The Senate

Legal and Constitutional Affairs Legislation Committee

Regulator of Medicinal Cannabis Bill 2014

August 2015

ISBN 978-1-76010-240-1

This document was produced by the Senate Legal and Constitutional Affairs Committee secretariat and printed by the Senate Printing Unit, Department of the Senate, Parliament House, Canberra.

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Recommendation 1

5.6 The committee supports, in principle, the access to products derived from cannabis for use in relation to particular medical conditions where the use of those products has been proven to be safe and effective.

Recommendation 2

5.7 The committee recommends that the Bill is amended, if necessary, to establish mechanisms by which scientific evidence about medicinal cannabis products can be assessed to determine their suitability for use in the treatment of particular medical conditions.

Recommendation 3

5.10 The committee recommends that the Bill is amended to address issues raised about its interaction with the existing Commonwealth regulatory framework for medicinal products, including the *Therapeutic Goods Act 1989*, the *Narcotics Drug Act 1967* and relevant customs legislation.

Recommendation 4

5.13 The committee recommends that the Bill is amended to ensure that medicinal cannabis products can be made available in Australia consistent with Australia's international obligations, including under Articles 23 and 28 of the *Single Convention on Narcotic Drugs (1961)*.

Recommendation 5

5.16 The committee recommends that the Commonwealth government consult with its state and territory counterparts about the interrelationship of relevant laws to ensure a consistent approach to accessing medicinal cannabis and to facilitate compliance with any such access scheme and Australia's international obligations.

Recommendation 6

5.18 Subject to the preceding recommendations, the committee recommends that the Bill be passed.

Chapter 1
Introduction

Referral of the inquiry

1.1 On 12 February 2015, the Senate referred the Regulator of Medicinal Cannabis Bill 2014 (Bill) to the Senate Legal and Constitutional Affairs Legislation Committee (committee) for inquiry and report by 21 April 2015.[1] On 26 March 2015, the Senate agreed to extend the reporting date for the inquiry to 21 May 2015.[2] Several further extensions were subsequently granted by the Senate, with the final reporting date being set for 11 August 2015.[3]

1.2 The Bill is a private senator's Bill, introduced by Senator Richard Di Natale into the Senate on 27 November 2014 and co-sponsored by Senators Di Natale, Macdonald, Leyonhjelm and Urquhart.[4] The Bill seeks to establish a new Commonwealth body, the Regulator of Medicinal Cannabis, with responsibility for regulating the production, transport, storage and usage of cannabis products for medicinal purposes in Australia.

Conduct of the inquiry

1.3 In accordance with usual practice, the committee advertised the inquiry on its website and wrote to a number of organisations and individual stakeholders inviting submissions by 13 March 2015. Details of the inquiry were placed on the committee's website at http://www.aph.gov.au/senate_legalcon.

Submissions

1.4 In total, the committee received 261 submissions to this inquiry. The public submissions are published on the committee's website and are listed at Appendix 1.

1.5 A significant number of the submissions received by the committee contained detailed accounts of individuals' experiences using cannabis products in Australia to treat a variety of medical conditions. Given the sensitivities around the usage of medicinal cannabis in Australia, the committee resolved to withhold from publication the names of any individuals whose submissions included details of cannabis use in Australia, unless this information was already on the public record (for example, in newspaper articles or other public media).

1.6 Of the submissions received, 50 were 'form letter' submissions in support of the Bill, with identical or substantially similar wording. For administrative reasons,

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1 *Journals of the Senate*, 12 February 2015, p. 2156.

2 *Journals of the Senate*, 26 March 2015, p. 2461.

3 See: *Journals of the Senate*, 12 May 2015, p. 2555; *Journals of the Senate*, 15 June 2015, p. 2644; *Journals of the Senate*, 18 June 2015, p. 2707; *Journals of the Senate*, 25 June 2015, p. 2841.

4 *Journals of the Senate*, 27 November 2014, p. 1897.

the committee resolved not to publish all of these submissions, but rather a single example on its website.

Public hearings

1.7 The committee held three days of public hearings for this inquiry: in Canberra on 30 March 2015, in Sydney on 31 March 2015, and on 1 April 2015 in Brisbane. Details of witnesses who gave evidence at the hearing are listed at Appendix 2.

Acknowledgment

1.8 The committee thanks those individuals and organisations who made submissions to the inquiry and appeared as witnesses at the public hearings.

1.9 The committee particularly thanks those who courageously shared their individual stories in relation to medicinal cannabis, many of which included highly personal accounts of struggles with serious medical conditions and the reality of trying to access appropriate treatment and care. It is these individuals who stand to benefit the most from the increased understanding of both the potential and the limitations of medicinal cannabis that could be developed through the implementation of a stronger regulatory framework in Australia.

Structure of the Report

1.10 This report is divided into 5 chapters.

1.11 Chapter 2 provides an overview of the background issues relevant to this inquiry, including: the nature of the cannabis plant and the science relating to its use in therapeutic contexts; the current regulation of cannabis in Australia; and examples of international approaches to regulating medicinal cannabis.

1.12 Chapter 3 includes an overview of the Bill and outlines its key provisions.

1.13 Chapter 4 discusses the key issues raised by submitters and witnesses in relation to the Bill and the broader issue of regulating medicinal cannabis in Australia.

1.14 Chapter 5 presents the committee's views and recommendations.

Chapter 2

Background issues

Cannabis and its medicinal uses

2.1 The cannabis plant is an annual hemp plant that grows in many temperate and tropical zones of the world including Australia.[1] Cannabis has a long history of being used as a herbal remedy, while hemp obtained from the cannabis plant is used in an industrial setting with various applications including cloth and twine. While there are many recognised strains of the cannabis plant that have been developed through selective breeding, *Cannabis sativa* is the primary strain of relevance.[2]

2.2 The cannabis plant contains numerous different chemical compounds, many of which are classified as cannabinoids. *Cannabis sativa* contains more than 100 different cannabinoids, as well as roughly 300 non-cannabinoid compounds.[3]

2.3 A submission to the inquiry from Dr David Allsop, Clinical Associate Professor Nick Lintzeris, Associate Professor Jonathon Arnold and Professor Iain McGregor, all associated with cannabinoid research at the University of Sydney (referred to in this report as the University of Sydney academics group) explained that cannabinoid science is a rapidly developing field:

> Cannabinoid science is one of the fastest moving frontiers in pharmacology and is poised for a period of great scientific and medical discovery in coming years. This is based on our relatively new understanding of the *endocannabinoid* system of the brain and body. Endocannabinoids are cannabis-like signalling molecules that play a role in nearly every physiological process that is known to mankind. Endocannabinoids act through cannabinoid CB1 and CB2 receptors to influence appetite, cognitive function, pain, anxiety, immune function, bone growth and tumour proliferation. The development of medicines that modulate these processes has remarkable potential to influence human disease and wellbeing.[4]

2.4 The two most well-understood cannabinoids are *delta*-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Emeritus Professor David Penington AC explained the roles of these two compounds:

> The most potent cannabinoid in its influence on mood (relaxation and euphoria) is [THC]. The effect of high dosage is termed "stoned" in the vernacular. It also has significant analgesic effects. Over the past

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1 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, p. 7.

2 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, pp 6-8.

3 University of Sydney academics joint submission, *Submission 52*, p. 4; Emeritus Professor David Penington AC, *Submission 9*, p. 1.

4 *Submission 52*, p. 3.

> 10-15 years, marijuana has been bred to produce a high content of this product to serve the market demand for its effects. This is derived particularly from the reproductive seed and adjacent leaves of the plant This type of product is colloquially termed skunk. It acts on the endogenous CB1 and CB2 receptors, the former being widely represented in the brain. CB2 on the other hand is wieldy distributed in body tissues and cells, responding to the body's own endo-cannabinoids influencing immunity and inflammation.
>
> The second most extensively studied component has been cannabidiol (CBD) which counteracts, to a significant extent, the excitatory effects of THC mediated through its influence on excitation of the body's endogenous cannabinoid receptors CB1and CB2, substantially modifying the effects of stimulation by THC. It derives especially from the stalk of the leaves and is commonly contained in the marketed product of hash or hashish. It has strong anti-emetic and analgesic effects and may also have anti-inflammatory effects. It is reported to improve symptoms of developing psychosis. There is much recent research in this field.[5]

2.5 The University of Sydney academics group noted that, in addition to THC, at least 10 of the other cannabinoids present in the cannabis plant are currently under investigation as showing promise for potential therapeutic benefits.[6]

Submitter views on the indications for which medicinal cannabis may be used

2.6 Submitters and witnesses to the inquiry expressed a range of views on the efficacy of cannabis products in medicinal settings, and the current state of the scientific literature in relation to medicinal cannabis.

2.7 Emeritus Professor Laurence Mather, a chemical and clinical pharmacologist with four decades of academic research experience in the disciplines of anaesthesia and pain medicine, including cannabinoid research, provided a summary of the known and possible uses for cannabis and preparations thereof, as reported in peer-reviewed scientific literature, as follows:

Historically recognized uses for cannabinoid pharmacotherapy

- management of migraine pain;
- management of painful cramps of dysmenorrhoea;
- glaucoma treatment (temporary relief);
- epilepsy treatment (and possible treatment for intractable seizures, for example in paediatric Dravet syndrome);
- bronchodilation (associated with asthma treatment);

5 *Submission 9*, pp 1-2.

6 *Submission 52*, pp 4-5.

Agreed and prospective uses for cannabinoid pharmacotherapy

- control of refractory nausea and vomiting (for example from cancer chemotherapy);
- appetite stimulation (for example in patients with HIV-related or cancer-related wasting syndrome);
- control of muscle spasticity (for example from multiple sclerosis or spinal cord injury);
- pain management (analgesia, especially from neuropathic pain, and as an anti-inflammatory agent);
- anti-convulsant effects (for example in patients with epilepsy);

Under investigation for cannabinoid pharmacotherapy

- Anti-tumorigenic uses and direct (local) anticancer treatments;
- endocrine-metabolic modification (for example in diabetes);
- treatment of post-traumatic stress syndrome;
- delaying progression of neurodegenerative conditions (for example Alzheimer's disease); and
- treatment of various forms of inflammatory bowel disease.[7]

2.8 Emeritus Professor Laurence Mather stated in his submission:

> [H]aving studied a great deal of the relevant scientific and medical peer-reviewed published evidence about cannabis, I maintain that this evidence inarguably demonstrates cannabis to be a useful medication, and ought to be available to Australian patients in need. I thus maintain that the evidential literature strongly supports appropriate changes to the law, at both Federal and State levels, to enable cannabis and preparations thereof to be reintroduced into the range of medicines available for the treatment of an already identified number of medical conditions, with sufficient flexibility to enable future uses.[8]

2.9 Dr Alexander Wodak AM, who worked as director of the alcohol and drug service at St Vincent's Hospital in Sydney for three decades, stated his view that medicinal cannabis was useful in a range of circumstances:

> [T]he evidence is clear that it is a useful medication. At this stage of our knowledge it is probably only a second line medication; in other words, the standard medicines should be used first, but they fail often enough, leaving patients in considerable distress. That happens often enough to…justify the use of medicinal cannabis for those patients. We are often talking about

7 *Submission 17*, p. 3.

8 *Submission 17*, p. 3.

> very distressing symptoms in terminal conditions or serious medical conditions that are limiting the quality and quantity of life.[9]

2.10 Some other submitters and witnesses were more equivocal about the potential of medicinal cannabis. For example, Professor Wayne Hall, Director of the Centre for Youth Substance Abuse Research at the University of Queensland, expressed the view that the current research indicated medicinal cannabis is 'at best, modestly effective for some purposes (for example vomiting and nausea) and probably for others (for example chronic pain, depression, muscle spasm)'.[10] Professor Hall stated:

> An informed policy towards the medical use of cannabinoids requires much better evidence than we currently have…we need clinical trials of the safety and efficacy of CBD and other cannabinoids in treating intractable epilepsy and chronic pain. Evidence from these trials is essential for rational decisions to be made about the medical use of cannabinoids.[11]

2.11 The Royal Australasian College of Physicians considered that 'while medicinal marijuana shows some potential for certain patients, further research is required to determine its efficacy and it should be subject to the same scrutiny as any other medicine'.[12]

2.12 Painaustralia expressed the view that, for individuals with chronic non-cancer pain, there is little proven evidence for the effectiveness of cannabinoids in helping patients, and that it did not endorse the use of cannabinoids for this group of patients 'until such time as a clear therapeutic role for [cannabinoids] is identified in the scientific literature'.[13]

2.13 Associate Professor Lintzeris of the University of Sydney argued that a balance must be struck when assessing the potential of medicinal cannabis:

> there are a lot of claims and counterclaims about the role of cannabinoids—that they will cure everything, on the one hand; there is a group of advocates saying, "This is better than sliced bread and should be in the drinking water" and, at the other extreme, we have got other people who identify that the evidence is not there and we really should not be progressing, it is too risky and, for a range of reasons, we do not want to go down that track…It is a fine balance about how governments, professional societies, regulators, consumer groups…keep abreast of the evidence and are able to make sure that, where we know that there is a role for the cannabinoids and they can be provided safely, those markets are then opened up, whilst not necessarily promoting the use of cannabinoids where there is not evidence.[14]

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9 *Committee Hansard*, 31 March 2015, p. 47.

10 *Submission 4*, p. 12.

11 *Submission 4*, p. 13.

12 *Submission 29*, p. 1.

13 *Submission 56*, [p. 5].

14 *Committee Hansard*, 31 March 2015, p. 7.

The 'ensemble' or 'entourage' effect

2.14 Some submissions to the inquiry noted that an active area of research in cannabis science is the so-called 'ensemble' or 'entourage' effect, which suggests that it is the effect of the various cannabinoids and terpinoids in the cannabis plant working together, rather than the action of any single cannabinoids present in the plant, that produce the most beneficial medicinal effects.[15]

2.15 Professor McGregor of the University of Sydney commented on this issue in evidence to the committee:

> The ensemble or entourage effect is much spoken about. It is often people who want to defend smoked cannabis as the primary therapeutic who say you are not going to get a therapeutic effect until you have 100 cannabinoids and 200 terpenoids all together in the one mix. The evidence is actually not that strong. We have good evidence for CBD moderating some of the psychosis-inducing effects of THC and some of the other adverse effects. We have a little bit of work on THCV antagonising some of THC's effects. But what we really need to do is to go back to basics with preclinical work looking at these different ratios…and play with the different ratios using pure cannabinoids and work out what is therapeutically best and see if an entourage effect actually does exist.[16]

Grades of medicinal cannabis products

2.16 The National Drug and Alcohol Research Centre at the University of New South Wales (NDARC) noted in its submission that there are three possible grades of cannabis and cannabis products that are used in medicinal contexts, namely pharmaceutical, medical-grade herbal and herbal, as follows.

Pharmaceutical grade products

2.17 NDARC described this class of products as 'a medical grade product with standardised content of the active constituents, presented as a medication (with standardised packaging, dosing and so on)'. NDARC noted that this is effectively the same as for any pharmaceutical preparation that adheres to the requirements of the Therapeutic Goods Administration (TGA), the agency that oversees the registration of medications in Australia, and that most clinical trials examining medicinal cannabis have been conducted with pharmaceutical preparations, rather than with herbal cannabis.[17]

Medical-grade herbal products

2.18 NDARC stated that the second form of cannabis for medicinal use is herbal cannabis that is produced and processed in controlled and standardised conditions, and as such is described as 'medical-grade herbal cannabis':

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15 See, for example: Emeritus Professor Laurence Mather, *Submission 17*, p. 6; National Drug and Alcohol Research Centre, *Submission 19*, pp 5-6.

16 *Committee Hansard*, 31 March 2015, p. 4.

17 *Submission 19*, p. 6.

> This means that its cultivation has to be standardised to produce stable levels of cannabinoids (THC and CBD), and the product has to be free of any harmful adulterants. The Dutch licensed grower "Bedrocan" provides an example of this type of process.[18]

Illicit or unrefined herbal cannabis

2.19 In addition to pharmaceutical preparations and medical-grade herbal cannabis, the final grade of product is regular herbal cannabis, available through the illicit market:

> [This cannabis] has an unknown and potentially unstable content of THC, CBD, and of other active constituents is a third option. It may have adulterants and moulds as a result of improper air circulation and drying, heavy metals taken up from the soil and air, and pesticides or other chemical residues from pest protection and fertilisation.[19]

Types of medicinal cannabis products and routes of administration

2.20 Submitters to the inquiry noted that, other than smoking cannabis, medicinal cannabis preparations come in a variety of forms, including:

- oral administration of pills (for pharmaceutical preparations);
- oromucosal spray;
- tinctures and ointments;
- ingestion of oils derived from cannabis plants; and
- vaporisation of the herbal product.[20]

Difficulties associated with using cannabis as medicine

2.21 Submitters and witnesses noted several difficulties associated with using cannabis as a medicinal treatment, namely that: as a plant-based remedy, cannabis does not readily fit into the pharmaceutical model of medication that is predominant in Australia; and the proven harms associated with cannabis usage is an additional complication when assessing its potential therapeutic uses.

2.22 Emeritus Professor Mather noted that the composition of cannabis makes it more complicated to use in medical contexts:

> Apart from its regulation according to international treaties and consequent Australian laws, the most serious complication affecting the use of cannabis as medicine lies in its composition, or rather the uncertainty in its composition. Unless selectively modified, cannabis is a variable mixture of natural products, and not a single substance for which purity and strength

18 *Submission 19*, p. 6.

19 *Submission 19*, p. 6 (internal citations omitted).

20 See National Drug and Alcohol Research Centre, *Submission 19*, pp 6-7.

> can be ascertained or be regulated by the operation of the Therapeutic Goods Administration.[21]

Harms associated with cannabis use

2.23 Submitters and witnesses to the inquiry noted that cannabis is a substance that can cause significant harm, and that examinations of the medicinal uses of cannabis products must be viewed in this light. Emeritus Professor Penington identified that cannabis with high THC content has been clearly linked to the precipitation of psychotic symptoms, and that further, cannabis use has been shown to have a negative effect on brain development in users aged between 15 and 25 years.[22]

2.24 The Royal Australian & New Zealand College of Psychiatrists stated that caution must be exercised in relation to medicinal cannabis, as cannabis 'is a substance that may cause significant psychiatric morbidity and can alter the trajectory of an individual's mental illness for the worse'.[23]

2.25 Submitters noted that the act of smoking the cannabis plant poses clear health risks, and may be a risk factor in the development of respiratory diseases and some cancers.[24]

2.26 Associate Professor Lintzeris noted that the issues of medical substances also being harmful in some circumstances is not unique to cannabis:

> Cannabinoids are like any other drug: used well, used correctly, they can have some therapeutic benefits; used poorly, used incorrectly, they are associated with harms. Cannabis is not unique in that. Most of our medications, even penicillin—if you give it to the wrong person, people die from adverse reactions to penicillin. So this is not an unusual balance that governments and regulators need to get right.[25]

Effects on other public health issues

2.27 Professor Allison Ritter from the NDARC informed the committee that comparisons between states in the US with and without medicinal cannabis laws showed emerging trends in terms of corollary effects on other public health issues. These include a lowering of alcohol consumption and a significant reduction in opioid overdose fatalities in states where medicinal cannabis was available.[26]

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21 *Submission 17*, p. 4.

22 *Submission 9*, pp 3 and 4.

23 *Submission 51*, p. 1.

24 Cancer Council Australia & Clinical Oncology Society of Australia, *Submission 37*, p. 5; Australian Medical Association, *Submission 44*, p. 1; Professor Wayne Hall, *Submission 4*, pp 5-6.

25 *Committee Hansard*, 31 March 2015, p. 7.

26 *Committee Hansard*, 31 March 2015, p. 42.

2.28 Emeritus Professor Mather also commented on the issue of a reduction in opiate overdoses in these jurisdictions:

> One paper suggested that in patients prescribed chronic doses of opioids for persistent conditions such as chronic pain there was in the order of 25 per cent fewer opioid related deaths in jurisdictions where cannabis was available. I think another paper reported 10 per cent. Nonetheless, whether it is 10 per cent, 25 per cent or some other percentage, cannabis is a relatively fail-safe medicine. The nonsteroidals that might be used in those patients can cause kidney damage and liver damage. The opioids that might be used can stop breathing and cause death that way. Cannabis is not known to cause fatalities.[27]

Popular support for the use of cannabis for medicinal purposes in Australia

2.29 The Australian Institute of Health and Welfare noted in its submission that data from the 2013 National Drug Strategy Household Survey shows widespread support for the use of medicinal cannabis in Australia, including:

- 75 per cent of people aged 14 or over would support a clinical trial of cannabis to treat medical conditions; and
- 69 per cent of people would also support a change to the legislation permitting the use of cannabis for medicinal purposes.[28]

2.30 NDARC noted in its submission that this level of support in Australia has been consistent for over a decade.[29]

Existing regulation of cannabis products in Australia

2.31 At the present time cannabis and cannabis products are regulated in Australia through a combination of Commonwealth and state-based legislation. Australia's obligations under international narcotics treaties also impact on the control of cannabis in Australia.

International obligations in relation to cannabis plants and cannabis products

2.32 Australia is a party to three international agreements which impact on the regulation of cannabis for medicinal purposes, namely:

- the *Single Convention on Narcotic Drugs (1961)* (the Single Convention), which specifies the obligations of signatory states for narcotic drugs listed in schedules annexed to the Convention (including cannabis);
- the *Convention on Psychotropic Substances (1971)*; and
- the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)*, which aims to promote cooperation between

27 *Committee Hansard*, 31 March 2015, p. 14.

28 *Submission 45*, p. 2.

29 *Submission 19*, p. 3.

parties to address various aspects of illicit traffic in narcotic drugs and psychotropic substances.[30]

2.33 The Department of Health noted in its submission that the Commonwealth is responsible for the implementation of Australia's treaty obligations:

> The Commonwealth is responsible for the implementation of international agreements that it enters into and generally has the power to make legislation to implement Australia's treaty obligations. Accordingly, the Commonwealth is responsible for ensuring that any Commonwealth, State or Territory medicinal cannabis scheme is consistent with Australia's treaty obligations under the three drug control conventions[.][31]

Relevant obligations under the Single Convention

2.34 Under Article 30 of the Single Convention, controls on the production of opium poppy contained in Article 23 of that convention also apply to any permitted cultivation of cannabis plants. Under Article 23, State Parties must establish and maintain a government agency with responsibilities to:

- designate the areas in which cultivation is permitted;
- grant licenses for cultivation;
- purchase and take physical possession of crops produced by licensed cultivators;
- hold the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers, of medicinal cannabis or cannabis preparations.

2.35 Article 28 of the Single Convention requires State Parties to adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

2.36 Under Paragraph 3 of Article 29 and paragraph 2(a) of Article 30 of the Single Convention, Australia is required to prevent the accumulation, in the possession of drug manufacturers, traders, distributors, state enterprises or duly authorised persons, of quantities of drugs in excess of those required for the normal conduct of business having regard to the prevailing conditions.[32]

Commonwealth legislation governing cannabis

2.37 A number of Commonwealth laws impact on the cultivation, production and usage of cannabis and cannabis products in Australia, as follows:

- the availability of cannabis as a therapeutic substance is regulated under the *Therapeutic Goods Act 1989* (TG Act);

30 Department of Health, *Submission 67*, p. 2.

31 *Submission 67*, p. 2.

32 Department of Health, *Submission 67*, p. 3.

- the manufacture of narcotic drugs including cannabis is controlled under the *Narcotic Drugs Act 1967* (Narcotic Drugs Act);
- the import and export of cannabis into and out of Australia is regulated under the *Customs Act 1901* (Customs Act) and the *Customs (Prohibited Imports) Regulations 1956* and *Customs (Prohibited Exports) Regulations 1958* (Customs Regulations); and
- offences relating to the cultivation, import and export, possession of controlled plants and drugs (including cannabis) are found in the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* as well as Part 9.1 of the *Criminal Code Act 1995* (Criminal Code).[33]

Authorised cultivation and production under the Narcotic Drugs Act

2.38 The Department of Health provided a synopsis of the Narcotic Drugs Act in its submission:

> The *Narcotic Drugs Act 1967* (ND Act) regulates the manufacture of all narcotic drugs under the requirements of the Single Convention through a similar licence and permit regime. The ND Act provides a mechanism to ensure the manufacture of all narcotics is in accordance with global licit demand, and to enable Australia to meet its set reporting obligations. A licence and permit to manufacture may be granted if a prospective manufacturer is able to provide the required information on the quantity of narcotic material to be manufactured and the premises on which it is being manufactured, to a delegate of the Minister for Health. The current manufacturing licensing and permit regime takes into consideration the State legislative framework in relation to the manufacture of narcotic drugs from opium poppy straws.[34]

2.39 Officials from the TGA and the Department of Health confirmed that, in relation to the cultivation of poppy straw in Australia for manufacture into medicinal products, state legislation governs the cultivation of poppy straw, while both the TGA and state governments play interrelated roles in relation to the manufacture of poppy straw into final products.[35]

2.40 It was also noted that the Commonwealth and state and territory governments are currently in the process of negotiating a new national agreement in relation to the cultivation of opium poppies in Australia.[36]

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33 Any plant of the *Cannabis* genus is listed as a 'controlled plant' under Division 3.2 of the *Criminal Code Regulations 2002*.

34 *Submission 67*, p. 4.

35 Dr Lisa Studdert, TGA and Mr Nathan Smyth, Department of Health, *Committee Hansard*, 30 March 2015, pp 38-39.

36 Mr Nathan Smyth, Department of Health, *Committee Hansard*, 30 March 2015, p. 39.

Commonwealth restrictions on the importing and exporting of cannabis

2.41 The import and export of cannabis into and out of Australia is regulated under the Customs Act and Customs Regulations.

2.42 Under section 51A of the Customs Act, 'border controlled' drugs and plants (including cannabis) are taken to be prohibited imports. A system of licences and permissions in relation to the importation of prohibited goods is established under the Customs Regulations. The Department of Health explained:

> [A] person wishing to import a drug must apply in writing for both a licence and a permit from the Secretary of the Department of Health. Cannabis is included in Schedule 4 of the Customs [Regulations], which includes drugs in Schedules I and II of the Single Convention (as well as those with additional controls in Schedule IV). Permits for import of Schedule 4 drugs must specify the quantity of the drug planned for import in order to estimate the total amount of that drug authorised for import into Australia that year. The amount approved for import is reported annually by the Department of Health to the [International Narcotics Control Board].[37]

Scheduling of cannabis and cannabis products under the TG Act

2.43 The TG Act provides for a national system of controls relating to therapeutic goods in Australia. Additionally, it provides a framework for the states and territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.[38]

2.44 The TG Act requires that therapeutic goods that are intended to be supplied in Australia (whether produced in Australia or elsewhere), exported from Australia, and imported into Australia, be entered in the Australian Register of Therapeutic Goods (ARTG) (unless the goods are exempt from that requirement or are otherwise approved or authorised under other provisions of the TG Act).[39]

2.45 Therapeutic goods (include medicines) are goods that generally are presented, or for any other reason are likely to be taken for therapeutic use. The definition of 'therapeutic use' under the TG Act includes use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, and influencing, inhibiting, or modifying a physiological process in persons.[40]

2.46 In addition to the ARTG, the TG Act also provides for the creation and maintenance of a Poisons Standard, under which substances are classified into schedules according to their assessed purpose of use, toxicity, safety in use and potential for abuse. The scheduling classification sets the level of control on the

37 *Submission 67*, p. 3.

38 *Therapeutic Goods Act 1989*, section 4.

39 Department of Health, *Submission 67*, p. 2.

40 Department of Health, *Submission 67*, p. 2.

availability of poisons, which is then implemented through relevant state and territory legislation.[41]

2.47 Cannabis is currently listed as a Schedule 9 Prohibited Substance under the Poisons Schedule.[42] Schedule 9 substances are those assessed as substances 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 or Territory Health Authorities'.[43] An exception to this scheduling is made for processed hemp fibre containing 0.1 per cent or less THC content.[44]

2.48 Dr Lisa Studdert of the Markets Authorisation Group at the TGA, explained in evidence to the committee the general process for applying to have a product listed through the TGA:

> [A] company would invest in the development of a dossier for registration purposes. That would involve clinical trial data—usually phase 1, 2 and 3—other evidence around the pharmacokinetics, the toxicology and a range of other chemical and ingredient-related information that would make up a complete dossier. That is submitted to the TGA. The costs for an application for a new chemical entity are around $250,000. The process is then undertaken at TGA to review that, and that involves a range of evaluators reflecting the nature of the data—clinical delegates, toxicologists, pharmacologists, other experts as needed and appropriate to the particular application. The time for reviewing that application varies but our statutory requirement is to do that within 255 working days—around a year.

2.49 Dr Studdert continued:

> Through that process there are interactions with the company, that we refer to as the "sponsor"; it is not always a commercial company, and that would be in response to specific questions the evaluators may have around the data. So it is an iterative process, it is intensive, and it is pretty standard around the world that regulators have a process similar to that. We have an advisory committee on prescription medicines that will review many applications and provide advice to the delegate in response to specific questions. That comes close to the end of the process and then the delegate makes a decision. If that is a positive decision within a few weeks it is entered onto the Australian Register of Therapeutic Goods.[45]

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41 *Poisons Standard 2015*, Introduction ii.

42 *Poisons Standard 2015*, Schedule 9.

43 *Poisons Standard 2015*, Classification iii.

44 Hemp seed oil is also exempted from Schedule 9 if it contains 50 mg/kg or less of tetrahydrocannabinols and is labelled with a warning statement 'Not for internal use' or 'Not to be taken'.

45 *Committee Hansard*, 30 March 2015, pp 36-37.

Listing of nabiximols and current clinical trials of Sativex®

2.50 One cannabis-derived product, nabiximols, is currently listed as a Schedule 8 Controlled Drug under the Poisons Standard.[46] This product is an oral mucosal spray marketed under the brand name Sativex®, and was registered in Australia for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis.[47]

2.51 Palliative Care Australia noted that phase three clinical trials into the use of Sativex for pain relief in cancer patients, involving 300 patients in Australia and a number of other countries, are currently in progress.[48] Associate Professor Lintzeris informed the committee that clinical trials into the effectiveness of the nabixomols cannabinoid medication Sativex, have been ongoing in Australia since 2012, with funding assistance from the National Health and Medical Research Council.[49]

2.52 Professor Wayne Hall of the University of Queensland noted in relation to the use of Sativex to assist Multiple Sclerosis patients:

> The evidence on Sativex has not convinced regulatory authorities in Australia to support its medical use in MS. [In 2013 the] TGA only approved Sativex in MS patients who failed to respond to other treatments and who showed a clinical response within 2 weeks of initiating treatment. The Australian Pharmaceutical Benefits Advisory Committee (PBAC) decided against publicly subsidising Sativex for MS patients. It concluded that the modest clinical benefits and serious adverse side effects did not justify taxpayers paying the manufacturer's asking price.[50]

State and territory regulation

2.53 Enforcement of drug laws in Australia occurs through individual states and territories, and legislation in each Australian jurisdiction treats 'minor' cannabis offences differently. Three jurisdictions (the Australian Capital Territory, South Australia and the Northern Territory) have decriminalised minor cannabis offences, with possession of limited amounts of cannabis being subject to civil fines rather than criminal penalties. In the other states, diversion programs are generally offered for first-time offenders before criminal sanctions are imposed. A summary of the treatment of cannabis possession under state and territory laws in Australia is provided in Table 2.1.

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46 Schedule 8 Controlled Drugs are substances that are assessed as suitable to be made available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

47 Department of Health, 'Medicinal Cannabis', 17 December 2014, http://www.health.gov.au/internet/main/publishing.nsf/Content/MC14-007515-medicinal-cannabis (accessed 22 May 2015).

48 *Submission 23*, p. 6.

49 *Committee Hansard*, 31 March 2015, pp 2-3.

50 *Submission 4*, pp 3-4.

Table 2.1 – Treatment of minor cannabis offences in Australian jurisdictions[51]

Jurisdiction	*Treatment of minor cannabis offences*
Australian Capital Territory	The ACT introduced a civil penalty system for the possession of 'small amounts' of cannabis in 1993. If someone is caught with up to two non-hydroponic cannabis plants, or up to 25 grams of marijuana (cannabis plant material), they receive a $100 fine with 60 days to expiate (pay the fine) instead of a criminal charge. Instead of paying the fine, the person may choose to attend a drug assessment and treatment program.
South Australia	In 1987, South Australia was the first state to decriminalise minor cannabis offences. The possession of up to 100 grams of marijuana, 20 grams of hash, one non-hydroponic plant or cannabis smoking equipment leads to a fine from $50 to $150 with 60 days to expiate.
Northern Territory	Since 1996, adults found in possession of up to 50 grams of marijuana, one gram of hash oil, 10 grams of hash or cannabis seed, or two non-hydroponic plants can be fined $200 with 28 days to expiate rather than face a criminal charge.
New South Wales	If someone is caught with up to 15 grams of cannabis, they may receive a 'caution' from the police officer, which includes information about the harms associated with cannabis use and a number to call for drug-related information or referral. Only two cautions are allowed to be given to the same person before criminal charges are laid.
Victoria	A police officer may give someone a caution and offer them the opportunity to attend a cannabis education program if they are caught with no more than 50 grams of cannabis. Like NSW, only two cautions are allowed to be given to the one person.
Tasmania	Someone found in the possession of up to 50 grams of cannabis can be given a caution up to three times in ten years. For the first caution, information and referral is provided. A brief intervention is given with the second caution. On the third and final caution, the offender must be assessed for drug dependence and attend either a brief intervention or treatment program.
Queensland	Police officers in Queensland offer someone the option of diversion, rather than prosecution, if they are found in possession of up to

51 Source: National Cannabis Prevention and Information Centre, 'Cannabis and the law', https://ncpic.org.au/professionals/publications/factsheets/cannabis-and-the-law/ (accessed 25 May 2015).

	50 grams of cannabis. The diversion includes a mandatory assessment and brief intervention program. Only one offer of diversion is allowed per person.
Western Australia	Individuals in possession of not more than 10 grams of harvested cannabis and/or a used smoking implement who have no prior cannabis offences will be required to attend a Cannabis Intervention Session within 28 days or receive a cannabis conviction for the offence. All cannabis cultivation offences will attract a criminal conviction.

State and territory initiatives relating to medicinal cannabis

2.54 Several jurisdictions in Australia have announced initiatives relating to medicinal cannabis that are currently in progress or scheduled to commence in the near future.

Council of Australian Governments agreement on medicinal cannabis

2.55 At a meeting of the Council of Australian Governments (COAG) Health Council on 10 October 2014, Commonwealth, state and territory health ministers discussed the issue of medicinal cannabis and 'agreed to work collaboratively to share knowledge and information on issues relating to the use of appropriate therapeutic products derived from cannabis for medicinal purposes'.[52]

New South Wales Terminal Illness Cannabis Scheme

2.56 The NSW government announced in September 2014 that it was issuing new guidelines for NSW police that would enable officers to exercise discretion not to charge terminally ill adults who use cannabis to alleviate their symptoms, or their carers.[53] Under the Terminal Illness Cannabis Scheme, NSW residents over the age of 18 who have a terminal illness (as certified by a medical practitioner involved in their ongoing care) may apply to be registered for the scheme, and may additionally nominate up to three individuals to be registered as carers.[54] Registered individuals may then possess and administer cannabis leaf, oil and resin, up to specified maximum amounts, without being cautioned or charged by police.[55]

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52 COAG Health Council, 'COAG Health Council Communique', 10 October 2014, http://www.coaghealthcouncil.gov.au/Publications/Communiques/ArtMID/522/ArticleID/10/10-October-2014-COAG-Health-Council-Communique (accessed 10 August 2015).

53 New South Wales Government, 'NSW leads the way on medical cannabis', 16 September 2014, http://www.nsw.gov.au/news/medical-cannabis-trial (accessed 25 May 2014).

54 New South Wales Government, 'Terminal Illness Cannabis Scheme', http://www.nsw.gov.au/tics (accessed 25 May 2015).

55 New South Wales Government, 'Terminal Illness Cannabis Scheme: Frequently Asked Questions', http://www.nsw.gov.au/tics-frequently-asked-questions (accessed 25 May 2015).

2.57 Professor Ritter, Director of the Drug Policy Modelling Program at the NDARC, stated that, as at the end of March 2015, around 20 individuals had been granted exemptions under this scheme.[56]

New South Wales clinical trials for the medical use of cannabis

2.58 Also in September 2014, the NSW government announced that it would be initiating clinical trials for medical cannabis in NSW for patients suffering from debilitating or terminal illness.[57] These trials were to be undertaken with up to $9 million in funding provided over five years by the NSW government.[58]

2.59 In December 2014 it was announced that a clinical trial of cannabis derived products would be established for children with severe, drug-resistant epilepsy, through a partnership with the Sydney Children's Hospitals Network.[59] It is expected that this trial will start enrolling patients in 2016, with results available 'within two to five years'.[60]

2.60 It was also announced that two further trials are being investigated, with NSW Health stating that it will 'work with the research community to assess interest in proceeding with trials' in the areas of:

- adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting; and
- adults with chemotherapy-induced nausea and vomiting, where standard treatment is ineffective.[61]

2.61 In April 2015, it was announced that the Queensland and Victorian state governments had agreed to take part in the clinical trials being conducted in NSW, allowing patients from those states to apply to be part of the upcoming trials.[62]

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56 *Committee Hansard*, 31 March 2015, p. 39.

57 New South Wales Government, 'NSW leads the way on medical cannabis', 16 September 2014, http://www.nsw.gov.au/news/medical-cannabis-trial (accessed 25 May 2014).

58 New South Wales Government, 'Clinical Trials of Cannabis Products', http://www.health.nsw.gov.au/cannabis/Pages/clinical-trials.aspx (accessed 25 May 2015).

59 ABC News Online, 'Medicinal marijuana: NSW to run trials for epileptic children, terminally ill adults and cancer patients', 21 December 2014, http://www.abc.net.au/news/2014-12-21/medicinal-marijuana-nsw-govt-to-run-trial-for-epileptic-children/5981648 (accessed 5 May 2015).

60 New South Waled Government, 'Clinical Trials: Medical Use of Cannabis Fact Sheet', available at http://www.health.nsw.gov.au/cannabis/Pages/clinical-trials.aspx (accessed 25 May 2015).

61 New South Waled Government, 'Clinical Trials: Medical Use of Cannabis Fact Sheet', available at http://www.health.nsw.gov.au/cannabis/Pages/clinical-trials.aspx (accessed 25 May 2015).

62 ABC News Online, 'Medical cannabis: Queensland, Victoria and New South Wales join forces on cannabis oil in medical trials', http://www.abc.net.au/news/2015-04-19/queensland-victoria-join-nsw-medicinal-cannabis-trial/6403760 (accessed 25 May 2015).

Victorian Government commitment to legalising medicinal cannabis

2.62 In December 2014, the Victorian Government announced its intention to legalise medical cannabis for individuals with terminal illnesses or life-threatening conditions,[63] and referred the matter of options for implementing this proposed reform to the Victorian Law Reform Commission (VLRC).[64] The VLRC published an issues paper on medicinal cannabis on 17 March 2015, stating that the two primary lines of inquiry being pursued by the VLRC were:

- how to define the exceptional circumstances in which a person should be allowed to be treated with medicinal cannabis; and
- how the law could be amended to enable an authorised person to receive the treatment they need while continuing to prevent unauthorised access in other circumstances by other persons.[65]

2.63 The VLRC issues paper came to the conclusion that:

> A comprehensive medicinal cannabis scheme could be introduced in Victoria, although it would rely on collaboration with the Commonwealth, which has a broad role in regulating the importation, manufacture and distribution of pharmaceutical goods in Australia. A more limited scheme could be introduced by Victoria acting alone.[66]

2.64 Community consultations relating to the issues paper were scheduled to continue until the end of May 2015, with the VLRC scheduled to produce a final report to the Victorian Government by the end of August 2015.[67]

Regulatory approaches to medical cannabis in international jurisdictions

2.65 The *Medicinal Cannabis: Issues Paper* (issues paper) notes that a number of jurisdictions permit the use of cannabis for medicinal purposes in some form, including Canada, the Czech Republic, Finland, Germany, Israel, Italy, the Netherlands and 23 states of the United States of America (US). The issues paper states that:

> A further 12 US states…permit use of low-THC, high-CBD cannabis, in some cases for research and trials only…In addition, Uruguay and the US

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63 ABC News Online, 'Victorian Government moves ahead with plans to legalist medical marijuana', 19 December 2014, http://www.abc.net.au/news/2014-12-19/victorian-government-moves-ahead-with-plans-to-legalise-medical/5980636 (accessed 25 May 2015).

64 Victorian Law Reform Commission, 'Terms of Reference – Medicinal cannabis', 23 December 2015, http://www.lawreform.vic.gov.au/projects/medicinal-cannabis/terms-reference-medicinal-cannabis (accessed 25 May 2015).

65 Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper*, March 2015, p. 3.

66 Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper*, March 2015, p. 166.

67 Victorian Law Reform Commission, 'Medicinal Cannabis – Issues Paper', 17 March 2015, http://www.lawreform.vic.gov.au/projects/medicinal-cannabis/medicinal-cannabis-issues-paper (accessed 25 May 2015).

> states of Alaska, Colorado, Oregon and Washington have legalised cannabis for recreational use.[68]

2.66 The issues paper provides a comprehensive analysis of the means employed by different jurisdictions to regulate the use, manufacture and distribution of cannabis products, making particular reference to the nature and form of authorised cannabis products, the class of person who can legally access cannabis products and the role of health practitioners in accessing cannabis products.[69]

2.67 NDARC explained that the legislative basis for the availability of medicinal cannabis in international jurisdictions:

> …ranges from simple removal of criminal sanctions for patients whose medical doctor has recommended the use of cannabis, to state-level provisions of medicinal-grade herbal cannabis or pharmaceutical preparations obtained by the patient from a pharmacy with a doctor´s prescription...[The] variety of approaches offer different advantages and limitations in terms of treatment availability, product quality and its adherence to medicinal product standards, as well as in their overlap with the recreational market, and adherence to the international treaties...They also differ in the range of supply options.[70]

2.68 NDARC identified two scales, the form of patient authorisation and the source of supply, which it used to examine the available regulatory options for medicinal cannabis.[71] A table providing an overview of the pros and cons of currently deployed modes of patient access and supply of medicinal cannabis across the globe as submitted by NDARC is included at Appendix 3 to this report.

2.69 To better understand the range of international models currently used, examples are briefly discussed below of legislative models where supply is less regulated (California), where supply is more regulated (Washington) and where supply is highly regulated (the Netherlands).

The Californian approach

2.70 In 1996, California voters passed Proposition 215, the *Compassionate Use Act of 1996*, making it the first US state to allow for the medical use of marijuana.[72] Proposition 215 was supported by Senate Bill 420 which amended the Health and Safety Code of California to require the California Department of Public Health to

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68 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, pp 108–109.

69 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, ch. 6.

70 National Drug and Alcohol Research Centre of the University of New South Wales, *Submission 19*, p. 9.

71 National Drug and Alcohol Research Centre of the University of New South Wales, *Submission 19*, pp 9–11.

72 National Conference of State Legislatures, *State Medical Marijuana Laws*, http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (accessed 2 June 2015).

oversee the creation of the medical marijuana program (MMP).[73] The MMP adopted a medical marijuana identification card (MMIC) to give registered patients and caregivers access to a card, valid for one year, that provides the holder with immunity from prosecution for possession of up to 8 ounces (approximately 228 grams) of dried marijuana and up to 6 mature or 12 immature marijuana plants.[74] Where a patient has been diagnosed as suffering from a prescribed serious medical condition, he or she may approach his or her medical practitioner for a recommendation. The diagnosis and the recommendation that the use of medical marijuana would be appropriate for the patient must be documented in the patient's medical records.[75] The patient may then enrol in the MMP at the county (local government) level by providing a copy of the recommendation, proof of identity and residency, and by paying the requisite fees.[76] A patient may also apply for a supplementary card for a primary caregiver, that is, a person who is consistently responsible for the housing, health, or safety of a qualified patient.[77]

2.71 A minor (under 18 years of age) may apply as a patient or caregiver under certain conditions. Minors may apply for themselves as qualified patients if they are lawfully emancipated or have declared self-sufficiency status. If a minor has not declared self-sufficient status or is not emancipated, the relevant local government must contact the minor's parent, legal guardian, or person with legal authority to make medical decisions for the minor.[78]

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73 California Department of Public Health, ' What are Proposition 215 (Prop 215), the Compassionate Use Act of 1996, and Senate Bill (SB) 420', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#1 (accessed 2 June 2015).

74 California Department of Public Health, ' How much marijuana can I have in my possession?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#31 (accessed 2 June 2015).

75 California Department of Public Health, ' How do I know if I qualify for a MMIC?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#4 (accessed 2 June 2015).

76 California Department of Public Health, 'I am a qualified patient. How and what documentation do I need to apply for a MMIC?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#6 (accessed 2 June 2015).

77 California Department of Public Health, 'What is a primary caregiver?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#9 (accessed 2 June 2015).

78 California Department of Public Health, ' Can a minor apply for a MMIC?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#26 (accessed 2 June 2015).

2.72 The Californian MMP is not authorised to provide information on the type of marijuana that should be used, nor the means of acquiring the dried marijuana, seeds or plants. It follows that the supply of the product is not regulated.[79]

2.73 In 2010 Californian voters rejected Proposition 19, which would have legalised various marijuana-related activities and allowed local governments to regulate and tax these activities.[80] As at May 2015, three competing Bills were being considered by the Californian legislature, two in the assembly and one in the senate, each attempting to create a framework that would codify how medical marijuana is grown and sold in California.[81]

The State of Washington approach

2.74 In 1998, the voters of the State of Washington approved Initiative Measure No. 692, which changed public policy to permit the medical use of marijuana. Since 1998, the concept of medicinal use of marijuana has been clarified to better protect the welfare of patients, ensuring that they had access to a safe, consistent and adequate source of marijuana. However, although permitted possession amounts were defined by legislation, the legislation did not provide protection from arrest. The legislation only provided a patient with a defence at trial.[82]

2.75 In 2012, voters passed Initiative Measure No. 502 which also resulted in Chapter 314–55 of the Washington Administrative Code on marijuana licensing of coming into effect. The initiative allows for the possession and use of marijuana for recreational purposes. The recreational scheme runs parallel to the medicinal marijuana scheme. The initiative decriminalises possession of marijuana by a person of 21 years or older, up to the prescribed amounts [83] and permits the sale of marijuana to individuals over the age of 21. An individual may possess up to 1 ounce (28.5 grams) of dried marijuana, 16 ounces (approximately 456 grams) of marijuana-infused product in solid form or 72 ounces (approximately 2.13 litres) of marijuana-infused product in liquid form.[84] The initiative only allows for private use of marijuana,

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79 California Department of Public Health, 'Where can I get the seeds or plants to start growing marijuana for my medical use? How can I get related products?', *Medical Marijuana Program Frequently Asked Questions*, https://www.cdph.ca.gov/programs/MMP/Pages/MMPFAQ.aspx#32 (accessed 2 June 2015).

80 California Legislative Analyst's Office, *Proposal*, http://www.lao.ca.gov/ballot/2009/090512.aspx (accessed 2 June 2015).

81 Anita Chabria, 'California looks to bring law and order to decades-old medical marijuana market', *The Guardian*, http://www.theguardian.com/us-news/2015/may/03/california-law-and-order-medical-marijuana-market (accessed 2 June 2015).

82 *Medical Marijuana Regulation, Second Substitute Senate Bill 5052, Chapter 70 of 2015*, s. 2, http://lawfilesext.leg.wa.gov/biennium/2015-16/Pdf/Bills/Session%20Laws/Senate/5052-S2.SL.pdf (accessed 2 June 2015).

83 *Washington Initiative Measure No. 502*, ss. 20(3), http://sos.wa.gov/_assets/elections/initiatives/i502.pdf (accessed 2 June 2015).

84 *Washington Initiative Measure No. 502*, ss. 15(3), http://sos.wa.gov/_assets/elections/initiatives/i502.pdf (accessed 2 June 2015).

making it unlawful to open a package containing marijuana or consume the drug in view of the general public.[85] The regulatory scheme is administered by the state Liquor and Cannabis Board (formerly the Liquor Control Board) and provides for strict regulation of the production, processing, and distribution of marijuana. Under the initiative, marijuana is traceable from seed to sale and may only be sold or grown under license. Marijuana must also be tested for impurities and purchasers of marijuana must be informed of the THC level in the marijuana.[86]

2.76 In October 2013, the then Liquor Control Board adopted detailed rules for implementing Initiative 502. These rules describe the marijuana license qualifications and application process, application fees, marijuana packaging and labelling restrictions, recordkeeping and security requirements for marijuana facilities, and reasonable time, place, and manner advertising restrictions. Under the rules, Washington State imposes an excise tax of 25% of the selling price on each licenced marijuana sale, taxing each point of the sales process: from producer to processor, from processor to retailer, and from retailer to consumer.[87]

2.77 On 24 April 2015, the *Medical Marijuana Regulation, Second Substitute Senate Bill 5052, Chapter 70 of 2015* (Cannabis Patient Protection Act 2015 or CPPA) was made law.[88] The CPPA was intended to shift the regulation of medicinal cannabis to fall under the same regulations developed under Initiative Measure No. 502, regulating the recreational cannabis market. The CPPA was also designed to ensure that patients retain their ability to grow their own marijuana for their own medical use and that patients have the ability to possess more marijuana-infused products, useable marijuana, and marijuana concentrates than what is available to a non-medical user. It further allows for medical-specific regulations to be adopted as needed, after consultation with the departments of health and agriculture, so that safe handling practices and testing standards for medical products meet or exceed those standards in use in the recreational market.[89]

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85 *Washington Initiative Measure No. 502*, s. 21, http://sos.wa.gov/_assets/elections/initiatives/i502.pdf (accessed 2 June 2015).

86 *Medical Marijuana Regulation, Second Substitute Senate Bill 5052, Chapter 70 of 2015*, s. 2, http://lawfilesext.leg.wa.gov/biennium/2015-16/Pdf/Bills/Session%20Laws/Senate/5052-S2.SL.pdf (accessed 2 June 2015).

87 Congressional Research Service, *State Legalization of Recreational Marijuana: Selected Legal Issues*, 13 January 2014, p. 3, http://www.fas.org/sgp/crs/misc/R43034.pdf (accessed 2 June 2015).

88 Washington State Department of Health, 'What's New' *Medical Marijuana (Cannabis)*, http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/MedicalMarijuanaCannabis (accessed 2 June 2015).

89 *Medical Marijuana Regulation, Second Substitute Senate Bill 5052, Chapter 70 of 2015*, s. 2, http://lawfilesext.leg.wa.gov/biennium/2015-16/Pdf/Bills/Session%20Laws/Senate/5052-S2.SL.pdf (accessed 2 June 2015).

The Dutch approach

2.78 In the Netherlands, the production of medicinal cannabis is overseen by the *Bureau voor Medicinale Cannabis* (the Office for Medicinal Cannabis or OMC), which supervises both growers and distributors and guarantees the quality of medicinal cannabis products sold in the Netherlands. The OMC also has a monopoly on the import and/or export of medicinal cannabis and its supply.[90]

2.79 Cannabis is cultivated in the Netherlands by a single, state-licenced supplier, Bedrocan BV, a limited liability company. Cultivation is strictly controlled ensuring a highly standardised product with a consistent genetic profile.[91] To be sold in the Netherlands, medicinal cannabis must meet certain quality criteria and must not contain any pesticides, heavy metals, fungi or bacteria. To ensure quality control, an independent company contracted by the government tests each batch of cannabis and provides a certificate of analysis, which is made available for inspection by patients and doctors.[92]

2.80 The OMC allows for selected varieties of cannabis to be purchased on prescription through Dutch pharmacies, each with a different composition and strength to best target the symptoms of the individual patient. Although the method of administering the medicinal cannabis is not regulated, it is recommended that the patient avoid smoking the medicinal cannabis, but instead employ methods such as drinking a tea made from the cannabis or inhaling the product through an inhaler.[93]

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90 Bureau voor Medicinale Cannabis, 'What is the Office of Medicinal Cannabis?', http://www.cannabisbureau.nl/en/ (accessed 1 June 2015).

91 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, p. 110.

92 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper*, 17 March 2015, p. 111.

93 Bureau voor Medicinale Cannabis, *Medicinal Cannabis: Information for patients*, pp 5-7, http://www.cannabisbureau.nl/en/doc/pdf/5089-A5-BMC-Pat-ENG-web_35842.pdf (accessed 1 June 2015).

Chapter 3

Overview and key provisions of the Bill

3.1 As noted in chapter 1, the Bill seeks to establish a Regulator of Medicinal Cannabis (Regulator) as a listed entity under the *Public Governance, Performance and Accountability Act 2013*.

3.2 The Explanatory Memorandum to the Bill (EM) states that the Regulator would 'be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis'.[1]

Overview of the Bill and general provisions

3.3 The Bill is divided into five Parts, as follows:

- Part 1—Preliminary outline: includes commencement provisions, an objects clause, relevant definitions, and application provisions;
- Part 2—Medicinal cannabis: contains seven divisions outlining the responsibilities of the Regulator in relation to medicinal cannabis, including maintaining a register of medicinal cannabis products, developing standards in relation to medical cannabis products and related activities, maintaining an authorised patients and carers scheme, and developing licensing schemes relating to the production, transport, import and export, and provision of medicinal cannabis products;
- Part 3—Regulator of Medicinal Cannabis: contains provisions to establish the Regulator as a listed entity under the *Public Governance, Performance and Accountability Act 2013* and sets out the Regulator's functions, powers and procedures;
- Part 4—Monitoring and investigation powers: contains provisions enabling authorised officers to undertake monitoring and investigation activities in relation to the Bill; and
- Part 5—Miscellaneous: includes provisions relating to reviewable decisions, protection from criminal or civil actions, and a rule-making power enabling the Regulator to prescribe matters relating to the Bill.

3.4 Clause 3 of the Bill states that its objects are to:

(a) establish a Regulator of Medicinal Cannabis to perform the functions of the agency referred to in Article 23 of the Single Convention on Narcotic Drugs 1961, as it applies in relation to cannabis because of Article 28 of the Convention; and

(b) provide for a national system, to apply in participating States and Territories, for regulating the production and use of medicinal cannabis

1 Explanatory Memorandum to the Bill (EM), p. 1.

products, and related activities such as research, in accordance with the Convention.

3.5 Several overarching issues are noteworthy in terms of the construction of the Bill, namely: the stated relationship between the Bill and other Commonwealth laws; the rule-making power to be vested in the Regulator in order to accomplish many of the purposes of the Bill; and the proposed application of the Bill within Australia.

Exemption from the operation of other Commonwealth laws

3.6 The EM states that the Regulator would provide an alternate regulatory framework to the current system, in which cannabis products are regulated under the *Therapeutic Goods Act 1989* (TG Act):

> This Bill provides for a system of regulating medicinal cannabis that is entirely separate from the [TG Act]. A number of provisions of the Bill make it clear that the [TG Act] does not apply to things done in accordance with licences or authorisations issued by the new Regulator of Medicinal Cannabis. However, this would not prevent pharmaceutical companies applying to the Therapeutic Goods Administration to sell medicinal cannabis instead of using the scheme established by this Bill. They will effectively have a choice about which system to use (although the cultivation of medicinal cannabis will only be covered by this Bill).[2]

3.7 In some instances, the application of the TG Act would still apply for limited purposes under specific provisions of the Bill; these are discussed in further detail below.

Rule-making power

3.8 The EM states that the Regulator 'will be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis'.[3] The rule-making power of the Regulator is contained in clause 63 of the Bill, which states that the Regulator may, by legislative instrument, make rules prescribing matters: required or permitted by the Bill to be prescribed by the rules; or necessary or convenient to be prescribed for carrying out or giving effect to the Bill.

3.9 Key aspects of the regulatory framework envisaged by the Bill are to be established under the rules, rather than codified in the Bill itself, including aspects relating to the medicinal cannabis licensing scheme, authorised patients and carers scheme, experimental cannabis licensing scheme, import and export licensing scheme, and medicinal cannabis standards.

Application of the Bill only in participating states and territories

3.10 Clause 7 of the Bill provides that the Bill would only apply in participating states or territories in Australia. Under subclause 7(2) of the Bill, the minister may

2 EM, p. 1.

3 EM, p. 1.

make a determination in writing that a state or territory is a participating state or territory if that state or territory has entered into an agreement with the Commonwealth for the Bill to apply in that jurisdiction.

3.11 The EM states:

> The medicinal cannabis system set up by the Bill is to be implemented cooperatively between the Commonwealth and the States and Territories. The States and Territories are likely to have to change their own laws relating to cannabis if they wish to participate.
>
> The Minister may make a determination that a State or Territory that has entered into an arrangement with the Commonwealth to participate in the system is a participating State or Territory. The Ministerial determination is a legislative instrument, but is not subject to disallowance. This reflects the fact that it represents the existence of an agreement between a State or Territory and the Commonwealth.[4]

Responsibilities and powers of the Regulator

3.12 Part 2 of the Bill contains the detailed responsibilities of the Regulator in relation to medicinal cannabis in Australia. Clause 11 of the Bill outlines that the new Regulator would be responsible 'for maintaining a register of regulated medicinal cannabis products, which lists cannabis products approved by the regulator', and that the Regulator would be empowered to make various schemes in relation to the regulation of medicinal cannabis in Australia, namely:

- a medicinal cannabis licensing scheme, under which licenses may be given for the cultivation, production and distribution of medicinal cannabis;
- an authorised patients and carers scheme, for authorising patients, carers and medical practitioners;
- an experimental cannabis licensing scheme, under which licenses may be given for the experimental production and use of medicinal cannabis;
- standards for medicinal cannabis; and
- an import and export licensing scheme, under which licenses may be given for the import and export of medicinal cannabis.

Register of regulated medicinal cannabis products

3.13 Division 2 of Part 2 of the Bill would provide for a register of regulated medicinal cannabis products (Register). Clause 12 of the Bill states that the Regulator must maintain such a Register in the manner prescribed by any rules made by the Regulator.

3.14 Subclause 13(1) of the Bill would provide that a person may apply to the Regulator for a cannabis product to be included in the Register in relation to that person. Subclause 13(2) states that the Regulator may include a cannabis product in the Register in relation to the person that has made the application if it is satisfied that:

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4 EM, p. 3.

- the cannabis product is suitable for medicinal use;
- the cannabis product complies with any standard made under the Bill that applies to the product;
- including the cannabis product in the Register in relation to the person would be consistent with the Single Convention;
- it is appropriate in all the circumstances for the cannabis product to be regulated under the Bill; and
- any requirements prescribed by the rules are met.[5]

3.15 Subclause 13(3) provides that the rules made by the Regulator (under clause 63 of the Bill) may prescribe: the manner in which an application is to be made; matters to which the Regulator may, or must, have regard in making a decision about whether to approve an application; and procedures to be followed by the Regulator in making such a decision.

3.16 Clause 14 of the Bill states that the rules may provide for an entry in the Register to be removed or varied, either on application by the person in relation to whom the entry is registered, or on the Regulator's own initiative.

3.17 The EM states in relation to the Register:

> The register is modelled on the Australian Register of Therapeutic Goods…The Bill leaves detail, such as the manner in which the register is to be maintained, to the rules rather than setting it out in the Bill. The rationale for the register being set out in the rules is to give the Regulator the flexibility to make arrangements appropriate for a new medicinal cannabis industry and to allow the Regulator to align the register with the Australian Register of Therapeutic Goods, as appropriate.[6]

Medicinal cannabis licensing scheme

3.18 Division 3 of Part 2 of the Bill would provide for the creation of a medicinal cannabis licensing scheme.

3.19 Under subclause 16(1) of the Bill, the rules made by the Regulator may prescribe a scheme for the Regulator to issue licences authorising persons to engage in one or more of:

- producing cannabis for medicinal or experimental use;
- transporting or storing cannabis for medicinal or experimental use;
- manufacturing regulated medicinal cannabis products;
- transporting or storing regulated medicinal cannabis products; and

5 Regulator of Medicinal Cannabis Bill 2014, paragraphs 13(2)(b)-(f).

6 EM, pp 3-4.

- providing regulated medicinal cannabis products to authorised patients and authorised carers.[7]

3.20 Under subclause 16(3) of the Bill, the scheme must provide for any medicinal licence granted to be subject to such conditions as would ensure that:

- all cannabis produced, and all cannabis products manufactured, in accordance with the scheme are accounted for; and
- any relevant standards are complied with; and
- the scheme operates in accordance with the Single Convention.[8]

3.21 Under clause 17 of the Bill, a medicinal licence holder would commit an offence if they failed to comply with any conditions imposed under the licence.[9]

Application of other Commonwealth laws to the medicinal cannabis licensing scheme

3.22 Subclause 16(4) of the Bill states that the *Narcotic Drugs Act 1967* (Narcotic Drugs Act) and the *Therapeutic Goods Act 1989* (TG Act) 'do not apply in relation to an activity engaged in, or a thing dealt with, in accordance with a medicinal licence' granted under the Bill.

3.23 Subclause 16(5) would provide, however, that preceding subclause does not prevent the TG Act from applying in relation to:

> (a) the manufacture of therapeutic goods (within the meaning of 3 that Act) from cannabis produced, transported or stored in accordance with a medicinal licence; or
>
> (b) therapeutic goods manufactured as referred to in paragraph (a);
>
> if the goods are not included in the register of regulated medicinal cannabis products in relation to the manufacturer.

3.24 The EM explains these provisions as follows:

> Subclause 16(5) allows for cannabis to be produced under a medicinal licence and then used in the manufacture of cannabis-based medicines that are regulated under the Therapeutic Goods Administration (TGA) instead of under this Bill.
>
> The medicinal licence that will be issued will therefore sit outside of the scope of Narcotics Drug Act and the TGA. This does not stop applications to the TGA in relation to the manufacture of cannabis-based medicines.[10]

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7 Regulator of Medicinal Cannabis Bill 2014, paragraphs 16(1)(a)-(e).

8 Regulator of Medicinal Cannabis Bill 2014, paragraphs 16(2)(a)-(d).

9 Similar offence provisions are contained in clause 21 (in relation to experimental licences) and clause 25 (in relation to import and export licence holders).

10 EM, p. 4.

Authorised patients and carers scheme

3.25 Division 4 of Part 2 of the Bill would provide for the creation of an authorised patients and carers scheme.

3.26 Under subclause 19(1) of the Bill, the rules may prescribe an 'authorised patients and carers scheme' to provide for the authorisation of patients to use regulated cannabis products, carers to supply such products to authorised patients, and medical practitioners to prescribe regulated medicinal cannabis products.

3.27 Under subclause 19(2), authorisations to patients or carers must only be given on request by a medical practitioner, and be subject to any conditions necessary to ensure that the scheme operates in accordance with the Single Convention.

3.28 Subclause 19(3) would provide that the scheme may be set up to allow for authorisations to be made by the Regulator or by appropriate authorities of participating states and territories.

3.29 Subclause 19(4) states that the Narcotic Drugs Act and TG Act would not apply in relation to actions taken under the authorised patients and carers scheme.

Experimental cannabis licensing scheme

3.30 Division 5 of Part 2 of the Bill deals with the establishment of an experimental cannabis licensing scheme.

3.31 Under subclause 20(1) of the Bill, the rules may prescribe an experimental cannabis licensing scheme for the Regulator to issue experimental licences authorising persons (experimental licence holders) to: produce, manufacture, transport, store, provide, administer, and perform tests on cannabis or cannabis products for an experimental purpose.

3.32 Subclause 20(2) lists a number of purposes to be included as 'experimental purposes' under the scheme, including

- developing and testing varieties of cannabis for medicinal use;
- improving methods of cultivating cannabis for medicinal use;
- developing and testing cannabis products for medicinal use;
- evaluating the efficacy or safety of cannabis products for medicinal use;
- improving methods of using or administering cannabis products for medicinal purposes; and
- performing tests, trials and other experiments for the purposes of making or supporting an application under the Bill or the TG Act, or considering whether to make such an application.[11]

3.33 The EM states in relation to this scheme:

> Research and development of medicinal cannabis is a growing field of science. It is important that research into types and strains of cannabinoids

11 Regulator of Medicinal Cannabis Bill 2014, paragraphs 20(2)(a)-(f).

> and medicinal cannabis be encouraged and furthered by the Regulator… The Regulator will…be responsible for issuing licences and prescribing a scheme for research and experiments with medicinal cannabis.
>
> For example, an experimental purpose may include experimentation in the development of cannabis products, and varieties of cultivated cannabis, that have reduced psychoactive effects while still having therapeutic effects.[12]

3.34 Under subclauses 20(5)–(6), the Narcotic Drugs Act and TG Act would not apply in relation to authorised actions taken under the experimental licensing scheme, except insofar as they would allow the results of an experiment or trial conducted in accordance with an experimental licence being taken into account in a decision made for the purposes of the TG Act.

Medicinal cannabis standards

3.35 Division 6 of Part 2 of the Bill would provide for the determination of standards in relation to medicinal cannabis.

3.36 Under subclause 23(1) of the Bill, the rules may provide for the Regulator to determine, by legislative instrument, standards for cannabis or cannabis products, and activities that may be carried out under a medicinal licence or an experimental licence.

3.37 Subclause 23(2) of the Bill states that such standards may:

- be specified by reference to: quality or quantity of a cannabis product; characteristics of a cannabis variety;
- require that a matter relating to the standard be determined in accordance with a particular test; or
- relate to the packaging and labelling requirements for particular cannabis products or classes of products.

Import and export licensing scheme

3.38 Division 7 of Part 2 of the Bill deals with the creation of an import and export licensing scheme for cannabis and cannabis products.

3.39 Under clause 24, the rules may prescribe a scheme for the regulator to issue licences authorising persons to import and export cannabis or cannabis products for medicinal or experimental purposes. Subclause 24(3) specifies that any import or export licenses granted must be subject to conditions that ensure for the accounting of all cannabis products imported or exported, and ensure that the scheme operates in accordance with the Single Convention.

3.40 Subclause 24(4) states that the Narcotic Drugs Act and TG Act would not apply in relation to actions taken under the import and export licensing scheme.

Establishment of the Regulator

3.41 Part 3 of the Bill deals with the establishment, functions, appointments, staffing and procedures of the Regulator.

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12 EM, pp 4-5.

3.42 Clause 28 of Division 2 of Part 3 of the Bill would establish the Regulator as a listed entity for the purposes of the *Public Governance, Performance and Accountability Act 2013*, with officials consisting of members, a Chief Executive Officer, and staff.

Functions and powers of the Regulator

3.43 Clause 30 of the Bill details the functions and powers of the Regulator. It provides that the Regulator would have the functions of the state agency referred to in Article 23 of the Single Convention, as it applies in relation to cannabis. Additionally, the functions of the Regulator would include:

- to enter into contracts with medicinal licence holders, experimental licence holders, import licence holders and export licence holders;
- to supply cannabis and cannabis products within Australia, for medicinal or experimental purposes, as well as for the manufacturing regulated medicinal cannabis products;
- to investigate possible breaches of the Bill or the rules;
- to advise and make recommendations to the minister on matters relating to medicinal or experimental cannabis and cannabis products;
- to collect, analyse, interpret and disseminate information and statistics relating to medicinal or experimental cannabis and cannabis products;
- to educate and inform patients, carers, health workers and the community about the medicinal use of regulated medicinal cannabis products, and provide relevant training to health workers; and
- to cooperate with its counterparts in other countries and with law enforcement agencies in Australia and overseas.[13]

3.44 Subclause 30(5) specifies that the Narcotic Drugs Act and the TG Act do not apply in relation to the performance of the Regulator's functions or the exercise of its powers.

3.45 Clause 32 of the Bill would allow the minister, by legislative instrument, to give directions to the Regulator if the minister considered that a direction was necessary to ensure that Australia complies with its obligations under the Single Convention.

Membership of the Regulator and staffing arrangements

3.46 Under clause 29 of the Bill, the Regulator would consist of a Chair and 5 other members. The appointment of members is outlined in clause 34 of the Bill, with the Chair to be a full-time appointment made by the minister, and the other members to be part-time appointments made by the minister. Members would be appointed for a period of up to five years.

13 Regulator of Medicinal Cannabis Bill 2014, paragraphs 30(1)(a)-(l).

3.47 Under subclauses 34(3)–(4), appointees would have to have knowledge or experience in one or more of the following fields: medicine, pharmacology, palliative care, botany, horticulture, law, law enforcement, or patient advocacy. Further, the minister would be required to ensure that the membership of the Regulator included at least one medical practitioner, one member of the Australian Federal Police and one member representing patients and users. The EM states that this arrangement 'provides a balance of interests and ensures law enforcement is at the centre of decision making by the Regulator'.[14]

3.48 Clause 49 of the Bill specifies that the Chair should also be appointed as the Chief Executive Officer (CEO) of the Regulator, to be responsible for the management and administration of the Regulator. Under clause 51, staff for the Regulator may be engaged under the *Public Service Act 1999*.

Monitoring and investigation powers

3.49 Part 4 of the Bill contains the monitoring and investigation powers that would be performed by the Regulator. The EM states in relation to these provisions:

> Cannabis is a drug that is not legal in Australian states and territories. As with the Australian poppy industry, cannabis can be used for medicinal purposes as well as being a drug that is not legally available and carries criminal sanctions for cultivation, transport, possession and trafficking. It is necessary that sanctions and penalties apply to any authorised person who abuses or misuses their obligations to the Regulator to provide, supply or use cannabis for medicinal purposes.
>
> Both the public and law enforcement agencies must be confident that there are strict provisions in place so that only those authorised have access to medicinal cannabis and that manufacture and use is conducted under strict guidelines.[15]

3.50 Clause 55 of the Bill would provide that the Regulator may authorise its members, staff and any officers or employees of participating states and territories assisting the Regulator, to carry out monitoring and investigation powers.

3.51 Under clause 56 of the Bill, the monitoring powers available under the Bill would be those contained in Part 2 of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act). The Bill notes that Part 2 of the Regulatory Powers Act creates a framework for monitoring whether specified provisions have been complied with, including powers of entry, search and inspection.

3.52 Under subclause 56(1), the provisions of the Bill subject to these monitoring provisions would be those provisions of Part 2 relating to the proposed register of medicinal cannabis products, medicinal cannabis licensing scheme, experimental cannabis licensing scheme, import and export licensing scheme, and medicinal cannabis standards.

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14 EM, p. 6.

15 EM, p. 6.

3.53 Clause 57 of the Bill outlines investigation powers that would be available to the Regulator. Under subclause 57(1), any offences committed against the offence provisions of the Bill, as well as offences against the *Crimes Act 1914* or the *Criminal Code Act 1995* that relate to the Bill, would be subject to investigation under Part 3 of the Regulatory Powers Act.[16] Under subclause 57(4), any person authorised under clause 55 of the Bill would be authorised to exercise investigative powers as outlined in Part 3 of the Regulatory Powers Act.

3.54 In relation to why the Bill takes the approach of vesting the Regulator with standard powers under the Regulator Powers Act, the EM notes:

> The monitoring and investigative powers in the Bill apply only to people authorised by the Regulator to cultivate, supply, import, export or experiment with medicinal cannabis. A person or persons applying to the Regulator for a licence will be advised of the monitoring and investigative powers.
>
> That is why this Bill takes the approach of applying the Regulatory Powers (Standard Provisions) Act 2014 (the RP(SP) Act) to give the Regulator certain monitoring and investigation powers. The RP(SP) Act provides a set of standard powers that other Acts establishing regulatory agencies can apply.
>
> The powers conferred by these provisions, such as search, entry and seizure powers, may appear intrusive; however they only apply to people who have applied to become licence holders or authorised users of medicinal cannabis. The powers in the provisions do not apply to the general public or anyone not licenced or authorised by the Regulator.[17]

Other provisions

3.55 Several provisions in Part 5 of the Bill are also of note.

3.56 Clauses 59–60 of the Bill outline a process for reviewing decisions made by the Regulator, including decisions relating to the granting of licences, the inclusion or removal of products from the register of medicinal cannabis products, and authorisations made under the authorised patients and carers scheme. Under clause 60, these decisions would be reviewable on application to the Administrative Appeals Tribunal.

3.57 Clause 62 of the Bill would provide protection against criminal or civil actions for actions taken by a person in good faith in accordance with the Bill or in performance of the Regulator's functions or exercise of its powers. This protection would be available to the minister, members and staff of the Regulator, other Commonwealth authorities, other statutory office holders, and other persons appointed to assist the Regulator in its duties.

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16 The Bill notes that Part 3 of the Regulatory Powers Act created a framework for investigating whether offences that are subject to investigation have been committed, and it includes powers of entry, search, inspection and seizure.

17 EM, p. 7.

Chapter 4

Key Issues

4.1 Submitters and witnesses to the inquiry raised various issues relating to the regulation of medicinal cannabis.

4.2 The first part of this chapter examines the issues associated with the way medicinal cannabis is currently regulated in Australia, drawing on evidence from academics, organisations and individuals who contributed to the inquiry.

4.3 The second part of this chapter explores comments made by submitters and witnesses in relation to the specific reforms proposed by the Bill.

Issues arising from Australia's current regulatory approach to medicinal cannabis

4.4 Submitters and witnesses presented evidence that the current regulatory environment in Australia is not conducive to the proper evaluation and implementation of medicinal cannabis products. Issues raised over the course of the inquiry included: the lack of information available about the current use of illicit cannabis in Australia for medicinal purposes; the inability of state and territory governments to implement reforms in this area without Commonwealth assistance; and the difficulties associated with gaining approval for medicinal cannabis products through the Therapeutic Goods Administration (TGA).

Information about the use of cannabis for medicinal purposes in Australia

4.5 One issue complicating the debate surrounding the regulation of medicinal cannabis in Australia is the absence of any clear data in relation to current usage of illicit cannabis for medicinal purposes. Professor Allison Ritter, Director of the Drug Policy Modelling Program at the National Drug and Alcohol Research Centre (NDARC), confirmed that there is currently no data available or independent researchers trying to objectively assess this issue in Australia.[1] Despite this lack of official data, the committee did receive information from various groups that help illuminate, at least partially, the level of use of medicinal cannabis in Australia.

4.6 Medicinal cannabis advocacy user groups that contributed evidence to the inquiry included the Medicinal Cannabis Users Association of Australia, which claims to represent over 6,000 Australians currently involved in the production or use of cannabis for medicinal purposes.[2]

4.7 Mr Lance Feeney, Policy Analyst at the National Association of People Living with HIV Australia, stated that recent survey data from HIV-positive

1 *Committee Hansard*, 31 March 2015, p. 40.

2 *Submission 145*, pp 1 and 18.

individuals in Australia indicates that approximately 20 per cent of respondents use cannabis for therapeutic and symptom relief.[3]

4.8 Epilepsy Action Australia commented on the current usage of medicinal cannabis products for epileptic conditions:

> We understand from social media and other sources that a number of consumers (parents) in Australia are gaining access to cannabis derivatives to treat seizures in the form of tinctures and oils. Given the catastrophic and debilitating nature of their children's epilepsy conditions it is not difficult to understand their desperation. These parents report immense improvement in the severity and frequency of their children's seizures and overall quality of life.[4]

4.9 Throughout the course of this inquiry, the committee received evidence from many individuals who relayed how medicinal cannabis products had assisted them or their family members in alleviating the symptoms associated with a range of medical conditions, many of extreme severity. Two of their stories are included here as case studies.

4.10 The first case study is of Mrs Lucy Haslam, who gave evidence at the committee's public hearing in Sydney about her son Daniel's use of medicinal cannabis to provide relief during chemotherapy treatment for bowel cancer, from which he sadly passed away in early 2015.

Case Study 1 – Mrs Lucy Haslam

Daniel was diagnosed with stage 4 bowel cancer when he was 20. He had three years of treatment, which involved a lot of major surgeries but also a lot of chemotherapy. He was three years into chemotherapy and he was told basically that for as long as he lived he would require chemotherapy.

But for him chemotherapy was not just something that you slotted into your routine; it was a major issue for our whole family because he became so violently ill from the chemotherapy. Daniel developed what is called anticipatory nausea, which is quite common in young people who are on very strong chemotherapy. Just the thought of chemotherapy would actually make him vomit. So, the day before chemotherapy, he would start being unwell. He would initiate all sorts of stalling tactics on the day of chemotherapy, because he would start vomiting, and he would usually vomit on the way to chemotherapy. He would vomit all through chemotherapy. He would vomit on the way home. And usually, invariably by midnight that night, after hours of vomiting, it would be an emergency trip to Accident and Emergency to have some fluids and to have more IV antiemetics. He tried literally every antiemetic that was available pharmaceutically…They worked to a degree, but this became such a psychological issue as well—a bit like Pavlov's dog, I guess. We tried to seek help for this in all number of ways, and nobody really was equipped to help us deal with it.

3 *Committee Hansard*, 31 March 2015, p. 17.

4 *Submission 31*, p. 1.

At the point where Daniel tried cannabis, he was three years into this treatment. The chemotherapy was not working. They were saying he needed to go back to the original chemotherapies that they had tried, which did not last very long with him because the side effects were so severe… [The next time Daniel had chemotherapy], he had a couple of puffs on a cannabis joint, and it was amazing. I really cannot understate that. It was as near to a miracle as I have ever seen… He would come home with a chemotherapy pump on, so he would be out of the clinic but effectively still hooked up to chemotherapy, and he would be [extremely white] for days. He had a couple of drags; the colour came back into his face, and he just went: 'Wow! I'm hungry. Mum, can I have something to eat?' We just went: 'What is going on here? This has never happened'—because this kid would lie in a hospital room for days and days not eating. This was just such an incredible change. It was life-changing for all of us. We just looked at each other and thought, 'Well, if this is what it takes, this is what it takes.'[5]

4.11 The second case study is of Mrs Joelle Neville, who gave evidence to the committee at its Brisbane public hearing in relation to using cannabis oil as a last resort treatment for her daughter's severe seizures.

Case Study 2 – Mrs Joelle Neville

I am the mother of a ten year old child that was diagnosed with Tuberous Sclerosis at the age of five months. As a result of the genetic condition she has been severely epileptic since birth. Prior to starting medication she was having 15-20 seizures a day.

Over her short life she has trialled over twenty anti-epileptics, had two brain surgeries and trialled various diets/ supplements. Other than a six month period when she was 18 months old, when we briefly managed to find the perfect balance of medication and brain development, she has never been seizure free. As a result of her epilepsy, she has an intellectual disability diagnosis and currently attends a special needs school. She has also never slept more than a four hour period. She has needed constant care and supervision all her life. As you can imagine, this has placed a huge strain on our family and massive limitations on our lives.

August of 2014 saw us hit a particular low point when Ava's seizures became worse despite being on maximum doses of four anti-epileptics, one of which we were trialling off-label and was costing us almost $4000 a month. Each of the drugs have horrible, potential side effects. At this time, Ava was having 6-8 seizures a day, some of which were lasting up to ten minutes and sending her back to sleep for hours.

I was able to obtain a few syringes of 18% CBD Hemp Oil and began her at a tiny dose (approx. 1/6ml twice a day). Within a week Ava's seizures completely stopped. Now, six months later, we have completely weaned Ava off of all her medications and she is currently on approx. 1/3ml twice a day. She has the occasional, very small seizure that probably only my husband or myself would notice. A month ago she started sleeping 9-10 hours a night, unbroken.

5 Mrs Lucy Haslam, *Committee Hansard*, 31 March 2015, pp 26-27.

> As you can imagine, this has been absolutely life changing for all of us. We have been able to explore normal lives and realise the potential in our child…I don't have a specific dollar amount that Ava's prior medication regime was costing the government but I would imagine (especially if you take into account surgeries, doctors and therapies) that it was in the hundreds of thousands per year.[6]

Reliance on unrefined cannabis products in the illicit market

4.12 A significant problem for individuals currently using medicinal cannabis is the fact that, as an unregulated and illicit activity, there is little control over the quality or standardisation of the products being used. The University of Sydney academics group noted in its submission:

> Medicinal cannabis use is widespread in Australia despite the prevailing regulatory framework. Vulnerable patients source cannabis preparations from the black market. These preparations are unregulated with potential for inappropriate cannabinoids for certain indications (e.g. high THC for paediatric epilepsy), contamination with pesticides or heavy metals, tinctures with no cannabinoids sold as medicine, and poor understanding of appropriate dosing schedules.[7]

4.13 Their submission confirmed that black market cannabis available in New South Wales is not generally optimised for therapeutic applications:

> In 2013, in conjunction with the NSW Police and the National Drug and Alcohol Research Centre (NDARC), our group preformed the first ever chemical analysis of street cannabis seized by the police at various sites in NSW…Our results showed that typical street cannabis (more than 200 samples were analysed) was high in THC and very low in the therapeutically useful, non psychoactive cannabinoids such as CBD and THCV. This illustrates a major potential problem with the current regulatory environment whereby person seeking to use medicinal cannabis are likely to end up with illicitly obtained, high THC preparations, that may be devoid of the phytocannabinoid ingredients that would best treat their condition... At present, consumers have no ability to determine the type or strength of cannabinoid products they are consuming, and it remains illegal for analytical laboratories to even test these products. These are major impediments to the safer use of medical cannabis, and may more than likely be exacerbating the harms experienced by consumers.[8]

4.14 Professor Iain McGregor of the University of Sydney expanded on this argument in evidence to the committee:

> [In the illicit market] there is no quality control. We have had parents of epileptic children get in touch and say: 'Suddenly the new tincture is not working. The old one was fine and controlled the seizures. Now my child is

6 *Submission 70*, p. 1.

7 *Submission 52*, p. 2.

8 *Submission 52*, pp 5 and 6.

> fitting again with this new bottle that we got, and we don't know why. Can you help? Can you tell us what has changed and why it is not working anymore?' These are desperate people that should be helped.[9]

4.15 Several patient groups that gave evidence also commented that concerns about quality control were a significant issue for individuals seeking to use cannabis products for therapeutic purposes.[10] These concerns were echoed in written submissions by other individuals currently using medicinal cannabis.

4.16 Several submitters and witnesses expressed the view that a regulated medicinal cannabis industry would be better than the current situation in which many individuals access cannabis products illegally. The University of Sydney academics group stated:

> A regulated industry is far preferable to the existing situation of consumers relying on unregulated and illegal products, no authoritative consumer information from health professionals, and researchers being restricted to pharmaceutical products – of which there remain a very limited number of cannabinoids available from a small number of pharmaceutical companies.[11]

Difficulties associated with getting TGA approval for cannabinoid products

4.17 Several submitters and witnesses commented on the process and difficulties associated with gaining approval for a cannabis-based product through the TGA. As noted in chapter 2, getting a product listed on the Australian Therapeutic Goods Register (ARTG) involves a sponsoring organisation presenting a dossier of evidence including clinical trial data to the TGA, which then assesses the application in an iterative process that can take up to a year to complete.[12] The TGA informed the committee that costs for an application for a new chemical entity are around $250,000.[13]

4.18 Emeritus Professor Laurence Mather noted that the herbal nature of the cannabis plant means that it is difficult for pharmaceutical companies to gain patent protection in relation to cannabis-derived products:

> When used as a medicine, cannabis cannot be regarded as a single drug, and therein lies an issue. Conventional regulatory bodies have no framework for examination and approval of potentially variable mixes of drugs. Conventional pharmaceutical companies have little to gain from investing in natural products that cannot be patented or bear an illegal drug level.[14]

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9 *Committee Hansard*, 31 March 2015, p. 9.

10 Mr Lance Feeney, National Association of People Living with HIV Australia, *Committee Hansard*, 31 March 2015, pp 17-18; Ms Carol Ireland, Epilepsy Action Australia, *Committee Hansard*, 31 March 2015, p. 18.

11 *Submission 52*, p. 8.

12 See evidence from the TGA at paragraphs 2.44-2.49.

13 Dr Lisa Studdert, TGA, *Committee Hansard*, 30 March 2015, pp 36-37.

14 *Committee Hansard*, 31 March 2015, p. 11.

4.19 When questioned on why more companies were not sponsoring cannabis-based products for registration with the TGA, Dr Lisa Studdert of the TGA agreed that patent protection is an issue:

> [T]he economics of medicine registration are such that companies need some patent protection to recoup costs over a period of time. We know that many of the development costs of new medicines vary but they can be in the hundreds of thousands if not up to billions of dollars.[15]

4.20 Professor Philip Morris of the Royal Australian and New Zealand College of Physicians agreed that:

> with cannabis…I do not think there is any big commercial organisation that will be coming forward to sponsor this drug's application, and we will have to think about ways of having the drug's pros and cons presented to the TGA so that it can be assessed in that way.[16]

4.21 Associate Professor Lintzeris observed that the relatively small pharmaceuticals market in Australia is another factor that means companies are unlikely to invest significantly in getting new cannabinoid medications listed through the TGA.[17]

4.22 Professor Hall stated that, in additional to regulatory barriers, pharmaceutical companies have not developed new cannabinoids or methods of delivering them because 'it is costly to develop and test new cannabinoids and difficult to recoup these costs when the conditions for which they may be medically used are uncommon'.[18]

Difficulties associated with conducting research into medicinal cannabis products

4.23 Several of the academic groups in Australia conducting research into medicinal cannabis noted that undertaking research in this area is extremely difficult. The University of Sydney academics group submission stated:

> Over the past decade there has been immense international growth in this area of research as the significance of the endocannabinoid system in human health and disease becomes increasingly apparent. Despite this, we conduct our research in a tight regulatory environment that makes sourcing, holding and administering cannabinoids extremely difficult and expensive. Cannabinoid preparations typically have to be imported from the USA or Europe at great expense, and with time consuming paperwork and processes imposed by the TGA and state regulatory authorities. This is despite the fact that the vast majority of cannabinoids we research have no psychoactive or addictive properties in humans.[19]

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15 *Committee Hansard*, 30 March 2015, p. 37.

16 *Committee Hansard*, 31 March 2015, p. 53.

17 *Committee Hansard*, 31 March 2015, p. 5. See also: Professor Wayne Hall, *Committee Hansard*, 1 April 2015, p. 26.

18 *Submission 4*, p. 6.

19 *Submission 52*, p. 2.

4.24 Dr Alexander Wodak of the Australian Drug Law Reform Initiative (ADLRI) commented that research restrictions have been problematic overseas as well as in Australia:

> In the United States cannabis is still on schedule 1, which means it is as dangerous as heroin and more dangerous than cocaine, which is on schedule 2. That gives you an idea of how serious the obstacles are. But getting funding, getting approval from an ethics committee and, most importantly of all, getting supplies of lawful medicinal cannabis in Australia, the United States and many other countries at the moment is virtually impossible.[20]

4.25 Professor Iain McGregor, an academic at the University of Sydney, elaborated on the practical challenges associated with conducting cannabinoid research in Australia:

> We are involved in everything from cellular studies through animal studies through to clinical trials, and all we encounter along the way is hurdles imposed by state and federal legislation. For example, I am interested in the mechanism whereby CBD affects epilepsy, but to get CBD I have to fill in dozens of forms, deal with New South Wales Health, deal with the TGA and often wait six to 12 months and spend thousands of euros to bring that into Australia. Yet the industrial hemp manufacturers that are currently present in New South Wales could easily extract CBD from their plants and give it to me for research purposes.[21]

4.26 In relation to the current clinical trials in Australia of the nabiximols Sativex, Associate Professor Lintzeris commented:

> [I]t is a very long, difficult process to do this kind of research and there is only one pharmaceutical company in the world from which we can access these medications. So we are beholden to GW Pharmaceuticals' board decisions. These are financial interests that they have, just like any other drug company…In the studies that we are doing, GW Pharmaceuticals have been supportive of us…We have estimated that the medication that GW Pharmaceuticals will be providing us for the research [costs the company] well in excess of half a million dollars…That is comparable to the total grant we received from NHMRC to do this research. That really puts in perspective just how expensive it is to do this kind of research and, at this point in time, how beholden we are upon the drug company to provide us these medications.[22]

Supply-specific issues

4.27 Professor McGregor noted that supply of cannabis for research purposes at the current time is entirely dependent on overseas suppliers, stating that researchers 'are really at their mercy with our clinical trials at the moment because we have no local

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20 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, p. 47.

21 Professor Iain McGregor, *Committee Hansard*, 31 March 2015, pp 1-2.

22 *Committee Hansard*, 31 March 2015, pp 2-3.

supply of cannabinoids'.[23] He also explained, however, that if regulatory restrictions were relaxed in Australia it would be relatively straightforward for existing industrial hemp producers to start growing cannabis strains for specific research purposes:

> [T]here is quite a vibrant industrial hemp industry in Australia…In discussions with industrial hemp manufacturers, I have said to them, 'What would it take for you to switch over to different plants that will express some of the therapeutically important cannabinoids and extract them?' Basically, they could do that this year…[T]hey have more than 200 strains of cannabis plants available that express different levels of these cannabinoids. So, if we wanted to, say, have a plant that was very high in THCV that might be good for obesity or diabetes, that is certainly doable within their existing stocks and strains.[24]

4.28 The committee received evidence from companies and individuals involved in the production of industrial hemp in Australia, who confirmed that it would be possible for existing growers to produce cannabis plants with specific cannabinoid profiles, including low-THC strains, and controlled for contaminants in order to advance the use of and research into medicinal cannabis products.[25]

Inability for state and territory governments to progress the issue

4.29 Several submitters and witnesses noted that state and territory governments are currently unable to progress bringing medicinal cannabis inside a legal regulatory framework, due to the *Therapeutic Goods Act 1989* (TG Act) 'covering the field' in relation to the regulation of cannabis as a therapeutic good. The ADLRI stated:

> All State or Territory based initiatives to allow, or trial, medical cannabis come up against the jurisdictional supremacy of the Commonwealth law, in particular the [TG Act].
>
> The central problem is that the [TG Act] covers the field – that is, the Commonwealth has sole jurisdiction for therapeutic goods and the States have no (or very little) authority in this area. Further, the [TG Act] applies to any substance that is marketed and/or traded as a therapeutic good. Therefore, as soon as cannabis is provided as a therapeutic good, any affect of State laws is overridden by the [TG Act]…Given this, it is essential that the Commonwealth pass legislation allowing States to have self-determination over their medical cannabis policies. The simplest way for this to happen is for legislation that clearly states that the [TG Act] does not apply to medical cannabis.[26]

4.30 Mr Ben Mostyn of the ADLRI expanded further on how this issue currently plays out in New South Wales:

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23 *Committee Hansard*, 31 March 2015, p. 2.

24 *Committee Hansard*, 31 March 2015, pp 5-6.

25 See: Mr Paul Benhaim, *Committee Hansard*, 1 April 2015, pp 30-31; Mr David Gillespie, *Submission 47*.

26 *Submission 36*, p. 2.

> We have the perverse situation in New South Wales at the moment where every party has expressed support for medical marijuana; there seems to be very strong support in the community, where 75 or 80 per cent of people do not want to see people who use medical marijuana facing prosecution; and unfortunately the New South Wales parliament just seems to not have the authority or the jurisdiction to do anything about it. Any attempt that they make to try medical marijuana will have to be a very laissez-faire trial…because it will have to try and completely avoid the [TG Act]. They will have to be doing something completely outside that therapeutic framework.[27]

Comments on the regulatory model proposed in the Bill

4.31 Many submitters and witnesses expressed support for the intention of the Bill to provide a national framework for the regulation of medicinal cannabis that facilitates the acceleration of research in this area and increases access to medicinal cannabis products where these are show to be effective.[28]

Broad comments on the regulatory approach taken by the Bill

4.32 The evidence presented to the inquiry by submitters and witnesses, including cannabis researchers and drug policy experts was that the two extremes in terms of approaches to regulating medicinal cannabis are:

- approaches which legalise or decriminalise medicinal cannabis, providing high availability to patients but limited quality control and greater risk of leakage into the illicit market; and
- approaches which only allow for pharmaceutical-grade medicinal cannabis products subject to stringent testing regimes, with supply being tightly controlled.[29]

4.33 Several submitters and witnesses commended the Bill's attempts to strike a middle ground between these two extremes of regulation. For example, Associate Professor Lintzeris commented:

> This legislation, the way we see it, provides at least a framework. It does not have all the answers on how we are going to do it but it provides a framework and, importantly, it is somewhat independent of direct government roles. It allows appropriate experts and community players to

27 *Committee Hansard*, 31 March 2015, p. 50.

28 See, for example: Palliative Care Australia, *Submission 23*, p. 3; Public Health Association of Australia, *Submission 26*, p. 4; Australian Medical Association, *Submission 44*, p. 1; ACT Government, *Submission 147*, p. 2; Emeritus Professor Laurence Mather, *Submission 17*, p. 8; National Centre for Education and Training on Addiction, *Submission 66*, p. 1.

29 See: Associate Professor Nicholas Lintzeris, *Committee Hansard*, 31 March 2015, p. 3; Professor Allison Ritter, National Drug and Alcohol Research Centre, *Committee Hansard*, 31 March 2015, pp 38-39.

> drive this agenda moving forward. So we see it as striking a fairly useful and important balance between those two competing poles of the debate.[30]

Views on the necessity of a standalone regulator

4.34 Some stakeholders to the inquiry argued that the current system of regulation in Australia is adequate and does not require significant change. The Australian Medical Association (AMA), for example, argued that the necessity for any medicinal cannabis products to be of pharmaceutical quality means that an alternative scheme to regulate medicinal cannabis would be detrimental:

> The public discourse on the use of medicinal cannabis for a limited number of health conditions ignores the fact that consuming cannabis for recreational purposes is harmful…This is why medicinal cannabis should be subject to the [TG Act] and not regulated separately.
>
> While this stance may be seen as conservative in the context of the current debate on the merits of medicinal cannabis, it is critical that medical practitioners have confidence in the integrity of the pharmaceutical products that are available to treat patients. Similarly, all patients including those being treated for terminal illness, must be confident in the quality of the therapeutic products that are prescribed to them by their treating medical practitioner.[31]

4.35 The Australian and New Zealand Society for Palliative Medicine similarly argued:

> With patient safety paramount, Medicinal Cannabis use should be evidence-based and as a prescribed medication, regulators should establish the use of pharmaceutical quality products only, which are managed in the same way as other prescribed medications, via the existing mechanisms established by the [TG Act].[32]

Role of the proposed Regulator versus the current role of the TGA

4.36 Discussion about whether a new standalone regulator for medicinal cannabis was justified focussed on the question of whether the functions proposed to be granted to the new Regulator could already be performed by the TGA.

'Duplication' of regulatory functions with the TGA

4.37 Some submitters and witnesses argued that creating the proposed regulator, as envisaged under the Bill, would generate a duplication of regulatory functions with the TGA. The Pharmacy Guild of Australia argued that the creation of a new regulator solely to regulate medicinal cannabis 'has the potential to fragment the regulation of medicines in Australia as well as lead to confusion and unnecessary duplication of

30 *Committee Hansard*, 31 March 2015, p. 3.

31 *Submission 44*, p. 1.

32 *Submission 42*, p. 6.

regulatory processes'.[33] Medicines Australia agreed that a new regulator would 'introduce an additional level of regulation that is unnecessary'.[34]

4.38 Cancer Voices Australia stated its concern that the Bill would circumvent and add complexity to the current process of listing and approving medical drugs by the TGA.[35]

4.39 Representatives from the TGA presented the view that the TGA would be able to perform some but possibly not all of the functions proposed for the Regulator to perform under the Bill. Dr Lisa Studdert of the Market Authorisation Group within the TGA stated:

> Certainly for the approval of a product for therapeutic use, [the TGA does] have that expertise...there is a precedent with the product Sativex, which is a cannabis based product which has been approved for market registration in Australia. For that function there is the expertise, but I think the scope of the bill and perhaps what is being anticipated goes much beyond what is covered in the [TG Act].[36]

4.40 Ms Philippa Horner, Principal Legal Advisor at the TGA, continued:

> [The TGA] really only gets involved in terms of pharmaceuticals like Sativex in that bit about approving the medicine. Before that and after that there are the customs prohibited imports regulations, which determined whether drugs can come into Australia to be manufactured in Australia, and there are then the states and territories who have all the rules about what pharmacists and wholesalers can do with drugs that have got schedule 8 substances in them. So we are just a kind of slice of a whole system that is set up already.[37]

4.41 The Pharmacy Guild of Australia argued that any expanded regulatory powers in relation to medicinal cannabis should be granted to the TGA through amendments to the TG Act, rather than the creation of a new regulator:

> [P]owers and responsibilities [relating to medicinal cannabis] should be delegated to the relevant regulatory area within the Therapeutic Goods Administration (TGA) and any required amendments to the law should be made to the *Therapmtic Goods Act 1989*…[The TGA's] key roles include classifying medicines based on their risk, implementing appropriate regulatory controls for manufacturing of medicines and the monitoring of medicines which includes a comprehensive adverse event reporting programme. Therefore, the TGA is the most appropriate regulatory body to

33 *Submission 18*, p. 1.

34 *Submission 24*, p. 2.

35 *Submission 10*, p. 2.

36 *Committee Hansard*, 30 March 2015, p. 34.

37 *Committee Hansard*, 30 March 2015, p. 36.

> oversee the supply and export of medical cannabis as they possess the necessary experience and expertise in this area.[38]

4.42 By contrast, Emeritus Professor David Penington expressed the view that the TGA does not have the experience required to handle the complexities associated with coordinating the issue of medicinal cannabis across Australia:

> [T]he TGA traditionally has dealt with clear-cut proposals which lead to drugs which can be commercialised and so on. It would not be a body that would be able to liaise with other state health departments and the like in the way that I believe is going to be essential to get effective control of medical cannabis. The control will need to be at a state level with programs that are flexible and can be adjusted as more knowledge emerges as to which particular forms of disease would benefit from treatment. I think the TGA wants clear-cut proposals that are all supported by factual evidence of trials and the like. But it is not likely to be able to handle the complexities of production of the appropriate cannabis product, nor is it likely to be in a position to handle the liaison that will be needed between the various state programs.[39]

4.43 Professor Penington argued further that this national coordination would require a body other than the TGA to implement, regardless of whether the Regulator proposed by the Bill was to eventuate:

> I think it is very important that there be tight regulation—that is, regulation which needs to be implemented by the states, in my view, rather than a national regulation. That regulation hopefully ought to be consistent, so that even under COAG it is possible that you could have a special group established that could handle these sorts of issues with the Commonwealth agreeing to operate it. It may not have to be an agency comparable to the TGA in any sense. But it may need to be an agency or committee or structure that has the authority to coordinate activities for the various programs that would be advised, medically as well as legally, on the sorts of conditions that it is agreed should commonly be used and the sorts of ways in which the new trials of emerging new things can be tested…I do not think [the TGA] can be the body that will persuade the states to come together and have sensible, ongoing agreement as to what are the conditions that should apply and so on.[40]

'Parallel' operation of the TGA and the Regulator

4.44 Professor Wayne Hall expressed caution in relation to creating a parallel system of regulation for one particular class of medicinal product:

> I would be wary of creating special regulatory systems for one drug. I think we should try and do what we can to deal with it within the existing pharmaceutical structure. It might need bit of tweaking, but I think creating

38 *Submission 18*, p. 1.

39 *Committee Hansard*, 30 March 2015, p. 21.

40 *Committee Hansard*, 30 March 2015, p. 23.

> a parallel system for distribution, a special access scheme, adds to the expense. One could easily imagine other people coming along making similar demands about other products that they want to see introduced in a medical practice, so I think one has to worry about precedents.[41]

4.45 Conversely, the Public Health Association of Australia stated:

> PHAA fully supports the approach of having the Regulator operate in parallel to the TGA. We note the intention to have its processes align with the TGA insofar as that is appropriate, particularly as new cannabis-based therapeutic products that meet TGA standards come onto the market.[42]

4.46 The University of Sydney academics group stated its support for an independent regulator being able to operate synergistically with the existing TGA system:

> We believe that a dedicated medical cannabis regulator can coexist in parallel with the TGA's existing procedures and processes but provide a much more lean, efficient and specialized approach to regulation. While there is a role for medical cannabis products as identified in this bill, it does not obviate the role of the TGA in the development of medical cannabinoids as pharmaceutical products. Pure pharmaceutical grade products will be an inevitable result of the current research trajectory in the medicinal cannabinoid area and may be the most desirable end product for certain patient populations. The new regulator can explore alternate yet parallel and synergistic policy models for the regulation of research into medical cannabis products, as well as their use.[43]

4.47 Dr Wodak expressed the view that a dedicated regulator would allow the difficult issues surrounding the regulation of medicinal cannabis to be worked through and address concerns raised about the prospect of using cannabis medicinally:

> There are a lot of people in the community and in the professions who would welcome [the introduction of medicinal cannabis], but there are some people who are very nervous about that, and I think we should try to allay their fears, and say that this is going to be done seriously and properly. I think an office of medicinal cannabis would do that. It is a very difficult area…and I think that having a dedicated office that does this and does not do other things would allow them to focus and concentrate and sort out some of the thorny issues.[44]

4.48 Dr Wodak argued that a standalone regulator would be required for the time being, but may later be able to be subsumed within the TGA as the science of

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41 *Committee Hansard*, 1 April 2015, p. 24.

42 *Submission 26*, p. 4.

43 *Submission 52*, pp 6-7.

44 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, p. 47.

medicinal cannabis becomes better understood and the regulatory processes for medicinal cannabis are firmly established.[45]

Applications made both to the Regulator and the TGA

4.49 The Bar Association of Queensland questioned whether the Bill would result in 'forum shopping' from companies seeking to list medicinal cannabis products:

> It appears from the [EM] to the Bill that pharmaceutical companies will have a choice as to which regime they apply to for approval to sell medicinal cannabis products.
>
> It is unclear if two separate applications may be submitted concurrently to these authorities (the TGA and the…Regulator). It is also unclear if an application is rejected by one Regulator that fact and reasons for that rejection are required to be disclosed to the other Regulator should the company make a subsequent application pursuant to the alternative scheme. This should be clarified.[46]

4.50 The Pharmacy Guild noted that 'if the majority of companies elect to have their products registered through the TGA, then the proposed new regulator becomes redundant'.[47]

4.51 On the issue of the high costs of listing products through the TGA, the Pharmacy Guild argued:

> If the cost of registering a cannabis product through the TGA is deemed to be a potential barrier to market entry, consideration should be given to reducing the application fees for these types of products. This approach will ultimately be a more efficient option than establishing a new separate regulator.[48]

Application of the TG Act and Narcotic Drugs Act 1967 to activities undertaken in accordance with the Bill

4.52 Evidence presented to the inquiry by the Department of Health (department) and the TGA raised concerns that the system of regulation envisaged under the Bill could create legal uncertainty in relation to whether the TG Act would apply to activities purportedly taken in accordance with the Bill in certain circumstances.

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45 Dr Alexander Wodak, Australian Drug Law Reform Initiative, *Committee Hansard*, 31 March 2015, pp 47-48.

46 *Submission 53*, p. 3.

47 *Submission 18*, p. 1.

48 *Submission 18*, p. 2.

An opt in/opt out system?

4.53 The department questioned how the "opt in/opt out" system proposed in the Bill might work, stating that it was unclear when the Bill would apply versus the TG Act:

> The…Bill appears to operate in parallel with the TG Act on the basis of choice by a person to opt into the [Bill's] Scheme and opt out of the TG Act scheme. The implication of the opting in and opting out mechanism could be significant. This is particularly the case in relation to the application of the TG Act, as the definitions of "medicinal cannabis" and "medicinal use" are not clearly articulated in the [Bill] and it is not clear how they would not be caught by the definition of "therapeutic goods" in the TG Act. The complexity of this opting in and opting out system can be confusing for the regulated persons, the regulator and other agencies such as the TGA. Without a clear definition, it is not clear to consumers, health professionals, the industry and the regulators which law applies and what their legal obligations and responsibilities would be. It would be difficult for the regulators to determine what their powers are and whether they have the right to take regulatory action in relation to a particular product or activity.[49]

4.54 The TGA shared similar concerns. The TGA argued that, while licensees granted authorisations under the Bill's schemes would be exempt from the operation of the TG Act so long as they complied with their licence or authorisation, any activity outside the scope of their license may then come under the coverage of the TG Act. Ms Phillipa Horner, Principal Legal Advisor at the TGA, stated:

> The way we understand the bill works is that it fundamentally says that if you are acting in a way that is compliant with a licence or authorisation you have been given under this legislation then, for instance, the [TG Act] does not apply…[W]here it becomes complicated is where someone does something that is not in conformity with a licence—whether or not it is a breached condition, it is an offence under this Act. Then every provision of the [TG Act] would come into play, so that a person would be committing an offence under the [TG Act] in relation to that. Until you know whether someone has committed an offence you do not know whether you have got jurisdiction to investigate them. So you might be in this rather difficult position of purporting to use powers that you do not know you are able to use. It is a bit of a catch-22 position, because…the provisions come in and out, depending on whether you are compliant or not. It makes it quite difficult.[50]

4.55 When asked whether this potential difficulty could be overcome, Ms Horner suggested:

> I do not know that this would work in every situation, but another way you might do it is to make it so the [TG Act] applies whether the drug you are

49 *Submission 67*, p. 2.

50 *Committee Hansard*, 30 March 2015, pp 34-35.

> talking about is regulated under this Act or not; but that would [then] require a whole suite of offences to be in [the Bill] when the person did not behave.[51]

4.56 The department argued in its submission that a similar issue would arise in relation to the interaction between the Bill and the Narcotic Drugs Act, whereby license holders under the Bill would be exempt from the operation of the Narcotic Drugs Act when acting in accordance with that licence. However, where a licensee is non-compliant with licence conditions and the activity in which a licensee is engaged is not accordance with the medicinal licence they would be, based on the current wording of the Bill, subject to the Narcotic Drugs Act again.[52]

4.57 Accordingly, the department questioned whether under the Bill there could be 'several offence provisions from different legislative schemes potentially applying to the same activity', and concluded:

> Further consideration should be given to the interrelationship between the…Bill and the [Narcotic Drugs Act] and whether there is value in dealing with the regulation of medicinal cannabis by amendments to the [Narcotic Drugs Act] rather than creating a completely separate and free-standing regime. Building on the existing legislative framework may assist in ensuring consistency, achieving clarity and avoiding duplication of regulation due to several applicable laws.[53]

Register of regulated medicinal cannabis products

4.58 The TGA also questioned what would happen if the Regulator made a decision to take a product off the proposed register of regulated medicinal cannabis products:

> [I]f a drug were taken off the register…that would immediately mean that everybody down the line who was using that drug would immediately be committing offences under the therapeutic goods legislation and probably under the state legislation as well—that means the people who had an authorisation—because suddenly the drug is no longer the defined drug; it is a drug that has been removed. I am not sure how that would work and whether people would have an opportunity to appeal against that decision, but you can imagine that could create a fair degree of legal uncertainty.[54]

Interaction with other Commonwealth legislation

4.59 The department also raised concerns about the Bill's interaction with the Customs (Prohibited Imports) Regulations 1956 and Customs (Prohibited Exports) Regulations 1958 (together the Customs regulations) and the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*.

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51 *Committee Hansard*, 30 March 2015, p. 35.

52 *Submission 67*, p. 4.

53 *Submission 67*, pp 4-5.

54 *Committee Hansard*, 30 March 2015, p. 35.

4.60 The department highlighted that the Bill appears to overlap with some aspects of the Customs regulations with regard to the importation and exportation of cannabis and other cannabis products.[55] The department stated that the Bill 'does not appear to override the prohibition on importation or exportation of cannabis products under the customs legislation' and that '[f]urther consideration on the best way to achieve consistency and avoid duplication between the…Bill and the customs legislation with respect to import and export licences' would be required.[56]

4.61 The department indicated that the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*, which contains offences relating to the cultivation, import and export, and possession of controlled plants and drugs including cannabis, may also interact with the operation of the Bill. The department stated that further consideration needed to be given to whether amendments to this Act are required in relation to the production of cannabis for medicinal or experimental use sanctioned under the Bill.[57]

Adherence to Australia's international treaty obligations

4.62 Several submitters and witnesses commented on whether the functions and powers of the proposed Regulator were sufficiently articulated in the Bill to satisfy Australia's obligations under the *Single Convention on Narcotics Drugs* (the Single Convention), the *Convention on Psychotropic Substances* and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*.

4.63 The Penington Institute noted that other signatories to the international narcotics treaties have already approved the use of cannabis for therapeutic purposes through various regulatory structures.[58]

4.64 The department expressed the view that there are aspects of the Bill 'which may not adequately implement Australia's obligations under the drug control conventions, in particular the Single Convention'. In particular, the department argued that the Regulator's functions in relation to fulfilling Australia's obligations under the Single Convention should be more clearly defined:

> [C]lause 30 of [the Bill] provides that the Regulator has the functions of the Agency referred to in Article 23 of the Single Convention. However, [the Bill] does not specifically provide that the Regulator will be the sole agency that can authorise and licence cultivation of cannabis plants in Australia, nor that it is required to purchase and take physical possession of cannabis crops, as required by Article 23.
>
> Article 23 also requires that the Agency must have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers, of medicinal cannabis or cannabis

55 *Submission 67*, pp 3–4.

56 *Submission 67*, p. 4.

57 *Submission 67*, p. 5.

58 *Submission 75*, p. 1.

> preparations. To ensure clarity of the functions of the Regulator and to ensure that Australia meets its international obligations, it would be preferable if the functions and powers of the proposed Regulator were drafted in a way that more clearly conforms with all the requirements of Articles 28 and 23, rather than simply referencing relevant articles of the Single Convention, and generally requiring that the scheme operate in accordance with the Single Convention.[59]

4.65 The department further argued that the ability for Australia to prevent excess accumulation of cannabis and limit the total quantities of cannabis manufactured in or imported to Australia, as required under the Single Convention, may be compromised 'by the potential existence of more than one agency under Commonwealth and State and Territory law that can grant authorisations and licences with regard to dealings in cannabis'.[60]

4.66 The department also noted that Australia is required under the Single Convention to provide the United Nations International Narcotics Control Board (INCB) by 30 June each year with statistical returns in relation to of production, manufacture, consumption, stocks and seizures of narcotic drugs, and stated that 'it is unclear from [the Bill] whether the Regulator would be responsible for meeting these obligations' in relation to cannabis.[61]

Application of the Bill to participating states and territories

4.67 Another significant issue discussed throughout the inquiry was whether the Bill would be able to improve the current arrangements between the Commonwealth and states and territories in relation to the regulation of medicinal cannabis products.

4.68 Emeritus Professor Mather highlighted that several states are advancing the regulation of medicinal cannabis, and that the existence of a single, federal regulator as proposed under the Bill would be preferable to individual states and territories advancing their own schemes:

> Various of the state and territory governments are presently examining the evidence concerning medicinal uses of cannabis, and how it should be dealt with by legislation. This includes whether and how it should be lawfully prescribed and dispensed as a pharmaceutical preparation, or at least lawfully allowed to be used, with the patient and/or carer being responsible for its acquisition and quality. However, it is proceeding in a state-by-state or territory basis, with notable differences, and this will inevitably lead to problems, unforeseen and otherwise.
>
> How to permit and regulate cannabis and cannabis preparations for medicinal use has been a major stumbling-block to present state and territory governmental inquiries. If this Bill will allow a mechanism for the

59 *Submission 67*, p. 3.

60 *Submission 67*, p. 3.

61 *Submission 67*, p. 3.

> Federal production, regulation and permission of cannabis use as a medicine, including production and research, and to allow State and Territory governments to adopt the code of regulation afforded Federally, then surely this seems a beneficial way of precluding inharmonious local legislation and the errors of the past. A nation-wide code seems both sensible and economical.[62]

4.69 Medicines Australia agreed that the current federated model of regulation is unsatisfactory, but did not support a new regulator as proposed by the Bill:

> [T]he foremost barrier that Medicines Australia members have experienced in attempting to supply medicinal cannabis products in Australia have arisen from state and territory poisons legislation. In particular, differences in permit, prescription and risk-management plan requirements. These issues would not be overcome by the introduction of the [Bill] without appropriate changes to state and territory legislation…[T]he focus should be placed on harmonising state and territory legislation, rather than introducing a new level of national regulation, where appropriate and functional regulation already exists.[63]

4.70 The National Centre for Education and Training on Addiction (NCETA) cautioned that implementing a regulatory scheme in conjunction with participating states and territories would be complex:

> This will likely require States and Territories to amend legislation and undertake activities on behalf of the Commonwealth. These cooperative arrangements will be complex and will vary between jurisdictions due to differences in jurisdictional…[law] enforcement approaches to illicit cannabis [and regulatory] structures and approaches in place for Schedule 8 drugs.
>
> It will be important not to underestimate the complexities of these legislative and regulative arrangements in establishing the Regulator.[64]

4.71 The Law Institute of Victoria argued that it was unclear to what degree states would be required to reform existing legislation to incorporate the parallel system of regulation proposed by the Bill.[65]

Comments from state and territory governments

4.72 The committee received submissions to the inquiry from both the Victorian and ACT governments.

4.73 The Victorian Government confirmed its commitment to investigating legislative reform options to allow people to be treated with medicinal cannabis in exceptional circumstances, noting that 'the use of medicinal cannabis is a matter of

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62 *Submission 17*, pp 7-8.

63 *Submission 24*, p. 2.

64 *Submission 66*, p. 2.

65 *Submission 61*, p. 2.

high sensitivity and complexity'.[66] It stated that the Victorian Law Reform Commission's (VLRC) final report into these issues, due to be completed in August 2015, would inform its deliberations on the matter of legislative reform in relation to medicinal cannabis:

> The Victorian Government is committed to working collaboratively with the Commonwealth Government and other states and territories, to share information on issues relating to the use of appropriate therapeutic products derived from cannabis.
>
> The Victorian Government will consider the recommendations made by the VLRC before forming a final position on the proposed Regulator of Medicinal Cannabis Bill 2014.
>
> If the Regulator of Medicinal Cannabis Bill 2014 progresses, the Victorian Government will seek to further engage with the Commonwealth Government regarding issues raised in the Bill. In particular, consideration will need to be given to the scope of the Regulator's proposed functions and the interaction between the operation of Victoria's legislation and any new proposed national regulatory framework.[67]

4.74 The ACT Government stated its belief that a national approach to the regulation of the medicinal use of cannabis is required, and expressed support for the compassionate intent of the Bill.[68] It noted that if the ACT agreed to enter into an arrangement with the Commonwealth to participate in the scheme, it would need to amend its laws relating to the unlawful possession and administration of cannabis.[69]

Appropriateness of the rule-making power in the Bill

4.75 Several submitters and witnesses commented on the nature of the Bill as a 'framework' piece of legislation, with many significant features of the regulatory structure in relation to medicinal cannabis to be determined by the Regulator through the proposed rule-making power.

4.76 Ms Phillipa Horner of the TGA suggested that the proposed broad discretion of the Regulator to create rules relating to its operation is uncommon:

> [I]t is very unusual I think for an agency to be set up that makes its own rules—and you can see a lot of the detail of this is going to be in the rules—grants licences, enters into contracts with people in licences…[a]nd then it presumably does some enforcement and presumably prosecutes people if they breach. It also would then take things off the register—it would take licences away. That is a pretty unusual kind of set up.[70]

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66 *Submission 69*, p. 1.

67 *Submission 69*, p. 1.

68 *Submission 147*, p. 2.

69 *Submission 147*, p. 3.

70 *Committee Hansard*, 30 March 2015, pp 35-36.

4.77 In relation to the rule-making power, the ACT Government submitted that the absence of draft or indicative principles or processes for the development of the rules 'creates uncertainty about the efficacy of the scheme to prevent or minimise diversion and threats to public health and safety'.[71] It argued that consideration could be given to including principles in the Bill to serve as a guide for the development of the rules, and that the rules should be made by executive government rather than the Regulator.[72]

4.78 The AGT Government further commented that, should the Bill be enacted, it would 'be eager to participate in the development of the rules', with a view to ensuring that the relevant issues and perspectives are satisfactorily addressed and incorporated.[73]

4.79 Some stakeholders expressed the view that the flexibility afforded by the rule-making power in the Bill was a positive feature. For example, Professor Ritter of the NDARC stated:

> [An] advantage, from my reading of this draft bill, is that it has the capacity to be flexible and the regulator can then change over time. One of the problems with public policy is that decisions get made and then there is no ability to then change those decisions once one starts to see either very positive consequences or unintended negative consequences. It seems to me that there is the opportunity for enormous flexibility. If you look at the United States experience, many of the states have changed and resharpened some of their regulatory approaches over time. You really want to have that ability, and I think the bill gives that.[74]

Proposed register of medicinal cannabis products

4.80 In relation to the Regulator's proposed role of approving and registering medicinal cannabis products, various submitters and witnesses argued that the Regulator would need to maintain similar standards in relation to these products as apply to other medicines. For example, the Cancer Council Australia & Clinical Oncology Society of Australia in a joint submission stated that 'any product for medicinal purposes must be evaluated against objective criteria to ensure a high standard of safety, efficacy and quality for a particular use or uses'.[75]

4.81 NCETA, which supported the creation of the Regulator, submitted that the Regulator should maintain similar standards to the TGA in its decision-making on medicinal cannabis products:

> It will be critical to ensure that an appropriate level of rigour is maintained in the Regulator's decisions concerning the ways in which medicinal

71 *Submission 147*, p. 3.

72 *Submission 147*, p. 3.

73 *Submission 147*, p. 4.

74 *Committee Hansard*, 31 March 2015, p. 41.

75 *Submission 37*, p. 9.

> cannabis is made available and used. Given that pharmaceutical companies will also be able to apply to the Therapeutic Goods Administration to sell medicinal cannabis products under the TGA's legislation, it will be important to ensure the new approval mechanisms established under the Bill are both complementary to, and as rigorous as, those that currently apply to the TGA. Any short cuts to obtaining regulatory approval should be avoided at all costs.[76]

4.82 In arguing against the necessity for a new regulator, the AMA stated:

> Medicinal cannabis should be held to the same standards of evidence, safety, quality, and efficacy as other therapeutic narcotic products. This will ensure that medicinal cannabis can be standardised and regulated in its pharmaceutical preparations and administration, thereby reducing the harm to potential users.[77]

Process for the Regulator to approve products as 'suitable for medicinal use'

4.83 Under paragraph 13(2)(b) of the Bill the Regulator would be required to be 'satisfied that the cannabis product is suitable for medicinal use' in order to include a cannabis product on the proposed register of medicinal cannabis products.

4.84 Cancer Council of Australia & Clinical Oncology Society of Australia noted in a joint submission:

> This subjective assessment does not acknowledge any process undertaken by an applicant in seeking a product to be registered, including responding to specific criteria such as clinical outcomes and patient safety. The absence of a structure to objectively evaluate the application should also be noted. A rigorous review process is critical, for example, the review of therapeutic products prior to registration on the Australian Register of Therapeutic Goods. In the context of the Bill this is essential as people will be exposed to the product either through access (medicinal license) or research (experimental license). Assessment determines whether any risks associated with the product outweigh the benefit to the patient.[78]

4.85 Painaustralia expressed the view that the proposed Regulator should adhere to the principle that substances intended for therapeutic purposes be fully characterised chemically, pharmacologically and toxicologically, and argued that providing a clear definition of 'medicinal cannabis' in the Bill would address this concern:

> Painaustralia believes that in this context "medicinal" should refer to cannabinoid preparations of sufficient and consistent quality to be capable of being tested for efficacy and safety, and calls for a *specific definition of medicinal cannabis* to be incorporated into the Bill.
>
> It is not clear that [paragraph 13(2)(b)]…satisfies this requirement.[79]

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76 *Submission 66*, p. 1.

77 *Submission 44*, p. 1.

78 *Submission 37*, p. 7.

79 *Submission 56*, [pp 3-4].

4.86 Bedrocan, a medicinal cannabis producer responsible for supplying medicinal cannabis products in the Netherlands and Canada, commented that scientific findings in relation to different strains of cannabis should underpin listings by the Regulator:

> [Under the Bill] it is not clear what scientific evidence may be required to market specific cannabis products as effective for different indications.
>
> Claims are often made connecting certain cannabis strains with specific indications. While anecdotal reports of patients are useful and necessary, these claims are often not supported by scientific evidence. Such claims become particularly problematic in referring to cannabis that is non-standardized, as a claim of efficacy may be made for products that are marketed under the same name, but which may vary significantly in their chemical composition batch-to batch.
>
> The marketing of different strains of cannabis for specific indications, without proper evidence to support those claims, may create confusion among patients and doctors. Care should be taken that the evidence required to make claims of efficacy of a medical product for a certain indication should remain at a high level of quality.[80]

4.87 Palliative Care Australia called for the Bill to provide further details about the evidence that would be required by the Regulator in approving products.[81]

4.88 In contrast to these stakeholders, the Cannabis Policy Project contended that the current wording of paragraph 13(2)(b) 'gives the regulator the option to place a very narrow definition on the suitability of a cannabis product', and argued it is 'conceivable that as it currently reads the regulator could refuse all products'.[82]

Cost of medicinal cannabis products

4.89 Cancer Council Australia & Clinical Oncology Society of Australia noted that the cost of medicinal cannabis products made available by the Regulator may be an issue:

> By not requiring registration by the TGA, a product cannot apply to the Pharmaceutical Benefits Advisory Committee for reimbursement. Therefore a product cannot be available to a patient at a reduced price. Pricing of products on the register for regulated medicinal cannabis products must be public and transparent with an aim to provide products at a reasonable price.[83]

80 *Submission 48*, p. 11.

81 *Submission 23*, p. 8.

82 *Submission 43*, [p. 3].

83 *Submission 37*, p. 9.

4.90 Mrs Joelle Neville, whose daughter is currently being treated with high-CBD cannabis oil, expressed concern that pricing would need to be considered in order to make medicinal cannabis products affordable:

> [W]e are currently out of pocket about $6,000 a year. If we got to the point where it was being grown in Australia being produced here I would hope that that would bring the cost down slightly, but my fear is that if it was regulated to such an extent that government needs to recoup that cost somehow it would then become unviable for an average family to purchase. That is certainly a concern at the moment for most families. I know many families that would like to be on hemp oil, or cannabis oil, but financially it is not available to them, which leads, unfortunately, to shopping around on the internet.[84]

Medicinal cannabis licensing scheme

4.91 Some submitters commented on the processes proposed to be undertaken by the Regulator when granting licenses. NCETA expressed the view that ensuring the integrity of the licensing scheme proposed under the Bill would be of significant importance:

> The Regulator will…have an important role in ensuring that only fit and proper individuals are involved in the production, distribution and dispensing of medicinal cannabis. This will involve ensuring that appropriate probity checks are undertaken to ensure that those involved in the industry have no significant relevant criminal history or links to organised crime.[85]

4.92 On the issue of the criminal history of licensees, Palliative Care Australia opined that the Bill should clarify whether a person with previous convictions around cultivating or supplying cannabis would be able to gain a licence to cultivate or manufacture medicinal cannabis under the proposed medicinal cannabis licensing scheme.[86]

4.93 Cancer Council Australia & Clinical Oncology Society of Australia stated that the Bill was not clear about how a license application would be made and assessed, including against what selection criteria a license application would be evaluated, and recommended:

> Specific application processes, conditions of a license and the obligations of a license holder for each area of approval (e.g. distribution, cultivation etc.) must be clear and transparent to the applicant and general public. It is essential that post license monitoring and reporting be enforced especially the licensee's responsibility to report any adverse events.[87]

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84 *Committee Hansard*, 1 April 2015, p. 15.

85 *Submission 66*, p. 2.

86 *Submission 23*, p. 8.

87 *Submission 37*, p. 11.

Authorised patients and carers scheme

4.94 Several issues were raised in relation to the proposed authorised patients and carers scheme, including:

- processes for determining what kinds of medical conditions would qualify patients to access the scheme;
- the requirement under the Bill for access to the scheme to be subject to the prescription of a medical professional;
- implications for prescribing medical professionals, including liability issues; and
- means of ensuring that authorised patients and carers are sufficiently protected from law enforcement activities.

Determining access to the scheme for different conditions

4.95 Stakeholders to the inquiry presented varying views about how the Regulator should determine which patients, or classes of patients, should qualify for access to regulated medicinal cannabis products.

4.96 Emeritus Professor David Penington argued that the legislation should allow for the listing of recipient groups in line with emerging research and clinical trial results:

> Legislation will need to designate processes for approval of further recipient groups, which will no doubt emerge. It is suggested that the initial categories of pain in cancer, nausea and distress with cancer chemotherapy, painful neurological conditions and refractory juvenile epilepsy also provide for further categories when strongly recommended by two or more recognised specialists with a commitment to data collection and reporting or formal clinical trials.[88]

4.97 Professor Wayne Hall argued that the government should not be involved in supplying medicinal cannabis to patients outside of the context of clinical trials:

> If that were to happen, I think it would make clinical trials harder to do because people could get the drug without participating in trials, and we are talking about relatively small numbers of some of these cases, which would make it difficult to recruit patients into trials. There are also equity issues that are raised by governments supplying an unapproved, unevaluated substance at substantial cost when the pharmaceutical regulatory process decides not to fund drugs for which there is evidence of efficacy and safety because they are too expensive.[89]

88 *Submission 9*, p. 4.

89 *Committee Hansard*, 1 April 2015, p. 22.

4.98 Professor Hall stated that if medicinal cannabis was made available outside of clinical trials, this 'should be for registered patients and for a time limited period (e.g. 5 years) rather than an open ended commitment'. He further argued:

> Governments should fund long term follow-up studies of patients who use cannabis preparations and medical cannabinoids over periods of years to assess: the risks of developing cannabis dependence; exacerbating cardiovascular disease; precipitating psychotic disorders; and developing cancer.[90]

4.99 The Royal Australian and New Zealand College of Psychiatrists (RANZCP) was concerned that, given the link between cannabis use and psychiatric illness in some individuals, the Bill does not have a provision to identify patients who have experienced negative psychiatric consequences as a result of cannabis use:

> Without such a register, there would be the potential for medical practitioners to prescribe something that - while it may be the appropriate treatment for a medical concern - could have a significant detrimental impact on a person's mental health and would not be in the best interests of both patients and prescribers.[91]

Necessity for a doctor's prescription

4.100 As noted in chapter 3, under subclause 19(2) of the Bill, the proposed authorised patients and carers scheme (to be established by the rules) must stipulate that authorisations to patients or carers must only be given on request by a medical practitioner.

4.101 Submitters and witnesses commented on how 'medical practitioner' should be defined for these purposes, with the main three options being considered to be:

- allowing all doctors and some allied health professionals (for example, physiotherapists or occupational therapists) to prescribe medicinal cannabis;
- allowing all doctors to prescribe (but excluding allied health professionals); or
- allowing only some doctors to prescribe through a registered scheme.

4.102 Dr Alex Wodak suggested that all doctors should be given the ability to prescribe medicinal cannabis under the scheme, but that allied health professionals should be excluded from the initial scope of the authorisation scheme.[92]

4.103 Professor Ritter from the NDARC considered that it would be appropriate to allow health professionals other than doctors to prescribe products under the scheme, as long as they had access to appropriate accreditation, training and support.[93]

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90 *Submission 4*, p. 13.

91 *Submission 51*, p. 1.

92 *Committee Hansard*, 31 March 2015, p. 48.

93 *Committee Hansard*, 31 March 2015, p. 43.

Issues for prescribing medical professionals

4.104 The AMA did not support the establishment of an authorised patients and carers scheme as proposed by the Bill, nor the requirement that a medical practitioner should be required for a patient authorisation:

> [T]he requirement that patients and their carers be authorised to use medicinal cannabis at the request of their medical practitioner, is problematic. This may see undue pressure being put upon doctors to support applications for authorisation, purely as a means of access to cannabis products. There is a risk that if a doctor does not support a patient's application for authorisation it may undermine the doctor/patient relationship.[94]

4.105 RANZCP noted that the issue of individuals seeking cannabis for non-medical reasons was an issue that needed to be considered:

> It is the experience of many psychiatrists that patients who express a wish to obtain cannabis lawfully are motivated more by experience of its 'recreational' use than by reputed target symptoms that they may have, or claim to have. The alleged benefits of cannabis (some of them unproven) have been widely promulgated, and for doctors, the problems of assessment and control will probably be comparable to those associated with the prescription of opioids.[95]

4.106 Professor Philip Morris, of the Royal Australasian College of Physicians (RACP), claimed that doctors would be unwilling to prescribe medicinal cannabis products unless those products had been assessed to the standards required by regulators such as the TGA:

> You are going to be asking doctors to prescribe this medication for certain conditions. Once you start doing that, the physicians that are doing this need to know that the medication has been appropriately approved and that the pros and cons and the safety versus effectiveness in that particular condition have been assessed adequately. Anything less than that means that basically you are using a form of regulation which does not meet the usual medical standards. Now, if you are going to have medication or the thing prescribed by people other than doctors, then perhaps you could use a different standard. If you are going to ask doctors to be responsible for patients and to prescribe medication, then you need to go through the TGA experience.[96]

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94 *Submission 44*, p. 2. See also: Australian and New Zealand Society for Palliative Medicine, *Submission 42*, p. 8.

95 *Submission 51*, [p. 5].

96 *Committee Hansard*, 31 March 2015, pp 53-54.

4.107 The Australian and New Zealand Society for Palliative Medicine (ANZSPM) queried what would occur in the event that one only practitioner operating as part of a treatment team obtained a licence to be able to prescribe medicinal cannabis products:

> Issues of ongoing supply may be problematic. Should one clinician within a palliative care service decide to support the use of cannabis and apply for a licence, there would need to be consideration by the greater team as to issues of responsibility for ongoing care and support, particularly at times of recreational leave for the licensee, etc. This adds another level of complexity to patient care when one clinician holds the licence but is not available to care for the client.[97]

Exposure to liability for prescribing medical practitioners

4.108 The ANZSPM raised concerns relating to the potential liability of medical practitioners licensed to prescribe medicinal cannabis products:

> The medico-legal ramifications with being responsible for the outcomes associated with the use of this drug, particularly if there are breaches of the rules such as drug diversion, may also be of great concern to many ANZSPM members.
>
> The Regulator would be yet another body which doctors, who apply for a licence, will be answerable to, with possible serious legal ramifications if breaches occur.
>
> It is not known how Medical Indemnity Societies will support clinical members if there are legal implications arising, especially as the use of these drugs is not supported by good practice guidelines within a medical setting.[98]

4.109 The RACP echoed these concerns, arguing that the authorised patients and carers scheme as currently proposed offers medical practitioners insufficient protection from liability.[99]

Education for prescribing medical practitioners

4.110 Several submitters and witnesses discussed the need for education in relation to medicinal cannabis for prescribing medical practitioners. NCETA argued that clear guidelines would need to be developed for doctors:

> If medical practitioners are to have a role in prescribing cannabis it will be crucial that they have access to evidence informed guidelines about its appropriate medicinal uses. Such guidelines will need to be developed in consultation with relevant medical colleges and experts and supported by an extensive educational program to support practitioners in their prescribing decisions.[100]

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97 *Submission 42*, p. 8.

98 *Submission 42*, p. 9.

99 *Submission 29*, p. 1.

100 *Submission 66*, p. 2.

4.111 ANZSPM expressed similar views:

> Expanded teaching of health professionals who will be dealing with patients that have access to the drug will need to be considered. Patients are not isolated to one health professional (the licencee), and general education will be required to enable pharmacists, nursing staff and medical practitioners who have clinical responsibilities of patients using the medicinal cannabis, to ensure ongoing safety and good clinical practice. This will be important particularly for Palliative Care and Mental Health Specialists where many of the drugs used for symptom control have additive properties to the effects of cannabis.[101]

4.112 The ANZSPM stated that if the Bill was passed, health professionals would need guidance on the use of medicinal cannabis in practice, and argued that such guidelines would need to consider 'assessment criteria for prescribing, monitoring patient response, monitoring any potential misuse and for identifying possible drug interactions' as well as the relevant licensing arrangements.[102]

4.113 Palliative Care Australia noted that some medical bodies have developed guidelines for the use of medical cannabis, including in countries such as Canada where mechanisms for the use of medical cannabis have been introduced. It argued that these guidelines may be worth considering by the Regulator in the development of guidance materials for Australia.[103]

4.114 The Pharmacy Guild suggested that, rather than a new regulator providing standards and guidelines in relation to medicinal cannabis:

> The National Health and Medical Research Council (NHMRC) could…develop clinical guidelines to assist health professionals in determining the suitability of medicinal cannabis treatment for individual patients as well as ongoing management of symptoms and side effects.[104]

Ensuring protection for authorised individuals

4.115 ADLRI stated that practical safeguards would be needed to ensure that authorised patients and carers were not unwittingly targeted by state and territory law enforcement:

> Whilst a class of people will be created who are free from prosecution, it may be hard to ensure this freedom is absolute. There may be a need for strong policy to be drafted for State police forces giving direction on how to deal with people found with cannabis, who claim to be authorised under the Commonwealth scheme to use medical cannabis.[105]

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101 *Submission 42*, p. 8. See also: Bedrocan, *Submission 48*, p. 12.

102 *Submission 42*, p. 9.

103 *Submission 23*, p. 7.

104 *Submission 18*, p. 2.

105 *Submission 36*, p. 3.

4.116 ADLRI noted that while various options could be considered to help identify authorised patients and carers, including a patient register or a card system, none of these options were ideal:

> Although a card may be issued to people within the defined class, this is no guarantee that such people will be safe from search, arrest, and detention. A registry may need to be created that Police can check before arresting people, however significant thought will have to be given to how such a registry is constructed and maintained to avoid concerns about accuracy and patient privacy.[106]

4.117 Epilepsy Action Australia expressed concern that authorised persons carrying regulated medicinal cannabis products may not be protected whilst transiting through or temporarily visiting any Australian states and territories not participating in the scheme implemented by the Bill.[107]

4.118 The Bar Association of Queensland argued that it should be made clear that medicinal use of approved cannabis products by registered patients is a complete defence against any criminal charges relating to the possession or use of those products in participating states and territories.[108]

Experimental cannabis licensing scheme

4.119 Many submitters and witnesses expressed support for the intention of increasing access to cannabis for research and experimental purposes in Australia, in order to establish a broader evidence base in relation to the efficacy of medical cannabis.

4.120 The University of Sydney academics joint submission, which highlighted the difficulties in obtaining cannabis strains for research purposes in Australia, expressed strong support for the Bill's intention to allow for cultivation of cannabis for research purposes:

> [The Bill's] proposed mandate of setting up a system for the cultivation and production of cannabis for medical use and research in Australia, based on the Tasmanian poppy industry for opioids, would greatly accelerate basic, clinical and translational research in the cannabinoid area. This not only has the potential to facilitate access to medicinal cannabinoids for the research and broader community, but also may help position Australia as a global leader in the fast moving area of cannabinoid therapeutics... As we develop a greater understanding of the role of different "big 10" cannabinoids (e.g. CBD, THCV) for different medical indications (e.g. epilepsy, chronic pain, neurodegenerative conditions, PTSD, obesity, cancer), we will need to grow strains of cannabis that maximize the content of these cannabinoids to

106 *Submission 36*, p. 3; *Committee Hansard*, 31 March 2015, pp 49-50.

107 *Submission 31*, p. 2.

108 *Submission 53*, p. 1.

> facilitate therapeutic efficacy and the extraction and purification of these compounds for high quality medications.[109]

4.121 Emeritus Professor Mather lauded the inclusion of the proposed experimental cannabis licensing scheme in the Bill as a means of furthering research and development activities in the field of cannabis science.[110] NCETA agreed, stating that by enhancing access to cannabis for research purposes, the proposed regulatory arrangements would assist researchers address a number of knowledge gaps concerning the potential role of medicinal cannabis.[111]

Research standards

4.122 The joint submission from Cancer Council Australia & Clinical Oncology Society of Australia noted that the Bill does not acknowledge any requirement to comply with Australian guidelines or policies for proposing or conducting research on humans, or mention the need to fulfil a formal assessment process or seek authorisation from a Human Research Ethics Committee to commence cannabis product research on humans.[112] The submission argued:

> The Bill must promote research integrity and ethical compliance within the conditions of granting an experimental medicinal cannabis license. This must include: the *Australian Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*, including approval from a Human Research Ethics Committee to undertake the proposed research.[113]

Composition of the Regulator and membership requirements

4.123 Cancer Voices Australia supported the mandatory inclusion of a consumer (patient) representative as part of the Regulator's membership.[114] This proposal was also suggested by the Public Health Association of Australia in its submission.[115]

4.124 Palliative Care Australia argued that the inclusion of palliative care expertise in the composition of the Regulator was important, and stated that strong medical representation would be important to ensure that issues such as who may use medicinal cannabis, the impacts of long term use and the level of use were addressed properly.[116]

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109 *Submission 52*, pp 5 and 6.

110 *Submission 17*, p. 8.

111 *Submission 66*, p. 1.

112 *Submission 37*, pp 10-11.

113 *Submission 37*, p. 11.

114 *Submission 10*, p. 2.

115 *Submission 26*, p. 5.

116 *Submission 23*, p. 6.

4.125 The department stated that the establishment of the Regulator as a separate statutory entity with a CEO and staff 'is not in keeping with the Government's policy on a smaller and more rational government'. Further:

> [The Bill] also proposes that the CEO of the entity be the Chair of the regulator. It is not clear whether there may be any potential conflicts for a person to hold these dual statutory positions, [or] whether the person would be entitled to remuneration for each role. Further consideration should be given to whether existing government agencies could support the work of the Chair and members of the regulator.[117]

Appropriateness of the monitoring and investigatory powers of the Regulator

4.126 ADLRI expressed concern about the monitoring and investigatory powers of the Regulator proposed under the Bill:

> While we accept the argument that law enforcement and the public must be able to be confident about the security of the scheme, extending these powers to a new office, the Regulator, with no experience in police investigative powers may be ill-advised. The Committee must give serious consideration to whether a new agency should be given police powers or whether it is appropriate for police to monitor medical users.
>
> The preferred approach is to confine the use of powers of entry, search and seizure to police organisations that are trained and experienced in exercising these powers and that have appropriate oversight and accountability...It may be simpler for the office of the regulator to report concerns to local Police. Creating another investigative force may lead to over-policing of sick people.[118]

4.127 Mr Ben Mostyn of the ADLRI suggested that local police may already have adequate powers to deal with suppliers licensed by the Regulator who breach the terms of their licence:

> It would seem that…those monitoring and investigative powers [in the Bill] may not be necessary in the sense that either people who are licensed suppliers will be supplying it in accordance with their licence or they will not be…It would appear that, once they overstep the powers of the licence, they would quite clearly then come within the jurisdiction of the local police because they would be supplying cannabis without lawful authority. So it may be simpler and preferable to just leave any of that unlawful supply to the current systems in place.[119]

117 *Submission 67*, p. 5.

118 *Submission 36*, p. 3.

119 *Committee Hansard*, 31 March 2015, p. 50.

Impact on state and territory law enforcement agencies

4.128 Both the ACT Government and ADLRI expressed concern about the implications of the Bill for state and territory law enforcement agencies. The ACT Government argued that the Bill 'does not consider the impacts on law enforcement':

> Law enforcement agencies will be responsible for dealing with instances involving the diversion of authorised medicinal cannabis products to the illicit market, and to enforce other associated ACT legislation (for example, the *Road Transport (Alcohol and Drugs) Act 1977*).
>
> While the…Bill proposes to give the Regulator powers to monitor compliance with the Act and the rules (including powers to investigate breaches), there is no way to assess the possible impact on other law enforcement agencies.[120]

4.129 Similarly, ADLRI acknowledged that the Bill could place state and territory police in a difficult situation:

> …because they are the ones who need to enforce the regular cannabis laws whilst not overstepping the boundaries in any Commonwealth system. Unfortunately…we can point to the problem, but we do not necessarily have the solution.[121]

Review of decisions by the Administrative Appeals Tribunal

4.130 The TGA questioned whether the lack of definition of 'medicinal cannabis' in the Bill may create a large number of applications for decisions of the Regulator to be reviewed by the Administrative Appeals Tribunal (AAT):

> In the AAT, any person with an interest in a decision can come along and apply to have the decision overturned—not just the person who has the licence. Whether that is going to result in thousands and thousands of people wanting to go to the AAT, because either they have been refused an authorisation or the drug that they were getting has been taken off the register, will depend on how we define 'medicinal cannabis'. That is not very clear, so it is a bit hard to know whether it is a practical problem or not…If it mirrored the [TG Act], though perhaps not at the pharmaceutical level of prescription medicines, then presumably the drugs you are talking about would not be very many. But, if you are talking about a much wider group of drugs that would be approved, then I suspect you would have some practical issues about people wanting to appeal against any decisions about, or if any changes were made to, accessibility.[122]

Other issues

4.131 Stakeholders raised several other issues relating to the impact of the Bill that did not relate to its specific provisions, including resourcing, reporting requirements and the need for community education.

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120 *Submission 147*, p. 3.

121 *Committee Hansard*, 31 March 2015, p.

122 *Committee Hansard*, 30 March 2015, p. 35.

Resourcing issues for the proposed Regulator

4.132 NCETA noted that in order to be effective, the Regulator would need to be adequately resourced:

> It will be necessary to financially compensate States and Territories for activities related to the medicinal cannabis system. The Regulator's activities and those to be undertaken by States and Territories will need to be fully costed and appropriately resourced. Given that the Bill contains no appropriation, funds will need to be allocated by the Parliament for this purpose. Failure to ensure full and sufficient funding to the Regulator will result in regulatory gaps and inconsistency in approaches as are currently seen the regulation of Schedule 8 drugs across jurisdictions.[123]

4.133 The NSW Bar Association argued that it would also be important that adequate resources were devoted to law enforcement in order to prevent the diversion of 'licit' cannabis to the illicit market.[124]

Reporting requirements of the Regulator

4.134 The Cannabis Policy Project noted that there are currently no reporting requirements imposed on the Regulator, and that in order to enhance transparency and good governance, the Regulator should be required to provide an annual report to Parliament detailing its activities and decisions.[125]

The need for community education and measures to prevent 'commercialisation'

4.135 NCETA argued that, should the Regulator be established as proposed by the Bill, community education in relation to the changes would be important:

> The introduction of arrangements such as those outlined in the Bill will also require an extensive community education process. In particular, the introduction of medical cannabis should not come at the expense of cannabis coming to be regarded as a harmless, natural product. The adverse effects of cannabis use have been well documented…Any move to enhance the medicinal use of cannabis should not leave the broader community with the impression that cannabis use (particularly smoking) is a health promoting activity or not associated with a range of potential significant risks.[126]

4.136 A joint submission from Australian Federation of AIDS Organisations, the National Association of People With HIV Australia, ACON and Positive Life NSW also highlighted the importance of community education:

> The provision of information and education to communities that are likely to utilise and benefit from the medicinal use of cannabis would also be valuable. This should include the engagement of community, service

123 *Submission 66*, p. 2.

124 *Submission 3*, p. 2.

125 *Submission 43*, pp 3 and 6.

126 *Submission 66*, p. 3.

> providers and doctors to ensure that reliable information is available to consumers and doctors.[127]

4.137 The NSW Bar Association argued that if the Bill was successful in increasing access to regulated medicinal cannabis products, measures would need to be taken to prevent the commercialisation of the cannabis industry:

> A concern often expressed is the potential for the 'commercialisation' of cannabis use that could flow from regulated availability of medicinal cannabis (similar to the commercialisation of tobacco and alcohol). If a regulatory scheme for medicinal cannabis was introduced, it would be necessary to have very strict restrictions on advertising, to ensure that some of the mistakes in America are not replicated here.[128]

127 *Submission 30*, p. 2.

128 *Submission 3*, p. 2.

Chapter 5

Committee comments and recommendations

5.1 As outlined throughout this report, the committee heard much evidence in support of the intent of the Bill as well as evidence highlighting potential issues requiring attention.

5.2 With regard to the use of cannabis for medicinal purposes and research into medicinal cannabis products, there remain significant gaps in our scientific understanding. The committee was informed that there are numerous conditions for which cannabinoid therapy is under investigation, including treatments for tumours and cancer, seizures in patients with severe forms of epilepsy, endocrine-metabolic modification in diabetes, post-traumatic stress syndrome, Alzheimer's disease, and inflammatory bowel disease. As discussed in chapter 2, academics from the University of Sydney explained that cannabinoid science is a rapidly developing field and has 'remarkable potential to influence human disease and wellbeing'.

5.3 The committee is encouraged by and supportive of the research activity in this space. While medical experts and researchers voiced differences of opinion over the effectiveness of medicinal cannabis during the course of the inquiry, further research will demonstrate in what circumstances medicinal cannabis is a safe and effective remedy, and where it is ineffective or inappropriate.

5.4 This medical perspective was put into context by the personal accounts of witnesses such as Mrs Lucy Haslam and Mrs Joelle Neville. The committee again thanks those submitters and witnesses willing to share their personal experiences with the committee: this evidence gave the committee an insight into the dire and sometimes tragic circumstances in which patients and families find themselves where conventional therapeutic options have failed or are intolerable. The committee acknowledges the relief from symptoms many patients experience as a result of medicinal cannabis and the difficulties they face in obtaining a remedy they have found to be of benefit.

5.5 The committee is particularly persuaded by the personal accounts it heard and is unanimously in support of patient access to products derived from cannabis. However, for the safety of patients and the protection of medical professionals the committee believes it is important that medicinal cannabis is used to treat identified medical conditions where it has been proven to be safe and effective.

Recommendation 1

5.6 The committee supports, in principle, the access to products derived from cannabis for use in relation to particular medical conditions where the use of those products has been proven to be safe and effective.

Recommendation 2

5.7 The committee recommends that the Bill is amended, if necessary, to establish mechanisms by which scientific evidence about medicinal cannabis products can be assessed to determine their suitability for use in the treatment of particular medical conditions.

5.8 Some submitters and witnesses raised concerns about the interaction between the Bill and Australia's existing regulatory framework as well as its obligations under international law. For example, the Department of Health (the department) and Therapeutic Goods Administration (TGA) raised concerns about the interaction of the Bill with the *Therapeutic Goods Act 1989*, the *Narcotics Drug Act 1967*, customs regulations in respect of prohibited imports and exports and the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* (see chapter 4). Both the department and the TGA were concerned about the Bill's interactions with this Commonwealth legislation and the potentially confusing and contradictory regulatory regime which could result.

5.9 While the committee is supportive of patients' access to medicinal cannabis in appropriate circumstances, the committee does not believe it is appropriate to burden regulators, industry or medical professionals with unnecessary red tape. The committee shares the concerns of the department and the TGA: any duplication, contradiction or uncertainty arising from the Bill's implementation must be resolved. The committee therefore recommends that the Bill is amended to address the issues raised by the department and the TGA about its interaction with the existing Commonwealth regulatory system for medicinal products, including but not limited to the *Therapeutic Goods Act 1989*, the *Narcotics Drug Act 1967* and relevant customs legislation.

Recommendation 3

5.10 The committee recommends that the Bill is amended to address issues raised about its interaction with the existing Commonwealth regulatory framework for medicinal products, including the *Therapeutic Goods Act 1989*, the *Narcotics Drug Act 1967* and relevant customs legislation.

5.11 The committee also notes the significant concerns raised not only in relation to the Bill's interaction with existing Commonwealth legislation but also with Australia's international obligations. As discussed in chapters 2 and 4, Australia is party to the *Single Convention on Narcotic Drugs* (the Single Convention), the *Convention on Psychotropic Substances* and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*. In particular, the department highlighted inconsistencies between the Bill and Australia's international obligations, and the risk that passage of the Bill in its current form may result in Australia breaching these obligations.

5.12 To address these concerns, the committee recommends that the Bill is amended to ensure that medicinal cannabis products can be made available in

Australia in way that is consistent with Australia's international obligations, including under Articles 23 and 28 of the Single Convention.

Recommendation 4

5.13 The committee recommends that the Bill is amended to ensure that medicinal cannabis products can be made available in Australia consistent with Australia's international obligations, including under Articles 23 and 28 of the *Single Convention on Narcotic Drugs (1961)*.

5.14 The operation of the regulatory regime proposed by the Bill and its intersection with state and territory laws and approaches to cannabis (both medicinal and illicit) was the subject of some discussion during the course of the inquiry. The committee notes that some submitters were supportive of a Commonwealth medicinal cannabis scheme providing clarity and consistency, while others indicated that imposition of a Commonwealth regulator would complicate regulation and enforcement by the states and territories as well as confuse patients accessing the scheme.

5.15 This confusion and any contradiction or conflict between the operation of the proposed Commonwealth regulator and the states and territories should be addressed to ensure the effective implementation of a scheme to access medicinal cannabis in Australia. The committee urges the Commonwealth government to consult with the states and territories about the inter-relationship of relevant laws to ensure a consistent approach and to facilitate compliance not only with any medicinal cannabis access scheme but also with Australia's international obligations.

Recommendation 5

5.16 The committee recommends that the Commonwealth government consult with its state and territory counterparts about the interrelationship of relevant laws to ensure a consistent approach to accessing medicinal cannabis and to facilitate compliance with any such access scheme and Australia's international obligations.

5.17 If the concerns raised in this chapter and detailed elsewhere in this report are addressed, the committee recommends that the Bill, as amended, is passed.

Recommendation 6

5.18 Subject to the preceding recommendations, the committee recommends that the Bill be passed.

Senator the Hon Ian Macdonald
Chair

Appendix 1

Public submissions

1	Ms Debra Cliff
2	The Don Medicinal Cannabis
3	New South Wales Bar Association
4	Professor Wayne Hall, University of Queensland
5	Ms Frances McDonald
6	Mrs Sharee Barker
7	Ms Pam Kniese
8	Phytotech Medical Ltd
9	Emeritus Professor David Penington
10	Cancer Voices Australia
11	Mr Troy Stone
12	Mr Brett Caton
13	Mr Thomas Forrest
14	Ms Kim Reader
15	Mr Peter Halliburton
16	Ms Erica Mass
17	Emeritus Professor Laurence Mather
18	Pharmacy Guild of Australia
19	Drug Policy Modelling Program, National Drug and Alcohol Research Centre, UNSW
20	Ms Estelle Ross
21	Mr Peter Burnheim
22	Mr Marcelo Lederman
23	Palliative Care Australia
24	Medicines Australia
25	Ms Anne Layton-Bennett
26	Public Health Association of Australia's (PHAA)
27	Ms Kate Dalton

28 Australian Lawful Use of Cannabis Alliance

29 Royal Australasian College of Physicians

30 Australian Federation of AIDS Organisations, the National Association of People with HIV Australia, ACON and Positive Life NSW

31 Epilepsy Action Australia

32 Mrs Colleen Morgan

33 Mr Joseph Sepe

34 Australian Cannabis Industry Association

35 Mrs Rebecca Eager

36 Australian Drug Law Reform Initiative

37 Cancer Council Australia & Clinical Oncology Society of Australia

38 Joynt Venture

39 Eros Association

40 Mr David King

41 Australian Christian Lobby

42 Australian and New Zealand Society of Palliative Medicine

43 Cannabis Policy Project

44 Australian Medical Association

45 Australian Institute of Health and Welfare (AIHW)

46 Ms Nicole Cowles

47 Mr David Gillespie

48 Bedrocan

49 MS Australia and MS Research Australia

50 AusCann Group Holdings Pty Ltd

51 Royal Australian and New Zealand College of Psychiatrists

52 Dr David Allsop, Clinical Associate Professor Nick Lintzeris, Associate Professor Jonathon Arnold and Professor Iain McGregor (University of Sydney)

53 Bar Association of Queensland (

54 FamilyVoice Australia

55 Australian Lawyers Alliance

56 Painaustralia

57 Fagron Compounding Supplies Australia

58 ACES Group

59 Drug Policy Alliance

60 Queensland Council for Civil Liberties

61 Law Institute of Victoria

62 Happy Herb Company

63 Peter, Beverly and Hannah Rubenach

64 Ms Lyn Cleaver

65 Elixinol LLC

66 National Centre for Education and Training on Addiction

67 Department of Health

68 Mrs Lucy Haslam

69 Victorian Government

70 Ms Joelle Neville

71 The Hon David Ipp

72 Mr Gary Anderson

73 Ms Belinda Doonar

74 Mr Andrew Kavasilas

75 Penington Institute

76 Dr Ross MacPherson

77 Ms Candice Germana

78 Ms Ellen Lloyd

79 Dr Andrew Katelaris

80 Ms Alison Alsop

81 Mr Sergio Pagliazzi, Mr Abdul Rehman Mohammad, Dr Tina Soulis and Professor Terence O'Brien

82 Families and Friends for Drug Law Reform (ACT)

83 Mr Nevil Schoenmakers

84 Mr David Stevens

85 Ecofibre Industry Operations

86 Cannabis Compassion Australia

87 Ms Dannielle Slater

88 Ms Candy Walton

89 Mr Alan Roncan
90 Mrs Hazel Lloyd
91 Mr Peter jaggle
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100 Name Withheld
101 Name Withheld
102 Name Withheld
103 Name Withheld
104 Mr Rowan Jacka
105 Ms Stephanie Gleeson
106 Piper Burnett
107 Macciza Macpherson
108 Randev Seneviratne
109 Ms Cheri O'Connell
110 Mr Grant Beale
111 Ms Gisela Stieglitz
112 Ms Breen Rose
113 Aljen Project
114 John Reeves
115 Ms Sherri Hickey
116 Wellness Clinic Newcastle
117 Name Withheld
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131 Name Withheld
132 Name Withheld
133 Name Withheld
134 Name Withheld
135 Name Withheld
136 Mr Jesse Birch
137 Ms Angela Dawe
138 Visko van der Marwe
139 Ms Tania Williams
140 Mr Simon Case
141 Mr Alex Gifford
142 Mr Geoff Cox
143 Ms Debra Lynch
144 Mr Michael Balderstone
145 Medical Cannabis Users Association
146 Cannabis Social Club Australia
147 ACT Government
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163 Name Withheld
164 Miss Matilda Haley-Kerr
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179 Name Withheld
180 Name Withheld
181 Name Withheld
182 Ms Deborah McGregor
183 Ms Marie Cowling
184 Kane Cordin

185	Mrs Lanai Carter
186	Name Withheld
187	Mr Phil Lebedev
188	Ms Kaylee Winter
189	Mr Rohan Richardson
190	Mr Matthew Taylor
191	Mr Malcolm Wilson
192	Name Withheld
193	Ms Margriet Hendriksen
194	Mr Douglas Brown
195	Confidential
196	Confidential
197	Confidential
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200	Confidential
201	Confidential
202	Confidential
203	Confidential
204	Confidential
205	Confidential
206	Ms Althea Giuliani
207	Gis Sun
208	Confidential
209	Name Withheld
210	Medicann Pty Ltd
211	Mr Jack Thomson
212 to 261	Form Letter Example (50 submissions of similar form were received)

Answers to questions on notice

1 Emeritus Professor David Penington - answers to questions taken on notice at a public hearing on 30 March 2015 (received 2 April 2015)

2 Cancer Council Australia – response to a question taken on notice at a public hearing on 31 March 2015 (received 10 April 2015)

3 Therapeutic Goods Administration – response to a question taken on notice at a public hearing on 30 March 2015 (received 22 April 2015)

4 Novartis – answers to written questions taken on notice (received 8 June 2015)

Tabled documents

1 Ms Lucy Haslam - Document tabled at public hearing 31 March 2015

2 Australian Drug Law Reform - Document tabled at public hearing 31 March 2015

Additional information

1 Information provided Professor Robert Batey AM, Royal Australian College of Physicians (received 31 March 2015)

2 Information provided by Mr Paul Benhaim (received 1 April 2015)

3 Information provided by Mrs Lanai Carter (received 17 April 2015)

Appendix 2

Public hearings and witnesses

Monday, 30 March 2015—Canberra

HORNER, Ms Philippa, Principal Legal Advisor, Therapeutic Goods Administration, Department of Health

LEAHY, Mr Denis, National Councillor (New South Wales), Pharmacy Guild of Australia

LINKSON, Ms Marita, Executive Officer, Australian and New Zealand Society of Palliative Medicine

McDONALD, Mr David Neil, Secretary, Australian Capital Territory Branch, Public Health Association of Australia

MITCHELL, Dr Maureen, Member, Australian and New Zealand Society of Palliative Medicine

MOORE, Adjunct Professor Michael John, Chief Executive Office, Public Health Association of Australia

PENINGTON, Professor David, Emeritus Professor, University of Melbourne

SMYTH, Mr Nathan, First Assistant Secretary, Population Health Division, Department of Health

STUDDERT, Dr Lisa, Market Authorisation Group, Therapeutic Goods Administration, Department of Health

TODD, Mr Ian, National Councillor (South Australia), Pharmacy Guild of Australia

Tuesday, 31 March 2015—Sydney

ALLSOP, Dr David John, Private capacity

BATEY, Professor Robert Gordon, Fellow, Australasian Chapter of Addiction Medicine; Fellow, Royal Australasian College of Physicians

CALLAGHAN, Ms Liz, Chief Executive Officer, Palliative Care Australia

CHYE, Associate Professor Richard, Board Member, Palliative Care Australia

CROSSING, Ms Sally, Convener, Cancer Voices Australia

FEENEY, Mr Lance, Policy Analyst, National Association of People with HIV Australia, Australian Federation of AIDS Organisations, Positive Life New South Wales and ACON

HANSEN, Ms Linda, Executive Officer, Palliative Care New South Wales

HASLAM, Mrs Lucy Anne, Private capacity

HUNTIR, Mr Alex, Manager, Volunteer Support Services, Palliative Care New South Wales

IRELAND, Ms Carol, Chief Executive Officer, Epilepsy Action Australia

KRISHNASAMY, Professor Mei, President, Clinical Oncology Society of Australia

LINTZERIS, Associate Professor Nicholas, Private capacity

MATHER, Emeritus Professor Laurence Edward, Private Capacity

McGREGOR, Professor Iain Stewart, Private capacity

MELTON, Dr Lisa, Research Development Manager, MS Research Australia and MS Australia

MORRIS, Professor Philip LP, Fellow, Royal Australian and New Zealand College of Psychiatrists; Fellow, Australasian Chapter of Addiction Medicine; Fellow, Royal Australasian College of Physicians

MOSTYN, Mr Benjamin Thomas, Member, Australian Drug Law Reform Initiative

RITTER, Professor Alison, Director, Drug Policy Modelling Program, National Drug and Alcohol Research Centre, University of New South Wales

TODD, Ms Lisa, Clinical Governance Manager, Epilepsy Action Australia

WHITTAKER, Ms Kate, Manager, Cancer Care Policy, Cancer Council Australia

WODAK, Dr Alexander David, AM, Member, Executive Committee, Australian Drug Law Reform Initiative

Wednesday, 1 April 2015—Brisbane

BENHAIM, Mr Paul, Founder and Chief Executive Officer, Elixinol LLC

CARTER, Ms Lanai, Private capacity

COPE, Mr Michael James, President, Queensland Council for Civil Liberties

CRAWFORD, Ms Janice, Member, Criminal Law Committee, Bar Association of Queensland

GILLESPIE, Mr David, Chief Executive Officer, Agricultural Microbes Pty Ltd

HALL, Professor Wayne Denis, Private capacity

MILES, Mrs Rhonda, Private capacity

NEVILLE, Mr Paul Christopher, Private capacity

NEVILLE, Mrs Joelle Elizabeth, Private capacity

RANSLEY, Mr John Edward, Executive Member, Queensland Council for Civil Liberties

WACHTEL, Mr Boaz, Managing Director, Phytotech Medical Ltd

WILSON, Ms Elizabeth Sybil, QC, Chair, Criminal Law Committee, Bar Association of Queensland

Appendix 3

Medicinal cannabis across the globe – overview of currently deployed modes of patient access and supply of medicinal cannabis

Source of medicinal cannabis within the country	Official medicinal cannabis dispersion to patients	Where applied	PROs	CONs	Adherence to international treaties
1) No official source of medicinal cannabis (patients exempted from criminal procedures upon doctor's recommendation / certification (i.e. patient registry / cards)	State-level tolerance to patient´s own cannabis cultivation under medical certification expands to caregivers	U.S. - selected states (Alaska, Hawaii, Maryland), Canada	– patients and caregivers not criminalised for medicinal cannabis use, own cultivation and cultivation / administration by a 3rd person	– not medicinal grade cannabis – treatment follow-up with the doctor not required – no control on cannabis diversion to the recreational market	It is rightful not to proceed with use and personal possession of cannabis under the criminal law.
2) Supply of medicinal cannabis tolerated upon doctor´s recommendation	Specific state or county level laws for medicinal cannabis dispensaries	U.S. - selected states (Arizona, California, Colorado, Delaware, District of Colombia, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington, Canada	– quality competition between producers – patients (caregivers) and suppliers not criminalised for medicinal cannabis use, own cultivation	– medicinal quality control dependent on state-level regulations – treatment follow-up with the doctor not required – low control over dispensaries and conflation with recreational users´ market (prescription regime lacking due to federal laws)	Non-adherence to 1961 U.N. treaty on medicinal cannabis - the U.S. federal scheduling doesn´t recognise cannabis as a medicinal drug, and therefore dispensing is not controlled by a prescription regime. It is, however, rightful not to proceed with use and personal possession of cannabis under the criminal law, and such provision has been applied to cultivation for own use.

3) Medicinal cannabis trial	Certified small-scale provisions of federally- cultivated marijuana	U.S. National Institute of Drug Addiction (NIDA)– selected states (Therapeutic Research Program)	- control over the number and conditions of patients - medicinal grade product - low chances for diversion into recreational market on the wholesale level due to single production point - low chances for diversion into recreational market due to restricted no. of patients	- limited patients´ access - monopoly-originated product, patients complaints about quality	In adherence with 1961 Single convention on medicinal provisions of controlled substances.
4) Outsourcing herbal cannabis / pharmaceutical preparations from abroad (Option 1)	Herbal cannabis: Individual imports based on prescription and further administrative approvals (herbal cannabis from the Netherlands, Sativex from the UK)	Finland, Denmark	- no specific regulatory system needed, administratively managed by the substance control act authority - medicinal grade herbal product - treatment follow-up with the doctor required as with any other medication - low chances for diversion into recreational market given the restricted no. of patients and lack of domestic production	- individual imports are costly and a heavy administrative burden is imposed on the patient	In adherence with 1961 Single convention on medicinal provisions of controlled substances.

4) Outsourcing herbal cannabis / pharmaceutical preparations from abroad (Option 2)	Pharmaceutical preparations: Prescription and pharmacy dispersion of synthetic cannabinoids	Dronabinol or marinol available in Austria, Canada, Germany, France, Spain, Switzerland, UK, U.S., Sativex available in Austria, Canada, New Zealand, UK, Australia	- existing medicine regulatory system used - treatment follow-up with the doctor required as with any other medication - medicinal-grade product - low chances for diversion into recreational market (herbal cannabis not available)	– narrow range of available cannabis medication (lack of herbal products)	In adherence with 1961 Single convention on medicinal provisions of controlled substances.
5) Licensing of growers by an agency (Option 1)	Agency that doesn´t take possession of all domestically grown cannabis; herbal cannabis dispensed via an auxiliary system on doctor´s recommendation	Israel, Canada	- quality competition between producers (e.g. Canada has recently transferred from state-owned production to licensing system due to concerns of product quality under monopoly production) - low chances for diversion into recreational market on wholesale level given the control via agency	- costs of setting up an agency or of assigning its tasks to one of the existing agencies within the country - medicinal quality not guaranteed by the system - treatment follow-up with the doctor not required - chances for diversion into recreational market on consumer level given lack of control via prescription	Partially in adherence with 1961 Single convention on medicinal provisions of controlled substances; control under prescription system is required by the treaty. The possession of cannabis by the agency is rather symbolic.

5) Licensing of growers by an agency (Option 2)	Agency that takes possession of all domestically grown cannabis ; herbal cannabis dispensed in pharmacies upon doctor´s prescription	The Czech Republic, The Netherlands, Uruguay, The United Kingdom (herbal production for Sativex)	- quality competition between producers (e.g. Canada has recently transferred from state-owned production to licensing system due to concerns of product quality under monopoly production) - full adherence to medical and prescription system (herbal cannabis classified as a source substance to compounding pharmacists) - treatment follow-up with the doctor required as with any other medication - low chances of diversion into recreational market on wholesale level given the control via agency and on consumer level given the control via prescription.	- costs of setting up an agency or of assigning its tasks to one of the existing agencies within the country	In adherence with 1961 Single convention on medicinal provisions of controlled substances.

Source: Drug Policy Modelling Program, National Drug and Alcohol Research Centre, UNSW, *Submission 19*, pp 15-18.