Medicinal cannabis in Queensland: Draft Public Health (Medicinal Cannabis) Bill 2016

Discussion paper

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Medicinal cannabis in Queensland: Draft Public Health (Medicinal Cannabis) Bill 2016 - Discussion paper

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Purpose of this document

The purpose of this discussion paper is to explain the Draft Public Health (Medicinal Cannabis) Bill 2016 (the Bill). The Bill proposes a framework for regulating the lawful supply and use of medicinal cannabis products in Queensland.

The paper provides general information about the regulation of medicinal cannabis in Australia, and explains the relationship between the proposed Queensland regulatory framework and Commonwealth legislation, including the recently-passed amendments to the *Narcotic Drugs Act 1967 (Cth)* to permit the lawful cultivation and manufacture of medicinal cannabis in Australia. Public consultation regarding the Bill will help to ensure that any new legislation introduced by the Queensland Government takes into consideration the views of the Queensland community.

The Bill has been released for public consultation, and you are invited to provide feedback on the Bill by 1 April 2016. The Bill, supporting documents and consultation feedback form are available from the Queensland Government *Get involved* website: https://www.getinvolved.qld.gov.au/.

Submissions will not be made publicly available but may be subject to disclosure under the *Right to Information Act 2009*. Access to applications for submissions will be determined in accordance with that Act.

Background

In its broadest sense, 'medicinal cannabis' means cannabis used for medicinal purposes. In this paper 'medicinal cannabis' means cannabis plant extracts and synthetic compounds that mimic the effect of substances found in the cannabis plant, where these products are used for a therapeutic purpose.

A growing body of clinical evidence points to the potential therapeutic benefits of certain forms of medicinal cannabis for treating particular medical conditions or their symptoms. For example, there is evidence to suggest medicinal cannabis may be used effectively to manage the symptoms of some forms of epilepsy, multiple sclerosis, and to relieve the side effects of treatments for cancer and HIV/AIDS.

Medicinal cannabis products are not readily available in Australia and are generally imported after obtaining approval from the Commonwealth Therapeutic Goods Administration (TGA). To allow patients lawful access to medicinal cannabis, particularly cannabis products manufactured in Australia, law reform is required at Commonwealth and state level.

Australia's international obligations and existing Commonwealth legislation mean Queensland and other States cannot introduce effective legislation to permit the cultivation and manufacture of medicinal cannabis. This is why the Commonwealth Government recently passed amendments to the *Narcotics Drugs Act 1967 (Cth)*, to permit the cultivation and manufacture of medicinal cannabis under a licencing and permit scheme. The Queensland Government has now developed a comprehensive regulatory framework that will operate together with this Commonwealth legislation to allow patients to lawfully access medicinal cannabis products, whether imported or produced locally under the Commonwealth scheme, to treat serious illnesses or their symptoms.

The quality, safety and efficacy of most medicinal cannabis products have not been verified to the exacting standards that apply to prescription medications. For this reason, the regulatory framework proposed in the Bill will only permit a patient to have access to medicinal cannabis where the chief executive of Queensland Health is satisfied the patient is a suitable person to undergo treatment.

Despite it being unlawful, it is clear some Queenslanders already use illicit cannabis products for medicinal purposes. This unregulated use of cannabis raises serious concerns due to the potential risks of patient addiction, medication intolerance and the possibility of abuse, misuse or diversion. The regulatory framework proposed in the Bill seeks to allow patients to realise the therapeutic benefits of medicinal cannabis, while guarding against the potentially serious problems arising from the unlawful use of cannabis.

Cannabis, whether used for recreational or therapeutic purposes, is a prohibited substance in Queensland. While the Queensland Government intends to allow the lawful use of medicinal cannabis products, it does not intend to legalise or decriminalise recreational use of cannabis.

Existing regulatory framework

Under the existing regulatory framework comprising the Commonwealth *Therapeutic Goods Act 1989 (Cth)* and *Narcotic Drugs Act 1967 (Cth),* and the Queensland *Drugs Misuse Act 1986* and *Health (Drugs and Poisons) Regulation 1996,* cannabis is a prohibited substance.

In Queensland, the *Drugs Misuse Act 1986* makes it an offence to produce, possess and supply cannabis without authorisation, justification or lawful excuse. As an interim step to allow greater access to medicinal cannabis products, the Queensland Government recently amended the *Health (Drugs and Poisons) Regulation 1996* to allow the chief executive of Queensland Health to approve the use of medicinal cannabis products for a clinical trial or where the TGA has approved an individual using medicinal cannabis products for therapeutic purposes.

However, a more comprehensive regulatory framework is required to effectively regulate the use of medicinal cannabis products. If the Bill is passed, the changes made in the Regulation will be incorporated into the Bill, and the relevant sections of the Regulation repealed.

Scheduling

A national classification system controls how medicines and poisons are made available to the public. Medicines and poisons are classified into schedules according to the level of regulatory control required to protect public health and safety.

Medicines and poisons are scheduled under the national *Poisons Standard 2015*, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The Schedules are given legal effect through state and territory legislation.

The *Therapeutic Goods Act 1989 (Cth)* establishes a uniform, national system of regulatory controls for therapeutic goods. The TGA is the national regulatory authority for therapeutic goods and is responsible for scheduling substances. Most therapeutic goods must be approved by the TGA before they may be used for human treatment.

Schedule 9 and Schedule 8

Schedule 9 substances are classified as poisons and their use is generally prohibited. These substances include drugs of dependence that are prone to misuse and abuse. Cannabis is classified as a schedule 9 prohibited substance due to its potential toxicity, potential for abuse and other unknown harms, and generally cannot be used for therapeutic purposes.

The *Health (Drugs and Poisons) Regulation 1996* does permit the chief executive of Queensland Health to approve the use of a schedule 9 cannabis product in Queensland:

- in a clinical trial, or
- by an individual, if an approval has been granted under the *Therapeutic Goods Act 1989* (Cth) - for example, by the TGA under its Special Access Scheme.

Schedule 8 substances are medicines and generally classified as controlled drugs. The *Health (Drugs and Poisons) Regulation 1996* prescribes some Schedule 8 controlled drugs as 'regulated controlled drugs', meaning they are subject to additional controls and the chief executive of Queensland Health must approve their use.

The TGA has approved three cannabis products, nabiximols (also known as Sativex), dronabinol and nabilone, for therapeutic use. These products are schedule 8 controlled drugs and can be used lawfully in Queensland, subject to restrictions due to their composition and high illicit value.

Sativex is the only pharmaceutical medicinal cannabis product registered on the Australian Register of Therapeutic Goods (ARTG). Once registered on the ARTG, a therapeutic good may be lawfully supplied and sold in Australia. Sativex is used to treat adult patients with spasticity due to multiple sclerosis, and has the advantage of providing relief without the unwanted psychological-related effects caused by tetrahydrocannabinol (THC), which is the main psychoactive substance found in cannabis.

Dronabinol and nabilone have a variety of uses which include treating loss of appetite in people with HIV/AIDS, severe nausea and vomiting caused by cancer chemotherapy and spasticity due to multiple sclerosis. As Schedule 8 substances, the use of dronabinol and nabilone is not unlawful. However, as they are not registered on the ARTG, the TGA must approve their use before they can be lawfully supplied.

The Bill regulates all S9 medicinal cannabis products, and those S8 medicinal cannabis products (dronabinol and nabilone) not registered on the ARTG.

In addition to other reforms currently being pursued by Commonwealth, state and territory governments, consideration is being given to whether Schedule 9 Cannabis should be rescheduled, for example, as schedule 8 substances. As drafted, the provisions of the Bill will apply to medicinal cannabis products regardless of how they are scheduled, provided they are not ARTG-registered goods.

Developments in other jurisdictions

In all states and territories in Australia, it is illegal to use, possess, cultivate, manufacture or sell cannabis. However, a number of Australian jurisdictions are pursuing or considering law reform.

On 24 February 2016, the Commonwealth Government passed a Bill amending the *Narcotic Drugs Act 1967* (Cth), to establish a licensing and permit scheme for the domestic cultivation and manufacture of medicinal cannabis. The scheme is intended to ensure a sustainable, legal supply of safe medicinal cannabis products for approved Australian patients.

The Commonwealth scheme is designed to ensure Australia meets its obligations under the United Nations Single Convention on Narcotic Drugs 1961. These obligations require that any scheme regulating the cultivation, distribution and use of cannabis must be sufficiently secure and robust to account for all medical and scientific use of cannabis, and prevent diversion of the substance for illicit purposes.

To cultivate cannabis for a therapeutic or research purpose, a Commonwealth licence must be obtained. Permits will regulate the types and quantities of cannabis plants that may be cultivated. The subsequent manufacture of a medicinal cannabis product will be jointly licenced by the Commonwealth and states/territories, as happens in relation to the manufacture of other therapeutic goods.

However, to allow patients to access medicinal cannabis product cultivated and manufactured under the Commonwealth scheme, states and territories must enact complementary legislation. The regulatory framework proposed in the Bill achieves this purpose.

New South Wales initiatives include the Terminal Illness Cannabis Scheme (TICS) that enables adults who have a terminal illness to register for the use and possession of cannabis for medical use. The Centre for Medicinal Cannabis Research and Innovation in New South Wales researches cannabis for therapeutic purposes, supports evidence-based innovation, and also monitors the clinical trials and educates the community.

The Victorian Government has introduced the Access to Medicinal Cannabis Bill 2015. The Victorian Bill proposes a state-based scheme to allow the lawful cultivation and manufacture of medicinal cannabis products for use by a limited cohort of patients with particular medical conditions and symptoms (to be prescribed in regulation at a later date). The co-operation of the Commonwealth is required to make this scheme effective, and it remains to be seen how the scheme intersects with the Commonwealth licensing and permit scheme discussed above.

The Queensland government is carefully monitoring developments in other Australian jurisdictions and has taken these into consideration in drafting the Bill.

Internationally, medicinal cannabis has been approved for use in many countries including Austria, Canada, the Czech Republic, Denmark, Germany, Israel, Italy, New Zealand, Spain and Sweden, and in many states within the United States. There is a high degree of variation in the approach taken in each country, including the extent to which use of medicinal cannabis is authorised.

Objectives of the Bill

The purpose of the Bill is to create a new regulatory framework under which medicinal cannabis products may be prescribed and dispensed to patients in Queensland.

A key objective of the Bill is to minimise the complexity and regulatory burden of the scheme on patients, medical practitioners and pharmacists while ensuring the quality, safety and efficacy of medicinal cannabis products where possible.

The Bill will permit the use of medicinal cannabis products,under medical supervision and integrated into the patient's treatment plan. This will ensure controlled use of medicinal cannabis products, and enable effective monitoring of treatment and prompt identification of any unwanted side effects.

To support decision making and evidence-based treatment, the Bill will also facilitate information gathering about medicinal cannabis use for evaluation and research purposes. Evidence about medicinal cannabis use may enable any long-term risks to be more accurately characterised and give medical practitioners increased knowledge and certainty when prescribing medicinal cannabis.

The Bill does not change the law to enable recreational use of cannabis. Queenslanders will not be able to obtain medicinal cannabis products from illegal sources or cultivate cannabis plants for individual use. Cannabis used outside of the proposed regulatory framework will remain illegal.

The Bill will facilitate access to medicinal cannabis, but will not regulate its cultivation, manufacture or supply. Until medicinal cannabis products are manufactured in Australia, they must be imported, and this requires TGA and customs approvals.

As noted above, the Commonwealth Government recently passed amendments to the *Narcotics Drugs Act 1967 (Cth)* to allow for controlled cultivation of cannabis for medical and scientific purposes. The Queensland Government supports these amendments, and will continue to advocate for additional reforms to streamline the TGA approval processes that enable lawful access to medicinal cannabis.

Proposed regulatory framework

The Bill establishes a regulatory framework to facilitate treatment with medicinal cannabis, while preventing unauthorised use. The steps involved in a patient obtaining approval to use medicinal cannabis products are:

- The medical practitioner treating a **patient** must discuss treatment with **medicinal cannabis** with the patient, and obtain their written consent to the treatment. The **medical practitioner** may be a general medical practitioner or specialist medical practitioner.
- The medical practitioner must apply to the chief executive of Queensland Health for a **medicinal cannabis approval**. This approval authorises the medical practitioner to treat their patient with medicinal cannabis. The application must include:
    - a copy of the patient's written consent
    - a copy of any specialist medical opinion previously obtained in relation to the patient's treatment with medicinal cannabis.
- When deciding the application, the chief executive may have regard to a range of factors, including:
    - the suitability of the medical practitioner to be granted a medicinal cannabis approval
    - the suitability of the patient to be treated with medicinal cannabis
    - the patient's medical condition
    - the form and dosage of the medicinal cannabis proposed by the medical practitioner to treat the patient
    - whether treatment with medicinal cannabis can be integrated into the patient's existing medical treatment
    - any alternative treatments suitable for the patient's medical condition.
- When deciding the application, the chief executive must be satisfied the TGA has approved access to the specific medicinal cannabis products, or is capable of approving access. This is because medicinal cannabis products cannot lawfully be supplied without both TGA and Queensland government approval.
- Before deciding the application, the chief executive may do the following:
    - require the medical practitioner to provide additional information or documents
    - require the medical practitioner to provide an opinion from a specialist medical practitioner, or from a different specialist medical practitioner if such an opinion has already been provided

    - refer the application to the **expert advisory panel**, being the panel of experts established to provide advice and make recommendations to the chief executive.
- The timeframes within which the chief executive must decide an application are:
    - within 90 days after receiving the application
    - if the chief executive has requested the applicant provide further information, within 90 days after the further information is received
    - if the application is complex, within a reasonable time after the standard period, as decided by the chief executive.
- If granted, the medicinal cannabis approval must note the following:
    - details of the medical practitioner and the patient
    - the form, dosage and dispensing intervals of the medicinal cannabis product
    - details of the pharmacy from where the medicinal cannabis will be dispensed (called the **dispensing pharmacy**)
    - details of any **carers** responsible for the immediate care and safety of the patient
    - the term of the approval (which must not exceed one year).
- The medicinal cannabis approval is subject to any standard conditions prescribed by regulation. The chief executive may also impose additional conditions.
- A medical practitioner granted a medicinal cannabis approval is called an **approved prescriber**, and is authorised to prescribe medicinal cannabis to treat a particular patient in their care, but only in accordance with the terms and conditions of the medicinal cannabis approval.
- If the medicinal cannabis approval is not granted, the medical practitioner may apply for an internal review by Queensland Health of the decision. If that original decision is affirmed by the internal review, the medical practitioner may apply to Queensland Civil and Administrative Tribunal (QCAT) for a review of the original decision.

To support this process, the chief executive will grant **dispensing approvals** to specific pharmacists (then called **approved pharmacists)** to dispense medicinal cannabis. To lawfully dispense medicinal cannabis prescribed for a patient, an approved pharmacist must work in the dispensing pharmacy noted on the medicinal cannabis approval. A **secondary dispenser** noted on the dispensing approval may also lawfully dispense the medicinal cannabis at the dispensing pharmacy.

The carer noted on the medicinal cannabis approval is authorised to obtain the medicinal cannabis prescribed for the patient from the dispensing pharmacy, possess the medicinal cannabis, and supply or administer the medicinal cannabis to the patient.

Sometimes, the patient's medical condition may prevent them from self-administering medicinal cannabis. Alternatively, the patient may be unable to possess or self-administer their medicinal cannabis because they are in an institution such as a hospital, school, nursing home or prison. In these circumstances, a patient is called a **restricted access patient**, and a person with regular access to the patient (called a **facilitator**) is authorised to possess, supply or administer medicinal cannabis to the patient. If the restricted access patient is in an institution, the person in charge of the institution (called a **responsible person**) must develop a **medicinal cannabis management plan** to manage the risks associated with possessing, supplying or administering medicinal cannabis at that institution.

In addition to authorising treatment of a specific patient under a medicinal cannabis approval, the chief executive may also grant a **clinical trial approval** to facilitate the treatment of patients enrolled in a recognised medicinal cannabis clinical research trial.

The key terms used in the Bill, including those noted in bold above, are explained in the glossary. A diagram illustrating the process described above is also included in this discussion paper.

Medicinal cannabis

The Bill defines 'medicinal cannabis' as a cannabis product used for human therapeutic purposes, but does not include a therapeutic product already registered on the ARTG.

This definition is intended to ensure the regulatory framework is sufficiently flexible to authorise all medically-supported cannabis treatment options, without duplicating existing mechanisms for accessing ARTG-registered products (e.g. Sativex).

The Queensland medicinal cannabis approval authorises treatment with medical cannabis, but a separate TGA approval is required to authorise access to the specific medicinal cannabis product to be used in the treatment.

As noted above, medicinal cannabis products are not readily available in Australia at this time. As a consequence, most medicinal cannabis products must be imported after obtaining TGA approval.

In future, the recent changes to Commonwealth laws mean medicinal cannabis products are likely to be available locally. However, unless amendments are made to the *Therapeutic Goods Act* 1989 (Cth), TGA approval will still be required in most cases before a patient can be lawfully supplied with a domestic product.

TGA approval may be obtained before or after granting a medicinal cannabis approval.

Eligible patients

To be eligible to apply to use medicinal cannabis under the Bill, a person must be the patient of an approved prescriber.

When deciding whether to grant an approval, the chief executive of Queensland Health may have regard to a range of considerations. The Bill aims to give the chief executive flexibility to approve the use of medicinal cannabis where more traditional treatment options have failed, or where the potential benefits of using medicinal cannabis appear to outweigh the risks of unwanted side effects. While the Bill does not prescribe which conditions or symptoms are suitable for treatment with medicinal cannabis, it is expected the chief executive will typically give serious consideration to granting an approval in cases such as the following:

- severe muscle spasms or pain resulting from multiple sclerosis
- severe nausea, severe vomiting or severe wasting resulting from cancer or HIV/AIDS (or the treatment thereof)
- severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated intolerable side effects
- palliative care, particularly related to terminal health conditions.

Approval for medicinal cannabis

A medicinal cannabis approval authorises the approved prescriber to prescribe medicinal cannabis for the treatment of a specific patient. An approval may only be issued for one year because that is the maximum length of the corresponding TGA approval. A medicinal cannabis approval cannot be transferred to another medical practitioner. The Bill provides for the approval to be cancelled, amended, suspended or surrendered at the discretion of the chief executive.

An approval will always be subject to any conditions prescribed by regulation, and any specific conditions imposed by the chief executive when granting the approval. Conditions may include a requirement for the approved prescriber to monitor the effectiveness and side effects of the treatment, or for the approved prescriber to comply with a stated code, guideline, protocol or standard.

Medicinal cannabis prescriptions

A patient is issued a prescription by an approved prescriber, and the pharmacy approved to dispense the medicinal cannabis will be noted in the medicinal cannabis approval.

Approved pharmacists

The Bill provides for a pharmacist to apply for a dispensing approval by making an application to the chief executive.

The chief executive may issue a dispensing approval if satisfied the pharmacist is a suitable person to hold the approval. An approval may only be issued for one year and cannot be transferred to another pharmacist, but may be renewed. The Bill makes

provisions for the approval to be cancelled, suspended or surrendered at the discretion of the chief executive.

An approved pharmacist is the pharmacist to whom a dispensing approval is granted, or a pharmacist who works in a hospital pharmacy. The proposed regulation will prescribe the specific obligations of an approved pharmacist, in relation to the storage, record keeping and dispensing of medicinal cannabis.

Expert advisory panel

The Bill provides for an expert advisory panel to be established. The panel will provide advice to the chief executive on a range of issues including, but not limited to, technical, medical and scientific developments. The panel is strictly an advisory body, and has no executive powers.

The chief executive may refer an application to the expert advisory panel, and the panel may provide advice, and make recommendations, to the chief executive about the application.

The expert advisory panel may also make recommendations about current or proposed research related to therapeutic use of cannabis products, undertake ongoing monitoring of the use of medicinal cannabis in Queensland, and provide advice about advancements and developments in the field.

Expert panel members may include, for example, experts in the following fields:

- science, pharmacy or medicine
- justice and law
- ethics, culture or sociology
- agriculture.

The role of the expert advisory panel is particularly important as the medicinal cannabis used will not be an ARTG-registered substance, and therefore not subject to the usual monitoring of pharmaceutical products undertaken by the TGA.

Offence provisions

The Bill will establish offences in relation to the misuse of medicinal cannabis. Key offences include:

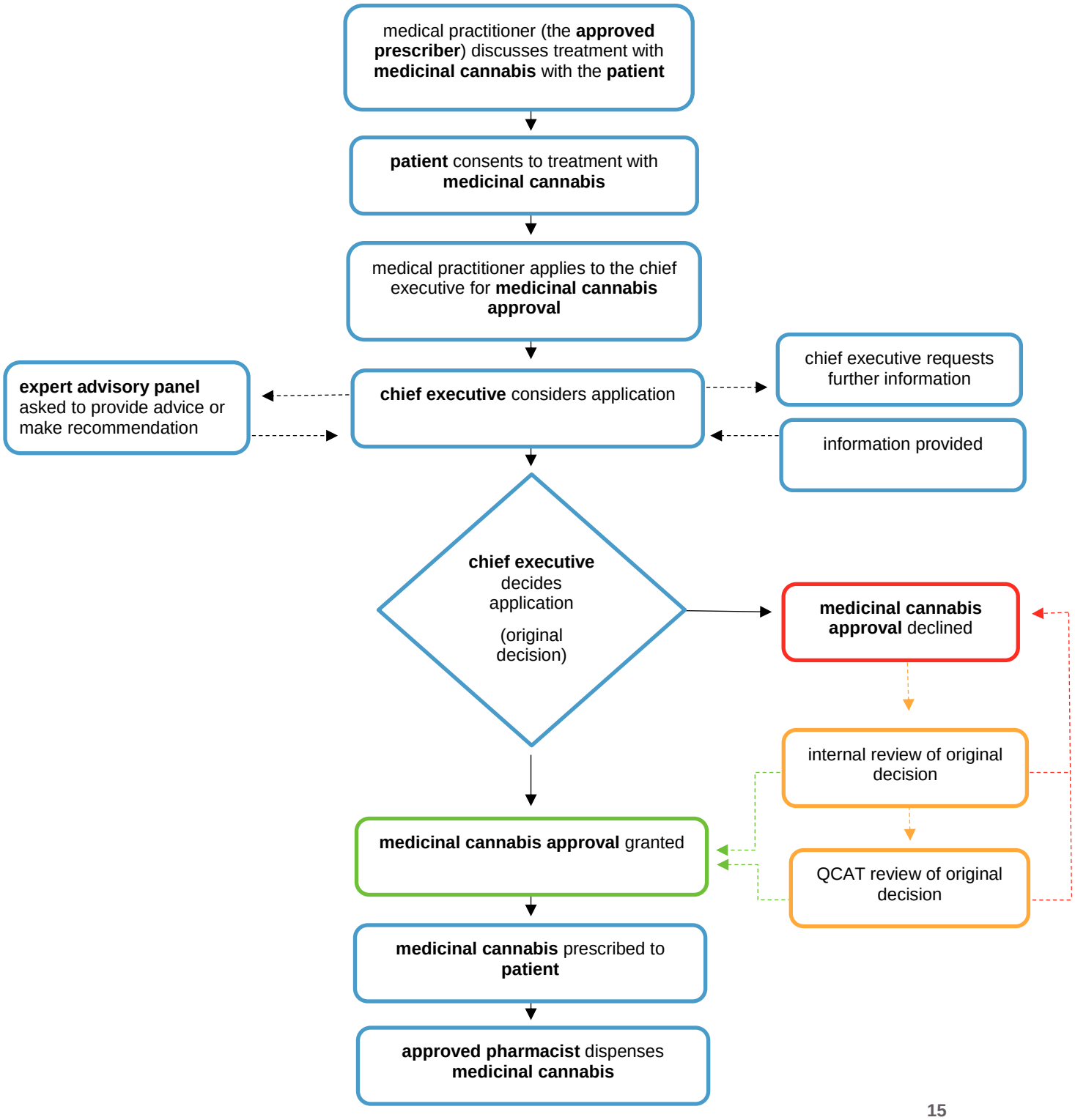
- a person must not prescribe, possess, dispense or administer medicinal cannabis, or attempt to perform any of those regulated activities, unless the person is authorised to do so under the Bill
- a person must not unlawfully change a prescription for medicinal cannabis, and an approved prescriber must not prepare a prescription for medicinal cannabis in their own name

- a carer or authorised prescriber must not administer the medicinal cannabis to any person other than the patient who is the subject of the approval.

Queensland approval process - diagram

This diagram represents the steps in the Queensland medicinal cannabis approval process. In order for medicinal cannabis to be lawfully supplied in Queensland, a TGA approval is also required (this approval process is not represented). TGA approval can be obtained before or after a medicinal cannabis approval is sought from the chief executive.

In this diagram, the boken lines represent optional steps.



Glossary

The following are the key terms used throughout the Bill:

- *'medicinal cannabis'* – a cannabis product used for human therapeutic purposes, but not a product already registered on the Australian Register of Therapeutic Goods (ARTG)

- *'approval'* - a medicinal cannabis approval, dispensing approval or a clinical trial approval

- *'medicinal cannabis approval'* – an approval granted to a medical practitioner to treat a patient with medicinal cannabis

    - *'approved prescriber'* – the general medical practitioner or specialist medical practitioner to whom the medicinal cannabis approval is granted

    - *'patient'* – the person to whose treatment the medicinal cannabis approval applies

    - *'dispensing pharmacy'* – the pharmacy or public hospital pharmacy stated in the medicinal cannabis approval as being where the medicinal cannabis will be dispensed

    - *'carer'* – the person stated in the medicinal cannabis approval as being responsible for the immediate care and safety of the patient

- *'dispensing approval'* – an approval granted to a pharmacist to dispense medicinal cannabis

    - *'approved pharmacist'* – the pharmacist to whom a dispensing approval is granted, or a pharmacist who works in a hospital pharmacy

    - *'secondary dispenser'* – the pharmacist stated in the dispensing approval as being the secondary dispenser

- '*restricted access patient'* – a patient not reasonably able to possess or self-administer medicinal cannabis due to their medical condition or location

    - *'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

    - *'responsible person'* - the person in charge of the institution (e.g. hospital, school, nursing home or prison) in which a restricted access patient is located

- *'medicinal cannabis management plan'* – a document detailing how the responsible person for an institution (or an approved prescriber or approved pharmacist, if this is a condition of their approval) will manage the risks associated with performing activities with medicinal cannabis

- *'authorised person'* – an inspector appointed under the Bill
- *'carrier'* – a person engaged by an approved prescriber, a patient, carer or the chief executive or authorised person, to transport and deliver medicinal cannabis
- *'expert advisory panel'* - the panel of experts providing advice and making recommendations to the chief executive
- *'clinical trial approval'* – an approval granted to facilitate a clinical trial using medicinal cannabis
- *'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

Further information

For further information please visit our website: http://www.health.qld.gov.au/system-governance/legislation/reviews/medicinal-cannabis/default.asp