

The Senate

Community Affairs References
Committee

Current barriers to patient access to
medicinal cannabis in Australia

March 2020

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Table of Contents

Committee Members	iii
Terms of Reference	ix
Abbreviations	xi
List of Recommendations	xiii
Chapter 1—Introduction	1
Purpose of the inquiry.....	1
Report structure.....	1
Conduct of the inquiry.....	2
Acknowledgements.....	2
Note on terminology and references.....	2
Medicinal cannabis.....	2
Medicinal uses.....	3
The role of the Therapeutic Goods Administration (TGA).....	3
Scheduling of medicines.....	3
Registration of medicines.....	4
Access pathways for medicinal cannabis.....	5
The role of the Office of Drug Control (ODC).....	7
The role of state and territory governments.....	7
SAS online system.....	9
Chapter 2—Education and information	11
Education about medicinal cannabis.....	12
Medical cannabis efficacy.....	12
Treatment of last resort.....	13
Stigma.....	14
Training.....	15
Training available.....	16
Training needs.....	16
Information about accessing medicinal cannabis.....	17
Patients' perspectives.....	17
Health practitioners' perspectives.....	18

Medicinal cannabis products	19
Committee view	19
Chapter 3—Access pathways and regulatory hurdles.....	23
Introduction	23
Special Access Scheme.....	23
Use of SAS-A	24
Recent increase in SAS-B applications	24
Concerns about using the SAS-B pathway.....	26
Authorised Prescriber scheme	31
Clinical trials.....	35
Alternatives proposed to the current TGA pathways	36
Proposal for an independent regulatory framework.....	37
Committee view	39
Notification pathways.....	39
Approval pathways.....	40
Committee view	41
Jurisdiction-specific regulatory requirements	43
The 'postcode lottery'	44
Tasmania – the odd state out	46
Need for harmonisation.....	47
International jurisdictions and their access models.....	48
The Canadian model	49
Committee view	50
Chapter 4—Products and supply	53
Regulating medicinal cannabis products	53
Scheduling in the Poisons Standard.....	54
Registration of medicinal cannabis products in the ARTG	57
Regulating cannabinoids as complementary medicines.....	62
Committee view	63
Medicinal cannabis supply in Australia	64
Locally-manufactured medicinal cannabis products	65
General concerns about stock and supply.....	70

Committee view	73
Chapter 5 – Costs and other barriers	75
The costs of accessing medicinal cannabis	75
Medical appointments.....	76
Filling a prescription	77
Current subsidies for medicinal cannabis	82
The 'green market' – illicit cannabis for medicinal purposes	84
Cost of illicit cannabis	85
Quality of illicit cannabis.....	87
Criminal implications.....	87
Driving laws and medicinal cannabis.....	88
Committee view	91
Appendix 1 – Submissions and additional information	95
Appendix 2 – Public hearings.....	101

Terms of Reference

The current barriers to patient access to medicinal cannabis in Australia, including:

- (a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials;
- (b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;
- (c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;
- (d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;
- (e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;
- (f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;
- (g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;
- (h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;
- (i) the current status of the domestic regulated medicinal cannabis industry;
- (j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;
- (k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;
- (l) the significant financial barriers to accessing medicinal cannabis treatment;

- (m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that; and
- (n) any related matters.

Abbreviations

ACMS	Advisory Committee on Medicines Scheduling
ACNEM	Australasian College of Nutritional and Environmental Medicine
AMA	Australian Medical Association
AP	Authorised Prescriber
ARTG	Australian Register of Therapeutic Goods
CAS	Controlled Access Scheme
CBD	Cannabidiol
COAG	Council of Australian Governments
CTN	Clinical Trials Notification Scheme
Department	Department of Health
DVA	Department of Veterans' Affairs
EAA	Epilepsy Action Australia
Ethics committee	Human research ethics committee
GMP	Good Manufacturing Practice
GP	General practitioner
Lambert Initiative	Lambert Initiative for Cannabinoid Therapeutics, University of Sydney
MBS	Medicare Benefits Schedule
McMillan review	<i>Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967</i>
MCIA	Medicinal Cannabis Industry Australia
MCUA	Medical Cannabis Users Association of Australia
ND Act	<i>Narcotic Drugs Act 1967</i>
NICM HRI	National Institute of Complementary Medicine Health Research Institute
ODC	Office of Drug Control
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
Poisons Standard	Uniform Scheduling of Medicines and Poisons
RACGP	Royal Australian College of General Practitioners
RPBS	Repatriation Pharmaceutical Benefits Scheme
S2, S3, etc.	Schedule 2, Schedule 3, etc. in the Uniform Scheduling of Medicines and Poisons
SAS	Special Access Scheme
SAS-A, SAS-B, SAS-C	Special Access Scheme Category A, Special Access Scheme Category B, Special Access Scheme Category C
TG Act	<i>Therapeutic Goods Act 1989</i>
TGA	Therapeutic Goods Administration

TGO 93	Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017
THC	Delta-9-tetrahydrocannabinol
UIC	United in Compassion
UN Single Convention	United Nations Single Convention on Narcotic Drugs

List of Recommendations

Recommendation 1

- 2.56 The committee recommends that the Department of Health, in collaboration with the Australian Medical Association, the Royal Australian College of General Practitioners and other specialist colleges and health professional bodies, develop targeted education and public awareness campaigns to reduce the stigma around medicinal cannabis within the community.

Recommendation 2

- 2.59 The committee recommends that the Department of Health allocate funds to relevant medical colleges and peak bodies to support the development and delivery of accredited face-to-face and online training programs on medicinal cannabis for medical practitioners.

Recommendation 3

- 2.61 The committee recommends that the Australian Medical Council, as part of its role in the accreditation of Australian medical education providers, make mandatory the inclusion of modules on the endocannabinoid system and medicinal cannabis in curriculums delivered by primary medical programs (medical schools).

Recommendation 4

- 2.64 The committee recommends that the Department of Health commission the development of a suite of printed and online resources for patients, aimed at explaining the regulatory framework and process to access medicinal cannabis.

Recommendation 5

- 3.94 The committee recommends that, if after 12 months from the tabling of this report the Commonwealth Government through the Therapeutic Goods Administration has failed to address the barriers to appropriate, regulated patient access to medicinal cannabis in Australia, a new Independent Regulator be considered, using the Regulator of Medicinal Cannabis Bill 2014 as a basis.

Recommendation 6

- 3.105 The committee recommends that the Therapeutic Goods Administration review and improve its online resources for health professionals relating to the regulations and processes for prescribing medicinal cannabis through the Special Access Scheme and Authorised Prescriber pathways.

Recommendation 7

3.107 The committee recommends that the Therapeutic Goods Administration immediately clarify the clinical justification requirements of Special Access Scheme Category B in its instructions to prescribers.

Recommendation 8

3.109 The committee recommends that the Department of Health make amendments to the Special Access Scheme Category B pathway to allow for approval of:

- multiple medicinal cannabis products in a single application; and/or
- medicinal cannabis as a class of drug for the treatment of a patient for a particular indication.

Recommendation 9

3.113 The committee recommends that the Department of Health modify the operation of the Authorised Prescriber scheme for health professionals seeking to prescribe medicinal cannabis to ensure that:

- completion of an accredited medicinal cannabis course be a requirement to obtain Authorised Prescriber status;
- relevant specialist colleges be resourced to grant Authorised Prescriber status to their members;
- the pathway to authorised prescriber status through the National Institute of Integrative Medicine be clarified and communicated to doctors; and
- authority be granted to prescribe all medicinal cannabis products, rather than on a product-by-product basis.

Recommendation 10

3.156 The committee recommends that the COAG Health Council develop a National Framework for Medicinal Cannabis Access to set out goals for further harmonisation of Commonwealth, state and territory legislation to ensure that there are appropriate, clear and consistent regulatory pathways for accessing medicinal cannabis in Australia into the future.

Recommendation 11

3.158 The committee recommends that the Tasmanian Government immediately join all other jurisdictions in participating in the Therapeutic Goods Administration's single national online application pathway for accessing unregistered medicinal cannabis and reducing state-based requirements for medicinal cannabis approval.

Recommendation 12

4.55 The committee recommends that the Therapeutic Goods Administration, as a matter of priority, conduct broad public consultation on the future scheduling of cannabidiol and other non-psychoactive cannabinoids.

Recommendation 13

4.58 The committee further recommends that, as soon as practicable after a safety review and public consultation process is completed, the Department of Health make any appropriate application to the Advisory Committee on Medicines Scheduling in relation to the down-scheduling or de-scheduling of cannabidiol and other non-psychoactive cannabinoids.

Recommendation 14

4.112 The committee recommends the Australian Government immediately review the resourcing and staffing levels of the Office of Drug Control to ensure licence applications are processed without delays.

Recommendation 15

4.115 The committee recommends the Australian Government support the World Health Organization Expert Committee on Drug Dependence's recommendations for changes to the scheduling of cannabis and cannabis-related substances in international drug control conventions.

Recommendation 16

4.116 The committee recommends the Department of Health, through the Therapeutic Goods Administration and the Office of Drug Control, continue to monitor how any future changes to Australia's obligations under international drug control conventions can facilitate streamlining regulations relating to the scheduling, approval, manufacture and handling of cannabis.

Recommendation 17

5.92 The committee recommends that the Medicare Benefits Scheme Review Taskforce accept the General Practice and Primary Care Clinical Committee's recommendation to introduce a 'Level E' consultation item for general practice consultations of 60 minutes or longer, and includes this item in recommendations to the Australian Government relating to changes to Medicare Benefits Scheme items for primary care.

Recommendation 18

5.100 The committee recommends that medicinal cannabis industry peak bodies, such as Medicinal Cannabis Industry Australia and the Medical Cannabis Council, work with their members to implement compassionate pricing models for patients facing significant financial hardship in accessing medicinal cannabis products to treat their health conditions.

Recommendation 19

5.103 The committee recommends that, until medicinal cannabis products are subsidised through the Pharmaceutical Benefits Scheme, the Australian Government:

- investigate the establishment of a Commonwealth Compassionate Access Subsidy Scheme for medicinal cannabis, in consultation with industry and based on the best available evidence of efficacy for certain conditions; and
- encourage all states and territories, through the COAG Health Council, to expand the provision of their own Compassionate Access Schemes to patients requiring treatment with medicinal cannabis.

Recommendation 20

5.107 The committee recommends that the Australian Government, through COAG, encourage a review of state and territory criminal legislation in relation to:

- amnesties for the possession and/or cultivation of cannabis for genuine self-medication purposes; and
- current drug driving laws and their implications for patients with legal medicinal cannabis prescriptions.

Chapter 1

Introduction

- 1.1 Over the past decade, there has been an increasing demand for access to medicinal cannabis by patients and their families. As the social and political debate intensified in the 2010s, Commonwealth, state and territory governments passed legislation to facilitate and regulate greater access to medicinal cannabis.
- 1.2 However, anecdotal evidence strongly suggests that many patients still struggle to access medicinal cannabis. Understanding and addressing the current barriers to patient access to medicinal cannabis are at the core of this inquiry.

Purpose of the inquiry

- 1.3 The inquiry was referred to the committee on 14 November 2019. The committee was tasked to examine the current barriers to patient access to medicinal cannabis, including:
 - the current regulatory regime to access medicinal cannabis and the interactions between state and territory and the Commonwealth schemes;
 - Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;
 - the education and training of health practitioners and sources of information about access to medicinal cannabis;
 - the domestic regulated medicinal cannabis industry;
 - the delays in accessing medicinal cannabis products;
 - the financial barriers to accessing medicinal cannabis treatment and the appropriateness of the Pharmaceutical Benefits Scheme for subsidising patients;
 - the unregulated supply of medicinal cannabis and its impacts;
 - the impacts of current barriers on the wellbeing of patients; and
 - any other related matters.¹

Report structure

- 1.4 This report is comprised of five chapters:

¹ The full terms of reference are available at p. xi of this report and on the committee's website: www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Medicinalcannabis/Terms_of_Reference.

- this chapter (Chapter 1) outlines the context and administration of the inquiry, and provides background information on medicinal cannabis and its regulatory framework;
- Chapter 2 examines the range of issues related to the knowledge, attitudes and education of health professionals in relation to medicinal cannabis and its access for patients;
- Chapter 3 discusses the adequacy of the current regulatory regime and its access pathways;
- Chapter 4 focuses on product regulations and supply; and
- Chapter 5 discusses other key barriers to patient access to medicinal cannabis, including costs of products, car driving regulations and issues related to reliance on the black market.

Conduct of the inquiry

- 1.5 The committee received 146 submissions to the inquiry from individuals and organisations. These submissions are listed in Appendix 1.
- 1.6 The committee also conducted a public hearing on 29 January 2020 in Melbourne.
- 1.7 Transcripts from the hearing, together with submissions and answers to questions on notice are available on the committee's website. Witnesses who appeared at the hearing are listed in Appendix 2.

Acknowledgements

- 1.8 The committee would like to thank the individuals and organisations that made written submissions to the inquiry, as well as those who gave evidence at the public hearing. We are grateful for their time and expertise.

Note on terminology and references

- 1.9 References to submissions in this report are to individual submissions received by the committee and published on the committee's website. References to Committee Hansard are to official transcripts.

Medicinal cannabis

- 1.10 Cannabis is a genus of flowering plants that contain a number of carbon alkaloids called cannabinoids. The plant contains over 500 compounds (cannabinoids), including 120 phytocannabinoids. The two most important naturally occurring cannabinoids that have medicinal qualities are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a psychotropic substance (or intoxicant), while CBD is non-psychoactive.²

² Department of Health, *Review of the Narcotic Drugs Act 1967*, Final report, 10 July 2019, p. 17.

1.11 Different strains of cannabis contain different quantities and types of cannabinoids and may offer different therapeutic benefits and/or psychoactive profiles.³

Medicinal uses

1.12 Cannabinoids have been found to have anti-emetic (anti-vomiting), analgesic (pain relieving), neuroprotective and anti-inflammatory effects.⁴

1.13 There is no predetermined list of conditions for which a cannabis medicine can be prescribed in Australia. According to the Department of Health, patients want to access medicinal cannabis to treat and/or alleviate symptoms associated with numerous health conditions, including most commonly for:

- epilepsy in children and adult patients;
- multiple sclerosis;
- chronic non-cancer pain;
- chemotherapy-induced nausea and vomiting in cancer; and
- palliative care.⁵

The role of the Therapeutic Goods Administration (TGA)

1.14 The Therapeutic Goods Administration (TGA), part of the Commonwealth Department of Health, administers the *Therapeutic Goods Act 1989* (TG Act). The TG Act establishes the Australian regulatory framework for all therapeutic goods, including medicines.⁶

1.15 TGA's remit relevant to medicinal cannabis includes scheduling, product registration, unapproved access pathways and quality standards.⁷

Scheduling of medicines

1.16 Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into 'schedules' in the Uniform Scheduling of Medicines and Poisons (Poison Standard) according to the risk of harm and the level of access control required to protect health and safety.⁸

³ Mills Oakley, *Submission 61*, p. 2.

⁴ F Grotenhermen and K Muller-Vahl, *The therapeutic potential of cannabis and cannabinoids*, *Deutsches Arzteblatt International*, vol. 109, no. 29–30, 2012, pp. 495–501, <https://doi.org/10.3238/arztebl.2012.0495>.

⁵ Department of Health, TGA, *Medicinal cannabis products: Patient information*, 29 May 2018.

⁶ Department of Health, *Access to medicinal cannabis products*, www.tga.gov.au/access-medical-cannabis-products-1 (accessed 11 February 2020).

⁷ Department of Health, *Submission 10*, p. 5.

⁸ Department of Health, *Submission 10*, p. 5.

Cannabis scheduling

- 1.17 Cannabis for medicinal purposes currently falls under two schedules of the Poisons Standard in Australia: Schedule 4 – Prescription Only Medicine, and Schedule 8 – Controlled Substances.
- 1.18 Cannabis and THC for purposes other than those listed in Schedules 4 and 8, except where occurring naturally in minute amounts in hemp fibre or oil products, are still classed as Schedule 9 – Prohibited Substances.⁹

Schedule 4 – Prescription Only Medicine

- 1.19 Schedule 4 drugs can be accessed with a prescription from someone who is authorised to prescribe the drug in that state or territory.
- 1.20 CBD preparations, where CBD makes up at least 98 per cent of the cannabinoid in the product, have been listed in Schedule 4 since 2015. These CBD preparations generally include oils, liquids, sprays or gels, and may be manufactured in Australia or imported from overseas.¹⁰

Schedule 8 – Controlled Substances

- 1.21 Schedule 8 drugs are 'substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence'.¹¹
- 1.22 Medicinal cannabis products in Schedule 8 include:
- cannabis (including seeds, extracts, resins and the plant or any part of the plant) and THC (when extracted from cannabis) when prepared or packed for human therapeutic use in accordance with the *Narcotic Drugs Act 1967* and the TG Act; and
 - the manufactured drugs nabiximols (brand name Sativex), nabilone (Cesamet, Canemes), and dronabinol (Marinol, Syndros).¹²

Registration of medicines

- 1.23 Generally, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG). For a prescription medicine to be registered in the ARTG, a sponsor of the product (usually a pharmaceutical

⁹ Poisons Standard December 2019; Department of Health, *Access to medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 11 February 2020).

¹⁰ Department of Health, *Scheduling of medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 12 February 2020).

¹¹ Poisons Standard December 2019, introduction.

¹² Department of Health, *Scheduling of medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 12 February 2020).

company) is required to submit evidence on the clinical efficacy, safety and manufacturing quality for evaluation by the TGA.¹³

- 1.24 Any Schedule 4 or 8 medicinal cannabis product which is included in the ARTG can be prescribed by a registered medical practitioner, subject to state and territory law, without any additional approval from the TGA.
- 1.25 Nabiximols (Sativex), a treatment for spasticity in certain patients with multiple sclerosis, is the only medicinal cannabis product currently included in the ARTG.¹⁴

Access pathways for medicinal cannabis

- 1.26 Under the provisions of the TG Act, the TGA administers a number of mechanisms to enable access to 'unapproved' therapeutic goods, which are not registered on the ARTG. These mechanisms include the Special Access Scheme (SAS), the Authorised Prescriber (AP) pathway and access through clinical trials.¹⁵

Special Access Scheme (SAS) pathways

- 1.27 The SAS provides a pathway for prescribers to access unapproved products for individual patients on a case-by-case basis. It is the responsibility of the prescriber making the application to specify for which indication they are intending to use the unapproved medicinal cannabis product.¹⁶

SAS Category A

- 1.28 SAS Category A (SAS-A) allows a registered medical practitioner to access and prescribe an unapproved medicinal cannabis product for a patient who is seriously ill.
- 1.29 'Seriously ill' is defined as having a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment, and is determined by the patient's medical practitioner.¹⁷

SAS Category B

- 1.30 SAS Category B (SAS-B) is an application pathway through which a registered health practitioner applies to the TGA for approval to prescribe an unapproved medicinal cannabis product for a patient under their care.

¹³ Department of Health, *Submission 10*, p. 5.

¹⁴ Department of Health, *Submission 10*, p. 10.

¹⁵ Department of Health, *Submission 10*, p. 5.

¹⁶ Department of Health, *Access to medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 11 February 2020).

¹⁷ Department of Health, *Submission 10*, p. 10.

- 1.31 The applicant must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the ARTG are not suitable for treatment of the patient.¹⁸
- 1.32 The majority of medicinal cannabis being prescribed in Australia is through SAS-B.¹⁹
- 1.33 At 31 January 2020, the TGA has approved over 31 000 SAS-B applications for unapproved medicinal cannabis products. The number of approvals per month has steadily increased since 2018.²⁰

Authorised Prescriber (AP) pathway

- 1.34 Under the AP pathway, the TGA is able to grant a medical practitioner the authority to prescribe a specified unapproved medicinal cannabis product for particular conditions to a class of patients in their immediate care.²¹
- 1.35 A medical practitioner applying to be an AP must seek either approval for their application from an ethics committee or endorsement from a specialist college, who will assess not only the safety of the cannabis product for the condition, but also the suitability of the medical practitioner.²²
- 1.36 Once a medical practitioner becomes an AP they are not required to notify the TGA each time they prescribe the unapproved product, but they must report to the TGA the number of patients treated with the unapproved product every six months.²³

Clinical Trial Notification (CTN) scheme

- 1.37 The TGA regulates the use of medicinal cannabis supplied in clinical trials in Australia via the CTN scheme.
- 1.38 CTN only involves a notification to the TGA. A human research ethics committee is responsible for the review and approval of trial protocols as well as for monitoring the conduct of trials.²⁴

¹⁸ Department of Health, *Submission 10*, p. 10.

¹⁹ Department of Health, *Submission 10*, p. 10.

²⁰ Department of Health, *Access to medicinal cannabis products*, 17 February 2020, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 18 February 2020).

²¹ Department of Health, *Submission 10*, p. 11.

²² Department of Health, *Authorised prescribers*, www.tga.gov.au/obtaining-approval-human-research-ethics-committee-or-endorsement-specialist-college (accessed 11 February 2020).

²³ Department of Health, *Submission 10*, p. 11.

²⁴ Department of Health, *Submission 10*, p. 11.

The role of the Office of Drug Control (ODC)

- 1.39 The *Narcotic Drugs Act 1967* (ND Act) and the Narcotic Drug Regulations 2016 provide the framework for a licensing and permit scheme regulating the cultivation and production of medicinal cannabis for research purposes or for medicinal use, as well as for manufacturing medicinal cannabis products.²⁵
- 1.40 The Office of Drug Control (ODC), part of the Commonwealth Department of Health, receives and assesses applications for licenses and permits. There are three types of licence:
- medicinal cannabis licence, authorising cultivation or production or both;
 - cannabis research licence, authorising a similar process for research purposes; and
 - manufacturing licence, authorising the manufacture of a drug or product.²⁶
- 1.41 The licensee needs to hold the relevant permit(s) issued under the ND Act before any cultivation or production commences.²⁷
- 1.42 Provided domestic supply is not affected, the export of medicinal cannabis is permitted under the following conditions:
- where medicinal cannabis products are manufactured in Australia under a Good Manufacturing Practice (GMP) licence;
 - where medicinal cannabis products are listed as export-only, or registered, on the ARTG; and
 - where extracts of cannabis (or extracts of cannabis resin) are manufactured under an ND Act licence and are not in the final dosage form.²⁸

The role of state and territory governments

- 1.43 States and territories, as regulators of the prescribing and pharmacy supply of prescription medicines, are responsible for controlling medicines within their jurisdiction in accordance with their own drugs and poison regulations.²⁹
- 1.44 Each state and territory therefore has the power to implement its own regulatory requirements for supply of medicinal cannabis products, which has resulted in different prescribing and authorisation requirements.³⁰ Table 1.1

²⁵ Department of Health, *Submission 10*, p. 11.

²⁶ Department of Health, *The Office of Drug Control – Medicinal cannabis*, www.odc.gov.au/medicinal-cannabis (accessed 17 February 2020).

²⁷ Department of Health, *Submission 10*, p. 12.

²⁸ Department of Health, *The Office of Drug Control – Import and export*, www.odc.gov.au/import-and-export (accessed 17 February 2020).

²⁹ Department of Health, *Submission 10*, p. 24.

³⁰ Department of Health, *Submission 10*, p. 25.

provides an overview of the jurisdictional requirements for prescribing medicinal cannabis.

Table 1.1 Jurisdictional requirements for prescribing medicinal cannabis

Jurisdiction	Prescriber eligibility	Authorisation requirements	Other considerations
Australian Capital Territory (ACT)	Any registered medical practitioner, but GPs may require specialist support	Applications from specialists for certain indications may be approved; applications for other conditions require clinical justification and may be referred to Medicinal Cannabis Medical Advisory Panel for advice	Requirements must be met if dispensing or supply occurs in the ACT
New South Wales (NSW)	Any registered medical practitioner	Authorisation required to prescribe or supply Schedule 8 medicine (S8) if patient is drug dependent (incl. treated under the Opioid Treatment Program); exemption is required for S8 if patient is aged under 16 years	Requirements must be met if prescribing or supply occurs in NSW
Northern Territory (NT)	Any registered medical practitioner	No requirements for prescriber authorisation; notification required if prescribing S8 for more than 8 weeks	S8 prescription must be written and dispensed in the NT
Queensland (Qld)	Any registered medical practitioner	Instrument of approval required for any S8 if health professional is not a specialist, or if patient is drug dependent	Only lawful to possess if health professional has Qld approval
South Australia (SA)	Any registered medical practitioner	Authority required to prescribe any S8 for longer than 2 months, unless patient is aged over 70 years or a notified	Authority required if prescriber practice location is in

		palliative care patient	SA
Tasmania (Tas)	Specialists only	Authorisation required for S4 and S8 cannabis medicines; all applications on case-by-case basis by panel of expert clinicians and dispensed from Tas Health Service pharmacies only	Where authorisation issued, prescription is to be written and dispensed in Tas according to the requirements of the Medical Cannabis Controlled Access Scheme
Victoria (Vic)	Any registered medical practitioner	Authorisation permit required for S8; exemptions from requirements for certain cohorts of patients	Requirements to be met if prescriber practice location is in Vic
Western Australia (WA)	Any registered medical practitioner	Authorisation permit required for cannabis-based S8	Authorisation required if dispensing or supply occurs in WA

Source: Adapted from Department of Health, *Submission 10*, pp. 25–26.

SAS online system

- 1.45 The Commonwealth, states and territories have worked to streamline access to medicinal cannabis products by agreeing to a TGA online portal through which a single application can be lodged by a medical practitioner for the SAS and relevant state/territory approval where required.³¹
- 1.46 Currently all states and territories except Tasmania are participating in the SAS online system, and approvals from relevant jurisdictions are issued to practitioners within two working days of the application.³²

³¹ Department of Health, *Access to medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 17 February 2020).

³² Department of Health, *Submission 10*, p. 26.

1.47 Tasmania operates its own medicinal cannabis approval process, which still requires separate applications to the Commonwealth and to the Tasmanian Department of Health and Human Services.³³

³³ Department of Health, *Access to medicinal cannabis products*, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 17 February 2020).

Chapter 2

Education and information

- 2.1 The committee heard that the first hurdle in a patient's journey to access medicinal cannabis is to find a medical practitioner who is knowledgeable about medicinal cannabis, understands how to prescribe it, and who has an understanding of the range of products available.¹
- 2.2 As pointed out by the Medical Cannabis Knowledge Network, the role of health practitioners is fundamental and unavoidable:
- ... unless Parliament can be persuaded that a formal doctor's prescription should not be the avenue through which cannabis products are made available ... then regardless of what arrangement is employed to facilitate access administratively speaking, the decision-making of doctors remains the sole route by which such products may legally be obtained.²
- 2.3 The committee received considerable evidence in relation to health practitioners refusing to prescribe medicinal cannabis to patients.³ The reasons for refusing to prescribe medicinal cannabis are explored throughout this chapter and broadly reflect a lack of education about medicinal cannabis and a lack of knowledge about the process to prescribe it.
- 2.4 The chapter first examines the issues related to health practitioners' limited knowledge of medicinal cannabis. It then discusses the adequacy of the training available to health professionals in relation to medicinal cannabis.
- 2.5 The second part of the chapter discusses the appropriateness of the information made available to patients and health professionals in relation to the process to prescribe medicinal cannabis, the range of products available, and likely costs to patients.

¹ See, for example, United in Compassion, *Submission 6*, pp. 4–5; Ms Carol Ireland, Chief Executive Officer and Managing Director, Epilepsy Action Australia, *Committee Hansard*, 29 January 2020, p. 8; Mrs Lucy Haslam, Director, United in Compassion Ltd, *Committee Hansard*, 29 January 2020, p. 5; Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6.

² Medical Cannabis Knowledge Network, *Submission 13*, p. 2.

³ See, for example, Australian Pain Management Association, *Submission 32*, p. 9; Name Withheld, *Submission 60*, p. 2; Medical Cannabis Users Association of Australia, *Submission 9*, p. 20; Name Withheld, *Submission 42*, p. 1; Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6.

Education about medicinal cannabis

- 2.6 Submitters were of the view that most health practitioners lack knowledge in relation to medicinal cannabis.⁴
- 2.7 At a public hearing in Melbourne, Professor Iain McGregor, Academic Director at the Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative), gave an account of the findings of a survey of general practitioners (GPs) conducted by the organisation in 2018:
- A clear majority were in favour of having medicinal cannabis as an option that they could prescribe, but they did not feel comfortable talking to their patients about it, because they didn't feel well educated ... they want to have it in their doctor's bag, if you will, but they feel uneducated.⁵
- 2.8 In addition to a general lack of knowledge about medicinal cannabis, doubts about the efficacy and safety of medicinal cannabis, the view that medicinal cannabis should be only prescribed as a last-line therapy, and the ongoing stigma attached to cannabis make it difficult for patients and medical practitioners to discuss the use of medicinal cannabis as part of a treatment plan. This this often results in patients leaving their doctors' surgery without a prescription.⁶

Medical cannabis efficacy

- 2.9 The contentious issue of the efficacy of medicinal cannabis was mentioned on numerous occasions as a reason for health practitioners to be reluctant or refuse to prescribe medicinal cannabis to their patients.⁷
- 2.10 The Australian Pain Management Association reported that some patients advised them that their GPs had refused to prescribe them medicinal cannabis because there was 'no evidence of its efficacy'.⁸

⁴ See, for example, Mr Michael Balderstone, President, Nimbin HEMP Embassy, *Committee Hansard*, 29 January 2020, p. 19; Dr Christina Xinos, Medical Director, Australia and New Zealand, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 53; Associate Professor Kate Sear and Springvale Monash Legal Service, *Submission 21*, p. 14; Ms Dianah Walter, *Submission 76*, p. 2.

⁵ Professor Iain McGregor, Academic Director, Lambert Initiative, *Committee Hansard*, 29 January 2020, p. 24.

⁶ See, for example, Ms Dianah Walter, *Submission 76*, p. 2; Australian Pain Management Association, *Submission 32*, p. 5; Australian Pain Management Association, *Submission 32*, p. 5; New South Wales Nurses and Midwives' Association, *Submission 118*, pp. 11–12.

⁷ See, for example, Pain Australia, *Submission 129*, p. 4; Name Withheld, *Submission 72*, p. 2; Dr Harry Nespolon, President, Royal Australian College of General Practitioners (RACGP), *Committee Hansard*, 29 January 2020, p. 31.

⁸ Australian Pain Management Association, *Submission 32*, p. 5.

- 2.11 A patient who participated in the inquiry also mentioned that he had dealt with GPs and specialists who did not want to prescribe cannabis because there was not enough evidence.⁹
- 2.12 Dr Harry Nespolon, President of the Royal Australian College of General Practitioners (RACGP) explained that some GPs are unwilling to prescribe because of their concerns about the lack of evidence for the use of medicinal cannabis:
- There are a lot of GPs who don't want to prescribe, because they don't believe that medicinal cannabis does have enough evidence behind it for them to be prescribing it for their patients.¹⁰
- 2.13 In their submission, Professors Wayne Hall and Michael Farrell, cited a research paper published in the *Medical Journal of Australia* in 2018, which identified 'the absence of good evidence of safety and efficacy as a major reason why many medical practitioners are reluctant to prescribe cannabis-based medicines'.¹¹
- 2.14 Pain Australia acknowledged that the lack of evidence about suitable doses of individual cannabis products 'makes it difficult for practitioners to prescribe, despite community expectations that these products will be made available to treat chronic pain'.¹²
- 2.15 The Australian Medical Association (AMA) is of the view that 'for medicinal cannabis to be taken up by more medical practitioners, we must have a clinical, evidence base'.¹³
- 2.16 While this report will not attempt to provide the definitive compilation of evidence for the efficacy of medicinal cannabis as a treatment for many conditions, there is substantial evidence available from around the world to that effect, which should be made available for prescribing doctors to consider.

Treatment of last resort

- 2.17 The view that medicinal cannabis should be used as a treatment of last resort was mentioned as an additional barrier to health practitioners considering prescribing medicinal cannabis.¹⁴

⁹ Name Withheld, *Submission 72*, p. 2.

¹⁰ Dr Nespolon, RACGP, *Committee Hansard*, 29 January 2020, p. 31.

¹¹ Professors Wayne Hall and Michael Farrell, *Submission 68*, p. 4.

¹² Pain Australia, *Submission 129*, p. 4.

¹³ Australian Medical Association, Answers to questions on notice, received 5 February 2020, p. 1.

¹⁴ See, for example, Medicinal Cannabis Industry Australia, *Submission 5*, p. 3; United in Compassion, *Submission 6*, Attachment 2, p. 38; Australasian College of Nutritional and Environmental Medicine, *Submission 29*, p. 5.

- 2.18 As further discussed in Chapter 3 of this report, this view stems from the interpretation of the guidance for accessing unregistered medicines through the Special Access Scheme (SAS), which states that health practitioners 'will have considered all appropriate treatment options before considering accessing an unapproved medicine under the SAS for their patients'.¹⁵
- 2.19 For example, a patient with chronic pain reported that 'doctors are told that cannabis should only be prescribed once all other avenues have been exhausted, that it should be a last ditch attempt for people living with chronic pain, cancer and other disability'.¹⁶
- 2.20 Mrs Joylene Donovan, the mother of a child born with Dravet Syndrome, is of the view that 'the attitude of our medical profession is that you will only be considered for cannabis once you have failed all other options' and added:
- I believe our daughter has the right to all treatments on offer, as we choose, and that cannabis should not be a last option treatment but one of the treatments available to try.¹⁷

Stigma

- 2.21 Mr Justin Sinclair, Research Fellow at the National Institute of Complementary Medicine Health Research Institute, and other submitters identified the stigma and prejudice associated with cannabis as a key barrier to patient access.¹⁸
- 2.22 In their submission, Associate Professor Kate Seear and Springvale Monash Legal Service noted 'with disappointment' reports of 'persistent stigmatising attitudes held by some doctors'.¹⁹
- 2.23 A patient with chronic conditions reported his experience with his GP when he tried to discuss the suitability of medicinal cannabis:
- He is dismissive, uneducated and displays the well-entrenched perspective promulgated that cannabis is addictive and usually results in the emergence of psychological conditions and poor mental health. Thus, in the case of my GP, and his peers at the clinic I attend, medical practitioners in the Ballarat region dispense prejudice as opposed to informed advice.²⁰

¹⁵ Department of Health, *Special Access Scheme: Guidance for health practitioners and sponsors*, Version 1.1, September 2017, www.tga.gov.au/special-access-scheme-guidance-health-practitioners-and-sponsors (accessed 23 February 2020).

¹⁶ Name Withheld, *Submission 96*, p. 2.

¹⁷ Mrs Joylene Donovan, *Submission 80*, p. 2.

¹⁸ See, for example, Mr Justin Sinclair, Research Fellow, National Institute of Complementary Medicine Health Research Institute, *Committee Hansard*, 29 January 2020, p. 37; New South Wales Nurses and Midwives' Association, *Submission 118*, pp. 11–12.

¹⁹ Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 14.

²⁰ Name Withheld, *Submission 56*, p. 2.

Impacts on patients

2.24 The Alcohol and Drug Foundation pointed out that stigma about medicinal cannabis and its relationship to illicit drug use may impact on patients who are legitimately prescribed cannabis, and added:

The impact of stigma and discrimination towards people cannot be understated. While it is illegal to promote the use of any Schedule 4 or 8 medication, appropriate information given to patients to share with others may be of use to help reduce this stigma.²¹

Need for targeted campaigns to reduce stigma

2.25 The Queensland Nurses and Midwives' Union is of the view that education and public awareness campaigns will assist in reducing the stigma around medicinal cannabis and demonstrating that medicinal cannabis products are not illegal and may be suitable as part of a treatment plan.²²

2.26 A patient shared a similar view and believes that the development of a Department of Health public campaign would remove the stigma and encourage GPs to start prescribing medicinal cannabis.²³

2.27 Epilepsy Action Australia also recommended that funding education materials for healthcare consumers and professionals would 'demystify' medicinal cannabis for Australians.²⁴

Training

2.28 Inquiry participants identified a critical need to train health professionals.²⁵ As Mr Justin Sinclair from the National Institute of Complementary Medicine Health Research Institute pointed out, a lot of doctors have not had any training in the endocannabinoid system during their studies:

I gave a talk at a hospital in Queensland late last year where I asked everyone in attendance—some 130 nurses, doctors, et cetera—whether they had had any training in the endocannabinoid system during their undergraduate training, and not one hand was raised.²⁶

²¹ Alcohol and Drug Foundation, *Submission 26*, p. 8.

²² Queensland Nurses and Midwives' Union, *Submission 20*, p. 3.

²³ Name Withheld, *Submission 49*, p. 2.

²⁴ Epilepsy Action Australia, *Submission 22.1*, p. 1.

²⁵ See, for example, Dr Xinos, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 53; New South Wales Nurses and Midwives' Association, *Submission 118*, p. 12; Alcohol and Drug Foundation, *Submission 26*, p. 5.

²⁶ Mr Sinclair, National Institute of Complementary Medicine Health Research Institute, *Committee Hansard*, 29 January 2020, p. 37.

Training available

- 2.29 According to United in Compassion, there are only three RACGP accredited training courses about medicinal cannabis for healthcare professionals.²⁷
- 2.30 Professor Kylie O'Brien, Member of the Australasian College of Nutritional and Environmental Medicine (ACNEM), told the committee that ACNEM was running a two-day course about medicinal cannabis but could only offer it twice a year because of funding constraints:
- Twice a year at the moment, and that's really just because we're all not-for-profit organisations, so we don't have any government backing on this, so we actually rely on sponsorship from some of the medicinal cannabis companies, and nutritional medicine companies as well, to be able to run these things.²⁸
- 2.31 Professor O'Brien added that other options available include 'fairly clunky' online courses from the US, which is why ACNEM is currently developing some online modules about medicinal cannabis and its applications.²⁹
- 2.32 Epilepsy Action Australia contended that 'in the absence of a government lead [sic] medical education program, smaller entities have attempted to fill this gap with seminars and conferences of variable quality'.³⁰

Training needs

- 2.33 Submitters advocated for the development and delivery of training and education on medicinal cannabis to enable health practitioners to relay informed advice to their patients regarding the use, applications, side effects and costs of medicinal cannabis.³¹
- 2.34 Dr Christina Xinos, Medical Director at Canopy Growth Australia, is of the view that more training options should be developed, including a peer-to-peer mentorship program and added:

And we can also learn from other countries. The New Zealand Ministry of Health has budgeted to facilitate education for GPs, and we think that Australia should follow suit.³²

²⁷ United in Compassion, *Submission 6*, Attachment 2, p. 37.

²⁸ Professor Kylie O'Brien, Member, Australasian College of Nutritional and Environmental Medicine, *Committee Hansard*, 29 January 2020, p. 38.

²⁹ Professor O'Brien, Australasian College of Nutritional and Environmental Medicine, *Committee Hansard*, 29 January 2020, p. 38.

³⁰ Epilepsy Action Australia, *Submission 22*, p. 8.

³¹ See, for example, Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 14; Mills Oakley, *Submission 61*, p. 18; Epilepsy Action Australia, *Submission 22*, p. 8.

³² Dr Xinos, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 54.

2.35 Entoura submitted that the availability of high-quality education via Continuing Professional Development conducted by independent not-for-profit organisations such as ACNEM should be expanded and supported through government funding.³³

Universities and colleges

2.36 The Medical Cannabis Council and other submitters recommended that modules on the endocannabinoid system and medicinal cannabis be included in medical, nursing and pharmacy courses at colleges and universities.³⁴

2.37 The Lambert Initiative pointed out that the training of doctors should not be left to the medicinal cannabis industry:

We need to better weave medicinal cannabis education into the syllabus of current medical degrees, and not simply leave the medicinal cannabis industry, with its inherent conflict of interest, to educate our doctors.³⁵

Information about accessing medicinal cannabis

2.38 Both patients and health practitioners mentioned the lack of information on the process to access medicinal cannabis as a significant barrier for medical practitioners to prescribe medicinal cannabis.³⁶

2.39 At present, it appears that the main source of information on how to access medicinal cannabis is the TGA website.

2.40 In an effort to assist GPs and their patients, the RACGP advised the committee that it has developed a 'prescribing medicinal cannabis products' checklist to assist with the TGA and state and territory governments' approval processes.³⁷

Patients' perspectives

2.41 A submitter who was interested in cannabis oil to treat his chronic pain told the committee:

I was overwhelmed by the lack of information available for people interested in seeking out alternative medical treatments. I went around in circles for days and did not find anything that got me any closer to the process.³⁸

³³ Entoura, *Submission 25*, pp. 4–5.

³⁴ See, for example, Medical Cannabis Council, *Submission 37*, p. 10; Entoura, *Submission 25*, p. 4; Ms Dianah Walter, *Submission 76*, p. 4.

³⁵ Lambert Initiative, *Submission 36*, p. 6.

³⁶ See, for example, Mr Mark Thomas, *Submission 106*, p. 2; Australian Medical Association, *Submission 24*, p. 4.

³⁷ RACGP, *Submission 11*, p. 1.

³⁸ Name Withheld, *Submission 96*, p. 1.

2.42 Due to the lack of information on how to access medicinal cannabis, Mr Mark Thomas, a young veteran residing in the Northern Territory, sought out a clinical education session delivered by the Northern Territory Chief Health Officer to understand the process:

The session ... began with [the doctor] joking he had illegal cannabis in a pouch on stage. This set the tone for the presentation and trivialised the clinical benefits of medicinal cannabis and did not provide clinical pathways or [the] ability to find prescribers in the NT.³⁹

2.43 A patient reported that his doctors, whilst being supportive of trying medicinal cannabis, did not want to prescribe it as they were not familiar with the TGA application process and felt it was too complicated.⁴⁰

2.44 Another patient pointed out that some doctors are confused about the process and eligibility criteria for access to medicinal cannabis:

I was told by my doctor that legal medicinal cannabis can only be prescribed to cancer sufferers, where I think that is not correct.⁴¹

Health practitioners' perspectives

2.45 Health professionals mentioned their lack of adequate knowledge of the access pathways to prescribe cannabis as a key barrier to discussing medicinal cannabis with patients and prescribing it.⁴²

2.46 The Australian and New Zealand Society of Palliative Medicine suggested that there were issues around the quality, availability and suitability of the TGA guidance documents, and many doctors have had limited interface with the TGA pathways in their day-to-day work.⁴³

2.47 The RACGP and other submitters also noted particular concerns about the difficulty for practitioners in understanding the variations in prescribing requirements in each state and territory.⁴⁴

Development of resources

2.48 The RACGP is of the view that there is a need for the ongoing development of resources on the legislative and clinical aspects of prescribing cannabis

³⁹ Mr Mark Thomas, *Submission 106*, p. 2.

⁴⁰ Name Withheld, *Submission 78*, p. 1.

⁴¹ Name Withheld, *Submission 58*, p. 1.

⁴² See, for example, Professor McGregor, Lambert Initiative, *Committee Hansard*, 29 January 2020, p. 24; Dr Tamara Nation, General Practitioner, National Institute of Integrative Medicine, *Committee Hansard*, 29 January 2020, p. 36.

⁴³ Australian and New Zealand Society of Palliative Medicine, *Submission 117*, p. 3.

⁴⁴ RACGP, *Submission 11*, p. 1; Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6; FreshLeaf Analytics, *Submission 14*, p. 3.

products, as well as guidance on clear governance processes on prescribing medicinal cannabis products.⁴⁵

- 2.49 The Royal Australian and New Zealand College of Psychiatrists submitted that education and training activities about the regulation of medicinal cannabis could be facilitated and delivered by the TGA:

The TGA could provide holistic training, which addresses the relevant regulatory, medical, therapeutic and legal considerations involved in the regulation of medicinal cannabis.⁴⁶

Medicinal cannabis products

- 2.50 The lack of information on medicinal cannabis products that are available for prescribing is another barrier for both patients and health practitioners.⁴⁷
- 2.51 The AMA reported that 'some doctors expressed frustration that they are not sufficiently informed about what cannabis products are available and for what conditions'.⁴⁸
- 2.52 For example, a patient reported that he had spoken to three GPs who were willing to write a script, but the issue was that each GP did not know what product should be prescribed and said that the process was all 'too hard'.⁴⁹
- 2.53 Mr Ray Hill, a patient who has been prescribed medicinal cannabis, reported that he was unable to source any information about the likely costs of his medicine by phoning companies that supply medicinal cannabis in Australia, and concluded:

I would have liked to contact all 13 suppliers to get the best price for the medicine supplied by them but this is not possible in this country ... it is not fair to the patient seeking to lessen the burden of the costs of their legally prescribed medicine as in all other products.⁵⁰

Committee view

- 2.54 The committee heard on many occasions during the inquiry that patients had negative experiences with their GPs or specialists when they tried to discuss using medicinal cannabis as part of their treatment plan. At best, patients are not being prescribed medicinal cannabis because their clinician acknowledges their lack of knowledge about medicinal cannabis, and may refer them to a

⁴⁵ RACGP, *Submission 11*, p. 2.

⁴⁶ Royal Australian and New Zealand College of Psychiatrists, *Submission 23*, p. 1.

⁴⁷ See, for example, Dr Nespolon, RACGP, *Committee Hansard*, 29 January 2020, p. 30; Cancer Voices Australia, *Submission 34*, p. 2.

⁴⁸ Australian Medical Association, *Submission 24*, p. 4.

⁴⁹ Name Withheld, *Submission 54*, p. 1.

⁵⁰ Mr Ray Hill, *Submission 90*, p. 1.

colleague or another health practice. At worst, the committee was told that patients were simply rebuffed and felt ostracised by the negative or dismissive attitude of the clinician they consulted.

- 2.55 Alarming, the stigma attached to medicinal cannabis remains a live issue throughout the health profession. This needs to change. Trust is one of the central features of the patient–clinician relationship and is the cornerstone of good medical practice. Patients should feel comfortable discussing medicinal cannabis and treatment options with their clinicians. Patients should not feel ostracised for seeking potential medical cannabis treatments.

Recommendation 1

- 2.56 **The committee recommends that the Department of Health, in collaboration with the Australian Medical Association, the Royal Australian College of General Practitioners and other specialist colleges and health professional bodies, develop targeted education and public awareness campaigns to reduce the stigma around medicinal cannabis within the community.**
- 2.57 As noted by submitters, access to any form of medicinal cannabis in Australia is currently not possible without a script from a medical practitioner. Therefore educating medical practitioners about the endocannabinoid system and medicinal cannabis is fundamental to ensure patients can have access to medicinal cannabis treatment options.
- 2.58 The committee noted the paucity of training options available for existing health professionals. Given that GPs and other clinicians are time-poor, the committee is of the view that a range of courses, including online, should be developed to ensure medical practitioners are equipped to discuss medicinal cannabis with their patients and prescribe it when deemed appropriate.

Recommendation 2

- 2.59 **The committee recommends that the Department of Health allocate funds to relevant medical colleges and peak bodies to support the development and delivery of accredited face-to-face and online training programs on medicinal cannabis for medical practitioners.**
- 2.60 The committee believes that including modules on medicinal cannabis in the curriculum of medical degrees would ensure that doctors are equipped to discuss and respond to patients' queries and requests about medicinal cannabis. It would also contribute to eliminating the stigma around medicinal cannabis.

Recommendation 3

- 2.61 **The committee recommends that the Australian Medical Council, as part of its role in the accreditation of Australian medical education providers, make**

mandatory the inclusion of modules on the endocannabinoid system and medicinal cannabis in curriculums delivered by primary medical programs (medical schools).

- 2.62 In addition to a lack of education about medicinal cannabis and its medicinal properties, it is clear that the lack of information about the process to get a prescription and the types of products available is significantly impeding patient access. There is evidence that many patients and doctors are ignorant, confused or misinformed about the process and regulatory framework supporting access to medicinal cannabis in Australia.
- 2.63 There is an urgent need to develop information resources for both patients and health professionals. In the absence of such resources being quickly developed, patients will continue to miss out on potentially beneficial treatment options, and, worryingly, may continue to turn to the black market in a bid to access medicinal cannabis products. The issues related to the reliance on the unregulated market (black market) are discussed in Chapter 5.

Recommendation 4

- 2.64 **The committee recommends that the Department of Health commission the development of a suite of printed and online resources for patients, aimed at explaining the regulatory framework and process to access medicinal cannabis.**
- 2.65 The committee is aware that information aimed at medical practitioners about the process to prescribe medicinal cannabis is available on the TGA website. Based on the evidence received by the committee, this information is insufficient as many health professionals appear to remain unaware of these resources or do not use them. The impact of this is discussed in Chapter 3.
- 2.66 The committee noted that both patients and medical practitioners also felt that there was not enough information about medicinal cannabis products. The issues related to the manufacture, supply and dispensing of medicinal cannabis products are explored in Chapter 4.

Chapter 3

Access pathways and regulatory hurdles

Introduction

- 3.1 Access to medicinal cannabis is subject to the same access pathways as all other medicines in Australia: a combination of Commonwealth, state and territory legislation and regulations which relate to both how approved and unapproved medicines are prescribed and dispensed by health professionals to their patients.
- 3.2 As described in Chapter 1, medicinal cannabis, included in Schedules 4 and 8 of the Uniform Scheduling of Medicines and Poisons (Poisons Standard), requires a prescription from a health professional to access in all states and territories. All medicinal cannabis products, except for nabiximols (Sativex), also require some prescribing approval from the Therapeutic Goods Administration (TGA), as they are not currently approved medicines included in the Australian Register of Therapeutic Goods (ARTG).
- 3.3 As outlined in Chapter 1, the *Therapeutic Goods Act 1989* (TG Act) provides a number of mechanisms to enable access to unapproved therapeutic goods. For unapproved medicinal cannabis products, these pathways include:
- Special Access Scheme (SAS);
 - Authorised Prescriber (AP) scheme; and
 - access via clinical trials.
- 3.4 Access through each of these pathways also requires varying levels of state or territory approval, as summarised in Table 1.1.¹
- 3.5 This chapter examines the various pathways through which medicinal cannabis is accessed in Australia and the hurdles which they present to patients.
- 3.6 It also considers some of the regulatory pathways for medicinal cannabis prescription and access in other countries, and how models such as these could improve access in Australia.

Special Access Scheme

- 3.7 The SAS, which is managed by the TGA, is designed to provide prescribers with a pathway to prescribe unapproved medicines for individual patients on a case-by-case basis in 'exceptional clinical circumstances'.²

¹ See Chapter 1, pp. 8–9.

² Therapeutic Goods Administration (TGA), *Special Access Scheme*, 18 September 2019, www.tga.gov.au/form/special-access-scheme (accessed 4 February 2019).

- 3.8 There are two SAS categories relevant to medicinal cannabis, as defined in Chapter 1:
- SAS Category A (SAS-A), a notification pathway for health professionals who prescribe an unapproved medicine to a seriously ill patient; and
 - SAS Category B (SAS-B), an application pathway for health professionals who wish to prescribe an unapproved medicine to a patient who does not meet SAS-A requirements.
- 3.9 A third SAS category, Category C (SAS-C), is a notification pathway for certain therapeutic goods with an established history of use. Medicines which can be accessed through SAS-C are specified in a list with their indications and the type of health practitioner authorised to supply them. Medicinal cannabis, in any form, is not a medicine currently specified for SAS-C.³
- 3.10 Evidence received by the committee indicates that health practitioners are generally supportive of the SAS, in particular SAS-B, as the appropriate access pathway for medicinal cannabis, viewing it as a necessary clinical safeguard to ensure appropriate prescribing.⁴

Use of SAS-A

- 3.11 There appeared to be some confusion from submitters as to whether medicinal cannabis could in fact be accessed through SAS-A.⁵
- 3.12 This confusion has occurred in part due to the attempt by the Commonwealth Government to restrict the use of the SAS-A, both in their initial *Narcotic Drugs Amendment Act 2016* legalising medicinal cannabis and in a further legislative instrument which was disallowed by the Senate in 2017.
- 3.13 Due to SAS-A access to medicinal cannabis being secured by the Senate, over 360 notifications have been received by the TGA under SAS-A.⁶

Recent increase in SAS-B applications

- 3.14 As noted in Chapter 1, in 2018 the Commonwealth, states and territories (except Tasmania) streamlined access to medicinal cannabis products through

³ [Therapeutic Goods \(Authorised Supply of Medicines\) Rules 2019](#).

⁴ See, for example, Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE), *Submission 15*, p. 1; MedReleaf Australia, *Submission 18*, p. 2; Alcohol and Drug Foundation, *Submission 26*, p. 2; Pharmacy Guild of Australia, *Submission 27*, p. 2; Cann Group Limited, *Submission 30*, p. 3; Professor James Angus, *Submission 53*, [p. 2]; Clinical Oncology Society of Australia, *Submission 124*, p. 2.

⁵ See, for example, Medicinal Cannabis Council, *Submission 37*, [p. 2]; United in Compassion (UIC), *Submission 6*, p. 5. See also, Ms Lanai Carter, *Submission 136*, pp. 7–9.

⁶ Statistics available from Department of Health, *Submission 10*, p. 17; TGA, *Access to medicinal cannabis products*, 17 February 2020, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 18 February 2020).

the introduction of the TGA's SAS online system. Through this system, a single application can be lodged by a medical practitioner for both SAS-B and any relevant state or territory approvals.

3.15 The Department of Health (Department) submitted that:

Use of this online system reduces administrative burden on health practitioners and provide users with additional ability to manage their SAS applications and notifications.⁷

3.16 The Department noted that there had been 'excellent uptake' of the online system, with 91 per cent of all medicinal cannabis applications and notifications in 2019 submitted through the online system.⁸

3.17 The Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative) described that the introduction of the online system for applications has been a 'key facilitator' for improving access to medicinal cannabis in recent years.⁹ Submitters noted positive aspects of the SAS online system which have facilitated this improved access, including:

- the speed of approval, with a TGA service standard of 48-hour turn-around of applications made through the system, and a median approval time of just over one day;¹⁰ and
- the ability to make applications to the Commonwealth and to the relevant state or territory, if required, in a single form.¹¹

3.18 One patient described her positive experience of accessing medicinal cannabis through the SAS-B pathway:

I thought the process was straightforward and worked quite well. The TGA approvals occurred in a reasonable time frame and subsequent modifications to my prescription were processed without issues.¹²

3.19 Improvements in access are also evidenced in the significant increase in the number of SAS-B applications for medicinal cannabis following the introduction of the online portal in late July 2018 (see Figure 3.1).¹³

⁷ Department of Health, *Submission 10*, p. 20.

⁸ Department of Health, *Submission 10*, p. 26.

⁹ Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative), *Submission 36*, p. 3.

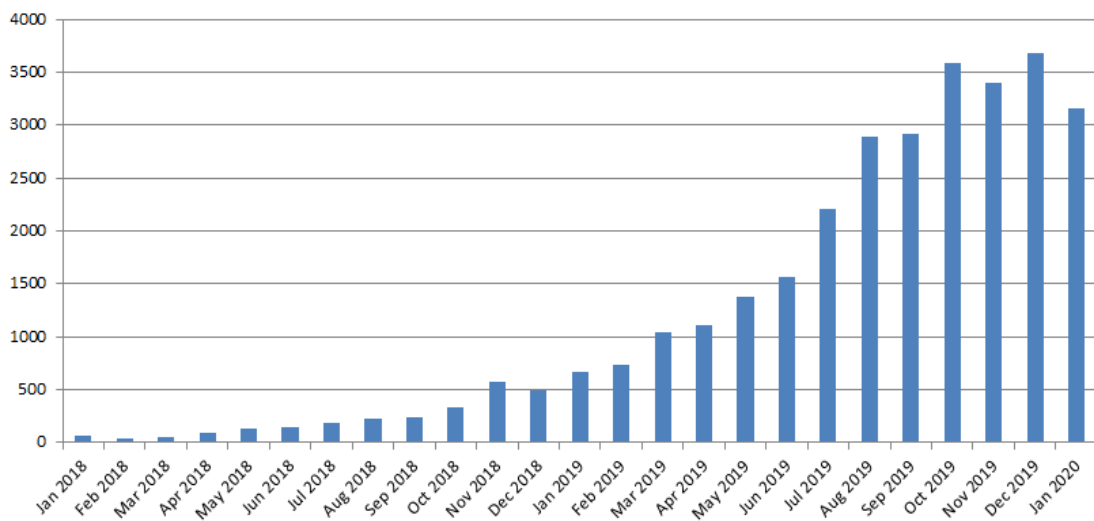
¹⁰ Lambert Initiative, *Submission 36*, p. 3; National Institute of Complementary Medicine Health Research Institute (NICM HRI), *Submission 7*, p. 4; Department of Health, *Submission 10*, p. 20; Professor Wayne Hall and Professor Michael Farrell (Hall and Farrell), *Submission 68*, p. 3.

¹¹ NICM HRI, *Submission 7*, p. 4; Lambert Initiative, *Submission 36*, p. 3; Hall and Farrell, *Submission 68*, p. 3; Professor James Angus, *Submission 53*, [p. 3].

¹² Name withheld, *Submission 82*, p. 2.

¹³ Department of Health, *Submission 10*, pp. 12–13.

Figure 3.1 Total SAS-B approvals, January 2018 to January 2020¹⁴



- 3.20 In 2019, the approximately 25 000 medicinal cannabis applications made through SAS-B represented one quarter of the total SAS-B applications made to the TGA – a significant proportion.¹⁵
- 3.21 It is important to note that the high number of SAS-B applications for medicinal cannabis does not directly correlate to the number of individual applicants accessing medicinal cannabis through this pathway, as the figure does include multiple applications for some patients. The TGA told the committee that over 19 000 patients had been granted access to medicinal cannabis through the SAS and Authorised Prescriber pathways combined.¹⁶
- 3.22 As will be discussed in Chapter 5, there is also likely to be a considerable cohort of individuals using illicit cannabis products to self-medicate who are not captured by the TGA statistics.¹⁷

Concerns about using the SAS-B pathway

- 3.23 While submitters and witnesses acknowledged that the new online system had streamlined some aspects of the SAS-B application and approval process, many still described the process as inadequate, time-consuming, unnecessarily

¹⁴ Department of Health, *Submission 10*, p. 18; TGA, *Access to medicinal cannabis products*, 17 February 2020, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 18 February 2020).

¹⁵ Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 29 January 2020, pp. 63 and 70.

¹⁶ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 70; Department of Health, *Submission 10*, pp. 13–14, 20.

¹⁷ See Chapter 5. See also, Lambert Initiative, *Submission 36*, p. 4.

complicated and a deterrent for health professionals wishing to prescribe medicinal cannabis to their patients.¹⁸

3.24 A patient told the committee:

As a patient, I feel our current regulatory regime through the TGA SAS ... is extremely inappropriate. It's stressful, tediously slow, very very expensive ... I approached 9 Doctors to get a prescription. ... Finally I found a clinic which has allowed access, but only with great financial costs. And delays. And excuses.¹⁹

3.25 In a survey of patients conducted by the Lambert Initiative shortly after the introduction of the SAS online system, 91 per cent of respondents thought that the current regulatory model for accessing medicinal cannabis did not work well and 87 per cent expressed a view that it is extremely difficult for patients to negotiate. However, this survey has not been repeated since the wider uptake of the system.²⁰

3.26 The readiness of health professionals to use the SAS-B application pathway has been raised as a key barrier to access for many patients,²¹ with LeafCann Group summarising that the efficacy of the SAS:

... is limited by the health professionals prepared to prescribe medicinal cannabis and negotiate the online application process.²²

3.27 As outlined in Chapter 2, many of the key issues affecting health professionals' willingness to use SAS-B are education-based barriers.²³

3.28 United in Compassion submitted that the SAS-B process can require 'a significant element' of research from patients and their carers because of health professionals' 'lack of motivation and knowledge' of the pathway.²⁴

Time pressures on health professionals

3.29 A significant concern appears to be the time pressures that the SAS-B pathway places on health professionals, both the time it takes to acquire the knowledge to use SAS-B and the time it takes to complete an application.²⁵

¹⁸ See, for example, Cancer Voices Australia, *Submission 34*, p. 1; Tilray, *Submission 62*, p. 4; Name withheld, *Submission 58*, p. 1; Name withheld, *Submission 102*, p. 3; Lanai Carter, *Submission 136*, p. 10.

¹⁹ Name withheld, *Submission 102*, p. 3.

²⁰ Lambert Initiative, *Submission 36*, p. 4.

²¹ See, for example, Entoura, *Submission 25*, [p. 1]; Medical Cannabis Council, *Submission 37*, p. 1.

²² LeafCann Group, *Submission 4*, p. 1.

²³ See Chapter 2, pp. 9–10.

²⁴ UIC, *Submission 6*, p. 5.

²⁵ See, for example, Dr Teresa Nicoletti, Partner, Mills Oakley; Director, Medical Cannabis Council; and Member, Australian Lawyers Alliance, *Committee Hansard*, 29 January 2020, p. 13; Mrs Lucy

3.30 The National Institute of Complementary Medicine Health Research Institute submitted that the 'extensive amount of time' required for health professionals to gain an understanding of the SAS-B process and system:

...may not suit the time poor nature of busy medical clinicians, with many simply too busy to engage in the process and/or referring patients to speciality cannabis clinics.²⁶

3.31 Submitters and witnesses described that the SAS-B application can take 20 to 45 minutes to complete, much longer than a standard consultation time for a general practitioner.²⁷

Treatment of last resort

3.32 The TGA's SAS guidance document for health practitioners and sponsors, which outlines the requirements for SAS-B applications, states that:

It is expected that the prescribing health practitioner will have considered all appropriate treatment options that are included on the ARTG and available in Australia prior to considering accessing an unapproved good under the SAS for their patient(s).²⁸

3.33 The Department submitted that it is intended that a SAS-B applicant prescriber consider available treatments and must 'provide a suitable clinical justification' for using medicinal cannabis, 'including reasons why products included in the ARTG are not suitable for treatment of the patient'.²⁹

3.34 Evidence received by the committee suggests that there is significant confusion amongst health professionals, patients and advocates about what constitutes the consideration of all appropriate treatment options prior to accessing medicinal cannabis through the SAS-B pathway, and how this information should be included in a SAS-B application.

3.35 Mills Oakley submitted that, by their understanding of the guideline, SAS applications require 'evidence that all other ARTG-entered treatment options have been tried and have failed'.³⁰

Haslam, Director, UIC, *Committee Hansard*, 29 January 2020, p. 5; Ms Carol Burford, *Submission 69*, p. 2.

²⁶ NICM HRI, *Submission 7*, p. 5.

²⁷ Mr Peter Crock, Chairman, Medicinal Cannabis Industry Australia, *Committee Hansard*, 29 January 2020, p. 60; Dr Christina Xinos, Medical Director, Australia and New Zealand, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 60. See also, Canopy Growth Australia, *Submission 31*, [p. 2].

²⁸ Department of Health, *Special Access Scheme: Guidance for health practitioners and sponsors*, Version 1.1, September 2017, <https://www.tga.gov.au/special-access-scheme-guidance-health-practitioners-and-sponsors> (accessed 20 February 2020).

²⁹ Department of Health, *Submission 10*, pp. 10 and 15.

³⁰ Mills Oakley, *Submission 61*, p. 8.

3.36 This view was shared by Dr Christina Xinos, Medical Director at Canopy Growth Australia:

In the Special Access Scheme, to use an unregistered product the guidelines suggest that you have to have tried every registered medication first ... And, when a patient is applying for the unregistered medicine, the doctor has to list, in the clinical justification, every single medicine that the patient has tried, explain why they think medicinal cannabis is going to work and attach clinical papers or other justification as to why they feel it's appropriate. It's part of the TGA guidelines.³¹

3.37 A health professional described that completing the SAS-B paperwork with this level of detail:

... to prescribe this treatment to a single patient (one who could afford it) would require at least four hours of my time.³²

3.38 However, the TGA told the committee that the SAS-B form does not require a significant level of detail from an applicant.³³

3.39 The TGA provided the committee with a copy of the two-page SAS-B application form, as well as a de-identified copy of a typical completed SAS-B application for medicinal cannabis, to demonstrate the detail required in the clinical justification part of the form.³⁴

Requirements for reapplications

3.40 The other main frustration with the SAS-B process raised by submitters was the requirement for reapplications where a product was not available or not effective for the patient, or when an approval had expired.³⁵

3.41 Under SAS-B, an applicant applies for approval for one formulation of a medicine only. Unlike single-molecule medicines, which are likely to have limited available formulations, medicinal cannabis is available in a wide range of formulations which health professionals may wish to prescribe for a wide range of indications.³⁶

3.42 If the formulation a health professional receives SAS-B approval for is unavailable, or the approved product does not have the clinical benefit hoped for, the approval process has to be repeated for a new product. Dr Teresa

³¹ Dr Xinos, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 60.

³² United In Compassion, *Submission 6*, p. 6.

³³ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 79.

³⁴ Department of Health, answers to questions on notice, 29 January 2020 (received 17 February 2020).

³⁵ See, for example, UIC, *Submission 6*, p. 25; Name withheld, *Submission 70*, p. 2; Name withheld, *Submission 86*.

³⁶ UIC, *Submission 6*, p. 25.

Nicoletti, a lawyer and scientist with expertise in medicinal cannabis regulation, explained that:

This can be as simple as starting with, say, a 20:1 CBD product and finding out that, instead, you need a 15:1 product or you need a higher dose or you need an oil instead of a capsule. Each of those are separate and distinct goods which require a separate application.³⁷

3.43 Shortage of supply can also lead to reapplications, as one patient told the committee:

In the short time I have been a Medical Cannabis patient I have had to have my doctor approve me via the TGA for a number of products due to shortage of supply, this has caused delays to my access to the medicine.³⁸

3.44 There are some measures in place to streamline the online reapplication process, including that the application form can be 'cloned' or copied to reduce administrative burden of filling out the entire form again.³⁹ However depending on the circumstances of the initial application, a health professional may still need to have further consultation with a patient to undergo the reapplication process when a product is unavailable.⁴⁰

3.45 Practitioners are also generally granted a 12-month approval for SAS-B applications from both the TGA and the relevant state or territory authority to reduce the need to re-apply regularly.⁴¹

3.46 However, this is not the experience of all patients. One patient described their experience of reapplications through a speciality medicinal cannabis clinic:

Third time ordering I was told by Cannvalate that my TGA approval was initially 3 months only and that if I wanted to continue to use the medication, I'd have to pay for another doctor consultation. I had to pay \$80 again for 5 mins phone time with the Cannvalate doctor which would give me TGA approval for another year.⁴²

3.47 While not unique to the prescription of medicinal cannabis, the reapplication processes under SAS-B appear to be contributing to the costs and delays faced by patients seeking to access medicinal cannabis.⁴³

³⁷ Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 14.

³⁸ Name withheld, *Submission 86*, p. 1.

³⁹ Dr Xinos, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 55; Adjunct Professor Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 63.

⁴⁰ Dr Grant Pegg, Assistance Secretary, Pharmacovigilance and Special Access Branch, Department of Health, *Committee Hansard*, 29 January 2020, p. 79; Mr John Jackson, President, Victorian Branch, Pharmaceutical Society of Australia, *Committee Hansard*, 29 January 2020, p. 44; Department of Veterans' Affairs, *Submission 135*, pp. 3–4.

⁴¹ Department of Health, *Submission 10*, p. 40.

⁴² Name withheld, *Submission 70*, p. 2.

⁴³ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 79.

3.48 The broader issues around the interactions of supply and cost on access are discussed in greater detail in Chapters 4 and 5.

Is SAS-B fit for purpose?

3.49 Submitters noted that the SAS-B pathway was not necessarily designed for such a large volume of applications for a single class of medicine, on the scale seen for medicinal cannabis, as it is a system intended to be used only in 'exceptional clinical circumstances'.⁴⁴

3.50 United in Compassion submitted that the increasing number of applications received through SAS-B:

... is an indicator that the system is not fit for purpose, yet this is the main route for the majority of patients under a TGA administered model, clearly demonstrating that the majority of patients acquiring the medication via SAS B are not 'exceptional' but rather, represent common illnesses and conditions being approved in rapidly increasing numbers.⁴⁵

3.51 Indeed, evidence received from the TGA indicates that SAS-B was not anticipated to be the main pathway to access medicinal cannabis in Australia:

Originally it had been anticipated that individual practitioners who prescribed medicinal cannabis on a regular basis would seek to become authorised prescribers, so as to remove the necessity to apply for SAS B access for each prescription.⁴⁶

3.52 Dr Nicoletti also raised concerns about the suitability of the SAS-B pathway for medicinal cannabis as a class of drugs:

In relation to how the scheme was originally introduced, it was intended to be more applicable to conventional medicines where you have a synthetic mechanism that has a known pharmacological action and a single molecule that has a well-defined safety net because it's profiled and tends to be approved overseas but may not be approved in Australia. The scheme works well for those types of drugs. I don't think it works well for medicinal cannabis.⁴⁷

3.53 Ways in which the SAS-B pathway could be potentially adapted to be more suited to prescribing medicinal cannabis are discussed later in this chapter.

Authorised Prescriber scheme

3.54 As outlined in Chapter 1, the AP scheme is a kind of notification pathway for prescribing medicinal cannabis. Rather than requiring a patient-by-patient

⁴⁴ See, for example, Epilepsy Action Australia (EAA), *Submission 22*, p. 7; UIC, *Submission 6*, p. 24; Medical Cannabis Council, [p. 15].

⁴⁵ UIC, *Submission 6*, p. 5.

⁴⁶ Department of Health, *Submission 10*, p. 21. See also: Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 66.

⁴⁷ Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 14.

application to prescribe medicinal cannabis, as is required under SAS-B, an AP is approved to prescribe certain medicinal cannabis products for certain indications and is only required to report to the TGA every six months the number of patients to whom they have prescribed these products.⁴⁸

- 3.55 Although the AP scheme was anticipated by the TGA to be the main pathway through which regular prescribers of medicinal cannabis would seek access for their patients, as at 31 December 2019 only 74 medical practitioners had been granted authorisation, in only four states and for only a limited number of indications (see Table 3.1 below).
- 3.56 According to the Department, the majority of authorisations have been granted for management of cancer-related pain and/or symptoms.⁴⁹
- 3.57 These authorisations have amounted to at least 655 notified prescriptions of medicinal cannabis in total,⁵⁰ a significantly lower number of prescriptions than seen through SAS-B.

Table 3.1 Authorised Prescribers of medicinal cannabis, as at 31 December 2019

Location of medical practitioner	Number of Authorised Prescribers	Indication categories	Total product authorisations
New South Wales	31	Cancer pain and symptom management	81
		Chronic non-cancer pain	
		Intractable epilepsy	
		Refractory epilepsy/paediatric refractory epilepsy	
Queensland	18	Refractory paediatric epilepsy	87
		Cancer pain and symptom management	
		Chronic non-cancer pain	
		Palliative care management	
Victoria	21	Cancer pain and symptom	58

⁴⁸ Department of Health, *Submission 10*, p. 10.

⁴⁹ Department of Health, *Submission 10*, pp. 21–22.

⁵⁰ Department of Health, *Submission 10*, p. 21.

		management	
		Chronic non-cancer pain	
		Compassionate access to medicinal cannabis (small group of children with very severe intractable epilepsy)	
		Continuation of Compassionate Access Paediatric Scheme Pilot trial for young people with Refractory Anxiety disorders	
		Severe refractory epilepsy	
		Patient meets the inclusion criteria and are approved by an independent panel of the Office of Medicinal Cannabis, Department of Health and Human Services Victoria	
Western Australia	4	Cancer pain and symptom management	53

Source: Adapted from Department of Health, *Submission 10*, pp. 21–22.

- 3.58 The low number of health professionals seeking to become APs has been attributed to a number of factors, including:
- the limitation of an AP to only prescribe specific medicinal cannabis products for the certain indications for which they are approved;
 - problems in getting authorisation, including the time taken to undertake the requisite research for the application and difficulties in then gaining appropriate ethics approvals or specialist endorsements; and
 - the need to still apply for state and territory authority, in some circumstances, in order to prescribe Schedule 8 products.⁵¹
- 3.59 The Department told the committee that, as a result of these factors and the comparative ease of use and flexibility of the SAS-B online portal, prescribers had reported that they do not see a significant benefit undergoing the authorisation process.⁵²

⁵¹ See, for example, Entoura, *Submission 25*, p. 2; UIC, *Submission 6*, p. 6; EAA, *Submission 22*, p. 7.

⁵² Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 66; Department of Health, *Submission 10*, p. 21. See also, MedReleaf Australia, *Submission 18*, p. 3.

- 3.60 AusCann noted that the time taken to complete an AP application, in addition to the wait required for consideration by an ethics committee and then the TGA, can limit a health professional's responsiveness to their patient's needs.⁵³
- 3.61 Epilepsy Action Australia further submitted that:
- Medical Practitioners have stated that they maintain greater clinical freedom in selecting the most appropriate medication for their patients from a wider range of products and cost points by choosing not to become Authorised Prescribers.⁵⁴
- 3.62 For those health professionals who do chose to apply to become APs, the process can be long and laborious. Entoura, a supplier of medicinal cannabis products, provided the committee with a case study which demonstrates the typical experience of a health professional seeking to become an AP:
- It should be noted that recently a GP received a letter from TGA suggesting that they apply to become an authorised prescriber of medicinal cannabis, based on their experience and the number of SAS B applications they had approved. To ensure all the required detail was included for the conditions and products this GP utilised, the application was 195 pages in length. Once this application was approved by TGA the GP needed to upload >70 inputs to the TGA online portal. This is a process that very few doctors are prepared to undertake and those that are prepared are not doing so without significant assistance and cost.⁵⁵
- 3.63 Another health professional, quoted by United in Compassion, found that her ethics application to prescribe five medicinal cannabis products for seven clinical indications 'stretched to 52 pages'.⁵⁶
- 3.64 There also appears to be some confusion among submitters and witnesses as to whether a single Authorised Prescriber application can include multiple products and indications for endorsement.⁵⁷ Some submitters contended that a major barrier to health professionals pursuing AP status was a requirement to complete a separate application for each product and indication,⁵⁸ although it appears this may only be required for seeking new and additional approvals after an initial application.⁵⁹
- 3.65 An application to become an AP must also receive either approval from a human research ethics committee (ethics committee) or endorsement from a

⁵³ AusCann Group Holdings (AusCann), *Submission 122*, p. 2.

⁵⁴ EAA, *Submission 22*, p. 7.

⁵⁵ Entoura, *Submission 25*, p. 2.

⁵⁶ UIC, *Submission 6*, p. 6.

⁵⁷ See, for example, Pain Australia, *Submission 129*, p. 6; EAA, *Submission 22*, p. 7.

⁵⁸ See, for example, EAA, *Submission 22*, p. 7; Mills Oakley, *Submission 61*, p. 8.

⁵⁹ AusCann, *Submission 122*, p. 2.

specialist college to be considered by the TGA. This is not unique to medicinal cannabis, and is a requirement of any Authorised Prescriber approval for any medicine, biological or medical device.⁶⁰

- 3.66 No specialist colleges, such as the Royal Australian College of General Practice or the Royal Australian and New Zealand College of Psychiatrists, are currently endorsing applications for authorised prescription of medicinal cannabis.⁶¹ The TGA told the committee that the hope had been for specialist colleges to endorse their members' applications, however:

Those colleges ... have taken the view that they don't have the resources and they don't really have a research ethics role. We can't force them to do it, so sadly they are not doing it at the moment.⁶²

- 3.67 To further complicate matters, the National Institute of Integrative Medicine ethics committee appears to currently be the only ethics committee with a process in place to consider applications for authorised prescribing of medicinal cannabis outside of clinical trials.⁶³
- 3.68 At the public hearing, the committee questioned whether the AP scheme could be adapted to allow a practitioner to become an AP after completing an accredited education course, instead of requiring the current model of approval or endorsement. The TGA informed the committee that a change to section 19 of the TG Act would be needed to make such an adaptation.⁶⁴

Clinical trials

- 3.69 The third recognised legal pathway for accessing medicinal cannabis in Australia is through clinical trials. The TGA regulates the use of medicinal cannabis for clinical trials through its Clinical Trial Notification scheme, outlined in Chapter 1.
- 3.70 As of 31 December 2019, the TGA had received 61 notifications of clinical trials using unapproved medicinal cannabis in Australia. However, as the TGA does not hold data on the number of patients in these clinical trials, it is unclear how many individuals are accessing medicinal cannabis in this way.⁶⁵

⁶⁰ For further details of the Authorised Prescriber approval process, see TGA, [Authorised Prescriber Scheme: Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors](#), July 2017.

⁶¹ See, for example, Royal Australian and New Zealand College of Psychiatrists, *Submission 23*, [p. 2]; Australasian College of Nutritional and Environmental Medicine (ACNEM), *Submission 29*, p. 4; UIC, *Submission 6*, Attachment 2, p. 26.

⁶² Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 75.

⁶³ ACNEM, *Submission 29*, pp. 4–5; UIC, *Submission 6*, Attachment 2, p. 26. See also, Professor Kylie O'Brien, Member, ACNEM, *Committee Hansard*, 29 January 2020, p. 39.

⁶⁴ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 75.

⁶⁵ Department of Health, *Submission 10*, p. 22.

- 3.71 The Medical Cannabis Users Association of Australia submitted that it was not aware of any of its 18 500 members accessing medicinal cannabis through an official clinical trial.⁶⁶
- 3.72 Additionally, as with the AP scheme, access to medicinal cannabis through clinical trials is currently limited to only some jurisdictions: there are currently no notifications of clinical trial sites in the Northern Territory or Tasmania.⁶⁷ The Northern Territory Government submission noted that there may be opportunities in the future for the territory to 'partner with health services in other jurisdictions to participate in clinical trials'.⁶⁸
- 3.73 Adjunct Professor John Skerritt from the TGA told the committee that these kinds of cross-jurisdictional partnerships could be used to increase access to medicinal cannabis clinical trials both in regional areas and in states without current trial locations. He also described that regional access to clinical trials is an ongoing issue for other medicines, such as cancer treatments, not just medicinal cannabis, and told the committee that:
- The government has brought in a measure to encourage clinical trials—I'm now talking more broadly on clinical trials—in rural and remote areas, but it has been an ongoing challenge globally as far as access to clinical trials once you're outside major cities.⁶⁹
- 3.74 Some of the broader concerns about geographical differences in access are discussed later this chapter.
- 3.75 Issues relating to the outputs of clinical trials, and their role in the approval of therapeutic goods, are explored in Chapter 4.

Alternatives proposed to the current TGA pathways

- 3.76 Due to their concerns about the suitability of the current TGA access pathways for medicinal cannabis, witnesses and submitters have suggested a number of ways in which these pathways could be adjusted to improve health professional engagement and patient access.⁷⁰

⁶⁶ Medical Cannabis Users Association of Australia (MCUA), *Submission 9*, p. 5.

⁶⁷ Department of Health, *Submission 10*, p. 23.

⁶⁸ Northern Territory Government, *Submission 2*, p. 1.

⁶⁹ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 68.

⁷⁰ See, for example, AusCann, *Submission 122*, pp. 3–4; Mr Crock, Medicinal Cannabis Industry Australia, *Committee Hansard*, 29 January 2020, p. 58.

Proposal for an independent regulatory framework

3.77 Some submitters expressed the view that the current regulatory framework is not suited for medicinal cannabis and called for the introduction of an independent regulator of medicinal cannabis.⁷¹

3.78 For example, Lucy Haslam from United in Compassion told the committee:

I firmly believe we've chosen the wrong regulatory framework. It's so broken I think even fixing it is going to be difficult. I think we need a new system. I think we need to go back to the beginning and back to what was recommended originally by the Senate inquiry in Canberra in 2014, 2015.⁷²

3.79 Witnesses from key patient and research advocacy bodies Epilepsy Australia, Multiple Sclerosis Australia and Multiple Sclerosis Research Australia, all also backed an Independent Regulator for medicinal cannabis products.

3.80 Ms Carol Ireland, Chief Executive Officer and Managing Director, Epilepsy Action Australia said:

I spoke at the 2014 Senate inquiry and strongly supported the establishment of a regulator. My view hasn't changed. I think there has been progress and lots of effort to make the existing system work. There has been improvement, but we still overwhelmingly hear about the barriers and the difficulties. I think we're trying to force a square peg into a round hole.⁷³

3.81 Mr Giles, National Policy Officer, Multiple Sclerosis Australia said:

From MS Australia's point of view, I would say that if in setting up the independent regulator it speeds up access but still ensures that there are safe, affordable products available to people in the MS community then, yes, we'd be up for it.⁷⁴

3.82 This was echoed by Dr Luker, Research Development Coordinator, Multiple Sclerosis Research Australia, who said:

MS Research Australia completely agrees with both MS Australia and Epilepsy Action. As long as it speeds everything, it's still clinically proven and there is quality assurance, then I completely agree.⁷⁵

⁷¹ United in Compassion (UIC), *Submission 6*, p. 3; Professor Laurence Mather, *Submission 113*, p. 5; Ms Dianah Walter, *Submission 76*, p. 2; Country Women's Association of Australia, *Submission 120*, [pp. 2–3]; Ms Carol Ireland, Chief Executive Officer and Managing Director, Epilepsy Action Australia, *Committee Hansard*, 29 January 2020, p. 11. See also, Mr Andrew Giles, National Policy Officer, Multiple Sclerosis Australia, *Committee Hansard*, 29 January 2020, p. 11; Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 15.

⁷² Mrs Haslam, UIC, *Committee Hansard*, 29 January 2020, p. 3.

⁷³ Ms Ireland, Epilepsy Action Australia, *Committee Hansard*, 29 January 2020, p. 11.

⁷⁴ Mr Giles, Multiple Sclerosis Australia, *Committee Hansard*, 29 January 2020, p. 11.

⁷⁵ Dr Tennille Luker, Research Development Coordinator, *MS Research Australia*, *Committee Hansard*, 29 January 2020, p. 11.

3.83 Dr Teresa Nicoletti, Partner, Mills Oakley; Director, Medical Cannabis Council; and Member, Australian Lawyers Alliance, agreed that creating an Independent Regulator would solve the problems in the current system:

...why would you try and adapt a scheme that has, for the last 30 or 40 years, been focused on conventional medicines and try and adapt that scheme to fit what is a very different group of medicines? I don't understand why there should be any resistance to a separate regulator to deal with this type of product.⁷⁶

3.84 Several submitters referred to the Regulator of Medicinal Cannabis Bill 2014, a private senator's bill which proposed the establishment of such a body.⁷⁷

3.85 The bill was subject to an inquiry by the Senate Legal and Constitutional Affairs Legislation Committee in 2015, and lapsed at the end of the 44th Parliament without passing either house.⁷⁸

3.86 United in Compassion noted that the proposal of an independent regulatory body was 'accepted and widely supported across the political spectrum' as the best regulatory framework for Australia, particularly due to the 'complex nature of the cannabis plant and the many cannabinoids and chemical compounds it contains'.⁷⁹

3.87 However, some submitters did not share this view and maintained that the TGA and Office of Drug Control (ODC) are the appropriate bodies to regulate medicinal cannabis products, although some refinements to their processes may be required.⁸⁰

3.88 Mr Anthony Tassone from the Pharmacy Guild of Australia told the committee:

... we support the medicinal use of cannabis preparations following appropriate consideration and assessment. To that end, we believe the Therapeutic Goods Administration, the TGA, as the existing regulatory body, is the most appropriate framework for this to occur, and therefore do not believe that the creation of a new separate regulator to oversee the medicinal cannabis supply chain is required.⁸¹

3.89 The Medicinal Cannabis Industry Australia observed:

⁷⁶ Dr Nicoletti, Committee Hansard, 29 January 2020, p. 15.

⁷⁷ UIC, *Submission 6*, p. 21; Professor Laurence Mather, *Submission 113*, p. 5; Medical Cannabis Knowledge Network, *Submission 13*, p. 2.

⁷⁸ [Regulator of Medicinal Cannabis Bill 2014](#).

⁷⁹ UIC, *Submission 6*, p. 3.

⁸⁰ Mr Anthony Tassone, National Councillor, Pharmacy Guild of Australia, *Committee Hansard*, 29 January 2020, p. 43; Australian and New Zealand Society of Palliative Medicine, *Submission 117*, p. 2. See also, Mrs Elizabeth de Somer, Chief Executive Officer, Medicines Australia, *Committee Hansard*, 29 January 2020, p. 51.

⁸¹ Mr Tassone, Pharmacy Guild of Australia, *Committee Hansard*, 29 January 2020, p. 43.

... the regulation of medicinal cannabis under a dual ODC/TGA framework assists to provide confidence to doctors and the healthcare sector along with acceptance of medicinal cannabis as a 'medicine'. Thus, MCIA supports improving the current system rather than introducing a new regulatory framework.⁸²

3.90 Cann Group also submitted that:

Australia's regulatory regime for the manufacture and supply of therapeutic goods ... is among the best practice models in the world. As a result, Australia enjoys a reputation of manufacturing therapeutic goods to the highest standard of quality, complemented with a well-established system of prescribing and dispensing drugs (both registered and unregistered) in a safe and responsible manner.⁸³

Committee view

3.91 It is clear that there remains strong support from many stakeholders for an independent regulator for medicinal cannabis, in line with the 2014 private senator's bill. They believe this would address many of the access issues associated with the current system of regulation through the TGA.

3.92 Many patient groups have identified problems accessing medicinal cannabis as a result of the current regulatory processes through the TGA. This report will consider these barriers in detail and should they fail to be addressed within the course of 12 months following the release of this report, then the government should move to consider an independent regulator for medicinal cannabis.

3.93 Any new regulator should be designed by experts, to provide the appropriate level of regulation for this discrete class of therapeutic products. The regulator would ensure safety, efficacy and consistency of product, while ensuring that doctors can prescribe medicinal cannabis to patients as seamlessly as they currently prescribe other common pharmaceutical products.

Recommendation 5

3.94 The committee recommends that, if after 12 months from the tabling of this report the Commonwealth Government through the Therapeutic Goods Administration has failed to address the barriers to appropriate, regulated patient access to medicinal cannabis in Australia, a new Independent Regulator be considered, using the Regulator of Medicinal Cannabis Bill 2014 as a basis.

Notification pathways

3.95 Some submitters proposed that a notification pathway be introduced, whereby health professionals notify the TGA of their intention to prescribe medicinal

⁸² Medicinal Cannabis Industry Australia, *Submission 5*, p. 2.

⁸³ Cann Group Limited, *Submission 30*, p. 2.

cannabis to a patient without needing to first seek approval. For example, AusCann submitted that:

A move to a framework based primarily on a notification process, with the responsibility of prescription firmly placed on the prescriber ... would decrease resource requirements of the TGA. It also enables flexibility of treatment options for the doctor, with the patient benefiting from a timely and individualised treatment approach.⁸⁴

3.96 Canopy Growth suggested to the committee that medicinal cannabis products for certain indications should be included in the SAS-C list, as this notification pathway does not require the 'lengthy process' of clinical justification.⁸⁵ This proposal was supported by the Medicinal Cannabis Industry Association, which agreed that using the SAS-C notification pathway would 'accelerate access' for patients.⁸⁶

3.97 However, the TGA raised concerns about the suitability of SAS-C for medicinal cannabis:

Generally, the other Special Access Scheme drugs, such as those on Special Access Scheme C, have a long history. They might have been in the German and French markets for 20 years and the Australian market's too small. ... With medicinal cannabis, we actually don't have that. With those particular products we don't have that history of use anywhere in the world, regarding evidence of quality, safety and efficacy in the long run, so there are additional unknowns with medicinal cannabis compared even with many of the other drugs on the Special Access Scheme.⁸⁷

3.98 The SAS-C list also does not contain medicines from Schedules 8 of the Poisons Standard, which would currently limit its potential utility for medicinal cannabis products other than CBD.⁸⁸

Approval pathways

3.99 Some submitters have proposed that the SAS-B and AP pathways be streamlined to allow for approvals of medicinal cannabis as a class of drug and/or for a particular indication, rather than on a product-by-product basis.⁸⁹

3.100 A carer who had experienced both the Canadian and Australian medicinal cannabis access schemes told the committee that the approval of medicinal

⁸⁴ AusCann, *Submission 122*, pp. 3–4.

⁸⁵ Dr Xinos, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 53.

⁸⁶ Mr Crock, Medicinal Cannabis Industry Australia, *Committee Hansard*, 29 January 2020, p. 58.

⁸⁷ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 70.

⁸⁸ Department of Health, *Special Access Scheme: Guidance for health practitioners and sponsors, Version 1.1*, September 2017, <https://www.tga.gov.au/special-access-scheme-guidance-health-practitioners-and-sponsors> (accessed 20 February 2020).

⁸⁹ See, for example, MedReleaf Australia, *Submission 18*, p. 3; Tilray, *Submission 62*, p. 2; Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 13; EAA, *Submission 22*, p. 5.

cannabis as a broad class of product with a daily dosage limit, rather than a specific product, had a significant advantage when products were not available for her son:

... [In Canada] it was very easy to switch to an alternative product ... without any paperwork or applications because the doctor had recommended a daily authorised limit of cannabis that could be consumed for the patient ...⁹⁰

3.101 Epilepsy Action Australia proposed that APs should be able to be endorsed to prescribe medicinal cannabis as a class of drug to a particular cohort of patients.⁹¹

3.102 Noting that many health professionals do not have an interest in pursuing the AP pathway, MedReleaf Australia instead suggested a modified SAS scheme, which could involve a health professional seeking approval for the general supply of medicinal cannabis to a single patient for a single indication, and that the health professional could then send a regular report to the TGA outlining the products prescribed under that approval.⁹²

Committee view

3.103 The committee recognises that while medicinal cannabis remains a largely unapproved class of drugs there is a role for the TGA in approving its prescription through the established pathways for unapproved drugs.

3.104 Health practitioners' limited knowledge of the Special Access Scheme and Authorised Prescriber pathways and requirements appears to be hindering access to medicinal cannabis for many patients and, as discussed in Chapter 2, the information currently provided on the TGA's website in relation to these pathways does not appear to be meeting the needs of practitioners who wish to use them.

Recommendation 6

3.105 The committee recommends that the Therapeutic Goods Administration review and improve its online resources for health professionals relating to the regulations and processes for prescribing medicinal cannabis through the Special Access Scheme and Authorised Prescriber pathways.

3.106 The committee is aware that practitioners would benefit from greater clarity about the exact requirements for applications under the SAS-B pathway, particularly relating to the use of medicinal cannabis as a 'last line' therapy after consideration of approved medicines. The current popular understanding

⁹⁰ Ms Lanai Carter, *Submission 136*, p. 7.

⁹¹ EAA, *Submission 22*, p. 5.

⁹² MedReleaf Australia, *Submission 18*, pp. 3–4.

of these requirements appears to be leading to a large amount of work and a significant time commitment for already time-poor practitioners and does not reflect the expectations of the TGA.

Recommendation 7

3.107 The committee recommends that the Therapeutic Goods Administration immediately clarify the clinical justification requirements of Special Access Scheme Category B in its instructions to prescribers.

3.108 The committee recognises that another frustration for health professionals applying for SAS-B approval for their patients is the requirement to reapply when the approved medicinal cannabis product is not available or does not have the desired clinical benefit. If they were to seek SAS-B approval for multiple products at once, or for medicinal cannabis as a broader class of drug, this would remove some of the need for reapplications, reduce the time required to fill out forms and wait for approvals, and allow them to be more responsive to the needs of their patients.

Recommendation 8

3.109 The committee recommends that the Department of Health make amendments to the Special Access Scheme Category B pathway to allow for approval of:

- **multiple medicinal cannabis products in a single application; and/or**
- **medicinal cannabis as a class of drug for the treatment of a patient for a particular indication.**

3.110 It is clear from the evidence received by the committee that the Authorised Prescriber pathway has not been as well-utilised for medicinal cannabis as originally anticipated.

3.111 The low uptake of the Authorised Prescriber pathway appears to stem chiefly from the difficulties health professionals face in seeking approval from ethics committees or endorsement from specialist colleges for their applications, and the inflexibility of being approved for only certain products. By comparison, in most jurisdictions, the SAS-B pathway does not require any additional expert endorsement or approval and provides health professionals with the flexibility to change products as needed for their patient.

3.112 However, the committee received insufficient evidence as to whether these difficulties are unique to medicinal cannabis or reflect broader inflexibilities in the Authorised Prescriber scheme.

Recommendation 9

3.113 The committee recommends that the Department of Health modify the operation of the Authorised Prescriber scheme for health professionals seeking to prescribe medicinal cannabis to ensure that:

- completion of an accredited medicinal cannabis course be a requirement to obtain Authorised Prescriber status;
- relevant specialist colleges be resourced to grant Authorised Prescriber status to their members;
- the pathway to authorised prescriber status through the National Institute of Integrative Medicine be clarified and communicated to doctors; and
- authority be granted to prescribe all medicinal cannabis products, rather than on a product-by-product basis.

Jurisdiction-specific regulatory requirements

3.114 Australian states and territories have regulatory responsibility for controlling medicines within their jurisdiction in accordance with their own drug and poison regulations. Although the Commonwealth administers the Poisons Standard to promote a uniform approach to the regulation of medicines, the ultimate responsibility for deciding how medicines are prescribed and dispensed rests with states and territories.⁹³

3.115 In relation to medicinal cannabis, jurisdiction-specific regulatory requirements for prescribing fall into one of two categories:

- General requirements relating to the prescription of any Schedule 8 (Controlled Substance) medicine in that jurisdiction, such as rules around the duration of a prescription, or prescribing to children or people with a history of drug addiction.
- Specific requirements relating to the prescription of medicinal cannabis, such as requiring a specific permit to prescribe a cannabis-based Schedule 8 drug, or rules relating to which patients and indications are eligible to be prescribed medicinal cannabis.⁹⁴

3.116 Before the introduction of the TGA online application system, many patients and health professionals found the process for seeking Commonwealth and jurisdiction-specific approvals for medicinal cannabis to be slow and inconsistent, resulting in a major barrier to access.⁹⁵

⁹³ Department of Health, *Submission 10*, p. 24.

⁹⁴ These requirements are summarised in Table 1.1, Chapter 1 of this report. See also: Department of Health, *Submission 10*, pp. 24–5; Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 63.

⁹⁵ See, for example, Cancer Voices Australia, *Submission 34*, p. 1; Tilray, *Submission 62*, p. 4; Name withheld, *Submission 58*, p. 1; Name withheld, *Submission 102*, p. 3.

3.117 As previously discussed, the introduction of the online system, combined with a series of regulatory improvements in 2018 and 2019 in several jurisdictions to reduce the number of additional requirements, appears to have addressed many of the complexities around this approval process.⁹⁶ Dr Nicoletti told the committee that:

The streamlining has had a major positive effect on removing a lot of that state layer of regulation. ... I applaud the government for taking the steps needed to remove that state layer of regulation.⁹⁷

3.118 However there are concerns that, despite process improvements, inconsistencies in jurisdiction-specific requirements for prescribing are resulting in ongoing inequitable patient access to medicinal cannabis.

The 'postcode lottery'

3.119 The inequitable access to medicinal cannabis across jurisdictions has been described by United in Compassion, among others, as the 'postcode lottery', whereby patients in certain locations can access medicinal cannabis, while patients in others, such as in Tasmania or in rural and remote communities, are almost completely unable to do so.⁹⁸

3.120 Several submitters described how this 'postcode lottery' is forcing some patients to travel or relocate to other regions or jurisdictions, or even overseas, in order to access medicinal cannabis.⁹⁹

3.121 The Australian Pain Management Association submitted that 20 per cent of surveyed medicinal cannabis users had to travel outside of their local area to find a health professional willing to prescribe.¹⁰⁰

3.122 One patient told the committee:

I rang around until I found Dr X in Baulkham Hills. I required a referral which I was lucky enough to get from one of my open-minded doctors ... As there were no local certified GPs I had to travel 120 km to see Dr X. Public transport would have been very difficult.¹⁰¹

⁹⁶ See, for example, Department of Health, *Submission 10*, pp. 24–5; AusCann, *Submission 122*, p. 1; Tilray, *Submission 62*, pp. 3–4; Hall and Farrell, *Submission 68*, p. 3; Professor Angus, *Submission 53*, [p. 3].

⁹⁷ Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 14.

⁹⁸ UIC, *Submission 6*, Attachment 2, p. 26.

⁹⁹ NICM HRI, *Submission 7*, p. 4. See also, EAA, *Submission 22*, p. 8; Entoura, *Submission 25*, [p. 3]; Medical Cannabis Research Australia, *Submission 121*, p. 3.

¹⁰⁰ Australian Pain Management Association, *Submission 32*, p. 7.

¹⁰¹ Name withheld, *Submission 49*, [p. 1].

- 3.123 The key 'postcode lottery' issue faced by patients is whether they can see a health professional who is both willing and able to prescribe medicinal cannabis to them.
- 3.124 Following changes in 2018 and 2019, Tasmania is now the only jurisdiction which requires a specialist prescription in all circumstances; however some states still require specialist consultation or support for particular patient groups.¹⁰²
- 3.125 A requirement for specialist approval of a medicinal cannabis prescription can impact on the ability of GPs to make appropriate clinical choices for their patients,¹⁰³ and can increase patients' costs in accessing medicinal cannabis.¹⁰⁴

Rural and regional Australia

- 3.126 The role of GPs as the primary prescribers of medicinal cannabis is especially significant for patients in rural and remote areas, who have limited access to a range of health professionals in general, let alone access to specialists.¹⁰⁵
- 3.127 Patients in rural and remote areas have reported difficulties if their local health professional is unwilling to consider prescribing medicinal cannabis or does not have sufficient knowledge of medicinal cannabis, particularly if they are unable to meet the costs of travelling into cities to access health services.¹⁰⁶
- 3.128 The time pressures on rural GPs were also cited, with the family member of one patient noting:
- Living in a rural area does impact your ability to access Medicinal Cannabis. GP's are overworked everywhere (and in rural areas I feel even more so) you can wait 2 weeks for a doctor's appointment. I had to wait 6 weeks just to get a flu shot! ... most simply don't have the time (nor the adequate knowledge) to prescribe Medicinal Cannabis ...¹⁰⁷
- 3.129 To address some of these issues of access, some submitters recommended that all jurisdictions consider extending medicinal cannabis prescribing rights to nurse practitioners, particularly in rural and remote communities.¹⁰⁸

¹⁰² Department of Health, *Submission 10*, pp. 25–6. See also, FreshLeaf Analytics, *Submission 14*, p. 3.

¹⁰³ ACNEM, *Submission 29*, p. 5.

¹⁰⁴ FreshLeaf Analytics, *Submission 14*, p. 5.

¹⁰⁵ Medical Cannabis Council, *Submission 37*, [p. 3]; Dianah Walter, *Submission 76*, p. 3; LeafCann Group, *Submission 4*, p. 7; Country Women's Association of Australia, *Submission 120*; MIGA, *Submission 12*, p. 4; Alcohol and Drug Foundation, *Submission 26*, p. 9; Australian and New Zealand Society of Palliative Medicine, *Submission 117*, p. 2.

¹⁰⁶ LeafCann Group, *Submission 4*, p. 7; EAA, *Submission 22*, p. 10; Ms Aurora Pearce, *Submission 48*, p. 2.

¹⁰⁷ Mrs Carol Burford, *Submission 69*, p. 2. See also, Ms Dianah Walter, *Submission 76*, p. 3.

¹⁰⁸ LeafCann Group, *Submission 4*, p. 7; New South Wales Nurses and Midwives' Association, *Submission 118*, pp. 8, 10.

Tasmania – the odd state out

- 3.130 Overwhelming, the most serious concerns about jurisdiction-level differences in medicinal cannabis prescribing were raised in relation to Tasmania.
- 3.131 Tasmania is the only jurisdiction which has not agreed to participate in the SAS online system and the ordinary access pathways used by other states and territories. Instead, Tasmania administers a medical cannabis Controlled Access Scheme (CAS) which applies to all unapproved Schedule 4 and 8 medicinal cannabis products.
- 3.132 Under the CAS, any patient seeking to access medicinal cannabis must be referred to a specialist, who must then make an application to the Tasmanian Department of Health for assessment by a multidisciplinary expert panel of clinicians. If the prescription is authorised, the medicinal cannabis product must then be dispensed through a Tasmanian hospital pharmacy. The scheme is fully funded, and patients who do receive access pay only the equivalent of their applicable Pharmaceutical Benefits Scheme patient co-payment.¹⁰⁹
- 3.133 The number of patients who have accessed medicinal cannabis in Tasmania through the CAS is very low, apparently no more than 17 patients in total.¹¹⁰
- 3.134 While some submitters praised the fact that the CAS subsidises the cost of accessing medicinal cannabis to some patients, it was a widely held view that not allowing Tasmanian patients to access medicinal cannabis outside of the CAS is putting them at a significant disadvantage compared to the rest of the country.¹¹¹
- 3.135 A key recommendation to the committee was that GPs in Tasmania should be permitted to prescribe medicinal cannabis, in line with other jurisdictions.¹¹²
- 3.136 Tasmanian patients and carers also described their experience with the CAS, explaining the frustrations in waiting to see a specialist, only to then have a specialist's application to prescribe medicinal cannabis rejected by the CAS

¹⁰⁹ Tasmanian Government Department of Health, *Medical Cannabis Controlled Access Scheme*, www.dhhs.tas.gov.au/psbtas/publications/medical_cannabis/medical_cannabis_controlled_access_scheme (accessed 20 February 2020).

¹¹⁰ The actual number of patients isn't clear, however evidence from the public hearing in January suggested the latest count is between 12 and 17 patients. See Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 66; Ms Lyn Cleaver, Private Capacity, *Committee Hansard*, 29 January 2020, p. 20.

¹¹¹ FreshLeaf Analytics, *Submission 14*, p. 4; Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 14; Medical Cannabis Research Australia, *Submission 121*, p. 3.

¹¹² Ms Cleaver, *Committee Hansard*, 29 January 2020, pp. 19–20. See also, Dr Harry Nespolon, President, Royal Australian College of General Practitioners, *Committee Hansard*, 29 January 2020, pp. 29, 32.

panel.¹¹³ Ms Lyn Cleaver, the parent of a man with severe refractory epilepsy, told the committee:

[The application] came back that, in order for Jeremy to be eligible for the state's controlled access scheme, he must try and fail all conventional anticonvulsant drugs. At the time we started cannabis we were already being told that the neurologist had nothing to prescribe, that he'd emptied his toolbox. So, that the panel should determine that Jeremy should try these other drugs didn't seem acceptable and didn't seem right.¹¹⁴

3.137 The Department explained that the Tasmanian Government had made a sovereign choice not to take part in the streamlined access process agreed by the COAG Health Ministers in April 2018 and is within its legal rights to determine how medicinal cannabis is prescribed in that state.¹¹⁵ The Department assured the committee that that the federal Minister for Health has committed to continue to raise the issue of medicinal cannabis access in Tasmania 'at every opportunity he has'.¹¹⁶

Need for harmonisation

3.138 Witnesses and submitters expressed a strong support for continued harmonisation of jurisdiction-specific regulatory requirements to further streamline the process of medicinal cannabis prescribing approval in Australia and to reduce inequities of access.¹¹⁷

3.139 Medicinal Cannabis Industry Australia recommended that the COAG Health Council Ministers remove any remaining jurisdiction-based replications of the TGA approval process and any processes specific only to medicinal cannabis, making the point that:

The unregistered medicine aspect is under the remit of the TGA, and existing processes around prescription and narcotic management at the State level are well established.¹¹⁸

¹¹³ See, for example, Name Withheld, *Submission 85*; Medical Cannabis Users Association of Tasmania, *Submission 116*.

¹¹⁴ Ms Cleaver, *Committee Hansard*, 29 January 2020, p. 19.

¹¹⁵ COAG Health Council, [Communique](#), 13 April 2013.

¹¹⁶ Dr Skerritt, Department of Health, *Committee Hansard*, 29 January 2020, p. 67.

¹¹⁷ UIC, *Submission 6*, p. 15; LeafCann Group, *Submission 4*, pp. 1–2; MIGA, *Submission 12*, p. 2; Medical Cannabis Knowledge Network, *Submission 13*, p. 10; ACRE, *Submission 15*, p. 2; Alcohol and Drug Foundation, *Submission 26*, p. 3; Pharmacy Guild of Australia, *Submission 27*, p. 3; Cann Group Limited, *Submission 30*, p. 4; Country Women's Association of Australia, *Submission 120*, [p. 2]; FreshLeaf Analytics, *Submission 14*, p. 4.

¹¹⁸ Medicinal Cannabis Industry Australia, *Submission 5*, p. 3. See also AusCann, *Submission 122*, p. 4; FreshLeaf Analytics, *Submission 14*, p. 4.

- 3.140 Other medicinal cannabis organisations have called for all jurisdiction-specific approvals for medicinal cannabis to be abolished entirely,¹¹⁹ although such a change would also require COAG agreement.
- 3.141 To facilitate further regulatory harmonisation between the Commonwealth, states and territories, the Royal Australian College of General Practitioners and other submitters have proposed that a national framework for medicinal cannabis access be developed.¹²⁰

International jurisdictions and their access models

- 3.142 Throughout the inquiry, submitters and witnesses have drawn international examples of medicinal cannabis regulation to the attention of the committee.¹²¹ The NSW Nurses and Midwives' Association told the committee:
- Australia must draw on the lessons learned internationally, and aim for implementation of a best practice model of care – one that prioritises patients' needs foremost.¹²²
- 3.143 Most countries which allow patients to access medicinal cannabis products are similar to Australia, in that they require a doctor's prescription and/or a government approval, but some have taken different and less restrictive approaches to access.¹²³
- 3.144 In several countries, including the United Kingdom and Switzerland, CBD-only products are able to be sold over-the-counter and therefore do not need any prescription or approval for purchase.¹²⁴
- 3.145 Other countries, such as Germany and Israel, have chosen to regulate medicinal cannabis through specialised medicinal cannabis agencies, outside of their normal medicine regulation pathways.¹²⁵
- 3.146 Some jurisdictions, including several US states, Canada and the Netherlands, have also legalised access to recreational cannabis, meaning that patients can choose to self-medicate with cannabis products without any interaction with a health professional. However, recreational cannabis legalisation has had some

¹¹⁹ Medical Cannabis Research Australia, *Submission 121*, p. 2; LeafCann Group, *Submission 4*, p. 1; MedReleaf Australia, *Submission 18*, p. 2; Cann Group Limited, *Submission 30*, p. 4.

¹²⁰ Royal Australian College of General Practitioners, *Submission 11*, p. 1; Cancer Voices Australia, *Submission 34*, p. 2; Medical Cannabis Knowledge Network, *Submission 13*, p. 2.

¹²¹ See, for example, Medical Cannabis Users Association of Tasmania, *Submission 116*; Lambert Initiative, *Submission 36*, p. 9; Medical Cannabis Knowledge Network, *Submission 13*.

¹²² New South Wales Nurses and Midwives' Association, *Submission 118*, p. 8.

¹²³ Department of Health, *Submission 10*, p. 30; Hall and Farrell, *Submission 68*, p. 9.

¹²⁴ Professor O'Brien, ACNEM, *Committee Hansard*, 29 January 2020, p. 35; Lambert Initiative, *Submission 36*, p. 9.

¹²⁵ UIC, *Submission 6*, Attachment 2, p. 26; Hall and Farrell, *Submission 68*, p. 9.

unintended impacts on the manufacture of medicinal cannabis in some areas, with submitters noting that:

Cannabis legalisation has not served medical cannabis patients well in Canada or the USA. It has removed incentives for cannabis growers and processors to produce medical cannabis products because their largest profits come from daily cannabis users who account for 80% of their business. Legalisation has also removed incentives for the industry to fund controlled clinical research into the safety and effectiveness of cannabis based medicines. It has also not increased researchers' access to medical cannabis products for investigator-initiated clinical trials.¹²⁶

The Canadian model

3.147 Patients have been able to access medicinal cannabis in Canada since 2001, although the scope of the initial scheme was limited and only 7900 patients registered in the first 13 years. Regulations were introduced in 2016 to allow registered patients, authorised by health professionals, to produce their own cannabis for medicinal purposes. These regulations were repealed in October 2018, when Canada passed the *Cannabis Act* which made cannabis legal for recreational purposes and changed the rules for access to medicinal cannabis products. The number of registered medicinal cannabis patients in Canada plateaued at around 370 000 in 2019 following the availability of recreational cannabis.¹²⁷

3.148 Submitters and witnesses particularly favoured the current Canadian model of cannabis regulation which, in addition to providing access to approved cannabis medicines through usual drug regulation pathways and cannabis for recreational use, allows individual patients to be authorised by a prescriber to legally purchase cannabis products from a licensed seller or produce their own supply in a larger-than-recreational quantity.¹²⁸

3.149 This model effectively allows individuals to access a range of unregistered cannabis products without requiring a prescription. These unregistered cannabis products are not subject to any pre-market review for quality, safety or efficacy, and cannot be sold as health products making any claims of health benefits.¹²⁹

¹²⁶ Hall and Farrell, *Submission 68*, p. 10.

¹²⁷ Government of Canada, *Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations*, July 2018, pp. 1–3; Alcohol and Drug Foundation, *Submission 26*, p. 4. See also, Department of Health, *Submission 10*, p. 13.

¹²⁸ Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 10; MUA, *Submission 9*, pp. 10–11; Medical Cannabis Knowledge Network, *Submission 13*, p. 2; ACRE, *Submission 15*, p. 9. See also, Department of Health, *Submission 10*, p. 13.

¹²⁹ Government of Canada, *Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations*, July 2018, pp. 1–3; Government of Canada, *For people registered or designated to produce cannabis for medical purposes*, 2017,

- 3.150 The health professional authorisation required to access unregistered cannabis products for medicinal purposes is not a prescription; instead, the two-page form is used by health professionals to indicate their support for a patient using cannabis for medical purposes. This authorisation specifies a quantity of cannabis and duration of use, for no more than one year. The patient then registers either with Health Canada to produce their own cannabis, or with a licensed seller to purchase product from them.¹³⁰
- 3.151 Individuals can also access approved CBD health products over-the-counter, and approved prescription cannabis medicines (i.e. nabiximols) with a prescription from their health professional. These products are subject to pre-market review for quality, safety and efficacy in accordance with traditional therapeutic goods regulations in Canada.¹³¹
- 3.152 While the federal Canadian government oversees most aspects of medicinal cannabis production and distribution, each province and territory still has its own rules relating to cannabis more broadly, including possession limits and minimum age for access. These provincial rules also relate to the operation of licensed sellers, also known as dispensaries, which are responsible for selling cannabis products for medical and non-medical uses which have not been registered as health products.¹³²
- 3.153 Witnesses and submitters have proposed that a similar model, where authorised patients can access a legal dispensary to select the medicinal cannabis products (including whole plant and CBD-only products) which meet their needs, be adopted in Australia.¹³³

Committee view

- 3.154 The committee acknowledges that harmonisation of Commonwealth, state and territory legislation and regulations for medicinal cannabis is an ongoing task and supports a streamlined regulatory framework which reduces duplication

www.canada.ca/en/health-canada/services/people-registered-designated-produce-cannabis-medical-purposes.html (accessed 20 February 2020).

¹³⁰ Government of Canada, *Medical document authorizing the use of cannabis for medical purposes*, 2019, www.canada.ca/en/health-canada/services/drugs-medication/cannabis/licensed-producers/sample-medical-document-marihuana-medical-purposes-regulations.html (accessed 20 February 2020).

¹³¹ Government of Canada, *Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations*, July 2018, pp. 1–3.

¹³² Government of Canada, *Cannabis for medical purposes under the Cannabis Act: information and improvements*, www.canada.ca/en/health-canada/services/drugs-medication/cannabis/medical-use-cannabis.html (accessed 20 February 2020).

¹³³ Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 10; MCUA, *Submission 9*, pp. 10–11. See also: Nimbin Hemp Embassy, *Submission 28*, p. 2; Mr Glenn Lynch, *Submission 98*, p. 3; Dr Deborah Waldron, *Submission 126*, pp. 5–6.

across jurisdictions. The committee is aware of the significant role which the COAG Health Council has played in this regulatory harmonisation to date.

- 3.155 The committee recognises that further harmonisation of jurisdiction-based legislation is still required to make the rules around patient access to medicinal cannabis more consistent across Australia.

Recommendation 10

- 3.156 The committee recommends that the COAG Health Council develop a National Framework for Medicinal Cannabis Access to set out goals for further harmonisation of Commonwealth, state and territory legislation to ensure that there are appropriate, clear and consistent regulatory pathways for accessing medicinal cannabis in Australian into the future.**

- 3.157 Despite the significant strides made in harmonisation in the past few years, Tasmania remains the odd state out. The committee has serious concerns about the low number of patients who have been able to access medicinal cannabis in Tasmania and the very strict requirements around prescribing, which are not at all in line with other jurisdictions.

Recommendation 11

- 3.158 The committee recommends that the Tasmanian Government immediately join all other jurisdictions in participating in the Therapeutic Goods Administration's single national online application pathway for accessing unregistered medicinal cannabis and reducing state-based requirements for medicinal cannabis approval.**

- 3.159 The committee notes the international models of access to medicinal cannabis raised by submitters. The proposal to introduce some of these international models in Australia, such as rescheduling CBD-only products to sell them over-the-counter, are discussed further in Chapter 4.

Chapter 4

Products and supply

- 4.1 Some of the key concerns raised throughout the inquiry related to the regulation, manufacture, sale and availability of medicinal cannabis products in Australia.
- 4.2 As outlined in Chapter 1, medicinal cannabis products in Australia are subject to all of the same requirements for production and sale as any other medicine under the *Therapeutic Goods Act 1989* (TG Act) and related regulations.¹
- 4.3 Additionally, Australia is a party to the United Nations Single Convention on Narcotic Drugs (UN Single Convention) which currently lists cannabis in its prohibition schedule. This means that Australia also has certain requirements under international law in relation to the manufacture and distribution of medicinal cannabis.²
- 4.4 The committee heard throughout the inquiry that medicinal cannabis does not neatly fit within the traditional frameworks for the approval and manufacture of therapeutic goods in Australia. Mr John Jackson, President of the Victorian Branch of the Pharmaceutical Society of Australia, told the committee that:
- We are used to working with products that, by their nature, are standardised and able to be replicated, and consequently can be registered. The definition of medicinal cannabis arose in terms of a therapeutic use, without being clear as to exactly what the product would be.³
- 4.5 This chapter first examines the pathways for therapeutic goods approval in Australia, and considers how changes to the scheduling, approval or registration of medicinal cannabis products could improve access for patients.
- 4.6 It then explores the current regulatory requirements for the domestic production of medicinal cannabis, the impact of these requirements on supply and availability, and broader concerns about stock and supply of medicinal cannabis products in Australia.

Regulating medicinal cannabis products

- 4.7 All therapeutic goods in Australia are regulated by the Therapeutic Goods Administration (TGA), as outlined in Chapter 1. When discussing the TGA

¹ See Chapter 1, p. 3.

² Department of Health, *Submission 10*, pp. 3, 11, 27–28; Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative), *Submission 36*, p. 9.

³ Mr John Jackson, President, Victorian Branch, Pharmaceutical Society of Australia, *Committee Hansard*, 29 January 2020, p. 44.

regulation and approval of medicinal cannabis products, there are two key aspects to be considered:

- the type and concentration of cannabinoids, for example cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), in the product and how this results in its scheduling under the Uniform Scheduling of Medicines and Poisons (Poisons Standard); and
- whether the product has been approved and entered into the Australian Register of Therapeutic Goods (ARTG).

Scheduling in the Poisons Standard

4.8 As noted in Chapter 1, cannabis is currently included in three schedules of the Poisons Standard:

- Schedule 4 – Prescription Only Medicine (S4). S4 includes CBD products containing at least 98 per cent CBD;
- Schedule 8 – Controlled Substance (S8). S8 includes three manufactured medicines containing cannabis (nabiximols, nabilone and dronabinol), and cannabis and THC when prepared or packed for human therapeutic use in accordance with the *Narcotic Drugs Act 1967* (ND Act) and the TG Act; and
- Schedule 9 – Prohibited Substance (S9). S9 includes cannabis and THC for purposes other than those listed in S4 and S8.

4.9 As CBD products represent around one third of all medicinal cannabis products available for patient access in Australia,⁴ several submitters have suggested that moving CBD, particularly in lower doses, from S4 to Schedule 2 – Pharmacy Medicine (S2) or Schedule 3 – Pharmacist Only Medicine (S3) would increase patient access to these products by no longer requiring a prescription.⁵

4.10 As noted in Chapter 3, some CBD products are already sold over-the-counter, without a prescription, in countries such as the United Kingdom, Canada and Switzerland.⁶

4.11 LeafCann told the committee that down-scheduling CBD products to S3:

... would allow for faster access without having to get a script approved through SAS [Special Access Scheme] every time a patient wants to renew a prescription. Given the safety profile of CBD these products can be dispensed with confidence under the supervision of a pharmacist.⁷

⁴ Department of Health, *Submission 10*, p. 17; Lambert Initiative, *Submission 36*, p. 10.

⁵ See, for example, Lambert Initiative, *Submission 36*, p. 10; LeafCann Group, *Submission 4*, p. 2; Epilepsy Action Australia, *Submission 22*, p. 7.

⁶ See Chapter 3, p. 23.

⁷ LeafCann Group, *Submission 4*, p. 2.

4.12 The Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative) agreed, suggesting that CBD products containing low to moderate doses be scheduled as S2 and S3 and noting that such a change:

... would remove the requirement of many patients to engage in difficult, expensive and time-consuming engagement with an (often reluctant) medical profession, allow the tens of thousands of Australians using illicitly procured THC-dominant cannabis for conditions such as anxiety and insomnia to trial quality assured CBD-only products for their condition, and bring our policy framework into alignment with some of our closest international companions ...⁸

4.13 Epilepsy Action Australia proposed that a model of scheduling based on the concentration of CBD in the product could be introduced:

... with lower concentration medicines being classified as Schedule 2 Pharmacy Medicines; intermediate concentration medicines being classified as Schedule 3 Pharmacist Only Medicine; whilst higher concentrations remaining Schedule 4 Prescription Only Medicine.⁹

4.14 Mills Oakley and Bod Australia submitted that CBD-rich products which do not meet the 98 per cent CBD threshold but contain low THC and higher concentrations of non-psychoactive cannabinoids are still listed in S8, and that this would complicate their inclusion in lower schedules or as complementary medicines.¹⁰

4.15 Bod Australia proposed that products such as these, containing less than 0.3 per cent THC, could be down-scheduled from S8 in line with other CBD products:

This should see these products available over the counter in pharmacies under Schedule 3 of the Poisons Standard and would remove the need for Special Access Scheme (SAS) prescribing, thereby reducing cost to the Government.¹¹

4.16 Bod Australia also recommended that products containing greater than 0.3 per cent of the psychoactive THC should continue to be regulated as a controlled drug.¹²

4.17 The Department advised that the process for changing the scheduling of medicines in the Poisons Standard entails the following:

- any individual or organisation can apply to reschedule a particular substance, and the Department can also submit an application;

⁸ Lambert Initiative, *Submission 36*, p. 10.

⁹ Epilepsy Action Australia, *Submission 22*, p. 7.

¹⁰ Bod Australia, *Submission 19*, [p. 1]; Mills Oakley, *Submission 61*, p. 9.

¹¹ Bod Australia, *Submission 19*, [p. 2].

¹² Bod Australia, *Submission 19*, [p. 2].

- the Advisory Committee on Medicines Scheduling (ACMS) considers the application and public submissions relating to the application; and
 - the scheduling decision is made by a senior departmental medical officer, who is advised by ACMS.¹³
- 4.18 The Department submitted that it is currently undertaking a safety review of CBD at lower doses, to determine whether 'relaxation of the scheduling status of low dose CBD (e.g. to over the counter) could be considered during 2020'.¹⁴
- 4.19 At the public hearing in January, the TGA noted that the question of down-scheduling CBD would also possibly be put out for public consultation following this review:
- But we're a couple of months away from that, and it would be an extensive public consultation because ... there will be hundreds and hundreds of submissions with a wide diversity of views.¹⁵

UN Single Convention and the Poisons Standard

- 4.20 Submitters and witnesses informed the committee about proposed changes to the scheduling of cannabis in the UN Single Convention, which would change Australia's international obligations in relation to the storage, manufacture and handling of certain medicinal cannabis products and may have an impact on their scheduling in the Poisons Standard.¹⁶
- 4.21 Specifically, submitters raised the following changes which had been recommended by the World Health Organization's Expert Committee on Drug Dependence:
- removing cannabis and cannabis resin from Schedule IV, the prohibition schedule;
 - adding certain products containing THC into Schedule III; and
 - removing (de-scheduling) CBD from the convention entirely.¹⁷
- 4.22 These proposals were due to be considered in early March 2020 at the 63rd session of the United Nations Commission on Narcotic Drugs, but the vote was postponed until December 2020 'in order to clarify the implications and

¹³ Department of Health, *Submission 10*, p. 7. See also, Therapeutic Goods Administration (TGA), Scheduling committees meeting dates and decisions timeframes, December 2019, www.tga.gov.au/scheduling-committees-meeting-dates-and-decisions-timeframes (accessed 12 March 2020).

¹⁴ Department of Health, *Submission 10*, p. 8.

¹⁵ Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 29 January 2020, p. 74.

¹⁶ See, for example, Lambert Initiative, *Submission 36*, p. 9; Mills Oakley, *Submission 61*, Attachment 1, [p. 23].

¹⁷ Lambert Initiative, *Submission 36*, p. 9; Mills Oakley, *Submission 61*, Attachment 1, [p. 23].

consequences of, as well as the reasoning for' the proposed scheduling changes.¹⁸

- 4.23 The TGA clarified for the committee that any de-scheduling of CBD from the UN Single Convention would be unrelated to an Australian decision about down-scheduling CBD in the Poisons Standard:

So the United Nations Commission on Narcotic Drugs has this WHO recommendation to take cannabidiol out of the class of schedules ... as drugs of dependence. ... But that is about whether cannabidiol is or isn't a drug of dependence. ... And while that may have implications for how hemp is handled that does not relate to whether scheduling, for example, low-dose cannabidiol products could be considered for over-the-counter use.¹⁹

- 4.24 However, the Department noted that the down-scheduling of other cannabis products in the UN Single Convention could have an impact on the Poisons Standard, as the Scheduling Policy Framework for S8 and S9 makes reference to a drug's status in the Schedules of the UN Single Convention and the United Nations Convention on Psychotropic Substances.²⁰

Registration of medicinal cannabis products in the ARTG

- 4.25 One of the main barriers to accessing medicinal cannabis raised by submitters is the lack of medicinal cannabis products in the ARTG, with only nabiximols (Sativex) currently registered.²¹

- 4.26 In Australia, all approved therapeutic goods are entered into the ARTG. Therapeutic goods entered in the ARTG can be lawfully supplied and do not require special approval from the TGA for their use.²² The Department submitted that:

... where it is anticipated that particular products will be used to a significant extent in the future, sponsors are encouraged to develop the data required for ... registration. Potential advantages of registration may include wider prescriber confidence in the quality, safety and efficacy of the product; availability at community pharmacies on a standard

¹⁸ United Nations Economic and Social Council, Commission on Narcotic Drugs, [Draft decision submitted by the Chair: Changes in the scope of control of substances: proposed scheduling recommendations by the World Health Organization on cannabis and cannabis-related substances](#), 1 March 2020.

¹⁹ Dr Skerritt, *Committee Hansard*, 29 January 2020, p. 64.

²⁰ Department of Health, *Submission 10*, p. 7. See also: Australian Health Ministers' Advisory Council, [Scheduling Policy Framework for Medicines and Chemicals](#), January 2018.

²¹ See, for example, LeafCann Group, *Submission 4*, p. 3; UIC, *Submission 6, Attachment 2*, p. 29; Australian Centre for Cannabinoid Clinical and Research Excellence, *Submission 15*, p. 2. See also, Mrs Elizabeth de Somer, Chief Executive Officer, Medicines Australia, *Committee Hansard*, 29 January 2020, p. 50.

²² TGA, *How we regulate medicines*, June 2019, www.tga.gov.au/how-we-regulate-medicines (accessed 12 March 2020).

prescription; and the ability of the sponsor to apply for PBS [Pharmaceutical Benefits Scheme] subsidy for the product.²³

- 4.27 There are three categories of medicines in the ARTG – Listed, Assessed Listed and Registered – as outlined in Table 4.1. The categories determine the level of evaluation required before a product is included in the ARTG, as do the status of the product's ingredients either in the Poisons Standard or in Therapeutic Goods (Permissible Ingredients) Determination (the list of approved complementary medicine ingredients) and the indications for which the product is intended.²⁴

Table 4.1 Categories and requirements in the Australian Register of Therapeutic Goods

	Listed – AUST L	Assessed Listed – AUST L(A)	Registered – AUST R
Pre-market efficacy assessment	No	Yes	Yes
Ingredients	From list in Therapeutic Goods (Permissible Ingredients) Determination only	From list in Therapeutic Goods (Permissible Ingredients) Determination only	Ingredients assessed pre-market
Indications	From list in Therapeutic Goods (Permissible Indications) Determination only	Conditions assessed pre-market	Conditions assessed pre-market
Available off-the-shelf	Yes	Yes	Some
Requires a prescription	No	No	Some

Source: Adapted from www.tga.gov.au/how-we-regulate-medicines.

- 4.28 Any prescription medicine is subject to the highest level of evaluation before being registered in the ARTG, requiring a sponsor of the product (usually a

²³ Department of Health, *Submission 10*, p. 6.

²⁴ TGA, *How we regulate medicines*, June 2019, www.tga.gov.au/how-we-regulate-medicines (accessed 12 March 2020).

pharmaceutical company) to submit a dossier of evidence on the clinical efficacy, safety and manufacturing quality for evaluation by the TGA.²⁵

- 4.29 The Department anticipates that an ARTG registration application will soon be made for Epidiolex, a CBD-only medicine for patients with epilepsy. In late 2019, this product received a priority review determination, which provides for an expedited assessment, and an orphan drug designation, which allows for application and evaluation fees to be waived, in anticipation of an application.²⁶
- 4.30 There are also up to 20 commercial clinical trials for other medicinal cannabis products currently underway in Australia 'with the expectation that they will seek ARTG approval'.²⁷

Willingness to seek registration for medicinal cannabis

- 4.31 Submitters have raised concerns about the willingness of medicinal cannabis manufacturers to participate in the ARTG registration process for their products, in particular willingness to gather the large amount of clinical evidence required for an application.²⁸
- 4.32 FreshLeaf Analytics told the committee:
- There is little commercial incentive for any company to invest in the kinds of clinical trials required ... as their products are botanically derived generics and not protected by patent monopoly rights.²⁹
- 4.33 This issue was also raised by Mills Oakley, which told the committee that:
- The investment into preparing such a dossier is prohibitive, running into tens of millions of dollars, and not commercially viable when it is weighed against the inability to obtain [intellectual property] protection and the difficulties in obtaining PBS listing.³⁰
- 4.34 In response to concerns that the medicinal cannabis industry does not have an interest in pursuing ARTG registration for products, the Department has made clear that it has 'no power to compel a sponsor to make a submission to the TGA for registration in the ARTG'.³¹

²⁵ Department of Health, *Submission 10*, p. 5. See also, TGA, *Prescription medicines overview*, November 2019, www.tga.gov.au/prescription-medicines-overview (accessed 12 March 2020).

²⁶ Department of Health, *Submission 10*, p. 10; Dr Skerritt, *Committee Hansard*, 29 January 2020, p. 73.

²⁷ Dr Skerritt, *Committee Hansard*, 29 January 2020, p. 64.

²⁸ See, for example, Medical Cannabis Users Association of Australia (MCUA), *Submission 9*, p. 16; Medical Cannabis Knowledge Network, *Submission 13*, p. 6; UIC, *Submission 6*, p. 9; Entoura, *Submission 25*, [p. 3].

²⁹ FreshLeaf Analytics, *Submission 14*, p. 6.

³⁰ Mills Oakley, *Submission 61*, p. 7.

³¹ Department of Health, *Submission 10*, p. 5.

4.35 However, Mrs Elizabeth de Somer, Chief Executive Officer of Medicines Australia, noted that the TGA has previously worked with the pharmaceutical industry to find a sponsor for products which were not commercially viable, citing the example of tamoxifen for the prevention of breast cancer:

... working with sponsors, the TGA was able to identify a sponsor that was willing to put in the effort for that expanded access to be made. I think that there is opportunity and willingness between sponsors and the TGA to find a solution that still reviews evidence, is still evidence based and puts some effort in capturing ongoing evidence as it emerges—so building that evidence base over time and making a decision based on what they have in front of them.³²

Changing the clinical trial evidence requirements of registration

4.36 Medicinal Cannabis Industry Australia (MCIA) and other submitters proposed that applications for ARTG registration of medicinal cannabis products should be allowed to include evidence from 'n-of-1' clinical trials, where the entire trial cohort is a single patient, to reduce the burden for sponsors in conducting large-scale trials.³³

4.37 The Medical Cannabis Council explained:

Results of n-of-1 studies can be collected and collated to provide scientific rationale for further controlled clinical trials for specific indications being implemented. ... We therefore request that N-of-1 trials be ... an optional source of evidence to enable medicinal cannabis companies to register their products in the ARTG. This would enable registration of products without the considerable burden of running large, expensive and challenging up-front controlled clinical trials.³⁴

4.38 However, other submitters were adamant that ARTG requirements should not be relaxed or changed for the registration of prescription medicinal cannabis products and that further clinical evaluation is required before these medicines are approved for use.³⁵

4.39 Professor James Angus, Chair of the Australian Advisory Council on the Medicinal Use of Cannabis, submitted that:

If the TGA moved to register cannabis products under our present state of knowledge of efficacy and safety it would set a precedent and potentially jeopardise the regulatory system as we know it. The gaps are substantial in current knowledge about the dose, delivery of different products, therapeutic use as add-on therapy or stand-alone therapy in the treatment

³² Mrs de Somer, Medicines Australia, *Committee Hansard*, 29 January 2020, p. 51.

³³ Medical Cannabis Council, *Submission 37*, p. 3; Professor Laurence Mather, *Submission 113*, p. 3; MCIA, *Submission 5*, p. 23; Entoura, *Submission 25*, [p. 3].

³⁴ Medical Cannabis Council, *Submission 37*, p. 3.

³⁵ See, for example, Australian Centre for Cannabinoid Clinical and Research Excellence, *Submission 15*, p. 1; GW Pharmaceuticals, *Submission 119*, pp. 3–4.

of a broad spectrum of conditions and diseases. This poses an unacceptable risk in my view to changing the current requirements of registration that have a remarkable track record.³⁶

- 4.40 The Australian Medical Association also made the point that clinical trials provide the sort of evidence that health professionals rely upon in making decisions to prescribe a medicine:

What GPs are asking for is an opportunity to be informed about exactly where the evidence is going. One of the reasons we're doing the clinical trials is to understand its efficacy and the actual formulations that are available and how they should be used.³⁷

A separate ARTG registration for medicinal cannabis

- 4.41 LeafCann and Entoura, two organisations from the medicinal cannabis industry, proposed that an additional category of 'AUST C' could be introduced into the ARTG specifically for the assessment and listing of medicinal cannabis products.³⁸

- 4.42 LeafCann submitted that:

This would be parallel to the "TGA Listed Assessed" (AUSTLA) category which is intermediate between TGA Listed (AUSTL) and TGA Registered (AUSTR) and would require a dossier of data that supports efficacy for particular indications, but not the same level of safety data as required for AUSTR, because of the inherent safety profile of cannabinoids.³⁹

- 4.43 Entoura described that an 'AUST C' category could require:

... a dossier of data supporting the efficacy for stated indications that would have minimum requirements of clinical studies, including the use of observational n=1 studies as supporting data. This category should be required to have specific Product Information (PI) and Consumer Medicines Information (CMI) available following the Black Triangle Scheme for new prescription medicines.⁴⁰

³⁶ Professor James Angus, *Submission 53*, [p. 2].

³⁷ Dr Tony Bartone, President, Australian Medical Association, *Committee Hansard*, 29 January 2020, p. 29.

³⁸ LeafCann Group, *Submission 4*, p. 2; Entoura, *Submission 25*, [p. 3].

³⁹ LeafCann Group, *Submission 4*, p. 2.

⁴⁰ Entoura, *Submission 25*, [p. 3]. For more information about the TGA's Black Triangle Scheme for new medicines, see www.tga.gov.au/black-triangle-scheme.

Regulating cannabinoids as complementary medicines

4.44 The Medical Cannabis Users Association of Australia and other submitters made the argument that cannabis, as a plant, is a 'herbal' medicine and therefore should be regulated as a complementary medicine.⁴¹

4.45 The Medical Cannabis Users Association of Tasmania submitted that:

The prescription medicine system is suited towards single molecule synthetic products not multi molecule botanicals which are much better suited to the Complimentary Medicines category for herbal and natural products.⁴²

4.46 Australasian College of Nutritional and Environmental Medicine and other submitters recommended that non-psychotropic cannabinoids, in particular CBD, be removed from the Poisons Standard and be listed in the Therapeutic Goods (Permissible Ingredients) Determination instead.⁴³ This would effectively grant them complementary medicine status and:

... would then open up access to patients, and it would also allow it to be prescribed by other qualified healthcare practitioners.⁴⁴

4.47 Including certain cannabinoids in the Therapeutic Goods (Permissible Ingredients) Determination would also allow medicinal cannabis products to be listed as AUST L or AUST L(A) in the ARTG and would remove the need for more detailed registration applications.

4.48 However, the inclusion of complementary medicine ingredients in this determination is still subject to TGA reviews for safety.⁴⁵ Medicines Australia told the committee that:

It would be a decision of the [TGA] to determine ... whether cannabinoids fit into that criteria.⁴⁶

4.49 Some witnesses disagreed with the proposal of treating medicinal cannabis as a complementary medicine. Mr Anthony Tassone, a member of the National Council of the Pharmacy Guild of Australia, warned that:

⁴¹ MCUA, *Submission 9*, p. 21; Nimbin Hemp Embassy, *Submission 28*, [p 2]; Medical Cannabis Users Association of Tasmania (MCUAT), *Submission 116*, p. 2; Dr Deborah Waldron, *Submission 126*, p. 3.

⁴² MCUAT, *Submission 116*, p. 2.

⁴³ See, for example, MCUA, *Submission 9*, p. 4; MCUAT, *Submission 116*, p. 2; Mills Oakley, *Submission 61*, p. 9; Australasian College of Nutritional and Environmental Medicine (ACNEM), *Submission 29*, pp. 5–6.

⁴⁴ Professor Kylie O'Brien, Member, ACNEM, *Committee Hansard*, 29 January 2020, p. 39.

⁴⁵ TGA, *Changes to the Permissible Ingredients Determination*, March 2020, www.tga.gov.au/changes-permissible-ingredients-determination (accessed 12 March 2020).

⁴⁶ Mrs de Somer, Medicines Australia, *Committee Hansard*, 29 January 2020, p. 50.

... if we classified [medicinal cannabis] products as a complementary or herbal medicine ... and were only looking at quality and safety but not efficacy or effectiveness as we do for prescription medicines, we would be doing our patients a disservice.⁴⁷

4.50 Mr Jarrod McMaugh from the Pharmaceutical Society of Australia also reflected that the plant origin of medicinal cannabis products was not sufficient to class them as 'herbal' medicines:

... the scheduling processes are there to look at not just the safety of medicines but also the specific reason that we use a medicine ... it's not just about, 'Well, it's from a plant; therefore, it's a herbal product,' otherwise we would have opiates and cocaine available that way—both are from plants.⁴⁸

Committee view

4.51 The committee notes significant support from submitters and witnesses for cannabidiol-based products to be made available over-the-counter, either through down-scheduling in the Poisons Standard or by being regulated as complementary medicines. The committee also recognises that there are a wide range of views about whether cannabidiol and other non-psychoactive cannabinoids should be regulated as pharmaceutical or complementary medicines.

4.52 Allowing medicinal cannabis products containing low-dose cannabidiol with very low levels of psychoactive cannabinoids to be accessed over-the-counter would greatly increase the accessibility of these products for patients. It would also bring Australia in closer in line with models of access in countries such as the United Kingdom and Canada.

4.53 The committee also notes that the Therapeutic Goods Administration is currently undertaking a safety review of low-dose cannabidiol and anticipates that the question of de-scheduling or down-scheduling these substances may be put to public consultation in the near future.

4.54 However, the committee is unclear whether it is intended that this public consultation is to be part of the ordinary public consultation process in response to a specific scheduling application to the Advisory Committee on Medicines Scheduling, or if it is intended as a broader review by the TGA.

⁴⁷ Mr Anthony Tassone, National Councillor, Pharmacy Guild of Australia, *Committee Hansard*, 29 January 2020, p. 48.

⁴⁸ Mr Jarrod McMaugh, Project Pharmacist, Pharmaceutical Society of Australia, *Committee Hansard*, 29 January 2020, pp. 47–48.

Recommendation 12

- 4.55 The committee recommends that the Therapeutic Goods Administration, as a matter of priority, conduct broad public consultation on the future scheduling of cannabidiol and other non-psychoactive cannabinoids.**
- 4.56 This public consultation should be conducted with the aim of the Department of Health making an application to the Advisory Committee on Medicines Scheduling, if deemed appropriate, and should therefore consider:
- the current inclusion of cannabidiol in the Uniform Scheduling of Medicines and Poisons (Poisons Standard) Schedule 4 – Prescription Only Medicine and other cannabinoids in Schedule 8 – Controlled Substance;
 - the suitability of down-scheduling these cannabinoids to Schedule 2 – Pharmacy Medicine and/or Schedule 3 – Pharmacist Only Medicine; and
 - the suitability of regulating these cannabinoids as complementary medicines, through removal from the Poisons Standard and inclusion in the Therapeutic Goods (Permissible Ingredients) Determination.
- 4.57 The committee is of the view that a safety review and public consultation process will provide the Therapeutic Goods Administration with the evidence required to determine the most appropriate pathway for the future regulation of cannabidiol and other non-psychoactive cannabinoids consistent with the requirements of safety and quality for all therapeutic goods in Australia.

Recommendation 13

- 4.58 The committee further recommends that, as soon as practicable after a safety review and public consultation process is completed, the Department of Health make any appropriate application to the Advisory Committee on Medicines Scheduling in relation to the down-scheduling or de-scheduling of cannabidiol and other non-psychoactive cannabinoids.**
- 4.59 The committee also notes that the scheduling of cannabis and cannabis-related products in international drug control conventions may have flow-on effects for Australian regulations, both in relation to the scheduling of cannabis and for the production of medicinal cannabis products. These effects are considered in further detail below.

Medicinal cannabis supply in Australia

- 4.60 A common theme throughout the inquiry was the availability and supply of medicinal cannabis products in Australia, in particular products which have been cultivated and produced domestically.

4.61 It is estimated by the Department that only 10 per cent of medicinal cannabis products prescribed through the Special Access Scheme in 2019 were locally cultivated and manufactured.⁴⁹

Locally-manufactured medicinal cannabis products

4.62 Evidence to the committee suggests that the current low level of locally cultivated and manufactured medicinal cannabis products is due to the following factors:

- the newness of the medicinal cannabis industry in Australia;
- the licensing processes of the Office of Drug Control (ODC) under the ND Act and related regulations, which were outlined in Chapter 1; and
- the costs and current inefficiencies of production.

An industry in infancy

4.63 Submitters noted that the medicinal cannabis industry in Australia is still 'in its infancy' and that this was a major factor in the low level of Australian product currently available.⁵⁰

4.64 While the ODC regulatory scheme for the cultivation, manufacture and production of medicinal cannabis was established in October 2016, the first licences were only granted in 2017.⁵¹ In 2018, Little Green Pharma, a company based in Western Australia, became the first company supply medicinal cannabis products locally grown and produced to Australian patients.⁵²

4.65 The Department commented that the medicinal cannabis industry's achievement of 'licensing, construction of facilities, production, manufacture and sale of a prescription medicine product' within less than two years was 'remarkable'.⁵³

4.66 FreshLeaf Analytics submitted that, although only two Australian companies have currently brought medicinal cannabis products to market, it is anticipated several more locally-cultivated products will become available early this year.⁵⁴

4.67 Officers from the Department explained that Australian companies are currently licenced to produce up to 35 000 kilograms of medicinal cannabis and that by the end of 2020 the market share of Australian products may be

⁴⁹ Department of Health, *Submission 10*, p. 39.

⁵⁰ See, for example, FreshLeaf Analytics, *Submission 14*, p. 7; Tasmanian Alkaloids, *Submission 63*, pp. 2, 7; Department of Health, *Submission 10*, p. 39.

⁵¹ Department of Health, *Submission 10*, p. 39.

⁵² Department of Health, *Submission 10*, p. 39; Little Green Pharma, *Submission 38*, p. 1.

⁵³ Department of Health, *Submission 10*, p. 39.

⁵⁴ FreshLeaf Analytics, *Submission 14*, p. 7.

significantly higher, possibly up to half of the market, once more production is underway.⁵⁵

Licensing and the Office of Drug Control (ODC)

4.68 Overwhelmingly, submitters cited the key barrier to local medicinal cannabis supply being the significant delays experienced by applicants in receiving appropriate licences from the ODC.⁵⁶

4.69 As outlined in Chapter 1, there are currently three types of licences:

- medicinal cannabis licence, authorising cultivation or production or both;
- cannabis research licence, authorising a similar process for research purposes; and
- manufacturing licence, authorising the manufacture of a drug or product.⁵⁷

4.70 It appears that delays in processing licences for cultivation, research, manufacturing and importation of medicinal cannabis products have been due to under-resourcing of the ODC.⁵⁸

4.71 The Department recognised that there have been some challenges for the ODC to process and issue licences:

Since the commencement of the Scheme in October 2016 there has been a significantly higher volume of licence applications than was forecast when the scheme was developed. This has created resourcing and processing challenges for ODC in administering the scheme.⁵⁹

4.72 The impact of the ODC receiving hundreds of applications for licences and permits has had a significant impact on the ability of researchers and industry alike to conduct their business.⁶⁰

4.73 For example, LeafCann, a medicinal cannabis manufacturer, submitted that the current ODC delays have caused the Australia medicinal cannabis industry to move 'at such a slow pace' that very few companies have been able to make finished products for domestic supply.⁶¹

⁵⁵ *Committee Hansard*, 29 January 2020, pp. 77–78.

⁵⁶ See, for example, UIC, *Submission 6*, p. 27; CANNATREK, *Submission 33*, p. 1; Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 13; ACNEM, *Submission 29*, p. 13; LeafCann Group, *Submission 4*, p. 5.

⁵⁷ See Chapter 1, p. 7.

⁵⁸ Ms Elisabetta Faenza, Director and Board Member, MCIA, *Committee Hansard*, 29 January 2020, p. 56; Department of Health, *Committee Hansard*, 29 January 2020, pp. 68–69.

⁵⁹ Department of Health, *Submission 10*, p. 28.

⁶⁰ LeafCann Group, *Submission 4*, p. 6; Medical Cannabis Research Australia, *Submission 121*, p. 6.

⁶¹ LeafCann Group, *Submission 4*, p. 6.

4.74 The Medical Cannabis Council explained that the ODC's approach to assessing applications as they are received has also contributed to this slow pace:

To date, the ODC has been processing separate licences on a strict queue basis, regardless of prior applications, incomplete applications or the quality of application. This has resulted, for example, in some applicants receiving their manufacturing licence but then having to wait 1-2 years for their cultivation licence to be issued ... such delays have already been extremely costly for many of our members.⁶²

4.75 Peter Crock, Chairman of MCIA, also told the committee:

For those who are through the process and looking to operate under a permit, we've had delays in getting timely responses to permits which are the key to the production of product to take through the system.⁶³

Issues with cannabis research licence

4.76 The Lambert Initiative explained that, in their experience, the mechanics of obtaining their research licences were 'routine and perfunctory', but that:

... under-resourcing of the ODC has led to increased delays in processing these permits from 20 working days (the stated estimates for processing Import Permits in ODC communications) to approximately 7-8 weeks (being verbal estimates provided in November 2019).⁶⁴

4.77 Medicines Australia told the committee about the importance of streamlined regulation for importing products for use in clinical trials:

The regulatory framework for initiating clinical trials can be lengthy and onerous ... and we have heard that there have been hold-ups to getting clinical trial materials through the border. It would be disappointing if clinical trials that were set up to examine medicinal cannabis were held up in accessing those products by barriers created by our borders. Accessible clinical trial products should be as streamlined, efficient and regulation free as possible.⁶⁵

Recommended way forward

4.78 In light of these concerns, submitters called for an increase in resourcing in both funding and staffing for the ODC to improve the speed of processing licences.⁶⁶

⁶² Medical Cannabis Council, *Submission 37*, [p. 7]. See also, Ms Faenza, MCIA, *Committee Hansard*, 29 January 2020, p. 56.

⁶³ Mr Peter Crock, Chairman, MCIA, *Committee Hansard*, 29 January 2020, p. 60.

⁶⁴ Lambert Initiative, *Submission 36*, pp. 8–9.

⁶⁵ Mrs de Somer, Medicines Australia, *Committee Hansard*, 29 January 2020, p. 52. See also, Professor Iain McGregor, Academic Director, Lambert Initiative, University of Sydney, *Committee Hansard*, 29 January 2020, p. 25.

⁶⁶ Cann Group Limited, *Submission 30*, pp. 2–3; CANNATREK, *Submission 33*, p. 1.

- 4.79 Submitters also noted the independent *Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967* conducted by Professor John McMillan AO (McMillan review), tabled in September 2019, which recommended changes to reduce some of the regulatory burden on the ODC.⁶⁷
- 4.80 Significantly, one of the key recommendations was to establish a new licence structure for medicinal cannabis products, providing for the issue of a single licence to authorise all or some of cultivation, production, manufacture and research of such products.⁶⁸
- 4.81 Submitters supported the proposal for streamlining the licence process into a single licence model.⁶⁹ MCIAC told the committee that:
- Improving and streamlining the existing legislation and operations of [the] Office of Drug Control will assist to facilitate patient access to timely, cost effective and quality Australian product.⁷⁰
- 4.82 The Minister for Health has committed to implementing all of the recommendations of the McMillan review.⁷¹
- 4.83 As part of the process in developing the single licence model, the ODC published a consultation paper in December 2019 and conducted public consultation meetings in February 2020 following written submissions.⁷²
- 4.84 The Department submitted that amendments to the ND Act to make the necessary changes to implement this streamlined model would be introduced into parliament in 2020.⁷³

Cultivation and production efficiencies

- 4.85 Low-THC hemp – a strain of the *Cannabis sativa* plant species – can be grown in Australia for non-medicinal purposes under state licencing schemes.⁷⁴

⁶⁷ MCIAC, *Submission 5*, p. 3; FreshLeaf Analytics, *Submission 14*, p. 6; Cann Group Limited, *Submission 30*, p. 2; Alcohol and Drug Foundation, *Submission 26*, p. 7.

⁶⁸ Professor John McMillan AO, [Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967](#), September 2018, Recommendation 7.

⁶⁹ Country Women's Association of Australia, *Submission 120*, [p. 2].

⁷⁰ MCIAC, *Submission 5*, p. 3.

⁷¹ Department of Health, *Submission 10*, p. 28.

⁷² Office of Drug Control (ODC), *Consultation: Single Licence Model*, December 2019, www.odc.gov.au/consultation-single-licence-model (accessed 12 March 2020); ODC, *Single Licence Model Consultation: Closing date for submissions*, January 2020, www.odc.gov.au/news-media/news/single-licence-model-consultation-closing-date-submissions (accessed 12 March 2020).

⁷³ Department of Health, *Submission 10*, p. 28. See also, Dr Skerritt, *Committee Hansard*, 29 January 2020, p. 64.

⁷⁴ ACNEM, *Submission 29*, pp. 13–14; Professor John McMillan AO, [Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967](#), September 2018, p. 20.

4.86 Several submitters raised that a potential area for improvement in the efficiency and cost of medicinal cannabis production in Australia would be to allow these industrial hemp crops to become 'dual use' and harvested for cannabinoids such as CBD.⁷⁵ The Australasian College of Nutritional and Environmental Medicine explained that most industrial hemp crops are used only for the fibre from the stalk of the plants, and that the buds and flowers could be used to extract CBD.⁷⁶

4.87 As Dr Les Baxter from Tasmanian Alkaloids explained, there is a significant potential in allowing the dual use of crops in this way:

If you assume that there's maybe two per cent CBD in the residual plant, you're talking about up to 200 tonnes of CBD [nationally] that is potentially there and currently not accessible to the pharmaceutical industry for extraction.⁷⁷

4.88 Dr Baxter further explained that hemp crops grown in Australia must be grown either for the purpose of industrial hemp or for medicinal cannabis, and are thus subject to either state/territory or Commonwealth law:

Currently, you have to nominate whether you're growing a crop for industrial hemp or medicinal cannabis. If you grow for industrial hemp, it's under state jurisdiction and you can't extract from it. If you want to grow it for extraction, it comes under medicinal cannabis legislation and that controls the way that it's grown. It has to be grown under the Commonwealth legislation and that limits what can be done.⁷⁸

4.89 These limitations on the cultivation of cannabis are also related to Australia's obligations under the UN Single Convention. MCIA explained that:

Under international law under the single convention, you cannot use a hemp crop for the extraction of cannabinoids. That's overarching.⁷⁹

4.90 Some submitters described that the interaction between state/territory and Commonwealth licencing for industrial hemp and medicinal cannabis was confusing and burdensome for producers, and that the costs of growing the same crop for different purposes were vastly different.⁸⁰ Dr Teresa Nicoletti described that:

A company that has a hemp licence can grow industrial hemp, broadacre. ... You may need some security fencing, but it's just two- or three-metre-

⁷⁵ Dr Ross Murdoch, Chief Executive Officer, Tasmanian Alkaloids, *Committee Hansard*, 29 January 2020, p. 57; Tasmanian Alkaloids, *Submission 63*, p. 3.

⁷⁶ ACNEM, *Submission 29*, pp. 13–14.

⁷⁷ Dr Leslie (Les) Baxter, Director, Agricultural Research and Development, Tasmanian Alkaloids, *Committee Hansard*, 29 January 2020, p. 61.

⁷⁸ Dr Baxter, Tasmanian Alkaloids, *Committee Hansard*, 29 January 2020, p. 61.

⁷⁹ Ms Faenza, MCIA, *Committee Hansard*, 29 January 2020, p. 61.

⁸⁰ Bod Australia, *Submission 19*, [pp. 1–3]; Mills Oakley, *Submission 61*, Attachment 1, pp. 32–36.

high fencing to comply with local requirements. If that same crop is used for medicinal purposes, you can spend \$10 million to \$20 million constructing a secure facility that regulates that product as a medicinal cannabis product.⁸¹

4.91 The committee notes that the McMillan review considered the issues surrounding hemp cultivation and supply in relation to the ND Act, the UN Single Convention and the consequences for the production of industrial hemp.⁸² While that review noted that deeper consideration of these issues were outside of its scope, it summarised that:

Australian law and the Single Convention are framed on the understanding that the rigorous requirements of the Convention do not apply to non-narcotic substances that are derived from the cannabis plant if used for industrial and horticultural purposes and not for medicinal or scientific purposes. That understanding is broadly reflected in Australian laws that differentiate between cultivation and manufacture of cannabis products to which the ND Act applies, and low-THC hemp production that is regulated by State and Territory laws.⁸³

4.92 The McMillan review noted that a new Single Licence Model could:

... enable fresh consideration of regulatory options for ensuring effective alignment and integration of ND Act licensing and State and Territory regulation, particularly of industrial/low-THC hemp.⁸⁴

General concerns about stock and supply

4.93 Due to the currently limited production of Australian medicinal cannabis products, there has been a reliance on imported products to meet the needs of patients and researchers.⁸⁵

4.94 The current reliance on overseas products has been cited by submitters as a major contributor to cost, as will be discussed in detail in Chapter 5.

4.95 Submitters have also raised concerns about the quality of these imported medicinal cannabis products, as well as issues relating to stock shortages and the time taken to import products, which are discussed below.

⁸¹ Dr Teresa Nicoletti, Partner, Mills Oakley; Director, Medical Cannabis Council; and Member, Australian Lawyers Alliance, *Committee Hansard*, 29 January 2020, p. 16.

⁸² Professor John McMillan AO, Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967, September 2018, pp. 47–48.

⁸³ Professor John McMillan AO, Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967, September 2018, p. 48.

⁸⁴ Professor John McMillan AO, Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967, September 2018, p. 50.

⁸⁵ See, for example, MCIA, *Submission 5*, p. 4; Nimbin Hemp Embassy, *Submission 28*, [p. 3]; Medical Cannabis Council, *Submission 37*, [p. 5]; UIC, *Submission 6*, Attachment 2, p. 32.

Quality of medicinal cannabis products

4.96 All unapproved medicinal cannabis products imported into, supplied and manufactured in Australia are required to meet the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017, commonly referred to as TGO 93.⁸⁶

4.97 Entoura and other submitters have raised concerns that medicinal cannabis products being imported into Australia – either for approved or illicit use – may not be meeting the standard set in TGO 93:

The delays experienced in the licence approvals for Australian manufacturers has led to an influx of imported medicinal cannabis products that may or may not be of an equivalent standard to those produced under TGA oversight in Australia.⁸⁷

4.98 However, as the Australasian College of Nutritional and Environmental Medicine noted, proving compliance with TGO 93 may not be straightforward for international manufacturers:

For Australian MC companies importing from the US and Canada, it is particularly problematic as many laboratories in those countries do not test all of the items required under TGO93 and for particular items, may use a different standard (eg. a different cut-off level for presence of a particular heavy metal).⁸⁸

4.99 Other submitters raised concerns that imported products are not required to be compliant with the TGA's Good Manufacturing Practice (GMP) requirements, which are principles and procedures for manufacturers of medicines in Australia.⁸⁹

4.100 The TGA's guidance on this matter notes that that imported medicinal cannabis products not on the ARTG and intended to be used through appropriate access pathways do not require GMP clearance, but:

... the medicinal cannabis product must be manufactured in accordance with an acceptable manufacturing standard. ... The countries that demonstrate compliance [with guiding principles for an acceptable standard] currently include Canada, Germany, the Netherlands, Switzerland and Israel.⁹⁰

⁸⁶ TGA, *Conforming with Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*, Version 1.2, May 2019, www.tga.gov.au/conforming-therapeutic-goods-standard-medicinal-cannabis-tgo-93-order-2017 (accessed 12 March 2020).

⁸⁷ Entoura, *Submission 25*, [p. 4]. See also, CANNATREK, *Submission 33*, [p. 4]; ACNEM, *Submission 29*, p. 7.

⁸⁸ ACNEM, *Submission 29*, p. 15.

⁸⁹ Mills Oakley, *Submission 61*, p. 19; Little Green Pharma, *Submission 38*, p. 2; AusCann Group Holdings, *Submission 122*, p. 5.

⁹⁰ TGA, *Access to medicinal cannabis products*, March 2020, www.tga.gov.au/access-medicinal-cannabis-products-1 (accessed 13 March 2020).

4.101 Little Green Pharma submitted that:

... it is a point of concern that imported medicinal cannabis products and active pharmaceutical ingredients (APIs) are not automatically subject to GMP-equivalent quality requirements, as are all other medicinal products imported from these jurisdictions.⁹¹

4.102 AusCann Group noted that a lack of GMP requirement for imported product also impacts upon the competitiveness of the Australian industry and proposed that the principles of GMP become a requirement for imported medicinal cannabis products:

It is critical that imported products are required to meet the same standards as domestically produced products to ensure a level playing field. Active monitoring of imported (and domestic) products is essential, coupled with appropriate action against a Sponsor supplying non-compliant products.⁹²

Stock shortages and delayed access

4.103 Submitters and witnesses also described how the reliance on overseas product is contributing to issues of stock shortages and delayed access for patients.⁹³

4.104 One patient described the frustration of stock shortages and delays when trying to access medicinal cannabis through SAS-B, which can require reapplications if stock is not available:

This past month due to a change in script requiring another approval from the TGA, and the product having to be imported from Canada, I ran out and was left without cannabis oil for almost three weeks. When I did receive the two bottles I had ordered, the expiry date was within the next two months, meaning about half a bottle was due to expire before I would have been able to finish it.⁹⁴

4.105 Epilepsy Action Australia described the impact of stock delays from overseas on a patient's treatment, and how this can have serious impacts on their health:

There have been recent disruptions in supply of particular pharmaceutical grade cannabinoid-based medicines which have impacted our clients. This has been of particular concern and source of anxiety, especially when the person has experienced a significant reduction in seizure frequency and severity and weaned off all other conventional antiepileptic medications. The sudden cessation of any medicine used as an anticonvulsant places the

⁹¹ Little Green Pharma, *Submission 38*, p. 2.

⁹² AusCann Group Holdings, *Submission 122*, p. 5. See also, FreshLeaf Analytics, *Submission 14*, p. 3.

⁹³ See, for example, Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 7; Entoura, *Submission 25*, [p. 6]; Alcohol and Drug Foundation, *Submission 26*, p. 9.

⁹⁴ Aurora Pearce, *Submission 48*, p. 2.

individual at significant risk of status epilepticus and life-threatening seizures.⁹⁵

4.106 The Australian Centre for Cannabinoid Clinical and Research Excellence proposed that measures should be put in place 'to mitigate imported cannabis medicines shortages and improve continuity of patient care', noting that:

In the event of stock shortages for NSW patients, the NSW Cannabis Medicines Advisory Service has assisted health practitioners with sourcing alternative, similar products, however ... there are no equivalent services in other states and territories.⁹⁶

4.107 The TGA explained that medicine shortage is 'one of the biggest threats we have to public health in Australia', but that reporting of shortages is only required for reportable, approved prescription medicines and not for unapproved medicinal cannabis products:

Because these are on the Special Access Scheme we lack the same powers we have for mandatory reporting of shortages. The Therapeutic Goods Act changed so ... it was mandatory for companies to report shortages only of the registered TGA approved ones, so we don't have good visibility of shortages of these products. It's another reason why we want more of these to be on the [ARTG].⁹⁷

Committee view

4.108 The committee is aware that as the Australian medicinal cannabis industry matures, more Australian-made products will become available to patients. The committee hopes that the availability of Australian products will reduce the current reliance on an overseas market, and will alleviate ongoing concerns about the quality and availability of imported medicinal cannabis products.

4.109 However, the growth in the production of Australian medicinal cannabis products is currently held up by inefficient licencing processes. This is causing significant delays in the cultivation, manufacturing and research of cannabis products.

4.110 The committee is pleased to see that the Australian Government has acknowledged the problems which exist in the Office of Drug Control's licencing processes and has committed to adopting all of the recommendations of the McMillan review through the introduction of new legislation this year. In particular, the committee is of the view that the introduction of a single licence model would address many of the inefficiencies and delays faced by the industry.

⁹⁵ Epilepsy Action Australia, *Submission 22*, p. 10.

⁹⁶ Australian Centre for Cannabinoid Clinical and Research Excellence, *Submission 15*, p. 4.

⁹⁷ Dr Skerritt, Committee Hansard, 29 January 2020, p. 79. See also, TGA, *Medicine Shortages Information Initiative*, <https://apps.tga.gov.au/prod/MSI/search> (accessed 13 March 2020).

4.111 However, the committee is concerned that any streamlining and improvement to licencing and other processes as proposed by the McMillan review will only be as good as the resources to implement them. Currently, it is clear that the Office of Drug Control is seriously under-resourced to manage demand.

Recommendation 14

4.112 The committee recommends the Australian Government immediately review the resourcing and staffing levels of the Office of Drug Control to ensure licence applications are processed without delays.

4.113 The committee recognises that some of the frustrations expressed by the medicinal cannabis industry in the production of medicinal cannabis products relate to the restrictions on the cultivation of cannabis due to Australia's obligations under the United Nations Single Convention on Narcotic Drugs and the United Nations Convention on Psychotropic Substances.

4.114 Evidence suggests that changes to these international drug control conventions, as have been proposed by the World Health Organization Expert Committee on Drug Dependence, may have wide-reaching and positive impacts on the regulation of cannabis production, both for medicinal cannabis and industrial hemp, and flow-on effects for the Poisons Standard scheduling of cannabis containing psychoactive cannabinoids.

Recommendation 15

4.115 The committee recommends the Australian Government support the World Health Organization Expert Committee on Drug Dependence's recommendations for changes to the scheduling of cannabis and cannabis-related substances in international drug control conventions.

Recommendation 16

4.116 The committee recommends the Department of Health, through the Therapeutic Goods Administration and the Office of Drug Control, continue to monitor how any future changes to Australia's obligations under international drug control conventions can facilitate streamlining regulations relating to the scheduling, approval, manufacture and handling of cannabis.

Chapter 5

Costs and other barriers

- 5.1 Throughout the inquiry, the committee received evidence that cost was one of the biggest barriers for patients struggling to access medicinal cannabis.¹
- 5.2 For many patients who do manage to overcome the obstacles of seeking approval for an appropriate medicinal cannabis product, the cost of actually accessing that product can be significant.² Medicinal Cannabis Industry Australia told the committee:
- Every day we see patients crying out for cheaper or subsidised products.³
- 5.3 The significant costs of accessing medicinal cannabis are contributing to some people choosing to access illicit cannabis products to self-medicate for a range of health conditions.⁴ Accessing cannabis through the illicit market has legal implications for individuals and raises concerns about quality and safety.
- 5.4 Another legal quandary, faced by patients accessing medicinal cannabis, is that people are not allowed to drive a car in Australia with any delta-9-tetrahydrocannabinol (THC) present in their body.⁵
- 5.5 This chapter first examines the issues around the costs of accessing medicinal cannabis and the ways in which they can be mitigated.
- 5.6 The chapter then explores issues surrounding the use of illicit cannabis for self-medication, before considering the legality of driving while being treated with medicinal cannabis.

The costs of accessing medicinal cannabis

- 5.7 The costs of accessing medicinal cannabis can be grouped broadly into two categories: the cost of seeing a health professional to get a prescription; and the cost of acquiring the medicine once it is prescribed.

¹ See, for example, Mrs Lucy Haslam, Director, United in Compassion (UIC), *Committee Hansard*, 29 January 2020, p. 3; Name Withheld, *Submission 49*, [p. 2]; Name Withheld, *Submission 56*, p. 3.

² See for example, Alcohol and Drug Foundation, *Submission 26*, p. 9; Mrs Joylene Donovan, *Submission 81*, pp. 1–2; Ms Lyn Cleaver, Private Capacity, *Committee Hansard*, 29 January 2020, p. 21.

³ Medicinal Cannabis Industry Australia, *Submission 5*, p. 15.

⁴ MCUA, *Submission 9*, p. 18; FreshLeaf Analytics, *Submission 14*, p. 7; ACNEM, *Submission 29*, p. 3.

⁵ Australasian College of Nutritional and Environmental Medicine (ACNEM), *Submission 29*, p. 3.

Medical appointments

5.8 Patients frequently described the significant costs they face in seeing health professionals in order to access a prescription for medicinal cannabis.⁶

5.9 For example, one patient told the committee:

It cost me \$200 for my initial appointment, \$59 for any subsequent scripts, \$80 follow up appt, \$59 whenever I have to adjust dose or product, which I was able to afford by making a debt with centrelink [sic] ...⁷

5.10 Due to the unwillingness or refusal of their usual general practitioner (GP) to prescribe medicinal cannabis, many patients resort to visiting specialised 'cannabis clinics' to receive a prescription, which comes at a substantial cost.⁸

5.11 The Medical Cannabis Users Association of Australia described that:

These clinics are charging fees to put in an application to the TGA that attracts no fee. They are charging "Specialist" consultation rates and monitoring fees for which patients can rarely get a Medicare or Health Fund rebate.⁹

5.12 A patient submitted their experience with one of these clinics:

Firstly because I can't sit in a car for very long due to severe pain, I could not visit the closest clinic ... So a Telehealth appointment was made only to discover there's no Medicare rebate for a Telehealth consultations (whereas a visit to actual clinic does attract a Medicare rebate). This first consult will cost \$199 which is out of reach for anyone on any form of welfare payment.¹⁰

5.13 The submission from Australian Pain Management Association also shared the experience of a number of patients using cannabis clinics, with patients describing costs of \$300 to \$500 for initial appointments with a health professional, often through telehealth set-ups.¹¹

5.14 Some submitters also referred to an additional 'prescribing charge' from one cannabis clinic for each repeat prescription.¹²

⁶ See, for example, Name withheld, *Submission 44*, p. 2; Medical Cannabis Users Association of Tasmania, *Submission 116*, pp. 2–3; Australian Pain Management Association, *Submission 32*, p. 8; Mrs Joylene Donovan, *Submission 81*, pp. 1–2.

⁷ Medical Cannabis Users Association of Australia (MCUA), *Submission 9*, p. 8.

⁸ Epilepsy Action Australia, *Submission 22*, p. 8; Medical Cannabis Council, *Submission 37*, [p. 3]; Dr Deborah Waldron, *Submission 126*, p. 2; Painaustralia, *Submission 129*, p. 6; UIC, *Submission 6*, p. 5.

⁹ MCUA, *Submission 9*, p. 7.

¹⁰ Name withheld, *Submission 44*, p. 2.

¹¹ Australian Pain Management Association, *Submission 32*, p. 8. See also, UIC, *Submission 6*, p. 5.

¹² Name withheld, *Submission 143*, p. 2; Name withheld, *Submission 70*, p. 2.

- 5.15 The Society for Hospital Pharmacists described the costs charged by these clinics as 'unreasonable', noting that its members had reported that some clinics 'charge exorbitant amounts for what would typically be considered regular healthcare'.¹³

Appointment subsidies through Medicare

- 5.16 Some submitters have proposed introducing a new Medicare Benefits Scheme (MBS) code for health professionals to use for the extended consultation time required for prescribing medicinal cannabis, noting that this would reduce costs for patients.¹⁴ Canopy Growth submitted:

The existing online TGA portal ... takes a long time to complete, and cannot be completed in one-standard [sic] consultation. A new MBS code, recognising the longer consultation required for patient work-ups and application, would address this barrier to prescribing medicinal cannabis. In addition, patients will also benefit from a higher medicare reimbursement for their appointment and ultimately reduce their out-of-pocket expense for seeking healthcare professional assistance.¹⁵

- 5.17 Mills Oakley and CA Clinics also proposed that a 'medicinal cannabis service' code could be introduced, which would include 'consultation with a medical practitioner and the supply of a medicinal cannabis product'.¹⁶
- 5.18 The committee notes that the General Practice and Primary Care Clinical Committee of the MBS Review Taskforce raised general concerns about the need for an MBS item code for extended GP consultations in 2018. That committee recommended the introduction of a new 'Level E' item code for GP consultations of 60 minutes or more.¹⁷ It is anticipated that the MBS Review Taskforce will make its recommendations to the Australian Government in relation to primary care item codes in mid-2020.¹⁸

Filling a prescription

- 5.19 Submitters described that the expense of medicinal cannabis products is the key barrier to access for many patients.¹⁹

¹³ Society of Hospital Pharmacists of Australia, *Submission 8*, [p. 2].

¹⁴ Applied Cannabis Research, *Submission 17*, p. 4; Medicinal Cannabis Industry Australia, *Submission 5*, p. 4.

¹⁵ Canopy Growth Australia, *Submission 31*, [p. 2].

¹⁶ Mills Oakley, *Submission 61*, p. 22; CA Clinics, *Submission 146*, p. 3.

¹⁷ Medicare Benefits Schedule Review Taskforce, *Report from the General Practice and Primary Care Clinical Committee: Phase 2*, August 2018, p. 102 (Recommendation 15).

¹⁸ [Medicare Benefits Schedule Review Taskforce, MBS Review Update, December 2019, \[p. 3\].](#)

¹⁹ Ms Carol Ireland, Chief Executive Officer and Managing Director, Epilepsy Action Australia, *Committee Hansard*, 29 January 2020, p. 8; UIC, *Submission 6*, p. 8; Mr Jarrod McMaugh, Project Pharmacist, Pharmaceutical Society of Australia, *Committee Hansard*, 29 January 2020, p. 47.

5.20 FreshLeaf Analytics have reported that patients are paying an average of \$5 to \$15 per day for medicinal cannabis in Australia, but that paediatric epilepsy patients pay on average more than \$50 per day.²⁰

5.21 Mrs Ireland from Epilepsy Action Australia told the committee that their clients reported that:

... when they do go through their general practitioner, neurologist or epileptologist, there are predicted costs of up to \$1,300 per month. That is what one person quoted. Another person quoted that one CBD bottle per week currently costs \$370. They're the kinds of costs that we're facing for epilepsy.²¹

5.22 Ms Lyn Cleaver told the committee that the annual cost quoted by her son's neurologist for a prescribed medicinal cannabis product was between \$60 000 and \$100 000.²²

5.23 The TGA acknowledged that prices for medicinal cannabis can 'vary tremendously' depending on the product and the dosage required:

Some of the low-dose THC products are as little as \$5 to \$6 a day. That's still a lot if you're on a pension, but if you're in a good job, like all of us here, that's affordable. The challenge is for the children, especially the larger children, who are on the cannabidiol medicines for epilepsy, because the amount of cannabidiol used for each child—the actual quantity, the size of pill—is quite large.²³

Delivery and storage costs

5.24 Part of the cost of filling a prescription for medicinal cannabis is the cost incurred by pharmacies in supplying the product, such as specialist delivery fees and storage costs.²⁴

5.25 Some submitters also noted that the cost of medicinal cannabis appears to be high due to the reliance on overseas products, as discussed in Chapter 4, which contributes to additional importation and delivery fees.²⁵

5.26 The Pharmaceutical Society of Australia explained that:

²⁰ FreshLeaf Analytics, *Submission 14*, p. 6.

²¹ Ms Ireland, Epilepsy Action Australia, *Committee Hansard*, 29 January 2020, p. 10.

²² Ms Cleaver, *Committee Hansard*, 29 January 2020, p. 21.

²³ Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 29 January 2020, p. 65.

²⁴ See, for example, Pharmaceutical Society of Australia, *Submission 16*, p. 6; Mr Andrew Giles, National Policy Officer, Multiple Sclerosis Australia, *Committee Hansard*, 29 January 2020, p. 7. See also, ACNEM, *Submission 29*, p. 21; Name withheld, *Submission 131*, p. 2.

²⁵ See, for example, Nimbin Hemp Embassy, *Submission 28*, [p. 3]; Medical Cannabis Council, *Submission 37*, [p. 5]; UIC, *Submission 6*, Attachment 2, p. 32.

At the higher end, the delivery fee may represent over 30% of the total cost of the order while some wholesalers may not charge a delivery fee if a large quantity of products is requested through a single order. Other wholesalers charge a Dangerous Drug (DD) handling fee to offset some of the costs associated with the special storage, delivery and inventory recording requirements of these products.²⁶

- 5.27 Multiple Sclerosis Australia shared the experience of a patient where delivery costs accounted for nearly half the cost of their script:

... I first tried my local pharmacy ... who charged me \$220 for a 25 ml bottle of the medicinal cannabis product. He told me that about \$100 of this was for a special security courier.²⁷

- 5.28 The Australasian College of Nutritional and Environmental Medicine (ACNEM) noted that changes to the scheduling of cannabidiol (CBD), as discussed in Chapter 4 of this report, could remove some of the more stringent security and delivery requirements and their resultant costs for pharmacists.²⁸

No products available on the PBS

- 5.29 One of the biggest frustrations expressed by patients is that the medicinal cannabis products they are being prescribed through the TGA's access pathways are not available for subsidy under the Pharmaceutical Benefits Scheme (PBS).²⁹

- 5.30 ACNEM submitted that:

Subsidisation of [medicinal cannabis] products under the Pharmaceutical Benefits Scheme (PBS) would have tremendous benefits for the Australian public, helping make [medicinal cannabis] more affordable.³⁰

- 5.31 The Department of Health (Department) explained that the Australian Government is unable to include a medicine in the PBS without a recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body:

When considering a medicine proposed for PBS listing, the PBAC is required by that legislation to give consideration to the effectiveness and

²⁶ Pharmaceutical Society of Australia, *Submission 16*, p. 6.

²⁷ Mr Giles, Multiple Sclerosis Australia, *Committee Hansard*, 29 January 2020, p. 7.

²⁸ ACNEM, *Submission 29*, p. 9.

²⁹ See, for example, Monday Discussion Group of Residents of St Vincent's Kangaroo Point, *Submission 1*, [p. 2]; Mr Raimond Hill, *Submission 90*, p. 2; Ms Debbie Ranson, *Submission 111*, [p. 2]; Ms Dimi Stathopoulos, *Submission 112*, [p. 1]; Name withheld, *Submission 49*, p. 1; Name withheld, *Submission 70*, p. 3. See also, Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 13; Medical Cannabis Research Australia, *Submission 121*, p. 3.

³⁰ ACNEM, *Submission 29*, p. 7.

cost of the medicine, including by comparing the effectiveness and cost with that of alternative treatments.³¹

- 5.32 For a product to be considered for inclusion on the PBS, it must also first be listed in the Australian Register of Therapeutic Goods (ARTG). Submitters noted that the lack of medicinal cannabis in the ARTG is one of the biggest barriers to seeing medicinal cannabis included in the PBS.³²
- 5.33 As discussed in Chapter 4, nabiximols (brand name Sativex) is the only medicinal cannabis product currently listed in the ARTG.³³ Some submitters noted that the sponsors of Sativex had made an application for it to be considered by the PBAC in March 2020, following a failed application for inclusion in 2013.³⁴ This application has been supported by patients with multiple sclerosis and their support groups.³⁵
- 5.34 The Pharmacy Guild of Australia and other submitters support the PBS as the most appropriate way to subsidise access to pharmaceuticals, including medicinal cannabis, in Australia.³⁶

Alternative subsidies to the PBS

- 5.35 Submitters noted that as most medicinal cannabis is currently unsuitable for inclusion in the PBS, alternative models of subsidy should be considered to assist patients in affording their prescriptions.³⁷
- 5.36 Despite these calls for medicine subsidies, the committee received only a small number of specific suggestions of what such a subsidy model could look like. For example, Epilepsy Action Australia suggested that:

³¹ Department of Health, *Submission 10*, p. 23.

³² LeafCann Group, *Submission 4*, p. 3; UIC, *Submission 6*, Attachment 2, p. 29; Australian Centre for Cannabinoid Clinical and Research Excellence, *Submission 15*, p. 2.

³³ See Chapter 4, p. 6.

³⁴ Mr Giles, Multiple Sclerosis Australia, *Committee Hansard*, 29 January 2020, p. 7. See also, Department of Health, *March 2020 PBAC Meeting*, February 2020, www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda/March-2020-PBAC-Meeting (accessed 13 March 2020).

³⁵ Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6; Alcohol and Drug Foundation, *Submission 26*, p. 3.

³⁶ See for example; Pharmacy Guild of Australia, *Submission 27*, p. 3; National Institute of Complementary Medicine Health Research Institute (NICM HRI), *Submission 7*, p. 4; Australian Centre for Cannabinoid Clinical and Research Excellence, *Submission 15*, p. 2; CANNATREK, *Submission 33*, p. 2; Professor James Angus, *Submission 53*, [pp. 2–3]; New South Wales Nurses and Midwives' Association, *Submission 118*, p. 7.

³⁷ See, for example, Medicinal Cannabis Industry Australia, *Submission 5*, p. 4; Canopy Growth Australia, *Submission 31*, [p. 2].

A temporary subsidy [be] made available to people with epilepsy who are prescribed pharmaceutical grade cannabinoid-based medicines, until these medicines are listed on the ARTG and the PBS.³⁸

5.37 Medical Cannabis Research Australia also proposed the introduction of a broader federal or state government compassionate subsidy scheme where a patient is qualified for subsidy through an (unspecified) eligible condition and means testing.³⁹

5.38 However, Professors Wayne Hall and Michael Farrell submitted that introducing blanket government subsidies for medicinal cannabis for all patients would be problematic for several reasons, including that providing a public subsidy 'in the absence of evidence of cost-effectiveness would create a publicly-funded special access scheme for unevaluated drugs'. They argued that this approach:

... would create a precedent that may be used by advocates for the use of other unevaluated drugs to demand a similar subsidy from state and Federal governments solely because some patients claimed to benefit from using them. Producers could ... demand a public subsidy for the medical use of the drug in the absence of evidence of safety, effectiveness and cost-effectiveness.⁴⁰

5.39 The Pharmacy Guild of Australia also submitted that it would be 'unnecessary and wasteful' to develop a parallel subsidy scheme to the PBS for medicinal cannabis, which would require:

... all the attendant bureaucracy and additional costs of evaluation, listing and claiming processes etc for medicinal cannabis products.⁴¹

Private health insurance

5.40 A small number of submitters also recommended that the cost of medicinal cannabis products could be subsidised through private health insurance, as with other non-PBS medicines.⁴²

5.41 Little Green Pharma noted that private health fund subsidy is currently used to assist access to medicinal cannabis in Germany.⁴³

5.42 The committee understands that refunds for prescription medicines through most private health insurance in Australia can only be for non-PBS medicines which have been approved and registered in the ARTG.⁴⁴

³⁸ Epilepsy Action Australia, *Submission 22*, p. 12.

³⁹ Medical Cannabis Research Australia, *Submission 121*, p. 7.

⁴⁰ Professor Wayne Hall and Professor Michael Farrell, *Submission 68*, pp. 7–8.

⁴¹ Pharmacy Guild of Australia, *Submission 27*, p. 3. See also, Clinical Oncology Society of Australia, *Submission 124*, p. 2.

⁴² Medicinal Cannabis Industry Australia, *Submission 5*, p. 4; Mills Oakley, *Submission 61*, p. 22.

⁴³ Little Green Pharma, *Submission 38*, p. 3; See also, Department of Health, *Submission 10*, p. 30.

Current subsidies for medicinal cannabis

5.43 The committee also received evidence about a number of existing subsidies available for certain patients receiving medicinal cannabis in Australia.

Compassionate access schemes

5.44 Under a compassionate access scheme, a sponsor – such as a drug company or a government body – pays for the full or partial cost of the prescribed medicinal cannabis product for the patient.

5.45 There are currently several state government-sponsored compassionate schemes currently available in Australia, summarised in Table 5.1 below.

Table 5.1 Compassionate access schemes for medicinal cannabis in Australian states⁴⁵

State	Schemes available
New South Wales	Compassionate Access Scheme for cannabidiol medicines (i.e. Epidiolex) for children with severe epilepsy, available through all paediatric neurologists in the state. Other compassionate access through Specialty Health Networks and Local Health Districts, where a clinician makes an application to access and fund a medicine through a Drugs and Therapeutics Committee.
Queensland	Compassionate Access Scheme for cannabidiol (Epidiolex) for children with severe epilepsy through clinical trials ceased in August 2019, but the Queensland government has indicated it will continue to subsidise the drug for scheme participants.
Tasmania	Controlled Access Scheme fully funds small number of patients approved by Tasmanian Department of Health, following application by a specialist. No

⁴⁴ See, for example, Finder, *Health insurance for non-PBS pharmaceuticals*, www.finder.com.au/non-pbs-pharmaceuticals (accessed 12 March 2020); HCF, *Can you claim for prescription medicine?*, February 2018, www.hcf.com.au/health-agenda/health-care/research-and-insights/drugs-and-health-cover (accessed 12 March 2020); Australian Unity, *The simple guide to claiming money back on pharmaceuticals*, www.australianunity.com.au/health-insurance/existing-members/wellplan-online/using-your-cover/how-to-claim-pharmaceuticals (accessed 12 March 2020).

⁴⁵ Adapted from Department of Health, answers to questions on notice, 29 January 2020 (received 17 February 2020). See also, Alcohol and Drug Foundation, *Submission 26*, p. 9; Canopy Growth Australia, *Submission 31*, [p. 3].

	other access to medicinal cannabis permitted in the state.
Victoria	Compassionate Access Scheme provides access to medicinal cannabis products for children suffering from severe intractable epilepsy, facilitated through hospitals participating in the scheme.
Western Australia	Compassionate Access Scheme for children with intractable, resistant epilepsy through the paediatric neurology service at Perth Children's Hospital.

- 5.46 Tilray, a medicinal cannabis provider, submitted that it has a compassionate access scheme in place for patients, and is the provider of products for some state government schemes.⁴⁶
- 5.47 It is not clear how many other drug companies currently offer compassionate access to their products in Australia. Evidence from one patient suggests that GD Pharma may be offering compassionate access,⁴⁷ while another patient described that their requests for compassionate access from MedReleaf had gone unanswered.⁴⁸
- 5.48 The Medical Cannabis Users Association of Australia submitted that, in their experience, 90 per cent of patients were unaware of the availability of compassionate access from a drug company sponsor.⁴⁹

Department of Veterans Affairs

- 5.49 The Department of Veterans Affairs (DVA) also currently subsidises medicinal cannabis for patients in certain circumstances.⁵⁰
- 5.50 DVA is able to fund access to medicines, including unapproved medicines like medicinal cannabis, through the Repatriation Pharmaceutical Benefits Scheme (RPBS), which does not have the same rules as the PBS for listing medicines. Any medicine supplied through the RPBS is done so at the concessional co-payment rate, \$6.60 per script in 2020.⁵¹
- 5.51 For a veteran eligible for DVA medical treatment to receive medicinal cannabis under the RPBS, the following is considered:

⁴⁶ Tilray, *Submission 62*, p. 3.

⁴⁷ Name withheld, *Submission 72*, [p. 1].

⁴⁸ Name withheld, *Submission 78*, [p. 2].

⁴⁹ MCUA, *Submission 9*, p. 16.

⁵⁰ Department of Veterans' Affairs, *Submission 135*, [pp. 2–3]; Canopy Growth Australia, *Submission 31*, [p. 1].

⁵¹ Department of Veterans' Affairs, *Submission 135*, [pp. 1–2].

- the clinical need for the quantity of medicinal cannabis prescribed;
- whether first-line treatments have been tried and failed;
- whether the medicinal cannabis product is on the ARTG, or has been approved through TGA access pathways for unapproved medicines; and
- a written assessment from a treating specialist that medicinal cannabis would benefit the patient.⁵²

5.52 While one submitter noted success in accessing medicinal cannabis through DVA as a treatment for post-traumatic stress disorder,⁵³ others told the committee that they had not yet been successful in gaining subsidies.⁵⁴

5.53 United in Compassion submitted that, for many veterans:

The struggle to obtain Department of Veteran's Affairs (DVA) funding of cannabinoid medications and device costs has also been arduous and inconsistent. This inconsistency puts further pressure on vulnerable people and exacerbates mental health trauma.⁵⁵

The 'green market' – illicit cannabis for medicinal purposes

5.54 The committee heard that many patients are choosing not to access medicinal cannabis legally due to the significant costs and the complexity of the legal access system, instead opting to self-medicate with illicit cannabis.⁵⁶

5.55 The National Institute of Complementary Medicine Health Research Institute submitted that:

If patients are not able to access affordable, quality-assured medicinal cannabis products that can be prescribed and monitored by their medical professional, then they will likely resort to the illicit market.⁵⁷

5.56 It is estimated that the number of people in Australia self-medicating with cannabis is around 100 000,⁵⁸ although some submitters believe this number could be much higher.⁵⁹

⁵² The full list of considerations is included in Department of Veterans' Affairs, *Submission 135*, [p. 2].

⁵³ Mr Lee Donnollan, *Submission 103*, p. 1.

⁵⁴ Mr Mark Thomas, *Submission 106*, [pp. 1–3]. See also, Name withheld, *Submission 104*.

⁵⁵ UIC, *Submission 6*, p. 7.

⁵⁶ Ms Karen Alleyne Taylor, *Submission 94*, pp. 1–2; Name withheld, *Submission 133*; Mr John Jackson, President, Victorian Branch, Pharmaceutical Society of Australia, *Committee Hansard*, 29 January 2020, p. 42; Dr Christina Xinos, Medical Director, Australia and New Zealand, Canopy Growth Australia, *Committee Hansard*, 29 January 2020, p. 54; Little Green Pharma, *Submission 38*, p. 2; Dr Deborah Waldron, *Submission 126*, p. 4.

⁵⁷ NICM HRI, *Submission 7*, p. 4.

⁵⁸ Mills Oakley, *Submission 61*, p. 11; Tilray, *Submission 62*, p. 7; Alcohol and Drug Foundation, *Submission 26*, p. 10.

⁵⁹ MCUA, *Submission 9*, p. 17; Medical Cannabis Knowledge Network, *Submission 13*, p. 3; Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative), *Submission 36*, p. 3.

- 5.57 A survey conducted by the Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative) at the University of Sydney found that only 25 out of the 931 respondents, less than 3 per cent, were accessing legal medicinal cannabis through the TGA schemes.⁶⁰
- 5.58 The illicit market of cannabis for self-medication was variously referred to as the 'black', 'grey' or 'green' market by submitters, and appears to encompass illicit products ranging from home-grown cannabis plants and home-made cannabis extracts and products to commercially-produced medicinal cannabis products that had been either imported illegally or diverted from the legal market in Australia.⁶¹
- 5.59 Some patients told the committee that they felt the risks of accessing cannabis illegally had been outweighed by the benefits they had found in self-medication.⁶²
- 5.60 A patient who had been unable to find a doctor willing to prescribe medicinal cannabis for his pain submitted that he has been accessing cannabis through the black market:

... because it's way easier, and as I'm unable to choose from a selection of quality products like Cannabis patients are allowed in other jurisdictions, just buying whatever is available from the guy down the road is really the same as our "legal approved unapproved approved system". And as a sick person I really don't get out much anyway, so the blackmarket [sic] delivering is very handy.⁶³

Cost of illicit cannabis

- 5.61 Submitters also described that illicit cannabis products accessed through these markets were much more affordable than legally prescribed medicinal cannabis, but in some cases these prices are still higher than for subsidised pharmaceutical medicines on the PBS.⁶⁴
- 5.62 One patient described their experience of the cost of illicit cannabis:

It is highly expensive on the black market and from what I have seen, even more expensive on the SAS. ... on the black market cannabis is about \$20

⁶⁰ Lambert Initiative, *Submission 36*, p. 4.

⁶¹ Name withheld, *Submission 133*; Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 8; MCUA, *Submission 9*, p. 10.

⁶² Mr Brett Falkner, *Submission 47*, [p. 1]; Ms Karen Alleyne Taylor, *Submission 94*, pp. 1–2; See also, Pharmaceutical Society of Australia, *Submission 16*, p. 5.

⁶³ Name withheld, *Submission 102*, p. 5.

⁶⁴ Ms Karen Alleyne Taylor, *Submission 94*, p. 3; Name withheld, *Submission 58*, [p. 2]; LeafCann Group, *Submission 4*, pp. 7–8; MedReleaf Australia, *Submission 18*, [p. 2]; Australian Pain Management Association, *Submission 32*, p. 8.

per gram. Under the SAS the gram price I have heard is about \$40 per gram. It is absurd and not affordable for poorer people.⁶⁵

5.63 Some submitters told the committee that they were not comfortable with accessing illicit products and were concerned about the risks of prosecution, but felt that they had no other choice.⁶⁶

5.64 One patient, a 60-year-old receiving a disability support pension, submitted:

The only options left for me are to grow cannabis plants and make the cannabis oil myself, or acquire a black market supply, and whilst both are far and away cheaper options, I am loathe to do so because of the criminal implications.⁶⁷

5.65 Another patient who had been prescribed legal medicinal cannabis, but could not afford to pay for his prescription, submitted:

Because I use black market supplies of cannabis I feel under constant threat of persecution from authorities and I worry that my supplier will be arrested and not be able to supply my needs which causes me great stress. I would like to not have to worry about these issues but the cost of legal medicinal Cannabis and the current pathways to access are huge barriers to me.⁶⁸

5.66 To combat cost as a barrier to access, some suppliers in the 'green market' offer compassionate access schemes for their products, offering illicit cannabis products at low or no costs to patients.⁶⁹

5.67 One submitter told the committee about the online illicit dispensary collective they had established to provide cannabis to around 350 people at low or no cost 'depending on how severe the medical condition was':

We did this because people were unable to get access to legal products due to the rigid regulations that have been put in place by the govt. The very few that were able to gain access to a legal product rated it both sub par compared to our "black market goods" and they said that the legal market was 2.5 - 5 times more expensive than our setup. Many were unable to continue treatment because of cost for products.⁷⁰

⁶⁵ Name withheld, *Submission 58*, [p. 2].

⁶⁶ Name withheld, *Submission 42*, [p. 1]; Name withheld, *Submission 44*, p. 3; Name withheld, *Submission 85*, p. 2; Name withheld, *Submission 144*, pp. 2–3. See also, Name withheld, *Submission 82*, p. 2.

⁶⁷ Name withheld, *Submission 44*, p. 2.

⁶⁸ Name withheld, *Submission 140*, p. 2.

⁶⁹ UIC, *Submission 6*, p. 4; Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 10; Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 5.

⁷⁰ Name withheld, *Submission 60*, p. 3.

Quality of illicit cannabis

5.68 There are serious concerns about the quality of black market cannabis products which people are accessing for self-medication.⁷¹

5.69 The Australasian College of Nutritional and Environmental Medicine told the committee that:

The danger associated with unregulated products is that they could contain contaminants such as heavy metals and pesticides, and that they may not contain the amount of active constituents they purport to.⁷²

5.70 United in Compassion cited a study by the Lambert Initiative which considered the black market products being accessed by parents of children with epilepsy:

It looked at cannabis that was being supplied to children with epilepsy through the black market. Parents thought they were giving their children high CBD. A lot of those products had high THC in them. It's important that people know what they're giving their loved ones.⁷³

5.71 Some submitters described the dangers of variability in the quality of illicit cannabis products,⁷⁴ with Mills Oakley sharing the experience of one patient experiencing a 'horrific tonic clonic seizure' due to a 'suspect batch' of an illicit cannabis product.⁷⁵

5.72 One patient described that they believed it was safest to grow their own supply in light of concerns about the quality of black market products:

My best solution is to grow my own medicinal cannabis so that I can grow it organically and know exactly what I'm getting. I don't want to go looking for black market products since I have no idea on the ratios of cannabinoids in them or whether they are contaminated with chemicals or come from generally poor growing conditions.⁷⁶

Criminal implications

5.73 People choosing to access illicit cannabis for self-medication, or who provide cannabis to patients, may be subject to criminal charges for possession or cultivation of a controlled substance, which carries varying penalties between states and territories.⁷⁷

⁷¹ Mr Paul John Parsons, *Submission 46*, [p. 1]; Mr Michael Oakley, *Submission 110*, [p. 5]; LeafCann Group, *Submission 4*, pp. 7–8; UIC, *Submission 6*, p. 4; Name withheld, *Submission 58*, [p. 2].

⁷² ACNEM, *Submission 29*, p. 19.

⁷³ Mrs Haslam, UIC, *Committee Hansard*, 29 January 2020, p. 5.

⁷⁴ Entoura, *Submission 25*, [p. 6]; Ms Dimi Stathopoulos, *Submission 112*, p. 2.

⁷⁵ Mills Oakley, *Submission 61*, p. 10.

⁷⁶ UIC, *Submission 6*, p. 10.

⁷⁷ Mr Glenn Lynch, *Submission 98*, [p. 1].

- 5.74 In recent high profile cases, individuals have been prosecuted for the 'green market' supply of cannabis on a compassionate basis to others, or for their own use of illicit cannabis. Many of these cases have resulted in good behaviour bonds and no convictions being recorded.⁷⁸
- 5.75 Associate Professor Kate Seear and Springvale Monash Legal Service found:
- Criminal justice responses to these developments have been inconsistent across Australia. These inconsistencies do not merely reflect differences between individual defendants and their circumstances (e.g. whether they have prior convictions) but fundamental differences in criminal law across the states and territories.⁷⁹
- 5.76 The Lambert Initiative and other submitters recommended to the committee that there should be an amnesty in all states and territories for individuals who are 'genuinely using illicit cannabis for medical reasons'.⁸⁰
- 5.77 The committee notes that New South Wales has introduced such an amnesty for people with terminal illness in that state. The Medicinal Cannabis Compassionate Use Scheme provides guidelines for police about using discretion to not charge adults certified by their doctor as having a terminal illness, or their carers, with possession of cannabis not lawfully prescribed.⁸¹
- 5.78 Some submitters have also proposed that broader decriminalised personal cannabis cultivation and use, such as recently introduced in the Australian Capital Territory, could alleviate some of the legal barriers to self-medication.⁸²

Driving laws and medicinal cannabis

- 5.79 Currently, in all states and territories in Australia, it is an offence to drive while having detectable levels of THC in the body.⁸³
- 5.80 Many submitters raised concerns about the interactions between medicinal cannabis and driving laws, including:
- drug tests which check for the presence of THC do not necessarily reflect the level of impairment that a driver may be experiencing, particularly as some tests can show positive results a month after exposure to cannabis;⁸⁴

⁷⁸ Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, pp. 5, 16–23.

⁷⁹ Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 5.

⁸⁰ Lambert Initiative, *Submission 36*, p. 10; MCUA, *Submission 9*, p. 21.

⁸¹ New South Wales Government, Centre for Medicinal Cannabis Research and Innovation, *Medicinal Cannabis Compassionate Use Scheme*, www.medicinalcannabis.nsw.gov.au/patients/medicinal-cannabis-compassionate-use-scheme (accessed 12 March 2020).

⁸² Lambert Initiative, *Submission 36*, p. 10; Ms Dianah Walter, *Submission 76*, p. 5; Mr Glenn Lynch, *Submission 98*, [p. 1]; UIC, *Submission 6*, pp. 10–11; Associate Professor Kate Seear and Springvale Monash Legal Service, *Submission 21*, p. 6.

⁸³ MCUA, *Submission 9*, p. 18; FreshLeaf Analytics, *Submission 14*, p. 7; ACNEM, *Submission 29*, p. 3.

- patients who have a legal prescription for medicinal cannabis may still be subject to automatic loss of licence, large fines and/or jail time if they drive while taking that treatment and test positive to THC;⁸⁵
- other prescription medicines, such as opioids and benzodiazepines, can cause significant impairment for drivers, but that these are not tested in current drug driving tests;⁸⁶ and
- patients in rural and remote locations are particularly disadvantaged by driving laws, as they are more likely to rely on their car for transport.⁸⁷

5.81 Submitters noted that these concerns are deterring patients from using medicinal cannabis products containing THC, as they do not want to face prosecution or be prevented from driving.⁸⁸ For example, Dr Nicoletti told the committee:

Patients who have a prescription may not want to fill it, because they have a job in which they have to drive every day and they would be at risk of prosecution for doing something which they took steps to do lawfully.⁸⁹

5.82 The National Institute of Complementary Medicine Health Research Institute submitted that patients who are prescribed opiates or benzodiazepines are not subject to the same restrictions and are instead 'essentially being told by their medical practitioner to not drive if they feel intoxicated'.⁹⁰

5.83 Submitters noted the findings of the Lambert Initiative on the accuracy and validity of current mobile drug testing technologies, which established two commonly used tests to be inaccurate, giving either false positives or false negatives, in around 20 per cent of cases.⁹¹

⁸⁴ Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6; LeafCann Group, *Submission 4*, p. 8; NICM HRI, *Submission 7*, p. 7; Applied Cannabis Research, *Submission 17*, p. 4; Entoura, *Submission 25*, [pp. 7–9]; Nimbin Hemp Embassy, *Submission 28*; Dr Teresa Nicoletti, Partner, Mills Oakley; Director, Medical Cannabis Council; and Member, Australian Lawyers Alliance, *Committee Hansard*, 29 January 2020, p. 17.

⁸⁵ UIC, *Submission 6*, p. 16; NICM HRI, *Submission 7*, p. 7; MCUA, *Submission 9*, p. 19.

⁸⁶ MCUA, *Submission 9*, p. 18; FreshLeaf Analytics, *Submission 14*, p. 7; medreleaf, *Submission 18*, [p. 2]; ACNEM, *Submission 29*, p. 21.

⁸⁷ MCUA, *Submission 9*, p. 19; UIC, *Submission 6*, p. 16.

⁸⁸ Name Withheld, *Submission 141*, [p. 2]; Name Withheld, *Submission 49*, [pp. 1–2]; ACNEM, *Submission 29*, p. 21; MCUA, *Submission 9*, p. 19.

⁸⁹ Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 17.

⁹⁰ NICM HRI, *Submission 7*, p. 7.

⁹¹ MCUA, *Submission 9*, p. 19; Medical Cannabis Research Australia, *Submission 121*, p. 8. See Thomas R Arkell et al, *Detection of Δ^9 THC in oral fluid following vaporized cannabis with varied cannabidiol (CBD) content: An evaluation of two point-of-collection testing devices*, vol. 11, no. 10, October 2019, <https://doi.org/10.1002/dta.2687>.

5.84 The Lambert Initiative has also completed a study into the effects of THC and CBD on driving impairment and is currently conducting research into the impact of CBD alone.⁹²

5.85 Professor Iain McGregor, Academic Director of the Lambert Initiative, told the committee that:

Cannabis and driving is actually a very complicated area. The tendency is to look at it through the prism of alcohol, but there are actually almost diametrically opposite effects for cannabis relative to alcohol. With alcohol, people overestimate their ability and tend to take risks as a result. With cannabis, people actually feel impaired. ... When they do drive, there are quite reliable effects like a lower speed and a bigger distance between them and the car in front. Then, when you look at the crash risk associated with cannabis, it's moderately increased but it's a very, very small statistical effect compared to alcohol and even compared to some prescription medications that are commonly prescribed like benzodiazepines and sedating antidepressants like mirtazapine.⁹³

5.86 Professor McGregor further explained that the level of impairment faced by a patient taking medicinal cannabis does not directly correlate with the level of THC in their system:

If you give someone cannabis for the first time, they'll be very impaired for a couple of hours after consumption, but, if someone is a patient and they have used cannabis for two years, chronically every day, you will really struggle to find any sort of impairment whatsoever. So we need more research and we need more enlightened information for patients rather than just saying: 'Don't drive.'⁹⁴

5.87 Some submitters noted that other jurisdictions have more relaxed laws around THC and driving than in Australia:⁹⁵

- in Canada it is only an offence to drive while impaired or intoxicated – there is no guidance about how much cannabis can be consumed before it is unsafe to drive or how long a driver should wait to drive after consuming cannabis;⁹⁶ and

⁹² Lambert Initiative, *Research: Driving*, www.sydney.edu.au/lambert/our-research/driving.html (accessed 12 March 2020).

⁹³ Professor Iain McGregor, Academic Director, Lambert Initiative, University of Sydney, *Committee Hansard*, 29 January 2020, p. 25.

⁹⁴ Professor McGregor, Lambert Initiative, *Committee Hansard*, 29 January 2020, p. 25.

⁹⁵ Multiple Sclerosis Research Australia and Multiple Sclerosis Australia, *Submission 3*, p. 6; ACNEM, *Submission 29*, p. 21.

⁹⁶ Government of Canada, *Drug-impaired driving*, February 2020, www.canada.ca/en/services/policing/police/community-safety-policing/impaired-driving/drug-impaired-driving.html (accessed 12 March 2020).

- the United Kingdom still takes a 'zero-tolerance' approach to THC, but currently allows a reading of 2µg/L of THC in blood testing, 'a level where any claims of accidental exposure can be ruled out'.⁹⁷

5.88 The Lambert Initiative and other submitters proposed that patients in Australia who are legally prescribed medicinal cannabis should be exempted from prosecution for driving with THC in their system, unless there is clear evidence of impairment.⁹⁸

Committee view

5.89 The committee recognises that, for many patients, the struggle to access medicinal cannabis to date has been frustrating, costly and difficult.

5.90 For many patients, the costs of seeing a health practitioner to receive a prescription are significant. The committee is aware that the time taken by doctors to conduct an appointment for medicinal cannabis, particularly to complete the paperwork for the legal access pathways, is contributing to these costs.

5.91 The committee notes that broader concerns about the need for a Medicare Benefits Scheme item for long consultations for general practitioners has been raised by the General Practice and Primary Care Clinical Committee of the Medicare Benefits Scheme Review Taskforce in its recommendations.

Recommendation 17

5.92 The committee recommends that the Medicare Benefits Scheme Review Taskforce accept the General Practice and Primary Care Clinical Committee's recommendation to introduce a 'Level E' consultation item for general practice consultations of 60 minutes or longer, and includes this item in recommendations to the Australian Government relating to changes to Medicare Benefits Scheme items for primary care.

5.93 The committee also recognises the significant cost barrier faced by patients in paying for the medicinal cannabis products they have been prescribed.

5.94 While the introduction of more Australian-made products into the market may decrease some of the costs of importation and delivery, the committee shares the view of many submitters that the best way to ensure that medicinal cannabis products are affordable and accessible for patients is to include them in the Pharmaceutical Benefits Scheme. Before any medicine can be included in

⁹⁷ United Kingdom Government, *Changes to drug driving law*, August 2017, www.gov.uk/government/collections/drug-driving#table-of-drugs-and-limits (accessed 12 March 2020).

⁹⁸ Lambert Initiative, *Submission 36*, p. 11; ACNEM, *Submission 29*, p. 21; Dr Nicoletti, *Committee Hansard*, 29 January 2020, p. 17; FreshLeaf Analytics, *Submission 14*, p. 7.

the Pharmaceutical Benefits Scheme, it must first be registered in the Australian Register of Therapeutic Goods and then be considered by Pharmaceutical Benefits Advisory Committee for its efficacy and cost in comparison with other treatments.

- 5.95 With Sativex (nabiximols) under consideration by the Pharmaceutical Benefits Advisory Committee this month, and Epidiolex (cannabidiol) expected to apply for Australian Register of Therapeutic Goods registration soon, the committee can see that the medicinal cannabis industry is slowly bringing products to market with the level of clinical evidence required for registration and future inclusion in the Pharmaceutical Benefits Scheme.
- 5.96 However, inclusion in the Pharmaceutical Benefits Scheme for these cannabis products may still take many years, so the committee recognises there will continue to be a need for compassionate access schemes for patients whose needs are not being addressed by registered and subsidised products.
- 5.97 The possible down-scheduling of low-dose cannabidiol to an over-the-counter medicine, as proposed in Chapter 4, may also alleviate some of the financial pressures faced by patients.
- 5.98 The committee hopes that the growth of the domestic medicinal cannabis industry, along with upcoming changes to the regulation of that industry, will ensure that more products are available quickly and at an affordable price for patients, and that the industry will be able to conduct the vital clinical research needed to seek regulatory approval for their products.
- 5.99 The committee notes that there is a key role for the medicinal cannabis industry to assist in compassionate supply of their products, but that evidence received suggests that patients' experiences in seeking this kind of compassionate access can vary between companies.

Recommendation 18

- 5.100 The committee recommends that medicinal cannabis industry peak bodies, such as Medicinal Cannabis Industry Australia and the Medical Cannabis Council, work with their members to implement compassionate pricing models for patients facing significant financial hardship in accessing medicinal cannabis products to treat their health conditions.**
- 5.101 Several states also have compassionate access schemes in place to address the high costs of medicinal cannabis faced by patients, particularly paediatric patients with severe refractory epilepsies.
- 5.102 Unfortunately, such schemes are not available nationally and this is contributing to the 'postcode lottery' faced by patients in being able to access medicinal cannabis treatment and, in most states, these schemes are also limited to only certain patient groups with certain conditions.

Recommendation 19

5.103 The committee recommends that, until medicinal cannabis products are subsidised through the Pharmaceutical Benefits Scheme, the Australian Government:

- **investigate the establishment of a Commonwealth Compassionate Access Subsidy Scheme for medicinal cannabis, in consultation with industry and based on the best available evidence of efficacy for certain conditions; and**
- **encourage all states and territories, through the COAG Health Council, to expand the provision of their own Compassionate Access Schemes to patients requiring treatment with medicinal cannabis.**

5.104 It is clear that the significant costs associated with accessing medicinal cannabis legally are causing a large number of Australians to purchase or grow illicit cannabis for self-medication.

5.105 The committee is concerned that people accessing the 'black', 'grey' or 'green' market are exposed to risks of self-medicating with unsafe products that may not contain what they say they do, and are opening themselves to significant legal risks in cultivating and possessing illicit cannabis.

5.106 The committee is also concerned about the legal implications faced by people who use medicinal cannabis products and drive. These people may be subject to serious legal penalties for the presence of THC in their system, even if there is no evidence of impairment at the time of driving.

Recommendation 20

5.107 The committee recommends that the Australian Government, through COAG, encourage a review of state and territory criminal legislation in relation to:

- **amnesties for the possession and/or cultivation of cannabis for genuine self-medication purposes; and**
- **current drug driving laws and their implications for patients with legal medicinal cannabis prescriptions.**

Senator Rachel Siewert
Chair

Appendix 1

Submissions and additional information

Submissions

- 1 Monday Discussion Group of Residents of St Vincent's Kangaroo Point
- 2 Northern Territory Government
- 3 Multiple Sclerosis Research Australia and Multiple Sclerosis Australia
- 4 LeafCann Group
- 5 Medicinal Cannabis Industry Australia
- 6 United in Compassion
 - 2 Attachments
- 7 NICM Health Research Institute (Western Sydney University)
- 8 Society of Hospital Pharmacists of Australia
- 9 Medical Cannabis Users Association of Australia
- 10 Department of Health
- 11 Royal Australian College of General Practitioners
- 12 MIGA
- 13 Medical Cannabis Knowledge Network
- 14 FreshLeaf Analytics
- 15 Australian Centre for Cannabinoid Clinical and Research Excellence
- 16 Pharmaceutical Society of Australia
- 17 Applied Cannabis Research
- 18 MedReleaf Australia
- 19 Bod Australia
- 20 Queensland Nurses and Midwives' Union
- 21 Associate Professor Kate Seear and Springvale Monash Legal Service
- 22 Epilepsy Action Australia
 - Supplementary submission
- 23 Royal Australian and New Zealand College of Psychiatrists
- 24 Australian Medical Association
- 25 Entoura Pty Ltd
- 26 Alcohol and Drug Foundation
- 27 Pharmacy Guild of Australia
- 28 Nimbin HEMP Embassy
 - Attachment
- 29 Australasian College of Nutritional and Environmental Medicine
- 30 Cann Group Limited
- 31 Canopy Growth Australia
- 32 Australian Pain Management Association
- 33 CANNATREK LTD

- 34 Cancer Voices Australia
- 35 Ecofibre
- 36 Lambert Initiative
- 37 Medical Cannabis Council
- 38 Little Green Pharma
- 39 *Confidential*
- 40 *Confidential*
- 41 *Confidential*
- 42 *Name Withheld*
- 43 *Confidential*
- 44 *Name Withheld*
- 45 *Name Withheld*
- 46 Mr Paul Parsons
- 47 Mr Brett Falkner
- 48 Miss Aurora Pearce
- 49 *Name Withheld*
- 50 *Name Withheld*
- 51 *Confidential*
- 52 *Name Withheld*
- 53 Professor James Angus
- 54 *Name Withheld*
- 55 *Name Withheld*
- 56 *Name Withheld*
- 57 *Name Withheld*
- 58 *Name Withheld*
- 59 Ms Leone Harker
- 60 *Name Withheld*
 - Supplementary submission
- 61 Mills Oakley
- 62 Tilray
 - Attachment
- 63 Tasmanian Alkaloids
 - Supplementary submission
- 64 *Confidential*
- 65 Mrs Lucy Haslam
- 66 Ms Anne Wilson
- 67 *Confidential*
- 68 Professors Wayne Hall and Michael Farrell
- 69 Mrs Carol Burford
- 70 *Name Withheld*
- 71 *Confidential*
- 72 *Name Withheld*

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- 73 *Name Withheld*
74 *Confidential*
75 *Confidential*
76 Ms Dianah Walter
• 5 Attachments
77 *Confidential*
78 *Name Withheld*
79 Dr Helen Jarvis
80 Ms Lyn Cleaver
81 Mrs Joylene Donovan
82 *Name Withheld*
83 Mr Anthony Adams
84 *Name Withheld*
85 *Name Withheld*
86 *Name Withheld*
87 *Name Withheld*
88 *Confidential*
89 *Confidential*
90 Mr Ray Hill
91 Mr Loren Paul Wiener
92 *Confidential*
93 *Name Withheld*
94 Ms Karen Alleyne Taylor
95 *Confidential*
96 *Name Withheld*
97 Mr Steve Peek
98 Mr Glenn Lynch
99 *Confidential*
100 *Name Withheld*
101 Mr Simon Eckermann
102 *Name Withheld*
103 Mr Lee Donnollan
104 *Name Withheld*
105 Ms Andreea Kindryd
106 Mr Mark Thomas
107 *Name Withheld*
108 *Confidential*
109 *Confidential*
110 Mr Michael Oakley
111 Ms Debbie Ranson
112 Ms Dimi Stathopoulos
113 Professor Laurence Mather
114 *Confidential*

- 115 Mr Peter Amstutz
- 116 Medical Cannabis Users Association of Tasmania
- 117 Australian and New Zealand Society of Palliative Medicine
- 118 New South Wales Nurses and Midwives' Association
- 119 GW Pharmaceuticals
- 120 Country Women's Association of Australia
- 121 Medical Cannabis Research Australia
- 122 AusCann Group Holdings Ltd
- 123 Parsl
- 124 Clinical Oncology Society of Australia
- 125 Queensland Government
- 126 Dr Deborah Waldron
- 127 *Confidential*
- 128 *Confidential*
- 129 Painaustralia
- 130 Drug Free Queensland
 - 2 Attachments
- 131 *Name Withheld*
- 132 *Name Withheld*
- 133 *Name Withheld*
- 134 Drug Free Australia
- 135 Department of Veterans' Affairs
- 136 Ms Lanai Carter
- 137 *Name Withheld*
- 138 *Name Withheld*
- 139 *Name Withheld*
- 140 *Name Withheld*
- 141 *Name Withheld*
- 142 *Name Withheld*
- 143 *Name Withheld*
- 144 *Name Withheld*
- 145 Mr and Mrs Peter and Beverley Rubenach
- 146 CA Clinics

Additional Information

- 1 Paper on aspects of medicinal cannabis regulatory reforms, from Penny Gleeson, received 13 January 2020
- 2 Information, from Mr Michael Balderstone, received 30 January 2020
- 3 Position paper on medicinal cannabis in Australia, sent to Federal Health Minister, the Hon. Greg Hunt, from Professor Kylie O'Brien, received 4 February 2020

- 4 Letter sent to Minister Hunt in reply to his response to the position paper, from Professor Kylie O'Brien, received 4 February 2020
- 5 List of recommendations, from Medical Cannabis Users Association of Tasmania, received 9 March 2020

Answer to Question on Notice

- 1 Answers to Questions taken on Notice during 29 January public hearing, received from Medicines Australia, 5 February 2020
- 2 Answers to Questions taken on Notice during 29 January public hearing, received from Australian Medical Association, 5 February 2020
- 3 Answers to Questions taken on Notice during 29 January public hearing, received from Department of Health, 5 February 2020

Tabled Documents

- 1 Correspondence received by United in Compassion from Ms Olivia Newton-John; Mr John Easterling; and Mr Jason Frost, tabled by United in Compassion, at Melbourne public hearing, 29 January 2020

Appendix 2

Public hearings

Wednesday, 29 January 2020

Edinburgh Room

Stamford Plaza Hotel

Melbourne

United in Compassion Ltd

- Mrs Lucy Haslam, Director

Multiple Sclerosis Australia

- Mr Andrew Giles, National Policy Officer

MS Research Australia

- Dr Tennille Luker, Research Development Coordinator

Epilepsy Action Australia

- Ms Carol Ireland, Chief Executive Officer and Managing Director

Australian Lawyers Alliance

- Dr Teresa Nicoletti, Member; Partner, Mills Oakley; and Director, Medical Cannabis Council

Mr Michael Balderstone, President, Nimbin HEMP Embassy

Ms Lyn Cleaver, Private capacity

Lambert Initiative for Cannabinoid Therapeutics, University of Sydney

- Professor Iain McGregor, Academic Director
- Associate Professor Jonathon Arnold, Deputy Academic Director

Australian Medical Association

- Dr Tony Bartone, President

Royal Australian College of General Practitioners

- Dr Harry Nespolon, President

Clinical Oncology Society of Australia

- Dr David Speakman, Expert Advisor

NICM Health Research Institute (Western Sydney University)

- Mr Justin Sinclair, Research Fellow

Australasian College of Nutritional and Environmental Medicine

- Professor Kylie O'Brien, Member

National Institute of Integrative Medicine

- Professor Avni Sali, Founding Director
- Dr Tamara Nation, General Practitioner
- Professor Ian Brighthope, Board Member; and Founder, ACNEM

Pharmaceutical Society of Australia

- Mr Jarrod McMaugh, Project Pharmacist
- Mr John Jackson, President, Victorian Branch

Pharmacy Guild of Australia

- Mr Anthony Tassone, National Councillor

Medicines Australia

- Mrs Elizabeth de Somer, Chief Executive Officer
- Dr Vicki Gardiner, Director, Policy and Research

Canopy Growth Corporation (Spectrum Therapeutics)

- Dr Christina Xinios, Medical Director, Australia and New Zealand

Medicinal Cannabis Industry Australia

- Mr Peter Crock, Chairman
- Ms Elisabetta Faenza, Director

Tasmanian Alkaloids

- Dr Ross Murdoch, Chief Executive Officer
- Dr Les Baxter, Director, Agricultural R and D

Department of Health

- Adjunct Professor John Skerritt, Deputy Secretary
- Mr George Masri, Assistant Secretary, Regulatory Services and Drug Control Branch
- Dr Grant Pegg, Assistant Secretary, Pharmacovigilance and Special Access Branch