Application form – Medicinal Cannabis Approval

Health Act 1937

Health (Drugs and Poisons) Regulation 1996

Prescribe, supply, administer & dispense

Pursuant to section 270B of the *Health (Drugs & Poisons) Regulation 1996* the Chief Executive of the Department of Health may approve the use of a Schedule 9 medicinal cannabis product where an approval has been given under section 19(1) of the *Therapeutic Goods Act 1989 (Cwlth)*.

The Chief Executive needs to be satisfied that treatment proposed with a Schedule 9 medicinal cannabis product, an unregistered drug, is an effective treatment option and appropriately manages the safe use of the product. Cannabis is a known dependence forming drug with established evidence of harms in young people in particular. Practices that prevent misuse and diversion of the drug must be incorporated into the Medicinal Cannabis Management Plan.

The *Health (Drugs & Poisons) Regulation 1996* provides lawful authority to use cannabis for therapeutic purposes. Cannabis use outside of this authority is considered to be use of an illicit drug and subject to penalties and enforcement provisions under the *Drugs Misuse Act 1986*.

About this application form

This form is to be used to apply for an approval to perform the following regulated activities with the medicinal cannabis in relation to treatment of an individual person:

a) prescribe
b) supply
c) administer
d) dispense

A separate approval is required for each individual patient that you are seeking to treat. A separate approval is required for the nominated pharmacist/s (if any) who will dispense the substance.

General information

- An approval cannot be granted for any other cannabis products that are not approved by the TGA.
- An approval granted by the Chief Executive does not in any way support your clinical decision to treat a person with dangerous drugs that are unregistered medical products with no established safety or efficacy profiles.
- Please write clearly or complete electronically, print and sign. Answer all questions in full and provide appropriate supporting documentation as requested.
- You will be notified by mail if an approval is granted.
- All forms requiring a signature must bear the original signature in ink. The Department of Health is not able to accept a photocopy, facsimile (fax) or emailed copy of the completed form.

Further information

t: (07) 3328 9890
f: (07) 3328 9821
e: MRQ@health.qld.gov.au
w: www.health.qld.gov.au
Health (Drugs & Poisons) Regulation, 1996:
www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HealDrAPoR96.pdf

Section 1 Medical Practitioner - Applicant details

Please provide details of individuals/partners as they appear on the applicant's birth certificate. If more than two individuals or partners please attach the additional relevant information with your application.

Title	Given Names	Surname *(include maiden name)*

Telephone	Mobile	Email

Practice address	Postal address—tick if same as residential address

Specialist registration: Please provide details of any specialist registration:	AHPRA Registration Number:

Section 2 – Therapeutic Goods Administration Approval for Medicinal Cannabis

Provide a copy of the approval issued by the TGA for the patient mentioned in this approval application.

Provide a full copy of the application made to the TGA for the above including all supporting documentation.

Section 3 – Patient Details

Patient — include name as it appears on person's birth certificate, or other approved form of identification.

Title	Given Name	Surname *(include maiden name)*

Date of birth	Town of birth	Country of birth

Residential address	

Carer 1 — include name as it appears on person's birth certificate, or other approved form of identification.

Title	Given Name	Surname *(include maiden name)*

Date of birth	Town of birth	Country of birth

Telephone	Mobile	Email

Residential address	Relationship to patient:

Carer 2 — include name as it appears on person's birth certificate, or other approved form of identification.		
Title	Given Name	Surname *(include maiden name)*
Date of birth	Town of birth	Country of birth
Telephone	Mobile	Email
Residential address	Relationship to patient:	

Are you satisfied that the persons listed as carers in this applications are fit and proper persons to manage this patient's care with medicinal cannabis? YES __ NO ___.

Section 4 Health condition requiring treatment with medicinal cannabis

Please attach relevant copies of any and all supporting specialist reports that supports the patient's diagnosis of their condition and their treatment with <u>each form of medicinal cannabis</u> you are seeking approval for.

Diagnosis:	Prognosis:

Please provide relevant medical history (attach extra pages if required):

Specialist reports attached: YES ____ NO____

Section Medicinal Cannabis products (Schedule 8 & 9 drugs)

Please provide details of the TGA approved medicinal cannabis products:

Product Name	THC (%)	CBD (%)	Dosage regimen	Form	Route of administration
1.					
2.					
3.					
4.					
5.					

Please provide any relevant safety and consumer information for the above products including evidence they meet standards of Good Manufacturing Practice for medicines.

Please provide supporting clinical or research evidence of the use of the above products for the treatment of the nominated conditions.

I understand that the above medicinal cannabis products are unregistered medications in Australia that do not satisfy recognised standards of safety and efficacy. I have appropriately informed the patient or their legal decision makers of the medical risks of using this product to the best of my ability. : YES ____ NO____

I have obtained written consent of the patient and/or their legal guardians and informed them of all the appropriate risks of exposure to cannabis products:

YES ____ NO____

Section 5 Storage of medicinal cannabis

If you are choosing to dispense the medicinal cannabis from your practice – you will need to prepare a **Medicinal Cannabis management plan (see Guidance Notes)** to demonstrate appropriate management and reporting of the use of this drug in your practice.

I am proposing to manage the supply, storage of medicinal cannabis at my medical practice

YES NO (If No please go to Section 6)

Practice name

Address

Section 6 Approved pharmacist

If you are not choosing to dispense the medicinal cannabis from your practice – you will need to nominate an approved pharmacist to undertake this dispensing and supply. Please provided these details below:

Title	Given Names	Surname

AHPRA Registration Number:

Telephone	Mobile	Email

Pharmacy Business name:

Pharmacy Business address:	Postal address— if not same as residential address

Section 8 Declaration

Please read the following statements and sign the declaration below. All applicants need to sign the declaration.

I consent to the making of enquiries and the exchange of information with the authorities of any State, Territory or Commonwealth regarding any matters relevant to this application.

I have read, understand and agree to comply with the relevant provisions of Health (Drugs and Poisons) Regulation 1996. (Legislation available online at www.legislation.qld.gov.au).

In making this application I agree to the following:

- I will comply with all the relevant conditions set out in the approval granted by the Therapeutic Goods Administration
- I accept responsibility for any adverse consequences of the therapy
- I have obtained fully informed consent of the patient or their legal decision makers.
- Details of any suspected adverse drugs reaction are to be immediately reported to the Chief Executive
- The Chief Executive is to be immediately notified of discontinuation of therapy under terms of your approval
- Details of the patients response to treatment are to be submitted to the Chief Executive on completion of treatment
- On completion of treatment or cancellation of approval all remaining supplies of the product will be destroyed.
- I accept responsibility for any defects in the drug supplied related to its manufacture, distribution or directions for usage, including dosage.

Signature	Date	Print full name

Privacy Statement: The Department of Health provides this form under the *Health Act 1937* so that you may apply for an approval. The information and documents collected for the purpose of this application may be accessible by authorised departmental persons. The department will not disclose your personal information or supporting documents to third parties without your consent unless required or authorised by law.

The *Information Privacy Act 2009* sets out the rules for the collection and handling of personal information by the Department of Health. For information about how the Department of Health protects your personal information, or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au.

What now?

The Chief Executive will consider your application and respond with a decision within 90 days.

The Chief Executive may refer your application to a specialist review committee to provide information to assist in his decision

The Chief Executive may seek further information from you in regards to this application.

Further information

Medicinal Cannabis Management Plan

As Medicinal Cannabis is a Schedule 9 drug and only an approved person such as the approved medical practitioner, approved pharmacist, or the patient or their approved carers are able to possess this drug at any time.

A pharmacy business or doctor's practice that is seeking to manage medicinal cannabis products under an approval is required to have a medicinal cannabis management plan. This plan should meet the following:

- **Recording** – a method of recording all incoming and outgoing supply of the drug is to be maintained in keeping with the controlled drug recording arrangements in the Health (Drugs & Poisons) Regulation, 1996
- **Storage** – medicinal cannabis must be stored at the same standards as that for controlled drugs as set out in the Health (Drugs & Poisons) Regulation, 1996. This means only the approval holder alone is only able to have access to these drugs, and a storage receptacle must meet requirements of Appendix D of the Regulation.
- **Labelling** – each dispensing or supply event to the patient must be labelled with a dispensing label in accordance with Section 85 of the Health (Drugs & Poisons) Regulation, 1996.
- **Reporting** – each dispensing or supply event to the patient is to be immediately reported to the Chief Executive.
- **Destruction** – any drug that is not dispensed or not used under the terms of the approval must be submitted to the State Analyst for destruction as per the requirements of the destruction of controlled drugs under the Regulation.
- **Adverse Event Reporting** - Details of any suspected adverse drugs reaction are to be immediately reported to the Chief Executive
- **Inspection and Compliance** – the approval must be immediately on request be able to provide details of above management plan and evidence of compliance with the plan to an authorised inspector or Queensland Police Officer.

Further information

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Applications must be forwarded by POST to:

Chief Executive
Medicines Regulation & Quality
Locked Bag 21
FORTITUDE VALLEY BC 4006

Queensland Government