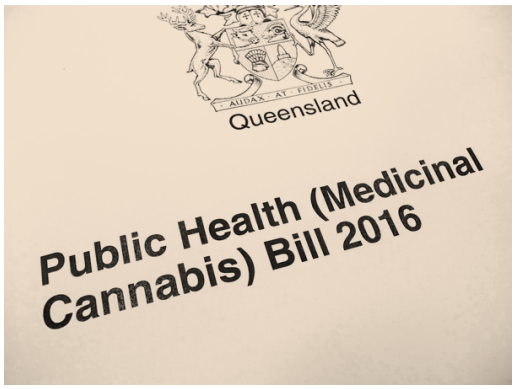
Parliamentary Committees



Public Health (Medicinal Cannabis) Bill 2016

Report No. 26, 55th Parliament
Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee
September 2016

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Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

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	Mr Aaron Harper MP, Member for Thuringowa
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Table of Contents

Abbreviations and glossary

AMAQ	Australian Medical Association Queensland
Approved pharmacist	The pharmacist to whom a dispensing approval is granted, or a pharmacist who works in a hospital pharmacy
ARTG	Australian Register of Therapeutic Goods
Authorised person	An inspector appointed by the chief executive
the Bill	Public Health (Medicinal Cannabis) Bill 2016
Carer	The adult responsible for the immediate care and safety of the patient
Carrier	A person engaged by a patient prescriber, a patient, carer, the chief executive or authorised person to transport and deliver medicinal cannabis
CBD	Cannabidiol
the chief executive	Chief Executive of Queensland Health
Clinical trial approval	An approval granted to facilitate a clinical trial using medicinal cannabis
the committee	Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee
Compliant medicinal cannabis	Medicinal cannabis prescribed in accordance with the medicinal cannabis approval, and dispensed in accordance with the medicinal cannabis approval and the prescription
Delta-8-THC	Delta-8-tetrahydrocannabinol
the department	Queensland Health
Dispensing approval	An approval granted to a pharmacist to dispense medicinal cannabis
Dispensing pharmacy	A pharmacy or public hospital pharmacy stated in the medicinal cannabis approval as being where the medicinal cannabis will be dispensed
DM Act	*Drugs Misuse Act 1986* (Qld)
Expert advisory panel	A panel of experts providing advice and making recommendations to the chief executive
Facilitator	A person who, because they have regular access to a restricted access patient is authorised to possess, supply or administer medicinal cannabis to the patient

FLPs	Fundamental legislative principles
Government	the Queensland Government
GP	General Practitioner
MCAGQ	Medical Cannabis Advisory Group Queensland
MCUAA	Medical Cannabis Users Association of Australia
Medicinal cannabis	A cannabis product used for therapeutic purposes, but not a product already registered on the Australian Register of Therapeutic Goods
Medicinal cannabis approval	An approval granted to a medical practitioner to treat a patient with medicinal cannabis
Medicinal cannabis management plan	A document detailing how risks associated with performing activities with medicinal cannabis will be managed
MIGA	Medical Insurance Group Australia
the Minister	the Minister for Health and Minister for Ambulance Services
MS	Multiple Sclerosis
ODPP	Office of the Director of Public Prosecutions
Patient-class prescriber	A specialist medical practitioner who is a member of a class of specialist medical practitioners prescribed by regulation to have an as-of-right authority to prescribe medicinal cannabis, subject to any stated limitations, and their registrar
PBS	Pharmaceutical Benefits Scheme
PHAA	Public Health Association of Australia
the POQA	*Parliament of Queensland Act 2001*
QCAT	Queensland Civil and Administrative Tribunal
QCCL	Queensland Council for Civil Liberties
QNADA	Queensland Network of Alcohol and Other Drug Agencies Ltd
QNU	Queensland Nurses' Union
QPS	Queensland Police Service
RACP	Royal Australasian College of Physicians
the Regulation	*Health (Drugs and Poisons) Regulation 1996*

Responsible person	The person in charge of an institution (e.g. hospital, school, nursing home or prison) in which a restricted access patient is located
Restricted access patient	A patient not reasonably able to possess or self-administer medicinal cannabis due to their medical condition or location
RIPENs	Rural and Isolated Practice Endorsed Nurses
SAS	Special Access Scheme
Secondary dispenser	A pharmacist stated in the dispensing approval as being the secondary dispenser, and authorised to dispense medicinal cannabis when the approved pharmacist is unavailable to do so
Single-patient prescriber	A general medical practitioner or specialist medical practitioner to whom a medicinal cannabis approval has been granted
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TG Act	*Therapeutic Goods Act 1989* (Cwlth)
THC	Delta-9-tetrahydrocannabinol

Chair's foreword

On behalf of the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee of the 55th Parliament, I present this report on the committee's examination of the Public Health (Medicinal Cannabis) Bill 2016.

The purpose of the Bill is to create a regulatory framework to prescribe medicinal cannabis to patients in Queensland, while preventing unauthorised use.

The committee's task was to consider the policy to be given effect by the Bill, and whether the Bill has sufficient regard to the fundamental legislative principles in the *Legislative Standards Act 1992*. The fundamental legislative principles include whether legislation has sufficient regard to the rights and liberties of individuals and to the institution of Parliament.

This report summarises the committee's examination of the Bill, including the views expressed in submissions and by witnesses at the committee's public hearings, and information provided by Queensland Health and the Commonwealth Department of Health.

The committee has recommended that the Bill be passed. The committee has also made two further recommendations aimed at addressing the issues raised by submitters during the course of the committee's examination of the Bill.

On behalf of the committee, I would like to thank those individuals and organisations who lodged written submissions and appeared at the committee's public hearings.

The committee also wishes to acknowledge the assistance provided by Queensland Health, the Commonwealth Department of Health, Hansard, Technical Scrutiny of Legislation Secretariat staff and the committee secretariat.

Finally, I would like to thank my fellow committee members for their contributions during the examination of the Bill.

I commend this report to the House.

Leanne Linard MP

Chair

Recommendations

The committee recommends that the Public Health (Medicinal Cannabis) Bill 2016 be passed.

The committee recommends that the Public Health (Medicinal Cannabis) Bill 2016 be amended to remove references to criminal history from clauses 10 and 11 and omit clauses 28 to 31, which provide for the chief executive to request a criminal history report about an applicant for an approval for medicinal cannabis or a patient.

The committee recommends that the Queensland Government, through the lead department – the Department of Agriculture and Fisheries, prioritise its investigation of options for obtaining a licence to cultivate and manufacture medicinal cannabis in Queensland.

1 Introduction

1.1 Role of committee

The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the committee) is a portfolio committee of the Legislative Assembly.[1] The committee's areas of portfolio responsibility are:

- health and ambulance services
- communities, women, youth and child safety
- domestic and family violence prevention, and
- disability services and seniors.[2]

The committee is responsible for examining each Bill in its portfolio areas to consider:

- the policy to be given effect by the legislation, and
- the application of fundamental legislative principles (FLPs).[3]

Further information about the work of the committee can be found on its website.

1.2 Referral and committee's process

On 10 May 2016, the Minister for Health and Minister for Ambulance Services, Hon Cameron Dick MP (the Minister), introduced the Public Health (Medicinal Cannabis) Bill 2016 (the Bill) into the Legislative Assembly. The Bill was referred to the committee on 10 May 2016, and the committee was required to report to the Legislative Assembly by 30 September 2016.

During its examination of the Bill, the committee:

- invited submissions from stakeholders. A list of the 69 submissions received by the committee is at **Appendix A**
- held public briefings on 15 June 2016 and 9 September 2016 attended by officers from Queensland Health (the department) and the Commonwealth, Department of Health - Therapeutic Goods Administration (TGA) and Office of Drug Control. A list of the officers who appeared at the briefings is at **Appendix B**, and
- held public hearings on 17 and 29 August 2016 to hear from invited witnesses. A list of the witnesses who appeared at the hearings is at **Appendix C**.

Copies of the material published in relation to this inquiry are available on the committee's website.

1.3 Outcome of committee considerations

Standing Order 132(1) requires the committee to recommend whether the Bill should be passed.

After its examination of the Bill and consideration of the information provided by the department, submitters and witnesses at its public hearings, the committee recommends that the Bill should be passed.

Recommendation 1

The committee recommends that the Public Health (Medicinal Cannabis) Bill 2016 be passed.

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1 The committee was formerly the Health and Ambulance Services Committee, which was established on 27 March 2015 under the *Parliament of Queensland Act 2001* (POQA) and the Standing Rules and Orders of the Legislative Assembly (Standing Orders). On 16 February 2016, the Parliament amended the Standing Orders, renaming the committee and expanding its areas of responsibility

2 POQA, section 88 and Standing Orders, Standing Order 194 and Schedule 6

3 POQA, section 93(1)

2 Background to the Bill

2.1 What is medicinal cannabis?

The term medicinal cannabis has been defined as cannabis used "as medical therapy to treat disease or alleviate symptoms".[4] The use of cannabis to attempt to cure an illness or to reduce the severity of symptoms due to illness distinguishes it from recreational cannabis use.[5]

There are three main species of Cannabis – S*ativa*, *Indica* and *Ruderalis* – and multiple strains within each type. Many more strains are produced through cross cultivation.[6] Generally, the species used for medicinal and recreational purposes are Cannabis *Sativa* and Cannabis *Indica*.[7]

There are around 400 chemical compounds in a typical cannabis plant. The four main compounds are:

- delta-9-tetrahydrocannabinol (delta-9-THC or THC)
- cannabidiol (CBD)
- delta-8-tetrahydrocannabinol (delta-8-THC), and
- cannabinol.[8]

Up to 300 other compounds in cannabis are claimed to contribute to its effect, including terpenes and flavonoids.[9]

CBD and THC are thought to be the two best-understood cannabinoids.[10] The effects of cannabis depend on the levels of THC and CBD and the areas of the brain in which the cannabinoids interact. THC is considered to have psychoactive properties, giving users a 'high' feeling. CBD, on the other hand, is believed to have an anti-psychoactive effect which may moderate the 'high' and some of the other perceived negative effects of THC.[11]

2.2 Potential health benefits of medicinal cannabis

There is evidence to suggest that medicinal cannabis can help patients with certain conditions, for example:

- muscle spasticity and other symptoms of Multiple Sclerosis (MS)
- arthritis
- chemotherapy-induced nausea and vomiting
- epilepsy with severe seizures
- HIV and AIDS-related symptoms, and
- chronic pain.[12]

The Explanatory Notes state that treatment with medicinal cannabis for these conditions and symptoms may have a positive impact on a patient's quality of life.[13]

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4 Whiting, Penny et. al., 'Cannabinoids for Medical Use: A Systematic Review and Meta-analysis', *Journal of the American Medical Association*, June 23/30, 2015, Vol 313, No. 24

5 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p xvi

6 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p xvii

7 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p 20

8 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p 22

9 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p 22

10 Victoria Law Reform Commission, *Medicinal Cannabis Report*, August 2015, p 194

11 National Cannabis Prevention and Information Centre, *Factsheet – Weeding out the differences between THC vs. CBD*, https://ncpic.org.au/professionals/publications/factsheets/cbd_thc/ accessed on 19 September 2016

12 Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper*, March 2015, pp 29 and 30

13 Public Health (Medicinal Cannabis) Bill 2016, Explanatory Notes (Explanatory Notes), p 1

Committee comment

The committee acknowledges the department's advice that there is a growing body of evidence that medicinal cannabis may be effective in treating certain medical conditions. The committee notes that submitters made a number of comments about the efficacy and safety of medicinal cannabis during the committee's inquiry.

It was not the role of the committee to assess the efficacy and safety of medicinal cannabis, as part of its examination of the Bill.

2.3 Current Queensland and Commonwealth legislation

Cannabis is a prohibited substance under the *Therapeutic Goods Act 1989* (Cwlth) (TG Act), *Narcotic Drugs Act 1967* (Cwlth) and the *Health (Drugs and Poisons) Regulation 1996* (Qld) (the Regulation). This legislation fulfils Australia's commitments under the *International Single Convention on Narcotic Drugs 1961*.

In Queensland, the *Drugs Misuse Act 1986* (DM Act) provides that it is an offence to produce, possess and supply cannabis without authorisation, justification or lawful excuse.

2.3.1 Access and supply of therapeutic goods

The use of therapeutic goods for patient treatment is regulated by state legislation, such as proposed in the Bill. The TG Act, however, regulates how a medicine may be supplied and accessed for use in Australia.

The TG Act establishes a uniform, national system of regulatory controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods for human use. The TG Act provides that before any drug, including medicinal cannabis, may be used for a therapeutic purpose in Australia, it must be approved and registered on the Australian Register of Therapeutic Goods (ARTG).

The TGA has approved three cannabis products: nabiximols (also known as Sativex), dronabinol and nabilone for therapeutic purposes. These products are classified as Schedule 8 (regulated controlled drugs), and can be used lawfully in Queensland, subject to restrictions, such as approval by the chief executive.[14] Nabiximols, which is used for MS, is currently the only medicinal cannabis product that has been registered on the ARTG.[15]

An application may be made to the TGA for approval to access an unapproved therapeutic good for treatment of a particular patient (Special Access Scheme (SAS)), a class of patient (Authorised Prescriber Scheme) or for use in a clinical trial.[16]

Special Access Scheme

The SAS provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. Under the SAS, patients are classified as:

- **Category A patients** – a medical practitioner who deems that their patient is seriously ill[17] may supply, with the patient's consent, an unapproved therapeutic good to the patient, except for those listed as Schedule 9 (prohibited poisons), but the TGA must be notified, or

[14] Queensland Government, *Medical Cannabis in Queensland: Draft Public Health (Medicinal Cannabis) Bill 2016 – Discussion Paper*, March 2016, p 7

[15] Explanatory Notes, p 20

[16] Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods – Authorised Prescribers*, October 2004, p 8

[17] *Therapeutic Goods Regulation 1990* (Cwlth), section 12A defines the term *seriously ill* as a patient with 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

- **Category B patients** – a medical practitioner must apply to the TGA for approval to supply an unapproved medicine to a category B patient (patients who are not deemed seriously ill).

  The application must address criteria about: the patient (personal details, diagnosis and clinical justification for use of unapproved therapeutic good (including why an unapproved medicine is preferred to an approved medicine)); the product (how it is to be used – dosage, method of administration and treatment duration, supplier details and appraisal of efficacy and safety); and the prescriber (practitioner's name, address and qualifications).[18]

  The TGA grants approvals subject to certain conditions being placed on a medical practitioner, including the maximum dosage and duration of treatment. [19]

Authorised Prescribers

The TG Act provides that an Authorised Prescriber may prescribe unapproved therapeutic goods to patients who are suffering from a life-threatening or otherwise serious illness or condition.[20]

In order to become an Authorised Prescriber, a medical practitioner must apply to the TGA and address criteria about: the class of recipients (the seriousness of the condition), the product (product details, dosage, method of administration, duration of treatment and efficacy and safety data) and the prescriber (personal details, qualifications, areas of specialty and ethics committee endorsements).[21]

An authorisation, once approved, is restricted in that it applies only to a specified product, the product can only be prescribed to a patient in the Authorised Prescriber's immediate care and the TGA may revoke the authorisation at any time.[22] An Authorised Prescriber must obtain the patient's consent to treatment with medicinal cannabis and comply with State legislation.[23]

2.3.2 National classification scheme

A national classification scheme regulates how medicines and poisons are made available to the public, including script, approval and reporting requirements.

Medicines and poisons are classified into schedules, under the *Poisons Standard 2015* (Cwlth), also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), according to the level of regulatory control required to protect public health and safety. The scheduling scheme is administered by the TGA.[24]

Schedule 9 substances are classified as 'prohibited poisons' because they are considered dangerous or dependence forming. Schedule 8 substances are classified as 'controlled drugs', while Schedule 4 substances are classified as 'restricted drugs' because they are considered medicines.[25]

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18 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods via the Special Access Scheme*, November 2009, pp 11 to 16

19 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods via the Special Access Scheme*, November 2009, pp 11 to 16

20 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods – Authorised Prescribers,* October 2004, p 12

21 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods – Authorised Prescribers,* October 2004, p 18

22 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods – Authorised Prescribers,* October 2004, p 14

23 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Access to unapproved therapeutic goods – Authorised Prescribers,* October 2004, p 18

24 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 1

25 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 1

Unless otherwise scheduled, cannabis and cannabis-derived products are automatically classified as Schedule 9 (prohibited poisons) due to their potential toxicity, potential for abuse and other unknown harms, and generally cannot be used for therapeutic purposes.[26]

In Queensland, the use of drugs and poisons is regulated under the Regulation, which adopts the SUSMP scheduling.[27]

2.3.3 Recent developments

In December 2015, the Queensland Government amended the Regulation to allow the chief executive to approve the use of Schedule 9 cannabis products in Queensland:

- for a clinical trial, or
- where the TGA has approved an individual accessing these products, for example under the SAS.

The Queensland Government is proposing to undertake a clinical drug trial at the Lady Cilento Hospital to explore whether medicinal cannabis products can be used to treat children with epilepsy.[28]

On 31 August 2016, the TGA rescheduled all botanical cannabis products and all botanically-derived cannabis extracts, when prepared and packed for therapeutic use as Schedule 8 (controlled drugs). The TGA's decision comes into force on 1 November 2016.[29]

In June 2016, the Queensland Government amended the Regulation to provide for an interim framework for access to medicinal cannabis in Queensland. The interim framework will apply from 1 November 2016, the date the TGA's re-scheduling decision comes into force. The interim framework will be repealed on commencement of the Bill, or 1 January 2017, whichever occurs earliest.[30]

The interim framework provides two pathways for patients to obtain treatment with medicinal cannabis which mirror the patient-class and single-patient prescriber pathways proposed in the Bill.

The department advised that the amendment to the Regulation will enable Queensland patients to take immediate advantage of the re-scheduling decision, without needing to wait for the Bill to be enacted.[31]

2.4 Approaches in other jurisdictions

The Commonwealth and a number of States and Territories are pursuing or considering law reform in relation to the use of medicinal cannabis products.

In February 2016, the *Narcotic Drugs Act 1967* (Cwlth) was amended to establish a national licensing and permit scheme for the lawful cultivation and manufacture of medicinal cannabis products. The scheme will permit a State or Territory which obtains a licence to cultivate cannabis for use in clinical trials and by specific patients where appropriate State and Territory arrangements are in place.[32]

New South Wales (NSW) has established a Medicinal Cannabis Compassionate Use Scheme. The scheme provides guidelines for police officers to determine the appropriate circumstances in which to

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26 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 2

27 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 2

28 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, Department, *Public Briefing Transcript*, 15 June 2016, p 1; *Health (Drugs and Poisons) Amendment Regulation (No. 1) 2015*

29 Commonwealth Government, *Final decisions and reasons for decisions by a delegate of the Secretary to the Department of Health*, 31 August 2016

30 *Health (Drugs and Poisons) Amendment Regulation (No.2) 2016*

31 Department, *Correspondence - Written Briefing on the Bill,* 9 June 2016, p 3

32 Queensland Government, *An Overview of Medicinal Cannabis – Current State of Play in 2016*, p 8; *Narcotic Drugs Amendment Act 2016* (Cwlth)

use their discretion not to charge adults with terminal illness, who have registered for the scheme, and who use cannabis to alleviate their symptoms, as well as carers who assist them.[33]

In NSW, the Compassionate Access Scheme – an agreement between the NSW Government and a pharmaceutical company – provides access to cannabinoid medicines through clinical trials, e.g. children with severe treatment resistant epilepsy.[34]

The NSW Government has established a Centre for Medicinal Cannabis Research and Innovation to undertake research, support evidence-based innovation, monitor clinical trials and educate the community. In May 2016, the NSW Government lodged an application for a licence from the Commonwealth to grow cannabis for medical research trials.

The Victorian Parliament passed the *Access to Medicinal Cannabis Act 2016* (Vic) on 12 April 2016 to enable access to locally-manufactured medicinal cannabis products for certain patients. Children with severe epilepsy will be able to access legal medicinal cannabis products from early 2017.

The Victorian Government intends to establish the Office of Medicinal Cannabis to oversee the manufacturing and dispensing of the drug, while an independent medical advisory committee on medicinal cannabis will also be created to provide advice in relation to the scheme.

To enable an ongoing and reliable supply of medicinal cannabis, the Victorian Government will oversee a cultivation trial at a Victorian research facility.

Other countries that allow medicinal cannabis use include Austria, Canada, the Czech Republic, Denmark, Germany, Israel, Italy, New Zealand, Spain, Sweden and certain States in the United States of America.[35]

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33 NSW Government, *Medicinal Cannabis Compassionate Use Scheme: Fact sheet for adults with a terminal illness and their carers*, https://www.medicinalcannabis.nsw.gov.au/regulation/medicinal-cannabis-compassionate-use-scheme, accessed on 5 September 2016, p 1

34 NSW Government, 'NSW children provided with compassionate access to cannabis based medicines', *Media Release*, 5 July 2016

35 Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont and Washington have passed legislation to allow medicinal cannabis use

3 Examination of the Bill

3.1 Objective of the Bill

The Bill's objective is to create a regulatory framework under which medicinal cannabis products may be prescribed and dispensed to patients in Queensland, while also preventing unauthorised use.[36]

The Bill would allow patients to obtain medicinal cannabis in one of two ways:

- a patient-class prescriber pathway, where specialist medical practitioners, and their registrars, have the authority to prescribe specific medicinal cannabis products for sufferers of specific conditions, without the need for approval from the chief executive of Queensland Health (chief executive), or
- a single-patient prescriber pathway, which allows a medical practitioner to apply to the chief executive for a *medicinal cannabis approval* to prescribe medicinal cannabis to a specific patient.[37]

Under the framework, patients will need to obtain their medicinal cannabis from a pharmacist approved to dispense it. The proposed processes for applying for and obtaining medicinal cannabis is outlined in the flowcharts at **Appendix D**.

The Bill would also allow for medicinal cannabis products to be provided for use in clinical trials, to help improve the evidence base for their safety and efficacy.

In his introductory speech, the Minister clarified that the Bill does not authorise people to grow their own cannabis, even if intended for their own therapeutic use, nor does it authorise any recreational use of cannabis. These activities will remain offences under the DM Act.[38]

3.2 Consultation on the Bill

From 1 March 2016 to 1 April 2016, the department consulted on an early draft of the Bill on the Queensland Government's *Get Involved* website and published a discussion paper explaining the Bill's proposals.

The department also ran a survey seeking people's views, with over 96 per cent of the 1,052 respondents in favour of allowing medicinal cannabis treatment.

In addition, the department consulted key industry stakeholders, including medical professionals in specialty areas for which patients may seek medicinal cannabis and health care workers likely to be involved in delivering treatment. The department also consulted government stakeholders, including the Department of the Premier and Cabinet, Queensland Treasury, the Department of Justice and Attorney-General and the Queensland Police Service.[39]

3.3 General comments on proposed approach

A number of submitters including the Medical Cannabis Advisory Group Queensland (MCAGQ), Medical Cannabis Users Association of Australia (MCUAA) and Queensland Council for Civil Liberties (QCCL) did not support the proposed approach set out in the Bill. These submitters preferred a scheme whereby patients were permitted to 'grow-their-own' cannabis for their own personal medicinal use.[40]

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36 Explanatory Notes, p 1

37 Explanatory Notes, p 2

38 Minister for Health and Minister for Ambulance Services (the Minister), *Introductory Speech*, Hansard, 10 May 2016, p 1551

39 Explanatory Notes, pp 7 and 8

40 Submissions 4, 8, 11, 18, 28, 38 49 and 69; John Ransley, Executive Member, Queensland Council for Civil Liberties (QCCL), *Public Hearing Transcript*, 29 August 2016, p 17

The MCUAA considered that the "Overcautiousness as demonstrated in this Bill will continue to hold up the process of alleviating people's suffering".[41] The MCUAA stated that "there is no valid reason or justification to keep cannabis wrapped up so tightly … This proposed legislation does not give ease of access and patients will be forced to continue to seek out illegal supplies that could be unsafe".[42]

The MCAGQ and MCUAA also raised concerns about the criminalisation of people who use cannabis because they believe it helps with their medical conditions.[43] The MCUAA stated that:

> *Our people live in fear: they fear their illnesses; they fear their treatments; they fear speaking out about their cannabis use; they fear being caught and prosecuted; and they fear having to deal with the criminal element to obtain their needs, leaving a great many Australians to suffer in silence. Sick people should not have to live in fear.*[44]

Those submitters who supported a 'grow-their-own' approach noted, there was significant anecdotal evidence of its effectiveness.[45] In addition, the QCCL stated that "… there is plenty of evidence from overseas trials … that medicinal cannabis can be very effective for a number of conditions".[46]

Other submitters, including Epilepsy Queensland, MS Australia and MS Research Australia, the Cancer Council Queensland, Royal Australasian College of Physicians (RACP), Queensland Nurses' Union (QNU) and the Australian Medical Association Queensland (AMAQ) supported the Bill.[47]

The AMAQ, RACP and Dr Jennifer Martin opposed any proposal to make cannabis widely available outside of a medical framework, including home grown cannabis for self-medication, due to the lack of quality control and safety concerns. Such submitters considered that more clinical trials needed to be undertaken to understand fully the efficacy and safety of medicinal cannabis.[48]

The department advised that the purpose of the Bill:

> *… is to provide a framework for such dangerous drugs [as medicinal cannabis] to be used safely as part of a patient's overall treatment plan. It is therefore important that any cannabis product used for a therapeutic purpose be cultivated or manufactured in accordance with good agricultural and manufacturing practices.*
>
> *For this reason, the Bill does not enable patients to grow their own cannabis for medicinal purposes because doctors and patients have no certainty about the concentrations of active ingredients in the products.*[49]

3.4 Medicinal cannabis products covered by the Bill

For the purposes of the Bill, the term *medicinal cannabis* is defined as a *cannabis product* used for human therapeutic purposes, but not a product already registered on the ARTG.[50] The Bill defines a *cannabis product* as being:

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41 Deb Lynch, Secretary, Medical Cannabis Users Association of Australia (MCUAA), *Public Hearing Transcript*, 17 August 2016, p 3

42 Deb Lynch, Secretary, MCUAA, *Public Hearing Transcript*, 17 August 2016, p 3

43 Submissions 49 and 69

44 Deb Lynch, Secretary, MCUAA, *Public Hearing Transcript*, 17 August 2016, p 2

45 Submissions 49, 57, 58 and 69

46 John Ransley, Executive Member, QCCL, *Public Hearing Transcript*, 29 August 2016, p 16

47 Submissions 7, 12, 20, 23, 24, 25, 27, 42, 53, 55, 62 and 64

48 Submissions 16, 21, and 53; Dr Jennifer Martin, *Public Hearing Transcript*, 17 August 2016, pp 18 and 19; Conjoint Professor Nicholas Lintzeris, Royal Australasian College of Physicians (RACP), *Public Hearing Transcript*, 29 August 2016, p 2

49 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 18

50 Explanatory Notes, p 10; Public Health (Medicinal Cannabis) Bill 2016, clause 6

- part of the cannabis plant
- derived from the cannabis plant, or
- a drug that has, or is intended to have, a substantially similar pharmacological effect to a part of the cannabis plant or something derived from the plant.[51]

The Explanatory Notes state that the definition of cannabis product "… ensures synthetic cannabis products will be included … for the purposes of the Bill".[52]

Submitters' views and the department's response

Some submitters, including MCUAA, Hemployment Australia and MCAGQ, suggested that medicinal cannabis products derived from the cannabis plant are superior to synthetic cannabis products. They also stressed the need to use the whole cannabis plant in a medicinal cannabis product to obtain the full therapeutic effect of medicinal cannabis.[53]

In response, the department stated that a broad range of medicinal cannabis products could potentially be approved under the proposed framework, including oils and other forms of medicinal cannabis.[54] The department stated that:

> *Although the bill allows medical practitioners to prescribe both botanical and synthetic medicinal cannabis products, most synthetic products remain in developmental stage and are unlikely to be available for patient treatment in the foreseeable future. For this reason, it is expected that most approvals granted under the bill will be for botanically derived products.*[55]

3.5 Patient-class prescriber pathway

The Bill provides that a regulation may specify a class of specialist medical practitioners (a patient-class prescriber), and their registrars, who have an 'as-of-right authority' to prescribe specific medicinal cannabis products for patients under their care for a specified range of conditions, without the need for approval from the chief executive.[56]

The department advised that "A national working party will decide the initial list of specialists", however, "Speciality areas are likely to include paediatric neurology, oncology for the treatment of symptoms arising from chemotherapy and palliative care medicine". [57]

The regulation may also specify standard conditions on patient-class prescribers' authority to prescribe medicinal cannabis, including a requirement to notify the chief executive when they prescribe, supply or use the product, and to specify the dispensing pharmacy or hospital pharmacy.

Additional conditions may include requiring the patient-class prescriber to monitor and report on the patient's condition, or comply with prescribing requirements or with a stated code, guideline, protocol or standard.[58]

The Bill provides that a patient-class prescriber may give a lawful direction for the issue or supply of medicinal cannabis for treating their patient. A patient-class prescriber may also obtain and possess medicinal cannabis until their patient can be treated.[59]

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51 Public Health (Medicinal Cannabis) Bill 2016, clause 7

52 Explanatory Notes, p 10

53 Submissions 1, 2, 3, 4, 8, 11, 13, 14, 18, 35, 36, 38, 39, 46, 47, 49, 51, 56, 57, 58, 60 and 69

54 Department, *Response to Submissions*, 2 August 2016, p 5

55 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 19

56 Public Health (Medicinal Cannabis) Bill 2016, clauses 52 and 53

57 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, Department, *Public Briefing Transcript*, 15 June 2016, p 2

58 Public Health (Medicinal Cannabis) Bill 2016, clause 53

59 Public Health (Medicinal Cannabis) Bill 2016, clause 53

As mentioned in section 2.3.1, as most medicinal cannabis products are not approved therapeutic goods, TGA approval must be sought for the supply or importation of a medicinal cannabis product, prior to a practitioner prescribing the medicinal cannabis product to a patient – under the Authorised Prescriber Scheme.

A patient-class prescriber must make a *medicinal cannabis management plan* for managing the known and foreseeable risks associated with an activity that involves medicinal cannabis.[60]

Submitters' views and department's response

A number of submitters, including the AMAQ, Queensland Network of Alcohol and Other Drug Agencies Ltd (QNADA), Medical Insurance Group Australia (MIGA), MS Australia and MS Research Australia and QCCL, supported the patient-class prescriber pathway.[61]

The QNADA considered that the provisions have the potential to reduce some of the burden around the application process for people who need urgent access to treatment.[62]

The MIGA supported the proposed list of specialists to be prescribed by regulation as patient-class prescribers, and suggested:

> *… wide consultation with peak professional bodies on classes of specialist medical practitioners to be included as patient-class prescribers, types of medicinal cannabis which may be used, and patients to be included as eligible for this aspect of the new regime, both initially and into the future.*[63]

The AMAQ supported the proposal to limit, at least initially, the types of practitioners who may prescribe medicinal cannabis. The AMAQ considered that:

> *Initially in the rollout of any new medication it is very useful to have a restriction on the group of doctors within subspecialties; for example, oncologists, paediatric neurologists and palliative care specialists … because it is in those three areas that medical cannabinoid products would probably have the most initial promise.*[64]

The QCCL, however, considered that the proposed list of specialists was too restrictive, and noted the lack of specialists with expertise in medicinal cannabis in Queensland.[65]

The RACP, MIGA, the Public Health Association of Australia (PHAA) and QNU raised concerns about timely access to patient-class prescribers in rural and remote areas.[66] The RACP suggested that rural and remote patients could be monitored through a shared care arrangement – involving general and specialist practitioners – after an application has been approved by a relevant specialist.[67]

The QNU suggested that accessibility issues be addressed by Rural and Isolated Practice Endorsed Nurses (RIPENs) having a role in the supply and administration of medicinal cannabis in rural and remote areas.[68]

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60 Public Health (Medicinal Cannabis) Bill 2016, clauses 69 to 75

61 John Ransley, Executive Member, QCCL, *Public Hearing Transcript*, 29 August 2016, p 14; Submissions 28, 42, 44, 45 and 53

62 Queensland Network of Alcohol and Other Drug Agencies Ltd (QNADA), Submission 44

63 Medical Insurance Group Australia (MIGA), Submission 45

64 Dr Jim Finn, Australian Medical Association Queensland (AMAQ), *Public Hearing Transcript*, 29 August 2016, p 6

65 QCCL, Submission 28

66 Submissions 21, 24, 45 and 59

67 RACP, Submission 21

68 Queensland Nurses' Union (QNU), submission 24

In response to the issues raised by submitters, the department stated that "It is expected the list of suitable patient conditions for medicinal cannabis treatment under the patient-class prescriber pathway may expand as more reliable scientific evidence becomes available".[69]

The department noted that patients in remote and rural areas will have access to the single-patient prescriber pathway, provided they can access a general practitioner (GP). The department also advised that where such patients cannot access a specialist or a GP, they may access health services via telehealth.[70]

3.6 Single-patient prescriber pathway - medicinal cannabis approvals

The Bill provides for a single-patient prescriber pathway under which a medical practitioner (a general medical practitioner or a specialist medical practitioner[71]) may, with the written consent of their patient, apply to the chief executive to prescribe medicinal cannabis for the patient – a *medicinal cannabis approval*.[72]

The application must be in an approved form, and include a copy of the patient's written consent and any specialist medical opinion obtained about the patient's treatment with medicinal cannabis.[73]

The Explanatory Notes state that the "medicinal cannabis approval will be specific to one patient and the medical condition being treated".[74]

3.6.1 Criteria for deciding applications

The Bill provides that the chief executive may have regard to a range of factors when deciding an application for a medicinal cannabis approval, including:

- the patient's medical condition and symptoms
- the form and dosage of medicinal cannabis proposed
- whether the proposed treatment can be integrated into the patient's existing treatment
- an opinion of a specialist medical practitioner
- alternative treatments
- the patient's history of drug dependence, and
- any other information included in the application.[75]

In addition, the Bill provides that the chief executive must be satisfied of the following prior to granting a medicinal cannabis approval:

- that the applicant (the medical practitioner) is a suitable person to hold a medicinal cannabis approval – factors include the applicant's qualifications and experience; character and standing; criminal history; conduct and knowledge; and understanding of their legislated obligations
- that the patient is a suitable person to undergo the proposed treatment – factors include the patient's personal circumstances and criminal history; the advice of the expert advisory panel; the advice of a specialist medical practitioner; and whether the patient will be able to comply with the legislation and any conditions, and

69 Department, *Response to Submissions*, 2 August 2016, p 5

70 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division Department, *Public Hearing Transcript*, 29 August 2016, p 24

71 Public Health (Medicinal Cannabis) Bill 2016, Schedule 1 – defines a *specialist medical practitioner* as a person registered under the Health Practitioner Regulation National Law to practise in the medical profession as a specialist registrant in a speciality

72 Public Health (Medicinal Cannabis) Bill 2016, clauses 14 and 15

73 Public Health (Medicinal Cannabis) Bill 2016, clause 12

74 Explanatory Notes, p 12

75 Explanatory Notes, p 14; Public Health (Medicinal Cannabis) Bill 2016, clause 24

- that the medicinal cannabis has, or will be, manufactured or imported and is, or will be, able to be supplied to the patient in accordance with the applicable Commonwealth legislation (see section 2.3.1 of this report).[76]

The Explanatory Notes state that "This provision seeks to ensure all relevant factors are carefully considered to ensure the use of medicinal cannabis is appropriate for the patient and their particular circumstances".[77]

When considering the application, the chief executive may require additional information from the medical practitioner (an information request notice), require the medical practitioner to provide an opinion from a specialist medical practitioner, or from another specialist medical practitioner if an opinion has already been provided, or refer the application to the expert advisory panel (see section 3.11 of this report).[78]

3.6.2 Approvals

The chief executive may decide to grant an application for a medicinal cannabis approval, grant the application subject to conditions, or refuse to grant the application.[79] The chief executive must, as soon as practicable, inform the applicant of his or her decision. A medical practitioner to whom a medicinal cannabis approval is granted is deemed a *single-patient prescriber*.

The chief executive must decide an application for a medicinal cannabis approval:

- within 90 days of receipt of the application
- if the chief executive has requested additional information, within 90 days of receipt of the requested information, or
- if the application is complex, within a reasonable time, as decided by the chief executive.[80]

If the chief executive fails to approve an application within these timescales, the application is considered to have been refused.[81]

A medicinal cannabis approval must note:

- the details of the single-patient prescriber
- the form, dosage and dispensing intervals of the medicinal cannabis product
- the details of the TGA approval
- the details of the pharmacy from where the medicinal cannabis will be dispensed (dispensing pharmacy), and
- the term of the approval, which must not exceed one year.[82]

A medicinal cannabis approval would be subject to the standard conditions prescribed in a regulation. The chief executive may also impose additional conditions on the approval.[83]

Once approved, a single-patient prescriber is authorised to give a lawful direction, instruction or prescription about the issue, supply or administration of medicinal cannabis to a patient. A single-patient prescriber is also permitted to obtain or possess medicinal cannabis until their patient can be treated.[84]

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76 Public Health (Medicinal Cannabis) Bill 2016, clauses 10, 11 and 24
77 Explanatory Notes, p 14
78 Public Health (Medicinal Cannabis) Bill 2016, clauses 21, 22 and 27
79 Public Health (Medicinal Cannabis) Bill 2016, clause 23
80 Public Health (Medicinal Cannabis) Bill 2016, clause 32; Explanatory Notes, p 3
81 Public Health (Medicinal Cannabis) Bill 2016, clause 33
82 Public Health (Medicinal Cannabis) Bill 2016, clauses 36 and 38
83 Public Health (Medicinal Cannabis) Bill 2016, clauses 34 and 35
84 Public Health (Medicinal Cannabis) Bill 2016, clause 57

As mentioned in section 2.3.1, TGA approval must be sought for the supply or importation of a medicinal cannabis product, prior to a practitioner prescribing the medicinal cannabis product to a patient – under the SAS.

A single-patient prescriber must make a *medicinal cannabis management plan* for managing the known and foreseeable risks associated with an activity that involves medicinal cannabis.[85]

A similar process, including the decision-making criteria, would apply to applications to amend, vary, renew or replace an approval.[86]

Submitters' views and department's response

A number of submitters raised concerns about the factors to be considered by the chief executive when determining an application. For example, the MCAGQ, QNADA and MIGA questioned the relevance of a patient's personal circumstances (e.g. socio-economic circumstances and history of drug dependence) and a medical practitioner's character and standing to clinical decisions about a patient's treatment.[87]

The MIGA raised concerns about the type of investigations and criteria that would be used to determine whether a practitioner was a suitable prescriber. To overcome these issues, it suggested:

> *… consideration be given to developing guidelines on what is expected of an applicant for approved prescriber status, particularly their qualifications and experience, character and standing, and knowledge and understanding of the requirements of the proposed regime.*[88]

The MIGA was also concerned that the chief executive was not mandated to seek the advice of the expert advisory panel, or seek a specialist medical practitioner's opinion, which may lead to uncertainty about when such advice would be considered necessary and relevant.[89]

The MCUAA noted that the chief executive, who is responsible for approving applications, has no medical experience or background.[90] In addition, the MCAGQ considered that:

> *The form, type, strain, of cannabis and the dose, route of administration, duration of cannabis treatment and the type of device used to vaporise cannabis should be left between the patient in consultation with his or her doctor, not bureaucrats who are so far removed from the patient's health and well being.*[91]

The QNU recommended that the Bill be amended to enable nurse practitioners to be approved to prescribe those medicinal cannabis products which are rescheduled as Schedule 8.[92]

In response, the department stated that the provisions to allow the chief executive to assess whether a prescriber is a fit and proper person are appropriate given the risk associated with the use of medicinal cannabis products.[93]

In relation to the chief executive's perceived lack of medical expertise, the department stated that the chief executive has the ability to seek the advice of the expert advisory panel when deciding applications for medicinal cannabis approvals.[94]

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85 Public Health (Medicinal Cannabis) Bill 2016, clauses 69 to 75
86 Public Health (Medicinal Cannabis) Bill 2016, clauses 42 to 48
87 Submissions 44, 45 and 69
88 MIGA, Submission 45, p 4
89 MIGA, Submission 45
90 MCUAA, Submission 49
91 MCAGQ, Submission 69, p 73
92 QNU, Submission 24
93 Department, *Response to Submissions*, 2 August 2016, p 23
94 Department, *Response to Submissions*, 2 August 2016, p 23

The department advised that given that the Bill is the first step in the legislative process for medicinal cannabis, and such products are not approved on the ARTG, the decision has been taken to limit prescribing to GPs and specialists, and not nurse practitioners, at this time.[95]

Further issues raised by submitters that relate to the single-patient prescriber pathway are discussed at section 3.13.

3.7 Clinical trial approvals

The Bill provides for a person to apply to the chief executive for an approval (*clinical trial approval*) to include medicinal cannabis in clinical trials.[96] The Bill outlines the factors the chief executive may consider when deciding an application, and provides that he or she must be satisfied that:

- the applicant is a suitable person to hold the approval – factors include the applicant's criminal history, and
- the medicinal cannabis to which the approval will apply has, or will be, manufactured or imported in accordance with the applicable law of the Commonwealth – see section 2.3.1 of this report.[97]

When considering the application, the chief executive may require additional information from the applicant (an information request notice).

A clinical trial approval must be issued in an approved form and contain the following information:

- the approval holder's name and qualifications
- details of the approval of the trial by the Commonwealth or an ethics committee
- the term of the approval, and
- conditions applying to the approval.[98]

A clinical trial approval remains in force for the term approved by the chief executive.[99]

A similar process, including the decision-making criteria, would apply to applications to amend, vary, renew or replace an approval.[100]

The Bill provides that a person can possess, obtain, dispense, issue, supply, sell, administer or self-administer medicinal cannabis for an approved clinical trial. A medical practitioner may also give a direction, instruction or prescription for medicinal cannabis for a trial.[101]

The department advised that clinical trials will allow a rigorous evidence base for medicinal cannabis to be established.[102] In addition, the department stated that the results of clinical trials will be used to inform future treatment decisions with medicinal cannabis under the regulatory framework.[103]

3.8 Approved pharmacists

To support both the patient-class prescriber and single-patient prescriber pathways, the Bill provides that the chief executive may grant *dispensing approvals* to specific pharmacists (*approved pharmacists*) to dispense medicinal cannabis.

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95 David Harmer, Director, Legislative Policy Unit, Department, *Public Hearing Transcript*, 29 August 2016, p 24; Department, *Response to Submissions*, 2 August 2016, p 15

96 Public Health (Medicinal Cannabis) Bill 2016, clause 20

97 Public Health (Medicinal Cannabis) Bill 2016, clause 26

98 Public Health (Medicinal Cannabis) Bill 2016, clause 40; Explanatory Notes, p 18

99 Public Health (Medicinal Cannabis) Bill 2016, clause 41

100 Public Health (Medicinal Cannabis) Bill 2016, clauses 42 to 48

101 Public Health (Medicinal Cannabis) Bill 2016, clause 66

102 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 7

103 Department, *Response to Submissions*, 2 August 2016, p 10

In order to dispense medicinal cannabis prescribed for a patient, an approved pharmacist would be required to work in the dispensing pharmacy noted on the medicinal cannabis approval.

The Bill outlines the criteria the chief executive may consider when deciding an application for a dispensing approval, including:

- the applicant's familiarity with the use of medicinal cannabis for therapeutic purposes
- the location and facilities of the pharmacy from which the medicinal cannabis will be dispensed
- any other information in the application for the approval, and
- any other matters the chief executive reasonably considers relevant.

Before granting a dispensing approval, the chief executive must be satisfied that the applicant is a suitable person to hold the approval, including the applicant's criminal history, character and standing and qualifications and experience.[104]

A dispensing approval must be issued in an approved form and contain the:

- approved pharmacist's name and qualifications
- name and business address of the pharmacy where the medicinal cannabis will be dispensed
- name, qualifications and address of any secondary dispenser
- term of the approval – a maximum of 12 months[105], and
- conditions applying to the approval.[106]

A similar process, including the decision-making criteria, would apply to applications to amend, vary, renew or replace an approval.[107]

An approved pharmacist is authorised to obtain and possess a medicinal cannabis product for the purpose of supplying or administering medicinal cannabis to a patient or carer. A secondary dispenser may possess, sell, supply and issue medicinal cannabis when the approved pharmacist is not present at the pharmacy.[108]

An approved pharmacist must make a *medicinal cannabis management plan* for managing the known and foreseeable risks associated with an activity that involves medicinal cannabis.[109]

3.9 Criminal history reports

The Bill provides that the chief executive may apply to the police commissioner for a criminal history report on an applicant or a patient, as part of the chief executive's consideration of whether they are suitable persons to hold an approval.[110]

The police commissioner must also notify the chief executive about any subsequent changes to an individual's criminal history, once an initial criminal history report has been provided.[111]

In addition, the Bill provides that the *Criminal Law (Rehabilitation of Offenders) Act 1986* will not apply to criminal history reports undertaken as part of granting approvals. This means spent convictions

104 Public Health (Medicinal Cannabis) Bill 2016, clauses 10 and 25
105 Public Health (Medicinal Cannabis) Bill 2016, clause 36
106 Public Health (Medicinal Cannabis) Bill 2016, clause 39
107 Public Health (Medicinal Cannabis) Bill 2016, clauses 42 to 48
108 Public Health (Medicinal Cannabis) Bill 2016, clause 58
109 Public Health (Medicinal Cannabis) Bill 2016, clauses 69 to 75
110 Public Health (Medicinal Cannabis) Bill 2016, clauses 28 and 29 provide that the chief executive may request a criminal history record when considering an application for a medicinal cannabis approval, clinical trial approval or a dispensing approval
111 Public Health (Medicinal Cannabis) Bill 2016, clause 30

under that Act would still form part of a person's criminal history report.[112] The potential FLP issues raised by this provision are discussed at section 4 of this report.

Submitters' views and the department's response

A significant number of submitters, including MCAGQ, MCUAA, QCCL, MIGA, PHAA and QNADA, opposed the chief executive's ability to request a criminal history report on medical practitioners and patients. Such submitters suggested that the proposals may hinder patients' access to medicinal cannabis, and that criminal history reports were not a relevant consideration in clinical determinations about a patient's medical treatment.[113] The QNADA stated that:

> *… it is difficult to understand how someone's criminal history actually is relevant information when making a clinical decision other than from the health practitioner's point of view. Opioids is the natural place that you compare this to. Opioids are far more dangerous than cannabis. We have systems in place where people who have been dependent on opioids in the past are still allowed access to them for pain relief purposes. Anything in this Bill that makes the process for accessing medicinal cannabis more onerous than accessing medicinal opioids is maybe getting the risk balance not quite right.*[114]

The MCAGQ considered that the provisions will discriminate against those patients who have: criminal records; been wrongly charged and convicted; been charged with minor drug offences, or spent convictions.[115]

The QNADA considered that the only other medical procedure where a patient was not allowed certain treatment, based on criminal history, was male prisoners in Queensland who may not access opiate replacement therapy.[116] In addition, the QNADA noted that medical practitioners are already required to undergo criminal history checks as part of their registration process.[117]

The MIGA highlighted inconsistencies with the patient-class prescriber pathway, where no criminal history checks are required.[118]

Submitters also objected to the proposal that spent convictions under the *Criminal Law (Rehabilitation of Offenders) Act 1986* be included in criminal history reports under the Bill. The QNADA stated that:

> *Spent convictions essentially recognise that a person who refrains from criminal offending for a significant length of time should not be unduly limited in their future endeavours. There is no justification for treating those who are seeking to access a medical intervention differently from other citizens in the State who have moved on from their criminal history.*[119]

The QNADA envisaged a circumstance where:

> *… somebody has a drug conviction from their teens or early 20s, when they were young and wild, then they pulled themselves together, got a job, went to university and are now productive members of society, and their behaviour from their youth is being used against them when they might derive a clinical benefit from being prescribed cannabis.*[120]

112 Public Health (Medicinal Cannabis) Bill 2016, clause 31
113 Submissions 28, 44, 45, 49, 52, 57, 58, 59 and 69
114 Rebecca MacBean, Chief Executive Officer, QNADA, *Public Hearing Transcript*, 17 August 2016, p 10
115 MCAGQ, Submission 69
116 Rebecca MacBean, Chief Executive Officer, QNADA, *Public Hearing Transcript*, 17 August 2016, p 13
117 Rebecca MacBean, Chief Executive Officer QNADA, *Public Hearing Transcript*, 17 August 2016, p 10
118 MIGA, Submission 45
119 QNADA, Submission 44, p 4
120 Rebecca MacBean, Chief Executive Officer, QNADA, *Public Hearing Transcript*, 17 August 2016, p 12

In response, the department stated that the provision reflects the Government's intent to strike a balance between facilitating treatment with medicinal cannabis products and creating the controls necessary to ensure these products are used safely and not diverted for unlawful purposes.[121]

The department advised that because the safety and efficacy of medicinal cannabis products has not been established, and they are not registered on the ARTG, such products required stricter safety and security controls than other Schedule 8 products, including criminal history checks.[122]

The department stated that the provisions were discretionary, and gave the chief executive the option to request a criminal history report about any of the parties to an application. The department stated that:

> *It is highly unlikely that any eligible patient will be denied medicinal cannabis treatment solely because of their criminal history. Rather, where a criminal history is sought it would inform the types of conditions imposed on the use of medicinal cannabis, such as dispensing restrictions to limit the amount of medicinal cannabis that a patient may possesses at any one time to prevent unlawful diversion.*[123]

The department stated that it:

> *… did not anticipate a specific situation [where a criminal history check would be required], but, given advice from other agencies about the need for appropriate protections, the capacity to ask for a criminal history check was included. One example might be where there was some reason for the department to suspect that there was some criminal association either from a member of the family or the applicant. In that context the chief executive might ask for a criminal history check. If the criminal history pointed to the fact that there was a criminal history of drug use, the chief executive would have the ability to consider what additional controls might be put in place before approval was granted.*[124]

The department acknowledged that the registration process for medical practitioners under the Health Practitioner Regulation National Law requires a practitioner to disclose any criminal history. The department stated, however, that "… we are just concerned to ensure that, if the chief executive feels they need information that is absolutely accurate at that point in time that they are making a decision, they have a legislative means to obtain that information".[125]

In relation to MIGA's concern about inconsistencies between the proposed pathways regarding criminal history checks, the department advised that:

> *… the patient-class prescriber carries additional safeguards above the single-patient prescriber pathway, in that it only applies to certain specialist doctors, certain medicinal cannabis products and a limited cohort of eligible patients. This patient cohort is expected to be restricted to persons either suffering particularly debilitating conditions or at the end of life. Accordingly, the Department considers the risk of misuse and diversion under the patient-class prescriber pathway are low and may be managed by conditions on the prescription, supply and storage of the medicinal cannabis to be included in the regulation.*[126]

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121 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 19

122 Department, *Correspondence - Written Briefing on the Bill*, 9 June 2016, p 6

123 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 19

124 David Harmer, Director, Legislative Policy Unit, Department, *Public Hearing Transcript,* 29 August 2016, p 19

125 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 20

126 Department, *Correspondence*, 20 September 2016, p 3

Committee comment

The committee shares submitters' concerns about the appropriateness of a practitioner's and patient's criminal history being a determining factor in the treatment of a patient's medical condition. The committee understands that criminal history checks are not undertaken on patients when determining appropriate treatment in any other circumstances in Queensland.

The committee notes the department's comments that the power to obtain a criminal history report is discretionary, and the chief executive would use a report to consider the imposition of conditions, rather than to reject an application for a medicinal cannabis approval.

The committee considers, however, that the department has not provided sufficient justification for the inclusion of the power. The committee also notes that medical practitioners are already required to disclose any criminal history as part of their registration process.

The committee considers that the Bill provides other safeguards, including significant penalties for unauthorised regulated activity and investigation, monitoring and enforcement powers to address any risk of diversion of medicinal cannabis from practitioners or patients. The committee, therefore, recommends that the power for the chief executive to request a criminal history report about an applicant or patient should be omitted from the Bill.

Recommendation 2

The committee recommends that the Public Health (Medicinal Cannabis) Bill 2016 be amended to remove references to criminal history from clauses 10 and 11 and omit clauses 28 to 31, which provide for the chief executive to request a criminal history report about an applicant for an approval for medicinal cannabis or a patient.

3.10 Lawful possession and use of medicinal cannabis - patients, restricted access patients, carers, carriers and facilitators

The Bill permits eligible patients, and their carers to obtain, possess, self-administer or issue *compliant medicinal cannabis*.[127] The Bill defines a *carer* as "an adult who has responsibility for the immediate care and safety of the patient".[128]

Where a patient is in an institution, such as a hospital, school, nursing home or prison, they may be unable to possess or self-administer medicinal cannabis (*restricted access patients*). In this situation, the Bill provides that a person with regular access to the patient will be authorised to facilitate the patient's treatment (*facilitator*), and the person in charge of the institution will be required to develop a *medicinal cannabis management plan* in relation to the risks associated with possessing, supplying or administering medicinal cannabis at that institution.[129]

In addition, the Bill provides for the lawful transportation and delivery of medicinal cannabis products by *carriers* engaged by a person who is authorised for the use of medicinal cannabis.[130]

Submitters' views and the department's response

The QNU and Carers Australia - Queensland raised concerns about the definition of the term *carer* in the Bill.

Carers Australia - Queensland suggested that the Bill should define a carer as an informal family and friend carer, as defined in the *Carers (Recognition) Act 2008*, and that paid staff of a registered facility or institution should be defined separately. The QNU suggested the Bill define a carer as an unpaid

127 Public Health (Medicinal Cannabis) Bill 2016, clauses 54, 55, 59 and 60
128 Public Health (Medicinal Cannabis) Bill 2016, Schedule 1
129 Public Health (Medicinal Cannabis) Bill 2016, clauses 61, 69 to 75
130 Public Health (Medicinal Cannabis) Bill 2016, clause 62

adult who has responsibility for the immediate care and safety of the patient and who is stated in the medicinal cannabis approval to be their carer.[131]

The department advised that the definition of carer in the Bill would enable a carer to be a family member, designated carer, doctor, nurse or other health provider who does not otherwise have authority under the Bill to administer the drug.[132] The department considered this approach would ensure continuity of treatment in circumstances where, without a carer's assistance, the patient could not be treated.[133]

3.11 Expert advisory panel

The Bill would establish an expert advisory panel, to advise and assist the chief executive in the administration of the Bill.

The expert advisory panel may advise the chief executive in determining the specific conditions and medicinal cannabis products for which a medicinal cannabis approval may be considered. The panel may also identify suitable alternative treatments and other specific medical concerns relevant to the chief executive's assessment of an application for a medicinal cannabis approval.[134]

The Minister explained that the expert advisory panel may also "make recommendations to the chief executive about research activities, including targeted clinical trials, to refine the safety and efficacy of these [medicinal cannabis] products".[135]

The expert advisory panel is to consist of members, a chairperson and a deputy chairperson appointed by the chief executive. In appointing members to the panel, the chief executive must have regard to the person's experience and expertise in relation to the manufacture and use of cannabis products for therapeutic purposes, including their experience and expertise in the areas of:

- science or medicine
- justice and law
- ethics, culture or sociology, and
- agriculture.[136]

Panel members' remuneration, terms and conditions, and allowances are to be determined by the chief executive. A panel member may resign and the chief executive may also remove a member from the panel for any reason or none.[137]

The expert advisory panel may conduct its operations and proceedings, including its meetings, as it considers appropriate and may establish working groups with the agreement of the chief executive.[138]

Submitters' views and the department's response

The establishment of the expert advisory panel was generally supported by submitters. Some submitters made suggestions about its membership, including:

- a physician from a specialty relating to the eligible conditions[139]
- a clinical pharmacologist, addiction specialist and Allied Health practitioners in the area of pharmacy[140]

131 Submissions 20 and 24
132 Department, *Response to Submissions*, 2 August 2016, p 11
133 Department, *Response to Submissions*, 2 August 2016, p 11
134 Public Health (Medicinal Cannabis) Bill 2016, clauses 170 to 178
135 Minister, *Introductory Speech*, Hansard, 10 May 2016, p 1550
136 Public Health (Medicinal Cannabis) Bill 2016, clause 172
137 Public Health (Medicinal Cannabis) Bill 2016, clauses 173 and 174
138 Public Health (Medicinal Cannabis) Bill 2016, clauses 177 and 178
139 RACP, Submission 21
140 Submissions 6 and 23

- lawyers experienced in both health care regulation and criminal law[141]
- medical professionals who are specialists in the fields of oncology, neurology, palliative care and pain management[142], and
- alcohol and drug treatment professionals.[143]

The MCUAA was concerned that the panel did not include people "with any specific on-the-ground experience in the area of cannabis therapeutics".[144] The MCAGQ did not support the establishment of an expert advisory panel, but suggested that if one were established, it should include patient advocates.[145]

The department advised that the expert advisory panel will include a range of specialists to advise on medical, legal and ethical issues arising from medicinal cannabis treatment. The department noted that the expert advisory panel may also seek advice from other experts, including medical specialists in particular fields, as required.[146]

3.12 Review of decisions

The Bill provides for review mechanisms for decisions taken by the chief executive. In the first instance, a person may apply for an internal review by the department of the *original decision*.[147] The term original decision means any decision made under the Bill, except for a decision to place conditions on an approval.[148]

If the applicant is not satisfied with the outcome of the internal review, they can apply to the Queensland Civil and Administrative Tribunal (QCAT) for an external review.[149] If the chief executive's original decision was to seize or forfeit a thing, and the applicant is dissatisfied with the decision, they may appeal to the courts.[150]

The MIGA raised concerns that an applicant would not be permitted to seek a review of any conditions imposed on an approval.[151] In response, the department stated that it:

> *… considers it is necessary to exclude the relevant conditions from review as a means of ensuring the approved medicinal cannabis treatment is safe and subject to appropriate monitoring while the original decision is reviewed.*[152]

3.13 Key issues raised about the proposed pathways

The key issues raised by submitters about the proposed pathways in the Bill for obtaining medicinal cannabis were:

- the timescales associated with obtaining medicinal cannabis
- potential duplication with TGA approval processes
- the cost of obtaining medicinal cannabis
- the current requirement to import medicinal cannabis products, and
- restrictions on varying the dosage of medicinal cannabis prescribed to patients.

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141 MIGA, Submission 45
142 Gregory McMahon, Submission 23
143 QNADA, Submission 44
144 MCUAA, Submission 49
145 MCAGQ, Submission 69
146 Department, *Response to Submissions*, 2 August 2016, p 15
147 Public Health (Medicinal Cannabis) Bill 2016, clauses 179 to 185
148 Explanatory Notes, p 49
149 Public Health (Medicinal Cannabis) Bill 2016, clauses 186 to 191
150 Public Health (Medicinal Cannabis) Bill 2016, clauses 187 to 191
151 MIGA, Submission 45
152 Department, *Response to Submissions*, 2 August 2016, p 27

In addition, submitters considered that the implementation of the framework would require education, training and guidelines for medical practitioners and other health professionals.[153] The RACP and the Queensland Family and Child Commission considered that the department should undertake a public information campaign about medicinal cannabis to coincide with the introduction of the Bill.[154]

3.13.1 Timescales associated with obtaining medicinal cannabis

A significant number of submitters raised concerns about delays in patients receiving medicinal cannabis due to the processes in the Bill, in particular under the single-patient prescriber pathway.[155] The MCAGQ stated that:

> *… the State has put in place so many unnecessary, complicated and time consuming processes and barriers at a state level that only serve to delay and obstruct access to cannabis medicines that are needed by terminally ill patients, patients with a life threatening condition and patients with chronic and disabling medical conditions.*[156]

Ms Carter stated that:

> *… we could get on a plane, travel back to the US and [her son] could receive his authorisation tomorrow and get the medicine he needs tomorrow, yet in this country we have to create all of these bureaucratic processes, hoops and hurdles for patients to jump through to get access to this plant.*[157]

Timely access to medicinal cannabis for severely and terminally-ill patients was raised by submitters. Certain submitters suggested that the proposed timeframes in the Bill would mean that some terminally-ill patients may not live long enough to access medicinal cannabis.[158]

To address this issue, the MIGA suggested that consideration be given to whether timeframes for approving applications for patients who have demonstrated urgent need, such as terminal illness or other compelling reason, can be expedited.[159]

Other submitters did not consider the proposed timeframes to access medicinal cannabis outlined in the Bill to be excessive. One submitter stated:

> *Whilst 90 days is quite a substantial amount of time with a sick loved one I appreciate that there is a deadline to be adhered to. Given how long we have all been waiting the idea of a 90 day turn around for an outcome brings me a great deal of happiness.*[160]

The department advised that the timeframes in the Bill are the maximum periods within which actions must occur, and that it will endeavour to process applications as quickly as possible.[161]

3.13.2 Potential duplication with TGA processes

Submitters also raised concerns about potential duplication between the arrangements proposed in the Bill and the existing TGA processes.[162] Epilepsy Queensland stated, for example, that "There is

153 Submissions 6 and 45
154 Submissions 21, 25 and 45
155 Submissions 21, 45, 49, 52 and 69
156 MCAGQ, Submission 69, p 52
157 Lanai Carter, MCAGQ, *Public Hearing Transcript*, 17 August 2016, p 1
158 Submissions 41, 49 and 67
159 MIGA, Submission 45
160 Name Suppressed, Submission 12
161 Kathleen Forrester, Deputy Director-General, Department, *Public Hearing Transcript*, 29 August 2016, p 19
162 Submissions 28, 49, 57, 67 and 69

confusion and negative expectations about the red tape and questions about why we need both the TGA and Queensland Health approval pathways".[163]

The RACP described the TGA process as a "particularly unwieldly process". The RACP stated that:

> *A patient has to find a doctor who is prepared to make the application for special access, have that reviewed by the TGA, then have the same issues reconsidered at a state level. That is then before we start addressing issues about how we import the medicine into Australia. On our reckoning, we think it is highly unlikely that any patients embarking on this process could actually achieve having medical cannabis products within three or six months of application.*[164]

The QCCL considered that "the Bill's reliance on the Commonwealth TGA scheme for supply of medicinal cannabis products—via importation from overseas in the short to medium term — is so flawed that this objective cannot be realised, at least in any timely or practical way".[165]

Dr Maureen Mitchell and Dr Martin, however, welcomed the TGA's inclusion in the proposed framework. Dr Mitchell stated that "Like all drugs that we give patients, we have to have the TGA involved. I do not believe this drug [medicinal cannabis] should be treated any differently from any other drug that we give patients".[166]

The MCAGQ suggested consultation between the department, the TGA and the Office of Drug Control to ensure State and TGA processes do not conflict and to avoid duplication.[167]

The RACP recommended that different parts of government should take responsibility for reviewing different components of the system. For example, decisions need to be made about the safety and efficacy of the proposed medicine, while other decisions need to be made about the individual patient, e.g. the severity of the patient's condition and monitoring the impact of the product on the patient.[168]

The department accepted there was a duplication of information requested by the State and TGA. However, the department advised that the Commonwealth and States play related and complementary roles in the regulation of medicinal cannabis.

The committee was advised that the TGA regulates what drugs are available for use through the *Narcotic Drugs Act 1967* (Cwlth) and the TG Act – in this instance, whether to allow the import and supply of an unapproved product,[169] while individual States and Territories regulate patient use of those products, including prescribing and dispensing.[170]

The department stated that it would liaise closely with the TGA to "identify ways of ensuring the approval process under both State and Commonwealth schemes can run efficiently and are not

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163 Helen Whitehead, Chief Executive Officer, Epilepsy Queensland, *Public Hearing Transcript*, 17 August 2016, p 14

164 Conjoint Professor Nicholas Lintzeris, RACP, *Public Hearing Transcript*, 29 August 2016, p 3

165 QCCL, Submission 28, p 8

166 Dr Maureen Mitchell, *Public Hearing Transcript*, 17 August 2016, p 20; Dr Jennifer Martin, *Public Hearing Transcript*, 17 August 2016, p 20

167 MCAGQ, Submission 69

168 Conjoint Professor Nicholas Lintzeris, RACP, *Public Hearing Transcript*, 29 August 2016, p 4

169 Dr Tony Gill MBBS MPH FAFPHM, Senior Medical Adviser, Pharmcovigilance and Special Access Branch, Health Products Regulation Group, Commonwealth Department of Health, Therapeutic Goods Administration, *Public Briefing Transcript*, 9 September 2016, p 2

170 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 18

unnecessarily duplicative in terms of the information requested".[171] The department also considered that the response times for applications would improve as more applications go through the system.[172]

3.13.3 Cost of obtaining medicinal cannabis

Submitters also highlighted the potential cost of obtaining medicinal cannabis, given that it will not be listed on the Pharmaceutical Benefits Scheme (PBS).[173]

As an indication of potential costs, one submitter stated that, "The annual cost to purchase Sativex is $16,000"[174], while the QCCL stated that "Sativex, for example, costs about $1500 a month".[175] Dr Mitchell noted:

> *As the cannabinoid products are not going to be subsidised under the PBS, this may also influence uptake on financial grounds. Many terminally ill patients and their families have invested much of their income and savings into therapies with the hope of prolonging life, with little financial resources left to use as the disease process becomes problematic. Additional costs of medicines can be prohibitive, as cost to benefit ratio becomes more important when discretionary income is minimal.*[176]

The MCAGQ submitted that:

> *Only the rich will be able to afford to pay for expensive imports and all the associated costs involved with specialist's reports and tests, as well as being able to find and afford a private doctor, and a pharmacist that are willing to navigate the complex TGA and State bureaucratic process.*[177]

The department stated that:

> *The State Government will not subsidise the cost of medicinal cannabis treatment. However, once there is local cultivation and manufacture of medicinal cannabis products under the Commonwealth licensing scheme, these costs may reduce.*[178]

3.13.4 Requirement to import medicinal cannabis

Submitters highlighted the added time and expense of accessing medicinal cannabis from overseas.[179] The QCCL stated that it is very difficult to import medicinal cannabis from overseas because of limited supplies and the fact that producing countries, such as the Netherlands, prohibit the exportation of medicinal cannabis.[180]

The department stated that "Eventually, once people apply for licences under the Commonwealth legislation, there will be products that will be able to be grown in Australia and they will be able to access those products".[181]

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171 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 18

172 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, Department, *Public Briefing Transcript*, 15 June 2016, p 8

173 Submission 4, 28, 49 and 57

174 Frances McDonald, Submission 4, p 13

175 QCCL, Submission 28, p 35

176 Dr Maureen Mitchell, Submission 41, p 5

177 MCAGQ, Submission 69, p 16

178 Department, *Response to Submissions*, 2 August 2016, p 14

179 Submissions 28, 52 and 69

180 QCCL, Submission 28, p 12; John Ransley, Executive Member, QCCL, *Public Hearing Transcript*, 29 August 2016, p 15

181 Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, Department, *Public Briefing Transcript*, 15 June 2016, p 9

3.13.5 Restrictions on the variation of dosages

Submitters considered that medical practitioners need to be able to vary a medicinal cannabis dosage for a patient, e.g. if the initial dosage proved ineffective or caused side-effects. The RACP noted that:

> *An approval is fixed to the form, dosage and dispensing intervals of the medicinal cannabis product. This does not allow for dosage adjustments that are sometimes required when monitoring patients on therapeutics, especially in this case as the listed agents do not have established dosage ranges.*[182]

The department advised that if a patient has been prescribed medicinal cannabis via the single-patient prescriber pathway "the clause gives the chief executive some flexibility when granting an approval (for example, to set a range when deciding the dosage)".[183] In relation to the patient-class prescriber pathway, the department advised that:

> *Provided a patient-class prescriber (a specialist) is prescribing a type of medicinal cannabis listed by regulation under the Bill, they will determine the dosage for a particular patient and will be able to vary the dosage as necessary provided the variation is consistent with relevant TGA requirements.*
>
> *The flexibility to vary dosage under the patient-class prescriber pathway is considered appropriate given the comparatively strong evidence base for the treatment of the conditions or symptoms listed by regulation and the fact all patient-class prescribers will be specialists.*[184]

3.13.6 Education, training and guidelines

The department stated an education and information campaign aimed at key stakeholders, including medical practitioners and other health care providers likely to be involved in prescribing and delivering medicinal cannabis treatment, would be delivered as part of the implementation process. The department also confirmed that training would be developed for relevant health care providers.[185]

In addition, the department advised that prior to commencement of the Bill, an education campaign would inform the public about the approval processes, eligibility criteria for approvals and the legality of medicinal cannabis as opposed to recreational use.[186] The department also advised that it would continue to work with the QPS and the Department of Transport and Main Roads to address enforcement and safety issues, e.g. driving and operating machinery whilst taking medicinal cannabis.[187]

3.14 Licences to cultivate and manufacture medicinal cannabis

To address issues around delays, costs and difficulties experienced with the TGA process and importation of medicinal cannabis, submitters, including Medicinal Cannabis Australia (MCA), the QCCL and AMAQ, recommended that Queensland should cultivate its own medicinal cannabis, similar to the approach in Victoria.[188] The MCA stated that:

> *There is the perfect weather in Queensland to cultivate; why not show the rest of Australia how it can be done? Instead of purchasing synthetic cannabinoid products or overpriced cannabinoid medicines that are weak and watered down with carry oils from overseas*

182 RACP, Submission 21, p 5
183 Department, *Response to Question on Notice*, 8 September 2016, p 1
184 Department, *Response to Question on Notice*, 8 September 2016, p 2
185 Department, *Response to Submissions*, 2 August 2016, p 7
186 Department, *Response to Submissions*, 2 August 2016, p 17
187 Department, *Response to Submissions*, 2 August 2016, p 20
188 QCCL, Submissions 28; John Ransley, Executive Member, QCCL, *Public Hearing Transcript*, 29 August 2016, p 14; Dr Jim Finn, AMAQ, *Public Hearing Transcript*, 29 August 2016, p 7

> *pharmaceutical companies, why not produce good-quality high-THC oils and high-CBD oils here in Queensland?*[189]

The AMAQ noted that Australia is already one of the world's leading producers of opioid products, and has a long tradition of probity and quality control of such substances.[190]

The QCCL recommended that Queensland should organise a medicinal cannabis industry, as is the case in Victoria, which would "go from cultivation right through to prescription, overseen by the government, with private suppliers wherever appropriate".[191]

The Minister stated that:

> *… my department is working closely with the Department of Agriculture and Fisheries about how Queensland industries can participate in the new Commonwealth licensing scheme for local cultivation and manufacture of medicinal cannabis.*
>
> *These opportunities will also be discussed with relevant Queensland industry representatives over the next few months in a series of roundtable meetings being jointly chaired by Queensland Health and the Department of Agriculture and Fisheries.*[192]

The department stated that:

> *We are quite keen to see the Commonwealth settle its legislation and enable an industry to be considered in Queensland, and for that reason we have been holding roundtables to ensure that people in Queensland are aware of the status of the development and potential development of the sector.*[193]

The department advised that the "Queensland Government is actively exploring ways in which the state can participate in the Commonwealth licensing scheme".[194]

The committee notes that following the Victorian Law Reform Commission's report into medicinal cannabis, the Victorian Parliament passed the *Access to Medicinal Cannabis Act 2016* (Vic) on 12 April 2016.

The Victorian Act provides for a scheme to permit the cultivation and manufacture of medicinal cannabis in Victoria under licences obtained from the Commonwealth under the *Narcotic Drugs Act 1967* (Cwlth). The legislation also provides for medical practitioners to treat eligible patients with medicinal cannabis products via authorised pathways, similar to those proposed in the Bill.

The committee notes that recent amendments to the *Narcotic Drugs Act 1967* (Cwlth), which provide for cultivation and manufacturing licences, will come into force on 30 October 2016. From that date, the Commonwealth Department of Health will start accepting licence applications to cultivate and manufacture medicinal cannabis. The committee notes that the Commonwealth Department of Health intends to publish guidelines on the licence application process shortly.

Under the Commonwealth framework, applicants will need to meet a 'fit and proper person' test, specified in regulations, prior to being approved for a licence. Similar suitability criteria for manufacturers are included in the Victorian Act.

189 Heath Kratzer, Director, Medicinal Cannabis Australia, *Public Hearing Transcript*, 17 August 2016, p 4

190 Dr Jim Finn, AMAQ, *Public Hearing Transcript*, 29 August 2016, p 7

191 John Ransley, Executive Member, QCCL, *Public Hearing Transcript*, 29 August 2016, p 14

192 Minister, *Introductory Speech*, Hansard, 10 May 2016, p 1551

193 Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Department, *Public Hearing Transcript*, 29 August 2016, p 24

194 Department, *Response to Submissions*, 2 August 2016, p 18

The committee understands that the supply of medicinal cannabis products cultivated and manufactured, under a Commonwealth licence, will be subject to TGA approval via the Special Access Scheme, Authorised Prescriber Scheme or for clinical trials.

Committee comment

The committee notes submitters' comments about the potential benefits of the approach adopted in Victoria.

The committee considers that the Victorian approach of permitting the cultivation and manufacturing of cannabis products locally may reduce some of the potential delays associated with the current TGA approval processes, including the TGA's assessment of products, as they would be manufactured locally under a licence regulated by the Commonwealth and the State. The committee also considers that the approach may resolve some of the delays associated with the current necessity to import medicinal cannabis products and reduce costs.

In addition to potential improvements in patient access to medicinal cannabis products, the committee considers that the cultivation and manufacturing of medicinal cannabis in Queensland may create agricultural and business opportunities.

The committee recommends that the Queensland Government, through the lead department – the Department of Agriculture and Fisheries, prioritise its investigation into options to obtain a licence to cultivate and manufacture medicinal cannabis in Queensland.

Recommendation 3

The committee recommends that the Queensland Government, through the lead department – the Department of Agriculture and Fisheries, prioritise its investigation of options for obtaining a licence to cultivate and manufacture medicinal cannabis in Queensland.

3.15 Monitoring, investigation and enforcement

The Explanatory Notes state that "the framework will ensure appropriate powers are available to prevent misuse and the risk of medicinal cannabis being dispensed, supplied or issued to a person not authorised under the Bill".[195] These provisions include:

- twenty-eight new offences – including the performance of a *regulated activity* with medicinal cannabis (e.g. prescribing, possessing, supplying or administering) without authorisation (maximum penalty is 750 penalty units ($91,425)) and misusing a lawful direction for the use of medicinal cannabis (maximum penalty is 100 penalty units ($12,190))
- empowering the chief executive to suspend, cancel, vary or impose conditions on a medicinal cannabis approval (*administrative action*), and
- the appointment of authorised persons to investigate, monitor and enforce compliance.

Any activity with medicinal cannabis that is not authorised by the Bill will also be an offence under the DM Act. These offences, which include unlawful possession, supply, production and trafficking of a dangerous drug, carry penalties ranging from 15 to 25 years imprisonment.

3.15.1 Suspension, cancellation, variation or conditions on approvals

The Bill provides that the chief executive may, after issuing a compliance notice and following a show cause process, take *administrative action* to suspend, cancel, vary or impose conditions on a medicinal cannabis approval, dispensing approval or a clinical trial approval. The chief executive may take administrative action in specified circumstances, including, if:

195 Explanatory Notes, p 4

- the holder of the approval contravenes the Bill or a condition of approval
- the action is necessary to minimise the risk of medicinal cannabis being dispensed, supplied or issued to an unauthorised person
- the action is necessary to minimise a risk of harm to the life, health or safety of a person, or
- the approval was granted on a materially false or misleading representation or declaration.[196]

The chief executive may take immediate administrative action, without a show cause process, if he or she considers there is an immediate and serious risk to the life, health or safety of a person. The chief executive may also amend a medicinal cannabis approval immediately, if the amendment is necessary in the circumstances or on the recommendation of the expert advisory panel.[197]

The Bill provides that the chief executive must give written notice of any administrative action taken against an approval holder to their profession's registered board (e.g. the Queensland Board of the Medical Board of Australia). The chief executive may also inform the practitioner's registered board, if he or she considers the practitioner has committed an offence against the Bill.[198]

3.15.2 Appointment and powers of authorised persons

The Bill provides for the appointment by the chief executive of *authorised persons* to:

- investigate, monitor and enforce compliance with the legislation, and
- investigate or monitor whether powers under the legislation should be exercised, and then facilitate the exercise of those powers, if needed.[199]

In discharging their functions under the Bill, an authorised person may:

- enter a place – with consent or without consent, in public places,[200] or under a warrant [201]
- after entering a place – search, inspect, examine, film, take things for examination, reproduce documents or seize evidence of an offence. An authorised person may also require the occupier of the place or another person to provide reasonable help[202]
- direct a person to stop a vehicle and bring it to a convenient place, not to move the vehicle or move the vehicle to a stated place to allow the authorised person to exercise their powers[203]
- require a person to give their name and address,[204] make available documents for inspection[205] or give information related to an offence at a stated time and place,[206] and
- take steps necessary to remove or reduce a diversion risk or a substance risk for medicinal cannabis at a place.[207]

A failure to comply with a requirement or direction issued by an authorised person is an offence attracting a maximum penalty of 50 penalty units ($6,095).

196 Public Health (Medicinal Cannabis) Bill 2016, clauses 76 to 81
197 Public Health (Medicinal Cannabis) Bill 2016, clauses 82 and 83
198 Public Health (Medicinal Cannabis) Bill 2016, clauses 84 and 85
199 Public Health (Medicinal Cannabis) Bill 2016, clauses 99 to 107
200 Public Health (Medicinal Cannabis) Bill 2016, Schedule 1 – defines the term *public place* as a place, or part of a place, that the public is entitled to use, is open to members of the public or is used by the public regardless of whether or not a payment of money has been made; a place, or part of a place, which the occupier allows members of the public to enter irrespective of whether or not there is payment of money; or a public place as defined by another Act
201 Public Health (Medicinal Cannabis) Bill 2016, clauses 110 to 116
202 Public Health (Medicinal Cannabis) Bill 2016, clauses 127 to 139
203 Public Health (Medicinal Cannabis) Bill 2016, clauses 123 to 126
204 Public Health (Medicinal Cannabis) Bill 2016, clauses 145 and 146
205 Public Health (Medicinal Cannabis) Bill 2016, clauses 147 to 149
206 Public Health (Medicinal Cannabis) Bill 2016, clauses 150 and 151
207 Public Health (Medicinal Cannabis) Bill 2016, clause 152

The Bill makes provisions for the processes to be followed to obtain a warrant and for dealing with seized things.[208] The Bill also provides that in exercising their powers an authorised person must take reasonable care to cause as little inconvenience and damage as possible, and makes provision for notifying owners of any damage and the payment of compensation.[209]

In addition, the Bill provides that it is an offence to: give an authorised person false or misleading information (maximum penalty 50 penalty units ($6,095)); obstruct an authorised person exercising a power, without a reasonable excuse (maximum penalty 100 penalty units ($12,190)), or impersonate an authorised person (maximum penalty 100 penalty units ($12,190)). [210]

3.15.3 Recall orders and public warnings

The Bill provides that the chief executive may issue a recall order to prevent or minimise risk or harm to a person's life, health or safety because of the use of medicinal cannabis. A recall order is to be issued to a person who is authorised to dispense, manufacture or give a direction for medicinal cannabis.[211]

In addition, the Minister or chief executive may, if it is in the public interest to do so, make or issue a public statement identifying and giving warnings or information, about contraventions of the Bill, unlawful practices and offences.[212]

3.15.4 Medicinal cannabis register

The Bill requires the chief executive to keep a register of approvals and administrative actions. The Bill makes provision about the content of the register, e.g. the name of the approval holder, details of the approval and the name of approval holders to whom administrative action has been taken. The Bill prohibits the register from being made public, however the chief executive may give the police commissioner information contained in the register on request.[213]

Submitters' views and the department's response

Submitters, including the QNADA and PHAA, noted that a significant proportion of the Bill deals with enforcement and criminal justice issues, rather than focusing on treating medicinal cannabis as a legitimate treatment for medical conditions.[214]

The QNADA suggested such enforcement powers may reinforce the perception that cannabis use is a criminal, rather than a medical matter.[215] The QNADA suggested that the provisions may impact on the take up rate of medicinal cannabis, as medical practitioners may "decide that it is too much hassle" and decide to wait and see how the system evolves, instead of making an application for a patient.[216]

Submitters, such as the QNADA and MIGA, noted that the proposed offences in the Bill duplicate existing criminal offences in the DM Act. The MIGA expressed discomfort about the lack of any available criteria to be used in the event of a potential contravention. [217]

The MIGA agreed with the need for a process to suspend or cancel an approval if there are issues relating to the approved prescriber, but was concerned that patients who may have done nothing wrong may be adversely affected by such actions. Accordingly, the MIGA suggested a mechanism by

208 Public Health (Medicinal Cannabis) Bill 2016, clauses 117 to 121
209 Public Health (Medicinal Cannabis) Bill 2016, clauses 156 to 158
210 Public Health (Medicinal Cannabis) Bill 2016, clauses 159 to 161
211 Public Health (Medicinal Cannabis) Bill 2016, clauses 163 to 168
212 Public Health (Medicinal Cannabis) Bill 2016, clause 169
213 Public Health (Medicinal Cannabis) Bill 2016, clauses 88 to 91
214 Submissions 44, 52 and 59
215 QNADA, Submission 44
216 Rebecca MacBean, Chief Executive Officer, QNADA, *Public Hearing Transcript*, 17 August 2016, p 10
217 Submissions 44, 45 and 52

which treatment with medicinal cannabis for such patients could be transferred to another approved provider, perhaps one retained on a register kept by the chief executive.[218]

The MIGA also suggested that the Bill be amended, so that the chief executive is first required to consider submissions made by an approved prescriber on any contemplated or proposed administrative action, prior to the prescriber's professional board being notified.[219]

The department stated that the Bill reflects the Government's intent to strike a balance between facilitating treatment with medicinal cannabis and creating the controls necessary to ensure medicinal cannabis products are used safely and not diverted for unlawful purposes.[220] The department stated that submitters' "feedback will be taken into account in implementing the regulatory framework".[221]

The department confirmed that a new approval would be required for a patient to continue receiving medicinal cannabis, if their practitioner's approval was cancelled or suspended. The department stated that it expects the chief executive would be mindful of the need to ensure continuity of treatment when considering an application in these circumstances.[222]

In relation to concerns about administration action, the department stated that the provisions include:

> *… a show cause process which will afford prescribers procedural fairness before administrative action is taken and a board is notified. The only circumstance in which the chief executive can take immediate administrative action without considering representations, is where it is necessary to take action because there is an imminent and serious risk to the life, health or safety of a person. In this circumstance, the Department does not consider it is necessary to allow an approved prescriber to make submissions.*[223]

The committee notes that offences proposed in the Bill regarding the performance of *regulated activity* without authorisation, duplicate offences currently provided for in the DM Act. The potential FLP issues raised by these provisions are discussed in section 4 of this report.

3.16 Protection from liability, confidentiality and requests for information

3.16.1 Protection from liability

The Bill provides that prescribed persons (i.e. members of the expert advisory panel, a single-patient prescriber, a patient-class prescriber and an approved pharmacist or secondary dispenser) are protected from civil liability for acts or omissions in relation to medicinal cannabis, provided they have acted in good faith and without negligence.[224] The Bill also provides protection from civil liability for persons who have applied for a review, or otherwise been involved in a review of a decision, providing they have acted in good faith and without negligence.[225]

The AMAQ supported the provision, and stated that:

> *We wish to provide our particular appreciation toward this element of the legislation as we know it will provide legal certainty to our members. It is our understanding that this Bill also provides protection to General Practitioners who have been authorised to treat patients using medicinal cannabis via a single patient pathway, and provides recourse for GPs who have not been approved to do so. This will be similarly appreciated by our GP members.*[226]

218 MIGA, Submission 45
219 MIGA, Submission 45
220 Department, *Response to Submissions*, 2 August 2016, p 5
221 Department, *Response to Submissions*, 2 August 2016, p 26
222 Department, *Response to Submissions*, 2 August 2016, p 26
223 Department, *Response to Submissions*, 2 August 2016, p 26
224 Public Health (Medicinal Cannabis) Bill 2016, clause 194
225 Public Health (Medicinal Cannabis) Bill 2016, clause 195
226 AMAQ, Submission 53, p 1

3.16.2 Confidentiality and information requests

The Bill makes provision aimed at safeguarding personal and confidential information obtained as part of the administration of the Bill. Confidential information may only be disclosed in the circumstances specified in the Bill, including disclosure:

- with the written consent of the person to whom the information relates, to the person whom the information relates, or in a way that could not identify any person[227]
- to entities *performing relevant functions* (e.g. a coroner investigating the death of a person, the health ombudsman conducting an investigation and TGA when performing its functions)[228]
- to a Commonwealth or State entity if there is a risk that medicinal cannabis may be dispensed, supplied or issued to an unauthorised person or there is a risk of harm to life, health or safety,[229] or
- to a health practitioner who is providing care or treatment to the person to whom the information relates. A single-patient prescriber may also disclose confidential information to the chief executive for a medicinal cannabis approval.[230]

The chief executive would, by notice, be able to ask a public entity, to give information to him or her to assist in the performance of his or her functions and to prevent an imminent risk of medicinal cannabis being dispensed, issued or supplied to an unauthorised person or a risk of harm to the life, health of safety of a person. The public entity must comply with the chief executive's request, except in the circumstances specified in the Bill, including if the disclosure would prejudice an investigation.[231]

Submitters' views and department's response

The MIGA raised concerns about the nature of the information that the chief executive may request from a prescriber, and suggested that it should be limited to information about their suitability to hold an approval.[232] The MIGA also suggested that the Bill should clearly state that prescribers can disclose confidential information for the purpose of seeking legal advice.[233]

In response to concerns about uncertainty in relation to information requests, the department stated:

> *The Bill provides for the chief executive to request the information necessary to decide an application. As the information required will vary from application to application depending on the circumstances, this flexibility is thought to be required.*[234]

In addition, the department advised that the chief executive will only seek information relevant to the suitability of the patient.[235]

3.17 Review of the proposed framework

The department advised that the proposed framework in the Bill would be reviewed after two years of operation to ensure it meets the needs of patients, health service providers and enforcement agencies, and complements related developments in this rapidly-evolving policy space, particularly with regards to the proposed domestic cultivation, production and manufacture of medicinal cannabis.[236]

227 Public Health (Medicinal Cannabis) Bill 2016, clauses 208 to 209
228 Public Health (Medicinal Cannabis) Bill 2016, clause 210
229 Public Health (Medicinal Cannabis) Bill 2016, clause 213
230 Public Health (Medicinal Cannabis) Bill 2016, clauses 211 and 212
231 Public Health (Medicinal Cannabis) Bill 2016, clause 214
232 MIGA, Submission 45
233 MIGA, Submission 45
234 Department, *Response to Submissions*, 2 August 2016, p 27
235 Department, *Response to Submissions*, 2 August 2016, p 24
236 Department, *Correspondence - Written Briefing*, 9 June 2016, p 6

Committee comment

The committee notes that the department will review the framework after two years. The committee expects that a significant part of the review will include an assessment of the time taken between a medical practitioner recommending a medicinal cannabis product and a patient receiving treatment.

4 Fundamental legislative principles and Explanatory Notes

4.1 Fundamental legislative principles

4.1.1 Introduction

Section 4 of the *Legislative Standards Act 1992* states that the *fundamental legislative principles* (FLPs) are the "principles relating to legislation that underlie a parliamentary democracy based on the rule of law". The principles include that legislation has sufficient regard to:

- the rights and liberties of individuals, and
- the institution of Parliament.

The committee has examined the application of the FLPs to the Bill and brings the following potential FLP issues to the attention of the Legislative Assembly.

4.1.2 Rights and liberties of individuals

Clause 92 – duplicate offence provisions

Clause 92 of the Bill provides that it is an offence to perform a *regulated activity* (e.g. prescribing, possessing, obtaining or manufacturing medicinal cannabis) without authorisation. The committee notes that the proposed offence duplicates current offences under the DM Act, which provide that unlawful possession, supply, production and trafficking of a dangerous drug (including cannabis) are criminal offences.

The proposed approach raises the issue of whether the Bill has sufficient regard to the rights and liberties of individuals, in accordance with section 4(2)(a) of the *Legislative Standards Act 1992,* as the same factual circumstances may constitute an offence under the Bill and a criminal offence under the DM Act.

Generally, the imposition of liability under legislation should provide for a single process for the liability, with all forms of double jeopardy avoided as far as possible.

The Explanatory Notes acknowledge that the "ability for the same circumstances to give rise to offences under both the Bill and the DM Act may cause some uncertainty about the possible prosecution action flowing from an unauthorised regulated activity under the Bill".[237]

The Explanatory Notes outline circumstances where a medical practitioner or pharmacist's actions may be considered 'non-compliance' with the Bill (e.g. prescribing a higher dosage than approved to their patient or not complying with security requirements imposed by a condition on an approval), and not criminal activity under the DM Act.[238]

The committee understands, however, that the QPS may still elect to charge a medical practitioner or pharmacist of a criminal offence in such circumstances, as the activity described above would meet the elements of an offence under the DM Act.

The committee notes that the penalties for a criminal offence under the DM Act are considerably higher than those proposed for an offence under the Bill – 15 to 25 years imprisonment under the DM Act, compared with a maximum of 750 penalty units ($91,425) under the Bill.

The Explanatory Notes state that the department intends to liaise with the QPS to formalise processes for respective enforcement action in the event of an unauthorised use of medicinal cannabis and undertake a public awareness campaign.[239]

237 Explanatory Notes, pp 6 and 7
238 Explanatory Notes, pp 6 and 7
239 Explanatory Notes, p 7

The committee requested further advice from the department about the provision. In response, the department stated that:

> *The misuse or unlawful diversion of some of these substances [including medicinal cannabis] is an offence under both the HDPR [the Regulation] and the DM Act, and therefore the issue of duplicate offences already exists. This is currently addressed without issue through liaison between the Department and QPS. The Bill also enables the Department to share confidential information with a law enforcement agency such as QPS for the purpose of detecting, preventing, investigating or prosecuting an offence involving medicinal cannabis.*[240]

In addition, the department advised that:

> *The question of whether to prosecute under the DM Act is a matter for the QPS and the Office of the Director of Public Prosecutions (ODPP), and will likely depend on the 'criminality' of any alleged breach. This determination will always be based on the individual circumstances of the matter. QPS apply the ODPP guidelines, being that a matter must satisfy both a sufficiency of evidence test and be in the public interest.*
>
> *Failure by a medical practitioner or pharmacist to comply with the requirements of their approval will be a technical breach of the Bill. Breaches may be dealt with by the Department through administrative action, such as limiting or removing the practitioner's prescribing or dispensing authority. The Department works closely with health professionals to ensure patient safety through education, information and training. Where the Department becomes aware of deliberate diversion of substances, the matter will be referred to QPS.*[241]

The department stated that medical practitioners, pharmacists and patients would be advised of possible consequences of acting unlawfully as part of an information and education campaign. The department also intends to develop a targeted campaign for medical practitioners and pharmacists. The department advised that information would also be published on its website and department staff will be available to advise practitioners and pharmacists. [242]

Committee comment

The committee notes the additional advice provided by the department. The committee considers that, on balance, the provisions of the Bill have sufficient regard to the rights and liberties of medical practitioners and pharmacists operating within the proposed regulatory framework.

Clauses 28 to 31 – criminal history reports

Clauses 28 to 31 of the Bill provide that the chief executive may apply to the police commissioner for a criminal history report about the applicant (the medical practitioner) or the patient, when considering an application for an approval for medicinal cannabis.

The Bill also disapplies the *Criminal Law (Rehabilitation of Offenders) Act 1986* for the purpose of the criminal history report provisions, which would mean that spent convictions would form part of a person's criminal history report provided to the chief executive.

The provisions raise potential FLP issues under section 4(2)(a) of the *Legislative Standards Act 1992* in relation to an individual's right to privacy in respect of their personal information.

The Explanatory Notes state that these provisions are "justified given the risk of diversion associated with medicinal cannabis".[243]

240 Department, *Correspondence*, 20 September 2016, p 1
241 Department, *Correspondence*, 20 September 2016, p 1
242 Department, *Correspondence*, 20 September 2016, p 1
243 Explanatory Notes, p 7

The committee requested further advice from the department about the provisions. In response, the department stated that "the non-application of the *Criminal Law (Rehabilitation of Offenders) Act 1986* will ensure the Department has a complete picture of relevant criminal history" and "QPS support the non-application criminal history provisions in the Bill".[244]

Committee comment

The committee notes the additional advice provided by the department and the justifications provided in the Explanatory Notes for the FLP issues raised by the proposed provisions.

The committee considers that, on balance, the provisions at clause 28 and 31 do not have sufficient regard to the privacy rights of applicants and patients. The committee has recommended that the provisions be omitted from the Bill – see Recommendation 2.

Clauses 124 and 126 – authorised person's power to stop or move a vehicle

Clause 124 of the Bill provides that an authorised person may, to exercise his or her powers, signal or otherwise direct the person in control of a moving vehicle to stop the vehicle and to bring the vehicle to a convenient place to allow the authorised person to exercise their powers. Clause 126 provides that a failure to comply with such a direction is an offence attracting a maximum penalty of 50 penalty units ($6,095).

A relevant factor when considering whether legislation has sufficient regard to the rights and liberties of individuals, in accordance with section 4(2)(a) of the *Legislative Standards Act 1992*, is the reasonableness and fairness of the treatment of individuals under the legislation.

An authorised person's power to direct a person in control of a vehicle to stop at a certain place and allow the authorised person to exercise their powers impacts on the driver of the vehicle's rights and liberties of free passage commonly afforded to individuals in public places.

The potential FLP issues raised by clauses 124 and 126 were not addressed in the Explanatory Notes.

Committee comment

The committee notes that the exercise of the power is limited to circumstances where the authorised person reasonably suspects, or is aware, that a thing in or on a vehicle may provide evidence of the commission of an offence against the Bill. The authorised person must also warn the person in control of the vehicle that it is an offence not to comply with a direction and identify themselves as an authorised person.

The committee considers that, on balance, the proposed powers at clause 124 have sufficient regard to the rights and liberties of individuals. In reaching this view, the committee had regard to the safeguards included in the provision and the fact that the power is limited in the circumstances in which it may be exercised.

Clauses 145, 146, 150 and 151 – authorised person's power to require a person's name and address and information about an offence

Clause 145 of the Bill provides that an authorised person may require a person to state their name and residential address in certain circumstances. The circumstances outlined in the Bill are, if the authorised person:

- finds the person committing an offence
- finds the person in circumstances that lead the authorised person to reasonably suspect the person has just committed an offence, or

[244] Department, *Correspondence*, 20 September 2016, p 2

- has information that leads the authorised person to reasonably suspect a person has just committed an offence.

Clause 146 provides that a person who does not comply with a direction to provide their personal information, without a reasonable excuse, commits an offence attracting a maximum penalty of 50 penalty units ($6,095).

Clause 150 provides that an authorised person, if he or she reasonably believes an offence has been committed, may require a person to provide information about the offence. Clause 151 provides that failure to comply with an information requirement, without a reasonable excuse, is an offence attracting a maximum penalty of 50 penalty units ($6,095). Clause 151 provides that it is a reasonable excuse for the person not to give the required information, if giving the information may tend to incriminate the individual or expose them to a penalty.

A relevant factor when considering whether legislation has sufficient regard to the rights and liberties of individuals, in accordance with section 4(2)(a) of the *Legislative Standards Act 1992*, is the reasonableness and fairness of the treatment of individuals under the legislation.

Clauses 145 and 150 require a person to provide personal information and information in relation to an offence. The committee considers these requirements have implications for the rights and liberties of individuals where the information provided to an authorised person is used for the purposes of furthering an investigation or prosecution.

The potential FLP issues raised by clauses 145, 146, 150 and 151 were not addressed in the Explanatory Notes.

Committee comment

The committee notes that an authorised person's powers at clauses 145 and 150 included a number of safeguards.

In relation to the power at clause 145, the authorised person must reasonably suspect certain circumstances exist, e.g. a person has committed an offence, prior to exercising their power and the authorised person must also warn the person that it is an offence not to provide the personal information. In addition, the person does not have to comply with the requirement, if they have a reasonable excuse. The committee also notes that a person may only be convicted of an offence for not providing their personal details, if they are found guilty of the offence in relation to which the personal information was requested.

In relation to the power to request information under clause 150, the committee notes that a person is not required to provide the requested information, if they have a reasonable excuse, including that providing the information may tend to incriminate the person or expose them to a penalty.

In light of these safeguards, the committee considers that, on balance, the proposed powers at clause 145, 146, 150 and 151 have sufficient regard to the rights and liberties of individuals.

Clauses 147, 148 and 162 – authorised person's powers to require the production of a document

Clause 147 provides that an authorised person may require a person to make available for inspection a document issued to the person or a document required to be kept by the person.

Clause 148 provides that a failure to comply with a document production requirement, without a reasonable excuse, is an offence attracting a maximum penalty of 50 penalty units ($6,095). The provision provides that it is not a reasonable excuse for a person to fail to comply on the basis that producing the document might tend to incriminate the person or expose them to a penalty.

The proposed provisions raise potential FLP issues in relation to an individual's rights and liberties regarding appropriate protection against self-incrimination. The committee notes that the principle of

protection against self-incrimination is based on the common law principle that an individual accused of an offence should not be obliged to incriminate himself or herself.[245]

The potential FLP issues raised by clauses 147 and 148 were not addressed in the Explanatory Notes.

Committee comment

The committee considers that, on balance, the proposed powers at clauses 147 and 148 have sufficient regard to the rights and liberties of individuals.

In reaching this view, the committee had regard to the fact that the documents that a person may be required to produce are limited to those documents that have been issued to the person or that they are required to keep.

The committee also notes that clause 162 limits the future use of a document produced by a person, under clause 147, in proceedings against the person, and the production of the document will not expose them to a penalty, unless the proceeding relates to the false or misleading nature of the document.

Clauses 206 and 207 – reverse onus of proof

Clause 206 provides that an act done or omitted to be done for a person by a representative (e.g. an employee or agent) of the person within the scope of the representative's actual or apparent authority is taken to have been done or omitted to be done by the person, unless the person proves he or she could not, by the exercise of reasonable diligence, have prevented the act or omission.

Clause 207 provides that if a corporation commits a serious offence (e.g. unauthorised regulated activity with medicinal cannabis or misuse of a lawful direction for medicinal cannabis), each executive officer of the corporation is taken to have also committed the offence. However, an executive officer may only be taken to have committed an offence, if they authorised or permitted the corporation to commit the offence or were, directly or indirectly, knowingly concerned in the corporation's conduct.

The provisions at clauses 206 and 207 are derivative liability provisions. Provisions of this type create a presumption of guilt or responsibility for the actions of other parties, and reverse the onus of proof in proceedings. Section 4(3)(d) of the *Legislative Standards Act 1992* provides that legislation should not reverse the onus of proof in proceedings without adequate justification.

The potential FLP issues raised by clauses 206 and 207 were not addressed in the Explanatory Notes.

Committee comment

Government members of the committee consider that, on balance, the provisions at clauses 206 and 207 have sufficient regard to the rights and liberties of individuals.

In reaching this view, government members had regard to the following safeguards provided for in the provisions.

Clause 206 provides that in order for a person to be liable for an act done or omitted to be done by their representative, the person's representative must have been acting within the scope of the person's actual or apparent authority. The person may also avoid liability, if they can establish that they could not, by the exercise of reasonable diligence, have prevented the act or omission from occurring.

Clause 207 provides that for an executive officer of a corporation to be deemed to have also committed a serious offence, they must have authorised or permitted the corporation's conduct constituting the offence or have been, directly or indirectly, knowingly concerned in the corporation's conduct.

[245] Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 52

Non-government members of the committee request that the Minister deal specifically with the potential FLP issues raised by the reverse onus of proof provisions during the Second Reading debate and explain the necessity of the provisions.

4.2 Explanatory Notes

Part 4 of the *Legislative Standards Act 1992* requires that Explanatory Notes be circulated when a Bill is introduced into the Legislative Assembly, and sets out the information the Explanatory Notes should contain.

Explanatory Notes were tabled with the introduction of the Bill. The Explanatory Notes are fairly detailed and contain the majority of the information required by Part 4 of the *Legislative Standards Act 1992*, and a reasonable level of background information and commentary to facilitate understanding of the Bill's aims and origins.

Committee comment

The committee notes, however, that the Explanatory Notes do not address all of the potential FLP issues raised by the Bill, in particular those relating to the powers of authorised persons and the derivative liability provisions at clauses 206 and 207, and do not identify the relevant clauses when discussing certain aspects of the Bill.

Appendix A – List of submitters

Sub #	Submitter
001	Frances Ottewill
002	Lenore Borgias
003	Sue Harrold
004	Frances McDonald
005	Confidential
006	Professor Jennifer Martin and Associate Professor Yvonne Bonomo
007	Cancer Council Queensland
008	Sheree Rutherford
009	Name suppressed
010	Heather Gladman
011	Margaux Dryland
012	Name suppressed
013	Tracey Oberle
014	Medicinal Cannabis Australia
015	Name suppressed
016	Dr Theo Shemansky
017	Justin Kander
018	Debbi Cliff
019	Deborah Camacho
020	Carers Australia – Queensland
021	Royal Australian College of Physicians
022	Brenda Johnson
023	Gregory McMahon
024	Queensland Nurses' Union
025	Queensland Family and Child Commission
026	Michael Harry
027	Deni Knuth
028	Queensland Council for Civil Liberties

029	Elizabeth Sands
030	Name suppressed
031	Confidential
032	Name suppressed
033	Confidential
034	Deb Ranson
035	Name suppressed
036	Name suppressed
037	Sonya Stacey
038	Gregory Newman
039	Rohan Moxley
040	Confidential
041	Dr Maureen Mitchell
042	Multiple Sclerosis Australia and Multiple Sclerosis Research Australia
043	Domogoj Frankic
044	Queensland Network of Alcohol and Other Drug Agencies Ltd
045	Medical Insurance Group Australia
046	Name suppressed
047	Lorraine Phillip
048	Confidential
049	Medical Cannabis Users Association of Australia
050	Name suppressed
051	Name suppressed
052	Frank Jordan
053	Australian Medical Association Queensland
054	Name suppressed
055	Leading Age Services Australia
056	Meghan Jewell
057	Name suppressed
058	Hemployment Australia
059	Public Health Association of Australia

060	Health Consumers Queensland
061	Name suppressed
062	Australian Christian Lobby
063	Name suppressed
064	Epilepsy Queensland
065	Name suppressed
066	Dr Alex Wodak and Professor Laurence Mather
067	Lanai Carter
068	Name suppressed
069	Medical Cannabis Advisory Group Queensland

Appendix B – Officers at the public briefings

Wednesday 15 June 2016 – Queensland Health
Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division
Mr David Harmer, Director, Legislative Policy Unit
Mr Mark Zgrajewski, Manager, Legislative Policy, Strategic Policy and Legislation Branch
Mr Gregory Perry, Manager, Medicinal Cannabis Team, Prevention Division

Friday 9 September 2016 – Commonwealth, Department of Health
Dr Tony Gill, MBBS MPH FAFPHM, Senior Medical Adviser, Pharmacovigilance and Special Access Branch, Health Products Regulation Group
Mr Bill Turner, Head, Office of Drug Control

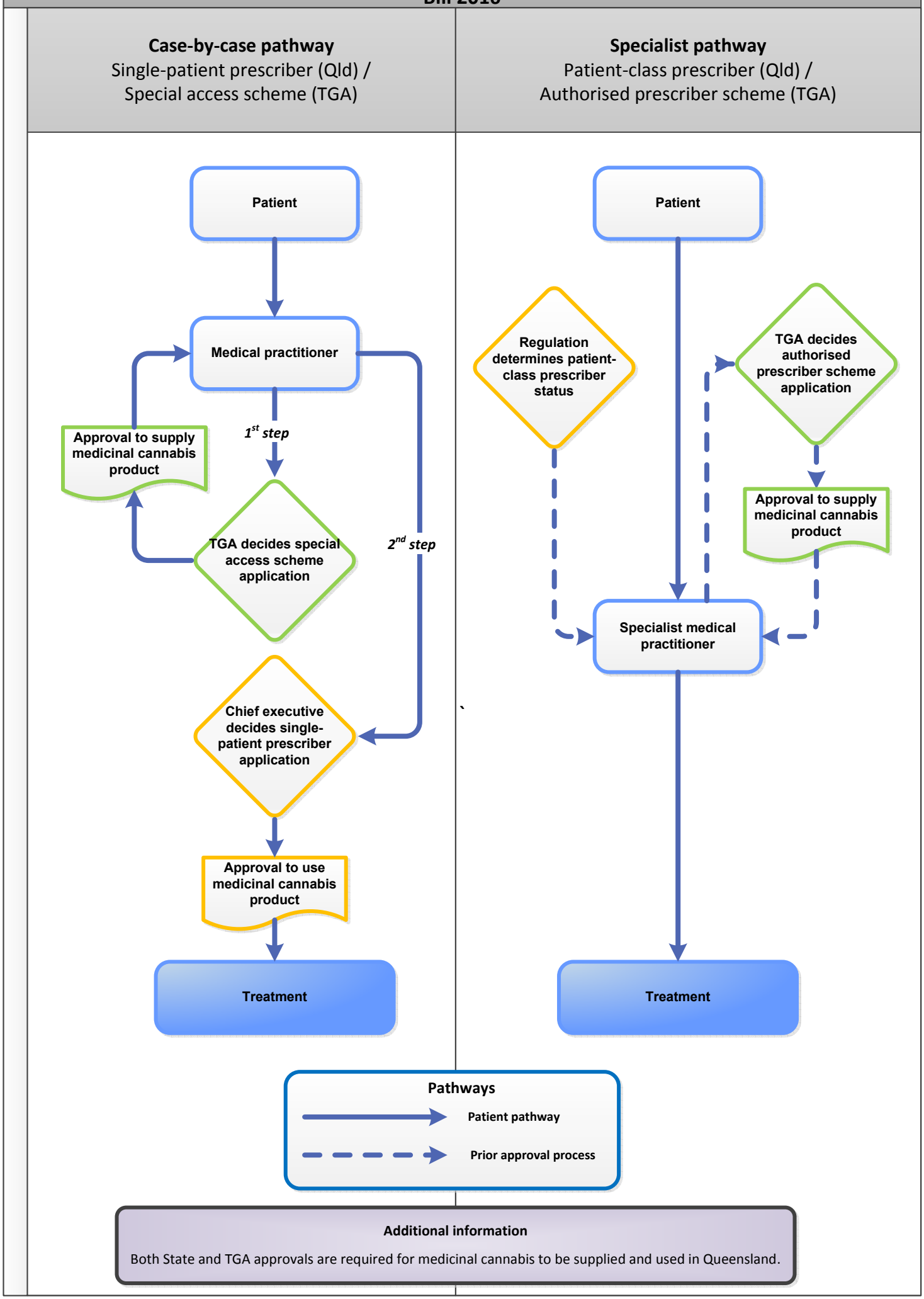
Appendix C – Witnesses at the public hearings

Wednesday 17 August 2016
Ms Lanai Carter, Medical Cannabis Advisory Group Queensland
Ms Grace Sands, Founder and Co-Chair, Medical Cannabis Advisory Group Queensland
Ms Gail Hester, President, Medical Cannabis Users Association of Australia
Ms Deb Lynch, Secretary, Medical Cannabis Users Association of Australia
Mr Heath Kratzer, Director, Medicinal Cannabis Australia
Ms Rebecca MacBean, Chief Executive Officer, Queensland Network of Alcohol and Other Drug Agencies
Dr Lisa Melton, Head of Research, MS Research Australia
Ms Helen Whitehead, Chief Executive Officer, Epilepsy Queensland
Dr Jennifer Martin
Dr Maureen Mitchell

Monday 29 August 2016
Conjoint Professor Nicholas Lintzeris, Royal Australasian College of Physicians
Dr Jim Finn, Australian Medical Association Queensland
Mr Timothy Bowen, Senior Solicitor, Advocacy Claims and Education, Medical Insurance Group Australia
Mr John Ransley, Executive Member, Queensland Council for Civil Liberties
Ms Kathleen Forrester, Deputy Director-General, Strategy, Policy and Planning Division, Queensland Health
Ms Dorothy Vincenzino, Executive Director, Healthcare Regulation Unit, Prevention Division, Queensland Health
Mr David Harmer, Director, Legislative Policy Unit, Queensland Health
Mr Mark Zgrajewski, Manager, Legislative Policy, Strategic Policy and Legislation Branch, Queensland Health

Appendix D – Patient-class and single-patient prescriber pathways

State and Commonwealth approval pathways relevant to the Public Health (Medicinal Cannabis) Bill 2016



Statement of Reservation

NON-GOVERNMENT MEMBERS STATEMENT OF RESERVATIONS

Public Health (Medicinal Cannabis) Bill 2016

The Non-Government Members raise the question of the duplication the Bill presents for individuals seeking to use therapeutic goods.

As stated at page 3 of the Report, at 2.3.1 *Access and Supply of Therapeutic Goods*;

"The use of therapeutic goods for patient treatment is regulated by State legislation such as proposed in the Bill. The TG Act, however, regulates how medicine may be supplied and accessed for use in Australia."

It further states:

"The TG Act provides that before any drug, including medical cannabis, may be used for a therapeutic use in Australia it must be approved and registered on the Australian Register of Therapeutic Goods (ARTG)."

Evidence before the Committee, particularly by the Medical Cannabis Advisory Group Queensland specifically raised the point. At page 8 of its submission this comment appears:

"The Bill proposes to put in place at a state level a process for doctors to obtain State approval when the doctor has already been approved by the TGA under the Special Access Scheme which is a duplication of the TGA process and approvals for doctors who have been approved by the TGA as authorised prescribers, another duplication of the TGA process as well as a State Approval only for TGA research trials."

The question raised needs to be fully explained as to whether a duplication exists, more importantly if the duplication exists why it exists and critically if that duplication does exist what steps the government is taking to rectify the concern raised.

The question is, how do we streamline this process to ensure that there is not overlap between the two bodies and delay the delivery of a therapeutic good to a patient in need?

The Non-Government Members further note the Commonwealth Legislation, the *Narcotic Drugs Act 1967*, which allows licences to be obtained for the cultivation and manufacture of medicinal cannabis. There is some concern as to what effect that will have in regard TGA and the State approval processes,

or whether it will relate to shortening the timeline in obtaining appropriate therapeutic drugs.

In particular, in evidence before the Committee on the 29th August 2016 the Director, Legislative Policy Unit in the Department of Health when asked about the process undertaken by the TGA made this comment:

"In answer to your question, yes, the TGA has its own criteria for assessment. They are set out, and it is accessed to unapproved therapeutic goods by the special access scheme document which I am happy to table. As the situation stands at the moment, the TGA would go through its own consideration of the patient's details, diagnosis and circumstances and its own consideration of the clinical justification of the drugs being sought. In that sense there is a duplication of the considerations occurring at State and Commonwealth level but as Ms Forrester has said, we are working with the TGA, as are other jurisdictions, to streamline that consideration. The end goal would be perhaps we get to a point where, if there is state-approved access the TGA will then endorse that approval."

That is a very important comment. If an agreement can be reached between the levels of Government then a streamlined process can be put in place. However the Bill as it currently stands does not achieve that and even with the capacity to seek a licence in Queensland there is some doubt as to the impact that would have on the duplication question. It is therefore critical the Government fully inform the House as to exactly where negotiations are at either directly with the Federal Department of Health or at a COAG level as this very serious matter impacts on many people throughout Queensland who are in need of Therapeutic Goods.

X

Mark McArdle MP
Member for Caloundra

X

Sid Cramp MP
Member for Gaven

X

David Janetzki MP
Member for Toowoomba South