



Victorian
Law Reform
Commission

Medicinal Cannabis

REPORT AUGUST 2015





Published by the Victorian Law Reform Commission

The Victorian Law Reform Commission was established under the *Victorian Law Reform Commission Act 2000* as a central agency for developing law reform in Victoria.

© Victorian Law Reform Commission 2015.

This work is protected by the laws of copyright. Except for any uses permitted under the *Copyright Act 1968* (Cth) or equivalent overseas legislation, no part of this work may be reproduced, in any matter or in any medium, without the written permission of the publisher. All rights reserved.

This publication of the Victorian Law Reform Commission follows the Melbourne University Law Review Association Inc, *Australian Guide to Legal Citation* (3rd ed., 2010).

This report reflects the law as at 1 August 2015.

National Library of Australia Cataloguing-in-Publication data

Medicinal Cannabis:
Report / Victorian Law Reform Commission 32

ISBN 9780994372314 (paperback)

Series: Report (Victorian Law Reform Commission)

Subjects: Cannabis—Law and legislation—Victoria.

Cannabis—Therapeutic use—Victoria.

Dewey Number: 364.177

Ordered to be published
Victorian Government Printer 2015
PP number 68, session 2014-2015.

CHAIR

The Hon. Philip Cummins AM

SPECIALIST COMMISSIONER

Dr Ian Freckelton QC

COMMISSIONERS

Liana Buchanan
Helen Fatouros
Bruce Gardner PSM
Dr Ian Hardingham QC
His Honour David Jones AM
Eamonn Moran PSM QC
Alison O'Brien
The Hon. Frank Vincent AO QC

CHIEF EXECUTIVE OFFICER

Merrin Mason

REFERENCE TEAM

Lindy Smith (team leader)
Michael Adams
Sharyn Broomhead
Claire Leyden-Duval

COVER DESIGN

Letterbox

TEXT LAYOUT

GH Design

Medicinal Cannabis

REPORT AUGUST 2015



Victorian
Law Reform
Commission

Victorian Law
Reform Commission
GPO Box 4637
Melbourne
Victoria 3001
Australia
DX 144, Melbourne

Level 3
333 Queen Street
Melbourne
Victoria 3000
Australia

Telephone
+61 3 8608 7800
Freecall
1300 666 555
(within Victoria)
Fax
+61 3 8608 7888

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

Contents

Preface	vii
Terms of reference	ix
Glossary	x
Executive summary	xvi
Recommendations	xxxiv
1. Introduction	2
Terms of reference	2
The Commission’s process	2
The Commission’s approach.....	3
Scope of the reference	3
Focus of inquiry	4
Regulatory objectives	4
Risks	11
Expectations about implementation.....	12
A regulator	12
An advisory body.....	13
Interim measures.....	13
Concurrent developments.....	14
Rescheduling of cannabidiol.....	14
Clinical trials.....	14
Regulator of Medicinal Cannabis Bill 2014 (Cth)	14
Draft Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT).....	15
Tasmanian parliamentary inquiry	16
Norfolk Island licence to cultivate and export cannabis	17
Structure of this report.....	17

2. The use of cannabis for medicinal purposes.....	20
Introduction	20
What is medicinal cannabis?	20
Scope of review	20
Characteristics of medicinal cannabis.....	21
Use of medicinal cannabis	23
Personal accounts of conditions where cannabis has provided relief	23
Access.....	27
Research support for efficacy	30
Breadth and variety of data	30
Evidence-based medicine and the quality of evidence	31
The quality of cannabis research.....	32
Determining efficacy	34
Issues for policy-makers	44
Evidence of side effects.....	46
3. Access to medicinal cannabis in ‘exceptional circumstances’	52
Introduction	52
Exceptional circumstances	53
The idea of ‘exceptionality’	53
Compassion as a basis for action.....	54
Eligibility criteria	55
Factors informing eligibility criteria	55
Methods of determining eligibility	56
Proposed conditions and symptoms	61
Recommendations	69
Incorporating flexibility.....	73
Authorisation of treatment	75
Overview of proposed procedure	75
Residence requirement.....	76
Which practitioners?	77
Practitioner’s role	81
Legal procedures.....	87
Patients’ rights and obligations.....	92
Other participants.....	93
A new category of poison.....	94
Implementation issues	94

4. Current regulation of cannabis	102
Introduction	102
Restriction of supply as a narcotic drug	102
Single Convention on Narcotic Drugs 1961	102
Commonwealth Narcotic Drugs Act	105
Victorian Drugs, Poisons and Controlled Substances Act	106
Control of quality, safety and efficacy as a therapeutic good	107
Commonwealth Therapeutic Goods Act	108
Approval by the Therapeutic Goods Administration (TGA)	108
Victorian Therapeutic Goods Act	109
Approval of cannabis products	110
Access to unapproved products	112
Implications for a Victorian medicinal cannabis scheme	114
A stand-alone Victorian scheme	114
A comprehensive scheme	115
Conclusion	117
5. Options for reform	120
Introduction	120
Importation under amended Commonwealth rules	121
The option	121
Comments	122
Conclusion	124
Exemption from prosecution for possession and use	125
The option	125
Comments	125
Conclusion	126
‘Grow your own’	126
The option	126
Comments	127
Conclusion	134
Regulated not-for-profit production and distribution	135
The option	135
Comments	136
Conclusion	138
Regulated distribution through dispensaries	138
The option	138
Comments	139
Conclusion	140
Government-enforced monopoly	140
The option	140
Comments	141
Conclusion	142

Multiple licensed producers	142
The option	142
Comments	143
Conclusion	146
6. Regulating supply.....	148
Introduction	148
Nature of Commonwealth/state collaboration	148
Cultivation and manufacture	150
Industry structure.....	150
Licensing cultivation	153
Licensing manufacture	159
.....	163
Selection of licensees	164
Distribution	165
Government as single purchaser.....	166
Distribution through pharmacies	167
7. Regulating the product	174
Introduction	174
Product control: form and regulation.....	175
Quality control	175
Objectives of quality control.....	175
Regulation of herbal medicines in Australia	176
Creating a framework for medicinal cannabis quality.....	178
Quality standards	179
Efficacy testing.....	183
Clinical testing of side effects	184
Product approval.....	184
Batch testing.....	186
Labelling	187
Post-market surveillance	187
Forms of medicinal cannabis.....	187
Smoking should be avoided	188
Formulations and delivery systems.....	190
Strains.....	191
Cannabinoid content.....	193
Whole-plant medicines versus isolated cannabinoids	195

8. Research and evaluation	198
Introduction	198
Enabling research and drug development.....	199
Access to cannabis by researchers	200
Treatment permits and clinical trials.....	201
Knowledge collection and information provision.....	202
Responsiveness to change	204
Legal developments	204
Alternative supply options	205
Scheme evaluation	205
9. Conclusion	208
Appendix A. Advisory committees.....	212
Appendix B. Submissions	214
Appendix C. Consultations	216
Appendix D. Tables of legislative amendments	218
Bibliography	232

Preface

On 19 December 2014 and pursuant to section 5(1)(a) of the *Victorian Law Reform Commission Act 2000*, the Victorian Attorney-General, the Hon. Martin Pakula MP, referred to the Commission for review and report options for changes to the law to allow people to be treated with medicinal cannabis in exceptional circumstances. The reference was not in relation to legalisation of cannabis generally, nor in relation to legalisation of cannabis for medical purposes generally; but rather, for treatment with medicinal cannabis in exceptional circumstances. Thus this report addresses as a central issue the proper definition of what should constitute exceptional circumstances.

In its review the Commission heard many compelling stories of personal suffering, and also received submissions emphasising the presently limited proven scientific knowledge about the potential and risks of medicinal cannabis. The report is driven both by personal compassion and by medical responsibility.

This report is necessarily a complex one. Because cannabis is a prohibited drug in Victoria, any legalisation of it, including for compelling personal medical circumstances, must take into account the complex of legal, administrative, medical and health considerations applicable within Victoria and also nationally and internationally. Where practicable, the Commission has recommended the use of, or adaptation of, existing administrative structures, systems and protocols.

The options reviewed in the report demonstrate that, for effective and sustainable reform to take place, there needs to be collaboration between the Victorian and Commonwealth governments. At the time of writing, the introduction of Commonwealth medicinal cannabis legislation appears possible. Any such action would affect the options open to Victoria. Should this occur, I trust that the discussion in this report will provide helpful guidance in addressing the issues that would arise under any national medicinal cannabis scheme.

I acknowledge and warmly thank everyone who contributed to the review by making submissions and participating in public consultations. The Commission drew upon the expertise of many clinical and regulatory experts who generously gave their time and ideas at advisory committee meetings and private consultations. Likewise, some two hundred members of the public attended meetings that the Commission held in Melbourne and across Victoria to discuss the issues encompassed by the review. I attended a number of these consultations and was moved by the stories I heard.

Although I was closely involved at all stages, the review was led by Dr Ian Freckelton QC, who was appointed Commissioner for this purpose. I thank him for the intellectual rigour and tireless dedication he brought to the task.

I would also like to thank my fellow Commissioners, all of whom worked on this reference, for their contribution and expertise.

Finally, I am grateful for the hard work of the research team, led by Lindy Smith and supported by research and policy officers Michael Adams and Sharyn Broomhead and research and executive associate Claire Leyden-Duval.

I commend the report to you.



The Hon. P. D. Cummins AM
Chair
Victorian Law Reform Commission
August 2015

Terms of reference

[Referred to the Commission pursuant to section 5(1)(a) of the *Victorian Law Reform Commission Act 2000* (Vic) by the Attorney-General of Victoria, 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
 - medical 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	Any plant in the genus <i>Cannabis</i> and any product derived from the plant, including dried cannabis (marijuana) and cannabis extracts. Includes the <i>Cannabis sativa</i> , <i>Cannabis indica</i> and <i>Cannabis ruderalis</i> types.
Cannabis extract	Any concentrated form of cannabis in which the chemical components of the cannabis plant have been extracted 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.
Dried cannabis	The dried flowers, leaves and/or 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.
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.
FDA	The Food and Drug Administration, a statutory agency of the United States Federal Government responsible for regulation of pharmaceutical products, among other activities.

Flavonoid	Compounds found in plants which contribute flavour, aroma and pigment and are thought to provide a range of health benefits.
GACP	Good Agricultural and Collection Practice.
GMP	Good Manufacturing Practice.
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)</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)</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.
Specialist medical practitioner	A person registered to practise in the medical profession in a recognised specialty under the <i>Health Practitioner Regulation National Law (Victoria)</i> .
SUSMP	The <i>Standard for the Uniform Scheduling of Medicines and Poisons</i> 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 compound 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 vapourisation. 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.
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.
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.
Anti-convulsant	Preventing or arresting seizures.
Anti-emetic	Preventing or arresting vomiting.
Anti-inflammatory	Reducing inflammation, without affecting the underlying cause.
Arrhythmia	An abnormal heart rhythm.
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.
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 5th edition of the American Psychiatric Association's <i>Diagnostic and Statistical Manual of Mental Disorders</i> , published in 2013.
Epilepsy	A chronic neurological disorder characterised by violent, uncontrolled seizures and usually associated with some alteration of consciousness.
Euphoria	A feeling of well-being or happiness.
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 intraocular pressure and damage to 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.
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.
Intractable	Resistant to treatment.
Intraocular pressure	The fluid pressure within the eyeball which maintains its round firm shape. Abnormally high intrarocular pressure is a risk factor for the development of glaucoma.
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 central nervous system, 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.
Neurological	Concerning the nervous system and the diseases affecting it.
Neuropathic pain	Pain caused by damage to 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.
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 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.

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.
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.
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.

Executive summary

Introduction

- 1 This report completes the Victorian Law Reform Commission’s review of law reform options that would allow people in Victoria to be treated with medicinal cannabis in exceptional circumstances. The Victorian Government has made clear its intention to change the law to this effect, and the Commission has explored how it could be done, in accordance with terms of reference provided by the Attorney-General on 19 December 2014.
- 2 The terms of reference call for the Commission not only to review how Victorian legislation could be amended, but also to consider its interaction with Commonwealth law and functions and international conventions. In addition, they extend to an examination of how a medicinal cannabis scheme could operate. The Commission was asked to examine prescribing practices, eligibility criteria, the role of doctors, the regulation of manufacture and distribution, and which forms of medicinal cannabis should be permitted.
- 3 The Commission published an issues paper in March 2015, based on its analysis of the current law and research into the use of cannabis for medicinal purposes overseas, and called for submissions. It then held a series of consultations in Melbourne and regional centres with members of the public, health and legal professionals and government officials. It consulted by telephone with regulators and others involved with medicinal cannabis schemes in other countries and, as required by the terms of reference, convened panels of medical and regulatory experts.
- 4 The Commission’s conclusions are summarised below and its 42 recommendations are listed at page xxxiv–xl.

Medicinal cannabis

Definition

- 5 In the broadest sense of the term, ‘medicinal cannabis’ is cannabis used for medicinal purposes, namely to cure or relieve the symptoms of medical conditions. The purpose for which it is used distinguishes ‘medicinal cannabis’ from cannabis utilised as food or as a recreational drug.
- 6 Between 80 and 100 cannabinoids and some 300 non-cannabinoid chemicals are produced by the cannabis plant. The cannabinoids that have been discovered to have therapeutic properties are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), although claims in this regard have also been made in relation to a number of other cannabinoids. THC is best known for its psychoactive, euphoriant qualities but has also been identified to have anti-emetic, analgesic, anti-inflammatory and anti-oxidant properties. To a certain degree CBD moderates the effects of THC, and is being

researched for its potential to treat epilepsy, schizophrenia and other psychotic disorders, type II diabetes, inflammatory bowel disease, gliomas and drug dependency, among other conditions. A range of other non-psychoactive cannabinoids are also showing promise for the treatment of a range of diseases.

7 There are three main types of Cannabis—*Sativa*, *Indica* and *Ruderalis*—and multiple strains within each type. Many more strains have been produced through cross-cultivation. The different strains contain varying amounts of cannabinoids and therefore can have different effects on the user. When consumed, certain cannabinoids found in the cannabis plant are understood to lock onto specific receptor sites in the body that interact with the endocannabinoid system. Non-cannabinoid chemicals such as terpenes are also claimed to contribute to the medicinal effects of cannabis.

8 The effect on the user depends not only on the strain and chemical composition of the cannabis but also on the form and the method of its application. Cannabis that is used for medicinal purposes takes a variety of forms and is administered in a number of ways. Medicinal cannabis schemes in other countries make the following forms available, in different combinations and on different terms and conditions:

- the dried flowering tops of the cannabis plant, taken through being smoked, vaporised or infused in tea
- cannabis resin, collected and compressed from the flowering tops
- infused cannabis products, such as alcohol-based tinctures, edible oils infused with cannabis and products made from these, creams and suppositories
- extracts of cannabis, containing concentrated extracts of cannabinoids, taken orally, topically or by vaporisation
- raw, undried cannabis leaves, consumed as a food.

9 Some of these forms and delivery methods are employed by recreational users as well.

10 In submissions and consultations, and indeed worldwide, the term ‘medicinal cannabis’ is variously interpreted, from a limited definition requiring specific medical intervention to a wide definition comprehending therapeutic use by non-qualified persons. As the terms of reference do not define the term ‘medicinal cannabis’, the Commission has adopted a broad approach in consideration of the issues, and which leads, for the reasons stated in this report, to the Commission’s recommendations.

11 The Commission uses the term ‘medicinal cannabis’ to refer to products containing cannabinoids that are derived from the cannabis plant by any process whatsoever—including drying, infusing and extracting—and which are consumed with the intention of achieving a therapeutic effect, namely curing or remediating the symptoms of medical conditions. While it includes pharmaceutical grade products that are extracted from the cannabis plant, for the purposes of this report medicinal cannabis is not taken to refer to synthetic pharmaceutical products that mimic the effects of cannabinoids in the body.

How medicinal cannabis is used in Victoria

12 A broad range of Victorians use medicinal cannabis for a variety of conditions and symptoms, notwithstanding its prohibition under Victorian and Commonwealth law.

13 The Commission heard compelling stories about the dramatic improvements to their health that some cannabis users have experienced. Many spoke of the ways in which cannabis had enabled them to stop using pharmaceutical drugs with serious side effects, or to ‘get their lives back’. People without experience of medicinal cannabis told the Commission about the desperation they felt in experiencing, or watching a loved one experience, the pain and suffering of a chronic illness, and expressed sincere hope that cannabis might be effective for them and made legally available.

- 14 The majority of medicinal cannabis users and their relatives who spoke to the Commission said they obtained it (at varying cost) from people who specialise in the unlawful cultivation and refining of cannabis for therapeutic purposes—in Victoria and interstate. Indeed, several such producers attended the Commission’s consultations and some made written submissions. They conveyed a detailed knowledge of the cannabis plant, its varieties and refined versions, and expressed strong views about its potential therapeutic applications. In addition, an expansive submission on behalf of the ‘cannabis community’ of Victoria provided an account of illicit medicinal cannabis production and use in Victoria.¹ Users who presently access cannabis for medicinal purposes receive significant advice and guidance from their suppliers, including instructions on strains, dosage and indications.

Evidence of efficacy

- 15 Cannabis has long been used by humans for therapeutic purposes, yet scientific knowledge about how it affects the body is relatively recent and incomplete. A substantial body of clinical evidence now exists in relation to the efficacy of certain forms of cannabis for particular medical conditions, although the evidence varies in its rigour. AMA Victoria acknowledges that there is ‘some evidence to suggest that cannabinoids are effective for the treatment of neuropathic pain, muscle spasticity for patients with [multiple sclerosis], and in controlling nausea for cancer patients’.²
- 16 While this body of evidence is expanding, it is not yet of adequate quality for definitive statements to be made about the efficacy of cannabis in treating the range of conditions for which it is being used illicitly. A refrain of the credible scholarly literature is that further suitably controlled, high quality studies need to be undertaken in order to evaluate whether the claims, anecdotes and aspirations for the efficacy of medicinal cannabis can be justified.
- 17 Studies that are commonly cited in support of the efficacy of medicinal cannabis often rely on case reports, make claims arising from small patient cohorts, or lack controls and methodological rigour. Others are of limited utility because they were conducted on animals or cell lines, not humans. For the most part, systematic reviews and meta-analyses have offered only very qualified support or have identified potential, rather than actual, efficacy in medicinal cannabis.
- 18 Comparatively few research trials have been undertaken under close medical supervision where medicinal cannabis of known constituency was tested with double-blind techniques or effective placebo-controls. Few clinical trials have been conducted using cannabis oil, tinctures or other herbal preparations.
- 19 It seems likely that these deficits will be addressed in research currently underway or soon to commence. When these results become available, scientific discussion about the efficacy of medicinal cannabis will be significantly more sophisticated and informed than the discussions that can currently take place.

Side effects

- 20 A major reason why some within the medical profession have reservations about providing access to medicinal cannabis is the risk of adverse health effects. Some of these risks are known, and could be serious for some patients. Other risks, particularly in the long term, are unknown and this uncertainty would need to be factored into any decision by a patient or their carer to use it.
- 21 The following side effects have been identified, and are well described, but all are also disputed:
- Smoking cannabis, particularly in combination with tobacco, raises a risk of respiratory and potentially carcinogenic effects.
 - Cannabis use is a risk factor for developing and exacerbating the symptoms of schizophrenia, and for the development of psychotic symptoms.
 - Cannabis may have an adverse impact on the user's mood, particularly if a new user, including by making them anxious, depressed or paranoid.
 - Although cannabis is not highly addictive or habit-forming, the potential does exist for a small percentage of users, at least in the recreational context, to become dependent upon it to a point where they experience withdrawal symptoms for a time when they stop using.
 - Heavy cannabis consumption is known to induce tachycardia, and can increase the risk of heart attack, notably for users with existing heart disease or arrhythmias (abnormal heart rhythm).
 - Cannabis use during pregnancy has been found to be associated with a number of undesirable effects.
 - Cannabis use is likely to impact adversely upon concentration, responsiveness to stimuli and psychomotor function.
- 22 Most studies on the adverse effects of cannabis have focused on unregulated, illegal cannabis used recreationally, rather than on a quality-controlled supply intended for medical use. A systematic review conducted in 2008 looking at the medical use of cannabinoids concluded that short-term use increased the risk of non-serious adverse events compared to a control group, but not the risk of serious adverse events. However, the authors concluded that further research was needed before long-term risks could be accurately characterised.³
- 23 The point made by many submissions to the Commission is that the proven level of adverse effects, even from unmonitored recreational abuse of herbal cannabis, is of modest dimensions. Unlike the experience of opiate drug use, no deaths have been attributed to cannabis abuse. The Commission is of the view that, nevertheless, the risks—especially the long-term risks—and the concerns raised by the medical profession about them, should be acknowledged. Any Victorian medicinal cannabis scheme should be designed so as to permit the use of cannabis only under medical supervision, thereby enabling attentive and prompt responses to, and management of, any side effects that are identified to be emerging from its use.

Forms available under a medicinal cannabis scheme

- 24 As the effects of cannabis depend to some extent on the form in which it is administered, any Victorian medicinal cannabis scheme would need to make a variety of forms available. International experience shows that otherwise patients will rely on illicit supplies. The Commission considers that the range of products should be determined by the scheme regulator, be broad, and be responsive to changes in patient needs, research findings and product development.
- 25 However, the Commission recommends against patients being permitted to smoke medicinal cannabis. It is not persuaded by the submission made on behalf of the cannabis community of Victoria, which echoed the views of many who attended public consultations in presenting reasoned arguments for permitting smoking as an efficient, effective, practicable and accessible method of THC delivery.
- 26 Cannabis is commonly administered by smoking and is the preferred method for many users, notably when used for recreational purposes. It has been said, however, that fewer than half of the regular users of cannabis in Australia smoke it.⁴
- 27 Although the findings are inconsistent, there has been some association between smoking and lung conditions and cancer risks that have not been observed for other modes of administration. There is also the possibility of accidental ingestion by third parties through passive smoking.
- 28 While noting these potential risks, the Commission's primary concern is that providing smokable products as a medicine under a government scheme would be inconsistent with the public health policy to reduce smoking in the community. Over the past three decades governments have passed increasingly more restrictive laws aimed at protecting public health by prohibiting or discouraging smoking, while the not-for-profit sector has run extensive public health campaigns to the same end. A scheme that enabled people with severe medical conditions to smoke, for medical reasons, a substance that is illegal for others to use, would send a confused public health message and thereby undermine the achievements of the programs that discourage the general community from smoking.
- 29 Another key concern of the Commission is the impact that supplying dried cannabis under a medicinal cannabis scheme would have on the risk of diversion. Although there could be an illicit market for any product produced under the scheme—particularly a product with significant THC content—it is likely that the demand for dried cannabis would be strongest because of its popularity for recreational use. While probably more expensive, the licit product would have been produced under controlled conditions, free of contaminants.
- 30 In addition, the Commission was told that, to continue to enforce the prohibition on recreational use, law enforcement agencies would need to be able to distinguish between licit and illicit cannabis, and this would be extremely difficult if licit dried cannabis were made available under the scheme.

Eligibility under a medicinal cannabis scheme

Identifying people in 'exceptional circumstances'

- 31 In developing eligibility criteria for access to medicinal cannabis, the Commission was guided by the policy intention, conveyed in the terms of reference, that the scheme should be limited to people in exceptional circumstances. The following factors were taken into account:
- the state of the clinical literature in relation to the efficacy or potential efficacy of medicinal cannabis for the condition suffered by the patient, particularly in relation to the potential for cannabis to provide therapeutic assistance
 - the extent to which medicinal cannabis is likely to improve the patient's quality of life
 - the seriousness of the medical condition, including the patient's prognosis and the extent of their disability
 - the extent to which the symptoms of the condition interfere with the patient's ability to function
 - the availability of standard treatments that may assist, how effective they are and what side effects they cause or may cause
 - the state of the clinical literature in relation to the risks or potential risks posed by medicinal cannabis for the patient.

Criteria based on conditions and symptoms

- 32 The Commission recommends that a patient's eligibility to receive medicinal cannabis should rely on a combination of symptoms and the condition which gives rise to the symptoms. The conditions should be ones for which there is a reasonable measure of research support in respect of efficacy, or in respect of which the research is weaker but the circumstances of the category of patient are particularly compelling.
- 33 The Commission has identified a set of conditions and symptoms as the basis for initially making medicinal cannabis available:
- severe muscle spasms or severe pain resulting from multiple sclerosis
 - severe pain arising from cancer, HIV or AIDS
 - severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
 - severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects which are intolerable for the patient
 - severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide superior pain management by contrast with other options.
- 34 The basis for these categories and the way they are formulated is the body of research as to their efficacy, the compassionate circumstances attaching to the distressing circumstances of the categories of patients, and the control of risks and options that is addressed by the formulations proposed. The proposals are structured to provide access for a number of different categories of patients in controlled circumstances that minimise the potential for abuse of the scheme and optimise the prospect of participation by medical practitioners.
- 35 The Commission suggests this list as a basis for further discussion between the government, the medical community and patients. This is particularly important as the research base is constantly changing.

- 36 The criteria would be set out in regulations, which could be revised from time to time on the advice of an independent advisory committee constituted by the Minister for Health. In addition, the Secretary of the Department of Health and Human Services, or a suitably qualified committee, would have the discretion to permit access, on a case-by-case basis, for patients who do not meet the criteria in rare and special cases.

Authorising patients to have access to medicinal cannabis

- 37 A decision that a patient should be treated with medicinal cannabis is not a legal decision: it is a medical decision. The Commission proposes that access to medicinal cannabis by patients who meet the eligibility criteria would be authorised by specialist medical practitioners. However, the patient's general practitioner would be responsible for the patient's ongoing treatment, between visits to the specialist, and for monitoring its efficacy and any side effects.
- 38 The specialist medical practitioner, and subsequently the general practitioner, would issue an authorisation that is similar to a prescription. The use of language relating to prescriptions is avoided because the circumstances in which medical practitioners would be facilitating medicinal cannabis being made available, and monitoring its use, would be different to some degree from the circumstances attaching to medication that they prescribe in the orthodox way.
- 39 The legal arrangements would be modelled on those that apply to the opioid replacement therapy program, under which methadone and other restricted drugs are made available to patients. Accordingly, the specialist medical practitioner would need to seek a permit from the Secretary of the Department of Health and Human Services before authorising a patient to use medicinal cannabis. The permit would be valid for 12 months.
- 40 In applying for the permit, the specialist medical practitioner would state that, among other things, the patient's condition and associated symptoms meet the eligibility criteria, it is appropriate in all the circumstances that the patient be treated with medicinal cannabis, and the patient has been informed that its efficacy and side effects have not been tested by the Therapeutic Goods Administration.
- 41 Although the permit requirement and the authorisation process to some degree constitute an impediment to access, they are necessary to enable treatment with medicinal cannabis in the community to be effectively monitored. Importantly, they ensure that a medical practitioner with the necessary expertise in the condition or symptom for which the patient would be using medicinal cannabis is consulted and is enabled to make the relevant medical decisions.

Options for changes to the law

Regulatory objectives

- 42 Drawing from the terms of reference and comments in submissions, the Commission has identified objectives that should be relevant to any law reform that allows people to use medicinal cannabis in exceptional circumstances. It referred to these objectives when reviewing the options for law reform and recommends that any Victorian medicinal cannabis scheme be designed so as to be compatible with them.

- **Allow compassionately for exceptional circumstances of medical need**

If the strict criteria of evidence-based medicine that normally apply to prescription medications were applied to cannabis, there would be negligible scope for medicinal cannabis products to be made available in Victoria today. Allowing medicinal cannabis to be used in exceptional circumstances conveys a policy intention, based on compassion, to depart from the stringency of the usual rules.

- **Integrate the use of medicinal cannabis products into the patient’s medical treatment**

Integrating the use of medicinal cannabis into the patient’s medical regime characterises the reform as a health initiative. It enables medicinal cannabis to be integrated as but one of a variety of therapeutic options to meet a patient’s needs. It also recognises that a scheme that allows medicinal cannabis to be used in exceptional circumstances would apply only to patients with severe illnesses and debilitating symptoms and a substantial medical history.

- **Ensure that patients are informed of clinical uncertainty about the safety and efficacy of medicinal cannabis products they use**

Patients who use medicinal cannabis products—or carers who make decisions on their behalf—must be informed about the risks, and the current limits of clinical knowledge about its efficacy and effects, including those which are long-term.

- **Ensure that medicinal cannabis products are of reliable quality and known composition**

Any regulation would provide a level of quality assurance that illicit production cannot guarantee, but the scheme would need to do more than this. It should impose standards that provide medical practitioners and their patients with confidence about the potency and contents of the products being administered.

- **Foster, and be responsive to, clinical research and developments in technology**

Any medicinal cannabis scheme established in Victoria would need to remain current as scientific knowledge, medical practices and technology continue to evolve.

- **Preserve the prohibition of unlawful trafficking, cultivation, supply and use of cannabis**

The proposed legislative reform would need to reinforce ongoing prohibitions on the trafficking, cultivation, possession and use of cannabis. The reform would not allow everyone who currently uses cannabis, or wants to use it, to do so legally.

- **Provide an equitable and accessible scheme**

Any scheme would need to provide the necessary amount of regulation to achieve its objectives while not becoming so complex, burdensome or expensive that it deters those on whom its success depends, and those it is intended to benefit, from participating.

Identifying the options

- 43 The Commission examined the current law to identify the options for reform. Few options could be introduced by Victorian legislation alone. Almost all would require the agreement or support of the Commonwealth Government. All need to be considered in view of Australia’s international obligations.
- 44 The *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* could be amended to modify existing prohibitions on the trafficking, cultivation, possession and use of cannabis, but this would be only a partial measure.
- 45 The importation, manufacture and sale of cannabis products for medicinal purposes is regulated by Commonwealth law. A Victorian scheme for patients to be dispensed medicinal cannabis products of known and stable composition and quality by pharmacists could be established only in collaboration with the Commonwealth Government.

-
- 46 Commonwealth law and policy on the regulation of cannabis is guided by Australia's international obligations under the *Single Convention on Narcotic Drugs 1961* and related treaties. These instruments require governments to impose controls on the amount of cannabis produced, the circumstances in which it is produced, and the purposes for which it is made available.
- 47 As with all international conventions to which Australia is a party, the obligations imposed by the *Single Convention on Narcotic Drugs* are not incorporated directly into domestic law unless given effect to by statute. Not all the obligations imposed on Australia have been incorporated into Australian law. However, Australia is a party to the Convention, which carries with it distinct obligations of significance. Further, if Australia failed to fulfil the obligations under the Convention to which Australia has agreed, Australia may be subject to international criticism and sanction for failing to implement the Convention's obligations.
- 48 Reporting on 11 August 2015 on a Bill to create a Commonwealth medicinal cannabis scheme, the Senate Legal and Constitutional Affairs Legislation Committee recommended that the Bill be amended to ensure that 'medicinal cannabis products can be made available in Australia consistent with Australia's international obligations, including under Articles 23 and 28 of the *Single Convention on Narcotic Drugs 1961*'.⁵
- 49 The Commission therefore considers that a Victorian medicinal cannabis scheme should be framed in accordance with the specific requirements and policy objectives of the Convention.

Review of the options

- 50 The Commission has identified and formed views on several options for law reform, as summarised below:
- Importation: Victoria could import cannabis for the purposes of a medicinal cannabis scheme by special arrangement under Commonwealth law.
 - Exemption from prosecution: eligible patients and their carers could be authorised to possess small quantities of cannabis for the patient's use.
 - 'Grow your own': eligible patients and their carers could be authorised to cultivate cannabis plants for the patient's use.
 - Regulated not-for-profit production and distribution: not-for-profit cooperatives could be licensed to cultivate, manufacture and distribute medicinal cannabis products among their members, all of whom would need to be eligible patients and their carers.
 - Regulated distribution through dispensaries: medicinal cannabis products could be distributed through single-purpose dispensaries.
 - A government-enforced monopoly: Victoria could authorise or license a single entity to cultivate and manufacture cannabis for distribution to patients through pharmacies.
 - Licensed producers: Victoria could issue multiple licences to cultivators and manufacturers to produce medicinal cannabis products for distribution to patients through pharmacies.
- 51 To create a legally stable scheme, all of the options for producing and distributing medicinal cannabis in Victoria would be contingent on the Commonwealth cooperating in either or both of the following ways:
- removing the production and distribution of medicinal cannabis products under the Victorian scheme from the reach of the *Therapeutic Goods Act 1989* (Cth)
 - issuing a licence to manufacture cannabis under the *Narcotics Drugs Act 1967* (Cth).

-
- 52 Most of these options would also generate obligations under the Single Convention on Narcotic Drugs. If Victoria were to regulate the cultivation of cannabis for medicinal purposes (as opposed to merely decriminalising its cultivation for personal use in small amounts), Australia's international obligations would require it to license the cultivators and take physical possession of the cannabis crops. It would also need to inform the Commonwealth about the amount of cannabis that it estimates would be used for medicinal purposes each year, so that the Commonwealth in turn could report to the International Narcotics Control Board.

Importation

- 53 Currently, cannabis can be imported under Commonwealth law and policy only if approved on a case-by-case basis by the Secretary of the Commonwealth Department of Health, exercising powers under the Therapeutic Goods Act and the *Customs Act 1901* (Cth). The Law Institute of Victoria proposed that the Commonwealth provide special access for state governments to import products for the purpose of their medicinal cannabis schemes. This would not require legislative reform, though, if ongoing, it could be desirable to have the security of a statutory avenue of access.
- 54 The appeal of this option is that it could reduce the cost to Victoria of administering a medicinal cannabis scheme while providing access to products that have been produced under regulated conditions. However, it does not appear feasible in the current international environment.
- 55 The only country that exports medicinal cannabis products is the Netherlands, and the total amount that the Dutch government permits to be exported each year is very low. Moreover, the products are only in the dried plant form that is supplied domestically and are able to be smoked. If imported to Victoria, it would need to be transformed into other forms by a manufacturer whose activities were regulated under Commonwealth and Victorian laws.

Exemption from prosecution

- 56 Patients who have been authorised to be treated with medicinal cannabis could be made exempt from criminal prosecution for use or possession of the amount they need. The Drugs, Poisons and Controlled Substances Act could be amended to create an exception to the offences of possessing or using a drug of dependence for small amounts of dried cannabis or cannabis extract where a person is an authorised medicinal cannabis user.
- 57 The exception would extend to the patient's carers, to allow them to possess the cannabis that the patient may lawfully use. It would also require an additional exception to be made to the offence of introducing a drug of dependence into the body of another person.
- 58 This option would protect patients and their carers from the risk of being prosecuted, and the associated uncertainty and stress. It may be useful as an interim measure, pending the establishment of a regulated supply of medicinal cannabis products under a government scheme. If it were introduced as an intermediate step, the Commission considers that it should apply only to those patients who would be eligible to participate in the fully operational scheme.
- 59 However, the Commission does not support this option. It is similar to a scheme in New South Wales to which there has been a muted response from patients, few of whom have participated. It fails to provide access to a safe and reliable supply of medicinal cannabis products. Thus, it would not integrate medicinal cannabis effectively into a health regime: doctors would authorise patient access to cannabis, but would not have any mechanism for controlling or supervising use. The products available to the patient would not necessarily be therapeutically appropriate, as they could have unknown or inappropriate THC/CBD levels and contain unsafe contaminants.

- 60 Because 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 illicit market.

‘Grow your own’

- 61 A large number of people who made submissions and attended consultations argued for a ‘grow your own’ scheme. Eligible patients could be licensed by the government to cultivate a designated number of cannabis plants at home for medicinal purposes and would be able to nominate carers to assist them. The patients and carers would be responsible for manufacturing the raw cannabis into a form appropriate for the patient to use.
- 62 Victoria’s Drugs, Poisons and Controlled Substances Act could be amended to provide that a licensed patient who operates within the conditions of the licence would not be engaging in the unauthorised trafficking, cultivation, possession or use of a drug of dependence within the meaning of the Act. The legislation would also need to permit the patient to possess the necessary substances, materials and equipment at their residential address for this purpose.
- 63 A grow your own scheme was recommended in 2000 by a New South Wales Working Party on the Use of Cannabis for Medical Purposes. More recently, it was proposed by a Bill that was introduced into the New South Wales Parliament in 2014 and lapsed during 2015, and a draft Bill that is currently under consideration by a committee of the Legislative Assembly of the Australian Capital Territory.
- 64 This option could provide eligible 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.
- 65 Medical and regulatory experts overwhelmingly rejected this option when discussed at consultations, as did a significant number of patients and their families who want medicinal cannabis to be made available in the same way as prescription medication. The Commission shares their concerns. A grow your own scheme would not provide all eligible patients with access to medicinal cannabis because it would exclude those who do not have the resources, skills and ability to grow their own plants or have them grown on their behalf. It would not ensure that the patient’s cannabis use is integrated with their other medical treatment because their medical practitioner would not know of, or be able to monitor, what they were using or the effects. A patient using home-grown cannabis may not be using a product of sufficient quality or consistent composition because of the significant variability caused by different cannabis strains and growing conditions, which only sophisticated growing operations are able fully to control.
- 66 As noted above, the Commission considers that the products that are made available under any medicinal cannabis scheme should not be able to be smoked. A grow your own scheme would bolster the production of dried plant products, as this is cheaper and easier than producing refined products and preferred by many users. There would also be a substantial diversion risk, as there would be no distinction between licit and illicit dried plant products and the limits on production and distribution would be very difficult to enforce. This would undermine efforts to preserve the continuing prohibition of unlawful trafficking, cultivation, possession and use. A study of Canada’s scheme in 2012 estimated that 36 per cent of personal cultivation licences were subject to ‘misuse’, defined as the sale of cannabis grown under such a licence to the illicit market. It would also generate the potential for both collateral criminal conduct and a risk of house fires and toxicity within domestic environments.

67 This option would not ease the regulatory burden and the related costs to the Victorian Government, compared to the other options, because an alternative scheme would still need to be introduced to produce medicinal cannabis products for patients who are unable—or do not wish—to be responsible for producing their own medicine.

Regulated not-for-profit production and distribution

68 Some submissions advocated the creation of regulated not-for-profit cooperatives, collectives or clubs which would arrange for the collective cultivation and manufacture of medicinal cannabis products for distribution to their members. Membership would be confined to authorised patients and their carers. The entity could engage contractors or rely on its members to grow the plants and manufacture the products.

69 Under current law, the Commonwealth would regulate the manufacture and distribution of therapeutic goods by any such entities. However, there is some scope for Victoria to legislate in this area. While the Commonwealth has direct jurisdiction over incorporated entities, its power to regulate unincorporated associations involved in manufacturing and distributing therapeutic goods is determined by Victorian legislation. The Commonwealth Therapeutic Goods Act applies to them by operation of the *Therapeutic Goods (Victoria) Act 2010* (Vic). To resume jurisdiction over unincorporated associations for the purposes of this option, Victoria could amend the Therapeutic Goods (Victoria) Act to exclude the operation of the Commonwealth law for the purposes of the production and distribution of medicinal cannabis by authorised unincorporated associations.

70 The authorised entities would still need to obtain a manufacturing licence from the Commonwealth under the Narcotic Drugs Act.

71 To create the scheme, Victoria could amend the Drugs, Poisons and Controlled Substances Act to provide for licences to be issued either to a cooperative (to produce medicinal cannabis products for its members), or to a person nominated by the cooperative (to cultivate a certain amount of cannabis, or produce products, as determined by the cooperative and approved by the government).

72 The licensees would need to comply with detailed rules, which could be a combination of licence conditions, statutory provisions and regulations, to ensure that the products are of good quality and are provided only to authorised patients.

73 Proponents of this option said that it would reduce the demand for illicit cannabis and provide hubs for treatment outside the conventional medical system. A submission made on behalf of the cannabis community of Victoria put forward a detailed proposal, based on the British Columbia Compassion Club, in which the cooperative would operate a closed system encompassing all steps of the production and supply of the product as well as patient care.

74 The Commission does not consider that this option is suited to Victoria. It was told on several occasions that patients and their families would like medicinal cannabis to be treated as much as possible like conventional medications. Having medicinal cannabis cultivated by and for closed communities of users could reinforce negative perceptions about using it, perpetuate doubts about its efficacy, and undermine efforts to encourage communication between patients and their medical practitioners. It would significantly exclude the participation of medical practitioners in monitoring the effectiveness of the medicinal cannabis and taking suitable measures to address any risks or side effects.

75 The Commission also notes that this option would provide little, if any, opportunity for the government to take possession of the medicinal cannabis before it is distributed to patients, as required by the Single Convention on Narcotic Drugs. This would make the system legally unstable and could deter the Commonwealth from agreeing to issue the manufacturing licences on which the scheme would depend.

Regulated distribution through dispensaries

- 76 Several submissions suggested that medicinal cannabis products could be distributed through dispensaries. Dispensaries have been established in a number of jurisdictions overseas as outlets for producers of medicinal cannabis products or in connection with a clinic that specialises in the use of those products.
- 77 This option could provide for the distribution of products by a publicly funded or commercial entity that has manufactured the products under licence, as an alternative to distribution through pharmacies. Again, as with the previous option, the government would be unable to meet the obligation under the Single Convention on Narcotic Drugs to take possession of the medicinal cannabis before it is distributed.
- 78 As the distribution of medicinal cannabis products is regulated under the Therapeutic Goods Act, Commonwealth support would be needed. This could take the form of an exemption under that Act to enable Victoria to regulate the distribution of medicinal cannabis products by entities that are licensed to do so under Victorian legislation.
- 79 The Drugs, Poisons and Controlled Substances Act could be amended to provide for a licence to be issued to an entity to distribute medicinal cannabis products. The amount and content of the associated rules would depend on the entity, but probably would be directed to the risk of diversion to the illicit market.
- 80 The form and function of medicinal cannabis dispensaries that operate overseas vary. The common elements are that they supply only cannabis products and usually offer the customer a variety of products, information about the characteristics and effects of each, and advice about which could be most suitable in treating their condition.
- 81 The Commission does not consider this option appropriate for a Victorian medicinal cannabis scheme. Unlike the United States, where not-for-profit dispensaries have been established under state medicinal cannabis schemes because federal government law effectively prevents the sale of cannabis by pharmacies, there is no regulatory incentive in Victoria to find an alternative to existing retail outlets.

A government monopoly

- 82 Under this option, a single entity with the necessary ability and capacity would cultivate and distribute cannabis and deliver it to the government, for distribution through pharmacies. The entity could be a government agency or government-owned corporation, a university or research institute, or a privately owned corporation.
- 83 It appears that Commonwealth support would be needed for each of these options, with the possible exception being an agency or statutory authority that does not generate revenue. The entity would need to be licensed under the Narcotic Drugs Act. In addition, an exemption from regulation under the Therapeutic Goods Act would be necessary.
- 84 The option could be established in either of two ways. The Drugs, Poisons and Controlled Substances Act could be amended to permit a specified government-funded or -owned entity to cultivate and manufacture cannabis for medicinal purposes and exempt it from Part V of the Act (concerning offences relating to drugs of dependence). Alternatively, the Act could be amended to provide for the Secretary of the Department of Human Services and Health to issue a licence to cultivate and manufacture cannabis products for delivery to the government. The government could then grant the licence to a suitable entity.
- 85 Because only one producer would ever be involved, the scheme would not involve a substantial regulatory burden. It would create a simple mechanism that is substantially compliant with international law and allow for an experienced entity to start producing cannabis medicines relatively quickly.

86 The government would have to identify a suitable producer that could consistently produce enough cannabis of sufficient quality to satisfy the requirements of a Victorian medicinal cannabis scheme. The scheme would turn on the capacity of that single producer to manage risks and to supply enough product without subcontracting its functions to other cultivators and manufacturers. If a suitable entity could be identified, this option could be an intermediate step in establishing a scheme that is sustainable in the long term. However, on balance it is not recommended.

Multiple licensed producers

87 Support was expressed in several submissions for a scheme based on the current arrangements for the cultivation of alkaloid poppies and the production of poppy straw under the Drugs, Poisons and Controlled Substances Act. On this model, the government would license multiple private cultivators and manufacturers to produce cannabis products for supply through pharmacies.

88 New provisions would be inserted into the Drugs, Poisons and Controlled Substances Act authorising various dealings that are currently illegal. Commonwealth support would be needed, exempting the manufacture and production of medicinal cannabis from regulation under the Therapeutic Goods Act and granting licences under the Narcotic Drugs Act.

89 This option would allow cultivators and manufacturers to be assessed against statutory criteria and be subject to other controls derived from Victoria's poppy scheme. The government would be able to exercise the degree of regulatory control required by the Single Convention on Narcotic Drugs. In addition, the scheme would be adaptable to any changes to law or policy, either in Victoria or at the Commonwealth level, which could affect the reach or focus of the scheme. It would not be dependent upon a single source of supply, which can be a logistical vulnerability.

90 This is the Commission's preferred option and it recommends that it be adopted as the model for a Victorian medicinal cannabis scheme.

Regulation of manufacture and distribution

91 The terms of reference require the Commission to examine the regulation of medicinal cannabis manufacture and distribution, including which forms of cannabis should be permitted for use. The Commission has developed detailed proposals that are based on the current arrangements for the cultivation of alkaloid poppies, the production of poppy straw and the manufacture of therapeutic goods.

92 New frameworks would be required to regulate activities connected with the production of medicinal cannabis in Victoria. A new framework would be required for cultivation because this activity is currently not allowed. A new framework would be required for product manufacture and approval because these activities are presently regulated by the Commonwealth. Importantly, though, the scale of the new regulation required turns on any agreement reached between Victoria and the Commonwealth, and the extent to which this results in a transfer of regulatory responsibility to Victoria.

93 In designing proposals for the regulation of the medicinal cannabis supply chain, the Commission has given priority to:

- integrating legislative changes with existing provisions wherever possible
- using familiar regulatory tools
- imposing the least regulatory burden necessary to achieve the scheme objectives
- allowing flexibility to the regulator to manage risks
- having regard to the requirements of the Single Convention on Narcotic Drugs.

Cultivation

- 94 All cannabis cultivated in Victoria would be cultivated under licence. Licences to cultivate would be granted by the Secretary of the Department of Economic Development, Jobs, Transport and Resources. Recipients could be either individuals or corporations. The Department would be responsible for monitoring and enforcing compliance with the licence conditions and the risk management plan.
- 95 The licensing scheme would be set out in the Drugs, Poisons and Controlled Substances Act in similar terms to the provisions allowing for licensing of alkaloid poppy cultivators.
- 96 Cultivators would be permitted to sell only to licensed manufacturers, and would be required to have a contract with a licensed manufacturer at all times.

Manufacture

- 97 Like cultivators, manufacturers of cannabis products would be required to hold licences issued by the State of Victoria. Licences to manufacture refined cannabis products would be granted by the Secretary of the Department of Health and Human Services. Recipients could be either individuals or corporations.
- 98 The arrangements would be modelled on those for the manufacturing of therapeutic goods under Commonwealth legislation.

Distribution

- 99 It is proposed that distribution be coordinated by a government agency, as required by the Single Convention on Narcotic Drugs, particularly Articles 23 and 28. In order to comply with the Single Convention, licensed manufacturers would need to deliver all of the medicinal cannabis products they make to the Victorian Government, specifically the Secretary of the Department of Health and Human Services.
- 100 The Secretary would be responsible for the distribution of medicinal cannabis products to pharmacies. Patients would be dispensed medicinal products by a local pharmacy that has opted into the scheme.
- 101 The rules imposed on pharmacies and pharmacy departments regarding the distribution of cannabis would be modelled on the program for opioid replacement therapy.

Quality control

- 102 Only one pharmaceutical-grade cannabis extract (Sativex) has been approved for sale by the Therapeutic Goods Administration but it is not marketed in Australia and therefore, to all practical intents and purposes, is not available. This means that no medicinal cannabis products have been marketed or manufactured to this point in Victoria.
- 103 A Victorian scheme that requires medicinal cannabis products to be approved by the Therapeutic Goods Administration would reinforce the status quo and not result in any additional approved products being made available to patients for a significant period of time. It follows that, if the quality of medicinal cannabis products is to be ensured, an alternative regulatory structure needs to be established.
- 104 The alternative structure must sensibly be one which does not create the same or similar hurdles to approval as those that apply to prescription medicines but does take a cautious approach to ensuring that the products supplied are of good quality.
- 105 For the separate character of the Victorian products to be preserved, and the pre-eminence of conventional approval to be maintained, it is important that the character of the products be distinctive. That is, the government should not endorse these products as replacements for conventional pharmaceuticals. Therefore, it is the Commission's view that medicinal cannabis products should be presented to patients as a form of less refined herbal medicine and that this be provided for by the regulatory structure.

-
- 106 The Victorian scheme should ensure that medicinal cannabis products produced under the scheme are free of unsafe components and are of known and stable composition. However, it would not be feasible or desirable for the scheme to make approval of a particular medicinal cannabis product contingent on proof (whether to conventional standards or otherwise) that the product is effective to treat a given indication. Clinical trials are costly and time-consuming to run, and placing similar barriers to product approval as already exist under the Therapeutic Goods Administration would not facilitate access to medicinal cannabis in any meaningful way.

Controlling risks

- 107 A Victorian medicinal cannabis scheme could be the first of its kind in Australia. A drug that would remain illegal for all other purposes in Victoria would be made legal, in controlled circumstances, for a limited group of people. The products would be new and the size of the patient group is initially difficult to predict. International experience in introducing medicinal cannabis schemes indicates that the regulatory scheme could need to be modified, possibly substantially, within a few years in response to unpredicted outcomes. For this reason, the Commission considers it prudent for the government to take a measured approach to the reforms and draw upon existing models that work in comparable contexts.
- 108 The Commission has identified a number of risks that are inherent to the proposal to make medicinal cannabis available to people in exceptional circumstances. It has taken them into account when formulating the regulatory objectives, the recommendations and the detailed proposals.

Patient safety

- 109 A risk to patient safety could arise from providing access to products that have not been required to meet the safety, quality and efficacy standards that apply to prescription medicines. The regulatory objectives address this risk by identifying the need to ensure that:
- Patients are informed of clinical uncertainty about the safety and efficacy of medicinal cannabis products they use.
 - Medicinal cannabis products are of reliable quality and known composition.
 - The use of medicinal cannabis products is incorporated into the patient's medical treatment.

Eligibility criteria

- 110 There is a risk that the circumstances in which treatment with medicinal cannabis is permitted are uncertain or controversial. The Commission's recommendation that eligibility be based on specified conditions and symptoms would make the criteria clear to patients as well as to medical practitioners. It is likely that any criteria that confine the coverage of the scheme to people in exceptional circumstances would be criticised by people who use medicinal cannabis for non-qualifying conditions. However, the recommended eligibility criteria are based on the best available evidence of efficacy, and the Commission has also recommended that they be subject to change, on the advice of an expert committee, as more evidence becomes available.

Commonwealth support

- 111 The viability of a Victorian medicinal cannabis scheme could be compromised should the Commonwealth not work with Victoria. The Commission considers that the preferred option, a comprehensive government licensing scheme, would comply with the Single Convention on Narcotic Drugs, and therefore would be compatible with Commonwealth government policies to support international measures to inhibit trade in narcotic drugs. It is also adaptable should the Commonwealth introduce a national scheme that regulates some elements centrally.

Diversion risk

- 112 A medicinal cannabis scheme could create new opportunities for cannabis to be supplied and used illegally. The need to enforce ongoing prohibitions is reflected in the regulatory objectives and the Commission proposes security measures at each step of the supply chain. Law enforcement authorities would be assisted further by the Commission's recommendations not to provide medicinal cannabis in smokable form, which is more popular among recreational users.

Costs to government

- 113 There is a risk of excessive cost to government in establishing and operating the scheme. Although the Commission was not requested to investigate, and has not investigated, the costs of the options, it appears financially prudent to build on existing infrastructure and capabilities. The detailed proposals on cultivation and manufacturing are drawn from the cultivation of alkaloid poppies and the regulation of therapeutic goods; the recommended approach to authorising the use of medicinal cannabis by patients follows the procedures for the opioid therapy replacement program. Using existing institutions and comparable regulatory methods should substantially reduce the time and expense of reform.

Concerns of the medical profession

- 114 Medical professional bodies and a number of members of the medical profession put forward the view, in submissions and at advisory committee meetings, that medicinal cannabis products should be made available to patients only if the products have satisfied the rigorous requirements of the Therapeutic Goods Administration. Although the opinions of individual practitioners vary, concern was expressed to the Commission about patients being treated with products that have not been subject to the approval processes that normally apply to medicines in Australia. These processes ensure that products are manufactured to high standards and have been comprehensively assessed for safety and therapeutic appropriateness for particular medical conditions. They also provide to the medical practitioner extensive information about a product's efficacy, its side effects, the recommended dosage, and other details that enable the practitioner to make a sound and defensible professional judgment about whether to recommend the treatment to their patients. The practitioner can draw on this information in ensuring that patients give informed consent.
- 115 The argument that all medicinal cannabis products should be subject to approval by the Therapeutic Goods Administration is an argument for the status quo. There would be no need for a Victorian medicinal cannabis scheme. However, as reflected in the regulatory objectives, it is important that the concerns of medical practitioners about medicinal cannabis are addressed.

-
- 116 For this reason, the Commission has identified means of creating mechanisms, based on existing practices and procedures, which respond to the concern that the medicinal cannabis products made available under the scheme will not have received Therapeutic Goods Administration approval. The proposed eligibility criteria give weight to clinical research; access to medicinal cannabis by individual patients requires the authorisation of a specialist medicinal practitioner who has expertise in the relevant condition; a medical practitioner specifies the products and dosage; provision is made for the effects of the treatment to be monitored; and the products themselves are prepared under conditions that ensure that they are of consistent quality and composition.
- 117 Importantly, too, unlike the position in jurisdictions such as the United States and Canada, where there remains some amount of reservation among medical practitioners about medicinal cannabis, the Victorian scheme would not provide a grow your own scheme or involve dispensaries that operate wholly or substantially outside the health system. Nor would it include smoking of dried cannabis. Rather, it would provide for medicinal cannabis to be dispensed by pharmacists in orthodox therapeutic forms such as oils, tinctures and vaporisable liquids. It is proposed that the Secretary of the Department of Health and Human Services assist medical practitioners by providing product information about medicinal cannabis products, as well as training in their application.
- 118 Thus, what is proposed is that medicinal cannabis be a form of medication that constitutes one of the available forms of pharmacotherapy for a small number of conditions, in ways which substantially enable medical practitioners to titrate dosage and monitor positive and negative effects as they would for Therapeutic Goods Administration-approved medications. It is thus consistent with standard medical practice with other medications.

Review of scheme

- 119 The Commission considers that the scheme should be reviewed after four years. By that time, the international and national regulatory environment for the control of cannabis could have changed, and knowledge about the efficacy of medicinal cannabis could have moved far beyond the evidence base on which the scheme rests. The health and safety risks could be different and the regulatory objectives outdated.
- 120 The review should consider how well the scheme has met its objectives and evaluate whether it should continue in the same form.

Concluding observations

- 121 Medicinal cannabis is not a panacea. Research into its efficacy has a significant way to travel before definitive conclusions can be drawn about the extent to which it can contribute to the alleviation of suffering. However, what can be said is that it has therapeutic potential. It appears that this potential is starting to be realised in the lives of people with very serious medical conditions. It needs to be integrated under medical supervision into the various options for treatment and management of the care of people with serious conditions without raising inappropriate expectations.
- 122 The opportunity exists for a combined Commonwealth and Victorian initiative to relieve suffering and to improve the quality of life for a vulnerable cohort of people within the community.
- 123 The passage of time and the opportunity for further research, along with evaluation of the scheme proposed by the Commission, would allow rigorous review of the success of this initiative to determine whether the proposed innovation is worthy of consolidation, extension or amendment.

Recommendations

Regulatory objectives

- 1 Law reform to allow people to be treated with medicinal cannabis in exceptional circumstances should be designed so as to be compatible with the following objectives:
 - (a) Allow compassionately for exceptional circumstances of medical need.
 - (b) Integrate the use of medicinal cannabis products into the patient's medical treatment.
 - (c) Ensure that patients are informed of clinical uncertainty about the safety and efficacy of medicinal cannabis products they use.
 - (d) Ensure that medicinal cannabis products are of reliable quality and known composition.
 - (e) Foster, and be responsive to, clinical research and developments in technology.
 - (f) Preserve the prohibition of unlawful trafficking, cultivation, supply and use of cannabis.
 - (g) Provide an equitable and accessible scheme.

Patient eligibility

- 2 Eligibility to be treated with medicinal cannabis in exceptional circumstances should be:
 - (a) determined by the patient's medical condition and symptoms arising from that condition or its treatment
 - (b) specified in regulations.
- 3 Eligibility for any Victorian medicinal cannabis scheme should be based initially on the following conditions and corresponding symptoms:
 - (a) severe muscle spasms or severe pain resulting from multiple sclerosis
 - (b) severe pain arising from cancer, HIV or AIDS
 - (c) severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
 - (d) severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects that are intolerable for the patient
 - (e) severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.

-
- 4 The Secretary of the Department of Health and Human Services, or a committee constituted by the Secretary under delegation, should be given power to permit patients on a case-by-case basis to be treated with medicinal cannabis in exceptional circumstances that do not otherwise fall within the eligibility criteria of the scheme.
 - 5 The Minister for Health should constitute an independent medical advisory committee on medicinal cannabis to provide ongoing advice about the conditions and corresponding symptoms on which eligibility to be treated with medicinal cannabis is based. Such advice should include reference to:
 - (a) the responsiveness by patients to medicinal cannabis provided under the scheme and any side effects experienced by them
 - (b) the state of the clinical literature in relation to the efficacy or potential efficacy of medicinal cannabis for particular medical conditions and symptoms
 - (c) the state of the clinical literature in relation to the risks or potential risks posed by medicinal cannabis for patients with particular medical conditions
 - (d) the seriousness of the medical conditions, including patients' prognoses and the extent of the disability caused by their conditions
 - (e) the extent to which symptoms of the conditions interfere with patients' ability to derive enjoyment and fulfilment in their lives
 - (f) the extent to which medicinal cannabis can reasonably be anticipated to improve patients' quality of life
 - (g) the availability of standard treatments that may assist, how effective they are, and what side effects they cause.
 - 6 Any medicinal cannabis scheme in Victoria should be applicable only to persons who ordinarily reside in Victoria.

Authorisation

- 7 Specialist medical practitioners should determine which eligible patients should receive treatment with medicinal cannabis, while general practitioners should have principal responsibility for monitoring the efficacy and side effects of the treatment.
- 8 A specialist medical practitioner who is registered with the Medical Board of Australia within a prescribed category for the medical condition on which their patient's eligibility is based should be able to apply to the Secretary of the Department of Health and Human Services for a permit to issue an Authority to Dispense Medicinal Cannabis in respect of that patient. The application should state that:
 - (a) The patient's condition and associated symptoms meet the eligibility criteria of the scheme.
 - (b) It is appropriate in all the circumstances that the patient be treated with medicinal cannabis.
 - (c) The patient has been informed and accepts that the medicinal cannabis product they will receive will not have been tested for efficacy and side effects by the Therapeutic Goods Administration, and has been informed of other treatments which have been so tested, along with the risks, potential benefits and side effects, including long-term effects, of each.
 - (d) The patient has been informed that information about their treatment will be collected and used for scheme evaluation and research purposes.

- 9 The Secretary of the Department of Health and Human Services should have the power to issue a permit to a specialist medical practitioner if satisfied that:
 - (a) the specialist medical practitioner is registered as a specialist with the Medical Board of Australia within a prescribed category for the medical condition on which patient eligibility is based
 - (b) the patient ordinarily resides in Victoria
 - (c) there is not an unacceptable risk that the patient will abuse the terms of the permit.
- 10 A valid permit should entitle the specialist medical practitioner, or a general practitioner identified on the permit, to issue an Authority to Dispense Medicinal Cannabis. An Authority to Dispense Medicinal Cannabis would:
 - (a) authorise a pharmacy or pharmacy department identified on the permit to dispense medicinal cannabis in accordance with specified instructions
 - (b) enable no more than three months' supply of the medicinal cannabis products to be dispensed to the patient or carer at a time.
- 11 The permit issued to a specialist medical practitioner by the Secretary of the Department of Health and Human Services should specify:
 - (a) the duration of the permit, not to exceed 12 months
 - (b) the name and address of the patient
 - (c) the name of the general practitioner or clinic with principal responsibility for monitoring the efficacy and side effects of the treatment
 - (d) the pharmacy at which the patient or carer will obtain medicinal cannabis
 - (e) the names of any carers who will collect or administer the medicinal cannabis
- 12 An Authority to Dispense Medicinal Cannabis issued by a specialist medical practitioner or a general practitioner should specify:
 - (a) the product and dosage
 - (b) the name and address of the patient
 - (c) the pharmacy at which the patient or carer will be dispensed medicinal cannabis
 - (d) the names of any carers who may collect or administer the medicinal cannabis.
- 13 New offences should be created, or existing offences expanded, proscribing dishonest conduct in relation to obtaining a permit or issuing or obtaining an Authority to Dispense Medicinal Cannabis.
- 14 The *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*, and the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)* should be amended to allow patients and carers nominated in a valid Authority to Dispense Medicinal Cannabis, as appropriate, to obtain, possess and use the medicinal cannabis products designated in the Authority.
- 15 The *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*, and the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)* should be amended to allow medical practitioners, registered nurses and pharmacists who participate in any Victorian medicinal cannabis scheme to obtain, have in their possession, administer, sell and supply medicinal cannabis products, as appropriate, for the purposes of the scheme.
- 16 The Secretary of the Department of Health and Human Services should provide suitable training and information materials to medical practitioners, pharmacists, patients and others with responsibilities under the scheme.

Commonwealth/State cooperation

- 17 The Victorian Government should seek to work in collaboration with the Commonwealth Government in establishing any medicinal cannabis scheme in Victoria.

Recommended option

- 18 The Victorian Government should create a scheme to regulate the production of medicinal cannabis by:
- (a) licensing private entities to cultivate and manufacture medicinal cannabis products under regulatory arrangements that are based on those that apply to the cultivation of alkaloid poppies, the processing of poppy straw and the manufacture of therapeutic goods
 - (b) establishing a process for approving medicinal cannabis products and ensuring that they are of appropriate quality
 - (c) providing the Secretary of the Department of Health and Human Services with the power to administer the scheme and the authority to take possession of medicinal cannabis products, account to the Commonwealth for those products, and arrange their transfer to pharmacies.

Cultivation

- 19 Cannabis should be grown for medicinal purposes by cultivators licensed by the Secretary of the Department of Economic Development, Jobs, Transport and Resources.
- 20 The licensing and regulation of medicinal cannabis cultivators should be modelled on Part IVB of the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* as it applies to alkaloid poppy cultivation. Key features of the scheme should be as follows:
- (a) Applicants for a cultivation licence would be subject to a fit and proper person test and be required to satisfy the Secretary of their intended commercial activities and pay a prescribed fee.
 - (b) The Chief Commissioner of Victoria Police would be able to oppose the issuing or renewal of a licence to an applicant, in which case the Secretary would be unable to issue or renew it.
 - (c) Licensees would be required to ensure that their employees are of suitable character.
 - (d) Licensees would be required to prepare and submit a risk management plan addressing safety and diversion risks associated with cultivation and how they would be addressed.
 - (e) Licensees would be required to comply with appropriate quality control measures.
 - (f) All cannabis grown would be required to be delivered to a licensed manufacturer or destroyed.
 - (g) Licensees would be required to have a contract with a licensed manufacturer at all relevant times.
 - (h) The Secretary would have the power to suspend or cancel a licence, including at the request of the Chief Commissioner of Police.
 - (i) Applications would be able to be made to the Victorian Civil and Administrative Review Tribunal for review of a decision by the Secretary to refuse to issue or renew a licence, or to suspend, cancel or amend it.

-
- 21 The Secretary of the Department of Economic Development, Jobs, Transport and Resources should:
- (a) monitor and enforce compliance by licensed cultivators with licence conditions and risk management plans
 - (b) be empowered to appoint inspectors for this purpose
 - (c) be resourced accordingly.

Manufacture

- 22 Medicinal cannabis products should be made by manufacturers licensed by the Secretary of the Department of Health and Human Services.
- 23 Medicinal cannabis products should be made by manufacturers licensed by the Secretary of the Department of Health and Human Services under arrangements modelled on those for licensing manufacturers under the *Therapeutic Goods Act 1989* (Cth) and processors of poppy straw under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic). Key features of the scheme should be as follows:
- (a) Applicants for a manufacturing licence would be subject to a fit and proper person test, required to satisfy the Secretary of their intended commercial activities, and required to pay a prescribed fee.
 - (b) Applicants for a manufacturing licence should be required to demonstrate to the Secretary their capability to comply with quality standards.
 - (c) The Chief Commissioner of Victoria Police would be able to oppose the issuing or renewal of a licence to an applicant, in which case the Secretary would be unable to issue or renew it.
 - (d) Licensees would be required to hold a manufacturing licence under the *Narcotic Drugs Act 1967* (Cth) at all relevant times.
 - (e) Licensees would be required to ensure that their employees are of suitable character.
 - (f) Licensees would be required to prepare and submit a risk management plan addressing safety and diversion risks associated with cultivation and how they will be addressed.
 - (g) Licensees would be required to comply with appropriate quality control measures.
 - (h) Licensees would be required to deliver all medicinal cannabis products to the Secretary within four months of the harvest date and destroy any unused material.
 - (i) The Secretary would have the power to suspend or cancel a licence, including at the request of the Chief Commissioner of Police.
 - (j) Applications would be able to be made to the Victorian Civil and Administrative Tribunal for review of a decision by the Secretary to refuse to issue or renew a licence, or to suspend, cancel or amend it.
- 24 The Secretary of the Department of Health and Human Services should:
- (a) monitor and enforce compliance by licensed manufacturers with licence conditions and risk management plans
 - (b) be empowered to appoint inspectors for this purpose
 - (c) be resourced accordingly.
- 25 All medicinal cannabis products made by licensed manufacturers should be purchased by the Secretary of the Department of Health and Human Services.

Dispensing

- 26 Medicinal cannabis products purchased by the Secretary of the Department of Health and Human Services should be dispensed to patients through pharmacies and pharmacy departments.
- 27 Dispensing of medicinal cannabis products to patients should be through pharmacies and pharmacy departments that elect to participate in the scheme.
- 28 Dispensing of cannabis by pharmacies and pharmacy departments should be modelled on the Victorian program for opioid replacement therapy and include the following features:
 - (a) Patients or carers specified in the Authority to Dispense Medicinal Cannabis would be able to obtain medicinal cannabis products only by attending at the specified pharmacy or pharmacy department.
 - (b) Pharmacies and pharmacy departments would be able to dispense to patients or carers only the medicinal cannabis product(s) specified in the Authority to Dispense Medicinal Cannabis.
 - (c) Pharmacies and pharmacy departments would be required to store medicinal cannabis products pursuant to requirements comparable to those that apply to the storage of Schedule 8 and Schedule 9 poisons.
- 29 The Secretary of the Department of Health and Human Services should require pharmacists to notify the Secretary about the amount and type of products they dispense to patients under an Authority to Dispense Medicinal Cannabis.
- 30 The Secretary of the Department of Health and Human Services should from time to time designate a price above which medicinal products cannot be sold, incorporating the mark-up able to be charged by pharmacists.

Regulation

- 31 Licensed cultivators should be required to comply with appropriate Good Agricultural and Collection Practice.
- 32 Licensed manufacturers should be required to comply with Good Manufacturing Practice, as reflected in the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.
- 33 The Secretary of the Department of Health and Human Services should have the power to determine which medicinal cannabis products may be manufactured under licence and dispensed in Victoria.
- 34 The Secretary of the Department of Health and Human Services should establish and publish a register of medicinal cannabis products approved for sale in Victoria. The register should specify, for each product:
 - (a) its THC and CBD content, as a percentage
 - (b) its formulation
 - (c) permitted ingredients
 - (d) the brand name under which it will be sold
 - (e) label contents.
- 35 The Secretary of the Department of Health and Human Services should have the power to authorise independent testing facilities in Victoria to test medicinal cannabis products.

- 36 All medicinal cannabis products manufactured under a Victorian scheme should be subject to testing by an authorised testing facility to confirm whether the cannabinoid content correlates with that specified on the label and to identify the presence of any contaminants.
- 37 Medicinal cannabis products supplied under any Victorian scheme should:
 - (a) not include products that can be smoked
 - (b) include a variety of delivery systems, such as tinctures, oils, capsules, sprays and vapourisable liquids
 - (c) provide for variation in cannabinoid content
 - (d) be kept under review in view of developments in technology and medical knowledge about the medicinal use of cannabis and specific cannabinoids.

Research and evaluation

- 38 Any Victorian medicinal cannabis scheme should foster research by providing for:
 - (a) licensed cultivators to supply cannabis to appropriately licensed manufacturers capable of producing or trialling pharmaceutical-grade cannabis-derived products
 - (b) researchers and those holding commercial cultivation licences to obtain experimental cultivation licences.
- 39 The Secretary of the Department of Health and Human Services should have the power to issue medical practitioners with permits to treat patients other than those who are eligible under the scheme with medicinal cannabis for trials and research.
- 40 The Secretary of the Department of Health and Human Services should collaborate with the clinical research community in developing methods and protocols for collecting and sharing information about the incidence and outcomes of treatment with medicinal cannabis products under any Victorian scheme.
- 41 The Secretary of the Department of Health and Human Services should:
 - (a) retain data collected on permit applications and Authorities to Dispense Medicinal Cannabis in a way that enables statistical information about the operation of the scheme to be compiled and used for evaluation purposes, and for non-identifying information to be made available for the purpose of research into the efficacy of medicinal cannabis
 - (b) ensure that a privacy impact assessment is conducted when designing the data collection and management systems in support of the medicinal cannabis scheme, to safeguard the information privacy of patients, carers, practitioners, pharmacists and other participants in the scheme.
- 42 The Minister for Health should cause an independent evaluation of the scheme to take place no later than four years from its date of commencement and should be required to report to Parliament on the findings and recommendations of the evaluation.

Introduction

- 2** Terms of reference
- 2** The Commission's process
- 3** The Commission's approach
- 12** Expectations about implementation
- 14** Concurrent developments
- 17** Structure of this report

1. Introduction

Terms of reference

- 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 by 31 August 2015 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 ix.
- 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.

The Commission's process

- 1.3 The Government appointed Dr Ian Freckelton QC as a Commissioner to lead the reference, with effect from 27 January 2015 to 31 August 2015.
- 1.4 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 conduct of the reference. All members of the Commission joined him on the Division.
- 1.5 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. 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.
- 1.6 Consequently, two advisory committees were 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.

- 1.7 The committees met separately in April 2015, and together in May 2015. The members are listed at Appendix A.
- 1.8 The Commission's usual practice when conducting reviews of this type is to release a comprehensive consultation paper after initial discussions with stakeholders. In view of the short time line for this reference, the Commission published an issues paper² before beginning the consultations. The issues paper provided background information and asked questions about issues arising from the terms of reference.
- 1.9 The issues paper was published on 17 March 2015. The Commission initially sought written submissions in response to the questions by 20 April 2015, to assist in planning the consultations, but continued to receive them until the end of July.
- 1.10 Ninety-nine submissions were received and are listed at Appendix B. The Commission also received many comments and further information informally from interested members of the public.
- 1.11 Formal consultations, led by the Commission Chair and Dr Freckelton, were held in Melbourne and eight regional centres in May and June 2015. In each location, members of the public were invited to attend an open meeting to express their views. Private meetings were also held with individual members of the public, legal practitioners and health professionals.
- 1.12 Over the course of the reference, the Commission consulted many other people in Victoria and overseas, including government officials involved in implementing medicinal cannabis programs. The consultations are listed at Appendix C.
- 1.13 The Commission records its appreciation for the substantial contribution made to its work by everyone who put forward their ideas and insights.

The Commission's approach

Scope of the reference

- 1.14 The Victorian Government has made a public commitment to introduce legislation that will enable cannabis to be used for medicinal purposes in exceptional circumstances. Announcing the reference to the Commission, the Premier said: 'We'll get the advice not on if we should do it, but how we should do it'.³ The government aims to present a bill to Parliament by the end of 2015.⁴
- 1.15 The terms of reference convey a policy intention that people will be allowed to be treated with medicinal cannabis only in exceptional circumstances, and that cannabis will be legalised only for that purpose. Growing, supplying, possessing and using cannabis for other purposes will remain illegal.
- 1.16 Arguments against this policy were made in some submissions and during consultations, but the Commission did not enter the debate. The scope of the review is determined by the terms of reference and the Commission has confined its investigations, comments and recommendations accordingly.

2 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015).

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

4 Vanessa Desloires, 'Premier Daniel Andrews Hope to Have Bill on Legalising Medical Marijuana Before Parliament Before End of Next Year', *The Age* (Online), 19 December 2014 <<http://www.theage.com.au/victoria/>>.

Focus of inquiry

- 1.17 The Commission discerned two fundamental lines of inquiry from the terms of reference:
- What should the ‘exceptional circumstances’ be?
 - How can the law be amended to enable people who are allowed to be treated with medicinal cannabis to obtain it, while preventing unauthorised use?

Exceptional circumstances

- 1.18 The question of who should be eligible to be treated with medicinal cannabis under a scheme that permits it in ‘exceptional circumstances’ is a health issue. The starting point for the Commission in pursuing this aspect of the reference was to consider the results of clinical research into the efficacy of cannabis in treating different medical conditions and symptoms, as well as the evidence for risks and side effects.⁵
- 1.19 The Commission also took account of the growing amount of material from other sources suggesting that cannabis can be as effective as, and the side effects less problematic than, opiate forms of analgesia and other pharmaceutical products. This includes less rigorous scientific research, substantial anecdotal evidence, testimonials, and surveys. The reliability of the claims varies, as does their evidentiary value for the purpose of developing eligibility criteria for a Victorian medicinal cannabis scheme.
- 1.20 There have been marked improvements in the quality of life of some severely ill Victorians after being treated with cannabis, with noticeably better results than prescription medicines had been able to achieve. The Commission met a number of these patients and their families, and many others in Victoria and interstate provided written submissions about their experiences. Their experiences provide compelling examples of the limits of prescription medicines in treating their conditions and of a groundswell of support for exploration of an alternative therapeutic option such as medicinal cannabis.
- 1.21 The Commission’s conclusions are discussed in Chapter 3 of this report.

Law reform options

- 1.22 In addressing the question of how the law could enable eligible patients to be treated with medicinal cannabis, the Commission determined whether the responsibility to regulate each step of the supply chain falls within Victoria’s jurisdiction, the Commonwealth’s jurisdiction, or both.⁶ It then explored the scope for Victoria to introduce reforms either with or without the assistance of the Commonwealth.
- 1.23 This analysis was set out in the issues paper and the Commission sought submissions on how the supply and distribution of medicinal cannabis in Victoria should be regulated. The views of the regulation advisory committee were sought, and the Commission also looked to the approaches taken in other countries.
- 1.24 A number of options emerged from the consultations and submissions. They are discussed in Chapter 5 of this report.

Regulatory objectives

- 1.25 The Commission’s recommendations about options for legislative change—as well as the Government’s decisions about which changes to make and how to implement them—need to be guided by clear expectations about what the reforms are intended to achieve.
- 1.26 For this reason, the Commission identified objectives that would be relevant to any law reform that allows people to use medicinal cannabis in exceptional circumstances, and invited comments on them. They have been derived from the policy conveyed in the terms of reference.

⁵ A comprehensive overview of the current state of clinical research was included in the issues paper and has not been replicated in this report. See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015).

⁶ Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) Ch 4.

Allow compassionately for exceptional circumstances of medical need

- 1.27 If the strict criteria of evidence-based medicine that normally apply to prescription medications were applied to cannabis products, there would be little scope for cannabis products to be prescribed in Victoria today.⁷ The medical profession is divided on the issue, but many practitioners consider it premature to change the law before more clinical evidence is available.⁸
- 1.28 Allowing medicinal cannabis to be used in exceptional circumstances conveys an intention to depart from the rules that normally apply under the Commonwealth Therapeutic Goods Administration (TGA) scheme. It suggests that, in some cases, medicinal cannabis products should be able to be used even if their quality, safety and efficacy have not been verified to the same exacting standards as apply to prescription medications.
- 1.29 The basis for such a policy is compassion. There are numerous examples of cannabis being used in Australia and other countries by people for whom prescription medicines have been ineffective or have caused debilitating and serious side effects. The particularly compelling cases are those where there is such a marked improvement in the patient's quality of life following treatment with medicinal cannabis—succeeding where prescription medications have failed—that the benefits are seen to outweigh the risks of unwanted side effects, including those which could emerge in the longer term.
- 1.30 Aaron Johnson, whose daughter suffers from Dravet syndrome,⁹ a rare form of epilepsy, described the conundrum facing the families of severely ill patients:
- Too many parents like myself are in desperate circumstances, law abiding citizens with a[n] unconscionable choice to make, break the law or watch your child suffer or possibly die, wondering why a government with the power to make change has failed them.¹⁰
- 1.31 AMA Victoria expressed concerns about terminology or concepts such as 'compassionate' or 'exceptional' circumstances, as they are 'vague, subjective terms and are likely to lead to lack of clarity in medical practice'.¹¹
- 1.32 The Commission agrees that compassion should not be the criterion for determining whether a person is eligible to use medicinal cannabis under a Victorian scheme. For the purposes of framing amendments to the law, the term provides insufficient guidance for a decision maker when determining if a patient is eligible, and would create uncertainty for the patient about their legal entitlements. The regulatory objective underscores the desirability of taking a compassionate approach when identifying what the eligibility criteria should be.

Integrate the use of medicinal cannabis products into the patient's medical treatment

- 1.33 Integrating the use of medicinal cannabis into the patient's medical regime is a necessary objective of a medicinal cannabis scheme. It characterises the reform as a health initiative. It also recognises that a scheme that allows medicinal cannabis to be used in exceptional circumstances would apply to patients with severe illnesses and debilitating symptoms and a substantial medical history. A patient in such circumstances is highly likely to be under the care of a medical practitioner.
- 1.34 Those calling for reform commonly assume that any treatment with medicinal cannabis would be under the care of a medical practitioner, in the same way as conventional treatment.¹²

7 Michael Vagg, 'Is the Medical Marijuana Debate Even Worth Having?' *The Conversation* (16 February 2015) <<http://theconversation.com>>.
 8 Advisory committee (Meeting 1); Submissions 27, 38, 40, 42, 47, 48; Consultation 16.
 9 Also known as severe myoclonic epilepsy of infancy, a rare and catastrophic form of intractable epilepsy that begins in infancy.
 10 Submission 33. See Appendix B for list of submissions.
 11 Submission 38.
 12 Submissions 2, 8, 42, 53, 56, 67; Consultation 13. See Appendix C for list of consultations.

- 1.35 AMA Victoria agrees that medical practitioners should have a ‘gatekeeper’ role that involves advising patients about the advantages, disadvantages and risks of treatment, but asserts that they are not currently equipped to do so:
- AMA Victoria reiterates that medical practitioners are only able to conduct this crucial educational role as part of good medical practice, once conclusive clinical trials are conducted on the efficacy and side effects of medicinal cannabis.¹³
- 1.36 Individual medical practitioners expressed divergent views. The Commission was told that doctors would not prescribe medicinal cannabis because there is insufficient evidence of its efficacy, no guidelines about its use, and no approved product available for sale in Australia.¹⁴ However, the view was also put that it would be better to supervise patients in using measured amounts of products of known quality and composition than have them experiment with illegal products without medical supervision. Concern was expressed that patients are declining conventional therapies because of the claims being made about cannabis.¹⁵
- 1.37 Some submissions argued that medical supervision is unnecessary and unlikely to be forthcoming. Amanda Newell, for example, said in her submission that:
- I personally don’t feel a GP is necessary. Colorado have a good thing going, Australia should take some advice from them. Otherwise, sell it over the counter at the chemist, similar to Codeine (that’s a far more dangerous and addictive drug than Cannabis though).¹⁶
- 1.38 Matthew Pallett identified a need for guidance but said that this should come from outside the medical profession:
- Nobody has ever died from using cannabis or whole plant cannabis extracts which have been around for a couple of centuries, even from uncontrolled illicit street supply. This indicates a need for use under medical supervision to be totally unnecessary but guidance for administration for inexperienced users by those experienced in the practices, would make reasonable sense in order to avoid unwanted side effects that can occur with incorrect strain choice.¹⁷
- 1.39 Other submissions called for a broad range and variety of health and allied health practitioners to advise and monitor patients about their use of medicinal cannabis.¹⁸
- 1.40 The question of who should be able to authorise medicinal cannabis treatment is discussed in Chapter 3. However, the objective of integrating the use of cannabis with the patient’s program of medical treatment extends beyond the ‘gatekeeper’ role. While no one may have died from cannabis, many have died from conditions that cannabis is being used to treat. A decision to use medicinal cannabis should not isolate the patient from broader medical care or undermine their other medical treatment. Rather, it should be integrated into broad medical management of the therapeutic needs of the patient.

13 Submission 38.

14 Advisory committee (Meeting 3); Consultations 8, 16.

15 Advisory committee (Meeting 1).

16 Submission 16.

17 Submission 59.

18 Submissions 1, 10, 84, 91, 95; Consultation 3.

Ensure that patients are informed of clinical uncertainty about the safety and efficacy of medicinal cannabis products they use

- 1.41 Patients with access to licit medicinal cannabis products that have not been approved by the TGA could wrongly assume that their quality, safety and efficacy have been tested to the same standards as prescription medicines. If they have read information on the internet promoting the many therapeutic benefits attributed to cannabis use, they may have a false impression about the probative value of some of the claims.
- 1.42 Accordingly, the scheme would need to ensure that patients who use medicinal cannabis—or carers who make decisions on their behalf—know about the risks and the current limits of clinical knowledge about its efficacy and effects, including its long-term effects.
- 1.43 The Law Institute of Victoria pointed out that, as part of their duty of care, medical practitioners must provide their patients with information that will enable them to give their informed consent to medical treatment. This includes information about all material risks. A medical practitioner who fails to do so is exposed to civil liability for the outcome, even if the treatment was not negligent:

With the example of a medicinal cannabis product that is not regulated under the Commonwealth TGA, medical practitioners would arguably need to provide an appropriate disclaimer as to the limited therapeutic research and the limited evidence of efficacy. The patient would need to assume the risk. This is more complicated in the situation of minors and people who lack capacity to give informed consent and their ability to assume that risk.

As the efficacy of the medicinal cannabis (without an established therapeutic product in an appropriate registered form) is still unclear (on a clinically trialed basis), this may cast doubt that express consent from a decision maker was adequately informed.¹⁹

- 1.44 Some medical practitioners have questioned how they could ensure that a patient gives informed consent to use medicinal cannabis when they themselves are unclear about the possible consequences of the decision.²⁰ The Royal Australasian Society of Physicians has noted that the potential risks and benefits will be very different from one patient group to the next.²¹ The Commission expects that concerns of this nature could be addressed to some extent by training and guidelines that could be offered under a medicinal cannabis scheme. In addition, clinical trials that are underway or proposed in Australia and internationally will continue to enrich knowledge about the medicinal properties of cannabis.
- 1.45 It is nevertheless clear that any scheme introduced in Victoria would need to accommodate the uncertainties surrounding a decision to use a medicinal cannabis product that has not been tested to the standards required by the TGA for prescription medicines. Patients would need to be informed (preferably verbally and in writing in language they are likely to understand) that aspects of the treatment such as the dosage, the best form of administration, immediate and long-term side effects and interaction with other medications have not been established authoritatively by clinical trials, and would need to take responsibility for the decision to proceed with the treatment in view of the information with which they are provided.
- 1.46 The scheme would also need to support the development of expertise among medical practitioners in the use of cannabis for medicinal purposes, and to ensure that only those with appropriate training would assess whether it should be made available to their patients.

19 Submission 63.
20 Submission 38; Advisory committee (Meeting 3).
21 Submission 52.

Ensure that medicinal cannabis products are of reliable quality and known composition

- 1.47 There are many reasons why products provided under a Victorian medicinal cannabis scheme would need to be of reliable quality and known composition:
- It is essential to patient safety.
 - It would enable a doctor to titrate dosage and monitor dose-response effect.
 - It would provide a superior product to what is available illegally.
 - It would enable useful data to be collected on the efficacy and side effects when treating particular conditions and symptoms.
- 1.48 Any regulation would provide a level of quality assurance that illicit production cannot guarantee, but the scheme would need to impose standards that provide medical practitioners and their patients with certainty about the potency and contents of the products being administered.
- 1.49 A number of submissions pointed out the need to ensure that the products to which patients are given access are of reliable and verifiable composition.²² Many members of the public who told the Commission that they wish to be able to use cannabis legally said that their main concern is to have access to products of a consistently good quality. As Shirley Humphris argued in her submission: 'We need a supply that is clean and grown under controlled conditions (street cannabis can be heavily laced with pesticide)'.²³
- 1.50 Possible approaches to regulating the quality of products are discussed in Chapter 7.

Foster, and be responsive to, clinical research and developments in technology

- 1.51 Any medicinal cannabis scheme established in Victoria would need to remain effective over time as scientific knowledge, medical practices and technology continue to evolve. Greater understanding about the therapeutic properties of cannabis could have an impact on the range of products made available in Victoria, the conditions under which they are provided, and the size and focus of the scheme. Accordingly, the scheme would need to keep pace with, and be responsive to, clinical research and developments in the medicinal cannabis industry.
- 1.52 Measures that would enable a Victorian medicinal cannabis scheme to be responsive to developments in clinical knowledge, and subject to ongoing monitoring and review, are discussed in Chapter 8.

Preserve the prohibition of unlawful trafficking, cultivation, supply and use of cannabis

- 1.53 The proposed legislative reform would need to reinforce ongoing prohibitions on the cultivation, supply and use of cannabis. The reform would not allow everyone who currently uses, or wants to use, cannabis to do so legally. It follows that the illicit market would continue to exist.
- 1.54 Depending on the features of the scheme that is established, it could create new opportunities for cannabis to be supplied and used illegally. For example, medicinal cannabis supplied under the scheme could be diverted to unauthorised users by:
- authorised patients who pass on some of their supply to others
 - medical practitioners who enable access by patients who do not meet the eligibility criteria
 - theft of cannabis seeds or plants under cultivation

- theft of medicinal cannabis products from distributors or patients.
- 1.55 Opinions vary on the impact that a Victorian medicinal cannabis scheme could have on the illicit market. Concerns that legitimising the use of cannabis for medicinal purposes ‘normalises’ recreational use among young people have not been supported by recent research findings.²⁴ However, international experience has shown significant diversion of cannabis produced in ‘grow your own’ schemes to the illegal market where adequate controls are not in place.²⁵
- 1.56 The Law Institute of Victoria indicated that the risk of diversion is affected by the balance of supply and demand and this should be borne in mind when establishing the scheme.²⁶ The Victorian Alcohol and Drug Association suggested that cannabis is so widely available and affordable illegally that legal products would have little street value.²⁷ Dr Andrew Katelaris pointed out there is no risk of CBD-dominant cannabis products being diverted for recreational use because CBD has no psychotropic effect.²⁸
- 1.57 In addressing the risk of diversion, law enforcement authorities would need to be able to determine whether a person in possession of medicinal cannabis is authorised under the scheme and to distinguish between products that have been made available under the scheme and diverted to the illegal market and products that have been produced illegally. In addition, security measures appropriate to the assessment of the risk would need to be put in place at every step of the supply chain. Many submissions commented on the security risks and suggested how they could be managed.²⁹ The Commission has taken such risks into account in developing its recommendations.

Provide an equitable and accessible scheme

- 1.58 This objective has been developed in response to comments that the Commission received on the issues paper, notably from the advisory committees.³⁰ It recognises the need for the reform to create a scheme that provides the necessary amount of regulation to achieve its objectives while not becoming so complex, burdensome or expensive that it deters those on whom its success depends, and those it is intended to benefit, from participating.
- 1.59 A concern frequently raised with the Commission is the importance of making the medicinal cannabis products that are sold under a Victorian scheme affordable for patients, particularly as many could be on low incomes because of disabilities stemming from their conditions.³¹
- 1.60 Otherwise, as a submission made on behalf of cannabis users and advocates pointed out, patients could resort to using less expensive illicit products:

Patients’ access to cannabis under any regulated scheme is vital to its success. If patients are unable to practically access cannabis, they will not embrace the system and return to buying their medicine from the illicit market.³²

24 Deborah S Hasin et al, ‘Medical Marijuana Laws and Adolescent Marijuana Use in the USA from 1991 to 2014: Results from Annual, Repeated Cross-sectional Surveys’ (2015) 2 *The Lancet Psychiatry* 601.

25 Submissions 37, 61, 74. Gerald Caplan, ‘Medical Marijuana: A Study of Unintended Consequences’ (2012) 43 *McGeorge Law Review* 127. Delsys Research Group, *Cost-Benefit Analysis of Regulatory Changes for Access to Marijuana for Medical Purposes, Final Report* (2012). Yu-Wei Luke Chu, ‘The Effects of Medical Marijuana Laws on Illegal Marijuana Use’ (2014) 38 *Journal of Health Economics* 43.

26 Submission 63.

27 Submission 46.

28 Submission 30.

29 Submissions 21, 23, 26, 29, 40, 42, 44, 58.

30 Advisory committee (Meetings 1 and 2).

31 Advisory committee (Meetings 1 and 2); Consultations 2, 4, 5, 6, 8, 23, 24, 26.

32 Submission 95.

-
- 1.61 This has been the experience overseas. This has been an important issue in the various iterations of the Canadian medicinal cannabis scheme.³³ In Italy, eligible patients were permitted in 2013 to access imported medicinal cannabis from the Netherlands. However, the imported cannabis was priced at ten times the cost of products purchased on the illicit 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.³⁴ Italy now produces its own medicinal cannabis.
- 1.62 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, the Office of Medicinal Cannabis sells all the medicinal cannabis provided under the scheme. It sets the prices based on the net costs it incurs in purchasing, analysing, packaging and distributing the cannabis.³⁵ The scheme is revenue-neutral.³⁶
- 1.63 Some states in the United States impose price controls by regulation rather than by government involvement in the distribution process. In Vermont, for instance, dispensaries are required to have ‘a sliding-scale fee system that takes into account a registered patient’s ability to pay’.³⁷ In New York, the government will set the ‘per dose price’ at which medicinal cannabis may be sold.³⁸ Prices are also controlled indirectly by the common requirement that distributors operate on a not-for-profit basis.
- 1.64 A view put forward in several submissions was that patients should be able to grow their own cannabis, to keep the costs affordable.³⁹ This would be only a partial solution, because not all patients have the ability, inclination or resources to grow their own. They would be reliant on products that have been manufactured under regulation and sold for a higher price.
- 1.65 A number of factors other than the purchase price of the products would be likely to affect the accessibility of the scheme for patients. Patients may be unable or unwilling to participate if:
- The authorisation process is expensive, difficult or protracted.
 - No local medical practitioners will supervise the treatment.
 - There are extensive delays in meeting demand for the products.
 - The monitoring and review obligations impose an unreasonable burden.
- 1.66 The obligations imposed by the scheme on other participants should also not be too onerous. Over-regulation of the cultivation and processing of cannabis, excessive licence fees, or duplication of regulation by Victoria and the Commonwealth would increase costs and act as a disincentive to potential licensees. If the qualifications or reporting requirements under the scheme are overly time-consuming, medical practitioners may choose not to be involved, or they may charge a higher fee to patients to recover their costs. Similarly, if the rules concerning distribution depart too much from existing practice and require new procedures and systems to be established, pharmacies may be reluctant to participate as well. Considerations such as these at any point of the process could affect the viability of the scheme.
- 1.67 The more efficient the design of any Victorian medicinal cannabis scheme, the lower would be the costs at each step of the supply chain. In turn, the extent to which the government may need to subsidise the purchase price of the products would be reduced. The Commission has been mindful of this consideration in evaluating the law reform options in this report.

33 Submission 95. See also Ian Freckelton, ‘Medicinal Cannabis Law Reform: Lessons from Canadian Litigation’ (2015) 22 *Journal of Law and Medicine* 719.

34 Steve Scherer, ‘To Grow Cheap Marijuana, Italy Calls in the Army’, *Reuters* (online), 12 October 2014 <<http://www.reuters.com>>.

35 Consultation 28.

36 Ibid.

37 18 Vt Stat Ann § 4474e(b)(2).

38 NY Public Health Law § 3366-D.

39 Submissions 6, 23, 53, 95.

Recommendation

- 1** Law reform to allow people to be treated with medicinal cannabis in exceptional circumstances should be designed so as to be compatible with the following objectives:
- (a) Allow compassionately for exceptional circumstances of medical need.
 - (b) Integrate the use of medicinal cannabis products into the patient's medical treatment.
 - (c) Ensure that patients are informed of clinical uncertainty about the safety and efficacy of medicinal cannabis products they use.
 - (d) Ensure that medicinal cannabis products are of reliable quality and known composition.
 - (e) Foster, and be responsive to, clinical research and developments in technology.
 - (f) Preserve the prohibition of unlawful trafficking, cultivation, supply and use of cannabis.
 - (g) Provide an equitable and accessible scheme.

Risks

- 1.68 The introduction of a scheme to allow Victorians to be treated with medicinal cannabis in exceptional circumstances would generate risks that need to be taken into account in considering the law reform options. The option preferred by the Commission has been developed with a view not only to the regulatory objectives but to the management of these risks.
- 1.69 There are hierarchies of risk at every level of any regulatory scheme. The Commission focused on those which are inherent to the proposed reform:
- Patient safety is compromised when using products that do not meet the safety, quality and efficacy standards that apply to prescription medicines under the national regime.
 - There is uncertainty or controversy about the circumstances in which access to cannabis is permitted.
 - Medicinal cannabis products are diverted to unauthorised users.
 - There are excessive costs to government in establishing and operating a scheme outside the national framework for regulating therapeutic goods.
 - Victoria does not secure the necessary support from the Commonwealth in establishing and operating an effective scheme.
- 1.70 The Commission discusses these risks throughout the report. Although they are relevant considerations in introducing the proposed reform, it is important to acknowledge that numerous other factors will inform the many decisions required in drafting legislative amendments and establishing and operating a medicinal cannabis scheme.

Expectations about implementation

- 1.71 The Commission's approach to identifying and assessing the options for reform is underpinned by a number of expectations about the features of any medicinal scheme that may be established in Victoria. The discussion about the options in this report assumes that each would have these features.

A regulator

- 1.72 Responsibility for establishing and administering the scheme would reside within the portfolio of the Minister for Health. The Commission is aware that preparatory work is already underway within the Department of Health and Human Services, driven by a newly established medicinal cannabis taskforce, pending the completion of this reference.
- 1.73 Depending on the features of the scheme that is adopted, the Commission expects that the Secretary of the Department of Health and Human Services would be responsible for functions such as:
- establishing and maintaining records in relation to eligible patients and carers, and participating medical practitioners and pharmacists
 - granting permits to medical practitioners
 - creating and enforcing quality assurance standards
 - controlling the manufacture and distribution of medicinal cannabis products
 - providing data to the Commonwealth in order to meet international reporting obligations
 - preparing guidelines and educational material for the public, medical practitioners and pharmacists.
- 1.74 The Secretary's lawful functions may need to be amended accordingly⁴⁰ and other government agencies may also need to be involved in regulating aspects of the scheme.⁴¹ In any event, the functions would be within the remit of existing government agencies and there are no compelling reasons to create an independent statutory authority for this purpose.⁴²
- 1.75 To the extent that there is a need for the Victorian Government to enter into contracts or own property, these powers could be exercised by an existing body corporate known as the 'Secretary to the Department of Health and Human Services'.⁴³ This body corporate and its predecessors have a long history of contracting and owning property for discharging various health-related functions.⁴⁴
- 1.76 The Commission also expects that, while the new regulatory powers would be formally reposed in the Secretary, in practice they would be exercised by, or on the advice of, a business unit within the Department of Health and Human Services. In this report, the Commission refers to this unit as the 'Office of Medicinal Cannabis'.

40 The Secretary's functions are set out in the *Public Health and Wellbeing Act 2008* (Vic) s 17 and can be expanded by regulation: s 17(1)(c). Alternatively, new provisions could be added to the Act.

41 The Commission expects that the Secretary of the Department of Economic Development, Jobs, Transport and Resources would regulate any cultivation of cannabis for medicinal purposes by licensed entities: see Chapter 6.

42 Victorian Public Sector Commission, *Legal Form and Governance Arrangements for Public Entities: Guidelines* (May 2013) [3.2].

43 Under the *Public Health and Wellbeing Act 2008* (Vic) s 16, the 'Secretary to the Department of Health' is established as a body corporate, which is capable of owning property and doing all other acts which may be done by body corporate. By force of the current Administrative Arrangements Order (No 219) 2014, the 'Secretary to the Department of Health' is to be read as the 'Secretary to the Department of Health and Human Services': Victoria, *Government Gazette*, No S 460, 24 December 2014, Table 2, Item 22.

44 See Victoria, *Parliamentary Debates*, Legislative Assembly, 10 March 2010, 748 (Daniel Andrews, Minister for Health).

An advisory body

- 1.77 The Commission has recommended above that one of the regulatory objectives of any medicinal cannabis scheme in Victoria should be to foster, and be responsive to, clinical research and advancements in technology. It was suggested to the Commission that the Government establish and use a panel of experts to guide it on the state of the science and how this should inform its decision making.⁴⁵
- 1.78 The Commission concurs with the thrust of these submissions. An Expert Advisory Committee on Medicinal Cannabis was established by the Department of Health and Human Services in 2014 and could form the basis of such an advisory body under a medicinal cannabis scheme.
- 1.79 Professor David Penington recommended the formation of a panel of patient advisors who are 'knowledgeable about alternative products and methods of administration.'⁴⁶ The Commission agrees that the Department of Health and Human Services should consult with patients and their carers about the operation of the scheme. However, while the panel proposed by Professor Penington could be useful, and community consultation is important, there may be better means of communicating with this disparate and widespread group of people.

Interim measures

- 1.80 There could be a considerable period of time between a decision being made by the Government about the type of scheme to introduce and the supply of medicinal cannabis products under the scheme. The duration would depend on how much of the supply chain is regulated by the scheme. In the meantime, it is reasonable to expect that the patients for whom the scheme is designed would continue to use, or could seek to use, illicit medicinal cannabis products.
- 1.81 Accordingly, the Commission acknowledges that the Government may consider introducing interim measures in anticipation of the scheme coming into operation. These could be introduced under interim legislation that is repealed upon the full scheme coming into effect. Such measures could include, for example, the establishment of a registration scheme for patients for whom specific services and authorisations could be created. The Commission makes no recommendations about any such measures as it would be beyond the scope of the terms of reference. However, the following observations are made for the Government's information.
- 1.82 In considering which interim measures, if any, to introduce, it would be prudent to be guided by the regulatory objectives that the full scheme is intended to achieve. An interim measure should not permit activities which again would be prohibited under the scheme; if it did, the final scheme would be undermined by the interim scheme that preceded it.
- 1.83 The immediate priorities identified by patients and their families who spoke with the Commission about their current illicit use of cannabis for medicinal purposes, and who would be eligible to participate in the scheme if the recommended eligibility criteria were applied, are to be protected from prosecution and be able to find out the composition of the products they use.⁴⁷
- 1.84 A number of submissions, and comments made during consultations, called for an amnesty for patients and their suppliers.⁴⁸ However, any 'amnesty' would need to take the form of an authorisation to conduct activities that are otherwise prohibited under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

45 Submission 60 proposes that an expert committee be used to review proposals to conduct clinical trials; Submission 61 suggests establishing an 'indication committee' to establish eligibility criteria, and an 'exemption committee' to consider special cases of eligibility.

46 Submission 24.

47 Consultations 2, 4, 6, 13.

48 Submissions 35, 43, 64, 71, 89, 95; Consultations 2, 5, 6, 9, 24, 26.

- 1.85 Interim measures could authorise specific classes of people to possess or administer cannabis for medicinal purposes, including for example:
- patients and carers who have been registered for the purposes of the interim measures
 - medical practitioners and nurses involved in their care
 - employees of testing facilities for the purpose of implementing any interim measures allowing for medicinal products to be tested.

Concurrent developments

Rescheduling of cannabidiol

- 1.86 On 1 June 2015, the cannabinoid cannabidiol (CBD) was rescheduled to Schedule 4 of the *Standard for the Uniform Scheduling of Medicines and Poisons*.⁴⁹ This means that a medicine containing cannabidiol and two per cent or less of other cannabinoids may be made available by prescription throughout Australia, as long as it has first been approved by the TGA.⁵⁰

Clinical trials

- 1.87 A number of clinical trials of medicinal cannabis are underway or planned in Australia.
- 1.88 New South Wales, Queensland and Victoria are sponsoring three trials to explore the efficacy of cannabis and/or cannabis-derived products. Led by New South Wales, the first trial is of children with severe, drug-resistant epilepsy. It will involve up to 200 participants, from mid-2016. The Victorian Government aims for at least a quarter to be from Victoria. The results of the trial are expected in two to five years.⁵¹
- 1.89 The other two trials are for adults. One will focus on relieving the pain symptoms of adults with terminal illness. The other will be for adults with chemotherapy-induced nausea and vomiting, where standard treatment is ineffective.
- 1.90 Following a donation of \$33.7 million for medicinal cannabinoid research, the University of Sydney recently announced that it will conduct a multi-year program to build on existing expertise to ultimately produce cannabinoid-based medicines. A priority will be to understand the potential for CBD and other cannabinoids to treat paediatric epilepsy.⁵² The University of Sydney is also involved in the government-sponsored trials.

Regulator of Medicinal Cannabis Bill 2014 (Cth)

- 1.91 In November 2014, the Regulator of Medicinal Cannabis Bill 2014 (Cth) was introduced to the Senate as a Private Member's Bill.⁵³ The Bill establishes the Regulator of Medicinal Cannabis, an agency that would:
- approve medicinal cannabis products for inclusion in a register of regulated cannabis products⁵⁴
 - make, and monitor compliance with, rules for licensing the production, use, experimental use and import and export of medicinal cannabis.⁵⁵

49 Therapeutic Goods Administration (Advisory Committee on Medicines Scheduling), *Final Decisions and Reasons for Decisions by Delegates of the Secretary to the Department of Health* (19 March 2015) 56–60.

50 Approval of medicines by the Therapeutic Goods Administration, the operation of the *Standard for the Uniform Scheduling of Medicines and Poisons* and the consequences of rescheduling CBD are discussed further in Chapter 4.

51 Premier of Victoria, 'Victoria to Participate in Medicinal Cannabis Trials' (Media Release, 19 April 2015) <<http://www.premier.vic.gov.au/victoria-to-participate-in-medicinal-cannabis-trials>>.

52 The University of Sydney, 'Lambert Donation Puts Australia at Forefront of Medicinal Cannabinoid Research' (Media Release, 12 June 2015) <<http://sydney.edu.au/news/>>.

53 Commonwealth, *Parliamentary Debates*, Senate, 27 November 2014, 9506 (Richard Di Natale). See rule 6.6.1.

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

55 *Ibid* cl 12.

- 1.92 The proposed office of Regulator is designed to satisfy the requirements of the Single Convention on Narcotic Drugs regarding government supervision of licensed cannabis cultivation.⁵⁶ The source of constitutional authority for the Bill is said to be the treaty implementation aspect of the external affairs power.⁵⁷ The scheme would apply only in those states and territories that opt in.⁵⁸
- 1.93 On 12 February 2015, the Senate referred the Bill to the Senate Legal and Constitutional Affairs Legislation Committee for report by 21 April 2015. On 11 August 2015 the report was tabled, supporting ‘in principle, the access to products derived from cannabis for use in relation to particular medical conditions where the use of those products has been proven to be safe and effective.’ The committee recommended amendments to the Bill to address issues in relation to its interaction with the existing Commonwealth regulatory framework for medicinal products, including the Therapeutic Goods Act 1989 (Cth), the Narcotic Drugs Act 1967 (Cth) and relevant customs legislation. It also recommended amendments to the Bill to ensure compliance with Australia’s international obligations, including under articles 23 and 28 of the Single Convention on Narcotic Drugs 1961.⁵⁹
- 1.94 The Commission is aware of active discussion at the political level, and among government agencies, about the possible introduction of Commonwealth legislation. Although Commonwealth legislation could modify the design of a Victorian scheme, the discussion in this report would remain relevant.

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

- 1.95 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 Justice⁶⁰ presented an exposure draft of the Bill and a discussion paper to the Legislative Assembly in August 2014. The exposure draft and paper were referred to the committee.⁶¹
- 1.96 The purpose of the draft Bill is to set up a licensing system for patients to possess and grow their own cannabis for medicinal purposes if approved by the Chief Health Officer.⁶² Patients would be able to make one of three types of application:
- Category 1 application: for the mitigation of symptom(s) of a terminal illness⁶³
 - 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)⁶⁴
 - Category 3 application: for the mitigation of a symptom of any other medical condition or its treatment.⁶⁵
- 1.97 The application would have to be supported by a statement from a doctor, with increasingly stringent requirements according to the category of application.⁶⁶ In all cases, the applicant would need to have tried or considered conventional treatment first.⁶⁷ Once approved, a patient would be permitted to possess cannabis. An approval would essentially amount to a licence to possess and use cannabis.⁶⁸

56 Explanatory Memorandum, Regulator of Medicinal Cannabis Bill 2014 (Cth) 1. The *Single Convention on Narcotic Drugs 1961* is discussed in Chapter 4.

57 Explanatory Memorandum, Regulator of Medicinal Cannabis Bill 2014 (Cth) 2.

58 Regulator of Medicinal Cannabis Bill 2014 (Cth).

59 Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Regulator of Medicinal Cannabis Bill 2014* (2015) ch 5.

60 Shane Rattenbury MLA.

61 Australian Capital Territory, *Parliamentary Debates*, Legislative Assembly, 7 August 2014, 2154 (Shane Rattenbury).

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

63 *Ibid* cl 7(3).

64 *Ibid* cl 7(4).

65 *Ibid* cl 7(5).

66 *Ibid* cl 8–9.

67 *Ibid* cl 8(2)–(3).

68 *Ibid* cl 14.

- 1.98 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.⁶⁹ In applying for a cultivation licence, the applicant would have to establish that they have appropriate security measures in place,⁷⁰ and only one patient would be able to be associated with any given cultivation site.⁷¹ The scheme would be reviewed after five years by a multi-stakeholder committee.⁷²
- 1.99 At the time of writing, the committee was due to report by the last sitting day of August 2015.⁷³ The outcome could also be affected by any decision by the Commonwealth to legislate in this area.

Tasmanian parliamentary inquiry

- 1.100 On 20 November 2014, Government Administration Committee 'A' of the Tasmanian Legislative Council released an interim report on the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medicinal purposes. 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.
- 1.101 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
 - 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.⁷⁴
- 1.102 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.⁷⁵ However, it rejected the Committee's recommendation to legislate immediately 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 inquiry.⁷⁶ The Committee presented its final report to the Legislative Council on 21 April 2015.⁷⁷ It said that continuing the inquiry in light of the introduction of the Regulator of Medicinal Cannabis Bill 2014 to the Senate and the New South Wales Government's commitment to clinical trials may be duplicative and unnecessary. The interim report stands as the substance of the final report.⁷⁸

69 Ibid cl 16–22.

70 Ibid cl 18(3)(d).

71 Ibid cl 18(3)(e).

72 Ibid cl 25.

73 Standing Committee on Health, Ageing, Community and Social Services, ACT Legislative Assembly (2015) <<http://www.parliament.act.gov.au>>.

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

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

76 Ibid.

77 Legislative Council Government Administration Committee 'A', Parliament of Tasmania, *Final Report on Legalised Medicinal Cannabis* (2015).

78 Ibid 1.

Norfolk Island licence to cultivate and export cannabis

- 1.103 In April 2015, the responsible minister announced that AusCann Group Holdings Pty Ltd had lodged an application for a licence to ‘import, export, plant, cultivate, tend or harvest and sell’ cannabis, for the purpose of establishing a medicinal cannabis industry on Norfolk Island.⁷⁹ Norfolk Island legislation permits the Minister to grant such a licence under ‘such conditions as the Minister thinks appropriate’⁸⁰ and the Administrator has the discretion to cancel it at any time.⁸¹
- 1.104 In May 2015, it was reported that the licence had been granted. The AusCann Managing director revealed that the company aimed to produce high quality medicinal-grade cannabis for export to importers that were licensed in accordance with the Single Convention on Narcotic Drugs.⁸² It had an initial order from Canada for one tonne and aimed to provide ten tonnes in the future. The first crop was to be planted in November 2015, to be harvested in May or June 2016.⁸³
- 1.105 Since then, the legal and governance framework for Norfolk Island has changed. The form of self-government that was established by the *Norfolk Island Act 1979* (Cth) has been abolished.⁸⁴ The Legislative Assembly and Executive Council will be replaced from 1 July 2016 by a regional council that will provide local and municipal services. State-level services will be provided by the New South Wales Government, and the law of New South Wales will apply. In the meantime an advisory council has been established as an interim body and the statutory office of Administrator will continue.
- 1.106 Norfolk Island laws will stay in place until they are specifically replaced by New South Wales law.⁸⁵

Structure of this report

- 1.107 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. Chapter 2 contains an overview of what cannabis is, how it is used, and what is currently known and claimed about its therapeutic properties.
- 1.108 The Commission’s conclusions and recommendations about the eligibility criteria for a scheme that allows for people to be treated with medicinal cannabis in exceptional circumstances are explained in Chapter 3. Discussion then turns to who could authorise an individual patient’s access to medicinal cannabis and the possible regulatory mechanisms involved.
- 1.109 The legislation that controls access to cannabis is discussed in Chapter 4. The *Drugs, Poisons and Controlled Substances Act 1981* (Vic) and the *Therapeutic Goods (Victoria) Act 2010* (Vic) and associated regulations constitute Victoria’s contribution to national legislative frameworks that control narcotic drugs and ensure the quality, safety and efficacy of therapeutic goods.

79 Robin Adams, Minister for Cultural Heritage and Community Services, ‘A Medicinal Cannabis Industry for Norfolk Island’ (Press Release, 24 April 2015).

80 *Dangerous Drugs Act 1927* (NI) s 7A.

81 *Dangerous Drugs Act 1927* (NI) s 13. The Administrator exercised this power to cancel a licence issued under s 7A to Tasman Health Cannabinoids (NI) Pty Ltd (Tascann) in 2014 after identifying a need for the social, economic and environmental impacts to be properly assessed and for the community to be adequately consulted. He also expressed doubt that the licence adequately addressed international obligations regarding the cultivation and trade of illicit drugs and noted that it had been issued without consulting the relevant federal authorities: Gary Hardgrave, Administrator, Australian Territory of Norfolk Island, ‘Tasman Health Cannabis Licence Cancelled’ (‘Non Daun’ taun (Government News from Kingston), 14 August 2014) <<http://norfolkonlinenews.com>>.

82 ‘Firm to export medical cannabis’, *Sky News* (online), 20 May 2015 <<http://www.skynews.com.au/news/national/>>.

83 3AW, ‘Medical Marijuana Grown on Norfolk Island’, 20 May 2015 <<http://www.3aw.com.au>>.

84 *Norfolk Island Legislation Amendment Act 2015* (Cth).

85 Department of Infrastructure and Regional Development, Australian Government, *Fact Sheet: Answers to Your Questions from the Information Sessions* (May 2015) <http://regional.gov.au/territories/norfolk_island/fact-sheets/Norfolk-Island-reforms-answers-from-info-fessions.aspx>.

- 1.110 Chapter 5 sets out the options for reform. The range of proposals put to the Commission is discussed. Some are not feasible because they are legally unstable or otherwise undesirable when considered in view of the regulatory objectives. An option that is feasible and most likely to achieve the regulatory objectives is identified and recommended. It is adopted as a model in the following chapters. Chapter 6 contains details of how medicinal cannabis products could be manufactured, supplied and distributed in Victoria under the recommended option.
- 1.111 Under the recommended option for the supply of medicinal cannabis products the Victorian Government would regulate the quality and type of products available. Ways in which this could be done are discussed in Chapter 7.
- 1.112 Any medicinal cannabis scheme introduced in Victoria could be the first of its kind in Australia, and would be implemented at a time when information about, attitudes toward and controls on the use of cannabis for medicinal purposes are changing rapidly. Chapter 8 discusses possible measures for ensuring that the operation of the scheme contributes to research and is subject to ongoing monitoring and review.
- 1.113 Chapter 9 concludes the report.

The use of cannabis for medicinal purposes

- 20** Introduction
- 20** What is medicinal cannabis?
- 23** Use of medicinal cannabis
- 30** Research support for efficacy

2. The use of cannabis for medicinal purposes

Introduction

- 2.1 This chapter provides an account of the Commission’s view of what constitutes medicinal cannabis, a discussion of the way cannabis is currently used medicinally in Victoria, and a record of information provided to the Commission about the effects of cannabis used for medicinal purposes. It also reviews the research base for:
- the efficacy of cannabis in alleviating the symptoms of particular conditions
 - the adverse effects that cannabis may have for patients when provided to them for medicinal purposes.

What is medicinal cannabis?

Scope of review

- 2.2 The Commission has been asked to review and report on options for changes to the law to allow people to be treated with ‘medicinal cannabis’ in exceptional circumstances. For the purposes of its review the Commission must therefore adopt a position on what is meant by ‘medicinal cannabis’.
- 2.3 ‘Cannabis’ refers to the flowering tops of plants in the genus *Cannabis L.*¹ Generally, the species used for medicinal and recreational purposes are *Cannabis sativa* and *Cannabis indica*,² with ‘hybrid’ plants also available.³ While the whole of the plant contains varying levels of between 80 and 100 cannabinoids, they are found in the highest concentrations in the flowering tops, meaning this part of the plant is most relevant for those wishing to use cannabis for medicinal purposes.⁴
- 2.4 The efficacy of cannabis for particular medical conditions is affected by the types and amounts of cannabinoids in the product. Products can contain high or low levels of delta-9-tetrahydrocannabinol (THC) or cannabidiol (CBD),⁵ in various combinations with the other cannabinoids. Some forms are psychoactive, principally because of their concentration of THC.⁶

1 In addition to being the commonly understood meaning of the term, this is also the meaning adopted in the *Single Convention on Narcotic Drugs 1961* art 1(1)(b).

2 A third species, *Cannabis ruderalis*, also exists, but the Commission was not told that it is used medicinally. See Karl W Hillig, ‘Genetic Evidence for Speciation in Cannabis (Cannabaceae)’ (2005) 52 *Genetic Resources and Crop Evolution* 161. See generally Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, 2014); Submission 95.

3 Recent literature has disputed whether the *sativa* and *indica* types are in fact separate species, with some arguing that only a single species, *Cannabis sativa*, exists: A Hazekamp and J T Fischeidick, ‘Cannabis—From Cultivar to Chemovar’ (2011) 4 *Drug Testing and Analysis* 660.

4 Some medicinal users assert that the leaves of the plant also have therapeutic value.

5 Such as the ‘Charlotte’s Web’ strain, which was developed by cross-breeding a strain of cannabis with industrial hemp to achieve a low-THC strain used in treating the epilepsy of Charlotte Figi: Epilepsy Foundation of Colorado, *Frequently Asked Questions* <<http://www.epilepsycolorado.org>>.

6 The level of psychoactivity depends chiefly on the THC content. Products which contain predominantly CBD or unconverted THCA are minimally psychoactive.

- 2.5 Cannabis is used for recreational purposes for its euphoriant effect, among other things, but also for medicinal purposes to cure or remedy symptoms of medical conditions.
- 2.6 'Medicinal' means 'relating to, having the properties of, a medicine; curative; remedial'.⁷ Thus, cannabis should be regarded as 'medicinal cannabis' when it is used for a medicinal objective—to achieve a curative or remedial effect.⁸ In this respect, medicinal purposes are to be equated with 'therapeutic' purposes.⁹ This is to be contrasted with its use for recreational purposes.
- 2.7 In consideration of the options for changes to the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*, the Commission comprehends cannabis to be used medicinally when it is both:
- taken by a person for the medicinal purpose of attempting to cure or remedy a medical condition,¹⁰ and
 - taken in a manner that enables the purported curative or remedial effect to be appropriately supervised and verified by a qualified medical professional.
- 2.8 Advances in the understanding of cannabis over the past half-century have enabled the development of synthetic pharmaceuticals that mimic the effects of cannabinoids on the body. For the purposes of this report, though, the Commission does not treat these products as falling within the meaning of 'medicinal cannabis'. On the other hand, products that are extracted from the cannabis plant and used for medicinal purposes are regarded as falling within the meaning of 'medicinal cannabis'.

Characteristics of medicinal cannabis

- 2.9 The Drug Policy Modelling Program at the University of New South Wales observed in its submission that cannabis products used medicinally can be categorised according to how their production is regulated:
- pharmaceutical-grade cannabis products, approved by conventional regulators such as the Therapeutic Goods Administration (TGA) and including the nabiximols (Sativex) and synthetic cannabinoids
 - controlled and standardised herbal cannabis, such as the products made in the Netherlands by Bedrocan BV, which have standardised levels of cannabinoids and have been tested to be free of harmful adulterants
 - unregulated illegal herbal cannabis, which is anything bought from the black market and generally has unknown concentrations of cannabinoids and potentially harmful contaminants.¹¹

7 *Macquarie Dictionary* (6th ed, 2013).

8 See Jonathan P Caulkins et al, *Marijuana Legislation: What Everyone Needs to Know* (Oxford University Press, 2012) 14.

9 See the etymological origin from the Greek of 'therapeutic', namely 'healing' and the definition 'relating to the treating or curing of disease, curative': *Macquarie Dictionary* (6th ed, 2013). Thus, in the *Therapeutic Goods Act 1989* (Cth) s 3(1), 'therapeutic use' is defined as, among other things, 'preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons'.

10 Often described as seeking a 'therapeutic effect', that being a drug's pharmacological effect on the body that translates into a clinical benefit for the patient: see David Warrell, Timothy M Cox and John D Firth (eds), *Oxford Textbook of Medicine* (Oxford University Press, 2003) 1013.

11 Submission 21.

- 2.10 Cannabis can also be differentiated by the form in which it is supplied. The categories of product made available for medicinal purposes in other jurisdictions include:
- the dried flowering tops of the cannabis plant, taken through being smoked, vaporised or infused in tea
 - cannabis resin, collected and compressed from the flowering tops
 - infused cannabis products, such as alcohol-based tinctures, edible oils infused with cannabis and products made from these, and suppositories
 - extracts of cannabis, containing concentrated extracts of cannabinoids, taken orally, topically or by vaporisation
 - raw, undried cannabis leaves, consumed as a food.
- 2.11 Some submissions provided to the Commission distinguished between the utility of *Cannabis sativa* and *Cannabis indica* for different purposes. Both forms contain a number of compounds that have the potential for medical application.
- 2.12 Views differ regarding what makes medicinal cannabis effective. Most submissions highlighted the therapeutic use of THC and CBD, and a number of people stressed the significance of the endocannabinoid system and the role of the Type 1 and 2 cannabis receptors.¹² CBD is known to moderate the effects of THC and is being researched for its potential to treat epilepsy, schizophrenia and other psychotic disorders, type II diabetes, inflammatory bowel disease, gliomas and drug dependency, among other conditions.¹³
- 2.13 THC and CBD are not the only compounds of interest in the cannabis plant. Besides THC, researchers at the University of Sydney have identified what they refer to as the ‘big 10’ non-psychoactive and non-addictive cannabinoids that show the most promising therapeutic potential. They are:
- cannabidiol (CBD) and its acid form (CBDA)
 - cannabidivarin (CBDV)
 - the acid form of THC (THCA)
 - tetrahydrocannabivarin (THCV) and its acid form (THCVA)
 - cannabigerol (CBG) and its acid form (CBGA)
 - cannabinol (CBN)
 - cannabichromene (CBC).¹⁴
- 2.14 Research as to the effects of these cannabinoids remains at an early phase, but the compounds have possible medical application in the treatment of epilepsy, pain, psychosis, cancer, diabetes, inflammation, anxiety and a host of other conditions.¹⁵
- 2.15 Besides cannabinoids, up to 300 other compounds found in the cannabis plant are asserted to contribute to its overall therapeutic effect. These include terpenes and flavonoids, which are not unique to the cannabis plant but contribute to each strain’s chemical ‘fingerprint’.¹⁶ Some with whom the Commission consulted emphasised the ‘entourage effect’, said to arise from the ‘whole’ cannabis plant which results in an overall beneficial effect beyond what could be obtained from each cannabinoid on its own.¹⁷

12 Submissions 13, 29, 30, 35, 59, 69, 90, 97. See Appendix B for list of submissions.

13 Government of WA Department of Health and Government of Victoria Department of Health, *Application to Amend the Poisons Standard (Substance: Cannabidiol)*, 6 October 2014, <<http://www.health.vic.gov.au/dpcs/medicinal-cannabis.htm>>.

14 David Allsop et al, Submission No 52 to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 2.

15 Ibid 4.

16 A Hazekamp and J T Fishedick, ‘Cannabis—From Cultivar to Chemovar’ (2011) 4 *Drug Testing and Analysis* 660.

17 Submissions 59, 95. See Ethan Russo, ‘Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects’ (2011) 163 *British Journal of Pharmacology* 1344.

Use of medicinal cannabis

- 2.16 It is apparent from the submissions received and consultations conducted by the Commission that cannabis is currently being used illegally by a wide range of Victorians to attempt to alleviate a broad array of health conditions. Others have informed the Commission that they would use it but are deterred by its current unlawful status.
- 2.17 As outlined in the issues paper, cannabis has a long history of medicinal use. It was introduced into Western medicine in the 19th century, at which time medicines were much less refined than contemporary pharmaceuticals. By the early 1900s, botanical extracts of cannabis were still in use, but the product was ‘difficult to store, its extracts were variable in potency, and the effects of oral ingestion were not constant’.¹⁸ At the same time, its recreational use increased, and by the mid-20th century its medicinal use had all but disappeared.¹⁹
- 2.18 The Commission heard compelling stories from users of medicinal cannabis regarding the dramatic changes they had experienced after starting treatment with medicinal cannabis. Many spoke of the ways in which cannabis had enabled them to stop using pharmaceutical drugs with serious side effects, or to ‘get their lives back’. Others without experience of medicinal cannabis told the Commission about the desperation they felt in experiencing, or watching a loved one experience, the pain and suffering of a chronic illness, and expressed sincere hope that cannabis might be effective for them.

Personal accounts of conditions where cannabis has provided relief

- 2.19 The following paragraphs summarise some of the personal accounts as to the efficacy of medicinal cannabis, as conveyed in submissions and consultations with members of the public.

Multiple sclerosis

- 2.20 Pain and muscle spasms associated with multiple sclerosis were reported as having been effectively treated through the use of medicinal cannabis. KF informed the Commission that she was diagnosed with multiple sclerosis in 2011 ‘after many years in limbo’. Her main symptoms were pins and needles, electric shocks, nerve pain in her feet and legs that made it very painful for her to walk, severe throat spasms, loss of sensation in the right side of her face, cognitive issues and extreme fatigue. She also suffered from alopecia areata for 10 years. She told the Commission that she started taking cannabis oil made according to the ‘Rick Simpson protocol’²⁰ in 2012. The result was that:

I no longer lose my hair, I no longer get the pins and needles or the electric shocks, I have recovered some of the feeling in my face but not all. If I take a small amount of cannabis oil every other day, I am able to do activities that include walking, without extreme pain. My MS has also not progressed.²¹

Epilepsy

- 2.21 The Commission heard from a number of people with children suffering from rare and severe forms of epilepsy. Many told of the dramatic reduction in symptoms their children had experienced following treatment with cannabis oil.

18 I Tomida, R G Pertwee and A Azuara-Blanco, ‘Cannabinoids and Glaucoma’ (2004) 88 *British Journal of Ophthalmology* 708, 708.

19 Ibid.

20 That is, by using a volatile solvent (usually naphtha or petroleum ether) to prepare a concentrated extract of cannabis: Luigi Romano and Arno Hazekamp, ‘Cannabis Oil: Chemical Evaluation of an Upcoming Cannabis-Based Medicine’ (2013) 7 *Cannabinoids* 1.

21 Submission 96.

2.22 The parents of Cooper Wallace told the Commission in person and in a written submission about the major symptom relief that he received from administration of cannabis oil. They acknowledged that it was not a cure for him but asserted that ‘it gives a quality of life for him, and our entire family’.²² Prior to using cannabis oil his condition had been deteriorating. After using cannabis oil for some time they have found that Cooper’s previously extensive fitting has become very limited and he is able to eat and drink instead of relying on tube-feeding. His conventional medications have been reduced and in some cases stopped.

We recently ran out of cbd oil, within days he was in hospital. One day alone he had over 900 seizures. On oil he has only 2–3 seizures. A dramatic change!²³

2.23 A similar account was given to the Commission by the parents of Tara O’Connell, who is treated with an ultra-low dose treatment using THC and THC Acid.²⁴ In 2012, Tara was suffering around 200 seizures per day and had been resuscitated eight times. She used a wheelchair, was not toilet-trained and had limited capacity to speak. Her medications had caused drug-induced anorexia. She was not expected to live for more than 24 months.²⁵ The Commission was told that, upon the administration of cannabis to Tara, her seizures stopped and the respite from the seizures has extended for over 24 months.²⁶ She no longer requires the use of a wheelchair and can attend school part-time. She has also ceased using all pharmacy drugs.²⁷

2.24 Michelle Whitelaw informed the Commission of a similar response obtained by her son, Jai, who was experiencing in the order of 500 seizures a day. She told the Commission that his incidence of seizures had fallen to three over the previous five months:

His pupils are no longer fixed nor dilated. He is eating/drinking without choking, attending school, able to write, speech is improving, walk steady, kick a ball and ride his bike, socialise, dress and toilet himself. All of these are FIRSTS. His personality is bubbly and he is so incredibly alive and well. Jai has not experienced any negative side effects.²⁸

2.25 The Commission also received submissions on behalf of adults suffering from intractable epilepsy. Lyn Cleaver wrote about her adult son, Jeremy, who suffers from epilepsy. In 2014, he experienced a drug-induced psychosis after one of his medications was increased on the advice of a neurologist. Subsequent adjustments to his dosages were of no effect, and the family decided to try medicinal cannabis. Ms Cleaver described the results as follows:

Almost immediately we saw improvements, his sleep patterns, behaviours and seizures were all much more tolerable! We knew then that we must find a way to source cannabis medicines to give him the best possible chance at a fulfilling life. ... Jeremy has been at the end of the line for available treatment for his seizures for years. We have been forced to wait for the next anti convulsant to be available on the market. ALL of the anti convulsants he has trialled have failed to control his seizures, ALL of them have caused unwanted side effects—some of them very serious. Cannabis is the first medicine we have been able to offer him that is both safe and effective.²⁹

22 Submission 50.

23 Ibid.

24 Submission 29.

25 Submission 51; Consultation 18. See also Cheri O’Connell, Submission 109 to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 2015.

26 See also Submission 29.

27 Cheri O’Connell, Submission 109 to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 2015, 1.

28 Submission 71.

29 Submission 81.

Relief from the symptoms of cancer

- 2.26 The Commission was informed by a number of people about the advantages in terms of pain relief and comfort obtained by patients with terminal cancer when they took one form or another of medicinal cannabis. Some provided powerful accounts of the help that they and their loved ones had received from different forms of cannabis during the later stages of their experience of terminal illnesses, particularly cancer.
- 2.27 Robert Wisbey spoke movingly at a public consultation in Geelong³⁰ about the experience of his son, Mason, who passed away from bowel cancer in April 2015. He told the Commission that when Mason received cannabis oil he was 'able to sleep, he was able to eat'.³¹ Mason had previously been unable to eat significantly for an extended period of time. In addition, according to his father, while cannabis did not remove Mason's pain, it rendered it manageable and significantly increased Mason's quality of life during the later period of his life.
- 2.28 In a subsequent written submission, Mr Wisbey described the unrelenting pain and discomfort from which Mason suffered until he began to take cannabis oil:
- As a human being Mason deserved BETTER he deserved to have a life without pain without suffering without the constant side effects caused by his medication and treatment, this was finally found in Cannabis Oil as much as I doubted its effect I could NOT refute what I was seeing before my eyes, my son was able to sleep, he was able to eat, an appetite that had left his body many months before returned with a vengeance he was not pain free but it was manageable at a level far far lower than what Doctors were able to give.³²
- 2.29 This account has many features in common with the experience of Dan Haslam in Tamworth, New South Wales who also experienced significant relief from the symptoms of bowel cancer from administration of cannabis oil.³³
- 2.30 The Australian Lawful Use of Cannabis Alliance relayed the story of another parent treating his child with cannabis oil:
- The recent tragic experience of one of our members, Mr Adam Koessler, is a sad example of this... He is currently facing criminal charges and family court proceedings for administering cannabis oil to his daughter who has terminal cancer and is undergoing a long process of chemotherapy.³⁴
- 2.31 A woman who attended the public consultation in Wodonga said that her husband's palliative care nurse had suggested cannabis for relief of cancer pain before he passed away. She said she was surprised at this, but that it did provide very good pain relief.³⁵
- 2.32 Many who communicated with the Commission lamented the effects of opiate medications which had adversely affected the mental state of cancer sufferers and had caused a variety of side effects including chronic and distressing constipation. However, they asserted that cannabis did not have such effects and was either as effective as, or more effective than, prescribed opiate medications.

30 Submission 64.

31 Ibid.

32 Ibid.

33 See James Robertson, 'Dan Haslam, Who Changed Mike Baird's Views on Medicinal Cannabis, Dies of Cancer', *Sydney Morning Herald*, 25 February 2015.

34 Submission 35.

35 Consultation 6. See Appendix C for list of consultations.

Chronic pain

- 2.33 Many accounts were given to the Commission of respite from chronic pain after using medicinal cannabis.³⁶
- 2.34 Matthew Corda has an acquired brain injury and many associated problems, and uses cannabis to treat pain and depression. He stated:
- I have tried nearly everything to no real solution to pain etc relief, but found cannabis a magic thing, kills the pain for longer, and am functioning adult. ... All [treatments] have been trialled and failed, or as in my case the strong pain [medications] gives the feeling of a zombie and difficult to function. ... [T]he benefits far outweigh what is wrote or discussed by people with no experience or used cannabis.³⁷
- 2.35 Danielle Rose-de Montignie used cannabis to treat her chronic pain caused by cancer from which she suffered 28 years ago. She also suffers from lymphoedema, which causes pain and swelling. She explained that she has successfully treated herself with cannabis, with her general practitioner's knowledge, and believes that she has avoided becoming an opiate user as a result.
- 2.36 Matthew Pallett described using cannabis medicinally for many years, referring to it as 'the only substance I have ever found to give relief from debilitating, neuropathic pain caused by spinal injury that occurred at 12 years of age'.³⁸
- 2.37 A large number of the people who attended the public consultations had used medicinal cannabis for chronic pain. At the Mildura public consultation, the Commission heard from a woman who suffered chronic pain from prolapsed discs and arthritis. Having taken morphine for 16 years to deal with the pain, she was unable to function and slept for up to 22 hours per day. She was unable to work a full-time job and could not attend university. She had contemplated suicide. After taking cannabis, she found that she can remain awake during the day.³⁹
- 2.38 Another person at the Mildura consultation described herself as suffering chronic pain due to car accidents that was so bad that she would 'vomit' from nausea. Her weight had dropped to 38kg and she was told she was at risk of death from organ failure. She had been prescribed morphine for over 15 years for the pain. After using cannabis, she found that her nausea disappeared and she was able to eat and eventually return to work.⁴⁰

Failure or harms of other treatments

- 2.39 As is apparent from the accounts described above, many of those who have resorted to medicinal cannabis have done so after the available treatments have failed or had unacceptable consequences.
- 2.40 Lindsay Milton started using cannabis after a spinal injury 25 years ago and subsequent surgery which left him in intense pain. He said that the medication he had been prescribed was ineffective, and he was taking extra medication to counteract the side effects of the pain killers:
- 2 days into using Cannabis I knew things could only get better if what was happening with pain relief continued and it did. I started sleeping better, was getting 5 times the pain relief pharmaceuticals were giving me and I got my appetite back all with no side effects whatsoever.⁴¹

36 Not all who had tried using cannabis for chronic pain had found it helpful. A participant in the Bendigo consultation (Consultation 4) told the Commission that it had not been useful for this purpose.

37 Submission 5.

38 Submission 59. Mr Pallett also states that cannabis 'helps to modulate the "intensity" associated with my particular variant of Aspergers Syndrome'.

39 Consultation 5.

40 Ibid.

41 Submission 92.

- 2.41 After another bad accident, which led to several operations and months in hospital being treated with pethidine for pain, he suffered withdrawal symptoms when he returned home. He was then given morphine, in increasing amounts as the pain continued to affect him:

When the family saw me [dying] on the bed taking 700mg a day of morphine and [diazepam] thrown in to help the morphine with pain family and friends had saw enough. I went from a fit 6' 4" 100 kilo man to a 160 kilo blob and I was slowly [dying], nothing surer, I was waiting on it. I had absolutely no recollection of anything that was going on around me and never spoke about anything anyone could understand. Then family and friends teamed up to firstly get me off the morphine which they did by reintroducing Cannabis back into my life for pain and slowly they kept lowering the morphine dose. It took 12 months to be free of it but my use in Cannabis was now part of my pain control and it works perfectly.⁴²

- 2.42 The Australian Lawful Use of Cannabis Alliance told the Commission about one woman who had turned to cannabis after exhausting conventional treatments:

The story of one of our members, Ms. Debra Lynch, perfectly encapsulates this tragic saga being played out in our communities. Debra suffers from an incurable illness called Raynaud's Phenomenon with Limited Scleroderma and Gastrointestinal Involvement. She is allergic to every available conventional pharmaceutical treatment option. The only therapeutic treatment she can tolerate is a course of medical-grade cannabis oil. Like many of our members, and the members of the Medical Cannabis Users Association of Australia, she is daily faced with the unconscionable choice of unlawfully accessing the only available treatment for her condition and its symptoms.⁴³

- 2.43 Some people informed the Commission that they take cannabis in addition to pharmaceutical preparations. Natalie Vassallo, for instance, said that she has a variety of conditions and is taking a range of medicines to treat them, but finds cannabis more helpful to her than most of her prescription medications:

When I cannot get hold of any Cannabis, my symptoms get worse. I suffer with pain in my neck, shoulders, arms, hands, lower back & knees. I suffer panic attacks that prevent me from leaving the house most of the time. It is debilitating to feel like this.⁴⁴

Access

Pathways to access

- 2.44 The Commission heard from many individuals who obtain cannabis from people who specialise in cultivating and refining cannabis for medicinal purposes. Indeed, several producers attended the Commission's consultations and made written submissions.⁴⁵ They showed a detailed knowledge of the cannabis plant, its varieties and refined versions, and expressed strong views about its potential medicinal applications.
- 2.45 People who presently access cannabis for medicinal purpose apparently receive significant advice and guidance from the suppliers of cannabis products, including instructions on strains, dosage and indications. The cost of obtaining medicinal cannabis through these illegal channels varies but was described as significant by some who spoke to the Commission.

42 Submission 92.

43 Submission 35.

44 Submission 80.

45 Consultations 1, 5, 7.

- 2.46 Clearly, for a sufficiently interested person, it is easy to find information regarding medicinal cannabis and its potential uses, particularly on the Internet. Many submissions referred the Commission to resources on the Internet. Some people described how they learnt online about the possible benefits of cannabis for their condition or that of a loved one. Several of them went on to seek out cannabis products through online stores and social media. Despite the illegal nature of all cannabis products in Australia, patients in Australia do not need to rely solely on local networks. They are able to access information or even the product itself from other jurisdictions where cannabis has been legalised for medicinal and/or recreational purposes.

Interest in medicinal cannabis

- 2.47 In addition to the accounts received on behalf of people already obtaining relief from cannabis, the Commission heard from a number who are interested in using it to treat a variety of conditions, having been unsuccessful with or disillusioned by conventional treatments.
- 2.48 Aaron Johnson and Kelli Russell told the Commission about their two-year-old daughter, Harper, who has Dravet Syndrome and suffers life-threatening seizures as a result. After reading on the Internet about the use of medicinal cannabis for seizures, they started investigating cannabis oil as a treatment for epilepsy. They read about the benefits and concluded that 'we need to give Australians numerous avenues to access cannabis based medicine legally'.⁴⁶
- 2.49 This account reflects a common theme among submissions: that the patient or their carers do not wish to try cannabis until it is made legal. A mother who attended the Shepparton public consultation, for example, stated that her son suffers from a rare form of epilepsy. She and her partner are desperate for relief, but they need to be able to act legally because they cannot afford to lose their jobs.⁴⁷
- 2.50 Joylene Donovan told the Commission about her 11-year-old daughter, Ava, who also suffers from Dravet Syndrome. She described severe side effects of anticonvulsant medications, and how attempts to wean her daughter off them have only led to increasing seizures and hospital admissions:

I would give anything to be able to have the opportunity to trial Medical Cannabis for Ava given the success we are seeing world wide for many children with the same condition as Ava. I see it as another option, another treatment and potentially a life changer for her. For some it will work, for others it won't and like any medication therapy it is definitely a trial and error thing due to the many combinations available. I understand the concern of long term effects but the reality is that what we are currently using to treat our children we don't even know if there is a long term, as we have already seen our beautiful children disappear in front of our eyes using pharmaceutical drugs, which are all addictive or toxic with long term use... Our pharmaceutical treatments may stop seizures but doses are often so high that our children become zombies and cause side effects that no parent should ever have to witness their child going through.⁴⁸

46 Submission 33.
47 Consultation 7.
48 Submission 78.

- 2.51 Other examples of carers interested in being able to legally access medicinal cannabis for their loved ones were Diane and Max Lock who spoke of the plight of their granddaughter, Madison, who has epilepsy:

Madison has been on many epilepsy drugs in the past few years, all of which have very nasty side effects, including aggression, pains in her head, psychotic episodes. This is devastating to see, and does not stop the seizures, nothing seems to work. Everything we have researched on medicinal cannabis seems favourable and not destructive like the prescribed medications the neurologist puts our Grand Daughter on. I know they are trying to help, but so far none of the prescription medications have worked.⁴⁹

- 2.52 Similar sentiments were expressed by Shirley Humphris about her granddaughter, Cambrie, who has intractable epilepsy. Cambrie has been trialled with 'over 12 antiepileptics all with frightening side effects and some with unknown long-term risks for children'.⁵⁰

- 2.53 People with adult epilepsy also expressed interest in trying medicinal cannabis. Derek Spence told the Commission about his wife, Elyse, who suffers from intractable epilepsy. He stated she 'has tried every drug available and they're all crap and don't work plus have numerous side effects.'⁵¹ Jan Hartwich told the Commission about her 55-year-old daughter, Karyn, who has suffered from epilepsy since birth. Ms Hartwich said that her daughter is on a number of drugs, which do not fully control her symptoms and have numerous side effects, such as blurred vision, anxiety and depression. They also cause her to sleep for more than 18 hours each day. Ms Hartwich advised that Karyn's neurologist believed cannabis could be of assistance to her but 'because [of] its illegal status we are unable to use it'.⁵²

- 2.54 A couple who attended the public consultation in Shepparton told the Commission about their adult son who suffers from epilepsy. He has seizures all day, and is severely incontinent. His condition has 'taken away the lives of three people'—his and his parents—and has the potential to break up families. If cannabis could reduce or eliminate his symptoms, they said, they might be able to get their lives back.⁵³

- 2.55 Mark Eastick, who experiences pain and muscle spasms as a result of a spinal cord injury, told the Commission he wished to try medicinal cannabis for his symptoms.⁵⁴

- 2.56 Another person told the Commission about his wife, who 'has been in constant pain for over 15 years', which has been categorised as fibromyalgia, and more recently as a type of pain believed to be nerve-based. He stated that she has received various forms of medical help, including pain medication, pain counselling and physiotherapy, but 'nothing seems to be working', leaving her confined to a wheelchair. She considered using morphine but her apparent drug sensitivities have left few options as regards medication. Although desperate for some relief, the person's wife has not yet tried cannabis:

The use of cannabis may or may not work, but given media reports that it has worked in unusual cases, it is [her] desire to at least test it to see if it can make a difference. Her current medical condition is now pushing us to look at what may be considered extreme approaches which may entail a measure of risk but we often wonder if it will be much worse than current efforts and associated risks. Given that all known conventional help has been exhausted with little relief from symptoms, an opportunity should be given anyone seeking help without undue hindrance to at least test the efficiency or otherwise when all other options are not proving effective.⁵⁵

49 Submission 67.
50 Submission 49.
51 Submission 62.
52 Submission 66.
53 Consultation 7.
54 Submission 72.
55 Submission 65.

- 2.57 The Commission also received a submission from a person suffering from a number of medical conditions, including a rare condition known as Idiopathic CD4 Lymphocytopenia, otherwise known as ‘non-HIV AIDS’—a form of AIDS which is not caused by HIV. The person described a grave illness, which has left them largely bedridden and causes a range of debilitating symptoms, including ‘chronic unrelenting’ pain. They cannot tolerate a number of medications, and experimental treatments have been suggested which would come at a high cost and require overseas travel. After researching cannabis online, the person has formed the view that ‘medicinal cannabis is the only realistic and comparatively safe treatment option available’. Notwithstanding this, the person has elected not to access cannabis because it is unlawful:

I have been tormented by thoughts of unlawful activity, experiencing feelings of great despair and loss that I have found myself in a position of having to choose between everything that I have believed in and stood for (the law) and trying to save my own life. The unlawful status surrounding cannabis, does not only affect me, it also affects those I live with. If prosecuted, my partner would stand to lose his current professional licence.⁵⁶

Research support for efficacy

Breadth and variety of data

- 2.58 The Commission’s issues paper posed the question: ‘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?’
- 2.59 In response, the Commission received submissions that, together, asserted that a wide variety of conditions can be cured or assisted by medicinal cannabis and thus should be viewed as ‘exceptional circumstances’ for the purpose of determining who should have access to medicinal cannabis under a Victorian scheme. These included asthma/breathing disorders,⁵⁷ HIV/AIDS,⁵⁸ Ebola,⁵⁹ cancer,⁶⁰ nausea from cancer,⁶¹ Crohn’s disease/gastrointestinal disorders/colitis,⁶² diabetes,⁶³ epilepsy,⁶⁴ glaucoma,⁶⁵ hepatitis C,⁶⁶ migraines/headaches,⁶⁷ muscle spasms and pain due to multiple sclerosis,⁶⁸ pain,⁶⁹ fibromyalgia,⁷⁰ arthritis,⁷¹ inflammation,⁷² menstrual pain,⁷³ menopause,⁷⁴ stress and anxiety,⁷⁵ insomnia/sleep disorders,⁷⁶ bipolar disorder,⁷⁷ depression,⁷⁸ psychotic illnesses,⁷⁹ attention deficit hyperactivity disorder (ADHD),⁸⁰ Tourette syndrome,⁸¹ nymphomania,⁸² post-traumatic stress disorder,⁸³ Alzheimer’s disease and dementia,⁸⁴ Parkinson’s disease,⁸⁵

56 Submission 43.
57 Consultation 5; Submissions 1, 3, 80, 95.
58 Consultations 2, 4, 9; Submissions 1, 13, 24, 39, 45, 56, 72, 91.
59 Submission 22.
60 Consultations 1, 2, 4, 5, 6; Submissions 1, 2, 3, 11, 12, 13, 19, 29, 30, 35, 39, 49, 56, 59, 68, 72, 74, 83, 85, 95, 97.
61 Consultation 4; Submissions 1, 7, 12, 24, 32, 38, 45, 57, 60, 70, 91; advisory committee (Meeting 1).
62 Submissions 1, 10, 13, 30, 35, 45, 91, 95, 97.
63 Submissions 11, 22, 35, 56, 60, 91, 95.
64 Consultations 1, 6, 7, 8, 9, 12, 13, 16; Submissions 1, 2, 3, 6, 11, 12, 24, 29, 30, 33, 35, 50, 51, 56, 60, 66, 67, 70, 71, 72, 74, 78, 81, 82, 90, 91, 95.
65 Consultation 6, 7; Submissions 1, 13, 35, 45, 95.
66 Submissions 1, 45, 95.
67 Consultation 6; Submissions 1, 11, 13, 95.
68 Consultations 1, 12, 18; Submissions 1, 13, 19, 24, 32, 35, 39, 45, 52, 56, 59, 72, 91, 95, 96; advisory committee (Meeting 1).
69 Consultations 1, 4, 5, 6, 7, 8; Submissions 1, 2, 5, 7, 10, 12, 13, 18, 19, 29, 37, 39, 45, 55, 59, 60, 61, 70, 71, 74, 80, 91, 93, 95.
70 Consultations 1, 5, 6; Submissions 12, 56, 59, 65, 80, 86, 88, 91, 95, 97.
71 Consultations 5, 8; Submissions 1, 10, 11, 28, 35, 45, 49, 53, 70, 74, 89, 95, 97.
72 Submissions 35, 45, 53, 55, 59, 95, 97.
73 Submissions 19, 95.
74 Submission 95.
75 Consultation 4; Submissions 10, 13, 28, 35, 70, 80, 95.
76 Submissions 19, 60, 95.
77 Submissions 3, 11, 19.
78 Consultations 4, 9; Submissions 5, 11, 13, 19, 35, 60, 80, 87, 93, 95.
79 Submissions 3, 11, 19, 32, 95.
80 Consultation 9, Submissions 3, 18, 74, 95, 97.
81 Consultation 6, Submissions 1, 45, 60, 95, 97.
82 Submission 19.
83 Consultations 6, 12; Submissions 3, 10, 12, 13, 30, 35, 45, 80, 89, 93, 95, 97.
84 Submissions 1, 35, 49, 60, 91, 95.
85 Consultation 2; Submissions 13, 19, 49, 95.

autism and Asperger’s disorder,⁸⁶ thyroid disorders,⁸⁷ ageing,⁸⁸ back pain, scoliosis, neck pain and spinal cord injury,⁸⁹ cardiovascular health and blood pressure,⁹⁰ eating disorders,⁹¹ haemorrhoids,⁹² heavy metal toxicity,⁹³ phlebitis and venous ulcerations,⁹⁴ skin conditions, dermatitis and psoriasis,⁹⁵ scars, ulcers, warts and moles,⁹⁶ weight management,⁹⁷ wounds, cuts, corns, acne, furuncles and nail fungus.⁹⁸

2.60 The supporting evidence for each of these claims varies in quality and quantity. Certainly the volume of information is vast. Matthew Pallett pointed out in his submission that:

The current literature base available in the recognised medical libraries and medical journals of the world amounts to over 30,000 peer reviewed studies and journal articles on Cannabis.⁹⁹

2.61 In determining what the eligibility criteria should be for a scheme that allows people to be treated with medicinal cannabis in exceptional circumstances, and when making clinical decisions about a patient’s treatment, not all evidence is of equivalent value.

2.62 A threshold consideration when making these types of decisions regarding medicinal cannabis is the clinical evidence for its efficacy in treating particular conditions and symptoms. The associated risks must also be taken into account.

2.63 Partly as a result of the broadly stated, often divergent, claims made regarding medicinal cannabis, it is important that, prior to introducing any kind of medicinal cannabis scheme, the available evidence is evaluated to determine which claims can be substantiated, and to what degree. The conventional means of doing so is by reference to evidence-based medicine.

Evidence-based medicine and the quality of evidence

2.64 Evidence-based medicine is an approach to the practice of medicine that has been described as the ‘conscientious, explicit, and judicious use of current best practice in making decisions about the care of individual patients.’¹⁰⁰ It aims to improve decision making by medical practitioners about the provision of treatment, by emphasising a systematic approach that critically appraises the available clinical evidence.

2.65 A cornerstone of evidence-based medicine is the hierarchical system of classifying evidence, often referred to as ‘levels of evidence’. This approach is used by the National Health and Medical Research Council (NHMRC). Medical practitioners are encouraged to find the highest level of evidence to answer clinical questions, including whether they should prescribe or encourage access to particular forms of medication.¹⁰¹

2.66 As Justice Perry observed in *Australian Competition and Consumer Commission v Consumer Plus! Australia Pty Ltd*:

The standard taxonomy of levels of evidence for intervention studies based on the NHMRC guidelines and starting with the highest quality of evidence, is as follows:

Level I: evidence obtained from a systematic review of Level II studies;

86 Submissions 22, 29, 35, 59, 71, 95, 97.

87 Submission 95.

88 Submission 69.

89 Submissions 18, 28, 30, 72, 80, 92, 93, 95.

90 Submissions 53, 95.

91 Submissions 11, 19, 95.

92 Submission 95.

93 Ibid.

94 Ibid.

95 Consultation 4; Submissions 35, 95.

96 Submission 95.

97 Submissions 45, 56, 95.

98 Submission 95.

99 Submission 59.

100 David L Sackett et al, ‘Evidence-Based Medicine: What It Is and What It Isn’t’ (1996) 312 *British Medical Journal* 71.

101 See Patricia B Burns, Rod J Rohrich and Kevin C Chung, ‘The Levels of Evidence and their Role in Evidence-Based Medicine’ (2011) 128 *Plastic and Reconstructive Surgery* 305.

Level II: evidence obtained from at least one properly designed randomised controlled trial of appropriate size;

Level III-1: evidence obtained from well-designed pseudo-randomised controlled trials;

Level III-2: evidence from comparative studies (including systematic reviews of such studies) with concurrent controls being a non-randomised experimental trial, a cohort study, an interrupted time series or matched case-controlled study;

Level III-3: evidence from a comparative study without concurrent controls, being a historical control study, two or more single arm studies (i.e. case series from two studies), or a well-designed interrupted time series trial without a parallel control group from more than one centre or research group or from case reports; and

Level IV: evidence obtained from a case series, either post-test or pre-test/post-test outcomes.¹⁰²

- 2.67 The evidence-based medicine hierarchy ranks clinical evidence according to the authoritativeness of the results. At the top of the hierarchy (at Level I) are systematic reviews and meta-analyses. These studies draw conclusions in a systematic way, based on high-level published studies in the literature.
- 2.68 Next are randomised, double-blind, placebo-controlled studies (Level II). These studies are particularly valuable because they are designed to be unbiased, and to have the lowest risk of errors.
- 2.69 Further down the hierarchy are 'cohort studies' and then 'case control' studies (Level III), considered to be less valuable because fewer controls are placed on the conduct of the research, making it more difficult for conclusions to be drawn from the findings.¹⁰³
- 2.70 Case series (Level IV) and case examples follow. They are at the lowest level of the hierarchy and do not normally form the basis of decision making about proposed drugs to be administered to patients.
- 2.71 The evidence cited in support of the medicinal properties of cannabis ranges across a number of these categories. In the next section, an overview is given of the status of current knowledge about the efficacy of cannabis for conditions regarding which particular claims have been made to the Commission.¹⁰⁴ The overview emphasises outcomes at the highest level of clinical evidence: systematic reviews and meta-analyses.

The quality of cannabis research

- 2.72 A substantial body of evidence now exists in relation to the efficacy of certain forms of cannabis for particular medical conditions. AMA Victoria, for instance, acknowledges that there is 'some evidence to suggest that cannabinoids are effective for the treatment of neuropathic pain, muscle spasticity for patients with MS, and in controlling nausea for cancer patients.'¹⁰⁵

102 [2014] FCA 1412, [67]. See also House of Commons Science and Technology Committee, United Kingdom Parliament, *Evidence Check 2: Homeopathy* (HC 45) Fourth Report of Session 2009–10 (2010).

103 For example, participants are not randomly selected for exposure and are not blinded to exposure. In addition, these types of trials are ordinarily retrospective, meaning that participants are recruited only after exposure has occurred.

104 In this report the term 'efficacy' is used to denote the actual effect of the administration of medicinal cannabis, by contrast with 'effectiveness' which may also be the product of a 'placebo effect'. See House of Commons Science and Technology Committee, United Kingdom Parliament, *Evidence Check 2: Homeopathy* (HC 45) Fourth Report of Session 2009–10 (2010).

105 Submission 38.

- 2.73 However, while this body of evidence exists—and, indeed, is rapidly expanding—it is of inadequate quality for definitive statements to be made about the therapeutic efficacy of cannabis for many conditions. This causes consternation in many quarters of medicine about claims of the legitimacy or advisability of prescribing medicinal cannabis. The Senate Legal and Constitutional Affairs Legislation Committee observed that: ‘there remain significant gaps in our scientific understanding’ and that ‘it is important that medicinal cannabis is used to treat identified medical conditions where it has been proven to be safe and effective.’¹⁰⁶
- 2.74 In an editorial in the *Journal of the American Medical Association* published in June 2015, for instance, D’Souza and Ranganathan argued that for most conditions that have been regarded as appropriate for medicinal cannabis:
- approval has relied on low-quality scientific evidence, anecdotal reports, individual testimonials, legislative initiatives, and public opinion. ... For most of the conditions that qualify for medical marijuana use, the evidence fails to meet [Food and Drug Administration] standards.¹⁰⁷
- 2.75 In May 2015 the College of Physicians and Surgeons of British Columbia prefaced its position on medicinal cannabis with the observation that: ‘Few reliable published studies are available on the medical benefits of marijuana’. However, it accepted that:
- there are sometimes circumstances in medical practice where exceptions to strong relative contraindications may be appropriate. When physicians utilize a therapeutic agent despite strong relative contraindications, the standard of care mandates detailed documentation of their rationale.¹⁰⁸
- 2.76 The Royal Australasian College of Physicians also expressed concern about the quality of the research base available as of 2015:
- the majority of the trials that have taken place on this issue have been small and weak and have not been tested against standards of care. Randomised controlled trials are required to establish the efficacy and benefits of treating particular conditions with medicinal cannabis and evidence of any harm that may arise as side effects.¹⁰⁹
- 2.77 A refrain of the credible scholarly literature is that further suitably controlled, high quality studies need to be undertaken to evaluate whether the claims, anecdotes and aspirations for the efficacy of medicinal cannabis can be justified. An example in this regard is the extensive review of the literature published in 2015 by Belendiuk, Baldini and Bonn-Miller who lament ‘the dearth of rigorous research on the effects of marijuana for the most common conditions for which it is currently recommended’.¹¹⁰ They observed that:
- It is paramount that well-designed [randomised controlled trials] with larger sample sizes be conducted to determine the actual medical benefits and adverse effects of marijuana for each of the [conditions for which claims of efficacy have been made].¹¹¹
- 2.78 It can be difficult to reconcile belief in medicinal cannabis with the strength of the clinical evidence. Views of the evidence for the efficacy of medicinal cannabis vary, and perceptions based on faith, hope and experience with cannabis, on the one hand, can depart substantially from views based on the assessment of the clinical trials.¹¹² A possible exception is in respect of multiple sclerosis.

106 Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Regulator of Medicinal Cannabis Bill 2014 (2015) [5.2], [5.5].

107 Deepak Cyril D’Souza and Mohini Ranganathan, ‘Medical Marijuana: Is the Cart Before the Horse?’ (2015) 313 *Journal of the American Medical Association* 2431.

108 College of Physicians and Surgeons of British Columbia, ‘Professional Standards and Guidelines: Marijuana for Medical Purposes’ (5 May 2015) 2.

109 Submission 52.

110 Katherine A Belendiuk, Lisa L Baldini and Marcel O Bonn-Miller, ‘Narrative Review of the Safety and Efficacy of Marijuana for the Treatment of Commonly State-Approved Medical and Psychiatric Disorders’ (2015) 10(10) *Addiction Science and Clinical Practice* 6.

111 Ibid 6.

112 See Submission 40.

- 2.79 To this must be added that there are obstacles to the accumulation of high-quality cannabis research which do not exist for other drugs. For example, conducting research with cannabis or cannabinoids tends to attract much more onerous regulatory complexity than for other drugs. To adapt the conclusion of an American writer describing this difficulty, '[t]his creates a vicious circle: marijuana is [a schedule 9 drug] and has no currently accepted medical use in treatment because there is no data on its safety and efficacy there is no data because marijuana is [schedule 9] and clinical testing is restricted.'¹¹³
- 2.80 Further, whole-plant forms of cannabis generally do not have a 'sponsor' with a financial interest in funding clinical trials, possibly resulting in fewer or smaller studies.

Determining efficacy

- 2.81 The Commission's issues paper reviewed the state of the clinical literature as of early 2015 regarding a number of the conditions asserted to be responsive to the administration of medicinal cannabis as a therapeutic agent. The following section isolates particular conditions that were identified in submissions and have also been the subject of recent systematic reviews, meta-analyses and other significant evaluations.

Multiple sclerosis

- 2.82 The results of a meta-analysis by Whiting et al published in the *Journal of the American Medical Association* in June 2015 indicate that there is 'moderate-quality evidence to suggest that cannabinoids may be beneficial for the treatment of spasticity due to [multiple sclerosis]'.¹¹⁴ The authors identified 11 placebo-controlled trials meeting the selection criteria, and concluded that:
- Studies generally suggested that cannabinoids were associated with improvements in spasticity, but this failed to reach statistical significance in most studies.¹¹⁵
- 2.83 Results of trials on the efficacy of cannabis to treat multiple sclerosis are complicated somewhat because there are a number of ways to measure spasticity. Some of these rely on objective measures of spasticity, while others rely on subjective measures,¹¹⁶ with subjective measures sometimes said to be more informative but complicating the interpretation of trial results.¹¹⁷ Often research findings depend upon patient self-reports.
- 2.84 On 26 November 2012 the TGA registered Sativex oromucosal spray¹¹⁸ to treat the symptoms of patients with moderate to severe spasticity due to multiple sclerosis, and included it in Schedule 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons*.¹¹⁹ However, Sativex was denied listing on the Pharmaceutical Benefits Scheme, which would have enabled it to be sold at a subsidised price.
- 2.85 Sativex was not listed on the Pharmaceutical Benefits Scheme because the Pharmaceutical Benefits Advisory Committee considered that there was insufficient evidence of its efficacy and its relative effectiveness compared to standard care. In summary it found:
- There is insufficient evidence to establish comparative effectiveness and safety

113 Joseph Gregorio, 'Physicians, Medical Marijuana and the Law' (2014) 16 *Virtual Mentor* 732.

114 Penny F Whiting et al, 'Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis' (2015) 313 *Journal of the American Medical Association* 2456, 2467.

115 Ibid 2463. The MUSEC (Multiple Sclerosis and Extract of Cannabis) trial, which was a double-blind, placebo-controlled study, found that a 12-week treatment with an oral cannabis extract was associated with a statistically significant improvement in patient-reported muscle stiffness, muscle spasms, body pain and sleep compared to placebo in patients with stable MS: JP Zajicek et al, 'Multiple Sclerosis and Extract of Cannabis: Results of the MUSEC Trial' (2012) 83 *Journal of Neurology, Neurosurgery and Psychiatry* 1125.

116 Advisory committee (Meeting 1).

117 In reconsidering the initial decision to refuse approval of the registration of Sativex, the Minister for Health's delegate noted that the subjective tool used in assessing Sativex 'is a valid and reliable tool for the measurement of spasticity and better corresponds to the patients' daily experience of spasticity than the objective measures currently in use.' However, the delegate accepted that the subjective tool has 'a large subjective element that could be affected by mood, fatigue, pain, strength and the possible unblinding of the subject, raising the possibility of substantial confounding': Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (27 September 2013) 198.

118 A whole-plant botanical extract of cannabis, administered as a mouth spray, containing THC and CBD in approximately equal proportions.

119 Department of Health, Australian Government, *Medicinal Cannabis* (27 May 2015) <<http://www.health.gov.au/internet/main/publishing.nsf/Content/>>.

compared with standard care alone in patients who are intolerant to anti-spasticity medication.

- There is no evidence of efficacy and safety provided in comparison with high dose baclofen alone, or in combination with dantrolene or diazepam as the second-line therapy.
- The nominated comparator was not appropriate (the second-line therapy of oral baclofen dose escalation alone or in combination with dantrolene or diazepam should have been included at least as a secondary comparator).
- Although the results of the key trial showed an improvement in the average rating of spasticity, the design of the trial meant that it was difficult to extrapolate this benefit to patients likely to be treated in the Pharmaceutical Benefits Scheme population.
- The clinical relevance of the benefit was not adequately substantiated; the claim for superior efficacy over standard care was inadequately supported; and nabiximols appeared to be inferior over standard care in terms of comparative safety.¹²⁰

2.86 Although not conclusive, there is a reasonable level of research support for the effectiveness of cannabis in relieving pain and spasticity for those suffering multiple sclerosis.

Epilepsy

2.87 The state of epilepsy research at the time of writing is characterised by uncertainty and change with respect to the efficacy of medicinal cannabis. The research collected to date has delivered results of limited significance. At the same time, considerable research energy is being committed to the further study of cannabinoids as a treatment for refractory epilepsy, particularly in juvenile patients.

2.88 In 2013, Canada Health issued this guidance for medical practitioners: 'Increasing evidence points to a role for the endocannabinoid system in the modulation of neuronal tone and excitability and possibly in epilepsy.'¹²¹ However, this does not mean that the evidence is yet clear. In 2014, the authors of an article in a medical journal on epilepsy argued that: '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.'¹²² Also in 2014, the American Society of Neurology expressed the view that the use of oral cannabinoids is of unknown efficacy in epilepsy and that there was not sufficient evidence to prescribe CBD or to recommend self-treatment with medicinal cannabis.¹²³

2.89 A Cochrane Review¹²⁴ published in 2014 on 'Cannabinoids for Epilepsy'¹²⁵ reviewed research literature to assess the efficacy and safety of cannabinoids when used as a single therapy or add-on treatment for people with epilepsy. It was very reserved in its findings. It found that 'no reliable conclusions' could yet be drawn regarding the efficacy of cannabinoids as a treatment for epilepsy. It identified only four studies from 1978 to 1990 that met the selection criteria of randomised controlled trials. All used CBD as the treatment agent. It observed that patient numbers in the studies were small (48 patients in total) and that there had been varying reports of reduction in seizure frequency and/or seizure freedom. The review's authors also expressed the view that, as the studies ran

120 The Pharmaceutical Benefits Scheme, 'Nabiximols, oral spray, 10 mL (90 actuations of 100 microlitres) Sativex', July 2013.
 121 Hanan Abramovici, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 4.5.
 122 Timothy E Welty, Adrienne Luebke and Barry E Gidal, 'Cannabidiol: Promise and Pitfalls' (2014) 14 *Epilepsy Currents* 250, 252.
 123 See Gary W Mathern, Laurie Beninig and Astrid Nehlig, 'Fewer Specialists Support Using Medical Marijuana and CBS in Treating Epilepsy Patients Compared with Other Medical professionals and Patients: Results of Epilepsia's Survey' (2014) 56 *Epilepsia* 1.
 124 Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care. They investigate the effects of interventions for prevention, treatment and rehabilitation. They also assess the accuracy of a diagnostic test for a given condition in a specific patient group and setting. They are published online in the Cochrane Library, and supported by the National Health and Medical Research Council of Australia.
 125 Gloss, David and Barbara Vickrey, 'Cannabinoids for Epilepsy: Review' (2014) 3 *Cochrane Database of Systematic Reviews* <<http://www.thecochranelibrary.com>>.

- for short periods of time (four weeks to 18 months) the safety of long-term cannabidiol treatment could not be reliably assessed.
- 2.90 In addition, a systematic review of the efficacy and safety of medical marijuana in treating selected neurological disorders, including epilepsy, was published by the American Academy of Neurology in 2014. It concluded that oral cannabinoids are of unknown efficacy in epilepsy, that the risks and benefits of medical marijuana should be weighed carefully, and that the comparative effectiveness of medical marijuana as against other therapies for epilepsy are unknown.¹²⁶
- 2.91 The position of Epilepsy Australia in relation to the efficacy of medicinal cannabis is also reserved:
- There have been several reports in the media of dramatically positive responses to derivatives of cannabis, medical marijuana in children with severe forms of epilepsy that have not responded to available therapies. While these reports give reason for hope, we must be mindful that these are anecdotal reports only. However such reports have brought attention to the potential for cannabis to provide a new anti-epileptic therapy and help us understand how epilepsy occurs.¹²⁷
- 2.92 However, there is optimism that research currently underway will deliver positive results, supportive of the efficacy of cannabis for treating severe forms of epilepsy.¹²⁸ Researchers from the United States presented results at the 2015 Annual Meeting of the American Academy of Neurology from an open-label trial on the treatment of children and young adults suffering from drug-resistant forms of epilepsy¹²⁹ with purified CBD (Epidiolex). The trial recruited 213 participants, of whom 123 were included in efficacy calculations. The data showed a median reduction in seizure frequency of 46 per cent by the twelfth week. Patients with Dravet Syndrome had a reduction in seizure frequency of 51 per cent by week 12, while those with Lennox-Gastaut Syndrome experienced a median reduction of 52 per cent. The researchers concluded that:
- CBD showed reductions in seizure frequency across multiple drug-resistant epilepsy syndromes and seizure types and was generally well tolerated in this open-label cohort. Controlled trials are indicated to characterize efficacy and safety.¹³⁰
- 2.93 Two Phase III trials using Epidiolex to treat Lennox-Gastaut Syndrome have also commenced, with data expected to become available in early 2016.¹³¹ The Commission notes that a particular component of the trials to be conducted in New South Wales, with the participation of Victoria and Queensland, is intended to be in respect of the efficacy of medicinal cannabis for paediatric epilepsy.
- 2.94 Therefore, there is emerging research support for the effectiveness of cannabis in relieving the symptoms of epilepsy, especially for those with juvenile syndromes.

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

127 Epilepsy Australia, *Medical Marijuana in the Treatment of Epilepsy* (30 October 2014) <http://www.epilepsyaustralia.net/Advocacy/Position_Statements/Medical_Marijuana_in_the_treatment_of_epilepsy.aspx>.

128 Anup Patel has commented that: 'Further robust research using strong scientific methodology is desperately needed to formally evaluate the role of medicinal cannabis products in children suffering neurological disorders.' Anup Patel, 'Medical Marijuana in Pediatric Neurological Disorders' (2015) *Journal of Child Neurology* (published online before print) <jcn.sagepub.com>.

129 Including Dravet Syndrome, Lennox-Gastaut Syndrome and ten other conditions.

130 American Academy of Neurology, 'Epidiolex (Cannabidiol) in Treatment Resistant Epilepsy' (Abstract of presentation to the American Academy of Neurology 67th Annual Meeting, Washington DC, 22 April 2015).

131 GW Pharmaceuticals, 'GW Pharmaceuticals Initiates Phase 3 Pivotal Study of Epidiolex (CBD) in Lennox-Gastaut Syndrome' (Press Release, 11 May 2015) <<http://www.gwpharm.com>>; GW Pharmaceuticals, 'GW Pharmaceuticals Initiates Second Phase 3 Pivotal Study of Epidiolex (CBD) in Lennox-Gastaut Syndrome', (Press Release, 11 June 2015) <<http://www.gwpharm.com>>.

Chronic pain

2.95 Assessment of the experience of pain is complex. It incorporates complicated overlaps between the physical and the psychological. The concept of exclusively ‘physical pain’ is no longer accepted in light of our understanding of the neurophysiology and psychology of pain as it has evolved over the past 80 years. The contemporary understanding of pain is now embodied in the definition adopted by the International Association for the Study of Pain:

Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life. Biologists recognize that those stimuli which cause pain are liable to damage tissue. Accordingly, pain is that experience we associate with actual or potential tissue damage. It is unquestionably a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience.¹³²

2.96 Importantly, according to the Association’s definition,

Many people report pain in the absence of tissue damage or any likely pathophysiological cause; usually this happens for psychological reasons. There is usually no way to distinguish their experience from that due to tissue damage if we take the subjective report. If they regard their experience as pain, and if they report it in the same ways as pain caused by tissue damage, it should be accepted as pain.¹³³

2.97 The fact that pain is both physical and psychological results in its intensity being difficult to measure and its impact upon different patients in terms of both subjective suffering and functionality being highly variable. As a result, a significant element of the contemporary therapeutic response to pain is that its management is more than just pharmacological; it incorporates multimodal and multidisciplinary forms of intervention, tailored to the needs of the individual patient and an assessment of what is most efficacious for the individual patient.¹³⁴

2.98 In evaluating the potential contribution of medicinal cannabis to alleviating the experience of patients’ pain, it is fundamental to acknowledge that it should only form part of an overall strategy for pain management—it is not the complete answer. Thus it should be integrated, and regulated as necessary, within a broad-based approach to the suffering caused by the experience of pain.

2.99 It is also important to distinguish between the potential effect of the THC component of cannabis in inducing euphoria and any effect it may have in relieving or alleviating pain.¹³⁵

2.100 A systematic review and meta-analysis of cannabis treatment for chronic pain was published in 2009.¹³⁶ It reviewed 18 trials and concluded that the evidence suggested that cannabis treatment was moderately efficacious for treatment of chronic pain but observed that its beneficial effects may be partially (or completely) offset by potentially serious harms. It concluded that more evidence from larger, well-designed trials was needed to clarify the true balance of benefits to harms.¹³⁷

132 International Association for the Study of Pain, Task Force on Taxonomy, *Classification of Chronic Pain* (2nd ed, 1994), 210 reproduced at <<http://www.iasp-pain.org>>.

133 Ibid.

134 See, eg, Kevin T Galloway et al, ‘War on Pain: Multimodal and Multidisciplinary Therapy for Pain Management’ (2011) 6(9) *American Nurse Today*.

135 Professor David Penington has argued that ‘[i]f a person in the late stages of painful cancer seeks the euphoria of THC, why should they not have it?’. David Penington, ‘Medicinal Cannabis: Time for Clear Thinking’ (2015) 202 *Medical Journal of Australia* 74, 75.

136 Eva Martin-Sanchez et al, ‘Systematic Review and Meta-Analysis of Cannabis Treatment for Chronic Pain’ (2009) 10 *Pain Medicine* 1353.

137 In 2015 Eric Baron noted some research literature supporting the role of medicinal cannabis in alleviating symptoms of headaches but concluded that: ‘Despite the limited evidence and research suggesting a role for cannabis and cannabinoids in some headache disorders randomised clinical trials are lacking and necessary for confirmation and further evaluation’: E P Baron, ‘Comprehensive Review of Medicinal Marijuana, Cannabinoids and Therapeutic Implications in Medicine and Headache: What a Strange Trip It’s Been ...’ (June 2015) 55 *Headache* 885.

- 2.101 A more recent systematic review and meta-analysis, published in June 2015 and including 79 trials with 6,462 participants, concluded that there is evidence of moderate quality to support the use of cannabinoids for the treatment of chronic pain.¹³⁸
- 2.102 In May 2015 Mark Ware, the Executive Director, Canadian Consortium for the Investigation of Cannabinoids and Director of Clinical Research at the Alan Edwards Pain Management Unit, McGill University Health Center, argued to the American Pain Society Annual Scientific Meeting that:
- much of what we know about medical marijuana is anecdotal, so the challenge is to recognize that patients who say they get pain relief by self medicating with marijuana may be right, and move forward in conducting more scientific studies to better understand its analgesic benefits and overall safety.¹³⁹
- 2.103 A 2011 systematic review of randomised controlled trials examining cannabinoids in the treatment of chronic non-cancer pain reported that 15 of the 18 trials that met the inclusion criteria demonstrated a significant analgesic effect of cannabinoids as compared with placebos and several reported significant improvements in sleep. No serious adverse effects were reported. This led the authors to conclude that there was evidence that cannabinoids were safe and modestly effective in neuropathic pain (nerve pain) with preliminary evidence of efficacy in fibromyalgia and rheumatoid arthritis. It called for further large studies of longer duration examining specific cannabinoids in homogeneous populations.¹⁴⁰
- 2.104 As discussed in the issues paper,¹⁴¹ a number of studies have suggested that medicinal cannabis, variably taken by vaporiser,¹⁴² oromucosal spray¹⁴³ or smoking,¹⁴⁴ may be efficacious for neuropathic and non-cancer pain. A Canadian review of the literature in 2014 recommended that smoked cannabis be prescribed by doctors only for severe neuropathic pain syndromes that have not responded to adequate trials for pharmaceutical cannabinoids and other analgesics.¹⁴⁵
- 2.105 The current status of the research indicates moderate, albeit emerging, support for the proposition that chronic non-cancer pain, including neuropathic pain, can be alleviated to some degree by medicinal cannabis. However, the Commission notes that medicinal cannabis generally has the potential only to be part of an overall and preferably multimodal strategy for medical management of a patient's chronic pain.

Palliative control of pain

- 2.106 There are many assertions that cannabis oil and other forms of cannabis are able to assist in reducing the severity of pain experienced by persons dying of terminal illnesses, in particular cancer and HIV/AIDS.¹⁴⁶ There is some research evidence which supports the capacity of medicinal cannabis (specifically cannabis with a significant THC content) to provide relief in these circumstances.

138 Penny F Whiting et al, 'Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis' (2015) 313 *Journal of the American Medical Association* 2456.

139 Mark Ware, 'Strong Evidence Still Lacking on Medical Marijuana for Pain' (15 May 2015) *Science Daily* <<http://www.sciencedaily.com>>.

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

141 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [3.23]–[3.27].

142 See Barth Wilsey et al, 'Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain' (2012) 14 *The Journal of Pain* 136.

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

144 See Mark A Ware et al, 'Smoked Cannabis for Chronic Neuropathic Pain: A Randomized Controlled Trial' (2010) 182 *Canadian Medical Association Journal* E 694.

145 Meldon Kahan et al, 'Prescribing Smoked Cannabis for Chronic Noncancer Pain: Preliminary Recommendations' (December 2014) 60 *Canadian Family Physician* 1083.

146 See, eg, *Dan's Story* <<http://www.dansstory.com.au>>; 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 Cairns Man Charged with Giving Medical-Grade Cannabis Oil to Cancer Patient Daughter', *ABC Online* 16 January 2015 <<http://www.abc.net.au>>.

- 2.107 There is evidence that cannabis (particularly smoked cannabis) is an effective treatment for pain caused by HIV-associated sensory neuropathy. A systematic review of treatments for the condition published in 2010 located two randomised controlled trials showing superior results for pain relief from cannabis as compared to the placebo.¹⁴⁷
- 2.108 In relation to cancer, there is limited high-quality research literature on the subject. The position of the American Cancer Society remains that it supports the need for more scientific research on cannabinoids for cancer patients, and recognises the need for better and more effective therapies that can overcome the often debilitating side effects of cancer and its treatment.¹⁴⁸
- 2.109 In 2013 Health Canada also observed a need for more research:
 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.¹⁴⁹
- 2.110 A 2014 review called for caution:
 the effectiveness of cannabinoids for the treatment of chronic cancer pain remains unclear, although any benefit is likely to be modest. The available evidence indicates a risk of potentially serious adverse effects, including alterations in perception, motor function, and cognitive function.¹⁵⁰
- 2.111 Research is ongoing. Sativex is currently undergoing trials for the treatment of cancer pain in the United States, but results to date have been equivocal.¹⁵¹ In 2015, medicinal cannabis will be administered in Chile to 200 patients with cancer to assess its analgesic effects.¹⁵² For the present, what can be said is that there is some evidence of the capacity of medicinal cannabis to alleviate the symptoms of patients with high levels of pain and discomfort from cancer and HIV/AIDS.

Relief from nausea and vomiting

- 2.112 The evidence indicates that medicinal cannabis in a variety of forms can assist in relieving nausea and vomiting and in enhancing appetite.¹⁵³ This has the potential to be of particular utility for chemotherapy-induced nausea and vomiting (CINV) and for persons with wasting (cachexia) caused by HIV/AIDS. For instance, a 2008 meta-analysis found that a synthetic cannabinoid was superior to a number of other options for reducing nausea. A variety of studies summarised by Kramer in 2015 have identified efficacy in both respects.¹⁵⁴
- 2.113 However, as Cancer Council Victoria pointed out in its submission, the research support is not unequivocal:
 a systematic review that considered cancer patient perceptions of the effectiveness of synthetic cannabinoids and natural cannabinoid extract products in comparison to traditional anti-emetic treatments showed that patients perceive these products as only slightly more effective than traditional anti-emetics; however, they also preferred cannabinoid use to alleviate the side effects of future chemotherapy.¹⁵⁵

147 Tudor J C Phillips et al, 'Pharmacological Treatment of Painful HIV-Associated Sensory Neuropathy: A Systematic Review and Meta-Analysis of Randomised Controlled Trials' (2010) 5(12) *PLOS ONE* e14433.

148 American Cancer Society, 'Marijuana and Cancer': <<http://www.cancer.org/treatment>>.

149 Hanan Abramovici, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (Health Canada, 2013) 34.

150 Michael Farrell, Rachele Buchbinder and Wayne Hall, 'Should Doctors Prescribe Cannabinoids' (2014) 348 *British Medical Journal* g2737.

151 GW Pharmaceuticals, *Cancer Pain* <<http://www.gwpharm.com>>. Recently reported results from Phase III trials found no statistically significant difference in effect between Sativex and placebo: Ben Hirschler, 'GW Pharma's Cannabis Drug Fails in Cancer Pain Study, Shares Fall', *Reuters*, 8 January 2015, <<http://www.reuters.com>>.

152 Jack Simpson, 'Chile Harvests First Marijuana Plants in Project to Help Ease the Pain of Cancer Sufferers', *The Independent* (online), 9 April 2015 <<http://www.independent.co.uk>>.

153 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.

154 Joan Kramer, 'Medical Marijuana for Cancer' (2015) 65 *CA: A Cancer Journal for Clinicians* 109.

155 Submission 57.

- 2.114 Therefore, there is a modest level of research support for the capacity of medicinal cannabis to reduce nausea and vomiting caused by chemotherapy and to reduce the wasting caused by HIV/AIDS.

Spinal cord injury

- 2.115 There is some research evidence to suggest that medicinal cannabis can assist with the symptoms associated with spinal cord injury, particularly pain and spasticity. Double-blind, placebo-controlled trials¹⁵⁶ 'suggested modest improvements in pain, spasticity, muscle spasms and sleep quality in patients with spinal cord injury'.¹⁵⁷
- 2.116 Although there is some evidence to support the contention that medicinal cannabis can alleviate some symptoms associated with spinal cord injury, at this stage the research on the issue is at a comparatively early juncture.

Post-Traumatic Stress Disorder

- 2.117 In a 2015 review of 46 articles in relation to treatment of Post-Traumatic Stress Disorder (PTSD) with medicinal cannabis, Yarnell noted that it has been suggested on a significant number of occasions that those with less perceived ability to withstand emotional distress were more likely to attempt to 'self-soothe' with cannabis in response to distressing emotions related to trauma.¹⁵⁸
- 2.118 Additionally, those with PTSD-related symptoms have been asserted to be more likely to use cannabis with the explicit purpose of coping.¹⁵⁹ It has been suggested too that patients with more severe PTSD symptoms may have an even stronger motivation to use cannabis. The literature establishes that the fact that a person is diagnosed with PTSD significantly increases his or her chance of using cannabis at some point in life.¹⁶⁰
- 2.119 Yarnell's conclusion was not positive:
- To date, there is no large-scale, randomized, controlled study investigating efficacy of marijuana and PTSD symptomatology; however, the literature that exists suggests that it may have an effect on decreasing PTSD symptoms, and the neurobiological and animal studies seem to suggest potential underlying mechanisms consistent with these findings. However, PTSD may also be related to problematic, pathological use of cannabis. Additionally, the overall literature may be limited by publication bias, and the lack of standardized, large-scale controlled trials at this time makes any final conclusions on the efficacy uncertain. As the number of people seeking medical marijuana as well as those self-medicating for PTSD continues to rise, there is a clear need for more research trials and monitoring of the long-term effects of using cannabis for the treatment of PTSD and other medical conditions.¹⁶¹
- 2.120 As yet it is premature to conclude that research has established that medicinal cannabis can alleviate the symptoms of PTSD.

156 See, eg, Derick T Wade, 'A Preliminary Controlled Study to Determine Whether Whole-Plant Cannabis Extracts Can Improve Intractable Neurogenic Symptoms' (2003) 17 *Clinical Rehabilitation* 21.

157 Health Canada, Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids (2013) 43 <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

158 Stephanie Yarnell, 'Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature' (2015) 17(3) *Primary Care Companion for CNS Disorders*. See also C M Potter et al, 'Posttraumatic Stress Disorder and Cannabis Use in a Nationally Representative Sample' (2011) 25 *Journal of Anxiety Disorders* 437.

159 See M O Bonn-Miller et al, 'Posttraumatic Stress Symptom Severity Predicts Marijuana Use Coping Motives Among Traumatic Event-Exposed Marijuana Users' (2007) 20 *Journal of Traumatic Stress* 577.

160 See J R Cougle et al, 'Posttraumatic Stress Disorder and Cannabis Use in a Nationally Representative Sample' (2011) 25 *Psychologically Addictive Behaviors* 554.

161 Stephanie Yarnell, 'Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature' (2015) 17(3) *Primary Care Companion for CNS Disorders*.

Schizophrenia

- 2.121 In 2014 a Cochrane Review reviewed the correlation between cannabis and schizophrenia, including the potential for medicinal cannabis to be used for treatment of psychotic illnesses such as schizophrenia. The study identified eight previously conducted randomised trials, involving 530 participants, which met the rigorous selection criteria of the Cochrane Collaboration. It particularly had regard to the contention that CBD has an antipsychotic effect and compared whether CBD was more effective as a treatment than the antipsychotic, amisulpride. It found the evidence 'insufficient' for such an assertion.¹⁶²
- 2.122 As yet it is premature to conclude on the basis of research that medicinal cannabis can inhibit the experience of the symptoms of schizophrenia. However, as noted below, there is concerning evidence that it can be detrimental for some persons who have a vulnerability to develop psychotic illnesses such as schizophrenia.

Anti-cancer properties

- 2.123 A number of people who made submissions or attended consultations asserted that cannabis has the capacity to reduce tumour size across a number of cancer types.¹⁶³ The 'antitumorigenic' properties of cannabinoids have been known for some time, with animal studies conducted as early as the 1970s.¹⁶⁴
- 2.124 Since that time, a 'vast range of cancer cell and tumour models' have been used to evaluate the anti-tumour properties of cannabinoids, and increased quantities of endocannabinoid receptors have been detected in various cancer cell lines, supporting the empirical findings. While these studies have shown cannabinoids in some cases reduce tumour cell growth, in others they have caused it to increase.¹⁶⁵
- 2.125 The authors of a 2013 review article concluded that:
- It is a distinct possibility that the cannabinoids may have a place in the future treatment of cancer. Several reports have shown that the synthetic cannabinoids in particular have the potential to show sufficient specificity and efficacy to be precursors to clinical treatments. However, at this point in time, the results from studies are lacking sufficient depth of understanding to allow this transition to occur. The contradictory nature of reports around the efficacy of compounds highlights our lack of detailed understanding of mechanisms of action. The resolution of the conflicting evidence around cannabinoid action will continue to be a research priority in the near future, and it is expected that developing a more robust understanding of the mechanisms of action underlying cannabinoid action will facilitate the acceptance of cannabinoid use in a clinical setting.¹⁶⁶
- 2.126 Significant human studies on the cancer-fighting properties of cannabis are yet to occur. However, a number of clinical trials are on the horizon for specific cancer types.¹⁶⁷ Cancer Council Victoria submitted that the available evidence does not support the use of cannabis as a treatment for cancer.¹⁶⁸ The National Cancer Institute in the United States supports this position.¹⁶⁹ The Clinical Oncology Society of Australia and the Cancer Council Australia stated their view clearly in a recent joint submission:

162 B C McLoughlin et al, 'Cannabis and Schizophrenia: Review' (2014) *Cochrane Database of Systematic Reviews* <<http://www.thecochranelibrary.com>>. See also B C McLoughlin et al, 'Cannabis and Schizophrenia' (2015) 41 *Schizophrenia Bulletin* 336.

163 Consultations 1, 2, 4, 5, 6; Submissions 1, 2, 3, 11, 12, 13, 19, 29, 30, 35, 39, 40, 49, 56, 57, 59, 60, 64, 68, 72, 74, 83, 85, 95, 97.

164 A E Munson et al, 'Antineoplastic Activity of Cannabinoids' (1975) 55 *Journal of the National Cancer Institute* 597. The study, which looked at the effect of cannabinoids on a mouse model of lung adenocarcinoma, found that cannabinol (CBN) and 8-THC inhibited tumour growth, while CBD and 9-THC had no effect.

165 Belinda J Cridge and Rhonda J Rosengren, 'Critical Appraisal of the Potential Use of Cannabinoids in Cancer Management' (2013) 5 *Cancer Management and Research* 301, 304.

166 Ibid 301, 310.

167 For example, an international phase I trial looking at the treatment of glioblastoma multiforme brain tumour using Sativex and temozolomide (an oral chemotherapy drug) is shortly to commence: Cancer Research UK, *A Trial Looking at Sativex with Temozolomide for Glioblastoma Multiforme Brain Tumour (GWCA1208)* (29 May 2015) <<http://www.cancerresearchuk.org>>. Researchers in Israel propose to undertake a trial looking at the use of pure CBD as a treatment, but the trial is yet to start recruiting participants: ClinicalTrials.Gov, *A Study: Pure CBD as a Single-Agent for Solid Tumor (NCT02255292)* (1 October 2014) <<http://www.clinicaltrials.gov>>.

168 Submission 57.

169 National Cancer Institute, *Cannabis and Cannabinoids* (6 November 2014) <<http://www.cancer.gov>>.

There is no current evidence that cannabinoids are effective at inhibiting tumour growth or treat or cure cancer in humans. In addition, there is no current evidence that cannabis or cannabinoids reduce risk or prevent cancer occurrence or promote good health.¹⁷⁰

- 2.127 On this evidence it is premature at yet to conclude that research has established that medicinal cannabis is able to reduce or curtail the progression of cancer.

Other conditions

- 2.128 The Commission received evidence that a number of other conditions can be assisted by the use of medicinal cannabis. For reasons of space it is not possible to set out in detail the most recent clinical research findings regarding each of these conditions. However, a few important conditions merit specific note and these are discussed briefly below.

Tourette syndrome

- 2.129 The 2015 meta-analysis by Whiting et al concluded that there was 'low-quality evidence' (two small, placebo-controlled studies) demonstrating the efficacy of cannabinoids for Tourette syndrome.¹⁷¹ An earlier Cochrane Review considering these same studies concluded that there was currently insufficient evidence to support the use of cannabinoids in treating Tourette syndrome.¹⁷²

Arthritis

- 2.130 There is a large incidence of patients using cannabis to treat the symptoms of arthritis. As at June 2013, 65 per cent of Canadian patients authorised to receive cannabis reported 'severe arthritis' as their diagnosis.¹⁷³ Many forms of arthritis are due to inflammation, and cannabinoids have potential anti-inflammatory properties, particularly those which act on the CB2 receptor.¹⁷⁴ However, there is scant research support for the efficacy of cannabinoids for pain caused by rheumatoid arthritis, with a 2014 review concluding that: 'In light of other available treatment options for the management of arthritis pain, lack of sound evidence for effect, and potential for harm, herbal cannabis cannot be recommended for arthritis pain management at this time.'¹⁷⁵ Preliminary studies using Sativex found a small but significant analgesic effect in patients with rheumatoid arthritis,¹⁷⁶ but it does not appear that follow-up studies were conducted. A clinical trial that reviewed the efficacy of vaporised herbal cannabis for painful osteoarthritis of the knee (a non-rheumatoid form) has been approved to take place in Canada and is currently recruiting patients.¹⁷⁷

170 Cancer Council Australia and Clinical Oncology Society of Australia, Submission 37 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 2015.

171 The studies, which included a total of 36 participants, suggested that THC capsules may be associated with a significant improvement in tic severity associated with Tourette syndrome: Penny F Whiting et al, 'Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis' (2015) 313 *Journal of the American Medical Association* 2456.

172 Adrienne Curtis, Carl E Clarke and Hugh E Rickards, 'Cannabinoids for Tourette's Syndrome' (2009) 4 *Cochrane Database of Systematic Reviews*.

173 Mary-Ann Fitzcharles et al, 'The Dilemma of Medical Marijuana Use by Rheumatology Patients' (2014) 66 *Arthritis Care and Research* 797, 797.

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

175 Mary-Ann Fitzcharles et al, 'The Dilemma of Medical Marijuana Use by Rheumatology Patients' (2014) 66 *Arthritis Care and Research* 797, 800.

176 D R Blake, 'Preliminary Assessment of the Efficacy, Tolerability and Safety of a Cannabis-based Medicine (Sativex) in the Treatment of Pain Caused by Rheumatoid Arthritis' (2006) 45 *Rheumatology* 50.

177 The trial is titled 'Cannabinoid Profile Investigation of Vaporized Cannabis in Patients with Osteoarthritis of the Knee' and is sponsored by Prairie Plant Systems Inc, a Canadian licensed producer of cannabis (trial identifier NCT0232477). See <<http://clinicaltrials.gov/ct2/show/NCT02324777>>.

Motor-neurone disease (also known as amyotrophic lateral sclerosis)

- 2.131 Cannabis has been suggested as a potentially useful treatment for motor-neurone disease because it possesses many properties with potential relevance to the disease (such as analgesia, muscle relaxation, saliva reduction and sleep induction).¹⁷⁸ Animal studies have shown that cannabinoids could delay progression of the disease.¹⁷⁹ A recent review concluded that 'Based on the currently available scientific data, it is reasonable to think that cannabis might significantly slow the progression of amyotrophic lateral sclerosis (ALS), potentially extending life expectancy and substantially reducing the overall burden of the disease. ... clinical trials with cannabis are the next logical step.'¹⁸⁰

Glaucoma

- 2.132 The progression of glaucoma has been shown to be slowed by the lowering of intraocular pressure. Many glaucoma drugs cause side effects which patients find unacceptable. THC is believed to reduce intraocular pressure, and a possible mechanism has been identified.¹⁸¹ Other studies have shown promising results using cannabinoids.¹⁸² However, it appears that the effects of cannabis on intraocular pressure are of short duration,¹⁸³ by contrast with other therapeutic options, and not sustained over time.¹⁸⁴ There are also other medications that address intraocular pressure. Use of cannabis for glaucoma has been dismissed due to the adverse effects associated with smoking cannabis,¹⁸⁵ the high quantities required to be consumed and because other available therapies provide 'round-the-clock' reductions in intraocular pressure without the psychoactive effects.¹⁸⁶ However, researchers have shown some interest in topical and oral cannabinoid preparations, composed of isolated cannabinoids or synthetic agonists.¹⁸⁷ According to a 2004 review article, cannabinoids have the 'potential of becoming a useful treatment for glaucoma', as they seem to have neuroprotective properties and effectively reduce intraocular pressure, but noted that difficulties associated with side effects and administration methods needed to be overcome.¹⁸⁸ It therefore appears that the most promising avenue of inquiry for glaucoma treatment is pharmaceutical preparations. The position of the American Glaucoma Society is that while medicinal cannabis can lower intraocular pressure, its short duration of action (3–4 hours), its side effects and the lack of evidence that its use alters the course of glaucoma preclude its being recommended.¹⁸⁹

-
- 178 Gregory T Carter and Bill S Rosen, 'Marijuana in the Management of Amyotrophic Lateral Sclerosis' (2001) 18 *American Journal of Hospice and Palliative Care* 264.
- 179 C Raman et al, 'Amyotrophic Lateral Sclerosis: Delayed Disease Progression in Mice by Treatment with a Cannabinoid' (2004) 5 *ALS and Other Motor Neuron Disorders* 33.
- 180 G T Carter et al, 'Cannabis and Amyotrophic Lateral Sclerosis: Hypothetical and Practical Applications, and a Call for Clinical Trials' (2010) 27 *American Journal of Hospice and Palliative Care* 347.
- 181 Anna Porcella et al, 'The Human Eye Expresses High Levels of CB1 Cannabinoid Receptor mRNA and Protein' (2001) 12 *European Journal of Neuroscience* 1123.
- 182 A randomised, double-blind, placebo-controlled, four-way crossover study conducted in 2006 with six participants found that a low dose of 9-THC administered sublingually was associated with significantly lower intraocular pressure than placebo, with mild side effects. CBD was not found to have beneficial effects: I Tomida et al, 'Effect of Sublingual Application of Cannabinoids on Intraocular Pressure: A Pilot Study' (2006) 15 *Journal of Glaucoma* 349.
- 183 Keith Green, 'Marijuana Smoking vs Cannabinoids for Glaucoma Therapy' (1998) 116 *Archives of Ophthalmology* 1433.
- 184 A J Flach, 'Delta-9-tetrahydrocannabinol (THC) in the Treatment of End-stage Open-angle Glaucoma' (2002) 100 *Transactions of the American Ophthalmological Society* 215.
- 185 See, eg, Keith Green, 'Marijuana Smoking vs Cannabinoids for Glaucoma Therapy' (1998) 116 *Archives of Ophthalmology* 1433.
- 186 Keith Green, 'Marijuana Smoking vs Cannabinoids for Glaucoma Therapy' (1998) 116 *Archives of Ophthalmology* 1433. The author refers to treatments such as once- or twice-a-day eye drops (blockers such as timolol maleate, or the prostaglandin agonist latanoprost).
- 187 Ibid.
- 188 I Tomida, R G Pertwee and A Azuara-Blanco, 'Cannabinoids and Glaucoma' (2004) 88 *British Journal of Ophthalmology* 708, 711.
- 189 American Glaucoma Society, *Position Statement on Marijuana and the Treatment of Glaucoma* (10 August 2009) <<http://www.americanglaucomasociety.net>>.

Parkinson's disease

- 2.133 The issues paper noted Parkinson's disease as a condition for which cannabis may provide relief, by reference to a number of clinical trials.¹⁹⁰ However, a systematic review published in 2014 concluded that oral cannabis extract is 'probably ineffective for treating levodopa-induced dyskinesias in patients with Parkinson disease'.¹⁹¹

Inflammatory bowel disease

- 2.134 Some studies¹⁹² have been conducted on the use of cannabis for inflammatory bowel disease. One placebo-controlled trial, conducted on sufferers of Crohn's disease in 2013, found that a short course of smoked THC-rich dried cannabis produced 'significant clinical, steroid-free benefits to 10 out of 11 patients in the treatment group, with some able to be weaned from steroid dependency. There were no significant side effects'.¹⁹³ The author of a recent review concluded that: 'During the forthcoming years, the plant might be widely used in the treatment of [inflammatory bowel disease] patients. ... It is, however, necessary to accurately confirm the safety and effectiveness of the plant by performing large clinical studies'.¹⁹⁴

Sleep disorders

- 2.135 Whiting et al concluded that there was 'low-quality evidence' to support the use of cannabinoids in the treatment of sleep disorders. The authors located two studies, one considering sleep apnoea and the other insomnia. The first trial, which was identified as having a high risk of bias, found that nabilone had a greater effect than a placebo. The second trial suggested that nabilone had a greater effect than placebo, but that it was less effective than amitriptyline in terms of sleep restfulness.¹⁹⁵

Anxiety and depression

- 2.136 Whiting et al found no research support for the use of cannabis as a treatment for depression. It did consider studies targeted at other conditions but where effects on depression were measured found that cannabinoids were no better than placebo.¹⁹⁶ In relation to anxiety, the authors located one 'small parallel-group' trial that found CBD to have a greater effect than placebo on generalised social anxiety disorder, but considered that this trial was 'at high risk of bias'. This trial was described by the authors as 'very low quality' evidence.¹⁹⁷

Issues for policy-makers

- 2.137 As summarised above, the evidence base for the clinical efficacy of medicinal cannabis remains of at best moderate quality for most conditions in respect of which claims of efficacy are made. There are several reasons for this. Many of the studies which are commonly cited in support of its efficacy are low in the evidentiary 'hierarchy' because they:
- rely on case reports
 - make claims arising from small patient cohorts
 - lack controls and methodological rigour.

190 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [3.55]–[3.59].

191 Barbara Koppel et al, 'Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders' (2014) 82 *Neurology* 1556.

192 See T Naftali et al 'Treatment of Crohn's Disease with Cannabis: an Observational Study' (2011) 13 *Israel Medical Association Journal* 455; S Lal et al, 'Cannabis Use Among Patients with Inflammatory Bowel Disease' (2011) 23 *European Journal of Gastroenterology and Hepatology* 891.

193 T Naftali et al, 'Cannabis Induces a Clinical Response in Patients with Crohn's Disease: A Prospective Placebo-Controlled Study' (2013) 11 *Clinical Gastroenterology and Hepatology* 1276. The primary end point (induction of remission) was, however, statistically not achieved.

194 Aikaterini Triantafyllidi et al, 'Herbal and Plant Therapy in Patients with Inflammatory Bowel Disease' (2015) 28 *Annals of Gastroenterology* 210, 216.

195 Penny F Whiting et al, 'Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis' (2015) 313 *Journal of the American Medical Association* 2456, 2464.

196 Ibid 2463. These studies used dronabinol and nabiximols.

197 Ibid 2463–4.

- 2.138 As of 2015 few systematic reviews or meta-analyses strongly support the efficacy of medicinal cannabis.
- 2.139 Some studies which might otherwise be regarded as promising are of limited utility because they were conducted on animals or cell lines, not humans. For the most part, systematic reviews and meta-analyses have been discouraging or have identified potential rather than actual efficacy in medicinal cannabis.
- 2.140 There is also a great level of variability in the type of medicinal cannabis used in the reported studies. Many studies are based on smoked cannabis leaf rather than medicinal cannabis products of known constituency—in terms of THC and CBD content—and known amounts of consumption. THC, CBD, THCA, and the entourage effect are claimed to be explanations for reported efficacy. However, there has been little correlation of successful outcomes with particular aspects, strains or constituents of the cannabis plant. This presents a difficulty when assessing the available evidence in relation to its prospective utility for Victorians in exceptional circumstances. Most of the anecdotal information communicated to the Commission arises from use of cannabis grown in a variety of unregulated circumstances and containing unknown and/or variable constituents.
- 2.141 Comparatively few research trials have been undertaken under close medical supervision, using medicinal cannabis of known constituency, for instance using cannabis oil of identified strength, with double-blind techniques or with effective placebo-controls. Some trials using pharmaceutical medicinal cannabis products (such as Sativex and Epidiolex¹⁹⁸) have been undertaken. However, for many conditions, the results of these trials have been equivocal at best.
- 2.142 The submission by the Drug Policy Modelling Program observed that most clinical trials have been conducted with one or another of the pharmaceutical-grade cannabis products, rather than with herbal cannabis:
- To date, cannabinoids other than CBD and THC have not been isolated into pharmaceutical preparations, and thus the synergistic effect has only been observed when herbal cannabis or its compounded extracts are used medically.¹⁹⁹
- 2.143 Put another way, little research has been done as yet in respect of the use of products such as cannabis oil or tinctures. AMA Victoria has also observed that most research conducted on cannabis has used pharmaceutical preparations, rather than ‘crude cannabis’.²⁰⁰
- 2.144 In principle, on the basis of anecdote and some trials, there is reason for optimism in relation to the efficacy of medicinal cannabis. The orthodox research-derived position is that medicinal cannabis shows promise²⁰¹ but it is too soon to state definitively that it is therapeutically efficacious for any medical condition. It seems likely that these deficits will be addressed in current or future research. When these results become available, scientific discussion about the efficacy of medicinal cannabis will be significantly more informed than it is now.

198 Reference to synthetic cannabinoids such as Marinol is not made in this context because of the view that they are significantly different from cannabis medications manufactured from plant extracts.

199 Submission 21.

200 Submission 38.

201 Notably Harold Kalant and Amy Porath-Waller have observed that: ‘It appears unlikely that cannabis will realize the full therapeutic potential implied by the endocannabinoid systems. ... Research is currently underway to develop a new generation of safe and effective cannabinoid medications that avoid the adverse effects associated with smoked cannabis. ...In summary, research supports the medical use of cannabis to relieve nausea, vomiting and chronic pain, but the research is still emerging in its application to disease conditions’: Harold Kalant and Amy J Porath-Waller, ‘Medical Use of Cannabis and Cannabinoids’ (2014) *Canadian Centre on Substance Abuse Clearing the Smoke on Cannabis Report Series* (No 5, 2014) <<http://www.ccsa.ca>>.

Evidence of side effects

- 2.145 A major reason for concern about the creation of a medicinal cannabis scheme is the identification of the risk of adverse health effects.
- 2.146 All medicines come with some risk of adverse side effects or toxicity. What is of interest is whether the medicine's benefits outweigh its risks. A medicine can be very risky—for example, because it is very toxic—and still be justified because it is necessary to treat a serious condition. What is of concern, particularly to medical practitioners, is that the risks of cannabis are inadequately known and so no assessment can be made of its benefit to a patient on balance. In particular, while there is reasonable knowledge of the risks posed by recreational use of cannabis, there are very few studies as yet on the side effects of medicinal cannabis, including non-smokable forms. This is especially so in respect of medium-term and long-term risks for different categories of patients with different vulnerabilities.
- 2.147 For instance, AMA Victoria has contended that 'the potency and safety of crude cannabis is unknown, variable and unregulated'. In addition, it has argued that the negative side effects produced by cannabis should not be disregarded 'merely because of a patient's age or health status, such as approaching the end of life.' It has also raised the issue of 'psychological side effects including psychosis-like symptoms in some patients'.²⁰²
- 2.148 Another expression of concern was from the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists, which said it was 'very concerned about the adverse event profile in cannabis users, especially in young people, including impaired respiratory function, psychotic symptoms and disorders, and cognitive impairment'.²⁰³
- 2.149 However, the point made by many submissions to the Commission is that the proven level of adverse effects, even from unmonitored recreational abuse of herbal cannabis, is of relatively well known and modest dimensions.²⁰⁴ Unlike in respect of opiate drugs, no deaths have been attributed to cannabis overdose or abuse.²⁰⁵
- 2.150 Most studies on the adverse effects of cannabis have focussed on unregulated, illegal cannabis used recreationally, rather than a quality-controlled supply intended for medical use, and may be of limited application to identifying the risks of the latter.²⁰⁶ There are important limitations on the extent to which it is legitimate to extrapolate from risks relating to recreational use of cannabis to risks arising from medicinal cannabis, in particular when use of medicinal cannabis is suitably supervised by a medical practitioner.
- 2.151 A systematic review conducted in 2008 looking at the medical use of cannabinoids, as distinct from the recreational use of cannabis, concluded that short-term use of cannabinoids increased the risk of non-serious adverse events compared to a control group, but not the risk of serious adverse events. However, the authors concluded that further research was needed before long-term risks could be accurately characterised.²⁰⁷

202 Submission 38.

203 Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists, 'Statement on "Medicinal Cannabis" with Particular Reference to its Use in the Management of Patients with Chronic Non-Cancer Pain' (2015).

204 Submissions 16, 19, 22, 29, 30, 59, 95.

205 Submission 95; see also Mark A Ware and Vivianne L Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research & Management* 31A, 33A.

206 Laurence Mather et al, '(Re)introducing Medicinal Cannabis' (2013) 199 *Medical Journal of Australia* 759. See also Laurence Mather, Alex Wodak and William Notcutt, 'Re: Should Doctors Prescribe Cannabinoids', response to article in the *British Medical Journal*, <<http://www.bmj.com/content/348/bmj.g2737/rtr/701867>>.

207 Tongtong Wang et al, 'Adverse Effects of Medical Cannabinoids: A Systematic Review' (2008) 178 *Canadian Medical Association Journal* 1669. See also Louisa Degenhardt and Wayne D Hall, 'The Adverse Effects of Cannabinoids: Implications for Use of Medical Marijuana' (2008) 178 *Canadian Medical Association Journal* 1685.

Types of side effects

- 2.152 As the submission made on behalf of the cannabis community of Victoria acknowledged: 'Cannabis ... is not "harmless"'.²⁰⁸ Cannabis use carries a range of known side effects which, while well described, are of disputed magnitude. The most important of these are summarised below.

Respiratory effects

- 2.153 If cannabis is smoked, particularly in combination with tobacco, a range of potentially carcinogenic effects may arise, as well as ones which are adverse for respiratory function.²⁰⁹

Psychotic effects

- 2.154 There is a small and relatively unresearched incidence of recreational users who have experienced psychoses in the context of cannabis use. This has been manifested in the commission of some violent crimes.²¹⁰ Cannabis use is a risk factor for developing schizophrenia²¹¹ and for the development of psychotic symptoms in young people.
- 2.155 While cannabis use is associated with precipitating and exacerbating schizophrenia, it is not clear whether the correlation is causative or due to a tendency for the affected group to use cannabis.²¹² Some submissions have argued that the presence of CBD in cannabis may counteract the psychotogenic properties of THC. As a result, a percentage of the cannabis psychoses which have been identified may well be attributable to very high THC-content cannabis, known as 'skunk', and used by some recreational users.²¹³
- 2.156 The relevance of this phenomenon to a scheme which is properly clinically monitored by medical practitioners, where the amount of THC ingested by the patient is known, is very limited. In addition, it is likely that some categories of patients, such as those with epilepsy, will receive medicinal cannabis with very low or no THC content. This removes the risk of THC-induced psychosis for these patients.

Mood effects

- 2.157 A further concern identified has been the potential for cannabis to impact adversely upon users' moods, including by making them anxious, depressed or paranoid. However, while often seen among new users, these effects are uncommon in regular users and tend to disappear after a few months of abstinence.²¹⁴ Again, this is a phenomenon that has been identified for a small percentage of recreational users but there is little information on the issue in respect of individuals who receive cannabis for medicinal purposes.

Impairment of learning ability, memory and motivation

- 2.158 Adults who use marijuana chronically have demonstrated poorer performance on tests of learning and memory, attention, visuospatial skills, processing speed, and executive functions. However, some studies have found no performance deterioration among heavy cannabis users. A meta-analysis examined 11 studies that met strict inclusion criteria, and ascribed impaired learning and memory to chronic recreational cannabis consumption,

208 Submission 95.

209 Mark A Ware and Vivianne L Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research and Management* 31A, 32A.

210 See, eg, *R v Giles* [1999] VSCA 208 [24] (Phillips CJ).

211 Stanley Zammit et al observed in 2012 that: 'Despite the inevitable uncertainty inherent when relying upon observational studies rather than [randomised controlled trials], we believe there is a strong body of evidence from epidemiological studies that use of cannabis increases the risk of developing psychotic disorders, supported by findings in other research fields': Stanley Zammit et al, 'Does Cannabis Use Cause Schizophrenia? The Epidemiological Evidence' in David Castle, Robin M Murray and Deepak Cyril D'Souza (eds), *Marijuana and Madness*, (Cambridge University Press, 2nd ed, 2012), 181.

212 Mark A Ware and Vivianne L Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research & Management* 34A.

213 Submission 24; Consultation 1.

214 Mark A Ware and Vivianne L Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research and Management* 31A, 32A–33A.

but determined that other cognitive domains remained unaffected.²¹⁵ Particular issues arise in this context in respect of children, whose brains are developing. Care would need to attend the monitoring of children by medical practitioners in this regard.

Dependency

- 2.159 An issue that has arisen in respect of recreational users of cannabis and that may be relevant in relation to long-term users of medicinal cannabis is the potential for them to become physically or psychologically dependent on it. In general, cannabis is not a highly addictive or habit-forming drug²¹⁶ but the potential does exist for a small percentage of users, at least in the recreational context, to become dependent on it to a point where they experience withdrawal symptoms for a time when they stop using. Symptoms may include craving for cannabis, decreased appetite, sleep difficulty and weight loss, as well as aggression, irritability, restlessness and strange dreams.²¹⁷ The American Psychiatric Association identified the diagnosis of ‘cannabis withdrawal’ in its 2013 edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*.²¹⁸ However, it has been suggested that its severity is similar to withdrawing from smoking tobacco.²¹⁹

Cardiac effects

- 2.160 Cannabis consumption is known to induce tachycardia, and can increase the risk of myocardial infarction (heart attack). However, these effects tend to be problematic only in conjunction with other cardiac risk factors, such as existing heart disease or arrhythmias.²²⁰

Pregnancy complications

- 2.161 Cannabis use during pregnancy has been found to be associated with a number of undesirable effects, but these findings are disputed.²²¹

Impairment of concentration and psychomotor response:

- 2.162 The evidence is compelling that using cannabis retards concentration and response to stimuli.²²² Critical tracking tests, reaction times, divided attention tasks, lane position variability and speeding have all shown cannabis-induced impairment in the driving context.²²³ Psychomotor performance generally is impaired by cannabis.²²⁴ It is also common for subjects not to appreciate their level of impairment.²²⁵ Impairment is exacerbated when combined with the consumption of alcohol.²²⁶ This has important ramifications for safety for those driving under the influence of medicinal cannabis and for safety in the workplace.²²⁷

-
- 215 I Grant et al, ‘Non-acute (Residual) Neurocognitive Effects of Cannabis Use: A Meta-Analytic Study’ (2003) 9 *Journal of the International Neuropsychological Society* 679.
- 216 See Wayne Hall, ‘What Has Research Over the Past Two Decades Revealed About the Adverse Health Effects of Recreational Cannabis Use?’ (2014) 110 *Addiction* 19, 22–7.
- 217 See David Castle, Robin M Murray and Deepak Cyril D’Souza, *Marijuana and Madness*, (Cambridge University Press, 2nd ed, 2012) 10.
- 218 American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2013) 514–515.
- 219 National Cannabis Prevention and Information Centre, *Cannabis Withdrawal* (1 November 2011) <<https://ncpic.org.au>>.
- 220 Mark A Ware and Vivianne L Tawfik, ‘Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids’ (2005) 10 *Pain Research & Management* 33A.
- 221 Ibid 34A.
- 222 See, eg, R Andrew Sewell, James Poling and Mehmet Soluoglu, ‘The Effect of Cannabis Compared with Alcohol on Driving’ (2009) 18(3) *American Journal of Addiction* 185.
- 223 R L Hartman and M A Huestis, ‘Cannabis Effects on Driving Skills’ (2013) 59 *Clinical Chemistry* 478; M G Lenne et al, ‘The Effects of Cannabis and Alcohol on Simulated Arterial Driving: Influences of Driving Experience and Task Demand’ (2010) 42 *Accident Analysis and Prevention* 859.
- 224 See Paul Armentano, ‘Cannabis and Psychomotor Performance: A Rational Review of the Evidence and Implications for Public Policy’ (2012) 5 *Drug Testing and Analysis* 52; Stephen Maisto, Mark Galizio and Gerard Connors, *Drug Use and Abuse* (Cengage Learning, 2014), 280.
- 225 See A Menetrey et al, ‘Assessment of Driving Capability Through the Use of Clinical and Psychomotor Tests in Relation to Blood Cannabinoids Levels Following Oral Administration of 20mg Dronabinol or of a Cannabis Decoction Made with 20 or 60mg Delta9-THC’ (2005) 29 *Journal of Analytical Toxicology* 327.
- 226 See eg LA Downey et al, ‘The Effects of Cannabis and Alcohol in Simulated Driving: Influences of Dose and Experience’ (2013) 50 *Accident Analysis and Prevention* 879; R Andrew Sewell, James Poling and Mehmet Soluoglu, ‘The Effect of Cannabis Compared with Alcohol on Driving’ (2009) 18 *American Journal of Addiction* 185.
- 227 See Jennan A Phillips, Michael G Holland and Debra D Baldwin, ‘Marijuana in the Workplace: Guidance for Occupational Health Professionals and Employers: Joint Guidance Statement of the American Association of Occupational Health Nurses and the American College of Occupational and Environmental Medicine’ (2015) 57 *Journal of Environmental Medicine* 459.

Guidance by College of Physicians and Surgeons of British Columbia

2.163 This combination of factors led the College of Physicians and Surgeons of British Columbia to conclude in May 2015 that dried cannabis is generally not appropriate for patients who:

- are under the age of 25
- have a personal history or strong family history of psychosis
- have a current or past cannabis use disorder
- have an active substance use disorder
- have cardiovascular disease (angina, peripheral vascular disease, cerebrovascular disease, arrhythmia) or respiratory disease
- are pregnant, planning to become pregnant or are breastfeeding.

2.164 In order to address such identified risks and ‘the paucity of evidence to support the use of marijuana for medical purposes’, it also required physicians to adopt the following measures:

Document that conventional therapies for the condition for which the authorization of marijuana for medical purposes was provided have been attempted to assist the patient in the management of his/her medical condition and have not successfully helped the patient.

Assess the patient for addiction and/or risk of addiction. For the latter, use a validated addiction risk tool and retain a copy in the patient record.

Discuss with the patient the risks of using marijuana and record in the patient’s medical record that a discussion occurred.

Review the patient’s PharmaNet information prior to issuing an authorization for marijuana for medical purposes and in any reassessment of patients receiving marijuana for medical purposes.

Retain a copy of the document provided for the authorization of marijuana for medical purposes in the patient’s medical record.

Include processes to identify any misuse/abuse/diversion by the patient in any reassessment of patients receiving marijuana for medical purposes.

Not sell or dispense marijuana for medical purposes to any patient.

Not complete a document for the authorization of marijuana for medical purposes for a patient unless

- the physician has a longitudinal treating relationship with the patient, or
- the physician is in direct communication with another physician or nurse practitioner who has a longitudinal treating relationship with the patient and both are in well-documented agreement with the issuance of a document for the authorization of marijuana for medical purposes.²²⁸

Managing risk

- 2.165 It is important that any medicinal cannabis scheme acknowledges the reality of a diverse range of actual and potential side effects for patients. For the most part, such risks were recognised by submissions made to the Commission.
- 2.166 However, such side effects generally arise from cannabis with a significant THC content and thus do not arise or are significantly less relevant in the context of cannabis that has a high CBD content.
- 2.167 Many potential side effects can be minimised by avoiding uncertain and excessive levels of consumption arising from self-administration and also by establishing a scheme that does not include smoked forms of cannabis.
- 2.168 Most prescribed medications have side effects for which appropriate warnings are given to patients by their medical practitioners (as well as by pharmacists) so that the consent that patients (or those responsible for them) provide is properly informed. In addition, a fundamental responsibility of medical practitioners is to review the condition of patients for whom they prescribe in order to identify not only the correct level of medication to address patients' symptoms but also the onset of any side effects, so that these can be addressed. Medicinal cannabis is no different from other medications in this regard, save that for the most part the side effects arising from the use of medicinal cannabis are unlikely to be life-threatening provided that suitable steps to avoid misuse are taken by medical practitioners.

Access to medicinal cannabis in 'exceptional circumstances'

- 52** Introduction
- 53** Exceptional circumstances
- 55** Eligibility criteria
- 75** Authorisation of treatment

3. Access to medicinal cannabis in ‘exceptional circumstances’

Introduction

- 3.1 Law reform to allow people to be treated with medicinal cannabis in exceptional circumstances needs to establish a way of distinguishing who is eligible and who is not. This chapter explores the concept of exceptional circumstances and how to convey it in legislation in the form of eligibility criteria. The criteria would be applicable to treatment with medicinal cannabis under any of the law reform options discussed in this report.¹
- 3.2 The conclusion reached is that the criteria should be based on two factors:
- evidence of the efficacy of cannabis in treating a medical condition
 - the extent to which it is likely to improve the patient’s quality of life.
- 3.3 Compassion demands that individual suffering be taken into account, but not that clinical efficacy be ignored. With this perspective as a guide, a number of conditions and associated symptoms are identified and a set of criteria proposed.
- 3.4 Because a decision to use medicinal cannabis is a medical one, participation in the scheme should not be determined by statutory provisions alone. For the treatment to be truly ‘medical’ in nature, the supply and administration of medicinal cannabis must take place under medical supervision. The reasons for this are twofold. First, treatment with medicinal cannabis must be rational—that is, it must be made available only where there is a reasonable prospect that it will provide a benefit to the patient. Second, the use of medicinal cannabis must be appropriately supervised so that its use does not harm the patient or interfere with other treatments received. It needs to be integrated into the healthcare holistically provided to the patient.
- 3.5 At the same time, the requirements of medical supervision must not present an insurmountable barrier to patients who could be assisted by the use of medicinal cannabis; nor should it be intolerable to patients wishing a reasonable measure of autonomy in the treatment they receive or unacceptable to the medical practitioners asked to act as ‘gatekeepers’ to the scheme. The regulatory framework should put the eligibility criteria into operation by allowing access by patients who meet the criteria, preventing access by those who do not, and addressing the risks of dishonest and criminal conduct by those who seek to divert medicinal cannabis products to people who are ineligible to participate in the scheme. Similar regulatory challenges are encountered in administering the opioid replacement therapy program. This chapter sets out a system for regulating access to medicinal cannabis that is based on that scheme.

Exceptional circumstances

The idea of ‘exceptionality’

- 3.6 ‘Exceptional circumstances’ conveys the notion of a limited group of individuals whose experience differs substantially from the norm. The term suggests that there must be something identifiably, objectively different and unusual about the circumstances in which medicinal use of cannabis is authorised that make them exceptional.
- 3.7 The task for the Commission is to demarcate these cases from those that are not ‘exceptional’.² They are not more worthy than other cases—rather, they are just far enough outside the usual experience to justify an exception being made.
- 3.8 The term ‘exceptional circumstances’ is found in a number of areas of Victorian law.³ It is frequently intended to convey a situation which is highly unusual, such that departure from the ordinary rules can be justified.⁴ Indeed, it conveys a situation where the exercise of discretion is compelled by considerations that are outside normal experience.⁵ While ‘exceptional circumstances’ is in some cases defined,⁶ courts and legislators have generally been reluctant to confine the application of the term to a rigid set of scenarios, reflecting the need for flexibility in compelling circumstances.⁷
- 3.9 This approach reflects the function of ‘exceptional circumstances’ in the context of the Commission’s review: to distinguish those cases in which a departure from the ordinary rules can be justified.
- 3.10 The ordinary rules are that cannabis is a prohibited substance unless provided in a form that has been approved by the conventional processes for regulating therapeutic goods.⁸ The Attorney-General’s terms of reference imply that an alternative regulatory approach is to be considered where circumstances require that an exception be made. The alternative approach being contemplated for such circumstances is to take certain products outside of the conventional, evidence-driven approval and treatment framework.
- 3.11 The challenge is to identify those matters that justify exceptionality.

2 A number of submissions opposed this exercise altogether. Heather Marie Gladman, Australian HEMP Party summarised the views of a number of people who communicated with the Commission: ‘It should be available to everyone who needs it ... All cannabis use is medical’: Submission 10. Others called for cannabis to be legalised for all purposes. The Australian Lawful Use of Cannabis Alliance asked why, in view of its potential protective and preventative benefits, only the sick should have access to cannabis: Submission 35. The Commission notes these objections but is confined to examine only those matters raised by the terms of reference.

3 As Hedigan J said in *Kent v Wilson* [2000] VSC 98, [20]: ‘The courts have frequently been obliged to consider the meaning of the phrase “exceptional circumstances” in a variety of contexts, perhaps most commonly in connexion with the granting of bail in murder cases and the taking of appeals out of time.’

4 See *Charter of Human Rights and Responsibilities Act 2006* (Vic) s 31 (regarding when a human rights override declaration will be made); *Children, Youth and Families Act 2005* (Vic) s 345 (regarding when a child can be prosecuted otherwise than on summons); *Serious Sex Offenders (Detention and Supervision) Act 2009* (Vic) s 183 (regarding when a court can authorise publication of information regarding an application for a sex offender’s continued detention or supervision); *Sentencing Act 1991* (Vic) ss 480, 69W, 154 (regarding when a community correction order, fines work order or community work permit can be suspended by the Secretary to the Department of Justice); *Road Safety Act 1986* (Vic) ss 51(12) and (12A) (regarding when a judge can cancel an immediate driver’s licence suspension imposed on a person found drink driving).

5 Redlich JA said that for something to amount to ‘exceptional circumstances’, it must be ‘clearly unusual or quite special or distinctly out of the ordinary’. He said it is not enough to find something which ‘falls within the range of normally anticipated consequences, behaviours or exigencies’: *R v Ioannou* (2007) 17 VR 563, 568. But, depending on the context, something does not have to be ‘beyond reasonable expectation or contemplation’ in order to be exceptional. Lord Bingham of Cornhill CJ understood the phrase in a similar way: ‘We must construe “exceptional” as an ordinary, familiar English adjective and not as a term of art. It describes a circumstance which is such as to form an exception, which is out of the ordinary course, or unusual, or special, or uncommon. To be exceptional a circumstance need not be unique, or unprecedented, or very rare; but it cannot be one that is regularly, or routinely, or normally encountered’: *R v Kelly* [2000] 1 QB 198, 208.

6 See, eg, *Road Safety Act 1986* (Vic) s 90L(4).

7 In *Kent v Wilson* [2000] VSC 98, Hedigan J stated at [22]: ‘Courts have been both slow and cautious about essaying definitions of phrases of this kind, leaving the content of the meaning to be filled by the ad hoc examination of the individual cases. Each case must be judged on its own merits, and it would be wrong and undesirable to attempt to define in the abstract what are the relevant factors’.

8 That is, only where a particular form is moved to a different schedule of the SUSMP and approved for inclusion on the Australian Register of Therapeutic Goods: see Chapter 4.

Compassion as a basis for action

- 3.12 In the Commission's view, the common factor that justifies a different approach for a small group of patients is compassion⁹—that is, empathy and an authentic desire to address another person's suffering.¹⁰ This is reflected in the recommended regulatory objective which refers to 'allowing compassionately for exceptional circumstances of medical need'.¹¹
- 3.13 Many submissions received by the Commission urge it to achieve a balance between the stern demands of conventional approval processes and the large number of reports and studies that have identified positive effects or potential from medicinal cannabis for patients with a variety of conditions. Some arguments were mounted from principle—identifying limitations of the research or medical practice—and others were generated by experience of the therapeutic assistance provided by medicinal cannabis. As discussed in Chapter 2, many people with a variety of painful and life-threatening conditions informed the Commission of assistance that they had derived from forms of medicinal cannabis that they had procured illegally.
- 3.14 Indeed, throughout the Commission's consultations it was evident that a tension exists between those who advocate a rigid adherence to provision of medication only on the basis of research of the kind demanded for conventional medicines, with no exception being made for medicinal cannabis, and those whose approach is more liberal— Influenced or even determined by anecdotal and experiential accounts of therapeutic efficacy, as well as by compassion. The Commission has received submissions at either end of this continuum and at many different points along it.
- 3.15 For cannabis to be included among the medicinal options available in Victoria, a compromise needs to be found between the extreme positions in order to cater to the present-day suffering of patients that is not being adequately alleviated by conventional forms of relief. It is evident that a tipping-point has been reached within the community which requires such a compromise to be brokered.
- 3.16 Laurence Mather and his co-authors argued in 2013 that compassion commands us to act, in spite of incomplete research:
- 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.¹²
- 3.17 The exercise of compassion to mitigate the harshness of a wholly evidence-based approach has been urged or drawn upon regularly in respect of medicinal cannabis. For instance, this was the hallmark of the approach of a report in 2013 by a committee of the New South Wales Parliament which emphasised the promise of medicinal cannabis in treating a number of painful conditions that do not respond to existing treatment, and advocated a 'compassionate approach'.¹³ In 2014, the Public Health Association of Australia similarly identified a 'need for a compassionate regime whereby seriously and terminally ill individuals who have been appropriately authorised may possess and use cannabis without penalty'.¹⁴

9 Etymologically, suffering with another. See generally Michelle Brenner, *Conversations on Compassion* (Create Space, 2015).

10 See Emma Seppala, 'The Compassionate Mind' (2013) 26(5) *Association for Psychological Science Observer* <<https://www.psychologicalscience.org>>.

11 See Chapter 1.

12 Laurence Mather et al, '(Re)introducing Medicinal Cannabis' (2013) 199 *Medical Journal of Australia* 759, 761.

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

14 Public Health Association of Australia, *Position Statement: Medicinal Cannabis in Australia* <<http://www.phaa.net.au/documents/item/365>>.

- 3.18 The medicinal cannabis community also draws on the concept of compassion,¹⁵ and clubs that have been established in Australia and internationally to supply medicinal cannabis call themselves ‘compassion clubs’.
- 3.19 In its submission to the Commission, in which it listed arguments for the legalisation of medicinal cannabis, the Macedon Ranges Group of Christian Business Men Australia gave primacy to compassion:
- Compassion for children who suffer from frequent and highly debilitating seizures and also for cancer sufferers who are in constant, severe pain where the only known effective treatment has been presently illegal medicinal cannabis. Compassion is also warranted in regard to the agonising dilemma of parents of affected children as they must currently break the law or watch their children suffer and deteriorate mentally and physically.¹⁶
- 3.20 The Commission endorses this approach. It is not an approach that renders irrelevant the state of research knowledge about the efficacy, safety and risks attaching to medicinal cannabis. However, it does mean that the strong feelings and hopes of patients, the potential of medicinal cannabis, and the proliferation of accounts about the apparent efficacy of medicinal cannabis for certain conditions should be taken into account in construing when it should be made available in ‘exceptional circumstances’.
- 3.21 The Commission’s incorporation of compassion as a relevant consideration for making medicinal cannabis available to some patients should not be mistaken for a suggestion that ‘compassion’ should explicitly be made the basis for eligibility under a Victorian medicinal cannabis scheme; this would fail to take account of other relevant considerations. As observed by AMA Victoria, ‘terminology or concepts such as ‘compassionate’ or ‘exceptional’ circumstances ... are vague, subjective terms and are likely to lead to a lack of clarity in medical practice.’¹⁷ Rather, the exercise of compassion has influenced the Commission’s identification of certain exceptional circumstances for the present in which access to medicinal cannabis should be allowed. It is not a threshold for access, but informs how that threshold should be determined.

Eligibility criteria

Factors informing eligibility criteria

- 3.22 Determining when a patient should be eligible for medicinal cannabis under any Victorian scheme is not a mechanical or purely scientific exercise; it is an approach that should respond humanely and empathically to the experience of pain and suffering which is not being effectively remediated by conventional forms of relief (such as opiates, anti-spasticity, anti-emetic or anti-epileptic drugs). At the same time, it should not disregard the evidence regarding the potential utility of cannabis as a medicinal agent. It follows that the eligibility criteria must take account of the experience of particular conditions, and whether there is a reasonable potential for medicinal cannabis to assist, while also placing particular emphasis on patients’ (subjective) experience of suffering and their desire for another therapeutic option.
- 3.23 Thus, the Commission has had regard to several factors in developing eligibility criteria for access to medicinal cannabis:
- the state of the clinical literature in relation to the efficacy or potential efficacy of medicinal cannabis for particular medical conditions and symptoms, particularly in relation to the likelihood that cannabis will assist

15 The theme of the 2014 conference of the Medical Cannabis Users Association in Tamworth was ‘United in Compassion’ <<http://www.unitedincompassion.com.au>>.

16 Submission 34. Christian Business Men Australia also provided the Commission with a copy of a petition they prepared, for presentation to Parliament, calling for a ‘Compassionate Use of Medical Cannabis Act’. See Appendix B for list of submissions.

17 Submission 38. The Commission’s medical advisory committee concurred with this view.

- the seriousness of the medical conditions, including patients' prognoses and the extent of the disability caused by their conditions
- the extent to which the symptoms of the conditions interfere with patients' ability to derive enjoyment and fulfilment in their lives
- the extent to which cannabis can reasonably be anticipated to improve quality of life
- the availability of standard treatments that may assist, how effective they are, and what side effects they cause or may cause
- the state of the clinical literature in relation to the risks or potential risks posed by medicinal cannabis for patients with particular medical conditions.

3.24 While there must be evidence supporting the likely efficacy of cannabis for a particular medical condition, such evidence should not be the sole criterion applied. Compassion demands that the extent of suffering should be taken into account, and compared with the relief the patient might receive. The level of evidence required (regarding efficacy and side effects) should respond to the severity of the patient's suffering and the availability of alternatives.

Methods of determining eligibility

- 3.25 Although a wide range of eligibility criteria are used for medicinal cannabis schemes in other countries, three main approaches can be identified:
- case-by-case decisions by a medical practitioner, who decides at their discretion whether a patient is eligible to be treated with medicinal cannabis
 - case-by-case decisions by a panel or a government official, which decides whether a patient is eligible by referring to a general statutory test
 - a categorical test.

Decision by medical practitioner

- 3.26 A number of submissions to the Commission put the view that eligibility should be determined by the patient's medical practitioner, exercising unfettered discretion.¹⁸ The practitioner's assessment would focus upon the condition and symptoms of the patient, but the decision about eligibility would be made by the practitioner independently, free of constraints imposed by statutory eligibility criteria.
- 3.27 This is the approach taken in the Netherlands. While the Office of Medicinal Cannabis suggests some conditions where there is strong evidence cannabis can assist, medical practitioners are free to prescribe cannabis for any indication.¹⁹ Toby Stewart called for this approach to be adopted in Victoria:

The law cannot and must not displace the judgement of doctors. If it does, doctors will become clerks who look up laws and dole out drugs for a profit. They will no longer have any ethical duty, no[r] any interest in the complex issues of suffering, dignity and death. It is not for the law to decide who uses what drug. It is for the law to decide which drugs doctors may prescribe to alleviate suffering, and which they may not. This issue for reform here is the treatment of a drug by the law. The issue is not the wholesale revision of medical professional competence, and the replacement of doctors by merry statute. We must let doctors continue to prescribe those drugs which are lawful, as they deem fit in their professional capacity. People will not accept a law that displaces doctors. It will be a farce, and a disgrace, to propose such a law.²⁰

18 Submissions 7, 23, 55, 84. Submission 97 also supported retaining discretion for medical practitioners.
19 Consultation 28.
20 Submission 23.

- 3.28 Notwithstanding such concerns, the Commission does not consider that the task of determining whether a particular patient is eligible should be a task entirely for the medical practitioner. The Commission's medical advisory committee strongly opposed a scheme where the determination was entirely left to medical practitioners. The committee stated that this would give medical practitioners excessive latitude and inadequate guidance to decide who should have access,²¹ with the risk of highly variable decision making. The conventional regulatory structure in Australia, the Therapeutic Goods Administration (TGA), limits the circumstances in which approved medicines can be prescribed, and practitioners' professional obligations allow them to go outside these restrictions only in limited circumstances.
- 3.29 Furthermore, while all decisions about a patient's treatment, including treatment with medicinal cannabis, should be made on a case-by-case basis, this approach does not provide a basis for determining which patient's circumstances are exceptional. It provides no objective standard against which to assess who should have access to medicinal cannabis when it is to be available only in exceptional circumstances.

Decision by a panel or government official

- 3.30 Another means of implementing a case-by-case determination would be for a government official or panel of doctors to determine, on application, whether a patient is eligible to be treated with medicinal cannabis, according to some very general statutory test of eligibility relating to the individual's circumstances. It was suggested at a public consultation that people other than doctors could be involved in the decision.²²
- 3.31 The Commission is unaware of a medicinal cannabis scheme that relies on this approach, but expects that it could work in a similar fashion to the Special Access Scheme, under which the Secretary of the Commonwealth Department of Health has the discretion to allow unapproved medicines to be imported for, or supplied to, a patient on a case-by-case basis.²³ A similar approach is taken in countries like Germany to manage requests to import medicinal cannabis products.²⁴
- 3.32 In the Commission's view, this approach is not desirable as a systematic means of controlling access in Victoria. It would create administrative costs for the Victorian Government and uncertainty within the medical profession about who is eligible. It could also generate administrative appeals and applications for judicial review of decisions not to approve access.²⁵ Importantly, the time taken to process applications for access would delay the treatment of gravely ill (possibly terminally ill) people with products that might assist them.²⁶

Categorical test

- 3.33 An alternative approach is for categories of patients who are eligible to receive medicinal cannabis under the scheme to be set out in legislation. This would give clarity to medical practitioners and the public. It would also reduce the pressure placed on medical practitioners to provide access to medicinal cannabis to treat minor conditions, where patients' symptomatology is not significant, or in other circumstances that clearly are not exceptional.²⁷ For this reason, the Commission's medical advisory committee expressed strong support for eligibility criteria which specifically identify the medical circumstances that qualify a person for access.
- 3.34 There are some drawbacks to adopting a categorical approach. JB, for instance, expressed

21 Advisory committee (Meeting 1).

22 Consultation 3. See Appendix C for list of consultations.

23 See Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (November 2009).

24 Federal Institute for Drugs and Medical Devices (Germany), *Glossary: Cannabis* (2013) <<http://www.bfarm.de>>; Marco Evers and Laura Höflinger, 'Legal Highs: Welcome to the Cannabis Revolution' *Australian Financial Review* (originally *Der Spiegel*) (10 July 2015).

25 Decisions to refuse applications under the Special Access Scheme can be appealed internally or to the Administrative Appeals Tribunal: *Therapeutic Goods Act 1989* (Cth) s 60(1)(ca).

26 A case-by-case assessment by a government official could, however, be a means of dealing with rare and unusual conditions.

27 Concern about the pressure that could be placed on doctors was expressed by the advisory committee (Meeting 1) and at Consultation 26.

concern about not taking account of the patient's individual circumstances:

Deciding who should be allowed access to medicinal cannabis should be on a patient by patient basis. All cases treated on their merits and not an umbrella decision affecting all people with the same condition.²⁸

- 3.35 The Drug Policy Modelling Program cautioned against the possibility of creating a division between those deemed to be 'deserving' as against 'undeserving'.²⁹ Another contributor argued that list-based tests are 'generally exclusionary rather than inclusionary' and 'contrary to the notions of a compassionate scheme. They are limited in their ability to alleviate suffering and exclude many people in need.'³⁰ It was also suggested that a categorical approach would limit the ability of the scheme to keep pace with scientific developments.³¹
- 3.36 Comments made in a confidential submission argued that many patient groups other than those which receive media attention could benefit from access to medicinal cannabis. It was said that using a test based on categories risks making the assessment of 'exceptional circumstances' more one of politics than clinical judgment.³²
- 3.37 Notwithstanding these reasoned objections, the Commission considers that a test which establishes eligibility for categories of patients would be far more workable than one that requires an independent decision to be made for each individual patient by a doctor, panel or government official. A common theme of comments made at advisory committee meetings and during consultations was that medical practitioners need clarity and certainty regarding when medicinal cannabis can be used. A categorical approach is the best way of achieving this.
- 3.38 Employing a categorical test does not mean that the patient's individual circumstances are not taken into account. As discussed later in this chapter, the Commission considers that patients who meet the eligibility criteria would be treated with medicinal cannabis only after assessment by a medical practitioner. It is also acknowledged that patients with rare conditions may be marginalised by tests based on categories and that, as the clinical evidence base for the efficacy of medicinal cannabis changes, so too should the categories. Ways in which residual flexibility for patients with rare conditions could be incorporated into the scheme, and for the scheme to be responsive to developments in clinical knowledge, are also discussed later in this chapter.

Criteria

- 3.39 A categorical test of eligibility could be based on:
- medical conditions
 - symptoms
 - symptoms and conditions.
- 3.40 These are discussed in turn below.

28 Submission 11.
29 Submission 21.
30 Submission 43.
31 Submission 43, 97.
32 Submission 32.

Condition-based test

- 3.41 Some submissions argued that eligibility should be based on whether the patient suffers from a particular medical condition.³³ For instance, Cancer Action Victoria argued that there should be access to medicinal cannabis for patients with a listed medical condition for which there is clinical knowledge about efficacy.³⁴
- 3.42 Some United States jurisdictions rely in whole or in part on lists of conditions to establish a patient's eligibility for medicinal cannabis.³⁵ For example, access to medicinal cannabis is available in Connecticut to patients with a 'debilitating medical condition', which includes 'cancer, glaucoma, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, cachexia, wasting syndrome, Crohn's disease, posttraumatic stress disorder' or other conditions approved by the government.³⁶
- 3.43 There are difficulties with a condition-based test. As cannabis alleviates specific symptoms and does not treat the underlying disease, it could be inappropriate to base eligibility on a person's condition alone. As Scott Hulley pointed out: 'A condition with no symptoms is just a title/name'.³⁷
- 3.44 In particular, a definition that relies on a person's condition alone would suggest a homogeneity of symptoms for each of the specified conditions which does not in fact exist. For example, not all multiple sclerosis patients suffer from intractable spasticity; likewise, not all HIV/AIDS patients experience wasting;³⁸ and a percentage of patients who have chemotherapy do not experience serious nausea and vomiting. Similarly, not all patients with epilepsy have fits which cannot be adequately controlled by means other than medicinal cannabis.
- 3.45 This is important because, for instance, a patient with a recent diagnosis of multiple sclerosis may as yet be asymptomatic, such that it would be inappropriate for them to be prescribed medicinal cannabis to deal with spasticity and pain that they do not yet experience. In this regard, the Royal Australasian College of Physicians observed that:
- Not all epilepsy variants are drug-resistant ... In many cases of apparent drug-resistance, the epilepsy diagnosis is incorrect after further assessment or the medication chosen in the first two instances is inappropriate. ... Furthermore, many patients regarded as drug-resistant may be appropriate candidates for potentially curative epilepsy surgery.³⁹
- 3.46 The Commission agrees with these concerns and considers that an eligibility test that required only that a person have a specified condition would capture individuals for whom medicinal cannabis would provide no medical benefit. It does not sufficiently satisfy the requirement for exceptionality.

Symptom-based test

- 3.47 Alternatively, a test for eligibility could be based on symptoms alone. In order to be eligible, a patient would need to have a designated level of symptoms, with no requirement that they be tied to a particular condition. In Maryland, for example, medicinal cannabis may be made available to patients who have a 'chronic or debilitating disease' that results in admission to palliative or hospice care or that produces 'cachexia, anorexia or wasting syndrome, severe pain, severe nausea, seizures or severe or persistent muscle spasms'.⁴⁰

33 Submissions 24, 37, 72, 74.

34 Submission 54.

35 Illinois relies on a condition-based test: 410 Ill Comp Stat 130/10(h). In addition, the jurisdictions listed at n 44 below have listed conditions as part of their eligibility test.

36 Conn Gen Stat § 21a-408(2).

37 Submission 22.

38 Consultation 1.

39 Submission 52.

40 Md Code Ann § 13-3307(c). The statute also allows for symptoms to be produced by the treatment of a condition, eg chemotherapy.

- 3.48 The Royal Australasian College of Physicians opposed a test based on symptoms alone:
- A symptoms list alone is not appropriate to determine a person’s eligibility because symptoms can be common across multiple conditions. ... For example, not all seizures are epileptic, some seizures are symptomatic of other remediable conditions such as alcohol abuse or electrolyte imbalance, therefore a thorough evaluation of the patient, condition and treatment options are required. ... The situation for multiple sclerosis is similar.⁴¹
- 3.49 In the Commission’s view, a definition which relies on symptoms alone would be undesirable. The mere existence of a symptom or symptoms, even if required to be ‘severe’, does not provide enough detail to determine whether medicinal cannabis would be of assistance. Further, it would not effectively ensure that medicinal cannabis was restricted only to patients in ‘exceptional circumstances’, as the symptoms for which medicinal cannabis has been found to assist include some that are commonly experienced by people without chronic illnesses (such as nausea). A qualification based on symptoms alone would not convey whether a patient’s state was serious and permanent.
- 3.50 For these reasons, a symptom-based test would afford doctors a substantial amount of latitude in authorising access to cannabis such that the scheme could become almost indistinguishable from one where eligibility is determined solely at their discretion. Criteria such as ‘severe pain’ or ‘severe nausea’ (wording used in other jurisdictions, either in isolation or in conjunction with a condition-based test) would require practitioners to engage in a subjective assessment while not conveying much about the therapeutic utility of cannabis in the particular case. UTT BioPharmaceuticals argued that this could lead to ‘exploitation and abuse of the system’.⁴²

Test based on conditions and symptoms

- 3.51 The third option is to adopt a test that makes eligibility contingent on the patient’s condition and the symptoms from which they suffer. Such a test could be structured in either of two ways:
- disjunctively, using separate lists of symptoms and conditions
 - conjunctively, where eligibility is based on the patient having a combination of symptoms and conditions.
- 3.52 A significant number of American states use disjunctive eligibility criteria: that is, they contain both stand-alone symptoms and stand-alone conditions.⁴³ For example, the Nevada statute defines a ‘chronic or debilitating medical condition’ as ‘acquired immune deficiency syndrome, cancer, or glaucoma’ or as ‘a medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following: cachexia, persistent muscle spasms, including, without limitation, spasms caused by multiple sclerosis, seizures, including, without limitation, seizures caused by epilepsy, severe nausea, or severe pain’.⁴⁴ Patients under such a test can qualify for medicinal cannabis by having a specified condition or a specified symptom. The Commission’s view is that such a model incorporates the weakness of both types of test—it is overly broad in the same way as the condition- and symptom-based tests are.
- 3.53 The conjunctive option is the one preferred by the Commission. That test would require a patient to show that they have a particular symptom or symptoms and that they are afflicted by a given condition. For example, while severe nausea would not be enough on its own, it could make a patient eligible if it was the result of cancer or its treatment.

41 Submission 52.

42 Submission 60.

43 Alaska (Alaska Stat § 17.37.070(4)); Arizona (Ariz Rev Stat Ann § 36-2801), Colorado (*Colo Constitution* Article XVIII); Delaware (16 Del Code Ann § 4902A); Hawaii (Haw Rev Stat § 329-121); Maine (22 Me Rev Stat § 2422); Michigan (Mich Comp Laws § 333.26423); Montana (Mont Code Ann § 50-46-302(2)); Nevada (Nev Rev Stat § 453A.050); New Mexico (although no symptoms are listed in the statute they have been added by rulemaking: NM Stat § 26-2B-3); Oregon (Or Rev Stat § 475.302(3)); Rhode Island (RI Gen Laws § 21-28.6-3); Vermont (18 Vt Stat Ann § 4472)

44 Nev Rev Stat § 453A.050.

A test of this kind was previously used in Canada,⁴⁵ has been proposed in the Australian Capital Territory⁴⁶ and is employed in some United States jurisdictions.⁴⁷ A test of this kind was preferred by the medical advisory committee.⁴⁸

- 3.54 In the Commission's view, a test which combines the requirements of a condition-based test and a symptom-based one addresses the shortcomings of each test. It ensures that the patient's condition is serious and long-lasting, and that the symptoms experienced are of a sort likely to be relieved by medicinal cannabis.
- 3.55 An exception to this conclusion exists for chronic pain. As explained elsewhere in this report, chronic pain is difficult for clinicians to manage and can be caused by a variety of underlying disorders, if a cause can be identified at all. The management of pain varies for different individuals, and the success of a particular treatment will depend on individual circumstances besides the underlying condition. For these reasons, the discipline of pain medicine has shifted towards the management of pain, rather than the diagnosis of its cause.⁴⁹ Given this landscape, should chronic pain be among the conditions for which medicinal cannabis is made available, it would not be possible or appropriate for the sufferer to also show they were affected by a particular condition or conditions. Chronic pain is considered in more detail below.
- 3.56 In addition, as set out below, particular considerations apply where medicinal cannabis, with its unresolved side-effect profile, is given to children. Thus, an additional requirement is proposed in respect of the provision of medicinal cannabis for epilepsy conditions, where many of the patients will be under-age.

Recommendation

- 2 Eligibility to be treated with medicinal cannabis in exceptional circumstances should be:**
- (a) determined by the patient's medical condition and symptoms arising from that condition or its treatment
 - (b) specified in regulations.

Proposed conditions and symptoms

- 3.57 The Commission considers that, in determining the eligibility criteria, the conditions and symptoms selected should only be those for which there is a reasonable measure of research support in respect of efficacy or for which the research is weaker but the circumstances of the patient are particularly compelling. Conditions and their symptoms which meet these criteria are:
- severe muscle spasms or severe pain resulting from multiple sclerosis
 - severe pain arising from cancer, HIV or AIDS

45 *Marihuana Medical Access Regulations*, SOR/2001-227 sch 1.

46 Exposure Draft of Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT) cl 7(4).

47 In Massachusetts (listed eligible conditions must be 'debilitating' with debilitating defined by regulations to mean 'causing weakness, cachexia, wasting syndrome, intractable pain, or nausea, or impairing strength or ability, and progressing to such an extent that one or more of a patient's major life activities is substantially limited': 2012 Mass Acts Ch 369, § 1(C) and 105 Mass Code Regs § 725.004); New Hampshire (NH Rev Stat Ann § 126-X:1(IX)); New York (NY Public Health Law § 3360(7)(a)). In some states, this type of test is only employed for some patients, while others can qualify solely on the basis of their condition: see Minnesota (where a cancer sufferer or terminally ill patient will only qualify if experiencing severe or chronic pain, nausea/severe vomiting, or cachexia/severe wasting: Minn Stat § 152.22(14)(1) and (9)); New Jersey (where cancer and HIV/AIDS sufferers must be experiencing severe or chronic pain, severe nausea or vomiting, cachexia or wasting syndrome resulting from the disease or its treatment: NJ Stat Ann § C:24:6I-3).

48 Advisory committee (Meetings 1 and 3).

49 Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine, 'Statement on Patients' Rights to Pain Management and Associated Responsibilities' (Position Statement No 45, 2010) <<http://www.fpm.anzca.edu.au>>.

- severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
 - severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects that are intolerable for the patient
 - severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.
- 3.58 The Commission does not assert that this set of conditions and symptoms is objectively the only formulation available and suggests this list as a basis for further discussion between the government and the medical community. This is particularly important as the research base is rapidly changing and will continue to do so for some time.

Multiple sclerosis

- 3.59 There is a reasonable level of research support for the efficacy of medicinal cannabis products, most particularly Sativex, in the treatment of pain and spasticity relating to multiple sclerosis. There are also strong circumstantial reasons for allowing patients to be treated with medicinal cannabis under the scheme for this purpose.
- 3.60 The incidence and impact of the spasticity in multiple sclerosis were described in a submission from MS Australia and MS Research Australia:
- Muscle spasticity is a significant problem for many people living with [multiple sclerosis], affecting over 80% during the course of the disease and negatively impacting mobility and personal independence. Spasticity can cause pain, sleep disturbance and reduced mobility. These symptoms can significantly limit a person's quality of life as they have less energy, ability to complete everyday tasks and social activity. It can also lead to an increased reliance on carers and the health system if symptoms progress to a stage where mobility is significantly hampered or hospitalisation is required.⁵⁰
- 3.61 MS Australia and MS Research Australia observed that, to date, medications to treat spasticity for people with multiple sclerosis have not always been effective and can have 'intolerable side effects'.⁵¹ The joint submission stated that this position was guided by a scientific evidence-based approach and advocated for a regulatory framework that would facilitate further clinical trials 'to determine the components, dosage and frequency of cannabis-based products and their effectiveness in managing a range of symptoms for people living with chronic conditions like MS.'⁵²
- 3.62 The Royal Australasian College of Physicians told the Commission that: 'Muscle spasticity is a significant problem for many people living with multiple sclerosis and therapeutic options are currently limited'. It stated that many multiple sclerosis specialists believe there is sufficient scientific evidence to develop guidelines to trial the medical prescription of cannabinoid products (Sativex) for the treatment of spasticity in some patients with multiple sclerosis.
- 3.63 Sativex 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. In Australia, it was registered in 2012 by the TGA 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.⁵³

50 Submission 25.

51 These can include fatigue, dryness of the mouth, dizziness, nausea, sleepiness, cognitive impairment, liver toxicity and addiction: Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (27 September 2013) 194.

52 Submission 25.

53 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>>.

- 3.64 The Commission's medical advisory committee informed the Commission that there is consensus that cannabis can be effective at treating spasticity where other treatments have failed. Not all patients experience spasticity, and for many patients conventional treatments (including pharmaceuticals and physiotherapy) can effectively control these symptoms. Members told the Commission that the symptoms of multiple sclerosis change over time, including the nature of the patient's spasticity, and accordingly the response to cannabis would need to be carefully monitored by the treating doctor.⁵⁴
- 3.65 There is also some evidence that medicinal cannabis can help relieve pain associated with multiple sclerosis. Sativex has conditional approval in Canada as an adjunctive treatment for neuropathic pain in multiple sclerosis. This approval is said to reflect the 'promising nature of the clinical evidence which must be confirmed with further studies'.⁵⁵ The Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists conceded that a possible exception to its adverse position on the use of medicinal cannabis would be for the treatment of pain in multiple sclerosis.⁵⁶
- 3.66 The authors of a 2014 review on cannabinoids were guarded in their findings on both spasticity and pain. They concluded that:
- ... the effectiveness of cannabinoids for the treatment of muscle spasticity or neuropathic pain in multiple sclerosis is unclear and any benefit is likely to be modest, while mild to moderate adverse events are common and long term safety has not been established.⁵⁷
- 3.67 Some advisory committee members argued that, as Sativex is already approved for use in treating multiple sclerosis, there would be no advantage in making an alternative form of medicinal cannabis available.⁵⁸
- 3.68 Although Sativex is licensed for use in Australia, it is not sold in this country and, if it were, the cost would not be subsidised under the Pharmaceutical Benefits Scheme. Therefore, practically speaking, Sativex is available for very few patients, due to the high out-of-pocket cost and bureaucratic complexity associated with obtaining it.
- 3.69 On balance, the Commission's view is that there are sound reasons to include multiple sclerosis patients suffering severe symptoms in a medicinal cannabis scheme. They are alone among the patient groups under consideration in that they have access to a cannabis-based drug that has been approved for use in their condition, but accessing this medicine is presently highly problematic. In addition, the evidence supporting the utility of cannabis for multiple sclerosis is among the strongest of all the groups considered here. Refusing this group access would be an unacceptable outcome, particularly given the limited treatment options otherwise available and the impact of spasticity on patients.⁵⁹

54 This observation was echoed in the TGA's initial assessment of Nabiximols, where the examiner stated 'a 4 week trial seems likely to identify most eventual responders. Clinicians would only be justified in proceeding to long-term treatment if there was a clear improvement in spasticity': Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (27 September 2013) 108.

55 Health Canada, *Approval of Sativex with Conditions: Fact Sheet* (13 April 2005) <<http://www.hc-sc.gc.ca>>.

56 Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetics, 'Statement on "Medicinal Cannabis" with Particular Reference to its Use in the Management of Patients with Chronic Non-Cancer Pain' (2015).

57 Michael Farrell, Rachele Buchbinder and Wayne Hall. 'Should Doctors Prescribe Cannabinoids' (2014) 348 *British Medical Journal* g2737.

58 Advisory committee (Meeting 1).

59 In deciding to overturn the initial decision to refuse TGA approval to Nabiximols, the delegate of the minister used similar reasoning to conclude that Nabiximols should be allowed to be registered, notwithstanding disputes over its efficacy: 'in view of the limited therapeutic options for treatment of spasticity in the proposed treatment population and the capacity to sufficiently mitigate the potential risks from Sativex ... the Delegate of the Minister considers this response rate provides sufficient evidence of efficacy to approve the registration of Sativex.' Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (27 September 2013).

Control of pain for cancer and HIV/AIDS patients

- 3.70 Many submissions called for cannabis to be made available to alleviate pain associated with cancer and HIV/AIDS.⁶⁰ Cancer Action Victoria argued that cancer should be incorporated on the list of medical conditions for which medicinal cannabis can be provided to patients.⁶¹
- 3.71 Between 30 and 50 per cent of cancer patients experience pain, while 70 to 90 per cent of patients with advanced cancer suffer from pain.⁶² However, the causes are complex and the mechanisms differ from those that cause inflammatory or neuropathic pain. Opioids, including morphine and oxycodone, are currently the primary therapy used to relieve pain in cancer patients, but have many undesirable side effects, including constipation, sedation, respiratory depression and tolerance formation.⁶³
- 3.72 Cancer Council Victoria observed in its submission that a clinical trial is underway in Australia to determine the efficacy of administering Sativex to relieve persistent chronic pain in patients with advanced cancer who have not responded to conventional medicines.⁶⁴ It also conducted a survey of Cancer Council Victoria Clinical Network members, to gain insight into their attitudes and experiences regarding the current use of medicinal cannabis in cancer care and the proposed medicinal cannabis scheme. The members who responded said that pain management was the most common reason for patients using cannabis medicinally, followed by nausea, vomiting and weight loss management associated with their cancer treatment:
- Although there is a level of skepticism about the effectiveness of medicinal cannabis, due to the current gaps in clinical evidence, many think that it should be an accepted part of standard medical care in the treatment of cancer-related symptoms. Some clinicians would be reluctant to prescribe medicinal cannabis, even if a scheme is introduced. Again, this is due in part to evidence gaps not only with regard to its effectiveness, but with respect to required dosing and administration routes. There was strong support for medicinal cannabis to be available to cancer patients only 'when conventional treatments have been tried and failed'.⁶⁵
- 3.73 The Commission was told by the medical advisory committee that although cannabis would be used relatively rarely in pain management for terminally ill patients, it could be helpful for a small subset of such patients. It would be unlikely to be used as a first- or second-line treatment. Cannabis was said to be less effective than drugs administered through new 'intrathecal' delivery system (where analgesic drugs are administered through the spinal cord fluid).⁶⁶
- 3.74 As discussed in Chapter 2, there is limited research evidence that addresses the utility of cannabis to treat pain specifically caused by cancer. The Commission does not comment on whether the research conducted on chronic pain has application to pain caused by cancer. The Commission notes that Sativex has conditional approval in Canada as an adjunctive treatment for moderate to severe pain in patients with advanced cancer. This approval is said to reflect the 'promising nature of the clinical evidence which must be confirmed with further studies'.⁶⁷

60 Submissions 12, 24, 45, 60, 64, 70, 83. Consultations 2, 4.

61 Submission 54.

62 Submission 57.

63 L J Kehl, 'A Cannabinoid Agonist Differentially Attenuates Deep Tissue Hyperalgesia in Animal Models of Cancer and Inflammatory Muscle Pain' (2003) 103 *Pain* 175.

64 Submission 57.

65 Submission 99.

66 Advisory committee (Meeting 1).

67 Health Canada, *Authorization with Conditions of Sativex* (1 August 2007) <<http://www.hc-sc.gc.ca>>.

- 3.75 The research evidence is stronger regarding HIV/AIDS. Approximately 40 per cent of people living with HIV and being treated with antiretroviral medications experience the painful condition ‘HIV-associated sensory neuropathy’.⁶⁸ There are few treatments available which are proven to relieve pain caused by this condition. Cannabis is among the few treatments which have been proven through randomised controlled trials.⁶⁹
- 3.76 There are other considerations that are strongly supportive of the provision of medicinal cannabis to people experiencing pain associated with cancer or HIV/AIDS. These conditions have the potential to diminish a person’s quality of life in a profound way, as conveyed by the submissions received by the Commission,⁷⁰ and cannabis may provide a treatment option that offers relief from pain at a time when patients are in need of comfort. In addition, as these conditions are recommended below as legitimising access to cannabis for the treatment of nausea, vomiting and wasting, there seems little utility in preventing access to it for pain relief as well. Accordingly, the Commission’s view is that cannabis in medicinal forms should be available to patients suffering from cancer or HIV/AIDS and experiencing severe pain.

Relief from nausea, vomiting and wasting

- 3.77 Nausea and vomiting are common and distressing problems for cancer patients. Approximately 50 per cent of patients with cancer experience nausea or vomiting, either as a result of the cancer itself or its treatment. These symptoms have been summarised as follows:
- Nausea and vomiting are common problems in cancer patients throughout the trajectory of their illness. Whether these patients are receiving high-dose cisplatin 1 [a chemotherapy drug] with the best available antiemetic therapy or are experiencing the advanced stages of cancer, approximately one half will experience nausea or vomiting, or both. The causes of these distressing symptoms are diverse, and they include medication, radiation therapy, and the effect of the cancer itself. ... Although therapy that aims to correct the underlying cause is rational, for many patients, such an approach is not possible.⁷¹
- 3.78 Both cancer and HIV/AIDS patients can experience wasting as a result of their disease. Depending on the type of cancer, 30 to 80 per cent of cancer patients experience weight loss, which can be as a result of the condition or its treatment.⁷² Severe wasting, known as cachexia, ‘adversely affects the patients’ ability to fight against infection and withstand treatment by chemotherapy and radiotherapy. As a result of all these negative effects, the body begins to waste away.⁷³ This is counter-therapeutic in every sense.
- 3.79 In its submission to the Commission, Cancer Council Victoria supported making medicinal cannabis available for nausea and vomiting where other treatments have failed, and observed there is evidence supporting its efficacy.⁷⁴ Similarly the joint submission by the National Cancer Council and the Clinical Oncology Society of Australia to the Senate Legal and Constitutional Affairs Committee’s inquiry into the Regulator of Medicinal Cannabis Bill asserted there is evidence that medicinal cannabis could be useful for this purpose, and commented that: ‘Managing illness induced by chemotherapy, especially in patients with advanced cancer who have responded poorly to conventional relief options, is a significant problem for cancer patients and their doctors.’⁷⁵

68 Tudor J C Phillips et al, ‘Pharmacological Treatment of Painful HIV-Associated Sensory Neuropathy: A Systematic Review and Meta-Analysis of Randomised Controlled Trials’ (2010) 5(12) *PLOS ONE* e14433.

69 Ibid.

70 See, eg, Submission 64.

71 David Warr, ‘Chemotherapy- and Cancer-Related Nausea and Vomiting’ (2008) 15 *Current Oncology* S1.

72 Submission 57; Raghu Dhanapal, T R Saraswathi and Rajkumar N Govind, ‘Cancer Cachexia’ (2011) 15 *Journal of Oral and Maxillofacial Pathology* 257.

73 Raghu Dhanapal, T R Saraswathi and Rajkumar N Govind, ‘Cancer Cachexia’ (2011) 15 *Journal of Oral and Maxillofacial Pathology* 257

74 Submission 57.

75 Cancer Council Australia and Clinical Oncology Society of Australia, Submission 37 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 2015, 4.

- 3.80 In these circumstances, given the evidence for the effectiveness of medicinal cannabis in enhancing appetite and reducing nausea and wasting, the Commission is satisfied that in appropriate circumstances medicinal cannabis has a therapeutic role to play for this category of patient.

Epilepsy

- 3.81 The present state of research on the efficacy of cannabinoids (particularly cannabidiol) as a treatment for epilepsy does not yet allow firm conclusions to be drawn. The existing research lacks authoritativeness, and rigorous studies are only now starting to get underway, including in Australia, but there is emerging support for the efficacy of cannabis in relieving the symptoms of epilepsy, especially for those with juvenile syndromes.
- 3.82 The reality pointed out to the Commission in its consultative processes is that significant numbers of parents faced with epilepsy syndromes such as Dravet, Lennox-Gastaut and genetic forms of epilepsy such as CDKL5 are turning to cannabis in an attempt to address life-endangering seizures in their children, which can be hundreds daily and which may not be responsive to orthodox epilepsy medications. The Commission heard moving accounts from parents of children with such syndromes who maintained that various forms of medicinal cannabis had extremely positive effects on the experience of symptoms by their children.
- 3.83 While the clinical research on this application of cannabis does not itself provide a compelling basis for action, the other considerations affecting this patient group are overwhelming. The feature which sets this group apart from other conditions where research is lacking is the scale of the transformations anecdotally observed for epileptic patients treated with medicinal cannabis. It is true that the results seen by families have not been rigorously assessed, but anecdotally there are numerous children for whom medicinal cannabis has provided astonishing relief.
- 3.84 However, because both the risks associated with medicinal cannabis—particularly for children—and the benefits of treatment remain uncertain, at this stage treatment should be limited to only the most gravely ill sufferers of epilepsy, where other treatments have failed to bring the patient’s symptoms under control or have caused intolerable side effects. Thus, in respect of this category of patients, in part because of the unknown consequences of administration of medicinal cannabis over what may be an extended period of time to children with developing brains, the Commission is of the view that it is proper to require that other forms of treatment have been attempted and found ineffective before medicinal cannabis is used.

Chronic non-cancer pain

- 3.85 In 2015 the Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists issued a formal position in relation to the use of cannabinoids for patients with chronic non-cancer pain, concluding that:
- With the possible exception of pain and spasticity in multiple sclerosis, there is little evidence for the effectiveness of cannabinoids in chronic non-cancer pain situations, whether or not the pain attracts the descriptor ‘neuropathic’.⁷⁶
- 3.86 This statement does not apply to patients who are in palliative care.⁷⁷
- 3.87 A number of questions arise about:
- the capacity of medical practitioners to identify categories of patients within the chronic pain cohort effectively

76 Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists, ‘Statement on “Medicinal Cannabis” with Particular Reference to its Use in the Management of Patients with Chronic Non-Cancer Pain’ (2015).
77 Ibid.

- the role of patient-self-report of symptoms among sufferers of chronic pain
 - the distinctions between patients who seek medicinal cannabis for a combination of psychotropic effects and pain relief, as against those for who seek it solely for its analgesic qualities
 - whether the consequences of long-term provision of such medication are overall therapeutically advantageous.
- 3.88 In addition, it is apparent that modest numbers of United States and Canadian medical practitioners have been prepared to authorise/prescribe medicinal cannabis to patients with chronic pain,⁷⁸ this in turn creating difficult pressures for practitioners and potentially distorting effects on the doctor–patient relationship.⁷⁹ These matters need to be explored further by carefully constructed studies.
- 3.89 The Commission considers that, while there are likely to be advantages for some patients who experience chronic pain from a variety of conditions in being treated with medicinal cannabis, as against opiate analgesia,⁸⁰ further analysis needs to be undertaken before medicinal cannabis is made available as a first line or even an alternative form of treatment for patients who suffer or claim to suffer chronic symptoms of pain.
- 3.90 For this reason, the Commission does not propose that chronic pain be a qualifying condition or symptom on its own, and instead considers that additional conditions should be imposed in respect of it. Nor should particular underlying conditions be specified in the eligibility criteria.⁸¹
- 3.91 This stance will be controversial but it is a considered position on the part of the Commission. While it is conceded that a number of studies have demonstrated therapeutic potential for medicinal cannabis for neuropathic pain, this therapeutic option remains contested within the medical profession.
- 3.92 Allowing patients suffering from chronic pain to be treated with medicinal cannabis gives rise to other issues not raised by the other conditions discussed:
- As the ‘chronic’ pain is a long-term phenomenon, there is the potential for any treatment option to be sustained. This raises the issue of risk in a way that is more problematic in light of the limited clinical and research knowledge than is the case when the measure is relatively short-term, such as in treating symptoms of a terminal illness, or in circumstances of acute clinical need, such as in treating wasting or refractory epileptic conditions.
 - There is the potential for such conditions to be asserted by patients without medical practitioners being able effectively to evaluate the clinical accuracy of what is asserted. The blurring between asserted medical use of cannabis and recreational use, as arguably has occurred in jurisdictions such as California,⁸² should be avoided.
 - There is the potential for medical practitioners to be placed under uncomfortable pressures to authorise medicinal cannabis in such situations based upon patients’ unverifiable self-reports of chronic pain. There is a serious risk that a problematic number of medical practitioners could decide not to participate in the scheme. This could undermine its viability.

78 See, eg: Elin Kondrad and Alfred Reid, ‘Colorado Family Physicians’ Attitudes Toward Medical Marijuana’ (2013) 26 *Journal of the American Board of Family Medicine* 52, 52–53.

79 Samuel Fair noted that: ‘A formidable concern is that undue pressure will be placed on doctors to use the treatment experimentally, if a patient does not receive a desired response from more conventional treatment. ... The concern is that such pressure may pose a risk to the doctor/patient relationship’: Submission 40.

80 As discussed in the issues paper, among the benefits is a reduced incidence of opioid overdose deaths: 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; Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [3.33].

81 The Commission heard, for example, about fibromyalgia, complex regional pain syndrome and other conditions: Consultations 1, 7.

82 See J Michael Bostwick, ‘Blurred Boundaries: The Therapeutics and Politics of Medical Marijuana’ (2012) 87 *Mayo Clinic Proceedings* 172.

- 3.93 Thus the Commission is of the view that, if medicinal cannabis is to be provided to alleviate chronic pain, it is appropriate that two specialists should be required to arrive at the determination. While this is an extra burden for a patient who may be desirous of being treated with medicinal cannabis, the Commission has determined that for the present this is a reasonable requirement in light of:
- the risk of abuse
 - the fact that such pharmacotherapy may be long-term, with the ensuing risks
 - the fact that there are a variety of non-pharmacological options for the management of pain.
- 3.94 The Commission has concluded, on advice from the medical advisory committee, that the patient's chronic pain should not need to be refractory in the sense of its having failed to respond to other forms of analgesia. Rather, the decision in respect of the advisability of medicinal cannabis as against (or in conjunction with) other treatment options should be that of the specialists who are consulted.
- 3.95 The specialists' evaluation of the patient's suitability for treatment with medicinal cannabis would include the likelihood that the patient would respond beneficially, and also whether it is the best form of treatment for the patient's pain. This would be likely to take into account whether other measures have already been employed but found unsatisfactory—for a variety of reasons. It is common for there to be a variety of approaches to managing pain, and for pharmacotherapy to be only one of several components in the attempt to manage a patient's symptoms. It is the Commission's view that medicinal cannabis should only be made available to patients with chronic pain (not caused by cancer, HIV/AIDS or multiple sclerosis) where two specialists conclude that it may in all the circumstances provide superior pain management by contrast with other options.

Other conditions

- 3.96 As described in Chapter 2, there is a range of other conditions where claims of efficacy are made or preliminary research exists. However, there is not yet a strong evidence base for the efficacy of medicinal cannabis. In particular, there is insufficient research at this stage to support allowing patients with any of the following conditions routine⁸³ access to medicinal cannabis:
- spinal cord injury
 - post-traumatic stress disorder
 - schizophrenia
 - treatment of cancer (as opposed to its symptoms)
 - Tourette syndrome
 - inflammatory disorders
 - motor-neurone disease (also known as amyotrophic lateral sclerosis)
 - glaucoma
 - Parkinson's disease
 - inflammatory bowel disease (including Crohn's disease)
 - hepatitis C
 - sleep disorders
 - anxiety and depression.

- 3.97 In each of these cases, there is research which is promising, and future studies may produce evidence sufficient to support provision of medicinal cannabis to these patients. However, at present, the Commission considers the government should be cautious about enabling cannabis to be dispensed to these categories of patients.
- 3.98 While the Commission has adopted an approach which is not rigidly controlled by the outcomes of blinded, placebo-controlled trials, there is still a need to ensure that cannabis is supplied to patients on a rational basis⁸⁴—that is, where there is a base level of evidence suggesting that cannabis is likely to assist. In the case of the conditions listed above, for some there has been almost no controlled evidence collected and, for others, no human studies of any rigour have been performed. To allow access to cannabis on the basis of such limited evidence would lack a reasonable evidence base and would be speculative.
- 3.99 It is acknowledged that there is a degree of arbitrariness in selecting particular conditions as against others. Those selected by the Commission are in response to clinical scenarios of particular need and distress identified by written submissions and by persons whom the Commission has met during its consultative processes. In addition, each has been selected on the basis of credible evidence supporting the efficacy of cannabis, although the evidence is not at the highest level. As discussed later in this chapter, the scheme should allow for the conditions that are included to be kept under review, and also provide for case-by-case exceptions.⁸⁵

Recommendations

- 3.100 In light of the above discussion, the Commission considers that, at the outset of a Victorian medicinal cannabis scheme, patients who have certain designated conditions and are experiencing serious symptoms from those conditions should be eligible to be treated with medicinal cannabis. Whether an individual patient should receive such treatment would be determined under procedures that are discussed later in this chapter.

Recommendation

- 3 Eligibility for any Victorian medicinal cannabis scheme should be based initially on the following conditions and corresponding symptoms:**
- (a) severe muscle spasms or severe pain resulting from multiple sclerosis
 - (b) severe pain arising from cancer, HIV or AIDS
 - (c) severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
 - (d) severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side effects that are intolerable for the patient
 - (e) severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.

Other considerations

‘Severe’ symptoms

- 3.101 The qualifying adjective ‘severe’ is employed in these recommendations to require a high level of experience of the relevant symptoms of a designated category of condition.⁸⁶ This approach is adopted to communicate clearly that medicinal cannabis, like other medications such as opioid analgesics, should only be used when therapeutically necessary (namely to address a set of symptoms), rather than as a prophylactic or as a continuing therapeutic option if symptoms do not require it.

Medicinal cannabis as a ‘last resort’?

- 3.102 Some submissions called for medicinal cannabis to be used as a ‘last resort’—that is, after other conventional treatments have failed.⁸⁷ A small majority of clinicians surveyed by Cancer Council Victoria considered that eligibility should be defined by whether conventional treatments had been tried and failed.⁸⁸ Other submissions opposed making medicinal cannabis a last resort.⁸⁹ Some said it should be a matter of personal choice,⁹⁰ and that if it works patients should not be required to exhaust all other options before they can use it.⁹¹
- 3.103 Professor David Penington noted that ‘failed’ is not a neatly defined term, and queried whether a treatment like morphine, which might be partially effective but cause a distressing addiction, would be considered to have ‘failed’.⁹² Similarly, others drew attention to the many who suffer from side effects or allergies, and queried whether this would be a ‘failure’ of the treatment.⁹³ Along similar lines, Mullaways Medical Cannabis Pty Ltd asked, ‘how many years of failed conventional treatments, with all their side effects and cost, must a person with exceptional circumstances endure before they have a right to cannabis treatment?’⁹⁴
- 3.104 The Royal Australasian College of Physicians opposed making resistance to treatment a requirement of eligibility:
- It is not appropriate that all reasonable conventional treatments have failed before a person is eligible to use medicinal cannabis; this is not a requirement for antiepileptic drug trials or for potentially curative epilepsy surgery.⁹⁵
- 3.105 The Australian Nursing and Midwifery Federation—Victorian Branch told the Commission that it opposed restricting medicinal cannabis to those people for whom other treatments had failed. It stated:
- We are concerned that being required to meet this threshold may cause unnecessary delay in patients receiving effective treatment and result in prolonged and avoidable suffering. Additionally, it is unclear who would determine the length of time that would be required to decide that conventional treatments have failed and what criteria would be used to assess them as having failed. Alleviation of pain and the effective relief of adverse effects of treatment and symptoms of medical conditions should be provided in a timely way and not obstructed by a requirement to exhaust other treatment options.⁹⁶

86 See the spectrum of terms discussed in *Humphries v Poljak* [1992] 2 VR 129, 134: ‘slight’, ‘mild’, ‘moderate’, ‘significant’, ‘marked’, ‘serious’, ‘severe’.

87 Submissions 1, 5, 20, 31, 42, 49, 48, 50, 61; Consultation 8.

88 Submission 99.

89 Submissions 12, 22, 29, 54 and 75, Consultation 1.

90 Submissions 18, 35, 18, 74.

91 Submission 12; Consultation 26.

92 Submission 24.

93 Submissions 2, 43.

94 Submission 29.

95 Submission 52.

96 Submission 74.

- 3.106 The Commission acknowledges that, given the unproven, novel character of medicinal cannabis, it would be more appropriately used after proven, conventional treatments have been trialled. It would be very rare, for instance, for it to be an analgesic of first resort, and even rarer for it to be a therapeutic option on its own for the relief of chronic pain. In respect of other conditions, too, it is to be expected that other therapeutic options would first be tried for a patient.
- 3.107 However, the Commission does not recommend a rigid or statutory prerequisite of intractability or refractoriness of the condition to other forms of medication or medical intervention. The weighing of management options and combinations of treatment should be a matter for decision between a patient and their medical practitioner, as would ordinarily be the case. In addition, the Commission is concerned not to raise the bar too high for patients to be able to gain access to medicinal cannabis. This is justified by the fact that the known risks of medicinal cannabis are only moderate and, for the most part, should be able to be addressed by attentive monitoring and responsiveness by the patient's treating doctor.
- 3.108 There are two partial exceptions to this. For the reasons set out above, the Commission considers that medicinal cannabis should only be able to be authorised for the treatment of epilepsy where other treatment options have not proved effective or have generated side effects that are intolerable for the patient. In respect of chronic pain, there should be a requirement that specialists conclude that medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.

Terminal illnesses

- 3.109 The Commission considered whether to provide a standalone category for the terminally ill to qualify for medicinal cannabis. The Royal Australasian College of Physicians stated in its submission:
- In the case of terminally ill patients, the use of medicinal cannabis (if the patient wishes to trial its use) most likely holds limited potential for damage and can always be ceased if there is no useful response. The [Royal Australasian College of Physicians] acknowledges there are many anecdotes where the use of cannabinoids have greatly benefited terminal patients without the associated side effects that opioid use cause.⁹⁷
- 3.110 In some jurisdictions in the United States (such as the District of Columbia, Maryland, Montana, New Jersey and New Mexico) a patient can become eligible for medicinal cannabis solely because their condition is terminal or they are receiving palliative care.⁹⁸ Such a test has also been mooted in the Australian Capital Territory⁹⁹ and previously existed in Canada.¹⁰⁰ Incorporating such a test into a Victorian scheme would mean that the terminally ill could qualify for medicinal cannabis whether or not they were otherwise eligible by virtue of their condition and symptoms.

97 Submission 52.
 98 DC Code § 7-1671.01; Md Code §§ 13-3307(c) & 13-3301; Mont Code Ann § 50-46-302(2); NJ Stat § 24:61-3 & 24:61-5; NM Stat § 26-2B-3.
 99 Exposure Draft of Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (ACT) cl 7.
 100 *Medical Marihuana Access Regulations* (Can) (SOR 2001/227) s 1(1) (definition of 'category 1 symptom').

- 3.111 The Commission’s advisory committees and people who attended a consultation in Shepparton opposed this approach as unnecessary.¹⁰¹ Participants felt that the terminally ill would largely be captured by the proposed condition- and symptom-based criteria in any event, and that it would be counterproductive to provide medicinal cannabis to patients if it was unlikely to assist them.¹⁰² AMA Victoria observed that disregarding potential risks and side effects ‘solely based on the patients’ end of life status, diminishes the value of the lives of the terminally ill.’¹⁰³
- 3.112 The Commission agrees that separate eligibility criteria for patients who suffer from terminal conditions would be undesirable. As for all other patients, there should be some prospect that cannabis can assist the patient’s specific symptoms, which is ensured by the condition- and symptom-based test recommended above. Any alteration in the assessment of risk to respond to the position of a terminally ill person (for example, a diminished regard to long-term risks) would be taken into account in the medical practitioner’s clinical judgment.

The need for caution

- 3.113 There are significant pragmatic advantages to taking a gradual, step-by-step approach to the introduction of medicinal cannabis in Victoria, given the current limited reliable research base for its introduction as a lawful therapeutic option. The limitations in the current research literature are discussed in Chapter 2.
- 3.114 Most importantly, such an approach would allow for prompt intervention to assist those whose suffering is particularly severe. It also recognises that what is proposed is a significant social change—the removal of a drug from illegal status and its absorption in certain circumstances into the orthodox pharmacopoeia.
- 3.115 It would also allow a change in culture to start in respect of the recognition and use of medicinal cannabis as a therapeutic option, starting with a limited number of conditions. This is the approach most likely to engender confidence among medical practitioners, an issue which experience in jurisdictions such as Canada has demonstrated is fundamental for the viability of a medicinal cannabis scheme.¹⁰⁴ It keeps to a minimum the range of circumstances in which there is encroachment upon the paradigm of evidence-based medicine and thus preserves the standard of medicine based on high-level evidence in the form of double-blind, placebo-controlled trials as the principal determinant for the provision of treatment by contemporary medicine.
- 3.116 It would also allow for Victoria’s medicinal cannabis scheme to take advantage of fast-evolving global research into the efficacy and risks of medicinal cannabis, prior to extending it to a broader set of conditions.
- 3.117 More generally, it would allow for review of the medicinal cannabis scheme (recommended below after four years) to assess its success in all respects, including in relation to its effectiveness in alleviating suffering for the conditions initially designated.
- 3.118 Inevitably, this means that some people who want to obtain lawful access to medicinal cannabis will not be able to do so, at least for a time, but, on balance, the Commission considers that this is the best option to make the proposed scheme viable and to command community and professional confidence from the start.
- 3.119 In addition, it allows for development of the scheme in a way that protects against actual or potential abuses. The Commission has noted the profile of medicinal cannabis patients in jurisdictions where people who claim to suffer chronic pain can obtain access to medicinal cannabis. The statistical profiles of users suggest that these schemes may be

101 Advisory committee (Meeting 3), Consultation 26.

102 Consultation 26.

103 Submission 38.

104 See generally Ian Freckelton, ‘Medicinal Cannabis Law Reform: Lessons from Canadian Litigation’ (2015) 22 *Journal of Law and Medicine* 719.

serving more than the patient cohort with the greatest degree of suffering.¹⁰⁵ It is clear that a disproportionate number of consumers of medical cannabis in the United States seek the medication for relief of chronic pain, as well as for relaxation, in respect of which other options have not proved palatable or effective. This is not necessarily clinically inappropriate but it does create a real potential for abuse of a scheme and for medical practitioners to be placed under difficult pressures to enable access to medicinal cannabis when their ability to evaluate need objectively is limited.

- 3.120 The opportunity exists for Victoria to introduce a scheme which minimises the potential for abuse that could bring it into disrepute and imperil its viability by making medical practitioners reluctant to authorise access to medicinal cannabis. This opportunity should be realised by a conservative introduction of conditions and criteria enabling patient access to medicinal cannabis.

Incorporating flexibility

Allowing for exceptional cases

- 3.121 The Commission was told, both in written submissions and at its consultations, of patients with rare conditions who believe they have received therapeutic benefit from medicinal cannabis or think they might do so.¹⁰⁶ A number of submissions supported the notion of a mechanism for allowing people who would not otherwise be eligible to be treated with medicinal cannabis under the scheme to be treated with medicinal cannabis.¹⁰⁷ However, there was limited support for such a provision in the Commission's medical advisory committee.¹⁰⁸
- 3.122 Some submissions said that this should only occur in the context of a clinical trial.¹⁰⁹ Others supported a provision under which access by people in exceptional cases could occur if a second practitioner endorsed the use.¹¹⁰
- 3.123 The Commission is satisfied that it would be humane and reasonable to provide for a mechanism for a person outside the designated categories to request access to medicinal cannabis in exceptional circumstances. Applications would need to be supported by a specialist medical practitioner.

105 In Rhode Island, for instance, a 2015 review identified that the most common reason for receiving medicinal cannabis was chronic pain management: N Zaller et al, 'Profiles of Medicinal Cannabis Patients Attending Compassion Centers in Rhode Island' (2015) 47 *Journal of Psychoactive Drugs* 18. This study is consistent with a study of 1,655 patients seen in medical marijuana specialty practices in California, where Proposition 215 has permitted cannabis for cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine or 'any other illness for which marijuana provides relief' since 1996. 73% of applicants seeking a recommendation were male and half of the applicants were under 35. 82.6% of applicants reported using medical marijuana for pain relief, 70.6% for improved sleep, and 55.6% for relaxation. Physicians' diagnoses were consistent with high levels of diagnosis of low back pain, muscle spasm, arthritis and lumbar degenerative disc disease in applicants for medicinal cannabis entitlement: Helen Nurnberg, Beau Kilmer, Rosalie Licardo and James Burgdorf, 'An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California' (2011) 4 *Journal of Drug Policy Analysis* 1. Similarly, the 2014 annual report filed under the *Arizona Medical Marijuana Act* found that approximately 70% of those who received medical marijuana authorisations were male and 'severe and chronic pain' was either the sole debilitating condition (71%) or among the debilitating conditions (19.2%) reported by those who were authorised, while conditions such as those with cancer (2.7%) and seizures (1.0%) did not figure prominently: Arizona Department of Health Services, *Arizona Medical Marijuana Act (AMMA) End of Year Report* (2014) <<http://www.azdhs.gov>>. In Colorado, where patients have been able to receive medical marijuana since 2000, 93.1% of patients report the qualifying condition 'severe pain'. The next most common conditions were muscle spasms (17.5%) and severe nausea (10.8%), followed by cancer (3.6%) and seizures (2.3%): Colorado Department of Public Health & Environment, *Medical Marijuana Registry Program Statistics* (30 June 2015) <<https://www.colorado.gov>>.

106

Submissions 43, 68.

107 Submissions 3, 4, 6, 11, 13, 18, 24, 29, 32, 45, 48, 61, 63.

108 Advisory committee (Meeting 1).

109 Submissions 7, 52.

110 Submissions 7, 20, 32, 48.

- 3.124 These matters could be considered by a committee, comprising medical experts who could advise on the appropriateness of cannabis for the particular condition. Such decision making would be analogous to the decisions made by the TGA in the context of the Special Access Scheme.¹¹¹ The committee would undertake a similar inquiry to that undertaken by a Drug and Therapeutics Committee in determining whether to approve use of an unapproved drug,¹¹² but determine whether to permit use by particular patients on a case-by-case basis.

Recommendation

- 4 The Secretary of the Department of Health and Human Services, or a committee constituted by the Secretary under delegation, should be given power to permit patients on a case-by-case basis to be treated with medicinal cannabis in exceptional circumstances that do not otherwise fall within the eligibility criteria of the scheme.**

Flexibility for ongoing determination of eligibility

- 3.125 Ongoing clinical trials and research are likely to change the evidentiary landscape significantly with respect to both the efficacy and risks of medicinal cannabis. Within even five years there will be much better knowledge that could affect the evolution of the kind of medicinal cannabis scheme that is being recommended by the Commission.
- 3.126 It follows that a fundamental attribute of the proposed scheme should be flexibility to adapt to such developments in clinical knowledge. In particular, should evidence emerge regarding the conditions for which medicinal cannabis is likely to be effective, the eligibility criteria may need to be amended by the addition or removal of conditions or symptoms. This would mean amending the regulations that set out the criteria.
- 3.127 The Commission considers that an advisory body should be constituted to advise the Minister for Health about the operation of the scheme and, in particular, the ongoing suitability and effect of the eligibility criteria, including whether they need to be amended. It should have independence from the Minister for Health. This is important to maintain the confidence of the public and the medical profession by demonstrating that decisions which affect the scope and features of the scheme are informed by health practitioners and others with professional expertise in the efficacy of medicinal cannabis.
- 3.128 An advisory committee could be established in either of two ways:
- As a consultative council, by executive order of the minister using existing powers.¹¹³ No new legislation would be required. Under this option, the matters and functions of the council would be determined by the minister and specified in an Order.
 - As a statutory body, akin to the advisory committees that advise the Secretary of the Commonwealth Department of Health on the scheduling of medicines and chemicals. The Secretary is obliged to have regard to any recommendations or advice of these advisory committees when exercising relevant scheduling powers.¹¹⁴ Regulations set out how the committees are constituted and how meetings are to be conducted.¹¹⁵

111 A scheme under which applications may be made to import or supply an unapproved therapeutic good. See Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009).

112 See New South Wales Health, *Role of Drug and Therapeutics Committee in the Evaluation and Approval of Medicines for Use in Public Hospitals* (Policy Directive No PD2008_037).

113 Contained in s 33 of the *Public Health and Wellbeing Act 2008* (Vic).

114 *Therapeutic Goods Act 1989* (Cth) s 52E(3).

115 *Therapeutic Goods Regulations 1990* (Cth) Divs 3A and 3B.

- 3.129 The initiative to amend the eligibility criteria of the scheme, through regulation, should rest with the Minister for Health on the advice of the advisory body.

Recommendation

- 5** The Minister for Health should constitute an independent medical advisory committee on medicinal cannabis to provide ongoing advice about the conditions and corresponding symptoms on which eligibility to be treated with medicinal cannabis is based. Such advice should include reference to:
- (a) the responsiveness by patients to medicinal cannabis provided under the scheme and any side effects experienced by them
 - (b) the state of the clinical literature in relation to the efficacy or potential efficacy of medicinal cannabis for particular medical conditions and symptoms
 - (c) the state of the clinical literature in relation to the risks or potential risks posed by medicinal cannabis for patients with particular medical conditions
 - (d) the seriousness of the medical conditions, including patients' prognoses and the extent of the disability caused by their conditions
 - (e) the extent to which symptoms of the conditions interfere with patients' ability to derive enjoyment and fulfilment in their lives
 - (f) the extent to which medicinal cannabis can reasonably be anticipated to improve patients' quality of life
 - (g) the availability of standard treatments that may assist, how effective they are, and what side effects they cause.

Authorisation of treatment

Overview of proposed procedure

- 3.130 A decision that an individual patient is treated with medicinal cannabis is a medical one. While the recommended eligibility criteria would establish at law who may participate in the scheme, the question of whether medicinal cannabis is an appropriate form of treatment for each eligible patient needs to be determined by a medical practitioner. Further, in line with the recommended regulatory objectives, the use of medicinal cannabis should be under medical supervision.
- 3.131 Thus, the regulatory framework for any Victorian medicinal cannabis scheme needs to enable medical practitioners to authorise the medicinal cannabis products to be dispensed to those of their patients who meet the eligibility criteria and for whom it is appropriate in all the circumstances that they receive this form of treatment.
- 3.132 It was proposed to the Commission that the opioid replacement therapy program and procedures for providing access to Schedule 8 medicines provide useful models on which to base the regulatory framework for dispensing medicinal cannabis.¹¹⁶ These mechanisms are an established means of allowing certain categories of patients to have access to strictly controlled medicines.

- 3.133 There is merit in building on existing practices while accommodating the different objectives and risks in providing access to medicinal cannabis. The remainder of this chapter sets out a procedure for authorising the supply of medicinal cannabis to patients, under medical supervision. In summary, it comprises the following features:
- A medical practitioner who specialises in the medical condition on which their patient's eligibility is based applies to the Department of Health and Human Services for a permit to issue an Authority to Dispense Medicinal Cannabis.
 - The application for the permit conveys the specialist medical practitioner's opinion that the patient is eligible to participate in the scheme and it is appropriate in all the circumstances that they be treated with medicinal cannabis. It would also certify that the patient has been informed that the product has not been approved by the TGA, the approved alternatives, and the risks, potential benefits and side effects.
 - On obtaining the permit, the specialist medical practitioner issues an Authority to Dispense Medicinal Cannabis which, like a prescription, authorises a pharmacist to dispense the medicinal cannabis. The pharmacist is identified on the permit and on the Authority to Dispense.

Residence requirement

- 3.134 The Commission considers that only patients ordinarily resident in Victoria should be able to obtain medicinal cannabis under any Victorian scheme.¹¹⁷ If residents of other states or territories were eligible to access medicinal cannabis, they would be exposed to prosecution under their local laws if they took it back to their home jurisdiction, and the Victorian community would bear the additional costs of supporting a much larger patient population.¹¹⁸ The Law Institute of Victoria highlighted this as an issue:

Access to the regulated scheme in Victoria should be restricted to permanent Victorian residents and the drug may only be used when within Victorian borders. This would prevent issues with medical 'tourism' and the conflict with criminal sanctions in other jurisdictions.¹¹⁹

- 3.135 Because the Victorian scheme would be departing from the national therapeutic goods framework, it would not be lawful to possess medicinal cannabis products sold in Victoria in other states and territories of Australia unless reciprocal laws were passed. In addition, pharmacies outside Victoria would be unable to supply the product specified.¹²⁰
- 3.136 It would be undesirable for non-residents to travel to Victoria, obtain medicinal cannabis, then return to a part of Australia where the product is unlawful and cannot be purchased as they would therefore be unlikely to receive medical supervision. In some circumstances they would be liable to be prosecuted for use and possession of the drug. For similar reasons, patients who are authorised to obtain medicinal cannabis in Victoria should be warned not to take the product interstate or overseas.

Recommendation

- 6 Any medicinal cannabis scheme in Victoria should be applicable only to persons who ordinarily reside in Victoria.**

117 Cf *Firearms Act 1996* (Vic) s 46A, *Relationships Act 2008* (Vic) s 6, *Legal Aid Act 1978* (Vic) s 24(5). The Department of Health and Human Services would determine what supporting evidence for a person's residency should be required.

118 The Royal Australasian College of Physicians made this observation in Submission 52.

119 Submission 63.

120 Submission 52.

Which practitioners?

- 3.137 Registered health practitioners in Australia have diverse areas of expertise, ranging across the many facets of healthcare.¹²¹ Several categories of health practitioners have the capacity to prescribe medicines,¹²² and many have a range of sub-specialities.¹²³
- 3.138 In the issues paper, the Commission sought feedback on who should have the authority to assess whether a patient is an appropriate candidate to be treated with medicinal cannabis.¹²⁴

Health practitioners other than medical practitioners

- 3.139 Several submissions endorsed the involvement of registered health practitioners other than medical practitioners.¹²⁵ The Cannabis Policy Project recommended that a broad range of practitioners be considered, arguing that the inclusion of nurse practitioners in the Canadian scheme 'speaks to a continuing problem of accessibility to the program whilst doctors are the only gatekeepers'.¹²⁶
- 3.140 Cannabis Science Australia Ltd suggested that non-medically trained practitioners could effectively authorise treatment, under supervision.¹²⁷ Other submissions endorsed including health practitioners with prescribing entitlements.¹²⁸
- 3.141 Some submissions called for naturopaths to be involved.¹²⁹ Naturopaths are not legally registered health professionals in Victoria¹³⁰ and have no prescribing entitlements. In this regard, Victoria Police submitted that:
- It would be inappropriate for practitioners, such as alternative therapists who are not authorised to prescribe scheduled medicines, to be authorised to prescribe medicinal cannabis.¹³¹
- 3.142 The majority of submissions and other comments made to the Commission on this issue recommended that only medical practitioners, or a subset thereof, be able to authorise treatment with medicinal cannabis.¹³² It was submitted that involving other types of health practitioners would be too broad.¹³³ In endorsing this approach, Cheryl Wright stated:
- It should not be made difficult or impossible for patients to access medical cannabis, but it also needs to be monitored by practitioners who know what they're doing.¹³⁴
- 3.143 The Commission agrees. Only registered medical practitioners should be able to authorise access to medicinal cannabis. Given that eligibility would be confined to people with severe conditions and symptoms, the ability to authorise should be confined to medical practitioners.¹³⁵

121 Including Chinese medicine practitioners, dentists, medical practitioners, nurses, occupational therapists, optometrists, osteopaths, pharmacists, physiotherapists, podiatrists and psychologists: see *Health Practitioner Regulation National Law, s 4* (definition of 'health profession').

122 Namely, medical practitioners, nurse practitioners, dentists, optometrists and certain podiatrists: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) rr 8, 9, 10, 11 and 11A.

123 For example, medical practitioners can be registered as general practitioners or specialists: Medical Board of Australia, *Types of Medical Registration* (25 August 2014) <<http://www.medicalboard.gov.au>>. Nurses can seek endorsements on their registration enabling them to perform a greater range of functions: Nursing and Midwifery Board of Australia, *Registration & Endorsement* (31 July 2015) <<http://www.nursingmidwiferyboard.gov.au>>.

124 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [7.53]–[7.57].

125 Submissions 4, 11, 14, 16, 37.

126 Submission 37.

127 Submission 69.

128 Submissions 47, 48, 75. For example, nurse practitioners in Victoria are able to prescribe certain medicines (not including any substance listed in Schedules 8 or 9): *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 13(1)(ba) and Minister for Health, 'Approval under Section 14A' in Victoria, *Victoria Government Gazette*, No G 39, 25 September 2014.

129 Submission 4, Consultation 4, 7.

130 Naturopaths are generally registered with a private professional association (for example, the Australian Naturopathic Practitioners Association Inc) but are not subject to any government registration: Better Health Channel, *Naturopathy* (January 2015) <<http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Naturopathy?open>>.

131 Submission 44.

132 Advisory committee (Meetings 1, 3); Submissions 1, 2, 3, 5, 6, 7, 18, 19, 20, 23, 24, 28, 29, 31, 32, 38, 39, 42, 44, 45, 49, 52, 54, 60, 61, 64, 67, 72, 74.

133 Submission 23.

134 Submission 2.

135 Nurses and nurse practitioners should, however, be authorised to possess and administer medicinal cannabis products when authorised by a medical practitioner.

Which medical practitioners?

- 3.144 The Commission heard from many sources that only specialist medical practitioners¹³⁶ should be able to authorise access to medicinal cannabis.¹³⁷ Others opposed confining authorisation powers to specialists.¹³⁸ The debate primarily came down to a question of access against control and expertise.
- 3.145 The question of access raises issues such as cost, waiting times and the need to travel to a metropolitan centre. Few specialists routinely travel to regional centres, meaning that significant time and expense can be associated with arranging to see one.¹³⁹ Jeni Martin submitted that confining authorisation powers to specialists would 'impact heavily on invalid pensioners and people in rural and remote areas'.¹⁴⁰
- 3.146 On the other hand, it was observed that 'telemedicine' has made it easier for people in the regions to access specialists.¹⁴¹ Mullaways Medical Cannabis Pty Ltd stated that, even though specialists are seen infrequently, most people in exceptional circumstances 'have a team of doctors overseeing their treatment'.¹⁴²
- 3.147 Some on the Commission's medical advisory committee raised concern about the pressure that could be placed on general practitioners by their patients.¹⁴³ Equally, it was submitted that permitting only specialists to authorise would create a bottleneck, leading to long waiting lists.¹⁴⁴
- 3.148 The need for expertise in treating the patient's condition suggests that it should be specialists who can authorise access. The Royal Australasian College of Physicians recommended that only specialist medical practitioners in relation to the condition that cannabis is intended to treat¹⁴⁵ should be able to authorise access. For example, paediatric neurologists would authorise for paediatric epilepsy, while adult neurologists would authorise for multiple sclerosis:
- This restriction is proposed because... there is a long list of proposed conditions for which medicinal cannabis has been suggested. This would avoid a sudden influx of prescriptions that may be otherwise inappropriate and prior to other treatment options being explored.
- 3.149 Professor David Penington, on the other hand, drew attention to palliative care, where services are increasingly being offered at the primary care level, with more patients seeking to die at home. In these circumstances, he submitted, it would be appropriate for general practitioners to be able to authorise access.¹⁴⁶

Commission's conclusion

- 3.150 The Commission considers that access to cannabis should be able to be authorised only by specialist medical practitioners.¹⁴⁷ It acknowledges that this significantly limits access, particularly in regional areas, but considers that this compromise is necessary to ensure expertise, especially in the early phases of the scheme.

136 Namely, medical practitioners registered under the *Health Practitioner Regulation National Law* in a specialty approved by the Australian Health Workforce Ministerial Council under s 13 that Law: see *Health Practitioner Regulation National Law*, s 4 (definitions of 'specialist' and 'recognised specialty'). A current list of the approved specialties is available on the Medical Board of Australia website: <<http://www.medicalboard.gov.au>>

137 Advisory committee (Meeting 1); Submissions 31, 32, 42, 60.

138 Submission 7.

139 Consultations 23, 24.

140 Submission 7. Submission 49 agreed with this concern as it relates to remote patients.

141 Consultation 8.

142 Submission 29.

143 Advisory committee (Meeting 1).

144 Advisory committee (Meeting 1).

145 Analogously to high-cost cancer drugs, which may only be prescribed by oncologists. Commonwealth Department of Human Services, *Education Guide—Efficient Funding of Chemotherapy*, 11 March 2015 <<http://www.humanservices.gov.au>>.

146 Submission 24.

147 Cf *Poisons Regulations 1965* (WA) rr 38C–38P. These provisions state that, in Western Australia, certain named substances (eg thalidomide) shall not be prescribed except by certain specialists (eg a physician or a dermatologist). Substances like these are restricted using the 'warrant' system in Victoria: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) pt 2 div 9

- 3.151 The experience of other jurisdictions has shown the dangers of making the power to authorise too wide. In Arizona, the ‘vast majority’ of patient certifications have come from naturopaths, even though there are ten times as many medical doctors in the state. Arizona’s Director of Health Services reportedly said that ‘not all naturopaths are writing certifications, but a handful of them are clearly in the certification business’.¹⁴⁸ In Colorado as at 2012, more than two per cent of the state’s population had received a medicinal cannabis recommendation and 49 per cent of medicinal cannabis recommendations had been issued by only 15 medical practitioners.¹⁴⁹
- 3.152 One of the recommended regulatory objectives of any Victorian medicinal cannabis scheme is to ‘integrate the use of medicinal cannabis products into the patient’s medical treatment’,¹⁵⁰ which requires that the use is under medical supervision. At the outset of the scheme, it is important that focus is directed to developing and sharing knowledge about the effects of treatment with medicinal cannabis for patients with the medical conditions covered by the scheme. As specialists are better placed to review evidence and conduct research in their area of speciality, it would be more appropriate to place this responsibility with them. The Commission also notes concerns about the extent to which authorisation decisions could be influenced by the ideological views of the practitioner, and this would be easier to identify and contain where a smaller number of practitioners are involved.

Which specialists?

- 3.153 Some medicinal cannabis schemes in other jurisdictions require a practitioner who authorises access to have a pre-existing relationship with the patient. AMA Victoria opposed this approach, noting that ‘it is becoming increasingly uncommon for a person to have a long-standing physician-patient relationship with a specific medical practitioner’.¹⁵¹
- 3.154 Another submission, from an individual, also opposed requiring a pre-existing relationship:
- I currently must wait anywhere between 2–3 months to access my treating specialists. If an established relationship with such a physician is required (as is required in some overseas jurisdictions) before access is granted to a patient, it could realistically take patients like myself, 12 months or more, before they were able to have access to medicinal cannabis.¹⁵²
- 3.155 The Commission agrees and does not propose that the authorising specialist be required to have an existing relationship with the patient, although it notes that in many instances the authorising specialist will be the patient’s treating specialist practitioner.

148 Owen Dyer, ‘The Growth of Medical Marijuana’ (2013) *British Medical Journal* 347:f4755.

149 Elin Kondrad and Alfred Reid, ‘Colorado Family Physicians’ Attitudes Toward Medical Marijuana’ (2013) 26 *Journal of the American Board of Family Medicine* 52, 52–53.

150 See [1.33]–[1.40].

151 Submission 38.

152 Submission 43.

3.156 The precise categories of specialists would require consultation between government and medical professionals. However, the Commission notes that the following categories may be appropriate:

Condition	Specialist categories
Cancer	Specialist medical oncologists Specialist radiation oncologists Specialist palliative medicine physicians Specialist haematology physicians Specialist paediatric haematologists Specialist paediatric medical oncologists Specialist gynaecologists
HIV AIDS	Specialist infectious diseases physicians Specialist pain medicine physicians
Multiple sclerosis	Specialist neurologists Specialist paediatric neurologists Specialist rehabilitation physicians
Epilepsy	Specialist neurologists Specialist paediatric neurologists
Pain	Specialist pain medicine physicians

Involving general practitioners

3.157 Monitoring a patient’s use of medicinal cannabis is essential to ensure that their treatment is safe and medically appropriate, and in particular that dosages are correct and that adverse effects (including, potentially, the development of dependence or the experience of side effects) are monitored and suitably addressed. In the Commission’s view, return visits to a medical practitioner should be required at regular intervals—say, three monthly—to ensure continuing monitoring and care.

3.158 The Commission has noted that permitting only specialists to authorise treatment with medicinal cannabis would limit the accessibility of the scheme. The access considerations raised earlier apply to an even greater degree for this aspect of the scheme, such that making the specialist responsible for monitoring would compound the accessibility issues further. Therefore, the Commission considers that this supervisory role should be the principal responsibility of general practitioners; of course, it would generally be shared with the treating specialist practitioner.

- 3.159 To address this, some of those consulted by the Commission proposed that treatment with medicinal cannabis could be authorised at first by a specialist and then be supervised by a general practitioner.¹⁵³ The general practitioner would supervise the patient's use and response, but would be unable to authorise access. It was suggested that general practitioners would not need cannabis training, and that they could obtain sufficient guidance from the authorising specialist.¹⁵⁴
- 3.160 The Commission endorses this approach as one which strikes an appropriate balance between access and expertise. It is suggested that a person could be authorised by their specialist for a set period (say, 12 months), with continuing access contingent on their returning at set intervals (say, every three months) to a nominated general practitioner. The implementation of this aspect of the scheme should be careful to avoid a situation in which practitioners mechanically continue treatment without considering the patient's response.
- 3.161 At the conclusion of the period of authorisation, it would be standard (and necessary) practice for the general practitioner to report back to the authorising specialist regarding patient outcomes, adverse effects, dosage control and similar. The Commission considers that this need not be the subject of a specific recommendation.
- 3.162 General practitioners who are to be involved in the monitoring of a patient's use of medicinal cannabis would need to obtain satisfactory knowledge with respect to medicinal cannabis, as they would with respect to any new drug which they prescribe or whose effects they need to monitor.

Recommendation

- 7 Specialist medical practitioners should determine which eligible patients should receive treatment with medicinal cannabis, while general practitioners should have principal responsibility for monitoring the efficacy and side effects of the treatment.**

Practitioner's role

Authorisation models

- 3.163 A number of models for the type of authorisation system Victoria should adopt were proposed to the Commission and identified in the systems that exist overseas. The two most common models about which submissions were received were the certification and prescription models.
- 3.164 Under a 'certification' model,¹⁵⁵ a medical practitioner has no role other than to certify that a patient has at least one of the eligible conditions and/or symptoms. No product or dose is specified by the practitioner and, accordingly, patients may purchase whatever they wish, subject to any statutory purchase limits. Importantly, the certification decision does not require the practitioner to make an assessment of whether cannabis would be appropriate for the particular patient, including by considering the benefits and risks for them; rather, their role is merely to confirm the patient's diagnosis.

153 Advisory committee (Meeting 1); Submission 20.

154 Advisory committee (Meeting 1).

155 This is the model used in all United States jurisdictions where retail sales of medicinal cannabis are permitted, primarily because medical practitioners there are forbidden to prescribe cannabis, but permitted by their constitutional right to free speech to 'recommend' cannabis to patients: Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.103]. The previous Canadian model also used such a system: *Marihuana Medical Access Regulations* SOR/2001-227, s 6(1).

- 3.165 A ‘prescription’ model,¹⁵⁶ by contrast, involves a medical practitioner prescribing a particular form of cannabis, as they would for any other medicine. The practitioner specifies the product, dosage and frequency of administration, in the form of a ‘written direction... to a pharmacist for preparing and dispensing a drug’.¹⁵⁷ Practitioners are required to make an assessment of whether cannabis would be beneficial for the patient, having regard to its risks and benefits, and can decline to prescribe if they feel medicinal cannabis would be inappropriate.
- 3.166 The chief differences between these approaches are the depth of assessment of the patient’s circumstances made by the medical practitioner, and whether the practitioner is asked to specify the product the patient should receive.
- 3.167 Many submissions suggested there would be difficulties implementing the ‘prescription’ model without an approved product standardised in the usual way.¹⁵⁸ One member of the Commission’s medical advisory committee stated that, on the basis of the evidence currently available, they would not prescribe it.¹⁵⁹ The Royal Australasian College of Physicians made this point clearly:
- It is unacceptable for a doctor to be asked to authorise a patient’s use of or prescribe a substance of unknown composition and uncertain clinical effects.¹⁶⁰
- 3.168 Professor David Penington also thought that adopting the prescription model presented difficulties:
- Use of a herbal product without the usual rigorous trials with testing of outcomes, dose and side effects would be unlikely to be acceptable to medical practitioners for ‘prescription’.¹⁶¹
- 3.169 A number of other submissions advanced a certification model as their preferred option.¹⁶² That is, they proposed that the practitioner’s role be limited to confirming the patient’s diagnosis, and not extend any further.¹⁶³ The Royal Australasian College of Physicians was among those seeking a ‘certification’ model:
- In the absence of a reliable supply of cannabis products of known and certified composition, the doctor’s responsibilities must be confined to certification of a person’s eligibility ... and the monitoring of drug interactions and adverse effects.¹⁶⁴
- 3.170 Consistently with his reservations regarding prescriptions, Professor Penington also suggested that certification would be a more appropriate role for medical practitioners:
- Fears over medico-legal hazards in prescribing a herbal remedy can be overcome if effective regulation of the products is established, and the role of the medical practitioner is that of certifying, with the patient’s agreement, the nature of the patient’s clinical condition, in relation to those uses approved by legislation. The legislation could require this as a condition to register as a medicinal cannabis user. The relationship between doctor and patient would not be disturbed with the doctor free to give advice at any stage.¹⁶⁵
- 3.171 Shirley Humphris echoed these views:
- A doctor maybe would not exactly prescribe cannabis in the usual way (doctors may fear potential litigation for ‘prescribing’ an untested product with unknown dosage) but rather certify the illness or symptoms. It would then be legal to have the discussion

156 This is the model used in the Netherlands: Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.101].

157 *Oxford Concise Medical Dictionary* (9th ed, 2015) 612 (definition of ‘prescription’).

158 Submissions 24, 49.

159 Advisory committee (Meeting 3).

160 Submission 52.

161 Submission 24.

162 Submissions 10, 24, 29, 30, 35, 37, 72.

163 Heather Marie Gladman stated in Submission 10, for example, that the practitioner’s role should be limited to ‘[t]he ability to sign a form saying this person can use medicinal cannabis. That’s it.’

164 Submission 52.

165 Submission 24.

with the doctor re risks and benefits without fear of being informed on. Importantly the doctor would be able to run tests to monitor the effect cannabis may be having on existing meds (it is known ... the concentration of some epilepsy meds are affected by cannabis).¹⁶⁶

- 3.172 A number of other submissions advocated for the prescription model, supporting the maintenance of discretion for medical practitioners.¹⁶⁷ Jeni Martin stated, '[w]e need to trust that our medical professionals are generally conservative & unlikely to prescribe or recommend medicinal cannabis without adequate reasons.'¹⁶⁸

The preferred authorisation model

- 3.173 The system of authorisation should be acceptable to the medical profession. The effective participation of medical practitioners is a key to the success of any medicinal cannabis scheme.¹⁶⁹ The fact that medical practitioners were not comfortable with their role as gate-keepers in Canada has led to a number of the problems in consolidating the operation of the scheme in that country.¹⁷⁰

- 3.174 The Commission acknowledges that there are significant difficulties associated with asking medical practitioners to 'prescribe' medicinal cannabis. If Victoria were to make available medicinal cannabis products that are quality-controlled and standardised for cannabinoid content, they would not be in the nature of medicines 'approved' by the TGA¹⁷¹ and thus medical practitioners would not have the usual level of information to decide whether prescription was warranted and what product and dose should be prescribed.

- 3.175 Prescription-type models have given rise to objections from the medical profession in other jurisdictions. In opposing the shift from a 'certification' model to an 'authorisation' model, the College of Family Physicians of Canada stated:

In our view, Health Canada places physicians in an unfair, untenable and to a certain extent unethical position by requiring them to prescribe cannabis in order for patients to obtain it legally. If the patient suffers a cannabis-related harm, physicians can be held liable, just as they are with other prescribed medications. Physicians cannot be expected to prescribe a drug without the safeguards in place as for other medications—solid evidence supporting the effectiveness and safety of the medication, and a clear set of indications, dosing guidelines and precautions.¹⁷²

- 3.176 The 'certification' model has a range of drawbacks, however. In merely certifying a patient's diagnosis, the medical practitioner does not consider whether there are any particular features of the patient (such as history of drug dependency, poor cardiovascular health or a strong family history of psychosis) which might make cannabis inappropriate for them. It also ordinarily does not involve the practitioner in the selection of an appropriate formulation or strength, leaving the patient to determine this for themselves.¹⁷³ This is problematic for patients, with some of those currently using cannabis telling the Commission they did not believe patients should be left to work out the best product on their own.¹⁷⁴

166 Submission 49.

167 Submissions 2, 23. Many called for the doctor's role to be the same as for any other medicine: Submissions 9, 18, 28, 45.

168 Submission 7.

169 Submission 57.

170 See Ian Freckelton, 'Medicinal Cannabis Law Reform: Lessons from Canadian Litigation' (2015) 22 *Journal of Law and Medicine* 719.

171 See [4.64]–[4.65] and Chapter 7.

172 The College of Family Physicians of Canada, 'The College of Family Physicians of Canada Statement on Health Canada's Proposed Changes to Medical Marijuana Regulations' (Position Statement, February 2013).

173 Under the system of licensed producers in Canada, medical practitioners do not specify the type of cannabis to be used on a patient's 'medical document'. In addition, licensed producers are prohibited by Health Canada from recommending strains to patients as the best for treating a particular condition. As a result, a set of cannabis 'consultants' have started operations in Canada, in part to give patients advice on strain selection and administration methods, in a context where the strains a patient can obtain are virtually unlimited: Consultation 20.

174 Consultation 13.

- 3.177 The Commission considers that, notwithstanding the discomfort of many members of the medical profession with the ‘prescription’ model, a scheme which does not involve the medical practitioner in a consideration of the risks and benefits for the particular patient would be an intolerable policy outcome. Patients should not be left to determine, on their own, whether medicinal cannabis is appropriate for them, and what form of it they should obtain.
- 3.178 In the Commission’s view, a patient’s treating medical practitioner should be required to consider, for the patient before them, whether cannabis would be an appropriate treatment, having regard to the considerations that would usually inform their clinical decision making. This reinforces the notion, expressed above, that a medicinal cannabis scheme should be centred on treatment by a medical practitioner. It is also consistent with the requirement under international law that drugs such as cannabis be used in a ‘rational’ way.¹⁷⁵
- 3.179 Consequently, the Commission considers that, when deciding whether to authorise a patient to access medicinal cannabis, a medical practitioner should be required to make the same assessment as would be made for prescription medicines.¹⁷⁶ This would include a consideration of:
- the likely benefits for the patient,
 - the patient’s risk factors and the significance of those risks for the particular patient
 - the availability of other treatments the patient has not yet tried
 - whether there is a likelihood of abuse.
- 3.180 In addition, the medical practitioner should select the product and dosage the patient will receive. While the products would not be approved by the TGA, a Victorian scheme could limit and standardise the range of products available, giving practitioners confidence, as in the Netherlands, in the products they prescribe.¹⁷⁷ In the Commission’s view, such an approach is essential to fulfilling the regulatory objective of integrating medicinal cannabis into the patient’s medical treatment.
- 3.181 It is inevitable that some practitioners would hesitate at the outset to make decisions under this model in the absence of an approved product. However, analogous decisions are often made by medical practitioners in the context of off-label prescribing; by extension, they can be made in the context of medicinal cannabis. As the scheme evolves, and more information about dosage and effect is assembled and made available through continuing medical education programs, medical practitioners’ knowledge and experience will grow. This is reflected in the Canadian experience. At the start of the Canadian medicinal cannabis program, the number of practitioners signing authorisations was very small, while today significant numbers are involved in the scheme.¹⁷⁸ Practitioners are also reportedly growing in their acceptance of the scheme, with professional networks and training programs becoming more established.¹⁷⁹

Similarity to off-label and unlicensed prescribing

- 3.182 Medicinal cannabis products supplied under a Victorian scheme may have not been approved by the TGA, and this would place medical practitioners in the difficult position of dealing with substances for which dosages and reactions are not clearly quantified by virtue of research conducted methodically under controlled circumstances on human subjects with a variety of different conditions. However, models for this type of prescribing can be found in ‘off-label’ and ‘unlicensed’ prescribing.

175 See [4.10].

176 That is, whether a ‘therapeutic need’ exists for the medication: *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) reg 8. Consultation 28.

178 Ian Freckelton, ‘Medicinal Cannabis Law Reform: Lessons from Canadian Litigation’ (2015) 22 *Journal of Law and Medicine* 721.

179 Consultation 20.

- 3.183 Off-label prescribing involves the provision of approved drugs in situations¹⁸⁰ for which they are not approved.¹⁸¹ Unlicensed prescribing, on the other hand, involves the provision of drugs not approved for any indication. Off-label prescribing is widespread, particularly in areas such as paediatrics, oncology, psychiatry and palliative care.¹⁸²
- 3.184 Joe Collier explains the ‘clinical and ethical dilemmas’ associated with off-label and unlicensed prescriptions:
- The licensing arrangements ensure a rigorous assessment of each medicine, using volumes of data ... on the efficacy and safety of the product when used for a given indication. Tight controls are set on the quality of the product, and when it is given according to the recommendations in the [product information] the authority calculates that it is more likely to improve patient wellbeing than do harm. ... When a medicine is prescribed outside of these arrangements, this support is absent and treatment tends to be based more on assumptions and extrapolations.¹⁸³
- 3.185 Guidelines issued by the Council of Therapeutics Advisory Groups in 2013 state that off-label prescribing should ordinarily only be considered where all other options, including medicines approved by the TGA, are unavailable, exhausted, not tolerated or unsuitable.¹⁸⁴ They instruct practitioners that, if there is high-quality evidence to support a proposed use, off-label use is generally appropriate but if only lesser quality evidence exists and the potential benefits appear greater than the potential harms, use should be confined to exceptional cases or be allowed conditionally, subject to review. If there is no evidence at all, use should be confined to a clinical trial.¹⁸⁵
- 3.186 In this regard, the Royal Australasian College of Physicians drew a link between unapproved but standardised cannabis products and clinical trials:
- If a reliable and legal supply of a purified form of medicinal cannabis is established in Victoria, but an absence of trial data concerning efficacy, safety and dosing information persists, the doctor’s role in prescribing medicinal cannabis should be as per the conduct of a clinical trial.¹⁸⁶
- 3.187 The essential difference between a decision to prescribe a medicine off-label and the decision to prescribe in an approved way is that a practitioner must exercise greater judgment about whether a use is appropriate for the patient when prescribing off-label. In the case of unapproved medicines sought to be accessed through the Special Access Scheme, a similar judgment is required, but the ultimate decision maker is the TGA. These decisions are much more guided and constrained where a medicine is prescribed within the scope of its approval, where the risks and benefits have been assessed in advance by the TGA.

180 This could include prescribing an unapproved dose, for an unapproved indication, outside the approved age range or via an unapproved route: Council of Australian Therapeutics Advisory Groups, *Rethinking Medicines Decision-Making in Public Hospitals: Guiding Principles for the Quality Use of Off-Label Medicines* (November 2013) 4.

181 Off-label prescribing is not prohibited under Commonwealth or Victorian law, but a sponsor is not permitted to promote the use of a drug in an unapproved way: Council of Australian Therapeutics Advisory Groups, *Rethinking Medicines Decision-Making in Public Hospitals: Guiding Principles for the Quality Use of Off-Label Medicines* (November 2013) 6.

182 Council of Australian Therapeutics Advisory Groups, *Rethinking Medicines Decision-Making in Public Hospitals: Guiding Principles for the Quality Use of Off-Label Medicines* (November 2013) 6.

183 Joe Collier, ‘Paediatric Prescribing: Using Unlicensed Drugs and Medicines Outside Their Licensed Indications’ (1999) 48 *British Journal of Clinical Pharmacology* 5, 6.

184 Council of Australian Therapeutics Advisory Groups, *Rethinking Medicines Decision-Making in Public Hospitals: Guiding Principles for the Quality Use of Off-Label Medicines* (November 2013) 10.

185 *Ibid* 9.

186 Submission 52.

Children and vulnerable patients

3.188 By adopting usual practices for the authorisation of medicines, there would be no need to adopt special rules for the eligibility of children and other vulnerable patients—medical practitioners would apply the same considerations as they would for other types of medicines. As the Royal Australasian College of Physicians submitted, for such patients, provided the practitioner ensures there is a medical need for the prescription and it is in the patient’s best interests, the same considerations should apply as for any other treatment.¹⁸⁷

Acknowledging difference

3.189 In acknowledgement of the fact that medicinal cannabis remains of a fundamentally different nature to other medications ordinarily supplied on prescription—in particular, that the products made available under a Victorian scheme would not have received TGA approval—the Commission considers that a different name should be used for the document that authorises medicinal cannabis to be dispensed to a patient. It suggests that it be referred to as an ‘Authority to Dispense’.

Patient education and monitoring

3.190 There are a number of reasons why that the use of medicinal cannabis by patients should be closely supervised by a medical practitioner. These include:

- Potential psychiatric and other harms associated with cannabis, including the development of dependence or psychosis, should be monitored by an independent expert.
- Cannabis has the potential to interact with other medications.¹⁸⁸
- Dose-response effect should be reviewed regularly to ensure that the form of administration, type of medicinal cannabis and quantity of active constituents can be titrated and adjusted to achieve optimally beneficial effect.
- Patients should be encouraged not to cease other necessary medications.
- Cannabis should be used as only one part of treatment provided by medical practitioners to patients for serious conditions from which they suffer.

3.191 Submissions called for medical practitioners to play a role in educating and assisting patients. JB, for instance, stated that practitioners should:

provide educational material to a patient outlining the benefits, advantages, disadvantages, side effects (if any), dosages, follow up appointments to ascertain the benefits and progress of the patient after commencing medicinal cannabis¹⁸⁹

3.192 The Commission agrees with these comments and emphasises that monitoring by a medical practitioner of the authorised use of cannabis for medicinal purposes is essential, whichever model of authorisation is adopted.

187 Submission 52. The Royal Australian College of Physicians also observed that, for children, consent to be treated with medicinal cannabis would be a matter of parental responsibility, as set out in *Re: Sean and Russell (Special Medical Procedures)* [2010] FamCA 948, subject to whether the minor is capable of understanding the medical treatment proposed and of providing informed consent on their own behalf: *Gillick v West Norfolk Area Health Authority* [1986] AC 112.

188 For example, there is research to suggest that cannabis may interact with Atazanavir, an antiretroviral drug commonly used in the treatment of HIV: Q Ma et al, ‘Tobacco and Marijuana Use Significantly Decrease Atazanavir (ATV) Trough Concentrations in HIV-Infected Individuals’, paper presented to the 49th Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, 15 September 2009, cited in ACON and others, Submission to NSW Legislative Council *Inquiry into the Use of Cannabis for Medical Purposes* (February 2013).

189 Submission 11.

Legal procedures

3.193 The above passages considered the substantive obligations which should be imposed on medical practitioners in connection with authorising use of medicinal cannabis. This section will consider how those obligations should be reflected in law.

Permit requirement

- 3.194 In the Commission's view, the legal arrangements for patient authorisation should be modelled on the permit requirement for prescription of opioid replacement therapy.¹⁹⁰ A specialist medical practitioner who wishes to authorise medicinal cannabis to be dispensed should first seek a permit from the Secretary of the Department of Health and Human Services. A permit would have to be sought in all cases.¹⁹¹
- 3.195 The Secretary of the Department of Health and Human Services should have discretion to decline to issue a permit where the patient is identified as having diverted their supply of medicinal cannabis to an unauthorised person or deceived their medical practitioner concerning their eligibility. As medicinal cannabis would be supplied under the scheme to gravely ill people, this would not be appropriate as a general rule, but a discretionary power to refuse may be appropriate in particular cases.¹⁹² The Secretary should also have discretion to refuse in other scenarios, such as where false or misleading information has been supplied in seeking a permit¹⁹³ or where another practitioner has already been issued a permit in respect of that patient.
- 3.196 Because each permit application would be associated with a particular patient and a particular medical practitioner, the system would allow the Department to supervise patients and authorising practitioners. There would need to be a means for pharmacists dispensing medicinal cannabis to confirm that a permit has been granted for a patient. For consistency with other permits, appeal rights should be created for persons affected by permit refusal.¹⁹⁴
- 3.197 Regulations would control the content of the permit application form, thereby enabling the Secretary to collect data regarding the use of medicinal cannabis.¹⁹⁵ The permit itself would contain specified information, including:
- the duration of the permit, not to exceed 12 months
 - the name and address of the patient
 - the name of the general practitioner or clinic with principal responsibility for monitoring the efficacy and side effects of the treatment
 - the pharmacy at which the patient or carer will obtain medicinal cannabis
 - the names of any carers who will collect or administer the medicinal cannabis.
- 3.198 Following the issue of a permit to the specialist medical practitioner, an 'Authority to Dispense' could be issued in accordance with the permit. This document would perform the same function as a prescription, in that it would authorise a pharmacist at the nominated pharmacy to dispense a stated product and amount of medicinal cannabis to the patient or their nominated carer.

190 See *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 34. The scheme for opioid replacement therapy is technically a subset of the Schedule 8 permit scheme.

191 As for opioid replacement therapy. While opioid replacement drugs are Schedule 8 poisons, for which permits are only required in certain circumstances, they are always required if the patient is drug dependent, which opioid replacement therapy patients always are. See *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 34(1).

192 By way of comparison, pharmacotherapy (eg methadone) can continue to access opioid replacement drugs even if they have diverted their medication to third parties.

193 Cf *Medical Marijuana Access Regulations* (Can) (SOR 2001/227) s 12(1)(b).

194 If a permit to prescribe is refused by the Secretary under the existing scheme for permits to prescribe Schedule 8 or Schedule 9 drugs, any person who feels aggrieved by such a decision may appeal the decision to the Magistrates' Court within six months: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 37.

195 Cf *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 19 and sch 2 Form DP2A.

- 3.199 After the initial Authority to Dispense is made by the specialist, Authorities to Dispense would generally be given by the patient's general practitioner. This means that patients would need to consult their general practitioner periodically in order to continue the treatment, so that the general practitioner can monitor relevant symptoms. For this reason it is important for the general practitioner to be able to amend the product or dosage.
- 3.200 It should be noted that, under the opioid replacement therapy permit schemes, many aspects of prescribing and approval practices are set out in departmental policies.¹⁹⁶ This approach could be replicated for medicinal cannabis, so that the requirement for the applicant to be a specialist, refusal of permits, prescribing practices and so on can be governed more flexibly than if these matters were specified in legislation.

Recommendations

- 8** A specialist medical practitioner who is registered with the Medical Board of Australia within a prescribed category for the medical condition on which their patient's eligibility is based should be able to apply to the Secretary of the Department of Health and Human Services for a permit to issue an Authority to Dispense Medicinal Cannabis in respect of that patient. The application should state that:
- (a) The patient's condition and associated symptoms meet the eligibility criteria of the scheme.
 - (b) It is appropriate in all the circumstances that the patient be treated with medicinal cannabis.
 - (c) The patient has been informed and accepts that the medicinal cannabis product they will receive will not have been tested for efficacy and side effects by the Therapeutic Goods Administration, and has been informed of other treatments which have been so tested, along with the risks, potential benefits and side effects, including long-term effects, of each.
 - (d) The patient has been informed that information about their treatment will be collected and used for scheme evaluation and research purposes.
- 9** The Secretary of the Department of Health and Human Services should have the power to issue a permit to a specialist medical practitioner if satisfied that:
- (a) The specialist medical practitioner is registered as a specialist with the Medical Board of Australia within a prescribed category for the medical condition on which patient eligibility is based.
 - (b) The patient ordinarily resides in Victoria.
 - (c) There is not an unacceptable risk that the patient will abuse the terms of the permit.

Permit delegation

- 3.201 As noted above, while the initial power to authorise a patient to be treated with medicinal cannabis should rest with a specialist medical practitioner, supervision of the patient ought to be the role of approved general practitioners. The permit system could also be used to implement this. Under the existing permit system for Schedule 8 opioid replacement therapy drugs, medical practitioners can delegate to another practitioner at the same practice, who can prescribe to existing patients during times when they are absent. A similar approach could be taken for medicinal cannabis. While the permit would be sought by the authorising specialist medical practitioner, that practitioner could delegate to a general practitioner or clinic named on the permit to continue treatment with medicinal cannabis.
- 3.202 Authorities to Dispense medicinal cannabis would only authorise a set number of months' worth of medicinal cannabis to be dispensed. In order to continue receiving medicinal cannabis, a patient would need to return regularly to their general practitioner to obtain a further Authority to Dispense. The general practitioner should have the ability to select the product to be dispensed, and should not be constrained to select the product originally identified by the specialist. As with prescriptions, the Authority to Dispense would specify how much could be purchased and how often.

Recommendations

- 10** A valid permit should entitle the specialist medical practitioner, or a general practitioner identified on the permit, to issue an Authority to Dispense Medicinal Cannabis. An Authority to Dispense Medicinal Cannabis would:
- authorise a pharmacy or pharmacy department identified on the permit to dispense medicinal cannabis in accordance with specified instructions
 - enable no more than three months' supply of the medicinal cannabis products to be dispensed to the patient or carer at a time.
- 11** The permit issued to a specialist medical practitioner by the Secretary of the Department of Health and Human Services should specify:
- the duration of the permit, not to exceed 12 months
 - the name and address of the patient
 - the name of the general practitioner or clinic with principal responsibility for monitoring the efficacy and side effects of the treatment
 - the pharmacy at which the patient or carer will obtain medicinal cannabis
 - the names of any carers who will collect or administer the medicinal cannabis.
- 12** An Authority to Dispense Medicinal Cannabis issued by a specialist medical practitioner or a general practitioner should specify:
- the product and dosage
 - the name and address of the patient
 - the pharmacy at which the patient or carer will be dispensed medicinal cannabis
 - the names of any carers who may collect or administer the medicinal cannabis.

Informed consent

- 3.203 The likelihood that medicinal cannabis provided under a Victorian scheme would not have been approved in a conventional fashion (namely by the TGA) raises some risks of an uncertain level for patients. There is a need for medical practitioners to ensure that, in light of this uncertainty, they pay particular attention to obtaining properly informed consent from the patient prior to authorising the dispensing of medicinal cannabis.
- 3.204 The TGA's 'authorised prescriber' scheme, which allows medical practitioners to seek approval to supply individual patients with unapproved goods (such as those which are used in a clinical trial or have been withdrawn from the Australian market) recommends that patients be specifically informed of the following matters before giving consent to treatment:
- that the product is not approved (that is, registered or listed) in Australia
 - the possible benefits of treatment and any risks and side effects that are known
 - the possibility of unknown risks and late side effects
 - any alternative treatments using approved products which are available.¹⁹⁷
- 3.205 The Commission considers that a similar set of matters should be required to be part of the discussion between practitioner and patient in obtaining informed consent to treatment with medicinal cannabis. Importantly, this means that the patient assumes the risks associated with using a drug that is unapproved, but only in circumstances where they have been supplied with a sufficient level of information that they are able to do so in an informed way. The Department of Health and Human Services may wish to consider developing a standard patient consent form, similar to that used in clinical trials.¹⁹⁸

Liability and indemnity

- 3.206 Medical practitioners involved in a Victorian medicinal cannabis scheme may be concerned that, in authorising unapproved medicinal cannabis products, they could be liable civilly or professionally for consequences flowing from that decision, particularly where the available information regarding the efficacy and side effects of medicinal cannabis is comparatively limited. A medical practitioner may face legal consequences if they fail to inform a patient of a risk which they knew would be significant to the patient.
- 3.207 In *Rogers v Whitaker*, the High Court held that a medical practitioner has a duty to warn a patient of any 'material' risks inherent in a proposed treatment. A risk would be 'material' if, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to it if warned of its existence, or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.¹⁹⁹ However, liability in negligence will only be established if it can be proven that, had they been informed of the particular risk, the patient would not have proceeded to obtain the treatment.²⁰⁰

197 Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods: Authorised Prescribers* (October 2004) 12.

198 See the various patient information and consent forms available at Department of Health, *Clinical Trial Research: How to Make an HREC Application* (24 June 2015) <<http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm>>.

199 (1992) 175 CLR 479, 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).

200 *Rosenberg v Percival* (2001) 205 CLR 434, 443 (McHugh J). The test in Australia is a subjective test of causation; that is, it relies on what the specific patient would have done, not a hypothetical reasonable patient.

- 3.208 This analysis can become more complicated where a treatment is experimental, or little is known about its risks and efficacy. A practitioner would be obliged to give a patient a balanced overview of the evidence regarding such matters and, where little is known, to indicate this.²⁰¹ Medical practitioners also have a duty to stay informed regarding developments in the literature where experimental treatments are involved.²⁰² Ultimately though, the decision whether to consent to treatment, once properly advised, resides with the patient.²⁰³
- 3.209 In addition to civil liability, failure to obtain informed consent can give rise to breaches of a medical practitioner's professional obligations.²⁰⁴ This requirement is, at heart, about ensuring that the treatment undertaken by the patient is entirely voluntary.²⁰⁵ National guidelines state that a patient's informed consent must be obtained before treatment is administered, and specify the matters that must be brought to a patient's attention.²⁰⁶
- 3.210 In Canada, medical practitioners are required to make an individualised assessment of whether cannabis would be appropriate for the specific patient (although this assessment falls short of a prescription²⁰⁷). The Canadian Medical Protective Association, which is the main insurer of the Canadian medical profession, advises that practitioners:
- should not feel obligated to complete the medical document for medical marijuana if they are unfamiliar with its treatment or use, or if they feel it is medically inappropriate for a patient. Physicians who choose to complete a medical document should rely on sound medical judgment and comply with their College's relevant guideline or policy.²⁰⁸
- 3.211 Notably, too, practitioners have the advantage of a comprehensive document issued by Health Canada.²⁰⁹
- 3.212 The Commission was told by advisory committee members that providers of medical indemnity insurance in Australia may refuse to provide cover for medical practitioners' activities in connection with approving access to medicinal cannabis, or may impose an increased premium if such cover is desired.²¹⁰ This would be an unfortunate response, if it occurred.
- 3.213 The Commission notes that, although medicinal cannabis products would be in the nature of unapproved drugs, existing indemnity insurance policies do not automatically exclude such drugs from the scope of their coverage, and frequently include cover for practitioners taking part in clinical trials.

201 See *Chiropractic Board of Australia v Hooper* [2013] VCAT 878, [309]–[314].

202 See *South Eastern Sydney Area Health Service v King* [2006] NSWCA 2, [71].

203 See, eg, *Rosenberg v Percival* (2001) 205 CLR 434.

204 *Medical Board of Australia v Laska* [2011] VCAT 1888 (finding that failure to obtain informed consent to a medical procedure amounted to professional misconduct for the purposes of the *Health Professions Registration Act 2005* (Vic)).

205 Cf *Charter of Human Rights and Responsibilities Act 2006* (Vic) s 10(c), which establishes that every person has a right not to be subjected to medical treatment without his or her full, free and informed consent.

206 Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (March 2014) [3.5].

207 According to the Canadian Medical Protective Association, 'the medical document issued by physicians is distinct from a prescription. Prescriptions are required to access drugs approved for use and regulated by Health Canada. Health Canada does not currently approve nor regulate medicinal marijuana. Therefore, the medical document provided by physicians to allow patients to access medical marijuana can only be considered to be analogous to a prescription in limited ways': Canadian Medical Protective Association, *Medical Marijuana: New Regulations, New College Guidance for Canadian Doctors* (July 2015) <<http://www.cmpa-acpm.ca>>.

208 Canadian Medical Protective Association, *Medical Marijuana: New Regulations, New College Guidance for Canadian Doctors* (July 2015) <<http://www.cmpa-acpm.ca>>.

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

210 Advisory committee (Meeting 3).

- 3.214 In other contexts, medical practitioners are afforded immunity under certain statutory schemes, primarily when conducting drug and forensic tests (provided they act properly or in good faith).²¹¹ The Commission notes that it would be open to the Victorian Government to provide medical practitioners (both the original specialist and the supervising general practitioner) with an indemnity or immunity in respect of their decisions on medicinal cannabis.

Patients' rights and obligations

- 3.215 Patients for whom an Authority to Dispense has been issued should have certain rights under the scheme. They would be authorised to possess and use medicinal cannabis products obtained from a pharmacy in accordance with the Authority to Dispense.
- 3.216 It would remain illegal for non-authorised persons to possess medicinal cannabis, and a patient who supplied medicinal cannabis to anyone other than an authorised professional or their nominated carer would engage in trafficking, giving rise to an offence under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).²¹² Likewise, a carer who supplied cannabis to an unauthorised person would also engage in trafficking for the purposes of the legislation.
- 3.217 The legislation should also ensure that relevant offences in the *Drugs, Poisons and Controlled Substances Act 1981* are expanded to capture the following conduct:
- fraudulently obtaining or granting an Authority to Dispense²¹³
 - representations that a product is a lawfully produced medicinal cannabis product despite it not having been manufactured under the scheme²¹⁴
 - allowing an ineligible patient to access medicinal cannabis.
- 3.218 Appendix D sets out in detail other conduct which the legislation should ensure is captured by new or existing offences.

Recommendation

- 13** New offences should be created, or existing offences expanded, proscribing dishonest conduct in relation to obtaining a permit or issuing or obtaining an Authority to Dispense Medicinal Cannabis.

Consequential changes

- 3.219 The impact of medicinal cannabis on driving would need to be considered. It is an offence to be in control of a vehicle while under the influence of a drug of dependence or with any concentration of THC in blood or saliva.²¹⁵ The evidence strongly suggests that THC impairs a person's ability to drive.²¹⁶ While some jurisdictions overseas have set the

211 Various legislation provides that 'no action lies' against a medical practitioner who administers a forensic test: see, eg, *Crimes Act 1958* (Vic) s 464ZH (in respect of anything 'properly and necessarily done'), *Public Health and Wellbeing Act 2008* (Vic) s 142 (practitioner must act 'in good faith and with reasonable care'), *Road Safety Act 1986* (Vic) s 57(8) (in respect of anything done in accordance with the subject's consent).

212 Section 71AC.

213 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 78, which applies to fraudulently obtaining a prescription.

214 This may be covered under consumer protection laws.

215 *Road Safety Act 1986* (Vic) ss 49(1)(a), (ba), (bb), 4(1) (definitions of 'prescribed illicit drug' and 'prescribed concentration of drugs'). While the legislation in fact prohibits driving with more than a 'prescribed concentration' of THC in blood or saliva, that concentration is set at zero.

216 Submission 44; Rebecca Hartman and Marilyn Huestis, 'Cannabis Effects on Driving Skills' (2013) 59 *Clinical Chemistry* 478; Michael Lenné, Tom Triggs and Michael Regan, 'Cannabis and Road Safety: A Review of Recent Epidemiological Driver Impairment, and Drug Screening Literature' (Monash University Accident Research Centre Report No 231, 2004); Olaf Drummer et al, 'The Involvement of Drugs in Drivers of Motor Vehicles Killed in Australian Road Traffic Crashes' (2003) 943 *Accident Analysis and Prevention* 1; National Cannabis Prevention and Information Centre, *Driving Under the Influence of Cannabis: A Brief Review of the Literature* (2013) <<http://www.ncpic.org.au>>.

prescribed concentration of THC above zero,²¹⁷ the Commission does not recommend that this occur in Victoria. Accordingly, there would be a need to warn patients upon receipt of medicinal cannabis that their use of any THC-containing products could make them unable to drive.²¹⁸ Similar warnings should be included regarding the dangers of operating heavy machinery, aircraft, vessels and so on.²¹⁹

- 3.220 The Commission heard from people who have been adversely affected by workplace drug-testing following the use of cannabis, or feared they would be.²²⁰ Some overseas jurisdictions have introduced laws to protect lawful medicinal cannabis users from workplace discrimination as a result of their use of cannabis.²²¹ The Commission notes that Victorian anti-discrimination laws do not presently explicitly prevent discrimination on the basis of medical treatment.²²² Action taken as a result of workplace testing is primarily a private matter between an employer and employee, and employees would be protected from unreasonable actions by unfair dismissal laws,²²³ so the Commission does not recommend any changes to the law in this regard.

Other participants

- 3.221 It would not be sufficient to authorise patients alone to possess and use medicinal cannabis. Many patients, including children and the physically infirm, may be unable to travel to collect medicinal cannabis or to administer it to themselves, and would rely on others to do it for them. The scheme would need to ensure that it does not criminalise the actions of such people by failing to recognise their role and cater properly to it.
- 3.222 The legislation should therefore authorise nominated carers²²⁴ to possess medicinal cannabis, in the form and up to the amount the patient could possess themselves.²²⁵ Carers would also need to be authorised to administer the medicinal cannabis to the patient.²²⁶ The carer would not be authorised to use the medicinal cannabis themselves.²²⁷ The scheme should have a mechanism through which professionals, such as in-home carers and workers at palliative care facilities or nursing homes can also act as carers.

Recommendation

- 14** *The Drugs, Poisons and Controlled Substances Act 1981 (Vic), and the Drugs, Poisons and Controlled Substances Regulations 2006 (Vic) should be amended to allow patients and carers nominated in a valid Authority to Dispense Medicinal Cannabis, as appropriate, to obtain, possess and use the medicinal cannabis products designated in the Authority.*

217 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.110]. Washington state, where cannabis has been legalised for recreational use, allows drivers to have up to 5 nanograms of THC per millilitre of blood: Washington Department of Licensing, *Washington Driver Guide* <<http://www.dol.wa.gov>> 5-5.

218 As THC remains in a person's system for a significant time after consumption, patients may need to abstain from driving for longer than if they had consumed alcohol. *The Road Safety Act 1986* (Vic) offers a defence to people who are charged with the offence of driving a motor vehicle while impaired by a drug under s 49(1)(ba) if the drug they were impaired by was consumed in accordance with a medical practitioner's advice, and they did not and could not reasonably have known that the drug would impair their driving: s 49(3B). This defence would not, therefore, apply to a person consuming medicinal cannabis that was appropriately labelled, and in any event does not apply to the offence of driving with more than the prescribed concentration of THC in saliva.

219 See *Marine (Drug, Alcohol and Pollution Control) Act 1988* (Vic) s 28(1)(ba) and (bb); *Civil Aviation Act 1988* (Cth) s 36; *Rail Safety (Local Operations) Act 2006* (Vic) pt 6 div 3. Drug tests conducted pursuant to a court order may also be affected: Consultation 24.

220 Consultations 1, 7.

221 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.109].

222 While the *Equal Opportunity Act 2010* (Vic) prohibits discrimination on the basis of disability, disability is not defined by reference to loss or impairment of bodily functions, rather than by reference to the treatment of any such disorder: ss 6 and 4(1) (definition of 'disability').

223 See Jim Nolan, 'Employee Privacy in the Electronic Workplace Pt 2: Drug Testing, Out of Hours Conduct and References' (2000) 7 *Privacy Law & Policy Reporter* 139.

224 Nominated on the authority: see [3.197]. A definition of 'carer' can be found in the *Carers Recognition Act 2012* (Vic) s 4.

225 This could be achieved by an amendment to the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 5, which, among other things, authorises persons who have the care of or are assisting in the care of a patient authorised to possess a scheduled poison to do so themselves: item 7.

226 This would otherwise be an offence under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 74. If the patient is a child, the offence of supplying a drug of dependence to a child may also apply: s 71B.

227 This could be achieved by an amendment to the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 45, which states that a person must not administer or use a Schedule 4, 8 or 9 poison except in the treatment of the person for whom it was prescribed.

- 3.223 The legislation would also need to ensure that registered medical practitioners, pharmacists, nurses and nurse practitioners were authorised to possess, supply and/or administer medicinal cannabis products.²²⁸ This would be unnecessary if medicinal cannabis products were treated as Schedule 9 Poisons under the legislation. However, as explained below, a new category of substance would need to be created for medicinal cannabis products, meaning that cannabis-specific authorisation provisions would be required.

Recommendation

- 15** *The Drugs, Poisons and Controlled Substances Act 1981 (Vic), and the Drugs, Poisons and Controlled Substances Regulations 2006 (Vic) should be amended to allow medical practitioners, registered nurses and pharmacists who participate in any Victorian medicinal cannabis scheme to obtain, have in their possession, administer, sell and supply medicinal cannabis products, as appropriate, for the purposes of the scheme.*

A new category of poison

- 3.224 Because ‘Schedule 9 poison’ is defined in the *Drugs, Poisons and Controlled Substances Act* by reference to the *Standard for the Uniform Scheduling of Poisons (SUSMP)*,²²⁹ the existing rules regarding Schedule 9 poisons would continue to apply to cannabis and cannabis products under a Victorian scheme unless cannabis is moved to another Schedule in the SUSMP. This could cause practical difficulties regarding the storage and dispensing of cannabis.
- 3.225 This problem is best solved by removing authorised cannabis products from the definition of a ‘Schedule 9 Poison’ for the purposes of the *Drugs and Controlled Substances Act* and the Regulations. Instead, a new class of poison would be introduced into the Act: ‘medicinal cannabis’. Cannabis products created under the scheme would be treated as ‘medicinal cannabis’ when used lawfully, and as a drug of dependence when used unlawfully. ‘Medicinal cannabis’ would then be used throughout the Act and the Regulations to authorise certain persons to deal in medicinal cannabis. The Commission has identified the necessary changes in Appendix D.

Implementation issues

Practitioner training

- 3.226 Medical practitioners would need education and resources on the evidence supporting the use of cannabis, its pharmacology, adverse effects and so on. Knowledge of these matters is limited among medical practitioners at present due to the limited trial data available and a lack of experience with cannabis. Comments were made in several submissions and at consultations about the need for suitable training to be made available to medical practitioners.²³⁰ Cancer Council Victoria stated that ‘[a]ny change to legislation should coincide with educational support to health professionals’.²³¹ A respondent to Cancer Council Victoria’s clinician survey stated:

228 Cf *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* s 13(1)(ba) and (bb) and *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)* r 5(2). It is not necessary to specifically authorise medical practitioners and pharmacists as s 13(1)(a) already authorises them to possess, use, sell and supply drugs of dependence ‘in the lawful practice of [their] profession’, which would include medicinal cannabis products.

229 *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* s 4 (definition of ‘Schedule 9 Poison’).

230 Submissions 12, 35, 50, 69, 74; Consultation 1; advisory committee (Meeting 1).

231 Submission 57.

Although my knowledge is increasing, I do not feel I have an adequate understanding of the clinical use of cannabis or its derivatives. I don't think that until I have some degree of clinical experience I can identify suitable patients.²³²

- 3.227 Many in the cannabis community argued that medical practitioners have little understanding of concepts such as the endocannabinoid system.²³³ Matthew Pallett's views were typical of those received by the Commission on this point:

As there are no registered medical professionals within Australia with training in the application of cannabinoid medicines or the endocannabinoid system no meaningful 'medical oversight' is possible in Australia at present. ... the endocannabinoid system is NOT taught in medical or nursing schools at Australia and doctors therefore have little to no knowledge of this system.²³⁴

Should training be mandatory?

- 3.228 One means of ensuring that only appropriately trained practitioners are able to participate in the scheme would be to restrict the participation of practitioners to those who have completed relevant training. This approach is adopted in some United States jurisdictions.²³⁵

- 3.229 Dr David Bearman identified a training requirement as a way to 'marginalize those physicians who might wish to practice a form of minimalist medicine in making recommendations and/or writing prescriptions for the medicinal use of cannabis'. He suggested that:

You can do this by requiring any physician who makes twenty-five (25) or more cannabis prescriptions a year to be certified. Such certification could include having attended a certain amount of category I CME say twenty hours, passing a test and practicing an acceptable standard of medicine.²³⁶

- 3.230 The Australian Lawful Use of Cannabis Alliance proposed a register of qualified practitioners:

Victoria should establish a register of healthcare practitioners who intend to provide medical cannabis treatments. Entry on this Register should have, as a pre-requisite, the annual completion of a continuing professional education program specifically related to cannabis medicine and/or cannabis medical treatment options.²³⁷

- 3.231 Such an approach is also used in the context of opioid replacement therapy.²³⁸ Medical practitioners generally may only prescribe opioid replacement therapy drugs, such as methadone, if they have been appropriately trained and are presently approved by the Department of Health and Human Services.²³⁹ The approval system aims to ensure that prescribing practitioners are familiar with the principles of opioid replacement therapy and prescribing policies.²⁴⁰ A similar scheme could be adopted in order to oversee medical practitioners involved in authorising access to medicinal cannabis.

232 Submission 99.

233 Submissions 12, 45

234 Submission 59.

235 Such as Maryland, Massachusetts, New Jersey and New York: Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.99].

236 Submission 97.

237 Submission 35.

238 Opioid replacement therapy includes the provision of methadone and other drugs for the treatment of dependence on heroin or pharmaceutical opioids.

239 Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (2013) 13-14. Practitioners can prescribe combined buprenorphine/naloxone for up to five patients without being approved, but approval is required for all other types of pharmacotherapy.

240 Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (2013) 6, 13-14. The Department may withdraw approval for practitioners who do not comply with the requirements of the prescribing policy.

- 3.232 The approval system is also used in the context of opioid replacement therapy to manage the number of patients per doctor. That is, a medical practitioner's approval sets a maximum for the number of concurrent treatment permits the practitioner may hold. The maximum can be increased at the practitioner's request. This system could similarly be used in a medicinal cannabis scheme to limit the pressure on doctors by placing a cap on the number of patients permitted to be treated with medicinal cannabis under their care at any given time.
- 3.233 It is important that the Department encourage medical practitioners to access appropriate training on medicinal cannabis, and it may be constructive for the Department itself to provide information and training in respect of such matters, as in Canada. However, requiring practitioners to be approved by the Department, and making the completion of training a condition of approval, would be excessive and would unduly limit the number of practitioners able to authorise treatment with medicinal cannabis. The number of specialists registered in the specialisations that are relevant to the conditions that determine eligibility is relatively small, and imposing an approval requirement may restrict this further. If this requirement were imposed on the supervising general practitioners as well, patients could be unable to continue treatment with their regular general practitioner, potentially disrupting their existing medical care.
- 3.234 Further, the risks attached to opioid replacement therapy that the approval system is designed to control would be largely absent from a medicinal cannabis scheme. One key imperative behind the use of approvals in the opioid replacement therapy scheme is the desire to prevent 'doctor shopping' by enabling departmental supervision of prescribing patterns. This risk would be significantly reduced in the proposed medicinal cannabis scheme, as only certain specialists would be permitted to authorise access. Further, the risks associated with overuse of cannabis are not of the same scale as for opioid replacement drugs: a fatal overdose of methadone and like products can occur if a patient takes only a few times the daily dose, while a fatal overdose from the use of cannabis has not been recorded. For these reasons, the Commission does not consider that the medical practitioners involved in the scheme should be limited to those who have been approved by the Department on the basis of having completed mandatory training.
- 3.235 The Commission agrees that specialists involved in the medicinal cannabis scheme should be encouraged to undertake training on the medicinal use of cannabis prior to becoming involved in the authorisation decision. However, undertaking training should be voluntary.

Provision of training

- 3.236 The Commission considers that the Department of Health and Human Services should have a role in addressing the need for practitioners to receive education and support. Examples of how this could be done include:
- offering training courses
 - preparing guidelines to assist medical practitioners to determine when treatment with medicinal cannabis is appropriate
 - making available detailed information on products, their formulation and pharmacology.
- 3.237 In Canada, Health Canada co-ordinated the collation and publication of clinical data on the efficacy and side effects of cannabis, which is disseminated to the profession to guide and inform them on appropriate uses, dosing and monitoring.²⁴¹ This comprehensive document covers all aspects of cannabis use, and sets out the clinical evidence and pharmacology with extensive reference to research.

- 3.238 The Commission understands, however, that, while detailed, the document is not seen as particularly useful as a practical guide. In part to remedy this, at least one guidance document has been produced that, in addition to setting out the clinical evidence, sets out consequential recommendations, giving clearer guidance to practitioners about when treatment with medicinal cannabis is appropriate.²⁴²
- 3.239 The Department of Health and Human Services would also need to play an active role in communicating product information to practitioners. Because the Secretary would be the sole supplier of medicinal cannabis products,²⁴³ the Department should be regarded as responsible for conveying information about product content and administration. The Department would also need to collate any reports of adverse events relating to particular products and find ways of conveying this information to practitioners.

Recommendation

- 16** The Secretary of the Department of Health and Human Services should provide suitable training and information materials to medical practitioners, pharmacists, patients and others with responsibilities under the scheme.

Role of professional associations

- 3.240 In Canada the professional associations and Canadian regulations do not direct practitioners on how the decisions should be made in relation to authorisation of use of medicinal cannabis, but guidance has been issued by the Canadian Medical Association and provincial colleges.²⁴⁴ The Canadian Medical Association advises practitioners they should not feel obligated to authorise medicinal cannabis for a patient if they feel it is medically inappropriate.²⁴⁵ It also recommends to practitioners that, among other things:
- they consider authorising cannabis only after conventional therapies have proven ineffective, until there is compelling evidence of its efficacy and safety for specific indications
 - they assess the patient's medical history, conduct a physical examination and assess for the risk of addiction and diversion, using available clinical support tools and tests
 - they reassess the patient on a regular basis to establish the effectiveness of the medicinal cannabis in treating the medical condition for which it was authorised, as well as to assess possible addiction and diversion, and support maintenance, adjustment or discontinuation of treatment.²⁴⁶

242 The College of Family Physicians of Canada, *Authorizing Dried Cannabis for Chronic Pain or Anxiety: Preliminary Guidance* (September 2014).

243 See [6.68]–[6.72].

244 Canadian Medical Association, *CMA Statement Authorizing Marijuana for Medical Purposes (Update 2015)* (2015); Canadian Medical Protective Association, *Medical Marijuana: New Regulation, New College Guidelines for Canadian Doctors* (document number W14-005-E, July 2015) <<https://www.cmpa-acpm.ca>>.

245 Canadian Medical Protective Association, *Medical Marijuana: New Regulation, New College Guidelines for Canadian Doctors* (document number W14-005-E, July 2015) <<https://www.cmpa-acpm.ca>>.

246 Canadian Medical Association, *CMA Statement Authorizing Marijuana for Medical Purposes (Update 2015)* (2015).

- 3.241 In addition, the College of Family Physicians of Canada recently issued *Preliminary Guidance: Authorizing Dried Cannabis for Chronic Pain or Anxiety*, a detailed document that advises practitioners on:
- what is known about the potential harms and benefits of cannabis use in various populations and for treating different conditions, with a focus on pain and anxiety
 - regulations and suggested best practices to follow before authorising and continuing a patient's access to cannabis
 - tools to use when screening patients for misuse or addiction risk
 - information about the strains available from licensed producers
 - calculations for dosing.²⁴⁷
- 3.242 Among other guidance, the College sets out a number of categories of patient for whom it considers dried cannabis is 'not appropriate', including those who are under the age of 25; have a personal history or a strong family history of psychosis; have a cannabis use disorder or a substance use disorder; have cardiovascular disease; have respiratory disease; or are pregnant or breastfeeding.²⁴⁸
- 3.243 The Commission notes these developments and observes that professional colleges would have an important role to play in guiding and informing decision making by Victorian medical practitioners.²⁴⁹

Data collection, monitoring and evaluation

- 3.244 Through use of a permit system, a Victorian scheme could facilitate the collection of data regarding the use of medicinal cannabis. The system could also incorporate reporting requirements, whereby medical practitioners supply information to the Department on results achieved with medicinal cannabis. The data collected by medical practitioners and passed on to the Department would need to be the minimum required and not be unduly burdensome.
- 3.245 In determining the data to be collected under the scheme, consideration should be given to how it could usefully assist in evaluating whether the scheme is meeting its regulatory objectives and in contributing to research data about the use of cannabis for medicinal purposes.
- 3.246 The collection of data regarding patient health and treatment raises privacy concerns. Proposed data collection methods should be subject to a privacy impact assessment before implementation, and have appropriate safeguards built in, in consultation with the Commissioner for Privacy and Data Protection and the Health Services Commissioner.

Is a register of patients necessary?

- 3.247 Many submissions touched upon the idea of creating a 'register' of patients who have been authorised to access medicinal cannabis in Victoria.²⁵⁰ Registration would be a prerequisite for patients being treated with medicinal cannabis under the scheme.
- 3.248 Victoria Police suggested that a central registry of patients could be useful as a means of monitoring the scheme:

In the interests of conducting a fully informed trial of medicinal cannabis, Victoria Police recommends that consideration be given to maintaining a register of prescribers and patients in relation to medicinal cannabis. The purpose of the register would be to track and record the number and types of prescriptions made, and the conditions/symptoms for which cannabis is prescribed.²⁵¹

247 College of Family Physicians of Canada, *Preliminary Guidance: Authorizing Dried Cannabis for Chronic Pain or Anxiety* (September 2014) 2.
248 College of Family Physicians of Canada, *Preliminary Guidance: Authorizing Dried Cannabis for Chronic Pain or Anxiety* (September 2014) 3.
249 This was broadly endorsed by the advisory committee (Meeting 1).
250 Submissions 29, 44, 60, 64, 70.
251 Submission 44.

- 3.249 The data collection benefits of registration were also remarked on by Mullaways Medical Cannabis Pty Ltd:
- A Medical Cannabis Card would... record the amount of Cannabis/Cannabinoid medicine prescribed and the outcomes of the treatment. This will allow a big data analysis of the results which medical professionals can use to achieve the best outcome for the patient.²⁵²
- 3.250 The Commission considers it likely that the Department of Health and Human Services would create, or be able to generate, records of patients who participate in the scheme. This has parallels in respect of dependence-forming drugs (such as opiates) supplied to drug-dependent persons.²⁵³ The process of issuing a permit on the application of a specialist medical practitioner for each patient would generate a significant amount of data, which would be supplemented by records of medicinal cannabis products that are dispensed pursuant to those permits. It should be noted that the Office would be bound by the privacy and access provisions in the *Health Records Act 2001* (Vic).²⁵⁴
- 3.251 While some overseas jurisdictions do not maintain records of medicinal cannabis patients,²⁵⁵ the Commission considers that this should be an integral component of the Victorian scheme. Without it, the government would have no way of monitoring the conditions for which cannabis is being authorised, no way of contacting patients regarding their interest in clinical trials, and no way of supervising the medical practitioners involved in authorising access. This would severely compromise the integrity of the scheme, its ability to support research, and the capacity to review the scheme after a suitable period of time. It would also create the potential for abuse of the scheme.
- 3.252 However, the Commission does not consider it necessary to require patients to register with the Department or to be issued with identification cards, as occurs in some other countries that have medicinal cannabis schemes.²⁵⁶ It is not required for access to other controlled therapeutic goods and there are no features of the proposed medicinal cannabis scheme that would make it necessary for government or helpful for the patient.

252 Submission 29.

253 See *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 34B.

254 Section 10 of the *Health Records Act 2001* (Vic) provides that the legislation applies to the public sector.

255 In the Netherlands, medical practitioners may prescribe cannabis to patients, who collect it from a pharmacy like any other prescription medicine. There is no central registry of patients. In Canada, patients who possess a medical document signed by an appropriate health practitioner are entitled to register with a 'licensed producer', who deals with them directly and does not supply their details to the government.

256 This is necessary, for instance, where persons are permitted to have dried cannabis in their possession for medicinal purposes - they require to be able to prove straightforwardly to police enforcing the general law precluding cannabis use and possession that they are 'entitled' to use and possess the permitted amount.

Current regulation of cannabis

102 Introduction

102 Restriction of supply as a narcotic drug

107 Control of quality, safety and efficacy as a therapeutic good

114 Implications for a Victorian medicinal cannabis scheme

117 Conclusion

4. Current regulation of cannabis

Introduction

- 4.1 Two national frameworks of Commonwealth, state and territory legislation regulate access to cannabis in Australia. One restricts the cultivation, manufacture, supply and use of narcotic drugs in accordance with international obligations to act against drug abuse. The other ensures that therapeutic goods sold in Australia meet suitable standards of safety, quality and efficacy. Both combine Commonwealth, state and territory legislation and are intended to protect public health and welfare.
- 4.2 Victorian legislation has an important role to play in establishing and maintaining these frameworks. Currently, the supply and use in Victoria of cannabis for medicinal purposes is prohibited, unless it has been approved or specially exempted under Commonwealth law.
- 4.3 The options for changing the law in Victoria are influenced by the operation of the national frameworks. Conversely, the national frameworks could be affected by any Victorian reform. The frameworks are described in this chapter, and the options are discussed in Chapter 5.

Restriction of supply as a narcotic drug

- 4.4 Any law reform within Victoria to make cannabis available as a medicine must take account of the national framework that implements Australia's international obligations to control narcotic drugs.¹ Some of these obligations are incorporated into Australian law by the *Narcotics Drugs Act 1967* (Cth). They are also implemented indirectly through other legislative instruments, principally in Victoria by the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

Single Convention on Narcotic Drugs 1961

- 4.5 Australia is a signatory to three international conventions concerning the control of narcotic drugs. The most significant for a Victorian medicinal cannabis scheme is the *Single Convention on Narcotic Drugs 1961*.² The purpose of the Single Convention on Narcotic Drugs is to foster international efforts against the abuse of narcotic drugs.

¹ Cannabis is classified internationally as a narcotic drug.
² Opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964); the other relevant conventions are the *Convention on Psychotropic Substances 1971*, 1019 UNTS 175 (entered into force 16 August 1976), and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*, 1582 UNTS 165 (entered into force 11 November 1990).

- 4.6 The Single Convention on Narcotic Drugs is administered by two bodies:
- The **Commission on Narcotic Drugs of the Economic and Social Council of the United Nations** may make decisions about which substances are encompassed by the Single Convention on Narcotic Drugs and the controls that apply to them. It may also make recommendations for implementing the aims and provisions of the Single Convention on Narcotic Drugs.³
 - The **International Narcotics Control Board** comprises 11 members elected by the Economic and Social Council of the United Nations. It imposes quotas on the production of narcotic drugs in each country, based on estimates provided to it, and monitors compliance both with these quotas and with the provisions of the Single Convention on Narcotic Drugs. It can call upon a government that has not complied to adopt remedial measures.⁴

General obligations and control measures

- 4.7 Among other things, signatories to the Single Convention on Narcotic Drugs have a general obligation to take necessary legislative and administrative measures to:
- limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.⁵
- 4.8 The Single Convention on Narcotic Drugs categorises the drugs to which it applies into four schedules and sets out control measures that apply generally to them, depending upon their category. Some additional measures are specific to particular drugs. Cannabis,⁶ cannabis resin,⁷ the cannabis plant,⁸ and cannabis leaves⁹ are the subject of controls under the Convention.
- 4.9 The general control measures apply to cannabis, cannabis resin, and extracts and tinctures of cannabis.¹⁰ Cannabis and cannabis resin are also singled out for 'special measures of control'¹¹ on the grounds that they are particularly liable to be abused and produce ill-effects, and that this is not offset by having substantial therapeutic advantages compared to drugs that have not been singled out.¹²

Use of cannabis for medical and scientific purposes

- 4.10 The international community views only the 'rational' uses of cannabis for medical and scientific purposes as legitimate under the Single Convention on Narcotic Drugs.¹³ A controlled substance is used 'rationally' when it is prescribed and administered by a professional in response to a patient's clinical need, in a way that is efficacious for treating the patient's condition, at an adequate dosage at proper intervals.¹⁴ The need to ensure treatment is 'rational' is underpinned by Article 30 of the Convention.¹⁵

3 *Single Convention on Narcotic Drugs 1961* art 8.

4 *Ibid* arts 9–14.

5 *Ibid* art 4(c). A 'drug' is 'any of the substances in Schedules I and II [of the Single Convention], whether natural or synthetic'.

6 Defined in art 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'.

7 Defined in art 1(1)(d) of the Single Convention on Narcotic Drugs as 'the separated resin, whether crude or purified, obtained from the cannabis plant'.

8 Defined in art 1(1)(c) of the Single Convention on Narcotic Drugs as 'any plant of the genus Cannabis'.

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

10 This being the consequence of inclusion in Schedule I of the Single Convention on Narcotic Drugs: see art 2(1).

11 This being a consequence of inclusion in Schedule IV of the Single Convention on Narcotic Drugs: see art 2(5)(a).

12 Single Convention on Narcotic Drugs art 3.5.

13 United Nations Office of Drugs and Crime, *Drug Policy Provisions from the International Drug Control Conventions* (2014) 3; World Health Organisation, *Ensuring Balance in National Policies on Controlled Substances: Guideline for Availability and Accessibility of Controlled Medicines* (2011) 10, 20.

14 World Health Organisation, *Ensuring Balance in National Policies on Controlled Substances: Guideline for Availability and Accessibility of Controlled Medicines* (2011) 8.

15 In particular, the requirement in Article 30(2)(b)(i) of the Single Convention that the supply or dispensation of narcotic drugs be through medical prescription. See also Submission 21.

- 4.11 Cannabis is one of a limited number of drugs deemed by the Single Convention on Narcotic Drugs to be at high risk of diversion. If the lawful cultivation of cannabis poses a threat to public health and welfare, or if lawfully cultivated cannabis is being diverted into the illicit market, the Single Convention on Narcotic Drugs requires it to be prohibited.¹⁶

Cultivation and manufacturing for medical and scientific purposes

- 4.12 The Single Convention on Narcotic Drugs requires the cultivation and manufacture of cannabis for medicinal or scientific purposes to be undertaken in a very specific way. Cultivation may take place only under licence to a single national agency, which must take physical possession of the total crop from the licensee.¹⁷
- 4.13 A government-owned enterprise may then either manufacture the cannabis into another form, or issue licences permitting companies to engage in manufacturing.¹⁸ Stocks of cannabis must at all times be held by the national agency or by manufacturers of the medicinal cannabis products.¹⁹ This imposes an important logistical constraint for the creation of a Victorian medicinal cannabis scheme.
- 4.14 The Single Convention on Narcotic Drugs imposes these restrictions to ensure that stocks of cannabis produced for medical use are reserved for the patients to whom they are prescribed and are not diverted into illicit channels.²⁰

The international system of estimates and assessments

- 4.15 The requirements that the state license and take physical possession of cannabis enable signatories to report annually to the International Narcotics Control Board about the amount of cannabis they estimate will be legitimately used for medical and scientific purposes over the coming year.²¹ They must provide statistical information on 'estimates and assessments of requirements, manufacture, trade, consumption, utilization and stocks of internationally controlled substances' such as cannabis that are required for medicinal or scientific purposes.²²
- 4.16 Based on the estimates, the International Narcotics Control Board assigns the signatory an annual quota of the drug that is permitted to be consumed for legitimate purposes. A signatory that imports or manufactures more than its quota of a drug is in breach of the Single Convention on Narcotic Drugs.²³ These quotas prevent the oversupply of narcotic drugs and are therefore vital to preventing the diversion of those drugs into the illicit market.²⁴

Responsibility to adopt a nationally consistent approach

- 4.17 The Commonwealth Government, on behalf of Australia, has a responsibility to give effect to the rules of the Single Convention on Narcotic Drugs.²⁵ The International Narcotics Control Board considers that it has a further responsibility to ensure that the rules are not undermined by state governments.

16 *Single Convention on Narcotic Drugs* 1961 art 5(b).

17 *Ibid* arts 23(2)(d), 28. 'Crop' is not defined.

18 *Ibid* art 29.

19 *Ibid* art 23(2)(e), although the national agency may waive this right in respect of medicinal cannabis.

20 Report of the International Narcotics Control Board for 2014 (E/INCB/2014/1) 55.

21 International Narcotics Control Board, World Health Organization, *Guide on Estimating Requirements for Substances under International Control* (2012) 5.

22 *Report of the International Narcotics Control Board for 2014* (E/INCB/2014/1) 20–1.

23 *Single Convention on Narcotic Drugs* art 21.

24 *Report of the International Narcotics Control Board for 2014* (E/INCB/2014/1) 13.

25 *Single Convention on Narcotic Drugs* art 4(a).

If a State, irrespective of its constitutional framework and legal system, enters into an international agreement by acceding to the international drug control treaties, that State must ensure that all state and/or provincial policies and measures do not undermine its efforts to combat drug abuse and trafficking in narcotic drugs, psychotropic substances and precursor chemicals.²⁶

- 4.18 The International Narcotics Control Board recommends that federations such as Australia 'should contain, develop and continually evaluate a comprehensive system of intergovernmental coordination procedures in order to ensure that drug control laws and policies are nationally consistent'.²⁷

Commonwealth Narcotic Drugs Act

- 4.19 The Narcotic Drugs Act was introduced by the Commonwealth to 'regulate the manufacture of, and to make other provision with respect to, narcotic drugs in accordance with the Single Convention on Narcotic Drugs 1961'.²⁸ It applies throughout Australia and is central to the national framework of laws that restrict the supply of cannabis.
- 4.20 Consistent with the Single Convention on Narcotic Drugs, narcotic drugs may be manufactured in Australia only under a licence issued by the Minister for Health.²⁹ The amount that a licensed manufacturer may manufacture and possess, and over what period, is specified in a permit issued by the Secretary of the Department of Health.³⁰
- 4.21 The Minister for Health may determine and specify any licence conditions³¹ and the Chief Executive Officer of Customs may specify by written direction any additional requirements concerning security and how the drugs are labelled and handled.³² The Act also provides for government-appointed inspectors to check compliance with the licence conditions and other requirements.³³
- 4.22 In this way, licences issued under the Narcotic Drugs Act enable the Commonwealth both to control the amount and type of narcotic drugs produced in Australia, within the manufacturing quotas that the International Narcotics Control Board imposes, and to provide the Board with accurate estimates on which to base the future quotas.

Under [the Single Convention], estimates of consumption of narcotic drugs for medical and scientific needs are required to be submitted annually to the United Nations. The total quantity of each drug entering the domestic market, either by importation or by local manufacture, is then kept within these estimates by the allocation of quotas. To ensure that Australia's obligations under the Single Convention will be fulfilled the Commonwealth must continue to administer the estimates system which is an integral part of national and international control. It is considered essential, therefore, that the Commonwealth extend its legislation to cover all aspects of the manufacture of narcotic drugs.³⁴

- 4.23 Within Victoria, the Narcotic Drugs Act currently applies to the processing of poppy straw from alkaloid poppies and would apply to any manufacture of medicinal cannabis products.

26 International Narcotics Control Board, Contribution to the High-Level Review of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation Towards an Integrated and Balanced Strategy to Counter the World Drug Problem (2014) 42.

27 Ibid 43.

28 This being the long title of the *Narcotic Drugs Act 1967* (Cth).

29 *Narcotic Drugs Act 1967* (Cth) s 15(1). The term 'manufacture' is defined by the Act as 'the carrying out of any process by which the drug may be obtained, and includes the refining of a drug and the transformation of one drug into another drug, but does not include the separation of opium, coca leaves, cannabis or cannabis resin from the plants from which it is or they are obtained': *Narcotic Drugs Act 1967* (Cth) s 4(2) (definition of 'manufacture').

30 *Narcotic Drugs Act 1967* (Cth) s 11.

31 *Narcotic Drugs Act 1967* (Vic) s 9(4).

32 *Narcotic Drugs Act 1967* (Vic) s 12.

33 *Narcotic Drugs Act 1967* (Vic) s 24.

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

Victorian Drugs, Poisons and Controlled Substances Act

- 4.24 Victoria's contribution to the national framework for restricting the supply of cannabis and other substances controlled by the Narcotic Drugs Act can be found in the Drugs, Poisons and Controlled Substances Act.
- 4.25 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.³⁵ Cannabis³⁶ is regulated both as a poison and as a drug of dependence.

Regulation as a poison

- 4.26 Poisons and controlled substances are regulated in Victoria according to how they are categorised 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).³⁷ A range of factors are taken into account in deciding how a substance should be scheduled, including how a substance is scheduled internationally under the Single Convention on Narcotic Drugs.³⁸
- 4.27 State and territory governments voluntarily implement the SUSMP through their legislation. In Victoria, the SUSMP schedules have been incorporated into the Drugs, Poisons and Controlled Substances Act.³⁹
- 4.28 Cannabis is listed in Schedule 9 of the SUSMP. Schedule 9 contains prohibited substances. 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 use or scientific research.⁴⁰
- 4.29 Similarly, tetrahydrocannabinol (THC) and its alkyl homologues are listed as Schedule 9 poisons, but with the following exceptions:
- when they are included in Schedule 8
 - when 50 mg/kg or less of THC or its alkyl homologues is in hemp seed oil labelled as not for internal use
 - when 50 mg/kg or less of THC or its alkyl homologues is in other products not for human consumption.⁴¹
- 4.30 Nabiximols and dronabinol—synthetic formulations of cannabis—are listed in Schedule 8, which contains poisons that are controlled drugs. 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.⁴² The SUSMP recommends controls on its manufacture, supply, distribution, possession and use.
- 4.31 This review is principally concerned with the forms of cannabis that are contained in Schedule 9. Schedule 9 poisons are highly controlled. There are detailed and restrictive

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

36 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: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 4(1) (definition of 'drug of dependence').

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

38 Australian Health Ministers' Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals* (2015) 26–7.

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

40 *Poisons Standard 2015* (Cth) ('Classification').

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

42 *Poisons Standard 2015* (Cth) SUSMP ('Classification').

rules about record-keeping,⁴³ storage,⁴⁴ who may lawfully possess them,⁴⁵ and who may lawfully prescribe them.⁴⁶

- 4.32 Clinical and scientific research into poisons that fall within this category in Victoria require the approval of both the Commonwealth and state governments. To prescribe cannabis in Victoria, a medical practitioner must apply to the Secretary of the Victorian Department of Health and Human Services. In practice, applications to prescribe are not made.

Regulation as a drug of dependence

- 4.33 The Drugs, Poisons and Controlled Substances Act imposes penalties on people who unlawfully cultivate a narcotic plant or make a drug of dependence available. It is an offence to cultivate, traffic, administer, possess or use cannabis in Victoria without being authorised or licensed under the Act or Regulations to do so.⁴⁷
- 4.34 In general terms, those who may be authorised under the current law to cultivate, administer or possess cannabis are people who need access to a drug of dependence in the lawful practice of their profession, in connection with their work at a testing facility, or in performing a power, function or duty under the Act.⁴⁸

Control of quality, safety and efficacy as a therapeutic good

- 4.35 When cannabis is used medicinally, it is currently regulated as a therapeutic good. Australia has a national framework for the regulation of therapeutic goods that is designed to protect the health and welfare of the Australian public while minimising the costs associated with pharmaceutical regulation.⁴⁹ Like the framework for the regulation of narcotic drugs, it is the product of cooperation between the Commonwealth and several state governments.
- 4.36 The core of this framework is the *Therapeutic Goods Act 1989* (Cth) (Commonwealth Therapeutic Goods Act), as indicated by the objects of the Act:
- (1) The objects of this Act are to do the following, so far as the Constitution permits:
 - (a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:
 - (i) used in Australia, whether produced in Australia or elsewhere; or
 - (ii) exported from Australia;
 - (b) provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.⁵⁰
- 4.37 The Act is administered by the Therapeutic Goods Administration (TGA), a Division of the Commonwealth Department of Health.

43 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).

44 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.

45 '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.

46 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.

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

48 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 13.

49 Therapeutic Goods Administration, *Medicines Regulation and the TGA* (1999) 2; Kim Forrester, Debra Griffiths, *Essentials of Law for Medical Practitioners* (2013) 218.

50 *Therapeutic Goods Act 1989* (Cth) s 4(1).

Commonwealth Therapeutic Goods Act

- 4.38 The Commonwealth Therapeutic Goods Act regulates the importation, manufacture and supply of therapeutic goods. In particular:
- It establishes the SUSMP which, as discussed above, is incorporated into the Victorian Drugs, Poisons and Controlled Substances Act.
 - It specifies standards for the quality of therapeutic goods⁵¹ and the conditions of their manufacture.⁵²
 - It requires goods to be registered before they are sold in Australia.⁵³
- 4.39 The TGA:
- evaluates the safety, quality and efficacy of therapeutic goods and approves them for sale in Australia
 - licenses the manufacturers of therapeutic goods
 - ensures that therapeutic goods are properly labelled and advertised if they are to be sold on the Australian market.⁵⁴

Approval by the Therapeutic Goods Administration (TGA)

- 4.40 A therapeutic good may not be imported into or manufactured and supplied anywhere in Australia unless it is on the Australian Register of Therapeutic Goods. Before being registered, the TGA assesses its quality, safety and efficacy.
- 4.41 Different products are subject to different processes. Prescription medicines are rigorously assessed to ensure that they are fit for their intended purpose and that what is known about them can be stated clearly.⁵⁵ The risks and benefits associated with a prescription medicine will also inform the prescribing practices of medical practitioners by virtue of the evidence-based practice of contemporary medicine.⁵⁶
- 4.42 The TGA does not work proactively to approve a medicine. The process begins when a sponsor—typically a company that wishes to market a medicine in Australia—applies for approval to have the product included in the Australian Register of Therapeutic Goods for the treatment of a particular indication. The cost of an application for a new chemical entity is about \$250,000.⁵⁷
- 4.43 The applicant is required to develop a dossier that includes detailed product information. Sponsors bear the responsibility of satisfying the TGA that a medicine should be approved⁵⁸ because they stand to gain commercially from its approval.⁵⁹ To demonstrate a medicine's quality, safety and efficacy, sponsors will provide data typically obtained from randomised, double-blind, placebo-controlled clinical trials.⁶⁰

The process is then undertaken at TGA to review that, and that involves a range of evaluators reflecting the nature of the data—clinical delegates, toxicologists, pharmacologists, other experts as needed and appropriate to the particular application. The time for reviewing that application varies but our statutory requirement is to do that within 255 working days—around a year.... We have an advisory committee on prescription medicines that will review many applications and provide advice to the

51 *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.

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

53 *Therapeutic Goods Act 1989* (Cth) pt 3-2.

54 Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods: Clinical Trials in Australia* (2004) 8.

55 Some of that information is then used in the Australian Public Assessment Reports. See Therapeutic Goods Administration, *Australian Public Assessment Reports for Prescription Medicines* (28 July 2015) <<https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars>>.

56 Commonwealth Department of Health, *The National Strategy for Quality Use of Medicines: Executive Summary* (2002).

57 Evidence to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Canberra, 30 March 2015, 37 (Dr Lisa Studdert, Market Authorisation Group, Therapeutic Goods Administration, Department of Health).

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

59 Lloyd Sansom, Will Delaat and John Harvath, *Review of Medicines and Medical Devices Regulation* (2015) 135 (Figure 11).

60 Therapeutic Goods Administration, *Mandatory Requirements for an Effective Application* (2015) 7.

delegate in response to specific questions. That comes close to the end of the process and then the delegate makes a decision. If that is a positive decision within a few weeks it is entered onto the Australian Register of Therapeutic Goods.⁶¹

Risk assessment

- 4.44 Simply because a medicine is approved by the TGA does not mean that it is harmless. Medicines have risks, and a part of the assessment is to determine whether those risks are acceptable in light of the nature of the condition that is being treated and the benefits of the medicine overall.⁶²
- 4.45 Very toxic medicines may be approved because, for example, they improve a seriously ill patient's overall quality of life. This is why more latitude is given to medicines designed to treat seriously or terminally ill people, even though they may pose risks.⁶³
- 4.46 A medicine's risk can depend upon its side effects and toxicity. Toxicity aside, a medicine's risk can also reflect its potential for abuse. Therefore the scheduling of a medicine or its ingredients under the SUSMP will affect the risk assessment.⁶⁴

Continuing obligations and post-market monitoring

- 4.47 Sponsors have a number of continuing obligations in respect of medicines and other therapeutic goods that are approved to be sold on the Australian market. A sponsor is required, for example, to ensure that their good has been manufactured in accordance with Good Manufacturing Practice.⁶⁵ Sponsors are also required to label their good in accordance with the applicable standard.⁶⁶
- 4.48 To ensure that a product is properly marketed in Australia, consistently with the sponsor's obligations, the TGA engages in 'post-market monitoring'. For example, if a medical practitioner or the consumer of a prescription drug reports an adverse event to the sponsor, the sponsor must report the event to the TGA.⁶⁷ The TGA then investigates the event and disseminates relevant information throughout the medical community.⁶⁸

Victorian Therapeutic Goods Act

- 4.49 The Commonwealth relies upon the states to enact complementary legislation in order to fully implement the framework. Victoria has enacted the *Therapeutic Goods (Victoria) Act 2010* (Vic), which applies the Commonwealth Therapeutic Goods Act as a law of Victoria to every person in Victoria. Not all state governments have implemented the framework to the same extent as Victoria.⁶⁹
- 4.50 State governments are also responsible for enacting laws that implement the SUSMP. As noted above, Victoria has done so in the Drugs, Poisons and Controlled Substances Act. The SUSMP applies rules about labelling, advertising, prescription and use according to a medicine's risks. These risks include its toxicity, likelihood of abuse and the way it is controlled under international treaties. The prescription, supply and use of medicines and other therapeutic goods are then regulated by state governments according to how their ingredients are scheduled under the SUSMP.

61 Evidence to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Canberra, 30 March 2015, 37 (Dr Lisa Studdert, Market Authorisation Group, Therapeutic Goods Administration, Department of Health).

62 Therapeutic Goods Administration, *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods* (2011) 6.

63 Therapeutic Goods Administration, *Benefits Versus Risks Approach to Regulating Therapeutic Goods* (8 February 2015) <<http://www.tga.gov.au/benefits-versus-risks-approach-regulating-therapeutic-goods>>.

64 Therapeutic Goods Administration, *About the Work of the TGA—A Risk Management Approach* (15 August 2011) <<http://www.tga.gov.au/about-work-tga-risk-management-approach>>.

65 Therapeutic Goods Administration, *Good Manufacturing Practice* (29 April 2013) <<https://www.tga.gov.au/good-manufacturing-practice-overview>>.

66 Therapeutic Goods Administration, *TGA Labelling and Packaging Regulatory Framework* (28 October 2014) <<https://www.tga.gov.au/tga-labelling-and-packaging-regulatory-framework>>.

67 Therapeutic Goods Administration, *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities Of Sponsors Of Medicines* (4 June 2014) <<https://www.tga.gov.au/book/2-reporting-requirements>>.

68 Therapeutic Goods Administration, *Medicines and Vaccines Post-Market Vigilance—Statistics for 2014* (26 May 2015) <<https://www.tga.gov.au/medicines-and-vaccines-post-market-vigilance-statistics-2014>>.

69 Queensland and Western Australia have not implemented the *Therapeutic Goods Act 1989* (Cth).

- 4.51 The public health and consumer rights of Victorians are improved by their state's support of a national framework of quality control over medicines. Unapproved medicines that do not go through this process do not currently have their risks and benefits evaluated; nor are unapproved medicines subject to clear and enforceable standards for their manufacture.
- 4.52 To prevent unapproved medicines circumventing these protections, the Commonwealth Therapeutic Goods Act prohibits companies from importing or manufacturing them and places restrictions on their administration and wholesale supply.⁷⁰ The Victorian Therapeutic Goods Act extends this regulation beyond companies to prevent any Victorian person from marketing medicines in Australia that have not been assessed by the TGA for their potential impact.⁷¹

Approval of cannabis products

- 4.53 As discussed above, the TGA employs high-quality processes to evaluate scientifically the data on the quality, safety and efficacy of therapeutic goods. A number of submissions asserted that medicinal cannabis products should be made available in Victoria only if they have been tested and approved by the TGA.⁷² This was the position of Dr Roger McLennan who contended that 'it would be foolish to override the Therapeutic Goods Administration and ignore the Food and Drug Administration and the Medicines and Healthcare Products Regulatory Agency'.⁷³
- 4.54 AMA Victoria, for example, put the view that:
- Therapeutic cannabinoids that are scientifically evaluated to be safe and effective should be made available to patients for whom existing medications are not as effective. However, approval for these treatments must be subject to the same regulatory and quality control processes that are applied to other medicines in Australia.⁷⁴

Scientific testing and evaluation

- 4.55 The approval process for prescription medicines sets high standards of purity and consistency, as well as requiring rigorous clinical trials. Sponsors would need to do a great deal of work to 'standardise' cannabis so that its purported therapeutic effect can be measured against a stable and predictable dose in a clinical trial setting. Professor David Penington has argued that these standards are not appropriate:
- Cannabis can never be a pharmaceutical agent in the usual sense for medical prescription, as it contains a variety of components of variable potency and actions, depending on its origin, preparation and route of administration. Consequently, cannabis has variable effects in individuals. It will not be possible to determine universally safe dosage of cannabis for individuals based on a clinical trial.⁷⁵
- 4.56 Only one non-synthetic medicinal cannabis product has been approved by the TGA. Sativex, manufactured by GW Pharmaceuticals, is a whole-plant extract of cannabis and contains approximately equal parts of THC and CBD, along with a small amount of other cannabinoids. It is a pharmaceutical-grade medicine administered as an oro-mucosal spray. It was registered by the TGA 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-related symptoms during an initial trial of therapy.⁷⁶

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

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

72 Submissions 25, 27, 38, 40, 42, 47, 48, 52. See Appendix B for list of submissions.

73 Consultation 2. See Appendix C for list of consultations.

74 Submission 38. See also Consultation 16.

75 Professor David Penington, 'Medical cannabis: time for clear thinking' (2015) 202 *Medical Journal of Australia* 74, 74.

76 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>>.

- 4.57 Before any other medicinal cannabis product is approved for sale in Australia, it also would need to be standardised, subjected to clinical trials, and subsequently evaluated and approved by the TGA. The limited range of products currently being trialled suggests that it is likely to be some time before the state of knowledge develops to the point that an evaluation of another medicinal cannabis product by the TGA would have any realistic prospects of success.
- 4.58 The above observation applies equally to the rescheduling of cannabidiol to Schedule 4 of the SUSMP. How a medicine is scheduled affects how strictly it is regulated once it is available on the market, and influences how doctors assess its risks. But a CBD medicine would still have to be assessed by the TGA before it could be sold in Australia. Currently, no CBD medicine is included on the Australian Register of Therapeutic Goods.
- 4.59 Even the approval of a medicine after rigorous scientific evaluation does not ensure that it is sold in Australia. Sativex was withdrawn from the Australian market by its sponsor, Novartis, after the decision was made not to subsidise it under the Pharmaceutical Benefits Scheme.⁷⁷ The barriers to entry into the Australian medical market are commercial as well as scientific.

Commercial considerations

- 4.60 Sponsors provide the impetus for a medicine to be approved: they fund the clinical research and make applications to the TGA with the ultimate aim of accessing the Australian market. If the costs are unlikely to bring strong financial returns, there is no incentive to seek approval. The TGA responds to applications for approval; it does not seek out products that may meet community health needs.
- 4.61 Compounding this problem is that less refined cannabis products are becoming more widely available, both legally and illegally. This reduces the economic incentive for sponsors to bear the costs of undertaking clinical research with a view to having a product approved.⁷⁸ The economic incentive is further reduced because it can be difficult for a sponsor to protect its intellectual property in a cannabis product, and therefore to prevent competitors from selling something very similar or identical to that product on the market.⁷⁹
- 4.62 Others have observed that there is a lack of interest by sponsors in making cannabis medicines available in Australia. In 2013, the New South Wales Legislative Council's General Purpose Standing Committee No 4 noted during its enquiry into medicinal cannabis that 'the small market for [cannabis] medicine is not seen to justify the costs, as the indications for cannabinoids are uncommon and more effective drugs have emerged to treat conditions such as nausea and vomiting'.⁸⁰
- 4.63 The market-driven therapeutic goods regime has not resulted in cannabis-based medications becoming available in Australia. It follows that for the Victorian Government to achieve its policy of making cannabis available to people in exceptional circumstances, some alternative method of access must be considered.

77 Dan Harrison, Rania Spooner and Beau Donnelly, 'MPs Call for Compassion in Case of Mother Who Used Cannabis Oil to Help Sick Son', *Sydney Morning Herald* (20 July 2014).

78 Claire Frezza, 'Medical Marijuana: A Drug Without a Medical Model' (2013) 101 *Georgetown Law Journal* 1117, 1135.

79 New South Wales Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000) 59; Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013) [3.62]–[3.63].

80 Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013) 31–2.

Conclusion

- 4.64 Limiting a Victorian medicinal cannabis scheme to products that have been approved by the TGA would reinforce the status quo. There would be no change to the products available and the means by which they could be accessed. Apart from facilitating clinical trials of products with a view to approval by the TGA—an initiative which is already under way—there is no scope for the Victorian Government to expedite the approval of medicinal cannabis products under current Commonwealth law.
- 4.65 However, the Commission considers that the establishment of a Victorian medicinal cannabis scheme should supplement the national framework for the regulation of therapeutic goods only to the extent that the market does not produce affordable and appropriate medicinal cannabis products for eligible patients. The position of the TGA as the pre-eminent entity responsible for the evaluation and approval of medicines for commercial supply on the Australian market should be maintained and reinforced.

Access to unapproved products

Importation under the Special Access Scheme

- 4.66 The Secretary of the Commonwealth Department of Health has the discretion to allow unapproved medicines to be imported and/or supplied on a case-by-case basis.⁸¹ As a matter of policy, the Secretary exercises this discretion through the operation of a number of schemes established by the TGA, including the Special Access Scheme.⁸² It was proposed to the Commission that unapproved medicinal cannabis products could be imported for individual patients under the Special Access Scheme.⁸³
- 4.67 The Special Access Scheme allows an unapproved therapeutic good to be imported with the agreement of an overseas supplier.⁸⁴ 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.⁸⁵ The prior approval of the TGA is not required for a terminally ill patient, but is required for other patients. The use of unapproved medicines under the scheme is treated as experimental; the patient and their doctor bear personal responsibility for any adverse effects.⁸⁶
- 4.68 In practice, the Special Access Scheme provides medical practitioners with a way of seeking the Commonwealth Government's permission for their individual patients to have access to a medicine that is available in other countries but for which approval to supply in Australia has not been sought from, or given by, the TGA.
- 4.69 The scheme is not designed to facilitate systematic access to unapproved medicines by groups of patients suffering from a particular condition and associated symptoms. The guidelines for the scheme emphasise that it is not to be used in this way.⁸⁷

Importation of Sativex

- 4.70 Although Sativex has been approved by the TGA, if imported from overseas it would be as an unapproved product for the purposes of the Special Access Scheme. This is because Sativex as labelled and marketed overseas would not necessarily meet the requirements the TGA imposes on the local product.

81 *Therapeutic Goods Act 1989* (Cth) s 19(1).

82 Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009). The other schemes are the Authorised Prescriber Scheme and the Personal Importation Scheme. See Therapeutic Goods Administration, *Authorised Prescribers* (14 July 2015) <<https://www.tga.gov.au/form/authorised-prescribers>>; Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods: Personal Importation* (2004).

83 Consultations 1, 11; Submission 52.

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

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

86 Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009) 18.

87 *Ibid* 10.

4.71 It follows that a medical practitioner who forms the view that there is clinical justification for their patient to be treated with a 1:1 THC/CBD product may seek to import Sativex from GW Pharmaceuticals/Novartis under the Special Access Scheme.

4.72 The Commission was given notice of a number of anecdotal estimates of the cost of importing Sativex. These estimates ranged from \$500 to \$1200 per month.⁸⁸

Conclusion

4.73 The Special Access Scheme has features that are entirely appropriate for its limited purpose but which make it an inadequate basis for supply of medicinal cannabis under a Victorian scheme.

4.74 Only a few medicinal cannabis products have been approved by the overseas counterparts of the TGA and are therefore potentially available under the Special Access Scheme. Sativex is the most obvious candidate for importation under the scheme but would not be suitable for all the patients, and all the conditions and symptoms, that a Victorian medicinal cannabis scheme would encompass. For example, due to Sativex's psychotropic effect it would not be suitable to treat paediatric epilepsy.

4.75 To reduce the cost burden on patients who may benefit from being treated with Sativex, the Victorian Government could subsidise the cost to individual patients of importing Sativex under the Special Access Scheme. However, it could not expedite the process nor provide a means of broadening access to a wider patient group. The Special Access Scheme is an ad hoc evaluation tailored to a particular patient, which turns on the quality of the evidence able to be assembled by the medical practitioner in each instance.

4.76 Furthermore, if the scheme were able to be used to facilitate the systematic supply of an unapproved cannabis medicine to Victorians, it would undermine the general requirement that sponsors must apply to have their medicines included on the Australian Register of Therapeutic Goods before they are able to market it in Australia.⁸⁹

Access to unapproved products through clinical trials

4.77 By participating in clinical trials, patients can be provided with access to unapproved medicinal cannabis products. The TGA administers two schemes under which clinical trials for unapproved therapeutic goods may be conducted, and can permit unapproved medicines to be imported into Australia for the purposes of a clinical trial under its Clinical Trial Exemption scheme. The Commission received a number of submissions from people who expressed an interest in participating in clinical trials, to determine whether cannabis would be effective in their case.⁹⁰

Conclusion

4.78 While this form of access to medicinal cannabis may assist in individual cases, it is not a substitute for establishing a scheme that provides for a reliable supply of a variety of products to eligible patients. The results of clinical trials should inform which products may be supplied under a Victorian scheme and the eligibility criteria for the patients who participate.

88 Submissions 29, 90. See also Evidence to the Senate Legal and Constitutional Affairs Committee, Parliament of Australia, Canberra, 30 March 2015, 18–9 (Professor David Penington, Emeritus Professor, University of Melbourne).

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

90 Submissions 67, 78, 83.

Implications for a Victorian medicinal cannabis scheme

- 4.79 In introducing law reform to allow access to medicinal cannabis, the Victorian Government could either work within the existing regulatory frameworks or depart from them. The extent to which it could depart from them is determined by the scope of its jurisdiction and whether it has the support it needs from the Commonwealth Government for the changes it wants to make.
- 4.80 Victoria's jurisdiction to regulate the cultivation, manufacture, distribution, possession and use of medicinal cannabis within its borders is confined in two ways:
- The Commonwealth has overriding jurisdiction, granted by the Constitution and exercised under Commonwealth legislation, to regulate many parts of the supply chain, in particular production and manufacture.
 - Victoria has passed legislation that complements the Commonwealth legislation, in the interests of establishing national regulatory frameworks.
- 4.81 This means that Victoria can either establish a stand-alone medicinal cannabis scheme within the limits of its own jurisdiction or involve the Commonwealth in establishing and operating the scheme.⁹¹

A stand-alone Victorian scheme

- 4.82 A number of submissions urged Victoria to act independently in introducing a medicinal cannabis scheme.⁹² The Cannabis Policy Project, for example, put the view that:
- Whilst it is desirable to work with the Commonwealth the Commission should focus on recommending regulatory changes that can be achieved within the jurisdiction of Victoria.⁹³
- 4.83 Some individuals argued that Victoria should adopt the approach taken in the United States, where each state that has legalised medicinal cannabis has done so despite federal laws criminalising cannabis for all purposes. Marc Selan, for instance, said that:
- In the USA, the states that have legalised medicinal cannabis issue licences that protect users but the federal police do not accept them. Victoria should take the step to move against the Commonwealth.... If you allow cannabis production, as in the USA, you have wealth decentralisation, creating wealth throughout the community and vast employment opportunities.⁹⁴
- 4.84 Others, such as Cannabis Science Ltd, were cautious about Victoria working in opposition to the Commonwealth:
- It is of upmost [sic] importance to avoid the missteps taken by the United States, and to ensure that the various levels of government are on the same page. Additionally, it is important that we do not put further strain on our already under-resourced frontline services.⁹⁵

91 These alternatives are described in the issues paper. See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) 67–82.
92 Submissions 1, 5, 14, 28, 37, 72.
93 Submission 37.
94 Submission 74.
95 Submission 69.

- 4.85 The implications of establishing a stand-alone scheme in Victoria would be different from those in the United States of America, not least because the division of powers between the federal and state governments is not the same. Nevertheless, the experience in the United States of America illustrates both the feasibility and the difficulty of introducing a stand-alone medicinal cannabis scheme within a federal system. A problem common to all of the state schemes is that patients, industry members, and those who assist them are confused about their liability under federal criminal laws and uncertain about whether they will be enforced.
- 4.86 The scope for Victoria to establish a stand-alone scheme was discussed in the issues paper.⁹⁶ Comments made in submissions and consultations concurred with the Commission's analysis.⁹⁷
- 4.87 A medicinal cannabis scheme established solely by Victorian legislation and without Commonwealth support could not license corporations to cultivate and manufacture cannabis products. Individuals could be permitted to cultivate and possess cannabis but are unable to be authorised under Victorian law to manufacture cannabis. The importation of any cannabis seeds or medicinal cannabis products would still be subject to Commonwealth law.
- 4.88 To avoid the reach of the Therapeutic Goods Act, the Victorian Government could enter an agreement with unincorporated entities or natural persons to cultivate cannabis and manufacture medicinal cannabis products. Alternatively, the Victorian Government could create a statutory authority that did not generate revenue to perform these activities.
- 4.89 However, a stand-alone scheme involving unincorporated entities or a Victorian Government agency is still legally fragile and potentially exposes Victorians to criminal liability under Commonwealth law. Unincorporated entities and natural persons are clearly subject to the Commonwealth's Narcotic Drugs Act. Arguably, even a Victorian agency would require a licence under the Narcotic Drugs Act to manufacture cannabis products.⁹⁸ Participants in a stand-alone Victorian scheme who did not have a licence would be subject to a considerable risk of criminal liability.
- 4.90 Similar problems attend a stand-alone grow your own scheme. The Narcotic Drugs Act would apply to patients who manufactured their own refined forms of cannabis, exposing them to criminal liability.
- 4.91 This discussion shows that the participation of the Commonwealth in a Victorian scheme is vital to the scheme's regulatory and legal stability. A stand-alone Victorian medicinal cannabis scheme that is not supported by the Commonwealth is subject to unsatisfactory and arbitrary limitations on its form and scope.

A comprehensive scheme

- 4.92 Many submissions expressed support for a comprehensive Victorian scheme in which the Commonwealth has a role.⁹⁹ It was suggested that, by regulating every step of the supply chain, Victoria could avoid the quality control and law enforcement challenges experienced by some medicinal cannabis schemes in other countries. Mullaways Medical Cannabis Pty Ltd observed that:

Setting up a Medicinal Cannabis Industry will take a lot of investment to achieve. It requires infrastructure for the security, cultivation, manufacturing, processing, delivery and reporting of regulated Cannabis/Cannabinoid medications and the removal of criminal convictions from those Licensed to be involved in the Victorian medical Cannabis Industry.¹⁰⁰

96 A possible exception is a state agency or statutory authority that is not a 'constitutional corporation'. See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) 74–5.

97 Submission 63; advisory committee (Meeting 2).

98 Advisory committee (Meeting 2).

99 Submissions 24, 26, 27, 29, 31, 35, 41, 54, 63, 75, 76; advisory committee (Meeting 2).

100 Submission 29.

- 4.93 Others focussed on the need to retain a national approach to the regulation of narcotic drugs and therapeutic goods:

It would [be] unwise and bureaucratically very difficult to implement this outside of a national framework. So our recommendation is that if all other appropriate safeguards are in place, that a national system would need to be established, not independent state activities.¹⁰¹

- 4.94 As the Commission's review was conducted at the same time as an inquiry by the Senate Legal and Constitutional Affairs Legislation Committee into the Regulator of Medicinal Cannabis Bill, which proposed a national medicinal cannabis scheme which the states could opt into, those who commented did not always envisage that Victoria would be the architect or primary regulator of the scheme.¹⁰²

- 4.95 Professor David Penington, for example, presented both to the Commission and the Senate Committee a proposal for a national medicinal cannabis regulatory framework, of which a Victorian scheme would form a part:

A relatively simple arrangement, explicitly built around State legislation, with national consultation, through a Standing Committee of AHMAC, is preferable. This could provide communication and co-ordination between the Commonwealth and States in regulating the production and use of cannabis products for medicinal purposes. Such an approach would require full consultation seeking common ground on important matters, with expert and professional advice as necessary. Consensus could be sought on many issues to facilitate Commonwealth support. Appropriate agreement on sharing of information and products between States would be desirable. Commonwealth resolution of the legal obstacles could be made contingent on such common agreement between States; this would be a powerful incentive to gain consensus.¹⁰³

- 4.96 Having considered the legal ramifications of confining the scope of the scheme to the limits of Victoria's jurisdiction, the Law Institute of Victoria expressed the view that collaborating with the Commonwealth is the only viable option:

A comprehensive medicinal cannabis scheme in Victorian would need to rely on collaboration with the Commonwealth Government. A stand-alone Victorian scheme without Commonwealth amendments would be difficult. The Tasmanian Dam case has long established that, if the Commonwealth is a party to an international convention, it will retain the power to intervene in state legislation relevant to the international convention. As the manufacture of medicinal cannabis falls within Commonwealth obligations to three international conventions, it is unclear how Victoria could protect itself from potential interference from the Commonwealth without some form of collaboration.¹⁰⁴

- 4.97 Although not all parties to the Single Convention on Narcotic Drugs comply with all aspects of it, the Convention requires that the state take physical possession of medicinal cannabis stocks and distribute it to retail suppliers in a way that is generally consistent with Article 23. To foster collaboration, an option for law reform should be consistent with the Commonwealth's international obligations, as the Commonwealth evaluates proposals to produce and supply narcotic drugs against the requirements of the Convention.¹⁰⁵ The importance of such compliance was identified by the Senate Legal and Constitutional Affairs Legislation Committee's report of 11 August 2015 on the Regulator of Medicinal Cannabis Bill, including by its recommendation that the Bill be amended to ensure compliance with Australia's international obligations under the Single

101 Submission 42.

102 The Regulator of Medicinal Cannabis Bill is discussed in Chapter 1.

103 Submission 24.

104 Submission 63.

105 Commonwealth Department of Health, Submission No 67 to the Legal and Constitutional Affairs Legislation Committee, *Inquiry into Regulator of Medicinal Cannabis Bill 2014*, 30 March 2015, 2; Consultation 15.

Convention on Narcotic Drugs.¹⁰⁶ A system that enables Victoria to report accurately to the Commonwealth the amount of cannabis being produced annually, and which establishes a process of control that limits diversion to the greatest possible extent, should be an attribute of a Victorian scheme.

Conclusion

- 4.98 The Commission agrees with the Law Institute’s legal analysis. Victoria’s jurisdiction permits it to regulate only limited aspects of the supply chain, and the division of regulatory responsibilities between the Commonwealth and Victoria does not align clearly or easily with the practicalities of cultivating, processing, manufacturing, distributing, prescribing and using medicinal cannabis. The arbitrary and unclear reach of the respective jurisdictions would expose Victoria, and Victorians, to legal liability. It would be preferable for any Victorian medicinal cannabis scheme to be established in collaboration with the Commonwealth.

Recommendation

- 17** The Victorian Government should seek to work in collaboration with the Commonwealth Government in establishing any medicinal cannabis scheme in Victoria.

Options for reform

120 Introduction

121 Importation under amended Commonwealth rules

125 Exemption from prosecution for possession and use

126 'Grow your own'

135 Regulated not-for-profit production and distribution

138 Regulated distribution through dispensaries

140 Government-enforced monopoly

142 Multiple licensed producers

5. Options for reform

Introduction

- 5.1 This chapter sets out a number of options that would allow medicinal cannabis to be supplied and used in Victoria. In reviewing them, the Commission has drawn on its consultations with the public, professional stakeholders and the advisory committees. It has considered the written submissions it received in response to the issues paper and taken into account the experience of other jurisdictions.
- 5.2 All the options build on the assumption that the following regulatory mechanisms would be in place:
- an administrative unit within the Department of Health and Human Services, referred to in this report as the Office of Medicinal Cannabis, to administer the scheme either alone or in conjunction with other government agencies, as described in Chapter 1.¹
 - a system by which medical practitioners authorise eligible patients to be treated with medicinal cannabis, as recommended in Chapter 3.²
- 5.3 The Victorian Government's decisions as to what is desirable will be determined by many factors beyond the terms of reference for this review. For the purposes of assessing the options, the Commission has been mindful of the recommended regulatory objectives and inherent risks set out in Chapter 1, which it has inferred from the terms of reference.³
- 5.4 The options for law reform discussed in this chapter are:
- *Importation*—Victoria could import cannabis for the purposes of a medicinal cannabis scheme by special arrangement under Commonwealth law.
 - *Exemption from prosecution*—Eligible patients and their carers could be authorised to possess small quantities of cannabis for the patient's use.
 - *'Grow your own'*—Eligible patients and their carers could be authorised to cultivate cannabis plants for the patient's use.
 - *Regulated not-for-profit production and distribution*—Not-for-profit cooperatives could be licensed to cultivate, manufacture and distribute medicinal cannabis products among their members.
 - *Regulated distribution through dispensaries*—Medicinal cannabis products could be distributed through licensed, single purpose dispensaries.
 - *A government-enforced monopoly*—Victoria could authorise a publicly funded entity to cultivate and manufacture cannabis for distribution to patients through pharmacies.

1 See [1.72]–[1.76].
2 See [3.193]–[3.202].
3 See [1.68]–[1.70].

- *Licensed producers*—Victoria could issue multiple licences to cultivators and manufacturers to produce medicinal cannabis products for distribution to patients through pharmacies.
- 5.5 All of the options under which medicinal cannabis could be produced and distributed in Victoria, other than under a grow your own scheme, would be contingent on the co-operation of the Commonwealth Government in either or both of the following forms:
- removing the regulation of medicinal cannabis products that are produced and distributed under the Victorian medicinal cannabis scheme from the *Therapeutic Goods Act 1989* (Cth)
 - issuing a licence to manufacture cannabis, under the *Narcotics Drugs Act 1967* (Cth).
- 5.6 Most of these options would also have an impact upon the frameworks for the control of narcotic drugs and the quality of medicines described in Chapter 4. The Commission considers that Victoria should engage with these frameworks to the greatest possible extent by avoiding measures that depart substantially from Australia’s international obligations and preferring measures that:
- allow the quantity of medicinal cannabis produced in Victoria to be reported accurately to the Commonwealth, so that it may in turn provide accurate annual estimates to the International Narcotics Control Board⁴
 - minimise the risk that cannabis will be diverted into the illicit market,⁵ consistently with the regulatory objective to preserve the prohibition on illicit use of cannabis
 - develop medicinal cannabis products that medical practitioners can authorise ‘rationally’,⁶ consistently with the regulatory objectives to integrate medicinal cannabis into the patient’s medical treatment, to inform patients of any clinical uncertainty and to ensure the quality and composition of medicinal cannabis products.

Importation under amended Commonwealth rules

The option

- 5.7 Cannabis can be imported under current Commonwealth law and policy only if approved on a case-by-case basis by the Secretary of the Commonwealth Department of Health, exercising powers under the *Therapeutic Goods Act 1989* (Cth) and the *Customs Act 1901* (Cth). The Law Institute of Victoria proposed that the Commonwealth provide special access for state governments to import products for the purpose of their medicinal cannabis schemes:

As there are currently several states agitating for public access to medicinal cannabis, the states could negotiate with the Commonwealth Government over several options to assist, including facilitating importation. The states could make an application to the Secretary of the Commonwealth Department of Health to exercise its discretion to provide for a special access scheme and provide excluded goods declaration.⁷

- 5.8 This option would not require legislative reform though, if ongoing, it could be desirable to have the security of a statutory avenue of access.
- 5.9 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. As discussed in Chapter 4, the Secretary of the Commonwealth Department of Health has a discretion to make exceptions, which in practice is exercised through schemes administered by the Therapeutic Goods Administration (TGA).

4 See [4.15]–[4.16].

5 See [4.14].

6 See [4.10].

7 Submission 63. See Appendix B for list of submissions.

- 5.10 If the Commonwealth agreed to facilitate the approval of requests by the Victorian Government to import medicinal cannabis that has been produced under regulated conditions into Victoria, the Victorian Government would then need to enter into contracts with cultivators and manufacturers who would be willing and able to export it to Australia.

Comments

Advantages

- 5.11 The view that Victoria should import medicinal cannabis products from overseas, and that a way to facilitate this should be found, was put to the Commission on a number of occasions.⁸ The primary reasons identified in support were:
- The regulatory burden of importing medicinal cannabis products would be much lower than that of regulating their cultivation and manufacture.
 - It would also enable suitable products of a high quality to be made available in less time than it would take to establish a lawful and therapeutically appropriate local supply.⁹

Reduced regulatory burden

- 5.12 As noted by the advisory committees, importing medicinal cannabis could reduce the cost of administering a medicinal cannabis scheme while providing access to products that have been produced under regulated conditions.¹⁰ If it were possible to import sufficient quantities for all eligible patients, then the medicinal cannabis scheme could focus primarily on authorising and monitoring access. While it could be necessary to subsidise the cost of the imported product to allow it to be affordable to patients, the expenditure would be far less than that of establishing and regulating the cultivation and manufacture of medicinal cannabis products.
- 5.13 The cost advantages diminish if only a small amount of the demand for products could be met in this way, as local production would still need to be established and regulated as well.
- 5.14 Importation of the state's supply of medicinal cannabis would also accord with Australia's international obligations. Because it does not involve local cultivation or manufacture, importation would not engage Articles 23 and 28 of the *Single Convention on Narcotic Drugs 1961*. In addition, the Commonwealth would be able to meet its obligation to monitor how much cannabis had been imported each year and accurately estimate for the International Narcotics Control Board how much cannabis would be required for a Victorian scheme.

Quicker access to licit products

- 5.15 Even if the medicinal cannabis scheme were designed to provide for local cultivation and manufacture, importing high-quality products that have been produced under regulated conditions could be an interim measure while the industry is being established in Victoria.
- 5.16 Belinda Doonar said in her submission that it is unnecessary to import cannabis products because 'we have people on the ground with extensive knowledge ready to move ahead'.¹¹ However, under each of the options where medicinal cannabis products would be produced (other than grow your own), the government would have a role in selecting or licensing suppliers, creating quality controls and meeting international obligations to control and report on the amount of cannabis being cultivated. A time delay between the law being changed and licit products being made available is inevitable.

8 Advisory committee (Meetings 1 and 3); Submissions 48, 63, 70.

9 Advisory committee (Meetings 1 and 3); Submission 63.

10 Advisory committee (Meetings 2 and 3).

11 Submission 90.

Disadvantages

Scarcity of suppliers

- 5.17 The fundamental difficulty with relying on importation is the need to identify an exporter who is willing and able to supply Victoria with medicinal cannabis products. In order for the scheme to be viable, an exporter would have to be able to supply enough to meet patient demand, at a price that was sufficiently affordable to justify not having a domestic industry.
- 5.18 Securing an affordable and reliable supply of medicinal cannabis is ultimately a question for government, and the Commission does not exclude the possibility of securing an agreement to import. However, at the time of writing, only one country exports medicinal cannabis.¹²
- 5.19 The Netherlands, through its Office of Medicinal Cannabis, permits the export of the medicinal cannabis that is cultivated under government regulation by the sole supplier, Bedrocan BV.¹³ Cannabis is currently exported from the Netherlands to Italy, Germany, Finland, Canada, and the Czech Republic.¹⁴ However, the Commission understands that Bedrocan is unable to supply large quantities of cannabis. The Netherlands gives priority to meeting its domestic needs rather than facilitating a cannabis export industry, and it does not allow substantial quantities to be exported.¹⁵
- 5.20 Uruguay has indicated that it would like to export cannabis, and Israel, Canada and Chile have also reportedly expressed interest, but it appears that no arrangements are yet in place.¹⁶ In Canada, there is a process under the Marihuana for Medical Purposes Regulations for the export of medicinal cannabis. Only licensed producers may obtain an export permit.¹⁷ However, it appears that, while technically possible, exports are not generally allowed by Health Canada.¹⁸ Some Canadian companies have expressed a wish to become licensed exporters, but it appears this is unlikely in the near future.¹⁹ Health Canada states that it:
- does not support facilitating a regime premised on servicing global demand given the associated public health, safety and security risks. For the above reasons, importation and exportation would be permitted under very limited circumstances, such as, ... exporting a unique marijuana strain for scientific investigation in a foreign laboratory.²⁰
- 5.21 Although the medicinal cannabis industry in the United States thrives under the various state schemes, the products it produces may not be exported without the approval of the federal government's Attorney-General.²¹ As cannabis is considered illegal at the federal level, such approval seems unlikely to be granted.

12 Boaz Wachtel, *International Medical Cannabis Policy* (11 March 2013) <<http://www.slideshare.net/SafeAccess/asa-2013-medical-cannabis-in-israel-v3>>.

13 Office for Medicinal Cannabis, *Import and Export*, <<https://www.cannabisbureau.nl/en/ImportExport/>>.

14 Bedrocan BV, *Welcome to Bedrocan*, <<http://www.bedrocan.nl/english/home.html>>.

15 Consultation 28.

16 Patricia Rey Mallén, 'Uruguay To Export Marihuana To Canada, Chile, Israel For Medical Purposes', *International Business Times* (online), 8 January 2014 <<http://www.ibtimes.com/uruguay-export-marihuana-canada-chile-israel-medical-purposes-1530930>>.

17 Canada Border Services Agency, *Importation and Exportation of Controlled Substances and Precursors* (2014) [18]; *Marihuana for Medical Purposes Regulations*, SOR/2013-119, ss 82–88.

18 Tamara Cunningham, 'Medical Marijuana CEO Has Sights Set On Global Expansion', *Nanaimo News Bulletin* (online), 3 March 2015 <<http://www.nanaimobulletin.com/news/294699081.html>>.

19 Brandon Barrett, 'Whistler Medical Marijuana Company Has Licence Renewed', *Pique News Magazine* (online), 5 March 2015 <<http://www.piquenewsmagazine.com/whistler/whistler-medical-marijuana-company-has-license-renewed/Content?oid=2641294>>; Mike McConnell, 'Madison Heights businessman sees billions in medical pot', *The Daily Tribune* (online), 4 March 2014 <<http://www.dailytribune.com/general-news/20140304/madison-heights-businessman-sees-billions-in-medical-pot>>.

20 Health Canada, *Import and Export of Marijuana by Licensed Producers—Information Bulletin*, 8 June 2015 <<http://www.hc-sc.gc.ca>>.

21 *Controlled Substances Import and Export Act*, 21 USC § 953.

Limited choice of products

- 5.22 Another drawback of relying on imports is that the cannabis exported from the Netherlands is only in dried plant form because this is the only form available domestically. The Dutch government is currently preparing to amend the law so that cannabis oil can also be supplied, with scientists and pharmacists working on a method for its safe and consistent production.²² Similarly, if Canadian companies were to be permitted to export cannabis, it would be only in dried form or as an oil.²³
- 5.23 Israel may allow exports in the future. But while significant quantities of cannabis are grown and refined in Israel, in a range of strains and formulations,²⁴ quality control is said to be poor.²⁵
- 5.24 The United States produces a wide range of products and strains—in most jurisdictions producers are free to cultivate whatever strains and manufacture whatever products they wish, including a large number of refined products. However, as mentioned above, the United States does not permit export without a permit from the Attorney-General, which is unlikely to be granted.
- 5.25 If Victoria were to import cannabis in dried form, it could then be processed into other forms. As this would be manufacturing, it would need to be conducted under regulatory architecture that is compliant with Article 29 of the Single Convention on Narcotic Drugs. In any event, the cost advantage of importing rather than cultivating and processing locally would be significantly diminished, if not lost.

Conclusion

- 5.26 There may be benefit in Victoria reviewing with the Commonwealth the potential for streamlining the approval processes for the purpose of facilitating imports under the Victorian scheme. For example, it may be possible to facilitate the importation of Sativex for individual patients who are eligible to participate in the Victorian scheme or whose application is supported by the Office of Medicinal Cannabis. Perhaps this could be accompanied by a Victorian Government program to subsidise the cost of the product to patients and their families. It could also be useful if the importation processes were streamlined to facilitate the importation of cannabis seeds so that a suitable variety and quality of strains could be developed in Victoria. These measures could operate in tandem with any of the other options.
- 5.27 As a means of meeting all or most of the demand for medicinal cannabis under the scheme, however, importation is not feasible in the current international environment. The available products would need to be processed in Victoria under regulations that accord with Articles 23 and 29 of the Single Convention on Narcotic Drugs, and the quantity that could be sourced would not obviate the need to produce a local supply under such regulations.

22 Catherine Sandvos, 'Affidavit', *Allard v The Queen*, 20 January 2015, [13].

23 *Marihuana for Medical Purposes Regulations* SOR/2013-119 s 3; Health Canada, *Statement on Supreme Court of Canada Decision in R v Smith*, 7 July 2015 <<http://www.hc-sc.gc.ca>>.

24 See, eg, Tikum Olam, *Our Strains* <<http://www.tikunolam.com/our-Strains>>.

25 Bedrocan BV, *Global Cannabis Programs*, <<https://bedrocan.ca/resources/regulatory-compliance/global-cannabis-programs/>>.

Exemption from prosecution for possession and use

The option

- 5.28 The issues paper sought comments on whether the law should be amended to protect patients and their carers from prosecution for possessing or using cannabis for medicinal purposes. 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 dependence²⁶ for small amounts of dried cannabis or cannabis extract where a person is an authorised medicinal cannabis user.
- 5.29 The exception would extend to the patient's carers, to allow them to possess the cannabis that the patient may lawfully use, and would require an additional exception to the offence of introducing a drug of dependence into the body of another person.²⁷
- 5.30 This option was canvassed in the issues paper because a similar reform was recommended by General Purpose Standing Committee No 4 of the New South Wales Legislative Council in 2013.²⁸ 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 was to have applied to a patient or carer where the patient had been certified by their 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'.²⁹

Comments

Advantages

- 5.31 The advantage of this option is that it would protect patients and their carers from the risk of being prosecuted, and the associated uncertainty and pressure of sourcing cannabis for medicinal purposes illegally. The Commission was told on a number of occasions about the stress of being exposed to prosecution for using cannabis for medicinal purposes. The idea drew some support in submissions, but mostly only as an initial step in introducing broader reforms.³⁰ Others saw no need for it, because they want to see broader reforms introduced immediately.³¹

Disadvantages

- 5.32 Some submissions opposed this option because they did not agree that medicinal cannabis products that are not available on prescription should be used for medical treatment.³² One submission expressed concern about the wider implications for legislative reform:

There should be under NO circumstances any forms of raw product or cannabis derivatives in the possession of any 'patient' that have not been prescribed and supervised under strict medical and TGA guidelines. These exact caveats are exactly what the pro-pot lobby want [to] ensure lower accountability/scrutiny and a furtherance of 'self-medication' practices and ultimately recreational use.³³

26 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 73, 75.

27 *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).

28 Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013) 71 (Recommendation 2).

29 *Ibid*.

30 Submissions 12, 14, 28, 29, 30, 37, 49, 89, 95.

31 Submissions 4, 11, 16, 18, 19, 32, 35, 54, 84.

32 Submissions 42, 47, 48.

33 Submission 42.

- 5.33 The Royal Australasian College of Physicians noted that an option such as this would allow carers to administer cannabis without fear of prosecution but would not ensure the safety or reliability of the composition of the product consumed.³⁴ The Australian Lawful Use of Cannabis Alliance similarly observed that it ‘would not provide a safe and consistent system of access to medicinal cannabis treatments’.³⁵ The Law Institute of Victoria pointed out that it would not address the broader issues of cultivation, manufacture and supply.³⁶

Conclusion

- 5.34 The Commission is of the view that, when assessed against the regulatory objectives, the disadvantages of this option outweigh the advantages. It fails to provide access to a safe and reliable supply of medicinal cannabis products. Thus, it would not integrate medicinal cannabis effectively into a health regime: doctors would authorise patient access to cannabis, but would not have any mechanism for controlling or supervising use. The products available to the patient would not necessarily be therapeutically appropriate, as they could have unknown or inappropriate THC/CBD levels and may contain unsafe contaminants.
- 5.35 Because the cultivation and supply of cannabis would remain unlawful, any person selling cannabis to an authorised patient or their carer would still be committing a serious criminal 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 illicit market.

‘Grow your own’

The option

- 5.36 A large number of people who made submissions and attended consultations argued for a ‘grow your own’ scheme.³⁷ Eligible patients could be licensed by the government to cultivate a designated number of cannabis plants at home for medicinal purposes. They could be able to nominate carers to assist them. The patients and carers would be responsible for manufacturing the raw cannabis into a form appropriate for the patient to use.
- 5.37 This option was often put forward as a scheme that would co-exist with cultivation by community-based, government or commercial enterprises.³⁸ Marie Gladman of the HEMP Party summed up this view in her submission:
- People can grow, people can make medicine, people can do whatever they like with their own cannabis, but the minute they sell the cannabis or cannabis products, then they register a business and pay tax like everyone else.³⁹
- 5.38 Schemes of this type are most prevalent in the United States, notably in the jurisdictions that pioneered the legalisation of cannabis for medicinal purposes. Where patients are permitted to cultivate their own supply in the United States, the law will generally specify the maximum number of mature plants they are permitted to possess (ranging between two and six plants, with extra allowances for seedlings).⁴⁰ 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.⁴¹ 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.⁴²

34 Submission 52.

35 Submission 35.

36 Submission 63.

37 Consultations 2, 4, 5, 6, 7, 9 (See Appendix C for list of consultations); Submissions 6, 7, 9, 10, 11, 14, 18, 19, 23, 30, 33, 37, 53, 68, 72, 77, 80, 86, 87, 90, 93, 95.

38 Submissions 10, 11, 19, 28, 30, 37, 73, 95.

39 Submission 10.

40 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)).

41 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, 11362.71(f)).

42 Ariz Rev Stat Ann § 36-2804.02(A)(f).

- 5.39 In Australia, a grow your own scheme was recommended in 2000 by a New South Wales Working Party on the Use of Cannabis for Medical Purposes. More recently, it was proposed by a Bill that was introduced into the New South Wales Parliament in 2014 and lapsed during 2015, and a draft Bill that is currently under consideration by a committee of the Legislative Assembly of the Australian Capital Territory.
- 5.40 The Victorian Drugs, Poisons and Controlled Substances Act prohibits cultivation unless it is authorised by or licensed under the Act or regulations. The Act could be amended to provide that a licensed patient who operates within the conditions of the licence would not be engaging in the unauthorised trafficking, cultivation, possession or use of a drug of dependence within the meaning of the Act. The legislation would also need to permit the patient to possess the necessary substances, materials, and equipment at their residential address for this purpose. Cultivators would have to be exempted from the operation of the *Therapeutic Goods Act 1989* (Cth).⁴³
- 5.41 A licensed patient would be permitted to cultivate the designated number of cannabis plants at home without attracting the prohibitions in the Act. The legislation could also be amended so that a licensed patient who manufactures products at home from the cannabis they have grown, for personal use, would not be committing ‘trafficking’ within the meaning of the Act. The patient would be permitted to possess the necessary substances, materials or equipment at their residential address only for this purpose.
- 5.42 Further regulatory controls could include:
- requiring the patient to grow the cannabis indoors
 - requiring the patient to give the Office of Medicinal Cannabis a ‘cultivation plan’ containing information about the cultivation site
 - allowing authorised officers to conduct periodic inspections of any cultivation site and report any significant failure to comply with the cultivation plan to the Office of Medicinal Cannabis
 - treating the cultivation of more than the permitted amount of cannabis as the unauthorised cultivation of a narcotic plant within the meaning of sections 72–72B of the Drugs, Poisons and Controlled Substances Act. Outdoor cultivation would also be unauthorised cultivation and captured under sections 72–72B.

Comments

Advantages

- 5.43 This option could provide eligible 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.

43

Either by the Commonwealth, exercising s 7AA of the *Therapeutic Goods Act 1989* (Cth), or in Victoria, by making regulations under s 6(3) of the *Therapeutic Goods (Victoria) Act 2010* (Vic).

Patient autonomy

5.44 Ultimately, a grow your own scheme places responsibility on the patient for their own treatment. The core feature of such a scheme is that it gives patients the freedom to experiment with cannabis and determine the dosage and form that works for them. Many people who made submissions and attended consultations argued for a grow your own scheme on the basis that it would give them substantial personal freedom in and responsibility for their medical treatment.⁴⁴ Medical practitioners were said to have insufficient knowledge about the endocannabinoid system and for this reason should not be responsible for controlling access to cannabis or determining whether it was appropriate for a patient.⁴⁵

Ease of access

5.45 A grow your own scheme was favoured also because it was seen as accessible, in that medicinal cannabis was expected to be affordable and easy to obtain.⁴⁶ For some it was a matter of personal choice:

I just want to be able to access it myself, growing my own Cannabis medicine in my garden in a similar way that I grow my vegetables to sustain my lifestyle.⁴⁷

5.46 For others, it was a matter of principle:

I am not opposed to legal growing of a small supply of the plant if a manufactured supply becomes too expensive to those who need it but a medicine is more useful to us and we could pay.⁴⁸

5.47 Another sentiment that was expressed a number of times, and which is related to the issue of costs, was that a Victorian medicinal cannabis scheme should not be directed by the interests of 'big pharma'. Cheryl Wright said that cultivation 'should not be left to pharmaceutical companies who are interested only in profits, not people'.⁴⁹ Another submission put the view that cultivation should not be regulated at all, so 'big pharmaceutical business has some competition, FINALLY!'⁵⁰

Disadvantages

Product quality

5.48 Under a grow your own scheme, the patient may not obtain cannabis that is of a sufficient quality or consistent composition. Significant variability is caused by different cannabis strains and 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.⁵¹

5.49 Canada and Israel initially established grow your own schemes but then moved away from them for various reasons, including quality control concerns. In Canada, there were concerns about the quality of the product that the patients were using and the inability of doctors to adequately monitor its use.⁵² It was abandoned in Israel partly because there was 'no quality control on breeds, yield quantity and cannabis quality'.⁵³

44 Submissions 3, 6, 7, 9, 10, 14, 16, 43, 45, 90, 97.

45 Consultation 6; Submissions 12, 59.

46 Submission 6.

47 Submission 68.

48 Submission 49.

49 Submission 2.

50 Submission 9. Emphasis in original.

51 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) 153.

52 Health Canada, *Proposed Improvements to Health Canada's Marijuana Medical Access Program* (31 March 2013) <<http://www.hc-sc.gc.ca>>.

53 Submission 61.

- 5.50 One of the regulatory objectives recommended by the Commission is to ensure that patients have access to medicinal cannabis products of reliable quality and composition. This is a priority for many of the people who spoke to the Commission,⁵⁴ some of whom have encountered significant variability in the products they have obtained from well-meaning individuals.⁵⁵ There is no guarantee that personally cultivated cannabis will achieve standards appropriate for medical treatment.
- 5.51 This issue is not whether patients who want to grow cannabis have the skills to do so; it is whether the cannabis produced is of suitable and consistent composition and quality. This was noted in the submission from the Drug Policy Modelling Program:
- While it is possible for non-regulated growers to produce stable cannabis free from adulterants, the reliance on unregulated suppliers for the manufacturer of medicinal products poses substantial risks for patients who cannot be guaranteed product stability and purity.⁵⁶
- 5.52 The medical profession is generally opposed to a grow your own scheme primarily because of concerns about quality and dosage control.⁵⁷

Engagement with professional medical care

- 5.53 If cannabis is to be treated as a medicine on a rational basis, it is necessary to ensure that ‘the smallest dose is prescribed for the shortest period required to gain the desired therapeutic effect, under medical supervision’.⁵⁸ Under a grow your own scheme, little can be done by a medical practitioner to supervise how much cannabis the patient uses and in what form. It has been observed in the United States that ‘allowing [personal] cultivation for any qualifying patient sacrifices too much control over a substance currently classified as having a high risk of abuse’.⁵⁹
- 5.54 Supporters of a grow your own scheme have pointed out that cannabis has a relatively low risk profile and has the potential to help many people.⁶⁰ The Commission was informed that:
- To suggest that somehow strains becoming more potent is a problem for home growers is not based on any independent scientific or historical data.⁶¹
- 5.55 Valid points are made about the relative health risks of cannabis compared to some legal medications. Nevertheless, if participating in a grow your own scheme causes or encourages patients to disengage from or not engage with the care of a medical practitioner, the patient’s health could be put at risk. The patient’s health could deteriorate not because of the cannabis treatment but because of the absence of other treatment as well.
- 5.56 One of the regulatory objectives recommended by the Commission is to integrate the use of medicinal cannabis products into the patient’s medical treatment. As stated in Chapters 2 and 3, the Commission considers that an option for law reform must enable doctors to respond to the development of side effects in their patients and manage the titration of dosages and the forms of administration used. Where there is a grow your own scheme, doctors have little knowledge of or control over a patient’s dose of cannabis and lack the capacity to assess its efficacy.⁶² Their role in a grow your own scheme would be limited to certifying that a patient’s condition and associated symptoms make them eligible to use medicinal cannabis, and discussing with the patient the risks associated with excessive use.

54 Consultations 2, 4, 5, 6, 7, 8, 9.

55 Submission 49.

56 Submission 21.

57 Submissions 38, 39, 52, 57.

58 Laurence E Mather et al, ‘(Re)introducing Medicinal Cannabis’ (2013) 199 *Medical Journal of Australia* 759, 759.

59 Claire Frezza, ‘Medical Marijuana: A Drug Without a Medical Model’ (2013) 101 *Georgetown Law Journal* 1117, 1144.

60 Submissions 10, 59.

61 Submission 53.

62 Claire Frezza, ‘Medical Marijuana: A Drug Without a Medical Model’ (2013) 101 *Georgetown Law Journal* 1117, 1135.

- 5.57 Some advocates of a grow your own scheme supported the idea that doctors should only be peripherally involved,⁶³ the suggestion in one submission being that a medical practitioner should only have the 'ability to sign a form saying this person can use medicinal cannabis. That's it.'⁶⁴ Indeed, there is evidence that patients who grow their own cannabis begin to disengage from the conventional medical system.⁶⁵
- 5.58 A scheme that separates treatment with cannabis from the conventional principles of medical treatment means that a patient with a serious condition is not receiving care based upon a holistic understanding of the patient's treatment. Furthermore, a grow your own scheme provides little scope for a medical practitioner to determine whether a person's use of cannabis is therapeutically effective or is being abused.
- 5.59 Creating a system that prevents medical practitioners from monitoring their patient's use would be inconsistent with the national designation of cannabis as a Schedule 9 drug that is liable to abuse. Some argue that treating cannabis as a Schedule 9 drug is fundamentally wrong, and that cannabis should be rescheduled or de-scheduled from the SUSMP to facilitate wider access.⁶⁶ However, the reason why cannabis is presently a Schedule 9 poison is not because of its toxicity and capacity for physical damage but substantially because of the concern that it can be abused.⁶⁷ The dependence-forming tendencies of cannabis were discussed in the issues paper and the effects of its unmodulated recreational use are the subject of recent studies.⁶⁸
- 5.60 A Victorian grow your own scheme would compromise the ability of medical practitioners to prevent their patients from abusing cannabis, because a medical practitioner would have no option but to rely on the patient to report accurately the amount that was actually being used. Such reports would not be able to address the actual amount of active constituents that were being taken. There is very little that can be done to address these issues in a grow your own scheme. It is a consequence of a scheme that makes the patient responsible for deciding how much cannabis they will use and in what form, thereby removing the capacity from the medical practitioner, which exists in relation to orthodox medications, to titrate usage on the bases of dose-response and dose-side-effect.

Potential for diversion

- 5.61 Patients and their carers participating in other schemes of this type have been selling on the illicit market, or giving away, cannabis they have been licensed to cultivate for personal use.⁶⁹ Diversion in these and other ways could occur in a Victorian grow your own scheme as well.
- 5.62 A study of Canada's scheme in 2012 estimated that that 36 per cent of grow your own licences were subject to 'misuse', defined as the sale of cannabis grown under such a licence into the illicit market.⁷⁰ Another example is found in the United States, where the Chair of Oregon's Liquor Control Commission estimated that up to 75 per cent of Oregon's medicinal cannabis was diverted into the illicit market.⁷¹
- 5.63 The submissions that raised this issue noted that it is difficult to ascertain how much personally cultivated cannabis is moving into the illicit market,⁷² and this is reinforced by the research.⁷³

63 Submissions 2, 10, 30, 37, 52, 59, 64.

64 Submission 10.

65 Pekka Hakkarainen et al, 'Growing medicine: Small-scale cannabis cultivation for medical purposes in six different countries' (2015) 26 *International Journal of Drug Policy* 250.

66 Submission 59; Consultations 1, 9.

67 Advisory committee (Meeting 3).

68 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [3.75]–[3.79]; Wayne Hall, 'What Has Research Over The Past Two Decades Revealed About the Adverse Health Effects of Recreational Cannabis Use?' (2014) 110 *Addiction* 19, 22–7.

69 Yu-Wei Luke Chu, 'The Effects of Medical Marijuana Laws on Illegal Marijuana Use' (2014) 38 *Journal of Health Economics* 43, 45.

70 Delsys, *Final Report: Cost-Benefit Analysis of Regulatory Changes for Access to Marijuana for Medical Purposes* (2012) 74–75.

71 Jeff Mapes, 'Medical marijuana growers may see new limits as Oregon legislators move to curb black market', *The Oregonian* (online), 20 March 2015 <http://www.oregonlive.com/mapes/index.ssf/2015/03/medical_marijuana_growers_may.html>.

72 Submission 74.

73 Gerald Caplan, 'Medical Marijuana: A Study of Unintended Consequences' (2012) 43 *McGeorge Law Review* 127, 143–4.

- 5.64 Even a small crop of cannabis is worth a substantial amount of money on the illicit market, and this has led other governments to disallow grow your own because of the risk to patients. For example, in deciding to prohibit grow your own on the basis that it was a 'public nuisance', the Californian City of Galt estimated that six mature plants lawfully cultivated in an individual's cannabis garden would have a market value of US\$12,000.⁷⁴
- 5.65 Therefore, even with restrictions limiting cultivation to a small number of plants there remains the risk that patients will be targeted by criminals for their cannabis.⁷⁵ It was observed in one submission that 'we don't want people put at risk because they have a high value crop or having their medicine stolen and putting their health at risk'.⁷⁶ Another observed that '[t]he risk to growers may be significant, and thus invasion of private property and risk to personal safety, being the main concern'.⁷⁷
- 5.66 Victoria Police expressed the view in its submission that the police would not be able to protect personal cultivators from being targeted by criminals:
- Personal crops would be a likely target for theft. Theft has the potential to escalate into crimes against the person, for example through owners protecting their crops, or through retaliatory actions. It would be extremely difficult for police to protect potentially large numbers of personal crops and their owners from targeted criminal activity.⁷⁸
- 5.67 To reduce the risk that personally cultivated cannabis will be targeted by criminals, other jurisdictions have required cultivation to be undertaken indoors⁷⁹ or simply prohibited grow your own schemes entirely.⁸⁰ Indoor personal cultivation is thought to reduce the public visibility and smell of cannabis, making it less of a target.⁸¹ The Californian cities that permitted indoor cannabis cultivation prescribed the maximum dimensions of the cultivation space (both in area and height), restricted the maximum number of plants that could be grown (notwithstanding the number of qualified patients or caregivers engaging in cultivation) and prohibited exposing cannabis plants to public view.⁸²
- 5.68 Some supporters of a grow your own scheme argued for this approach:
- Cannabis cultivation can be controlled to a very high extent, meaning that it can be done indoors, under completely artificial conditions. It can also be strictly limited by such conditions, such as by a restriction on growing area or available lighting. It follows that a framework restricting a patients growing space indoors would limit the production of the medicine and prevent commercial cultivation. One should need to prohibit the outdoor cultivation absolutely, but there are legitimate security and public safety issues that justify such a policy in any case. As with potentially dangerous weapons, cannabis ought to be kept under lock and key, and restricted to a scale and 'firepower' commensurate with the need.⁸³

74 City of Galt, Ordinance No. 2015-01, s 1.

75 In Canada, these have become known as 'grow rips': see Ian Freckelton, 'Medicinal Cannabis Reform: Lessons from Canadian Litigation' (2015) *Journal of Law and Medicine* 719, 721.

76 Submission 53.

77 Submission 70.

78 Submission 44.

79 See for example the account of the city-by-city regulation of medicinal cannabis in California provided by the City of Martinez, *City Council Agenda* (April 16, 2014), 6–10. Berkeley, Oakland, San Diego and San Francisco are four prominent exceptions.

80 Stephen C Collett, Tom Gariffo and Marisa Hernandez-Morgan, Evaluation of the Medical Marijuana Program in Washington, DC, (University of California, Los Angeles Luskin School of Public Affairs, 2013) 15; Health Canada, Medical Marihuana Regulatory Reform 2011 Consultations Results, (31 January 2013) <http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-eng.php>.

81 City of Galt, Ordinance No. 2015-01, s 1. See also Submission 53.

82 City of Martinez, *City Council Agenda* (April 16, 2014), 6–10. See, eg City of Ferndale, Ordinance No. 2013-03 § 6.2.9.

83 Submission 23.

Safety

- 5.69 Indoor cultivation may reduce the risk that a patient will be targeted by criminals but only to a modest degree; risks remain of the commission of break and enter and robbery (including armed) offences to steal what is otherwise an illegal and valuable product.
- 5.70 In addition, there are significant risks to the health and safety of those who grow their own and to the health and safety of the community.
- 5.71 If cannabis is not cultivated responsibly and diligently, it can become contaminated in a way that threatens the health of the person who consumes it. For example, cannabis may become contaminated with mould or harmful bacteria;⁸⁴ pesticides;⁸⁵ or metals like lead, mercury, and zinc.⁸⁶ These risks are exacerbated by indoor cultivation.⁸⁷ Additionally, certain techniques for cultivating cannabis indoors use a great deal of power. If the electrical system of a residence is not designed to cope with the increased load or is poorly wired, it can cause fire or electrocution. In Canada, for example, the Royal Canadian Mounted Police found that the risk of fire was 24 times higher than in residences in which cannabis was not cultivated.⁸⁸
- 5.72 Contaminated cannabis poses an elevated risk to patients with serious illnesses. For example, patients with AIDS or otherwise compromised immune systems have reportedly developed lung infections when smoking cannabis contaminated with *Aspergillus*.⁸⁹
- 5.73 Consistently with their emphasis on personal freedom in medical treatment, advocates for a grow your own scheme tended to argue that avoiding these risks was a matter of 'due diligence' for the cultivator roughly equivalent to that required to cultivate vegetables safely.⁹⁰ The Commission was told on a number of occasions that cultivating cannabis does not require a great deal of expertise,⁹¹ although the opposite has also been suggested.⁹² Furthermore it was suggested that there is a significant amount of material available that could help patients and carers develop the necessary skills and that 'we need to learn how to deal with this'.⁹³

A partial solution

- 5.74 No matter how many patients were able to grow their own cannabis and make their own products safely, a grow your own scheme would be only a partial solution. The Commission also heard that many people did not want to prepare their own medicinal cannabis.⁹⁴ Some of them were unfamiliar with cannabis, cautious about personally cultivating cannabis and did not want to learn about it.⁹⁵ Michelle Whitelaw, for instance, was unequivocal: 'I do not wish to cultivate or be my son's pharmacist.'⁹⁶

84 John McPartland, 'Contaminants and adulterants in herbal cannabis' in Franjo Grotenhermen and Ethan Russo (eds) *Cannabis and Cannabinoids: Pharmacology, Toxicology, and Therapeutic Potential* (Haworth Press, 2002) 337–9; Jennifer McLaren et al, 'Cannabis potency and contamination: a review of the literature' (2008) 103 *Addiction* 1100, 1105.

85 John McPartland, 'Contaminants and adulterants in herbal cannabis' in Grotenhermen and Russo (eds) *Cannabis and Cannabinoids: Pharmacology, Toxicology, and Therapeutic Potential* (Haworth Press, 2002) 340.

86 'Symposium, 'Practical, Legal, and Ethical Perspectives on Medical Marijuana' (Transcription of Speakers' Remarks)' (2012) 16 *MSU Journal of Medicine and Law* 505, 522.

87 John W. Martyny et al, *Health Effects Associated with Indoor Marijuana Grow Operations* (2012) 18.

88 Ian Freckelton, 'Medicinal Cannabis Reform: Lessons from Canadian Litigation' (2015) *Journal of Law and Medicine* 719, 721–2.

89 Mark Ware and Vivianne Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research and Management* 31, 32.

90 Submission 53.

91 Submissions 6, 14, 53.

92 Alex Wodak and Laurence Mather, 'Australia Has No Reason To Disallow Medical Cannabis Use' *The Conversation* (online) 26 March 2014 <<http://theconversation.com/australia-has-no-reason-to-disallow-medical-cannabis-use-24717>>; Families and Friends for Drug Law Reform, Submission No 82 to the ACT Standing Committee on Health, Ageing, Community and Social Services, *Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014*, 16 February 2015, 5. The submission from the cannabis community of Victoria also noted these issues: Submission 95.

93 Submission 53.

94 Consultations 2, 13, 23; Submissions 29, 31, 42, 54, 70, 71

95 Consultation 13; Submissions 70, 71.

96 Submission 71.

5.75 The opponents of grow your own were generally eager to try medicinal cannabis products, but only if regulated and supplied in a way that is similar to prescription medicines.⁹⁷ Some were dealing with serious, debilitating conditions, or were parents caring for children suffering from such conditions. For them, requiring or encouraging seriously ill patients to cultivate cannabis was ‘unfair’:

This is not the dark ages and it seems quite disrespectful and unfair to those who are in need, to have to grow their own or suffer without. Those people who are so debilitated they can barely manage to get out of bed may qualify to grow their own, but it poses the question, how?... How will they maintain and grow a crop for personal use if they are physically infirm or in pain ... Would this not be a foolish exercise when the probability of gain may be ruined entirely by not having the appropriate skills necessary? A ruined crop may mean that person has to go without. This is certainly not a compassionate nor safe option.⁹⁸

5.76 These concerns were underscored by the submission from Cancer Action Victoria, which noted that it ‘was not in favour of a “grow your own” scheme. This is not feasible for patients who are debilitated by their illness’.⁹⁹ The problem is exacerbated by the issue that the most obvious method of ingesting cannabis under a grow your own scheme is through smoking,¹⁰⁰ which many people are unwilling to do for health reasons.¹⁰¹

5.77 As noted above, a number of the advocates for a grow your own scheme envisaged that it would operate alongside a scheme that provided for medicinal cannabis products to be produced by regulated community, government or commercial entities. This means that the Victorian Government would still need to establish a scheme for the production of medicinal cannabis products, in collaboration with the Commonwealth and in compliance with the Single Convention on Narcotic Drugs, but for a smaller patient group.

5.78 The co-existence of a grow your own scheme and production by regulated entities is not advisable. Some advocates have drawn analogies with home-grown and commercially grown vegetables. However, cannabis would remain illegal for most Victorians, and there would continue to be an illicit market for recreational and other unauthorised use.

5.79 One submission noted that, where both personal and government-regulated cultivation are permitted, it is more difficult to track what goes onto the black market.¹⁰² Mullaways Medicinal Cannabis Pty Ltd expressed the view that a grow your own scheme is ‘nearly the worst of all options’ for the patient, for medical practice and from a policing perspective.¹⁰³ The Law Institute of Victoria maintains that:

any schemes that would self-regulate the end user as a grower should be avoided, as it would undermine the regulatory system around cultivation and supply of drugs and weaken public confidence in the regulatory system.¹⁰⁴

97 Consultations 2, 4.

98 Submission 70.

99 Submission 54.

100 Arno Hazekamp and George Pappas, ‘Self-Medication with Cannabis’ in Roger Pertwee (ed) *Handbook of Cannabis* (Oxford University Press, 2014) 329–30.

101 Advisory committee (Meeting 1); Consultations 8, 9, 12, 13, 23; Submissions 47, 70, 74.

102 Submission 74.

103 Submission 29.

104 Submission 63.

Compliance with international law

5.80 Furthermore, any scheme that includes grow your own is at odds with the system of control prescribed by international law.¹⁰⁵ The International Narcotics Control Board has recently made clear its view that grow your own schemes do not comply with the Single Convention on Narcotic Drugs:

The Board has reviewed the issue of cultivation of cannabis for personal medical use and has determined that, in the light of the heightened risk of diversion it represents, such cultivation does not meet the minimum control requirements set out in the Single Convention. Accordingly, the Board has consistently maintained the position that a State which allows individuals to cultivate cannabis for personal use would not be in compliance with its legal obligations under the Single Convention.¹⁰⁶

5.81 Given this position, Australia's international obligations pose a major impediment to the adoption of a scheme that includes grow your own. This would affect the legal stability of a grow your own scheme in Victoria, because of the incompatibility of Australia's international obligations under the Convention and an essentially unregulated grow your own scheme.

Conclusion

- 5.82 Medical and regulatory experts overwhelmingly rejected this option when discussed at consultations, as did a significant number of patients and their families who want medicinal cannabis to be made available in the same way as prescription medication. The Commission shares their concerns. A grow your own scheme would not provide all eligible patients with access to medicinal cannabis because it would exclude those who do not have the wish, resources, skills and ability to grow their own plants or have them grown on their behalf. It would not ensure that the patient's cannabis use is integrated with their other medical treatment because their medical practitioner would not know of, or be able to monitor, what they were using or its effects. A patient using home-grown cannabis may not be using a product of sufficient quality or consistent composition because of the significant variability caused by different cannabis strains and growing conditions, which only sophisticated growing operations are able fully to control.
- 5.83 The Commission considers that the products that are made available under any medicinal cannabis scheme should not be able to be smoked, which is more likely in a grow your own scheme. It also considers that a grow your own scheme would be a substantial diversion risk, as there would be no distinction between licit and illicit dried plant products and the limits on production and distribution would be very difficult to enforce. This would undermine efforts to preserve the continuing prohibition of unlawful trafficking, cultivation, supply and use.
- 5.84 This option would not ease the regulatory burden and the related costs to the Victorian Government compared to other options, because an alternative scheme would still need to be introduced for patients who are unable—or do not wish—to be responsible for producing their own medicine.

105 Standing Committee on Health, Aging, Community and Social Services, ACT Legislative Assembly, *Inquiry into Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and Related Discussion Paper* (2015) 18.
106 *Report of the International Narcotics Control Board for 2014*, International Narcotics Control Board, E/INCB/2014/1 36.

Regulated not-for-profit production and distribution

The option

- 5.85 Some submissions advocated the creation of regulated not-for-profit cooperatives, collectives or clubs which would arrange for the collective cultivation and manufacture of medicinal cannabis products for distribution to their members.¹⁰⁷ A submission made on behalf of the cannabis community of Victoria described these cooperatives as follows:
- [M]embers of the Compassion Club or Co-operative join the club for an annual membership fee and come together sharing skills and resources to cultivate, distribute and or manufacture cannabis and cannabis products in accordance with a clubs constitution, rules and or regulations.¹⁰⁸
- 5.86 Victoria could exempt associations such as these from the *Therapeutic Goods Act 1989* (Cth) without the co-operation of the Commonwealth, as long as they are unincorporated. Victoria could make regulations under section 6(3) of the *Therapeutic Goods (Victoria) Act 2010* (Vic) to exclude the operation of the Commonwealth Act for the purposes of the production and distribution of medicinal cannabis by authorised unincorporated cooperatives.
- 5.87 As the submission on behalf of the cannabis community of Victoria noted, cooperatives can in principle be incorporated or unincorporated.¹⁰⁹ The Commonwealth would have to exempt medicinal cannabis from the *Therapeutic Goods Act 1989* (Cth) in order to allow incorporated cooperatives to produce medicinal cannabis products.
- 5.88 Any cooperative that wished to refine cultivated cannabis into other forms such as oils or tinctures would still need to obtain a manufacturing licence from the Commonwealth under the Narcotic Drugs Act. This option therefore relies on the Commonwealth agreeing to license cooperatives so they may provide patients with cannabis in a form that is appropriate for their medical needs, rather than forcing patients to resort to smoking.
- 5.89 To create the scheme, Victoria could amend the Drugs, Poisons and Controlled Substances Act to provide for licences to be issued either to a cooperative (to produce medicinal cannabis products for its members), or to a person nominated by the cooperative (to cultivate a certain amount of cannabis, or produce products, as determined by the cooperative and approved by the government).
- 5.90 The licensees would need to comply with detailed rules, which could be a combination of licence conditions, statutory provisions and regulations, to ensure that the products are of good quality and provided to authorised patients. The cannabis community of Victoria put forward a detailed proposal, based on the British Columbia Compassion Club Society, in which the cooperative would operate a closed system encompassing all steps of the production and supply of the product as well as patient care.

107 Consultation 1; Submissions 13, 15, 35, 95.
 108 Submission 95.
 109 Ibid.

Comments

Advantages

Simple and cheap to regulate

5.91 Regulating cooperatives is thought to be simple because its members are responsible for arranging for cultivation and guaranteeing the quality of the cannabis they purchase from cultivators and manufacturers. All of the activities associated with cannabis production and supply are concentrated in a single association of patients and carers, and this is said to reduce the regulatory burden and cost of medicinal cannabis.¹¹⁰ The submission made on behalf of the cannabis community of Victoria noted that the British Columbia Compassion Club Society screens its cultivators. The Society goes so far as to inspect cultivation sites for cleanliness, safety, plant quality, and security.¹¹¹

Viable alternative to illicit market

5.92 Because cooperatives are thought to provide a simple and cheap source of cannabis, they are asserted to undermine the illicit market for cannabis. For example, it was noted that cooperatives provide a viable alternative to the black market that can be taxed and that reduce diversion.¹¹² Trich from the Cannabis Social Club Australia said that criteria of access to medicinal cannabis should not be too restrictive because ‘one of the main aims of legalisation—to reduce the size of the criminal market—will not be met’.¹¹³ This reasoning is commonly associated with advocacy for legal cannabis for recreational purposes.¹¹⁴ Indeed, the advocates for this option generally assumed in their submissions that they would be permitted to supply cannabis to a large market. Trich said that ‘millions of reasonable users’ could be supplied under a compassion club scheme.¹¹⁵

5.93 The Commission notes that any scheme established by the government would provide an alternative to the illicit market, as well as creating a risk that products produced under the scheme would be diverted to it.

5.94 The purpose of the proposed reform, conveyed by the terms of reference, is on providing cannabis for medicinal purposes to a confined group of patients. This would limit the potential membership base for cooperatives of this type to people with complex medical needs.

Disadvantages

5.95 The Commission is concerned that adapting cooperatives to suit Victoria’s requirements would require significant regulatory intervention which is unlikely to be feasible. As has been identified in Chapter 4, for a scheme to support Australia’s international obligations it must take specific regulatory measures to limit diversion and ensure that accurate estimates can be reported to the Commonwealth. Furthermore, patients are entitled to expect that any medicine they receive is of sufficient quality and is not unduly harmful to their health.

110 Submission 95.

111 Ibid.

112 Submission 13.

113 Submission 15.

114 Pekka Hakkarainen and Jussi Perala, ‘With a Little Help From My Friends – Justifications of Small-Scale Cannabis Growers’ in Tom Decorte et al. (eds) *World Wide Weed: Global Trends in Cannabis Cultivation and its Control* (Ashgate, 2011) 83.

115 Submission 15.

An alternative to conventional medical treatment

- 5.96 A cooperative scheme is designed to concentrate expertise in growing and using cannabis within the cooperative. Some supporters of cooperatives argued that a system of distributing medicinal cannabis should not be merged with the general medical system.¹¹⁶ However, as is explained below in relation to dispensaries, the risk of concentrating treatment with cannabis in cooperatives is that patients may begin to disengage from the conventional medical system.¹¹⁷ This would be incompatible with the regulatory objectives. A scheme should ideally be integrated with a patient's conventional medical treatment, not act as a replacement.

Diversions risks

- 5.97 Substantial diversionary risks are associated with cooperatives. The submission made on behalf of the cannabis community rejected this, asserting that '[d]espite suggestions that these organizations may operate as a front for organised crime and diversion to the illicit market, there is little evidence to support these claims'.¹¹⁸ The submission claimed that in Canada 'police organizations recognize this fact and tolerate the operation of both Compassion Clubs /Medicinal Cannabis Dispensaries'.¹¹⁹ The Commission notes that in light of concerns about diversion¹²⁰ Canada moved to replace illegal cooperatives with what is effectively a regulated dispensary scheme.
- 5.98 Furthermore, there is some evidence in other jurisdictions that cooperatives are targeted by criminals who wish to take advantage of the legitimate front for cultivation and manufacture they provide. For example, in Belgium it has been reported that cooperatives are frequently approached by potential cultivators who are uninterested in complying with the cooperative's rules, have cultivated cannabis of poor quality deliberately to offset costs, and have cultivated more cannabis than is required in order to sell it to others illegally. Belgian cooperatives have reported that they are in greater fear of 'systematic violence from criminal entrepreneurs than of police intervention'.¹²¹ Spain, which permits the operation of not-for-profit cooperatives, also suffers from this problem.¹²²
- 5.99 The Commission notes that these risks could be managed through robust regulatory oversight. However, such regulation would reduce the capacity of the cooperative to self-regulate and weaken its autonomy. It would also increase the costs of the scheme, weakening the reasons for preferring it over alternatives. This calls into doubt a core rationale of a cooperative scheme: that it is cheap to regulate.

Quality control

- 5.100 As noted above, members of a cooperative could take steps to ensure that they are obtaining cannabis of sufficient quality from cultivators. However, there is some evidence that, like people who grow their own, cooperatives encounter difficulties ensuring the quality and safety of cannabis. For example, cooperatives in Belgium claim that they test their cannabis for contaminants but the practicality of their methods has been questioned.¹²³ The actual THC content of the cannabis produced by Belgian cooperatives is often unknown, making it impossible to estimate dosages with any accuracy.¹²⁴ The procedures Belgian cooperatives have adopted to guarantee quality control have been described as 'superficial and rather subjective'.¹²⁵

116 Submission 15.

117 See [5.113].

118 Submission 95.

119 Ibid.

120 Health Canada, *Proposed Improvements to Health Canada's Marihuana Medical Access Program* (31 March 2013) <<http://www.hc-sc.gc.ca>>; Ian Freckelton, 'Medicinal Cannabis Reform: Lessons from Canadian Litigation' (2015) *Journal of Law and Medicine* 719, 721.

121 Tom Decorte, 'Cannabis Social Clubs in Belgium: Organizational Strengths and Weaknesses, and Threats to the Model' (2014) 26 *International Journal of Drug Policy* 122, 126.

122 Jonathan Caulkins et al, *Considering Marijuana Legalisation: Insights for Vermont and other Jurisdictions* (RAND Corporation, 2015) 59.

123 Tom Decorte, 'Cannabis social clubs in Belgium: Organisational strengths and weaknesses, and threats to the model' (2014) 26 *International Journal of Drug Policy* 122, 126.

124 Ibid.

125 Ibid 129.

Compliance with international obligations

- 5.101 It would not be feasible for a cooperative to be compliant with Australia's obligations under international law. Advocates for a not-for-profit cooperative scheme argued that it complied with the Single Convention on Narcotic Drugs.¹²⁶ The argument is that the international conventions allow states to decriminalise cannabis for personal consumption, and that this latitude extends to the cultivation of cannabis for personal consumption.¹²⁷ Interpretations like these take cooperatives into 'uncertain territory' from an international law perspective.¹²⁸
- 5.102 If a decision were made to regulate cooperatives as a system of cultivation and distribution for the purposes of medical treatment, regulating them consistently with international law would become difficult. If the state took positive legislative steps to regulate the cultivation of cannabis for medicinal purposes, as opposed to merely decriminalising its personal cultivation and use in small amounts, the Single Convention on Narcotic Drugs requires a government agency to license cultivators¹²⁹ and take physical possession of the crops of cannabis.¹³⁰ If Victoria wished to impose these requirements, it would further increase the regulatory costs of a cooperative scheme.

Conclusion

- 5.103 The Commission does not consider that this option is suited to Victoria. The Commission was told on several occasions that patients and their families would like medicinal cannabis to be treated as much as possible like conventional medications. However, having medicinal cannabis cultivated by and for closed communities of users could reinforce negative perceptions about using it, perpetuate doubts about its efficacy, and undermine efforts to encourage communication between patients and their medical practitioners about whether it could provide them relief. It would also significantly exclude the involvement of medical practitioners in monitoring the effectiveness of the medicinal cannabis and taking suitable measures to address any risks or side effects.
- 5.104 The Commission also notes that this option would provide little, if any, opportunity for the government to take possession of the medicinal cannabis before it is distributed to patients, as required by the Single Convention on Narcotic Drugs. The lack of such an opportunity may deter the Commonwealth from agreeing to issue the manufacturing licences on which the scheme would depend.

Regulated distribution through dispensaries

The option

- 5.105 Many submissions suggested that medicinal cannabis products could be distributed through dispensaries.¹³¹ Dispensaries have been established in a number of jurisdictions overseas as outlets for producers of medicinal cannabis products or in connection with a clinic that specialises in the use of those products.
- 5.106 Dispensaries arrange for the production by cultivators and manufacturers of medicinal cannabis products, which they then supply. This would make dispensaries 'sponsors' within the Commonwealth's therapeutic goods framework. Accordingly, the Commonwealth would need to provide an exemption under the Therapeutic Goods Act enabling Victoria to regulate the distribution of medicinal cannabis products by dispensaries.

126 Submission 15.

127 Amber Marks, *The Legal Landscape for Cannabis Social Clubs in Spain* (Observatorio Civil De Drogas, 2015) 10.

128 David Bewley-Taylor, *International Drug Control: Consensus Fractured* (Cambridge University Press, 2012) 190.

129 *Single Convention on Narcotic Drugs 1961* art 23(2)(b).

130 Ibid.

131 Submissions 12, 30, 37, 53, 54, 55, 61, 71, 76, 84, 91.

- 5.107 The Drugs, Poisons and Controlled Substances Act could be amended to provide for a licence to be issued to the entity to distribute medicinal cannabis products.¹³² The amount and content of the associated rules would depend on the entity, but probably would be directed to the risk of diversion to the illicit market.
- 5.108 The form and function of medicinal cannabis dispensaries that operate overseas vary. The common elements are that they supply only cannabis products and usually offer the customer a variety of products, information about the characteristics and effects of each, and advice about which could be most suitable in treating their conditions.

Comments

Advantages

- 5.109 By specialising only in the distribution of cannabis products, dispensaries are able to provide patients with a broad choice in obtaining the cannabis they are permitted to use, together with advice about which products could be most suitable for them.¹³³

Disadvantages

Replacing medical decision making

- 5.110 The operation of dispensaries, like not-for-profit cooperatives, could discourage or replace the need for medical professionals to make decisions about whether the patient's use of cannabis is therapeutically appropriate.
- 5.111 Like cooperatives, dispensaries purport to perform many functions conventionally performed by a prescribing doctor.¹³⁴ The submission on behalf of the cannabis community of Victoria observed that medicinal cannabis dispensaries 'provide health care services to the patient and assist patients in achieving therapeutic outcomes', and 'educate and assist patients in selecting appropriate cannabis strains and or products... for specific therapeutic needs and or desired outcomes'. The submission stated that dispensaries provide detailed advice on the risks, benefits, contra-indications, undesired effects, dosage, application, and safe use of cannabis.¹³⁵
- 5.112 Some argued that this was an advantage of dispensaries, and that the current lack of medical or pharmacist expertise or interest in cannabis made dispensaries necessary.¹³⁶ For example, Fred Andronikos argued that dispensaries would be necessary in Victoria because '[m]ainstream doctors and pharmacy preparations are a decade or more away and until then its going to take a specialist dispensary doctors, to work with the patients specialist physicians to make this work'.¹³⁷
- 5.113 The role that the Commission recommends that medical practitioners would have under a Victorian scheme is intended to encourage them to increase their knowledge about medicinal cannabis and engage with their patients about using it in tandem with any other medications. Without such integration, specialists may refuse to treat patients who use cannabis because it does not form part of the patient's conventional treatment. Patients in this situation may be forced to choose between dispensaries and specialist doctors, which may negatively affect the patient's health.¹³⁸

132 As required by the *Single Convention on Narcotic Drugs 1961* art 30(1).

133 Arno Hazekamp and George Pappas, 'Self-Medication with Cannabis' in Roger Pertwee (ed) *Handbook of Cannabis* (Oxford University Press, 2014) 328.

134 Rita Marcoux, E Paul Larrat and F Randy Vogenberg, 'Medical Marijuana and Related Legal Aspects' (2013) 38 *Pharmacy and Therapeutics* 615, 618.

135 Submission 95.

136 Submissions 37, 53, 76, 84, Consultation 3.

137 Submission 53. Dispensaries in which specialist doctors work were described by the cannabis community of Victoria as 'medicinal cannabis clinics'.

138 As has been reported in other jurisdictions: Rod Meloni, 'University of Michigan Doctor Refuses To Treat Girl Who Is Using Medical Marijuana to Stop Seizures' *Click on Detroit*, 1 April 2015 <<http://www.clickondetroit.com/news/university-of-michigan-doctor-refuses-to-treat-girl-who-is-using-medical-marijuana-to-stop-seizures/32134060>>.

Compliance with international obligations

- 5.114 It would be very difficult to create an opportunity for the state to take possession of medicinal cannabis under a dispensary system without imposing a substantial and contrived regulatory burden. Dispensaries typically purchase cannabis wholesale from producers. If the state were to take possession of cannabis and arrange for its distribution to dispensaries it would increase the regulatory costs of the scheme. These costs would either be passed on to patients by dispensaries (as usually occurs in private markets) or be absorbed by the state of Victoria.
- 5.115 Nor does the introduction of dispensaries resolve the problem of how to regulate cultivation and manufacture. As the submission on behalf of the cannabis community of Victoria indicated, dispensaries operate as stand-alone operations that contract with independent cultivators, or act as a retail front for commercial cultivators or a cooperative.¹³⁹ It would be necessary to create an additional layer of regulation to allow dispensaries to be lawfully supplied with, and then distribute, cannabis.
- 5.116 The Commission is not persuaded that there is such a need for dispensaries as to justify additional regulation. It considers it appropriate that pharmacies dispense cannabis, in light of the views expressed in submissions and at consultations that pharmacies are convenient, form part of conventional medicine, employ trained staff and are already established throughout urban and rural Victoria.¹⁴⁰
- 5.117 Accordingly, setting up a dispensary system is not likely to reduce the regulatory costs of a Victorian scheme or reduce the cost of cannabis supplied under that scheme. On the contrary, it would add an additional, unnecessary layer of regulation.

Conclusion

- 5.118 The Commission does not consider this option appropriate for a Victorian medicinal cannabis scheme. Unlike the United States, where not-for-profit dispensaries have been established under state medicinal cannabis schemes because the federal government prohibits the sale of cannabis for profit, there is no regulatory incentive in Victoria to find an alternative to distribution by pharmacies.

Government-enforced monopoly

The option

- 5.119 Under this option, a single entity with the necessary ability and capacity would cultivate and distribute cannabis and deliver it to the government, for distribution through pharmacies. The entity could be any of the following:
- a government agency or government-owned corporation
 - a university or research institute
 - a privately owned corporation.
- 5.120 For this option to be legally stable, Commonwealth support would be needed for each of these alternatives. The entity would need to be licensed under the Narcotic Drugs Act and granted an exemption from regulation under the Therapeutic Goods Act. It is possible, however, that neither of these requirements applies to a Victorian agency or a statutory authority that does not generate revenue from its activities.¹⁴¹

139 Submission 95.
140 Submissions 2, 20, 24, 29, 39, 48, 69, 97; Consultations 1, 9, 13, 18, 26.
141 Advisory committee (Meeting 2).

- 5.121 The option could be established in either of two ways. The Drugs, Poisons and Controlled Substances Act could be amended to permit a specified government-funded or owned entity to cultivate and manufacture cannabis for medicinal purposes and exempt it from Part V of the Act (concerning offences relating to drugs of dependence). Alternatively, the Drugs, Poisons and Controlled Substances Act could be amended to provide for a licence to be issued to cultivate and manufacture cannabis products and deliver them to the government.

Comments

Advantages

- 5.122 A government-enforced monopoly would allow the Victorian Government to take advantage of an entity with existing expertise in producing plant products of high quality in a safe and controlled environment. Because only one producer can ever be involved, the scheme would not involve a substantial regulatory burden. The Secretary of the Department of Health and Human Services through the Office of Medicinal Cannabis would only have responsibility for administering a single producer. The amount and quantity, form and composition of the cannabis to be produced by the single producer would be set out in a contract negotiated with the Victorian Government.

Preventing diversion

- 5.123 Allowing for a single producer that is solely responsible for cultivating and manufacturing cannabis for delivery to the Victorian Government, and which acts under a monopoly granted by the government, would be unlikely to give rise to diversionary concerns and would enable the accurate and prompt reporting of estimates and quotas to the Commonwealth. Accordingly, the scheme would comply with the objectives of the Single Convention on Narcotic Drugs.

Concentrating expertise

- 5.124 The viability of such a scheme depends on whether Victoria could identify a single entity with a capacity to produce cannabis products 'in-house'. Potentially, a government-controlled scheme can be quite large. The University of Mississippi, for example, has had its contract to cultivate cannabis renewed at US\$68.8 million to grow 30,000 plants.¹⁴² However, the University has been cultivating cannabis for research purposes since 1968, operates a 'Marijuana Research Project', and is solely responsible for supplying cannabis to researchers for their clinical trials. This demonstrates the importance of the expertise and capacity of the entity, across every aspect of the production chain, to the success of a monopolistic, government-controlled scheme.¹⁴³

Disadvantages

- 5.125 Some submissions suggested that the experience overseas does not support, on balance, the use of a government-enforced monopoly to control the production of medicinal cannabis. For example, Alkman Management Services Pty Ltd argued against the Victorian Government exercising monopolistic control over the cultivation and manufacture of medicinal cannabis, asserting that a monopoly over cultivation and manufacture has contributed to problems with cost and quality in Canada and the Netherlands.¹⁴⁴ Similarly, UTT BioPharmaceuticals argued that 'a single entity is not advised, since it could create a monopolistic environment, which could slow down research and development of new drugs'.¹⁴⁵

142 'Uncle Sam Will Buy \$69 Million Worth of Pot from Ole Miss', *Time Magazine*, (online), 23 March 2015 <<http://time.com/3755253/university-mississippi-marijuana/>>.

143 Evan Halper, 'Mississippi, Home to Federal Government's Official Stash of Marijuana', *Los Angeles Times*, (online), 28 May 2014 <<http://www.latimes.com/nation/>>.

144 Submission 41.

145 Submission 60.

Reliance on a single producer

- 5.126 Furthermore, if a single agency, university, or government-owned corporation is solely responsible for producing and supplying cannabis, a great amount of risk is concentrated in that single producer. If any step in the production chain failed—for example, if a crop of cannabis were lost—it would significantly reduce the amount of medicinal cannabis available to patients.

Inflexibility

- 5.127 Although a government monopoly scheme is relatively straightforward, it is also inflexible. The scheme is not designed to evaluate the eligibility of multiple producers. Jurisdictions that allow medicinal cannabis have increasingly adopted regulatory structures that can accommodate multiple producers (regardless of whether multiple producers actually participate in the scheme).

Conclusion

- 5.128 Because only one producer would ever be involved, the scheme would not involve a substantial regulatory burden. It would create a simple mechanism that is substantially compliant with international law and allow for an experienced entity to start producing cannabis medicines relatively quickly.
- 5.129 The government would have to identify a producer that it trusts to operate across all aspects of the production chain and which can consistently produce enough cannabis of sufficient quality to satisfy the requirements of a Victorian medicinal cannabis scheme. The scheme turns on the capacity of that single producer to manage risks and supply enough product without subcontracting its functions to other cultivators and manufacturers. If a suitable entity could be identified, this option could be an intermediate step in establishing a scheme that is sustainable in the long term.
- 5.130 Unlike the licensed producer scheme set out below, a government-enforced monopoly would not provide the regulatory framework to accommodate multiple cultivators and manufacturers. It would be preferable, given the risks associated with a single producer, to establish a flexible regulatory framework that is capable of accommodating multiple producers.

Multiple licensed producers

The option

- 5.131 Many submissions proposed that Victoria should license multiple private-sector cultivators and manufacturers similarly to the framework used to regulate poppies.¹⁴⁶ This option would provide ‘a comprehensive scheme regulated through every step of the supply chain which includes cultivation, manufacturing, processing, distribution and use’.¹⁴⁷
- 5.132 This option resembles the Israeli and Dutch arrangements for the production and distribution of cannabis, using the Victorian poppy straw regulatory framework and drawing on the Commonwealth scheme for licensing manufacturers of therapeutic goods. Broadly, it would involve the cultivation and manufacturing of cannabis by licensed cultivators and manufacturers respectively. Standards would need to be established to ensure that licensed cultivators and manufacturers produce products of sufficient quality to be used as a medicine.

146 Advisory committee (Meeting 2); Consultations 3, 4, 5, 12, 26; Submissions 24, 26, 29, 41, 44, 49, 54, 60. Others expressed a more general preference for a closely regulated system of private cultivators and manufacturers: Consultations 8, 13, 24.
147 Submission 29.

- 5.133 To implement controls akin to those in Article 23 of the Single Convention on Narcotic Drugs, the State of Victoria would have to take possession of the products from commercial producers and arrange for their labelling and distribution to pharmacies.
- 5.134 This option would allow multiple cultivators and manufacturers to be assessed against statutory criteria and other checks and balances derived from Victoria's poppy scheme. The government would be able to exercise the degree of regulatory control required by the Single Convention on Narcotic Drugs. In addition, the scheme would be adaptable to any changes to law or policy, either in Victoria or at the Commonwealth level, which could affect the reach or focus of the scheme.
- 5.135 To enable the scheme, a new Part could be inserted into the Drugs, Poisons and Controlled Substances Act authorising various dealings that are currently illegal. Commonwealth support would be needed, by exempting the manufacture and production of medicinal cannabis from regulation under the Therapeutic Goods Act and by granting licences under the Narcotic Drugs Act.

Comments

Advantages

- 5.136 The submissions that supported this option argued that it was a tested and successful model for managing the risks associated with cultivating prohibited substances that have a value on the illicit market.

Building on an existing framework that is preferred by industry

- 5.137 Mullaways Medicinal Cannabis Pty Ltd observed that 'it is not necessary to reinvent the wheel' and that 'any medical cannabis system set in place should follow similar guidelines to that of Opium Poppies in Australia':

The cultivation of high grade Opium Poppies are allowed in Tasmania (and Victoria) under regulation, to produce medication of varying dosages, as long as the end product meets the designated medication criteria for safety and effectiveness there is no current concern.¹⁴⁸

- 5.138 Similarly, TPI Industries observed that: '[u]sing the opium poppy framework, the legislation and regulations would enable cultivation to occur in a highly controlled and regulated environment with complete government oversight'.¹⁴⁹ TPI observed that: 'the cultivation, manufacture and supply of medicinal cannabis and its extracts is the same process and involves compounds of similar Schedules in the SUSMP as the cultivation, manufacture and supply of NRM and Active Pharmaceutical Ingredients'.¹⁵⁰ UTT BioPharmaceuticals made a similar point, suggesting that: '[c]annabis and opium have a lot in common, as they contain many compounds of therapeutic use and at the same time can be abused for their psychoactive properties'.¹⁵¹
- 5.139 However, the Commission notes Mullaways' observation that the poppy scheme was not a 'blueprint' because it would still be necessary to develop manufacturing, reporting and labelling standards such as are required by the TGA.¹⁵² In other words, the system of licences established by the poppy scheme could underpin the cultivation and manufacture of cannabis but its transformation into a medicine would require other regulation.

148 Submission 29.
 149 Submission 26.
 150 Ibid.
 151 Submission 60.
 152 Submission 29.

Building on an established framework for reporting to the Commonwealth

5.140 The poppy scheme is designed to enable commercial producers to report to the Commonwealth on the amount of poppy straw produced per year.¹⁵³ As John Ramsay & Associates noted in its review of the Tasmanian scheme:

The [poppy] processor role in the identification and reporting of the area of crop sown and harvested, and the volumes processed and product recovered is absolutely critical to Australia's ability to report on activity to the INCB and to meet its Convention obligations.¹⁵⁴

5.141 The Commission notes that cannabis is treated differently to poppy straw under the Single Convention on Narcotic Drugs. The Single Convention requires the state to take physical possession of cultivated cannabis, providing an opportunity to take stock of the amount of cannabis for report to the Commonwealth. Regardless, the accountability frameworks established under the poppy scheme provide an established, alternative basis upon which to build in order to ensure that reporting is as accurate as is possible. In particular, it would be important for manufacturers in a Victorian scheme to accurately account for the wholesale stocks of medicinal cannabis they hold.¹⁵⁵

Limiting diversion and promoting quality

5.142 The terms of reference indicate that the prohibition on unlawful uses of cannabis would need to be preserved under any Victorian medicinal cannabis scheme, and the poppy scheme provides a successful template by which to achieve this regulatory objective. As UTT BioPharmaceuticals observed:

The whole idea behind Poppy cultivation for the production of opioids for clinical [use], is to have stringent controls in place to make sure there is not illicit businesses... generated from the cultivation/production activity. Production of cannabis raw material must be for clinical purpose only, unless legislation modifications are enacted in the future.¹⁵⁶

5.143 The security arrangements put in place by the Tasmanian poppy scheme, which has existed since 1971, have successfully prevented diversion of opium poppies into the illicit market.¹⁵⁷ Victoria Police supported an adaptation of the poppy scheme as a way of addressing the potential for diversion of cannabis. It suggested that the value of cannabis on the illicit market would require any industrial scale production of medicinal cannabis to be strictly regulated, and that 'the regulations surrounding the poppy industry provide an instructive example' for the Commission in dealing with issues of diversion.¹⁵⁸

5.144 Others expressed the view that adapting the poppy scheme to the regulation of cannabis would resolve problems around the quality as well as the security of the product.¹⁵⁹ Shirley Humphris suggested that the regulation of cultivation and manufacture should be '[p]resumably similar to the poppy industry. It must be possible to grow and manufacture a secure supply' and 'a supply that is clean and grown under controlled conditions'.¹⁶⁰

153 Victoria, *Parliamentary Debates*, Legislative Assembly, 11 December 2013, 4539.

154 John Ramsay & Associates, *Review of the Tasmanian Poppy Industry Regulation: Report* (July 2013) 28.

155 This being permitted under art 23(2)(e) of the *Single Convention on Narcotic Drugs 1961*.

156 Submission 60.

157 Australian Lawyers Alliance, Submission No 55 to the Senate Legal and Constitutional Affairs Legislation Committee, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 13 March 2015, 11–12.

158 Submission 44.

159 Consultation 8.

160 Submission 49.

Research, innovation and product choice

- 5.145 A scheme in which multiple cultivators and manufacturers participate could foster research and innovation, consistently with the recommended regulatory objectives. The success of the poppy scheme model in fostering research was reinforced by John Ramsay & Associates, which in its review of the Tasmanian scheme made a similar observation regarding the importance of using industry investment and expertise:

The success of the Tasmanian industry is in no small way due to the expertise and efficiency of these two processors who both occupy a significant position in the international market. They have maintained continued research and development programs. Innovation has resulted in the developments of different varieties of poppies and improvements to alkaloid extraction methods, both to significant product recovery advantage.¹⁶¹

- 5.146 Allowing for the creation of a range of products that cater to the spectrum of patient demand is integral to encouraging patients to choose those products over the products available on the illicit market. The lack of choice has created problems in the Netherlands and initially in Canada, where patients have been supplied cannabis by a single producer.¹⁶²

Adaptability

- 5.147 The Commission's view is that a scheme that permits multiple cultivators and manufacturers to participate would be adaptable to further changes in the regulation of medicinal cannabis. If the market expanded because other states or territories established medicinal cannabis schemes, more licences could be issued or the conditions of the existing ones could be varied. If the Commonwealth entered the field, some aspects of the Victorian scheme could be discontinued. If demand for new products emerged, mechanisms would be in place to assess and approve them for manufacture and sale in Victoria.

Disadvantages

- 5.148 This option is the most comprehensive of the options reviewed and is therefore administratively more complex to establish. Once the regulatory framework is in place, however, the ongoing administration would be more straightforward.
- 5.149 Some submissions expressed concern that the market for poppies is significantly different from that for cannabis. For example, the Law Institute of Victoria observed that the poppy scheme is different because it relates to 'an established and regulated pharmaceutical product approved under the *Therapeutic Goods Act 1989* (Cth)... that had a large international demand'.¹⁶³ Given that a Victorian scheme is expected to supply cannabis only to patients in exceptional circumstances, the consumer base could—initially—be small, and the costs of production would have to be offset by the Victorian Government. The Commission notes that this would be true of any scheme that involves the industrial production of cannabis for the purposes of purchase and distribution by the state.
- 5.150 What is attractive for these purposes about the poppy scheme is that it serves as a template for the secure cultivation and manufacture of a product with high illicit value that has received the support of the Commonwealth. The Commission also notes that the Dutch medicinal cannabis scheme, although not as comprehensive as this option, is self-funding.

161 John Ramsay & Associates, *Review of the Tasmanian Poppy Industry Regulation: Report* (July 2013) 26.

162 Philippe Lucas, 'It Can't Hurt to Ask; A Patient-Centred Quality of Service Assessment of Health Canada's Medical Cannabis Policy and Program', (2012) 9 *Harm Reduction Journal* 2. See also Amanda Reiman, 'Cannabis Distribution: Coffee Shops to Dispensaries', *Handbook of Cannabis* (Oxford University Press, 2014) 349.

163 Submission 63. Similar concerns were expressed at Consultation 8.

Conclusion

5.151 A system of multiple licensed producers is the Commission's preferred option and it recommends that it be adopted as the model for a Victorian medicinal cannabis scheme.

Recommendation

- 18** The Victorian Government should create a scheme to regulate the production of medicinal cannabis by:
- (a) licensing private entities to cultivate and manufacture medicinal cannabis products under regulatory arrangements that are based on those that apply to the cultivation of alkaloid poppies, the processing of poppy straw and the manufacture of therapeutic goods
 - (b) establishing a process for approving medicinal cannabis products and ensuring that they are of appropriate quality
 - (c) providing the Secretary of the Department of Health and Human Services with the power to administer the scheme and the authority to take possession of medicinal cannabis products, account to the Commonwealth for those products, and arrange their transfer to pharmacies.

Regulating supply

148 Introduction

148 Nature of Commonwealth/state collaboration

150 Cultivation and manufacture

165 Distribution

6. Regulating supply

Introduction

- 6.1 There are several reform options available to the Victorian Government to supply eligible patients with medicinal cannabis, surveyed in the previous chapter. The supply option which best meets the Commission's regulatory objectives is one in which cannabis is cultivated and manufactured under licence by private entities under regulatory arrangements that are based on those that apply to the cultivation of alkaloid poppies, the processing of poppy straw and the manufacture of therapeutic goods. This chapter details how this option could be put into effect.
- 6.2 New regulatory frameworks would need to be created. In the case of cultivation, a new framework would be required because cultivation of cannabis for medicinal purposes is currently not allowed. In the case of manufacture and product approval, a new framework would be needed because this activity is not presently regulated by the Victorian Government, but by the Commonwealth. Importantly, though, the scale of the new regulation required turns on what agreement is reached between Victoria and the Commonwealth, and the extent to which this results in a transfer of regulatory responsibility to Victoria.
- 6.3 Subject to the scope of collaboration between Victoria and the Commonwealth, the Commission has produced a model that incorporates all of the new regulatory frameworks into Victorian legislation. In doing so, it has sought to:
- integrate legislative changes with existing provisions wherever possible
 - use familiar regulatory tools
 - impose the least regulatory burden necessary to achieve the scheme objectives
 - give flexibility to the regulator to manage risks
 - have regard to the requirements of the *Single Convention on Narcotic Drugs 1961*.

Nature of Commonwealth/state collaboration

- 6.4 As discussed in Chapter 4, for Victoria to enact laws giving effect to a legally stable medicinal cannabis scheme, collaboration with the Commonwealth should be pursued. This could take a number of different forms, but in each case would have the effect of removing medicinal cannabis from the *Therapeutic Goods Act 1989* (Cth) and placing the regulation of medicinal cannabis with the Victorian Government.

- 6.5 The most efficient solution, in the Commission’s view, would be for the Commonwealth Minister for Health to determine that medicinal cannabis products of a specified kind would be more appropriately regulated under a Victorian scheme, by way of a declaration under section 7AA of the Therapeutic Goods Act.¹ The effect of such action would be that medicinal cannabis products intended to be used therapeutically would be excluded from the application of the Therapeutic Goods Act and instead regulated under cannabis-specific Victorian laws. Only medicinal cannabis products manufactured in compliance with the Victorian scheme and approved for sale in Victoria would be included in such an arrangement.
- 6.6 Before making such a determination, the minister would need to have regard to (but is not limited to considering):²
- the likelihood that, if not regulated under the Therapeutic Goods Act, the goods could cause harm to the public
 - whether it is appropriate to regulate the goods under the Therapeutic Goods Act
 - whether the risks posed by the goods would be dealt with more appropriately under another scheme.³
- 6.7 The purpose of affording the minister this power was intended to:
- ensure the Therapeutic Goods Administration (TGA) is not involved in the regulation of products for which there is no public health focus or for which there may be sound public policy reasons for their not being regulated under the therapeutic goods legislation.⁴
- 6.8 If an exclusion determination were made in respect of Victorian-compliant cannabis products, the products covered by the determination would cease to be ‘therapeutic goods’ for the purposes of the Therapeutic Goods Act.⁵ Because other legislation relies on this definition, consequential amendments to avoid cannabis products being captured by other schemes would be needed.⁶
- 6.9 An alternative form of Commonwealth-state collaboration would be for the Commonwealth Health Minister to partially exempt certain medicinal cannabis products from portions of the Therapeutic Goods Act.⁷ In the Commission’s view, this option would not serve the regulatory objectives as well as a declaration that excluded Victorian medicinal cannabis products from the legislation entirely, and could lead to regulatory confusion.⁸

1 A section 7AA exclusion determination is a legislative instrument. While the determination is the decision of the Commonwealth Minister, it can be disallowed by Parliament: Explanatory Memorandum, Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013 (Cth) 20. Such a declaration would ensure that the manufacture of cannabis products that are considered ‘unapproved goods’, the manufacture of cannabis products without a manufacturing licence granted by the Therapeutic Goods Administration, and the wholesale supply of unapproved cannabis products could take place under a Victorian scheme without involving a contravention of the *Therapeutic Goods Act 1989* (Cth): ss 19B, 35. See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [4.85], [4.107].

2 *Therapeutic Goods Act 1989* (Cth) s 7AA(4).

3 Ibid s 7AA(3).

4 Explanatory Memorandum, Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013 (Cth) 21.

5 *Therapeutic Goods Act 1989* (Cth) s 3(1) (definition of ‘therapeutic goods’, para (g)).

6 For example, the *Food Act 1984* (Vic) operates on the principle that products should not be regulated as food if they are regulated as medicines. Consistently with this, the legislation excludes ‘therapeutic goods’ as defined in the *Therapeutic Goods Act 1989* (Cth): *Food Act 1984* (Vic) s 4A and s 4(1) (definition of ‘therapeutic good’). Consequential amendments may also be required to the *Therapeutic Goods (Victoria) Act 2010* (Vic) and the *Public Health and Wellbeing Act 2008* (Vic).

7 That is, by doing one of two things: (1) removing the registration requirements in pt 3-2 of the Act, which generally requires therapeutic goods supplied in Australia to be listed or registered on the Australian Register of Therapeutic Goods, by exempting cannabis products produced in compliance with a Victorian scheme from that Part pursuant to s 18 of the Act; or (2) removing the manufacturing restrictions in pt 3-3 of the *Therapeutic Goods Act 1989* (Cth) by exempting cannabis products produced in compliance with a Victorian scheme from that part pursuant to s 34 of the *Therapeutic Goods Act 1989* (Cth).

8 The difficulty arises from the interlocking system of controls over product approval and manufacturing licensing operated by the TGA. On the one hand, a s 18 exemption, which would remove registration requirements but continue to require manufacturers to hold licences issued by the TGA, would lead to regulatory confusion because, for example, should the Victorian Department of Health and Human Services receive notification that a cannabis product supplied to a patient was contaminated or somehow dangerous, it would have no power to inspect the relevant facility or impose conditions on the relevant manufacturing licence, because these functions would remain the responsibility of the TGA. On the other hand, a s 34 exemption, removing only the manufacturing requirements, would mean that manufacturers would no longer require licences from the TGA, but would be constrained to manufacture of products which were approved or already exempt, something which is unlikely if their manufacture is not regulated by the TGA.

- 6.10 Whichever option is agreed on, Victoria would also need Commonwealth support in the form of licences and permissions for cultivators and manufacturers to operate under the Victorian scheme. First, the Commonwealth Health Minister would need to grant licences to Victorian-licensed manufacturers under section 9 of the *Narcotic Drugs Act 1967*.⁹ This would enable relevant entities in Victoria to manufacture cannabis products without contravening the prohibitions in the Narcotic Drugs Act. Second, Commonwealth assistance would be required to import cannabis seeds and/or plants for use by cultivators in starting their crops. An import permission would need to be granted by the Commonwealth Secretary of the Department of Health.¹⁰ In addition, an import permit would be required from a Director of Quarantine for the importation of cannabis seeds or live plants.¹¹

Cultivation and manufacture

- 6.11 In considering how cultivation and manufacture should be regulated in Victoria, the following questions must be answered:
- Who should be allowed to cultivate and manufacture cannabis products?
 - Who should be required to hold a licence and what form should licences take?
 - What regulatory tools should be used to uphold quality and ensure security, and who will be responsible for their enforcement?
 - How can the government ensure that the quantity of cannabis produced is appropriate to satisfy patient demand?
 - How should the cultivation and manufacturing scheme interact with the chosen distribution model?

Industry structure

- 6.12 Two options are available for the Victorian Government to structure the cannabis production industry:¹²
- separate entities to cultivate cannabis plants and manufacture refined medicinal cannabis products
 - single entities to cultivate cannabis and convert it to refined products.
- 6.13 Each option has its advantages. In the case of separate cultivation and manufacture, the expertise necessary to cultivate cannabis is distinct from the expertise involved in making extracts,¹³ so that using separate companies may allow specialist expertise to be utilised more effectively. Separation also mitigates the risks associated with crop failure, although with cannabis grown indoors this may be less of a concern than in other industries.¹⁴ Some United States jurisdictions operate on a separate licensing model, most notably

9 The Health Minister must grant the licence unless the applicant had failed to furnish requested materials, the manufacturing premises had been stated inaccurately or it appeared the proposed manufacturer would be inconsistent with the Single Convention on Narcotic Drugs: *Narcotic Drugs Act 1967* (Cth) s 9(3).

10 'Cannabis' is a 'drug' for the purposes of the *Customs (Prohibited Imports) Regulations 1956* (Cth) and a person wishing to import it must obtain an import licence and import permission: r 5(1)(a) and Sch 4. While not stated explicitly, the regulations presumably capture seeds and living plants. Note that r 5(10)(b)(i) requires the importer to hold a licence under the *Narcotic Drugs Act 1967* (Cth) if they intend to use the imported product to manufacture cannabis products.

11 *Quarantine Act 1908* (Cth) s 13(1)(f) and (2A); *Quarantine Proclamation 1998* (Cth) ss 63 and 65. No species of cannabis appears in the list of 'permitted seeds' in sch 5 of the Quarantine Proclamation, meaning that cannabis seeds would require an import permit: s 63(1). All species of plants require an import permit if living, as they can be used for propagation: *Quarantine Proclamation 1998* (Cth) s 65(3). Some cannabis producers have, when setting up operations in a new jurisdiction, obtained permission to import live plants with which to start their cultivation, which are propagated by cloning—for example, when Bedrocan set up its Canadian arm.

12 As detailed at [7.79]–[7.83] below, manufacturing of cannabis extracts and other products will be required if, as recommended, only non-smokable forms of cannabis are sold.

13 Marc Selan noted that 'different qualifications, skills and knowledge are needed for the different products': Submission 74.

14 Crop failure is an issue in the poppy industry, where crops are grown outdoors and are susceptible to disease. A fungal disease, downy mildew, has caused the destruction of large amounts of poppy crops in Tasmania in recent years: Alex Blucher, 'A Systemic Mildew That's Causing Entire Paddock Losses in Poppy Crops Across Tasmania has Sparked an Industry-Wide Response', *ABC Rural* (online), 7 November 2014 <<http://www.abc.net.au>>. It is not known whether cannabis grown indoors would be susceptible to crop failure due to disease; however, it is assumed that because exposure to climatic conditions and contaminants can be more readily controlled, the risks would be lower.

Colorado.¹⁵ It is possible that the benefits associated with separate cultivation and manufacture are only seen when the industry has reached quite a large scale, as is the case in Colorado.

- 6.14 Other jurisdictions which allow the production of refined cannabis products tend to regulate the industry on the basis that a single entity will both cultivate and refine cannabis.¹⁶ There are many benefits to doing so. There are fewer security concerns where cannabis does not have to be transported from a cultivator to a manufacturer. There are fewer entities for the authorities to oversee, reducing the cost of administering the scheme. More sophisticated research and development may be able to take place where the company controls both aspects of production. It may also be easier to regulate the quality of the finished product, as many features of cannabis quality control relate to cultivation conditions. The selection of licensees would also be simpler. Finally, cannabis for medicinal purposes tends to be grown indoors, and it may be inefficient to prevent a cultivator from incorporating a manufacturing section into their existing facility.
- 6.15 These and other factors that would influence a decision as to whether to keep the cultivation of cannabis plants separate from the manufacture of refined medicinal cannabis products, or whether a single entity should be able to be both a cultivator and manufacturer of medicinal cannabis, are discussed in more detail in the following sections.

Coordination of regulatory processes

- 6.16 Expertise associated with regulating alkaloid poppy cultivators, which could be employed in regulating the cultivation of cannabis, is concentrated in the Department of Economic Development, Jobs, Transport and Resources (DEDJTR). The supervision of the manufacture of medicinal cannabis products would more naturally be a function performed by the Department of Health and Human Services. However, the need to have separate licences, administered by different government agencies, does not mean that single entities could not perform both functions. It would simply mean that a single licensed cultivator and manufacturer would be subject to inspections from two different agencies in respect of different aspects of its commercial activity.

Comparison with alkaloid poppy industry

- 6.17 Although the Commission's proposals draw from the regulatory mechanisms that are already in place for the alkaloid poppy industry,¹⁷ there are features of that industry that set it apart from the proposed cannabis industry and limit the extent to which the way its regulations can be replicated in a medicinal cannabis scheme.
- 6.18 The structure of the alkaloid poppy industry is premised on a different model of production from the proposed manufacture of cannabis. The end product of poppy cultivation is a set of pharmaceuticals—various opiates, all of which have been approved by the TGA. These products are manufactured by companies that hold manufacturing licences under the Therapeutic Goods Act. Separate licences for the cultivators are required, in part because cultivation is regulated by the Victorian Government while the

15 Colorado provides two categories of licence: Medical Marijuana Center Licenses, which permit the cultivation of cannabis and its sale to the public (i.e. 'dispensaries'), and Medical Marijuana-Infused Products Manufacturing Licenses, which permit the (optional) cultivation of cannabis and the manufacture of oils, tinctures and other infused products, but not sale to the public: Colo Rev Stat §§ 12-43.3-401 to 404. Medical Marijuana Centers can supply the cannabis they cultivate to manufacturers for refinement, and manufacturers must sell their products to Medical Marijuana Centers for sale to patients: Colo Rev Stat §§ 12-43.3-404. A company can hold both a Medical Marijuana Center License and a Manufacturing License.

16 Israel's licensed producers both cultivate and manufacture (for example, Tikun Olam). In Minnesota, where dried cannabis must be converted to a refined form, manufacturers cultivate and process cannabis at a single facility, from which the product must also be sold (Minn Stat § 152.29), with the same approach to be adopted in New York (NY Public Health Law § 3364). Alternative treatment centres in New Jersey both cultivate and refine cannabis (NJ Stat Ann § 24:61-7), as do registered dispensaries in Maine (22 Me Rev Stat Ann § 2428).

17 As recommended by Submissions 24, 26, 41, 44, 49, advisory committee (Meeting 2), Consultation 3.

regulation of manufacture is the responsibility of the Commonwealth.¹⁸

- 6.19 Because poppies are grown outdoors and are harvested only once per year, there is a need for a large amount of land to cultivate them, and this activity is more naturally carried out by specialist farmers. Similarly, the process of manufacturing the opiates is a sophisticated, industrial-scale exercise, requiring significant plant and capital.¹⁹ In short, the cultivation activities are not well suited to the entities carrying out the manufacture, and vice versa. For this reason, the industry involves a small number of licensed manufacturers purchasing poppy straw from a large number of licensed cultivators. This is also partly a consequence of the large demand for opiates (domestically and internationally).²⁰

The Single Convention on Narcotic Drugs

- 6.20 Article 23(2)(d) of the Single Convention on Narcotic Drugs provides that all cultivators of cannabis plants shall be required to deliver their total ‘crops’ of cannabis (that is, flowering tops and resin) to the government agency that has responsibility for regulating cannabis production.²¹ It is possible that, by allowing licensed cultivators to deliver products to a separately licensed manufacturer, which then delivered finished products (not the ‘crop’) to the government agency, Victoria’s scheme would not be in strict compliance with the Single Convention on Narcotic Drugs. The counter-argument is that the system of licences proposed below, while not demanding delivery of crops to the state, is nonetheless set up to ensure that cannabis products cannot be delivered to any entity other than the government, thereby upholding the purpose of Article 23.

Allowances for alternatives within recommendations

- 6.21 The decision as to how to structure the industry is a complex one that requires detailed economic analysis by government and consultation with industry. The recommendations in this chapter are advanced on the assumption that separate licences would be granted in respect of the cultivation function and the manufacturing function.
- 6.22 If the government were to decide to proceed with an industry structured around combined cultivating and manufacturing facilities, the structure conveyed in the discussion below could still be used, with dual licensing of these facilities.²² Alternatively, the licences for cultivation and manufacture could be merged, with responsibility for administering the combined licence concentrated in a single agency. This is a matter for government to resolve.
- 6.23 A further variation, not discussed below, would be for cannabis to be cultivated by licensed cultivators and turned into refined cannabis products (such as oils and tinctures) by compounding pharmacists. Pharmacists are exempt from the requirement to hold a TGA manufacturing licence and from the prohibition on the supply of unapproved goods, provided they ‘extemporaneously’ compound a medicine, on the premises where it is to be supplied, for a particular person.²³ A pharmacist could obtain dried cannabis from the Secretary of the Department of Health and Human Services (which would have

18 As a consequence of this arrangement, the companies that manufacture opiates in Australia are dually licensed: they hold a manufacturing licence from the Commonwealth under the *Therapeutic Goods Act 1989* (Cth) and a ‘processing licence’ from Victoria under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic). The processing licence allows only rudimentary steps to be taken, involving essentially the chopping of poppy heads and their separation from the seeds. This would not be required under a medicinal cannabis scheme, as the state would control both aspects of licensing and could include simple processing of this kind (including trimming, chopping and drying) in the activities allowed under one of the licences.

19 The Law Institute of Victoria observed that the manufacture of opiates results in an established and regulated pharmaceutical product, for which there is significant commercial demand, which may not be the case for cannabis: Submission 63. Advisory committee (Meeting 2).

20 Further consequences of this clause, regarding distribution arrangements, are discussed at [6.68]–[6.72] below.

21 This could be made somewhat like the process now adopted in Canada for the production of cannabis oil. Following the recent decision of the Supreme Court of Canada (*R v Smith* [2015] SCC 34), which held that the Canadian prohibition on forms of cannabis other than dried marijuana was unconstitutional, Health Canada announced that licensed producers of dried cannabis will be permitted, in addition to cultivating and processing dried cannabis, to refine it into oils. However, prior to doing so, licensed producers will have to obtain a ‘supplemental licence’, making them subject to separate regulations on quality: Health Canada, *Section 56 Class Exemption for Licensed Producers Under the Marihuana for Medical Purposes Regulations to Conduct Activities with Cannabis* (8 July 2015) <<http://www.hc-sc.gc.ca>>.

23 *Therapeutic Goods Regulations 1990* (Cth) r 18 and sch 8 item 2, r 12(1) and sch 5 item 6. See also Pharmacy Board of Australia, *Background on the Regulation of Compounding by Pharmacists* (March 2015) <<http://www.pharmacyboard.gov.au>>.

been purchased from a licensed cultivator) and refine it at the premises of a pharmacy or pharmacy department.

- 6.24 The Commission considers that this would not be a useful option. Although exempt from the listing and manufacturing requirements of the Therapeutic Goods Act when compounding, pharmacists would still be subject to the Narcotic Drugs Act, such that without a licence under that legislation their compounding activity would be unlawful. There would also be administrative difficulties regarding reporting of quantities of drugs manufactured. Finally, as cannabis products are no longer included in pharmacopoeias and formularies to which pharmacists turn for reference, few may consider themselves qualified to prepare cannabis-derived products.²⁴

Licensing cultivation

- 6.25 Licences to cultivate should be granted by the Secretary of DEDJTR. Recipients could be either individuals or corporations. The licensing scheme should be set out in the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) in very similar terms to the provisions allowing for licensing of alkaloid poppy cultivators.²⁵

Recommendation

- 19 Cannabis should be grown for medicinal purposes by cultivators licensed by the Secretary of the Department of Economic Development, Jobs, Transport and Resources.**

Managing the risks

- 6.26 Submissions and consultations drew attention to the diversion risks associated with the cultivation of cannabis by private industry. They are addressed in the proposed scheme, as they are in the alkaloid poppy scheme,²⁶ through the use of licences, licence conditions, risk management plans, inspections and potential enforcement.
- 6.27 Victoria Police recommended that ‘if commercial cultivation is to be included in the scheme, then strong consideration must be given to the security of the product’.²⁷ ACES Group submitted that ‘proper and robust security measures will need to be a focal point in the current debate’.²⁸ Against this, it was observed that cannabis is the most accessible illicit drug and one of the most affordable, meaning that there would low incentives for diversion.²⁹

24 See Pharmacy Board of Australia, *Guidelines on Compounding of Medicines* (April 2015) <<http://www.pharmacyboard.gov.au>>, which set out standards and other references to which compounding pharmacists must have regard. The Guidelines also state that, when compounding medicines, ‘pharmacists must ensure that there is good clinical and pharmaceutical evidence to support the quality, stability (including appropriate expiry periods), safety, efficacy and rationality’ of the treatment, and ‘must be satisfied that the dispensing and supply of a compounded medicine is consistent with the safety of the patient’: [6]. This would be difficult for pharmacists to assess in relation to cannabis preparations.

25 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) pt IVB. Pt IVB establishes a licensing regime with a significant amount of detail regarding the grant of licences, licence conditions, inspections and so on. This stands in contrast to the Tasmanian legislative arrangements for licensing poppy cultivators, which is extremely brief: *Poisons Act 1971* (Tas) s 52(1). Instead of cultivators being regulated through legislation or regulation, the bulk of the rules are contained in licence conditions: John Ramsay & Associates, *Review of the Tasmanian Poppy Industry Regulation: Report* (July 2013) 17.

26 See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [4.156].

27 Submission 44. Submission 23 also commented that owners, workers and distributors would be tempted by financial incentives to sell to recreational users. See Appendix B for list of submissions.

28 Submission 58.

29 Submission 46.

6.28 The way in which specific risks would be addressed under the proposed scheme is set out in the following table:

Table 2: Risks associated with cultivation of medicinal cannabis and the regulatory responses proposed to control these risks

Risk	Regulatory response
Diversion occurs because of criminal intervention by third parties (potentially causing risks to public safety)	Risk management plan addresses facility security measures, location, secrecy, surveillance
Diversion occurs because of criminal conduct by employees or contractors	Risk management plan addresses assessment, training and supervision of employees and contractors Criminal record checks required for employees Licence conditions require destruction of unused cannabis
Diversion occurs because of criminal conduct by managers/owners	Fit and proper person test before licence is granted Chief Commissioner of Police has veto power Licence conditions require: <ul style="list-style-type: none"> • that all cannabis cultivated is delivered to a licensed manufacturer or destroyed • that all unused cannabis is destroyed
Diversion occurs during transport	Risk management plan addresses how transportation will be securely undertaken
Cannabis grown is of poor quality	Addressed through quality control regime

6.29 Controlling diversion to the illicit market is also a requirement of international law. The Single Convention on Narcotic Drugs requires states to ‘adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant’.³⁰

6.30 As observed in consultations, the scheme must be designed to control the risk that cannabis will be diverted to the illicit market at ‘weak points’ in the supply chain.³¹ This requires careful assessment, properly resourced. It would be inappropriate merely to duplicate the policies associated with the alkaloid poppy scheme, because the risks associated with cultivating poppies are different from those associated with the cultivation of cannabis. For example:

- Cannabis with significant THC content can readily be used illicitly, while alkaloid poppies require sophisticated processing, making cannabis a more attractive target for theft.³²
- The waste products of medicinal cannabis production (the leaves) have value on the illicit market, if they have significant THC content, while poppy straw remnants do not.
- Medicinal cannabis tends to be grown indoors, while alkaloid poppies are grown in the field, meaning the risk of theft of cannabis by third parties is lower.

30 *Single Convention on Narcotic Drugs 1961*, art 28(3).
 31 Advisory committee (Meeting 2); Consultations 4, 19.
 32 Submission 44.

- Alkaloid poppies are typically grown as a rotation crop (alternated with other crops), while there is no need to rotate cannabis, meaning that cannabis licensees would probably only grow cannabis.
- Recreational use of alkaloid poppies can result in harm or death to the user, which is not the case for cannabis.
- Organised crime would be likely to have a greater interest in high-THC cannabis, as it is easier to transform into an illicit substance, and less interest in high-CBD cannabis.
- There is a greater illicit market for cannabis than heroin, making cannabis a more attractive criminal target than alkaloid poppies.³³

6.31 Victoria Police underlined the need for careful consideration of the risk of diversion in its submission:

If commercial cultivation is to take place in Victoria, Victoria Police recommends that strong consideration be given to implementing mandatory, stringent security requirements around cannabis cultivations to prevent theft and diversion. Such security requirements should be developed by subject matter experts, and these requirements will need to be heightened in comparison to poppy cultivations.³⁴

6.32 Submissions made a range of suggestions for how security should be safeguarded, including through background checks, auditing and inspection of potential cultivators, location of cultivation facilities, security systems and monitoring of facilities, tracking of products, harvesting and transport of raw material, and destruction of waste.³⁵ ACES Group observed that a security framework around medicinal cannabis could be drawn from 'overseas jurisdictions, particularly in the US where extensive security regulations and experience with managing security around medicinal and retail cannabis provides valuable insights for any future development'.³⁶

6.33 In the Commission's view, risk management plans are a better tool for controlling diversion risks than prescriptive regulations. This approach allows the controls to be calibrated to the level of risk.³⁷ The detail of the government's industry-wide risk assessment would then be reflected in departmental policies on and the assessment of risk management plans, rather than uniform regulations. Diversion should also be controlled by requirements, described below, requiring that licensed cultivators deliver to licensed manufacturers.³⁸

Who could obtain a licence?

6.34 The requirements for an applicant to obtain a cultivation licence should be based on the requirements in the alkaloid poppy scheme. In particular, to obtain a licence, a cultivator should be required to overcome the following hurdles:³⁹

- satisfying the Secretary that they are a fit and proper person⁴⁰ to hold a cultivation licence, entailing criminal history checks of the applicant and associates and an assessment of the suitability of the applicant, including consideration of their reputation and character, whether they have a history of non-compliance with cultivation obligations, their corporate structure and ownership, and their financial circumstances

33 Ibid.

34 Ibid.

35 Submissions 26, 58, 69, 74.

36 Submission 58.

37 Diversion risks could vary from one cannabis cultivator to the next. A cultivation facility in a remote area may attract a greater diversion risk than one in a built-up area. A facility at which only high-CBD cannabis was cultivated would be at a lower risk of diversion than high-THC forms of cannabis.

38 This requirement operates on a similar principle to the 'secured and closed medicinal cannabis circuit' implemented in some United States jurisdictions, where 'the aim of security measures and controls... has essentially been [to] create a secure and closed circuit where medicinal cannabis will only circulate between cultivation centres, dispensaries, patients and/or their caregivers': Submission 58.

39 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69O.

40 Cf Ibid s 69NB.

- suitability of the premises, including location, facilities and proposed security arrangements
- submission of a satisfactory risk management plan
- satisfying the Secretary of their intended commercial activities
- payment of the prescribed fee.

6.35 The Secretary should be enabled to investigate the above matters for the purpose of determining whether to grant a licence, including by inspecting the nominated premises and requesting criminal record checks.⁴¹ The Chief Commissioner of Police should have the power to object to the issue of a cultivation licence.⁴²

Risk management plans and licence conditions

6.36 As mentioned above, the risk management plan submitted by the applicant would be an opportunity for the applicant to prove its capacity to control the following matters:

- secure facility (building type, alarms and surveillance, lighting, signage, fencing and so on)
- appropriate location
- employee and contractor management
- auditing and record-keeping processes
- transportation without diversion.⁴³

6.37 As in the poppy cultivation scheme, DEDJTR officers should assess the risk management plan of each applicant against departmental guidelines, to ensure that sufficient security measures have been implemented. Experience with the alkaloid poppy scheme suggests that this should not be an overly burdensome exercise, with only a modest number of personnel required for the task (depending on the number of licensees). The cost could be borne by the cultivator.

6.38 Terms and conditions imposed on the licence should allow DEDJTR to control the activities of the cultivator. Conditions would include at a minimum:⁴⁴

- that all cannabis grown must be delivered to a licensed manufacturer or destroyed⁴⁵
- that the cultivator must comply with their risk management plan⁴⁶
- specification of the amount and area of cannabis that may be grown⁴⁷
- that only suitable employees may be employed.⁴⁸

6.39 Other optional conditions could also be specified by DEDJTR on grant of the licence.

6.40 Under the alkaloid poppy scheme, a further mandatory condition of a cultivation licence is that cultivators must at all times have a current contract with a licensed processor.⁴⁹ This would not be necessary if the industry were based around combined cultivator-manufacturer entities. If single licences were granted, the condition would be removed; if dual licences were granted to single entities, the condition could be altered to require that the two types of licence be held concurrently.

41 Ibid s 69OA.

42 Ibid s 69OA(4).

43 Australian Concert and Entertainment Security Pty Ltd provided a detailed overview of relevant security systems in their submission: Submission 58.

44 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69OC.

45 This is not an express statutory licence condition under the poppy scheme. DEDJTR may impose conditions relating to the disposal of harvested material and crop residue, or relating to the destruction of alkaloid poppies, poppy straw and material derived from poppies: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69OC(6)(f) and (h). The Commission suggests that, due to the higher diversionary risk associated with unused cannabis (particularly cannabis leaves), this should be made an express statutory condition.

46 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69OC(4).

47 The purpose of this condition is to satisfy the requirements of the *Single Convention on Narcotic Drugs 1961*, which requires member states to ensure that cultivation licences specify the extent of the land on which cultivation may take place: arts 23(2)(c), 28.

48 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69OC(3).

49 Ibid s 69OC(7).

- 6.41 Chapter 7 of this report considers the quality-control standards that should be imposed on cultivators. As set out there, the Commission considers that it is appropriate for quality standards to be imposed on cultivators of medicinal cannabis. These standards should be enforced through licence conditions.
- 6.42 The various decisions that could be made that would adversely affect the holder of a cultivation licence should be capable of review by the Victorian Civil and Administrative Tribunal.⁵⁰

Recommendation

- 20** The licensing and regulation of medicinal cannabis cultivators should be modelled on Part IVB of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) as it applies to alkaloid poppy cultivation. Key features of the scheme should be as follows:
- (a) Applicants for a cultivation licence would be subject to a fit and proper person test, required to satisfy the Secretary of their intended commercial activities, and pay a prescribed fee.
 - (b) The Chief Commissioner of Victoria Police would be able to oppose the issuing or renewal of a licence to an applicant, in which case the Secretary would be unable to issue or renew it.
 - (c) Licensees would be required to ensure that their employees are of suitable character.
 - (d) Licensees would be required to prepare and submit a risk management plan addressing safety and diversion risks associated with cultivation and how they will be addressed.
 - (e) Licensees would be required to comply with appropriate quality control measures.
 - (f) All cannabis grown would be required to be delivered to a licensed manufacturer or destroyed.
 - (g) Licensees would be required to have a contract with a licensed manufacturer at all relevant times.
 - (h) The Secretary would have the power to suspend or cancel a licence, including at the request of the Chief Commissioner of Police.
 - (i) Applications would be able to be made to the Victorian Civil and Administrative Tribunal for review of a decision by the Secretary to refuse to issue or renew a licence, or to suspend, cancel or amend it.

Inspections and enforcement

- 6.43 The holder of a cultivation licence would be inspected regularly by DEDJTR inspectors to ensure compliance with the conditions of the licence.⁵¹ In particular, inspectors would review the cultivator's adherence to their risk management plan.⁵² A variety of enforcement actions (such as imposition of licence conditions, product forfeiture and infringement notices) would be available to inspectors if non-compliance were observed, with the ultimate sanction of licence suspension, cancellation or non-renewal available.⁵³ Licence sanctions would also be available if information came to the attention of DEDJTR suggesting that the licensee was no longer fit and proper to hold a licence.⁵⁴

Recommendation

- 21** The Secretary of the Department of Economic Development, Jobs, Transport and Resources should:
- (a) monitor and enforce compliance by licensed cultivators with licence conditions and risk management plans
 - (b) be empowered to appoint inspectors for this purpose
 - (c) be resourced accordingly.

Authorised low-THC cannabis producers

- 6.44 As discussed in the issues paper, it is already possible for a person to cultivate cannabis in Victoria. However, they are only able to do so under an authority, and are only permitted to cultivate cannabis with less than 0.35 per cent THC,⁵⁵ for non-therapeutic purposes.⁵⁶ This variety of cannabis is known as low-THC cannabis or industrial hemp. Therefore, at present, authorised low-THC cannabis producers could not cultivate cannabis (even low-THC cannabis) for the purposes of producing medicinal cannabis.
- 6.45 It would be a straightforward legislative amendment to expand the activities permitted to be conducted by authorised low-THC cannabis cultivators, so that they could cultivate cannabis to be used in the manufacture of medicinal cannabis products.⁵⁷ However, the Commission's view is that this would not be a good policy outcome. The risk assessment undertaken in the decision to grant an authority to a low-THC cannabis cultivator in Victoria is specific to the purposes for which cultivation occurs (and to the cultivation practices adopted) and would not be well adapted to medicinal cannabis. In addition, both Commonwealth and international law draw a clear distinction between low-THC cannabis grown for fibre and seed, on the one hand, and cannabis grown for its

51 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69R-69RR.

52 This is a consequence of compliance with the risk management plan being a condition of the licence.

53 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 69Q (imposition of licence conditions); 69RM (crop forfeiture, harvest and destruction); 69RQ (infringement notices). Licences may be suspended or cancelled under s 69QA. The Secretary has discretion to refuse to renew a licence under s 69PI, but will take into account more than just compliance with licence conditions in doing so.

54 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 69NB(2)(b), 69OI, 69QA(1)(d), (g).

55 This is the maximum quantity in the leaves and flowering heads; a different maximum THC concentration applies to cannabis which is supplied to third parties.

56 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [4.145]–[4.148]; *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 61–62. While not prohibited by Victorian legislation, low-THC cannabis cannot be processed into or sold as food in Australia: *Australia and New Zealand Food Standards Code*, Standard 1.4.4. The matter remains under review by the Ministerial Forum: 'Australia and New Zealand Ministerial Forum on Food Regulation', (Final Communiqué, Auckland, 30 January 2015 and Final Communiqué, Hobart, 3 July 2015).

57 By way of illustration, s 62 of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) could be amended to remove the restriction on non-therapeutic use.

cannabinoids (whether medicinal or recreational) on the other.⁵⁸

- 6.46 Nonetheless, cultivators of low-THC cannabis already authorised to operate in Victoria⁵⁹ may have useful expertise which could be harnessed in the establishment of a Victorian medicinal cannabis scheme. It may be appropriate to allow low-THC cannabis cultivators to supply seeds to licensed medicinal cannabis cultivators,⁶⁰ or to hold a medicinal cannabis cultivation licence in addition to their existing low-THC cannabis authority, for the purpose of obtaining cannabinoids other than THC.

Licensing manufacture

- 6.47 Like cultivators, manufacturers of cannabis products should be required to hold licences issued by the State of Victoria. Licences to manufacture refined cannabis products should be able to be granted by the Secretary of the Department of Health and Human Services, but as a practical matter would be administered and supervised by the Office of Medicinal Cannabis. Recipients could be either individuals or corporations.

Recommendation

- 22 Medicinal cannabis products should be made by manufacturers licensed by the Secretary of the Department of Health and Human Services.**

Interaction with *Therapeutic Goods Act 1989* (Cth)

- 6.48 The Commission assumes for the purposes of this section that entities producing medicinal cannabis in Victoria would be licensed by the Secretary of the Department of Health and Human Services to manufacture cannabis products. They would not be regulated by the TGA,⁶¹ nor be required to hold concurrent manufacturing licences under the *Therapeutic Goods Act*.⁶² However, as discussed above, the division of regulatory responsibility is a matter for negotiation between the Commonwealth and the State of Victoria.

58 See *Single Convention on Narcotic Drugs 1961*, art 28.2 ('This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes'); the SUSMP definition of 'cannabis' (which excludes 'processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre') and its definition of THC (which excludes THC found in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement 'not for internal use' or 'not to be taken').

59 Several individuals are cultivating low-THC cannabis in Victoria at present: Consultation 19.

60 This activity appears to be presently prohibited by s 62(1)(a) of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic), which permits authorised low-THC cannabis cultivators to sell or supply seeds harvested from low-THC cannabis, but only for purposes 'relating to non-therapeutic use'. Supply of seeds to a medicinal cannabis cultivator could be considered supply for a therapeutic use.

61 See the *Therapeutic Goods Act 1989* (Cth) pt 3-3. If, as specified elsewhere, medicinal cannabis products supplied in Victoria are not approved by the TGA, there would be fundamental problems with the scheme relying on the TGA to regulate manufacturers. The supervision of products and sponsors by the TGA relies on information about their products and facilities that is extensively interconnected. Regulatory supervision which looked at only the quality of manufacturing facilities, and had no role in product approval, could lead to inefficient and fragmented oversight: see Evidence to Senate Legal and Constitutional Affairs Committee, Parliament of Australia, Canberra, 30 March 2015, 41 (Dr Lisa Studdert and Philippa Horner).

62 That is, a Victorian manufacturing licence would not be 'added on' to a Commonwealth manufacturing licence granted by the TGA. It would be entirely separate. Such a requirement could be problematic, as holders of TGA manufacturing licences are required to specify upon application the therapeutic goods they intend to manufacture at the relevant premises: *Therapeutic Goods Act 1989* (Cth) s 37(1)(b).

Managing the risks

6.49 As is the case with cultivation, there are risks that would need to be addressed under the proposed scheme. In broad terms, this is how the recommended legal arrangement would respond to the major risks:

Table 3: Risks associated with manufacture of medicinal cannabis products and the regulatory responses proposed to control these risks

Risk	Regulatory response
Diversion occurs because of criminal intervention by third parties (potentially causing risks to public safety)	Risk management plan addresses facility security measures, location, secrecy, surveillance
Diversion occurs because of criminal conduct by employees or contractors	Risk management plan addresses assessment, training and supervision of employees Criminal record checks required for employees Licence conditions require destruction of unused cannabis
Diversion occurs because of criminal conduct by managers/owners	Fit and proper person test before licence is granted Chief Commissioner of Police power to oppose Licence conditions require: <ul style="list-style-type: none"> • that all cannabis products are delivered to the government or destroyed • that all unused cannabis is destroyed
Diversion occurs during transport	Risk management plan addresses how transportation will be securely undertaken
Cannabis products are of variable quality	Manufacturing licences may only be granted where applicant satisfies Secretary of capacity to comply with production standards Products are subjected to testing
Cannabis products contain unsafe contaminants and harm public health	Manufacturing licences may only be granted where applicant satisfies Secretary of capacity to comply with production standards Products subject to testing for contaminants Premises subject to inspections Recall procedures in place

6.50 Like the licensing of cultivators, the regulation of licensed manufacturers by the Department of Health and Human Services would have as its objective both ensuring security and maintaining quality standards. In addition to licence conditions, because the state would be the sole purchaser of cannabis products, it could also exercise control through the terms on which cannabis is purchased.⁶³

Who could obtain a licence?

- 6.51 The requirements for an individual or corporation to be granted a manufacturing licence ought to include all those set out above for cultivation licences.⁶⁴ The Secretary of the Department of Health and Human Services should have equivalent powers to investigate licence applications in this regard.⁶⁵ Only entities which succeeded in the competitive selection process would be eligible to be granted a licence.⁶⁶
- 6.52 In addition, an applicant for a manufacturing licence should be required to demonstrate, to the satisfaction of the Secretary of the Department of Health and Human Services, that it is capable of complying with the relevant quality standards and that its proposed operating facilities are appropriate.⁶⁷ The applicant's suitability would be established by submitting documentation showing its ability to comply with the standards, together with an initial inspection by a delegate of the Secretary. Further detail on the possible quality standards and their enforcement is described in Chapter 7.

Risk management plans and licence conditions

- 6.53 The risk management plan submitted by an applicant for a manufacturing licence should serve a similar function to that submitted by an applicant for a cultivation licence. In addition, applicants should be required to submit details of the manufacturing processes they will follow, and how these are compliant with applicable standards (set out in Chapter 7).
- 6.54 As would be the case for cultivators, the terms and conditions imposed on the manufacturing licence would allow the Secretary of the Department of Health and Human Services to exercise control over the activities of the manufacturer. Conditions should include:⁶⁸
- where manufacture is permitted to take place⁶⁹
 - that only suitable employees may be employed
 - compliance with manufacturing quality standards⁷⁰
 - that all cannabis products must be delivered to the Secretary of the Department of Health within four months of the harvest date⁷¹ or be destroyed⁷²
 - that the licence holder must at all times hold a manufacturing licence under the Narcotic Drugs Act.⁷³

64 Namely, a 'fit and proper' assessment, suitability of premises, a satisfactory risk management plan, proof of intended commercial activities and payment of a fee. See [6.34].

65 See [6.35].

66 See [6.58]–[6.62].

67 Cf *Therapeutic Goods Act 1989* (Cth) s 38(1), under which an applicant for a licence to manufacture must be able to comply with the manufacturing principles (that is, the PIC/S Guide to GMP) and propose to carry out the manufacture at a suitable location.

68 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69PC.

69 To satisfy the requirements of art 29(2)(b) of the *Single Convention on Narcotic Drugs 1961*. Note that the licence granted to the manufacturer under the *Narcotic Drugs Act 1967* (Cth) will also specify the premises at which manufacture is to take place: s 9(1).

70 Described in Chapter 7.

71 This is required in order to comply with the *Single Convention on Narcotic Drugs 1961*, which requires member states to ensure that cultivators deliver their total crops of cannabis to the government within four months after the end of harvest: arts 23(2)(c) and 28.

72 The *Single Convention on Narcotic Drugs 1961* requires that states 'prevent the accumulation, in the possession of drug manufacturers, of drugs [including cannabis, cannabis tinctures, extracts and so on] in excess of those required for the normal course of business': art 29(2)(c). A licence requirement along these lines should satisfy this requirement in the *Single Convention*.

73 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69PC(8).

-
- 6.55 The holder of a manufacturing licence should be subject to inspection by appointed inspectors working in the Department of Health and Human Services to ensure their compliance with the conditions of the licence. A new category of inspectors should be created under the Drugs, Poisons and Controlled Substances Act, to inspect manufacturers.⁷⁴ The Department of Health and Human Services already has a body of authorised officers responsible for inspections relating to, among other things, food safety,⁷⁵ radiation,⁷⁶ and public health generally.⁷⁷ Staff could be appointed specifically to inspect cannabis manufacturers, or the Department's existing authorised officers could be given an additional role as inspectors of medicinal cannabis manufacturing facilities (as currently occurs for alkaloid poppies in the DEDJTR).
- 6.56 Inspectors should review both whether the manufacturers had adhered to their risk management plans and applicable quality rules (discussed in detail below). A variety of enforcement actions (including licence conditions, product forfeiture and infringement notices) would be available to inspectors if non-compliance were observed, with the ultimate sanction of licence non-renewal, suspension or cancellation available to penalise unrectified non-compliance.⁷⁸ As with cultivation licences, if information came to the attention of the Department suggesting that the licensee was no longer fit and proper, action could be taken in relation to the manufacturing licence.⁷⁹
- 6.57 As in the case of cultivation licences, any decision of the Secretary that would adversely affect the holder of a manufacturing licence should be capable of review by the Victorian Civil and Administrative Tribunal.⁸⁰

74 *The Drugs, Poisons and Controlled Substances Act 1981* (Vic) allows inspectors to be appointed for the purpose of monitoring compliance by licensees (s 69R) and gives them a range of powers (ss 69RB–69RR)

75 *Food Act 1984* (Vic) pt IV.

76 *Radiation Act 2005* (Vic) pt 7 div 2.

77 *Public Health and Wellbeing Act 2008* (Vic) s 30.

78 Cf ss 69Q (imposition of licence conditions); 69RM (crop forfeiture, harvest and destruction); 69RQ (infringement notices). Licences may be suspended or cancelled under s 69QA. The Secretary has discretion to refuse to renew a licence under s 69PI, but will take into account more than just compliance with licence conditions in doing so.

79 Cf *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 69NB(2)(b), 69PI, 69QA(1)(d) and (g).

80 Cf *Ibid* ss 69U–69UF.

Recommendations

- 23** Medicinal cannabis products should be made by manufacturers licensed by the Secretary of the Department of Health and Human Services under arrangements modelled on those for licensing manufacturers under the *Therapeutic Goods Act 1989* (Cth) and processors of poppy straw under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic). Key features of the scheme should be as follows:
- (a) Applicants for a manufacturing licence would be subject to a fit and proper person test, required to satisfy the Secretary of their intended commercial activities, and required to pay a prescribed fee.
 - (b) Applicants for a manufacturing licence should be required to demonstrate to the Secretary their capability to comply with quality standards.
 - (c) The Chief Commissioner of Victoria Police would be able to oppose the issuing or renewal of a licence to an applicant, in which case the Secretary would be unable to issue or renew it.
 - (d) Licensees would be required to hold a manufacturing licence under the *Narcotic Drugs Act 1967* (Cth) at all relevant times.
 - (e) Licensees would be required to ensure that their employees are of suitable character.
 - (f) Licensees would be required to prepare and submit a risk management plan addressing safety and diversion risks associated with cultivation and how they will be addressed.
 - (g) Licensees would be required to comply with appropriate quality control measures.
 - (h) Licensees would be required to deliver all medicinal cannabis products to the Secretary within four months of the harvest date and destroy any unused material.
 - (i) The Secretary would have the power to suspend or cancel a licence, including at the request of the Chief Commissioner of Police.
 - (j) Applications would be able to be made to the Victorian Civil and Administrative Tribunal for review of a decision by the Secretary to refuse to issue or renew a licence, or to suspend, cancel or amend it.
- 24** The Secretary of the Department of Health and Human Services should:
- (a) monitor and enforce compliance by licensed manufacturers with licence conditions and risk management plans
 - (b) be empowered to appoint inspectors for this purpose
 - (c) be resourced accordingly.

Selection of licensees

- 6.58 If it were intended that the production of cannabis products in Victoria would result in a commercial, market-driven industry, limited only by consumer demand for medicinal cannabis, there would be no need to control the number of entities permitted to take part in the industry. Any entity capable of satisfying the legal requirements would be eligible to be granted a cultivation or manufacturing licence, and the market would determine how many such entities could be accommodated. Some would see this as a preferable state of affairs—for example, Cannabis Science Australia submitted that ‘any farming concern that can meet the necessary standards should be allowed to grow the product’, because otherwise companies that are financially sound but know little about the medical science around cannabis would be able to ‘buy their way into the industry’.⁸¹
- 6.59 However, this is not the system suggested by the terms of reference, which reflect the intention to make medicinal cannabis available only to patients in ‘exceptional circumstances’. In practice, this amounts to a cap on the demand for medicinal cannabis products. Therefore, if private industry were to be involved in the production of medicinal cannabis in Victoria, the government would need to control the number of companies and/or individuals licensed to cultivate and manufacture cannabis products for medicinal purposes, or at least restrict significantly the amount of cannabis each could cultivate/manufacture; otherwise the amount of cannabis produced could greatly exceed the amount required to be supplied, leading to significant diversion risks.⁸²
- 6.60 The Law Institute of Victoria also made this observation, noting that ‘a regulated scheme should balance supply and demand to limit the risk of diversion’.⁸³ This is also necessary to ensure that, as required by international law, the state government can ‘control’ the cultivation and distribution of cannabis.⁸⁴ The Single Convention on Narcotic Drugs places obligations on signatories to limit the amount of cannabis produced to that which has been ‘estimated’ in advance to the International Narcotics Control Board.⁸⁵ The Commonwealth would be unable to comply with this obligations unless Victoria exercised control over the number of market participants and the amount they were permitted to produce.
- 6.61 Some jurisdictions limit the number of entities that are permitted to cultivate and/or manufacture cannabis by stating in legislation how many licences of each kind may be granted, and running a ‘competitive selection’ process to choose those that will receive the licences.⁸⁶ However, these jurisdictions allow for the private distribution of medicinal cannabis (that is, directly from producer to patient). Under the Victorian scheme, all medicinal cannabis produced would be purchased by the state government, meaning that it would also have the ability to exercise control over licensees’ activities through contract.⁸⁷

81 Submission 69.

82 Media reports suggest significant commercial interest in producing medicinal cannabis in Australia: Mandie Sami, ‘Australian Company Granted First License to Grow and Export Medicinal Cannabis’, *ABC The World Today*, 21 May 2015; Scott Hannaford, ‘Investors Lining Up to Make Canberra the Cannabis Capital’, *The Canberra Times*, 19 June 2015; Sally Rose, ‘New CEO of Cannabis Group Michael Sautman Wants Australia to Legalise It’, *Sydney Morning Herald*, 19 March 2015; Christopher Harris, ‘Australia a New Growth Market for Medicinal Cannabis’, *Sydney Morning Herald*, 1 February 2015. Cannabis Science Ltd agreed, commenting that ‘there will be a very high demand to become a preferred grower. Most successful business people are quick to seek the next big thing to go, and the opportunity in this industry will be no different. Already we can see this happening ... that in itself will create a demand on the government when issuing licenses’:
Submission 69.

83 Submission 63.

84 *Single Convention on Narcotic Drugs 1961*, art 28.

85 *Ibid* arts 19 and 21.

86 See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [6.62]; Minn Stat § 152.25(1); Consultation 25.

87 It is likely the purchase of medicinal cannabis would be subject to Victorian Government Purchasing Board policies, made under the *Financial Management Act 1994* (Vic) s 54L. While a health-specific procurement body exists (Health Purchasing Victoria), it appears that this activity would fall outside its statutory functions: *Health Services Act 1988* (Vic) s 131.

6.62 The Commission considers that the Victorian Government should control the number of entities granted cultivation and manufacturing licences,⁸⁸ and that this process should be integrated with the purchasing process. This exercise would be simpler and faster if cultivation and manufacturing were carried out by single entities. The Commission also considers that the government should use its position as sole purchaser of medicinal cannabis products to set standards for the production of medicinal cannabis—for example, to establish more stringent production practices, set performance targets, set an expected product range or quantity, or provide research and development incentives.⁸⁹

Licence duration

6.63 Under the poppy scheme, cultivation licences can be granted for a period of up to three years⁹⁰ while processing licences can be granted for up to one year.⁹¹ This arrangement was considered necessary in order to comply with the system of estimates imposed on the Commonwealth by the International Narcotics Control Board.⁹²

6.64 In the Commission's view, it would be undesirable to limit the duration of medicinal cannabis manufacturing licences to one year, as occurs for processors in the poppy scheme. While acknowledging the importance of making arrangements that enable the Commonwealth to comply with the system of annual quotas and estimates, the Commission does not consider it necessary to limit licence duration to one year in order to do so.

6.65 Should the government need to alter the amount produced from year to year, it could do so through contractual arrangements and licence conditions. More importantly, the cultivation and manufacturing licences issued must be of sufficient duration for the licensees to develop compliant cultivation and refining technology and expertise,⁹³ and to make engagement with the competitive selection process financially worthwhile.

Distribution

6.66 A Victorian medicinal cannabis scheme would need to provide for cannabis products to be distributed to patients. As reflected in submissions received, there is a tension between two key concepts in designing a distribution system: accessibility and control.

6.67 Having regard to Australia's obligations under the Single Convention on Narcotic Drugs, the Commission considers that the system of distribution should be as follows:

- All licensed manufacturers are obligated by the terms of their licence to deliver all cannabis products they make to the Victorian Government, specifically the Secretary of the Department of Health and Human Services.
- The Secretary of the Department of Health and Human Services distributes the finished cannabis products to pharmacies.
- Patients are dispensed cannabis products by their local pharmacy, which has been designated by their doctor.

88 Processes already exist for the granting of licences where the total number is limited: see, eg, *Mineral Resources (Sustainable Development) Act 1990* (Vic) s 23, which requires that, where multiple applications for certain mining licences are received, the application that ranks the highest on merit and against the objectives of the Act must be given priority in the assessment process (see also s 15).

89 In the Netherlands, Bedrocan BV is subject to constraints on its production practices through the purchasing process which go beyond those required by the regulations: Consultation 28. In Minnesota, where licensed cultivator/manufacturers were selected through a competitive selection process, applicants were asked to address, among numerous other issues, production capacity (including capacity to expand), proposed product range, pricing, anticipated number of customers, marketing plan (including education of patients and medical practitioners), security of premises, how contaminants will be minimised and cannabinoids will be made consistent, proposed chemical usage, recall protocols, proposed extraction methods and solvent control, testing and stability control, packaging and labelling: Consultation 25; Minnesota Department of Health—Office of Medical Cannabis, *Request for Application for the Registration of Medical Cannabis Manufacturers* (5 September 2014) <<http://www.health.state.mn.us>>.

90 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 69OC(1).

91 *Ibid* s 69PC(1).

92 Victoria, *Parliamentary Debates*, Legislative Assembly, 11 December 2013, 4540 (Peter Walsh, Minister for Agriculture and Food Security). The estimates requirement imposed by the *Single Convention on Narcotic Drugs 1961* is described above at [4.15]–[4.16].

93 The Commission was told that it can take some time to develop appropriate strains and to sufficiently control cannabinoid content, as each crop takes 3–4 months to cultivate, and several crops may need to be grown before consistency is achieved: Consultation 30. Similar considerations would apply to the development of extraction technology, product stability and so on. See Chapter 7 for more detail on the quality standards that licensees would be expected to attain.

Government as single purchaser

- 6.68 As explained in Chapter 4, the Single Convention on Narcotic Drugs requires distribution to be co-ordinated by a government agency. Countries which permit the cultivation of the cannabis plant for the flowering tops or resin must set up a system in which '[a]ll cultivators of [the cannabis plant] shall be required to deliver their total crops of [cannabis]'⁹⁴ to 'a government agency',⁹⁵ which must 'purchase and take physical possession' of them.⁹⁶
- 6.69 A system in which the government purchases all medicinal cannabis produced has been implemented in the Netherlands and Israel, although those nations adopt slightly different models in practice. In the Netherlands, there is only one licensed producer⁹⁷ (Bedrocan BV), which produces a number of strains of cannabis. The cannabis produced is supplied to the government in dried form, in bulk. The product is divided, packed, labelled and distributed to pharmacies by a company under contract to the government. It is then dispensed on a doctor's prescription. The Dutch Office of Medicinal Cannabis does not itself process and distribute the products, but an employee of the Office attends at the time of delivery. The Dutch Office of Medicinal Cannabis also arranges for testing of the cannabis, to test for contaminants and cannabinoid content, and will only distribute cannabis that passes these quality tests.⁹⁸
- 6.70 In Israel, licensed producers, of which there are many, produce a range of cannabis products, including dried plant matter, edibles, oils, tinctures and so on, and deliver these to Sarel Corporation, a government-affiliated company.⁹⁹ Sarel then delivers the cannabis products to patients. Unlike the Netherlands, patients do not fill prescriptions, but are associated with a particular producer and registered with the government.¹⁰⁰
- 6.71 One World Cannabis drew on the Israeli system to comment on the advantages of the state controlling distribution:
- Israel ... decided for a division between growers and supply to patients for the same reasons Israel does not allow any pharma companies straight access to patients. ... This [separate] distributor will also be the long arm of the national cannabis agency to purchase and hold all the cannabis products that [have] been harvested. The distributor will also perform quality assurance on the cannabis it buys from the cultivators or refuses to buy due to lack of quality.¹⁰¹
- 6.72 As mentioned above, manufacturers should be required, under the conditions of their licence, to deliver all finished cannabis products to the Secretary of the Department of Health and Human Services (formally, pursuant to a contract with the associated body corporate).¹⁰² The price would be set by agreement with the government. The Secretary could elect, as other jurisdictions have, to arrange for a contractor to complete deliveries to pharmacies. The purchasing process would also specify whether dividing and packaging should be the role of the government or licensed manufacturers.

94 'Cannabis' is defined in Schedule 1 as including cannabis resin, extracts and tinctures.

95 It is not clear whether the government agency must be set up specifically for the purposes of regulating cannabis production: see art 23(1), which states 'A Party that permits the cultivation of the [cannabis plant] for the production of [cannabis and cannabis resin] shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.'

96 *Single Convention on Narcotic Drugs 1961*, Arts 23(2)(d) and 28.

97 The Dutch legislation does not limit production to one entity; rather, the contract is regularly put out to tender and Bedrocan was recently the only successful applicant. In the past, two companies were licensed to cultivate cannabis, but one of these companies was unable to meet government requirements: Consultation 28.

98 Consultation 28. The cannabinoid content of the product delivered must be within 20% of the labelled quantity.

99 Sarel Corporation is owned by the Association of Public Hospitals for the Public, a not-for-profit organisation which may only serve public purposes. Its sole business is supplying goods and services to hospitals and medical institutions. It serves as a purchasing agent/group purchasing organisation for the Israeli Ministry of Health: Sarel Corporation, *Business Profile*, 23 September 2013, <<http://www.sarel.co.il>>.

100 The Government of Israel has recently indicated that it intends to move away from this policy towards a system of prescriptions: Jonathan Lis and Ido Efrati, 'Medical Marijuana—Coming Soon to an Israeli Pharmacy Near You', *Haaretz* (online), 28 July 2015 <<http://www.haaretz.com>>.

101 Submission 61.

102 That is, the body corporate established under s 16 of the *Public Health and Wellbeing Act 2008* (Vic). The body corporate has the functions set out in s 17 of that Act, which include performing any functions and exercising any powers conferred on the Secretary of the Department of Health and Human Services by any legislation. See above at [1.75].

Recommendation

- 25** All medicinal cannabis products made by licensed manufacturers should be purchased by the Secretary of the Department of Health and Human Services.

Distribution through pharmacies

- 6.73 A number of submissions supported distribution through pharmacies.¹⁰³ This was the main alternative proposed to collectives or ‘dispensaries’. As discussed in Chapter 5, neither a collective-based model nor a dispensary model would be well suited to achieving the Commission’s regulatory objectives.¹⁰⁴
- 6.74 The Commission considers that cannabis should be distributed to patients through pharmacies. There are many reasons for this. Pharmacists have expertise in advising patients on the use of medicines,¹⁰⁵ and patients are accustomed to collecting medication from their local pharmacy. Pharmacies have security arrangements in place so that cannabis can be stored securely.¹⁰⁶ Importantly, pharmacists and pharmacies are already licensed,¹⁰⁷ so that enforcement action can be taken if a pharmacist deals inappropriately with cannabis, and a new set of licences need not be established. Finally, pharmacies are already distributed throughout the state, making them readily accessible by patients, including in regional areas. There appears to be no legal impediment to the distribution of medicinal cannabis by pharmacies, even if such products are not approved by the TGA.¹⁰⁸
- 6.75 EROS raised concerns about distribution by pharmacies, contending that a pharmacy owner who has a personal objection to cannabis may decline to stock medicinal cannabis products.¹⁰⁹ The Commission acknowledges this is a possibility, but considers that the benefits of using the large number of pharmacies in Victoria outweigh this potential risk.
- 6.76 Where a patient is an inpatient in a hospital, pharmacy departments could be used to distribute medicinal cannabis to patients.¹¹⁰

Recommendation

- 26** Medicinal cannabis products purchased by the Secretary of the Department of Health and Human Services should be dispensed to patients through pharmacies and pharmacy departments.

103 Submissions 8, 20, 24, 39, 56 and 60; advisory committee (Meeting 2); Consultations 7, 13, 18, 24.

104 See above at [5.85]–[5.104] and [5.105]–[5.118].

105 Submission 39.

106 Namely, the requirements which exist for Schedule 8 poisons, set out in the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 35.

107 Under the *Health Practitioner Regulation National Law* (Vic) and the *Pharmacy Regulation Act 2010* (Vic) pt 3, respectively.

108 Pharmacists are already authorised to possess any drug of dependence in the lawful practice of their profession: *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 13(1)(a), (6). *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 7 would require pharmacists to hold a permit were cannabis to be treated as a Schedule 9 poison, but as discussed at [3.223], this approach is not recommended. In any event, pharmacies and pharmacists are regulated under Victorian law, as is the retail supply of therapeutic goods, so being asked to supply products endorsed by the Victorian Government should not raise objections from pharmacists. Pharmacists are, however, approved by the Commonwealth for the purposes of Pharmaceutical Benefits Scheme payments.

109 Submission 76.

110 Pharmacy departments are also registered under Victorian law (*Pharmacy Regulation Act 2010* (Vic) s 45) and participate in the opioid replacement therapy program.

- 6.77 The rules imposed on pharmacies and pharmacy departments regarding the dispensing of cannabis could be modelled on the program for opioid replacement therapy in Victoria, as suggested by the advisory committee and others with whom the Commission consulted.¹¹¹ While there would be a diversion risk associated with medicinal cannabis,¹¹² not all features of the opioid replacement therapy scheme would be required—for example, patients receiving opioid replacement therapy must in general consume their dose of methadone (or other product) while they are at the pharmacy unless specifically authorised to obtain a ‘take away’ dose. This would not be necessary or practical for cannabis. In addition, the therapeutic index¹¹³ of opioid replacement drugs such as methadone is very small, and the risk of overdose correspondingly high, while the dangers associated with patients ‘double dosing’ is much lower in relation to cannabis products.
- 6.78 An adapted version of the opioid replacement therapy scheme could function as follows:¹¹⁴
- A patient’s doctor nominates the pharmacy at which they will collect medicinal cannabis.
 - The patient may attend only the nominated pharmacy to collect medicinal cannabis.
 - The patient may be dispensed the medicinal cannabis product they have been prescribed, and may only receive a one-month supply.
 - Pharmacies would stock medicinal cannabis on an ‘opt in’ basis, and would need to notify the Department of their wish to participate. However, training on the system is available.
 - Pharmacies could charge a dispensing fee or mark up to patients, on top of the cost of the medicinal cannabis.¹¹⁵
 - Patients could be transferred to another pharmacy; the new pharmacy must make contact with the previous pharmacy to confirm the patient’s details, last dose and so on.¹¹⁶
 - Guidelines issued by the Office of Medicinal Cannabis would be used to encourage a dialogue between the pharmacy and the authorising medical practitioner.
- 6.79 Much of the above process could be established through departmental guidelines, as occurs with the opioid replacement therapy program. Pharmacists should be required to store cannabis in accordance with the requirements for Schedule 8 and Schedule 9 poisons.¹¹⁷ Once the scheme is established, consideration could be given to less restrictive arrangements, particularly for low-THC products. If the scheme established allowed for the production of vapourisable forms of cannabis (that is, cartridges or refill vials of liquid), patients would need to have a means of accessing vapourising devices.¹¹⁸

111 Advisory committee (Meeting 2); Consultations 2 and 24.

112 Advisory committee (Meeting 2); Consultations 23 and 24. This risk exists even for non-smokable forms (discussed below at [7.79]–[7.83]; Consultation 23.

113 The gap between a prescribed dose of the drug and a lethal dose.

114 See Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (2013) for detail on the pharmacotherapy program.

115 Subject to price controls imposed by the Victorian Government, discussed at [6.84].

116 This may not be necessary given the much lower risk of overdose for cannabis medications.

117 Set out in the *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 35. That regulation requires, in essence, that such drugs be held in a lockable storage facility meeting minimum requirements, that the pharmacy take reasonable steps to ensure that it is locked at all times except when used, and that it is only used to store Schedule 8 and Schedule 9 poisons. More stringent security may be needed at the outset of the scheme because of the novelty of medicinal cannabis.

118 It appears that the sale, use and possession of such devices, which heat a liquid form of cannabis to a temperature at which the cannabinoids form a vapour which can be inhaled, is not currently prohibited in Victoria. The sale and display for sale of cannabis water pipes, hookahs and bong kits is prohibited by ss 80U–80X of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic), but the definition of ‘cannabis water pipe’, while it includes devices which allow the drawing of fumes from cannabis by heating, requires that this be done ‘through water or another liquid in the device’. This does not occur with a vapouriser. Nonetheless, it may be prudent to explicitly authorise their sale and display by pharmacists to ensure patients can continue to access them if restrictions are later introduced.

6.80 In summary, the risks associated with the distribution of cannabis would be addressed under this scheme as follows:

Table 4: Risks associated with distribution of medicinal cannabis products to patients and the regulatory responses proposed to control these risks

Risk	Regulatory response
Patients give or sell their authorised supply to non-authorised users	Limited amounts may be dispensed
Patients use the same authority at a number of pharmacies, obtaining multiple quantities	Patients must attend a single pharmacy designated by their doctor and follow a set process if they wish to transfer to another.
Patients obtain cannabis using forged authorities	Communication encouraged between pharmacists and medical practitioners Forging an authority would be an offence
Pharmacists or pharmacy staff misappropriate cannabis	Professional obligations on pharmacists and regulatory obligations on pharmacies Record-keeping requirements for cannabis products
Theft of cannabis from pharmacies through burglary	Secure storage requirements for cannabis products

Recommendations

- 27** Dispensing of medicinal cannabis products to patients should be through pharmacies and pharmacy departments that elect to participate in the scheme.
- 28** Dispensing of cannabis by pharmacies and pharmacy departments should be modelled on the Victorian program for opioid replacement therapy and include the following features:
- (a) Patients or carers specified in the Authority to Dispense Medicinal Cannabis would be able to obtain medicinal cannabis products only by attending at the specified pharmacy or pharmacy department.
 - (b) Pharmacies and pharmacy departments would be able to dispense to patients or carers only the medicinal cannabis product(s) specified in the Authority to Dispense Medicinal Cannabis.
 - (c) Pharmacies and pharmacy departments would be required to store medicinal cannabis products pursuant to requirements comparable to those that apply to the storage of Schedule 8 and Schedule 9 poisons.

- 6.81 To combat diversion and ensure patient safety, a medicinal cannabis scheme would need to limit the amount of medicinal cannabis a patient could purchase at any one time. For prescription medicines, these restrictions are imposed largely through limits on Pharmaceutical Benefits Scheme payments,¹¹⁹ and these would need to be replicated in a Victorian scheme. Other restrictions placed on dispensing by Victorian law may also need to be replicated.¹²⁰ There would need to be a means for the Victorian Government to monitor the type and amount of medicinal cannabis dispensed to patients through pharmacies and pharmacy departments. This information would be important for an effective review to be undertaken of the scheme, and for preparing manufacturing estimates for the forthcoming year. These requirements could be imposed on pharmacists in conjunction with the record-keeping requirements that, consistently with Schedule 8 and Schedule 9 poisons, should be imposed in respect of medicinal cannabis.¹²¹

Recommendation

- 29** The Secretary of the Department of Health and Human Services should require pharmacists to notify the Secretary about the amount and type of products they dispense to patients under an Authority to Dispense medicinal cannabis.

Cost considerations

- 6.82 Several submissions drew attention to the importance of cost in any medicinal cannabis scheme, with many commenting on the need to ensure cannabis products were affordable.¹²² Cheryl Wright stated that '[t]he price needs to be regulated as well. Otherwise it will be out of the reach of the average family.'¹²³ A submission from the cannabis community of Victoria observed that '[m]any chronically and terminally ill patients suffer financial hardship.'¹²⁴ Cancer Council Victoria observed:

There is a risk that if patients cannot afford the approved product they will resort to sourcing illicit cannabis in respect of which product quality and consistency cannot be guaranteed.¹²⁵

- 6.83 As the Victorian Government would be the sole seller of medicinal cannabis under the scheme described above, it would have the ability to control the price. While pharmaceuticals listed on the Pharmaceutical Benefits Scheme are sold to pharmacists by private wholesalers, then subsidised by the Commonwealth through reimbursement on claim by the pharmacy, the proposed scheme would involve a direct transaction between the government and the pharmacy.

119 The maximum amount of a medicine that can be prescribed and the maximum number of repeats is set by the Pharmaceutical Benefits Advisory Committee. The maximum can be exceeded but only by using an 'authority prescription'. See Pharmaceutical Benefits Scheme, *Prescribing Medicines—Information for PBS Prescribers*, (1 July 2015) <<http://www.pbs.gov.au>>.

120 See, eg, *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) rr 26 (style and required particulars for prescriptions), 29 (labelling), 30 (duration of prescriptions) and 33 (retention of original prescriptions).

121 Cf *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 40.

122 Submissions 2, 3, 24, 49, 57, 63, 95; advisory committee (Meeting 2); Consultations 2, 3, 4, 5, 6.

123 Submission 2.

124 Submission 95.

125 Submission 57. David and Cheri O'Connell agreed with this observation: Consultation 18.

- 6.84 The government should impose price controls on pharmacies, consistently with arrangements for therapeutic goods subsidised under the Pharmaceutical Benefits Scheme.¹²⁶ This is because participation in the scheme at its outset is important, and price controls are fundamental to ensuring the scheme is accessible for vulnerable people. However, this must be balanced against the fact that pharmacists should be permitted to earn some mark-up or fee to make their participation in the scheme financially worthwhile.

Recommendation

- 30** The Secretary of the Department of Health and Human Services should from time to time designate a price above which medicinal products cannot be sold, incorporating the mark-up able to be charged by pharmacists.

126

For medicines which are subsidised through the Commonwealth's Pharmaceutical Benefits Scheme, there are caps placed on the maximum mark-up and dispensing fee pharmacists are permitted to charge, established by the Fifth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia: see <<http://5cpa.com.au>>.

Regulating the product

174 Introduction

175 Product control: form and regulation

175 Quality control

187 Forms of medicinal cannabis

7. Regulating the product

Introduction

- 7.1 This chapter considers the question of which products should be supplied under a Victorian medicinal cannabis scheme, assuming that they are produced under arrangements set out in Chapter 6.
- 7.2 These products would need to be quality controlled and available in therapeutically appropriate forms. In this regard, one of the Commission's recommended regulatory objectives is that the any Victorian medicinal cannabis scheme ought to 'ensure that medicinal cannabis products are of reliable quality and known composition'.¹
- 7.3 Several submissions received by the Commission endorsed this objective.² The Australian Nursing & Midwifery Federation (Victorian Branch) expressed its support for 'a clear legislative and regulatory framework to ensure quality, efficacy and reliability of the end product', which it said is 'necessary for the protection of patients'.³
- 7.4 In a joint submission to the Senate Legal and Constitutional Affairs Committee's inquiry into the Regulator of Medicinal Cannabis Bill, cannabis researchers from the University of Sydney emphasised the importance of quality control when something is used as a medicine:
- Vulnerable patients source cannabis preparations from the black market. These preparations are unregulated with potential for inappropriate cannabinoids for certain indications (eg high THC for pediatric epilepsy), contamination with pesticides or heavy metals, tinctures with no cannabinoids sold as medicine, and poor understanding of appropriate dosing schedules. These safety concerns could be controlled... to help deliver safe and reliable cannabis based medicines to those who would benefit.⁴
- 7.5 To date, only one pharmaceutical-grade cannabis extract (Sativex) has been made available in Victoria, and then only through special importation schemes,⁵ not through being marketed in Australia. No cannabis products have been lawfully marketed or manufactured in Victoria before. For this reason, it is essential that Victoria takes a cautious approach to ensuring that the cannabis products supplied are of good quality.
- 7.6 Likewise, medicinal cannabis supplied in Victoria should be available in forms that are appropriate to the patient's particular needs. In ensuring this, both the formulation and the cannabinoid content need to be controlled. Quality and consistency are also important to medical practitioners, who would be more likely to approve the use of medicinal cannabis where its quality and consistency could be guaranteed.⁶

1 See [1.47]–[1.49].

2 Submissions 14, 25, 35, 57, 60, 69; Consultation 13. See Appendices and C for lists of submissions and consultations.

3 Submission 75.

4 David Allsop et al, Submission No 52 to the Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 13 March 2015, 2.

5 For example, the Special Access Scheme and through clinical trials. See the *Therapeutic Goods Act 1989* (Cth) s 19.

6 Submission 99.

Product control: form and regulation

- 7.7 There is no single type of medicinal cannabis. Taking overseas experience as a guide, medicinal cannabis can be supplied as dried cannabis and/or in a range of refined forms. In addition, products can vary greatly in the stringency of regulation applied to them. A description of the products available under any given scheme must identify how the dual variables of form and regulation intersect.
- 7.8 As set out in Chapter 2, the products potentially available under a medicinal cannabis scheme can be placed into three groups: pharmaceutical-grade products approved by a regulator like the Therapeutic Goods Administration (TGA), quality-controlled products that have not been conventionally approved, and products that have not been approved or regulated. Examples of each type can be seen around the world:
- *Pharmaceutical grade*—The only non-synthetic medicinal cannabis product that has been approved to date is the cannabis extract Sativex, manufactured by GW Pharmaceuticals. No dried cannabis products have been given conventional approval to date.
 - *Quality controlled*—In Minnesota, for example, a range of non-smokable forms of medicinal cannabis are made available to patients, all of which are subject to quality regulations regarding manufacturing processes and testing. In the Netherlands, on the other hand, various forms of dried cannabis are supplied, and these are also quality controlled through strict rules and testing.
 - *Unregulated*—In Arizona, medicinal cannabis dispensaries supply patients with various cannabis extracts that are not subject to medical quality controls.⁷ Likewise, in Hawaii, which currently allows only ‘grow your own’ medicinal cannabis, dried cannabis is not subject to any regulation on quality.⁸
- 7.9 The Commission has sought to identify what combination of form and regulation should be adopted under a Victorian scheme. As explained below, the cannabis products the Commission considers should be provided in Victoria are quality-controlled cannabis extracts. While these products would not be approved as conventional pharmaceuticals, they would be standardised and regulated for quality.

Quality control

- 7.10 A system of quality control must specify: the standards to which manufacturers are required to adhere, how the standards are applied in law, and what measures can be used to ensure products have been produced in compliance with the standards.

Objectives of quality control

- 7.11 A ‘quality controlled’ product is one which is of a known and consistent composition, both in terms of ingredients and active compounds, and which does not contain dangerous levels of unsafe contaminants.⁹ A system of quality control for a herbal medicine therefore needs to address three aspects of the product:
- identity (containing just one plant)
 - purity (freedom from contaminants)
 - content (active constituents within defined limits).¹⁰

7 Regular food safety rules apply, but only to edible products: Ariz Admin Code r 9-17-319.

8 Hawaii’s medicinal cannabis scheme relied exclusively on patients and their carers ‘growing their own’ cannabis until this year. House Bill 321, which was signed into law on 15 July 2015, will enable the Hawaiian Department of Health to license dispensaries to distribute medicinal cannabis to Hawaiian patients. However, no such dispensaries will open until 2016.

9 Submission 21.

10 Arun Rasheed, Sravya Reddy B and Roja C, ‘A Review on Standardisation of Herbal Formulation’ (2012) 2 *International Journal of Phytotherapy* 74.

- 7.12 Consistency was a key focus of submissions.¹¹ It was observed that patients should receive a product which is known to be the same in every bottle,¹² and ‘legal standardisation’ was called for to ensure products are of ‘consistent quality and efficacy’.¹³ Cassie Batten and Rhett Wallace told the Commission that they do not know what is in the product they use, and that variation in what they receive (which they can only assess through the appearance and odour of the product) can cause variation in the condition of their son, Cooper.¹⁴ Consistency is particularly important because of the botanical, herbal nature of cannabis products. The cannabinoid content of the cannabis plant can vary greatly, depending on the genetic makeup of the plant and an array of growing conditions.¹⁵
- 7.13 The need for safety of medicinal cannabis products was also emphasised in submissions, with particular calls for pesticides to be banned or controlled.¹⁶ Cannabis which has not been regulated for quality, such as ‘street’ cannabis, has been found to have a range of safety issues, such as:
- unsafe levels of mould and bacteria¹⁷
 - unsafe levels of solvent residue in concentrates made using hydrocarbon extraction methods¹⁸
 - contaminants, including ground glass¹⁹ and fly spray²⁰
 - unsafe levels of toxic pesticides²¹
 - releasing ammonia when heated (including in a vapouriser)²²
 - heavy metal contamination.²³

Regulation of herbal medicines in Australia

- 7.14 Plant-based medicines are by no means uncommon in modern medical practice. Some common pharmaceuticals, including morphine, paclitaxel and a number of cancer drugs were isolated from and continue to be derived from plant sources.²⁴ Plant-based medicines are also made available for therapeutic use in less refined forms, containing more than just one isolated molecule.²⁵ ‘Herbal’ medicines of this kind are primarily found in the field of complementary medicine.

11 Submissions 2, 24, 25, 26, 34, 57, 75; Consultations 2, 13.

12 Submission 2.

13 Submission 34.

14 Consultation 13.

15 Consultation 30. Using genetically identical plants, controlling growing conditions and adopting a consistent manufacturing process can help to control this, but variation still occurs: Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [2.9].

16 Submissions 22, 29, 43, 49, 95; Consultation 6.

17 Arno Hazekamp, ‘An Evaluation of the Quality of Medicinal Grade Cannabis in the Netherlands’ (2006) 1 *Cannabinoids* 1, 6; ‘Bacteria in Bud Prompts Nanaimo Firm to Recall Medical Marijuana’, *The Canadian Press*, 23 March 2015 <<http://www.vancouversun.com>>. Some of the microbes detected in the unregulated cannabis include known carcinogens and neurotoxins, and are a particular danger for people with compromised immune system, such as those with AIDS. See also J M McPartland and P L Pruitt, ‘Medical Marijuana and Its Use by the Immunocompromised’ (1997) 3 *Alternative Therapies in Health and Medicine* 39; R Hamadeh et al, ‘Fatal Aspergillosis Associated with Smoking Contaminated Marijuana, in a Marrow Transplant Recipient’ (1988) 94 *Chest* 432 (note that while the bulk of studies associated with the harms of mould in cannabis relate to smoked cannabis, it is assumed that risks also exist when cannabis extracts are produced).

18 Luigi Romano and Arno Hazekamp, ‘Cannabis Oil: Chemical Evaluation of an Upcoming Cannabis-Based Medicine’ (2013) 7 *Cannabinoids* 1.

19 J Delourme et al, ‘Respiratory Consequences of Inhalation of Adulterated Cannabis’ (2009) 26 *La Revue des Maladies Respiratoires* 552.

20 Consultation 23.

21 Noelle Crombie, ‘It Doesn’t Pay to Be Honest’, *The Oregonian*, 11 June 2015 <<http://www.oregonlive.com>>; Los Angeles City Attorney, ‘City Attorney’s Office Secures Injunction Prohibiting Sales of Marijuana from Medical Marijuana Facility’ (Press Release, 29 January 2010) <<http://atty.lacity.org>>.

22 Roger Bloor et al, ‘Ammonia Release from Heated ‘Street’ Cannabis Leaf and Its Potential Toxic Effects on Cannabis Users’ (2008) 103 *Addiction* 1671.

23 Heavy metals can be taken up by the plant from soil: P Linger, A Ostwald and J Haensler, ‘Cannabis Sativa L. Growing on Heavy Metal Contaminated Soil: Growth, Cadmium Uptake and Photosynthesis’ (2005) 49 *Biologia Plantarum* 567.

24 Wai Liu, ‘Why Anti-Cancer Properties in Cannabis Must be Investigated’, *The Conversation (online)*, 26 June 2015 <<http://theconversation.com/why-anti-cancer-properties-in-cannabis-must-be-investigated-42653>>.

25 According to the World Health Organisation, a medicine ceases to be considered ‘herbal’ if it is a finished product containing a chemically defined isolated constituent from a plant. A ‘herbal preparation’, by comparison, ‘may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials ... produced by extraction, fractionation, purification, concentration, or other physical or biological processes.’ A ‘finished herbal product’ is made from one or more herbal preparations, and may contain excipients, provided no chemically defined active substances are added: World Health Organisation, *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine* (2000) UN Doc WHO/EDM/TRM/2000.1, 3.

Australian Register of Therapeutic Goods

- 7.15 Herbal medicines may be either 'listed' or 'registered' on the Australian Register of Therapeutic Goods to be sold in Australia, with the vast majority going through the listing route to approval.²⁶ Listed goods are considered to be lower risk than registered goods, and a correspondingly less intense level of scrutiny is applied to applications.²⁷
- 7.16 The medicinal cannabis products made available to patients overseas, and currently used illicitly in Australia, are in the nature of herbal medicines. The conventional way for such products to be regulated is through the 'listing' process.²⁸ However, products containing cannabis cannot be listed on the Australian Register of Therapeutic Goods.²⁹ This reflects an underlying purpose of the listing process, namely that it is to be used for lower-risk goods, the safety of which is known.

PIC/S Guide to Good Manufacturing Practice for Medicinal Products

- 7.17 Whether listed or registered, the manufacture of herbal medicines must comply with the same manufacturing standards as synthetic pharmaceuticals: a set of rules commonly referred to as 'Good Manufacturing Practice' (GMP).³⁰ Australia has adopted an international code, the 'Guide to Good Manufacturing Practice for Medicinal Products,' developed by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly known as PIC/S) as the standard to be observed in the manufacture of therapeutic goods.³¹
- 7.18 The PIC/S Guide to Good Manufacturing Practice for Medicinal Products and its annexes are not prescriptive as to what manufacturers must do or how their facilities need to be set up. Rather, they set out a series of aspirational, product-neutral statements to guide industry participants on the sorts of procedures they need to adopt and follow. While the PIC/S Guide frequently states that manufacturers 'should' do certain things, in Australia these are treated as compulsory requirements.³²
- 7.19 The PIC/S Guide has a number of Annexes. Annex 7 relates to the Manufacture of Herbal Medicinal Products. It is based on the following principle:

Because of their often complex and variable nature, and the number and small quantity of defined active ingredients, control of starting materials, storage and processing assume particular importance in the manufacture of herbal medicinal products.³³

26 Fewer than 200 of the 20,000 approved complementary medicines in Australia are 'registered' goods: Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation: Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015) 6. Medicines may be listed if they contain only certain compounds. Among the permitted ingredients are herbal substances other than those derived from specified (high risk) plants: *Therapeutic Goods Regulations 1990* (Cth) r 1, sch 4 Pt 1 and sch 4 pt 4 div 1.

27 Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation: Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015) 6. In addition, listed goods cannot make therapeutic claims about any disease, condition, ailment or defect listed in Part 1 or 2 of Appendix 6 of the *Therapeutic Goods Advertising Code 2007: Therapeutic Goods Regulations 1990* (Cth) sch 4. The prohibited claims generally relate to more serious conditions, and when considering the addition of conditions, consumer vulnerability and impacts on public health must be taken into account, including whether the claim would make consumers less likely to seek professional advice: *Therapeutic Goods Advertising Code 2007*. See also *Review of Medicines and Medical Devices Regulation, Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015) 6.

28 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [4.35].

29 The *Therapeutic Goods Regulations 1990* (Cth) r 10(b) and sch 4 pt 1 Items 3(d)(i) and 3(a)(i) provide that preparations are not listable if they contain herbal substances derived from specified plants (among which is cannabis: sch 4 pt 4 div 1) or if they are included in a schedule to the Poisons Standard (cannabis is in Schedule 9).

30 Internationally, the requirements of GMP are not uniformly applied to complementary medicines, with the United States, New Zealand and Singapore among the jurisdictions which apply different manufacturing standards to complementary medicines: Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation: Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015) 17. The Australian complementary medicines industry has proposed the development of a standard specific to complementary medicines, and has suggested different standards for, among other things, stability testing and validation testing: *Review of Medicines and Medical Devices Regulation, Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015) 17–18. The Review has asked for submissions on and will consider whether a different set of GMP standards should be adopted for complementary medicines. See Submission from the Australian Self Medication Industry (Stage 2), Submission from Complementary Medicines Australia (Stage 2).

31 The *Therapeutic Goods Act 1989* (Cth) s 36 permits the Commonwealth Minister for Health to determine written principles to be observed in the manufacture of therapeutic goods. Through the *Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2009* (Cth), the TGA has adopted the PIC/S 'Guide to Good Manufacturing Practice for Medicinal Products' (PE 009-8, 15 January 2009) for the purposes of s 36. Through the operation of s 36 and other provisions within the Act, the Guide has legal force in Australia.

32 *Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2009* (Cth) s 5(4).

33 PIC/S 'Guide to Good Manufacturing Practice for Medicinal Products' (PE 009-8, 15 January 2009) Annex 7, 48.

Other guidelines

7.20 International guidelines relevant to the production of herbal medicines also exist,³⁴ and various pharmacopoeias include guidance on the production of herbal drugs and extracts.³⁵ Domestically, the TGA has developed the Australian Regulatory Guidelines for Complementary Medicines.³⁶

Creating a framework for medicinal cannabis quality

- 7.21 Victoria should seek to make available a regulated source of medicinal cannabis products—notwithstanding that they are not proven, pharmaceutical-grade products—while still providing appropriate protections for vulnerable patients within the scheme. If this structure were to replicate the rigour of the TGA's assessment process for pharmaceutical-grade products, there would be no point in setting it up. The alternative structure must sensibly be one which does not require the same level of evidence to be supplied, or there would be no expansion of the availability of medicinal cannabis products within a satisfactory timeframe.
- 7.22 Equally, it is important that the products authorised under the Victorian medicinal cannabis scheme do not directly compete with or undermine conventional pharmaceuticals. For the reason that they are not as tightly regulated as products approved by the TGA, the products available under the Victorian medicinal cannabis scheme should be different from their pharmaceutical counterparts, including pharmaceuticals derived from cannabis. Patients and doctors would have reasons for preferring pharmaceutical-grade, thoroughly tested cannabinoid products, and as a result the two categories of product would not directly compete.³⁷
- 7.23 It is important that, for the separate character of the Victorian products to be preserved, and the pre-eminence of conventional approval to be maintained, the character of the products be distinctive. That is, the government should not endorse these products as replacements for conventional pharmaceuticals. The equivocal evidence base, surveyed in Chapter 2, shows this stance to be unavoidable. Therefore, it is the Commission's view that medicinal cannabis products should be presented to patients as a form of less-refined, herbal medicine.
- 7.24 The Commission considers that the regulation of medicinal cannabis quality should be as follows:
- Medicinal cannabis products should not be required to be tested for safety or efficacy prior to going to market, and patients should be informed of this fact when being supplied with products.³⁸
 - Medicinal cannabis products should be in the nature of herbal extracts, in that they would contain a range of compounds found in the plant, not isolated cannabinoids.³⁹
 - The concentration of cannabinoids in medicinal cannabis products should be permitted to vary within specified ranges. The uncertainty potentially generated by this would be addressed by requiring products to be tested, and labelled accordingly.

34 For example: European Medicines Agency *Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products* (CPMP/QWP/122/02, rev 1); European Medicines Agency *Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products* (CPMP/QWP/2819/00 Rev. 2); European Medicines Agency *Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products* (CPMP/QWP/2820/00 Rev. 2).

35 See, eg, the monographs of the British Pharmacopoeia on 'Herbal Drugs', 'Herbal Drug Preparations' and 'Extracts'.

36 Currently published as version 5.2, May 2015.

37 That this is the case can be seen in the example of GW Pharmaceuticals. Despite cannabis being widely available for medical and recreational users in the United States, the company is investing significant sums in trialling its pharmaceutical-grade cannabinoid products with a view to obtaining regulatory approval for their sale in the United States. (Sativex is currently undergoing clinical trials for cancer pain, while Epidiolex is being trialled for Dravet Syndrome and Lennox-Gastaut Syndrome.) See GW Pharmaceuticals, *Press Releases* <<http://www.gwpharm.com>>.

38 See [3.203]–[3.205].

39 This is consistent with the definition of 'herbal substance' in the *Therapeutic Goods Regulations 1990* (Cth) r 2—'herbal substance means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin): (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.'

- Medicinal cannabis products should be subject to manufacturing standards equivalent to those imposed on medicines approved by the TGA.
- 7.25 The proposed regulation is less strict than for products approved by the TGA, in that products would not be as rigorously assessed or purified, but they would still be subject to quality control. The government would fail to protect patients if it were to endorse the provision of products without taking steps to ensure their quality. One objective of legalising and regulating medicinal cannabis is to reduce the harms associated with patients accessing cannabis for medical use on the black market, harms which include uncertainty about content, possibility of contamination and an unreliable source of supply.⁴⁰
- 7.26 Some submissions in support of a parallel system for the regulation of the quality of medicinal cannabis supported this type of regulation. Professor David Penington stated he believes medicinal cannabis ‘will end [up] being designated as a regulated “herbal” product’.⁴¹ Along the same lines, Laurence Mather, in his submission to the Senate Committee, endorsed the Dutch approach, of standardised herbal cannabis.⁴²
- 7.27 It is acknowledged that cannabis is not free of risks, and in many ways is quite distinct from the types of goods ordinarily regulated as herbal medicines. For this reason, the Commission does not suggest that Victoria merely replicate the system of controls for listed complementary medicines. As described below and elsewhere in this report, herbal cannabis products should be subject to the following additional controls:
- Medicinal cannabis should only be made available to eligible patients, namely those in defined ‘exceptional circumstances’ where there is some evidence cannabis may assist.⁴³
 - Medicinal cannabis should only be supplied to and possessed by someone who has been authorised by a medical practitioner.⁴⁴
 - Medicinal cannabis products should be batch tested prior to their supply to patients, to quantify content and ensure the absence of contaminants.⁴⁵

Quality standards

- 7.28 For the quality of medicinal cannabis products to be controlled, there is a need to determine the set of standards to which they will be held. Victoria has the option of drawing on internationally accepted standards for agricultural products and drug manufacture, or developing its own set of standards, specific to medicinal cannabis.
- 7.29 There are sources on which the Victorian Government could draw to establish the standards with which cultivators and manufacturers must comply:
- Good Agricultural and Collection Practice
 - Good Manufacturing Practice
 - Codes of practice with specific rules for medicinal cannabis.

40 Thus the Commission’s regulatory objective of ‘ensuring that medicinal cannabis products are of reliable quality and known composition’. See also Laurence Mather, Submission No 17 to Senate Legal and Constitutional Affairs Committee, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 9 March 2015.

41 Submission 24.

42 Laurence Mather, Submission No 17 to Senate Legal and Constitutional Affairs Committee, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 9 March 2015, 8.

43 See Chapter 3.

44 See Chapter 3.

45 See [7.59]–[7.62].

Good Agricultural and Collection Practice

- 7.30 Good Agricultural and Collection Practice (GACP) is a set of procedures that govern the cultivation, harvesting, processing and storage of botanical products used for the production of medicines. Their purpose has been described as follows:
- In the case of herbal preparations the production and primary processing of the medicinal plant/herbal substance has a direct influence on the quality of the [active pharmaceutical ingredient]. Due to the inherent complexity of naturally grown medicinal plants/herbal substances and the limited analytical techniques to characterise constituents solely by chemical or biological means, reproducible quality of starting materials of herbal origin requires an adequate quality assurance system for the collection and/or cultivation, harvest and primary processing.⁴⁶
- 7.31 In addition, GACP seeks to ensure that medicinal plants and herbal substances are produced hygienically, reducing microbial contamination to a minimum, and are handled with care, to avoid adversely affecting the herbal substance during its collection, cultivation, processing or storage.⁴⁷
- 7.32 GACP comprises a set of procedures that producers of many types of plant products should follow in order to ensure a safe finished product for consumers. There is, in fact, not one single version of GACP, but a number of guidelines for different industries. The standards most relevant to the production of botanical medicines are those produced by the European Medicines Agency⁴⁸ and the World Health Organisation.⁴⁹
- 7.33 Producers of medicinal plants in Australia are not directly required by law to comply with GACP. However, manufacturers using herbal ingredients are required to undertake testing and treatment of botanical source materials,⁵⁰ and must be able to provide specifications for any herbal starting products.⁵¹ In this respect, quality control of plant-derived medicines is made the responsibility of the manufacturer. In the case of the alkaloid poppy industry, for example, cultivators licensed by Victoria are not subject to any regulation of their cultivation and harvesting practices from a quality perspective, with quality obligations imposed solely on manufacturers through the licensing and approval processes of the TGA and international pharmaceutical regulators.⁵²
- 7.34 Notwithstanding this, in the Commission's view, cultivators in the Victorian medicinal cannabis scheme should be required to comply with standards of some kind. UTT BioPharmaceuticals agreed with this, recommending that the system regulate the finished product, the botanical ingredients it contains, and the cultivation process.⁵³ While this would depart from the approach adopted through the listing/registration processes in the *Therapeutic Goods Act 1989* (Cth), the Commission considers that the novelty of cannabis demands a cautious, transparent approach.
- 7.35 It should be noted that Victorian and Commonwealth legislation that restricts the activities of all agricultural producers would also apply to cannabis cultivators.⁵⁴

46 European Medicines Agency, *Guideline on Good Agricultural and Collection Practice (GACP) for Starting Materials of Herbal Origin* (2006) (EMA/HMPC/246816/2005) [1].

47 European Medicines Agency, *Guideline on Good Agricultural and Collection Practice (GACP) for Starting Materials of Herbal Origin* (2006) (EMA/HMPC/246816/2005) [2.2].

48 Ibid.

49 World Health Organisation, *WHO Guidelines On Good Agricultural and Collection Practices (GACP) for Medicinal Plants* (2003).

50 Annex 7 to the PIC/S 'Guide to Good Manufacturing Practice for Medicinal Products' (PE 009-8, 15 January 2009) requires manufacturers to ensure botanical products are tested for constituents, pesticides, fungal/microbial contamination, toxic metals and foreign materials: clause 5. It also highlights that treatments to reduce fungal/microbial contamination might be applied.

51 European Medicines Agency *Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products* (EMA/CPMP/QWP/2820/00 Rev 2).

52 Consultation 19.

53 Submission 60.

54 See, eg: the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (Vic), which restricts pesticides and other chemicals that may be used; the *Environmental Protection Act 1970* (Vic) and policies associated with it which restrict certain activities that have environmental impacts, such as runoff, offensive smells and waste disposal.

Recommendation

- 31** Licensed cultivators should be required to comply with appropriate Good Agricultural and Collection Practice.

Good Manufacturing Practice

- 7.36 In the Commission's view, manufacturers in the Victorian medicinal cannabis scheme should be required to comply with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.⁵⁵ Several submissions called for these standards to be applied.⁵⁶ As explained above, because they are worded in general terms, Good Manufacturing Practice (GMP) can be applied to the manufacturers of botanical products just as they can to manufacturers of synthetic compounds. Relevant international guidelines⁵⁷ could also be supplied to guide manufacturers.

Recommendation

- 32** Licensed manufacturers should be required to comply with Good Manufacturing Practice, as reflected in the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.

Cannabis-specific codes of practice

- 7.37 In connection with the licensing of manufacturers, the TGA has detailed protocols and a body of inspectors and officials with specialised knowledge about the practical requirements of GMP. This expertise does not presently exist in the Department of Health and Human Services because the Department does not have responsibility for the regulation of drug/herbal product manufacturers or the enforcement of GMP.⁵⁸ In addition, the Department would need to determine how to apply the general standards of GMP to cannabis production—for example, the standards refer to acceptable limits of pesticides and microbes, but there is no specification of precisely what that level would be.⁵⁹ In summary, the supervision exercised by the TGA over manufacturers cannot be replicated in the Victorian scheme merely through the application of the PIC/S Guide.
- 7.38 To address these possible practical difficulties, the Department could prepare new rules, specifically for application to cannabis production.⁶⁰ This would provide certainty to businesses seeking to participate in the scheme, and to government inspectors in determining whether licensees are compliant. The new rules could be used in substitution for or in addition to GACP or GMP. If operating alongside them, the rules could function to explain how GACP/GMP are considered to apply in the context of cannabis production.

55 (PE 009-8) 15 January 2009.

56 Submissions 24 and 60, advisory committee (Meeting 2), Consultation 1.

57 Examples are given at [7.20].

58 The Department has a role in food safety, but this field applies a different set of standards and relies on a different set of expertise.

59 Standards exist, but they are not contained in the PIC/S Guide to GMP. Finished products regulated by the TGA must have microbial levels below set standards, laid out in the Therapeutic Goods Order No 77, *Microbiological Standards for Medicines* (2008). TGA guidelines set out maximum levels of pesticide and solvent residues in finished products: TGA, *Australian Regulatory Guidelines for Complementary Medicines* (version 5.2, May 2015) 71. Even fresh produce is subject to maximum pesticide residue concentrations, which are determined by Food Standards Australia and New Zealand: *Food Standards Code*, s 1.4.2.

60 Comparative guidelines in Victoria are Codes of Practice in the dairy industry (*Dairy Act 2000* (Vic) ss 31-34) and the meat industry (*Meat Industry Act 1993* (Vic) ss 13A-13E).

This approach is adopted in the Netherlands.⁶¹ Cannabis-specific production guidelines have also been adopted in, among other places, Canada,⁶² Colorado and Minnesota.⁶³

Enforcing the standards

7.39 There are a number of tools through which the Victorian Government could apply quality standards to manufacturers (from least to most restrictive):

- allow the industry (licensed cultivators and manufacturers) to self-regulate, and for optional accreditation schemes to give consumers information about the standards applied
- arrange for manufacturers to make cannabis products under contract to the Victorian Government, and make production standards terms of the contract
- make compliance with manufacturing standards a condition of the licences held by cultivators and/or manufacturers
- set out rules in legislation.

7.40 Self-regulation would not be appropriate, as patient safety should be paramount under the scheme. Conversely, setting out specific rules in legislation would be too restrictive, preventing the government from updating procedures and standards as the industry develops. Applying standards to licensed manufacturers through contractual terms would not be sufficiently transparent to give patients and medical practitioners confidence in the scheme, and would deprive inspectors of necessary enforcement powers.

7.41 In the Commission's view, the GMP standards referred to above and any local guidelines developed for cannabis should be applied to manufacturers and cultivators through incorporation of the relevant standards in regulations⁶⁴ and through licence conditions.

7.42 Standards could be practically enforced through a combination of the following mechanisms:

- inspections at the time of application to ensure facilities and operators are set up to comply with GACP/GMP⁶⁵
- requiring licensees to prepare and submit production plans⁶⁶
- regular inspections throughout the period of the licence to ensure ongoing compliance⁶⁷
- record-keeping and reporting obligations imposed on licensees⁶⁸
- audits conducted by third parties⁶⁹
- infringement notices, improvement notices⁷⁰ and licence variation available where noncompliance is observed.

61 The Netherlands has produced a set of guidelines specific to cannabis, which are applied to cultivators. The guidelines are based on the European Medicines Agency's guidelines. See *Guidelines for Cultivating Cannabis for Medicinal Purposes* [Voorschriften voor de Verbouw van Cannabis voor Medicinale Doeleinden], Annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, English translation reproduced in (2003) 3 *Journal of Cannabis Therapeutics* 51.

62 Canada's *Marihuana for Medical Purposes Regulations*, SOR/2013-119 set out procedures for the cultivation and processing of cannabis which are based on the GMP provisions of the *Natural Health Product Regulations*, SOR/2003-196 ss 52–63; Part 3: Consultation 31.

63 Marijuana Enforcement Division (Colorado), *Sales, Manufacturing and Dispensing of Medical Marijuana Rules*, 1 CCR 212-1; *Permanent Rules Pertaining to Medical Cannabis Manufacturers*, Minnesota Rules 4700.0100-4770.2800.

64 Like the incorporation of the Guide at the Commonwealth level through s 36 of the *Therapeutic Goods Act 1989* (Cth): see [4.38]–[4.39].

65 Comparable to inspections of applicants for manufacturing licences under the *Therapeutic Goods Act 1989* (Cth).

66 Cf *Dairy Act 2000* (Vic) ss 38–39, under which certain categories of licence holders can be required to have a food safety program, setting out how the licence holder will comply with the applicable Code of Practice; *Meat Industry Act 1993* (Vic) ss 10–11, under which licence holders can be required to have a quality assurance program.

67 By way of contrast, the TGA adopts a risk-based approach to inspections, under which the frequency of inspections depends on the risks associated with the relevant product and process, together with the licensee's compliance history, while the duration and conduct of inspections depends on the type of processes used. See: Commonwealth Department of Health—Therapeutic Goods Administration, *Manufacturer Inspections—An Overview*, (1 May 2013) <<https://www.tga.gov.au/manufacture-inspections-overview>>.

68 Cf *Meat Industry Act 1993* (Vic) s 29, imposing record keeping obligations on licensees.

69 Cf *Dairy Act 2000* (Vic) s 41, under which Dairy Food Safety Victoria can require licence holders to audit their food safety program; *Meat Industry Act 1993* (Vic) s 12A.

70 Cf *Dairy Act 2000* (Vic) s 46, setting out the powers of authorised officers to order licence holders to undertake cleaning, to shut down particular equipment, to suspend delivery of orders, etc.

Efficacy testing

- 7.43 The approval process undertaken by the TGA evaluates products for ‘safety, quality and efficacy’.⁷¹ Sponsors seeking to register a therapeutic good must present to the TGA evidence that the good is efficacious for the requested indication.⁷² The less rigorous listing process does not evaluate efficacy, but requires manufacturers to possess evidence supporting any therapeutic claims they wish to make.⁷³
- 7.44 This raises the question of whether products should be permitted to be sold under the scheme if they have not been specifically tested in humans for effect. One submission stated that it would be ‘unfair’ to apply the efficacy criteria for registered medicines to medicinal cannabis products and argued that departure from ordinary standards is justified where ‘medical science and regulatory processes are failing to meet the needs of society’.⁷⁴ However, a number of other submissions advocated for clinical trials, on the basis that the efficacy of cannabis was not yet adequately established.⁷⁵
- 7.45 In the Commission’s view, the scheme should operate on the basis that the efficacy of Victorian medicinal cannabis products has not been established. The Victorian scheme should ensure a product is free of unsafe components and its composition is sufficiently known. However, it would not be feasible or desirable for the scheme to make approval of a particular medicinal cannabis product contingent on proof (whether to conventional standards or otherwise) that the product is effective to treat a given indication. Clinical trials are costly and time-consuming to run, and placing similar barriers to product approval as already exist under the TGA would not facilitate access to medicinal cannabis in any meaningful way.
- 7.46 Because their efficacy has not been specifically proven, products offered under the medicinal cannabis scheme would be clinically less useful than those approved through conventional channels. While this would provide patients and their treating medical practitioners with fewer assurances than approval by the TGA, this is a tolerable outcome because the scheme would complement, not supplant, the approval processes of the TGA, to allow access to less-proven substances in exceptional circumstances.
- 7.47 There is a risk that products would be offered to patients despite having no therapeutic value, or with their therapeutic value overstated.⁷⁶ However, as the government would be the sole distributor, there is no risk of a third-party manufacturer making inaccurate efficacy claims.
- 7.48 It is important for patients to be clearly informed when deciding to take medicinal cannabis dispensed under the Victorian scheme that the products have not been subjected to the conventionally rigorous tests of efficacy imposed by the TGA, and that other conventional products exist which have that status. By opting for the ‘alternative’ of medicinal cannabis, the patient must be informed that that the product may not be effective for them. There is a risk that attaching the imprimatur of the state to these regulated products would lead consumers to assume that they have been clinically tested for efficacy. The advice given to patients by doctors and the government in authorising them to use cannabis would therefore be fundamental to ensuring that patients’ consent to use such products is informed.⁷⁷

71 *Therapeutic Goods Act 1989* (Cth) s 25(1)(d).

72 Therapeutic Goods Administration, *Product Regulation According to Risk*, (28 October 2014), <<http://www.tga.gov.au>>.

73 *Therapeutic Goods Act 1989* (Cth) s 26A(2)(j).

74 Submission 43. Submission 95 also opposed the testing of efficacy for cannabis products under a Victorian scheme.

75 Submissions 25 and 38.

76 Consumers of health products are frequently misled by overstated therapeutic claims attached to unproven treatments. By way of example, in 2013 the National Health and Medical Research Council issued a warning to patients travelling overseas to seek treatment with stem cell therapies, noting that ‘The science of stem cells offers great potential for treating a number of conditions, however in many cases further research is required to demonstrate safety and effectiveness. ... Unproven stem cell treatments can result in serious health complications such as infection, allergic reaction or immune system rejection and in some cases, the development of cancer. In addition to the health and safety risks, these treatments often involve significant financial costs. Undergoing unproven treatments may also interfere with or delay a patient accessing proven and potentially beneficial therapies or treatment plans’: National Health and Medical Research Council, ‘NHMRC Warns of the Risks Associated with Unproven Stem Cell Therapies in Australia and Overseas’, (Media Release, 19 December 2013) <<http://www.nhmrc.gov.au>>.

77 See [3.203]–[3.205].

Clinical testing of side effects

- 7.49 For a therapeutic good to be included on the Australian Register of Therapeutic Goods, its safety must be known. In the case of listed goods, safety is ensured by requiring that the product only contain ingredients already known to be safe. In the case of registered medicines, considered to be higher risk, the sponsor must present evidence regarding the product's safety. That is, the medicine must have been tested for side effects prior to obtaining approval.
- 7.50 The risks and side effects of cannabis are relatively few and minor.⁷⁸ In addition, they are reasonably well documented, although mostly not in a clinical setting, and in this sense cannabis is not comparable to a drug containing a new molecule. Where a new complementary medicine is sought to be used, its safety can be established by documenting historical evidence of its use.⁷⁹ Cannabis has been extensively used and studied, and while it is by no means completely safe or free of side effects, the Commission considers that quantifying cannabinoid content and disseminating educational materials about known attributes and side effects of medicinal cannabis to medical practitioners would be sufficient to allow the patient and their treating doctor to identify risks for the patient, and render safety testing of individual products unnecessary.

Product approval

- 7.51 Any Victorian medicinal cannabis scheme should only provide medicinal cannabis products that have been approved by the government. A list of approved products would be publicly available, and new products could be added by the Secretary of the Department of Health and Human Services. A submission made on behalf of the cannabis community of Victoria opposed a scheme in which the available products are limited by the government in this way, stating that it would not satisfy patient needs.⁸⁰ The Commission considers, however, that this regulatory mechanism is essential to give clarity to law enforcement, to satisfy doctors about products' reliability and to maintain government control over the available products.
- 7.52 By requiring that medicinal cannabis products be approved, the scheme could draw a clear line between products that are lawful and those that are not. Amendments to the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) would authorise medicinal cannabis patients to possess only the approved product specified in the Authority to Dispense. Nominated carers would be similarly authorised.⁸¹
- 7.53 Medical practitioners issuing an Authority to Dispense would specify the product to be dispensed, in a similar way to prescriptions for conventional medicines. To this end, the Department of Health and Human Services should make available to medical practitioners a list of approved products and their properties.
- 7.54 A product approval should specify at least the following matters:
- its THC content, as a percentage
 - its CBD content, as a percentage
 - its formulation (for example: extraction, tincture, oil)
 - permitted ingredients
 - the brand name under which it will be sold
 - the contents of its label.

78 See [2.145]–[2.164]. According to Laurence Mather, medicinal cannabis has side effects, like all medicines, but they are 'minimal and acceptable', and it 'lacks life threatening acutely toxic effects even in large overdoses': Laurence Mather, Submission No 17 to the Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 9 March 2015, 4, 7.

79 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Complementary Medicines* (version 5.2, May 2015) 76.

80 Submission 95.

81 See [3.198], [3.215], [3.222].

- 7.55 Upon taking possession of cannabis products from manufacturers, the government should ensure that the product corresponds with its approval. In particular, through testing (detailed below), it should ensure that the cannabinoid content of the product is consistent with the approval, within a specified tolerance range.⁸²
- 7.56 Unlike the process for including new products on the Australian Register of Therapeutic Goods, obtaining approval of a medicinal cannabis product should not be initiated by the proposed manufacturer, nor require the manufacturer to test the product in clinical trials before approval is granted. This is because the design of the scheme is such that the government orders specific quantities of designated cannabis products, which are then delivered to it by the licensed manufacturers. That is, the government controls the levels of supply and, correspondingly, should control the range of products that are made available.⁸³ However, the process for obtaining new products would involve consultation between the manufacturer and the Department, as the introduction of a new product would depend on the ability of the manufacturer(s) to produce it safely and consistently.
- 7.57 The Secretary's discretion to approve new products should be unfettered. In practice, the Secretary would be likely to take into account scientific developments regarding the utility of different types of cannabis for eligible conditions, patient demand for new products, patient safety, and pharmacological considerations regarding rate, intensity and duration of absorption.
- 7.58 A process should be established by which products would be considered for approval. This should include consultation with the medical profession and the Expert Advisory Committee on Medicinal Cannabis or a successor advisory body.⁸⁴ The Department would issue guidelines regarding the product development and testing which would need to take place before the product is approved—for example, a manufacturer may be asked to demonstrate their ability to control cannabinoid concentration before a particular product is approved.

Recommendations

- 33** The Secretary of the Department of Health and Human Services should have the power to determine which medicinal cannabis products may be manufactured under licence and dispensed in Victoria.
- 34** The Secretary of the Department of Health and Human Services should establish and publish a register of medicinal cannabis products approved for sale in Victoria. The register should specify, for each product:
- (a) its THC and CBD content, as a percentage
 - (b) its formulation
 - (c) permitted ingredients
 - (d) the brand name under which it will be sold
 - (e) label contents.

82 In the Netherlands, cannabinoid content can vary from the specified concentration by up to +/- 20%: Bedrocan BV, Submission No 48 to Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 13 March 2015.

83 This is the process adopted by the Office of Medicinal Cannabis in the Netherlands: Consultation 28.

84 See [1.77]–[1.79].

Batch testing

- 7.59 Medicinal cannabis products would be tested for two reasons:
- to ensure the quality of products (namely, to ensure that the actual quantity of cannabinoids in the product matches the concentration listed on the product approval)
 - to ensure the safety of products (namely, to ensure that the product does not contain unsafe concentrations of contaminants, such as moulds, microbes, harmful or prohibited pesticides, solvent residue and so on).
- 7.60 Consistently with the requirements of the TGA, testing should be conducted to ensure that any 'quantitative claim' made (that is, any claim made regarding the THC or CBD content of a product) is verified, and this testing should take place on every batch produced.⁸⁵ Testing should be performed on the finished product (the oil, tincture or other product), not on the raw plant matter.⁸⁶ The specified cannabinoid content on the approval would need to be within a prescribed tolerance, and failure to do so would enable the Secretary to reject the batch.⁸⁷
- 7.61 Testing could either be performed by the manufacturer or by a third party. For transparency reasons, the Commission considers that testing by a third party would be preferable.⁸⁸ If internal testing is to be used, no additional legislative change would be required. If third parties are to be used for testing, the legislation would need to authorise certain facilities to possess medicinal cannabis for the purpose of testing. It is suggested that the provisions authorising certain facilities to undertake testing could be based on current provisions empowering the Chief Commissioner of Police to declare testing facilities to undertake forensic testing of drugs.⁸⁹
- 7.62 In determining whether to authorise a particular facility, the Secretary would have regard to whether it would use appropriate technologies to give an accurate indication of product strength.⁹⁰ The technology used would need to be adapted to the purpose of the testing. While some testing technologies have as their purpose determining which compounds are present in a sample, others are intended to quantify the amount of particular compounds present in a sample. A facility would need to be properly equipped to test the potency⁹¹ of cannabis, and to test for an appropriate range of pesticides, solvents, heavy metals and microbial contaminants.

Recommendation

35 The Secretary of the Department of Health and Human Services should have the power to authorise independent testing facilities in Victoria to test medicinal cannabis products.

85 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Complementary Medicines* (version 5.2, May 2015) 125.

86 TGA guidelines allow botanical medicines to be 'quantified by input' in certain circumstances—that is, it allows the manufacturer to omit testing of the finished product if the composition of its ingredients is known. However, testing is required where a 'quantitative claim' is made on the product label. Because, as stated at [7.64], the Commission recommends that cannabis products be labelled with their cannabinoid content, testing of each batch would be required under the scheme: Therapeutic Goods Administration, *Australian Regulatory Guidelines for Complementary Medicines* (version 5.2, May 2015) 123–6.

87 This is the approach adopted in the Netherlands. There, cannabinoid content is permitted to vary by +/- 20% of the set value for the product, consistently with European Medicines Agency guidelines: Consultation 28.

88 Submissions 60, 95.

89 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ss 97–98.

90 The Secretary should also ensure the facility is accredited by the National Association of Testing Authorities.

91 In particular, the testing facility would need to be able to test cannabis products for their concentration of THC and THCA, and to be able to differentiate the two cannabinoids when stating the concentration. Because only THC is psychoactive, and it appears that THCA is not metabolised to THC in the human body (see: Julia Jung et al, 'Studies on the Metabolism of the Δ 9-Tetrahydrocannabinol Precursor Δ 9-Tetrahydrocannabinolic Acid A (Δ 9-THCA-A) in Rat Using LC-MS/MS, LC-QTOF MS and GC-MS Techniques' (2009) 44 *Journal of Mass Spectrometry* 1423), an accurate statement of the potency of a cannabis product must be capable of distinguishing THC from THCA. It has been asserted that GC-MS, which heats the product sample in the testing process above the temperature at which decarboxylation occurs, converts THCA in the sample into THC, leading to results which overstate the concentration of THC in the finished product, unless the sample is 'derivatised' before testing: Luigi L Romano and Arno Hazekamp, 'Cannabis Oil: Chemical Evaluation of an Upcoming Cannabis-Based Medicine' (2013) 7 *Cannabinoids* 1, 4. Submission 95 also made this point.

Recommendation

- 36** All medicinal cannabis products manufactured under a Victorian scheme should be subject to testing by an authorised testing facility to confirm whether the cannabinoid content correlates with that specified on the label and to identify the presence of any contaminants.

Labelling

- 7.63 Submissions highlighted the value of labelling as a means of conveying information about the product to patients.⁹² Matthew Pallett submitted that '[a]ll commercial cannabis products should carry labelling stating percentage of active constituents so consumers can make an informed decision about the type of cannabis they wish to consume'.⁹³
- 7.64 As noted above, the scheme should allow for cannabinoid content to vary slightly from the specified content on the approval. Therefore, medicinal cannabis products should be labelled with the precise cannabinoid content of the product. Labels could also convey warnings regarding the risk of driving,⁹⁴ the untested nature of the product, penalties attached to diversion and so on.

Post-market surveillance

- 7.65 Even cannabis products that have been subject to quality control regulations could later be found to be unsafe. For this reason, the regulation of therapeutic goods always includes a system to monitor products after they go onto the market. This allows the regulator both to monitor rare or long-term adverse effects, and to undertake recalls and investigations if unexpected contamination is detected.
- 7.66 The TGA has a system for reporting adverse events. Reports are primarily made by patients, manufacturers, medical practitioners and pharmacists. The information received is logged, and may lead to further evaluation. Should a safety concern be identified, the TGA can take actions including information bulletins, labelling changes, withdrawing or limiting a product's registration, or requesting that further studies be undertaken.⁹⁵ An analogous system should be adopted in any medicinal cannabis scheme.⁹⁶

Forms of medicinal cannabis

- 7.67 Submissions frequently argued for the scheme to make available a range of medicinal cannabis products, to allow for the varying preferences and medical needs of patients.⁹⁷ In addition to a variety of strains, the scheme should allow for a variety of delivery modes. This is important as different patients and conditions are asserted to respond better to different products.
- 7.68 A considerable amount of knowledge exists, both in industry overseas and in the Australian illicit market, regarding the composition of cannabis, the ways it can be refined and how products can be adapted to suit the needs of patients. The Commission heard from many people who had become expert on the topic of medicinal cannabis, both through reviewing the literature and cultivation experience.⁹⁸

92 Submissions 59, 60, 69, 97.

93 Submission 59.

94 See [3.219].

95 Commonwealth Department of Health—Therapeutic Goods Administration, *Reporting Medicine and Vaccine Adverse Events* (28 October 2014) <<https://www.tga.gov.au/reporting-medicine-and-vaccine-adverse-events-0>>.

96 Consultation 25.

97 Submissions 19, 45, 59, 63, 74, 75, 84, 95; Consultations 6, 7. Members of the Commission's advisory committees also commented upon the need for a range of products to be made available: advisory committee (Meeting 3).

98 Submissions 29, 59, 93, 95; Consultation 7.

7.69 However, there is also a good deal to learn, and many assertions that are frequently made regarding cultivation practices, extraction methods and pharmacology do not appear to be based on science—indeed, this is not surprising given that there are few legal means for this information to be tested and improved.

Smoking should be avoided

7.70 Historically, cannabis has been commonly administered by smoking.⁹⁹ As discussed in the Issues Paper,¹⁰⁰ smoking has a number of adverse health consequences and is an unreliable way of dosing. Many of the side effects associated with smoking cannabis are not observed for other modes of administration.¹⁰¹ There is also the possibility of accidental ingestion by third parties through passive smoking.¹⁰² A number of submissions urged that smoking be discouraged or prevented under the proposed scheme, or remarked upon the harmful health effects of this mode of administration.¹⁰³ However, as noted by Cancer Action Victoria, the risks associated with smoking are of less importance for a person with a terminal illness.¹⁰⁴

7.71 In addition, over the past three decades governments have passed increasingly restrictive laws aimed at protecting public health by prohibiting or discouraging smoking,¹⁰⁵ while the not-for-profit sector has run extensive public health campaigns to the same end. A scheme which made cannabis available and enabled or encouraged smoking as a delivery method would be inconsistent with the outcomes and messages that successive governments have worked hard to achieve in this area.

7.72 There are two distinct means by which a medicinal cannabis scheme could seek to avoid the smoking of cannabis:

- by allowing dried cannabis (in addition to other forms) but prohibiting or discouraging patients from consuming it by smoking
- by only allowing forms of cannabis that cannot be smoked.

Allowing dried cannabis but discouraging smoking

7.73 It would be possible to establish a scheme which provided dried cannabis but did not promote smoking. The Victorian Government could provide advice to patients and health professionals regarding other forms of delivery, such as vaporisation and ingestion through food or tea. Pharmacists could supply informational material and be able to sell vaporisers, which heat cannabis without combusting it, avoiding many of the negative health effects observed with smoking. Alternatively, legislation could be enacted which seeks to prevent or limit smoking of cannabis by users who have obtained it for medicinal use.

7.74 In the Netherlands, patients can only purchase dried cannabis, in the form of whole dried flowers or flowers which have been ‘granulated’. Government information programs encourage consumption by vaporisation, in a tea or in edible/baked goods.¹⁰⁶ However, in practice a large number of patients administer their medicinal cannabis by smoking it—up to 80 per cent of patients are estimated to do so.¹⁰⁷

99 Smoking in a cigarette and smoking in a water pipe/bong are not differentiated here.

100 See Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [3.81].

101 Ibid [3.81]–[3.85], Submission 52.

102 Submission 52.

103 Submissions 38, 45, 47, 49, 52, 57, 63, 91, 99; Consultations 13, 16, 23.

104 Submission 54.

105 Including location-based bans, advertising and marketing restrictions and taxation policies. See M M Scollo and M H Winstanley (eds), *Tobacco in Australia: Facts & Issues* (4th ed, 2012, Cancer Council Victoria) <<http://www.tobaccoaustralia.org.au>>.

106 See Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (2015) [6.12]–[6.13], [6.23].

107 Consultation 28.

- 7.75 Several submissions called for dried plant matter to be among the forms of cannabis available under the scheme.¹⁰⁸ One expressed the view that, if dried cannabis were made available, few patients would smoke it in any event.¹⁰⁹
- 7.76 Cancer Council Victoria stated that it ‘would not support a scheme where the smoking of cannabis is the predominant delivery method for patients.’ It encouraged the consideration of models ‘where alternative delivery methods, such as the use of oils and vaporisers, are the primary approach’.¹¹⁰
- 7.77 Victoria Police opposed the provision of dried plant cannabis to patients, commenting that ‘[i]t would not be forensically possible to differentiate crude cannabis grown illicitly from crude cannabis grown for medicinal purposes.’¹¹¹ Appropriately labelled, non-smokable cannabis would be more easily differentiated from illicit cannabis by law enforcement authorities.
- 7.78 While there are a range of educational measures and offence provisions the government could adopt to discourage users from smoking the dried plant form of cannabis, and there are ways of administering the dried plant form which do not involve smoking, the inevitable reality is that if dried cannabis is available, some patients will probably smoke it. A law which purported to prohibit the act of smoking medicinal cannabis, including on private property, would not be enforceable. If Victoria wishes to prevent medicinal cannabis supplied under the scheme from being smoked, an alternative approach will be required.

Allowing only non-smokable forms

- 7.79 The Victorian Government could elect to only make available forms of medicinal cannabis that cannot be smoked. Non-smokable forms could include extracts such as oils and concentrates, which can be swallowed or vaporised, pills, capsules and tinctures.¹¹²
- 7.80 There are many challenges involved in allowing only non-smokable forms of medicinal cannabis to be sold. Requiring producers to refine cannabis before it is sold would increase the cost of the product to the government¹¹³ and the cost of administering the regulatory system. Non-smokable extracts of cannabis can be highly potent, much more so than dried cannabis, making the risk of unwanted psychoactive effects much higher (this risk is heightened with oral forms, due to the slow rate of onset).¹¹⁴ Finally, because patients have less control over the way the cannabis is prepared and administered, prohibiting smokable forms may reduce levels of engagement with the system and promote continued reliance on the black market.

108 Submissions 1, 3, 11, 12, 15, 16, 18, 19, 22, 24, 37, 57, 74, 84, 95.

109 Mullaways Medicinal Cannabis Pty Ltd observed that ‘[t]he future of medicinal cannabis does not involve smoking cannabis. Most patients will find relief with other preparations ... very few if any will end up smoking it as a medical option’: Submission 29. Marc Selan expressed a similar view in Submission 74, while the submission made on behalf of the cannabis community of Victoria observed that ‘long term use [of smoking] is rare’: Submission 95.

110 Submission 57.

111 Submission 44.

112 Administration as a sublingual/buccal spray, as used for Sativex, may not be available to be used in Victoria, as GW Pharmaceuticals hold patents on, among other things, the delivery of cannabinoids using a mouth spray: see, eg, GW Pharmaceuticals, Cannabinoid Liquid Formulations for Mucosal Administration, Patent No 2009202434.

113 Submission 57.

114 Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015) [2.39].

-
- 7.81 A further drawback to allowing only non-smokable forms of cannabis to be sold is that patients would be deprived of safe administration methods which have a low production cost. Research and knowledge is growing about the use of vaporisers (devices which use heat to release cannabinoids and other volatile compounds) to administer dried cannabis.¹¹⁵ Research indicates that this method allows patients to obtain the benefits of inhalation (fast uptake and short duration of effect) while avoiding many of the harms associated with smoking (bronchial irritation, potential carcinogenesis and the effects of second-hand smoke on other people).¹¹⁶
- 7.82 In addition, licit non-smokable cannabis products are very new, making the task of regulating them difficult and uncertain. Information on the safety and efficacy of cannabis is limited, but the information that does exist mostly pertains to dried cannabis. As a result, the introduction of a scheme involving only non-smokable forms is to some degree a foray into the unknown—indeed, to the Commission’s knowledge, only two jurisdictions (Minnesota and New York) have introduced medicinal cannabis schemes that do not allow the dried plant form, and only one scheme has so far commenced. A number of states in the United States, however, do allow non-smokable forms of cannabis to be sold alongside dried plant cannabis, with highly variable regulations imposed. In addition, non-smokable forms are harder to regulate and the system for licensing manufacturers outlined above would be largely unnecessary if oils and other extracts were not provided under the scheme.
- 7.83 Nonetheless, the Commission is persuaded that a scheme which allows smoking should be avoided, and accepts that the only feasible way of ensuring this is through providing only non-smokable forms of medicinal cannabis. This approach would also have the advantage of enabling more accurate purity control and dosing.

Formulations and delivery systems

- 7.84 A Victorian medicinal cannabis scheme should enable production of a variety of formulations and delivery systems. Different patients have different needs and preferences in relation to medicinal cannabis – for example, children will generally require a product taken by mouth, for ease of administration, while people affected by nausea and vomiting may not want a product they need to swallow.¹¹⁷

115 Many submissions highlighted vaporisers as a useful mode of administration, such as Submissions 24, 29, 45, 49, 61, 72, 74, 91, 95.

116 Vaporising dried cannabis is said to be a ‘popular choice’ and ‘favoured by overseas Medicinal Cannabis Practitioners’: Submission 95. See, eg, D I Abrams et al, ‘Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study’ (2007) 82 *Clinical Pharmacology and Therapeutics* 572; Mallory Loflin and Mitch Earleywine, ‘No Smoke, No Fire: What the Initial Literature Suggests Regarding Vaporized Cannabis and Respiratory Risk’ (2015) 51 *Canadian Journal of Respiratory Therapeutics* 7. See also Submission 95.

117 Consultation 8.

7.85 Submissions called for the scheme to make available cannabis in the following extracted forms:

- oils¹¹⁸
- tinctures¹¹⁹
- edibles¹²⁰
- tablets/capsules¹²¹
- creams/ointments¹²²
- extracts¹²³
- patches¹²⁴
- raw cannabis.¹²⁵

7.86 Many overseas jurisdictions allow the sale of ‘edibles’—foods such as chocolate and cookies that contain an extract of cannabis—through their medicinal cannabis schemes. A number of concerns were raised in submissions regarding such products. One submission argued that edible products should be strictly controlled on the basis that they can cause bad publicity for a medicinal cannabis scheme.¹²⁶ Others observed that edible products present a risk to children¹²⁷ and to patients, who are less aware of the dose they are receiving.¹²⁸ The Commission agrees and does not recommend that they be included at the outset of the scheme.

7.87 If dried cannabis is not supplied under the scheme, this precludes patients from ‘vapourising’ cannabis, as explained above. The Commission heard anecdotal reports that inhalation is a better mode of delivery for people using cannabis to treat pain¹²⁹ and that its onset is quicker.¹³⁰ So that the inhalation route can be among those available for some categories of patient, the Secretary of the Department of Health and Human Services should evaluate the advantages and disadvantages of vaporisable concentrates, like those used in e-cigarettes, as a means of delivery of medicinal cannabis.¹³¹

7.88 The government should ensure, through the licensee selection process and selecting products for approval, that the range of available products spans a range of administration routes and pharmacological properties.

Strains

7.89 The cannabis plant comes in an extensive number of strains.¹³² These strains, which represent particular subtypes of cannabis, can be differentiated using a number of characteristics, including the dominant species (sativa or indica), the cannabinoid content (THC, CBD and others) and the terpene profile.

118 Submissions 1, 11, 12, 16, 18, 22, 24, 29, 31, 37, 45, 49, 59, 74, 80, 91, 95; Consultations 4, 13.

119 Submissions 1, 11, 12, 29, 37, 49, 74, 91, 95; Consultation 13.

120 Submissions 1, 16, 29, 37, 45, 74, 84, 91, 95.

121 Submissions 29, 45, 74; Consultation 13.

122 Submissions 12, 29, 74, 95.

123 Submissions 29, 54, 60. The submission on behalf of the cannabis community of Victoria notes the distinction between ‘cold’ extracts and converted extracts, and between those made with polar and nonpolar solvents: Submission 95.

124 Submission 29.

125 Submissions 91, 95; Consultation 5.

126 Submission 55.

127 Submissions 27, 49.

128 Submission 22. In medical terms, it is difficult for patients to titrate dosing, increasing the risk of under- or over-dosing: Ryan Vandrey et al, ‘Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products’ (2015) 313 *Journal of the American Medical Association* 2491.

129 Consultation 8.

130 Submission 95.

131 Vaporisable oils are made available by the two medicinal cannabis suppliers in Minnesota, Leafline Labs LLC (see: <<http://www.leaflinelabs.com/our-medicine>>) and Minnesota Medical Solutions LLC (see: <<http://www.minnesotamedicalsolutions.com/for-patients>>).

132 Submission 59.

- 7.90 In some overseas jurisdictions, medicinal cannabis producers market many ranges of strains to patients, under colourful and distinctive strain names not dissimilar to the branding for alcohol and food.¹³³
- 7.91 A submission made on behalf of the cannabis community of Victoria asserted that it:
does not support the idea of limiting forms of medicinal cannabis under the operation of a proposed medicinal cannabis scheme for Victoria. This submission has promoted the unique applications and circumstances in which various forms of cannabinoid medicines serve particular patient ailments and needs. A patient's ability to access cannabis medicine is a key requirement of any proposed scheme. That implies that the medicine must be appropriate and in the form appropriate for the patient.¹³⁴
- 7.92 Professor Laurence Mather has also drawn attention to the complex nature of cannabis products:
It is well known that medicinal preparations made from the cannabis plant typically contain several hundreds of known chemical substances, and many of these demonstrate activity in relevant pharmacological models. Moreover, these substances occur in varying concentrations in different strains of cannabis plants, with additional variations introduced by conditions of plant growing, harvesting, storage and processing. Thus 'cannabis' cannot be regarded as a particular drug and therein lies an issue for regulatory bodies and for intellectual property acquisition by pharmaceutical companies.¹³⁵
- 7.93 Medicinal cannabis users often differentiate between strains of cannabis based on the type of cannabis from which they are derived ('sativa dominant', 'indica dominant' or 'hybrid'). The species is perceived to affect the nature of the psychoactive effects which the user experiences. The indica strain is considered, for example, to provide pain relief without the 'high'. However, the reason for the perceived differences between sativa and indica varieties of cannabis is as yet inadequately understood, and complicated to assess due to the number of potential compounds involved. Cannabinoid and terpene content can vary as much within each category as between them.¹³⁶ Increasingly, in the United States the distinctions between different strains are complicated by commercial competition in the marketplace.
- 7.94 Notwithstanding this, producers respond to and influence consumer demand by providing a number of strains in all three categories, even where extracts are supplied, allowing patients to try a range of strains to determine which best addresses their symptoms. At the start of its medicinal cannabis scheme, the Netherlands Office of Medicinal Cannabis made available only sativa strains of cannabis; later, in response to patient demand, it introduced an indica strain (marketed as 'Bedica').¹³⁷
- 7.95 The Commission agrees that the approval system put in place should allow for producers to cultivate and market a range of strains. There are many compounds in the cannabis plant, and the quantities of each vary from strain to strain. However, while the level of strain variation seen in countries such as Canada and the United States caters well to patient demand, in that it caters to a range of preferences and allows them to look for a strain that 'works well for them',¹³⁸ it is difficult to incorporate this level of variation

133 Canadian licensed producer Tweed Inc, for example, sells strains under brand names including 'Bogart', 'Mayberry' and 'Strangelove'. Products vary in price per gram, and for each product, patients can view a diagram showing the terpene balance of the plant (referred to as its 'terpography'), and view its percentage of THC and CBD. It also sells blends of strains, designed to achieve specific THC and CBD levels: Tweed Inc, 'Available Strains' <<http://www.tweed.com/collections/available>>.

134 Submission 95.

135 Laurence Mather, Submission No 17 to Senate Legal and Constitutional Affairs Committee, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 9 March 2015, 2.

136 A Hazekamp and J T Fishedick, 'Cannabis—From Cultivar to Chemovar' (2011) 4 *Drug Testing and Analysis* 660. The authors analysed the cannabinoid and terpene 'fingerprint' of a number of cannabis strains, finding similar profiles across the *sativa/indica* divide.

137 Consultation 28.

138 In relation to the Dutch medicinal cannabis market, Hazekamp and Fishedick observe: 'An important reason for patients to keep purchasing their materials from illicit markets is the fact that, by trial and error, they have found a strain that works optimally for treatment of their specific symptoms. With the limited choice of Cannabis varieties currently available from official sources, it is hard to deny the value of such choice.' A Hazekamp and J T Fishedick, 'Cannabis—From Cultivar to Chemovar' (2011) 4 *Drug Testing and Analysis* 660.

under the distribution model required by the *Single Convention on Narcotic Drugs 1961*. That is, where the government is the sole purchaser of cannabis products, there is no interface between the patient and the manufacturer, limiting the extent to which the patient can communicate with them about their needs.¹³⁹ The Victorian Government will need to specify, in issuing manufacturing licences, which products it wishes to procure. Further, were an unlimited number of strains provided, doctors would be incapable of selecting the strain that is most therapeutically appropriate for patients - this could only be determined through a process where the patient had the freedom to select their own product. Therefore the Commission considers that only a modest number of strains should be made available under the Victorian scheme, described by neutral terminology.¹⁴⁰

Cannabinoid content

- 7.96 Cannabis is known to contain between 80 and 100 cannabinoids. The medicinal effects of these are only slowly coming to be understood, with some hypothesising that the effect of certain cannabinoids is greater in combination than in isolation (referred to as the 'entourage effect').¹⁴¹ It will be some time before the precise mechanism is known for many of the apparent benefits observed by patients using the plant form of cannabis or cannabis extracts.
- 7.97 Nonetheless, it is apparent that variation in cannabinoid levels between different cannabis products results in differing patient outcomes. The Victorian scheme should therefore allow for cannabis products to be supplied that vary in cannabinoid content. Under the Minnesota medical cannabis scheme, by way of example, manufacturers supply products with three or four different THC/CBD concentrations.¹⁴² Similarly, in the Netherlands, Bedrocan supplies five strains of cannabis, each with a specified level of THC and CBD.¹⁴³ The Commission notes that the submission on behalf of the cannabis community of Victoria opposed this model, stating that '[c]annabis medicine cannot be approached in this way. It must be specifically tailored for and to, a patient's individualized needs'.¹⁴⁴
- 7.98 Some people called for products high in CBD and low in THC to be made available on the basis of their efficacy for certain conditions such as epilepsy.¹⁴⁵ It was noted in several submissions too that products with very little THC would have a minimal or non-existent psychoactive effect, and would therefore be of limited interest for recreational users.¹⁴⁶ The Commission agrees with this perspective. In addition, the lack of psychoactive effects means high-CBD products would have a better safety profile than high-THC products.¹⁴⁷ As a result, the government may consider approving products high in CBD more readily than those with a high level of THC.
- 7.99 Others called for products containing a balanced ratio of THC and CBD to be made available.¹⁴⁸ Professor David Penington submitted that Victoria should develop a product with equivalent levels of THC and CBD, drawing on evidence showing that CBD

139 It should be acknowledged that the scheme operating in Israel uses a state-aligned entity to distribute cannabis through pharmacies, similarly to the model proposed below, and does enable patients to access a variety of cannabis strains. See Tikun Olam, *Our Strains* <<http://www.tikun-olam.info/our-Strains>>. However, in Israel the doctor merely authorises a patient's use of cannabis, and does not determine the product they may be supplied or the dose.

140 New York intends to make available non-smokable cannabis in a limited number of approved product lines, each of which must be sold under a 'distinct name which has been approved by the department, consisting of only letters and/or numbers', which must not 'be coined or fanciful' or 'include any "street", slang or other name', to differentiate it from other states where it is marketed with evocative names: 8 NY Comp Codes R & Regs § 1004.11(c)(6).

141 See Ethan Russo, 'Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects' (2011) 163 *British Journal of Pharmacology* 1344. Both cannabinoids and terpenes are posited as contributing to the overall effects of cannabis products.

142 Leafline Labs supplies three 'strengths': Tangerine (THC > CBD), Heather (THC = CBD) and Cobalt (THC < CBD). Each strength is available in a range of formats, including capsules, syrups/suspensions, oils for vaporisation, tinctures and sublingual sprays. Leafline Labs, *Our Medicine*, <<http://leafline.com/our-medicine/>>. Minnesota Medical Solutions' range was not published at the time of writing.

143 Each of Bedrocan's five strains has a specified approximate THC (and in some cases CBD) concentration, which can be accessed online. The strains are: Bedrocan (THC 22%, CBD <1%), Bedrobinol (THC 13.5%, CBD <1%), Bediol (THC 6.5%, CBD 8%), Bedica (THC 14%, CBD <1%) and Bedrolite (THC 0.4%, CBD 9%).

144 Submission 95.

145 Submission 50; Consultation 8.

146 Submissions 46, 50.

147 See Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (September 2013).

148 Submissions 22, 59.

‘counteracts the negative effects of the potent and psychotogenic THC on the brain’, reducing or eliminating its tendency to induce psychosis.¹⁴⁹ Others also drew attention to the antipsychotic and neuroprotective properties of CBD.¹⁵⁰

- 7.100 Some submissions argued for products containing high levels of tetrahydrocannabinolic acid (THCA) to be made available under a Victorian scheme.¹⁵¹ THCA is the precursor chemical to THC, and is not believed to be psychoactive¹⁵² nor to be metabolised to THC in the body.¹⁵³ The cannabis plant contains predominantly THCA, which is progressively converted to THC through the drying process, and can be converted further by heating. It has been asserted that THCA is an effective treatment for the symptoms of epilepsy,¹⁵⁴ diabetes¹⁵⁵ and autism.¹⁵⁶ However, the research on THCA, as distinct from THC, is at an early stage. Studies have been carried out on animals¹⁵⁷ and in cultures,¹⁵⁸ but rigorous human studies of the isolated cannabinoid are yet to be conducted.¹⁵⁹ Although the accounts provided to the Commission regarding results achieved with THCA tinctures have been strongly expressed,¹⁶⁰ the lack of research on this compound means that the Commission cannot recommend that THCA extracts be made available outside trials at this stage.
- 7.101 The Commission considers that the Victorian medicinal cannabis scheme should be able to provide cannabis products with varying quantities of the two best-understood cannabinoids: THC and CBD.¹⁶¹ At this stage, there is insufficient evidence to warrant the provision of products that are differentiated by other cannabinoids, and medical practitioners would lack the ability to select an appropriate product. As science develops and production methods improve, the Secretary of the Department of Health and Human Services may decide to approve further products.
- 7.102 The Secretary could ensure that a variety of cannabinoid compositions are available under the scheme through the competitive selection of licensees. The Secretary could also build incentives into the contract for the development of products, and allow licensees to cultivate cannabis for experimental purposes separately to their medical allowance. A mechanism for obtaining expert advice should also be incorporated.

149 Submission 24.

150 Consultation 23; Submission 22.

151 Submissions 29, 71.

152 E M Rock et al, ‘Tetrahydrocannabinolic Acid Reduces Nausea-Induced Conditioned Gaping in Rats and Vomiting in *Suncus murinus*’ (2013) 170 *British Journal of Pharmacology* 641, 642.

153 Julia Jung et al, ‘Studies on the Metabolism of the 9-Tetrahydrocannabinol Precursor 9-Tetrahydrocannabinolic Acid A (9-THCA-A) in Rat Using LC-MS/MS, LC-QTOF MS and GC-MS Techniques’ (2009) 44 *Journal of Mass Spectrometry* 1423.

154 Submissions 29, 71.

155 Submission 71.

156 Submission 29.

157 E M Rock et al, ‘Tetrahydrocannabinolic Acid Reduces Nausea-Induced Conditioned Gaping in Rats and Vomiting in *Suncus murinus*’ (2013) 170 *British Journal of Pharmacology* 641; Kazuhito Watanabe et al, ‘Marijuana Extracts Possess the Effects Like the Endocrine Disrupting Chemicals’ (2005) 206 *Toxicology* 471.

158 R Moldzio et al, ‘Effects of Cannabinoids (9)-tetrahydrocannabinol, (9)-Tetrahydrocannabinolic Acid and Cannabidiol in MPP+ Affected Murine Mesencephalic Cultures’ (2012) 19 *Phytomedicine* 819; Kitty C M Verhoeckx et al, ‘Unheated Cannabis Sativa Extracts and its Major Compound THC-Acid Have Potential Immuno-Modulating Properties Not Mediated By CB1 And CB2 Receptor Coupled Pathways’ (2006) 6 *International Immunopharmacology* 656.

159 No such studies were able to be located on PubMed or the ClinicalTrials.gov portal. No published studies were drawn to the Commission’s attention in submissions (the submission on behalf of the cannabis community of Victoria referred to a number of studies involving THCA but none of these involved trials in humans: Submission 95).

160 Submissions 29, 51, 71, 95. The submission on behalf of the cannabis community of Victoria stated that ‘[t]here are many children with pediatric forms of epilepsy currently taking THC based cannabis medicine in Australia, with great success’: Submission 95. Mullaways Medical Cannabis Pty Ltd did, however, report the results of a patient survey, in which patients reported results achieved with a tincture reported to be high in THCA: Submission 29.

161 A product range similar to that on offer in Minnesota might include products with low THC, medium THC, high THC and predominantly CBD.

- 7.103 It would also be possible for rules to be made in legislation or regulations, stipulating the maximum concentration of THC, the minimum concentration of CBD or the minimum THC:CBD ratio that Victorian medicinal cannabis products would be permitted to contain. This would enable the Secretary to ensure that highly potent forms of cannabis are not available,¹⁶² and that protective levels of CBD are included. However, the Commission does not consider that the government should adopt this approach. As stated elsewhere, there is little scientific research on the 'safe' levels of THC and CBD, so it would not be possible at this point to set out limits of this kind. As research develops, the government should be in a position to respond flexibly, and regulated concentration limits would present an obstacle to this. The Secretary could address safety concerns by maintaining control over the products approved.

Whole-plant medicines versus isolated cannabinoids

- 7.104 Several submissions called for only 'whole plant' or 'natural' cannabis to be provided, and for 'pharmaceutical' cannabis, or forms of cannabis which isolate one cannabinoid or a few cannabinoids to be avoided.¹⁶³ Others submitted that cannabinoids need to be extracted and studied in order for cannabis to be studied.¹⁶⁴
- 7.105 While not containing raw plant material, nonsmokable products made available under a Victorian medicinal cannabis scheme would be in the nature of 'whole plant extracts', in that they would contain a range of cannabinoids and other substances, not isolated or synthetic cannabinoids. At the same time, though, they would be subject to strict controls regarding cultivation and manufacture, as set out above. This is consistent with their regulation as a herbal product.¹⁶⁵

Recommendation

- 37** Medicinal cannabis products supplied under any Victorian scheme should:
- (a) not include products that can be smoked
 - (b) include a variety of delivery systems, such as tinctures, oils, capsules, sprays and vapourisable liquids
 - (c) provide for variation in cannabinoid content
 - (d) be kept under review in view of developments in technology and medical knowledge about the medicinal use of cannabis and specific cannabinoids.

162 New, highly concentrated extracts of cannabis known as 'wax' and 'shatter', made from cannabis using hydrocarbon-based extraction techniques and taken by inhalation, have raised law enforcement concerns in other jurisdiction and may present health risks: Consultation 25. New Canadian regulations on cannabis oil have set an upper limit on the amount of THC: Health Canada, *Section 56 Class Exemption for Licensed Producers Under the Marihuana for Medical Purposes Regulations to Conduct Activities with Cannabis* (8 July 2015) <<http://www.hc-sc.gc.ca>>.

163 Submissions 2, 6, 10, 30, 68, 69, 80, 93, 95; Consultations 5, 13. It is important to note that 'whole plant' and 'pharmaceutical' cannabis preparations are not mutually exclusive. For example, Sativex, produced by GW Pharmaceuticals, is a botanical extract of the cannabis plant. The plant matter is heated, then the cannabinoids are extracted using liquid carbon dioxide. The finished product achieves a 1:1 ratio of THC and CBD by blending together extracts from plants selectively bred to express high concentrations of each cannabinoid. Importantly, neither THC nor CBD has been isolated from the plant to make the finished product, which contains a range of other compounds found in the cannabis plant (approximately 7%): Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols* (September 2013) 12–13.

164 Submissions 26, 60.

165 See [7.23] above. It should be noted, though, that when extracts are prepared, the cannabis used to produce them is commonly 'decarboxylated' first to convert the acids (THCA, CBDA) into their corresponding form (THC, CBD). This heating causes large amounts of terpenes to be released as vapours, decreasing the terpene content of the finished extract: Luigi Romano and Arno Hazekamp, 'Cannabis Oil: Chemical Evaluation of an Upcoming Cannabis-Based Medicine' (2013) 7 *Cannabinoids* 1.

Research and evaluation

198 Introduction

199 Enabling research and drug development

202 Knowledge collection and information provision

204 Responsiveness to change

205 Scheme evaluation

8. Research and evaluation

Introduction

- 8.1 Victoria's medicinal cannabis scheme should ensure that it fosters, and responds to, clinical knowledge about cannabis as a medicine. This regulatory objective, recommended in Chapter 1, is designed to ensure that any Victorian scheme evolves in response to clinical developments and changes in the medicinal cannabis industry.
- 8.2 Research into cannabinoids has been described as 'one of the fastest moving frontiers in pharmacology'.¹ Research using cannabis is taking place around the world, in animal models, cell cultures and humans, with new cannabinoids and uses for them being discovered and evaluated.
- 8.3 In spite of this, as indicated in Chapter 2, there are limits on the research that has been conducted in Australia and other countries, with researchers attributing this not to a lack of scientific interest but to regulatory obstacles:
- Over the past decade there has been immense international growth in this area of research as the significance of the endocannabinoid system in human health and disease becomes increasingly apparent. Despite this, we conduct our research in a tight regulatory environment that makes sourcing, holding and administering cannabinoids extremely difficult and expensive.²
- 8.4 Such obstacles to research activity give rise to a dilemma: without the research basis, restrictions on cannabis production and administration are currently in place; because such restrictions persist, the research cannot take place. Some obstacles are not within the power of the Victorian Government to address—for example, access to cannabinoids or cannabis through importation, and approval of clinical trials, are the responsibility of the Commonwealth. Nonetheless, a Victorian scheme should seek, so far as is possible, to break down the existing constraints on research and allow inquiry and innovation in this area to flourish.
- 8.5 To achieve this regulatory objective, so far as is possible by way of changes to Victorian law, a number of recommendations are made in this chapter to promote research into medicinal cannabis. They are designed to enable Victorian medicinal cannabis products to be used in clinical research, and to ensure that decision making about patient eligibility and use of medicinal cannabis would be informed by a developing evidence base. It also makes recommendations regarding how the scheme could be responsive to scientific and technological change, through review and evaluation.

1 David Allsop et al, Submission No 52 to Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 3.

2 Ibid.

Enabling research and drug development

- 8.6 Research and development of medicinal cannabis should be a central consideration in the design of a Victorian medicinal cannabis scheme. Patient interests are much better served if research and product development continues and, indeed, is encouraged.
- 8.7 Developing new cannabinoid-based drugs and running the necessary trials to have them approved is a time-consuming and resource-intensive exercise.³ In addition, if left to the market, it relies on there being companies with a sufficient interest in the development of products for particular indications to fund research. Much is made of the success of GW Pharmaceuticals in the United Kingdom, and their revolutionary development of cannabinoids at the pharmaceutical grade.⁴ However, GW Pharmaceuticals could only have developed their refined cultivation techniques, novel extraction systems and delivery systems (over which they now hold an extensive patent portfolio) in an environment in which research and experimentation with the cannabis plant were allowed and enabled.
- 8.8 Australian researchers should have the same opportunity to explore new products and to test their potential, and the Victorian scheme should set out to foster technological innovation as the first step on this path, but acknowledging that this can and will occur at the same time as unrefined, unevaluated products are being supplied. Andrew Katelaris made this point, calling for the scheme to accommodate both 'larger scale' growing enterprises, supplying patients with products tested for potency and quality, and companies producing pharmaceutical preparations, such as GW Pharmaceuticals.⁵
- 8.9 By contrast to jurisdictions with medicinal cannabis schemes, however, the United Kingdom does not allow treatment with medicinal cannabis other than Sativex and like products. There is a risk that, by allowing access to medicinal cannabis for certain groups of patient before further research takes place, the scheme could put a brake on research and drug development for those patients,⁶ because there is little incentive for patients to sign up for a clinical trial if they can already access a satisfactory product.⁷ In the Commission's view, the best way of controlling this risk is to maintain a sharp distinction between the products accessible by eligible patients under the Victorian scheme (quality controlled but variable and untested) and products approved or intended to be approved by the TGA (standardised, characterised and evaluated).
- 8.10 A range of government actions could be taken to facilitate and enable research into cannabinoids and their application. Some of these, such as funding for clinical trials, participating in research, and offering research and development grants, involve non-legislative action, beyond the scope of the Commission's reference. Likewise, other actions which would enable trials to be conducted more readily, such as the rescheduling of cannabis or a subset thereof, amending the clinical trial approval process, or relaxing restrictions on the importation of cannabinoids, are responsibilities of the Commonwealth that Victoria has no power to control. Besides these, though, there are a number of legislative reforms available to Victoria which would enable and facilitate research into cannabinoids and development of pharmaceutical-grade cannabinoid medications, such as:

3 Cancer Council Australia and Clinical Oncology Society of Australia, *Position Statement—Medical Use of Cannabis* (21 May 2015) <<http://www.cosa.org>>, 2.

4 Ethan Russo, 'The Solution to the Medicinal Cannabis Problem' in Michael Schatman, *Ethical Issues in Chronic Pain Management* (Informa, 2007) 165.

5 Submission 30. See Appendix B for list of submissions.

6 'The flip side of those who passionately shout for the "legalisation of cannabis" is that their call may inadvertently hamper the medical development of cannabinoids, which is a shame': Wai Liu, 'Why Anti-Cancer Properties in Cannabis Must be Investigated', *The Conversation* (online), 26 June 2015 <<http://theconversation.com/why-anti-cancer-properties-in-cannabis-must-be-investigated-42653>>

7 Consultation 32. See Appendix C for list of consultations.

- providing for licensed cultivators to supply cannabis to researchers and manufacturers licensed by the TGA, and permitting licensed cultivators to cultivate cannabis for experimental purposes⁸
- ensuring that medical practitioners wishing to prescribe experimental cannabinoid products within a clinical trial can access treatment permits without undue difficulty.

8.11 Importantly, by ensuring that the Victorian scheme is limited to the manufacture and distribution of quality-controlled non-pharmaceutical extracts, which are distinct from any pharmaceutical-grade products available, the standards that apply to the development and approval of pharmaceutical-grade products would remain within the control of the Therapeutic Goods Administration.

Access to cannabis by researchers

- 8.12 The Commission understands that a key constraint on cannabinoid research in Australia has been limited access to cannabinoid products with which to conduct research.⁹ The argument to relax these restrictions is particularly compelling in light of the number of non-psychoactive cannabinoids presently generating research interest.¹⁰
- 8.13 A Victorian medicinal cannabis scheme should facilitate the development of new cannabis strains and the transfer of these to research institutes and pharmaceutical companies for the purpose of research and development. Clearly, research into cannabinoids cannot take place without a source of cannabinoids, such as raw cannabis.
- 8.14 Enabling pharmaceutical companies to access cannabis grown under a Victorian scheme would require a simple addition to the cultivator licensing scheme recommended in Chapter 6. To limit the possibility of diversion of raw cannabis, the Commission has recommended that licensed cultivators be required, through conditions on their licence, to deliver all the cannabis they produce to a manufacturer licensed under the Victorian scheme (with any remaining cannabis to be destroyed) and at all times be party to a contract with a manufacturer licensed under the Victorian scheme.
- 8.15 To enable research to take place, cultivators should also be permitted to deliver cannabis to TGA-licensed manufacturers, universities and research institutes. To control diversion, the scheme could require research entities to apply for and obtain licences analogous to the 'processing licences' available under the alkaloid poppy scheme.¹¹
- 8.16 It may be the case that researchers wish to cultivate cannabis themselves, to exercise greater control over the breeding and cultivation process. The Victorian Government could consider issuing researchers experimental licences to cultivate outside the scheme for supply to patients. These licences could equally be available to cultivators already licensed to produce, to enable them to test new strains and assess the impact of growing conditions.¹² Quantities of cannabis cultivated under an experimental licence would be the subject of separate reporting to the International Narcotics Control Board.

8 An example definition of 'experimental purposes' was included in cl 20(2) of the Regulator of Medicinal Cannabis Bill 2014 (Cth). It included: '(a) developing and testing varieties of cannabis for medicinal use; (b) improving methods of cultivating cannabis for medicinal use; (c) developing and testing cannabis products for medicinal use; (d) evaluating the efficacy or safety of cannabis products for medicinal use; (e) improving methods of using or administering cannabis products for medicinal purposes; (f) performing tests, trials and other experiments for the purposes of making or supporting an application under [the Regulator of Medicinal Cannabis Bill 2014] or the *Therapeutic Goods Act 1987* [sic], or considering whether to make such an application.'

9 David Allsop et al, Submission No 52 to Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014*, 3.

10 Ibid 6.

11 Governed by the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) Part IVB Div 3. Processing licences for alkaloid poppies are issued to the companies that are involved in converting the poppy straw into pharmaceutical opiates. These entities must hold a current manufacturing licence issued by the TGA (or a current export licence, which would enable them to export poppy straw to a manufacturer located overseas): s 69PC(8). That is, the Victorian 'processing' licence is held in parallel to a licence allowing them to refine or export the poppy straw.

12 These licences would be analogous to those available under s 69O(2), which permit a licence to cultivate alkaloid poppies to be granted for research purposes not intended for therapeutic use. The limitation regarding therapeutic use would not, however, be appropriate for the creation of experimental drugs used in human or animal trials: see definition of 'therapeutic use' in s 4 of the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

Recommendation

- 38** Any Victorian medicinal cannabis scheme should foster research by providing for:
- (a) licensed cultivators to supply cannabis to appropriately licensed manufacturers capable of producing or trialling pharmaceutical-grade cannabis-derived products
 - (b) researchers and those holding commercial cultivation licences to obtain experimental cultivation licences.

Treatment permits and clinical trials

- 8.17 Many medical practitioners urged that medicinal cannabis be made available through a clinical trial framework. The Commission agrees that clinical trials can and should continue after any Victorian scheme is introduced.
- 8.18 At present, a medical practitioner who wishes to administer, supply or prescribe cannabis to a patient, including under the auspices of a clinical trial, requires a permit to prescribe cannabis to that patient, due to the status of cannabis as a Schedule 9 poison.¹³ Any such permit, if granted, would be specific to the patient under treatment, in that it would authorise treatment of that person alone. In practice, however, Schedule 9 poison treatment permits are not sought in Victoria and there are no guidelines setting out when they may be issued.
- 8.19 Under any Victorian scheme there would be a need to ensure that people can be treated with medicinal cannabis products within a clinical trial, even if they do not fall within the eligibility criteria and/or the product has not yet been approved. For this reason, the scheme should provide for a type of experimental treatment permit, which a specialist can obtain for any person. Such a permit could also be used to facilitate the conduct of so-called 'n of 1' trials, recommended to the Commission as a means of testing the utility of cannabis in treating particular patients or conditions.¹⁴ The permit provisions could specifically apply to medicinal cannabis, or be incorporated into an existing treatment permit.¹⁵
- 8.20 At present, treatment permits for Schedule 9 poisons are required at all times, with no exceptions. This contrasts with Schedule 8 poisons, where permits are only required if the patient is drug dependent or the treatment lasts for more than eight weeks.¹⁶ The government may wish to consider simplifying the process for obtaining experimental treatment permits for medicinal cannabis, or limiting them to particular situations only.¹⁷

13 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 33A. Unlike permits to administer, supply or prescribe Schedule 8 poisons, permits are always required for Schedule 9 poisons, not just in certain circumstances. Cf s 34 stating that Schedule 8 poison permits are only required where the person is drug-dependent or where the duration of use exceeds eight weeks, and ss 34D–34F setting out a number of exemptions.

14 N-of-1 or n=1 clinical trials are 'empirical tests using a within-patient randomised, double-blind, cross-over comparison of drug and placebo (or another drug), principally to study individual patients' responses where there is uncertainty about the effectiveness of a medication for a chronic condition': Jane Nikles et al, 'Stakeholders' Views on the Routine Use of N-of-1 Trials to Improve Clinical Care and to Make Resource Allocation Decisions for Drug Use' (2010) 34 *Australian Health Review* 131, 131. They involve a practitioner administering alternating placebo (or other drug) and active (drug under investigation) treatment to a patient and measuring their response, to test whether the drug induces a different response to the placebo/alternative. The alternating placebo/active doses must be produced by a third party, so that both the practitioner and the patient are unaware of what is being administered (that is, the trial is 'double blind'): Consultation 32.

15 Medicinal cannabis may no longer be treated as a Schedule 9 poison, depending on the model adopted.

16 *Drugs, Poisons and Controlled Substances Act 1981* (Vic) s 34. A range of other exceptions to the permit requirement also apply: ss 34D–34F.

17 For example, the *Drugs, Poisons and Controlled Substances Amendment (Clinical Trials) Bill 2014* (Vic) would have simplified the process for obtaining Schedule 9 treatment permits, by enabling medical practitioners to seek a permit to treat a group of patients, not just a single individual (as is the case presently). The Cancer Council Victoria supported incorporating such a measure into a medicinal cannabis system: Submission 57.

Recommendation

- 39** The Secretary of the Department of Health and Human Services should have the power to issue medical practitioners with permits to treat patients other than those who are eligible under the scheme with medicinal cannabis for trials and research.

8.21 An implementation issue for consideration by the Victorian Government is when permits to treat patients with medicinal cannabis within a clinical trial should be granted. Clinical trials in Australia are generally required to be conducted consistently with national guidelines,¹⁸ and are permitted to be conducted using unapproved goods if ethics committee approval is obtained.¹⁹ Depending on the scope of any Commonwealth action giving Victoria authority over the regulation of medicinal cannabis products, Victoria could need to establish a procedure for the approval and supervision of clinical trials using medicinal cannabis products.²⁰

Knowledge collection and information provision

- 8.22 The government should ensure that any Victorian medicinal cannabis scheme supports the development of knowledge and its dissemination to medical practitioners and researchers.²¹
- 8.23 The scheme could achieve this in a number of ways. Education of medical practitioners would be essential, particularly as expertise is presently very limited. An important component of education is that it be continually updated and improved, so the scheme should also facilitate data collection and the distribution of results to practitioners.²²
- 8.24 In addition, as discussed in Chapter 3, medical practitioners enabling a patient to be treated with medicinal cannabis would first be required to seek a permit from the Secretary of the Department of Health and Human Services. The application for a permit would be in a prescribed form,²³ through which the Secretary would have the ability to determine what information is collected about patients within the scheme. The collection and analysis of this information would provide practitioners and researchers with a useful source of data regarding those currently treated under the scheme.

Clinical registries

- 8.25 One way in which the data could be collected and analysed is through the establishment by practitioners of a clinical registry. These registries are designed to allow practitioners in a field of medicine to compile data from their patients in order to measure the results of intervention.²⁴
- 8.26 In the field of chronic pain, for example, Australian practitioners have established the electronic Persistent Pain Outcomes Collaboration (ePPOC) database at the University of Wollongong. Pain practitioners and services submit data to the ePPOC about their patients' experience of pain and the manner in which that pain was treated. The data are aggregated by the ePPOC and made publicly available.²⁵

18 Such as, National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (2007).

19 *Therapeutic Goods Regulations 1990* (Cth) sch 5A, item 3.

20 For example, if only Victorian-approved medicinal cannabis products are able to be supplied in Victoria without attracting the provisions of the *Therapeutic Goods Act 1989* (Cth), any other products would need to comply with TGA requirements for clinical trials.

21 Submissions 11, 22, 69, 76, 91, 99.

22 The education of medical practitioners is discussed in Chapter 3. See [3.226]–[3.239] above.

23 Cf *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) Sch 2.

24 Several respondents to the Cancer Council Victoria's clinician survey recommended that a program be established to monitor patient use, responses and adverse effects: Submission 99.

25 Enterprise One Pain Management Service, *Patient Outcomes in Pain Management* (31 December 2014).

- 8.27 A registry of this kind could allow practitioners to share aggregated information about how they had resolved problems around the authorisation and withdrawal of medicinal cannabis, which would inform the development of common standards. For example, Associate Professor Carolyn Arnold at Alfred Health suggested that a ‘medical cannabis chronic pain treatment’ registry should include data about:
- if cannabis use is ceased, the reason and any adverse effects observed
 - details of the specific medical cannabis form and dose used.²⁶
- 8.28 As an alternative to condition-specific registries, Victorian health practitioners could establish a general clinical registry dedicated to the general monitoring of all patients who have been authorised to use medicinal cannabis. For example, the Québec Cannabis Registry is intended to be a database of all patients authorised to use medicinal cannabis in Québec, to enable clinical research into cannabis. This allows medical practitioners to comply with their professional obligations, as the position of the Collège des Médecins du Québec is that the prescription of cannabis is only ethically authorised ‘within a research framework’.²⁷ Accordingly, the Registry will seek to:
- develop and answer future questions on the medical use of cannabis, such as who uses it, for what reasons, through which methods, and at what dose. ... [The Registry] will be used to compile and store clinical data collected directly from patients who use medical marijuana. The data will be gathered from sites and clinics across Quebec, and each participant will provide data for four years after recruitment. Any licensed doctor practising in the province wishing to authorise cannabis for their adult patients can enrol participants in the registry.²⁸
- 8.29 The patient information collected through the issuing of permits, or in creating and maintaining a clinical registry, could also be used to invite patients taking part in the scheme to be involved in clinical trials of pharmaceutical-grade cannabinoids.

Recommendation

- 40** The Secretary of the Department of Health and Human Services should collaborate with the clinical research community in developing methods and protocols for collecting and sharing information about the incidence and outcomes of treatment with medicinal cannabis products under any Victorian scheme.

Dissemination of information

- 8.30 Subject to privacy requirements, data collected by the government could be aggregated and disseminated to improve knowledge and understanding among practitioners. Data could also help support the production of guidelines and information documents to be circulated to practitioners, particularly where adverse effects are observed. The data would also be used in any scheme evaluation, discussed below.

26 Submission 98.

27 Collège des Médecins du Québec, *Guidelines Concerning the Prescription of Dried Cannabis for Medical Purposes* (April 2014) 2.

28 Québec Cannabis Registry, ‘World First: Launch of Quebec Registry for Users of Medical Cannabis’ (Press Release, 11 May 2015, Montreal) <<https://registrecannabisquebec.com>>.

Recommendation

- 41** The Secretary of the Department of Health and Human Services should:
- (a) retain data collected on Permit applications and Authorities to Dispense Medicinal Cannabis in a way that enables statistical information about the operation of the scheme to be compiled and used for evaluation purposes, and for non-identifying information to be made available for the purpose of research into the efficacy of medicinal cannabis
 - (b) ensure that a privacy impact assessment is conducted when designing the data collection and management systems in support of the medicinal cannabis scheme, to safeguard the information privacy of patients, carers, practitioners, pharmacists and other participants in the scheme.

Responsiveness to change

- 8.31 The science and technology around the use of medicinal cannabis is a rapidly evolving field. Trials into the utility of cannabis are ongoing and commencing to deliver results which enable evaluations of efficacy to be made. Jurisdictions overseas with medicinal cannabis programs continue to develop innovative delivery systems.²⁹
- 8.32 Any Victorian scheme must therefore be sufficiently flexible to allow for legal, scientific and technical change. As Mullaways Medical Cannabis Pty Ltd observed, '[t]he legislation must allow for research... Limiting the scheme to current Australian knowledge would leave a Victorian Medicinal Cannabis Scheme stuck in the past based on outdated research.'³⁰
- 8.33 In particular, as discussed in Chapter 3, the scheme should be flexible enough to allow for new cannabis-based products to be made available to patients, and for new sets of conditions and symptoms, as new evidence emerges. In addition, changes to Australian or international law and the emergence of sources of cannabis overseas could require the Victorian scheme to respond.

Legal developments

- 8.34 There are a number of ways that laws and policies could change at the Commonwealth level or in other states, necessitating alterations to the Victorian scheme:
- medicinal cannabis schemes could be introduced in other Australian states and territories
 - 'cannabis' or a subset thereof could be moved to another Schedule in the SUSMP
 - the TGA could change its procedures to allow cannabis products to be regulated as listed (herbal) medicines.

29 See, eg, the Syqe dose-controlled medical cannabis inhaler, supplying a metered dose of vaporised cannabis <<http://www.syqemedical.com>>; Echo Pharmaceuticals' lipophilic drug delivery technology, Alitra, used to deliver a standardised dose of THC with high bioavailability, under the name Namisol <<http://www.echo-pharma.com>>; and a cannabis-based CBD-rich chewing gum <<http://www.aximbiotech.com>>.

30 Submission 29.

Alternative supply options

- 8.35 Medicinal cannabis schemes and industries in jurisdictions around the world are in a state of flux. National policies on export and import are subject to change, meaning that in the future, the products available for import may be quite different from those available today. In addition, should other Australian states or territories begin cultivating cannabis or manufacturing cannabis products, a domestic source may become available. Likewise, cannabis-based products (like Sativex or Epidiolex) may be approved for sale in Australia through conventional TGA channels.
- 8.36 A Victorian scheme should accommodate the potential supply of any such products. While any importation would require the co-operation of the Commonwealth, the scheme could allow, for example, for particular overseas-made products to be designated as approved medicinal cannabis products for the purposes of Victorian law.

Scheme evaluation

- 8.37 Research on, and the availability of, medicinal cannabis is constantly changing and will continue to do so after the commencement of the scheme. Changes could include:
- clinical trials determine whether cannabis or cannabinoids are effective in the treatment of conditions or symptoms not currently within the statutory eligibility criteria
 - new technologies for manufacturing cannabis extracts or administering them to patients are developed
 - international export opportunities emerge
 - new cannabinoids are discovered
 - new cannabis-based pharmaceuticals are approved by the TGA to be sold in Australia.
- 8.38 The scheme should therefore be established in such a way that it is subject to evaluation. The evaluation should consider how well the scheme is meeting its objectives. It should also consider the cost of the scheme and whether it is functioning in a sufficiently cost-effective way.
- 8.39 Specifically, the following matters should be taken into account in the evaluation:
- participation rates in the scheme, including for each condition
 - findings of the scheme regarding the efficacy and side effects of cannabis
 - the cost of the scheme
 - findings of clinical trials
 - the availability (if any) of cannabinoid drugs approved by the TGA and/or listed on the Pharmaceutical Benefits Scheme
 - legislative and regulatory changes (if any) at the Commonwealth level and in other States or Territories since the scheme was introduced.

Recommendation

- 42** The Minister for Health should cause an independent evaluation of the scheme to take place no later than four years from its date of commencement and should be required to report to Parliament on the findings and recommendations of the evaluation.

Conclusion

9. Conclusion

- 9.1 The Commission has been told that reform to Victoria's laws to allow people to be treated with medicinal cannabis in exceptional circumstances is both overdue and premature. It is said to be overdue by those in the community who are already using it to relieve the symptoms of a broad range of medical conditions, some of which are severely disabling and others of which are causing high levels of pain and suffering. It is said to be premature by those who caution against providing access to an otherwise illegal drug before conventional and reliable clinical evidence of its efficacy in treating specific conditions, and its side effects, is comprehensively available.
- 9.2 In this report, the Commission has favoured an evidence-based approach to determining the exceptional circumstances in which medicinal cannabis would be made available, but for compassionate reasons one that extends in limited circumstances beyond the exacting clinical standards that apply to the scheduling of prescription medicines. The recommended eligibility criteria encompass severe conditions and symptoms regarding which there are multiple examples of significant improvement after patients have begun using cannabis, and where returning to prescription medicines presents an unacceptable risk to their health and quality of life.
- 9.3 Thus, the Commission's recommendations endeavour to balance evidence of efficacy with knowledge of potential risks of side effects and abuse. The recommendations incorporate extension of compassion to take account of the suffering arising from certain medical conditions and to be responsive to the wishes of patients and their carers in respect of conditions that impact upon them in often extreme ways.
- 9.4 The Commission's recommendations give weight to research assessments of the efficacy of medicinal cannabis but accord less significance to assertions and anecdotes. They are framed on the basis of the legitimacy of the current preclusion of recreational use of cannabis and identify major deficits in the option of a grow your own scheme which bypasses medical practitioners and is substantially unregulated and unmonitored. The Commission's recommended approach looks to integrate medicinal cannabis within the pharmacopoeia available to medical practitioners. It recognises that medicinal cannabis is not a panacea; it is simply another pharmacological option with great promise in some contexts and which is the subject of strong levels of confidence in some sectors within the community. It has the potential to play a constructive role in the management of some conditions and the alleviation of pain and suffering.
- 9.5 These aspects of the Commission's recommendations are a matter of compromise. They endorse and support a system of testing medications that protects the community against foreseeable risks posed by untested preparations that have the potential to have a range of adverse consequences for patients. In addition, they make only a modest and controlled inroad upon the criminal status of using, possessing, cultivating and trafficking

in cannabis. In this regard, it is acknowledged that many cannabis users, including some who use it for medicinal purposes, will be deeply disappointed with the approach that the Commission has taken; they will continue to use cannabis covertly and illegally without the involvement of medical practitioners.

- 9.6 However, it is the Commission's view that it is important for a medicinal cannabis scheme to be significantly weighted in favour of strong evidence bases; any other approach is unlikely to secure the confidence and endorsement of the medical profession. International experience has shown that, without the support of a significant percentage of medical practitioners, any medicinal cannabis scheme will face significant hurdles as a public health measure.
- 9.7 Australia's medical practitioners are not ideologically averse to the development of new medical options or to employment of innovative measures in difficult clinical scenarios where there is a high level of suffering by their patients and those who care for them and about them. However, for the present they are divided on the question of whether medicinal cannabis is a proper alternative to orthodox prescription medications. They are reticent about the provision of any medicinal cannabis products that have not been approved by the Therapeutic Goods Administration. In addition, they have little knowledge about the therapeutic properties of medicinal cannabis in its various forms and strengths, and do not have experience in administering it or supervising its effects.
- 9.8 In order to elicit the confidence of the medical profession in a reform to the law so as to permit access to cannabis for medicinal purposes, it is prudent to adopt a graduated and conservative approach to making it legally available and to ensure that medical practitioners (and pharmacists) are assisted to provide the information necessary for patients to provide informed consent. This means that under the Commission's recommended option medicinal cannabis would not be legally available for patients with some conditions and that there would be regulatory oversight of the growing, manufacturing, authorising and dispensing of medicinal cannabis. These measures are proposed as means to provide reassurance to medical practitioners, pharmacists and the general community alike about what is a novel medico-legal step for Victoria.
- 9.9 Meanwhile, clinical evidence concerning the medical use of cannabis is growing, as are medical breakthroughs in preventing and treating many of the diseases for which prescription medicines are only part of the therapeutic answer. Experience in participating in a medicinal cannabis scheme is likely to provide an additional option for treating patients with serious conditions, to enrich the medical profession's understanding about the use and effects of medicinal cannabis, and to address the wishes of a significant cohort of patients. The Commission considers it essential that the eligibility criteria—and the scheme itself—are reviewed and modified as more and better evidence of the efficacy, potential and side effects of cannabis becomes available.
- 9.10 The legislative basis for a Victorian medicinal cannabis scheme should rest upon regulatory objectives that would improve patients' quality of life through appropriate treatment without unreasonably inflating their expectations of positive therapeutic effects or exposing them to undue risks. It needs to minimise any adverse consequences that may arise from departing from the national frameworks for controlling narcotic drugs and regulating therapeutic goods.
- 9.11 The Commission has considered the options proposed in submissions and consultations and has concluded that an approach based on the existing regulation of the cultivation of alkaloid poppies, the production of poppy straw, and the delivery of opioid replacement therapy would be most likely to achieve the regulatory objectives. This approach utilises well-trodden and familiar regulatory paths and thus does not involve the creation of a plethora of new bodies to enable regulatory oversight. It is likely to generate a consistent

availability of high quality medicinal cannabis whose properties are known. In addition, it should enable medical practitioners to titrate the strengths and monitor the effects in their patients of active constituents such as THC and CBD. This will constitute a very significant safeguard against risks and side effects from the use of cannabis for medicinal purposes.

- 9.12 The way in which the Commission has structured its proposed scheme enables Australia to satisfy its international obligations and requires only a modest set of enabling steps by the Commonwealth in a collaborative partnership with Victoria. The initiative that is recommended preserves the integrity of Australia's therapeutic regulatory framework but caters compassionately and humanely to the needs of a vulnerable group of patients whose suffering has been documented in Chapter 2 of this report.
- 9.13 The cost of establishing and operating a scheme that provides a limited number of people affordable access to a prohibited substance is likely to be significant, although levels of uptake of the scheme cannot be forecast with accuracy at this stage. Thus the scheme needs to be carefully designed and well managed to ensure that the cost is not disproportionate to its advantages and that it is efficiently run. The opportunity exists to reduce the unsatisfactory incidence of resort to illegal medicinal cannabis of uncertain quality and strength and that does not incorporate medical oversight.
- 9.14 The potential outcome of the scheme recommended by the Commission is the relief of high levels of suffering and avoidance of the pressures and stigma that currently attach to illegal procurement for therapeutic purposes of a drug principally used recreationally for its euphoriant effects. It will enable a drug with significant medicinal potential to be used in properly and safely controlled circumstances under the supervision of medical practitioners, thereby maximising its efficacy as a treatment and guarding against potentially adverse side effects.

Appendices

- 212 **Appendix A. Advisory committees**
- 214 **Appendix B. Submissions**
- 216 **Appendix C. Consultations**
- 218 **Appendix D. Tables of legislative amendments**

Appendix A. Advisory committees

Purpose

The terms of reference ask the Commission 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.

It is the Commission's usual practice to convene committees of individuals with specialist expertise to assist in identifying and exploring issues and generating ideas for reform. Participation is by invitation.

For the medicinal cannabis reference, the Commission convened two advisory committees:

- a medical advisory committee, to advise on prescribing practices that could impact upon access to medicinal cannabis
- a regulation advisory committee, to advise on the regulation of the potential manufacture and distribution of medicinal cannabis.

Membership

The individuals and organisations listed below accepted the Commission's invitation to participate on the committees.

Medical Advisory Committee

Individuals

Associate Professor Carolyn Arnold

Laureate Professor Sam Berkovic AC

Associate Professor Noel Cranswick

Dr Matthew Frei

Professor Carl Kirkpatrick

Associate Professor Brian Le

Dr Maurice Magner

Professor Paul Myles

Professor Ingrid Scheffer AO

Professor Duncan Topliss

Professor John Zalcborg OAM

Organisations

AMA Victoria

Australian Pain Society; Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists; Pain Australia

Department of Health and Human Services (Victoria)

Epilepsy Australia

MS Australia

Palliative Care Victoria

Regulation Advisory Committee

Individuals

Emeritus Professor Arie Freiberg AM

Professor Margaret Hamilton AO

Peter Hanks QC

Dr Kim Sweeny

Organisations

Department of Economic Development, Jobs, Transport and Resources (Victoria)

Department of Health and Human Services (Victoria)

Law Institute of Victoria

Office of Public Prosecutions

Office of the Chief Parliamentary Counsel

Royal Australia College of General Practitioners

The Pharmacy Guild of Australia—Victoria

Victoria Legal Aid

Victoria Police

Victorian Therapeutics Advisory Group

Meetings

The committees met separately and together on the following dates:

Meeting 1: 1 April 2015 (Medical Advisory Committee)

Meeting 2: 2 April 2015 (Regulation Advisory Committee)

Meeting 3: 6 May 2015 (both committees).

Appendix B. Submissions

1. Jayden Armstrong
2. Cheryl Wright
3. Leaf Van Amsterdam
4. Name withheld
5. Matthew Corda
6. Confidential
7. Jeni Martin
8. Dr Robert Kawaldi
9. Elizabeth
10. Heather Marie Gladman
11. JB
12. Sandy Popple
13. Cannabis Social Club Australia
14. Confidential
15. Trich, Cannabis Social Club Australia
16. Amanda Newell
17. Cannabis Social Club Australia
18. Name withheld
19. Name withheld
20. Vic Camilleri
21. Drug Policy Modelling Program
22. Scott Hulley
23. Toby Stewart
24. Emeritus Professor David Penington AC
25. MS Australia & MS Research Australia
26. Confidential
27. Family Voice Australia
28. Confidential
29. Mullaways Medical Cannabis Pty Ltd
30. Dr Andrew Katelaris
31. Name withheld
32. Confidential
33. Aaron Johnson & Kelli Russell
34. Christian Business Men Australia,
Macedon Ranges Group
35. The Australian Lawful Use of Cannabis
Alliance
36. Les McDonald, Bebuybac the Concerned
Australians
37. Cannabis Policy Project
38. AMA Victoria
39. Confidential
40. Samuel Fair
41. Alkman Management Services Pty Ltd
42. Name withheld
43. Name withheld
44. Victoria Police
45. Confidential
46. Victorian Alcohol & Drug Association
47. Name withheld
48. Name withheld
49. Shirley Humphris
50. Cassie Batten & Rhett Wallace
51. Cheri O'Connell
52. The Royal Australian College of Physicians

53. Fred Andronikos
54. Cancer Action Victoria Inc
55. Name withheld
56. Confidential
57. Cancer Council Victoria
58. ACES Group
59. Matthew Pallett
60. UTT BioPharmaceuticals Pty Ltd
61. One World Cannabis Ltd
62. Derek & Elyse Spence
63. Law Institute of Victoria
64. Robert Wisbey
65. Name withheld
66. Jan Hartwich
67. Max & Diane Lock
68. Name withheld
69. Cannabis Science Australia Pty Ltd
70. Leah Bisiani
71. Michelle Whitelaw
72. Mark Eastick
73. Ivan Schparyk
74. Marc Selan
75. Australian Nursing & Midwifery Federation
(Victorian Branch)
76. EROS The Adults Only Association
77. Aboriginal Embassy Victoria
78. Joylene Donovan
79. Confidential
80. Natalie Vassallo
81. Lyn Cleaver
82. Confidential
83. Kevin Sammon
84. Loren W
85. Iain Fredin
86. Name withheld
87. Name withheld
88. Name withheld
89. Heather Marie Gladman
90. Belinda Doonar
91. Rangi Faulder
92. Lindsay Milton
93. Rodd
94. Fred Andronikos
95. Michelle O'Dea, with the assistance of a
working group of the cannabis community
of Victoria
96. KF
97. Dr David Bearman
98. Associate Professor Carolyn Arnold
99. Cancer Council Victoria

Appendix C. Consultations

Public

The Commission invited interested members of the public to attend meetings in Melbourne and regional centres to discuss their views on the legalisation of medicinal cannabis, as listed below.

1. Melbourne (5 May 2015)
2. Geelong (8 May 2015)
3. Ballarat (18 May 2015)
4. Bendigo (19 May 2015)
5. Mildura (12 June 2015)
6. Wodonga (15 June 2015)
7. Shepparton (16 June 2015)
8. Bairnsdale (22 June 2015)
9. Morwell (23 June 2015)

Private

The Commission consulted privately about the questions raised in the issues paper with the people and organisations listed below in chronological order.

10. Department of Health and Human Services (Victoria)
11. Health Law Committee, Law Institute of Victoria
12. Emeritus Professor David Penington AC
13. Cassie Batten and Rhett Wallace
14. Participants at a public symposium on the legalisation of medicinal cannabis, organised by Fred Andronikos and other members of the community in Melbourne
15. Department of Health (Commonwealth)
16. Dr Roger McLennan FRACP, FRCP, Clinical Haematologist and Medical Oncologist
17. Glen Ludbrook, Central Highlands Community Legal Centre
18. David and Cheri O'Connell

19. Department of Economic Development, Jobs Training and Resources (Victoria)
20. Terry Roycroft, President, Medicinal Cannabis Resource Centre, Vancouver, Canada
21. Victoria Police Drug Analysis Unit
22. Professor David Castle, Professor of Psychiatry at the University of Melbourne and St Vincent's Hospital
23. Melissa Lonsdale and Matthew Fulton, Sunraysia Community Health Services
24. Ester Vanhinnisdael, Charlotte Byrne (Gateway Health) and Ray Stephens (Gateway Health)
25. Office of Medicinal Cannabis, Minnesota Department of Health
26. Colleen Garrick (Rumbalara Aboriginal Cooperative), Kaz Gurney (Goulburn Valley Community Legal Centre), Sue Spence (FamilyCare), Dr Zee Wan Wong (Goulburn Valley Health) and staff from the Goulburn Valley Hospice
27. Canadian Medical Association
28. Office of Medicinal Cannabis, Netherlands
29. Arizona Department of Health Services
30. Bedrocan BV
31. Health Canada
32. Associate Professor Noel Cranswick

Appendix D. Tables of legislative amendments

The following tables list amendments that would support the Commission’s recommended option for changes to the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*, and to the *Drugs, Poisons and Controlled Substances Regulations 2006*, to allow people to be treated with medicinal cannabis in exceptional circumstances.

- Table 1: Cultivating and manufacturing medicinal cannabis products
- Table 2: Treating medicinal cannabis as a class of poison or controlled substance
- Table 3: Deeming classes of patients to be eligible to access medicinal cannabis
- Table 4: Lawful possession of medicinal cannabis
- Table 5: Lawful supply of medicinal cannabis
- Table 6: Lawful storage of medicinal cannabis
- Table 7: Recording transactions in medicinal cannabis
- Table 8: Lawful administration of medicinal cannabis
- Table 9: Lawful destruction of medicinal cannabis
- Table 10: New offences under a Victorian medicinal cannabis scheme

Table 1: Establishing a scheme for the lawful cultivation and manufacture of medicinal cannabis products in the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*

Purpose	Explanation
Define ‘cannabis’	<p>It would be necessary to define ‘cannabis’ in order to identify the raw product that cultivators and manufacturers are licensed to turn into ‘medicinal cannabis’ products. The Commission anticipates that it is the process of cultivation, manufacturing, labelling and quality testing that turns cannabis into a product that is appropriate for medicinal consumption and is as such ‘medicinal cannabis’.</p> <p>The definition could refer to the definition of cannabis in section 70 of the Act: ‘any fresh or dried parts of a plant of the genus <i>Cannabis</i> L’.</p>

Purpose	Explanation
Define 'Commonwealth licence to manufacture'	<p>As in the poppy scheme, cannabis manufacturers would need to have a licence under the <i>Narcotic Drugs Act 1967</i> (Cth) and a definition is accordingly required.</p> <p>The definition could draw upon the definition of 'Commonwealth licence to manufacture' in s 69N of the Act: 'a licence to manufacture narcotic drugs which relates to the manufacturing of cannabis, cannabis resin, extracts or tinctures of cannabis under the <i>Narcotic Drugs Act 1967</i> of the Commonwealth'.</p>
Create a 'cannabis cultivation licence'	<p>A division could deal with 'cannabis cultivation licences', administered by the Secretary of the Department of Economic Development, Jobs, Transport and Resources. This division and associated definitions could be modelled on Division 2 of Part IVB of the Act.</p> <p>As in the poppy scheme, the activity of cultivation would have to be defined. The definition could take on the meaning it is given in s 70 of the Act: to 'sow a seed of a narcotic plant', to 'plant, grow, tend, nurture or harvest a narcotic plant' or to 'graft, divide or transplant a narcotic plant'.</p> <p>Of particular importance is the requirement, following s 69OC(7), that the holder of a cannabis cultivation licence is only permitted to conduct activities under a contract that has been registered in the 'Cannabis register'.</p>
Enable the Secretary of the Department of Economic Development, Jobs, Transport and Resources to amend or suspend cannabis cultivation licences	<p>This division would grant the Secretary of the Department of Economic Development, Jobs, Transport and Resources powers to amend, suspend or cancel cannabis cultivation licences issued under the scheme. It could be modelled on Division 4 of Part IVB of the Act.</p>
Enable the Secretary of the Department of Economic Development, Jobs, Transport and Resources to appoint inspectors to supervise the activities of cannabis cultivation licensees and the enforcement of breaches of their licences or the provisions of the Act.	<p>This division would grant the Secretary of the Department of Economic Development, Jobs, Transport and Resources powers to appoint inspectors to conduct various functions under the scheme. Inspectors would have powers similar to the powers conferred on inspectors under the poppy scheme by s 69RB of the Act.</p> <p>The Division could be modelled on Division 5 of Part IVB of the Act.</p>

Purpose	Explanation
Create a 'cannabis manufacturing licence'	<p>It would be necessary to deal with 'cannabis manufacturing licences', administered by the Secretary of the Department of Health and Human Services. This division and associated definitions could be modelled on Division 3 of Part IVB of the Act.</p> <p>'Manufacturing' could be defined with reference to the definition in s 4(1) of the Act, providing that it 'includes any process of refining, manipulating and mixing cannabis'.</p> <p>Of particular importance is to create a requirement, following s 69PC(8), that the holder of a cannabis manufacturing licence have a current Commonwealth licence to manufacture.</p>
Enable the Secretary of the Department of Health and Human Services to amend or suspend cannabis manufacturing licences	<p>This division would grant the Secretary of the Department of Health and Human Services powers to amend, suspend or cancel cannabis manufacturing licences issued under the scheme.</p> <p>The Division could be modelled on Division 4 of Part IVB of the Act.</p>
Enable the Secretary of the Department of Health and Human Services to authorise the inspection of the activities of cannabis manufacturing licensees and enforce breaches of their licences or the provisions of the Act.	<p>This division would grant the Secretary of the Department of Health and Human Services powers to authorise inspectors to conduct various functions under the scheme relating to cannabis manufacture. Inspectors would have powers similar to the powers conferred on inspectors under the poppy scheme by s 69RB of the Act.</p> <p>The Division could be modelled on Division 5 of Part IVB of the Act.</p>
Set out offences for non-compliance with various aspects of the scheme.	<p>The division would impose penalties on licensed cannabis cultivators and licensed cannabis manufacturers which failed to comply with their statutory obligations or licence conditions.</p> <p>It could be modelled on Division 6 of Part IVB of the Act.</p>
Establish a register for contracts between licensed cultivators and licensed manufacturers of cannabis.	<p>The Alkaloid Poppy Register is used to determine which contracts between licensed processors and cultivators are compliant under the scheme. Details of the contract are kept on the Register, including the parties to the contract, the location of cultivation and the period of the contract.</p> <p>It is a condition of every poppy cultivation licence that the cultivator have a contract with a processor of poppy straw that is on the Register.</p> <p>A Cannabis Register, modelled on the Alkaloid Poppy Register, could be used to monitor the existence and particulars of contractual agreements and restrict the range of contracts that are able to be acted on by licensees.</p> <p>The provisions could be modelled on Division 7 of Part IVB of the Act.</p>

Purpose	Explanation
Establish avenues for review by the Victorian Civil and Administrative Tribunal	<p>Under the poppy scheme, applicants may apply to VCAT for a review of adverse decisions of a Secretary relating to licences under the Act. A similar avenue of review should be permitted in respect of adverse decisions about cannabis cultivation licences and cannabis manufacturing licences.</p> <p>The provisions could be modelled on Division 8 of Part IVB of the Act.</p>
Create a register of medicinal cannabis products approved for sale in Victoria	<p>The Commission recommends that a new register of approved products be established, specifying a range of details about each registered product, which this new Division would establish.</p> <p>The Division would set out the relevant rules and powers relating to that approval. The Secretary of the Department of Health and Human Services would be granted the power to approve new products.</p>
Create a process by which authorised officers are permitted to take possession of medicinal cannabis	<p>Under the medicinal cannabis scheme, authorised officers of the Victorian Government would be required to take physical possession of cannabis, potentially arrange for it to be tested and labelled (rendering it 'medicinal cannabis') and deliver it to participating pharmacies. This Division would authorise those activities.</p>
Confer power on the Governor in Council to make regulations	<p>Section 69V of the Act provides that the Governor in Council may make regulations with respect to a wide range of matters pertaining to the poppy scheme.</p> <p>Similar powers would be needed in respect of the cannabis scheme. This new Division could confer upon the Governor in Council the power to make enforceable standards about the quality of cannabis cultivated or manufactured under the scheme.</p> <p>The provisions could be modelled on Division 9 of Part IVB of the Act.</p>

Table 2: Treating medicinal cannabis as a class of poison or controlled substance by amending the *Drugs, Poisons and Controlled Substances Act 1981* (Vic)

Purpose	Explanation
Define 'medicinal cannabis'	<p>Medicinal cannabis products that are lawfully cultivated, manufactured and labelled as such by the state under a Victorian scheme would need to be identified in s 4(1) of the Act.</p> <p>The definition should make it clear that 'medicinal cannabis' is still 'cannabis' and as such is a drug of dependence.</p>
Include 'drug of dependence' in the definition of medicinal cannabis	<p>This amendment is not strictly necessary, because 'cannabis' is already identified in Schedule 11 of the Act as a drug of dependence and should be understood to include medicinal cannabis. However, for the purposes of clarity it may be preferable to expressly identify the medicinal cannabis products produced under the scheme as drugs of dependence in s 4(1) of the Act.</p>

Purpose	Explanation
Amend 'poison or controlled substance' to include medicinal cannabis	<p>Various rules in the Act apply to 'poisons and controlled substances' as a class, the definition applying to all scheduled medicines. It is desirable for the bulk of these rules to also apply to medicinal cannabis.</p> <p>Where rules should not apply to medicinal cannabis, a specific exemption has been suggested, as occurs with other scheduled medicines.</p>
Exempt medicinal cannabis from the poisons schedules	<p>The Commission regards it as appropriate to treat medicinal cannabis as a wholly separate 'schedule' of medicine. This allows rules applying to different schedules of medicine to be applied to medicinal cannabis as is desired, and also permits new rules specific to medicinal cannabis to be created.</p> <p>This could be achieved by introducing medicinal cannabis into Part 3 of the Poisons List, in reliance on s 12A(1)(b) of the Act.</p>
Exempt medicinal cannabis from the offences the Act imposes for breaching the Commonwealth <i>Standard for the Uniform Scheduling of Medicines and Poisons'</i> rules with respect to the labelling, containing, storing and packaging, and advertising of poisons and controlled substances	<p>Medicinal cannabis medicines should not be subject to the SUSMP's rules about labelling, containing, storing, packaging, and advertising. New rules will be created under the Victorian scheme.</p> <p>This would require an additional provision to be introduced into s 27A of the Act.</p>
Add medicinal cannabis to the rules about registered nurses administering certain medicines to residents in aged care services who are in high-level residential care	<p>Registered nurses are currently permitted to manage the administration of drugs of dependence, Schedule 4, 8 and 9 poisons that have been prescribed to residents of aged care services who are in high-level residential care.</p> <p>A new section may be required to ensure registered nurses can administer medicinal cannabis. Section 36E refers to 'prescription' and s 36F refers to national guidelines of the Nursing and Midwifery Board. These may not be features of a Victorian medicinal cannabis scheme.</p>
Exempt the medicinal cannabis scheme from the requirement that the Secretary of the Department of Health maintain a public list of persons holding licenses, permits or warrants.	<p>Like the poppy scheme and the low-THC hemp scheme, it is not desirable to require the Secretary to make public the details of licence-holders under a Victorian medicinal cannabis scheme.</p> <p>Section 118 of the Act is used to exempt the poppy scheme and can be used to similarly exempt medicinal cannabis licence-holders.</p>

Table 3: Establishing a mechanism by which classes of patient may be deemed eligible to access medicinal cannabis products under the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*

Purpose	Explanation
Enable the Governor in Council to make regulations setting out categories of eligibility to the scheme	The Commission has recommended that the conditions and symptoms that entitle patients to access medicinal cannabis be set out in regulations.

Table 4: Enabling medicinal cannabis to be lawfully possessed by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Enable a person who holds a licence to cultivate or manufacture medicinal cannabis under the Act to possess medicinal cannabis to the extent authorised by the licence.	<p>If medicinal cannabis is exempted from the poisons schedules, it would be necessary to re-apply certain regulations about possession to medicinal cannabis.</p> <p>This would mean authorising the holder of a cannabis cultivation licence or cannabis manufacturing licence, and their employees and contractors, to possess medicinal cannabis in the way permitted by the licence.</p> <p>It could be achieved through amending r 5(1) item 1, or, more likely, through the creation of a new regulation so as to better separate out medicinal cannabis licences from other licences, permits and warrants.</p>
Enable the carriers or employees of a carrier to possess medicinal cannabis for delivery to the person to whom it is addressed, as consigned to them by a licence-holder or a medical practitioner	<p>If medicinal cannabis is exempted from the poisons schedules, it would be necessary to re-apply certain regulations about possession to medicinal cannabis.</p> <p>This would mean enabling a carrier service to transport medicinal cannabis from a licence-holder, or a medical practitioner or pharmacist to the person to whom it is addressed.</p> <p>It could be achieved through amending r 5(1) item 2, or through the creation of a new regulation.</p>
Enable a person to possess medicinal cannabis supplied to them by a registered medical practitioner or pharmacist to the extent and for the purpose for which it is supplied.	<p>If medicinal cannabis is exempted from the poisons schedules, it would be necessary to re-apply certain regulations about possession to medicinal cannabis.</p> <p>This amendment would enable a person who has lawfully received medicinal cannabis from a doctor or pharmacist to possess it for the purpose intended, most obviously medical use.</p> <p>It could be achieved through amending r 5(1) item 3, or through the creation of a new regulation.</p>

Purpose	Explanation
<p>Enable a nurse to possess medicinal cannabis to the extent necessary for administration to a patient in accordance with the instructions of a registered medical practitioner</p>	<p>If medicinal cannabis is exempted from the poisons schedules, it would be necessary to re-apply certain regulations about possession to medicinal cannabis.</p> <p>This would mean enabling a nurse to administer medicinal cannabis to their patient on the instructions of a registered medical practitioner.</p> <p>It could be achieved through amending r 5(2), or through the creation of a new regulation.</p>
<p>Enable a nurse to possess medicinal cannabis while not under the direct supervision of a registered medical practitioner, on determination by the Secretary of the Department of Health and Human Services.</p>	<p>If medicinal cannabis is exempted from the poisons schedules, it would be necessary to re-apply certain regulations about possession to medicinal cannabis.</p> <p>This amendment would enable a nurse to administer medicinal cannabis to their patient while not being directly supervised by a medical practitioner. The power is only to be used by the Secretary of the Department of Health and Human Services when necessary. It could be achieved through amending rr 5(3) and (4), or through the creation of a new regulation.</p>
<p>Enable a registered medical practitioner to authorise treatment with medicinal cannabis</p>	<p>A new regulation should be inserted setting out the assessment to be made by a medical practitioner about whether it is appropriate to authorise the patient to access cannabis. Currently, r 8 requires that the medical practitioner assess a patient's therapeutic need for any drug of dependence before prescribing it to the patient. Amendments could use the same wording or adopt a new test.</p>
<p>Prohibit a pharmacist from supplying medicinal cannabis to a person for their therapeutic use otherwise than on the basis of an Authority to Dispense.</p>	<p>Currently, r 12 requires that a pharmacist may supply a drug of dependence to a person without a prescription after making an assessment of the person's therapeutic need.</p> <p>The Commission has recommended that pharmacists be permitted to dispense medicinal cannabis only upon receiving an Authority to Dispense from a medical practitioner. Regulation 12 should be changed to reflect this. The term 'drug of dependence' in r 12 should be qualified by 'other than medicinal cannabis'.</p> <p>A new regulation should be inserted prohibiting a pharmacist from supplying cannabis based on an assessment of a patient's therapeutic need.</p>
<p>Enable a pharmacist to supply medicinal cannabis to a person who provides them with an Authority to Dispense issued by a medical practitioner in relation to the person.</p>	<p>There is no regulation authorising pharmacists to administer, sell or supply medicinal cannabis to patients. A new regulation is required allowing a pharmacist to administer, sell or supply medicinal cannabis upon being presented with an Authority to Dispense by a patient.</p> <p>This could be achieved by amending r 15 or through the creation of a new regulation.</p>

Purpose	Explanation
Enable the Secretary of the Department of Health to issue permits to specialist medical practitioners to authorise treatment with medicinal cannabis	<p>There is no regulation authorising the Secretary to issue medicinal cannabis permits to specialist medical practitioners. A new regulation is required granting the Secretary this power.</p> <p>This could be achieved through amending r 22B or through the creation of a new regulation.</p>

Table 5: Enabling medicinal cannabis to be lawfully supplied by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Enable medical practitioners with the requisite permit to authorise patients to obtain medicinal cannabis from pharmacists.	<p>There is no regulation identifying the medical practitioners who can authorise patients to access medicinal cannabis.</p> <p>A new regulation is required enabling eligible medical practitioners who are authorised by the requisite permit to authorise treatment with medicinal cannabis.</p> <p>This would require a new regulation modelled on r 25.</p>
Enable the Secretary of the Department of Health and Human Services to determine the style and particulars of an Authority to Dispense medicinal cannabis.	<p>There is no regulation setting out the style and particulars of a medicinal cannabis Authority to Dispense.</p> <p>A new regulation is required enabling the Secretary of the Department of Health and Human Services to establish the manner of writing that constitutes a valid Authority to Dispense, in the manner of r 26(1)(b). Like r 26(2), the Secretary should have regard to security, legibility and anything else the Secretary regards as relevant.</p> <p>Appropriately modified versions of subss (4) (prohibiting an Authority to Dispense being in secret code) and (5) (prohibiting the inclusion of particulars that are false or misleading) should be incorporated into any new regulation.</p>
Require pharmacists to verify the details of an Authority to Dispense before supplying medicinal cannabis.	<p>There is no regulation requiring pharmacists to verify the details of an Authority to Dispense medicinal cannabis. Such verification is required for prescriptions for medicines in Schedules 8 and 9.</p> <p>A modified version of r 28 could require the pharmacist to take reasonable steps to ensure the Authority to Dispense is from the eligible registered medical practitioner from whom it purports to have been issued.</p>
Require the suppliers of medicines to label medicinal cannabis products with certain details.	<p>There is no regulation requiring the supplier of a medicinal cannabis product to label it with information about the name of the patient, the date of recording, the name, address and phone number of the supplier and the name of the medicinal cannabis product.</p> <p>A modified version of r 29 should indicate to pharmacists (in particular) when they have to label medicinal cannabis products with instructions about their use.</p>

Purpose	Explanation
<p>Require pharmacists to label medicinal cannabis products with details about when supplied and the date of the supply.</p>	<p>There is no regulation requiring the supplying pharmacist to identify that a medicinal cannabis product has been supplied and mark the date and premises of the supply.</p> <p>Further, r 30 prohibits the supply of a prescription medicine where more than 12 months have passed since the date of the prescription (in the case of a Schedule 4 poison) or 6 months have passed since the prescription date (in the case of Schedule 8 and 9 poisons).</p> <p>A modified version of r 30 should indicate to pharmacists how they must label and date the supply of a medicinal cannabis product, and the circumstances in which they must not supply it because the Authority to Dispense is out of date.</p>
<p>Set out the circumstances where a pharmacist must not supply on an Authority to Dispense</p>	<p>There is no regulation directing a pharmacist not to supply a medicinal cannabis product when presented with an Authority to Dispense that is forged, altered, illegible, or concerns a product that has already been supplied. Nor is there a requirement that a pharmacist not supply medicinal cannabis products in excess of the Authority to Dispense.</p> <p>A modified version of r 31 should require a pharmacist not to supply medicinal cannabis products upon a defective Authority to Dispense or in excess of the amount authorised. Like r 31, a pharmacist should be required to notify Victoria Police and the Secretary when presented with a defective Authority to Dispense.</p> <p>Alternatively, a supply of a medicinal cannabis product in excess of the amount specified in the Authority to Dispense could be treated as unauthorised supply of a drug of dependence as prohibited by Part V of the Act.</p>
<p>Require pharmacists to notify the authorising medical practitioner when they believe a patient has sought multiple authorisations from multiple medical practitioners</p>	<p>There is no regulation requiring a pharmacist to notify a medical practitioner when they believe the authorised patient has obtained medicinal cannabis from them in the past eight weeks by using an Authority to Dispense issued by another medical practitioner.</p> <p>A modified version of r 32 could require the pharmacist to notify an authorising medical practitioner if they believe multiple authorities to dispense have been obtained. Such a requirement may not be necessary, because the permit system proposed by the Commission may adequately prevent multiple authorities being sought by a patient.</p>
<p>Require pharmacists to retain Authority to Dispense</p>	<p>There is no regulation requiring pharmacists to take possession of and retain an Authority to Dispense once all of the medicinal cannabis it authorises has been supplied.</p> <p>A modified version of r 33 could impose this requirement, and require it to be made available to authorised officers on request.</p>

Table 6: Establishing rules for the lawful storage of medicinal cannabis by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Require anyone entitled to possess medicinal cannabis to store it as a Schedule 8 or 9 poison	<p>There is no regulation that specifically requires medicinal cannabis to be stored. If medicinal cannabis is exempted from the poisons schedules, it is necessary to re-apply the rules around storage to medicinal cannabis.</p> <p>Regulation 35 could be amended to include medicinal cannabis to be stored similarly to Schedule 8 and 9 poisons.</p>
Require anyone entitled to possess medicinal cannabis to fix and secure their storage facility	<p>There is no regulation requiring medicinal cannabis to be kept in a locked storage facility that is fixed to the ground, as is required with Schedule 8 and 9 poisons.</p> <p>Regulation 36(1)(b) could be amended to extend these requirements to medicinal cannabis. Amendments may also be required to r 36(2) to clarify which people would be subject to the storage requirement.</p>
Provide the Secretary with the power to require additional security for medicinal cannabis	<p>There is no regulation authorising the Secretary to direct persons who store cannabis to provide additional security. This power should be introduced into the regulations. Medicinal cannabis would have to be incorporated into r 37 or a new regulation made.</p>

Table 7: Establishing rules for recording transactions in medicinal cannabis by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Identify which transactions must be recorded, what must be recorded and who must keep the record	<p>Obligations around record-keeping apply to ‘transactions’ as defined in r 38, described as the ‘manufacture, preparation, use, transfer within and between premises, administration, sale, supply, disposal and destruction’ of Schedule 4, 8 and 9 poisons. If the obligations in Division 5 are to be extended to medicinal cannabis, it will be necessary to extend the definition of transaction.</p> <p>Under r 39(a), medical practitioners and pharmacists are always required to keep records of transactions. It would be necessary to extend these obligations to cover medicinal cannabis.</p> <p>People who have record-keeping obligations as conferred by r 39 must record certain details about ‘transactions’, under r 40. Sub-r 40(e), (f) and (h) impose recording obligations specifically on Schedule 8 and 9 poisons. These obligations would need to be specifically extended to medicinal cannabis.</p>
Require records to be retained and retrieved in a particular way	<p>Under r 41, records of Schedule 8 and 9 poisons must be in English and readily sorted by the type of poison, the quantity held of each poison, and indicate who has engaged in transactions in respect of each poison. These requirements should be adapted to apply to different types of medicinal cannabis.</p>
Require records to be accurate	<p>Regulation 42 prohibits persons from knowingly making or causing an entry in their records that is false and misleading in respect of Schedules 4, 8 and 9 poisons. This obligation should be extended to medicinal cannabis records.</p>

Table 8: Establishing rules for administering medicinal cannabis by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Require a person supplied medicinal cannabis for treating a specific person only to administer it to that person	Currently, persons are prohibited by r 45 from administering poisons in Schedules 4, 8 and 9 to a person other than the person for whom the poison was supplied. These obligations should be extended to medicinal cannabis. In the absence of such an extension, because medicinal cannabis is a drug of dependence, this administration could amount to unauthorised supply and fall within Part V of the Act.
Require orders for the administration of medicinal cannabis to be legible and durable	A registered medical practitioner who orders the administration of a poison in Schedules 4, 8 or 9 is required by regulation 46 to do so in a way that is legible and durable, and must date and sign the order. These requirements should be extended to orders to administer medicinal cannabis.
Set rules for the administration of medicinal cannabis by nurses	Regulation 47(1) sets out the circumstances in which a nurse may administer a Schedule 9 poison consistently with the directions for use or instructions by a registered medical practitioner. These rules should be adapted to the administration of medicinal cannabis by a nurse. If a new regulation on the possession of medicinal cannabis were inserted, attention would have to be given to r 47(1)(e), which refers to r 5(2) and (3) to determine when a nurse may administer cannabis.
Restrict the self-administration and prohibiting the self-authorisation and self-supply of medicinal cannabis	Regulation 48 restricts the circumstances in which a person can self-administer poisons in Schedules 4, 8 and 9. It prohibits medical practitioners from self-prescribing or self-administering cannabis. The prohibitions on Schedule 9 poisons should be extended to medicinal cannabis. In adapting r 48(a), it would be necessary to reflect that cannabis is not 'prescribed' like a Schedule 9 poison, but is authorised. Because medicinal cannabis is a drug of dependence, self-administration by a medical practitioner would be unauthorised supply and also fall within Part V of the Act.
Prohibit the supply or administration of medicinal cannabis to support drug dependency	Regulation 49 prohibits persons from administering, 'prescribing', selling or supplying drugs of dependence merely for the purpose of supporting a person's drug dependence. In adapting r 49, it would be necessary to reflect that medicinal cannabis is not 'prescribed' like a Schedule 9 poison, but is authorised.

Table 9: Establishing rules for the destruction of medicinal cannabis by amending the *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Purpose	Explanation
Prohibit the wilful destruction of medicinal cannabis	Currently, r 50 prohibits persons from wilfully destroying poisons in Schedules 8 and 9. This prohibition should be extended to medicinal cannabis.
Create exceptions to the rule that medicinal cannabis must not be wilfully destroyed	Regulation 51 creates a number of exemptions allowing poisons in Schedules 8 and 9 to be destroyed in certain circumstances. These exemptions should be extended to medicinal cannabis.

Table 10: New offences under a Victorian medicinal cannabis scheme to be provided in the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)* and *Drugs, Poisons and Controlled Substances Regulations 2006 (Vic)*

Conduct to be prohibited	Section capturing conduct	Explanation
An authorised patient supplies medicinal cannabis to an unauthorised person	Section 71AC No new offence required	An authorised patient would only be authorised to possess and use medicinal cannabis; if they supplied it to another person they would be trafficking without being authorised.
A carer supplies medicinal cannabis to an unauthorised person	Section 71AC No new offence required	A nominated carer would only be authorised to possess medicinal cannabis and to administer it to their registered patient; if they supplied to another person they would be trafficking without being authorised.
A patient misleads or deceives medical practitioner in order to obtain an Authority to Dispense to obtain medicinal cannabis	Section 78 Amendment required	Additions may be required to reflect the 'Authority to Dispense' procedure proposed for medicinal cannabis – presently references are only to prescriptions and orders.
A doctor seeks a permit in relation to a patient who is not eligible for medicinal cannabis	Closest offence is r 8 New offence is required	An amendment or new provision would be required because regulation 8 refers to a 'prescription'. Medicinal practitioners who issued an Authority to Dispense medicinal cannabis would not be required to 'prescribe'. Authorising a person who is ineligible should still be penalised.
A pharmacist supplies cannabis products which were not made under government licence	Sections 71 to 71AC No new offence required	Pharmacists would only be authorised to possess and supply 'medicinal cannabis products' made under licence and supplied by the Secretary of the Department of Health and Human Services. Supply of other products would contravene the prohibition on trafficking.
A person other than a pharmacist supplies cannabis products (whether or not made under government licence)	Sections 27, 71 to 71AC No new offence required	Only pharmacists would be authorised to supply medicinal cannabis products. Anyone else who does so would engage in: <ul style="list-style-type: none"> • the sale of a poison or controlled substance when not authorised or licensed to do so, and • trafficking.

Conduct to be prohibited	Section capturing conduct	Explanation
A person other than a licensed cultivator grows cannabis for medicinal purposes	Sections 72 to 72B No new offence required	Under the scheme, only licensed cultivators would be authorised to cultivate cannabis for medicinal purposes. Anyone else who does so engages in cultivating a narcotic plant without being authorised or licensed to do so.
A person other than a licensed manufacturer produces medicinal cannabis products	Sections 23, 71 to 71AC No new offence required	<p>Under the scheme, only licensed manufacturers would be authorised to manufacture medicinal cannabis products. Anyone else who did so would engage in:</p> <ul style="list-style-type: none"> • trafficking a drug of dependence in contravention of s 71AC (manufacture is within the meaning of traffick) • and the manufacture of a poison or controlled substance when not authorised or licensed to do so in contravention of s 23. <p>If the manufacturer did not have a licence from the Commonwealth, they would also probably breach the <i>Narcotic Drugs Act 1967</i> (Cth).</p>
An employee of a cultivator or manufacturer misappropriates cannabis without authority of the employer or outside of the terms of their statutory authorisation	<i>Crimes Act 1958</i> (Vic) s 74 No new offence required	This would be theft. If the cannabis was sold or given to a third party it would also be trafficking.
A licensed cultivator or manufacturer supplies cannabis to someone other than a licensed manufacturer/the Office of Medicinal Cannabis	Sections 71 to 71AC No new offence required	This conduct would be outside what cultivators and manufacturers are licensed to do, and would therefore amount to trafficking in a drug of dependence.
A person represents that a product they are selling is an approved medicinal cannabis product when it is not.	The closest offence is that of 'trafficking' in sections 71 to 71AC New offence could be created	<p>This conduct would punish persons who sold unapproved medicinal cannabis products under false pretences. Such conduct would be trafficking in a drug of dependence in a way that is unauthorised by the Act and captured by ss 71 to 71AC.</p> <p>If the government wished to punish this offence differently or make the fault elements of the offence clearer, it could create a new offence covering this conduct.</p>



Bibliography

Bibliography

2012 Symposium: 'Practical, Legal, and Ethical Perspectives on Medical Marijuana (Transcription of Speakers' Remarks)' (2012) 16 *Michigan State University Journal of Medicine and Law* 505

Abrams, D I et al, 'Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study' (2007) 82 *Clinical Pharmacology and Therapeutics* 572

ACON and others, *Submission to NSW Legislative Council Inquiry into the Use of Cannabis for Medical Purposes* (February 2013)

Allsop, David et al, *Submission No 52 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014* (March 2015)

American Academy of Neurology, 'Epidiolex (Cannabidiol) in Treatment Resistant Epilepsy', Abstract of presentation to the American Academy of Neurology 67th Annual Meeting, 22 April 2015

American Glaucoma Society, *Position Statement on Marijuana and the Treatment of Glaucoma*, 10 August 2009 <www.americanglaucomasociety.net>

American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed, 2013)

Arizona Department of Health Services, *Arizona Medical Marijuana Act (AMMA) End of Year Report* (2014) <www.azdhs.gov>

Armentano, Paul, 'Cannabis and Psychomotor Performance: A Rational Review of the Evidence and Implications for Public Policy' (2012) 5 *Drug Testing and Analysis* 52

Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine, *Statement on Patients' Rights to Pain Management and Associated Responsibilities* (Position Statement No 45, 2010) <www.fpm.anzca.edu.au>

Australian Health Ministers' Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals* (2015)

Australian Lawyers Alliance, *Submission No 55 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014* (March 2015)

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

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

Baron, E P, 'Comprehensive Review of Medicinal Marijuana, Cannabinoids and Therapeutic Implications in Medicine and Headache: What a Strange Trip It's Been...' (June 2015) 55 *Headache* 885

- Bedrocan BV, *Submission No 48 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014* (March 2015)
- Belendiuk, Katherine A, Lisa L Baldini and Marcel O Bonn-Miller, 'Narrative Review of the Safety and Efficacy of Marijuana for the Treatment of Commonly State-Approved Medical and Psychiatric Disorders' (2015) 10(10) *Addiction Science & Clinical Practice*
- Bewley-Taylor, David, *International Drug Control: Consensus Fractured* (Cambridge University Press, 2012)
- Blake, D R, 'Preliminary Assessment of the Efficacy, Tolerability and Safety of a Cannabis-Based Medicine (Sativex) in the Treatment of Pain Caused by Rheumatoid Arthritis' (2006) 45 *Rheumatology* 50
- Bloor, Roger et al 'Ammonia Release from Heated "Street" Cannabis Leaf and Its Potential Toxic Effects on Cannabis Users' (2008) 103 *Addiction* 1671
- Bonn-Miller, M O et al, 'Posttraumatic Stress Symptom Severity Predicts Marijuana Use Coping Motives Among Traumatic Event-Exposed Marijuana Users' (2007) 20 *Journal of Traumatic Stress* 577
- Bostwick, Michael J, 'Blurred Boundaries: The Therapeutics and Politics of Medical Marijuana' (2012) 87 *Mayo Clinic Proceedings* 172
- Brenner, Michelle, *Conversations on Compassion* (Create Space, 2015)
- Burns, Patricia B, Rod J Rohrich and Kevin C Chung, 'The Levels of Evidence and Their Role in Evidence-Based Medicine' (2011) 128 *Plastic Reconstructive Surgery* 305
- Canada Border Services Agency, *Importation and Exportation of Controlled Substances and Precursors* (2014)
- Canadian Medical Association, *CMA Statement Authorizing Marijuana for Medical Purposes (Update 2015)* (2015)
- Canadian Medical Protective Association, *Medical Marijuana: New Regulations, New College Guidance for Canadian Doctors*, (Document number W14-005-E, May 2014, revised July 2015) <www.cmpa-acpm.ca>
- Cancer Council Australia and Clinical Oncology Society of Australia
- *Submission No 37 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014*
 - *Position Statement—Medical Use of Cannabis*, 21 May 2015 <www.cosa.org>
- Cancer Research UK, *A Trial Looking at Sativex with Temozolomide for Glioblastoma Multiforme Brain Tumour (GWCA1208)*, 29 May 2015 <www.cancerresearchuk.org>
- Caplan, Gerald, 'Medical Marijuana: A Study of Unintended Consequences' (2012) 43 *McGeorge Law Review* 127
- Carter, G T et al, 'Cannabis and Amyotrophic Lateral Sclerosis: Hypothetical and Practical Applications, and a Call for Clinical Trials' (2010) 27 *American Journal of Hospice and Palliative Care* 347
- Carter, Gregory T and Bill S Rosen, 'Marijuana in the Management of Amyotrophic Lateral Sclerosis' (2001) 18 *American Journal of Hospice & Palliative Care* 264
- Castle, David, Robin M Murray and Deepak Cyril D'Souza (eds), *Marijuana and Madness*, (2nd ed, Cambridge University Press, 2012)
- Caulkins, Jonathan et al, *Considering Marijuana Legalisation: Insights for Vermont and Other Jurisdictions* (RAND Corporation, 2015)

Caulkins, Jonathan P et al, *Marijuana Legislation: What Everyone Needs to Know* (Oxford University Press, 2012)

Chu, Yu-Wei, 'The Effects of Medical Marijuana Laws on Illegal Marijuana Use' (2014) 38 *Journal of Health Economics* 43

ClinicalTrials.Gov, *A Study: Pure CBD as a Single-Agent for Solid Tumor (NCT02255292)*, 1 October 2014, <www.clinicaltrials.gov>

Collège des Médecins du Québec, *Guidelines Concerning the Prescription of Dried Cannabis for Medical Purposes* (April 2014)

College of Family Physicians of Canada

— *Authorizing Dried Cannabis for Chronic Pain or Anxiety: Preliminary Guidance* (September 2014)

— *Statement on Health Canada's Proposed Changes to Medical Marijuana Regulations* (Position Statement, February 2013)

College of Physicians and Surgeons of British Columbia, *Professional Standards and Guidelines: Marijuana for Medical Purposes* (5 May 2015)

Collett, Stephen C, Tom Gariffo, Marisa Hernandez-Morgan, *Evaluation of the Medical Marijuana Program in Washington, DC*, University of California, Los Angeles Luskin School of Public Affairs (2013)

Collier, Joe, 'Paediatric Prescribing: Using Unlicensed Drugs and Medicines Outside Their Licensed Indications' (1999) 48 *British Journal of Clinical Pharmacology* 5

Colorado Department of Public Health & Environment, *Medical Marijuana Registry Program Statistics*, 30 June 2015 <www.colorado.gov>

Commonwealth Department of Health

— *Medicinal Cannabis* (27 May 2015) <www.health.gov.au>

— *Submission No 67 to the Legal and Constitutional Affairs Legislation Committee, Inquiry into Regulator of Medicinal Cannabis Bill 2014*

— *The National Strategy for Quality Use of Medicines: Executive Summary* (2002)

Commonwealth Department of Health—Therapeutic Goods Administration

— *About the Work of the TGA—A Risk Management Approach* (15 August 2011)

— *Access to Unapproved Therapeutic Goods via the Special Access Scheme* (2009)

— *Access to Unapproved Therapeutic Goods: Personal Importation* (2004)

— *Australian Public Assessment Report for Nabiximols* (27 September 2013)

— *Australian Regulatory Guidelines for Complementary Medicines* (version 5.2, May 2015)

— *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines* (4 June 2014)

— *Authorised Prescribers* (14 July 2015)

— *Benefits Versus Risks Approach to Regulating Therapeutic Goods* (8 February 2015)

— *Good Manufacturing Practice* (29 April 2013)

— *Mandatory Requirements for an Effective Application* (2015)

— *Manufacturer Inspections—An Overview* (1 May 2013)

— *Reporting Medicine and Vaccine Adverse Events* (28 October 2014)

— *Medicines and Vaccines Post-Market Vigilance—Statistics for 2014* (26 May 2015)

- *Medicines Regulation and the TGA* (1999)
- *Role of the Sponsor* (28 March 2013)
- *TGA Labelling and Packaging Regulatory Framework* (28 October 2014)
- *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods* (2011) 6

Commonwealth Department of Health—Therapeutic Goods Administration (Advisory Committee on Medicines Scheduling), *Final Decisions and Reasons for Decisions by Delegates of the Secretary to the Department of Health, March 2015* (19 March 2015)

Commonwealth Department of Infrastructure and Regional Development, Australian Government, Fact Sheet: *Answers to Your Questions from the Information Sessions* (May 2015)

Cogle, J R et al, 'Posttraumatic Stress Disorder and Cannabis Use in a Nationally Representative Sample' (2011) 25 *Psychologically Addictive Behaviors* 554

Council of Australian Therapeutics Advisory Groups, *Rethinking Medicines Decision-Making in Public Hospitals: Guiding Principles for the Quality Use of Off-Label Medicines* (November 2013)

Cridge, Belinda J and Rhonda J Rosengren, 'Critical Appraisal of the Potential Use of Cannabinoids in Cancer Management' (2013) 5 *Cancer Management and Research* 301

Curtis, Adrienne, Carl E Clarke and Hugh E Rickards, 'Cannabinoids for Tourette's Syndrome' (2009) 4 *Cochrane Database of Systematic Reviews*

Decorte, Tom, 'Cannabis Social Clubs in Belgium: Organisational Strengths and Weaknesses, and Threats to the Model' (2014) 26 *International Journal of Drug Policy* 122

Decorte, Tom et al (eds) *World Wide Weed: Global Trends in Cannabis Cultivation and Its Control* (Ashgate, 2011)

Deepak Cyril D'Souza and Mohini Ranganathan, 'Medical Marijuana: Is the Cart Before the Horse?' (2015) 313 *Journal of the American Medical Association* 2431

Degenhardt, Louisa and Wayne D Hall, 'The Adverse Effects of Cannabinoids: Implications for Use of Medical Marijuana' (2008) 178(13) *Canadian Medical Association Journal* 1685

Delourme, J et al, 'Respiratory Consequences of Inhalation of Adulterated Cannabis' (2009) 26 *La Revue des Maladies Respiratoires* 552 (French)

Delsys Research Group, *Final Report: Cost-Benefit Analysis of Regulatory Changes for Access to Marijuana for Medical Purposes* (2012)

Dhanapal, Raghu, T R Saraswathi and Rajkumar N Govind, 'Cancer Cachexia' (2011) 15 *Journal of Oral and Maxillofacial Pathology* 257

Downey, L A et al, 'The Effects of Cannabis and Alcohol in Simulated Driving: Influences of Dose and Experience' (2013) 50 *Accident Analysis and Prevention* 879

Drummer, Olaf et al, 'The Involvement of Drugs in Drivers of Motor Vehicles Killed in Australian Road Traffic Crashes' (2003) 943 *Accident Analysis and Prevention* 1

Dyer, Owen, 'The Growth of Medical Marijuana' (2013) *British Medical Journal* 347:f4755

Enterprise One Pain Management Service, *Patient Outcomes in Pain Management* (31 December 2014)

Epilepsy Australia, *Medical Marijuana in the Treatment of Epilepsy* (30 October 2014)

European Medicines Agency

- *Guideline on Good Agricultural and Collection Practice (GACP) for Starting Materials of Herbal Origin* (EMA/HMPC/246816/2005)
- *Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products* (CPMP/QWP/122/02, rev 1)
- *Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products* (CPMP/QWP/2819/00 Rev. 2)
- *Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products* (EMA/CPMP/QWP/2820/00 Rev 2)

Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists, *Statement on 'Medicinal Cannabis' with Particular Reference to its Use in the Management of Patients with Chronic Non-Cancer Pain* (PM 10, 2015)

Families and Friends for Drug Law Reform, *Submission No 82 to the ACT Standing Committee on Health, Ageing, Community and Social Services, Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014*, 16 February 2015

Farrell, Michael, Rachele Buchbinder and Wayne Hall, 'Should Doctors Prescribe Cannabinoids?' (2014) 348 *British Medical Journal* g2737

Federal Institute for Drugs and Medical Devices (Germany), *Glossary: Cannabis*, 2013

Fitzcharles, Mary-Ann et al, 'The Dilemma of Medical Marijuana Use by Rheumatology Patients' (2014) 66 *Arthritis Care & Research* 797

Flach, A J, 'Delta-9-tetrahydrocannabinol (THC) in the Treatment of End-Stage Open-Angle Glaucoma' (2002) 100 *Transactions of the American Ophthalmological Society* 215

Forrester, Kim, Debra Griffiths, *Essentials of Law for Medical Practitioners* (2013)

Freckelton, Ian, 'Medicinal Cannabis Law Reform: Lessons from Canadian Litigation' (2015) 22 *Journal of Law and Medicine* 719

Frezza, Claire, 'Medical Marijuana: A Drug Without a Medical Model' (2013) 101 *Georgetown Law Journal* 1117

Galloway, Kevin T et al, 'War on Pain: Multimodal and Multidisciplinary Therapy for Pain Management' (2011) 6(9) *American Nurse Today* <www.americannursetoday.com>

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

Gloss, G and B Vickrey, 'Cannabinoids for Epilepsy: Review' (2014) 3 *Cochrane Database of Systematic Reviews*

Grant, I et al, 'Non-Acute (Residual) Neurocognitive Effects of Cannabis Use: A Meta-Analytic Study' (2003) 9 *Journal of the International Neuropsychological Society* 679

Green, Keith, 'Marijuana Smoking vs Cannabinoids for Glaucoma Therapy' (1998) 116 *Archives of Ophthalmology* 1433

Gregorio, Joseph, 'Physicians, Medical Marijuana and the Law' (2014) 16 *Virtual Mentor* 732

Grotenhermen, Franjo and Ethan Russo (eds) *Cannabis and Cannabinoids: Pharmacology, Toxicology, and Therapeutic Potential* (Haworth Press, 2002)

GW Pharmaceuticals, *Cancer Pain* <www.gwpharm.com>

Hakkarainen, Pekka et al, 'Growing Medicine: Small-Scale Cannabis Cultivation for Medical Purposes in Six Different Countries' (2015) 26 *International Journal of Drug Policy* 250

Hall, Wayne, 'What has Research Over the Past Two Decades Revealed About the Adverse Health Effects of Recreational Cannabis Use?' (2014) 110 *Addiction* 19

Hamadeh, R et al, 'Fatal Aspergillosis Associated with Smoking Contaminated Marijuana, in a Marrow Transplant Recipient' (1988) 94 *Chest* 432

Hartman, Rebecca and Marilyn Huestis, 'Cannabis Effects on Driving Skills' (2013) 59 *Clinical Chemistry* 478

Hasin, Debra S et al, 'Medical Marijuana Laws and Adolescent Marijuana Use in the USA from 1991 to 2014: Results from Annual, Repeated Cross-sectional Surveys' (2015) *The Lancet Psychiatry* <[http://dx.doi.org/10.1016/S2215-0366\(15\)00217-5](http://dx.doi.org/10.1016/S2215-0366(15)00217-5)>

Hazekamp, A and J T Fischedick, 'Cannabis—From Cultivar to Chemovar' (2011) 4 *Drug Testing and Analysis* 660

Hazekamp, Arno, 'An Evaluation of the Quality of Medicinal Grade Cannabis in the Netherlands' (2006) 1 *Cannabinoids* 1

Health Canada

- *Approval of Sativex with Conditions: Fact Sheet* (13 April 2005)
- *Authorization with Conditions of Sativex* (1 August 2007)
- *Import and Export of Marijuana by Licensed Producers—Information Bulletin*, 8 June 2015
- *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (February 2013)
- *Medical Marihuana Regulatory Reform 2011 Consultations Results*
- *Proposed Improvements to Health Canada's Marihuana Medical Access Program* (31 March 2013)
- *Section 56 Class Exemption for Licensed Producers Under the Marihuana for Medical Purposes Regulations to Conduct Activities with Cannabis* (8 July 2015)
- *Statement on Supreme Court of Canada Decision in R v Smith* (7 July 2015)

Hillig, Karl W, 'Genetic Evidence for Speciation in Cannabis (Cannabaceae)' (2005) 52 *Genetic Resources and Crop Evolution* 161

House of Commons Science and Technology Committee, United Kingdom Parliament, *Evidence Check 2: Homeopathy* (HC 45) Fourth Report of Session 2009–10 (2010)

IASP Task Force on Taxonomy, *Classification of Chronic Pain* (2nd ed, 1994)

International Narcotics Control Board

- *Contribution to the High-Level Review of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation Towards an Integrated and Balanced Strategy to Counter the World Drug Problem* (2014)
- *Guide on Estimating Requirements for Substances under International Control* (2012)
- *Report of the International Narcotics Control Board for 2014* (E/INCB/2014/1)

John Ramsay & Associates, *Review of the Tasmanian Poppy Industry Regulation: Report* (July 2013)

Jung, Julia et al, 'Studies on the Metabolism of the Δ^9 -Tetrahydrocannabinol Precursor Δ^9 -Tetrahydrocannabinolic Acid A (Δ^9 -THCA-A) in Rat Using LC-MS/MS, LC-QTOF MS and GC-MS Techniques' (2009) 44 *Journal of Mass Spectrometry* 1423

Kahan, Meldon et al, 'Prescribing Smoked Cannabis for Chronic Noncancer Pain: Preliminary Recommendations' (2014) 60 *Canadian Family Physician* 1083

- Kalant, Harold and Amy J Porath-Waller, 'Medical Use of Cannabis and Cannabinoids' (2014) *Canadian Centre on Substance Abuse Clearing the Smoke on Cannabis* (Report Series No 5, 2014)
- Kehl, L J, 'A Cannabinoid Agonist Differentially Attenuates Deep Tissue Hyperalgesia in Animal Models of Cancer and Inflammatory Muscle Pain' (2003) 103 *Pain* 175
- Kondrad, Elin and Alfred Reid, 'Colorado Family Physicians' Attitudes Toward Medical Marijuana' (2013) 26 *Journal of the American Board of Family Medicine* 52
- Koppel, B S et al, 'Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurological Disorders: Report of the Guideline Subcommittee of the American Academy of Neurology' (2014) 82 *Neurology* 1556
- Kramer, Joan, 'Medical Marijuana for Cancer' (2015) 65 *CA: A Cancer Journal for Clinicians* 109
- Lal, S et al, 'Cannabis Use Among Patients with Inflammatory Bowel Disease' (2011) 23 *European Journal of Gastroenterology & Hepatology* 891
- Legislative Council General Purpose Standing Committee No 4, Parliament of New South Wales, *The Use of Cannabis for Medical Purposes* (2013)
- Legislative Council Government Administration Committee 'A', Parliament of Tasmania, *Interim Report on Legalised Medicinal Cannabis* (2014)
- Lenné, M G et al, 'The Effects of Cannabis and Alcohol on Simulated Arterial Driving: Influences of Driving Experience and Task Demand' (2010) 42 *Accident Analysis and Prevention* 859
- Lenné, Michael, Tom Triggs and Michael Regan, *Cannabis and Road Safety: A Review of Recent Epidemiological Driver Impairment, and Drug Screening Literature* Report No 23, Monash University Accident Research Centre (2004)
- Linger, P, A Ostwald and J Haensler, 'Cannabis Sativa L. Growing on Heavy Metal Contaminated Soil: Growth, Cadmium Uptake and Photosynthesis' (2005) 49 *Biologia Plantarum* 567
- Liu, Wai, 'Why Anti-Cancer Properties in Cannabis Must be Investigated', *The Conversation UK*, 26 June 2015
- Loflin, Mallory and Mitch Earleywine, 'No Smoke, No Fire: What the Initial Literature Suggests Regarding Vapourized Cannabis and Respiratory Risk' (2015) 51 *Canadian Journal of Respiratory Therapeutics* 7
- Lucas, Philippe, 'It Can't Hurt to Ask; A Patient-Centred Quality of Service Assessment of Health Canada's Medical Cannabis Policy and Program', (2012) 9 *Harm Reduction Journal* 2
- Lynch, Mary E and Fiona Campbell, 'Cannabinoids for Treatment of Chronic Non-Cancer Pain; A Systematic Review of Randomised Trials' (2011) 72 *British Journal of Clinical Pharmacology* 735
- Mack, Alison and Janet Joy, *Marijuana as Medicine? The Science Beyond the Controversy* (National Academy Press, 2001)
- Maisto, Stephen, Mark Galizio and Gerard Connors, *Drug Use and Abuse* (Cengage Learning, 2014)
- Marcoux, Rita, E Paul Larrat and F Randy Vogenberg, 'Medical Marijuana and Related Legal Aspects' (2013) 38 *Pharmacy and Therapeutics* 615
- Marks, Amber, *The Legal Landscape for Cannabis Social Clubs in Spain* (Observatorio Civil De Drogas, 2015)
- Martin-Sanchez, E et al, 'Systematic Review and Meta-Analysis of Cannabis Treatment for Chronic Pain' (2009) 10 *Pain Medicine* 1353
- Mather, Laurence, *Submission No 17 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014* (2015)

Mather, Laurence, Alex Wodak and William Notcutt, 'Re: Should Doctors Prescribe Cannabinoids?' <www.bmj.com/content/348/bmj.g2737/rr/701867>

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

Mathern, Gary W, Laurie Beninig and Astrid Nehlig, 'Fewer Specialists Support Using Medical Marijuana and CBS in Treating Epilepsy Patients Compared with Other Medical Professionals and Patients: Results of Epilepsia's Survey' (2014) 56 *Epilepsia* 1

McLaren, Jennifer et al, 'Cannabis Potency and Contamination: A Review of the Literature' (2008) 103 *Addiction* 1100

McLoughlin, B C et al, 'Cannabis and Schizophrenia' (2015) 41 *Schizophrenia Bulletin* 336

McLoughlin, B C et al, 'Cannabis and Schizophrenia: Review' (2014) 10 *Cochrane Database of Systematic Reviews*

McPartland, J M and P L Pruitt, 'Medical Marijuana and Its Use by the Immunocompromised' (1997) 3 *Alternative Therapies in Health and Medicine* 39

Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (March 2014)

Menetrey, A, M Augsburger, B Favrat et al, 'Assessment of Driving Capability Through the Use of Clinical and Psychomotor Tests in Relation to Blood Cannabinoids Levels Following Oral Administration of 20 mg Dronabinol or of a Cannabis Decoction Made with 20 or 60 mg Delta9-THC' (2005) 29 *Journal of Analytical Toxicology* 327

Moldzio, R et al, 'Effects of Cannabinoids $\Delta(9)$ -Tetrahydrocannabinol, $\Delta(9)$ Tetrahydrocannabinolic Acid and Cannabidiol in MPP+ Affected Murine Mesencephalic Cultures' (2012) 19 *Phytomedicine* 819

Munson, A E et al, 'Antineoplastic Activity of Cannabinoids' (1975) 55 *Journal of the National Cancer Institute* 597

Naftali, T et al, 'Cannabis Induces a Clinical Response in Patients with Crohn's Disease: A Prospective Placebo-Controlled Study' (2013) 11 *Clinical Gastroenterology & Hepatology* 1276

Naftali, T et al, 'Treatment of Crohn's Disease with Cannabis: An Observational Study' (2011) 13 *Israel Medical Association Journal* 455

National Cancer Institute, *Cannabis and Cannabinoids*, 6 November 2014 <www.cancer.gov>

National Cannabis Prevention and Information Centre

— *Cannabis Withdrawal* (1 November 2011)

— *Driving Under the Influence of Cannabis: A Brief Review of the Literature* (2013)

National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (2007)

Netherlands Minister for Health, Welfare and Sport, *Guidelines for Cultivating Cannabis for Medicinal Purposes* [Voorschriften voor de Verbouw van Cannabis voor Medicinale Doeleinden], Annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, English translation reproduced in (2003) 3 *Journal of Cannabis Therapeutics* 51

New South Wales Health, *Role of Drug and Therapeutics Committee in the Evaluation and Approval of Medicines for Use in Public Hospitals* (Policy Directive No PD2008_037)

New South Wales Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes* (2000)

Nikles, Jane et al, 'Stakeholders' Views on the Routine Use of N-of-1 Trials to Improve Clinical Care and to Make Resource Allocation Decisions for Drug Use' (2010) 34 *Australian Health Review* 131

- Nolan, Jim, 'Employee Privacy in the Electronic Workplace Pt 2: Drug Testing, Out of Hours Conduct and References' (2000) 7 *Privacy Law & Policy Reporter* 139
- Nurmikko, Turo J et al, 'Sativex Successfully Treats Neuropathic Pain Characterised by Allodynia: A Randomised, Double-Blind Placebo-Controlled Clinical Trial' (2007) 133 *Pain* 210
- Nurnberg, Helen et al, 'An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California' (2011) 4 *Journal of Drug Policy Analysis* 1
- O'Connell, Cheri, *Submission No 109 to the Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Inquiry into the Regulator of Medicinal Cannabis Bill 2014*
- Patel, Anup, 'Medical Marijuana in Pediatric Neurological Disorders' (2015) *Journal of Child Neurology (advance)* <jcn.sagepub.com>
- Penington, David, 'Medicinal Cannabis: Time for Clear Thinking' (2015) 202 *Medical Journal of Australia* 74
- Pertwee, Roger (ed) *Handbook of Cannabis* (Oxford University Press, 2014)
- Pharmaceutical Benefits Advisory Committee, *Public Summary Document: Nabiximols* (July 2013)
- Pharmaceutical Benefits Scheme, *Nabiximols, Oral Spray, 10 mL, Sativex*, July 2013
- Pharmacy Board of Australia
- *Background on the Regulation of Compounding by Pharmacists* (March 2015)
 - *Guidelines on Compounding of Medicines* (April 2015)
- Phillips, Jennan A, Michael G Holland, Debra D Baldwin, 'Marijuana in the Workplace: Guidance for Occupational Health Professionals and Employers. Joint Guidance Statement of the American Association of Occupational Health Nurses and the American College of Occupational and Environmental Medicine' (2015) 57 *Journal of Environmental Medicine* 459
- Phillips, Tudor J C et al, 'Pharmacological Treatment of Painful HIV-Associated Sensory Neuropathy: A Systematic Review and Meta-Analysis of Randomised Controlled Trials' (2010) 5(12) *PLOS ONE* e14433
- Pharmaceutical Inspection Convention: Pharmaceutical Inspection Co-Operation Scheme, *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-8, 15 January 2009)
- Porcella, Anna et al, 'The Human Eye Expresses High Levels of CB1 Cannabinoid Receptor mRNA and Protein' (2001) 12 *European Journal of Neuroscience* 1123
- Potter, C M et al, 'Posttraumatic Stress Disorder and Cannabis Use in a Nationally Representative Sample' (2011) 25 *Journal of Anxiety Disorders* 437
- Public Health Association of Australia, *Position Statement: Medicinal Cannabis in Australia*
- Raman, C et al, 'Amyotrophic Lateral Sclerosis: Delayed Disease Progression in Mice by Treatment with a Cannabinoid' (2004) 5 *ALS and Other Motor Neuron Disorders* 33
- Rasheed, Arun, Sravya Reddy B and Roja C, 'A Review on Standardisation of Herbal Formulation' (2012) 2 *International Journal of Phytotherapy* 74
- Review of Medicines and Medical Devices Regulation, *Regulation of Complementary Medicines—Addendum to Discussion Paper* (February 2015)
- Rock, E M et al, 'Tetrahydrocannabinolic Acid Reduces Nausea-Induced Conditioned Gaping in Rats and Vomiting in *Suncus Murinus*' (2013) 170 *British Journal of Pharmacology* 641
- Rom, Slava and Yuri Persidsky, 'Cannabinoid Receptor 2: Potential Role in Immunomodulation and Neuroinflammation' (2013) 8 *Journal of Neuroimmune Pharmacology* 608

- Romano, Luigi and Arno Hazekamp, 'Cannabis Oil: Chemical Evaluation of an Upcoming Cannabis-Based Medicine' (2013) 7 *Cannabinoids* 1
- Russo, Ethan
- 'Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects' (2011) 163 *British Journal of Pharmacology* 1344
 - The Solution to 'the Medicinal Cannabis Problem' in Michael Schatman, *Ethical Issues in Chronic Pain Management* (Informa, 2007)
- Sackett, David L et al, 'Evidence-Based Medicine: What It Is and What It Isn't' (1996) 312 *British Medical Journal* 71
- Sansom, Lloyd, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation* (2015)
- Scollo, M M and M H Winstanley (eds), *Tobacco in Australia: Facts & Issues* (4th ed, 2012, Cancer Council Victoria)
- Senate Legal and Constitutional Affairs Committee, Parliament of Australia, *Inquiry into the Regulator of Medicinal Cannabis Bill 2014* (2015)
- Seppala, Emma, 'The Compassionate Mind' (2013) 26 *Association for Psychological Science Observer* <<https://www.psychologicalscience.org>>
- Sewell, Andrew R, James Poling and Mehmet Soluoglu, 'The Effect of Cannabis Compared with Alcohol on Driving' (2009) 18 *American Journal of Addiction* 185
- Standing Committee on Health, Aging, Community and Social Services, ACT Legislative Assembly, *Inquiry into Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and Related Discussion Paper* (March 2015)
- Tomida, I et al, 'Effect of Sublingual Application of Cannabinoids on Intraocular Pressure: A Pilot Study' (2006) 15 *Journal of Glaucoma* 349
- Tomida, I, R G Pertwee and A Azuara-Blanco, 'Cannabinoids and Glaucoma' (2004) 88 *British Journal of Ophthalmology* 708
- Tramèr, Martin R et al, 'Cannabinoids for Control of Chemotherapy Induced Nausea and Vomiting: Quantitative Systematic Review' (2001) 323 *British Medical Journal* 16
- Triantafyllidi, Aikaterini et al, 'Herbal and Plant Therapy in Patients with Inflammatory Bowel Disease' (2015) 28 *Annals of Gastroenterology* 210
- Vandrey, Ryan et al, 'Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products' (2015) 313 *Journal of the American Medical Association* 2491
- Verhoeckx, Kitty C M et al, 'Unheated Cannabis Sativa Extracts and Its Major Compound THC-acid Have Potential Immuno-Modulating Properties Not Mediated by CB1 and CB2 Receptor Coupled Pathways' (2006) 6 *International Immunopharmacology* 656
- Victorian Department of Health, *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (2013)
- Victorian Law Reform Commission, *Medicinal Cannabis: Issues Paper* (2015)
- Victorian Public Sector Commission, *Legal Form and Governance Arrangements for Public Entities: Guidelines* (May 2013)
- Wachtel, Boaz, *International Medical Cannabis Policy* (11 March 2013) <<http://www.slideshare.net/SafeAccess/asa-2013-medical-cannabis-in-israel-v3>>
- Wade, Derick T, 'A Preliminary Controlled Study to Determine Whether Whole-Plant Cannabis Extracts Can Improve Intractable Neurogenic Symptoms' (2003) 17 *Clinical Rehabilitation* 21

- Wang, Tongtong et al, 'Adverse Effects of Medical Cannabinoids: A Systematic Review' (2008) 178 *Canadian Medical Association Journal* 1669
- Ware, Mark A et al, 'Smoked Cannabis for Chronic Neuropathic Pain: A Randomized Controlled Trial' (2010) 182 *Canadian Medical Association Journal* E694
- Ware, Mark and Vivianne Tawfik, 'Safety Issues Concerning the Medical Use of Cannabis and Cannabinoids' (2005) 10 *Pain Research and Management* 31
- Warr, David, 'Chemotherapy- and Cancer-Related Nausea and Vomiting' (2008) 15 *Current Oncology* S1
- Warrell, David, Timothy M. Cox, John D Firth (eds), *Oxford Textbook of Medicine* (Oxford University Press, 2003)
- Watanabe, Kazuhito et al, 'Marijuana Extracts Possess the Effects Like the Endocrine Disrupting Chemicals' (2005) 206 *Toxicology* 471
- Welty, Timothy E, Adrienne Luebke and Barry E Gidal, 'Cannabidiol: Promise and Pitfalls' (2014) 14 *Epilepsy Currents* 250
- Western Australian Department of Health and Victorian Department of Health, *Application to Amend the Poisons Standard (Substance: Cannabidiol)*, 6 October 2014
- Whiting, Penny F et al, 'Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis' (2015) 313 *Journal of the American Medical Association* 2456
- Wilsey, Barth et al, 'Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain' (2012) 14 *Journal of Pain* 136
- World Health Organisation
- *Ensuring Balance in National Policies on Controlled Substances: Guideline for Availability and Accessibility of Controlled Medicines* (2011)
 - *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants* (2003)
- Yarnell, Stephanie, 'Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature' (2015) 17(3) *Primary Care Companion for CNS Disorders* <<http://www.psychiatrist.com>>
- Zajicek, J P et al, 'Multiple Sclerosis and Extract of Cannabis: Results of the MUSEC Trial' (2012) 83 *Journal of Neurology, Neurosurgery and Psychiatry* 1125
- Zaller, N et al, 'Profiles of Medicinal Cannabis Patients Attending Compassion Centers in Rhode Island' (2015) 47 *Journal of Psychoactive Drugs* 18



**Reports published by the
Victorian Law Reform Commission**

- 1 Criminal Liability for Workplace Death and Serious Injury in the Public Sector (2002)
- 2 Disputes between Co-owners (2002)
- 3 Failure to Appear in Court in Response to Bail (2002)*
- 4 People with Intellectual Disabilities at Risk: A Legal Framework for Compulsory Care (2003)
- 5 Sexual Offences (2004)
- 6 Defences to Homicide (2004)
- 7 Workplace Privacy (2005)
- 8 Implementing the *Uniform Evidence Act 1995* (2006)
- 9 Uniform Evidence Law (2006)
- 10 Review of Family Violence Laws (2006)
- 11 Residential Tenancy Databases (2006)*
- 12 Assisted Reproductive Technology and Adoption (2007)
- 13 Review of the *Bail Act 1997* (2007)
- 14 Civil Justice Review (2008)
- 15 Law of Abortion (2008)
- 16 Assistance Animals (2008)*
- 17 Jury Directions (2009)
- 18 Surveillance in Public Places (2010)
- 19 Protection Applications in the Children's Court (2010)
- 20 Review of the *Property Law Act 1958* (2010)
- 21 Supporting Young People in Police Interviews (2010)*
- 22 Easements and Covenants (2010)
- 23 Sex Offenders Registration (2011)
- 24 Guardianship (2012)
- 25 Birth Registration and Birth Certificates (2013)*
- 26 Succession Laws (2013)
- 27 Jury Empanelment (2014)
- 28 Review of the *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (2014)
- 29 The Forfeiture Rule (2014)
- 30 Trading Trusts—Oppression Remedies (2015)
- 31 Photographing and Filming Tenants' Possessions for Advertising Purposes (2015)*
- 32 Medicinal Cannabis (2015)

* community law reform

**For a full list of publications see
www.lawreform.vic.gov.au**



Victorian
Law Reform
Commission

Medicinal Cannabis

REPORT

GPO Box 4637
Melbourne
Victoria 3001
Australia

Level 3
333 Queen Street
Melbourne
Victoria 3000
Australia

Telephone

+61 3 8608 7800

Freecall

1300 666 555 (*within Victoria*)

Fax

+61 3 8608 7888

Email

law.reform@lawreform.vic.gov.au

www.lawreform.vic.gov.au