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Parliament of Tasmania

LEGISLATIVE COUNCIL
GOVERNMENT ADMINISTRATION COMMITTEE "A"

INTERIM REPORT

ON

Legalised Medicinal Cannabis

Members of the Committee Inquiry:

Hon Robert Armstrong MLC

Hon Craig Farrell MLC (Committee Chair)

Hon Ruth Forrest MLC (Inquiry Chair)

Hon Mike Gaffney MLC

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ABBREVIATIONS

AHPRA	Australian Health Practitioner Regulation Agency
ANMF	Australian Nursing and Midwifery Federation
ARTG	Australian Register of Therapeutic Goods
ATDC	Alcohol, Tobacco and Other Drugs Council
CBD	Cannabidiol
COAG	Council of Australian Governments
DUI	Driving under the influence
EOT	Essential Oils of Tasmania
MS	Multiple Sclerosis
RANZCP	Royal Australian and New Zealand College of Psychiatrists
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TFGA	Tasmanian Farmers and Graziers' Association
TGA	Therapeutic Goods Administration
THC	Tetrahydrocannabinol

EXECUTIVE SUMMARY

Government Administration Committee "A" (the Committee) was established on 4 July 2014 to investigate the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.

Since the establishment of the Committee there has been significant debate and progress in the political environment with regard to the medicinal use of cannabis. There have been a number of policy changes proposed at federal, state and territory levels generally supporting the facilitation of access to medicinal cannabis for patients suffering serious and debilitating medical conditions.

In light of the evidence received and the community's interest in this area, some matters require the urgent attention of Government, therefore the Committee considered it important to release this Interim Report.

This Interim Report contains a number of findings and recommendations, some that require immediate action by the Tasmanian Government.

The primary purposes for producing this Interim Report include:

1. The need for urgent legislative reform in Tasmania. It is evident that there are a significant number of Tasmanians who are currently using medicinal cannabis for serious medical conditions in circumstances where other medications have not been effective. These individuals and those involved in the supply and administration of this medication, are at risk of prosecution under current Tasmanian law.

2. The medicinal use of cannabis is a matter of significant national interest and has been raised as an agenda item at a Council of Australian Governments (COAG) meeting. This Report will provide the Tasmanian Government with evidence received by the Committee in order to inform further debate at the next COAG meeting.

3. The expertise exists within Tasmania to participate in research and development, cultivation, processing and the botanical extraction of cannabinoids to produce a quality controlled pharmaceutical product. The policy and legislative support of the Tasmanian Government is necessary to progress this opportunity and provide an economic benefit to the State.

Further information addressing the above and other matters raised during the inquiry will be detailed when the Committee completes the inquiry and tables a Final Report in 2015.

The Committee's Terms of Reference were limited to the investigation of cannabis for medicinal purposes. Despite the narrowly targeted Terms of Reference, some witnesses and members of the community expressed concern and at times confusion regarding the inquiry in terms of the other associated areas of industrial hemp and recreational cannabis use. The Committee made it very clear that industrial hemp and recreational cannabis were not part of this Inquiry.

It should be noted that industrial hemp was the subject of a House of Assembly inquiry in 2013.

This Interim Report should be read in conjunction with the evidence received that is available on the Committee website.

KEY FINDINGS

Legislative and Regulatory Impediments

1. The current Tasmanian law does not reflect the reality that cannabis is a substance already widely in use as a form of pain relief, as an antiemetic and a means to control other medical conditions, including rare forms of intractable epilepsy.

2. The current Tasmanian law does not:

   a) provide legal access for individuals who currently use medicinal cannabis;

   b) provide protection for those who assist with the administration of medicinal cannabis;

   c) provide protection for those who cultivate or prepare medicinal cannabis; or

   d) provide protection for those who procure or supply medicinal cannabis.

3. The Tasmanian Law does provide certain exemptions to allow for the research and development of cannabinoids; within a registered organisation and with the support of specialist clinicians. The law requires the Minister for Health to issue a licence to approve such clinical trials.

4. Legislative change or the issuing of a licence from the Minister for Health is required to facilitate extraction of cannabinoids from cannabis cultivars with THC levels greater than 0.35% for commercial purposes.

5. The current unregulated environment means that there is no independent quality control, thus the safety and reliability of the product is questionable.

Clinical Trials and Medical Research

6. There is no consensus regarding the quantum, scope and adequacy of research into the medicinal use of cannabis.

7. More research is needed in areas including: the long term effects of medicinal cannabis use, the risks and benefits for individuals currently using medicinal cannabis that incorporate trials to compare the effects of

currently available medication with medicinal cannabis, and drug interactions between recognised pharmaceutical products and medicinal cannabis.

8. International jurisdictions have approved the use of medicinal cannabis and have adopted regulatory frameworks on the basis of the research available.

9. Clinical trials are costly and time consuming. Tasmanian research institutions such as the University of Tasmania and the Menzies Research Centre, should collaborate with mainland states/territories to undertake clinical trials in order to provide meaningful and reliable results.

10. Cultivars of cannabis containing high levels of cannabidiol (CBD) do not pose the same threat to public health as cultivars containing high levels of tetrahydrocannabinol (THC).

Public Health and Safety

11. Smoking is not recommended as a method of administration.

12. Risks associated with driving under the influence of medicinal cannabis can be managed through road safety laws and medicinal product labelling requirements.

Security

13. Security risks are manageable and should not constitute an impediment to the cultivation and processing of medicinal cannabis in Tasmania.

14. Growing cannabis for medicinal use, if appropriately secured, would not contravene the international conventions including the *Single Convention on Narcotic Drugs 1961*.[1]

Local Skills and Expertise

15. Tasmania's world class research facilities have the capabilities to contribute to clinical trials into the use of medicinal cannabis.

16. The capacity and necessary technology to extract pure cannabinoids to produce a high quality pharmaceutical product exists within Tasmania.

[1] https://www.unodc.org/pdf/convention_1961_en.pdf

RECOMMENDATIONS

The Committee makes the following recommendations that:

1. 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.

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.

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

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.

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 of medicines.

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.

Hon Craig Farrell MLC
Committee Chair
19 November 2014

Hon Ruth Forrest MLC
Inquiry Chair
19 November 2014

INTRODUCTION

At the meeting of the Legislative Council Government Administration Committee "A" on Friday 4 July 2014, it was resolved that an inquiry be established to investigate the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes, with the following Terms of Reference:

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

2. If, and how, natural botanical medicinal cannabis flower and extracted cannabinoids could and/or should be supplied for medical use.

3. The legal implications and barriers to the medicinal use of natural botanical medicinal cannabis flower and extracted cannabinoids in Tasmania.

4. The legal implications and barriers to the growing and commercialisation of cannabis flower and extracted cannabinoids in Tasmania to ensure:

    a. a scientific-based approach;

    b. quality control;

    c. consistency;

    d. reliability; and

    e. ongoing research and development of cannabis-based medicines.

5. The potential impact on agricultural or other sectors within Tasmania.

6. Any other matters incidental thereto.

Seventy-seven submissions were received by the Committee. Public hearings were held in Hobart on 18, 19 and 22 September 2014. Twenty-three groups or individuals gave verbal evidence to the Committee at these hearings:

- Ms Nicole Cowles
- Dr Eric Ratcliff (Royal Australian and New Zealand College of Psychiatrists)
- Mr Emilio Reale (Huon Valley Council)
- Mr Brenton West and Mayor Martyn Evans (Think South)
- Mayor Martyn Evans (Derwent Valley Council)

- Dr Andrew Katelaris
- Dr Adrian Reynolds, Dr Max Sarma, Mr Peter Edwards, Mrs Debra Salter, Ms Deidre Wilson, Ms Cheryl Hislop and Mr Jim Galloway (Tasmanian Government)
- Mr Andrew Clifford and Mr Bernard Sim (Green Acres Hydroponics)
- Ms Cheri O'Connell
- Mr Ken Dorsey (MedCann Tasmania)
- Mr Keith Rice and Mr Glynn Williams (Poppy Growers' Association)
- Ms Neroli Ellis and Ms Roseanne O'Keefe (Australian Nursing Federation Tas Branch) Ms Jannette Smith and Dr Raimondo Bruno (Alcohol, Tobacco and Other Drugs Council)
- Mr Peter Skillern (Tasmanian Farmers and Graziers' Association)
- Ms Lisa Estreich (Hemp Australia)
- Professor Ray Lowenthal
- Mr Troy Langman (Tasman Health Cannabinoids)
- Mr Ian and Mrs Inga Oates
- Mr Stephen Sullings (Gallagher Security Fencing)
- Mr John Reeves (Medical Cannabis Tasmania)
- Mr David King
- Mr Greg Barns
- Mr Peter Fehre, Mr Stephen Gleeson, Mr Rob EcEldownery, Dr Teresa Nicoletti (Essential Oils of Tasmania)

The Hansard transcripts of these hearings are available at http://www.parliament.tas.gov.au/ctee/Council/GovAdminA_LMC.htm. The transcripts should be read in conjunction with this report.

Due to the marked change in the political and social environment in Tasmania since the establishment of this Committee, and the recent Federal and interstate attention focussed on this issue, it is considered appropriate that the Committee report on its preliminary findings. The Interim Report will be released prior to the next Council of Australian Governments (COAG) meeting.

It is noted that the Committee inquiry will be ongoing and that the Committee intends to conduct further hearings with witnesses in NSW, the ACT and Victoria prior to release of its final report.

KEY OBSERVATIONS

1. Legislative and Regulatory Impediments

The current Tasmanian law does not reflect the reality that cannabis is a substance already widely in use as a form of pain relief, as an antiemetic and a means to control other medical conditions, including rare forms of intractable epilepsy. There is significant anecdotal evidence that medicinal cannabis is already being widely used in Tasmania and around the world.

- There are a number of legislative and regulatory barriers impeding the legal use of medicinal cannabis in Tasmania, primarily that:
    - cannabis is classified as a Schedule 9 prohibited substance on the national poisons list;
    - medicinal cannabis (with the exception of Sativex™) is not registered on the Australian Register of Therapeutic Goods (ARTG); and
    - current Tasmanian legislation prohibits the extraction, isolation and purification of THC for commercial purposes.
- An application may be made under Section 52EAA of the *Therapeutic Goods Act 1989* to reschedule medicinal cannabis from a Schedule 9 'Prohibited Substance' to either a Schedule 8 'Controlled Drug' or Schedule 4 'Prescription Only Medication' for high CBD cultivars, and Schedule 8 'Controlled Drug' for high THC cultivars. This option of differing scheduling (Schedule 4 for high CBD, low THC cultivars) recognises that CBD is a non-psychotropic compound.
- Medicinal cannabis is not currently registered on the ARTG. The development of a pharmaceutical drug that qualifies for ARTG registration is a lengthy and expensive process. Gaining the support of pharmaceutical companies to obtain patents for naturally occurring compounds including cannabis may be problematic.
- Legislative change will be required in Tasmania to facilitate the commercial development of medicinal cannabis, particularly in preparations that have levels of THC above 0.35%. Currently there is no legislative barrier to the extraction and purification of CBD from strains of hemp with levels of THC lower than 0.35%.

- Current legislation is preventing patients legally accessing medicinal cannabis on compassionate grounds as a medication of last resort.

2. Clinical Trials and Medical Research

- There is a notable lack of consensus on the quantum of reliable and peer reviewed medical research into the therapeutic use of medicinal cannabis. Evidence provided did indicate a significant number of scientific peer reviewed research articles and papers demonstrating the therapeutic benefits of cannabinoids including multiple sclerosis (MS), epilepsy, pain, nausea related to chemotherapy and Alzheimer's disease. Evidence suggests that there is a significant amount of literature on the therapeutic use of medicinal cannabis, in some cases more than there is on some other drugs in use at present.

- An Australia-wide clinical trial of medicinal cannabis would be expensive, raise significant ethical issues in its implementation, and it is arguable whether it would yield any useful result. At the Federal level, Prime Minister Abbott[2] indicated that no further testing should be needed of the drug if it is legally administered in similar jurisdictions. There are mature regulatory models in place overseas (including the Dutch or Israeli models) which can be used by Australia for guidance.

- Future research effort would be better focused on the development of various cultivars and strains, post-market surveillance and monitoring of the product to provide data on the effects of long-term usage. Such research would facilitate the development of high quality medical grade products at prescribed dosages that would be consistent and reliable for the management and treatment of various conditions. In an unregulated environment without any formal quality control measures, the safety of reliability of the product is questionable.

3. Public Health and Safety

- Public health and safety concerns were raised regarding the increased risk of schizophrenia in susceptible individuals, the effects of driving under the influence of medicinal cannabis and the risks associated with smoking medicinal cannabis.

- Evidence suggests that formulations containing high proportions of THC may increase the risk of the development of schizophrenia in susceptible individuals. Approximately 1 in 10 people have a genetic predisposition

[2] Letter from Tony Abbott to Alan Jones, 23 August 2014, Sydney Morning Herald, retrieved from http://www.alcp.org.nz/node/684#sthash.H4KzWJdS.dpuf.

that makes them more susceptible to the development of schizophrenia. CBD is not the agent responsible for this risk. Evidence suggests that CDB interacts synergistically with THC to counter the psychoactive effects of THC.

- The risk of driving under the influence (DUI) can be addressed via standard warnings and existing legislation.

- It is recognised that smoking has a range of adverse health effects and is not recommended as a mode of administration.

- Concern was also raised regarding cultivars containing high THC levels emerging from the unregulated recreational market and the risks associated with the use of such products for medicinal purposes.

4. Security

- Security is not a barrier to the legalisation of medicinal cannabis in Tasmania. Evidence indicated that the comparatively small areas required for growing medicinal cannabis (whether indoor or outdoor) can be fully secured and this security regime would not be prohibitively expensive.

- International jurisdictions have introduced effective measures to allow secure growing and management of medicinal cannabis.

- The potential for diversion into illicit markets exists in the area of recreational use rather than when used for medicinal purposes. Cultivars containing low THC levels do not contain the psychotropic compound in levels that result in the hallucinogenic effects as occurs with cultivars containing high THC levels. A targeted education strategy emphasising the lack, or extremely low level of the psychoactive compound (THC) in medicinal cannabis, would reinforce this message.

5. Local Skills and Expertise

- Tasmanian enterprises currently have the skills and expertise to progress the extraction of CBD immediately without financial assistance from the Tasmanian Government. The Tasmanian Government, through the Minister for Health, would need to issue a licence to enable the extraction, isolation and purification of cultivars with levels of THC greater than 0.35% for commercial purposes. There are no barriers to the extraction, isolation and purification of CBD extracted from Indian hemp which contains low or no concentrations of THC.

- The University of Tasmania and the Menzies Research Centre are recognised as world class research facilities that have the capability to undertake clinical trials of medicinal cannabis, in cooperation with specialist clinicians prepared to initiate and supervise the work.

EVIDENCE

1. Legal and Regulatory Framework

There are currently legal and regulatory barriers to the use of medicinal cannabis in Tasmania. The primary barriers include:

1. The scheduling of cannabis as a Schedule 9 substance on the national poisons list;
2. The lack of inclusion on the ARTG; and
3. A legislative framework in Tasmania that prohibits the extraction, isolation and purification of cultivars containing THC for commercial purposes.

Australia's need to comply with its international obligations, notably the *Single Convention on Narcotic Drugs 1961*, is not a barrier to progressing the cultivation of cannabis for medicinal purposes within Tasmania.

The identified barriers, and the practical pathways for overcoming them, are outlined as follows:

1.1 Scheduling of Medicines

Scheduling is a national classification system that controls how medicines and poisons are made available to the public.

Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety.

The Schedules are published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and are given legal effect through state and territory legislation.[3]

[3] Australian Government Department of Health, 2014, Therapeutic Goods Administration, *Scheduling Basics*, http://www.tga.gov.au/industry/scheduling-basics.htm

The Schedules are defined in the following table.

Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance

The genus 'Cannabis' is currently listed as a Schedule 9 prohibited substance, meaning that; '*the manufacture, possession, sale or use is prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with government approval.*'

The current scheduling of the various components of cannabis, their effects and potential therapeutic application is outlined below.[4]

[4] Dr Teresa Nicoletti (on behalf of EOT) PowerPoint Presentation presented at the hearing, 22 September 2014.

Compound	Effects	Potential Medicinal Application	Classification under the Poisons List
THC	Psychotropic effects (alteration of visual, auditory and olfactory senses).	• Relaxation • Pain Relief • Stimulation of appetite • Reduction of nausea	Schedule 9, except: (a) when separately specified in Poisons list Schedule or processed hemp fibre with 0.1% or less THC; (b) dronabinol when prepared and packed for therapeutic use; and (c) nabimixols where THC and CBD comprise not less than 90% of the total cannabinoid.
CBD	Not psychoactive	• Relief of convulsions, inflammation, anxiety and nausea. • May have neuroprotective properties	Not listed in the Poisons List, except from its listing in Schedule 8 as component in nabimixols (1:1 ratio of CBD:THC)

There are limited exceptions, including Sativex which has been listed as a Schedule 8 drug. The rescheduling of medicinal cannabis to Schedule 4 'Prescription Only Medicine' or Schedule 8 'Controlled Drug' drug would enable legal access.[5]

[5] Dr Teresa Nicoletti (on behalf of EOT), *Transcript of Evidence*, 22 September 2014, pp.62-3; Hemp Australia, *Submission*, p.2.

In order to overcome the barriers resulting from the Schedule 9 classification of 'cannabis', an application may be made pursuant to Section 52EAA of the *Therapeutic Goods Act 1989,* to amend the SUSMP. Such amendments may relate to the scheduling of new medicines or the rescheduling of currently listed medicines/poisons.

An application made under Section 52EAA would generally be made by the sponsor company at the time of lodging a submission for a medicine with the Therapeutic Goods Administration (TGA). The application can also be made independent of a product application to the TGA.[6] The application is considered by the Advisory Committee on Chemical Scheduling and the finding is published pursuant to Section 42ZCZS of the Therapeutic Goods Regulations 1990.

1.2 Therapeutic Goods Act 1989 (Cth)

The *Therapeutic Goods Act 1989* establishes the ARTG, and records therapeutic goods approved for supply in Australia. The Act also makes provision for unregistered goods that are intended for use in clinical trials. At present, there is only one cannabis or cannabinoid product registered on the ARTG - Sativex Oromucosal Spray.[7]

In order for any product to be marketed in Australia, it must be registered on the ARTG. Consequently, a product containing any cannabinoid from a natural or synthetic source would have to be registered. To obtain approval for registration, the application must provide pharmaceutical, toxicological and clinical information. This information is carefully evaluated by the TGA to establish the quality, safety and efficacy of the product put forward for registration. Given that it is an expensive and lengthy process, applications are not usually lodged unless the sponsor considers the product commercially viable.[8]

While a desirable outcome would be for medicinal cannabis to be registered on the ARTG, the Committee recognises that the process and time required for this to occur does not provide an immediate solution for individuals currently using medicinal cannabis as a medication of last resort. This is recognised at the Commonwealth level when Prime Minister Abbott observed that "*the regulation of medicines is a thicket of*

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[6] Australian Government Department of Health, 2014, *Application to Amend the Poisons Standard,* http://www.tga.gov.au/industry/scheduling-forms-poisons-standard-amend.htm

[7] Sativex is a mouth (oromucosal) spray formulated from two chemical extracts derived from the cannabis plant and contains delta-9 tetrahydrocannabinol (THC) and Cannabidiol (CBD). Sativex is treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication.

[8] New South Wales Parliamentary Research Services (NSWPRS), Issues Backgrounder: Medical Cannabis, Number 5/June 2014, p.5.

complexity, bureaucracy and corporate and institutional self-interest."[9] The Committee has sought to identify and clarify other pathways that should be further explored by the Tasmanian Government, with the support of the other State and Commonwealth Governments, in order to provide a more immediate solution and remove the current impediments to achieve safe and legal access to medicinal cannabis.

The Committee recognises the concerns expressed by some witnesses, including Tasmanian Government witness Dr Max Sarma (Persistent Pain Service, Royal Hobart Hospital) that "*by not going through the standard TGA process as we have for over 50 years, we are effectively bypassing it and adopting a different system of accrediting medications for use.*"[10] It is noted that Dr Sarma does recognise that the TGA system is not perfect and he acknowledged that there is a delay getting drugs from inception out to market. In addition, given the naturally occurring components of cannabis, "*obtaining patents over those is going to be an issue in itself.*"[11]

1.3 Tasmanian legislative framework

Cannabis and cannabinoids cannot currently be supplied in Tasmania due to the prohibitions in the *Poisons Act 1971* and *Misuse of Drugs Act 2001*.

The only exceptions to this are supply of nabimixols (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.[12]

The current listing of cannabis as a Schedule 9 drug limits opportunities for research into the safety and efficacy of medicinal cannabis, and ethical approval for trials in this area will be challenging to obtain whilst cannabis remains listed as a Schedule 9 Prohibited Substance.

1.3.1 Misuse of Drugs Act 2001 (Tas)

The Tasmanian *Misuse of Drugs Act 2001* creates offences for the cultivation, possession, use, sale and supply of a controlled plant. According to Schedule 1, Part 3, a controlled plant includes cannabis, cannabis oil and cannabis resin.

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[9] Letter from Tony Abbott to Alan Jones, 23 August 2014, Sydney Morning Herald, retrieved from http://www.alcp.org.nz/node/684#sthash.H4KzWJdS.dpuf.
[10] Dr Max Sarma (Tasmanian Government), *Transcript of Evidence*, 18 September 2014, p.55.
[11] Dr Sarma, *op. Cit.*, p.52.
[12] Tasmanian Government, *Submission*, p.16.

1.3.2 Poisons Act 1971 (Tas)

Pursuant to Section 55 of the *Poisons Act 1971* (Tas) it is an offence to import, make, refine, prepare, sell, possess or use a prohibited substance unless in partnership with an exempted public institution; and must be for educational, experimental or research purposes.

A prohibited substance is defined in Section 3 of the Poisons Act as a "*a substance or prohibited plant (other than Indian hemp) that is, for the time being, specified in Schedule 9 to the Poisons List.*"

THC extracted from cannabis is therefore classified as a prohibited substance, and the current Tasmanian legislation prohibits the extraction, isolation and purification of THC for commercial purposes.

Indian hemp, on the other hand, is defined by the Poisons Act as a 'prohibited plant,' however it is not a 'prohibited substance'. Dr Teresa Nicoletti, on behalf of Essential Oils of Tasmania (EOT), suggested that a licence can be approved by the Tasmanian Minister for Health to grow, cultivate, possess, sell and supply a prohibited plant. As a consequence CBD extracted from a strain of Indian hemp with low or no THC should not be a 'prohibited substance'.

Essential Oils of Tasmania concluded that under the current legislation "*there should be no barrier to it [EOT] extracting, isolating and purifying CBD from hemp for commercial purposes.*"[13]

1.3.3 Regulation of cannabis in other states (NSW)

By way of comparison EOT noted that the equivalent NSW legislation (*Poisons and Therapeutic Goods Act 1966*) allows for the manufacture, possession, use and supply of a Schedule 9 substance apart from a prohibited drug. THC is a prohibited drug, however CBD is not, therefore authorisation may be given under this legislation, unconditionally or subject to conditions.

The NSW legislation also allows for the cultivation and supply of industrial hemp with a THC concentration of <1% in leaves and flowering heads.

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[13] Dr Teresa Nicoletti, *op. Cit.*, p.62.

A licence can be issued under the *Hemp Industry Act 2008* for the purpose of commercial production, use in manufacturing and/or scientific research, instruction, analysis or study.

1.3.4 Legislative Reform

Amendment to the Tasmanian legislation to allow for medicinal cannabis use through the adoption of a framework consistent with the NSW legislative framework would facilitate the cultivation of high CBD, low THC cultivars in Tasmania. Further legislative amendment would be required to the *Misuse of Drugs Act 2001* and the *Poisons Act 1971* to facilitate access to a consistent and tested product to those individuals with acute conditions such as rare and intractable forms of epilepsy or chronic pain, already using the drug as a medication of last resort.

As the tinctures and other forms of medicinal cannabis currently being used are unregulated and not subject to any quality control, the supply of a quality controlled and regulated substance is important in terms of patient health and public safety.

In an unregulated environment, individuals currently using medicinal cannabis as a medication of last resort are not protected from prosecution for possession of such products for personal medicinal use.

Amendments to the *Poisons Act 1971* are needed to respond to concerns raised by the medical and nursing professions that despite being in support of decriminalisation of medicinal cannabis, they are not able to administer medicinal cannabis under the current regulatory regime without fear of criminal charges or being reported to the Australian Health Practitioner Regulation Agency (AHPRA).[14]

1.4 International Obligations

Australia is a signatory to international agreements that aim to restrict production, manufacture, export, import, distribution, trade and possession of narcotic drugs (including cannabis) for medical and scientific purposes. The two key agreements relevant to cannabinoid product for medical use are *the United Nations' Single Convention on*

[14] ANMF (Tas), *Transcript of Evidence*, p. 40.

Narcotic Drugs 1961 and the UN *Convention Against Illicit Traffic in Narcotic Dangerous Psychotropic Substances 1988*.[15]

The Commonwealth is responsible for the implementation of international agreements that it is signatory to and has the power to override inconsistent State legislation to ensure national implementation of Australia's international obligations. As a result, the Commonwealth would have to be satisfied that any proposed State scheme would not place Australia in breach of its treaty obligations. It is noted that the relevant international conventions recognise the possibility of exceptional circumstances in which the use of narcotic drugs may be necessary *'for medical and scientific purposes'* therefore it is possible that the controlled availability of cannabis or cannabinoids for medical or scientific purposes would not place Australia in breach of its international treaty obligations.[16]

The Committee notes that a number of countries including the United States, Israel, the Netherlands and Canada have legalised medicinal cannabis without breaching their international obligations.

[15] NSWPRS, *op. Cit.*, p.4.
[16] *Ibid.*

2. Clinical Trials and Research

Substantial evidence supporting the introduction of clinical trials to demonstrate safety and efficacy of medicinal cannabis was presented. However, there was a lack of consensus regarding the current gaps in knowledge, whether sufficient peer-reviewed research has been undertaken to date and precisely what additional currently unknown information could be gained from a clinical trial. The scheduling of cannabis as a Schedule 9 prohibited substance limits opportunities for research and adds to the challenges of gaining ethical approval for trials in this area.

Dr Adrian Reynolds (Clinical Director, Alcohol and Drugs Service), when speaking to the Tasmanian Government submission, provided a summary of some of the existing and ongoing research in the field:

> *Lisa Maher, who works at the National Drug and Alcohol Research Centre, said last year to the New South Wales parliamentary inquiry that she thought the best bets were control of nausea and vomiting from cancer chemotherapy; appetite stimulation in patients with HIV-AIDS-related wasting syndrome - Cochrane has said no to that one, it appears; the control of muscle spasticity from multiple sclerosis or spinal cord injury; and pain management for neuropathic pain and possibly for anti-inflammatory treatment... It appears that there is not consensus among the pain physicians around the country that this shows a lot of promise. Finally, she said, bronchodilatation for asthma but of course we wouldn't want that to be smoked obviously.*
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> *Then Mike Farrell and Wayne Hall, who are both eminent scientists with peer-reviewed publications in the thousands - Mike Farrell is the director of our National Drug and Alcohol Research Centre and Wayne Hall is a previous director of that centre and now works in Queensland at the university and both have done extensive work for the World Health Organisation in the area of cannabis and health. Farrell and Hall said on the basis of existing evidence, medical world-renowned researchers have concluded that the number of medical conditions for which cannabis might be beneficial is small but Sativex or Nabiximols show most promise.*
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> *We heard there are trials of CBD in children for epilepsy so we wait to see the results of that. That could be very vital and helpful.*
>
> *Jan Copeland, the director of the National Cannabis Prevention and Information Centre and also a very eminent scientist on the international level, said the cannabinoid family of drugs is under-researched, which is your presentation. She said some have potential for medical application, which is your and our hope. She said the current state of evidence is not particularly strong and it is at best for two or three conditions and then only as a second line or adjunctive medication. She said CBD or CPD and THCV or cannabidivarin are of most interest. Both are less potent agonists on the cannabinoid system, that drug effect that might worry us and be anxiogenic, causing anxiety or psychotic reaction. There is some evidence that CBD might moderate the effects of THC. Mind you, it has been grown out of strains, we read as well, which is not good. She said those are both less potent so they might be a better bet for therapeutic purposes. She said potentials as anxiety,*

> *anti-psychotic and other indications for CBD need to be researched, bearing in mind that THC might have the opposite effect.*[17]

Furthermore, Dr Raimondo Bruno, an Associate Professor (School of Psychology, University of Tasmania) suggested that in relation to the evidence base:

> *There is high quality evidence that supports their effectiveness for a small number of conditions. For conditions such as neuropathic pain, spasticity associated with multiple sclerosis, inflammatory pain such as rheumatism, nausea, vomiting and appetite suppression, there is good randomised control trial evidence that supports their effectiveness. They have not been head to head trials against existing medications but they have been well run placebo controlled studies that we rate at the highest level of quality of evidence.*
>
> *This is for a constrained number of disorders. Questions remain in terms of whether some types of preparations are more beneficial than others. We are still trying to understand, at a neurochemical level, the way that the endocannabinoid system works in the brain and the body and how that might contribute to treatment outcomes.*[18]

Mr Jim Galloway (Chief Pharmacist, Tasmanian Government) suggested that in terms of quality, safety and efficacy:

> *The Cochrane database, the internationally recognised database around medical care, in respect of investigating the efficacy of the use of cannabinoids to reduce frequency in epilepsy, it found that the reports investigated were of low quality and no reliable conclusion could be drawn regarding the efficacy of the use of cannabinoids for the treatment of epilepsy. That is the best medical knowledge at this point in time... In terms of safety, there is not sufficient evidence for any Cannabidiol treatment for the long term."*[19]

The submission by the Royal Australian and New Zealand College of Psychiatrists asserts that "*the efficacy of the drug for any purpose has not been investigated by modern systematic methods*"[20] and that the anecdotal reports of the efficacy of cannabis preparations cannot be regarded as scientific evidence sufficient to justify their lawful prescription.

In contrast, the Australian Nursing and Midwifery Federation (Tasmania) ANMF submitted that:

> *No longer are the medicinal properties of cannabis still only delineated by anecdotal reports but that it is clear cannabis has genuine medical utility. However*

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[17] Dr Adrian Reynolds, *Transcript of Evidence*, 18 September 2014, pp.67-8.
[18] Dr Raimondo Bruno, *Transcript of Evidence*, 19 September 2014, p.43.
[19] Dr Jim Galloway, *Transcript of Evidence*, 18 September 2014, p. 55.
[20] Dr Eric Ratcliff (RANZCP), *Submission*, p.1.

> *this has largely been overlooked, with research and the community gaze directed toward the hazards of recreational use rather than the benefits for medicinal use.*[21]

The Committee notes that there is a notable absence of research regarding the effects of long term use of opiates which suggests that cannabinoids may have been demonised at a political level, whereas opiates have not.

Notwithstanding the lack of consensus on the knowledge gaps, the Committee heard evidence from Barrister Greg Barns[22] that there are a number of legislative models in the United States based on peer reviewed scientific research that can guide the regulation of use of medicinal cannabis in Australia. This evidence supports Mr Barns' view that there has been sufficient robust research and that no additional trials are required to justify the use of medicinal cannabis in Australia. This approach has also been endorsed at the Commonwealth level by Prime Minister Abbott, who in a letter to talkback radio host Alan Jones dated 23 August 2014, asserted that "*no further testing should be needed on the drug if it is legal in similar jurisdictions.*"[23]

Furthermore, evidence was received from Professor Ray Lowenthal that the cost of running trials is substantial for new drugs and that a trial undertaken in Tasmania in isolation could not be meaningful or reliable. Literature suggests that a number of trials have been undertaken with cannabis, but many of these trials have been criticised for being very small, making them statistically unreliable.[24] Professor Lowenthal suggests that it may be possible for Tasmania to participate in nationwide trials, such as that proposed by NSW.

To further illustrate this point, Mr Barns provided evidence that there are a number of reliable jurisdictions around the world (including United States, Canada and Israel) that have adopted a regulatory framework specifically based on scientific research and evidence on the beneficial use of medicinal cannabis for particular conditions and symptoms.

A recent example is the conservative jurisdiction Illinois, US where Governor Pat Quinn recently signed into law an Act that Amends the *Compassionate Use of Medical Cannabis Pilot Program Act 2013*. The new law:

> *Amends the Compassionate Use of Medical Cannabis Act to allow children under 18, with a parents consent, to be treated with non-smokeable forms of medical marijuana for the same range of conditions now available to adults. The bill also adds seizures, including those characteristic of epilepsy, to the list of debilitating medical conditions that can legally be treated with medical marijuana. The Illinois*

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[21] ANMF (Tasmania), *Submission*, p.6.
[22] Greg Barns, *Transcript of Evidence*, 22 September 2014.
[23] Letter from Tony Abbott to Alan Jones, 23 August 2014, Sydney Morning Herald, retrieved from http://www.alcp.org.nz/node/684#sthash.H4KzWJdS.dpuf.
[24] Ray Lowenthal, *Transcript of Evidence*, 19 September 2014, p.68.

> *Department of Public Health (IDPH) will create rules for the treatment of children using medical marijuana. The legislation is effective Jan. 1 2015."*[25]

Section 5 of that 2013 Act sets out the justification for the medical use of cannabis:

> *(a) The recorded use of cannabis as a medicine goes back nearly 5,000 years. Modern medical research has confirmed the beneficial uses of cannabis in treating or alleviating the pain, nausea, and other symptoms associated with a variety of debilitating medical conditions, including cancer, multiple sclerosis, and HIV/AIDS, as found by the National Academy of Sciences' Institute of Medicine in March 1999.*
>
> *(b) Studies published since the 1999 Institute of Medicine report continue to show the therapeutic value of cannabis in treating a wide array of debilitating medical conditions. These include relief of the neuropathic pain caused by multiple sclerosis, HIV/AIDS, and other illnesses that often fail to respond to conventional treatments and relief of nausea, vomiting, and other side effects of drugs used to treat HIV/AIDS and hepatitis C, increasing the chances of patients continuing on life-saving treatment regimens.*
>
> *(c) Cannabis has many currently accepted medical uses in the United States, having been recommended by thousands of licensed physicians to at least 600,000 patients in states with medical cannabis laws. The medical utility of cannabis is recognized by a wide range of medical and public health organizations, including the American Academy of HIV Medicine, the American College of Physicians, the American Nurses Association, the American Public Health Association, the Leukaemia & Lymphoma Society, and many others.*

The case study illustrates that frameworks can be easily established to regulate medicinal cannabis and that "*legalising medical cannabis is an act of compassion and consistent with Australia's international human rights obligations and the obligation of the state to ensure health care for its citizens is based on science and evidence, not on prejudice and failed law enforcement strategies.*"[26]

Medicinal cannabis is already being used in Tasmania and the Committee was provided with significant anecdotal evidence of individual cases where medicinal cannabis has brought pain relief and positive changes to the lives of individuals with illnesses. In this context, and particularly for conditions and symptoms that there is an evidence base regarding the beneficial effect of the product, it may be more appropriate to conduct future research into comparisons with currently available pharmaceutical drugs, as well as appropriate dosage and the "*cultivars or strains and looking into the ratios so that we can make sure we provide a really good quality, medical grade product that is consistent and reliable.*"[27] It may also be appropriate to focus effort on post market surveillance monitoring of the product, including long-term impacts or differing dosages for different

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[25] Governor Pat Quinn (2014), Medical Release, 20 July Accessed at http://www3.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=3&RecNum=12433
[26] G. Barns, *Transcript of Evidence*, 22 September 2014, p. 6.
[27] Nicole Cowles, *Transcript of Evidence*, 18 September 2014, p.8.

conditions, the development of tolerance and issues related to dependence, as well as withdrawal on discontinuation of the use of the medication.

3. Public Health and Safety

3.1 Schizophrenia

Concerns regarding health and safety issues associated with the use of medicinal cannabis were raised by some members of the medical profession. Dr Eric Ratcliff from the Royal Australian and New Zealand College of Psychiatrists (RANZCP) raised concern regarding the safety of medicinal cannabis for those susceptible to schizophrenia.

> *In psychiatry we are very much aware that it is very unsafe in a number of ways. Preparations containing a high proportion of THC are associated with psychotic reactions and the most serious one is the accumulating evidence that if it is used by children or adolescents, particularly around the age of 14, there is a greatly enhanced risk of developing the most serious psychosis, which is schizophrenia. Thirty years ago it looked as though schizophrenia was starting to fade and become less common and less severe, but over the last 30 years it has become more severe and more common. The basis of this is that probably approximately one in 10 of us have inherited the genes that make us susceptible to schizophrenia. It is not the cause of it, but there is susceptibility in about 10 per cent of the population.*[28]

Dr Ratcliff conceded that CBD, so far as is known, is not the causal agent that may have the effect of being the precursor to psychotic episodes or schizophrenia, and qualified this by stating that "*I don't think we can be certain of that until it is properly trialled.*"[29]

Dr Andrew Katelaris, a medical professional who was deregistered in 2005 for providing and prescribing medicinal cannabis, suggested that "*despite the hysterical rhetoric attempting to link cannabis use with schizophrenia, it has now been established and published that 1500mg of CBD is as effective as Risperidone in the control of schizophrenia, but without the multiple side effects associated with the allopathic approach.*"[30]

The Committee note that a randomised control trial that would be required to test this may be very difficult to obtain ethics approval for. Dr Ratcliff was in agreement with this view.[31]

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[28] Dr Ratcliff, *Transcript of Evidence*, 18 September 2014, p.14.
[29] *Ibid.*, p.20.
[30] Dr Andrew Katelaris, *Submission*, p.2.
[31] *Ibid.*

3.2 Polypharmacy

Dr Ratcliff also raised concerns over the effect of polypharmacy, suggesting that in conjunction with cannabis, particularly products with higher levels of THC, anti-psychotic drugs become relatively ineffective.[32]

The Committee also heard evidence of several instances of patients ceasing to take other pharmaceutical medications due to the beneficial effects of the medicinal cannabis.

3.3 Smoking

The Tasmanian Government Chief Pharmacist expressed concern about the effects of smoking medicinal cannabis. An article was provided via email to the Committee by Chief Pharmacist Jim Galloway which "*puts our concerns on medicinal cannabis as health providers, policymakers and regulators together in a nutshell.*" The primary issues raised in that article relate to the risks associated with smoking cannabis.

> *Benefits notwithstanding, the potential harms associated with medical marijuana and need to be carefully considered. No other prescription medication is smoked; concerns remain about the long-term risks of respiratory problems associated with smoking marijuana, which are a subject of active investigation.*[33]

The Dutch model, for example, advises against the smoking of medicinal cannabis because smoking cannabis is just as harmful as tobacco in causing lung complaints and possibly lung cancer. A more desirable mode of administration recommended by the Dutch Ministry of Health, Welfare and Sport is inhalation using a vaporiser.[34]

3.4 Driving under the Influence

The focus of the Department of Police and Emergency Management is to ensure that public safety remains the highest consideration in this process.[35] This includes the potential for individuals to be driving under the influence of cannabis. Any risk associated with the potential for individuals to be driving under the influence of cannabis needs to be managed through existing road safety law, implemented through road safety programs and public education.

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[32] *Ibid.*
[33] Wilkinson, S. 2014, *Problems with the Medicalization of Marijuana*, JAMA, 18 June 2014, Volume 311, Number 23, p.2377.
[34] http://www.cannabisbureau.nl/en/MedicinalCannabis/Doctorsandpharmacists/Vaporisers/
[35] Peter Edwards (DEPM), *Transcript of Evidence*, 18 September 2014, p.72,

If medicinal cannabis with low levels of THC can be shown to not have an adverse impact on a driver of a motor vehicle, legislation should reflect this. Should there be an adverse impact on a person's capacity to safely drive a motor vehicle, product warnings as seen on a range of other Schedule 4 and Schedule 8 medications currently available, advising patients taking these medications to avoid driving and operation of machinery, should be included.

It may be appropriate to issue certain patients, for example those suffering from conditions that would benefit from medicinal cannabis containing higher THC cultivars, with a restricted licence which would limit their ability to drive at certain times, or with a specified amount of medicinal cannabis in their systems.

These measures can only occur effectively under a regulated environment.

4. Security

Security risks do not constitute an impediment to the legalisation of medicinal cannabis in relation to the administration and cultivation of cannabis for use within and beyond Tasmania.

Mr Peter Edwards, Acting Assistant Commissioner, (Department of Police and Emergency Management), stated that:

> *The growing of high THC cannabis would require a sound level of security in relation to the growing site, transport, and processing facilities to prevent interference with crops and diversion into illicit drug markets. Importation requirements of cannabis or cannabis oil would also need to be considered if this is sanctioned as a method of supply.*[36]

Mr Edwards went on to say that:

> *It is our view that the increased availability of any illicit substance must involve police in determining the regulatory environment in which this occurs. There are some established examples of medicinal cannabis models, particularly in Canada and the Netherlands that are significantly regulated and support what are now mature industries. Tasmania Police advocates learning from these models should the medicinal use of cannabis be supported in this State.*[37]

In relation to the level of security required in comparison with the poppy industry, the Poppy Growers' Association suggested that medicinal cannabis would require a higher level of security because:

> *The security of cannabis as another and distinct narcotic drug crop with its ready-made opportunities for diversion into the black market and street market for illegal drugs contrasts very markedly with negligible levels of diversion with poppies. Whilst it is true that there have been, and may be in the future, opportunistic grabs of poppy heads, we do not have a black market for opiates in Tasmania."*[38]

Cannabis is very unlikely to be a broad acre crop such as poppy crops. Rather, medicinal cannabis would most likely be grown in a very controlled and contained environment, generally inside a building, or in relatively small and secure outdoor production areas. This is for reasons of integrity as well as security.[39]

Security of indoor and smaller outdoor production areas can be adequately achieved through measures such as security fencing, the installation of CCTV

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[36] P. Edwards, *Transcript of Evidence*, 18 September 2014, p. 72.
[37] *Ibid.*
[38] Glynn Williams, Poppy Growers' Association, *Transcript of Evidence*, 19 September 2014, p.23.
[39] Deirdre Wilson (DPIPWE, Tasmanian Government), *Transcript of Evidence*, 18 September 2014, p.84.

cameras and electronic monitoring systems. These measures would require initial financial investment but would not be prohibitively expensive.[40]

The arrangements for securing the cultivation of medicinal cannabis in Tasmania could be required to follow a more stringent regime to that required by poppy growers due to the relative size of the area required to be secured. The greater ease of diversion if higher THC cultivars were being grown and the subsequent consequences of interference with the crop were also raised as areas that may require additional security. For low THC cultivars, a lower level of security could be supported, however a consistent regulatory framework is preferred.

Following a comprehensive risk assessment, assessing the risk of diversion into the illicit market, ease of use for recreational purposes, consequences of interfering with the crop and having regard to the provisions of the *Single Convention on Narcotic Drugs 1961*, it may be appropriate for the security and regulatory regime to be no more stringent than that required of the poppy industry.

[40] Stephen Sullings (Gallaghers Security Fencing), *Transcript of Evidence*, 19 September 2014, p.27; T. Langman, *Transcript of Evidence*, 22 September 2014, p.12.

5. Local Skills and Expertise

Businesses and other institutions within Tasmania have the skills and capabilities to undertake research and development in the area of the medicinal use of cannabinoids. This capacity exists within Tasmania's research institutes and also within existing businesses with cutting edge technology in the field of botanical extraction. These areas provide Tasmania with the opportunity to demonstrate leadership in an area of significant public interest.

Dr Nicoletti, speaking on behalf of EOT, suggested that the local biotechnical company based in Kingston has the capabilities to investigate:

> *...processes to extract high concentrations of pure CBD, and processes to extract high concentrations of pure THC, and then to investigate other cannabinoids that may demonstrate therapeutic benefits. In terms of looking at CBD in the initial stages, what EOT's commercial endeavours would be directed at is identifying suitable low-THC strains of hemp, which provide optimum concentrations of CBD which can be extracted from the plant and then purified.*
>
> *That will allow EOT to reproduce a genetic equivalent of a strain of hemp that contains high levels of CBD and very low or no concentrations of THC. There are obviously already growers of hemp in Tasmania so EOT could look at sourcing, at least in the early stages, hemp from existing growers or growing a plant that has a high concentration of CBD. In the next stage of it, they will be looking at optimising the extraction, fractionation and purification processes. They have state-of-the art-facilities at EOT itself, including supercritical CO2 extractors. They also have a good relationship with the University of Tasmania so if they need additional expertise they would be able to draw on the expertise at an academic level.*[41]

Dr Nicoletti stated that EOT wish to engage in a long term partnership with the Tasmanian Government, so that it can;

> *...develop processes to extract high concentrations of CBD from low-THC cannabis as a starting point, and also to look at developing processes to extract pure forms of THC from cannabis, and then to investigate other cannabinoids extracted from cannabis for therapeutic use. A partnership with the Tasmanian Government would enable EOT to be at the forefront of developing these sorts of processes and establishing a smallish industry to develop cannabinoids for therapeutic end use.*
>
> *In order to [do] this for the entire objective to be achieved, we believe that it would assist to make some amendments to the legislation to allow less restricted investigation of THC because that does seem to be quite an important constituent for pain relief, and also for nausea associated with chemotherapy. If appropriate amendments are made to the legislation and EOT is able to develop commercially viable extraction processes for CBD, THC and other cannabinoids, it is likely that EOT will then set up a production facility in Tasmania. Such a facility will*

[41] Dr Nicoletti, *op. Cit.*, pp.67-8.

> *obviously have flow-on benefits to the Tasmanian economy through the creation of new jobs and there would be an economic stimulus in Tasmania.*[42]

EOT emphasised that the partnership it is seeking is in the form of legislative change, rather than financial assistance, as the technology (supercritical CO2 extractor) is already in place and is not in use anywhere else in Australia.

In addition, the University of Tasmania and the Menzies Research Centre are world class research facilities that have the skills and capabilities to undertake a clinical trial of this nature, in cooperation with specialist clinicians.[43]

[42] *Ibid.*, p.69.
[43] Dr Bruno, *Transcript of Evidence*, 19 September 2014, pp.45-6.