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

---

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]

---

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':

---

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]

---

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]

---

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]

---

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.

---

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]

---

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]

---

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 VLRC's *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

---

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

---

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]

---

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,

---

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]

---

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]

---

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).