



Victorian
Law Reform
Commission

Medicinal Cannabis

ISSUES PAPER MARCH 2015





Victorian
Law Reform
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Preface

The Victorian Government has asked the Victorian Law Reform Commission to review and report on options for legislative change to allow people to be treated with medicinal cannabis in exceptional circumstances. The Commission has not been asked whether such a change is desirable, which is a matter for government. However, in reviewing options for legislative change, the Commission necessarily will examine the benefits, efficacy, risks and dangers involved in each.

The Commission has not been asked the wider question of whether cannabis production and use more generally should be permitted. The review is confined to medicinal cannabis in exceptional circumstances. A central question in the review is the definition of what properly constitutes exceptional circumstances for this purpose.

Developing options for legislative change is not merely a technical exercise in removing some of the existing prohibitions on possessing and using cannabis; it is also necessary to build an avenue of health care. Medicinal cannabis, if allowed, would need to be administered as an integral part of the treatment the patient receives, based on a safe and reliable supply, under the supervision of a health practitioner. Thought needs to be given to how any medicinal cannabis scheme introduced in Victoria could focus most effectively on helping the patient. This issues paper provides background information about the therapeutic benefits and risks of medicinal cannabis, the interconnecting Commonwealth and Victorian laws that need to be considered when developing options for change, recent developments in Australia and the approaches taken overseas to legalising cannabis for medicinal purposes.

The issues involved are complex and will attract a range of views. I encourage anyone with an interest in them to make a written submission to the Commission by 20 April 2015. The method of making a submission is stated on page viii of this issues paper.



The Hon. P. D. Cummins AM
Chair, Victorian Law Reform Commission

Call for submissions

The Victorian Law Reform Commission invites your comments on this issues paper.

What is a submission?

Submissions are your ideas or opinions about the law under review and how to improve it. This issues paper contains a number of questions, listed on page 170, that seek to guide submissions. You do not have to address all of the questions to make a submission.

Submissions can be anything from a personal story about how the law has affected you to a research paper complete with footnotes and bibliography. We want to hear from anyone who has experience with the law under review. Please note that the Commission does not provide legal advice.

What is my submission used for?

Submissions help us understand different views and experiences about the law we are researching. We use the information we receive in submissions, and from consultations, along with other research, to write our reports and develop recommendations.

How do I make a submission?

You can make a submission in writing, or verbally to one of the Commission staff, if you need assistance. There is no required format for submissions, though we prefer them to be in writing and we encourage you to answer the questions on page 170.

Submissions can be made by:

Completing the online form at www.lawreform.vic.gov.au

Email: law.reform@lawreform.vic.gov.au

Mail: GPO Box 4637, Melbourne Vic 3001

Fax: (03) 8608 7888

Phone: (03) 8608 7800, 1300 666 557 (TTY) or 1300 666 555 (cost of a local call)

Assistance

Please contact the Commission if you need an interpreter or other assistance to make a submission.

Publication of submissions

The Commission is committed to providing open access to information. We publish submissions on our website to encourage discussion and to keep the community informed about our projects.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments, or which are outside the scope of the reference. Before publication, we may remove personally identifying information from submissions that discuss specific cases or the personal circumstances and experiences of people other than the author. Personal addresses and contact details are removed from all submissions before they are published. The name of the submitter is published unless we are asked not to publish it.

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, those views by the Commission.

We keep submissions on the website for 12 months following the completion of a reference. A reference is complete on the date the final report is tabled in Parliament. Hard copies of submissions will be archived and sent to the Public Records Office Victoria.

The Commission also accepts submissions made in confidence. Submissions may be confidential because they include personal experiences or other sensitive information. These submissions will not be published on the website or elsewhere. The Commission does not allow external access to confidential submissions. If, however, the Commission receives a request under the *Freedom of Information Act 1982* (Vic), the request will be determined in accordance with the Act. The Act has provisions designed to protect personal information and information given in confidence. Further information can be found at www.foi.vic.gov.au.

Confidential submissions

When you make a submission, you must decide whether you want your submission to be public or confidential.

- Public submissions can be referred to in our reports, uploaded to our website and made available to the public to read in our offices. The names of submitters will be listed in the final report. Private addresses and contact details will be removed from submissions before they are made public, but the name of the submitter is published unless we are asked not to publish it.
- Confidential submissions are not made available to the public. Confidential submissions are considered by the Commission but they are not referred to in our final reports as a source of information or opinion other than in exceptional circumstances.

Please let us know your preference when you make your submission. If you do not tell us that you want your submission to be treated as confidential, we will treat it as public.

Anonymous submissions

If you do not put your name or an organisation's name on your submission, it will be difficult for us to make use of the information you have provided. If you have concerns about your identity being made public, please consider making your submission confidential rather than submitting it anonymously.

More information about the submission process and this reference is available on our website: www.lawreform.vic.gov.au

Submission deadline: 20 April 2015

Terms of reference

[Matter referred to the Commission pursuant to section 5(1)(a) of the *Victorian Law Reform Commission Act 2000* (Vic) by the Victorian Attorney-General, the Hon. Martin Pakula MP on 19 December 2014.]

1. The Victorian Law Reform Commission is asked to review and report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations to allow people to be treated with medicinal cannabis in exceptional circumstances, and to make the recommendations for any consequential amendments which should be made to the:
 - *Therapeutic Goods (Victoria) Act 2010*
 - Any other relevant legislation.
2. In conducting the review, the Commission is asked to consider:
 - the operation of Victoria's *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations, and how this interacts with Commonwealth law, functions and any relevant international conventions.
 - medicinal use of cannabis in other jurisdictions.
3. The Commission is asked to appoint expert panels to assist in its review, specifically to examine:
 - Prescribing practices for medicinal cannabis, including eligibility criteria for access to medicinal cannabis and the role of doctors in managing the use of medicinal cannabis by patients
 - The regulation of medicinal cannabis manufacture and distribution, including which forms of medicinal cannabis should be permitted for use.
4. The Commission should report no later than 31 August 2015.

Glossary

Key terms

Cannabinoids	Substances that bind to biological receptors to produce the pharmacological effects demonstrated by cannabis, including both natural and synthetic cannabinoids.
Cannabis	Reference to the cannabis plant and any product derived from the plant, including dried cannabis (marijuana) and cannabis extracts. Includes the species <i>Cannabis sativa</i> , <i>Cannabis indica</i> and <i>Cannabis ruderalis</i> .
Cannabis extract	Any concentrated form of cannabis in which the chemical components of the cannabis plant have been removed from the plant material, using a solvent or infusion method (includes cannabis oil and tinctures).
Cannabis oil	A liquid produced by infusing cannabis leaves and flowers in a solvent (such as an oil or an alcohol) to produce a concentrated extract, which can be thinned using oil. Sometimes known as 'hash oil'.
Cannabis resin	The resin of the cannabis plant, contained in trichomes on the flowering heads of the plant, and collected by being scraped or shaken from the buds and flowers. The resin can also be separated from the plant using ice-water.
CBD	Cannabidiol, a non-psychoactive cannabinoid found in the cannabis plant.

Dabbing	A method for consuming concentrated cannabis oil, whereby a dab of concentrate is placed on the end of a heated rod and its vapours inhaled by the user.
Dried cannabis	The dried flowers, leaves and stems of the cannabis plant.
Dronabinol	A pharmaceutical formulation of synthetically produced THC (specifically the isomer delta-9-tetrahydrocannabinol), available in the United States and Canada under the trade name Marinol.
Endocannabinoid	An endogenous substance that activates the same receptors as phytocannabinoids.
FDA	The Food and Drug Administration, a statutory agency of the United States Federal Government responsible for regulation of pharmaceutical products in the US, among other activities.
Flavonoid	Compounds found in plants which contribute flavour, aroma and pigment and are thought to provide a range of health benefits.
Hash/hashish	Cannabis resin which has been dried. Hash is often compressed into blocks.
Health practitioner	An individual who practises a health profession, as defined in the <i>Health Practitioner Regulation National Law (Victoria) Act 2009</i> .
Hemp	Varieties of cannabis which contain low levels of THC (generally 1 per cent or lower by weight), and are commonly used to produce fibre (for use in cloth, rope and so on) or hemp oil (made from pressed hemp seeds used in cosmetics and, in some places, food).
Infused products	Cannabis products produced by the infusion of dried or fresh cannabis in a solvent.
Medical practitioner	A person registered to practise in the medical profession under the <i>Health Practitioner Regulation National Law (Victoria) Act 2009</i> .

Nabilone	A synthetic cannabinoid that is chemically similar to THC and mimics its effects, and is used pharmaceutically in the form of a capsule. Nabilone is sold in the US under the trade name Cesamet.
Nabiximols	A whole-plant botanical extract of cannabis, administered as a mouth spray, containing THC and CBD in approximately equal proportions and comprising not less than 90 per cent of the total cannabinoid content, and which may contain other trace cannabinoids. The trade name for nabiximols is 'Sativex'.
Pharmaceutical grade	Describing a substance manufactured in accordance with good manufacturing practice and a chemical purity standard established by a recognised publication.
Phytocannabinoid	Any plant-derived cannabinoid or plant-derived substance which interacts with the endocannabinoid system or is similar in structure to a cannabinoid.
SUSMP	The Standard for the Uniform Scheduling of Medicines and Poisons No 6, contained in Schedule 1 to <i>The Poisons Standard 2015</i> , a legislative instrument made under the <i>Therapeutic Goods Act 1989</i> (Cth).
Synthetic cannabinoid	Cannabinoids of synthetic origin, including compounds which are not chemically identical to but mimic the effect of cannabinoids found in the cannabis plant.
Terpene	Volatile compounds found in the cannabis plant.
TGA	The Therapeutic Goods Administration, a division of the Commonwealth Department of Health.
THC	Tetrahydrocannabinol, the principal psychoactive constituent (or cannabinoid) of the cannabis plant. An isomer of THC, delta-9-tetrahydrocannabinol, sometimes referred to as dronabinol, is believed to be the most active version of the compound.

THCA	Tetrahydrocannabinolic acid, the precursor chemical to THC. THCA is converted to THC as fresh cannabis dries, and when cannabis is subjected to heat, such as by smoking, baking or vaporisation. THCA lacks the psychoactive effects of THC but acts on the same receptors.
Tincture	A solution of cannabis infused in alcohol, administered under the tongue or taken orally.
Titrate	Measure and adjust the dosage of a drug.
Vaporiser	A device which heats dried cannabis or a cannabis extract to a temperature at which a vapour containing cannabinoids is released.

Medical terms

Acute pain	Pain which lasts for a short time, provoked by a specific disease or injury.
Adjuvant	A type of therapy or treatment that enhances the activity of the primary therapy or treatment. Often used to describe chemotherapy or radiotherapy.
Agonist	A drug or chemical which acts on a receptor to produce a reaction similar to that provoked by a naturally occurring substance.
AIDS	Acquired Immunodeficiency Syndrome, the final stage of HIV infection. AIDS is a chronic, potentially life-threatening condition, which damages the body's immune system.
Alzheimer's disease	A progressive, degenerative disorder that attacks the brain's nerve cells (neurons), resulting in loss of memory, thinking and language skills, and behavioural changes. Alzheimer's disease is the most common cause of dementia among those aged 65 and older.
Anti-oxidant	A substance which inhibits oxidation. In the body, by removing free radicals which could otherwise cause cell damage.

Analgesia	The moderation of painful stimuli so that they are no longer painful, but still perceived. An analgesic is a substance which has this effect
Anorexia nervosa	A personality disorder manifested by extreme fear of becoming obese, resulting in weight loss and an aversion to eating.
Anti-convulsant	Preventing or arresting seizures.
Anti-emetic	Preventing or arresting vomiting.
Anti-inflammatory	Reducing inflammation, without affecting the underlying cause.
Anxiolytic	Reducing anxiety.
Arthritis	A group of diseases (the arthritides) involving inflammation of a joint, resulting in pain, swelling and limited movement.
Cachexia	Weight loss and wasting occurring during a chronic disease.
Cannabis use disorder	Recurrent use of cannabis causing clinically and functionally significant impairment, such as health problems, disability and failure to meet responsibilities at work, school or home. Symptoms listed in the DSM-5 include disruptions in functioning, development of tolerance, cravings for cannabis and the development of withdrawal symptoms within a week of ceasing use.
Carcinogen	A cancer-producing substance or organism.
Chemotherapy	Treatment of disease (especially cancer) by means of chemical substances.
Chronic pain	Pain which persists beyond the time of healing of surgery, trauma or other condition, frequently without a clearly identifiable cause.
CNS	Central nervous system.

Crohn's disease	A type of inflammatory bowel disease affecting the digestive tract, which can lead to abdominal pain, severe diarrhoea, fatigue, weight loss and malnutrition.
Dravet Syndrome	A rare form of severe, intractable epilepsy beginning in infancy, causing frequent seizures. Children with Dravet Syndrome typically experience poor development of language and motor skills, hyperactivity, and difficulty relating to others. Also known as Severe Myoclonic Epilepsy of Infancy.
DSM-5	The 5 th edition of the American Medical Association's <i>Diagnostic and Statistical Manual of Mental Disorders</i> , published in 2013.
Dyskinesia	Abnormal or impaired movement, including involuntary muscle movements and diminished voluntary movement.
Endocannabinoid system	A signalling system in the human body, comprising receptors, ligands (endocannabinoids) and associated proteins and enzymes. The receptors include those activated by THC and other cannabinoids. The system has a key role in controlling nervous system functions and many other aspects of human physiology.
Epilepsy	A chronic neurological disorder characterised by violent, uncontrolled seizures and usually associated with some alteration of consciousness.
Fibromyalgia	A condition of unknown cause, characterised by widespread pain, abnormal pain processing, sleep disturbance, fatigue and often psychological distress, and often co-occurring with other rheumatic conditions.
Glaucoma	A disease of the eye characterised by increased interocular pressure and damage to the the optic nerve, which produces vision defects and can result in blindness.
HIV	Human Immunodeficiency Virus, a virus spread through bodily fluids that weakens a person's immune system. HIV can lead to AIDS.

Immunosuppressive	Inducing prevention or interference with the development of immunologic response. An immunosuppressant is a compound having these qualities.
Inflammatory bowel disease	One of a number of conditions which cause chronic or recurring immune response and inflammation of the digestive tract. Includes Crohn's disease and ulcerative colitis.
Interocular pressure	The fluid pressure within the eyeball which maintains its round firm shape. Abnormally high interocular pressure is a risk factor for the development of glaucoma.
Intractable	Resistant to treatment.
Lennox-Gastaut Syndrome	A form of epilepsy which begins in childhood and causes frequent seizures of varying types. It often results in some degree of impaired intellectual functioning or information processing, developmental delays and behavioural disturbances.
Multiple sclerosis (MS)	A condition involving an abnormal response by the body's immune system directed against the CNS, which attacks nerve fibres and the fatty tissue that surrounds them, resulting in the formation of scar tissue (sclerosis) around nerves and the distortion and interruption of nerve impulses. Symptoms vary but can include fatigue, numbness, weakness, dizziness and vertigo, pain, cognitive changes, difficulty walking, spasticity, bladder and bowel problems and mood changes.
Myocardial infarction	Commonly known as a heart attack, a condition where a coronary artery or one of its smaller branches becomes suddenly blocked.
Myoclonic	Describing quick, shock-like muscle jerks.
Neurological	Concerning the nervous system and the diseases affecting it.
Neuropathic pain	Pain caused by damage or dysfunction in the peripheral or central nervous system.

Neuroprotective	Having the effect of protecting neurons from injury or degeneration or restoring or regenerating them.
Nociceptive	Capable of the appreciation or transmission of pain.
Palliative care	Medical care to improve the quality of life of patients and their families facing life-threatening illnesses, including support systems and pain relief.
Parkinson's disease	A neurological syndrome, usually resulting from a dopamine deficiency, as the consequence of changes to the basal ganglia, characterised by rhythmical muscular tremors and rigidity of movement.
Psychoactive	Affecting mental activity, behaviour or perception, such as a drug.
Psychosis	A mental and behavioural disorder causing gross distortion or disorganisation of a person's mental capacity, affective response and capacity to recognise reality, communicate and relate to others. An anti-psychotic is a substance used to treat psychotic disorders.
Psychotogenic	Capable of inducing psychosis.
Psychotropic	Synonym for psychoactive.
PTSD	Post-traumatic stress disorder.
Schizophrenia	A chronic, severe and disabling brain disorder, which can cause hallucinations, delusions, thought and movement disorders, along with disruptions to normal emotions and behaviours and compromised cognitive functioning. A diagnosis of a schizophreniform disorder may be made if symptoms of schizophrenia exist but have not been present for sufficient time for schizophrenia to be diagnosed.
Spasticity	Stiff or rigid muscles, with unusual tightness or increased muscle tone.

Tourette's syndrome A neurological disorder characterised by repetitive, stereotyped, involuntary movements and vocalisations (tics).

Tachycardia A faster-than-normal resting heart rate.

Botanical terms

Genus In biological taxonomy, the classification one level above species.

Strain A group of plants distinguished from other plants of its category by a particular trait, such as a high yield, but not considered a separate variety.

Trichomes A hair-like growth on a plant's outer surface. The glandular trichomes of cannabis are considered to be the primary location on the plant for medically useful cannabinoids.

Research terms

Clinical trial A research study that prospectively assigns participants to one or more treatments (interventions) to evaluate their effect on health outcomes.

Crossover study A study in which groups of participants receive two or more treatments in a particular order. For example, the first of two groups may receive treatment A then treatment B, with the second group receiving treatment B then treatment A.

Double-blind Where two or more parties (typically the investigator and the participant) do not know which participants have been assigned to which treatments.

Observational study A study in which participants are assigned to study groups and observed. While treatments may be applied, participants are not assigned to particular treatments.

Phase I clinical trials	A category of drug trial used by the FDA. Phase I clinical trials are conducted with healthy volunteers, with the aim of finding out the drug's most frequent and serious adverse events, and how the drug is metabolised and excreted.
Phase II clinical trials	A category of drug trial used by the FDA. Phase II clinical trials gather preliminary data on effectiveness (that is, whether the drug works for certain conditions), which may involve comparing the drug's effects with a placebo. Safety is also evaluated.
Phase III clinical trials	A category of drug trial used by the FDA. Phase III clinical trials gather more information about safety and effectiveness, by studying different dosages, populations and drug combinations. The final stage before marketing approval is granted.
Placebo-controlled	Describing a study in which the effectiveness of drug is compared with the effect of a placebo (a substance which resembles the drug but does not contain the active ingredient).
Randomised study	Describing a study in which participants are assigned to treatment groups by chance.

Pharmacological terms

Decarboxylate	Removal of a molecule of carbon dioxide from a carboxylic acid, for example the conversion of THCA to THC.
Lipophilic	Tending to or capable of dissolving in oil.
Oromucosal	Of a preparation, intended for administration via the mouth and/or throat.
Opiate	A derivative of opium.
Opioid	A narcotic substance.

Receptor	A chemical group or molecule on the surface of or inside a cell which binds to a particular compound or chemical group (such as a hormone, antigen or neurotransmitter).
Sublingual	Of a preparation, intended to be administered under the tongue.
Supercritical carbon dioxide	Carbon dioxide held at or above its critical temperature and critical pressure, in which state it behaves as both a gas and a liquid. Can be used instead of an organic solvent to extract desired compounds.
Topical	Of a preparation, intended for administration via the skin.
Transmucosal	Of a preparation, intended for administration via a mucous membrane, such as the nose or mouth cavity.

Introduction

- 2 Referral to the Commission
- 2 Conduct of this reference
- 3 Summary of this paper

1 Introduction

Referral to the Commission

- 1.1 On 19 December 2014, the Attorney-General, the Hon. Martin Pakula, MP, asked the Victorian Law Reform Commission, under section 5(1)(a) of the *Victorian Law Reform Commission Act 2000* (Vic), to review and report on options for changes to Victorian law to allow people to be treated with medicinal cannabis in exceptional circumstances. The terms of reference appear at page xi.
- 1.2 The Victorian Government is committed to enabling the lawful use of cannabis for medicinal purposes in exceptional circumstances.¹ The terms of reference do not invite the Commission's views on this policy, nor on the separate question of whether the prohibition on the cultivation, production, supply and use of cannabis should be fully lifted. Accordingly, the Commission makes no comment on these matters and will not explore them in its consultations.
- 1.3 The Commission is to report by 31 August 2015.

Conduct of this reference

Specialist Commissioner

- 1.4 The Government appointed Dr Ian Freckelton QC as a Commissioner to lead the reference, with effect from 27 January 2015 to 31 August 2015. Dr Freckelton is widely experienced in medico-legal and scientific matters.

Division

- 1.5 The Chair of the Commission exercised his powers under section 13(1)(b) of the Victorian Law Reform Commission Act to constitute a Division to guide and oversee the

¹ 'Victorian Government Moves Ahead with Plans to Legalise Medical Marijuana', *ABC* (online), 19 December 2014 <<http://www.abc.net.au/news>>.

conduct of the reference. All members of the Commission have joined him on the Division.

Advisory committees

- 1.6 The terms of reference ask the Commission to appoint expert panels specifically to examine prescribing practices and the regulation of the manufacture and distribution of medicinal cannabis.
- 1.7 Committees of experts have often assisted the Commission in identifying issues and exploring options for reform, though they are not involved in developing or voting on the Commission's recommendations. They are a valuable source of advice and the Commission appreciates the time and expertise that the members contribute.
- 1.8 Two advisory committees have been formed for the medicinal cannabis reference:
- a medical advisory committee, comprising experts in the therapeutic use of cannabis and current clinical research in the area
 - a regulation advisory committee, comprising experts in effective regulation and the operation of current law and overseas reforms.

Issues paper and submissions

- 1.9 In order to meet the report deadline, the Commission has not followed its usual practice of releasing a comprehensive consultation paper, after initial discussions with stakeholders, seeking comments on law reform options. The publication of this issues paper marks the beginning of consultations. It provides background information and asks questions about the issues arising from the terms of reference.
- 1.10 The Commission is seeking written submissions in response to the questions by 20 April 2015. Information about how to make a submission is set out on page viii.
- 1.11 Follow-up discussions with members of the community, to identify law reform options, will be scheduled after the closing date for submissions.

Summary of this paper

- 1.12 Two lines of inquiry can be discerned from the terms of reference:
- how to define the exceptional circumstances in which a person should be allowed to be treated with medicinal cannabis
 - 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.
- 1.13 This paper provides the context for exploring these areas of investigation.
- 1.14 Any approach to determining the exceptional circumstances in which a person could lawfully use cannabis for medicinal purposes should be grounded in an understanding of its therapeutic benefits, efficacy, risks and dangers. Scientific knowledge about cannabis is steadily expanding, as is anecdotal information about the results experienced by people who are using it to relieve a range of medical conditions and symptoms.

Chapter 2 describes what cannabis is and how it is used, and Chapter 3 summarises what is currently known about its therapeutic properties.

- 1.15 Chapter 4 explains the current laws that control access. There is some scope for Victoria to act alone in introducing a medicinal cannabis scheme. Broader change would affect the functions and powers of the Commonwealth and its laws.
- 1.16 Although this is the first review of options for changing the law to allow the medicinal use of cannabis in Victoria, it follows reports on similar issues in New South Wales in 2000² and 2013,³ the Australian Capital Territory in 2005,⁴ and Tasmania in 2014.⁵ These and other initiatives that may facilitate the use of cannabis, or cannabinoids, for medicinal purposes in Victoria, other Australian jurisdictions, or nationally are discussed in Chapter 5.
- 1.17 Chapter 6 provides an overview of the approaches that have been taken in other countries. There are many models from which Victoria's medicinal cannabis scheme can be drawn. Among others, Canada, Israel, the Netherlands, Italy, the Czech Republic and more than 20 states in the United States have introduced laws that allow cannabis to be used for medicinal purposes.
- 1.18 Although overseas experience and perspectives can assist in identifying regulatory tools, regulatory reform in Victoria should establish a scheme that is coherent, humane and directed to achieving clear objectives. Chapter 7 identifies regulatory objectives that are relevant in assessing options for legislative change, and then discusses the options.
- 1.19 Chapter 8 concludes the paper and invites submissions by 20 April 2015.
- 1.20 The Commission is proceeding upon the basis that its review should be evidence-based, open and balanced.

² Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000).

³ Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013).

⁴ Legislative Assembly for the Australian Capital Territory, *Report on the Medicinal Use of Cannabis* (2005).

⁵ Legislative Council Government Administration Committee 'A', Parliament of Tasmania, *Interim Report on Legalised Medicinal Cannabis* (2014).

Cannabis and cannabinoids

- 6 Introduction
- 7 What is cannabis?
- 12 Preparation of the cannabis plant for use
- 19 Synthetic cannabinoids
- 23 Identifying therapeutically appropriate forms

2 Cannabis and cannabinoids

Introduction

- 2.1 Cannabis has an extensive history as a medicinal agent across many cultures and civilisations.¹ Early Chinese accounts dating back to the legendary Emperor Shen-Nung (c2700BC) cite cannabis as an important herbal remedy.² By the first century CE Chinese oral traditions concerning cannabis asserted that it could be used for more than 100 medical conditions. It was incorporated in the first Chinese pharmacopoeia, *Pen-ts'ao Ching*. Cannabis was ranked as the most important of all known medicinal plants in the *Avesta*, the religious text of Zoroastrianism.³ The Persian physician Mohammad-e Zakaria-ye Razi (865–925AD) identified a wide range of medicinal uses of cannabis.
- 2.2 Sir Joseph Banks, the botanist on Captain Cook's 1770 voyage to Australia, is credited with bringing the first recorded cannabis seeds to Australia. Thereafter, it was widely and successfully grown without legal inhibition, principally for hemp. However, a variety of cannabis-based remedies was sold, either by prescription or over the counter.⁴ The best known was Dr J Collis Brown's Chlorodyne, a mixture of black Nepalese hashish, dissolved in chloroform and topped up with morphine.⁵ Attempts were made in 1904 in Australia to ban over-the-counter sales of the preparation but they failed.

¹ Tod H Mikuriya (ed), *Marijuana: Medical Papers, 1839–1972* (Symposium Publishing, 2007); Robert C Clarke and Mark D Merlin, *Cannabis: Evolution and Ethnobotany* (University of California Press, 2013) ch 8.

² Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014) 12.

³ Ethan Russo, 'Cannabis in India: Ancient Lore and Modern Medicine' in Raphael Mechoulam (ed), *Cannabinoids as Therapeutics* (Springer, 2005) 1–22.

⁴ In colonial New Zealand, 'Chlorodyne also included cannabis, another drug widely available for medical purposes ... Indian hemp cigarettes were advertised for the treatment of asthma, coughs and painful menstruation, and Mother Mary Joseph Aubert, founder of the Sisters of Compassion, included it in her remedies. Cannabis was, like opium, included in J F Neil's very popular book, *New Zealand Family Herb Doctor* (1889). Cannabis resin was used to cure corns, while cannabis seeds were fed to poultry. The drug was cheap and freely available': 'Drugs: Colonial Drug Taking' in *Te Ara—The Encyclopedia of New Zealand* (at 10 February 2015) <<http://www.teara.govt.nz/en/drugs/page-1>>.

⁵ John Jiggins, 'The Origins of Marijuana Prohibition in Australia' (2008) 5 *StickyPoint Magazine* <<http://drjiggins.com>>.

- 2.3 By the 1920s, the use of cannabis for any medicinal purpose was prohibited in Australia. New and often better synthetic drugs took their place. By the end of the century, however, there was renewed interest in the therapeutic benefits of cannabis and significant advances were being made in scientific knowledge about its potential and how it operates.
- 2.4 This chapter provides an overview of what cannabis is, how it can be prepared, its biochemistry and pharmacology. Chapter 3 follows with a summary of clinical research into its therapeutic effects and a discussion about determining who should be permitted to use cannabis for medicinal purposes in Victoria.

What is cannabis?

The cannabis plant

- 2.5 The cannabis plant⁶ is an adaptive and hardy annual hemp plant which grows in many temperate and tropical zones of the world, including in Australia.⁷ It can reach a height of up to five metres during a four-to-six-month growing season and is dioecious—occurring as male and female. Reproduction only occurs when male and female plants are in proximity so that microspores from the male plant can be transferred to the megaspores of the female plant. It is anemophilous (wind-pollinated), relying on air currents for pollination of the female plant by the male plant.
- 2.6 Cannabis plants produce hemp fibre,⁸ which has multiple applications (including coarse cloth, twine and paper), and seeds which are to be found within its resin-covered female flowers. A typical female cannabis plant produces hundreds of very small flowers which are clustered in a large mass at the top of the plant that in Spanish is called a ‘cola’. Colas can reach a metre in height.⁹ It is the flowering tops of the female plant, the ‘buds’, that have the highest concentrations of the psychoactive component in cannabis, followed by the leaves. Stalks and seeds have much lower concentrations of psychoactive components.
- 2.7 Flowers in the cannabis plant contain a single curled leaf, known as a bract, each one of which is covered by large numbers of hair-like gland-cells called trichomes. When the trichomes are ruptured, resinous oil which is sticky to the touch is released. This oil contains high quantities of active compounds, including the psychoactive components of cannabis.
- 2.8 The concentration of the various components having medicinal value varies with both the genetic profile of the plant and its growing conditions. To ensure consistency of

⁶ Etymologically derived from ‘kannabis’, the Greek word for hemp, which derived from the Sanskrit ‘cana’.

⁷ Tom Bassindale, Anne Coxon and Sarah Russell, ‘Illicit Drugs and Toxicology’ in Ian Freckelton and Hugh Selby, Thomson, *Expert Evidence*, vol 4 [70.620].

⁸ The name deriving from the Old English ‘hænep’. Hemp, among other things, has been used to produce fibre (for rope and cloth and oil).

⁹ Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014) 22.

plant chemistry, cultivators of cannabis to be used for medicinal purposes seek to control both of these variables.

- 2.9 Cannabis is generally propagated by cloning (taking cuttings), making all plants genetically the same. Growers also control as much as possible the temperature, humidity, light type and intensity, plant density, watering schedule and nutrient levels, to minimise variation in the plant content. However, even when these variables are stringently controlled, it is impossible to eliminate variations in the quantities of active chemicals,¹⁰ and various impurities can be incorporated.

Cannabis terminology

- 2.10 Cannabis received its botanical name, *Cannabis sativa*, in 1753 from Carolus Linnaeus, the Swedish 'father of botany'. It is also called 'narrow leaf hemp'.¹¹
- 2.11 In 1783 the French naturalist, Jean-Baptiste Lamarck, reclassified the plant, retaining Linnaeus' *Cannabis sativa* for the European form of the plant and coining the name *Cannabis indica* for the Indian form, which is shorter and bushier than *Cannabis sativa* and has a more compact root system.
- 2.12 In 1924 a Russian botanist, Dmitri Janischewski, identified the plant growing in the region of the Volga and classified it as *Cannabis ruderalis*. It is even smaller than *Cannabis indica* and tends to have low content of the psychoactive aspects of the drug.
- 2.13 More than 100 strains of cannabis have been generated by technologies using cross-breeding for particular purposes, such as to allow growth indoors or outdoors.¹² For Australian purposes *Cannabis sativa* is most relevant. It has many street names.¹³ However, its internationally agreed descriptor is 'cannabis'—hence the use of the term in instruments such as the *Single Convention on Narcotic Drugs 1961*.

Cannabis pharmacology

- 2.14 Knowledge of the biochemistry and pharmacology of the cannabinoids has evolved over an extensive period. Until the last two decades, 'marijuana research was a rather esoteric field of interest to a small number of scientists'¹⁴ but it has accelerated dramatically in recent years.¹⁵ It is likely to continue to do so, at least in the short term, because of the amount of research into the medicinal uses of cannabis that is being published.

¹⁰ Arno Hazekamp, *An Introduction to Medicinal Cannabis* (self-published, 2013) 4–5.

¹¹ See Robert C Clarke and Mark D Merlin, *Cannabis: Evolution and Ethnobotany* (University of California Press, 2013) 8.

¹² Some of the better known strains are: Afghani, Amsterdam, Indica, Aussie Blues, Big Bud, Charas, Durban Poison, Haze Marijuana, Island Lady, Kush, Light of Jah, Maui Wau, New York Diesel, Purple Haze Marijuana, Super Skunk, Swiss Miss, and White Queen: see David E Newton, *Marijuana* (ABC-CLIO, 2013) 6.

¹³ Including marijuana, dope, pot, grass, hooch, smoke, mull, weed, head, mary jane, bud, ganja and reefer.

¹⁴ Pál Pacher, Sándor Bátkai and George Kunos, 'The Endocannabinoid System as an Emerging Target of Pharmacotherapy' (2006) 58 *Pharmacological Reviews* 389, 389.

¹⁵ See Vincenzo Di Marzo, 'A Brief History of Cannabinoid and Endocannabinoid Pharmacology as Inspired by the Work of British Scientists' (2006) 27 *Trends in Pharmacological Sciences* 134.

- 2.15 *Cannabis sativa* contains a number of chemical compounds, some of which are classified as cannabinoid, and some of which are unique to the plant. There are more than 100 such compounds¹⁶ and some 300 non-cannabinoid chemicals within the cannabis plant. In addition, there are compounds about which less is known, such as terpenes and flavonoids (its flavour and fragrance components), which are thought to have a broad spectrum of action, including anti-oxidant, anxiolytic, anti-inflammatory, anti-bacterial, anti-neoplastic, and anti-malarial.¹⁷ However, as yet, clinical trials do not support a number of these claims.¹⁸
- 2.16 As discussed earlier, there are several species within the Cannabis genus, and within those species a number of strains. Different strains contain varying amounts of the different cannabinoids and therefore can be used to treat different medical conditions. Some strains contain extremely low amounts of the cannabinoid THC, such as the 'Charlotte's Web' strain,¹⁹ used to treat epilepsy,²⁰ and are therefore not considered to be psychoactive.

Cannabinoid receptors

- 2.17 The various cannabinoid compounds (as well as synthetic cannabinoids such as nabilone and dronabinol) interact with the two known cannabinoid receptors in the human body—CB1 (discovered in 1988) and CB2 (discovered in 1992). CB1 receptors are found mainly in central and peripheral neurons, whereas CB2 receptors are mostly found in immune cells.²¹ However, CB1 receptors can be located in immune cells and CB2 receptors in neurons.
- 2.18 CB1 receptors in the brain combine to form a 'circuit breaker' modulating the release of neurotransmitters.²² CB2 receptors are found in blood cells, tonsils and the spleen from which, among other things, they control the release of cytokines (immunoregulatory proteins) which are associated with inflammation and immune function throughout the

¹⁶ Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014) 42. See also Laurence E Mather et al, '[Re]introducing Medicinal Cannabis' (2013) 199 *Medical Journal of Australia* 757; Roger Pertwee (ed), *Cannabinoids* (Springer-Verlag, 2005).

¹⁷ See Ethan B Russo, 'Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects' (2011) 163 *British Journal of Pharmacology* 1344.

¹⁸ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 11 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

¹⁹ See Carly Schwartz, 'Meet the Children Who Rely on Marijuana to Survive', *Huffington Post* (online), 31 January 2014 <<http://www.huffingtonpost.com>>.

²⁰ See Mae Ryan, 'Charlotte's Web: The Families Using Medical Marijuana to Help their Kids', *The Guardian* (online), (26 June 2014) <<http://www.theguardian.com>>. The strain was developed by Josh Stanley and his brothers for Charlotte Figi, a child who suffered from about 350 seizures per week as a result of having Dravet Syndrome, prior to being administered high-CBD cannabis oil: 'Creator of Charlotte's Web Marijuana Strain Says Canada Legislation is Archaic', *Canada TV News* (online), (29 April 2014) <<http://canadaam.ctvnews.ca>>.

²¹ Slava Rom and Yuri Persidsky, 'Cannabinoid Receptor 2: Potential Role in Immunomodulation and Neuroinflammation Review' (2013) 8 *Journal of Neuroimmune Pharmacology* 608.

²² M Steffens et al, 'Modulation of Electrically Evoked Acetylcholine Release Through Cannabinoid CB1 Receptors: Evidence for an Endocannabinoid Tone in the Human Neocortex' (2003) 120 *Neuroscience* 455.

body.²³ They play an important role in modulating glial activation (a driving force for neural pain, especially chronic pain) in response to nerve injury.²⁴ Both endocannabinoids (the group of neuromodulatory lipids and their receptors in the brain that are involved in physiological processes including appetite, pain-sensation, mood and memory) and synthetic cannabinoid agonists are the subject of escalating research optimism in respect of their medicinal potential.²⁵

Cannabinoids

2.19 The best known cannabinoids are delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerol (CBG) and cannabinol (CBN).²⁶

THC

2.20 THC is best known for its psychoactive, euphoriant qualities but has also been identified to have anti-emetic, anti-inflammatory and anti-oxidant properties. It interacts with the CB1 and CB2 endocannabinoid receptors. It is found in the resin that covers the dried flowering tops and leaves of the female plant.²⁷ It is present in very low quantities in the hemp varieties of cannabis.

2.21 THC is highly lipophilic (tending to dissolve in lipids or fats) and is not soluble in water. It is rapidly absorbed into the blood stream from inhaled smoke.²⁸ The bioavailability of THC, and therefore its efficacy, from smoking is affected by factors such as the THC strength of the cannabis, which varies significantly, the depth of inhalation, puff and breath-holding. Because of the psychoactive qualities of THC, the tendency over the last 20 years has been for those who grow cannabis illegally to cultivate increasingly high THC, low CBD strains of cannabis.²⁹ When cannabis is smoked, THC levels peak within

²³ Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014) 41; C Benito et al, 'Cannabinoid CB2 Receptors in Human Brain Inflammation' (2008) 153 *British Journal of Pharmacology* 277.

²⁴ Ildiko Racz et al, 'Crucial Role of CB2 Cannabinoid Receptor in the Regulation of Central Immune Responses during Neuropathic Pain' (2008) 28 *The Journal of Neuroscience* 12125.

²⁵ See Pedro Ruiz and Eric C. Strain, *Lowinson and Ruiz's Substance Abuse: A Comprehensive Textbook* (Lippincott, Williams & Wilkins, 2011) 218; Roger Pertwee, 'Emerging Strategies for Exploiting Cannabinoid Receptor Agonists as Medicine' (2009) 156 *British Journal of Pharmacology* 397; Sangdon Han et al, 'Therapeutic Utility of Cannabinoid Receptor Type 2 (CB2) Selective Agonists' (2013) 56 *Journal of Medicinal Chemistry* 8224. See, eg, Liting Deng et al, 'Chronic Cannabinoid Receptor 2 Activation Reverses Paclitaxel Neuropathy Without Tolerance or Cannabinoid Receptor 1-Dependent Withdrawal' (2015) 77 *Biological Psychiatry* 475.

²⁶ See, eg, cannabichromene (CBC) which results from the oxidation of THC as it breaks down.

²⁷ See Wayne Hall and Rosalie L Pacula, *Cannabis Use and Dependence: Public Health and Public Policy* (Cambridge University Press, 2003). An analysis of cannabis seizures in NSW obtained in 2010–2012 showed high median THC levels and low levels of CBD: Wendy Swift et al, 'Analysis of Cannabis Seizures in NSW, Australia: Cannabis Potency and Cannabinoid Profile' (2013) 8 *PLoS ONE* e70052.

²⁸ See Harold Kalant, *Medicinal Use of Cannabis: History and Current Status* <<http://www.parl.gc.ca/content/sen/committee/371/ille/presentation/kalant-e.htm>>.

²⁹ J McLaren et al, 'Cannabis Potency and Contamination: A Review of the Literature' (2008) 103 *Addiction* 1100, 1100–9; Zlatko Mehmedic et al, 'Potency Trends of Δ^9 -THC and Other Cannabinoids in Confiscated Cannabis Preparations from 1993 to 2008' (2010) 55 *Journal of Forensic Science* 1209.

six to ten minutes. THC crosses the placenta and has been found in small levels in breast milk.³⁰

CBD

2.22 By contrast, CBD does not have the same psychoactive qualities as THC, although some high-CBD users have reported some mild psychoactive effects.³¹ It does not activate the CB1 and CB2 receptors but does interact with other signalling systems. Drugs such as Sativex (discussed below), combine THC and CBD. CBD is refined to high purity levels in drugs such as Epidiolex (also discussed below).

2.23 Paradoxically, CBD eliminates or mitigates some of the effects of THC, moderating its psychoactivity and reducing the incidence of THC-induced sedation, anxiety and tachycardia. It has been found to have analgesic, anti-inflammatory, anti-convulsant, anti-psychotic and anxiolytic (anti-anxiety) effects. However, in spite of the escalation in research interest in CBD, knowledge of its operation is still evolving—it was maintained in 2011, for instance, that *in vivo* studies, as well as randomised, double-blind placebo-controlled clinical studies, were still needed to assess cannabinoid effects in biological systems.³²

CBG

2.24 CBG is the precursor cannabinoid to THC and CBD—it is often produced more from hemp fibre than drug cannabis varieties. CBG appears to react with receptors other than those in the endocannabinoid system. It has been suggested that it has potential for treatment of cancer,³³ inflammatory bowel disease and as an antiseptic and antibiotic.³⁴ However, research on its therapeutic efficacy is at an early stage.

CBN

2.25 CBN is a by-product of the oxidation of THC and has about 10 per cent of its activity. It is little studied at this stage but is thought to have some immunosuppressive qualities.³⁵ It has been asserted also to have sedative qualities.³⁶

³⁰ Aurélia Garry et al, 'Cannabis and Breastfeeding' [2009] *Journal of Toxicology* 596149.

³¹ Michael Backes, *Cannabis Pharmacy* (Black Dog Leventhal, 2014) 44.

³² Mateus M Bergamaschi et al, 'Safety and Side Effects of Cannabidiol, a Cannabis Sativa Constituent' (2011) 6 *Current Drug Safety* 237.

³³ F Borrelli et al, 'Colon Carcinogenesis is Inhibited by the TRPM8 Antagonist Cannabigerol, a Cannabis-derived Non-Psychotropic Cannabinoid' (2014) 35 *Carcinogenesis* 2787.

³⁴ Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014) 44; Ethan B Russo and Franjo Grotenhermen (eds), *The Handbook of Cannabis Therapeutics: From Bench to Bedside* (Routledge, 2014) 176–177.

³⁵ See eg B L Faubert and N E Kaminski, 'AP-1 Activity is Negatively Regulated by Cannabinol Through Inhibition of Its Protein Components, c-fos and c-jun' (2000) 67 *Journal of Leukocyte Biology* 259.

³⁶ Caitlin Podiak, 'Cannabinol (CBN) Heralded as Sleep Aid' on 91 *Life Blog* <<http://91life.stickyguide.com/blog>>.

Preparation of the cannabis plant for use

- 2.26 The cannabis plant can be prepared for use in a number of ways. The different forms have variable potency.³⁷ Whatever form it is supplied in, in order for cannabinoids to be absorbed effectively in the body of the user, the raw plant material must be prepared in some way to allow the release of these active chemicals from the plant material into a form which allows their absorption by the human body. In particular, for cannabis to become psychoactive in its raw form it is generally heated to above 100 degrees Celsius—this decarboxylates the acid, among other things changing THCA into THC.³⁸
- 2.27 Cannabis can be administered medicinally from the raw plant (botanically) by way of being smoked or by an electronically heated vaporiser, by tincture, taken as an oil or other food product (such as cookies or sweets), in the form of capsules or a spray, dissolved in a tea or vaporised from a highly refined form, such as a concentrate or hashish oil.³⁹

Dried plant material (leaves and flowers)

- 2.28 The most basic form of cannabis consists of dried plant material. As the useful cannabinoids exist in the highest quantities in the flowers of the female plant, dried cannabis sold for medical purposes ordinarily consists primarily of the flower tips of the plant, dried to prevent degradation. It is also possible to convert cannabis flowers into a granular form, by drying the flowers and sifting out the larger pieces.⁴⁰ Cannabis prepared in this form is considered easier to use.⁴¹
- 2.29 Dried cannabis can be administered by the user by smoking, vaporising, consuming in food or infusing as a tea.⁴² The chemical composition, rate of onset, consistency of dosage and duration of effects vary across the various administration routes.⁴³ The

³⁷ The tips of the plant hairs secrete a resin which can be dried and then compressed to make one of the most potent forms of cannabis—hashish or ‘hash’. Pieces of hashish can be broken off and smoked in pipes or eaten. The name comes from the Arabic word for ‘grass’. It may be associated with the Ismaili leader, Hasan-I-Saban, who in 1090 founded the order of the Hashishiyans in Persia, often known as the ‘assassins’. See Gabriel G Nahas, ‘Hashish in Islam: 9th to 18th Century’ (1982) 58 *Bulletin of the New York Academy of Medicine* 814, 815.

³⁸ When cannabis is eaten, its acid is decarboxylated inefficiently so it has far less by way of psychoactive effect: see Robert C Clarke and Mark D Merlin, *Cannabis: Evolution and Ethnobotany* (University of California Press, 2013) 213.

³⁹ Other less used methods are per rectum and topically: Health Canada, ‘Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids’ (February 2013), 19 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁴⁰ Bedrocan Canada, ‘Bedrocan’s November Message’ (November 2014), 3–4 <<https://bedrocan.ca/wp-content/uploads/2014/12/2014-11-Nov.pdf>>.

⁴¹ Office of Medicinal Cannabis (Netherlands), *Medicinal cannabis* <www.cannabisbureau.nl/en/MedicinalCannabis>.

⁴² Arno Hazekamp, *An Introduction to Medicinal Cannabis* (self-published, 2013) 15–18.

⁴³ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 11, 17–19 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

average medicinal cannabis patient is reported to use between 0.5 and 1.5 grams per day.⁴⁴

Smoking

- 2.30 Dried cannabis can be smoked as marijuana leaf or flowers in a hand-rolled cigarette or 'joint', which may include tobacco to assist in burning. It can also be used via a water pipe or 'bong'. Cannabis smoke contains a number of known or suspected carcinogens and mutagens, many of which are also found in tobacco smoke.⁴⁵ For this reason, smoking as a method of administration of cannabis is thought to be more deleterious to health than vaporisation and non-inhalation methods.
- 2.31 Smoking cannabis is rejected by a significant percentage of patients and has been described as not 'medically acceptable—except, perhaps, in patients with a short life expectancy or as an expedient self-medication treatment.'⁴⁶

Vaporising

- 2.32 Dried cannabis can also be administered through use of a vaporiser. This method heats the dried cannabis electrically (either by conduction, using a heated element, convection, using heated air, or radiation, providing heat using a lamp), releasing the active compounds as a vapour. The vapour is either inhaled directly through a tube, or collected into a balloon then inhaled.⁴⁷ Vaporised cannabis has been evaluated in respect of its effects on conditions such as neuropathic pain⁴⁸ and is recommended by the Dutch Office of Medicinal Cannabis.
- 2.33 A vaporiser has advantages over smoked cannabis, in that it avoids some of the adverse respiratory side effects and gives the patient greater control over dosage by allowing them to control the temperature to which the cannabis is heated. The release of different cannabinoids varies according to the temperature applied to the cannabis. Dosage is also affected by the fineness of the cannabis, the duration of vaporisation and, where a balloon is used, the size of the balloon. Dried cannabis can be used for more than one vaporisation session.
- 2.34 Smoking, and even inhalation by vaporizer, are not highly accurate as dosage methods.⁴⁹ It has been claimed that the amount of THC delivered in the smoke varies between 20

⁴⁴ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) iii <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>, noting that the average Dutch medicinal cannabis patient consumed 0.65-0.82 grams per day, while the average Israeli medicinal cannabis patient used approximately 1.5 grams per day.

⁴⁵ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 11 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁴⁶ Laurence E Mather et al, '(Re)introducing Medicinal Cannabis' (2013) 199 *Medical Journal of Australia* 759, 760.

⁴⁷ See Leslie L Iversen, *The Science of Marijuana* (Oxford University Press, 2nd ed, 2007).

⁴⁸ See eg Barth Wilsey et al, 'Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain' (2013) 14 *The Journal of Pain* 136.

⁴⁹ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 18 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

per cent and 70 per cent, the rest being burnt or lost in side-stream smoke. This results in high variability of the fraction of the THC that reaches the user's blood—between 5 per cent and 24 per cent in cannabis cigarettes.⁵⁰

- 2.35 The inhalation of cannabis results in very rapid onset of effects when compared to ingestion methods, causing CNS and physiological effects within minutes. Oral methods of consuming cannabis take effect over a period of hours, and with a longer but less intense effect.⁵¹

Infused products

- 2.36 The useful compounds in cannabis can be made into infused products in a number of ways. Because THC and other cannabinoids are largely lipophilic, the cannabis must first be subjected to a process of infusion, by placing the plant matter into an oil or other solvent, thereby transferring the cannabinoids and other compounds from the plant to the solvent. Following this, it can be further refined into the form that is most useful to the patient.⁵²

Cannabis oil

- 2.37 The active compounds can be extracted from the plant material into a solvent to produce cannabis oil, which can be delivered orally or packaged in capsules.⁵³ Such oils can be made by infusing an edible oil (such as olive or coconut oil) with cannabis, causing the lipophilic cannabinoids to be dissolved into the oil. Alternatively, a non-edible solvent can be used (more commonly an alcohol), which is then evaporated off, producing a highly concentrated product which can be diluted using an edible oil.⁵⁴
- 2.38 A recently popular substance known as 'Full Extract Cannabis Oil' or 'Rick Simpson Oil' is produced by using isopropyl alcohol to extract concentrated oil from a strain of Cannabis indica. It is administered orally in small quantities, and can be mixed with food if desired.⁵⁵ In Australia it has been made available by some informal arrangements such as by 'cannabis clubs'.

Edible products

- 2.39 Cannabis can be made into edible products and eaten. Cannabis is first infused into an oil or fat, then baked or prepared into a food. The absorption of cannabis through ingesting edible products such as these has been described as 'slow and unreliable', and

⁵⁰ Wayne Hall and Rosalie L Pacula, *Cannabis Use and Dependence: Public Health and Public Policy* (Cambridge University Press, 2003) 14.

⁵¹ Health Canada, 'Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids' (February 2013), 17–18 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁵² See Tina Rappaport and Steven Leonard-Johnson, *CBD-Rich Hemp Oil: Cannabis Medicine is Back* (self-published, 2014).

⁵³ Arno Hazekamp, *An Introduction to Medicinal Cannabis* (self-published, 2013) 19.

⁵⁴ This process is described in A Holdcroft et al, 'Case Report: Pain relief with oral cannabinoids in familial Mediterranean fever' (1997) 52 *Anaesthesia* 483.

⁵⁵ Yadvider Singh and Chamandeep Bali, 'Cannabis Extract Treatment for Terminal Acute Lymphoblastic Leukemia with a Philadelphia Chromosome Mutation' (2013) 6 *Case Reports in Oncology* 585.

has been found to result in peak THC concentrations in the blood five to six times lower than by smoking an equivalent amount of dried cannabis.⁵⁶

Cannabis tea

- 2.40 Cannabis is also consumed in the form of a tea brewed from the flowers, leaves and stems of the plant. This is one of the methods of administration recommended to patients in the Netherlands. In India, this preparation is referred to as ‘bhang’. Patients in the Netherlands are advised to boil the dried cannabis for 15 minutes, and that absorption is improved if fatty food is consumed along with the tea.⁵⁷
- 2.41 The amount of THC capable of being absorbed from cannabis tea by a patient is lower than that available to a patient who smokes the same cannabis, because the THC is not soluble in water and is taken up by the liver before it can reach the blood stream.⁵⁸

Tinctures

- 2.42 Cannabis can also be processed into a tincture.⁵⁹ Tincture of cannabis, sometimes known as ‘green dragon’, is a solution of cannabis in alcohol.⁶⁰ Tinctures are administered by being placed under the tongue and absorbed through the mouth lining. This method of administration is similar to the manner in which nabiximols are taken by patients, as described below.
- 2.43 The ‘potency of cannabis tinctures varies wildly. Appropriate dosage will have to be determined by starting with a few drops, taken directly or added to a beverage, until the desired level of effect is achieved.’⁶¹

Newer concentrated forms

- 2.44 Other recently developed techniques also allow cannabis to be refined into highly concentrated forms. As described above, solvents can be used to produce concentrated oils. A recently popular method involves using the hydrocarbon butane to prepare a concentrate called butane hashish oil (BHO), which can be in the form of a solid mass

⁵⁶ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 18 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁵⁷ Office of Medicinal Cannabis, *Medicinal Cannabis: Information for Patients* (February 2011) 8.

⁵⁸ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 18 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>. This is due to the ‘hepatic first-pass effect’.

⁵⁹ General Purpose Standing Committee No. 4, NSW Parliament—Legislative Council, *The use of cannabis for medical purposes*, Report 27 (15 May 2013) 2.9–2.14. Historically, cannabis tinctures were very common: Graham Irvine, *Legalisation of medicinal cannabis in New South Wales* (PhD Thesis, Southern Cross University, 2011) 72–73.

⁶⁰ See J Russell Reynolds, ‘On the Therapeutical Uses and Toxic Effects of Cannabis Indica’ (1890) 135 *The Lancet* 637; Richard J Miller, *Drugged: The Science and Culture Behind Psychotropic Drugs* (Oxford University Press, 2013). It has been claimed to be effective by a Tasmanian mother for her daughter’s seizures: see Matt Smith, ‘Tasmanian Mother Defends Medicinal Cannabis, Takes Tincture in front of Premier Will Hodgman’, *The Mercury* (online), 18 September 2014 <<http://www.themercury.com.au/news/tasmania>>. See also Lee Romney, ‘On the frontier of medical pot to treat boy’s epilepsy’, *Los Angeles Times* (online), 13 September 2012 <<http://latimes.com>>.

⁶¹ Beverly Potter, Sebastian Orfali, and Dan Joy, *The Healing Magic of Cannabis* (Ronin Publishing, 2009) 97.

(known as 'shatter'), a crumbled solid (known as 'wax' or 'budder'), or a free-flowing oil. Cannabis concentrates can also be prepared using supercritical carbon dioxide. This product has the advantage of being free of residual solvent and is used with a vaporiser, or included in topical preparations and edible products.⁶² These products are highly concentrated and produce a more intense effect than the dried form of cannabis.

- 2.45 Cannabis in this form can also be taken via 'dabbing', whereby a dab of concentrated butane hashish oil is placed on the end of a glass or metal rod that has been heated (sometimes part of a purpose-built apparatus) and from which the vapours are inhaled by the user. The practice of both medicinal and recreational users of cannabis utilising it in this way was described in 2014 and concerns were expressed about the potential for such ingestion to cause a dependence or addiction syndrome.⁶³

Pharmaceutical forms of cannabis

- 2.46 The alternative to treatment with the raw product or its less refined extracts is the suite of refined cannabis-based medications produced by pharmaceutical companies. A number of forms of cannabinoid medications have been approved by government authorities in different parts of the world.
- 2.47 The advantage of such products is that their constituents are known and their dosages can be titrated with accuracy by prescribing medical practitioners. They are most commonly administered orally or by oromucosal spray. Contaminants which may otherwise impact upon the active elements of the drug or be noxious are absent.
- 2.48 The disadvantage of such products is that impediments persist in relation to their accessibility by reason of regulatory strictures and their high cost.
- 2.49 Pharmaceutical cannabis can be distinguished from synthetic cannabinoids in that they are extracted from the cannabis plant, not produced in a laboratory from other chemicals.

Nabiximols

- 2.50 The nabiximols are a whole-plant extract of cannabis, containing THC and CBD and described as part of a class of 'botanical cannabinoids'.
- 2.51 The best known, Sativex, produced by GW Pharmaceuticals, is an oral spray containing approximately equal parts of THC and CBD, along with a small amount of other cannabinoids. Unlike the preparations described in the previous section, this product is of a pharmaceutical grade, in that its composition is consistent and its dosage controlled.

⁶² See C Da Porto, D Decorti and F Tubaro, 'Fatty Acid Composition and Oxidation Stability of Hemp (Cannabis Sativa L) Seed Oil Extracted by Supercritical Carbon Dioxide' (2012) 36 *Industrial Crops and Products* 401. This process can also be applied to tobacco to produce the liquid used in e-cigarettes.

⁶³ Mallory Loflin and Mitch Earleywine, 'A New Method of Cannabis Ingestion: The Dangers of Dabs?' (2014) 30 *Addictive Behaviors* 1430, 1432.

- 2.52 Sativex is administered as an oral spray and results in a peak blood THC level lower than inhalation of the same dose of cannabis, with onset occurring over a period of hours.⁶⁴ Absorption appears to vary significantly between patients and as a result of consuming Sativex with food.⁶⁵
- 2.53 Sativex has been approved in Canada and the United Kingdom for treatment for neuropathic pain in multiple sclerosis and pain associated with cancer. It has been approved for multiple sclerosis-associated spasticity in Canada, New Zealand, the United Kingdom, Austria, the Czech Republic, Denmark, Germany, Sweden, Israel, Italy and Spain.
- 2.54 Sativex was registered by the Therapeutic Goods Administration in Australia on 26 November 2012 as a treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity-related symptoms during an initial trial of therapy.⁶⁶
- 2.55 However, in 2013, a submission to the Pharmaceutical Benefits Scheme of Australia seeking to list nabiximols for the treatment of moderate to severe spasticity due to multiple sclerosis for patients who are intolerant of anti-spasticity medication and/or have not responded adequately to such medication was rejected.
- 2.56 The primary reason why the Pharmaceutical Benefits Advisory Committee rejected the submission was that the 'claim for [nabiximols'] superior efficacy over standard care was inadequately supported and that nabiximols appeared to be inferior over standard care in terms of comparative safety.' This was in part due to issues with the design of the trial evidence presented in support of the submission. The Committee also noted that the likely cost of nabiximols was uncertain, because of 'potential wastage' of the product and the potential costs associated with adverse effects.⁶⁷
- 2.57 This means that although Sativex is licensed for use in Australia, it is not subsidised. Therefore, practically speaking, Sativex is available for very few patients, due to the high out-of-pocket cost associated with obtaining it.
- 2.58 GW Pharmaceuticals has also encountered difficulties persuading other governments that Sativex is a cost-effective treatment. In the UK, the drug is approved for use, but public funding is not available in all locations. Sativex receives no public subsidy in England, and in October 2014 a health spending body endorsed this conclusion, recommending that public subsidies not be available for Sativex, because it 'provides

⁶⁴ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 18 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁶⁵ Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (September 2013) 14, 38-39, 172 <www.tga.gov.au>.

⁶⁶ Pharmaceutical Benefits Advisory Committee, *Public Summary Document: Nabiximols* (July 2013) <<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/nabiximols>>.

⁶⁷ *Ibid.*

only a modest benefit' at a significant cost to the public.⁶⁸ However, Sativex receives a public subsidy in Wales.⁶⁹

- 2.59 Sativex is currently undergoing United States clinical trials for the treatment of pain. It is approved in Canada under Notice of Compliance with Conditions for treatment of some types of pain.⁷⁰

Epidiolex

- 2.60 Another form of medication, Epidiolex (produced by GW Pharmaceuticals), a liquid containing CBD without THC, is expected to become available soon in the United States through a clinical trial to treat Lennox-Gastaut syndrome⁷¹ and Dravet syndrome,⁷² both of which are rare forms of epilepsy that have an onset in childhood.⁷³

Canasol

- 2.61 In the 1970s, the University of the West Indies developed an extract of cannabis, named Canasol, for use in glaucoma treatment. Researchers at the University found that Canasol was effective in reducing interocular pressure caused by glaucoma, a disease which affects three per cent of the Jamaican population.
- 2.62 Canasol is delivered as an eyedrop and is marketed by a company based in Jamaica.⁷⁴

⁶⁸ National Institute of Health and Care Excellence, 'New guidance to tackle inequalities in multiple sclerosis care' (Press Release, 8 October 2014) <<https://www.nice.org.uk>>; National Institute of Health and Care Excellence, 'Multiple Sclerosis: management of multiple sclerosis in primary and secondary care' (Guideline CG186, October 2014) [1.5.23].

⁶⁹ All Wales Medicines Strategy Group, 'Delta-9-tetrahydrocannabinol/cannabidiol (Sativex®) 2.7 mg/2.5 mg oromucosal spray' (Final Appraisal Recommendation 1814, July 2014) <<http://www.awmsg.org/awmsgonline/app/appraisalinfo/644>>.

⁷⁰ See Joan L Kramer, 'Medical Marijuana for Cancer' (2015) 65(2) *CA: A Cancer Journal for Clinicians* 1, 4.

⁷¹ National Institute of Neurological Disorders and Stroke, *NINDS Lennox-Gastaut Syndrome Information Page* (3 February 2015) <<http://www.ninds.nih.gov/disorders/lennoxgastautsyndrome.htm>> states that: 'Lennox-Gastaut syndrome is a severe form of epilepsy. Seizures usually begin before 4 years of age. Seizure types, which vary among patients, include tonic (stiffening of the body, upward deviation of the eyes, dilation of the pupils, and altered respiratory patterns), atonic (brief loss of muscle tone and consciousness, causing abrupt falls), atypical absence (staring spells), and myoclonic (sudden muscle jerks). There may be periods of frequent seizures mixed with brief, relatively seizure-free periods. Most children with Lennox-Gastaut syndrome experience some degree of impaired intellectual functioning or information processing, along with developmental delays, and behavioral disturbances. Lennox-Gastaut syndrome can be caused by brain malformations, perinatal asphyxia, severe head injury, central nervous system infection and inherited degenerative or metabolic conditions. In 30–35 per cent of cases, no cause can be found.'

⁷² National Institute of Neurological Disorders and Stroke, *NINDS Dravet Syndrome Information Page* (29 September 2011) <http://www.ninds.nih.gov/disorders/dravet_syndrome/dravet_syndrome.htm> record that: 'Dravet syndrome, also called severe myoclonic epilepsy of infancy (SMEI), is a severe form of epilepsy. It appears during the first year of life with frequent febrile seizures—fever-related seizures that, by definition, are rare beyond age 5. Later, other types of seizures typically arise, including myoclonus (involuntary muscle spasms). Status epilepticus—a state of continuous seizure requiring emergency medical care—also may occur. Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity, and difficulty relating to others. In 30 to 80 percent of cases, Dravet syndrome is caused by defects in a gene required for the proper function of brain cells. Borderline SMEI (SMEB) and another type of infant-onset epilepsy called generalized epilepsy with febrile seizures plus (GEFS+) are caused by defects in the same gene. In GEFS+, febrile seizures may persist beyond age 5.'

⁷³ Joan L Kramer, 'Medical Marijuana for Cancer' (2015) 65(2) *CA: A Cancer Journal for Clinicians* 1, 4. See also Juliana Bunim, 'Marijuana-Derived Epilepsy Drug in Clinical Trial for Children with Uncontrolled Seizures' *University of California San Francisco* (online), 3 February 2014, <<http://www.ucsf.edu/news>>.

⁷⁴ See Manley West, 'The Use of Certain Cannabis Derivatives (Canasol) in Glaucoma' in Mary Lynn Mathre, *Cannabis in Medical Practice: A Legal, Historical and Pharmacological Overview of the Therapeutic Use of Marijuana* (McFarland, 1997) 103-111.

Namisol

2.63 Dutch pharmaceutical company Echo Pharmaceuticals BV is currently developing an oral tablet form of pure (>98 per cent) THC, named Namisol, which is derived from the cannabis plant. The formulation would utilise Echo's proprietary, lipophilic drug-delivery technology, Alitra. The drug is still being researched for indications including multiple sclerosis, Alzheimer's and chronic pain, and has now reached Phase II clinical trials.⁷⁵

Cannador

2.64 Cannador is a cannabis extract developed by IKF-Berlin. It contains THC and CBD in a ratio of approximately 2:1, and is delivered as a capsule. Its efficacy has been tested, with mixed results.⁷⁶ It does not appear to have been approved for sale anywhere in the world.

Synthetic cannabinoids

2.65 A series of synthetic cannabinoids has been developed since the 1980s, originally for medicinal purposes to isolate compounds in order to activate CB2 receptors selectively. Research work continues on their therapeutic application. Synthetic cannabinoids have also recently become popular as recreational drugs.

2.66 A relatively recent aspect of the evolution of synthetic cannabinoids was the identification of their intoxicant qualities.⁷⁷ They can be identical or functionally similar to cannabinoids, with the latter binding to the same cannabinoid receptors in the brain. It has 'proved difficult to separate their desired properties from unwanted psychoactive effects.'⁷⁸ There is the potential for them to have constructive therapeutic effects because of their strength, but for the present this is offset by their side effects.⁷⁹

2.67 This issues paper will not deal with the medicinal application of synthetic cannabinoids, other than to refer briefly below to the best-known versions which have been made available for medicinal use.

Medicinal use

2.68 Many patients who use cannabis for medicinal purposes have expressed a preference for phytocannabinoid products—those derived from the cannabis plant—over synthetically produced THC. This may be because of the capacity of CBD and other cannabinoids to

⁷⁵ Echo Pharmaceuticals, *Namisol* <<http://www.echo-pharma.com/en/products-and-pipeline/namisol>>.

⁷⁶ Ethan Russo, 'Cannabinoids in the management of difficult to treat pain' (2008) 4 *Therapeutics and Clinical Risk Management* 245, 251.

⁷⁷ See Jenny L Wiley et al, 'Hijacking of Basic Research: The Case of Synthetic Cannabinoids', *Methods Report (RTI Press)* (2011) <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3567606/>>.

⁷⁸ Slava Rom and Yuri Persidsky, 'Cannabinoid Receptor 2: Potential Role in Immunomodulation and Neuroinflammation Review' (2013) 8 *Journal of Neuroimmune Pharmacology* 608.

⁷⁹ See Marisol S Castaneto et al, 'Synthetic Cannabinoids: Epidemiology, Pharmacodynamics, and Clinical Implications' (2014) 144 *Drug and Alcohol Dependence* 12. But see Liting Deng et al, 'Chronic Cannabinoid Receptor 2 Activation Reverses Paclitaxel Neuropathy Without Tolerance or Cannabinoid Receptor 1-Dependent Withdrawal' (2015) 77 *Biological Psychiatry* 475.

moderate the psychoactive effects of THC, and also because of associations with their being 'natural'.

- 2.69 Two synthetic cannabinoid drugs were approved by the Federal Drug Administration (FDA) in 1985 and thus can be legally prescribed in the United States: Dronabinol and Nabilone. Other cannabinoid agonists remain under investigation, with promising results beginning to emerge.⁸⁰

Dronabinol

- 2.70 Dronabinol⁸¹ (manufactured by Unimed Pharmaceuticals as Marinol), contains a synthetically derived trans-isomer of THC,⁸² dissolved within a gelatine capsule. It was approved by the FDA in 1985 for chemotherapy-induced nausea and vomiting and in 1992 for weight loss for patients with AIDS. Marinol is not marketed in Australia and has been discontinued by the manufacturer in Canada.⁸³

Nabilone

- 2.71 While being chemically distinct, Nabilone mimics the action of THC. It is marketed in the United States, the United Kingdom and Canada as Cesamet. It was approved by the FDA to treat chemotherapy-induced nausea and vomiting, but only became readily available in 2006.
- 2.72 Nabilone is included in Schedule 8 of the Commonwealth's *Standard for the Uniform Scheduling of Medicines and Poisons No.6 (SUSMP)*⁸⁴ but is not marketed in Australia. It is hypothesised to have other applications in terms of anxiolytic effects, anti-inflammatory and anti-hyperalgesic actions, as well as sedative effects.⁸⁵
- 2.73 A 2008 randomised, double-blind placebo-controlled trial evaluated the efficacy of nabilone for pain management and quality of life improvement for 40 patients with diagnosed fibromyalgia. Decreases were found in the nabilone-treated group at four

⁸⁰ See Roger Pertwee, 'Emerging Strategies for Exploiting Cannabinoid Receptor Agonists as Medicine' (2009) 156 *British Journal of Pharmacology* 397. Recently reported animal trials on the compound AM1710, a cannabinoid CB2 agonist, showed its potential to suppress chemotherapy-induced pain, while avoiding the tolerance and side effects associated with THC: Liting Deng et al, 'Chronic Cannabinoid Receptor 2 Activation Reverses Paclitaxel Neuropathy Without Tolerance or Cannabinoid Receptor 1-Dependent Withdrawal' (2015) 77 *Biological Psychiatry* 475.

⁸¹ MedlinePlus Drug Information, *Dronabinol* (1 September 2010) There is also Levonantradol, a synthetic cannabinoid analogue of dronabinol and a CB1 agonist, although use of this substance is confined to research: see Carol M Cronin et al, 'Antiemetic Effect of Intramuscular Levonantradol in Patients Receiving Anticancer Chemotherapy' (1981) 21 *Journal of Clinical Pharmacology* 43S–50S; R C Stuart-Harris, C A Mooney and I E Smith, 'Levonantradol: A Synthetic Cannabinoid in the Treatment of Severe Chemotherapy-Induced Nausea and Vomiting Resistant to Conventional Anti-Emetic Therapy' (1983) 9 *Clinical Oncology* 143.

⁸² A trans-isomer is an isomer where the functional groups appear on opposite sides of the double bond.

⁸³ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 29 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁸⁴ The *Standard for the Uniform Scheduling of Medicines and Poisons No 6* sets out categories of poisons and controlled substances. It is used when determining which regulatory controls apply to each category. It is contained in Sch 2 of the *Poisons Standard 2015 (Cth)*, which is a legislative instrument made under the *Therapeutic Goods Act 1989 (Cth)*.

⁸⁵ David M Berlach, Yoram Shir and Mark A Ware, 'Experience with the Synthetic Cannabinoid Nabilone in Chronic Noncancer Pain' (2006) 7 *Pain Medicine* 25.

weeks while there were no significant improvements in the placebo group. It was concluded that it appeared to be 'a beneficial, well-tolerated treatment option for fibromyalgia patients, with significant benefits in pain relief and functional improvement.'⁸⁶

Development of synthetic CBD

- 2.74 Insys Therapeutics Inc, an American company, is currently conducting research into a synthetic form of CBD. Recent analysis showed that Insys's synthesised CBD was chemically identical to CBD derived from the cannabis plant.
- 2.75 Insys plans to start Phase I clinical trials on this product in early 2015. It claims to be the only United States company with the 'capacity to produce pharmaceutical cannabinoids in scalable quantities'.⁸⁷

Rimonabant

- 2.76 Another drug, rimonabant, best known as Acomplia, was the first CB1 receptor blocker to be approved. It emerged from research on endocannabinoids and was made available in many countries for use in weight reduction, having been approved for sale by the European Union in 2006. Its function was to block the action of endocannabinoids produced by the brain that stimulate appetite. Considerable optimism was held for its therapeutic potential.⁸⁸ It was submitted to the FDA for approval but declined.
- 2.77 In October 2008, the European Medicines Agency's Committee for Medicinal Products for Human Use recommended that it no longer be prescribed and it was officially withdrawn from the market in January 2009. Research has shown that rimonabant can induce symptoms of anxiety and depression.⁸⁹

Recreational use

- 2.78 Synthetic cannabinoids sold to recreational users have become known under names such as 'Spice', 'Kronic', 'Karma', 'Voodoo', 'Kaos' and 'K2'. Sellers frequently sold products by spraying synthetic cannabinoids onto dried herbs and selling the resulting product to be smoked as a 'legal high'.⁹⁰ Synthetic cannabinoids have become notorious in the popular media by having been associated with a number of deaths,⁹¹ but there is little

⁸⁶ Ryan Q Skrabek et al, 'Nabilone for the Treatment of Pain in Fibromyalgia' (2008) 9 *Journal of Pain* 164.

⁸⁷ Insys Therapeutics Inc, 'Parallel Comparison Analyses Confirm That Insys Therapeutics' Synthetic CBD Is Identical in Chemical Structure to Plant-Derived CBD' (Press Release, 4 December 2014) <<http://www.insysrx.com/investors/recent-news>>.

⁸⁸ See eg Maurizio Bifulco et al, 'Rimonabant: Just an Antiobesity Drug? Current Evidence on Its Pleiotropic Effects' (2007) 71 *Molecular Pharmacology* 1445.

⁸⁹ See eg Robin Christensen et al, 'Efficacy and Safety of the Weight-Loss Drug Rimonabant: A Meta-Analysis of Randomized Trials' (2007) 370 *The Lancet* 1706.

⁹⁰ Therapeutic Goods Administration, 'Scheduling: Delegates' reasons for final decisions' (July 2011), Section 1.1 ('Synthetic cannabinoids') 1–2.

⁹¹ See eg Andre A Monte et al, 'Letter: An Outbreak of Exposure to a Novel Synthetic Cannabinoid' (2014) 370 *New England Journal of Medicine* 389; S M R Gurney et al, 'Pharmacology, Toxicology, and Adverse Effects of Synthetic Cannabinoid Drugs' (2014) 26 *Forensic Science Review* 53; Nadine Schaefer et al, 'A Fatal Case Involving Several Synthetic Cannabinoids' (2013) 80 *Toxicchem Krimtech* 248.

reliable evidence of their adverse effects due to the short period in which they have been available.⁹²

- 2.79** On 6 July 2011, the Therapeutic Goods Administration added a number of synthetic cannabinoids, including JWH-018, the active ingredient in Kronik, to Schedule 9 (prohibited substances) of the SUSMP.⁹³ In February 2012, a further entry for all 'synthetic cannabinomimetics', along with a number of known chemical classes of synthetic cannabinoids, was added to Schedule 9.⁹⁴

⁹² Therapeutic Goods Administration, 'Scheduling: Delegates' reasons for final decisions' (July 2011), Section 1.1 ('Synthetic cannabinoids') 6–7.

⁹³ See Andatech, *Australian Legislation Relating to Synthetic Cannabinoids—Kronic—K2* <<http://documents.andatech.com.au/fact-sheets/k2-urine-drug-test-legislation-fact-sheet.pdf>>

⁹⁴ Therapeutic Goods Administration, 'Scheduling: Delegates' reasons for final decisions' (February 2013) Section 2.7 ('Synthetic cannabinoids').

Identifying therapeutically appropriate forms

- 2.80 As canvassed above, cannabis is available in a wide and constantly expanding range of forms. These vary in their potency (including their THC-content), ease of use, contaminants, safety and therapeutic effect. In particular, the patient experience is dramatically different between forms, largely in terms of the rate of uptake of cannabinoids and the duration and intensity of their effect. Certain preparations will be inappropriate for certain patient groups (for example, smoking for children, or swallowing a tablet for a patient experiencing severe nausea); others raise particular dangers of side effects.
- 2.81 In determining the forms of cannabis which should be permitted for medicinal use, consideration needs to be given to the full range of methods of administration, including their dangers, risks, side effects and benefits, and including for specific categories of patient. The categories of patient which should be authorised to access cannabis are considered in Chapter 3.
- 2.82 In addition, the availability of pharmaceutical preparations and synthetic cannabinoids must be taken into account in determining which conditions or individuals will qualify for access to cannabis for medicinal use. If, by way of example, a readily available, synthetic form of a cannabinoid exists, or becomes available, which is effective in treating a particular condition or symptom, the argument for allowing such a patient to have access to products derived from the cannabis plant may be less compelling. The cost of the alternative remedies must also be taken into account in this context. The efficacy of such products is considered in Chapter 3.
- 2.83 Finally, if more refined forms of cannabis are to be permitted, consideration must be given to how a regulatory scheme might be designed to guard against the risks associated with producing such a preparation. In the case of substances taken orally, there may be a need for standards analogous to those for safe food preparation to be applied. Particular facilities, security measures and safe manufacturing standards might need to be imposed. The detail and level of oversight of any associated licensing or regulatory scheme should increase as the risks become more serious. Approaches to controlling these risks in other jurisdictions are set out in Chapter 6.

The use of cannabis for medicinal purposes

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3 The use of cannabis for medicinal purposes

Introduction

- 3.1 The proposed reform to Victorian law to allow cannabis to be used lawfully for medicinal purposes would apply only to people in exceptional circumstances. In order to identify what those circumstances might be, it is first necessary to consider the research findings, and the claims arising from personal experience, about the efficacy of cannabis. It is then necessary to identify, in light of the evidence, and the personal circumstances of people who could benefit from its use, how the government should appropriately, and compassionately, delineate the circumstances which would qualify a patient to gain legal access to cannabis.
- 3.2 A number of reviews of the medicinal uses of cannabis in the 1990s expressed optimism about its potential, such as those produced by the British Medical Association (1997),¹ the United Kingdom House of Lords Select Committee on Science and Technology (1998)² and the United States Institute of Medicine (1999).³ Since then, as the use of cannabis for medicinal purposes has been legalised in a number of countries and much of the United States, scientific knowledge and anecdotal experience have continued to grow.
- 3.3 In Victoria, public debate about whether medicinal cannabis should be legalised has drawn attention to a number of sufferers of chronic and severe conditions. There has been substantial media reporting of the circumstances of several families in Victoria whose children are affected by serious medical conditions and whose symptoms are said to have been significantly alleviated by the use of cannabis oil and tinctures.

¹ British Medical Association, *Therapeutic Uses of Cannabis* (CRC Press, 1997).

² Select Committee on Science and Technology, House of Lords, *Cannabis* (9th Report, 1998) <<http://www.parliament.the-stationery-office.co.uk>>.

³ Janet E Joy, Stanley J Watson Jr and John A Benson Jr (ed) and Institute of Medicine (US), *Marijuana and Medicine: Assessing the Science Base* (1999).

- 3.4 The Commission will consider those cases, with proper respect for the most difficult circumstances affecting those families and individuals. At present it is unknown how many other persons are in a similar position.
- 3.5 This chapter provides an overview of the state of clinical research for the most prominent potential medicinal uses for cannabis. It also discusses the risks and side effects observed with the use of cannabis. It then explores the question of how to identify the exceptional circumstances in which people could be permitted to use it in Victoria, and how these exceptional circumstances could be enshrined in law.

Reviews of the clinical literature

- 3.6 Research into the medicinal effects of cannabis was significantly inhibited by its criminalisation, but has escalated in recent years.
- 3.7 In 1998 the House of Lords Select Committee on Science and Technology concluded in the light of the evidence before it that:
- There is not enough rigorous scientific evidence to prove conclusively that cannabis itself has, or indeed has not, medical value of any kind. Nevertheless we have received enough anecdotal evidence ... to convince us that cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of MS [multiple sclerosis] and in the control of other forms of pain.⁴
- 3.8 Much of the information regarding matters such as the acute effects of smoking cannabis comes from studies conducted on recreational users; there is much less information available from clinical studies of patients who have used cannabis for medical purposes.⁵
- 3.9 As of 2001, a review of clinical literature on the efficacy and safety of cannabinoids for pain and spasticity revealed only nine randomised studies of acceptable quality.⁶
- 3.10 To that point many published studies on the medicinal application of cannabis contained significant research deficits—they involved small numbers of participants, failed to use placebos, omitted properly designed controls, and involved high levels of patient drop-out. This led to their being criticised for lack of research rigour by reason of their design flaws.⁷

⁴ Select Committee on Science and Technology, House of Lords, *Cannabis* (9th Report, 1998) [8.2]–[8.13] <<http://www.parliament.the-stationery-office.co.uk>>.

⁵ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 14.

⁶ Fiona A Campbell et al, 'Are Cannabinoids an Effective and Safe Treatment Option in the Management of Pain? A Qualitative Systematic Review' (2001) 323 *British Medical Journal* 13.

⁷ R D Hosking and J P Zajicek, 'Therapeutic potential of cannabis in pain medicine' (2008) 101 *British Journal of Anaesthesia* 59.

3.11 Over the succeeding years,⁸ though, there has been a significant improvement in the quality, as well as the scope, of cannabinoid research. Among other things, it has employed cannabis, cannabis-based extracts, and synthetic cannabinoids delivered by smoking, vaporisation, oral, and sublingual or transmucosal routes.

3.12 However, a considerable degree of proselytising zeal still attends much of the literature about the medicinal uses of cannabis.⁹ This led a United States medico-legal review in 2009 to argue that:

Advocacy is a poor substitute for dispassionate analysis, and ... popular votes should not be allowed to trump scientific evidence in deciding whether or not marijuana is an appropriate pharmaceutical agent to use on modern medical practice.¹⁰

3.13 Similarly Robson has observed that:

In the modern world, no other forbidden drug has provoked such polarization between its defenders and detractors, with reason frequently swamped by rhetoric.¹¹

3.14 The issues raised in this regard are not just a question of scholarly methodology. An important warning note about the need to avoid overly liberal access to unproven treatments was sounded in a related context by the United States Supreme Court in a 1979 decision involving patients who claimed that an unapproved drug, Leatril, represented their last hope:

Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss, arrangements of colored floodlamps; pastes made from glycerine and Limburger cheese. In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetril's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.¹²

3.15 Fitzcharles and others, referring to issues related to the application of cannabis to rheumatology, but speaking more broadly, expressed a similar view in 2014:

⁸ See, as early as 2004, Geoffrey W Guy, Brian A Whittle and Philip J Robson (eds), *The Medicinal Uses of Cannabis and Cannabinoids* (Pharmaceutical Press, 2004).

⁹ Meredith K Converse, *Medical Cannabis: A Balanced, Evidence Based Look Beyond the Propaganda* (Digital Delta Publishing, 2014).

¹⁰ Peter J Cohen, 'Medical Marijuana: The Conflict between Scientific Evidence and Political Ideology' (2009) 23(1), 23 *Journal of Pain and Palliative Care* 4, 12.

¹¹ Philip Robson and Ethan Russo, 'Cannabis' in Philip Robson (ed), *Forbidden Drugs* (Oxford University Press, 3rd ed, 2009) 59.

¹² *United States v Rutherford*, 442 US 554, 557–558 (1979).

Simply acceding to patient demands for a treatment on the basis of popular advocacy, without comprehensive knowledge of an agent, does not adhere to the ethical standards of medical practice ... any recommended therapy requires proof of concept by sound scientific study that attests to both efficacy and safety.¹³

- 3.16 The counter-argument is that it would be inappropriate to deny patients access to promising and potentially life-changing treatments on the basis that cannabis is not yet fully understood:

A civilised and compassionate country that supports evidence-based medicine and policy should acknowledge that medicinal cannabis is acceptably effective and safe, and probably also cost-effective, especially when the costs of resource use and improvement to the lives and functionality of patients and carers are considered. There is certainly more to learn about medicinal cannabis, but we know more than enough to act now.¹⁴

Current significant medicinal applications of cannabis

- 3.17 The following section identifies some of the current medicinal applications of cannabis. There is an extensive clinical literature on the subject. As identified above, until recently, much of the clinical literature had significant limitations.

- 3.18 Claims have been made as to the efficacy or potential efficacy of cannabis as:
- an anti-spasticity agent, and thus as an adjuvant therapy for multiple sclerosis¹⁵
 - an analgesic or at least a means of reducing the experience of pain¹⁶
 - an anticonvulsant and thus as an adjuvant treatment for paediatric epilepsy¹⁷
 - a bronchodilator, useful for instance in the treatment of asthma¹⁸
 - an agent for reducing intra-ocular pressure, and thus for treating glaucoma¹⁹
 - an anti-nauseant and anti-emetic, relevant for patients receiving radiation therapy or chemotherapy for AIDS or cancer²⁰

¹³ MA Fitzcharles et al, 'The Dilemma of Medical Marijuana Use by Rheumatology Patients' (2014) 66 *Arthritis Care Research* 797.

¹⁴ Laurence E Mather et al, '(Re)introducing medicinal cannabis' (2013) 199 *Medical Journal of Australia* 759. See also David G Pennington, 'Medical cannabis: time for clear thinking' (2015) 202 *Medical Journal of Australia* 74.

¹⁵ See, eg, MS Chong et al, 'Cannabis Use in Patients with Multiple Sclerosis' (2006) 12 *Multiple Sclerosis* 646.

¹⁶ See, eg, David J Rog et al, 'Randomized, Controlled Trial of Cannabis-Based Medicine in Central Pain in Multiple Sclerosis' (2005) 65 *Neurology* 812; Barth Wilsey et al, 'Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain' (2012) 14 *The Journal of Pain* 136.

¹⁷ See, eg, Joseph I Sirven, 'Medical Marijuana for Epilepsy: Winds of Change' (2013) 29 *Epilepsy and Behavior* 435.

¹⁸ See, eg, DP Tashkin et al, 'Effects of Smoked Marijuana in Experimentally Induced Asthma' (1975) 112 *American Review of Respiratory Disease* 377; Beverly Potter, Sebastian Orfali and Dan Joy, *The Healing Magic of Cannabis* (Ronin Publishing, 2009) 113.

¹⁹ British Medical Association, *Therapeutic Uses of Cannabis* (CRC Press, 1997) 57; I Tomida, R G Pertwee and A Azuara-Blanco, 'Cannabinoids and Glaucoma' (2004) 88 *British Journal of Ophthalmology* 708.

²⁰ Ethan Russo (ed), *Cannabis Therapeutics in HIV/AIDS* (Routledge, 2001).

- an appetite enhancer, helpful for patients with wasting symptoms as a result of radiation therapy or chemotherapy, AIDS or anorexia²¹
- an immunosuppressant in the treatment of autoimmune diseases or to prevent rejection of transplanted organs or tissues²²
- a treatment for arthritides (including osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, gout etc)²³
- an agent for reducing painful menstrual symptoms, post-partum, dysmenorrhea and menopausal symptoms²⁴
- a treatment for inflammatory bowel disease²⁵
- a treatment for Parkinson's Disease²⁶
- a treatment for Tourette's syndrome²⁷
- a treatment for HIV-associated neuropathy²⁸

²¹ See eg Jeffrey E Beal et al, 'Long-term Efficacy and Safety of Dronabinol for Acquired Immunodeficiency Syndrome-Associated Anorexia' (1997) 14 *Journal of Pain Symptom Management* 7; Florian Strasser et al, 'Comparison of Orally Administered Cannabis Extract and delta-9-tetrahydrocannabinol in Treating Patients with Cancer-Related Anorexia-Cachexia Syndrome: A Multicenter, Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial from the Cannabis-In-Cachexia-Study-Group' (2006) 24 *Journal of Clinical Oncology* 3394.

²² Franjo Grotenhermen and Ethan Russo (eds), *Cannabis and Cannabinoids: Pharmacology, Toxicology and Therapeutic Potential* (Routledge, 2002).

²³ However, a Cochrane Collaboration found the evidence for efficacy to be at best moderate: Bethan L Richards et al, 'Neuromodulators for Pain Management in Rheumatoid Arthritis: A Cochrane Systematic Review' (2012) 90 *Journal of Rheumatology Supplement* 21. Grave reservations about the widespread treatment of rheumatism with cannabinoids in Canada were expressed in Mary-Ann Fitzcharles and Shahin Jamal, 'Expanding Medical Marijuana Access in Canada: Considerations for the Rheumatologist' (2015) 42 *The Journal of Rheumatology* 143.

²⁴ Ethan Russo, 'Cannabis Treatments in Obstetrics and Gynecology: A Historical Review' in Ethan Russo, Melanie Dreher and Mary Lynn Mathre (ed), *Women and Cannabis: Medicine, Science and Sociology* (Haworth Press, 2002).

²⁵ See, eg, Rudolf Schicho and Martin Storr, 'Cannabis Finds its Way into Treatment of Crohn's Disease' (2014) 93 *Pharmacology* 1; Timna Naftali et al, 'Cannabis for Inflammatory Bowel Disease' (2014) 32 *Digestive Diseases* 468, referring to an observational study of 30 patients with Crohn's disease, in which medical cannabis was associated with improvement in disease activity and reduction in the use of other medications, and to a placebo-controlled study of 21 patients with Crohn's disease, where there was a reduction in disease activity.

²⁶ See K Venderova et al, 'Survey on Cannabis Use in Parkinson's Disease: Subjective Improvement of Motor Symptoms' (2004) 19 *Movement Disorders* 1102; C B Carroll et al, 'Cannabis for Dyskinesia in Parkinson Disease' (2004) 63 *Neurology* 1245 (which did not find any pro- or anti-parkinsonian effects from orally administered cannabis).

²⁷ See eg Kirsten R Müller-Vahl, 'Treatment of Tourette Syndrome with Cannabinoids' (2013) 27 *Behavioural Neurology* 119 at 123: 'THC is recommended for the treatment of TS in adult patients, when first line treatments fail to improve the tics.'; see also K R Müller-Vahl et al, 'Treatment of Tourette Syndrome with delta-9-tetrahydrocannabinol (delta 9-THC): No Influence on Neuropsychological Performance' (2003) 28(2) *Neuropsychopharmacology* 384. Cannabis was approved by the Israel Health Ministry for treatment in Parkinson's disease and Tourette's syndrome on 5 April 2013, but in January 2015 Connecticut's Medicinal Marijuana Board of Physicians voted against adding Tourette's to the list of conditions for which cannabis could be prescribed in that state.

²⁸ See D I Abrams et al, 'Cannabis in Painful HIV-Associated Sensory Neuropathy: A Randomized Placebo-Controlled Trial' (2007) 68 *Neurology* 515.

- a treatment for a range of psychiatric disorders, including post-traumatic stress disorder and a number of psychotic disorders²⁹
- a treatment for Alzheimer-type dementia.³⁰

3.19 However, each of these illnesses/disorders has other forms of treatment. The role of cannabis and the cannabinoids is generally (although not exclusively) as an adjunct to other drugs or as a second-line treatment.

3.20 This paper does not purport to be comprehensive in its treatment of such literature but it endeavours to highlight the main areas in respect of which claims of therapeutic efficacy of cannabis products have been made.

Pain relief

3.21 It has been asserted that cannabis can provide therapeutic assistance in respect of both chronic pain and acute pain, including pain experienced in the course of terminal illnesses.

Chronic pain

3.22 Chronic pain has been estimated to affect approximately one person in twelve, and in the region of one person in four over the age of 65.³¹ It is often said to fall into two categories: nociceptive pain resulting from activity in neural pathways, secondary to actual tissue damage or potentially tissue-damaging stimuli, and neuropathic pain resulting from nervous system lesions or dysfunction.³²

3.23 The evidence base for use of cannabinoids for nociceptive pain has been described as 'not particularly compelling' but the picture in relation to treatment for neuropathic pain is said to be 'more encouraging'. The issue is important as non-steroidal anti-

²⁹ See, generally, C D Schubart et al, 'Cannabidiol as a Potential Treatment for Psychosis' (2014) 24 *European Neuropsychopharmacology* 51; F M Leweke et al, 'Cannabidiol Enhances Anandamide Signaling and Alleviates Psychotic Symptoms of Schizophrenia' (2012) 2 *Translational Psychiatry* E94; Celia J A Morgan and H Valerie Curran, 'Effects of Cannabidiol on Schizophrenia-like Symptoms in People Who Use Cannabis' (2008) 192 *British Journal of Psychiatry* 306; Alline C Campos et al, 'Multiple Mechanisms Involved in the Large-Spectrum Therapeutic Potential of Cannabidiol in Psychiatric Disorders' (2015) 367 *Philosophical Transactions B* 3364. Robson has argued that: 'Since laboratory evidence suggests that CBD may have a significant impact on both iatrogenic metabolic abnormalities and chronic systemic inflammation, it appears to have the potential to prove a useful medicine for both the psychological and physical manifestations of the disease': P J Robson, 'Therapeutic Potential of Cannabinoid Medicines' (2014) 6 *Drug Testing Analysis* 24.

³⁰ However, a Cochrane systematic review of cannabinoids for the treatment of dementia did not find sufficient evidence to establish efficacy in improving disturbed behaviour in dementia or in the treatment of other dementia symptoms: Sarada Krishnan, Ruth Cairns and Robert Howard, 'Cannabinoids for the Treatment of Dementia'[2009] *Cochrane Database of Systematic Reviews*. See also Ester Ato and Isidre Ferrer, 'Cannabinoids for Treatment of Alzheimer's Disease: Moving Toward the Clinic' (2014) 5(37) *Frontiers in Pharmacology*.

³¹ William Notcutt, 'Cannabis in the Treatment of Chronic Pain' in Geoffrey W Guy, Brian A Whittle and Philip J Robson (eds), *The Medicinal Uses of Cannabis and Cannabinoids* (Pharmaceutical Press, 2004) 271. Cohen notes its incidence as between 5 and 10% of the United States population: Mark Cohen, 'Prescribing Cannabis for Harm Reduction' (2012) 9(1) *Harm Reduction Journal* 1.

³² See B Nicholson, 'Differential Diagnosis: Nociceptive and Neuropathic Pain' (2006) 12 (9 Suppl) *American Journal of Managed Care* S256.

inflammatory drugs have a variety of adverse effects and opioids have limitations in terms of their application.³³

- 3.24 In 2005, Sativex was found better than a placebo on pain scores and improvements in sleep in a double-blind control trial lasting four weeks and involving patients with multiple sclerosis with intractable neuropathic pain.³⁴ This in turn generated a long-term further study in Canada whose mean duration of treatment was 463 days. During that time the findings were that the effectiveness of Sativex was maintained for at least two years for those without tolerance to the drug.³⁵
- 3.25 In a highly publicised double-blind, placebo-controlled, crossover study 39 patients with central and peripheral neuropathic pain underwent a standardised procedure for inhaling medium-dose, low dose or placebo THC, administered by vaporiser. It was found that cannabis had analgesic efficacy, with the low dose being as effective as a reliever of pain as the medium dose. Psychoactive effects were minimal and well tolerated.³⁶
- 3.26 A later double blind, randomised, placebo-controlled trial over five weeks of treatment with Sativex of 125 patients with peripheral neuropathic pain of mixed aetiology showed significant improvements for pain intensity.³⁷ Other studies, albeit with modest samples, have also been encouraging in respect of efficacy,³⁸ including in respect of neuropathic pain associated with HIV.³⁹ A systematic review of randomised trials examining the effect

³³ Opioids have been found to have limited or variable long-term effectiveness in the treatment of chronic non-cancer pain, while at the same time being implicated in overdoses, accidental deaths and diversion to illicit (non-medical) use: A M Trescot, 'Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians Guidelines' (2008) 11 *Pain Physician* 55; Eija Kalso et al, 'Opioids in chronic non-cancer pain: systematic review of efficacy and safety' (2004) 112 *Pain* 372; Amanda Roxburgh et al, 'Prescription of opioid analgesics and related harms in Australia' (2011) 195 *Medical Journal of Australia* 280. Non-steroidal anti-inflammatory drugs (which include the common analgesics aspirin, ibuprofen, naproxen and diclofenac) are known to have a range of undesirable side effects, including indigestion, stomach ulcers and stomach bleeding, and less commonly adverse renal, cardiovascular and hepatic effects. They can also interact harmfully with alcohol and other medications: see, eg, Shetine E Gabriel, Liisa Jaakkimainen and Claire Bombardier, 'Risk for Serious Gastrointestinal Complications Related to Use of Non-Steroidal Anti-Inflammatory Drugs: A Meta-Analysis' (1991) 115 *Annals of Internal Medicine* 787; Sven Trelle et al, 'Cardiovascular Safety of Non-Steroidal Anti-Inflammatory Drugs: Network Meta-Analysis' (2011) 342 *British Medical Journal* c7086.

³⁴ David J Rog et al, 'Randomized, Controlled Trial of Cannabis-Based Medicine in Central Pain in Multiple Sclerosis' (2005) 65 *Neurology* 812.

³⁵ David J Rog, Turo J Nurmikko and Carolyn A Young, 'Oromucosal delta-9-tetrahydrocannabinol/cannabidiol for Neuropathic Pain Associated with Multiple Sclerosis; An Uncontrolled, Open-Label, 2-Year Extension Trial' (2007) 29 *Clinical Therapeutics* 2068.

³⁶ Barth Wilsey et al, 'Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain' (2012) 14 *The Journal of Pain* 136. But see Brett R Stacey and Jeffrey L Moller, 'Marijuana for Pain Relief: Don't Jump to Conclusions' (2013) 14 *The Journal of Pain* 1250.

³⁷ Turo J Nurmikko et al, 'Sativex Successfully Treats Neuropathic Pain Characterised by Allodynia: A Randomised, Double-Blind, Placebo-Controlled Clinical Trial' (2007) 133 *Pain* 210.

³⁸ See, eg, Mark A Ware et al, 'Smoked Cannabis for Chronic Neuropathic Pain: A Randomized Controlled Trial' (2010) 182 *Canadian Medical Association Journal* E694

³⁹ See, eg, Ronald J Ellis et al, 'Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial' (2009) 34 *Neuropsychopharmacology* 672.

of cannabinoids in the treatment of chronic non-cancer pain in 2011 identified 15 trials which showed a significant analgesic effect of cannabinoids as against placebos and no significant adverse effects.⁴⁰

- 3.27 The mechanism for the pain-relieving efficacy of cannabis is little understood as yet. It has been suggested that THC may make the experience of pain more bearable, rather than actually reducing the intensity of pain:

Cannabis does not seem to act like a conventional pain medicine. Some people respond really well, others not at all, or even poorly. Brain imaging shows little reduction in the brain regions that code for the sensation of pain, which is what we tend to see with drugs like opiates. Instead cannabis appears to mainly affect the emotional reaction to pain in a highly variable way.⁴¹

- 3.28 Users of cannabis have also expressed views about the effectiveness of cannabis as an analgesic for chronic pain. In 2014, 100 patients who returned in Hawaii for re-certification for their use of cannabis were polled. The response rate was 94 per cent. Average reported pain relief from medicinal cannabis was substantial—average pre-treatment pain was 7.8 on a scale of 1-10 and average post-treatment pain was 2.8. Other reported therapeutic benefits included relief from stress/anxiety (50 per cent of respondents), relief of insomnia (45 per cent), improved appetite (12 per cent), decreased nausea (10 per cent), increased focus/concentration (9 per cent) and relief from depression (7 per cent).⁴²

Acute/terminal illness pain

- 3.29 There is only a modest literature on the capacity of cannabinoids to be able to reduce acute pain significantly. A 2012 study expressed major reservations about the state of knowledge on the subject at that time.⁴³
- 3.30 However, there have been a number of assertions from patients and family members that cannabis is effective for relieving pain for those suffering cancer and not receiving sufficient assistance from other forms of analgesia.⁴⁴ The so-called Brompton cocktail (containing cannabis and opioids) from the nineteenth century was regularly given to

⁴⁰ Mary E Lynch and Fiona Campbell, 'Cannabinoids for Treatment of Chronic Non-Cancer Pain: A Systematic Review of Randomized Trials' (2011) 72 *British Journal of Clinical Pharmacology* 735.

⁴¹ University of Oxford, 'Brain Imaging Insight into Cannabis as a Pain Killer', (press release, 21 December 2012) <<http://www.ox.ac.uk/news>>, discussing Michael C Lee et al, 'Amygdala Activity Contributes to the Dissociative Effect of Cannabis on Pain Perception' (2013) 154 *Pain* 124.

⁴² Charles W Webb and Sandra M Webb, 'Therapeutic Benefits of Cannabis: A Patient Survey' (2014) 73(4) *Hawaii Journal of Medicine and Public Health* 109. See also Louisa Degenhardt et al, 'Experience of Adjunctive Cannabis Use for Chronic Non-Cancer Pain: Findings from the Pain and Opioids IN Treatment (POINT) Study' (2014) 147 *Drug and Alcohol Dependence* 144.

⁴³ B Kraft, 'Is There any Clinically Relevant Cannabinoid-Induced Analgesia?' (2012) 89 *Pharmacology* 237.

⁴⁴ See, eg, Ovarian Cancer National Alliance, *Two Sides of Medical Marijuana: Anne's Story* (1 July 2010) <<http://www.ovariancancer.org>>; Francene Norton and Patrick Williams, 'Support for Man Who Gave Cannabis Oil to Daughter for Cancer Pain', (15 January 2015) ABC <<http://www.abc.net.au/news>>.

patients with cancer.⁴⁵ More often, though, what is said is that it is effective in alleviating the nausea, vomiting and poor appetite associated with chemotherapy.⁴⁶

- 3.31 Sativex was compared with THC whole-plant extract and a placebo as an add-on treatment in a two-week parallel group, randomised double blind trial. The subjects were 177 patients who had opioid-resistant pain arising from cancer. Sativex and the THC extract performed better than the placebo, and Sativex was reported as significantly preferable, but it produced a significant aggravation of nausea and vomiting.⁴⁷ In a separate study 360 patients were randomly allocated to groups receiving low, medium and high sprays of Sativex or a placebo as an add-on form of pain relief over five weeks. The results were superior for Sativex in the low- and middle-level doses.⁴⁸
- 3.32 A cannabinoid-opioid synergy has been proposed as a way to enhance the analgesic effects of opioids, without exacerbating their side effects. However, the clinical results of trials have been mixed and the view of Health Canada is that further study is required on this topic.⁴⁹ In 2013 it concluded:

Establishing the effectiveness of cannabis as a viable treatment option in a palliative care context requires a careful assessment of its effects in a wide range of conditions; such evidence is not yet abundant and further research is needed. Furthermore, while prescription cannabinoids demonstrate an acceptable safety profile according to some studies for certain medical conditions, the use of cannabis and cannabinoids in the clinic is known to be limited by their psychotropic effects. Certain patient populations (eg the elderly or those suffering from pre-existing psychiatric disease) may also be more sensitive or susceptible to experiencing adverse psychotropic, cognitive, psychiatric or other effects.⁵⁰

Potential to reduce opioid deaths

- 3.33 It has been postulated that opioid abuse in the context of pain relief has diminished with the availability of medicinal cannabis. Three states in the United States (California, Oregon and Washington) had medical cannabis laws prior to 1999. Ten states (Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island and Vermont) enacted such laws between 1999 and 2010.

⁴⁵ See Tim Dehnel, 'Cannabis, A New Option for Chronic Cancer Pain?' (2011) 12 *The Lancet Oncology* 995.

⁴⁶ See eg Kelly Fuller, 'A Tamworth Family's Plea to Make Cannabis Legal for Pain Relief', (23 July 2014) ABC <<http://www.abc.net.au>>.

⁴⁷ Jeremy R Johnson et al, 'Multicenter, Double-Blind, Randomised, Placebo-Controlled, Parallel-Group Study of the Efficacy, Safety and Tolerability of THC:CBD Extract and THC Extract in Patients with Intractable Cancer-Related Pain' (2010) 39 *Journal of Pain and Symptom Management* 167.

⁴⁸ Russell K Portenoy et al, 'Nabiximols for Opioid-Treated Cancer Patients with Poorly Controlled Chronic Pain: A Randomized, Placebo-Controlled, Graded-Dose Trial' (2012) 13 *The Journal of Pain* 438.

⁴⁹ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 52.

⁵⁰ *Ibid* 34.

A 2014 study identified that states with medical cannabis laws had a 24.8 per cent lower mean annual opioid overdose mortality rate compared with those without such laws. In addition, examination of the opioid death rates showed that such laws were associated with a lower overdose mortality that strengthened with each year.⁵¹

Nausea and vomiting suppression and appetite enhancement

- 3.34 One of the less controversial areas in respect of the effects of cannabis is its capacity, and particularly that of THC, to reduce nausea and vomiting, including that produced by cancer chemotherapy, and also to stimulate appetite—a phenomenon known as ‘the munchies’ by recreational users of cannabis.⁵²
- 3.35 The enhancement of appetite can be of particular application in relation to reduction of cachexia (wasting) and loss of appetite associated with cancer- and HIV/AIDS-induced anorexia. The issue of needing to enhance appetite for those with AIDS has now been largely addressed by the use of ante-retroviral treatments.
- 3.36 There is strong evidence that cannabis in a number of forms can assist in reduction of nausea and vomiting and in enhancing appetite⁵³ in a variety of contexts, although some studies have suggested concern about some dysphoric, depressive, hallucinatory and paranoid effects.⁵⁴
- 3.37 Rocha and others in 2008⁵⁵ conducted a meta-analysis. They found that dronabinol (by contrast with the synthetic cannabinoids, Nabilone and Levonantradol) was superior to placebo and prochlorperazine in reducing nausea.
- 3.38 George Annas has described poignantly the experience of the scientist, Stephen J Gould, who smoked marijuana to alleviate the nausea and discomfort he experienced during chemotherapy for abdominal mesothelioma:

Absolutely nothing in the available arsenal of anti-emetics worked at all. I was miserable and came to dread the frequent treatments with an almost perverse intensity. ... Marijuana worked like a charm. The sheer bliss of not experiencing nausea—and not having to fear it for all the

⁵¹ Marcus A Bachhuber et al, ‘Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010’ (2014) 174 *JAMA Internal Medicine* 1668.

⁵² See, eg, Philip Robson, ‘Therapeutic Aspects of Cannabis and Cannabinoids’ (2001) 178 *British Journal of Psychiatry* 107.

⁵³ See, eg, Jeffrey E Beal et al, ‘Long-term Efficacy and Safety of Dronabinol for Acquired Immunodeficiency Syndrome-Associated Anorexia’ (1997) 14 *Journal of Pain and Symptom Management* 7; Florian Strasser et al, ‘Comparison of Orally Administered Cannabis Extract and delta-9-tetrahydrocannabinol in Treating Patients with Cancer-Related Anorexia-Cachexia Syndrome: A Multicenter, Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial from the Cannabis-In-Cachexia-Study-Group’ (2006) 24 *Journal of Clinical Oncology* 3394.

⁵⁴ See eg Martin R Tramèr et al, ‘Cannabinoids for Control of Chemotherapy Induced Nausea and Vomiting: Quantitative Systematic Review’ (2001) 323 *British Medical Journal* 16.

⁵⁵ F C Machado Rocha et al, ‘Therapeutic Use of Cannabis Sativa on Chemotherapy-Induced Nausea and Vomiting Among Cancer Patients: Systematic Review and Meta-Analysis’ (2008) 17 *European Journal of Cancer Care* 431.

days intervening between treatments—was the greatest boost I received in all my year of treatment, and surely the most important effect upon my eventual cure.⁵⁶

- 3.39 As long ago as 1991, an anonymous survey of the American Society of Clinical Oncology with a response rate of 43 per cent (totalling 1035 participants) resulted in 44 per cent of respondents recommending the (illegal) use of marijuana for the control of vomiting (emesis) and 48 per cent saying they would prescribe marijuana if it was legal.⁵⁷
- 3.40 However, gauging the utility of cannabis as an option for reducing side effects of chemotherapy such as nausea and vomiting requires taking into account that newer anti-emetic agents have been developed and are now commonly administered, including in combination.⁵⁸ There appears to be a category of patients for whom the anti-emetics are not effective and for whom nausea and vomiting are intractable.⁵⁹ Cannabinoids may have a role in assisting them.
- 3.41 Both the British Medical Association⁶⁰ and the Institute of Medicine⁶¹ concluded that cannabis was unlikely to be effective for treating patients with anorexia nervosa. However, Health Canada observed in 2013 that ‘further research may be warranted’.⁶²

Anti-spasticity properties

- 3.42 A number of studies have attempted to identify the therapeutic benefit of cannabis in treating the symptoms of multiple sclerosis.⁶³ The outcomes are increasingly positive.
- 3.43 An important study, published in 2003, involved a large, randomised, placebo-controlled trial using 667 patients from 33 centres in the United Kingdom. Patients were randomised to receive synthetic THC in the form of dronabinol or a cannabis-plant extract containing both THC and cannabidiol (Cannador). The first 15 week phase of the trial showed no effect on the primary outcome measure of spasticity but there was a

⁵⁶ George J Annas, ‘Reefer Madness—the Federal Response to California’s Medical-Marijuana Law’ (1997) 337 *New England Journal of Medicine* 435, 436.

⁵⁷ R E Doblin and M A Kleiman, ‘Marijuana as Antiemetic Medicine: A Survey of Oncologists’ experiences and Attitudes’ (1991) 9 *Journal of Clinical Oncology* 1314.

⁵⁸ See eg R M Navari, ‘Pharmacological Management of Chemotherapy-Induced Nausea and Vomiting: Focus on Recent Developments’ (2009) 69 *Drugs* 515.

⁵⁹ See Howard S Smith, Joshua M Smith and Alyssa R Smith, ‘An Overview of Nausea/Vomiting in Palliative Medicine’ (2012) 1 *Annals of Palliative Medicine* 103. See also, in respect of positive patient reports of satisfaction: Gil Bar-Sela et al, ‘The Medical Necessity for Medicinal Cannabis: Prospective, Observational Study Evaluating the Treatment in Cancer Patients on Supportive or Palliative Care’[2013] *Evidence-Based Complementary and Alternative Medicine*.

⁶⁰ British Medical Association, *Therapeutic Uses of Cannabis* (CRC Press, 1997).

⁶¹ Janet E Joy, Stanley J Watson Jr and John A Benson Jr (ed) and Institute of Medicine (US), *Marijuana and Medicine: Assessing the Science Base* (1999).

⁶² Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 38.

⁶³ See, eg, MS Chong et al, ‘Cannabis Use in Patients with Multiple Sclerosis’ (2006) 12 *Multiple Sclerosis* 646.

positive effect on patient-reported measures of spasticity, pain levels, quality of sleep, and decreased spasms in both treatment groups. Those patients who were receiving THC experienced significant improvements in their muscle spasticity over 12 months and appeared to accrue less disability at the 12 month mark.⁶⁴

3.44 In 2012 Pryce and Baker reviewed the studies to date and concluded that:

The observations from experimental models of MS, and now increasingly from clinical trials, point to the therapeutic usefulness of cannabinoid-based medicines for the treatment of symptoms such as limb spasticity. In addition, increasing experimental evidence also demonstrates the neuroprotective properties of cannabinoids in slowing the rate of disease progression, which may also have an important potential in the treatment of MS.⁶⁵

3.45 In 2014, the American Academy of Neurology reported that oral cannabis extract is effective and nabiximols and THC are probably effective for treating patient-centred measures of spasticity and objective measures at the one year mark for multiple sclerosis.⁶⁶

Anti-convulsant properties

3.46 An area of research in which particular energy has been directed over the past decade has been paediatric epilepsy. As Dr Roberta Cilio, principal research and director of research at the University of California San Francisco Pediatric Epilepsy Centre observed:

It's important to get seizure control at any age, but in children, uncontrolled seizures may impact brain and neurocognitive development, which can have an extraordinary effect on quality of life and contribute to progressive cognitive impairment.⁶⁷

3.47 A Cochrane review in 2013 identified four randomised trial reports that included a total of 48 patients, and each used cannabidiol as the treatment agent. However, one report was an abstract and another a letter to the editor. Details of randomisation were not included in any of the studies and there was no investigation of whether the control and treatment participant groups were the same or different.

⁶⁴ John Zajicek et al, 'Cannabinoids for Treatment of Spasticity and Other Symptoms Related to Multiple Sclerosis (CAMS Study): Multicentre Randomised Placebo-Controlled Trial' (2003) 362 *Lancet* 1517; J P Zajicek et al, 'Cannabinoids in Multiple Sclerosis (CAMS) Study, Safety and Efficacy Data for 12 Months Follow-Up' (2005) 76 *Journal of Neurology, Neurosurgery & Psychiatry* 1664. See also R D Hosking and J P Zajicek, 'Therapeutic potential of cannabis in pain medicine' (2008) 101 *British Journal of Anaesthesia* 59.

⁶⁵ Gareth Pryce and David Baker, 'Potential Control of Multiple Sclerosis by Cannabis and the Endocannabinoid System' (2012) 11 *CNS & Neurological Disorders—Drug Targets* 624, 636.

⁶⁶ Barbara S Koppel et al, 'Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders: Report of the Guideline Development Subcommittee of the American Academy of Neurology' (2014) 82 *Neurology* 1556.

⁶⁷ See Juliano Bunim, 'Marijuana-Derived Epilepsy Drug in Clinical Trial for Children with Uncontrolled Seizures', *University of California San Francisco*, 3 February 2014 <<http://www.ucsf.edu/news>>.

3.48 The Cochrane review concluded that: ‘all of the reports were of low quality’ and that:

No reliable conclusions can be drawn at present regarding the efficacy of cannabinoids as a treatment for epilepsy. The dose of 200 to 300 mg daily was safely administered to small numbers of patients generally for short periods of time, and so the safety of long term cannabinoid treatment cannot be reliably assessed.⁶⁸

3.49 In 2013, Robson expressed a similar view, identifying human research on the efficacy of CBD on epilepsy as ‘in its infancy’.⁶⁹ To a similar effect, Szaflarski and Bebin in 2014 noted the anecdotal reports⁷⁰ of the efficacy of cannabis for epilepsy and acknowledged the role of the endocannabinoid system in seizure generation, maintenance and control in animal models of epilepsy. However, they cautioned:

Further data from well designed studies are needed regarding short- and long-term efficacy and side effects of CBD or high-CBD/low-THC products for the treatment of seizures and epilepsy on children and adults.⁷¹

3.50 Also in 2014 Welty, Luebke and Gidal questioned whether the use of cannabinoids for epilepsy is premature:

If this were any other uninvestigated pharmaceutical compound, would we feel as compelled to make the agent widely available before statistically valid class 1 evidence was available for review? Until data from well-designed clinical trials are available and reliable, and standardised CBD products that are produced using good manufacturing practices are available, caution must be exercised in any consideration of using CBD for the treatment of epilepsy. In the meantime, based upon promising preliminary data, further clinical research should be wholeheartedly pursued.⁷²

3.51 However, it is appropriate also to have regard to a survey of parents in relation to cannabidiol-enriched cannabis used in the treatment of paediatric treatment-resistant epilepsy.⁷³ There were 19 responses that met the criteria for reception. There were

⁶⁸ David Gloss and Barbara Vickrey, ‘Cannabinoids for Epilepsy’[2014] 3 *Cochrane Database of Systematic Reviews*.

⁶⁹ P J Robson, ‘Therapeutic Potential of Cannabinoid Medicines’ (2014) 6 *Drug Testing Analysis* 24, 28.

⁷⁰ See eg Joseph Gregorio, ‘Physicians, Medical Marijuana, and the Law’ (2014) 16 *American Medical Association Journal of Ethics* 732.

⁷¹ Jerzy P Szaflarski and E Martina Bebin, ‘Cannabis, Cannabidiol and Epilepsy—From Receptors to Clinical Response’ (2014) 41 *Epilepsy & Behavior* 277. See also the view expressed in an online survey showing a wide diversity of views about the use of medical marijuana and CBD in relation to the treatment of epilepsy: Gary W Mathern, Laurie Beninsig and Astrid Nehlig, ‘Fewer Specialists Support Using Medical Marijuana and CBD in Treating Epilepsy Patients Compared with Other Medical Professionals and Patients: Result of Epilepsia’s Survey’ (2014) 56 *Epilepsia* 1.

⁷² Timothy E Welty, Adrienne Luebke and Barry E Gidal, ‘Cannabidiol: Promise and Pitfalls’ (2014) 14 *Epilepsy Currents* 250, 252. Importantly, too, the American Society of Neurology expressed the view in 2014 that the use of oral cannabinoids is of unknown efficacy in epilepsy, and that there is not sufficient evidence to prescribe CBD or to recommend self-treatment with cannabis: see Barbara S Koppel et al, ‘Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders: Report of the Guideline Development Subcommittee of the American Academy of Neurology’ (2014) 82 *Neurology* 1556.

⁷³ Brenda E Porter and Catherine Jacobson, ‘Report of a Parent Survey of Cannabidiol-Enriched Cannabis Use in Pediatric Treatment-Related Epilepsy’ (2013) 29 *Epilepsy and Behavior* 574.

multiple seizure types in the study and the children ranged in age from two to 16 years, thirteen with Dravet syndrome, four with Doose syndrome, one with Lennox Gastaut syndrome and one with idiopathic early onset epilepsy. On average, they had experienced treatment-resistant epilepsy for more than three years before trying cannabis and had used an average of twelve failed anti-epileptic drugs.

3.52 Eighty-four per cent of the parents reported a reduction in their child's seizure frequency while taking the compound, two noting complete seizure freedom, eight a greater than 80 per cent reduction in seizure frequency, and six reported a 25–60 per cent seizure reduction. Other reported effects included better mood, improved alertness, and improved sleep, whereas negative effects that were reported included drowsiness and fatigue.

3.53 The authors concluded that:

Objective measurements of a standardised preparation of pure cannabidiol are needed to determine whether it is safe, well tolerated, and efficacious at controlling seizures in this pediatric population with difficult-to-treat seizures.⁷⁴

3.54 In an editorial in *Epilepsy & Behavior*, referring to the study, Sirven acknowledged the uncertain state of current research knowledge, observing:

We need more research. There is hope. ... Many more studies such as these need to be completed before any rational decisions are made. ... It is only by the process of science guided by rational and ethical advocacy for the best interest of the patient that we will come to an answer and not leave people to their own devices. Hopefully, there will be less polarity, less politicisation of this issue, and more focus on what is real and what is not. Nevertheless and whether we like it or not, it looks like the epilepsy community is in the crosswinds of change.⁷⁵

Capacity to inhibit or alleviate degenerative neurological conditions

3.55 A number of studies have suggested that cannabis may provide therapeutic assistance in relation to symptoms in conditions such as Parkinson's disease.⁷⁶ A common medication for the disease is levodopa, a natural chemical which passes into the brain and is converted into dopamine. However, its efficacy can lessen as the disease progresses.

⁷⁴ Ibid 577.

⁷⁵ Joseph I Sirven, 'Medical Marijuana for Epilepsy: Winds of Change' (2013) 29 *Epilepsy and Behavior* 435, 436.

⁷⁶ See Richard Secklin, *Marijuana for Parkinson's Disease* (Nettfit Publishing, 2012).

- 3.56 In 2001, for instance, a double-blind, randomised, placebo-controlled design reported that nabilone significantly reduced total levodopa-induced dyskinesia compared with a placebo.⁷⁷
- 3.57 In 2004, a survey of Parkinson's patients revealed that, of the 25 per cent of 300 patients who had used cannabis, 45.9 per cent reported benefits, including 145 who reported improvement in levodopa-induced dyskinesia⁷⁸.
- 3.58 In 2014, the authors of a study on a similar subject accepted that the results of previous studies had been contradictory⁷⁹ but gave a positive report in respect of 22 patients who attended a motor disorder clinic. They were evaluated at baseline and then after cannabis consumption. The mean function on the Unified Parkinson Disease Rating Scale improved from 33.8 to 23.2 after consumption. Analysis of specific motor symptoms revealed significant improvements after treatment in tremor, rigidity and bradykinesia. Improvements in sleep and pain scores were also reported.⁸⁰ There has been a suggestion that THC is neuroprotective in animal and cell culture models of Parkinson's disease.⁸¹
- 3.59 A major prospective, observational study is currently being conducted to describe the effects of cannabis on Parkinson's Disease tremor.⁸²

Capacity to inhibit intra-ocular pressure

- 3.60 Since at least 1971, cannabis and some cannabinoids have been recognised as having the potential to reduce intra-ocular pressure.⁸³
- 3.61 In glaucoma the pathway that leads to loss of sight is the selective death of retinal ganglion cells through apoptosis (cell death) initiated by axonal injury at the optic disk. It may be that the antioxidant properties of THC and CBD have the potential to inhibit neuronal damage. In addition, cannabinoids have vasorelaxant properties and thus the potential to increase ocular blood flow so it has been suggested they may have beneficial properties in ischaemia-induced optic nerve damage.

⁷⁷ See K Sieradzan et al, 'Cannabinoids Reduce Levodopa-Induced Dyskinesia in Parkinson's Disease: A Pilot Study' (2001) 57 *Neurology* 2108.

⁷⁸ See K Venderova et al, 'Survey on Cannabis Use in Parkinson's Disease: Subjective Improvement of Motor Symptoms' (2004) 19 *Movement Disorders* 1102.

⁷⁹ See, eg, C B Carroll et al, 'Cannabis for Dyskinesia in Parkinson Disease' (2004) 63 *Neurology* 1245, which did not find any pro- or anti-parkinsonian effects from orally administered cannabis.

⁸⁰ See Itay Lotan et al, 'Cannabis (Medical Marijuana) Treatment for Motor and Non-Motor Symptoms of Parkinson Disease: An Open-Label Observational Study' (2014) 37 *Clinical Neuropharmacology* 41.

⁸¹ See Marie-Louise Zeissler et al, 'Δ9- Tetrahydrocannabinol is Protective Through PPARγ Dependent Mitochondrial Biogenesis in a Cell Culture Model of Parkinson's Disease' (2013) 84(e2) *Journal of Neurology, Neurosurgery & Psychiatry* 150.

⁸² 'Cannabis and Parkinson's Disease Tremor: A Natural History Study' (2014) (ClinicalTrials.gov identifier NCT02028858).

⁸³ See eg Robert S Hepler and Ira Frank, 'Marihuana Smoking and Intraocular Pressure (letter)' (1971) 217 *Journal of the American Medical Association* 1392. See too Philip Robson, 'Therapeutic Aspects of Cannabis and Cannabinoids' (2001) 178 *British Journal of Psychiatry* 107.

3.62 This led Tomida, Pertwee and Azuara-Blanco in 2004 to assert that:

Cannabinoids have the potential of becoming a useful treatment for glaucoma, as they seem to have neuroprotective properties and effectively reduce intraocular pressure. However, several challenges need to be overcome, including the problems associated with unwanted systemic side effects (psychotropic, reduction in systemic blood pressure), possible tolerance, and the difficulty in formulating a stable and effective topical preparation. Some cannabinoids ... do not have psychotropic effects, while maintaining their intraocular pressure lowering action, so that further research on these compounds would be desirable.⁸⁴

3.63 In 2013, Health Canada concluded that:

while smoking or eating cannabis has been shown to reduce intra-ocular pressure, cannabinoid therapy appears to be limited by the short duration of cannabinoid action and unwanted physical and psychotropic effects.⁸⁵

3.64 Notably, an important aspect of modern research into glaucoma treatment is focussing on preservation of the optic nerve and retina, rather than on lowering the pressures.⁸⁶ This may reduce the utility of cannabinoids for glaucoma treatment.

Anti-psychotic properties

3.65 A double-blind study with 42 patients diagnosed with an acute episode of schizophrenia or schizophreniform disorder under the definitions of the American Psychiatric Association's DSM-IV showed that CBD significantly reduced psychotic symptomatology after two to four weeks and induced fewer side effects (such as extrapyramidal symptoms such as spasms and tremors), increased prolactin levels and weight gain, by comparison with the anti-psychotic, amisulpride.⁸⁷

3.66 A study has also suggested that CBD has potential without significant side effects in treating Generalised Social Anxiety Disorder.⁸⁸ However, much more research is required in these areas before confident statements can be made about the efficacy of cannabinoids.

⁸⁴ I Tomida, R G Pertwee and A Azuara-Blanco, 'Cannabinoids and Glaucoma' (2004) 88 *British Journal of Ophthalmology* 712.

⁸⁵ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013), 59.

⁸⁶ Mitch Earleywine, *Understanding Marijuana: A New Look at the Scientific Evidence* (Oxford University Press, 2002) 173.

⁸⁷ FM Leweke et al, 'Cannabidiol as an Antipsychotic: A Double-blind, Controlled Clinical Trial on Cannabidiol vs Amisulpride in Acute Schizophrenia' (2007) 22 *European Psychiatry* S14.02. See too BC McLoughlin et al, 'Cannabis and Schizophrenia (Review)' [2014] 10 *Cochrane Database of Systematic Reviews*.

⁸⁸ Mateus M Bergamaschi et al, 'Cannabidiol Reduces the Anxiety Induced by Simulated Public Speaking in Treatment-Naïve Social Phobia Patients' (2011) 36 *Neuropsychopharmacology* 1219.

Potential side effects of medicinal cannabis

3.67 There is a considerable literature that highlights the risks of cannabis usage, while acknowledging its potential clinical application. This literature tends to emphasise the unpredictable effects of cannabis on mood and anxiety and its deleterious effects on cognition, along with some physical side effects.

Psychiatric issues

3.68 A 2013 study of 1,714 persons from the general population, where 38 per cent reported a history of cannabis use, concluded that there was a significant correlation between paranoid ideation and cannabis use.⁸⁹ Various studies have suggested that cannabis use can exacerbate the symptoms of schizophrenia⁹⁰ and have linked cannabis use with an earlier age of onset and an increased incidence of schizophrenia and other psychoses. It has been suggested that those with schizotypal personalities may experience more psychosis-like symptoms during and after use—in other words, such a personality factor is a vulnerability for development of cannabis-related psychotic symptoms.⁹¹

3.69 For about ten per cent of persons newly exposed to cannabis it has been asserted that they will develop a cannabis use disorder which incorporates both the development of tolerance and a withdrawal syndrome, associated with sleep disturbance, anxiety, depressed mood and irritability.⁹² In 2012 the investigators of the United Kingdom Schizophrenia Commission concluded that cannabis use is the most preventable risk factor for psychosis and that research into the contribution of cannabis to the development of schizophrenia should be pursued.⁹³ It appears that the psychotogenic effect of cannabis (the likelihood of its playing a causative relationship in psychotic symptomatology) may well be related to the THC-potency of the cannabis used.⁹⁴

3.70 The fifth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, published in 2013 (DSM-5), retains 'Cannabis Use

⁸⁹ Daniel Freeman et al, 'Persecutory Ideation and a History of Cannabis Use' (2013) 148 *Schizophrenia Research* 122. Similarly, the 2010 *National Drug Strategy Household Survey Report* (Australian Institute of Health and Welfare, 2011) found that there appeared to be a relationship between cannabis use and mental health for persons aged 18 and older: those who had reported using cannabis in the previous 12 months (18.7%) or in the previous month (20.5%) were more likely to have been diagnosed or treated for mental illness than people who had not used in the previous 12 months (11.3%); those who had used cannabis in the previous month (19.1%) or previous 12 months (16.3%) were more likely to report high or very high levels of psychological distress compared with those who had not recently used cannabis (9.1%).

⁹⁰ See, eg, Deepak Cyril D'Souza, Richard Andrew Sewell and Mohini Ranganathan, 'Cannabis and Psychosis/Schizophrenia: Human Studies' (2009) 259 *European Archives of Psychiatry and Clinical Neuroscience* 413.

⁹¹ E Barkus and S Lewis, 'Schizotypy and Psychosis-like Experiences from Recreational Cannabis in a Non-Clinical Sample' (2008) 38 *Psychological Medicine* 1267.

⁹² See A Elkashef et al, 'Marijuana Neurobiology and Treatment' (2008) 29(3) *Substance Abuse* 17.

⁹³ Schizophrenia Commission, *The Abandoned Illness: A Report by the Schizophrenia Commission* (Rethink Mental Illness, 2012) <<https://www.rethink.org>>.

⁹⁴ See, eg, Neil Smith, 'High Potency Cannabis: The Forgotten Variable (letter)' (2005) 100 *Addiction* 1558.

Disorder’, observing, without differentiating between recreational and medicinal cannabis users, that:

Functional consequences of cannabis use disorder are part of the diagnostic criteria. Many areas of psychosocial, cognitive, and health functioning may be compromised in relation to cannabis use disorder. Cognitive function, particularly higher executive function, appears to be compromised in cannabis users, and this relationship appears to be dose dependent (both acutely and chronically) ... Cannabis use can contribute to the onset of an acute psychotic episode, can exacerbate some symptoms, and can adversely affect treatment of a major psychotic illness.⁹⁵

- 3.71 In addition, the same manual retains the disorder, ‘cannabis intoxication’ but states that: ‘if the clinical presentation includes hallucinations in the absence of intact reality testing, a diagnosis of substance/medication-induced psychotic disorder should be considered.’⁹⁶ A 2015 study published in *The Lancet* in relation to the risks of high-THC cannabis⁹⁷ contended that while CBD may ameliorate the psychotic-inducing effects of such cannabis, high-THC cannabis has an identifiably adverse effect on mental health.⁹⁸
- 3.72 A 2008 systematic review of the research on the adverse effects of medicinal cannabis use identified 23 randomised controlled trials and eight observational studies of the adverse effects of cannabinoids and cannabis extracts. It generated identification of 164 serious adverse events but there was no higher incidence of such events than among the control patients (namely, those not given cannabis). It concluded that the overwhelming majority of the adverse effects which had been reported (96.6 per cent) were not serious but of these the rate was 1.86 times higher than among the control patients. Among these effects the most common was dizziness.⁹⁹
- 3.73 Criminal law decisions throughout Australia have dealt on many occasions with arguments and expert evidence that persons have engaged in criminal conduct while suffering the symptoms of a cannabis-induced psychosis.¹⁰⁰ Some of this conduct is particularly serious, at times involving homicide. In *The Queen v Giles* the Chief Justice of Victoria stated:

⁹⁵ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2013) 514–515.

⁹⁶ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2013) 517, cross-referring to 111 (Substance/Medication-Induced Psychotic Disorder) in respect of which specific reference is made to cannabis.

⁹⁷ Often classified as ‘skunk’ by recreational users.

⁹⁸ See Marta Di Forti et al, ‘Proportion of Patients in South London with First-Episode Psychosis Attributable to Use of High Potency Cannabis: A Case-Control Study’ (2015) 2 *The Lancet Psychiatry* 233.

⁹⁹ Tongtong Wang et al, ‘Adverse Effects of Medical Cannabinoids: A Systematic Review’ (2008) 178 *Canadian Medical Association Journal* 1669.

¹⁰⁰ See, eg, *R v Martin* (2007) 20 VR 14; *Re Sorensen* [2010] QMHC 15; *Re LIH* [2002] QMHC 14.

This case is but one of those which have come before the courts where certain of the circumstances are alarmingly similar. They are cases of young men committing, apparently in a state of rage, appalling crimes of violence. These young men have no, or no significant, prior convictions, and in some cases, like the present, no diagnosable mental disorder; but these young men are heavy marijuana users. To the best of my knowledge, no scientific study has been undertaken of these cases, and in my opinion the time has come when such a study ought to be undertaken. Hopefully it would serve to throw some light on these extremely troubling matters.¹⁰¹

- 3.74 The findings in relation to the correlation between psychotic illnesses and cannabis relate to recreational users of cannabis, as against those using it medicinally in respect of whom there are few data.¹⁰² As some physical illnesses may be assisted by the THC content of cannabis, as against CBD, the studies in relation to the psychotogenic effects of THC are relevant to evaluation of the risks posed by the medicinal use of cannabis. However, caution should be exercised in applying these results to medicinal users because, as noted at [2.20] above, cannabis grown for illicit purposes tends to contain high levels of THC and low levels of CBD and other cannabinoids. Users of cannabis with a high THC/low CBD profile may be at greater risk of psychosis than users of cannabis with a greater quantities of CBD.¹⁰³

Dependence and withdrawal

- 3.75 A further side effect of cannabis usage that has been identified clinically is dependence. Cannabis dependence can be characterised by tolerance to the effects of cannabis, withdrawal symptoms when use ceases, over-use, a desire to cease use, unsuccessful attempts to cease use and giving up other activities in order to use cannabis.¹⁰⁴
- 3.76 Dependence on cannabis tends to be less severe than that observed with cocaine, opiates and alcohol.¹⁰⁵ It has been asserted that 'individuals with marijuana dependence meet fewer DSM dependence criteria; the withdrawal experience is not as dramatic; and the severity of the associated consequences is not as extreme. However, the apparently less severe nature of marijuana dependence does not necessarily mean that marijuana

¹⁰¹ *The Queen v Giles* [1999] VSCA 208, [24] (Phillips CJ)—a case of rape and murder by a 21 year old who had a history of cannabis and alcohol abuse but was not suffering psychosis.

¹⁰² See Louisa Degenhardt and Wayne Hall, 'The Adverse Effects of Cannabinoids: Implications for Use of Medical Marijuana' (2008) 178 *Canadian Medical Association Journal* 1685.

¹⁰³ Wendy Swift et al, 'Analysis of Cannabis Seizures in NSW, Australia: Cannabis Potency and Cannabinoid Profile' (2013) 8 *PLoS ONE* e70052, 2.

¹⁰⁴ National Cannabis Prevention and Information Centre, *Cannabis and Dependence* (2011) <<https://ncpic.org.au/professionals/publications/factsheets/cannabis-and-dependence>>. See also Thomas F Babor, 'The Diagnosis of Cannabis Dependence' in Roger Roffmann and Robert S Stephens (eds), *Cannabis Dependence: Its Nature, Consequences and Treatment* (Cambridge University Press, 2006).

¹⁰⁵ See eg Alan J Budney, 'Are Specific Dependence Criteria Necessary for Different Substances: How Can Research on Cannabis Inform this Issue?' (2006) 101(Suppl 1) *Addiction* 125.

addiction is easier to overcome.¹⁰⁶ A number of medicinal treatments have been trialled to address the symptoms of cannabis dependence.¹⁰⁷

- 3.77** Cannabis dependence results in withdrawal symptoms for some but not all users who experience a cannabis use disorder (which includes dependence). The 2013 Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines ‘cannabis withdrawal’ as ‘the presence of a characteristic withdrawal syndrome that develops after the cessation of or reduction in heavy and prolonged cannabis use’ (whether recreational or medicinal). Heavy and prolonged use is defined as usually or almost daily use over a period of at least a few months. A diagnosis looks at the following physical and non-physical consequences.
- Three (or more) of the following signs and symptoms, which develop within approximately one week after cessation of use:
 - irritability, anger, or aggression
 - nervousness or anxiety
 - sleep difficulty (eg, insomnia, disturbing dreams)
 - decreased appetite or weight loss
 - restlessness
 - depressed mood.
 - at least one of the following physical symptoms causing significant discomfort: abdominal pain, shakiness, tremors, sweating, fever, chills, or headache.
 - The signs or symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
 - The signs or symptoms are not attributable to another medical condition and are not better explained by another mental disorder, including intoxication or withdrawal from another substance.
- 3.78** The phenomenon of cannabis withdrawal, while not life-threatening, is a significant and not uncommon consequence of usage of cannabis when it is sustained and on a basis approximating to daily.
- 3.79** A 1999 study estimated that 31.7% of Australian cannabis users met the DSM-IV criteria for cannabis use disorder in the previous 12 months, with 21.0% of cannabis users

¹⁰⁶ Alan J Budney et al, ‘Marijuana Dependence and its Treatment’ (2007) 4 *Addiction Science & Clinical Practice* 4.

¹⁰⁷ See eg AM Weinstein and David A Gorelick, ‘Pharmacological Treatment of Cannabis Dependence’ (2011) 17 *Current Pharmaceutical Design* 1351; FR Levin et al, ‘Pharmacotherapy for Marijuana Dependence: A Double-Blind Placebo-Controlled Pilot Study of Divalproex Sodium’ (2004) 13 *American Journal on Addictions* 21; AL McRae, AJ Budney, KT Brady, ‘Treatment of Marijuana Dependence: A Review of the Literature’ (2003) 24 *Journal of Substance Abuse Treatment* 369.

meeting the criteria for cannabis dependence. Cannabis withdrawal symptoms were commonly reported amongst users.¹⁰⁸

Safety issues and mood changes

3.80 Among other things, absorption of THC impacts upon safety in working with heavy machinery, exercising judgment generally, and safety in driving motor vehicles and boats.¹⁰⁹ In addition, a number of studies have shown an association between cannabis usage and the onset of mood disorders and psychosis, as well as depression among regular users.¹¹⁰

Respiratory issues

3.81 Cannabis, when it is smoked, can generate a range of pathological lung conditions including a chronic cough and sputum, airway inflammation and damage, as well as growth of epithelial cells.¹¹¹ Reports have indicated an elevated incidence of myocardial infarction and other cardiovascular events associated with marijuana smoking.¹¹² While it appears that cannabis and tobacco are not equally carcinogenic, nonetheless cannabis is potentially a cause of cancer.¹¹³

¹⁰⁸ Wendy Swift, Wayne Hall and Maree Teesson, *Cannabis Use Disorders among Australian Adults: Results from the National Study of Mental Health and Wellbeing* (National Drug and Alcohol Research Centre, Technical Report No 78, 1999) 14 <<http://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/TR%2078.pdf>>.

¹⁰⁹ See eg Rebecca L Hartman and Marilyn A Huestis, 'Cannabis Effects on Driving Skills' (2013) 59 *Clinical Chemistry* 478. A 2014 study found that an increased prevalence of cannabinoids among drivers involved in fatal crashes was only detected in a minority of the states in the United States that had implemented medicinal marijuana laws: Scott V Masten and Gloriam V Guenzburger, 'Changes in Driver Cannabinoid Prevalence in 12 US States after Implementing Medical Marijuana laws' (2014) 50 *Journal of Safety Research* 35.

¹¹⁰ See, eg, Margriet Van Laar et al, 'Does Cannabis Use Predict the First Incidence of Mood and Anxiety Disorders in the Adult Population?' (2007) 102 *Addiction* 1251.

¹¹¹ See, eg, Mark J Pletcher et al, 'Association between Marijuana Exposure and Pulmonary Function over 20 Years' (2012) 307 *Journal of the American Medical Association* 173.

¹¹² David G E Caldicott et al, 'Keep Off the Grass: Marijuana Use and Acute Cardiovascular Events' (2005) 12 *European Journal of Emergency Medicine* 236; Murray A Mittleman et al, 'Triggering Myocardial Infarction by Marijuana' (2001) 103 *Circulation* 2805.

¹¹³ See, eg, Russell C Callaghan, Peter Allebeck and Anna Sidorchuk, 'Marijuana use and risk of lung cancer: a 40-year cohort study' (2013) 24 *Cancer Causes & Control* 1811 (finding that smoked cannabis might elevate the risk of lung cancer, even after controlling for tobacco use); J Berthiller et al, 'Cannabis smoking and risk of lung cancer in men: a pooled analysis of three studies in Maghreb' (2008) 3 *Journal of Thoracic Oncology* 1398 (finding cannabis smoking to be a potential risk factor for lung cancer based on pooled analysis of three case-control studies); S Sidney et al, 'Marijuana use and cancer incidence (California, United States)' (1997) 8 *Cancer Causes & Control* 722 (finding that marijuana use and cancer were not associated in an overall analysis, but that its use might affect certain site-specific cancer risks). But see, eg, Mia Hashibe et al, 'Epidemiologic review of marijuana use and cancer risk' (2005) 35 *Alcohol* 265 (finding earlier studies on the carcinogenic effects of cannabis inconclusive); Reena Mehra et al, 'The Association Between Marijuana Smoking and Lung Cancer: A Systematic Review' (2006) 166 *Archives of Internal Medicine* 1359 (finding that an association between cannabis smoking and lung cancer was biologically plausible but that no convincing evidence exists). Pharmacological differences between tobacco smoke and cannabis smoke appear to indicate that the former should present a greater cancer risk: Robert Melamede, 'Review: Cannabis and tobacco smoke are not equally carcinogenic' (2005) 2 *Harm Reduction Journal* 21.

Pregnancy issues

3.82 Russo has highlighted that the use of cannabis during pregnancy ‘remains a great concern’.¹¹⁴ A 1983 study which evaluated 12,424 pregnancies found association between low birth weight, shortened gestation and malformations but when logistic regression analysis was applied to control for confounding factors, the association failed to carry statistical significance.¹¹⁵ It has also been asserted that cannabis disrupts the menstrual cycle, suppresses oogenesis (creation of the egg cell), and impairs embryo implantation and development.¹¹⁶

Cardiac issues

3.83 A 2014 review of cardiac effects of cannabis when smoked¹¹⁷ identified an association between inhaled cannabis and heightened rates of acute myocardial infarction and increased cardiovascular mortality. The authors noted case reports of safety signal between cannabis use and stroke.

Medical responses to side effect issues

3.84 Concerns about side effects led Saxon and Browne, for instance, to conclude that in view of such risks ‘now is not the time for psychiatrists or other physicians to be prescribing or recommending non-pharmaceutical smoked marijuana for management of chronic pain.’¹¹⁸

3.85 Health Canada recommended in 2013 that doctors evaluate carefully the risk-benefit ratio for patients with the following medical conditions because of individual variation in response and tolerance to its effects:

Cannabis should not be used in any person under the age of 18, or in any patient who has a history of hypersensitivity to any cannabinoid or to smoke. The adverse effects of cannabis use on mental health are greater during development, particularly during adolescence, than in adulthood.

Cannabis should not be used in patients with severe cardio-pulmonary disease because of associated hypotension, possible hypertension, syncope, or tachycardia.

¹¹⁴ Ethan Russo, ‘Cannabis Treatments in Obstetrics and Gynecology: A Historical Review’ in Ethan Russo, Melanie Dreher and Mary Lynn Mathre (ed), *Women and Cannabis: Medicine, Science and Sociology* (Haworth Press, 2002).

¹¹⁵ Shai Linn et al, ‘The Association of Marijuana Use with Outcome of Pregnancy’ (1983) 73 *American Journal of Public Health* 1161. More recently, see L Karila et al, ‘Short- and Long-Term Consequences of Prenatal Exposure to Cannabis’ (2006) 35 *Journal de Gynécologie Obstétrique et Biologie de la Reproduction* 62.

¹¹⁶ Monica Bari et al, ‘The Manifold Actions of Endocannabinoids on Female and Male Reproductive Events’ (2011) 16 *Frontiers in Bioscience* 498.

¹¹⁷ Grace Thomas, Robert A Kloner and Shereif Rezkalla, ‘Adverse Cardiovascular, Cerebrovascular, and Peripheral Vascular Effects of Marijuana Inhalation: What Cardiologists Need to Know’ (2014) 113 *American Journal of Cardiology* 187.

¹¹⁸ Andrew J Saxon and Kendall W Browne, ‘Marijuana Not Ready for Prime Time as an Analgesic’ (2014) 36 *General Hospital Psychiatry* 4.

Smoked cannabis is not recommended in patients with respiratory insufficiency such as asthma or chronic obstructive pulmonary disease.

Cannabis should not be used in patients with severe liver or renal disease. Patients with ongoing chronic hepatitis C should be strongly advised to abstain from daily cannabis use, as this has been shown to be a predictor of steatosis severity in these individuals.

Cannabis should not be used in patients with a personal history of psychiatric disorders (especially schizophrenia), or a familial history of schizophrenia.

Cannabis should be used with caution in patients with a history of substance abuse, including alcohol abuse, because such patients may be more prone to abuse cannabis, which itself, is a frequently abused substance.

Patients with mania or depression and using cannabis or a cannabinoid should be under careful psychiatric monitoring.

Cannabis should be used with caution in patients receiving concomitant therapy with sedative-hypnotics or other psychoactive drugs because of the potential for additive or synergistic CNS depressant or psychoactive effects. Cannabis may also exacerbate the CNS depressant effects of alcohol and increase the incidence of adverse effects. Patients should be advised of the negative effects of cannabis/cannabinoids on memory and to report any mental or behavioural changes that occur after using cannabis.

Cannabis is not recommended in women of childbearing age not on a reliable contraceptive, as well as those planning pregnancy, those who are pregnant, or women who are breastfeeding.¹¹⁹

Defining 'exceptional circumstances'

Allowing compassionately for exceptional circumstances of need

3.86 Research knowledge about the therapeutic potential of cannabis products is evolving rapidly¹²⁰—the state of knowledge even in three years will be significantly different from that today. It is apparent that medical opinion,¹²¹ including in Australia,¹²² as well as

¹¹⁹ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013), 79. See also Australian National Council on Drugs, *Medicinal Use of Cannabis: Background and Information Paper* (25 August 2014) <<http://www.ancd.org.au>>.

¹²⁰ Noting that similar concerns have been raised for a lengthy period: 'Notwithstanding the large amount of labor which has been expended on Indian hemp, we know comparatively little of its pharmacology': C R Marshall, 'A Contribution to the Pharmacology of *Cannabis Indica*' (1898) 31 *American Medical Journal* 882.

¹²¹ See Anthony Charuvastra, Peter D Friedmann and Michael D Stein, 'Physician Attitudes Regarding the Prescription of Medical Marijuana' (2005) 24(3) *Journal of Addictive Diseases* 87; See Jonathan N Adler, and James A Colbert, 'Clinical Decisions: Medical Use of Marijuana—Poll Results' (2013) 368 *New England Journal of Medicine* e30; Elin Kondrad and Alfred Reid, 'Colorado Family Physicians' attitudes Toward Medical Marijuana' (2013) 26 *Journal of the American Board of Family Medicine* 52.

public sentiment,¹²³ are moving in favour of liberalisation of access to medicinal cannabis products for some categories of patient.

- 3.87** However, there remains a level of disjunction between, on the one hand, the outcomes of surveys within the general community and even within the medical profession and, on the other, the contemporary state of medico-scientific knowledge. Were strict criteria of evidence-based medicine to be applied at this stage, the scope for the therapeutic prescription of cannabis products would be relatively confined.¹²⁴ As yet, there is a gap in many respects between promise and proven efficacy of medicinal cannabis.
- 3.88** However, given the need for a compassionate response to the suffering of a number of categories of patient, many contend that there is a need for liberalisation of access to cannabinoid products. Recognition of this underpins the terms of reference given to the Commission.
- 3.89** The challenge that arises is to identify those patients who should be permitted to receive medicinal cannabis prior to definitive, orthodox medical trials establishing both efficacy and safety. This is a difficult balancing exercise to be engaged in with circumspection, sensitivity and flexibility—the categories of patient given access will need to be revisited at regular intervals because of the fast-evolving state of medical knowledge and research. This suggests that any model which is developed should be amenable to adjustment as the state of research knowledge requires.
- 3.90** A scheme that makes cannabis available ‘in exceptional circumstances’ for persons with particular health needs should be driven by compassionate considerations which provide treatment options that are not wholly established by orthodox double-blind, placebo-controlled trials.

¹²² Survey evidence shows that cannabis is currently used for medicinal purposes by a large number of Australians. A recent national study conducted by the National Drug & Alcohol Research Centre at the University of New South Wales (with 1,500 participants) found that one in six respondents who were prescribed opiates for pain relief also used cannabis to address their symptoms: Louisa Degenhardt et al, ‘Experience of Adjunctive Cannabis Use for Chronic Non-Cancer Pain: Findings from the Pain and Opioids IN Treatment (POINT) Study’ (2014) 147 *Drug and Alcohol Dependence* 144.

In addition, a small survey of New South Wales Northern Rivers doctors found them particularly to be aware of a potential to treat palliative care, chronic pain and AIDS-related wasting patients with medicinal cannabis. Overwhelmingly, they stated that they would consider prescribing medicinal cannabis were it to be legal, supported by their peers, and based on good quality clinical research evidence. All respondents approved of government-supported research or clinical trials for the use of medicinal cannabis: see Graham Irvine, ‘Rural Doctors’ attitudes to and Knowledge of Medicinal Cannabis’ (2006) 14 *Journal of Law and Medicine* 135.

¹²³ See, eg, *2010 National Drug Strategy Household Survey Report* (Australian Institute of Health and Welfare, 2011) <<http://www.aihw.gov.au>>, which showed community support for medicinal cannabis at 69% with 74% of respondents supporting research into its use.

¹²⁴ Michael Vagg, ‘Is the Medical Marijuana Debate Even Worth Having?’ *The Conversation*, (16 February 2015) <<http://theconversation.com>>.

- 3.91 This does not mean that the outcomes of such trials should be ignored. It is important and humane that unrealistic expectations not be created. Departure from the principles of evidence-based medicine should only take place where the potential benefits outweigh the potential risks, dangers and side effects. There must be some reasonable prospect of therapeutic benefit; otherwise the exercise is one of speculation and may raise false hopes of beneficial outcomes. In addition, the potential benefit must be one that cannot reasonably be obtained from another available form of treatment.¹²⁵
- 3.92 If a person has a terminal condition, for instance, the fact that they may acquire a level of dependence upon medicinal cannabis may be of little importance. However, their suffering from a terminal condition does not justify provision of a medication if clinical knowledge is not sufficient to hold out a reasonable prospect of an advantageous outcome, without an unacceptable down side.
- 3.93 An issue that may remain of significance, even for those who have a terminal condition, is if the medication impacts upon their mental state in such a way as to reduce their quality of life by reason, for instance, of inducing anxiety, depression or paranoia.
- 3.94 Another consideration that may be important for those who do not have a terminal condition is any consequence that is long term and deleterious. For instance, were there to be a significant risk of developmental harm from cannabis medications given to children, this could be a significant factor to take into account in terms of whether they should be made available. Similarly the cancer-causing properties of cannabis, when smoked, may also be significant.
- 3.95 The potential for side effects from usage of certain forms of cannabis products, for instance respiratory diseases by reason of smoking cannabis, or the development of tolerance and the need for withdrawal,¹²⁶ may be a relevant consideration if likely usage is long term and the person's condition is not terminal—for instance, if it is to address chronic pain.

¹²⁵ The Australian National Council on Drugs in 2014 expressed the view that 'there is a lack of clarity on how cannabinoid compare to other possible treatments. For example, although oral THC has been shown to be effective as an anti-emetic, it is not clear whether it is more efficacious than other products': Australian National Council on Drugs, *Medicinal Use of Cannabis: Background and Information Paper* (25 August 2014) <<http://www.ancd.org.au>>.

¹²⁶ Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 23.

Questions

- 1 **Which of the following considerations should determine whether there are exceptional circumstances for medicinal cannabis to be made available to a patient:**
 - (a) the circumstances of the patient
 - (b) the state of clinical knowledge about the efficacy or potential efficacy of using cannabis in treating the patient's condition
 - (c) both of the above?
- 2 **For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of cannabis to justify allowing sufferers to use it lawfully in Victoria?**
- 3 **What special considerations, if any, justify access to medicinal cannabis for:**
 - (a) patients who are under 18 years of age
 - (b) patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal cannabis?

Drawing the distinctions in law

- 3.96 Plainly, legislation allowing medicinal cannabis to be used in exceptional circumstances would not apply to all sufferers of the numerous medical conditions concerning which claims about its efficacy have been made. A threshold issue in designing Victoria's medicinal cannabis scheme is how to distinguish at law between the people it should cover as against others within the community.
- 3.97 The distinction can be based on a number of determining factors:
- the type of medical condition the person has
 - the type of symptoms for which relief is sought
 - whether conventional treatments are effective.
- 3.98 A combination of these criteria could also be used.

Distinction based on medical condition

- 3.99 Victoria could introduce legislation that lists the specific conditions for which medicinal cannabis may be used. Any sufferer of a listed condition could be eligible to seek access to medicinal cannabis. By basing eligibility on the type of medical condition that the person suffers, the scheme could focus on people whose symptoms are likely to be severe and not well or adequately managed by pharmaceutical preparations.

- 3.100 Several countries and parts of the United States have established schemes that specify the medical conditions for which medicinal cannabis can lawfully be used. The number of conditions varies, as does the level of specificity—for instance chronic pain conditions are incorporated in some, while in others the focus is upon conditions such as childhood epilepsy, chemotherapy-related nausea and vomiting, and intractable, opioid-resistant pain for those with terminal illnesses.
- 3.101 The advantage of this approach would be that it provides certainty for health practitioners, their patients and the wider community. The scope of the medicinal cannabis scheme could be contained and tightly controlled. The disadvantage of this approach would be that it would exclude people who might also deserve the community's compassion and whose quality of life may be able to be improved by lawful access to medicinal cannabis. For this reason, the legislation could provide a means of reviewing the list and departing from it in defined circumstances.

Distinction based on symptoms

- 3.102 Another approach to determining eligibility to use medicinal cannabis is to specify symptoms for which it can lawfully be used. This approach could be used to either reduce or widen the coverage of the scheme.
- 3.103 It can reduce coverage where a symptom is required to be associated with a specified medical condition. For example, the Canadian medicinal cannabis scheme initially linked symptoms with conditions, such as 'severe pain and/or persistent muscle spasms from a spinal cord disease'.
- 3.104 Alternatively, if any person suffering from a listed symptom for any reason were eligible to use medicinal cannabis, the coverage of the scheme would be far wider. In Maryland, for example, medicinal cannabis may be used to treat any medical condition that causes cachexia, anorexia, wasting, severe or chronic pain, severe nausea, seizures, or severe or persistent muscle spasms.¹²⁷ In Hawaii, it is available to people suffering severe pain, cachexia, severe nausea, seizures and persistent muscle spasms.¹²⁸ By utilising such descriptors, there is scope for variation in clinical opinion about the satisfaction of the relevant preconditions for eligibility.

Distinction based on efficacy of conventional treatments

- 3.105 Some jurisdictions stipulate that conventional treatments must have failed to provide effective relief.¹²⁹ This approach could allow a person with a debilitating but common medical condition to use medicinal cannabis if it is the best option for them. At the same time, by indicating that using medicinal cannabis should be a treatment of last resort, the scheme can still be directed towards people in special circumstances.

¹²⁷ Md Code Ann, Health - General § 13-3307(C).

¹²⁸ 19 Haw Rev Stat § 329-121.

¹²⁹ For example Israel, Delaware and Maryland.

- 3.106 There is also a public health benefit in requiring people to use clinically tested and approved treatments before moving to a treatment which could produce unpredictable, variable or less effective results. It could also reduce the pressure on health practitioners to provide access to medicinal cannabis when, in their opinion, it may be unlikely to be as effective as a pharmaceutical product.
- 3.107 However, on another view, whether a person should use medicinal cannabis in view of the options and risks is a matter best determined by their health practitioner.

Unusual and compelling circumstances

- 3.108 Regardless of how eligibility is determined, it could be advantageous to allow for exceptions in special cases. Compassion could be shown when medicinal cannabis is the safest or most effective treatment for a person who is suffering the debilitating effects of a severe condition in circumstances that do not align with the strict eligibility criteria of the scheme. While inevitably this would generate an administrative challenge for those with responsibility for determining eligibility, and even potential litigation, this would enable an individualised response to particular requests for access and would be distinct from any arrangements to review or add to the eligibility criteria.

Questions

- 4 **On which of the following should the law creating a medicinal cannabis scheme base a person's eligibility to use medicinal cannabis:**
- (a) a list of medical conditions
 - (b) a list of symptoms
 - (c) a list of symptoms arising from certain medical conditions
 - (d) evidence that all reasonable conventional treatments have been tried and failed?
- 5 **Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal cannabis? If so, what should that be?**

How cannabis is regulated

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4 How cannabis is regulated

Introduction

- 4.1 This chapter considers Victoria's regulatory options in light of the existing regulatory framework that governs the cultivation, processing, supply, administration and use of cannabis for medicinal purposes in Australia. When used for a medicinal purpose, cannabis engages multiple regulatory frameworks.
- 4.2 Any law reform to establish a medicinal cannabis scheme in Victoria is likely to involve the amendment of the two Acts that are identified in the terms of reference: the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) and the *Therapeutic Goods (Victoria) Act 2010* (Vic). Both pieces of legislation contribute to a nationwide system that regulates therapeutic goods and medicines in Australia. The Commonwealth has primary control of the system, with the result that the scope of the possible amendments to the two Victorian Acts is limited by the division of responsibilities between the Commonwealth and the states.
- 4.3 The Commonwealth regulates 'the quality, safety and efficacy of medicines',¹ while Victoria and the other states and territories regulate 'the sale, supply, possession, handling [and] use of medicines and poisons (including drugs and other substances)'.²
- 4.4 The cultivation, processing, supply and possession of cannabis are also criminalised under both Commonwealth and Victorian law, and its lawful importation is highly restricted by the Commonwealth.
- 4.5 Consequently, the Victorian legislation is best understood in the context of the Commonwealth legislation to which it relates. After providing an overview of the Victorian legislation, this chapter will describe the relevant Commonwealth laws, many of which in turn reflect international obligations.

¹ Shane Bullock and Elizabeth Manias, *Fundamentals of Pharmacology* (Pearson, 2013) 22.

² John S. Low, Laetitia Hattingh and Kim Forrester, *Australian Pharmacy Law and Practice* (Elsevier, 2013) 232.

- 4.6 Discussion will then turn to the regulatory options available to Victoria in order to enable authorised patients to obtain lawful access to medicinal cannabis.

Victorian laws

Drugs, Poisons and Controlled Substances Act

- 4.7 The Drugs, Poisons and Controlled Substances Act and the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) establish when the cultivation, processing, supply, administration and use of drugs, poisons and other controlled substances are legal or illegal in Victoria.³
- 4.8 Cannabis is regulated under the Act and Regulations, both as a poison and as a drug of dependence. These are terms of art that indicate how a substance is to be controlled. A substance may be a poison and controlled substance capable of lawful prescription and supply under the Act and regulations, and also a drug of dependence the misuse of which attracts criminal sanction.⁴

Cannabis as a poison

- 4.9 The rules that apply to poisons and controlled substances depend upon how they are categorised for regulatory purposes under a national system established by the Commonwealth. The categories are set out as Schedules 2 to 9 of the Commonwealth's *Standard for the Uniform Scheduling of Medicines and Poisons No 6* (SUSMP),⁵ and these categories are incorporated into Victoria's Drugs, Poisons and Controlled Substances Act.⁶
- 4.10 Cannabis is a poison found in Schedule 9 of the SUSMP, which contains prohibited substances.⁷ Nabiximols and dronabinol—pharmaceutical formulations of cannabis—are listed in Schedule 8, which contains poisons that are controlled drugs.⁸ This review is principally concerned with the forms of cannabis that are contained in Schedule 9.

³ Victoria, *Parliamentary Debates*, Legislative Assembly, 23 September 1981, 924 (Mr Borthwick).

⁴ See for example the requirement in s 33 of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) that a registered medical practitioner notify the Secretary when a 'drug-dependent person' seeks prescription of a Schedule 9 poison, a 'Schedule 8 poison or a Schedule 4 poison which is also a drug of dependence'. See also Victorian Department of Health Poisons and Regulations Group, *Key Legislative Requirements for Medical Practitioners* (2010) 3, which describes drugs of dependence as 'all [Schedule] 8 poisons plus specified [Schedule] 4 poisons that are subject to misuse and trafficking'.

⁵ *Poisons Standard 2015* (Cth) sch 1.

⁶ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 4(1) (definition of 'poison or controlled substance').

⁷ A 'prohibited substance' is a poison that may be abused and so its manufacture, possession, sale or use should be prohibited by law except for the purposes of medical or scientific research.

⁸ A 'controlled drug' is a substance that in principle is able to be made available by a limited range of health professionals, but may be abused by patients. The SUSMP recommends controls on its manufacture, supply, distribution, possession and use.

- 4.11 Similarly, THC and its alkyl homologues are listed as Schedule 9 poisons except:
- when they are included in Schedule 8
 - when 50 mg/kg or less is in hemp seed oil labelled as not for internal use
 - when, at 50 mg/kg or less, in other products not for human consumption.⁹
- 4.12 As a Schedule 9 prohibited substance, cannabis may be made available therapeutically only under strict conditions. Clinical and scientific research into poisons that fall within this category in Victoria would require the approval of both the Commonwealth and state governments. To prescribe it in Victoria, a practitioner must apply to the Secretary of the Victorian Department of Health and Human Services. In practice, applications to prescribe are not made.
- 4.13 Schedule 9 poisons are highly controlled. There are detailed and restrictive rules about record-keeping,¹⁰ storage,¹¹ who may lawfully possess them,¹² and who may lawfully prescribe them.¹³
- 4.14 One approach to making cannabis or cannabinoids available for medicinal purposes would be for the Commonwealth to reclassify them to another schedule that has less stringent restrictions. As noted in Chapter 5, an application of this kind has been made to reclassify cannabidiol to Schedule 4, which contains poisons used in prescription-only medicines.¹⁴ Another approach would be for the Commonwealth to establish separate regulatory arrangements for cannabis supplied for medicinal purposes. As noted in Chapter 5, a Bill to this effect has been introduced into the Commonwealth Parliament.

⁹ *Poisons Standard 2015* (Cth) SUSMP sch 9.

¹⁰ Records of Schedules 8 and 9 poisons must contain the name and address of the person who supplied the poison: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 40(1)(e), and must reflect a true and accurate balance of the poisons remaining in the person's possession after every transaction, and record the name of the person who carried out each transaction: r 41(1)(c).

¹¹ Schedules 8 and 9 poisons must be kept in a 10mm steel plate storage facility: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 35.

¹² 'A person for whom a Schedule 9 poison has been supplied by a registered medical practitioner, pharmacist or dentist in accordance with the Act and these Regulations' is authorised to have that poison 'to the extent and for the purpose for which it is supplied': *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 5(1) Item 3.

¹³ Only a registered medical practitioner, veterinary practitioner or dentist who has a permit under s 33A of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) may write prescriptions for a Schedule 9 poison: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 25(1). The permit is for a specific patient; it is not a standing authority to supply Schedule 9 poisons.

¹⁴ A 'prescription only drug' is a substance that should be available on prescription under state or territory law.

Cannabis as a drug of dependence

- 4.15 Cannabis¹⁵ is also a drug of dependence.¹⁶ The Drugs, Poisons and Controlled Substances Act imposes penalties on people who unlawfully make drugs of dependence available. It is an offence in Victoria to cultivate, traffick, administer, possess or use cannabis.¹⁷
- 4.16 The Act could be amended to create a specific exception permitting cannabis to be supplied for medicinal purposes, without unduly disturbing the general prohibitions on its use. The Act is flexible. Its provisions are already designed to respond to the legalisation of a substance such as cannabis for a limited purpose. It is only prohibited to make a drug of dependence such as cannabis available 'without being authorised by or licensed under this Act or the regulations to do so'.¹⁸

The Therapeutic Goods (Victoria) Act

- 4.17 The Therapeutic Goods (Victoria) Act extends the reach of the Commonwealth's therapeutic goods framework to everyone in Victoria. This is to allow for a national, uniform scheme for the regulation of therapeutic goods in every Australian state and territory. This is achieved by applying the Commonwealth's *Therapeutic Goods Act 1989* (Cth) as a law of Victoria¹⁹ and extending its operation to:
- (a) things done or omitted to be done by persons who are not corporations; and
 - (b) things done or omitted to be done in the course of trade and commerce within the limits of Victoria.²⁰
- 4.18 The effect of this provision is that the Commonwealth Therapeutic Goods Act applies to every natural or legal person in Victoria to whom it would not otherwise apply, including corporations which are not 'constitutional corporations',²¹ unincorporated associations, partnerships and firms without separate legal personality.

¹⁵ The plant *Cannabis L*, THC and various synthetic cannabinoids are all drugs of dependence: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) sch 11 pts 2 and 3. More broadly, the reference to cannabis includes the drug itself whether it has natural or synthetic forms; its fresh or dried parts; its salts, analogues, derivatives and isomers; or the salts of those analogues, derivatives and isomers; and any substance that contains any of those things. See the definition of 'drug of dependence' in the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 4(1).

¹⁶ By virtue of being listed in Schedule 11 of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

¹⁷ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 71–5.

¹⁸ See generally *Drugs, Poisons and Controlled Substances Act 1981* (Vic) pt 5.

¹⁹ *Therapeutic Goods (Victoria) Act 2010* (Vic) s 6(1). The provisions applied as a law of Victoria are described as the 'applied provisions': see s 3. The Act does this to avoid having to repeatedly amend the Act so as to reflect the Commonwealth's Act: Victoria, *Parliamentary Debates*, Legislative Assembly, 25 March 2010, 1146–7 (Mr Andrews). This is in contrast to Western Australia and Queensland, which have not applied the *Therapeutic Goods Act 1989* (Cth) as a law of the state.

²⁰ *Therapeutic Goods (Victoria) Act 2010* (Vic) s 6(2).

²¹ 'Constitutional corporation' is a legal term that describes corporations that are regulated by the Commonwealth. They are discussed again at [4.20].

- 4.19 Section 5 of the Commonwealth Therapeutic Goods Act binds the ‘Crown in right of the States’,²² which is taken to include the executive government of Victoria.²³
- 4.20 Victorian legislation is necessary in order to establish a national scheme, because the application of the Commonwealth Therapeutic Goods Act is limited²⁴ reflecting the extent of the powers granted to the Commonwealth by the Australian Constitution. The ‘persons’ regulated by the Commonwealth Therapeutic Goods Act of its own force are:
- ‘constitutional corporations’—corporations that can be regulated by the Commonwealth because a sufficient proportion of their activities are trading activities (revenue-generating activities such as the sale of goods or services) or financial activities (such as the making of loans), or because the corporation is foreign (was incorporated overseas)²⁵
 - natural persons or unincorporated associations, firms or partnerships engaged in interstate or overseas trade and commerce²⁶
 - natural persons or unincorporated associations, firms or partnerships when they are engaged in activities under a law of the Commonwealth relating to the supply of pharmaceutical or repatriation benefits²⁷
 - natural persons acting for the Commonwealth.
- 4.21 The application of the Commonwealth Therapeutic Goods Act in Victoria to persons and unincorporated entities outside of the Commonwealth's constitutional authority may be modified by regulations made under the Victorian Act.²⁸ The implications of this shall be discussed later in the chapter.

²² *Therapeutic Goods Act 1989* (Cth) s 5. See also *Therapeutic Goods (Victoria) Act 2010* (Vic) s 5.

²³ *Jacobsen v Rogers* (1995) 182 CLR 572, 585.

²⁴ *Therapeutic Goods Act 1989* (Cth) s 6. The limits of the Commonwealth's powers were described in the second reading speech for the Act: see Commonwealth, *Parliamentary Debates*, House of Representatives, 5 October 1989, 1614 (the Hon. Peter Stapes).

²⁵ The Commonwealth has the power to legislate with respect to ‘foreign corporations’ and ‘trading and financial corporations formed within the limits of the Commonwealth’: *Australian Constitution* s 51(xx). The power may be used to regulate ‘statutory corporations’ engaged in trading and financial activities: see *State Superannuation Board v Trade Practices Commission* (1982) 150 CLR 282; *Commonwealth v Tasmania* (1983) 158 CLR 1, 156 (Mason J), 179 (Murphy J), 240 (Brennan J) 292–3 (Deane J).

²⁶ The Commonwealth has the power to legislate with respect to ‘trade and commerce with other countries, and among the States’: *Australian Constitution* s 51(i). The Commonwealth cannot use this head of power to legislate with respect to trade and commerce that takes place entirely within a state. See eg *Redfern v Dunlop Rubber Australia Ltd* (1964) 110 CLR 194, 221 (Menzies J).

²⁷ The Commonwealth may legislate with respect to, amongst other things, ‘pharmaceutical benefits’, and ‘medical services’: *Australian Constitution* s 51(xxiiA). Those terms are not thought to allow the Commonwealth to directly regulate the medical and pharmaceutical schemes established by the States: see Geoffrey Lindell, ‘The Changed Landscape of the Executive Power of the Commonwealth after the Williams Case’ (2013) 39(2) *Monash University Law Review* 348, 358. See also *British Medical Association v Commonwealth* (1949) 79 CLR 201, 242–5 (Latham CJ).

²⁸ *Therapeutic Goods (Victoria) Act 2010* (Vic) ss 6(3), 16(3).

- 4.22 The national therapeutic goods framework was established, and is maintained, through the co-operative efforts of the Commonwealth and the states. There is a shared interest in supporting a national approach to the regulation of medicines.
- 4.23 In an exchange of letters out-of-session in 2005, the Council of Australian Governments accepted a recommendation that each state adopt and apply the Commonwealth Therapeutic Goods Act as a law of its jurisdiction.²⁹ The Therapeutic Goods (Victoria) Act implements this undertaking, while retaining Victoria's power to adjust the extent to which the Commonwealth legislation applies within Victoria's jurisdiction.³⁰
- 4.24 Ideally, any scheme introduced by Victoria to allow for patients to be treated with medicinal cannabis would be developed with the co-operation of the Commonwealth. This would create more options for law reform.

Other relevant legislation

- 4.25 Aside from the Therapeutic Goods (Victoria) Act and the Drugs, Poisons and Controlled Substances Act, there are also two other relevant Victorian Acts:
- The *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic) applies the *Health Practitioner Regulation National Law* as a law of Victoria.³¹ This is the law under which health practitioners are accredited to practise.
 - The *Food Act 1984* (Vic) incorporates the *Food Standards Australia New Zealand Code* (Cth), which prohibits hemp being included in food.

Relevant Commonwealth laws

- 4.26 The following Commonwealth Acts would need to be taken into account in establishing a medicinal cannabis scheme in Victoria:
- The *Therapeutic Goods Act 1989* (Cth), which establishes a framework by which therapeutic goods are evaluated and permitted to be sold in Australia.
 - The *National Health Act 1953* (Cth), which regulates the Pharmaceutical Benefits Scheme.
 - The *Narcotic Drugs Act 1967* (Cth), which establishes an Australian licensing scheme for the manufacture of narcotic drugs which are, like cannabis, the subject of an international treaty.

²⁹ Standing Committee on Uniform Legislation and Statutes, Parliament of Western Australia, *Review of the Medicines, Poisons and Therapeutic Goods Bill 2013* (2014) 14. The relevant recommendation was Recommendation 23 of the *Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (2001), led by Dr Rhonda Galbally AO. The review was itself undertaken at the request of the Council of Australian Governments pursuant to the *National Competition Policy* and the *Intergovernmental Agreement to Implement the National Competition Policy and Related Reforms* (11 April 1995).

³⁰ *Therapeutic Goods (Victoria) Act 2010* (Vic) s 6(3).

³¹ *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic) s 4.

- The *Customs Act 1901* (Cth), the *Customs (Prohibited Imports) Regulations 1956* (Cth), the *Psychotropic Substances Act 1976* (Cth) and the *Criminal Code* (Cth), which prohibit the unauthorised importation of cannabis.
- The *Criminal Code* (Cth), which also criminalises all steps involved making available drugs such as cannabis, unless authorised by a law of a state or territory. The *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* imposes similar criminal prohibitions, but is not designed to exclude state and territory law and is exercised only at the discretion of the Commonwealth Attorney-General.³²

The Therapeutic Goods Act

- 4.27 The Therapeutic Goods Act is at the core of the national scheme for regulating the importation, manufacture and supply of therapeutic goods. The Act establishes the SUSMP that is incorporated into the Victorian Drugs, Poisons and Controlled Substances Act.
- 4.28 The Act establishes standards for the quality of therapeutic goods³³ and the conditions of their manufacture.³⁴ It requires goods to be registered before they are sold in Australia.³⁵
- 4.29 The Therapeutic Goods Administration (TGA), a Division of the Commonwealth Department of Health, administers the Act. It is responsible for evaluating the safety, quality and efficacy of therapeutic goods and approving them for sale in Australia; licensing the manufacturers of therapeutic goods; and ensuring that therapeutic goods are properly labelled and advertised if they are to be sold on the Australian market.³⁶
- 4.30 The Act applies to things that are, are represented in any way to be, or are likely to be taken to be, 'therapeutic goods', which are goods that have 'therapeutic use' or are used as ingredients in such goods.³⁷ A good has a therapeutic use when it is used 'in or in connection with':
- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
 - (b) influencing, inhibiting or modifying a physiological process in persons; or

³² *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* (Cth) s 16.

³³ *Therapeutic Goods Act 1989* (Cth) pt 3-1. In the absence of a ministerial standard, 'default standards' apply as set out in the *British Pharmacopoeia*, *European Pharmacopoeia*, and *United States Pharmacopoeia—National Formulary: Therapeutic Goods Act 1989* (Cth) s 5.

³⁴ *Therapeutic Goods Act 1989* (Cth) pt 3-3.

³⁵ *Ibid* pt 3-2.

³⁶ Therapeutic Goods Administration, *Access to unapproved therapeutic goods: Clinical trials in Australia* (2004) 8.

³⁷ *Therapeutic Goods Act 1989* (Cth) s 3(1) (definition of 'therapeutic good').

- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons.³⁸

4.31 This is a broad definition, potentially capturing any good held out as being for therapeutic use. Its limits have not been the subject of definitive interpretation in the courts. The discussion below assumes that all forms of cannabis provided for medicinal purposes would be treated as being for therapeutic use and as such are therapeutic goods.³⁹

Goods on the Australian Register of Therapeutic Goods

4.32 A therapeutic good may not be imported into or manufactured and supplied in Australia unless it is on the Australian Register of Therapeutic Goods (the Register). Every 'separate and distinct'⁴⁰ therapeutic good must be entered on the Register.

Application procedure

4.33 Different types of therapeutic good are evaluated differently. Cannabis products are likely to fall within the definition of 'medicines'. For the purposes of the Act, a medicine is a therapeutic good that is not a 'biological'⁴¹ and which achieves its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human'.⁴²

4.34 In assessing an application for a medicine to be included on the Register, the Secretary of the Commonwealth Department of Health will assess its safety, quality and efficacy. This assessment will be done on the advice of an expert committee.⁴³ A number of other criteria are also taken into account. This includes whether the medicine includes a substance that is a prohibited import. It also includes an assessment of whether the good meets relevant standards for advertising, marketing and manufacture, and will be appropriately labelled and packaged.

4.35 Medicines, generally speaking, will be evaluated as 'registered goods' that pose a degree of risk to the consumer. The nature of the evaluation will depend on whether they are

³⁸ Ibid s 3(1) (definition of 'therapeutic use').

³⁹ This is the position taken by the Commonwealth Department of Health, *Medicinal Cannabis* (17 December 2014) <<http://www.health.gov.au/internet/main/publishing.nsf/Content/MC14-007515-medicinal-cannabis>>.

⁴⁰ Therapeutic Goods Administration, *Mandatory Requirements for an Effective Application* (28 October 2014) <<https://www.tga.gov.au/mandatory-requirements-effective-application>>. A therapeutic good is separate and distinct when it involves 'new chemical entities, new strengths, new dosage forms, different directions for use, formulation changes, changes in trade name, extension of indication': *ibid*. See also *Therapeutic Goods Act 1989* (Cth) s 16; *Therapeutic Goods Regulations 1990* (Cth) r 11.

⁴¹ Biologicals are goods that contain or are derived from human tissue or human cells and that are represented as having uses equivalent to the definition of therapeutic use in the Therapeutic Goods Act: *Therapeutic Goods Act 1989* (Cth) s 3(1).

⁴² *Therapeutic Goods Act 1989* (Cth) s 3(1) (definition of 'medicine').

⁴³ *Ibid* s 25.

'high-risk products' or 'low-risk products'.⁴⁴ Low-risk products, such as some over-the-counter medicines, are described as 'listed goods', the efficacy of which is not required to be assessed by an expert committee.⁴⁵ The evaluation process also requires that the labelling and packaging of the product be approved.⁴⁶

- 4.36 A good is listed on the Register in relation to the (natural or corporate) person who made the application. Only the person to whom the good relates has the right to import the therapeutic good into Australia, export it from Australia, and sell it in Australia.⁴⁷ Goods are identified on the Register as having 'indications', or approved uses,⁴⁸ and must not be supplied for other reasons.
- 4.37 In practice, the 'sponsor' is the party responsible for applying to include a good on the Register.⁴⁹ A sponsor is a person or company who wishes to arrange the export of a good from Australia, import it into Australia, or manufacture and supply the good in Australia—in short, whoever wishes to make the good commercially available in Australia.
- 4.38 Goods that are not included on the Register in the form approved by the Secretary are described as 'unapproved goods'.⁵⁰ Unapproved goods must not be imported into, or manufactured or supplied in Australia, unless they are excluded or exempted from the requirement that they be registered.⁵¹

Exclusions and exemptions

- 4.39 The Therapeutic Goods Act provides for goods to be 'exempted' from having to be included on the Register for particular purposes.⁵²

⁴⁴ John S. Low, Laetitia Hattingh, Kim Forrester, *Australian Pharmacy Law and Practice* (Elsevier, 2013) 214; Barbara von Tigerstrom and Katherine Ellena, 'Regulation of Complementary and Alternative Medicine: A Trans-Tasman Perspective' in Ian R. Freckleton (ed) *Regulating Health Practitioners* (Federation Press, 2005) 220.

⁴⁵ John S. Low, Laetitia Hattingh, Kim Forrester, *Australian Pharmacy Law and Practice* (Elsevier, 2013) 214. Cannabis is a 'plant material from which herbal substances in listable goods must not be derived': *Therapeutic Goods Regulations 1990* (Cth) sch 4 pt 4 div 1.

⁴⁶ Therapeutic Goods Administration, *TGA labelling and packaging regulatory framework* (28 October 2014) <<https://www.tga.gov.au/tga-labelling-and-packaging-regulatory-framework>>. Standards are established for the marketing of goods under the *Therapeutic Goods Act 1989* (Cth) s 10: see, eg, *Therapeutic Goods Order No. 69 — General requirements for labels for medicines; Medicines Advisory Statements Specification 2014* (Cth).

⁴⁷ Further, it is a criminal offence for person, to whom a good included on the Register does not relate, to import, export or manufacture that drug: *R v On Clinic Australia Pty Ltd* [1996] NSWSC 530 (6 November 1996); *Hui v Lane* [2003] SASC 401 (11 December 2003) [16].

⁴⁸ *Therapeutic Goods Act 1989* (Cth) s 3(1) (definition of 'indication').

⁴⁹ Therapeutic Goods Administration, *Role of the Sponsor* (28 March 2013) <<https://www.tga.gov.au/role-sponsor>>.

⁵⁰ Therapeutic Goods Administration, *Accessing unapproved products* (28 October 2014).

⁵¹ *Therapeutic Goods Act 1989* (Cth) ss 19B; 19D.

⁵² *Ibid* ss 18–19A. It is also possible to have goods exempted from the other requirements of the Act: see s 34 (in relation to manufacturing licences and principles).

4.40 The responsible Minister may also declare goods to be ‘excluded goods’ for the purposes of the Commonwealth Therapeutic Goods Act. The Minister may consider any matter he or she considers relevant, but specifically is obliged to consider:

- (a) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;
- (b) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;
- (c) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.⁵³

International Conventions

4.41 Some of the Commonwealth legislation discussed in this chapter is based on Australia's obligations as a signatory to three international conventions, created within the United Nations, which propose controls on various narcotic drugs, including cannabis. These are:

- the *Single Convention on Narcotic Drugs 1961*⁵⁴
- the *Convention on Psychotropic Substances 1971*⁵⁵
- the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*.⁵⁶

The Single Convention on Narcotic Drugs

4.42 This Convention co-ordinates international efforts against drug trafficking. It informs the operation of the Narcotic Drugs Act.

4.43 The Single Convention requires member states to limit the availability of narcotic drugs to medical and scientific purposes. Cannabis,⁵⁷ cannabis resin,⁵⁸ the cannabis plant,⁵⁹ and cannabis leaves⁶⁰ are the subject of controls under the Convention.

⁵³ Ibid s 7AA.

⁵⁴ Opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964) (abbreviated in the footnotes as the ‘*Single Convention on Narcotic Drugs*’).

⁵⁵ Opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976) (abbreviated in the footnotes as the ‘*Convention on Psychotropic Substances*’).

⁵⁶ Opened for signature 20 December 1988, 1582 UNTS 165 (entered into force 11 November 1990) (abbreviated in the footnotes as the ‘*Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*’).

⁵⁷ Defined in article 1.1(b) of the *Single Convention on Narcotic Drugs* as ‘the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated’.

⁵⁸ Defined in article 1.1(d) of the *Single Convention on Narcotic Drugs* as ‘the separated resin, whether crude or purified, obtained from the cannabis plant’.

⁵⁹ Defined in article 1.1(c) of the *Single Convention on Narcotic Drugs* as ‘any plant of the genus *Cannabis*’.

⁶⁰ Cannabis leaves are undefined by the *Single Convention on Narcotic Drugs*.

- 4.44 Cannabis, cannabis resin, and the extracts and tinctures of cannabis are ‘drugs’ to which the Single Convention’s control measures apply generally.⁶¹ State parties are required to control the cultivation, production, manufacture, trade and distribution, import and export of narcotic drugs like cannabis.
- 4.45 The Single Convention draws a distinction between production and manufacture, which informs the operation of the licensing system in the Narcotic Drugs Act by virtue of its First Schedule. When cannabis or cannabis resin is separated from the plant, it is ‘production’.⁶² Conversely, manufacture is ‘all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs’.⁶³
- 4.46 Cannabis and cannabis resin are singled out as requiring ‘special measures of control’⁶⁴ because the Single Convention adopts the position that such drugs are particularly liable to abuse and to produce ill effects and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs similarly signed out by the Single Convention for special measures.⁶⁵
- 4.47 If cannabis plants⁶⁶ are cultivated, the Single Convention prescribes that one or more government agencies (ideally a single national agency) must be established to:
- designate the areas where cannabis plants are to be cultivated
 - license the cultivators of cannabis plants
 - in each licence specify the exact amount of land on which cultivation is permitted
 - receive crops of cannabis from licensed suppliers.⁶⁷
- 4.48 The Commission notes that, by providing for licences, the Single Convention allows for a system of private cultivation of cannabis plants overseen by government.

The Convention on Psychotropic Substances

- 4.49 This Convention elaborates on the specific controls that are to be applied to psychotropic substances like cannabis.⁶⁸ It reinforces that cannabis should not be generally available,

⁶¹ This being the consequence of inclusion in Schedule I of the *Single Convention on Narcotic Drugs*: see art 2.1.

⁶² *Single Convention on Narcotic Drugs* art 1.1(t).

⁶³ *Ibid* art 1.1(n).

⁶⁴ This being a consequence of inclusion in Schedule IV of the *Single Convention on Narcotic Drugs*: see art 2.5(a).

⁶⁵ *Single Convention on Narcotic Drugs* art 3.5.

⁶⁶ *Ibid* art 2.7.

⁶⁷ *Ibid* arts 28.3, 23. This requirement has informed a Commonwealth Bill providing for the establishment of a national agency for the supply of medicinal cannabis, discussed in Chapter 5.

⁶⁸ It is listed in Schedule I of the *Convention on Psychotropic Substances* and is as such within the definition of ‘psychotropic substance’ given in art 1(e).

while maintaining that drugs containing these substances may be used for medical and scientific purposes.⁶⁹

- 4.50 The Convention forms the constitutional basis of the Commonwealth's *Psychotropic Substances Act 1976* (Cth), which establishes a procedure for the legitimate entry of psychotropic substances such as cannabis into Australia by aircraft or vessel.

The Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

- 4.51 The Convention requires State parties to 'adopt such measures as may be necessary' to establish criminal offences for any step involved in the making available of narcotic drugs and psychotropic substances.⁷⁰ Each State party must take 'appropriate measures' to eradicate plants that are used to create psychotropic substances, such as cannabis plants.⁷¹
- 4.52 The Convention forms the constitutional basis for the Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act and Part 9.1 of the Criminal Code, which prohibits the cultivation, trafficking and manufacture of cannabis.⁷²

Scope for regulating medicinal cannabis

- 4.53 This section explores the opportunities and constraints presented by the current legislative framework to the importation, processing, supply and possession of medicinal cannabis in Victoria.
- 4.54 Commonwealth laws apply, to different degrees, at each stage. Some steps can be taken by amending Victorian legislation alone, but in most cases the regulatory responsibilities are shared.
- 4.55 The options expressed are not recommendations, and have not been the subject of consultation. Their feasibility and desirability will be evaluated over the course of the reference.

Importation

- 4.56 A Victorian scheme that allowed for patients to be treated with imported medicinal cannabis could be established only with Commonwealth assistance.
- 4.57 Under the current regulatory framework, medicinal cannabis may not be imported because it is both:
- an unapproved therapeutic good for the purposes of the Therapeutic Goods Act

⁶⁹ *Convention on Psychotropic Substances* art 7.

⁷⁰ *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* art 3.1(a)(i).

⁷¹ *Ibid* art 14.2.

⁷² Explanatory Memorandum, Law and Justice Legislation Amendment (Serious Drug Offences and Other Measures) Bill 2005 (Cth), 6.

- a prohibited import under Customs (Prohibited Import) Regulations.

4.58 Exceptions may be made, on application to the Secretary of the Commonwealth Department of Health. Permission to import medicinal cannabis would need to be given under both the Therapeutic Goods Act and the Customs (Prohibited Import) Regulations.

Permission to import an unapproved therapeutic good

4.59 Cannabis, when imported for a medicinal purpose, is an unapproved therapeutic good because it is not on the Australian Register of Therapeutic Goods. It is unlawful to import an unapproved therapeutic good⁷³ unless permission is granted by the Secretary of the Commonwealth Department of Health.

4.60 The Secretary can grant permission to import unapproved medicines:

- (a) for use in the treatment of another person; or
- (b) for use solely for experimental purposes in humans.⁷⁴

4.61 In practice, the Secretary exercises this discretion through the operation of a number of schemes established by the TGA.

4.62 There are three schemes under which applications to import unapproved medicines 'for the treatment of another person' are considered.

- The **Special Access Scheme**, for applications to import an unapproved therapeutic good with the agreement of an overseas supplier.⁷⁵ The patient's circumstances are assessed against a set of criteria, and the nature of the assessment depends on whether the patient is seriously or terminally ill.⁷⁶ A terminally ill patient is entitled to access many medicines, but is not entitled to have access to any Schedule 9 medicines,⁷⁷ so cannabis could not be imported on their behalf under this scheme.

An application for a patient who is not terminally ill⁷⁸ needs to be made by a doctor with qualifications and/or expertise appropriate to the condition being treated and the proposed use of the product'.⁷⁹ It should contain 'adequate clinical justification for the use of the product'⁸⁰ and 'indicate how the product is to be used and include an appraisal of the efficacy and safety of the proposed use of the product'.⁸¹

⁷³ *Therapeutic Goods Act 1989* (Cth) s 19B. Greater penalties are applied if 'the use of the goods has resulted in, or will result in, harm or injury to any person' or if 'use of the goods, if the goods were used, would result in harm or injury to any person': see sub-ss (1) and (2). See also s 19D.

⁷⁴ *Therapeutic Goods Act 1989* (Cth) s 19(1)(a), (b).

⁷⁵ Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009) 8, 10.

⁷⁶ Terminally ill patients being referred to as 'Category A' and other patients being referred to as 'Category B'.

⁷⁷ Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009) 12.

⁷⁸ *Ibid* 15.

⁷⁹ *Ibid* 15–6.

⁸⁰ *Ibid* 15.

⁸¹ *Ibid* 15.

- The **Authorised Prescriber Scheme**, which provides for a medical practitioner to be granted the 'authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients'.⁸²

Under this scheme, the TGA will consider the evidence that the unapproved therapeutic good will benefit patients with a particular condition; the safety and efficacy of the unapproved good; and whether the medical practitioner has the appropriate qualifications to prescribe and supply the good.⁸³

- The **Personal Importation Scheme**, which provides for an unapproved therapeutic good to be imported when it is for use by an immediate relative, but cannabis may not be imported under this scheme.⁸⁴ Procedures to import unapproved therapeutic goods 'for use solely for experimental purposes in humans' would not be applicable to the importation of medicinal cannabis by an authorised user under a Victorian medicinal cannabis scheme. They are relevant to clinical trials. As a matter of policy, the Secretary allows the importation of unapproved goods for this purpose only when the clinical trial has been assessed by the TGA under the Clinical Trial Exemption (CTX) Scheme.⁸⁵

Permission to import a prohibited import

- 4.63 As a matter of law, if the Secretary of the Commonwealth Department of Health were to grant permission to import medicinal cannabis as an 'unapproved therapeutic good', the applicant would then need the Secretary's permission to import it as a 'prohibited import'.⁸⁶
- 4.64 In practice, the decision under the therapeutic goods framework is likely to be followed under the prohibited imports framework. The frameworks are designed to work together.⁸⁷

⁸² Therapeutic Goods Administration, *Access to unapproved therapeutic goods: authorised prescribers* (2004) 10. See also *Therapeutic Goods Act 1989* (Cth) s 19(5).

⁸³ *Ibid* 17–8.

⁸⁴ Therapeutic Goods Administration, *Access to unapproved therapeutic goods: Personal importation* (2004) 7, 12–3; see also *Therapeutic Goods Regulations 1990* (Cth) r 12A.

⁸⁵ *Ibid* 9, 22.

⁸⁶ Cannabis, cannabinoids, cannabis resin, and THC and its alkyl homologues are types of 'prohibited import'; 'drugs' the importation of which is prohibited, without the requisite authority: *Customs (Prohibited Imports) Regulations 1956* (Cth) r 5 and sch 4, lines 34–36, 233.

⁸⁷ See, eg, Therapeutic Goods Administration, *Access to unapproved therapeutic goods via the Special Access Scheme* (2009) 20.

- 4.65 Applicants seeking to import a prohibited import that is also an unapproved therapeutic good must supply evidence to the Secretary that they have a prescription for the substance that conforms to the laws of a state.⁸⁸ They also need to satisfy the Secretary that they are a fit and proper person whose agents, employees and business are also ‘fit and proper’.⁸⁹
- 4.66 As cannabis is listed in Schedules I and II of the Single Convention on Narcotic Drugs, a number of additional conditions would apply to the granting of a licence or permission.
- If it is required to manufacture another scheduled drug, the importer must have a manufacturing licence under the Narcotic Drugs Act.⁹⁰
 - If it is proposed to be sold or supplied, the importer must hold a licence under a law of a state or territory that permits them to do so.⁹¹
 - It may be imported if it is required for medical or scientific purposes.⁹²

Scope for Commonwealth/state collaboration

- 4.67 The existing avenues that permit unapproved and prohibited goods to be imported would not be used to import medicinal cannabis to treat patients who have been authorised under a state-regulated scheme to receive the treatment.
- 4.68 Using the Secretary's powers to approve the importation of cannabis in furtherance of a Victorian medicinal cannabis scheme would be a substantial shift away from present procedures, which are directed towards decision-making about individuals' specific cases.
- 4.69 However, it may be possible for the Commonwealth to amend its policies and practices to accommodate applications by persons and organisations that have been authorised under a Victorian medicinal cannabis scheme. The Commission has not undertaken consultations about these possibilities and would welcome comments about whether they are feasible or desirable.

Excluding medicinal cannabis from the therapeutic goods framework

- 4.70 One way for the Commonwealth to allow the importation of medicinal cannabis under the therapeutic goods framework would be to modify or supplement the existing schemes under which the Secretary grants permission. New criteria or procedures could be introduced for applications for the benefit of patients who have been authorised to receive treatment under Victoria's medicinal cannabis scheme.

⁸⁸ See, eg, Therapeutic Goods Administration, *Access to unapproved therapeutic goods: personal importation* (2004) 9; Therapeutic Goods Administration, *Access to unapproved therapeutic goods via the Special Access Scheme* (2009) 9.

⁸⁹ *Customs (Prohibited Imports) Regulations 1956* (Cth) r 5(7).

⁹⁰ *Ibid* r 5(10)(b)(i).

⁹¹ *Ibid* r 5(10)(b)(ii).

⁹² *Ibid* r 5(10)(b)(iii).

- 4.71 Alternatively, the Commonwealth Health Minister could exercise the power to exclude medicinal cannabis from the Therapeutic Goods Act.⁹³ When considering an application to import medicinal cannabis, the Secretary would not have to consider whether it should be imported within one of the schemes for the importation of unapproved goods.
- 4.72 The Secretary would still have to consider whether it was appropriate to allow the importation of medicinal cannabis as a prohibited import. It is likely that the structural integrity of a Victorian scheme, any relevant arrangements with the Commonwealth, and the application of other Commonwealth laws (such as the Narcotic Drugs Act) would be taken into account.

The authorised prescriber scheme

- 4.73 In theory, pharmaceutically-developed medicinal cannabis products that have been approved under overseas therapeutic goods regimes could be imported into and supplied in Victoria using the Commonwealth's authorised prescriber scheme. The TGA indicates that unapproved therapeutic goods that are prohibited imports can be imported under the scheme.⁹⁴
- 4.74 If Victoria created a scheme for the lawful supply, prescription and use of medicinal cannabis, in principle the Commonwealth could designate medical practitioners endorsed under the Victorian scheme as authorised prescribers. This would allow Victorian practitioners to import unapproved medicinal cannabis products that are available overseas through the Commonwealth. However, TGA policy states that the scheme is only intended to allow temporary access to unapproved therapeutic goods; it is not a substitute for seeking registration and marketing approval.⁹⁵ Also, in general, medical practitioners do not dispense medications.

Cultivation

- 4.75 Victoria is capable of acting on its own to permit the cultivation of medicinal cannabis.

The current framework

- 4.76 Victoria's Drugs, Poisons and Controlled Substances Act prohibits the cultivation of cannabis plants.⁹⁶ However, cultivation is only prohibited 'without being authorised by or licensed under the Act or regulations'. For example, the Secretary to the Victorian Department of Health and Human Services can authorise the cultivation of a large commercial quantity of narcotic plants intended for a non-therapeutic use.⁹⁷

⁹³ *Therapeutic Goods Act 1989* (Cth) s 7AA. See above at [4.40].

⁹⁴ Therapeutic Goods Administration, *Access to unapproved therapeutic goods: authorised prescribers* (2004) 23.

⁹⁵ *Ibid* 13.

⁹⁶ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 72B (a narcotic plant); 72A ('commercial quantity' of narcotic plants); 72 ('large commercial quantity' of narcotic plants).

⁹⁷ *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 52(1).

4.77 The cultivation of narcotic plants is also prohibited by the Commonwealth. However, when cultivation is authorised by a law of a state or territory, the Commonwealth Criminal Code does not prohibit it.⁹⁸

Scope for Commonwealth/state collaboration

4.78 Little action would be required by the Commonwealth to enable cultivation of cannabis for medicinal purposes in Victoria. The Commonwealth could provide clarity about the application of the Therapeutic Goods Act to the cultivation of cannabis plants.⁹⁹

Scope for Victoria to establish a standalone scheme

4.79 Victoria could provide for cannabis to be cultivated in Victoria by natural persons, unincorporated associations or an agency of the State of Victoria.¹⁰⁰ The involvement of constitutional corporations would require some consideration of the scope of the Commonwealth Therapeutic Goods Act, and may raise questions of the status of a corporation acting at the direction of the State of Victoria.¹⁰¹

Processing and manufacture

4.80 If Victoria is to permit the processing and manufacture of medicinal cannabis, consideration needs to be given to the operation of the Commonwealth Therapeutic Goods Act and the Narcotic Drugs Act.

The current framework

4.81 Victoria's Drugs, Poisons and Controlled Substances Act prohibits the manufacturing or preparing¹⁰² of cannabis for the purposes of trafficking.¹⁰³ However, these activities are

⁹⁸ *Criminal Code* (Cth) s 313.1. The *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* (Cth) also prohibits cultivation in Australia, but is only enforced at the discretion of the Commonwealth Attorney-General (s 9) and is 'not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory' (s 3). There is some ambiguity as to the extent to which s 3 sets aside Commonwealth law in favour of state law—called a 'roll-back' provision: see Mark Leeming, *Resolving Conflicts of Laws* (Federation Press, 2011) 158. It seems that it must have a roll-back effect, or many state schemes for cultivating, processing or otherwise making available prohibited drugs would involve unlawful behaviour. The 'roll-back' effect is reinforced in the explanatory memorandum, which provides that the Act is not intended to affect other Commonwealth, State or Territory laws 'in any way': Explanatory Memorandum, *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Bill 1990* (Cth) 4.

⁹⁹ Conceivably, the *Therapeutic Goods Act 1989* (Cth) may pose a barrier, because its definition of 'manufacture' is so broad: see [4.86]. Any restrictions on cultivation undertaken by a state agency, natural persons or unincorporated associations entirely in Victoria may be altered by using the mechanisms set out in the *Therapeutic Goods (Victoria) Act 2010* (Cth).

¹⁰⁰ Because ss 5 and 6 of the *Therapeutic Goods (Victoria) Act 2010* (Vic) apply the *Therapeutic Goods Act 1989* (Cth) to all persons not within the Commonwealth's legislative power, including any relevant activities of the Crown, this would involve some amendment to that Act, or the making of regulations under s 6(3).

¹⁰¹ See the discussion below at [4.99]–[4.102].

¹⁰² This falling within the definition of 'trafficking'; see *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 70.

¹⁰³ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 71AC. Greater penalties apply where the processing or manufacture is of a 'commercial quantity' (s 71AA) or a 'large commercial quantity' (s 71) or to a child (s 71AB).

prohibited only if they are undertaken ‘without being authorised by or licensed under this Act or the regulations to do so’.¹⁰⁴

- 4.82 Therefore, Victoria could specifically authorise or license the processing and manufacturing of medicinal cannabis without infringing the general prohibition of trafficking under Victorian legislation.
- 4.83 Similarly, no problematic constraints on permitting the manufacture or processing of medicinal cannabis in Victoria would arise under Commonwealth criminal law. This is because the processing or manufacturing of cannabis for the purposes of trafficking is not prohibited by the Criminal Code¹⁰⁵ if it is authorised by a law of a state or territory.¹⁰⁶ Victoria could give such an authorisation for medicinal cannabis.
- 4.84 The Narcotic Drugs Act presents a potential difficulty. It prohibits any activity fitting the description of ‘manufacture’ under the Single Convention on Narcotic Drugs without a manufacturing licence.¹⁰⁷ This captures a wide range of processing activities (other than the separation of cannabis or cannabis resin from cannabis plants, which for these purposes does not constitute manufacture).¹⁰⁸
- 4.85 A further difficulty arises because the Commonwealth Therapeutic Goods Act also prohibits any manufacture of cannabis for a medicinal purpose, as it would be the unlawful manufacture of a good that is unapproved for therapeutic use.¹⁰⁹ Under the Therapeutic Goods Act, to ‘manufacture’ means to ‘produce’ the goods as well as to ‘engage in any part of the process of producing the goods or of bringing the goods to their final state’.¹¹⁰

Scope for Commonwealth/state collaboration

- 4.86 As outlined above, the Commonwealth regulatory framework would provide two constraints on any Victorian scheme for the processing and manufacture of medicinal cannabis: the regulation of narcotics under the Narcotic Drugs Act and the reach of therapeutic goods legislation under the Therapeutic Goods Act.
- 4.87 However, these constraints could be managed by a collaborative approach on the issue between the Commonwealth and Victoria.
- 4.88 The Commonwealth Minister for Health could provide manufacturing licences under the Narcotic Drugs Act to manufacturers in Victoria—for instance, those manufacturers authorised under a state medicinal cannabis scheme.

¹⁰⁴ This qualification being expressed in ss 71–71AC of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

¹⁰⁵ *Criminal Code 1995* (Cth) div 302.

¹⁰⁶ *Ibid* s 313.1. See the discussion of the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* (Cth) at n 98.

¹⁰⁷ *Narcotic Drugs Act 1967* (Cth) s 15.

¹⁰⁸ See above at [4.45].

¹⁰⁹ *Therapeutic Goods Act 1989* (Cth) s 19B.

¹¹⁰ *Ibid* s 3 (definition of ‘manufacture’).

- 4.89 In addition, the Minister could exclude medicinal cannabis that is processed or manufactured under a Victorian scheme from the operation of the Therapeutic Goods Act.¹¹¹

Scope for Victoria to establish a standalone scheme

- 4.90 There is some potential for Victoria to take its own action to create a medicinal cannabis scheme that encompasses the manufacture and processing of cannabis. The scope depends upon interpretation of the reach of the two forms of Commonwealth legislation. This is a matter about which the Commission seeks submissions.
- 4.91 Amendments to the Therapeutic Goods (Victoria) Act could provide for natural persons, unincorporated associations, and partnerships to produce and manufacture cannabis. This would be of limited utility and would require a licence under the Narcotic Drugs Act.
- 4.92 The more complex and, arguably, important question is whether the State of Victoria itself, through an entity such as a statutory authority or a corporation acting at its behest, could produce or manufacture cannabis.
- 4.93 This depends upon whether either the Commonwealth Therapeutic Goods Act or the Narcotic Drugs Act binds the State of Victoria.
- 4.94 As a matter of law, there remains a presumption after the High Court's decision in *Bropho v Western Australia*¹¹² that the general words of a statute do not bind the Crown or its instrumentalities or agents.¹¹³ This is not an inflexible presumption and its strength depends upon the circumstances, including the content and purpose of a particular legislative provision and the identity of the entity in respect of which the provision arises.¹¹⁴
- 4.95 There is no stated intention in the Narcotic Drugs Act to bind the Crown in right of Victoria or any entity through which it might act. At the time the Act was enacted, Parliament would have used express words to do so. Further, the Act creates a licensing regime enforceable by criminal sanctions. These factors tend to suggest that the Act does not bind the Crown in right of Victoria.¹¹⁵
- 4.96 The ultimate question is whether it was the legislative intent that the relevant legislation should bind the Crown—in this instance the state of Victoria. Thus, the purpose of the

¹¹¹ See above at [4.40].

¹¹² (1990) 171 CLR 1, 22.

¹¹³ *Wynyard Investments Pty Ltd v Commissioner for Railways (NSW)* (1955) 93 CLR 376, 393–4 (Kitto J).

¹¹⁴ *Bropho v Western Australia* (1990) 171 CLR 1, 23.

¹¹⁵ *Bropho v Western Australia* (1990) 171 CLR 1, 23. See James A Taylor, 'Beyond Superficialities: Crown Immunity and Constitutional Law' (1990) 20(3) *University of Western Australia Law Review* 710; Greg Taylor, 'Commonwealth v Western Australia and the Operation of the Presumption that Statutes do Not Apply to the Crown' (2000) 24(1) *Melbourne University Law Review* 27; Anthony Gray, 'Immunity of the Crown from Statute and Suit' (2010) 9 *Canberra Law Review* 1.

Narcotics Drugs Act needs to be evaluated. As noted above, the Commonwealth introduced the Narcotics Drugs Act pursuant to its external affairs power in order for Australia to comply with, among other things, the Single Convention.

- 4.97 On one view, the purpose of the Act is to preclude all manufacture of Convention drugs (such as cannabis) other than within the controlled situation of a Commonwealth-granted licence, to ensure that Australia can meet its reporting obligations under the Convention.¹¹⁶ If so, it may be that no purpose is evinced to bind the Crown in right of a state such as Victoria. It could not readily be inferred that the Act was intended to apply where a state is integrally involved in conduct that would breach the Act and the Commonwealth is not impeded in its international reporting obligations. A statutory authority could be the entity manufacturing the relevant drug, and in a position to report on its activity to the Commonwealth.
- 4.98 By contrast, if the purpose of the Narcotic Drugs Act is regarded as being to prohibit the manufacture of Convention drugs without Commonwealth licence, *per se*,¹¹⁷ then it might be inferred that the purpose of the legislation is to bind the Crown in right of the states, and any entities which they might constitute.
- 4.99 Some similar considerations apply in relation to the application of the Commonwealth Therapeutic Goods Act. Section 5 provides that:
- This Act binds the Crown in right of the Commonwealth, of each of the States, of the Australian Capital Territory and of the Northern Territory, but nothing in this Act renders the Crown liable to be prosecuted for an offence or to be subject to civil proceedings for a contravention of a civil penalty provision.
- 4.100 However, the Crown is only bound on the Act's terms. Section 6 of the Commonwealth Therapeutic Goods Act provides that the legislation applies to 'things done by corporations', and 'things done by natural persons or corporations' engaging in particular activities (most notably interstate and overseas trade).
- 4.101 Therefore it is arguable that, in spite of the fact that the Commonwealth Therapeutic Goods Act is expressed in principle to bind the Crown in right of the states, Victoria remains free to establish a scheme operated by an agency, as long as it is not a 'constitutional corporation' (for example, because it is established as a body corporate and engages in sufficient trade to be found to be a trading corporation).

¹¹⁶ Commonwealth, *Parliamentary Debates*, House of Representatives, 16 May 1967, 2181 (Mr Howson).

¹¹⁷ *Ibid* 2180–1.

- 4.102 Further issues arise in respect of to the degree to which the Commonwealth Therapeutic Goods Act applies to a corporation established by statute or licensed and authorised by Victoria to manufacture medicinal cannabis.¹¹⁸

Question

- 6 If Victoria acted through a state agency, in what circumstances would it be legally entitled to establish a medicinal cannabis scheme which manufactured cannabis products without breaching the terms of the Therapeutic Drugs Act 1989 (Cth) or the Narcotic Drugs Act 1967 (Cth)?**

Supply and sale

- 4.103 Victoria could provide for the supply and sale of medicinal cannabis, but the Commonwealth's therapeutic goods framework would determine who the suppliers and sellers could be.

The current framework

- 4.104 Victoria's Drugs, Poisons and Controlled Substances Act prohibits the supply and sale of cannabis, which is treated as trafficking.¹¹⁹ However, these activities are only prohibited when they are engaged in 'without being authorised by or licensed under this Act or the regulations to do so'.
- 4.105 The Commonwealth's Criminal Code does not apply to conduct that the defendant can prove was undertaken entirely in a state or territory and was justified or excused by the law of that state or territory.¹²⁰ Therefore, the Code's prohibitions on the sale or supply of cannabis¹²¹ do not present barriers to a Victorian scheme.
- 4.106 However, the availability of any drug or medicine for supply is largely determined by the Commonwealth Therapeutic Goods Act. Criminal penalties apply to the supply of unapproved therapeutic goods.
- 4.107 The scope of the Therapeutic Goods Act is unclear in this respect. Some offences only punish the supply of unapproved therapeutic goods by 'sponsors'. It is a defence, under these laws, if the person who supplied the unapproved good did not import, export or

¹¹⁸ See *Australian Competition and Consumer Commission v Baxter Healthcare Pty Ltd* (2007) 232 CLR 1, 37 [70], in which the majority observed that 'statutes may produce the consequence that making or performing a contract is illegal for one party but not for the other'.

¹¹⁹ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 71AC. Greater penalties where the trafficking is in a 'commercial quantity': s 71AA, and a 'large commercial quantity': s 71; or to a child: s 71AB.

¹²⁰ *Criminal Code* (Cth) s 313.1.

¹²¹ *Ibid* div 302.

manufacture it.¹²² This appears to be why some states, which have also adopted the Therapeutic Goods Act as a law of their state, have enacted criminal laws designed to prevent the supply of unapproved therapeutic goods.¹²³ It has been observed in academic commentary that '[t]he *Therapeutic Goods Act 1989* (Cth) does not extend to retailing'.¹²⁴ However, some sections of the Therapeutic Goods Act prohibit people, whether sponsors or not, from taking action to supply unapproved therapeutic goods.¹²⁵

Scope for Commonwealth/state collaboration

- 4.108 The Commonwealth has the capacity to set aside the restrictions imposed by the Therapeutic Goods Act. The Minister for Health could provide that medicinal cannabis supplied under the Victorian scheme is excluded from the scope of that Act.¹²⁶
- 4.109 This would allow constitutional corporations to supply medicinal cannabis in Victoria without attracting the penalties in the Therapeutic Goods Act. It would also provide a more attractive framework for the supply of medicinal cannabis by pharmacists.

Scope for Victoria to establish a standalone scheme

- 4.110 As noted above, there is some ambiguity about the degree of control the Therapeutic Goods Act imposes on the supply of therapeutic goods.
- 4.111 Less ambiguous is the situation in which an entity is responsible both for supply and for the manufacture, or importation, of therapeutic goods. In such a situation, the entity would be a sponsor and would be subject to the criminal prohibitions in section 19B of the Commonwealth Therapeutic Goods Act.
- 4.112 Even if the Therapeutic Goods Act effectively prohibits supply, a Victorian scheme could allow for the supply and sale of medicinal cannabis outside of the Commonwealth's therapeutic goods framework, but the reach of the scheme would still extend to constitutional corporations, which are clearly within the scope of the Commonwealth's powers.

Supply and the Therapeutic Goods Act

- 4.113 Victoria could exempt natural persons, unincorporated associations, partnerships and firms without separate legal personality from any controls in the Therapeutic Goods Act relating to the supply of cannabis for medicinal purposes, and authorise them to supply

¹²² *Therapeutic Goods Act 1989* (Cth) s 19B(5).

¹²³ *Therapeutic Goods Act 2001* (Tas) s 23; *Poisons and Therapeutic Goods Act 1966* (NSW) s 36A.

¹²⁴ Lawbook, *The Laws of Australia* (at 1 January 2014) 20.11 Regulation of Drugs, [20.11.650].

¹²⁵ For example, any person is prohibited from claiming they can arrange the supply of unapproved goods: *Therapeutic Goods Act 1989* (Cth) s 22(6); and from supplying unapproved goods by wholesale: *Therapeutic Goods Act 1989* (Cth) s 21.

¹²⁶ *Therapeutic Goods Act 1989* (Cth) s 7AA.

medicinal cannabis in Victoria. It seems that Victoria could similarly authorise a state agency to supply medicinal cannabis in Victoria.¹²⁷

- 4.114 Difficulties would arise under the existing regulatory framework if a corporation or an incorporated statutory authority were authorised to supply cannabis for medicinal purposes in a way that generates revenue. Supplying cannabis in this way would be a trading activity. A corporation supplying medicinal cannabis would in all likelihood be engaged in enough trading activity to make it a 'constitutional corporation'. Accordingly, it would be subject to any prohibition on supply under the Therapeutic Goods Act (noting the ambiguities identified at [4.107]).
- 4.115 There may be scope for Victoria to authorise pharmacists to sell or supply medicinal cannabis, but this would need to be given careful attention. Without the extension of Commonwealth jurisdiction provided by the Therapeutic Goods (Victoria) Act, the pharmacists to whom the Therapeutic Goods Act applies would be limited to:
- pharmacists that are incorporated or owned by corporations¹²⁸
 - pharmacists who would source the cannabis from interstate or overseas
 - the activities of pharmacists under a law of the Commonwealth relating to the provision of pharmaceutical benefits.¹²⁹
- 4.116 The third dot point above refers to the supply by pharmacists of pharmaceutical benefits¹³⁰ under the National Health Act. The Commonwealth may impose controls on pharmacists insofar as they relate to those benefits.¹³¹ But the Commonwealth does not have the power to control every aspect of a pharmacy's business¹³² unless the pharmacy is incorporated¹³³ or otherwise falls within the Commonwealth's legislative power.
- 4.117 The supply of medicinal cannabis would not be a pharmaceutical benefit and, as such, would not be undertaken pursuant to a Commonwealth scheme. Accordingly, the supply of cannabis by unincorporated pharmacies would not be within the scope of the Commonwealth Therapeutic Goods Act, were Victoria to create an exception to the Commonwealth Act.
- 4.118 There is already a pathway in the Therapeutic Goods Act for the supply of unapproved therapeutic goods by pharmacists, incorporated or otherwise. Medicines compounded by a pharmacist for a specific person do not have to be on the Australian Register of

¹²⁷ See discussion at [4.99]–[4.102].

¹²⁸ Pharmacies may be owned by corporations under the *Pharmacy Regulation Act 2010* (Vic) 5(1)(b).

¹²⁹ *Therapeutic Goods Act 1989* (Cth) s 6. See above at [4.20].

¹³⁰ These being drugs declared to be pharmaceutical benefits by the Minister for Health under s 85 of the *National Health Act 1953* (Cth).

¹³¹ *Alexandra Private Geriatric Hospital Pty Ltd v Commonwealth* (1987) 162 CLR 271, 284 (Mason ACJ, Wilson, Brennan, Deane and Dawson JJ).

¹³² See the discussion above at n 27.

¹³³ Pharmacies may be owned by corporations under the *Pharmacy Regulation Act 2010* (Vic) 5(1)(b).

Therapeutic Goods.¹³⁴ A pharmacist who compounded medicinal cannabis for a person permitted to use it under a Victorian scheme would still have to comply with a number of Commonwealth and State laws.¹³⁵ There would have to be some consultation as to whether this pathway could form part of a Victorian scheme for the manufacture and supply of medicinal cannabis.

- 4.119 Furthermore, some consideration would need to be given to any obligation of pharmacists to independently assess whether medicinal cannabis is safe to dispense to a patient,¹³⁶ as well as to how the scheme could interact with the Pharmacy Board of Victoria's accreditation of pharmacists as able to possess, sell or supply particular scheduled poisons.¹³⁷

Food laws

- 4.120 A side issue is that, if certain forms of medicinal cannabis were not within the therapeutic goods framework, they may be considered 'food'.¹³⁸ The code prohibits the sale or supply of hemp or marijuana as food.¹³⁹ However, something that has therapeutic use, and is therefore a therapeutic good, is not food.¹⁴⁰

Supply in Victoria

- 4.121 Assuming the difficulties with the Commonwealth Therapeutic Goods Act can be overcome, the Drugs, Poisons and Controlled Substances Act already enables pharmacists,¹⁴¹ who are principally responsible for the supply and sale of medicinal products to:

¹³⁴ *Therapeutic Goods Regulations 1990* (Cth) r 12(1), sch 5 line 6. Pharmacists must compound and supply the medicine in a pharmacy open to the public, a Friendly Society dispensary, or a private hospital: *Therapeutic Goods Regulations 1990* (Cth) r 18, sch 8 line 2. Alternatively, pharmacists working for a public hospital may manufacture therapeutic goods for supply in hospitals or public institutions in the same State or Territory: sch 8 line 3, but the medicine would still have to be on the Register unless it was being made for a specific person. Certain other health practitioners may also manufacture a medicine for the purposes of supplying it to a patient: sch 8 line 1.

¹³⁵ Depending on what is being compounded, the pharmacist would have to comply with any applicable relevant standards, the defaults being those set out in the *British Pharmacopoeia*, *European Pharmacopoeia*, and *United States Pharmacopoeia—National Formulary*. If some form of cannabis was being compounded, the pharmacist would also need a licence to manufacture a narcotic drug under the *Narcotic Drugs Act 1967* (Cth). Authorisation under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) would be required (as dealing in cannabis in this way would, if unauthorised, be 'trafficking') and some provision would have to be made for packaging. Additionally, the pharmacist would have to comply with the rules for extemporaneous compounding in the *Guidelines on Compounding of Medicines* (2015).

¹³⁶ Pharmacy Board of Australia, *Guidelines for Dispensing of Medicines* (2010) 1.

¹³⁷ Under the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic) sch 2 s 94.

¹³⁸ A food includes 'any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared)', regardless of whether it is capable of human consumption: see *Food Standards Australia New Zealand Act 1991* (Cth) s 5.

¹³⁹ *Standard 1.4.4—Prohibited and Restricted Plants and Fungi* Sch 1.

¹⁴⁰ *Food Standards Australia New Zealand Act 1991* (Cth) s 5 (definition of 'food').

¹⁴¹ This is a person registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 4(1).

obtain and have in [their] possession and to use, sell or supply any poison or controlled substance (other than a Schedule 1 poison) or drug of dependence in the lawful practice of his profession...¹⁴²

- 4.122 Victoria could create a scheme that regulates the lawful supply of medicinal cannabis and this would fall within 'lawful practice'. When designing such a scheme, consideration would need to be given to whether it is worth retaining, adding to, or departing from the present controls imposed on the supply of poisons and controlled substances by pharmacists.

Prescription

- 4.123 Victoria could provide rules for how medicinal cannabis may be prescribed within state borders, assuming it could be lawfully supplied.¹⁴³

The current framework

- 4.124 The Drugs, Poisons and Controlled Substances Act and the Regulations provide a detailed set of rules about lawful prescription.
- 4.125 Rules are imposed on who may prescribe different medicines, according to their schedule in the SUSMP. Only a registered medical practitioner, veterinary practitioner or dentist may write prescriptions for a Schedule 9 poison.¹⁴⁴ In contrast, the prescription of a Schedule 8 poison may also be made by a nurse practitioner or an authorised registered midwife,¹⁴⁵ whereas Schedule 4 poisons may also be prescribed by an authorised optometrist or authorised podiatrist.¹⁴⁶
- 4.126 Poisons that are prohibited substances and listed in Schedule 9 of the SUSMP are tightly controlled by the state. A health practitioner must apply to the Secretary for a permit to administer, supply or prescribe a Schedule 9 poison.¹⁴⁷ If a health practitioner considers it necessary to 'manufacture, sell, supply, purchase or otherwise obtain, possess, administer, use or prescribe a Schedule 9 poison', they must have this permit.¹⁴⁸
- 4.127 The rules also extend to the things a practitioner must be satisfied of before they may lawfully prescribe a particular medicine. For example, an eligible practitioner who proposes to 'administer, prescribe, sell or supply' a drug of dependence, Schedule 8 poison or Schedule 4 poison may only do so if it 'is for the medical treatment of a person

¹⁴² *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 13(1)(a).

¹⁴³ The legality of prescription being a matter for the states: Victorian Department of Health, *Things Medical Practitioners Need to Know: Key Prescribing Requirements* (2014) 1.

¹⁴⁴ *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 25(1).

¹⁴⁵ *Ibid* r 25(2).

¹⁴⁶ *Ibid* r 25(3).

¹⁴⁷ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 33A.

¹⁴⁸ *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 7.

under his or her care' and if the practitioner 'has taken all reasonable steps to ensure a therapeutic need exists for that drug or poison'.¹⁴⁹

Scope for Commonwealth/state collaboration

4.128 Through the Therapeutic Goods Act, the Commonwealth controls the availability of medicines, including medicinal cannabis products, on the Australian commercial market. In that way, the Commonwealth affects the availability of any medicinal cannabis for prescription. It could make medicinal cannabis more easily available by exempting medicinal cannabis from the requirements of the Therapeutic Goods Act.

Scope for Victoria to establish a standalone scheme

- 4.129 Victoria has significant latitude as to the rules it could create for the prescription of medicinal cannabis.
- 4.130 A change to the law could have implications for how National Boards regulate Victorian medical practitioners. For example, in principle it could affect how pharmacists are accredited as qualified to supply particular scheduled poisons.¹⁵⁰
- 4.131 Consideration should be given as to how closely the rules on prescribing scheduled poisons in the Drugs, Poisons and Controlled Substances Act should be used in a scheme to provide medicinal cannabis, if at all.
- 4.132 Potentially, Victoria could provide for the prescription or medical authorisation of medicinal cannabis in a way that is entirely different to the usual conditions on the prescription of SUSMP scheduled substances. Victoria could also supplement the Drugs, Poisons and Controlled Substances Act or the regulations to apply special rules to the prescription of particular forms of medicinal cannabis. It has done this with nabiximols.¹⁵¹

Possession, administration and use

4.133 Victoria could legalise the possession, administration and use of cannabis within state borders, on any terms that it sees fit to establish.

The current framework

4.134 The possession¹⁵² and use of cannabis¹⁵³ are both prohibited by the Drugs, Poisons and Controlled Substances Act. It prohibits the introduction of a drug of dependence into the body of another person¹⁵⁴ or to a child.¹⁵⁵ All of these activities are only prohibited

¹⁴⁹ Ibid rr 8(1)(a),(c), 8(2)(a),(b).

¹⁵⁰ Under the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic) sch 2 s 94.

¹⁵¹ *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 21A (setting additional conditions that must be met before nabiximols, a Schedule 8 substance, may be administered, supplied or prescribed).

¹⁵² *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 73.

¹⁵³ Ibid s 75.

¹⁵⁴ Ibid s 74.

¹⁵⁵ Ibid s 71B.

‘without being authorised by or licensed under this Act or the regulations to do so’.

- 4.135 At the Commonwealth level, the Criminal Code prohibits the possession and use of cannabis for any purpose. However, this Part of the Criminal Code does not apply to conduct that the defendant can prove was undertaken entirely in a state or territory and that was justified or excused by the law of that state or territory.¹⁵⁶
- 4.136 The Therapeutic Goods Act prohibits unapproved goods being used to treat another person without authorisation under the Act where harm has resulted or could result.¹⁵⁷

Scope for Commonwealth/state collaboration

- 4.137 Commonwealth criminal law is already sufficiently flexible to accommodate Victoria legalising the possession and use of medicinal cannabis. The exclusion of medicinal cannabis from the scope of the Therapeutic Goods Act would resolve any concerns of carers about supplying unapproved therapeutic goods.

Scope for Victoria to establish a standalone scheme

- 4.138 Victoria may amend the Drugs, Poisons and Controlled Substances Act to establish a scheme for the lawful possession, administration and use of medicinal cannabis.
- 4.139 It would be prudent for Victoria to exclude carers from the scope of the Therapeutic Goods Act when they are engaging in the lawful administration of medicinal cannabis under a Victorian scheme. Such an exclusion would need to be clearly and carefully defined.

Special Victorian schemes

- 4.140 Several Parts of the Drugs, Poisons and Controlled Substances Act provide regimes for the cultivation, processing and supply of particular drugs. These schemes may be instructive for how to structure a scheme to provide cannabis for medicinal purposes.

The processing and supply of heroin

- 4.141 Heroin may be formulated, manufactured, and sold or supplied by wholesale under the Act.¹⁵⁸ This is the product of an agreement between the Commonwealth and Victorian governments.¹⁵⁹ The scheme is not used.¹⁶⁰
- 4.142 The Minister for Health is able to license a ‘fit and proper person’ to manufacture and sell or supply heroin by wholesale.¹⁶¹ The Minister is similarly able to license a ‘fit and

¹⁵⁶ *Criminal Code* (Cth) s 313.1.

¹⁵⁷ *Therapeutic Goods Act 1989* (Cth) s 21A(12),(13).

¹⁵⁸ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) pt III.

¹⁵⁹ Victoria, *Parliamentary Debates*, Legislative Assembly, 23 September 1981, 933 (Mr Borthwick).

¹⁶⁰ As is noted in Lawbook, *The Laws of Australia* (at 1 January 2014) 20.11 Regulation of Drugs [20.11.460]: ‘No such licences have yet been issued. When the legislation was introduced, there were suggestions that heroin had a unique role in the relief of pain but controlled studies have failed to show its superiority over morphine’.

proper person' to formulate heroin in a form that is suitable for therapeutic use.¹⁶² Only one licence of each kind may be issued.¹⁶³ Any activities under licence must be taken undertaken at the premises and in the quantities specified in the licence.¹⁶⁴

- 4.143 The Secretary of the Department of Health and Human Services may issue permits to medical practitioners and pharmacists to purchase or obtain specified quantities of heroin from a licensee. The permit will specify the quantity of heroin and the medicinal purposes for which the medical practitioner or pharmacist may use heroin.¹⁶⁵ Permits may also be issued to persons who wish to use the heroin for 'such educational experimental or research purposes and at such university or other institution as are specified in the permit'.¹⁶⁶
- 4.144 It is an offence for a licensee to manufacture or formulate heroin outside of the terms of the licence,¹⁶⁷ or to sell or supply it to a person without a permit or in a way outside the terms of that permit.¹⁶⁸ It is also an offence for a permit-holder to use, supply or administer heroin outside of the terms of the permit.¹⁶⁹

The cultivation, processing, sale and supply of low-THC cannabis

- 4.145 The Secretary of the Department of Environment and Primary Industries is also able to provide an authority, for up to three years,¹⁷⁰ for a person to cultivate and process low-THC cannabis. This is cannabis 'the leaves and flowering heads of which do not contain more than 0.35 per cent of THC'.¹⁷¹ The purpose of this scheme is to allow industrial-grade hemp to be processed in Victoria.¹⁷²
- 4.146 A person may apply to the Secretary for an authority if they intend to use the low-THC cannabis for 'commercial or research purposes related to non-therapeutic use'.¹⁷³ They may be authorised to possess, process, sell or supply cannabis seed harvested from low-THC cannabis; cultivate cannabis from that seed; and sell cannabis that is 'substantially

¹⁶¹ *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* s 56(1).

¹⁶² *Ibid* s 56(3),(4). To 'formulate' is to prepare or do 'any act for the purpose of or in the course of preparing heroin in a form suitable for therapeutic use': s 56(4).

¹⁶³ *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* s 56(2), (5).

¹⁶⁴ *Ibid* s 56(7), (8).

¹⁶⁵ *Ibid* s 56(9).

¹⁶⁶ *Ibid* s 56(10).

¹⁶⁷ *Ibid* s 56(14)(b).

¹⁶⁸ *Ibid* s 56(14)(a).

¹⁶⁹ *Ibid* s 56(14)(c).

¹⁷⁰ *Ibid* s 66(1).

¹⁷¹ *Ibid* s 61(1).

¹⁷² Victoria, *Parliamentary Debates*, Legislative Assembly, 23 April 1997, 829 (Mr McNamara).

¹⁷³ *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* s 62(1).

free of leaves and flowering heads' and that 'does not contain THC in excess of 0.1 per cent'.¹⁷⁴

- 4.147 The Secretary is obliged to consider whether the applicant or their associates have been found guilty of a serious offence within the past 10 years;¹⁷⁵ whether the applicant and their associates are each 'a suitable person' to cultivate, process, sell or supply low-THC cannabis,¹⁷⁶ focusing on their 'good repute', 'character, honesty and integrity', satisfactory business structure, and 'sound and stable financial background';¹⁷⁷ and the suitability of the proposed premises for such an endeavour.¹⁷⁸
- 4.148 An authority only permits the growing of low-THC cannabis at the premises identified in the application,¹⁷⁹ and contains terms and restrictions relating to the source of the cannabis seed; security and surveillance; record-keeping; and obligations to report to the Secretary.¹⁸⁰ The Secretary has the power to authorise inspectors to conduct investigations into whether low-THC cannabis activities are being conducted consistently with the authority.¹⁸¹

The cultivation of alkaloid poppies and the processing of poppy straw

- 4.149 In 2013, Victoria provided in the Drugs, Poisons and Controlled Substances Act for 'the commercial scale cultivation of alkaloid poppies in Victoria for therapeutic and research purposes'.¹⁸²
- 4.150 The scheme draws some distinctions between cultivation and processing, which it treats as within the competence of the State of Victoria, and manufacture, which it treats as within the competence of the Commonwealth's Narcotic Drugs Act. Cultivation includes the sowing of seeds, the growing and harvesting of plants, and the transplantation or division of those plants.¹⁸³ Processing means

to prepare or treat poppy straw in any manner other than refinement, concentration, extraction or reaction unless the refinement, concentration, extraction or reaction is for chemical analysis for non-therapeutic use.¹⁸⁴

¹⁷⁴ Ibid s 62(1)(a)–(c).

¹⁷⁵ Ibid s 64(1)(a).

¹⁷⁶ Ibid s 64(1)(b).

¹⁷⁷ Ibid s 64(2)(a)–(e).

¹⁷⁸ Ibid s 64(1)(c).

¹⁷⁹ Ibid s 66(2).

¹⁸⁰ Ibid s 66(3).

¹⁸¹ Ibid ss 69E–69L.

¹⁸² Victoria, *Parliamentary Debates*, Legislative Assembly, 13 December 2013, 4539 (Mr Walsh).

¹⁸³ *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 69N, 70(1).

¹⁸⁴ Ibid s 69N.

- 4.151** A person may apply for a poppy cultivation licence, which allows them to do one of two things for three years.¹⁸⁵ If the licence is for commercial purposes relating to therapeutic use, they may 'cultivate or possess alkaloid poppies' and 'sell and supply poppy straw to a licensed processor at premises specified in the licence'.¹⁸⁶ If the licence is for research purposes relating to non-therapeutic use, they may cultivate or possess alkaloid poppies, conduct measurements, analyses and extractions of those poppies, and supply those poppies to a licensed processor.¹⁸⁷ Only a person who has a contract with a licensed processor may hold a poppy cultivation licence, unless the Secretary permits.¹⁸⁸
- 4.152** Similarly, a poppy processing licence permits the licensed processor, for 12 months,¹⁸⁹ to process poppy straw for commercial purposes relating to therapeutic use or non-therapeutic research purposes. Only a person who has a licence under the Narcotic Drugs Act or the Customs Act may hold a poppy processing licence. The licensee may receive poppy straw for therapeutic use from a licensed grower, processor, or person authorised to possess and supply poppy straw in another jurisdiction. They may process the poppy straw at the premises specified in the licence, and may only possess the straw at that premises. They may only transport, sell or supply poppy straw to a person who holds a licence to manufacture under the Narcotic Drugs Act or to export under the Customs Act. The licensee may only export the poppy straw if they hold a licence under the Customs Act.¹⁹⁰¹⁹¹
- 4.153** The Secretary of the Department of Environment, Land, Water & Planning must consider in all of these instances whether the applicant is a fit and proper person to hold a licence.¹⁹² The Secretary must also consider any evidence that a commercial activity for therapeutic purposes is 'bona fide';¹⁹³ and whether a research activity for non-therapeutic purposes is to be conducted by a person with 'appropriate scientific training' using an 'appropriate scientific methodology'.¹⁹⁴
- 4.154** A wide range of matters are to be taken into account with respect to the assessment of a person as fit and proper. Similarly to the low-THC cannabis cultivation scheme, the assessment is of the applicant and their associates, and includes any serious offences committed by them in the last 10 years; an assessment of their suitability and the

¹⁸⁵ Ibid s 69OC(1).

¹⁸⁶ Ibid s 69O(1).

¹⁸⁷ Ibid s 69O(2).

¹⁸⁸ Ibid s 69OC(7).

¹⁸⁹ Ibid s 69PC(1).

¹⁹⁰ Ibid s 69P(1)(a)–(e).

¹⁹¹ Ibid s 69PC(8).

¹⁹² Ibid ss 69O(4)(a); 69P(4)(a).

¹⁹³ Ibid ss 69O(4)(b) 69P(4)(b).

¹⁹⁴ Ibid ss 69O(4)(c), 69P(4)(c).

suitability of the premises to be used to cultivate poppy straw; and any requirements prescribed in regulations.¹⁹⁵ The Secretary may consider the 'good repute', 'character, honesty and integrity' of applicants and their associates; any history of non-compliance with the Drugs, Poisons and Controlled Substances Act; any offences incurred over the last 10 years; the applicant's business structure; whether their financial background is sound and stable; and their capacity to finance the requirements of a licence.¹⁹⁶

- 4.155** The Secretary must provide applications to the Chief Commissioner of Police,¹⁹⁷ who will proceed to advise the Secretary on any matters the Secretary wishes, or that the Chief Commissioner considers to be appropriate or reasonably necessary.¹⁹⁸ The Chief Commissioner can 'support or oppose' the application and give reasons for that decision,¹⁹⁹ and if the decision is opposed the Secretary must not issue a licence.²⁰⁰
- 4.156** Licensees must supply and comply with a risk management plan.²⁰¹ Like the conditions on low-THC cannabis, a licence to cultivate or produce will specify restrictions around the premises at which the activity is to take place;²⁰² the appropriate security measures;²⁰³ record-keeping;²⁰⁴ reporting obligations to the Secretary about the conduct of the business;²⁰⁵ how crop residue or poppy straw is to be disposed of;²⁰⁶ and the inspection of the premises.²⁰⁷ A poppy cultivation licence must provide information on the species, subspecies or varieties of alkaloid poppy that will be cultivated.²⁰⁸ Poppy processing licences may only process a specified quantity of alkaloid poppy.²⁰⁹ Only suitable persons may be employed by a licensee to cultivate or process alkaloid poppy.²¹⁰

¹⁹⁵ Ibid s 69NB(1). This section applies to both poppy cultivation and poppy processing licences.

¹⁹⁶ Ibid s 69NB(3)(a)–(c), (f)–(h). Additional requirements apply for an application to renew the licence: (d)–(e).

¹⁹⁷ Ibid ss 69OB(2), 69PA(2).

¹⁹⁸ Ibid ss 69OB(3), 69PA(3).

¹⁹⁹ Ibid ss 69OB(3)(c), 69PA(3)(c).

²⁰⁰ Ibid ss 69OB(4), 69PA(4).

²⁰¹ Ibid ss 69OC(4), 69PC(4).

²⁰² Ibid ss 69OC(6)(b), 69PC(7)(a).

²⁰³ Ibid ss 69OC(6)(c), 69PC(7)(b).

²⁰⁴ Ibid ss 69OC(6)(d), 69PC(7)(c).

²⁰⁵ Ibid ss 69OC(6)(e), 69PC(7)(d).

²⁰⁶ Ibid ss 69OC(6)(e), 69PC(7)(d).

²⁰⁷ Ibid ss 69OC(6)(f),(h), 69PC(7)(e).

²⁰⁸ Ibid s 69OC(6)(a).

²⁰⁹ Ibid ss 69OC(3), 69PC(5).

²¹⁰ Ibid ss 69OC(3), 69PC(5).

Employees may only undertake cultivation or processing activities relevant to their employment,²¹¹ and they must have identification.²¹²

Conclusion

- 4.157 To enable persons and entities to participate in a medicinal cannabis scheme, the State of Victoria may make regulations to modify the application of the Commonwealth Therapeutic Goods Act. Carefully defined regulations could be made to exempt natural persons and unincorporated associations participating in a medicinal cannabis scheme. Regulations could also be made modifying the application of the Act to a state entity, as long as it is not a 'constitutional corporation'.
- 4.158 However, the State of Victoria cannot modify the operation of the Narcotic Drugs Act. It would apply to natural persons and unincorporated associations, but it does not appear to apply to the State of Victoria.
- 4.159 Constitutional corporations are so clearly within the Commonwealth's power to regulate under the Therapeutic Goods Act that they could not be a part of the scheme without Commonwealth authorisation or exemption. Only a corporation that acted on behalf of the Crown or that did not engage in trading or financial activities could plausibly take part in a stand-alone Victorian scheme.
- 4.160 In light of these considerations, Victoria could amend the Drugs, Poisons and Controlled Substances Act to allow individuals, unincorporated associations, and state agencies to
- cultivate cannabis for medicinal purposes
 - process medicinal cannabis
 - supply cannabis for a medicinal purpose in Victoria.
- 4.161 Victoria could also amend the Drugs, Poisons and Controlled Substances Act to:
- allow the possession and use of cannabis for medicinal purposes by certain individuals, without disturbing the criminal prohibitions against unauthorised use
 - create a system for prescribing, or authorising, the supply of medicinal cannabis.
- 4.162 The following would depend on Commonwealth authorisation:
- The Commonwealth Minister for Health could provide that medicinal cannabis supplied in a Victorian scheme was excluded from the Therapeutic Goods Act.
 - The Commonwealth Minister for Health could license entities to engage in the manufacturing of forms of medicinal cannabis under the Narcotic Drugs Act.
 - Victoria and the Commonwealth could come to an arrangement for the lawful importation of medicinal cannabis products.

²¹¹ Ibid ss 69OE(3), 69PE(3).

²¹² Ibid ss 69OF, 69PF.

4.163 Many of the restrictions on manufacture, processing and supply of medicinal cannabis under the scheme would cease to exist, if the Commonwealth provided authorisation. Corporations would be able to participate in the scheme.

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5 Comparable laws and proposed reforms in Australia

Introduction

- 5.1 Public debate in Australia and overseas about the regulation of cannabis, and whether it should be available to be used as a medicine, has both broadened and intensified in the past two decades. Governments and legislatures have generated a large body of legislative reforms, policy reviews and regulatory proposals in response to changing attitudes and growing anecdotal and empirical evidence. Victoria can learn from the way the field has been studied, the way the law has been changed or interpreted, and proposed reforms in other Australian jurisdictions.
- 5.2 Within Australia, a number of legislative proposals to allow sufferers of serious conditions to be treated with medicinal cannabis have arisen at both state/territory and federal levels in recent years. These proposals indicate options that Victoria could consider within the limits of its jurisdiction. Some of them would work within the existing framework for the regulation of therapeutic goods, and could be taken into account in any Victorian scheme. Victoria could also draw on the experience and mechanisms of comparable cultivation schemes for industrial hemp and opium poppies.

Reviews and inquiries into medicinal cannabis in other Australian jurisdictions

- 5.3 Victoria is not the first state to consider introducing a medicinal cannabis scheme. Governments and parliaments in other states and territories have also explored whether—and if so how—to make cannabis lawfully available to seriously ill people who may benefit from its use.
- 5.4 The most extensive of these reviews were conducted in New South Wales in 2000¹ and 2013.² Both called for more clinical trials but nonetheless recommended that cannabis

¹ Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000).

² Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013).

be made available in special circumstances to those in need on ‘compassionate grounds’. They both also had difficulty articulating a method of supply that would be workable and consistent with Commonwealth laws.

- 5.5 Meanwhile, in 2005, the Minister for Health for the Australian Capital Territory tabled a report on the medicinal use of cannabis.³ It summarised the scientific evidence and regulatory environment and identified five options to improve access. More recently, an interim report by a parliamentary committee in Tasmania has recommended legislative reform.⁴ These reports are discussed below.

2000 NSW working party review

- 5.6 In October 1999, the Premier of New South Wales convened a working party to investigate the therapeutic potential of cannabis. The working party submitted its report in August 2000.⁵
- 5.7 The working party was asked to advise on whether patients with some medical conditions should be allowed to use cannabis for therapeutic purposes and, if so, how this might be achieved without legalising or decriminalising the recreational use of cannabis.
- 5.8 In its final report, the working party found that:
- some compounds found in cannabis may have value in the treatment of a limited range of medical conditions⁶
 - more research is required to evaluate the therapeutic value of cannabis
 - crude cannabis cannot be, and is unlikely to be, prescribed in Australia
 - commercial and regulatory impediments exist to the prescription of medical cannabinoids, and such drugs are at best many years away.⁷
- 5.9 The working party recommended that the government enact a regime for the ‘limited compassionate provision’ of cannabis to patients who may benefit from it, as an ‘interim measure’ until medical-grade cannabis products become available. Specified patients with certification from an accredited doctor (and their carers) would be exempted from prosecution for the possession of small amounts of cannabis or the cultivation of a small number of plants.

³ Legislative Assembly for the Australian Capital Territory, *Report on the Medicinal Use of Cannabis* (2005).

⁴ Legislative Council Government Administration Committee ‘A’, Parliament of Tasmania, *Interim Report on Legalised Medicinal Cannabis* (2014).

⁵ Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000).

⁶ The working party referred specifically to HIV-related and cancer-related wasting; nausea and vomiting caused by cancer chemotherapy; muscle spasm in some neurological disorders (such as multiple sclerosis, Tourette’s syndrome and motor neurone disease); and pain not relieved by conventional analgesics: Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000) vol 1, 24.

⁷ Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000) vol 1, 24–26.

5.10 The working party also recommended that the government conduct a program of clinical trials, and that any importation or government-licensed production of cannabis be permitted only for this purpose.⁸ Finally, it made a range of other recommendations aimed at improving registration processes for new drugs, encouraging further research, implementing education programs and removing legislative obstacles to the proposed trials.⁹

Government response

5.11 The New South Wales Government responded to the working party's report by announcing it would release an exposure draft of a Bill which would provide for a four-year trial of the medicinal use of cannabis.

5.12 The options the Government considered included:

- decriminalising the cultivation of cannabis for personal use by eligible patients
- regulating supply and distribution
- seeking Commonwealth approval to import cannabis spray when it became available.¹⁰

5.13 However, it did not proceed with introducing the Bill because the preferred pharmaceutical preparations would not be available for some time and the New South Wales and Commonwealth Governments opposed any scheme involving home-grown cannabis or its purchase on the black market.¹¹

2005 Report to the ACT Legislative Assembly

5.14 During debate on a Bill to allow licensed patients to possess and grow cannabis for medicinal purposes in the Australian Capital Territory in 2004,¹² the Minister for Health undertook to report to the Legislative Assembly on the issues he had identified when explaining why the Government did not support the proposed legislation.¹³ The report was tabled in October 2005.¹⁴

5.15 The report drew extensively on the work of the 2000 New South Wales working party and a research paper that had subsequently been published by the New South Wales Parliamentary Research Service.¹⁵

⁸ Ibid 38–42.

⁹ Ibid.

¹⁰ Elsa Koleth (revised and updated by Daniel Montoya and Gareth Griffith), 'Medical cannabis', Issues Backgrounder No 5, Parliamentary Library Research Service, Parliament of New South Wales, (2014) 5.

¹¹ Ibid.

¹² Drugs of Dependence (Cannabis Use for Medical Conditions) Bill 2004.

¹³ Australian Capital Territory, *Parliamentary Debates*, Legislative Assembly, 25 October 2004, 4128–4132 (Simon Corbell).

¹⁴ Legislative Assembly for the Australian Capital Territory, *Report on the Medicinal Use of Cannabis* (2005).

¹⁵ Rowena Johns, 'Medical Cannabis Programs: A Review of Selected Jurisdictions' (Briefing Paper No 10, Parliamentary Library Research Service, Parliament of New South Wales, 2004).

5.16 It found that:

The evidence for the health benefits of cannabis/cannabinoids is not strong, but the effects are variable. Recent studies have demonstrated a higher than expected increase in the risk and severity of psychosis and depression in addition to impairment of psychomotor performance.¹⁶

5.17 Five options to improve access to cannabis/cannabinoids were identified:

- Continue with the present situation but improve access to nabilone by specific funding to designated persons.
- Participate in a New South Wales trial if/when it commences.
- Exempt cannabis users from the usual operation of the criminal law.
- Establish a medicinal cannabis program in the Australian Capital Territory to oversee cultivation and/or supply of cannabis.
- Seek the availability of the sub-lingual spray Sativex if, after further testing overseas it is found to be safe and effective, or support a clinical trial of Sativex in the Australian Capital Territory.¹⁷

Government response

5.18 The Health Minister said that, if Sativex were found to be safe and effective, the Australian Capital Territory would seek Commonwealth approval to import it for use by a select patient group.¹⁸

2013 NSW parliamentary inquiry

5.19 In November 2012, the New South Wales Legislative Council's General Purpose Standing Committee No 4 was asked to enquire into the use of cannabis for medical purposes. The purpose of the review was to investigate the efficacy and safety of cannabis for medical purposes and the methods by which such products could be legally supplied in New South Wales.¹⁹

5.20 The committee found that 'there is sufficiently robust scientific evidence to indicate that cannabis products can be an effective treatment for certain conditions in very specific circumstances'.²⁰ Pharmaceutical forms of cannabis were described as 'a promising and workable area of reform', but the committee made few recommendations regarding such products, as they are primarily within the purview of the Commonwealth.²¹ It did, however, recommend that the New South Wales Government write to the

¹⁶ Legislative Assembly for the Australian Capital Territory, *Report on the Medicinal Use of Cannabis* (2005), 3.

¹⁷ *Ibid* 5–6.

¹⁸ Simon Corbell, MLA, 'Report on Medicinal Use of Cannabis Tabled' (Media Release, 18 October 2005).

¹⁹ Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013) iv.

²⁰ *Ibid* xi.

²¹ *Ibid* xi–xiii.

Commonwealth Minister for Health and Ageing, expressing in-principle support for expansion of access to ‘approved cannabis pharmacotherapies’ and further clinical trials of pharmaceutical cannabis products.²²

- 5.21 In relation to what it called ‘crude cannabis’ (cannabis in plant, resin or liquid form), the committee recommended a ‘compassionate approach’ be taken. While emphasising the benefits of pharmaceutical-grade cannabis products, it noted that these products are presently of limited assistance and many patients are already using crude cannabis. The committee therefore recommended that crude forms of cannabis be made available to a very limited group of patients in specific circumstances (namely, patients with a terminal illness and people living with AIDS). It further proposed that such patients be given a complete defence to arrest and prosecution arising from their use of cannabis.²³
- 5.22 The report proposed that a patient seeking to qualify for such a scheme would have to be certified by a specialist medical practitioner as suffering from a specific incurable condition. It was suggested that the government maintain a register of such patients and their carers.²⁴ The committee rejected the submission put to it that sufferers of chronic pain should also be permitted to access cannabis.²⁵
- 5.23 Despite recommending that certain patients be permitted to obtain and use cannabis products lawfully, the committee did not deal with the question of how such products would be supplied, stating that time did not permit detailed consideration of this issue. It noted that it would be ‘preferable’ for patients to obtain cannabis legally, but that this ‘may not be realistic in the present environment’.²⁶

Government response

- 5.24 The New South Wales Government responded to the committee's recommendations in November 2013. It expressed its support for the development of cannabis products within the existing national regulatory framework for the registration of medicines. It did not support the medical use of crude cannabis outside that framework and did not believe that crude cannabis products would be approved under the *Therapeutic Goods Act 1989* (Cth) while their safety and quality were uncontrolled.²⁷
- 5.25 Apart from being concerned about the harms associated with cannabis use and the risk of illegal diversion of medically authorised crude cannabis products to recreational users,

²² Ibid xiii.

²³ Ibid xiii–xv.

²⁴ Ibid xiv–xv.

²⁵ Ibid xv.

²⁶ Ibid xv.

²⁷ New South Wales, *NSW Government Response to the Legislative Council General Purpose Standing Committee No 4 Report: The Use of Cannabis for Medical Purposes*, Parl Paper 3473 (2013).

the government noted that the creation of a legal market raised ‘complex administrative and legal challenges’ to which the committee had not found a solution.²⁸

- 5.26 The government rejected the committee's recommendations to allow a limited class of patients access to crude cannabis because ‘the potency and safety of these products cannot be guaranteed’. It also noted difficulties with the evidence base for the efficacy of cannabis, and referred to conventional programs and products which were available to respond to chronic pain and to assist palliative care patients. It emphasised the problems with going outside the established Commonwealth regime for the approval of medicines; the health and safety risks; and the risk of diversion to illicit markets.²⁹
- 5.27 The New South Wales Government subsequently introduced the Terminal Illness Cancer Scheme, which protects terminally ill cannabis users and their carers from prosecution, by way of police guidelines. This scheme is discussed in more detail below.
- 5.28 In late 2014, the government further announced that it would be funding three trials of the medical use of cannabis.³⁰ The subjects of the trials will include children with severe and drug-resistant epilepsy, adults with terminal illness, and adults with nausea and vomiting induced by chemotherapy.³¹

2014 Tasmanian parliamentary inquiry

- 5.29 In July 2014, Government Administration Committee ‘A’ of the Tasmanian Legislative Council commenced an inquiry into the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medicinal purposes. It released an interim report in November 2014. The interim report noted that many Tasmanians were already using cannabis medicinally and that the law did not provide protections for these users or those who supply them.
- 5.30 While acknowledging that more research was needed, the committee recommended immediate legislative change, on compassionate grounds, to protect users of medicinal cannabis from criminal charges associated with possession and administration. It also recommended that the Tasmanian Government:
- develop a legislative framework to enable medicinal cannabis to be used under medical supervision, including the preparation, cultivation and supply of medicinal cannabis
 - facilitate clinical research
 - adopt a cooperative approach with other jurisdictions regarding legalisation of the prescription, administration, possession and cultivation of cannabis for medicinal use

²⁸ Ibid.

²⁹ Ibid.

³⁰ Jacob Saulwick, ‘NSW Government to Fund Three Trials of Medical Cannabis’, *The Sydney Morning Herald* (online), 22 December 2014 <<http://www.smh.com.au>>.

³¹ NSW Health, *Clinical Trials: Medical Use of Cannabis* (undated) Fact Sheet <<http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf>>.

- engage with companies with appropriate expertise and capacity to progress the cultivation, extraction and processing of cannabinoids within the existing and/or future regulatory framework.³²

Government response

- 5.31 The Tasmanian Government responded to the interim report by expressing its support for clinical trials and the potential use of medicinal cannabis in Tasmania, subject to a proper evidence-based approach, strong regulatory framework and appropriate approvals from national regulators.³³
- 5.32 On the advice of the Tasmania Police that it was unnecessary, the government rejected the Committee's recommendation to immediately legislate to protect individuals who are using medicinal cannabis from criminal charges. The Police Commissioner had said that Tasmania Police would not criminally pursue terminally ill users of cannabis or people who had contributed to the Legislative Council Committee's inquiry.³⁴

Current and recent Bills

- 5.33 In addition to the parliamentary reviews described above, over the past two decades a number of Bills have been presented to Australian parliaments to permit access to cannabis for medicinal purposes. Some of the Bills that were first proposed would have made only modest changes to the law. They set out simple defences to prosecution for the possession of small quantities of dried cannabis or the cultivation of small numbers of plants, on the strength of appropriate medical certification or proof of medical need.
- 5.34 These Bills included:
- Poisons Amendment (Cannabis for Medical and Commercial Uses) Bill 1999 (WA)
 - Controlled Substances (Medical Use of Cannabis) Amendment Bill 2003 (SA)
 - Controlled Substances (Palliative Use of Cannabis) Amendment Bill 2008 (SA)
 - Misuse of Drugs Amendment Bill 2014 (Tas).
- 5.35 Recently, as the pace of change and pressure for reform have escalated, more expansive Bills to permit access to cannabis for medicinal purposes have been introduced into Australian parliaments by non-government members. They illustrate further options for the ways in which Victorian laws could be amended to allow cannabis to be used lawfully for medicinal purposes. They are discussed below.

³² Legislative Council Government Administration Committee 'A', Parliament of Tasmania, *Interim Report on Legalised Medicinal Cannabis* (2014) 7.

³³ Michael Ferguson, 'Interim Report on Medicinal Cannabis' (Media Release, 20 November 2014) <http://www.premier.tas.gov.au/releases/interim_report_on_medicinal_cannabis>.

³⁴ *Ibid.*

Regulator of Medicinal Cannabis Bill 2014 (Cth)

- 5.36 In November 2014, the Regulator of Medicinal Cannabis Bill 2014 (Cth) was introduced into the Senate as a Private Member's Bill.³⁵ The Bill would establish the Regulator of Medicinal Cannabis, an agency that would:
- approve medicinal cannabis products for inclusion in a register of regulated cannabis products³⁶
 - make, and monitor compliance with, rules for licensing the production, use, experimental use and import and export of medicinal cannabis.³⁷
- 5.37 Medicinal cannabis would be regulated under the proposed legislation rather than under the Commonwealth Therapeutic Goods Act. Pharmaceutical companies would be able to choose whether their cannabis-derived pharmaceutical products would be assessed under the Therapeutic Goods Act regime or the Regulator of Medicinal Cannabis regime.³⁸ Cannabis, for these purposes, would have the same meaning as it is given in the *Single Convention on Narcotic Drugs 1961*, and would include cannabis resin and cannabis plants as defined in the Single Convention.³⁹ Both natural cannabis and synthetic versions of products derived from cannabis would be regulated.⁴⁰ Cannabis products would be differentiated in much the same way as therapeutic goods are in the Therapeutic Goods Act.⁴¹
- 5.38 The regulator is designed to satisfy the requirements of the Single Convention regarding government supervision of licensed cannabis cultivation.⁴² The source of constitutional authority for the Bill is said to be the treaty implementation aspect of the external affairs power.⁴³ The scheme would apply only in those states and territories that opt in.⁴⁴
- 5.39 On 12 February 2015, the Senate referred the Bill to the Senate Legal and Constitutional Affairs Legislation Committee for report by 21 April 2015.⁴⁵

³⁵ Commonwealth, *Parliamentary Debates*, Senate (27 November 2014), 9506 (Senator Richard Di Natale).

³⁶ Regulator of Medicinal Cannabis Bill 2014 (Cth) pt 2.

³⁷ *Ibid* cl 12.

³⁸ Explanatory Memorandum, Regulator of Medicinal Cannabis Bill 2014 (Cth) 1.

³⁹ Regulator of Medicinal Cannabis Bill 2014 (Cth) cl 5.

⁴⁰ *Ibid*.

⁴¹ That is to say, based on their formulation, strength, dosage, name, indications, directions of use, and container: Regulator of Medicinal Cannabis Bill 2014 (Cth) cl 15.

⁴² Explanatory Memorandum, Regulator of Medicinal Cannabis Bill 2014 (Cth) 1.

⁴³ *Ibid* 2.

⁴⁴ Regulator of Medicinal Cannabis Bill 2014 (Cth).

⁴⁵ Senate Legal and Constitutional Affairs Committee, *Regulator of Medicinal Cannabis Bill 2014* <http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill>.

Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014 (NSW)

- 5.40 The Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014 (NSW) was a Private Member's Public Bill that was introduced to the New South Wales Parliament but not passed.⁴⁶ The Bill was designed to legalise cannabis for medical purposes in certain circumstances.
- 5.41 The Bill proposed to amend the *Poisons and Therapeutic Goods Act 1966* (NSW) and insert a Part 4A, which would permit the lawful cultivation, supply and use of cannabis for medicinal purposes. It was envisaged that a government agency would supply cannabis to patients and carers, some of whom would also be permitted to grow their own cannabis.
- 5.42 This scheme was designed to avoid the reach of Commonwealth laws. It relied on a government agency, and its employees and unincorporated contractors, being able to cultivate, process and supply cannabis to patients within New South Wales without attracting the operation of the Commonwealth Therapeutic Goods Act.⁴⁷ The Bill made no mention of the Commonwealth's Narcotic Drugs Act.
- 5.43 The cannabis that would have been supplied for medicinal purposes was defined in the Bill as a 'Schedule 9 substance'⁴⁸ comprising:
- (a) cannabis leaf, cannabis oil or cannabis resin, or (b) a preparation, admixture, extract or other substance containing any proportion of cannabis leaf, cannabis oil or cannabis resin except if it includes any proportion of a Schedule 9 substance other than cannabis.⁴⁹
- 5.44 Under the scheme, cannabis would have only been permitted to be supplied to an adult suffering symptoms associated with, or with the treatment of, the following:
- a terminal illness
 - HIV
 - severe, treatment resistant nausea and vomiting due to chemotherapy
 - cancer-related pain
 - neuropathic pain
 - conditions specified by the regulations as able to be relieved by cannabis
 - conditions certified by the patient's medical practitioner as able to be relieved by cannabis.⁵⁰

⁴⁶ Introduced by Dr John Kaye, MLC. The Bill was first introduced on 18 March 2014 and lapsed on 8 September 2014. The version discussed here was introduced on 20 November 2014 and lapsed when Parliament was prorogued, on 2 March 2015.

⁴⁷ Explanatory note, Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014, 4.

⁴⁸ This refers to Schedule 9 of the *Standard for the Uniform Scheduling of Medicines and Poisons No.5* (SUSMP) as set out in the *Poisons Standard 2014* (Cth). The SUSMP is incorporated into state and territory laws: see Chapter 4.

⁴⁹ Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014 (NSW) sch 1 cl 1.

- 5.45 Only children suffering from the symptoms of intractable childhood epilepsy or the symptoms associated with its treatment would have been eligible to obtain cannabis.⁵¹
- 5.46 Like the proposed Commonwealth Regulator of Medical Cannabis Bill discussed above, a register of patients and carers was proposed. Photo identification would have been supplied to patients and carers and they would have been immune from prosecution under the *Drug Misuse and Trafficking Act 1985* (NSW). Registered patients and carers would have been permitted to possess up to 15 grams of cannabis leaf, 1 gram of cannabis oil or 2.5 grams of cannabis resin, which could not have been administered in public.⁵²
- 5.47 A patient or carer on the register would have been able to register as a ‘cannabis producer’ and grow their own cannabis. Limits on the amount of cannabis plants that could lawfully be grown were proposed. A cannabis producer could not possess more than six budding or flowering cannabis plants or more than 24 cannabis plants in total.⁵³
- 5.48 In addition, the scheme would have authorised a government agency and its employees and contractors to cultivate, process and supply cannabis to registered patients and carers.⁵⁴

Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT)

- 5.49 The Standing Committee on Health, Ageing, Community and Social Services, of the Australian Capital Territory Legislative Assembly, is also considering proposed medicinal cannabis legislation—the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT). On behalf of the ACT Greens party, the Minister for Justice⁵⁵ presented an exposure draft of the Bill, and a discussion paper, to the Legislative Assembly in August 2014. The exposure draft and the paper were referred to the committee for report by the last sitting day in June 2015.⁵⁶
- 5.50 The purpose of the draft Bill is to set up a licensing system for eligible patients to possess and grow their own cannabis for medicinal purposes. The draft Bill is substantially identical to the Drugs of Dependence (Cannabis for Medical Conditions) Amendment Bill 2004 (ACT), introduced into the ACT Legislative Assembly in 2004.

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Ibid.

⁵⁵ Shane Rattenbury MLA.

⁵⁶ Australian Capital Territory, *Parliamentary Debates*, Legislative Assembly, 7 August 2014, 2154 (Shane Rattenbury). The last sitting day is currently scheduled to be 4 June 2015.

- 5.51 The draft Bill sets up a scheme whereby patients would be eligible to access cannabis for medicinal purposes if approved by the Chief Health Officer.⁵⁷ Patients would be able to make one of three types of application:
- Category 1 application: for the mitigation of symptom(s) of a terminal illness.⁵⁸
 - Category 2 application: for the mitigation of one or more listed symptoms associated with a listed condition, set out in a table (such as severe pain associated with cancer).⁵⁹
 - Category 3 application: for the mitigation of a symptom of any other medical condition or its treatment.⁶⁰
- 5.52 The application would have to be supported by a statement from a doctor, with increasingly stringent requirements according to the category of application.⁶¹ In all cases, the applicant would need to have tried or considered conventional treatment first.⁶² Once approved, a patient would be permitted to possess cannabis. An approval would essentially amount to a licence to possess and use cannabis.⁶³ The patient would also be permitted to seek a licence to cultivate cannabis either personally or on their behalf by a nominated carer. It would be valid for a limited time (no longer than a year) and would stipulate maximum possession amounts.⁶⁴ In applying for a cultivation licence the applicant would have to establish they have appropriate security measures in place,⁶⁵ and only one patient would be able to be associated with any given cultivation site.⁶⁶ The draft legislation provides for the scheme to be reviewed after five years by a multi-stakeholder committee.⁶⁷

Initiatives within the current regulatory framework

- 5.53 While there is no provision for the supply of cannabis for medicinal purposes in the current law, an elaborate structure does exist for the regulation of therapeutic goods and dangerous drugs in Australia. Reform proposals have been put forward which would expand access to medicinal cannabis, but within the existing regulatory framework. Three of these are discussed below.

⁵⁷ Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT) cl 14.

⁵⁸ *Ibid* cl 7(3).

⁵⁹ *Ibid* cl 7(4).

⁶⁰ *Ibid* cl 7(5).

⁶¹ *Ibid* cl 8–9.

⁶² *Ibid* cl 8(2)–(3).

⁶³ *Ibid* cl 14.

⁶⁴ *Ibid* cl 16–22.

⁶⁵ *Ibid* cl 18(3)(d).

⁶⁶ *Ibid* cl 18(3)(e).

⁶⁷ *Ibid* cl 25.

- 5.54 The first is a proposal to change the manner in which the cannabinoid CBD is regulated under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which would allow easier access to pharmaceutical preparations containing this compound. The second reform of interest is the New South Wales Government's Terminal Illness Scheme, which would assist terminally ill people with a medical authorisation and their carers to escape prosecution for possession and use of small quantities of cannabis. The third is a Bill presented to—but not passed by—the Victorian Parliament in 2014, to remove impediments to medical practitioners wishing to establish clinical trials.
- 5.55 Medicinal cannabis was discussed at the October 2014 meeting of the Council of Australian Governments, and a national agreement was reached. The Commonwealth agreed to work collaboratively with the states and territories to share knowledge and information regarding the medicinal use of appropriate therapeutic products derived from cannabis.⁶⁸
- 5.56 Also, in October 2014, the Commonwealth announced an Independent Review of the Regulation of Medicines and Medicinal Devices.⁶⁹ The review aims to simplify regulations around importing and approving medicines under the Commonwealth Therapeutic Goods Act. It aims to enhance Australia's regulatory framework in order to allow effective response to global trends and developments in medicine. The review will take place over the remainder of 2015.⁷⁰

Application to reschedule cannabidiol

- 5.57 In 2014, Victoria and Western Australia made a joint application to place the cannabinoid cannabidiol (CBD) onto Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).⁷¹ If approved, the application would have the effect of allowing CBD to be prescribed by a medical practitioner. CBD is not currently the subject of a separate entry in the SUSMP.⁷²
- 5.58 As discussed in Chapter 4, because cannabis is listed in Schedule 9 of the SUSMP, there are significant limitations on importing and distributing cannabis-based products. A separate entry for CBD, in Schedule 4, would relax these requirements insofar as that particular cannabinoid is concerned. However, it would not result in CBD products becoming immediately available for purchase, as this would require further approval steps.
- 5.59 In particular, adding CBD to Schedule 4 would not remove the requirement for it to be registered through the *Therapeutic Goods Act 1989* (Cth) when therapeutic claims are

⁶⁸ Council of Australian Governments Health Council, 'Communique' (10 October 2014) <<http://www.health.gov.au>>.

⁶⁹ Peter Dutton, 'Expert Panel to Review Medicines and Medical Devices Regulation' (Media Release, 24 October 2014).

⁷⁰ *Ibid.*

⁷¹ Application to Amend the Poisons Standard, 6 October 2014, Government of WA Department of Health, Government of Victoria Department of Health, 1 <<http://www.health.vic.gov.au/dpcs/medicinal-cannabis.htm>>.

⁷² CBD is mentioned in the entry for 'nabiximols' but exists in that product in combination with other compounds.

being made. Nor would it imply the efficacy of the substance for any particular therapeutic purpose.⁷³

- 5.60 On 5 February 2015, the delegate of the Secretary, exercising powers under the Commonwealth Therapeutic Goods Act, made an interim decision to include cannabidiol in Schedule 4 of the SUSMP. The proposed entry is as follows:

CANNABIDIOL in preparations for therapeutic use except when containing no more than 2 per cent of other cannabinoids found in cannabis.⁷⁴

- 5.61 The proposed implementation date of this decision is 1 June 2015.⁷⁵

- 5.62 In reaching this interim decision, the delegate remarked upon the safety profile of CBD and its low risk of misuse or abuse, including its lack of psychoactive properties. The delegate observed that, although there is no pure form of CBD currently available, impurities below two per cent are not clinically significant. Both synthetically produced and naturally derived CBD would be captured by the entry.⁷⁶

NSW Terminal Illness Cannabis Scheme

- 5.63 The New South Wales Terminal Illness Cannabis Scheme is intended to ‘extend compassion to adults with a terminal illness’ by enabling terminally ill people to escape prosecution for possessing and using cannabis. The scheme functions by way of guidelines for New South Wales police officers, which are to assist them to exercise their discretion to caution terminally ill adults (or their carers) who use cannabis medicinally.
- 5.64 In order to be eligible for the scheme, a person must be over 18, a resident of New South Wales and registered with the New South Wales Department of Justice. Patients require an Australian doctor's certification (which lasts for one year) that they are terminally ill before they can register. The intention of the scheme is that police officers will, upon presentation of the authorisation document, exercise their discretion not to prosecute a registered patient who is in possession of up to 15 grams of dried cannabis, one gram of cannabis oil or 2.5 grams of cannabis resin, and who administers cannabis only inside a domestic residence.
- 5.65 Carers who are registered with the government are also able to avoid prosecution for possessing cannabis or administering cannabis to the registered patient. However, the scheme is an administrative measure—there is no statutory protection from prosecution

⁷³ Application to Amend the Poisons Standard, 6 October 2014, Government of Western Australia Department of Health, Government of Victoria Department of Health, 10 <<http://www.health.vic.gov.au/dpcs/medicinal-cannabis.htm>>.

⁷⁴ Therapeutic Goods Administration, Reasons for Scheduling Delegate's Interim Decision and Invitation for Further Comment for the ACMS (5 February 2015) <<http://www.tga.gov.au/book/interim-decisions-matters-referred-expert-advisory-committee-acms-out-session-november-2014#005>>.

⁷⁵ Ibid.

⁷⁶ Ibid.

for patients or their carers—and does not provide registered patients with any lawful way to cultivate or purchase cannabis.⁷⁷

Proposal to streamline applications for clinical trials in Victoria

- 5.66 In September 2014, the former Victorian Government introduced a Bill to the Victorian Parliament that was intended to facilitate further scientific research into the medicinal properties of cannabis by removing impediments to medical practitioners wishing to establish clinical trials—the Drugs, Poisons and Controlled Substances Amendment (Clinical Trials) Bill 2014 (Vic).
- 5.67 The proposed legislation would have removed the requirement for a registered medical practitioner to apply to the Secretary of the Department of Health and Human Services for a separate permit for every patient to be engaged in a clinical trial involving cannabis.⁷⁸ The *Drugs, Poisons and Controlled Substances Act 1981* (Vic) would have been amended to allow a clinical trial permit to be issued for approved trials in relation to Schedule 8 and 9 poisons (cannabis and its related products being a Schedule 9 poison). A medical practitioner administering such a trial would have applied to the Secretary for a clinical permit, covering the trial, and would then be able to administer cannabis products to the patients taking part in the approved trial.
- 5.68 The changes would have also meant that possession and use of cannabis products for the sake of the trial would not be considered an offence.⁷⁹
- 5.69 The Bill passed the Legislative Council shortly before the 2014 State election, but was not considered by the Legislative Assembly before the 57th Parliament expired. As a result the Bill lapsed.

Comparable cultivation schemes

- 5.70 Other jurisdictions around Australia have, like Victoria, enacted regimes for the regulated cultivation of plants that are seen to pose safety and security risks. They could provide regulatory models for the cultivation of medicinal cannabis to Victoria.
- 5.71 Significantly, opium poppies, used to manufacture morphine and other opiates, have been cultivated in Tasmania for almost 50 years. Tasmania's experience and legislation provide useful insights into on how security and regulatory risks can be controlled. More recently, Tasmania and other jurisdictions have legislated to permit the cultivation of cannabis in the form of hemp, for use in the production of fibre and oil, in some cases including the cultivation of high-THC cannabis.

⁷⁷ NSW Government, *Terminal Illness Cannabis Scheme*, <<http://www.nsw.gov.au/tics>>; NSW Government, *TICS fact sheet for adults with a terminal illness and their carers*, (2015) <http://www.nsw.gov.au/sites/default/files/initiatives/carers_factsheet.pdf>.

⁷⁸ Drugs, Poisons and Controlled Substances Amendment (Clinical Trials) Bill 2014.

⁷⁹ Victoria, *Parliamentary Debates*, Legislative Council, 17 September 2014, 3091 (David Davis, Minister for Health).

Poppy cultivation

- 5.72 As discussed in Chapter 4, Victoria recently introduced legislation to permit the cultivation and processing of opium poppies in this state. Victoria's legislation drew upon Tasmania's scheme.
- 5.73 Tasmania has a long-standing and highly productive opium poppy industry. Opium poppies are used to produce valuable alkaloids, such as morphine and codeine, and have been cultivated commercially in Tasmania since the 1960s. There are currently about 800 poppy growers in Tasmania, cultivating around 25,000 hectares of crop annually.⁸⁰
- 5.74 The opium poppy industry is regulated under Commonwealth, state and international law. Ultimate oversight is carried out by the International Narcotics Control Board, which determines annual quotas for poppy production based on international demand.⁸¹
- 5.75 Pursuant to an agreement struck between the Commonwealth and the states in 1971, regulation of the Tasmanian poppy industry is based on a co-operative regulatory partnership between the Commonwealth and the Tasmanian Government. Thus cultivators and producers are subject to both state and Commonwealth laws. At the Commonwealth level, the industry is subject to the obligations in the *Narcotic Drugs Act 1967* (Cth),⁸² and Tasmanian law states that processors must hold a licence under that Act if required.⁸³
- 5.76 It is an offence under Tasmanian law to cultivate, possess or process opium poppies without an appropriate licence granted under the *Poisons Act 1971* (Tas). The decision to grant a licence lies with the Minister for Health, who acts on the advice of the Poppy Advisory and Control Board, a statutory body established under the *Poisons Act*.⁸⁴
- 5.77 Detailed obligations are imposed on growers and processors by way of conditions imposed on the licences granted. Applicants for growing licences are subject to criminal history checks and must supply information about growing sites, employees and so on. Growers must have entered an agreement with a processor, who is separately licensed.⁸⁵
- 5.78 A review of the Tasmanian poppy industry in 2013 recommended a clearer separation between the industry development and regulatory functions in the system. Its recommendations aimed to simplify and streamline the licensing processes and

⁸⁰ Catriona Ross and Marianne Aroozoo, 'Drugs, Poisons and Controlled Substances (Poppy Cultivation and Processing) Amendment Bill 2013' (Research Brief No 3, Parliamentary Library and Information Service, Parliament of Victoria, 2014).

⁸¹ *Ibid.*

⁸² *Ibid.*

⁸³ *Poisons Act 1971* (Tas) s 46.

⁸⁴ *Ibid* s 59H.

⁸⁵ Catriona Ross and Marianne Aroozoo, 'Drugs, Poisons and Controlled Substances (Poppy Cultivation and Processing) Amendment Bill 2013' (Research Brief No 3, Parliamentary Library and Information Service, Parliament of Victoria, 2014).

strengthen the regulatory role of the Poppy Advisory and Control Board.⁸⁶ The Tasmanian Government accepted the recommendations with some minor variations.⁸⁷

Hemp cultivation in other states and territories

- 5.79 Hemp is a type of cannabis which contains very low levels of the psychoactive cannabinoid THC. It has long been used to produce fibre for rope and fabric, and to make hemp oil used in skin products and other cosmetics. It has the potential to be used in the production of high-CBD cannabis derivatives, but is currently not permitted to be sold as a food.⁸⁸ As discussed in Chapter 4, the cultivation of hemp has been permitted under licence in Victoria since 1998. Similar schemes also exist for the licensed cultivation of hemp in New South Wales, Queensland, the Australian Capital Territory, the Northern Territory and Tasmania.
- 5.80 The existence of a considerable hemp industry in Australia (including in Victoria) is relevant to the Commission's review because of the prospect that hemp crops could be used to produce the high-CBD oils of interest to epilepsy researchers.
- 5.81 Much like the poppy-growing scheme, Tasmanian farmers can apply for a licence under section 52 of the *Poisons Act 1971* (Tas), to cultivate industrial hemp. The Tasmanian Government is introducing reforms to simplify the regulation of the hemp industry. Recently, it replaced annual licences with a five year licence, and increased the maximum allowable THC threshold from 0.35 per cent to 1.0 per cent, aligning with New South Wales, Queensland and the Australian Capital Territory.⁸⁹
- 5.82 Cultivation of low-THC hemp fibre is permitted in New South Wales under controlled conditions. A licensing scheme has been established under the *Hemp Industry Act 2008* (NSW).⁹⁰ Under controlled conditions, cultivation, manufacturing and research into alternative uses of low-THC hemp can be carried out. Licence holders are subject to criminal record checks and must demonstrate their suitability to hold a licence.⁹¹
- 5.83 Queensland introduced legislation allowing for the licensing of industrial cannabis crops in 2002.⁹² However, unlike other Australian schemes, the Queensland provisions also permit the cultivation, processing and marketing of cannabis which contains THC in excess of one per cent, for research purposes. The purpose of these provisions is to enable researchers to develop new strains of hemp from plants which may contain more

⁸⁶ John Ramsay & Associates, *Review of the Tasmanian Poppy Industry Regulation Report* (2013) 8 <http://www.justice.tas.gov.au>.

⁸⁷ Department of Justice, Government of Tasmania, *Review of the Tasmanian Poppy Industry Regulation* (23 April 2014) <http://www.justice.tas.gov.au/corporate/reports_and_inquiries/current/tasmanian_poppy_industry_regulation_review>.

⁸⁸ *Australia and New Zealand Food Standards Code*, Standard 1.4.4: Prohibited and Restricted Plants and Fungi.

⁸⁹ *Tasmanian Industrial Hemp Position Statement* 29 January 2015 <<http://dpipwe.tas.gov.au/agriculture/plant-industries/industrial-hemp>>.

⁹⁰ *Hemp Industry Act 2008* (NSW) s 5.

⁹¹ *Ibid* ss 8–9.

⁹² *Drugs Misuse Act 1986* (Qld) Pt 5B.

than one per cent THC.⁹³ High-THC cannabis can only be grown under the supervision of a licenced researcher,⁹⁴ and all activities undertaken under these provisions must be carried out 'other than for the purpose, directly or indirectly, of producing anything for administration to, or consumption or smoking by, a person.'⁹⁵

⁹³ Explanatory Notes to the Drugs Misuse Amendment Bill 2002 (Qld); *Drugs Misuse Act 1986* (Qld) s 45.

⁹⁴ *Drugs Misuse Act 1986* (Qld) ss 50–52.

⁹⁵ *Drugs Misuse Act 1986* (Qld) s 44(b).

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6 International approaches to the legalisation of medicinal cannabis

Introduction

- 6.1 This chapter discusses approaches adopted in international jurisdictions to the treatment of people with medicinal cannabis.
- 6.2 As outlined in Chapter 2, cannabis has long been used for therapeutic purposes, but fell out of favour as a medicine in the 19th and 20th centuries, coinciding with international efforts to prohibit its recreational use. However, since the late 1990s, a number of states and countries overseas have moved to roll back prohibitions on cannabis for patients suffering from serious medical conditions.
- 6.3 A number of international jurisdictions now permit cannabis for medicinal purposes in some form, including:¹
- Canada
 - Czech Republic
 - Finland
 - Germany
 - Israel
 - Italy
 - The Netherlands
 - 23 states of the United States (Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon,

¹ In addition, Jamaica's Parliament recently passed the Dangerous Drugs (Amendment) Bill 2015, which would allow medical users to possess cannabis and for the establishment of a medical marijuana industry. Under the existing law, cannabis preparations (including refined medicinal forms) were legal, while dried cannabis was illegal. At the time of writing the Bill is awaiting the Governor General's assent.

Rhode Island, Vermont and Washington), along with the District of Columbia and Guam.²

- 6.4 A further 12 US states (Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, Virginia and Wisconsin) permit use of low-THC, high-CBD cannabis, in some cases for research and trials only.³
- 6.5 In addition, Uruguay and the US states of Alaska, Colorado, Oregon and Washington have legalised cannabis for recreational use.
- 6.6 The Commission has surveyed a wide range of jurisdictions in the course of preparing this issues paper. While the schemes as a whole defy simple categorisation, when separated into their regulatory components a number of common approaches emerge. In particular, at each part of the process, from the cultivation of cannabis to its use by a patient, jurisdictions overseas adopt a combination of common tools in seeking to achieve their objectives. A consistent theme of the laws considered is the government's desire to maintain control over the production and distribution process, and to maintain a clear distinction between lawful medicinal use, on the one hand, and recreational use (whether lawful or unlawful), on the other.
- 6.7 This chapter is divided according to the key stages of the process at which regulations apply, namely:
- the cannabis products that can be made available
 - who can obtain cannabis
 - production and distribution of cannabis products
 - what role doctors play
 - restrictions on how cannabis can be used.
- 6.8 Finally, this chapter reflects on the experiences of other jurisdictions and how regulations have evolved overseas.

Controlling the product

- 6.9 Many of the overseas jurisdictions that permit access to cannabis for medicinal purposes seek to limit or control the product to which users have access. There are multiple reasons for imposing such restrictions. In some cases the purpose is to prevent diversion

² National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>. While four of these states, Alaska, Colorado, Washington and Oregon (laws commence 1 July 2015) have expanded their programs to permit cannabis to be accessed by all adult users, for any purpose, they have retained their medical marijuana programs.

³ National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015), <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>; Becca Mitchell and Barbara Ciara, 'Governor McAuliffe Signs Bill Allowing Cannabis Oils to Treat Epilepsy', *News Channel 3* (online), 26 February 2015 <<http://wtkr.com/2015/02/26/governor-mcauliffe-signs-bill-allowing-cannabis-oils-to-treat-epilepsy/>>.

of the cannabis to non-authorised users, or to prevent access to psychoactive forms. In others, the restrictions are designed to maintain control over product quality and safety.

- 6.10 The controls that exist in overseas jurisdictions relate both to the types of cannabis that are cultivated and to the forms in which the plant material is made available to eligible users. To a certain extent, governments also indirectly control the products made available by imposing restrictions on who may cultivate cannabis and in what way. These restrictions are discussed below.

Quality control: consistency and contamination

- 6.11 There are concerns that, if unregulated, the quality of cannabis products can vary, and that governments should seek to ensure that products supplied to patients are safe and of a consistent strength.⁴ Products from the illicit market have been observed to contain pesticide and fungicide residues, and even dangerous substances like milled glass, all of which can have a highly detrimental effect on the health of already vulnerable users.⁵ Regulation and licensing systems in some overseas jurisdictions have therefore sought to ensure that patients receive products with predictable effects, without any harmful contaminants.
- 6.12 In the Netherlands, only selected varieties of cannabis are available to purchase for medicinal use. At the time of writing, four types of cannabis were available for sale, sold under the names Bedrobinol, Bedrocan, Bediol and Bedica.⁶ All cannabis is cultivated in the Netherlands under contract to the Office of Medicinal Cannabis by a single, state-licensed supplier, the for-profit corporation Bedrocan BV. Cultivation of the plant is tightly managed, and the company states that it can supply 'a highly standardised product', by ensuring consistency in the genetic make-up and growing conditions of the strains of cannabis it cultivates.⁷ As a result, the Dutch Office for Medicinal Cannabis is able to state on its website the approximate THC and CBD content of each of the four available strains, permitting medical practitioners to determine the appropriate strain and dosage quantities to suit the patient's particular needs,⁸ and allowing patients to control the effect on their body as the product is used.⁹

⁴ See, eg, Katrina Hinschen, 'Health of Mernda Preschooler Cooper Wallace on the Line After Medicinal Cannabis Supply Problems' *Whittlesea Leader* (online), 4 February 2015 <<http://www.heraldsun.com.au/leader>> ; Josh Gordon, 'Bogus medical cannabis putting chronically ill children at risk' *The Age* (online), 28 August 2014 <<http://www.theage.com.au>>.

⁵ Written evidence to the Home Affairs Committee, United Kingdom House of Commons, London, January 2012, (Tjalling Erkelens, co-owner and CEO of Bedrocan Beheer BV, parent company of Bedrocan BV) <<http://www.publications.parliament.uk>>.

⁶ Office of Medicinal Cannabis (Netherlands), *Medicinal cannabis* <www.cannabisbureau.nl/en/MedicinalCannabis>.

⁷ Arno Hazekamp, *An Introduction to Medicinal Cannabis* (self-published, 2013) 4–6. Bedrocan BV cultivates all its cannabis from plants propagated by cloning, ie from 'cuttings', resulting in crops where all plants are genetically identical. However, this alone does not ensure consistent quantities of THC, CBD and other cannabinoids. According to the company, 'even small differences in cultivation conditions may lead to significant changes in the final content of active components'. Bedrocan BV studies and controls the intensity and type of light, plant density, humidity and ventilation, watering schedule, plant nutrition and pest control methods. *Ibid* 4.

⁸ Office of Medicinal Cannabis (Netherlands), *Medicinal Cannabis* <www.cannabisbureau.nl/en/MedicinalCannabis>. New Jersey has adopted a similar approach, limiting distributors to only three strains of cannabis (low, medium and high dose). This limitation is

- 6.13 Cannabis produced for medicinal use in the Netherlands is also closely scrutinised by the government to ensure product safety and consistency. An independent company contracted by the government, Farmalyse, tests each batch of cannabis to ensure it has the desired quantity of cannabinoids. The company also tests the cannabis for the absence of contaminants, such as pesticides, heavy metals, fungi, mould or bacteria. The results of the testing are stated in a 'Certificate of Analysis', which is available for inspection by patients and doctors. The product is also assessed for flower appearance, absence of hair/insects, moisture content and terpene profile.¹⁰
- 6.14 In Canada, producers can grow and supply any strain or type of cannabis. This is a recent change. Prior to 2014, when all cannabis purchased had to be obtained from the government, only one strain of marijuana was available. Each batch would be tested for its THC content, with this content stated on the label. However, patients had no choice regarding the product they were supplied.¹¹
- 6.15 As in the Netherlands, quality is regulated. Canadian producers must test each batch for the percentage of THC and CBD using validated analytical methods, and must print these quantities on the packaging.¹² Microbial and chemical contamination must be within the tolerance limits for herbal medicines generally.¹³ Only approved pesticides may be used in the production of cannabis, whether before, during or after the drying process.¹⁴ If products are found to contain contaminants or their cannabinoid content is incorrectly labelled, the producer must arrange for a product recall.¹⁵

justified as a means of ensuring patients have a reliable and standardised choice of products, and preventing diversion by enabling law enforcement to determine whether cannabis was lawfully distributed. See *Medicinal Marijuana Program Rules*, NJ Admin Code, § 8:64-10.7(a), New Jersey Department of Health and Senior Services, *NJ Admin Code 8:64 - Public Comments and Agency Responses* (2011) 12 <www.state.nj.us/health/medicalmarijuana/documents/final_rules.pdf> (response to comment 21).

⁹ Arno Hazekamp, *An Introduction to Medicinal Cannabis* (self-published, 2013) 5.

¹⁰ *Ibid.*

¹¹ Health Canada, *Policy on Health Canada's Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes* (at 30 November 2009) (no longer in force); Health Canada, *About Health Canada's Marihuana Supply for Medical Purposes* (archived content) (29 July 2013) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apos/supply-approvis-eng.php>>.

¹² *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 66(c)(iii) & (iv).

¹³ *Ibid* s 53(1).

¹⁴ *Ibid* s 54. The allowable pesticides are those registered for use on marihuana under relevant pest control legislation.

¹⁵ A product recall was undertaken by a producer recently in relation to cannabis which contained 50% more THC than stated on its label: 'Health Canada recalls overly potent medical marijuana', *Toronto Sun* (online), 11 February 2015 <<http://www.torontosun.com>>.

- 6.16** In Illinois, which passed laws allowing medicinal cannabis in 2013, highly detailed regulations seek to ensure that all medical cannabis is grown in sanitary environments and that its potency is controlled. Applicants for a cultivation centre licence must submit cultivation, inventory and packaging plans.¹⁶ In selecting applicants for approval, the state must consider their capacity to cultivate cannabis (including product testing) effectively and safely, to maintain a consistent supply and to ensure purity and consistency.¹⁷ Cannabis plants must be cultivated in hygienic environments,¹⁸ and must be stored so as to prevent the growth of microorganisms on the plant.¹⁹ Cultivation centres must have recall procedures in place.²⁰ Only pesticides approved for use on cannabis may be used, and they may be applied only in the early stages of plant growth; records must be maintained for each time pesticides are used.²¹ All products to be sold in Illinois must be registered with the government.²² As in Canada, each batch of product must be tested for quantities of THC and CBD, and for the presence of contaminants, with results to be stated on the product packaging.²³
- 6.17** Jurisdictions in the United States have also turned their attention recently to the safe production of infused products, such as oils and tinctures. Illinois, for example, requires that cannabis-infused food products be manufactured by an approved staff member at the cultivation facility and sold only through dispensaries. Products must also comply with rules regarding packaging and labelling, and products requiring refrigeration or hot-holding may not be sold.²⁴ Specific regulations seek to ensure that manufacture is undertaken in sanitary surroundings.²⁵ Health authorities can conduct inspections of manufacturing areas to ensure compliance,²⁶ and pre-operational inspections are required.²⁷ A certified food services sanitation manager must supervise any cultivation centre where infused products are produced.²⁸

¹⁶ 8 Ill Admin Code § 1000.100(d)(5).

¹⁷ *Ibid* § 1000.110(b).

¹⁸ *Ibid* §§ 1000.400(j) and 1000.410(a).

¹⁹ *Ibid* § 1000.400(11).

²⁰ *Ibid* § 1000.410(c)(1).

²¹ *Ibid* § 1000.470.

²² *Ibid* § 1000.420(a).

²³ *Ibid* §§ 1000.420(d) and 1000.510. An individual package of medical cannabis may contain no more than 100mg of active THC: § 1000.420(f).

²⁴ 410 Ill Comp Stat 130/80(a), 8 Ill Admin Code § 1000.420.

²⁵ 8 Ill Admin Code § 1000.405(d).

²⁶ 410 Ill Comp Stat 130/80(b).

²⁷ 8 Ill Admin Code § 1000.405(e).

²⁸ *Ibid* § 1000.405(h).

Controls on form

6.18 There is wide variation between jurisdictions regarding the forms in which cannabis is made available. Restrictions on form can be motivated by concerns about safety and consistency of the product, and are in some cases intended to restrict the means by which users can self-administer the product.

Bans on edibles and extracts

6.19 In Canada, only dried marijuana (that is, dried flowers and leaves of the cannabis plant) can be possessed by or provided to eligible patients.²⁹ Cannabis resins, oils, extractions and edible marijuana products cannot be sold.³⁰ If children are to use cannabis, they must do so by smoking or vaporising cannabis, as the medical cannabis scheme in place only allows access to dried leaves and flowers.³¹

6.20 However, media reports suggest that patients in Canada nonetheless access preparations such as cannabis oil. In one reported case, a parent seeking access to cannabis oil for her child obtains marijuana through the government program, then ships it to a 'compassionate society', or 'compassion club' which processes it by extracting the active compounds into coconut oil and ships it back to her. The parent then ships it to a laboratory for analysis of the oil's precise CBD and THC content, so that she can control dosage.³² The extraction process is not permitted under Canadian law.

6.21 In August 2014, the British Columbia Court of Appeal held that prohibiting possession of forms other than dried marijuana was unconstitutional.³³ The case arose as a challenge to the prosecution of a man who manufactured cannabis cookies, oils, gels, capsules and ointments as an employee of a 'compassion club', whose members all held authorisations to possess cannabis.³⁴ As the case was brought under the pre-2014 regulations, the Court suspended the effect of the judgment for one year to 'enable the government to enact amendments to the regulatory scheme such that those authorized are permitted to consume cannabis marijuana or its derivatives orally, topically, or by inhalation'.³⁵ The Court suggested that medical practitioners might play a role in

²⁹ Health Canada, *Medical Use of Marihuana* (23 December 2014) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/index-eng.php>>; *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 3.

³⁰ Health Canada, *Medical Use of Marijuana: Frequently Asked Questions* (22 December 2014) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/faq-eng.php>>.

³¹ See *R v Smith* [2014] BCCA 322 (British Columbia Court of Appeal). Although decided under the predecessor to the current regulations, in this respect the new regulations are the same.

³² Marie Danielle-Smith, 'Six-year-old Medical Marijuana User Runs Afoul of Health Canada Rules' *Ottawa Citizen* (online), 16 July 2014 <<http://ottawacitizen.com/news>>.

³³ *R v Smith* [2014] BCCA 322 (British Columbia Court of Appeal).

³⁴ *Ibid* [5]–[7].

³⁵ *Ibid* [143] (Garson JA, with whom Levine JA agreed) (British Columbia Court of Appeal).

allowing patients access to edible and topical forms of cannabis.³⁶ The State has appealed the Court of Appeal's ruling to the Supreme Court of Canada.³⁷

- 6.22 Like Canada, Israel also does not permit certain derivatives. It only allows the sale of cannabis oil and smokeable cannabis (dried plant matter),³⁸ with other edible products not permitted for sale. The government has stated that these products were prohibited so that there is more control over the quantity of cannabinoids consumed by patients, as the baking process leads to the loss of active ingredients.³⁹ Some suppliers continue to sell edibles such as chocolate, sweets and cookies.⁴⁰
- 6.23 The Netherlands does not permit the sale of cannabis oil, edible or other infused products. The Office of Medicinal Cannabis is currently investigating whether to make cannabis oil available.⁴¹

Allowing only non-smokeable forms

- 6.24 Some jurisdictions only permit forms of cannabis which cannot be smoked, such as infusions (oils, foods) and forms which can be vaporised but not smoked. In Minnesota, cannabis supplied for medicinal purposes will only be provided as a liquid (including oils and tinctures), pill or vaporised delivery method that does not require use of the dried plant form of cannabis.⁴² Producers were selected in part based on their ability to supply a variety of cannabinoid compositions to patients.⁴³
- 6.25 Similarly, New York's scheme will permit only approved forms of cannabis, and will not permit smoking as a method of delivery.⁴⁴ The vast majority of US states do not impose such a restriction. The New York legislature justified the limitation in these terms:

³⁶ Ibid [142] (British Columbia Court of Appeal).

³⁷ *R v Smith* (Supreme Court Docket No 36059). The appeal is scheduled to be heard in March 2015. The appeal is as of right, and leave to appeal is not required.

³⁸ The dried plant matter is also packaged inside gel capsules to be taken orally.

³⁹ Dan Even, 'Israel's Health Ministry to Begin Regulating Medical Marijuana' *Haaretz* (online), 19 April 2013 <<http://www.haaretz.com>>.

⁴⁰ Simone Wilson, 'Light-up Nation: What Israel Can Teach America About Medical Marijuana' *Jewish Journal* (online), 2 October 2013 <<http://www.jewishjournal.com>>. See also Tikun Olam, *Edibles* <<http://www.tikun-olam.info/Edibles>>.

⁴¹ Email from Catherine Sandvos, Office of Medicinal Cannabis, The Hague, Netherlands, to Sharyn Broomhead, 20 February 2015.

⁴² Minnesota Department of Health, *General Information about the Minnesota Medical Cannabis Program* <<http://www.health.state.mn.us/topics/cannabis/overview/factsheet.html>>; Minn Stat § 152.22(6) (2014). As medical marijuana products will not be made available to patients until 1 July 2015, there is no information available regarding the success or otherwise of this limited approach.

⁴³ Minnesota Department of Health, *Medical Cannabis Manufacturer Selection Questions and Answers*, question PD13 <<http://www.health.state.mn.us/topics/cannabis/manufacture/selection/mfrqa.html>>.

⁴⁴ New York State Department of Health, *About the Medical Marijuana Program: Frequently Asked Questions* (October 2014) <https://www.health.ny.gov/regulations/medical_marijuana/faq.htm>. As with Minnesota, the New York scheme is yet to commence, so the practicability of this approach cannot be assessed.

The negative health consequences of smoking of marijuana are well-established. ... In addition to its direct negative effects on users' health, the widespread smoking of medical marijuana has the potential to undermine New York State's decades-long and successful effort to decrease smoking more broadly. However well-intentioned, any effort that reduces the stigma associated with smoking, and that has the potential to lead to an increase in smoking rates among New Yorkers, especially young New Yorkers, presents an unwarranted public health risk. This legislation would avoid that risk.⁴⁵

Allowing only low-THC cannabis

6.26 As mentioned earlier, a number of US states permit access to cannabis for medicinal purposes, but only allow patients to possess products which have low levels of THC, or low levels of THC and high levels of CBD.⁴⁶ In almost all cases, these states allow only patients suffering from epilepsy or other seizures to access the products.⁴⁷ In South Carolina, the only permitted forms are extracts (such as oil) produced in an approved laboratory, containing at least 98 per cent CBD and no more than 0.9 per cent THC, and access is limited to patients participating in a clinical trial.⁴⁸ Alabama, Iowa, Mississippi and Utah also permit only extracts to be provided.

Restricting access to those in need

6.27 Many jurisdictions have grappled with the question of how to define the categories of patients who should be permitted to access cannabis for medicinal purposes, resulting in diverse approaches. In some jurisdictions, policymakers have been quite explicit in demarcating who is to have access to medicinal cannabis, for example by identifying in legislation the list of conditions for which cannabis should be available. In other jurisdictions, the decision whether to allow a patient access to cannabis for medicinal purposes is entirely in the hands of a health practitioner. Some jurisdictions define eligibility according to the symptoms a patient experiences, or how they have responded to conventional (that is, non-cannabis) treatments.

Eligibility based on conditions and symptoms

Condition-based models

6.28 A number of jurisdictions list the specific conditions for which medicinal cannabis products may be made available, particularly in the United States. For example,

⁴⁵ Sponsor's Memo, *Compassionate Care Act*, A 6357 (2013).

⁴⁶ National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>. The scope of products allowed differs, with 'low THC' set at various points between 0.3 and 3%, and 'high CBD' set between 5 and 10%. Some states require that the product not be 'psychoactive'.

⁴⁷ National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>.

⁴⁸ *Medical Cannabis Therapeutic Treatment Research Act*, SC Code Ann §§ 44-53-110(27) and 44-53-1810–1840. Mississippi allows access to similar extracts.

Connecticut,⁴⁹ Hawaii,⁵⁰ Illinois,⁵¹ Massachusetts,⁵² Minnesota⁵³ and other states name in legislation those conditions that qualify a patient for access to medical marijuana.

- 6.29 Israel also limits access to patients who are suffering from one of a list of conditions, and in some cases requires that other treatments be tried before cannabis is supplied.⁵⁴ For some patients, such as the terminally ill and those undergoing chemotherapy, cannabis is available to all who are within the category. For certain conditions (for example, Crohn's disease and cancer), the patient must have failed to respond to conventional treatments, while for others (for example, Parkinson's disease, multiple sclerosis and Tourette's syndrome) the patient must have sufficiently severe symptoms *and* have failed to respond to treatment. In the case of neuropathic pain, the patient must have been treated at a recognised pain clinic for at least one year and have exhausted conventional options before access will be allowed.⁵⁵ Note that Vermont and Washington adopt a similar approach to pain, requiring that it be intractable and non-responsive to alternative treatments.⁵⁶

Symptom-based models

- 6.30 Some jurisdictions describe eligible patients according to the symptoms they experience. For example, in Maryland, the statute 'encourages' the authorising authority to make medicinal cannabis available to patients with any 'chronic or debilitating disease or medical condition' which results in them being placed in hospice/palliative care, or results in wasting, severe pain, severe nausea, seizures, or severe/persistent muscle spasms, regardless of the specific underlying cause. In addition, the authority may permit use by patients who do not experience the listed symptoms but rather suffer from another severe condition for which other medical treatments have been ineffective, 'if the symptoms reasonably can be expected to be relieved by the medical use of marijuana'.⁵⁷

⁴⁹ Conn Gen Stat, § 21a-408.

⁵⁰ Haw Rev Stat, § 329-121 (definition of 'debilitating medical condition').

⁵¹ 410 Ill Comp Stat 130/10(h).

⁵² *An Act for the Humanitarian Medical Use of Marijuana*, 2012, No 369, § 2(C), 2012 Mass Acts 369.

⁵³ Minn Stat § 152.22(14).

⁵⁴ Ruth Levush, 'Israel: New Directives on Use of Marijuana for Medical Purposes', *Library of Congress—Global Legal Monitor* (online) 6 January 2014 <<http://www.loc.gov/lawweb>>.

⁵⁵ Tikun Olam, Indications <<http://www.tikun-olam.info/Indications>>.

⁵⁶ Sue O'Connell, *Emerging Issue: Medical Marijuana - Variations Among State Laws.*, Montana Legislature Children, Families, Health and Human Services Subcommittee on Medical Marijuana, Paper (August 2010) <http://leg.mt.gov/content/Committees/Interim/2009_2010/Children_Family/Emerging-Issue/variations-among-state-laws-aug12.pdf>.

⁵⁷ Md Code Ann, Health - General § 13-3307(c) (Lexis).

Hybrid models

- 6.31 A number of jurisdictions adopt a test which is a hybrid of conditions and symptoms. In Oregon, for example, patients must suffer from one of a list of conditions (cancer, HIV/AIDS, PTSD etc), or be presently affected by a condition or treatment which produces one or more of a list of symptoms (seizures, severe pain, severe nausea, etc).⁵⁸
- 6.32 Prior to its replacement, Canada's Marihuana Medical Access Program required patients to possess a symptom in one of two categories:

Category 1 Symptoms

Any symptom treated within the context of compassionate end-of-life care; or

Symptoms related to specific medical conditions, namely:

- Severe pain and/or persistent muscle spasms from multiple sclerosis
- Severe pain and/or persistent muscle spasms from a spinal cord injury
- Severe pain and/or persistent muscle spasms from a spinal cord disease
- Severe pain, cachexia, anorexia, weight loss, and/or severe nausea from cancer
- Severe pain, cachexia, anorexia, weight loss, and/or severe nausea from HIV/AIDS infection
- Severe pain from severe forms of arthritis
- Seizures from epilepsy

Category 2 Symptoms

A debilitating symptom that is associated with a medical condition or with the medical treatment of that condition, other than those described in Category 1.⁵⁹

- 6.33 Both Category 1 and Category 2 symptoms were sufficient to support patient access to medicinal cannabis.⁶⁰ These categories have been replaced by a system of authorisation entirely at the medical practitioner's discretion. Canadian practitioners supported this change because determining that a patient qualified required consultation with a specialist, which often took a considerable amount of time.⁶¹
- 6.34 In addition, some jurisdictions require the practitioner to consider whether cannabis will be an appropriate treatment for the patient in the circumstances. For example, in Alaska, the authorising practitioner must state that he or she has considered alternative medications and treatments that are reasonably available to and could be tolerated by

⁵⁸ Oregon Health Authority, *Medical Marijuana Program - Physicians* <<http://public.health.oregon.gov>>.

⁵⁹ Health Canada, *How to Apply for Marihuana for Medical Purposes—Are you Eligible?* (archived content) (30 July 2013) <<http://hc-sc.gc.ca/dhp-mps/marihuana/how-comment/eligible-admissible-eng.php>>. Earlier versions of the Canadian model used differently structured lists of conditions and symptoms.

⁶⁰ Health Canada, *How to Apply for Marihuana for Medical Purposes—Are you Eligible?* (archived content)(30 July 2013) <<http://hc-sc.gc.ca/dhp-mps/marihuana/how-comment/eligible-admissible-eng.php>>.

⁶¹ Health Canada, *Medical Marihuana Regulatory Reform 2011 Consultations Results* (archived content) (31 January 2013) <http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-eng.php>.

the patient, and has concluded that the patient 'might benefit from medical marijuana'.⁶²

Expanding the list as evidence emerges

- 6.35 While some jurisdictions using a 'list' model leave expansion of eligibility to the legislature, many jurisdictions permit the executive to add and/or remove conditions from eligibility as new evidence becomes available.⁶³ In some cases there are requirements that must be satisfied before a condition is added, or an expert panel/commission is involved in the decision. In Illinois, for example, citizens may petition for new conditions to be listed, and the state may receive submissions and hold public hearings in determining whether to add the condition.⁶⁴
- 6.36 In Colorado, physicians and patients can petition the state to add conditions. Upon receipt of a petition, a government official conducts searches of the medical literature for 'peer-reviewed published literature of randomized controlled trials or well-designed observational studies' regarding the use of medical marijuana for the condition. The petition must be denied summarily if any of the following circumstances exist:
- no such studies have been conducted
 - the studies that have been conducted showed harm to the patients and there are conventional treatments available
 - the condition is already captured by the listed symptoms.
- 6.37 If the petition is not denied summarily, it is referred to a scientific advisory panel for consideration. An ad hoc member can be appointed with expertise in the specific area under consideration and the panel may hold hearings in the course of making its decision.⁶⁵ Notably, since the Colorado medicinal cannabis program commenced in 2001, no new conditions have been added to the eligibility list. However, a number of petitions have been denied, including for conditions which are eligible in other jurisdictions, such as Crohn's disease, Hepatitis C, PTSD and Tourette's syndrome.⁶⁶

At the discretion of a health practitioner

- 6.38 Canada now permits a health practitioner to approve any patient for access to cannabis for medicinal purposes. However, physicians' colleges in the various Canadian provinces

⁶² Alaska Stat § 17.37.010(c)(1)(C).

⁶³ For example, Illinois (410 Ill Comp Stat 130/45); Maine (*Rules Governing the Use of the Maine Medical Use of Marijuana Program*, 10-144 Me Code R Ch 122 § 3.2).

⁶⁴ 410 Ill Comp Stat 130/45.

⁶⁵ 5 Code Colo Regs § 1006-2-6(D) and (E).

⁶⁶ Colorado Department of Health and Environment, *Debilitating Conditions for Medical Marijuana Use* (2013) <https://www.colorado.gov/pacific/sites/default/files/CHEIS_MMJ_Debilitating-Medical-Conditions.pdf>.

constrain practitioners through guidelines and policies. The rules imposed include:⁶⁷

- requiring that the practitioner state in the authorisation document that other treatments have been tried but were unsuccessful
- requiring that the practitioner assess the patient's risk of addiction prior to authorising their access
- limiting practitioners to a new list of conditions
- requiring practitioners to authorise a patient's access only when they have the necessary clinical knowledge to engage in a meaningful discussion about consent with them.

6.39 In the Netherlands, the decision regarding which patients will be permitted to access medicinal cannabis is also entirely at the doctor's discretion. Certain conditions are noted as being assisted by cannabis, but doctors are not restricted to this list.⁶⁸

Licensing and registration

6.40 A large number of jurisdictions require patients to obtain ID cards before they can claim the benefit of protections aimed at medicinal cannabis users. Many US states alternatively or additionally require that the patient be registered in a searchable, electronic database of approved patients.

6.41 Issuing patients with an ID card enables them to prove to suppliers, employers and law enforcement officers that they are eligible to possess and use medicinal cannabis. A majority of jurisdictions in the United States issue patients with ID cards, and some issue them to caregivers as well. Those that do not issue ID cards on the whole still require registration, or for patients to prove their eligibility through other means (for example, a document signed by their medical practitioner).⁶⁹

6.42 Some states require patients to register through a web-based system.⁷⁰ These systems allow law enforcement officials and others to verify the patient's registration status. In Arizona, all patients are registered on the web-based registry, and have QR codes⁷¹ printed on their ID cards that are linked to their registration details. Law enforcement

⁶⁷ Canadian Medical Protective Association, *Medical marijuana: New regulations, New College Guidance for Canadian Doctors* (document number W14-005-E, October 2014) <<https://www.cmpa-acpm.ca>>.

⁶⁸ Office for Medicinal Cannabis, *Doctors & pharmacists: Grounds for use* <<http://www.cannabisbureau.nl/en/>>.

⁶⁹ Alaska, Arizona, California, Colorado, Connecticut, District of Columbia, Delaware, Maryland, Michigan, Nevada, New Hampshire, New Mexico, New York, Oregon, Rhode Island and Vermont all issue ID cards to eligible patients. Some jurisdictions, while offering ID cards, allow patients with genuine conditions but no ID card to assert certain defences, but the prevailing approach is to require registration. Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 9–11.

⁷⁰ Arizona's system is discussed here by way of example, but other states, such as Illinois, also have electronic verification systems.

⁷¹ 'Quick Response' code, a type of two-dimensional barcode.

officials, employers and dispensaries have access to an online portal⁷² where they can search for registered users after logging in. They can then view the amount of marijuana obtained by the patient in the past 60 days, and whether the patient is authorised to grow cannabis (employers have more limited access).⁷³

- 6.43 Many jurisdictions also require that the government assess the patient's eligibility to access cannabis—merely having the approval of a health practitioner is not enough. At this stage, registration may be refused if the patient is not a resident of the jurisdiction,⁷⁴ or the application or supporting documents have been falsified.⁷⁵ Registration may be revoked in the event of non-compliance, for example, if the patient sells their supply of cannabis to a non-eligible person.⁷⁶
- 6.44 In Canada, patients must possess an authorisation from their medical practitioner before they can access the medicinal cannabis program. After obtaining such an authorisation, they are required to register with their chosen producer, by sending the producer the original version of their practitioner's approval (a patient can only be registered with one producer). There is no separate requirement to register with the government. Proof of eligibility is demonstrated to law enforcement by showing either the package label or the shipping documentation.⁷⁷

Authorising treatment of children

- 6.45 Different considerations are often applied to the authorisation of supply of medicinal cannabis to children. In Maine, for instance, the government may not authorise a child to access medicinal cannabis unless:
- the child's doctor has explained the potential risks and benefits of the medicinal use of cannabis to the child and his or her parent/guardian and
 - the parent/guardian consents in writing to the child using cannabis, to serve as the child's primary caregiver, and to control the acquisition of cannabis, along with its dosage and frequency of use by the child.⁷⁸

⁷² Accessed at <https://azmmvs.azdhs.gov/>.

⁷³ Arizona Department of Health Services, *Arizona Medical Marijuana Program: ID Card Verification—Law Enforcement* (16 January 2015) <<http://www.azdhs.gov/medicalmarijuana/>>; Ariz Rev Stat Ann, §§ 36-2806.02 and 36-2807.

⁷⁴ See, eg, 5 Code Colo Regs § 1006-2-2(F)(4); Conn Agencies Regs § 21a-408-6; Md Code Ann, Health - General § 13-3301(k) (Lexis).

⁷⁵ See, eg, 5 Code Colo Regs § 1006-2-2(F); 410 Ill Comp Stat 130/65(a)(4); 22 Me Rev Stat Ann § 2425(3); Minn Stat § 152.27(6)(a)(5).

⁷⁶ See, eg, Maine: 22 Me Rev Stat Ann § 2425(9).

⁷⁷ Health Canada, *How to Access Dried Marijuana for Medical Purposes Under the Marihuana for Medical Purposes Regulations* (29 August 2014) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/access-acceder-eng.php>>; *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 125.

⁷⁸ 22 Me Rev Stat Ann § 2425(2).

Production and distribution

6.46 The problem of how medicinal cannabis should be grown lawfully has been a consistent challenge for policymakers in other jurisdictions. Some jurisdictions with medicinal cannabis laws have chosen to avoid large-scale production in favour of ‘grow your own’ models, whereby eligible patients or their caregivers can cultivate their own personal supply of medicinal cannabis. Other jurisdictions have made cultivation the responsibility of the government, or a few government-licensed growers. Cannabis products are in some cases imported, either as the sole source of product or in addition to a locally produced supply.

‘Grow your own’ models

6.47 ‘Grow your own’ models are a commonly implemented solution to the question of how cannabis supplied to eligible patients should be cultivated, particularly in the United States. Where patients are permitted to cultivate their own supply, the law will generally state the maximum number of mature plants they are permitted to possess (ranging between two and six plants, with extra allowances for seedlings).⁷⁹ A number of states, but not all, require that the patient be registered with the state or hold an ID card in order to be permitted to grow cannabis.⁸⁰ In Arizona, patients are only permitted to grow their own supply if they are sufficiently geographically distant (at least 25 miles) from a licensed dispensary.⁸¹

6.48 Many American states also allow a caregiver or designated grower to grow cannabis on the patient’s behalf.⁸² To control the risk that this system could be misused to grow cannabis for non-medicinal purposes or to divert excess supply to recreational use, some states have introduced additional restrictions on growers and caregivers. In Oregon, for example, where a patient can designate a grower to grow cannabis on their behalf, each grower can grow for up to four patients. Cannabis grown by a caregiver or grower is the property of the patient. Caregivers and growers are prohibited from charging the patient for the cannabis supplied, but can be reimbursed for operating costs. Both are prohibited from consuming any of the cannabis they grow, and patients may only share excess cannabis with other registered patients.⁸³ Notwithstanding these restraints, media reports have asserted that there is widespread illicit trafficking of cannabis grown in Oregon for medicinal purposes. As designated growers are able to produce much more

⁷⁹ For example, California has a maximum of six mature or 12 immature plants (Cal Health & Safety Code §§ 11362.77); Oregon has a maximum of six mature and 18 immature plants (Or Rev Stat § 475.320); Vermont permits a maximum of two mature and seven immature plants (18 Vt Stat Ann § 4472(10)).

⁸⁰ ID cards must be possessed by growers in Oregon (Or Rev Stat § 475.320) and Vermont (18 Vt Stat Ann § 4474b); Licences are not required in California (Cal Health & Safety Code §§ 11362.5 and 11362.71(f)).

⁸¹ Ariz Rev Stat Ann § 36-2804.02(A)(f).

⁸² For example, California (Cal Health & Safety Code § 11362.5), Oregon (Or Rev Stat § 475.320); Vermont (18 Vt Stat Ann § 4474).

⁸³ Oregon Government, *Oregon Medical Marijuana Act—Frequently Asked Questions*, <http://www.oregon.gov/osp/des/docs/med_mj_patient_info.pdf>.

dried cannabis than their patients are permitted to possess, a large trade has developed whereby they sell the excess supply onto the illicit market, both in Oregon and other states.⁸⁴

- 6.49 Under Canada's previous regulatory system, the Marihuana Medical Access Program, eligible patients could purchase cannabis grown by the federal government or apply for a licence to grow cannabis for their own personal use, by themselves or through a caregiver. The licence set the maximum number of plants the patient would be permitted to grow. Licence-holders could purchase seeds from the government, but on a 'one time only' basis, and at a set ratio to the maximum number of plants stated in the licence (three seeds: one plant).⁸⁵
- 6.50 The use of 'grow your own' licences in Canada attracted strong criticism. While the scheme was intended to permit only 'backyard garden' cultivation of cannabis, in practice the licences were relied upon to create commercial, large-scale cultivation facilities in residential premises.⁸⁶ Law enforcement authorities considered that the model led to the diversion of cannabis grown for medicinal purposes to the illicit market, and increased the risk of home invasion. The cultivation of cannabis in people's homes was believed to pose electrical and fire safety risks, and to jeopardise public health by leading to excess mould and poor air quality in homes where cannabis was grown.⁸⁷ As a result, the Canadian government phased out 'grow your own' licences (and delegation of such licences to others) in 2014.⁸⁸
- 6.51 While, under this previous regime, Canada implemented a system for supplying patients with seeds, enabling them to cultivate cannabis legally, this has not been the case in all the American states where patients may lawfully grow their own cannabis. Several states permit patients to grow cannabis, but refuse to provide seeds to start their crop. As the exemptions to the law relate only to plants and dried marijuana, patients must purchase seeds illegally in order to start their crop.⁸⁹

⁸⁴ Noelle Crombie, 'Drug Traffickers Exploit Oregon Medical Marijuana Program's Lax Oversight and Loose Rules', *The Oregonian* (online), 22 September 2012 <<http://www.oregonlive.com>>.

⁸⁵ Health Canada, *About Health Canada's Marihuana Supply for Medical Purposes* (archived content) (29 July 2013) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/supply-approvis-eng.php>>; *Policy on Health Canada's Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes* (at 30 November 2009) (no longer in force).

⁸⁶ John A Fowler, 'Allard v. Canada (Health Canada): Why the Injunction Is Good for the Medical Marijuana Business' (2014) 35 *Health Law In Canada* 54, 55.

⁸⁷ Health Canada, *Medical Marihuana Regulatory Reform 2011 Consultations Results* (archived content) (31 January 2013) <http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-eng.php>.

⁸⁸ A constitutional challenge was brought to the decision to abolish 'grow your own' licences: *Allard v Canada* [2014] FC 280. Without deciding the merits of the case, on 21 March 2014 a judge of the Federal Court of Canada granted the plaintiffs an interlocutory injunction, which had the effect of continuing existing licences until the date of final decision. As no decision has been yet handed down, it remains possible for existing licence-holders to continue to grow their own cannabis for medicinal purposes. See John A Fowler, 'Allard v. Canada (Health Canada): Why the Injunction Is Good for the Medical Marijuana Business' (2014) 35 *Health Law In Canada* 54, 54–56.

⁸⁹ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) vii.

Government-controlled cultivation

Sole government-authorised plantation

- 6.52 In the Netherlands, all cannabis used for medicinal purposes is grown by a single, for-profit, state-licensed company, Bedrocan BV, which operates under contract to the Office of Medicinal Cannabis.⁹⁰ The grant of a licence requires security screening, review of financial reports, and consideration of the likelihood of illegal diversion.⁹¹ While it is possible for other companies to be licensed to grow cannabis in the Netherlands,⁹² at present only one company is licensed. Bedrocan exports medicinal cannabis to Canada, the Czech Republic, Finland, Germany and Italy, among other nations, but all export is conducted through the Office of Medicinal Cannabis.⁹³
- 6.53 Prior to the 2014 revision of its laws, cannabis for medicinal purposes was sold exclusively in Canada by the federal government (which, as discussed above, also granted licences to individual patients to grow their own supply). Marijuana was cultivated and harvested by Prairie Plant Systems, under contract to Health Canada.⁹⁴

Using existing government institutions

- 6.54 Several states in the United States have legislated to allow access to high-CBD cannabis oil for the treatment of epilepsy. Twelve states passed legislation in 2014-2015 permitting production and administration of low-THC primarily for sufferers of intractable seizure disorders or epilepsy.⁹⁵ In many cases, the laws permit use only in the context of research or trials.⁹⁶ In Mississippi⁹⁷ and Tennessee,⁹⁸ the government intends to obtain cannabis oil from crops grown by state universities. The University of Mississippi currently holds the only federal licence to cultivate cannabis for drug research, and the state of Mississippi intends to utilise its facilities in support of its medicinal

⁹⁰ Office of Medicinal Cannabis, *Medicinal Cannabis* <www.cannabisbureau.nl/en/MedicinalCannabis>. A second producer was previously licensed, but was unable to supply cannabis of sufficient quality.

⁹¹ *Policy Guidelines Opium Act Exemptions*, Regulation of the Minister of Health, Welfare and Sport (9 January 2003) GMT/BMC 2340685, s 5.

⁹² *Ibid.*

⁹³ Bedrocan Canada, 'Bedrocan Receives License Renewal from Health Canada' (media release, 3 December 2014).

⁹⁴ Health Canada, *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013) 11 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

⁹⁵ National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>; Becca Mitchell and Barbara Ciara, 'Governor McAuliffe Signs Bill Allowing Cannabis Oils to Treat Epilepsy', *News Channel 3* (online), 26 February 2015 <<http://wtkr.com>>.

⁹⁶ National Conference of State Legislatures, *State Medical Marijuana Laws* (29 January 2015) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>.

⁹⁷ Scott Simmons, 'Gov Bryant Signs Bill to Allow Form of Medical Marijuana', *WAPT News* (online), 17 April 2014 <<http://www.wapt.com>>.

⁹⁸ Jason Lamb, 'Tennessee Tech Makes Preparations To Legally Grow Medical Marijuana', *News Channel 5* (online), 23 April 2014 <<http://www.jrn.com/newschannel5>>.

cannabis program.⁹⁹ Tennessee Technical University does not currently hold a federal licence, but intends to seek one so that it can also cultivate cannabis.¹⁰⁰

- 6.55** Italy also appears set to make use of an existing state institution to grow cannabis. Cannabis was made legal for medicinal purposes in Italy in 2007, but relying on importation as the source of cannabis has meant that costs are high (ten times the cost of equivalent product on the illicit market) and probably as a result participation rates are very low. As an alternative, the government has announced that it will make use of a military laboratory currently used to make 'orphan drugs' to produce medicinal cannabis. It does not intend to allow private companies to cultivate cannabis for medicinal purposes. The army is expected to receive assistance from a scientist who currently grows cannabis for research purposes, under licence from the government.¹⁰¹

Licensed use for clinical/research purposes

- 6.56** As mentioned above, the University of Mississippi holds a federal licence to cultivate and administer cannabis for the purpose of conducting medical research. The University has cultivated, harvested and processed cannabis under contract to the National Institute on Drug Abuse since 1968, and ships dried cannabis to researchers around the United States.¹⁰²
- 6.57** Some of the cannabis grown in Mississippi is supplied to patients through the Food and Drug Administration's Single Patient Investigational New Drug Program, pursuant to a 1976 settlement agreement in litigation brought by a glaucoma sufferer.¹⁰³ Under the program, the United States government supplied cannabis cigarettes to 20 people suffering from debilitating diseases.¹⁰⁴ While the program was closed to new patients in 1991, four patients were continuing to receive cannabis under this program as at 2011.¹⁰⁵
- 6.58** GW Pharmaceuticals manufactures its cannabis-derived drug Sativex from cannabis grown in the United Kingdom. GW was granted a licence under the *Misuse of Drugs Act 1971* (UK) in 1998, to undertake a research and development program into cannabis and the chemical compounds it contains. The program was to include development of

⁹⁹ University of Mississippi National Center for Natural Products Research, *Cannabis Research* <<http://pharmacy.olemiss.edu/ncnpr/research-programs/cannabis-research>>.

¹⁰⁰ Jason Lamb, 'Tennessee Tech Makes Preparations To Legally Grow Medical Marijuana', *News Channel 5* (online), 23 April 2014 <<http://www.jrn.com/newschannel5>>.

¹⁰¹ Steve Schere, 'To Grow Cheap Marijuana, Italy Calls in the Army', Reuters (online), 12 October 2014 <www.reuters.com>; Steve Scherer, 'Secure Italian Military Lab to Grow Medical Marijuana' Reuters (online), 18 September 2014 <www.reuters.com>

¹⁰² Mike Ahlers and Jeanne Meserve, 'Government Runs Nation's Only Legal Pot Garden', *CNN* (online) 18 May 2009 <<http://edition.cnn.com>>.

¹⁰³ Mohamed Ben Amar, 'Cannabinoids in Medicine: A Review of Their Therapeutic Potential' (2006) 105 *Journal of Ethnopharmacology* 1, 2.

¹⁰⁴ *Ibid.*

¹⁰⁵ '4 Americans Get Medical Pot from the Feds', *Associated Press* (online), 28 September 2011 <<http://www.cbsnews.com/news>>.

standardised extracts of cannabis and to explore delivery methods other than smoking.¹⁰⁶ Cannabis is designated under section 7(4) of the *Misuse of Drugs Act 1971* (UK), meaning that its production, possession and supply are unlawful except for 'research or other special purpose'.¹⁰⁷ Sativex has now been approved for sale in a number of countries, and is manufactured on a commercial scale. GW continues to cultivate cannabis for the production of Sativex in England under a Home Office licence,¹⁰⁸ and it appears likely that the purpose of this licence remains medical research;¹⁰⁹ however, there has been no clear statement by the United Kingdom government as to the nature of the licence held by GW.¹¹⁰ GW is responsible for all steps in the Sativex supply chain.¹¹¹

- 6.59 Kentucky, which in 2014 passed a law giving epilepsy and seizure patients access to high-CBD oil, plans to source the oil from industrial hemp crops. The state recently reintroduced hemp cultivation for research purposes, and intends to draw on this supply to produce the oil, which at this stage may only be prescribed by doctors working in the state's two university research hospitals.¹¹² Farmers may apply to the state to participate

¹⁰⁶ GW Pharmaceuticals, 'Home Office Licenses Research into Medical Uses of Cannabis' (press release, 11 June 1998) <<http://www.gwpharm.com>>.

¹⁰⁷ See *Misuse of Drugs (Designation) Order 2001* (UK), Sch. Under the *Misuse of Drugs Regulations 2001* (UK), the Secretary of State can issue a licence to cultivate cannabis (regulation 12) or a licence to produce, supply, offer to supply or possess a controlled drug, such as cannabis (regulation 5).

¹⁰⁸ GW Pharmaceuticals, 'GW Pharmaceuticals Cannabinoid-Medicine Sativex Moved to Schedule 4 of UK Drugs Act' (Press Release, 10 April 2013) <<http://www.gwpharm.com>>. ('[Sativex is m]anufactured under Home Office licence at an undisclosed location in the UK'.)

¹⁰⁹ An FOI release regarding the first ten cannabis licences issued in 2010 reveals that, of these, seven are irrelevant as relating to hemp, one is to 'enable the activities associated with medical research to further the development of a cannabis based medicine' and the remaining two are to allow cultivation and possession of cannabis in connection with the same research. In other words, it appears that, of the first ten licences granted in 2010, the only ones relating to non-hemp cannabis were to enable medical research. United Kingdom Home Office, 'Purpose of first ten cannabis licences granted in 2010' (FOI Release 18992, 11 July 2011) <<https://www.gov.uk/government/publications/>>. In the period 2010-2013, five licences were granted for the cultivation of high-THC cannabis in England and Wales, but it is not known to whom: United Kingdom Home Office, 'Licences Granted for Cultivation of THC Cannabis Plants, 2010 to 2013' (FOI Release 29795, 11 February 2014) <<https://www.gov.uk/government/publications/>>.

¹¹⁰ A number of freedom of information requests have been submitted to the UK Home Office by private individuals seeking information regarding the nature of the cultivation licence held by GW Pharmaceuticals: WhatDoTheyKnow, *Search results for 'GW Pharmaceuticals'* <<https://www.whatdotheyknow.com/search/gw%20pharmaceuticals/all>>. A response dated 16 December 2011 to one such request declined to supply copies of the licences held by GW, on the basis that release of the information could prejudice GW's commercial interests or make them the target of criminal activity. Letter from Lee Smith, Drugs Licensing and Compliance Unit, United Kingdom Home Office to Peter Reynolds, 16 December 2011 <https://www.whatdotheyknow.com/request/details_of_gw_pharmaceuticals_li>.

¹¹¹ GW Pharmaceuticals, 'GW Receives Commercial Manufacturing Licence for Sativex' (Press Release, 16 July 2009) <<http://www.gwpharm.com>>.

¹¹² Adam Beam, 'Beshear signs cannabis oil bill', *Associated Press* (online), 10 April 2014 <<http://www.cincinnati.com>>. Senate Bill 50 of 2013 exempted industrial hemp from being a controlled substance for the purpose of Kentucky law, while the Federal Farm Bill of 2014 made the necessary changes to federal law to allow industrial hemp farming for research purposes: Kentucky Department of Agriculture, *Industrial Hemp Program* <<http://www.kyagr.com/marketing/hemp-pilot.html>>.

in the research program (which includes research of high-CBD oil among its objectives).¹¹³

Vertically integrated cultivation and distribution

- 6.60 In a number of the jurisdictions considered, local laws require the cultivation and distribution of cannabis to be carried out by a single licensed entity. This model is found in 11 US states, where single cultivation and distribution licences or registrations are granted. These entities are often referred to as 'dispensaries'.¹¹⁴
- 6.61 Under Canada's current scheme, the country's medicinal cannabis supply is grown entirely by licensed producers. Only licensed producers are permitted to sell cannabis to patients. There are currently 23 licensed producers, of which 15 are permitted to sell to patients.¹¹⁵ Two licensed producers are listed on the Canadian stock exchange.¹¹⁶ Licensed producers distribute medical marijuana directly to patients. They must do so by shipping the product directly to their clients (or their medical practitioner), and are not permitted to operate a storefront.¹¹⁷ Licensed producers are subject to government inspection, and Health Canada can suspend or revoke licences if remedial action is not taken in response to adverse findings.¹¹⁸
- 6.62 The vertically integrated producers found in many United States jurisdictions share a number of common features. To ensure vertical integration, the licensed producers are often prohibited from purchasing cannabis from anyone other than another licensed producer,¹¹⁹ and may be required to produce a minimum amount of the cannabis they sell 'in house'.¹²⁰ Cultivation is often required to occur at the retail site or a second secure, registered location.¹²¹ Jurisdictions often cap the maximum number of

¹¹³ Kentucky Department of Agriculture, Industrial Hemp Program <<http://www.kyagr.com/marketing/hemp-pilot.html>>.

¹¹⁴ Arizona, Delaware, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Rhode Island and Vermont all issue a single licence for cultivation and production, meaning that producers sell directly to patients: Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 14–15.

¹¹⁵ Health Canada, *List of Authorized Licensed Producers under the Marihuana for Medical Purposes Regulations* (19 February 2015) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/list-eng.php>>.

¹¹⁶ Tommy Humphreys, 'A weed deal with merit, coiled for mid-August stock market debut', CEO.CA (online), 1 August 2014 <<http://ceo.ca>>.

¹¹⁷ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 122.

¹¹⁸ Health Canada, *List of Authorized Licensed Producers under the Marihuana for Medical Purposes Regulations* (19 February 2015) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/list-eng.php>>.

¹¹⁹ Arizona (can also receive 'donations' of cannabis from patients and caregivers: Ariz Rev Stat Ann, § 36-2806); Colorado (Colo Rev Stat § 12-43.3-402); Delaware (16 Del Code Ann § 4914A(g)), Vermont (18 Vt Stat Ann § 4474e(k)(1)(B)).

¹²⁰ See, eg, Colorado (producers must themselves cultivate at least 70% of the marijuana they sell: Colo Rev Stat § 12-43.3-402(4)).

¹²¹ See, eg, Arizona (must be at one or other of the two: Ariz Rev Stat Ann § 36-2804(B)(1)(ii)), Delaware (16 Del Code Ann § 4919A(f)), Maine (22 Me Rev Stat Ann, § 2428(2)(A)(3)), Vermont (18 Vt Stat Ann § 4474f(a)(1)).

producers,¹²² and select licensees through a competitive process.¹²³ In many locations, some or all of the licensed producers must be run on a 'not for profit' basis.¹²⁴ Licences can be suspended or revoked as a result of violations.¹²⁵

- 6.63** In Vermont and Maine, the vertically integrated production regimes in place are similar to Canada's, in that patients may only be supplied by one producer at a time. Following registration, patients must designate a chosen producer (dispensary), and must obtain cannabis exclusively from that producer unless they change their designation. Producers may provide cannabis to patients either by appointment or by delivering to them directly.¹²⁶ In addition, the amount of prepared cannabis¹²⁷ and plants a producer may possess is capped by reference to the number of patients that have designated it as their supplier.¹²⁸ In Vermont, patients may only enter a producer's premises to purchase cannabis products by appointment.¹²⁹
- 6.64** In Minnesota, where only refined forms of cannabis may be sold, producers must conduct cultivation, harvesting, manufacture and packaging at the same location, and must operate four distribution centres (which can only hold the finished product).¹³⁰ Producers must contract with a laboratory to perform testing (content, contamination, consistency),¹³¹ and must be able to provide a reliable and ongoing supply of product.¹³²

Separate cultivation and distribution licences

- 6.65** Jurisdictions which operate a licence-based cultivation scheme, but do not require vertically integrated production and distribution, issue cultivation licences to approved producers separately from licences to distribute products to patients. This approach is

¹²² See, eg, Arizona (cap is set at 1 per every 10 pharmacies: Ariz Rev Stat Ann § 36-2804(C)), Maine (minimum of eight, which can be increased: 22 Me Rev Stat Ann, § 2428(11)), New York (maximum of five, with each permitted to have no more than four dispensing locations: Public Health Law § 3365(9)), Vermont (maximum of four: 18 Vt Stat Ann § 4474f(b)).

¹²³ See, eg, Delaware (competitive, scored process; no licences issued to date; criteria include: suitability of location, including convenience to patients, character and experience of management, capacity to operate as a viable business, security plans, ability to make marijuana available at a reasonable price: 16 Del Code Ann § 4914A), Vermont (competitive, criteria include: geographic convenience to patients, ability to provide adequate supply to patients, experience of management, patient submissions, record keeping and security plans: 18 Vt Stat Ann § 4474f(e)).

¹²⁴ See, eg, Arizona (Ariz Rev Stat Ann § 36-2806(A)), Delaware (16 Del Code Ann § 4919A(a); note that no licences had been issued at the time of writing), Maine (22 Me Rev Stat Ann, § 2428(6)(A)), *An Act for the Humanitarian Medical Use of Marijuana*, 2012, No 369, § 1(H), 2012 Mass Acts 369, Vermont (18 Vt Stat Ann § 4474e(b)(1)).

¹²⁵ See, eg, Delaware (16 Del Code Ann § 4919A(p)); Maine (22 Me Rev Stat Ann, § 2428(3)(E)); Massachusetts (*An Act for the Humanitarian Medical Use of Marijuana*, 2012, No 369, § 14, 2012 Mass Acts 369).

¹²⁶ Maine (22 Me Rev Stat Ann, § 2428(1-A)), Vermont (18 Vt Stat Ann §§ 4474e and 4474h).

¹²⁷ Meaning dried plant matter or preparations such as edibles and tinctures: 22 Me Rev Stat Ann § 2422(14).

¹²⁸ Maine (22 Me Rev Stat Ann § 2428(1-A)(A) and (B)); Vermont (18 Vt Stat Ann § 4474e(a)(3) - exemptions are available to allow for the production of cannabis oil).

¹²⁹ Vermont (18 Vt Stat Ann § 4474e(d)(2)).

¹³⁰ Minn Stat § 152.29(1)(a).

¹³¹ Ibid § 152.29(1)(b).

¹³² Ibid § 152.29(2)(a).

adopted in five American states.¹³³ Likewise, Israel licences a number of cultivators, while distribution is carried out by a separate entity.¹³⁴ The Czech Republic is also expected to move to a system of licensed production, after a trial period of importation-only supply.¹³⁵

- 6.66 Schemes permitting the separate issuing of cultivation licences operate in a similar fashion to schemes for the licensing of vertically integrated producers and distributors. The separate licensing of these aspects of supply is more a feature of recent medicinal cannabis schemes, passed into law in the past five years. Separate licensing gives governments more flexibility in how cultivation and distribution licence-holders are regulated. For example, if there are caps on the number of cultivators and distributors allowed to operate in the jurisdiction, the government can impose different caps in each category.¹³⁶

Importation

- 6.67 In a number of European countries, including Finland, Germany and Italy, patients have access to cannabis imported from the Netherlands (produced by Bedrocan BV, the sole Dutch supplier). Patients in those countries can obtain a prescription for cannabis from their doctor, and seek cannabis on the basis of this prescription from a pharmacy or wholesaler. The pharmacies and wholesalers then apply for import licences in their home jurisdiction, which form the basis for export approval to be granted by the Dutch government.¹³⁷ It is also possible for companies in other jurisdictions to seek import licences.¹³⁸ The Czech Republic also intends to make arrangements for importation from the Netherlands.¹³⁹ Not all countries permit their lawfully grown medicinal cannabis and cannabis products to be exported—for instance, Israel's cannabis producers have expressed interest in exporting products to other jurisdictions, and other jurisdictions are

¹³³ Colorado (revisions passed in 2010), Connecticut, Illinois (law passed in 2012), Maryland (law passed in 2014), Nevada (revisions passed in 2013) and provide licences to cultivation-only facilities. In Colorado and Maryland, although separate licences are issued, both are generally held by a single entity. This appears to be a result of the requirement that a cultivation licence must be issued to a person who cultivates cannabis at a location contiguous to a medical marijuana center (retailer). Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 14–20. While Oregon is sometimes cited as having a system of this kind, in fact it permits 'designated growers' to grow cannabis on behalf of up to four patients, and only requires such growers to register, not obtain a licence (registration may be refused if the applicant has serious prior drug convictions): Or Rev Stat § 475.304.

¹³⁴ Ido Efrati, 'Israel's Wannabe Medical Cannabis Farmers Have High Hopes', *Haaretz* (online) 5 January 2015 <<http://www.haaretz.com>>.

¹³⁵ The government is initially making cannabis available by importation only. 'Czech MPs Vote to Legalise Marijuana for Medical Use', Reuters (online), 7 December 2012 <<http://uk.reuters.com>>.

¹³⁶ For example: Conn Gen Stat §§ 21a-408h to 408i.

¹³⁷ Bedrocan Canada, *Global Cannabis Programs* <<https://bedrocan.ca/resources/regulatory-compliance/global-cannabis-programs>>; Office of Medicinal Cannabis, *Import & Export—Foreign patients & businesses* <<http://www.cannabisbureau.nl/en/ImportExport/Foreignpatientsandbusinesses>>.

¹³⁸ Office of Medicinal Cannabis, *Import & Export—Foreign Patients & Businesses* <<http://www.cannabisbureau.nl/en/ImportExport/Foreignpatientsandbusinesses>>.

¹³⁹ Bedrocan Canada, *Our Leadership Team* (2015) <<https://bedrocan.ca/our-leadership>>.

interested in obtaining cannabis from Israeli sources, but the government has not yet allowed this to occur.¹⁴⁰

- 6.68** Canada allows the importation of cannabis (seeds, plants and dried plant matter) by a person holding an import permit.¹⁴¹ Only licensed producers may obtain an import permit.¹⁴² The government is permitted to impose conditions on an import permit for the purpose of controlling a public health, safety and security risk, or to comply with international obligations.¹⁴³ Dried cannabis must be tested for THC and CBD content before being imported.¹⁴⁴ Bedrocan BV, which, as set out above, appears to be the world's leading exporter of cannabis, has a Canadian arm (recently listed on the Canadian stock exchange) and grows cannabis in Canada as a licensed producer, thereby not relying on importation to make its product available to Canadian patients.¹⁴⁵
- 6.69** It is possible in principle for a resident of the United Kingdom to apply on an individual basis for a licence to import cannabis. In the period October 2012–October 2013, three applications were made to the Home Office for a licence to import the Dutch cannabis product Bedrocan, pursuant to a prescription. All three applications were refused.¹⁴⁶

Producing refined products

- 6.70** A number of United States jurisdictions where infused products (such as edible oils and baked goods) are sold require manufacturers to hold a separate manufacturing licence/authorisation for this activity.¹⁴⁷ Other restrictions are placed on manufacturers, such as requirements that the facilities used be dedicated exclusively to the manufacture of infused products,¹⁴⁸ and caps on the number of cannabis suppliers the manufacturer may purchase from,¹⁴⁹ along with sanitary and labelling requirements.¹⁵⁰

¹⁴⁰ Stuart Winer, 'Czechs Look to Israel for Medical Marijuana' *Times of Israel* (online), 17 March 2013 <<http://www.timesofisrael.com>>; Ido Efrati, 'Israel Shying Away from Being World's "Pot Dealer"' *Haaretz* (online) 2 April 2014 <<http://www.haaretz.com>>.

¹⁴¹ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 74(1).

¹⁴² *Ibid* s 76(b).

¹⁴³ *Ibid* s 75(2).

¹⁴⁴ *Ibid* s 78.

¹⁴⁵ See the Bedrocan Canada website at <<http://www.bedrocan.ca>>.

¹⁴⁶ United Kingdom Home Office, 'Licences for the Importation of Medicinal Cannabis' (FOI Release 29252, 20 December 2013) <<https://www.gov.uk/government/publications/licences-for-the-importation-of-medicinal-cannabis>>.

¹⁴⁷ Including Arizona (9 Ariz Admin Code R9-17-319); Colorado (Colo Rev Stat § 12-43.3-404).

¹⁴⁸ See, eg, Colo Rev Stat § 12-43.3-404(2).

¹⁴⁹ See, eg, Colo Rev Stat § 12-43.3-404(3).

¹⁵⁰ See, eg, Colo Rev Stat § 12-43.3-404(4)–(5).

Distribution systems

State as sole supplier

6.71 It is possible for the government to supply cannabis directly to patients.¹⁵¹ This was the previous system in place in Canada, and it operated alongside a system of ‘grow your own’ licences. The government sold only one strain of cannabis, in the form of dried plant material. The cannabis was grown by a company¹⁵² under contract, as detailed above. Patients were required to be approved by the government, and could then order up to one month's supply at a time from the government, which would be shipped to them (or their doctor) by the contracted grower.¹⁵³ Surveys found that satisfaction with the government-supplied cannabis was very low. The major complaints were around quality and lack of choice, and consequently very few patients obtained their cannabis from the government.¹⁵⁴

Involving pharmacists

6.72 In the Netherlands, cannabis is supplied to patients through pharmacies. Pharmacies are in turn supplied with cannabis by the Office of Medicinal Cannabis, which purchases it from the contracted producer (currently Bedrocan BV) pursuant to a contract. Licences to produce are granted on the condition that they do not supply the market directly.¹⁵⁵ Pharmacies are also involved in the distribution of cannabis to patients in European countries that permit importation of cannabis from the Netherlands, as described above.

6.73 Israel adopts a similar distribution system to the Netherlands. Cannabis growers must deliver all of their product to a logistical centre operated by a company part-controlled by the government,¹⁵⁶ where it is packaged in dosage form. From there, the products are delivered to selected pharmacies. Only pharmacies which have been chosen through a competitive tender process are permitted to sell cannabis products.¹⁵⁷

¹⁵¹ Alternatively, the government may control distribution, but leave patient-level dispensing to pharmacists. This system operates in Israel and the Netherlands.

¹⁵² Prairie Plant Systems Incorporated.

¹⁵³ Health Canada, *About Health Canada's Marihuana Supply for Medical Purposes* (archived content) (29 July 2013) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/supply-approvis-eng.php>>.

¹⁵⁴ Only 8.2% of patients reported that they obtained cannabis from Health Canada. Of those who had tried it, over 75% of patients rated the cannabis as 1 or 2, on a scale of 1 (Very Poor) to 10 (Excellent). 90.9% of patients stated that not all strains were equally effective in relieving their symptoms. 97.6% stated they would rather obtain cannabis from a source offering a ‘large selection of strains’. Philippe Lucas, ‘It Can’t Hurt to Ask; A Patient-Centered Quality of Service Assessment of Health Canada’s Medical Cannabis Policy and Program’ (2012) 9(2) *Harm Reduction Journal* 5–6.

¹⁵⁵ *Policy Guidelines Opium Act Exemptions*, Regulation of the Minister of Health, Welfare and Sport (9 January 2003) GMT/BMC 2340685, s 5.

¹⁵⁶ The company was established by the government but is owned by a not-for-profit organisation representing Israeli hospitals, and has government representatives on its Board.

¹⁵⁷ Ruth Levush, ‘Israel: New Directives on Use of Marijuana for Medical Purposes’, *Library of Congress—Global Legal Monitor* (online) 6 January 2014 <<http://www.loc.gov/lawweb>>; Simone Wilson, ‘Light-up Nation: What Israel Can Teach America About Medical Marijuana’, *Jewish Journal* (online), 2 October 2013 <<http://www.jewishjournal.com>>.

- 6.74 In Minnesota, where only non-smokeable forms of cannabis may be sold, cannabis products must be sold directly by the manufacturer to patients (the ‘vertically integrated’ model described above). However, cannabis must be dispensed to patients by employees of the manufacturer who are registered pharmacists.¹⁵⁸ Upon supplying the cannabis to a patient, the pharmacist must consult with the patient to determine an appropriate dosage, after consideration of the compositions of the cannabis products available and the recommended dosages.¹⁵⁹ However, although pharmacists are involved in the process, the distribution of cannabis in this case is not through pharmacies.
- 6.75 Connecticut also involves pharmacists in the distribution of cannabis, by only permitting pharmacists to hold a dispensary licence.¹⁶⁰ However, as in Minnesota, this does not mean that pharmacies distribute cannabis; rather, it limits the class of people who are permitted to operate dispensaries.

Through specialist sellers

- 6.76 As mentioned above, American states where cannabis is permitted to be distributed to patients have favoured a regulatory model which enables specialist sellers, either independent from or integrated with producers, to sell cannabis to patients. These outlets are called ‘dispensaries’, ‘compassion centres’ and ‘alternative treatment centres’ among other titles. Pharmacies are not permitted to sell cannabis in the United States, due to restrictions arising from federal law.¹⁶¹
- 6.77 These specialist sellers are usually licensed or registered with the government (either to distribute cannabis or to grow and distribute it, depending on the model).¹⁶² Sellers commonly distribute cannabis paraphernalia (such as vaporisers, dabbing equipment, sifting and cutting tools) in addition to cannabis itself.¹⁶³ All states impose limits on the maximum amount a patient can purchase,¹⁶⁴ and some require that a patient obtain cannabis from one, nominated dispensary.¹⁶⁵ Sellers in most jurisdictions are required to supply patients with educational materials or safety inserts regarding side effects, safety, dependence, dosage and other matters. Staff members of the specialist sellers are required in most states to undergo training regarding topics including:
- the risks, benefits and side effects of cannabis

¹⁵⁸ Minn Stat § 152.29(3)(a).

¹⁵⁹ Minn Stat § 152.29(3)(b)(4).

¹⁶⁰ Conn Gen Stat § 21a-408h(b)(B).

¹⁶¹ Todd Garvey and Charles Doyle, *Marijuana: Medical and Retail - Selected Legal Issues*, Congressional Research Service Report 7-5700 (25 March 2014) 8 <<http://fas.org/sgp/crs/misc/R43435.pdf>>.

¹⁶² Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 14–20.

¹⁶³ *Ibid* 16–20.

¹⁶⁴ *Ibid* 37–39.

¹⁶⁵ See, eg, 18 Vt Stat Ann § 4474h.

- signs of substance abuse or instability in users
- patient confidentiality
- strains of cannabis and methods of use.¹⁶⁶

6.78 Where specialist sellers exist, many jurisdictions have imposed rules designed to ensure that they are operated at a distance from medical practitioners, to ensure independence and to avoid conflicts of interest. Typical laws prohibit medical practitioners from having a financial interest in distribution businesses or deriving a benefit from authorising patients to access medicinal cannabis.¹⁶⁷ Other jurisdictions prohibit medical practitioners from being co-located with distribution sites.¹⁶⁸

Through co-operatives, collectives and compassion clubs

6.79 A co-operative or collective model has emerged in a number of jurisdictions that allow patients and caregivers to 'grow their own' cannabis. The essence of these structures is that they involve patients and/or caregivers working together to cultivate, distribute and manufacture cannabis and cannabis products co-operatively, allowing them to share resources and expertise. This structure is particularly common in California, where,¹⁶⁹ according to the federal government, it is widely used to conceal illegal (recreational) sales of cannabis.¹⁷⁰

6.80 Other jurisdictions have seen the emergence of compassionate clubs, even where the law does not specifically provide for growers to form such collectives. In Vancouver, for example, there are reported to be about 60 'unlicensed dispensaries', which generally purchase their product from small-scale, home-based growers, even though Canadian law does not allow this.¹⁷¹ Spain has a large community of cannabis clubs, which grow and distribute cannabis to members. While accessible by recreational and medicinal users, the clubs have assisted users to safely use cannabis for therapeutic purposes. The clubs are tolerated by the government but operate in a 'legal grey area'.¹⁷² The Catalan

¹⁶⁶ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 14–20.

¹⁶⁷ For example, Connecticut (Conn Agencies Regs § 21a-408-4(a) and (b)), Illinois (410 Ill Comp Stat 310/35(a)(3)); Maryland (Md Code Ann, Health - General § 13-3307(e)).

¹⁶⁸ For example, Connecticut (Conn Agencies Regs § 21a-408-4(a)(3)), Illinois (410 Ill Comp Stat 310/35(a)(3)).

¹⁶⁹ Californian law provides that patients may form such organisations: Cal Health & Safety Code § 11362.775 ('[q]ualified patients, persons with valid identification cards, and the designated primary caregivers of qualified patients and persons with identification cards, who associate within the State of California in order collectively or cooperatively to cultivate marijuana for medical purposes, shall not solely on the basis of that fact be subject to state criminal sanctions').

¹⁷⁰ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 14–20.

¹⁷¹ Bethany Lindsay and Tara Carman, 'Vancouver's medical marijuana dispensaries aren't getting pot legally', Vancouver Sun (online), 2 February 2015 <<http://www.vancouversun.com>>.

¹⁷² See Martin Barriuso Alonso, 'Cannabis Social Clubs in Spain: a Normalizing Alternative Underway' (January 2011) *Transnational Institute Series on Legislative Reform of Drug Policies No 9*, available at <<http://www.undrugcontrol.info>>.

government recently moved to regulate cannabis clubs, in particular opening hours, purchase limits, plant registration and so on.¹⁷³

Preventing diversion and maintaining public confidence

6.81 There is a risk in any system of supply that product will be misappropriated. In the case of a medicinal cannabis scheme, the risk is that products will be diverted from the legal (medicinal) market into the illegal (non-authorised) market. There is also a risk that, as distribution systems for medicinal cannabis become more dispersed, the legal, regulated image of the market is eroded, and public confidence in the regulation of the scheme diminishes.

Preventing diversion to the illicit market

6.82 Many jurisdictions that allow distribution to patients impose restrictions on cultivation and distribution agencies, which are intended to prevent the diversion and theft of medicinal marijuana products. In American states where cannabis may be cultivated on a large scale, it is generally required to be in an enclosed and locked facility, away from public view.¹⁷⁴ Additional requirements apply to storage and cultivation facilities, regarding video surveillance or alarm systems, single entrance/exit, fencing, lighting, parking and loitering prevention.¹⁷⁵ Where transport of marijuana products is necessary, security measures must be implemented.¹⁷⁶

6.83 Tracking and inventory-control measures are also used to control the risk of diversion. Producers and distributors are often required to keep an inventory of useable marijuana products and plants grown onsite. Illinois, for example, requires tracking of plants and products, in order to prevent theft and diversion.¹⁷⁷ In Minnesota, each quantity of dispensed cannabis is given a tracking number, so that it may be traced to the dispensary and specific purchasing patient.¹⁷⁸ Some states require cultivators/distributors to destroy excess product not required by patients.¹⁷⁹ In Canada, producers must report thefts or the 'unusual waste or disappearance of cannabis' to police and the minister.¹⁸⁰

¹⁷³ Ashifa Kassam, 'Barcelona's Booming Cannabis Clubs Turn Spain into "Holland of the South"', *The Guardian* (online), 5 August 2014 <<http://www.theguardian.com>>.

¹⁷⁴ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 40. For example, Minnesota (Minnesota Statutes 2014, Chapter 152, s 152.29(2)(b)); Vermont: (18 Vt Stat Ann § 4474e (2)(d)(1).

¹⁷⁵ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 42–43 (Table 4-8). See, eg, NJ Admin Code § 8:64-9.7(b).

¹⁷⁶ See, eg, NJ Admin Code § 8:64-10.11.

¹⁷⁷ 8 Ill Admin Code § 1000.435.

¹⁷⁸ Minn Stat § 152.29(3)(c)(3).

¹⁷⁹ See, eg, Vermont (18 Vt Stat Ann § 4474e(5)).

¹⁸⁰ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 19. New Jersey also imposes loss-reporting requirements: NJ Admin Code § 8:64-9.8.

6.84 Staff members are commonly required to undergo fingerprint and criminal history checks,¹⁸¹ and may require registration,¹⁸² while many jurisdictions also impose a ‘good character’ test on management-level staff.¹⁸³ In Canada, similar assessments are required for the ‘person in charge’ at the facility.¹⁸⁴

Maintaining public confidence

6.85 Many jurisdictions impose restrictions on the business practices of distributors, apparently as a means of avoiding corruption of their medicinal cannabis schemes or the deterioration of their public image.

6.86 Some jurisdictions impose advertising restrictions. In Canada, licensed producers are not permitted to market to their clients, including by promoting particular products to clients based on their condition (a rule which Health Canada vigorously enforces).¹⁸⁵ In New Jersey, a distributor’s premises must have a plain, unilluminated sign, no advertisements for cannabis outside the premises or cannabis products visible from the street, and may not produce promotional items such as t-shirts. The government has introduced these restrictions out of concern that commercial advertising would ‘unavoidably encourage or trivialize the sale and use of an illegal drug’.¹⁸⁶

6.87 American states commonly prohibit consumption of cannabis products on the retailer’s premises.¹⁸⁷ Many jurisdictions impose controls on where retailers may be located, commonly requiring that retailers be located a certain distance away from schools and other places where children are likely to be present.¹⁸⁸

Role of ‘caregivers’

6.88 Many United States jurisdictions and Canada recognise the role of ‘caregivers’ in the supply and administration of medicinal cannabis. Caregivers are sometimes permitted to be any person designated by the patient, or in some cases the class of eligible caregivers is more limited. In Colorado, for example, a person may only be caregiver to five patients at a time, and must provide support to the patient other than merely supplying them

¹⁸¹ See, eg, Minnesota (Minn Stat § 152.29(1)(i)); New Jersey (NJ Admin Code § 8:64-7.2(a)); Rhode Island (RI Code Reg R21-28.6-MMP § 5.5.3); Vermont (18 Vt Stat Ann § 4474g).

¹⁸² See, eg, Rhode Island (RI Code Reg R21-28.6-MMP § 5.5.4); Vermont (18 Vt Stat Ann § 4474g).

¹⁸³ See, eg, New Jersey (NJ Admin Code § 8:64-7.2(c)); Vermont (18 Vt Stat Ann § 4474g).

¹⁸⁴ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 24.

¹⁸⁵ David Pett and Peter Koven, “We Don’t Call it “Maui Wowie’’: Why Canadian Pot Producers are Facing a Marketing Challenge’, *Financial Post* (online), 30 January 2015, <<http://business.financialpost.com/2015/01/30/pot-producers-face-marketing-challenge>>; Health Canada, *Information Update - Marijuana for Medical Purposes - Advertising and Licensed Producers* (Information Update, No RA-42677, 25 November 2014) <<http://www.healthycanadians.gc.ca>>.

¹⁸⁶ NJ Admin Code § 8:64-12.1; New Jersey Department of Health and Senior Services, *NJ Admin Code 8:64 - Public Comments and Agency Responses* (2011) 12 <www.state.nj.us/health/medicalmarijuana/documents/final_rules.pdf> (response to comment 21).

¹⁸⁷ See, eg, District of Columbia (22 DCMR § 5705.1); Vermont (18 Vt Stat Ann § 4474e(e)).

¹⁸⁸ See, eg, District of Columbia (22 DCMR § 5201.1); Vermont (18 Vt Stat Ann § 4474e(c)).

with cannabis.¹⁸⁹ Many jurisdictions require the caregiver to be registered, in addition to the patient,¹⁹⁰ and some disqualify caregivers with prior convictions.¹⁹¹

- 6.89** Caregivers are able to take advantage of a range of legal protections connected with medicinal cannabis, by extension from the rights of the patient they care for. Depending on the jurisdiction, caregivers can be permitted to buy, grow and assist in the administration of cannabis, where this would be prohibited for a person outside the scheme.¹⁹²
- 6.90** Jurisdictions in which caregivers can grow cannabis on behalf of a person in their care appear to have seen the system used for more than just small-scale growing. While some jurisdictions (notably Oregon) specifically permit persons with no pre-existing relationship to grow for a patient (or multiple patients), other jurisdictions confine delegated growing rights to ‘caregivers’. Notwithstanding this, websites such as Marijuana Caregiver, which advertises itself as ‘a free service for patients to find medical marijuana caregivers in order to facilitate recent legislation allowing for the use of medical marijuana’, appear to promote and enable use of the caregiver system in ways that were not intended.¹⁹³

Role of health practitioners

- 6.91** In Canada, the Netherlands, Israel and all American states (other than where cannabis is available generally for recreational use), eligible users cannot access medicinal cannabis without first receiving approval from a health practitioner.¹⁹⁴ Beyond that, there are a number of possible approaches to the role of doctors in the selection of patients and the supervision of their use of cannabis.
- 6.92** The experience of other jurisdictions, in addition to providing models of regulation, also shows the dangers of implementing a system which relies on health practitioners but does not have their support. Following the introduction of the Medical Marijuana Access Regulations in 2001, the Canadian Medical Association recommended that doctors not

¹⁸⁹ 5 Code Colo Regs § 1006-2, regulation 9(B) and (L).

¹⁹⁰ See, eg, Minnesota (Minn Stat § 152.27(4)); Arizona (Ariz Rev Stat § 36-2804.02; Vermont (18 Vt Stat Ann § 4474).

¹⁹¹ Connecticut (Conn Agencies Regs §§ 21a-408-7(b)(2) and 21a-408-1(30)); Illinois (410 Ill Comp Stat 130/10(i) and (l), 130/65(c)(1)); Minnesota (Minn Stat § 152.27(4)(b)).

¹⁹² Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 8–11.

¹⁹³ *Marijuana Caregiver* <<http://marijuanacaregiver.com>>.

¹⁹⁴ Even in Colorado and Washington, where cannabis has been legalised for all adult users, there remains a separate medicinal cannabis scheme, which is limited to patients with a doctor’s authorisation. Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) ix; *Marijuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 3(2); Office of Medicinal Cannabis, *Medicinal Cannabis: Information for Patients* (Brochure, February 2011); Ruth Levush, ‘Israel: New Directives on Use of Marijuana for Medical Purposes’, *Library of Congress—Global Legal Monitor* (online) 6 January 2014 <http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205403817_text>.

participate in the program, because of a lack of information on dosage, side effects and alternatives to smoking. The Association stated in 2003 that ‘Physicians should not be the gatekeeper for a substance for which we do not have adequate scientific proof of safety or efficacy’. This resistance may have contributed to low participation in the program at its commencement.¹⁹⁵

Practitioners as gatekeepers

6.93 As mentioned above, in all jurisdictions considered by the Commission where medicinal cannabis is permitted, health practitioners act as gatekeepers to the medicinal cannabis market—that is, patients must receive approval from them before they can access the product. However, the authorisation given to medical practitioners in performing this function is rarely absolute, with the class of practitioners often limited for the purpose of:

- preventing non-genuine patients from accessing cannabis
- ensuring the authorising practitioner has appropriate knowledge and expertise
- providing the state with control over doctors, particularly to give it options for dealing with doctors who inappropriately authorise patients.

Genuine relationship

6.94 To prevent inauthentic or uninformed authorisations, several jurisdictions require patients to show that they have a genuine or long-standing physician-patient relationship with the medical practitioner.¹⁹⁶ In Oregon, which provides a typical example, a physician may only authorise a patient's access to medicinal cannabis if they have:

- reviewed a patient's medical records
- conducted a thorough medical examination of the patient
- provided or planned follow-up care
- documented each of these activities in the patient's medical records.¹⁹⁷

6.95 Vermont also requires that there be a ‘bona fide health care professional-patient relationship’ in existence. This is defined to mean a treating or consulting relationship for a period of at least six months (cancer, HIV/AIDS and terminally ill patients are exempt

¹⁹⁵ Philippe Lucas, ‘It Can’t Hurt to Ask; A Patient-Centered Quality of Service Assessment of Health Canada’s Medical Cannabis Policy and Program’ (2012) 9:2 *Harm Reduction Journal* 2–3.

¹⁹⁶ See, eg, Connecticut (require a ‘medically reasonable’ assessment made in the course of a bona-fide physician-patient relationship: Conn Gen Stat § 21a-408c(c)(3)), Illinois (requires that the patient be ‘under the physician's care’ for the relevant condition and that there be a bona-fide physician-patient relationship: 410 Ill Comp Stat 130/10(y)).

¹⁹⁷ Oregon Health Authority, *Medical Marijuana Program - Physicians* <<http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/MedicalMarijuanaProgram/Pages/Physicians.aspx>>; Or Admin R 333-008-0010(23) (definition of ‘primary responsibility’).

from this requirement), during which the practitioner has conducted a full assessment of the medical history, along with a physical examination.¹⁹⁸

- 6.96 Province-based guidelines in Canada seek to ensure the relationship and consultation are genuine, including by requiring that the patient be seen in person, or by only permitting the primary treating physician to authorise access to cannabis.¹⁹⁹

Ensuring appropriate knowledge and expertise

- 6.97 As may be expected, the main health care professionals able to authorise access to medicinal cannabis in other jurisdictions are medical doctors.²⁰⁰ However, authority to permit access is expanded in some jurisdictions beyond medical practitioners. Vermont, for example, allows other practitioners to authorise patients, including specified naturopaths, physician assistants and registered nurses.²⁰¹ In Canada, nurse practitioners can authorise patient access if they have the authority to write prescriptions.²⁰²
- 6.98 In Israel, only certain specialist medical practitioners approved by the government can authorise patient access to cannabis.²⁰³ Family physicians are not permitted to sign authorisations.²⁰⁴

Providing state control

- 6.99 In other jurisdictions, such as Maryland, Massachusetts, New Jersey and New York, medical practitioners must obtain state approval or a licence before being permitted to endorse patient access to cannabis.²⁰⁵ Some jurisdictions make cannabis education a condition of licence renewal.²⁰⁶

¹⁹⁸ Vermont Crime Information Center, *Marijuana Registry - Health Care Professional Information*(2015) <http://vcic.vermont.gov/marijuana_registry/physicians>; 18 Vt Stat Ann § 4472(1).

¹⁹⁹ Canadian Medical Protective Association, *Medical Marijuana: New Regulations, New College Guidance for Canadian Doctors* (document number W14-005-E, October 2014) <<https://www.cmpa-acpm.ca>>.

²⁰⁰ A number of states only permit doctors to authorise access, eg: Hawaii (19 Haw Rev § 329-121), Oregon (Or Admin R 333-008-0010(3)).

²⁰¹ Vermont permits any of the following to authorise patient access: an individual licensed to practice medicine in Vermont, an individual licensed as a naturopathic physician in Vermont who has a special license endorsement authorizing the individual to prescribe, dispense, and administer prescription medicines to the extent that a diagnosis provided by a naturopath under this chapter is within the scope of his or her practice, an individual certified as a physician assistant in Vermont, or an individual licensed as an advanced practice registered nurse in Vermont: Vermont Crime Information Center, *Marijuana Registry - Health Care Professional Information*(2015) <http://vcic.vermont.gov/marijuana_registry/physicians>; 18 Vt Stat Ann § 4472(6)(A).

²⁰² *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, ss 1 (definition of 'health practitioner') and 128.

²⁰³ Ruth Levush, 'Israel: New Directives on Use of Marijuana for Medical Purposes', *Library of Congress—Global Legal Monitor* (online) 6 January 2014 <http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205403817_text>.

²⁰⁴ Israel Ministry of Health, 'Clarification Regarding Cannabis' (press release, 17 September 2014), <http://www.health.gov.il/English/News_and_Events>.

²⁰⁵ See, eg, Maryland (Md Code Ann, Health - General § 13–3307); Massachusetts (105 Mass Code Regs § 725.005), New Jersey (NJ Admin Code § 8:64-2.5(a)); New York (Medical Marijuana Program Proposed Regulations § 80-1.1(a)(4), proposing changes to 10 NY Comp Codes R & Regs 80-1).

²⁰⁶ See, eg, Massachusetts (105 Mass Code Regs§ 725.010(A)); proposed regulations in New York (Medical Marijuana Program Proposed Regulations § 80-1.1(a)(4), proposing changes to 10 NYCRR 80-1). New York's proposed regulations state that the education program will be a four-hour course that covers 'the pharmacology of marihuana; contraindications; side effects; adverse

6.100 American states that do not require doctors to hold special licences to authorise cannabis use appear to leave the sanctioning of doctors who authorise cannabis use where there is no basis to the relevant professional society.²⁰⁷

Supervising use

6.101 As noted above, in the Netherlands doctors supervise their patients' use of cannabis by writing prescriptions that are required to specify the product deemed suitable by the doctor, and the appropriate dosage.²⁰⁸

6.102 Canada also utilises a prescription-like system for doctors to authorise patient access to cannabis. Doctors authorise patient access to cannabis by completing a 'medical document' that states both the daily quantity of dried marijuana the patient is to use, and the period over which they can use it, which cannot exceed one year.²⁰⁹ In addition, doctors are regulated by the medical regulatory authority, or 'college', in their home province, and guidelines issued by these bodies in some cases impose additional supervisory obligations. For example, doctors in Alberta are instructed by their college to evaluate a patient in person every three months, while doctors in Newfoundland and Labrador are advised to prepare a protocol for periodic reassessment of eligible patients.²¹⁰

6.103 Practitioners in the United States are prohibited under federal law from prescribing medicinal cannabis, so cannot supervise patient use in this way.²¹¹ However, they are permitted to 'recommend' use of cannabis to patients,²¹² a proviso which some jurisdictions utilise to allow practitioners to control patient use of cannabis. In New Jersey, for example, doctors who certify patients for access to medicinal cannabis can do so for 30, 60 or 90 days. The patient may only purchase cannabis for the selected period before they must be re-evaluated. The doctor must also state the amount of cannabis the patient will be permitted to purchase every 30 days, up to a maximum of two

reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; abuse and dependence': § 80-1.1(b).

²⁰⁷ See, eg, Illinois (410 Ill Comp Stat 310/25(e)).

²⁰⁸ Office of Medicinal Cannabis, *Medicinal Cannabis: Information for Patients* (Brochure, February 2011).

²⁰⁹ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 129(1) and (2).

²¹⁰ Canadian Medical Protective Association, *Medical Marijuana: New Regulations, New College Guidance for Canadian Doctors* (document number W14-005-E, October 2014) <https://www.cmpa-acpm.ca>.

²¹¹ Cannabis is a controlled substance under the *Controlled Substances Act 1970*, 21 USC Ch 13, and cannot be prescribed by doctors otherwise than in accordance with the statute. The DEA may withdraw a doctor's authority to prescribe controlled substances if they fail to comply with their obligations under the statute: Todd Garvey and Charles Doyle, *Marijuana: Medical and Retail - Selected Legal Issues*, Congressional Research Service Report 7-5700 (25 March 2014) 8 <<http://fas.org/sgp/crs/misc/R43435.pdf>>.

²¹² Todd Garvey and Charles Doyle, *Marijuana: Medical and Retail - Selected Legal Issues*, Congressional Research Service Report 7-5700 (25 March 2014) 8 <<http://fas.org/sgp/crs/misc/R43435.pdf>>. The distinction arises because of a decision of the United States Court of Appeal for the Ninth Circuit, *Conant v Walters*, 309 F 3d 629 (9th Cir, 2002), which held that a doctor's prescribing authority should not have been withdrawn solely because he recommended marijuana to his patients.

ounces.²¹³ In addition, doctors may only continue treatment with medicinal cannabis if satisfied that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological dependence.²¹⁴

Regulating use

Patient protections and responsibilities

- 6.104 In many jurisdictions, legislatures have sought to give comfort to users of medicinal cannabis by protecting them from prosecution. This is achieved by removing the penalties that attach to possession of cannabis (and cannabis paraphernalia) in relation to acts connected with the jurisdiction's medicinal cannabis program.²¹⁵ Very few jurisdictions have created a defence to prosecution for patients in possession of cannabis products without establishing a scheme to enable them also to grow or purchase cannabis.²¹⁶
- 6.105 Most jurisdictions that do not require patients to hold prescriptions impose maximum possession and purchase limits on patients. In Canada, patients may only possess up to 30 times the daily quantity specified in their medical document,²¹⁷ and may only purchase a 30-day supply in any given month from their licensed producer.²¹⁸ Most US states express the maximum possession amount as a set weight (between 1 and 24 ounces),²¹⁹ although some states set it according to the patient's daily dose, as in Canada.²²⁰ States which permit patients to purchase cannabis also express the maximum purchase amount in one of these two ways.²²¹

²¹³ New Jersey Department of Health, Medical Marijuana Program - Check List for Physicians Certifying Patients (2015) <http://www.state.nj.us/health/medicalmarijuana/pat_checklist.shtml>.

²¹⁴ NJ Admin Code § 8:64-2.5(a).

²¹⁵ See Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 8–11 (regarding US state approaches), *Controlled Drugs and Substances Act* (Can), SC 1996, c 19, s 4(1) (prohibiting possession of cannabis unless authorised by regulation, which regulations have been promulgated). The sale of paraphernalia is exempted from prosecution in Illinois (410 Ill Comp Stat 310/25(e)) and other states.

²¹⁶ Wisconsin, which recently passed legislation legalising 'cannabidiol', only permits eligible persons to possess cannabidiol. It does not, however, provide any mechanism for patients to obtain cannabidiol: Wis Stat § 961.14(4)(t).

²¹⁷ *Marihuana for Medical Purposes Regulations* (Can), SOR/2013-119, s 5(a).

²¹⁸ *Ibid* s 124(1).

²¹⁹ Fixed-weight maximums are: 1 oz (Alaska, Montana), 2 oz (Colorado, New Hampshire, New Jersey, Vermont), 2.5 oz (Arizona, Illinois, Maine, Michigan, Nevada, Rhode Island), 3 oz (Hawaii), 6 oz (Delaware, New Mexico), 8 oz (California), 24 oz (Oregon, Washington): Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 9–11 (Table 3-1).

²²⁰ Dose-based maximums are: 1 month/30 day supply (Connecticut, Maryland, Minnesota, New York) or a 60 day supply (Massachusetts): Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 9–11 (Table 3-1).

²²¹ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 38–39 (Table 4-7).

6.106 Patients in some jurisdictions must comply with additional requirements in order to claim the legal protection afforded to them. As mentioned above, patients in many United States jurisdictions must carry their state-issued ID card in order to avoid arrest.²²² Patients in Canada must carry cannabis in its original packaging, as must patients in New York.²²³

Restrictions on use

6.107 In jurisdictions where medical marijuana is permitted, authorised patients are frequently restricted regarding the manner and locations in which they may use cannabis products. These restrictions focus particularly on use of cannabis in public places, in places where children are likely to be present, and where the use could have a detrimental effect on other people. In many jurisdictions, patients are prohibited from carrying and/or using medicinal cannabis products in one or more of the following places:

- public places
- schools and universities
- correctional facilities
- workplaces
- public transport
- in the presence of children.²²⁴

Interaction with other activities

6.108 Authorised patients using medicinal cannabis may seek to participate in other activities which may be affected by their use of the substance, such as driving a car or attending work. This raises issues related to the risk associated with patients participating in these activities, as well as their right not to be discriminated against because of their treatment.

6.109 While most United States jurisdictions explicitly prohibit patients from using medicinal marijuana in the workplace,²²⁵ a number also prevent employers from discriminating against authorised patients on the basis of their status as a medicinal cannabis user.²²⁶ In Delaware, Arizona and Minnesota, patients are also protected if they have a positive

²²² Ibid 9–11 (Table 3-1).

²²³ 5 Code Colo Regs § 1006-2, r 12; Conn Gen Stat § 21a-408a(2).

²²⁴ See, eg, Colorado (5 Code Colo Regs § 1006-2, r 12); District of Columbia (22 DCMR § 1001.1(a)); Maine (*Rules Governing the Use of the Maine Medical Use of Marijuana Program*, 10-144 Me Code R Ch 122 § 2.12; Vermont (18 Vt Stat Ann § 4474c(a)(3)).

²²⁵ Hunton & Williams LLP, 'Anti-Discrimination Provisions in State Medical Marijuana Laws Raise Additional Considerations for Workplace Drug Testing' on Hunton Employment & Labor Perspectives (22 January 2015) <<http://www.huntonlaborblog.com>>. See, eg, Minnesota (Minn Stat § 152.32(3)(c)); Connecticut: (Conn Gen Stat § 21a-408a(b)(2)).

²²⁶ Hunton & Williams LLP, 'Anti-Discrimination Provisions in State Medical Marijuana Laws Raise Additional Considerations for Workplace Drug Testing' on Hunton Employment & Labor Perspectives (22 January 2015) <<http://www.huntonlaborblog.com>>. For example, Minnesota (Minn Stat § 152.32(3)(c)), Delaware (16 Del Code Ann § 4905A), Connecticut (Conn Gen Stat § 21a-408p(3)) and New York (Public Health Law § 3369(4)).

drug test, except where there is a safety issue or the patient used or was impaired by cannabis while at work.²²⁷

- 6.110 US states do not tend to make special allowances for registered patients who drive while under the influence of cannabis.²²⁸ New Mexico and New Hampshire specify that participation in a medicinal cannabis program does not exempt a patient from prosecution arising from driving a vehicle or operating heavy machinery while under the influence of cannabis.²²⁹

Regulatory design issues

Operating a medicinal cannabis scheme within a federal system

- 6.111 The jurisdictions considered in this issues paper have wrestled with the question of how to operate a medicinal cannabis scheme within a federal framework. Issues of cross-jurisdictional recognition and ‘jurisdiction shopping’ arise, with regulators addressing the problems in inconsistent ways. Some jurisdictions have also observed the spill-over of cannabis produced for medicinal purposes into illicit markets outside their jurisdiction. The United States has experienced stark and unresolved inconsistency between its federal laws criminalising cannabis for all purposes, on the one hand, and the state laws designed to put medicinal cannabis schemes in place, on the other.
- 6.112 In Europe, patients resident in a European Union country are permitted to travel to another European Union country with cannabis which has been prescribed to them for medicinal purposes, provided certain conditions are met.²³⁰ Patients must obtain a certificate in the prescribed form from their home country, and present it at any border check.²³¹
- 6.113 Similar cross-border recognition questions have arisen in the United States, where some states have legalised the medicinal use of cannabis, but the majority maintain an absolute prohibition on high-THC cannabis. A minority of jurisdictions recognize

²²⁷ Hunton & Williams LLP, ‘Anti-Discrimination Provisions in State Medical Marijuana Laws Raise Additional Considerations for Workplace Drug Testing’ on Hunton Employment & Labor Perspectives (22 January 2015) <<http://www.huntonlaborblog.com>>. See, eg, Minnesota (Minn Stat § 152.32(3)(c)).

²²⁸ While Nevada allows driving while under the influence of cannabis, up to a prescribed concentration (2 nanograms per mL of blood of marijuana or 5 nanograms per mL of blood of marijuana metabolites: Nev Rev Stat § 484C.110), this maximum concentration applies to all drivers, not just authorised medical marijuana patients.

²²⁹ NH Rev Stat Ann § 126-X:3(II); NM Stat § 5(A)(2).

²³⁰ *Convention Implementing the Schengen Agreement of 14 June 1985*, signed 19 June 1990, OJ L 239, 22.09.2000, art 75(1).

²³¹ *Ibid* art 75(1) and (2). See Office of Medicinal Cannabis, *Import & Export - Dutch Patients and Businesses* <<http://www.cannabisbureau.nl/en/ImportExport/Dutchpatientsandbusinesses>> for an example declaration.

practitioner credentials and patient registrations from other states, but the law is uneven.²³²

6.114 The discrepancy between federal law and state laws in the United States has limited how states can design their schemes, and resulted in some unintended consequences. As mentioned above, the authorised patient schemes, and the ‘dispensary’ or specialist retailer model prevalent in the United States are in part a consequence of federal laws prohibiting doctors and pharmacies from prescribing and selling cannabis. In some states, the government has had to countenance or overlook illegality in the setting up of new cultivation businesses, as there is practically no way of starting up a new business without contravening federal law.²³³ In addition, cannabis businesses in the United States have had difficulty opening bank accounts and obtaining finance, as banks and credit providers are leery of contravening federal laws.²³⁴ This has meant that cannabis businesses are frequently cash-based, putting them at high risk of robbery and break-in.²³⁵

Providing a cost-effective system

6.115 Other jurisdictions have confronted the question of how to provide a system which is both cost-effective to run and allows cannabis to be supplied to patients in an affordable manner. These considerations are important because, as some jurisdictions have found, a scheme which does not supply cannabis in a cost-effective way is scarcely better than no scheme at all.²³⁶

²³² Arizona, Maine, Michigan and Rhode Island recognise out-of-state ID cards for possession purposes, but it appears that none of these jurisdictions allows non-residents to purchase cannabis in the state. New Hampshire only recognises ID cards of patients who have conditions which are eligible for medicinal cannabis in New Hampshire, and purchasing is also not permitted. Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 9–11.

²³³ In states with new medicinal cannabis schemes, there is no way of new cultivation businesses setting up without bringing plants or seeds across the state line, which amounts to a breach of federal law. In Illinois, the bill’s author stated, ‘We purposely left the bill silent. It’s either grown illegally in Illinois or brought in inappropriately. Admittedly, the first seed is not technically a legal seed.’ Phil Rogers, ‘Feds Must Look the Other Way in Acquisition of First Medical Marijuana Seeds’ *NBC Chicago* (online) (4 December 2014) <<http://www.nbcchicago.com/news/local/Seeds-for-Medical-Marijuana-Must-Magically-Appear-in-State--284818031.html>>.

²³⁴ Todd Garvey and Charles Doyle, *Marijuana: Medical and Retail - Selected Legal Issues*, Congressional Research Service Report 7-5700 (25 March 2014) 24–28 <<http://fas.org/sgp/crs/misc/R43435.pdf>>. Federal guidelines introduced in February 2014 seek to encourage banks to offer financial services to cannabis businesses: Department of the Treasury Financial Crimes Enforcement Network, *BSA Expectations Regarding Marijuana-Related Businesses* (Guidance FIN-2014-G001, 14 February 2014). Notwithstanding this, it appears that, to some extent, the problems remain: Danielle Douglas, ‘Banks Are Slowly Welcoming Legal Marijuana Dealers’, *The Washington Post* (online), 12 August 2014, <<http://www.washingtonpost.com>>.

²³⁵ Tony Dokoupiland and Bill Briggs, ‘High Crimes: Robber Gangs Terrorize Colorado Pot Shops’, *NBC News* (online), 4 February 2014 <<http://www.nbcnews.com>>; Julie Andersen Hill, ‘Why Won’t Banks Dance With Mary Jane’, *The Conversation* (online), 27 October 2014 <<http://theconversation.com>>.

²³⁶ Italy began permitting eligible patients to access imported medicinal cannabis from the Netherlands in 2013. However, the imported cannabis was priced at ten times the cost of products purchased on the black market, at €38 per gram, or €1,000 per month for a typical patient. As a result, only a ‘few dozen’ Italian patients signed up for the program. Steve Scherer, ‘To Grow Cheap Marijuana, Italy Calls In The Army’, *Reuters* (online), 12 October 2014 <<http://www.reuters.com>>.

- 6.116 Many American jurisdictions fund their regulatory system through taxes and licence fees. Frequently, a small registration fee is imposed on patients and caregivers, while significant application and licence fees are levied on cultivators and distributors (sometimes in excess of US\$50,000 per year).²³⁷ In some jurisdictions, the fees collected have completely offset the cost of running the program.²³⁸
- 6.117 In a number of jurisdictions, retail prices for medicinal cannabis are set by the government because of its involvement in the market. In the Netherlands, as all cannabis is sold by the Office of Medicinal Cannabis, it sets the prices based on the costs it incurs in purchasing, analysing, packaging and distributing the cannabis. At the time of writing, the price of all strains available in the Netherlands was €38 for five grams.²³⁹ Canada controlled the price of cannabis under its prior regime (where the government was the sole seller) and set the price at C\$5 per gram, which was said to be cost price.²⁴⁰
- 6.118 Some US states impose price controls by regulation, not by government involvement in the distribution process. In Vermont, dispensaries are required to have 'a sliding-scale fee system that takes into account a registered patient's ability to pay'.²⁴¹ In New York, the government will set the 'per dose price' at which medicinal cannabis may be sold.²⁴² Prices are also controlled indirectly by the common requirement, referred to above, that distributors be operated on a not-for-profit basis.²⁴³
- 6.119 In New Jersey, distributors cannot advertise the price of the cannabis they sell, except by advising patients directly or by printing a catalogue which is available to patients and care-givers at the physical premises. The government justifies this measure as a way of preventing black market sellers from undercutting legal distributors.²⁴⁴

Learning from experience

- 6.120 Some jurisdictions appear to have laboured under poorly designed schemes of regulation because a court or a citizen vote required them to implement a medical marijuana scheme, leaving them to prepare regulations to fit a pre-determined agenda, sometimes

²³⁷ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 21–22.

²³⁸ See Marijuana Policy Project, *State Medical Marijuana Programs' Financial Information* (18 October 2013) <<http://www.mpp.org/assets/pdfs/library/State-Medical-Marijuana-Programs-Financial-Information.pdf>>.

²³⁹ Office of Medicinal Cannabis, *Medicinal Cannabis*, <<http://www.cannabisbureau.nl/en/MedicinalCannabis>>.

²⁴⁰ Health Canada, *About Health Canada's Marihuana Supply for Medical Purposes* (archived content) (29 July 2013), <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/supply-approvis-eng.php>>.

²⁴¹ 18 Vt Stat Ann § 4474e(b)(2).

²⁴² Public Health Law § 3366-D.

²⁴³ See paragraph [6.63] above.

²⁴⁴ NJ Admin Code § 8:64-12.1(d); New Jersey Department of Health and Senior Services, *NJ Admin Code 8:64 - Public Comments and Agency Responses* (2011) 12 <www.state.nj.us/health/medicalmarijuana/documents/final_rules.pdf> (response to comment 21).

in haste. In Canada, for example, the federal government did not set out to legalise medicinal cannabis (indeed, it continues to recommend against the use of cannabis as a medicine on health and safety grounds²⁴⁵). Rather, a decision of the Canadian Supreme Court²⁴⁶ found that patients had a right to access medical marijuana, and ‘forced the government to cross the Rubicon and authorize the use of an otherwise illegal drug for medical purposes’.²⁴⁷ Subsequent regulatory changes (and further court actions) have reshaped the Canadian system, which now barely resembles the model that was first introduced in 2001. Similarly, schemes in a number of American states commenced as a result of citizen-initiated ballots, with the government left to fit regulations around their terms.

- 6.121 A number of United States jurisdictions have refined their regulatory systems over time to assert greater state control over the production and distribution of medicinal cannabis. Some states, such as Colorado and Maine, which began their medicinal cannabis programs with only slim volumes of rules, have recently enacted detailed regulations regarding cultivation and distribution, designed to fill gaps in earlier versions of the rules.²⁴⁸ While the initial wave of state laws focused on ‘grow your own’ production of cannabis, now only five out of 23 states do not provide some sort of distribution mechanism.²⁴⁹
- 6.122 A jurisdiction which recently introduced medicinal cannabis, Illinois, expressly set out to avoid the mistakes of states which acted sooner. An Illinois Department of Health official stated that Illinois ‘[had] really considered the difficulties other states have faced... I think already we’re starting it as one of the most regulated programs in the entire country.’²⁵⁰ Consequently, Illinois’s statute and accompanying regulations are extremely prescriptive. The scheme will sunset four years after its commencement, on 1 January 2018.

²⁴⁵ The Health Canada website displays the following message, as at the time of writing: ‘Dried marijuana is not an approved drug or medicine in Canada. The Government of Canada does not endorse the use of marijuana, but the courts have required reasonable access to a legal source of marijuana when authorized by a physician.’ Health Canada, *Medical Use of Marijuana* (23 December 2014) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/index-eng.php>>.

²⁴⁶ *R v Parker* (2000) 188 DLR (4th) 385 (Ontario Court of Appeal).

²⁴⁷ *R v Smith* [2014] BCCA 322, [131] (discussing *Parker*).

²⁴⁸ See, Michael Dohr, ‘Medical Marijuana in Colorado’ (June 2012) XXVII *The Legislative Lawyer*, (National Conference of State Legislatures) <<http://www.ncsl.org/legislators-staff/legislative-staff/legal-services/medical-marijuana-in-colorado.aspx>>; Maine State Law and Legislative Library, *Maine’s Medical Marijuana Law* (16 December 2014) <<http://www.maine.gov/legis/lawlib/medmarij.html>>.

²⁴⁹ Lance Ching and Johnny Brannon (Legislative Reference Bureau of Hawaii), *Is the Grass Always Greener? An Updated Look at Other State Medical Marijuana Programs*, Report 1 (2014) 8. This shift in the law was motivated in part by the federal government’s 2009 announcement that it would not prosecute people who distributed medical marijuana in accordance with state law: see David Johnston and Neil Lewis, ‘Obama Administration to Stop Raids on Medical Marijuana Dispensers’, *New York Times* (online), 18 March 2009 <<http://www.nytimes.com/2009/03/19/us/19holder.html>>.

²⁵⁰ Phil Rogers, ‘Feds must look the other way in acquisition of first medical marijuana seeds’, *NBC Chicago* (online), 4 December 2014 <<http://www.nbcchicago.com>>.

6.123 Victoria is able to observe and consider the experience of other jurisdictions which have experimented with various systems and approaches to the regulation and supply of cannabis for medicinal purposes. The contrasting approaches and experiences (both good and bad) of other jurisdictions can be considered in the context of Australia's federal legal framework, and selectively applied to Victoria. Caution must be exercised, however, in assessing schemes in other jurisdictions, as many are very new and are either not yet implemented, or so new as to provide few useful insights.

Regulatory objectives and options

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7 Regulatory objectives and options

Introduction

- 7.1 Victoria is able to learn from overseas experience in regulating the use of cannabis for medicinal purposes. As discussed in Chapter 6, other jurisdictions have adopted a variety of approaches to allowing cannabis to be used medicinally by different groups of patients.
- 7.2 When considering how Victoria's laws could be changed, it is useful to look at regulatory tools that have been effective elsewhere. When deciding which changes, if any, to make, the focus should be on what they are intended to achieve and the feasibility of achieving such objectives.
- 7.3 This chapter sets out six objectives that would be applicable to any regulatory scheme that allows cannabis to be used for medicinal purposes in exceptional circumstances. They were derived from the terms of reference to help identify law reform options for Victoria. They should not be taken as a statement of the Commission's position on the legalisation of cannabis for therapeutic purposes.
- 7.4 The chapter then explores the possible regulatory approaches that could be taken in Victoria in view of:
- the regulatory objectives
 - the regulatory framework within which any change can occur (discussed in Chapter 4)
 - recent and concurrent developments in Australia (discussed in Chapter 5)
 - international experience (discussed in Chapter 6).

Regulatory objectives

- 7.5 The following regulatory objectives are relevant to any law reform that allows people to use medicinal cannabis in exceptional circumstances. They reflect the Government's policy as conveyed in the terms of reference. It is important to have regard to the current state of clinical knowledge about the benefits, efficacy, risks and dangers of medicinal cannabis in the context of ensuring that patients receive treatment that is in fact, as well

as intention, therapeutic, and does not give rise to collateral consequences which are unacceptable.

- **Allow compassionately for exceptional circumstances of need**

The question of who should be permitted to use cannabis for medicinal purposes in Victoria is not solely a legal issue: it is a health issue that of necessity also incorporates economic considerations related to patients' access. Possible approaches to determining eligibility are discussed in Chapter 3.

- **Ensure that the use of medicinal cannabis is effectively integrated into the user's program of medical treatment**

A core purpose of any medicinal cannabis scheme would be to improve the quality of life of the people for whom cannabis can provide therapeutic benefit. In designing a scheme for Victoria, attention would need to be given to ensuring optimal safety for authorised users, including by integrating their use of cannabis with conventional treatments for their medical condition, under appropriate and informed medical supervision.

- **Ensure that informed consent is given to the use of medicinal cannabis and that there are not unacceptable side effects from its use**

It is apparent that there are issues in relation to the side effects that medicinal cannabis may have. These are relevant to the designation of categories of patients who might receive medicinal cannabis, the particular patients who may receive it, the communications that need to take place with patients for whom it is prescribed, and the ongoing care and monitoring that such patients are given.

- **Ensure that medicinal cannabis is safe and of reliable quality and composition**

As discussed in Chapter 2, the therapeutic benefits of cannabis are determined largely by the type of cannabis used: for instance, if raw plant material is used, how it is prepared and the form in which it is administered. An objective of legalising medicinal cannabis should be to make appropriate products available and to achieve certainty, or at least as much confidence as possible, about their therapeutic properties.

- **Foster, and be responsive to, clinical research and advancements in technology**

Any medicinal cannabis scheme established in Victoria would need to remain effective over time as scientific knowledge, medical practices and technology continue to evolve. In addition, the operation of the scheme should be subject to ongoing monitoring and re-evaluation as it would be likely to generate information that could contribute to the body of knowledge about the efficacy and properties of cannabis-based medications.

- **Enable the ongoing and effective enforcement of the prohibition on unauthorised cultivation, production, supply and use of cannabis**

New Victorian legislation would need to reinforce the prohibitions on the cultivation, supply and use of cannabis, which would continue to apply in all but exceptional circumstances. The possible impact on law enforcement, in Victoria and in other jurisdictions, would need to be taken into account at each step in developing the details of how the scheme would operate.

- 7.6 In putting these objectives forward to frame discussion about the issues, the Commission recognises that they may be incomplete or could be refined.
- 7.7 Some additional objectives will be valid but secondary. For example, the need for the scheme to be cost-effective, and thereby that medicinal cannabis is affordable for patients, is likely to influence decisions at all stages of implementing the government's policy. In particular, it is important that the cost of medicinal cannabis made available under a state scheme, and administrative requirements enabling access to it, not be such as to render illegal access to cannabis preferable for legitimate patients. Although these considerations are important in making any Victorian medicinal cannabis scheme viable, they have not been identified as a regulatory objective because cost considerations are inherent in decisions across government.

Question

- 7 **Are the regulatory objectives identified by the Commission appropriate? What changes, if any, would you make to them?**

Options

- 7.8 Although referring to regulatory objectives can be useful in discerning which reforms to the law may be desirable, the range of choices available in practice is determined by how the Commonwealth and the states share control over the cultivation, processing, supply and use of cannabis. As discussed in Chapter 4, therapeutic goods are regulated by a complex framework of international, national and state-based mechanisms.
- 7.9 An option solely within Victoria's jurisdiction would be to create a defence to prosecution for authorised medicinal cannabis users. However, this option has significant disadvantages when assessed against the regulatory objectives. It does not ensure that the patient receives individualised treatment, under medical supervision, with cannabis that is safe and of a reliable quality and composition.
- 7.10 A comprehensive scheme that regulated every step in the cannabis supply chain (importation, cultivation, manufacture, processing, distribution and use) could achieve all six regulatory objectives but could not be achieved without the involvement of the

Commonwealth. For instance, Victoria does not have the power to allow cannabis to be imported. In addition, there is uncertainty in relation to its powers that intersect with other Commonwealth legislation.

- 7.11 Further, Victoria has no control over the availability and price of pharmaceutical products derived from the cannabis plant or containing synthetically produced cannabinoids or cannabinoid analogues. Any medicinal cannabis scheme in Victoria would need to operate alongside the national scheme for evaluating and approving the supply of pharmaceutical products, which is administered under the *Therapeutic Goods Act 1989* (Cth) and supplementary state legislation.
- 7.12 All of the options discussed in this chapter would need to be supported by a robust system for identifying the authorised patients, carers and medical practitioners, and for ensuring the safety and security risks associated with cultivation are managed. As discussed in Chapter 6,¹ these risks are substantial if not adequately managed.
- 7.13 The following sections of this chapter outline possible approaches that Victoria could take to achieve the regulatory objectives. The Commission welcomes comments about the options and, in particular, responses to the questions it poses throughout the discussion.

Defence to prosecution for possession and use

- 7.14 An eligible patient who has been authorised to be treated with medicinal cannabis could be made exempt from criminal prosecution for use or possession of the amount they need. This option could be achieved by amending the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) to create an exception to the offences of possessing or using a drug of dependence² for small amounts of dried cannabis or cannabis extract where a person is an authorised medicinal cannabis user.
- 7.15 The exception would probably need to extend to the authorised patients' carers, to allow them to possess the cannabis their patients may lawfully use, and could require an additional exception to the offence of introducing a drug of dependence into the body of another person.³
- 7.16 An option of this nature was recommended for New South Wales in 2013 by General Purpose Standing Committee No 4 of the New South Wales Legislative Council.⁴ The committee recommended a complete defence to the offences of possession and use for terminally ill patients and those who had moved from HIV to AIDS, for possession of up to 15 grams of dried cannabis or equivalent amounts of cannabis products. The defence would have applied to a patient or carer where the patient had been certified by their

¹ See [6.49] and [6.51].

² *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 73, 75.

³ *Ibid* s 74. Consideration may also need to be given to amending section 71B of the Act (supply of drug of dependence to a child).

⁴ Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013) 71 (Recommendation 2).

treating specialist medical practitioner as having been diagnosed with a specified condition and had been listed on a register of 'authorised cannabis patients and carers'.⁵

- 7.17 The advantage of this option is that it would protect patients and their carers from the risk of being prosecuted for using cannabis for medical purposes in exceptional circumstances, and the associated uncertainty and pressure. By applying to the possession and use, but not the cultivation of medicinal cannabis, it also avoids the risk of lawfully-grown cannabis finding its way onto the illicit market.
- 7.18 When assessed against the regulatory objectives, this approach has a number of disadvantages. Although it relieves users of medicinal cannabis and their carers of the risk of prosecution, it fails to provide access to a safe and reliable supply of cannabis or cannabis products. As the cultivation and supply of cannabis would remain unlawful, any person selling cannabis to an authorised patient or their carer would still be committing an offence. The legislative change would only assist users willing to purchase cannabis that has been grown and supplied illegally. This in turn would strengthen the illegal market. Doctors would authorise patient access to cannabis, but would not have any mechanism for controlling or supervising use. The products obtained may not be therapeutically appropriate, as cannabis grown primarily for recreational use could have unknown or inappropriate THC/CBD levels, and may contain unsafe contaminants.

Question

- 8 Would the creation of a defence to prosecution for authorised patients and carers in possession of small amounts of dried cannabis or cannabis products be an adequate way of providing for people to be treated with medicinal cannabis in exceptional circumstances?**

Cultivation

- 7.19 There are three possible approaches to allowing cannabis to be grown for medicinal purposes in Victoria:
- a 'grow your own' scheme
 - cultivation by licensed growers
 - state-controlled cultivation.

⁵ Ibid.

A 'grow your own' scheme

- 7.20 An eligible patient could be authorised to grow their own personal supply of cannabis. The New South Wales Working Party on the Use of Cannabis for Medical Purposes recommended in 2000 that not only should authorised patients be exempt from prosecution for possession and use, they should be permitted to cultivate a small amount of cannabis for personal, medical use in their own homes.⁶
- 7.21 The Victorian Drugs, Poisons and Controlled Substances Act prohibits cultivation unless it is authorised by or licensed under the Act or regulations. Allowing limited cultivation for medicinal purposes would not require substantial changes to the law.
- 7.22 The advantage of this option is that it could provide patients with a readily available and inexpensive supply of cannabis. They would have control over their dosage, frequency of use, and form of administration. They would no longer need to rely on the illicit market for the purchase of prepared cannabis (provided they were able and inclined to grow their own) and they would be aware of the conditions in which the cannabis is grown and processed.
- 7.23 As not all patients would be able to grow their own cannabis plants and prepare the dried plant material, some would need to be able to authorise others to grow it for them, as has occurred overseas.
- 7.24 When considered in view of the regulatory objectives identified at the beginning of this chapter, there are a number of disadvantages of a 'grow your own' scheme. Significantly, the patient may not obtain cannabis that is of a high enough quality or consistent composition, due to the significant variability caused by different cannabis strains and by growing conditions, which only sophisticated growing operations are able fully to control. In addition, patients and their authorised growers may have limited expertise in producing refined products, which can be difficult and dangerous to produce. Technological innovations would also be unlikely to be developed at the domestic scale.
- 7.25 From a law enforcement perspective, and based on overseas experience, it would be difficult under this option to prevent cannabis that has been grown legally from entering the illicit market. It would be indistinguishable from illegally grown plants.
- 7.26 Patients and their carers could be required to follow strict rules on the amount of cannabis they grow and the facilities used to grow it. Enforcing these rules would require close monitoring of their activities, which would be labour intensive and could be seen as intrusive. It may also not be very effective from the perspective of law enforcement. International experience has shown that poorly regulated 'grow your own' schemes can increase the supply of cannabis on the illicit market.

⁶ Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000) vol 1, 40 (Recommendations 16 and 17).

- 7.27 A further concern is that the patients or carers who legally grow plants may be at greater risk of home invasion, electrical and fire safety risks, and excess mould and poor air quality where cannabis is grown in the home.
- 7.28 Finally, a telling factor in considering whether to introduce a 'grow your own' scheme in Victoria is that the negative consequences led Canada to commence phasing out its 'grow your own' scheme in 2014. In addition, the trend in the United States is to avoid allowing home cultivation of medicinal cannabis because of the difficulty that the jurisdictions that do allow it have encountered in attempting to confine its use to legitimate therapeutic purposes.

Cultivation by licensed growers

- 7.29 The Victorian Government could issue a limited number of licences to cultivate cannabis for the purpose of supplying authorised patients. This could be either instead of, or in addition to, a 'grow your own' scheme.
- 7.30 An example of this approach is the cultivation of alkaloid poppies, which is permitted by the Drugs, Poisons and Controlled Substances Act. Applicants would be able to apply to the Secretary of the Department of Environment, Land, Water & Planning for a licence. In considering the application, the Secretary would be required to take into account a range of factors to determine whether the person is fit and proper and had the capacity to fulfil the requirements of the licence. The application would need to be referred to the Chief Commissioner of Police, whose opinion on whether to issue a licence would prevail.
- 7.31 The licensee would be required to submit and comply with a risk management plan and be subject to close regulation of what they could grow, where they could grow it, and how much. Their employees and associates would also be vetted. Regular government inspections and the possibility of licence revocation or suspension would help to ensure compliance.
- 7.32 The degree of regulation would also safeguard against contamination by pesticides or fungicides or other chemicals and the presence of fungi, mould or bacteria.

State-controlled cultivation

- 7.33 The Victorian Government could be directly responsible for growing cannabis for medicinal purposes. This would give it the greatest control of the quality and quantity of cannabis grown legally under the medicinal cannabis scheme.
- 7.34 In effect, the task of cultivating medicinal cannabis could be outsourced. Following the approach taken in the Netherlands, the government could outsource to a single supplier, and limit the types and amount of cannabis available. Having a single cultivator would decrease the cost of overseeing and enforcing compliance, as compared with a 'grow your own' or licensed-cultivator scheme.
- 7.35 In Canada, before it revised its regulations in 2014, cannabis was cultivated and harvested by a company under contract to Health Canada, alongside a scheme where patients could grow their own cannabis. The state-controlled cultivation regime, which supplied only one strain of cannabis, was very poorly received by patients, who far

preferred being able to grow their own. Under the revised regulations, neither of these cultivation methods is available.

Question

9 What mechanism should Victoria use to regulate the cultivation of medicinal cannabis?

Processing and distribution

- 7.36 Cannabis plants must be prepared in some way in order for the cannabinoids to be absorbed effectively by the human body. A scheme which regulates how cannabis is processed could extend quality controls to this step in the supply chain. It would provide greater certainty to medical practitioners and their patients about the chemical composition of the treatment being administered, and result in a wider range of treatment options, as well as improving their capacity to evaluate dose-effect, side effects, and the overall clinical advantage or disadvantage to the ongoing prescription of the cannabis.
- 7.37 If cannabis were cultivated under state-controlled or licensed growers, regulation of both the processing and distribution would be essential to impeding the flow of legally produced cannabis onto the illicit market.
- 7.38 Because of the need to enforce the ongoing prohibition on unauthorised production and distribution, international approaches to regulating in this area are commonly a licensing scheme or a state-controlled scheme. Even when patients are able to grow their own cannabis for personal use, a regulated system of production and distribution is often set up for those who are unable or unwilling to produce their own supply.
- 7.39 Victoria could introduce either a licensing scheme or a state-controlled approach to the processing and distribution of cannabis. This could possibly, though not necessarily, be introduced in collaboration with the Commonwealth. One approach could be to follow the example of Canada and the many jurisdictions in the United States that require the cultivation, processing and distribution of cannabis to be carried out by the same entity. Vertical integration enables the production and supply of medicinal cannabis to be contained and monitored closely. In addition, it is easier to regulate one entity than to monitor the interactions among several entities that handle the cannabis between cultivation and delivery to the patient.

- 7.40 As discussed in Chapter 4, Victoria could amend the *Therapeutic Goods (Victoria) Act 2010* (Vic), or make regulations,⁷ with the effect that Commonwealth therapeutic goods legislation would not apply in Victoria to the processing and distribution of cannabis for medicinal purposes. Such a regulatory reform would allow natural persons and unincorporated associations, firms and partnerships in Victoria that are not engaged in interstate or overseas trade and commerce to process and distribute medicinal cannabis. Alternatively, or additionally, a state agency that is not a ‘constitutional corporation’ could be established for these and other purposes related to the operation of the scheme.
- 7.41 A disadvantage of this solution is that the field of entities that could be licensed would be narrow. A scheme that allowed corporations to participate may need to involve the Commonwealth. A shared approach already exists for the regulation of the processing of poppy straw in Victoria. A person cannot hold a poppy processing licence under the *Drugs, Poisons and Controlled Substances Act* unless they first obtain a manufacturing licence from the Commonwealth under the *Narcotic Drugs Act 1967* (Cth) or an export licence under the *Customs Act 1901* (Cth). Poppy cultivators are only permitted to sell or transfer poppy products to licensed processors.
- 7.42 The distribution of medicinal cannabis could involve pharmacists, either by creating a system of licensing which is available only to licencees, or building distribution licensing into the existing scheme for the licensing of pharmacists. Pharmacies can be owned by individuals and partnerships of individuals,⁸ and it appears that such businesses could be authorised to sell cannabis products by an amendment to Victorian law.⁹ In addition, compounding pharmacists may be able to play a role in the processing of patient-specific cannabis products.¹⁰
- 7.43 Whichever distribution system, if any, is adopted, there would need to be regulatory controls regarding the labelling of cannabis products, provision of advice to patients, supply of paraphernalia, purchase limits for authorised patients, and possibly a cap on the number of outlets. These measures would be necessary to prevent diversion of lawfully produced cannabis to the illicit market, assist law enforcement and ensure safe use of cannabis by authorised users.

⁷ Using the power in s 6(3) of the *Therapeutic Goods (Victoria) Act 2010* (Vic).

⁸ Section 5(1) of the *Pharmacy Regulation Act 2010* (Vic) states that a pharmacy business can only be owned by a registered pharmacist, a company whose directors and shareholders are all registered pharmacists, or a friendly society (and a few additional categories not relevant for present purposes). See also section 21 of the *Pharmacists Act 1974* (Vic), which has now been repealed.

⁹ A pharmacy that is, or is owned by, a corporation would fall under the scope of the Commonwealth Therapeutic Goods Act.

¹⁰ See Vendula Belackova et al, *Medicinal Cannabis in Australia—Framing the Regulatory Options* (2015) Paper of the Drug Policy Modelling Program, National Drug and Alcohol Research Centre, 12.

Questions

- 10** What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?
- 11** How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?

Importation

- 7.44 Enabling eligible patients under Victoria's scheme to import medicinal cannabis products could be quicker and easier than establishing a lawful and therapeutically appropriate local supply.
- 7.45 As discussed in Chapter 6, the Netherlands exports cannabis that is grown and processed under strict conditions. Cannabis from such a source, imported into Victoria under strict controls, could supplement local production—or replace the need for it altogether if only a small number of patients would potentially benefit from it. Refined cannabis products could also be imported.
- 7.46 Bringing in or importing cannabis is specifically prohibited by criminal law and customs regulations and is also unlawful because almost all forms of cannabis are unapproved therapeutic goods for the purposes of the Commonwealth Therapeutic Goods Act. Although the Secretary to the Commonwealth Department of Health has the discretion to make exceptions, the criteria for approval are so strict that any application to import cannabis other than for a clinical trial seems unlikely to succeed under existing policies. Any changes to the existing prohibitions would require action by the Commonwealth, as discussed in Chapter 4.

Use in exceptional circumstances

- 7.47 The issues concerning a patient's use of medicinal cannabis fall within three categories:
- identifying who is eligible to be treated with medicinal cannabis
 - authorising an eligible patient, in view of their personal circumstances, to use medicinal cannabis
 - ensuring that eligible patients receive treatment that is safe and therapeutically appropriate.
- 7.48 The first category concerns the question of determining the exceptional circumstances that will determine who is eligible to be treated lawfully with cannabis. It is discussed in Chapter 3.
- 7.49 Issues related to the other two categories are discussed below.

Authorisation to use

- 7.50 Any medicinal cannabis scheme established in Victoria would need to provide a way for people who are *eligible* to use medicinal cannabis to be *authorised* to use it. Although a person may meet the eligibility criteria of the scheme as set out in legislation, their access to medicinal cannabis should be determined by their individual health needs. This is a medical decision that requires a professional assessment by a designated medical practitioner.
- 7.51 If the designated practitioner concludes that the person should use medicinal cannabis as part of their treatment, the person could then be authorised to use it. This would be an administrative procedure.
- 7.52 As discussed earlier, there would need to be legislative change to put in place legal protections for patients who are authorised to possess and use cannabis medicinally. In particular, the Drugs, Poisons and Controlled Substances Act would have to be amended to create an exception to the offences of possession, use and administering to another, where appropriate authorisation had been obtained. This would protect authorised users from the risk of arrest, prosecution and confiscation of their supply.

Gatekeeper role of medical practitioners

- 7.53 Effective participation by medical practitioners is crucial to the success of any medicinal cannabis scheme. Not only do they need to meet their professional responsibilities to their patients, they would control who is authorised to participate in the scheme and have a key role in preventing unauthorised access. They would be responsible for advising patients of the advantages, disadvantages, options and risks of treatment, and would also play a role in supervising their dosage and response and in taking particular precautions in relation to high-risk patients (such as those who are at risk of dependence or psychosis).
- 7.54 Requiring health professionals to determine whether a person should be able to use medicinal cannabis in conformity with statutory criteria is consistent with access arrangements for all restricted medication. Similarly, it is within their normal professional responsibilities to determine the form and amount that can be used.
- 7.55 The gatekeeper role for the medicinal cannabis scheme would be complex because of conflicting claims about the therapeutic value of cannabis, developments in knowledge about it as the results of clinical research are published, limitations in the knowledge about side effects and the risk of misuse or diversion to the illicit market. It is likely that any medicinal cannabis scheme in Victoria would require additional regulation that would affect or apply to medical practitioners, or at least to a subset of such practitioners—such as, for instance, oncologists, neurologists, palliative care physicians and paediatricians.
- 7.56 In identifying appropriate controls, some of the practices adopted in overseas jurisdictions could be considered, such as:
- identifying, for the time being, particular conditions for which medicinal cannabis could be prescribed

- allowing only authorised or certain categories of specialist medical practitioners to assess whether a person is an appropriate candidate to be treated with medicinal cannabis
- setting out procedures that the practitioner should follow when making an assessment
- requiring two medical practitioners to certify that, in their view, the patient would receive (substantial) therapeutic or palliative benefit from medicinal cannabis
- limiting the period of authorisation in time, or requiring that patients return to the medical practitioner at regular intervals
- requiring certification from the medical practitioner that there is a bona fide doctor-patient relationship with a person whom they have assessed.

7.57 Another consideration is the form of any regulation. It could be appropriate for some matters to be regulated by professional standards.

Questions

- 12 **What responsibilities should be given to health practitioners in authorising a patient's use of medicinal cannabis?**
- 13 **Who should have the authority to assess whether a patient is an appropriate candidate to be treated with medicinal cannabis:**
- (a) all registered medical practitioners
 - (b) certain designated specialist medical practitioners
 - (c) registered health practitioners who have prescribing entitlements
 - (d) a subset of these?

Verification of authorisation

- 7.58 A register containing information about patients, caregivers, and medical practitioners would need to be created as part of the authorisation process. An important function of the register would be to enable a law enforcement officer or government official to verify a person's claim that they are authorised to use and possess medicinal cannabis. Some of the information could be highly sensitive and require additional privacy protections to be set out in the scheme legislation.
- 7.59 Another part of the authorisation process could be to issue the user a document identifying their entitlement to possess and use medicinal cannabis. A number of overseas jurisdictions require people who are authorised to use medicinal cannabis to register with the government and be issued with an identity card, or licence. Inevitably, this affects the privacy of the patients' health information and may involve some perceptions of stigmatisation. Whether users should be issued an identity card in Victoria may depend on how often they would be expected to produce it, to whom, and for what purpose. This, in turn, would be determined by the type of scheme introduced.

Limits of Victorian jurisdiction

- 7.60 The authorisation provided under Victorian law to use cannabis for medicinal purposes would not apply outside Victoria. A person who lawfully used cannabis in Victoria would be breaking the law in every other Australian jurisdiction (and most other countries) if they used or possessed cannabis there.
- 7.61 It may be constructive for Victoria to enter into discussions with other Australian jurisdictions about reciprocal arrangements that might be created to deal with when users authorised in Victoria take medicinal cannabis interstate.

Receiving treatment that is therapeutically appropriate

- 7.62 Most of the regulatory features of medicinal cannabis schemes are directed to controlling access, ensuring compliance with the rules, and preventing crime. However, the central purpose of such schemes is, within the law, to improve the quality of life of people for whom cannabis can provide therapeutic benefit. In designing a medicinal cannabis scheme for Victoria, attention needs to be given to ensuring that authorised users achieve optimal results from their treatment.
- 7.63 Scientific knowledge about the medical efficacy of cannabis, its interaction with pharmaceutical products, side effects and the risk of detrimental outcomes is incomplete. Information about recommended forms and dosage may be scarce and unreliable. This places prescribers in a difficult ethical and legal position.¹¹

¹¹ See David Pennington, 'Medical cannabis: time for clear thinking' (2015) 202 *Medical Journal of Australia* 74, 75.

- 7.64 As discussed above, measures could be introduced to ensure that the prescribing medical practitioner is assisted to give an informed assessment as to whether a person should be permitted to use medical cannabis.
- 7.65 In addition, it may be useful to provide training courses for practitioners on the medical indications, uses and side effects of medicinal cannabis. Completion of such courses could be a prerequisite to being authorised to assess whether a person would benefit from using medicinal cannabis, or to monitor people who use it as part of their treatment.
- 7.66 The training could be supplemented by guidelines on how to incorporate medicinal cannabis into a patient's treatment responsibly and effectively.

Questions

- 14 What requirements, restrictions, guidance or other assistance should health practitioners be given in monitoring a patient's use of medicinal cannabis?**
- 15 What additional restrictions or requirements, if any, should apply to patients who are vulnerable by reason of age or lack of capacity, so as to provide adequate protection for their welfare?**

Controls of form in which medicinal cannabis is used

- 7.67 As discussed in Chapter 2, the rate of onset, consistency and effect varies according to the way in which cannabis is administered. For this reason, it is important not only that the cannabis used is of high quality and known constituency, it should be available in a form that is safe and effective to administer. If it is not, the prescribing practitioner is not in a position ethically or professionally to evaluate, monitor and titrate its administration.
- 7.68 The most commonly available form of cannabis supplied for medicinal purposes overseas is the dried plant form (flowers and leaves). Some jurisdictions permit the supply of refined forms instead of or in addition to the dried form, while others limit access to just dried plant matter (namely not oils, tinctures or forms suitable for vaporisers), on the basis that the refined products are too new and insufficiently researched.¹²
- 7.69 The risks associated with making cannabis available in dried plant form include the higher risk of diversion to illicit markets, the health risks associated with smoking, and

¹² For a framework that analyses the link between the manner of authorisation and the source and forms of supply, see Vendula Belackova et al, *Medicinal Cannabis in Australia—Framing the Regulatory Options* (2015) Paper of the Drug Policy Modelling Program, National Drug and Alcohol Research Centre, 9–10.

the quality control issues arising from supply of an unrefined, herbal product. Jurisdictions outside Australia have sought to control the health risks by advising against smoking and providing patients with information about alternative administration methods. They have also imposed purchase limits and patient licensing systems to limit the diversion of supply.

- 7.70 A small number of overseas jurisdictions have prohibited cannabis in a smokable form, citing the risk of diversion and the adverse public health consequences of smoking. Because these schemes are in their infancy, their feasibility and effectiveness are yet to be evaluated satisfactorily. They may also prove to be more expensive to administer, as the government is required to oversee more than just cultivation. As the technology around refined forms of cannabis continues to advance, these schemes may become more viable.
- 7.71 Restrictions on the form in which medicinal cannabis may be made available can also assist in distinguishing lawful products from illicit cannabis, although it is important to note that many of the refined forms of cannabis capable of medicinal use are also popular among recreational users. An important means of enabling differentiation of authorised from non-authorised products is by packaging and labelling restrictions.
- 7.72 Some jurisdictions in the United States only permit access to low-THC/high-CBD, nonpsychoactive forms of cannabis. However, these forms of cannabis are useful only to a limited range of patients. Confining access to low-THC forms of cannabis may constitute an arbitrary or counter-therapeutic restriction on the types of products available and the patients able to benefit from its availability.

Question

16 In what form(s) should medicinal cannabis be permitted to be supplied and used?

Fostering and responding to clinical research and advances in technology

- 7.73 It is important that any medicinal cannabis scheme established in Victoria remains effective and justified while changes continue to occur in scientific knowledge, medical practices and technology.
- 7.74 There are many ways in which new information and ideas may affect future decisions by prescribing medical practitioners and users about the use of medicinal cannabis. For example:
- Clinical trials may reveal that medicinal cannabis is ineffective in treating a medical condition for which it is routinely used under the Victorian scheme, or is effective in treating a condition that is not covered by the scheme and perhaps should be.

- New pharmaceutical products that are more effective than medicinal cannabis in treating a condition for which medicinal cannabis is normally administered may be released onto the market.
- Innovative ways of preparing medicinal cannabis products that increase their effectiveness in treating certain symptoms may be developed.
- Medical practitioners whose patients use medicinal cannabis may observe, through experience, patterns in the circumstances in which those with a particular condition may benefit or may identify issues in respect of side effects or drug interactions.

7.75 Even a scheme that allowed for exceptions to be made in special cases for patients who would not otherwise be eligible could accommodate the possibility of ongoing systemic changes to a range of matters, including eligibility criteria.

Changes over time in the range of conditions for which medicinal cannabis is known to provide relief

7.76 If eligibility to use medicinal cannabis lawfully depends on whether the person has a specific condition, the list of relevant conditions would need to be reviewed periodically and updated as necessary. As ad hoc changes to the list could cause confusion about when medicinal cannabis can lawfully be used, it may be expedient for the legislation to require that the list of conditions is reviewed every two years (or other appropriate period of time).

7.77 Another approach would be to empower the Secretary of the Department of Health and Human Services, or a statutory entity constituted for such purposes, to determine whether the list should be amended, perhaps on the advice of a committee of professional experts. Although there would be a risk that the boundary between lawful and unlawful use of medicinal cannabis would become unclear if changed frequently, it would take the decision out of the political arena and place it where it more properly belongs—within a health context. However, the circumstances in which medicinal cannabis is able to be used lawfully have ramifications beyond the health arena, particularly for law enforcement.

7.78 Laws in other jurisdictions allow the list of eligible medical conditions to be updated by the government as new science emerges. In some jurisdictions, members of the public can petition the government to add conditions, and public hearings can be held if a base level of clinical literature exists.

Learning through experience of providing medicinal cannabis under the scheme

7.79 Potentially, the establishment of a medicinal cannabis scheme in Victoria could contribute to research and development in the treatment of severe medical conditions as well as improving general knowledge about the therapeutic properties of cannabis. By regulating rather than prohibiting the use of cannabis for medicinal purposes in certain circumstances, more comprehensive and reliable data could be compiled about its efficacy and side effects. For this reason, the collection of data for research purposes could be incorporated into the design of the scheme. It would require decisions about

who would collect the data, how it would be collected, and what privacy safeguards need to be put in place.

Question

- 17 In what ways could Victoria’s medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?**

Conclusion

8 Conclusion

- 8.1 By 31 August 2015, the Commission will be presenting the Attorney-General with its report on options for changes to Victorian legislation to allow people to be treated with medicinal cannabis in exceptional circumstances.
- 8.2 The legislative changes that may be introduced depend upon how many of the prohibitions on the supply and use of cannabis are modified. An option requiring only minimal variation from the current law could provide people who have been authorised to use medicinal cannabis with a defence against prosecution. More extensive legislative changes would enable patients to receive a safe, reliable and legal supply of medicinal cannabis in a therapeutically appropriate form.
- 8.3 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. The Commission welcomes submissions on the approaches Victoria could take and which of these should be preferred.
- 8.4 Even a modest medicinal cannabis scheme may have a significant regulatory impact. Internationally, there is a trend among jurisdictions that have recently established medicinal cannabis schemes to introduce stricter and more extensive controls than those adopted in the past. Quality control is an important issue, as is the actual and potential misuse of the system and the amount of lawfully produced cannabis that finds its way onto the illicit market. The methods employed by other countries in regulating medicinal cannabis are diverse and instructive, and the Commission seeks comments on which of them could appropriately be adopted in Victoria.
- 8.5 The Commission is also seeking comments on how to determine eligibility. Whatever the scope of the Victorian scheme, it would apply only to selected authorised patients. Therefore, the enabling legislation should provide robust eligibility criteria.
- 8.6 Although medical knowledge about the therapeutic properties of cannabis is evolving rapidly, it is incomplete. However, it is apparent that medicinal cannabis holds considerable potential for many different areas of treatment, and that some Victorians are already turning to it for relief. In determining who should be allowed to use cannabis for medicinal purposes, it is important to have regard to the current state of clinical

knowledge about the benefits, efficacy, risks and dangers in the context of ensuring that patients receive treatment that is in fact, as well as intention, therapeutic, and does not give rise to collateral consequences which are unacceptable.

8.7 The closing date for submissions is 20 April 2015.

Questions

Questions

- 1 Which of the following considerations should determine whether there are exceptional circumstances for medicinal cannabis to be made available to a patient:
 - (a) the circumstances of the patient
 - (b) the state of clinical knowledge about the efficacy or potential efficacy of using cannabis in treating the patient's condition
 - (c) both of the above?
- 2 For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of cannabis to justify allowing sufferers to use it lawfully in Victoria?
- 3 What special considerations, if any, justify access to medicinal cannabis for:
 - (a) patients who are under 18 years of age
 - (b) patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal cannabis?
- 4 On which of the following should the law creating a medicinal cannabis scheme base a person's eligibility to use medicinal cannabis:
 - (a) a list of medical conditions
 - (b) a list of symptoms
 - (c) a list of symptoms arising from certain medical conditions
 - (d) evidence that all reasonable conventional treatments have been tried and failed?
- 5 Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal cannabis? If so, what should that be?

- 6 If Victoria acted through a state agency, in what circumstances would it be legally entitled to establish a medicinal cannabis scheme which manufactured cannabis products without breaching the terms of the *Therapeutic Drugs Act 1989* (Cth) or the *Narcotic Drugs Act 1967* (Cth)?
- 7 Are the regulatory objectives identified by the Commission appropriate? What changes, if any, would you make to them?
- 8 Would the creation of a defence to prosecution for authorised patients and carers in possession of small amounts of dried cannabis or cannabis products be an adequate way of providing for people to be treated with medicinal cannabis in exceptional circumstances?
- 9 What mechanism should Victoria use to regulate the cultivation of medicinal cannabis?
- 10 What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?
- 11 How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?
- 12 What responsibilities should be given to health practitioners in authorising a patient's use of medicinal cannabis?
- 13 Who should have the authority to assess whether a patient is an appropriate candidate to be treated with medicinal cannabis:
 - (a) all registered medical practitioners
 - (b) certain designated specialist medical practitioners
 - (c) registered health practitioners who have prescribing entitlements
 - (d) a subset of these?
- 14 What requirements, restrictions, guidance or other assistance should health practitioners be given in monitoring a patient's use of medicinal cannabis?
- 15 What additional restrictions or requirements, if any, should apply to patients who are vulnerable by reason of age or lack of capacity, so as to provide adequate protection for their welfare?
- 16 In what form(s) should medicinal cannabis be permitted to be supplied and used?
- 17 In what ways could Victoria's medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?

You can respond to these questions by completing the online form at www.lawreform.vic.gov.au or by making a submission as described on page viii of this issues paper.



Victorian
Law Reform
Commission

Medicinal Cannabis
ISSUES PAPER

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