Medicinal cannabis access and use in Queensland

March 2017

Queensland Government

Contents

Purpose

This document provides guidance about the process for medical practitioners to access, prescribe and supply medicinal cannabis in Queensland. This document will also provide medical practitioners with information which they can then share with their patients if needed.

It should be noted that medicinal cannabis should not be considered a first line therapy for any indication and that while Queensland Health has provided pathways for access, this does not indicate that the use of medicinal cannabis in individual patients is endorsed by Queensland Health.

To allow patients lawful access to medicinal cannabis, particularly medicinal cannabis products manufactured in Australia, law reform has been progressed at both the Commonwealth and State levels.

The *Public Health (Medicinal Cannabis) Act 2016* *(PHMCA)* and associated Regulation specifies the requirements for approval to prescribe medicinal Cannabis in Queensland.

The pathways by which a medical practitioner may access medicinal cannabis to facilitate treatment include:

- clinical trials—a medical practitioner can be an investigator on a clinical trial using a specific medicinal cannabis product
- a single-patient prescriber, on a case-by-case basis.
- a patient-class prescriber pathway—a specific class of specialist medical practitioner authorised to prescribe a specified medicinal cannabis product for a specific medical condition/symptom. For example, a, oncology specialist will be able to prescribe certain medicinal cannabis products to patients experiencing chemotherapy induced nausea and vomiting.
- Additional requirements

In addition to the state pathways, a separate Therapeutic Goods Administration (TGA) approval is required to authorise the supply of specific medicinal cannabis products to be used for treatment. This is actioned through the Special Access Scheme, Category B or the Authorised Prescriber Scheme administered by the TGA.

In addition, importation licences and permits from the TGA are also required by either the pharmacist or the prescriber—depending on who wishes to undertake the importation process.

General information

Information contained in this document relates to the *Public Health (Medicinal Cannabis) Act 2016* that allows for the prescription and dispensing of medicinal cannabis products in Queensland.

- The cannabis-based product must have been lawfully obtained through importation from overseas, or, has been lawfully grown and manufactured by a licensed cultivator and manufacturer here in Australia. In both cases the Therapeutic Goods

Administration (TGA) must approve the supply of these products through the Special Access Scheme (Category B) or the Authorised Prescriber Scheme.

- Administration and possession of an illegally produced cannabis-based product, which has not been approved, remains an offence under the Drugs Misuse Act.
- The use of medicinal cannabis is supported:
  - where patients' responses to the standard of care (e.g. conventional antiemetic treatments) for the management of specified medical conditions has been shown to have been ineffective or intolerable.
- Outside of clinical trials, the cost associated with access and use of medicinal cannabis will be borne by the individual patient seeking access.
- Smoking of medicinal cannabis will not be approved however, a TGA approved vaporiser can be used.
- Precise dosages of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), (either singularly or in combination) may vary between individuals, the medical conditions being managed and the product being administered. The principle of **start low and go slow** to the maximum approved dosage for the prescribed product applies. Development of a national clinical guidance document is underway.
- It is recommended that not more than one month supply of product be dispensed per dispensing episode and the dispensing interval may be less than one month
- Term of Approval—a medicinal cannabis approval (other than a clinical trial approval) is for not more than one year, unless cancelled, suspended or surrendered. Any variations to the type of product used will require a new approval. The cancellation of a TGA approval will automatically cancel a State approval.
- No driving—it is a condition of a medicinal cannabis approval that the patient does not drive or operate heavy machinery while taking the medication. Roadside drug-driving testing may result in a positive test for patients taking THC based medicinal cannabis products.

The process in Queensland

Role of the Queensland Medicinal Cannabis Expert Advisory Panel

The Chief Executive (CE), Department of Health may grant an approval to use medicinal cannabis in Queensland. The CE may request advice from the Queensland Medicinal Cannabis Expert Advisory Panel concerning, but not limited to, the following:

- the acceptability, rigour and quality of the application in accordance with the specified guidance regarding applications
- statement of reasons for any recommendation(s) made
- whether there is a body of evidence to suggest a trial of medicinal cannabis is warranted for the medical condition or symptoms
- if the patient has attempted all reasonable conventional treatment options and the reasons for these not being suitable/successful
- whether further information is required from the applicant or another expert in the field of the medical condition the patient is presenting with.

Who can be a single-patient prescriber?

In order for medicinal cannabis to be lawfully supplied in Queensland, a single-patient prescriber (the applicant) **must**:

- be a medical practitioner (either specialist medical practitioners in the management of patients with the medical condition being treated with the product; or a general medical practitioner with the support of, or on the advice of a relevant specialist)
- be registered (without any relevant restrictions on their registration) with the Australian Health Practitioners Regulation Agency (AHPRA)
- have a longitudinal treating relationship with the patient, or the medical practitioner is in direct communication with another medical practitioner who has a longitudinal treating relationship with the patient and both are in well-documented agreement with the application for medicinal cannabis approval for therapeutic purposes.

How to apply

The medical practitioner must apply to the CE for a medicinal cannabis approval. This approval authorises the medical practitioner to treat an individual patient with a specified medicinal cannabis product.

Prior to making an application to the CE:

- The medical practitioner treating a patient must discuss risks of treatment with medicinal cannabis and record in the patient's clinical record that a discussion occurred
- Complete a comprehensive clinical assessment of the patient, including risk of addiction and mental health.
- Obtain the patients written informed consent to the treatment and an acknowledgement that they understand they are unable to drive while using the product.

The application **must**:

- be made on the specified application form (Application for a Medicinal Cannabis Approval)
- confirm that a patient has provided written informed consent
- include a copy of any specialist medical opinion supporting the patient's treatment with medicinal cannabis and specifying the treatment is for the indication identified in the approval request
- reference clinical evidence supporting the proposed use of the product
- document that conventional therapies for the condition for which the medicinal cannabis approval is being requested, have been attempted and the length of time these were applied in the management of his/her medical condition and have not successfully helped the patient
- document that the eligible patient has been assessed for addiction and/or risk of addiction and mental health risk factors. For the latter, use a validated addiction risk tool and retain a copy in the patient clinical record.

Standard conditions for a medicinal cannabis approval

A medicinal cannabis approval is for a period of up to 12 months

The authorised prescriber **must**:

- participate in product education/professional education prior to the initial administration of the product and remain up-to-date with evidence-based practice (where possible and available)
- ensure the medicinal cannabis product is stored in accordance with the manufacturers specifications and meets the requirements of the security standard if they are dispensing the medication from their practice
- prepare a medicinal cannabis management plan (if the prescriber is supplying/dispensing from their practice) under the medicinal cannabis approval
- notify Queensland Health when a medicinal cannabis management plan (if needed) is made
- comply with the requirements of the medicinal cannabis approval
- comply with any conditions imposed on a TGA approval relating to the medicinal cannabis product (s) being used.

Although the medicinal cannabis approval is valid for up to one year, the medical practitioner should clinically reassess patients using medicinal cannabis as to the appropriateness of treatment at least once every three months or more frequently, if required. Compare the outcome with the stated goal of treatment to determine whether treatment with medicinal cannabis should continue.

Advise the patient that if their medicinal cannabis contains THC then they cannot drive or operate heavy machinery. Other conditions may apply, depending on individual cases.

The following diagram illustrates the Queensland medicinal cannabis approval for single-patient prescribers (Diagram 1).

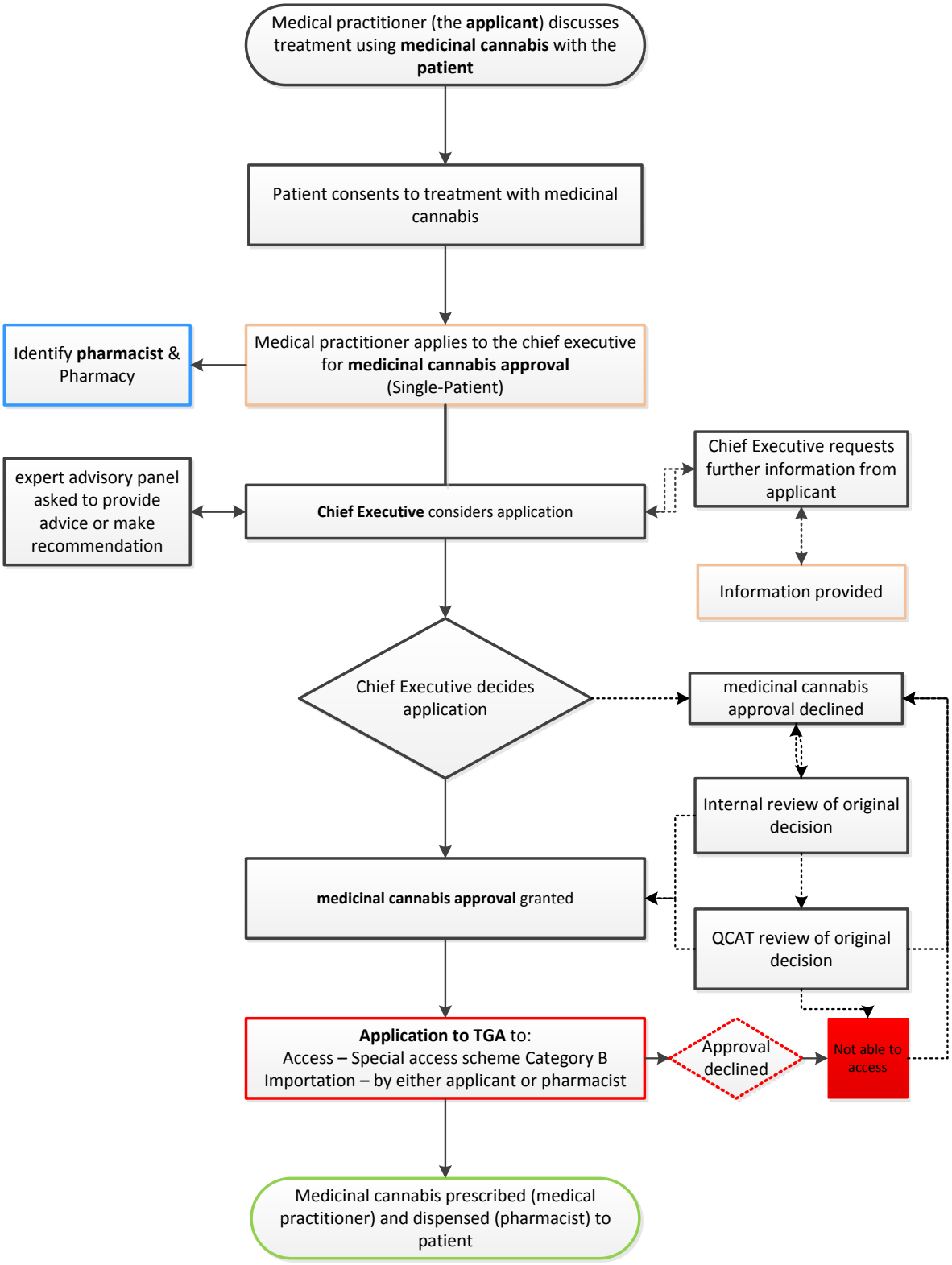

Diagram 1: Queensland Medicinal Cannabis Approval Pathway—Single-patient prescriber

Clinical trials

All medicinal cannabis trials will require approval from both a local Human Research Ethics Committee (HREC) and the CE. The prescription of all medicinal cannabis products is then based on the trial protocol.

As this is an evolving area of medicine, individual medical practitioners do not have to opt-in for clinical trial participation where this is against their individual clinical judgement.

The Principal Investigator will be required to complete an Application for a Clinical Trial Approval and attach evidence of the HREC approval for the use of the product for the clinical trial. (Note: The ethics committee must be a Human Research Ethics Committee that has been constituted in accordance with NHMRC Ethics Committee guidelines. The letter of approval should be attached to the application, or forwarded as soon as available).

Who can be a patient-class prescriber?

Under the PHMCA, a patient-class prescriber is defined as a specialist health practitioner, in the specialties of palliative medicine; general paediatricians; gynaecological oncologists; haematologist physicians; medical oncologists; neurologists; paediatric medical oncologists; paediatric neurologists; paediatric palliative medicine physicians or radiation oncologists.

How to apply

The medical conditions/symptoms and products to be used under the patient-class prescriber pathway have been published in the Clinical Guidance: for the use of medicinal cannabis products in Queensland (December 2016).

Specialists that wish to become a patient-class prescriber will need to register with Queensland Health (Application form – Approval as a Patient-class Prescriber) prior to commencing treating patients with specific medicinal cannabis products. Once a patient is commenced on medicinal cannabis therapy, the patient-class prescriber must notify Queensland Health.

Standard conditions for prescribing

In order for medicinal cannabis to be lawfully supplied in Queensland, the patient–class prescriber **must**:

- be a specialist medical practitioner, as specified in the PHMCA, and be listed with Queensland Health as a patient-class prescriber
- be registered (without any relevant restrictions on their registration) with the AHPRA
- have a longitudinal treating relationship with the patient, or be in direct communication with another medical practitioner who has a longitudinal treating relationship with the patient. Both should be in well-documented agreement with the application for medicinal cannabis approval for therapeutic purposes. For example, a shared care arrangement.

Responsibilities of a patient-class-prescriber

A patient-class prescriber has certain responsibilities that they must adhere to. These include to:

- obtain informed written consent for the treatment of the patient with the medicinal cannabis product (s) and retain a copy on the patient record
- obtain a written driving acknowledgement from the patient advising the patient that they are not able to drive if they are taking THC based medicinal cannabis products and retain a copy on the patient record
- ensure the medicinal cannabis product is stored in accordance with the manufacturers specifications and meets the requirements of the security standard if they are dispensing the medication from their practice
- prepare a medicinal cannabis management plan (if the prescriber is supplying/dispensing from their practice) under the medicinal cannabis approval
- comply with any conditions imposed on a TGA approval relating to the medicinal cannabis product (s) being used
- Notify the CE that they are commencing a patient on the medicinal cannabis product (link to form – Notice of Patient Commencement (Patient-class Prescriber))

The following diagram illustrates the Queensland pathway for patient-class prescribers (Diagram 2).

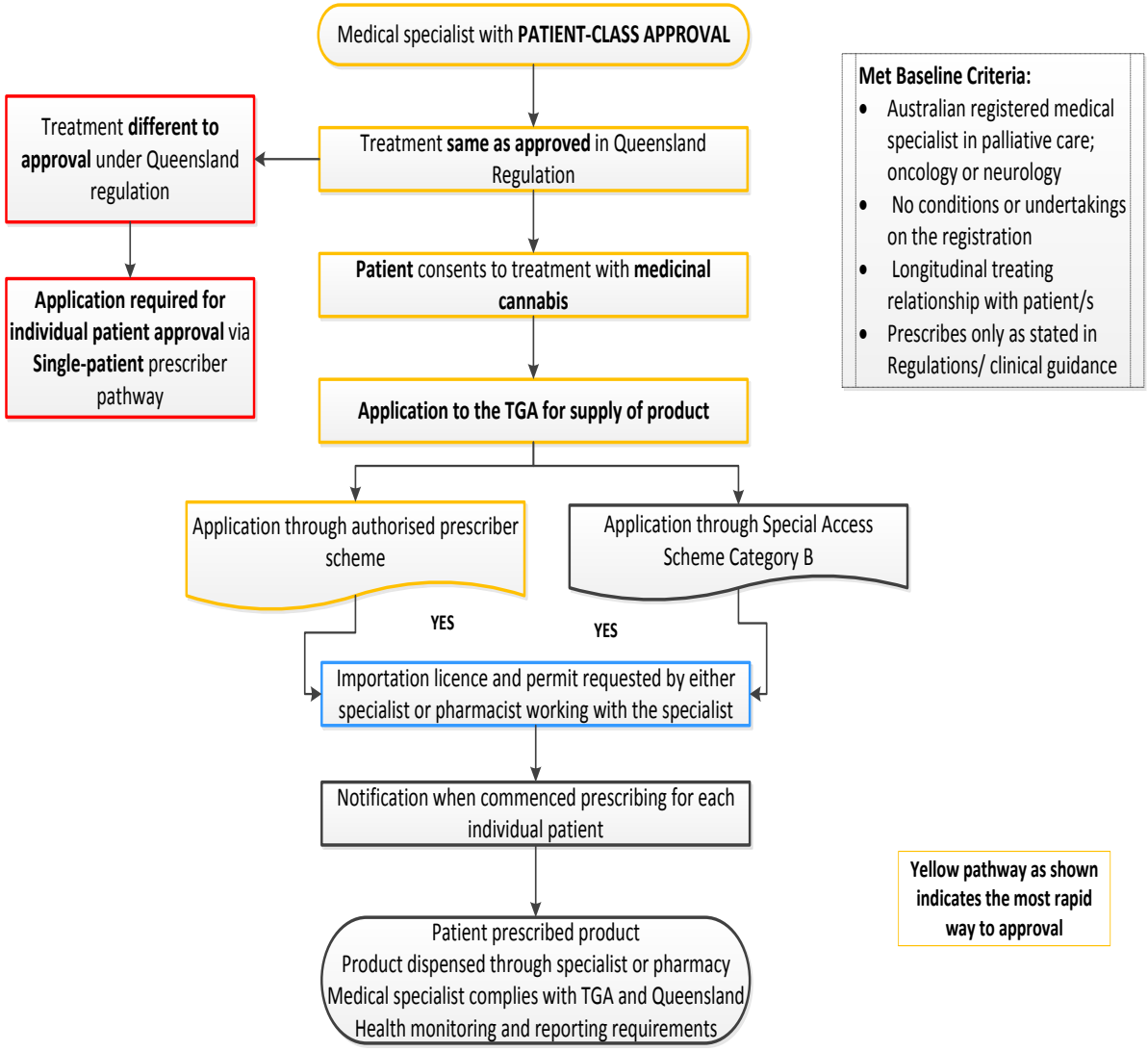

Diagram 2: Proposed Queensland Medicinal Cannabis Approval Pathway—Patient-class prescriber

Monitoring and reporting requirements—prescribers

A single-patient and patient-class prescriber **must**:

- provide a written treatment report to the CE at three-monthly intervals using the approved form. As with any drug, medical practitioners who prescribe medicinal cannabis must monitor patients for any emerging risks or complications. Prescribing should be discontinued where medicinal cannabis fails to meet the medical practitioner's therapeutic goals or the risks outweigh the benefits.
- The report must consider your opinion on patient response, monitoring outcomes, frequency of patients' use and if discontinued any reasons for doing so. This is to ensure Queensland Health builds a body of evidence about the use of medicinal cannabis products.
- report any adverse events, adverse reactions, serious adverse reactions and unexpected reactions to:
  - the Therapeutic Goods Administration through the Australian Adverse Drug Reactions System, and
  - the CE through Medicines Regulation Queensland (MRQ) by fax (07) 3328 9821, phone (07) 3328 9808 or email MRQ@health.qld.gov.au

Dispensing pharmacist

Under the PHMCA, a pharmacist is authorised to obtain, possess and supply an approved medicinal cannabis product to a patient and/or their carer(s) on prescription from an approved single-patient prescriber or patient–class prescriber.

A nominated pharmacist can be located at a public hospital, private hospital or in the community. The nominated pharmacist should not dispense more than requested by the prescriber per dispensing.

How to apply

The pharmacist must apply to the CE for a medicinal cannabis dispensing approval on the approved form.

Standard conditions for dispensing

In order for medicinal cannabis to be lawfully dispensed in Queensland, the pharmacist **must**:

- hold a current endorsement under section 64 of the Health (Drugs and Poisons) Regulation 1996 (i.e. endorsement must not be suspended or cancelled)
- be registered (without any relevant restrictions on their registration) with the AHPRA
- adhere to all conditions as detailed in any Australian Government Department of Health Therapeutic Goods Administration import licence or permit, if they are the importing party

- comply with any conditions imposed on a TGA approval relating to the medicinal cannabis product (s) being used
- only dispense medicinal cannabis in accordance with a prescription
- comply with the Guidelines for Dispensing of Medicines published by the Pharmacy Board of Australia
- prepare a Medicinal Cannabis Management Plan prior to obtaining, possessing or dispensing a medicinal cannabis product
- notify the CE on the approved form that the Medicinal Cannabis Management Plan has commenced

Monitoring and reporting requirements—pharmacist

The nominated pharmacist should:

- comply with all reporting and recording requirements, as set down by the *Public Health (Medicinal Cannabis) Regulation 2017 (PHMCR)*
- report each dispensing event to the CE by forwarding a copy of the medicinal cannabis prescription by fax to (07) 3328 9821 or a scanned copy by email to MRQ@health.qld.gov.au within 72 hours
- ensure any excess or unused stock is disposed of and destroyed in line with the requirements under the PHMCR

More information

- **Assistance with application process**

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- **Commonwealth Therapeutic Goods Administration**

Accessing unapproved products

Website: http://www.tga.gov.au/accessing-unapproved-products

Phone:

  - 02 6232 8106 (Clinical trials)
  - 02 6232 8644 (Special Access Scheme)
  - 02 6232 8101 (Authorised Prescriber Scheme).