannabis. The results of such trials, expected to commence in 2016, will then determine whether the Commonwealth and state governments should legislate to allow for medicinal cannabis.

Given the current lack of evidence for the efficacy and safety of medicinal cannabis, and the complexities in the regulatory framework which span across state, national and international spheres, the Tasmanian Government does not support a move to unilaterally develop a legislative framework to enable the use, preparation, cultivation or supply of medicinal cannabis.

# Government position: This recommendation is <u>not</u> supported.

# **Recommendation 3**

The Tasmanian Government support a cooperative approach between Tasmanian research institutions and mainland jurisdictions to facilitate clinical research in this area.



#### Discussion:

The Tasmanian Government is supportive of trials and the potential use of medicinal cannabis in Tasmania, subject to a proper evidence-based approach, strong regulatory framework and appropriate approvals being obtained prior to the commencement of trials from national regulators.

In 2014 NSW committed to undertaking trials to explore the use of cannabis and cannabis derived products in providing relief for patients suffering from debilitating or terminal illness. NSW has invited other states and territories to collaborate and participate in the trials.

The Tasmanian Government is investigating the opportunities for supporting the NSW Government in medicinal cannabis trials. Tasmania's involvement in the NSW trial is being furthered by the inclusion of the Department of Health and Human Services (DHHS) Chief Pharmacist as a member of the Inter-Jurisdictional Discussion Group on Cannabis for Medicinal Purposes. This Discussion Group is coordinated by NSW Health.

An Expert Panel, chaired by the NSW Chief Health Officer, will also review trial applications and continue to advise the NSW Government throughout the trials. The DHHS Chief Pharmacist is also an Observer to the Expert Panel's deliberations.

Investigation of local opportunities for involvement in the NSW trials is also occurring through discussion with the University of Tasmania and local physicians.

#### Government position:

This recommendation is supported and is being implemented.

#### **Recommendation 4**

The Tasmanian Government adopts a cooperative approach with other states and territories in relation to the legalisation of the prescription, administration, possession and cultivation of cannabis for medicinal use.

#### **Discussion:**

As stated in response to Recommendation 2, cannabis is an illegal drug under both Commonwealth and state laws, and is the most widely misused illicit substance in Tasmania and Australia. The regulatory framework for cannabis and cannabis derived products spans both Commonwealth and state laws, along with Australia's international obligations under specific Conventions. The current regulatory system on narcotic drugs also involves a significant number of Commonwealth and state agencies. The complexity and interrelationships of these agencies and legislation needs to be taken into consideration in the implementation of any reform or new legislation that may relate to cannabis and cannabis derived products.

As previously stated, the Tasmanian Government is open to the potential use of medicinal cannabis or its derivatives in Tasmania subject to a proper evidence-based approach, a robust and strong regulatory framework and appropriate approvals from national regulators first being obtained. Such approval is provided through the TGA, and only after an application is made with supporting data to assess the quality, safety and efficacy of medicinal cannabis. Prior to any legislative reform, it is important that there is appropriate assessment of whether cannabis or cannabinoids are a legitimate medical therapy, and this assessment should occur through the established drug approval process managed by the TGA.

In September 2014, the Premier wrote to the Prime Minister requesting that medicinal cannabis be added to the agenda for the Council of Australian Governments (COAG) and led discussions for a collaborative Australia-wide approach to medicinal cannabis. On 10 October 2014, COAG noted that NSW will lead trials of medicinal cannabis in collaboration with other interested states and territories.

As discussed in the response to Recommendation 3, Tasmania is currently adopting a cooperative approach with the NSW Government in medicinal cannabis trials. These trials are advancing the evidence base that will assist to inform any future decisions regarding therapeutic use of medicinal cannabis, and any future legislative reform.

#### Government position:

#### This recommendation is supported in-principle

#### **Recommendation 5**

Cultivars of cannabis containing low levels of THC should not be treated in the same way as cultivars of cannabis containing high levels of THC in terms of the national classification system of scheduling medicines.

#### **Discussion:**

Industrial hemp refers to varieties of cannabis that contain very low levels of delta-9tetrahydrocannabinol (THC) and at the allowable threshold there are no psychoactive inducing effects.

Industrial hemp is currently grown under licence from seed that will reliably produce plants of low THC content. The plant remains prohibited until its THC content is established as being below the permitted limit.

The listing of "industrial hemp seed" in Schedule 8 of the Poisons List allows for the trading of this commodity under licence. High THC varieties remain classified as Prohibited.

In January 2015 the Tasmanian Government announced that it is introducing reforms to simplify the regulation and support growth in the industrial hemp industry.

The key reform is the introduction of specific purpose industrial hemp legislation to be administered by the Department of Primary Industries, Parks, Water and Environment. The aim of the legislation is to provide sensible and practical regulation without compromising drug law enforcement or public safety.

While the new legislation is being developed, the Government will immediately introduce a five year hemp licence to replace the need to apply annually for a licence. This will immediately lift the regulatory burden on industry. In addition the Government has allowed for an increase to the maximum allowable THC threshold for industrial hemp grown in Tasmania from 0.35 per cent to 1.0 per cent (noting that crops must be grown from seed stock certified to produce plants containing no more than 0.5% THC content). This will align Tasmania with NSW, Queensland and the Australian Capital Territory and will allow for easier trade and transfer of plant material between these jurisdictions.

The Tasmanian Government supports the continuance and further development of the industrial hemp industry for the production of seed and fibre. The plant varieties used generate very low levels of THC and other cannabinoids.

In the national Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) cannabis and tetrahydrocannabinols and their alkyl homologues and derivatives (including cannabidiol) are included in Schedule 9 (Prohibited Substances). Schedule 9 substances are those "which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State and Territory Health Authorities".

The SUSMP recommends prohibitions on cannabis, tetahydrocannabinols and cannabinoids. Due to the recognised harms in the community these recommendations are adopted by all states and territories. Cannabis and cannabinoids cannot currently be supplied in Tasmania for medicinal use due to the prohibitions in the *Poisons Act 1971* and *Misuse of Drugs Act 2001*. The only exceptions to this are supply of nabiximols (Sativex®), dronabinol and nabilone when in Schedule 8 of the SUSMP and the importation, making, refining, preparation, possession or use of a prohibited substance in an exempted public institution for educational, experimental or research purposes.

The SUSMP was amended to include cannabidiol as a Schedule 4 drug from 1 June 2015. This change to scheduling means that regulation concerning cannabidiol is less restricted as it is no longer considered a prohibited substance, but rather a prescription only medicine under Schedule 4. It should be noted that the safety and efficacy of this substance has not been evaluated by the TGA. Whilst this change to scheduling means that cannabidiol will be a prescription drug, the production of it remains subject to the *United Nations Single Convention on Narcotic Drugs* (1961). Therefore, processing of cannabidiol is subject to Australian Government approval in the first instance.

## Government position: This recommendation is supported.

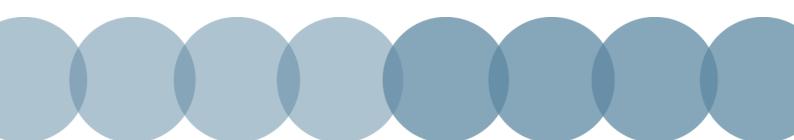
# **Recommendation 6**

The Tasmanian Government engages with companies which have the appropriate expertise and capacity to progress the cultivation, extraction and processing of cannabinoids within the existing and/or future regulatory framework.

#### Discussion:

The Tasmanian Government supports the current regulatory framework for medicines administered by the TGA.

As discussed in the response to Recommendation 5, the Tasmanian Government is introducing reforms to simplify regulation and support growth in the industrial hemp industry.

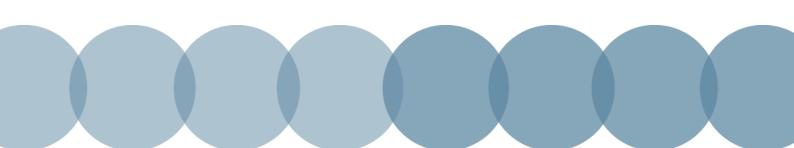


As outlined in the response to Recommendation 5, cannabis and tetrahydrocannabinols and their alkyl homologues and derivatives (except where explicitly excluded, such as cannabidiol) are included in Schedule 9, Prohibited Substances, of the SUSMP. The SUSMP recommends these prohibitions due to the recognised harms in the community, and these recommendations are adopted by all states and territories.

Whilst there are legislative changes proposed to reclassify cannabidiol as a Schedule 4 prescription only drug from 1 June 2015, the production of cannabidiol and other cannabinoids still remains subject to international and national approval. As discussed in the response to Recommendation 5, Tasmania cannot proceed to commercial growing or production of cannabidiol without the necessary approvals to ensure that the Australian Government is complying with the United Nations Single Convention on Narcotic Drugs (1961).

#### Government position:

This recommendation is supported.



# **Key Developments**

# The Regulator of Medicinal Cannabis Bill 2014 (The Senate)

Australia has a long standing requirement that potent medicines supplied to its citizens have demonstrable, high standard of evidence of quality, safety and efficacy. The Tasmanian Government supports the application of Australia's *Therapeutic Goods Act 1989* (the Act) which requires that medicinal cannabis derived products with high level therapeutic claims be assessed against these standards. These standards are necessary to the protection and advancement of public health.

Under the current TGA process, no form of cannabis can be approved for medicinal use unless an application is made with supporting data to assess its quality, safety and efficacy. The Tasmanian Government supports the Act and its provisions are fully adopted by reference in the Tasmanian *Therapeutic Goods Act 2001*.

The Regulator of Medicinal Cannabis Bill 2014 (the Bill) seeks to establish a Regulator who would be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use, and import and export of medicinal cannabis. The Regulator is also given authority to monitor compliance with the Bill. The Bill effectively establishes a framework that is specific to the regulation of medicinal cannabis, one that is entirely removed from the current rigorous process and standards of the TGA.

The Bill therefore effectively allows product proponents to choose which legislation they opt in to with regard to medicinal cannabis, which will result in confusion for regulated persons, the regulator, and state and Commonwealth agencies who are involved in the regulation of cannabis and cannabis derived products. Circumventing the current established TGA processes would set a dangerous precedent as the same scrutiny would not be applied to ensure adherence to the essential safeguards, being the rigorous assessment of quality, safety and efficacy.

There are also aspects of the Bill that do not adequately implement Australia's obligations under the United Nations Single Convention on Narcotic Drugs (1961) (the Single Convention). As Australia is a party to the Single Convention, any Commonwealth or state legislation that relates to medicinal cannabis must be consistent with Australia's international obligations. The Single Convention requires that Australia report quantities of cannabis manufactured and imported in any one year to the amount consumed, exported or manufactured, however the Bill does not address this reporting requirement. The Bill also requires the establishment of a statutory agency that will comprise of the Regulator, a Chief Executive Officer and staff. The establishment of a separate government agency is not in keeping with the Australian Government's policy on smaller and more rational government.

The Tasmanian Government is compassionate to the suffering of individuals who seek relief from pain, nausea and vomiting from cancer treatments, and chronic conditions such as epilepsy and multiple sclerosis. However, the assessment and regulation of medicinal cannabis should remain subject to the established drug approval process and be based on the current standard criteria for the regulation of all medicines, which is especially important for effectiveness and safety.

## New South Wales Government Clinical Trials

As discussed in recommendations 2, 3, and 4, the Tasmanian Government is supportive of trials and the potential use of medicinal cannabis in Tasmania, subject to a proper evidencebased approach, strong regulatory framework and appropriate approvals from national regulators.

The Tasmanian Government is investigating the opportunities for partnering with the NSW Government in medicinal cannabis trials. This is occurring through discussion with the University of Tasmania and local physicians.

Tasmania's involvement in the NSW trial is being further by the inclusion of the Department of Health and Human Services Chief Pharmacist as a member of the Inter-Jurisdictional Discussion Group on Cannabis for Medicinal Purposes. An Expert Panel has also been formed, chaired by the NSW Chief Health Officer. The Panel will review trial applications and continue to advise the NSW Government throughout the trials. The DHHS Chief Pharmacist is also an Observer to the Expert Panel's deliberations.

The NSW Government has also recently announced it will establish the Centre for Medicinal Cannabis Research and Innovation, to be headed up by the NSW Chief Scientist Professor Mary O'Kane, which will seek to enable experts to share their world-class research and support the production of safe, reliable and affordable cannabis based medicines.

The Tasmanian Government will look for the appropriate means to collaborate with the Centre as a matter of priority.