Application for Approval to Prescribe or Supply a Schedule 8 Cannabis Medicine for Human Therapeutic Use

as required under the Poisons and Therapeutic Goods Act 1966 (NSW)

Schedule 8 cannabis medicines include medicines derived from the cannabis plant, including nabiximols, and synthetic substances such as dronabinol and nabilone.

An application to NSW Ministry of Health for prescribing or supplying a Schedule 8 cannabis medicine is required where the patient is a drug dependent person (including a person treated under the Opioid Treatment Program).

Applications to prescribe and supply extemporaneously–compounded cannabis medicine are to be made using Application for Approval to Prescribe or Supply a Compounded Schedule 8 Product for Human Therapeutic Use.

All applications to prescribe and supply a Schedule 8 Cannabis Medicine for a clinical trial are to be made using Application for Authority to Prescribe and Supply a Substance for the Purpose of Human Research.

Are you prescribing or supplying:

☐ A **registered schedule 8 cannabis medicine**. Go to '***Before starting the application***'

☐ An **unregistered schedule 8 cannabis medicine**. Before prescribing or supplying an unregistered medicine, approval under the ***Therapeutic Goods Act 1989*** **(Commonwealth)** must be granted. Indicate under which scheme you are operating:

- ☐ ***Authorised Prescriber Scheme***: I am approved as an authorised practitioner to treat specified patients, with certain clinical indications. Authorised Prescriber approval number

  _____
  (please specify)

  For more information, visit Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme Go to '***Before starting the application***'

- ☐ ***Special Access Scheme (SAS)***: Use the TGA's SAS Online System. You **do not need to complete this application** when using the TGA system.

Before starting the application:

- **If the patient is currently enrolled on the Opioid Treatment Program (OTP)**, please make sure that you have obtained written agreement from the authorised OTP prescriber for this treatment.
- **Explain the following to the patient:**
  - unregistered medicines have not been assessed for safety or efficacy by the TGA
  - the nature of the treatment and potential harms (and obtained patient consent)
  - for products containing tetrahydrocannabinol, that driving, and workplace health and safety need to be considered when planning activities
  - why their personal health information is collected, how they can access their information, how it may be used, and who it may be disclosed to (see Privacy Statement below).

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Clinical Advice and Support

The NSW Ministry of Health recommends the use of **SafeScript NSW** to assist practitioners to make informed clinical decisions https://www.health.nsw.gov.au/safescript. Consider checking **SafeScript NSW** for evidence of alerts or other issues related to the prescribing and supply of high-risk monitored medicines.

The NSW Ministry of Health recommends that all prescribing and supply is in accordance with the approved **Product Information** (PI) and with published recommendations.

The TGA has a responsibility to encourage the use of medicines that are included in the Australian Register of Therapeutic Goods (ARTG), as these products have been evaluated to ensure they meet strict standards of safety, quality, and effectiveness. For this reason, it is expected that practitioners (prescribers) will have considered all clinically appropriate treatment options that are included in the ARTG before applying to access an unapproved cannabis medicine.

Applicants are advised to consider if the patient would benefit from a review by an **addiction medicine specialist** to manage any perceived drug dependence concerns.

Applicants can contact experienced clinical advisors and addiction medicine specialists to obtain general clinical advice and support when managing patients with drug and alcohol issues, by calling the free **Drug & Alcohol Specialist Advisory Service** (DASAS) on **Metropolitan Area: (02) 8382-1006; Regional, Rural & Remote NSW: 1800 023 687**, available 24/7. **This advice line cannot provide support for an application for an authority.**

All NSW community general practitioners and rural clinicians can contact HNELHD-JHHPharmacy@health.nsw.gov.au for expert clinical guidance and advice on prescribing cannabis medicines. Health practitioners working in public facilities in metropolitan local health districts should consult their local medicines information service. Further information can be found at Cannabis medicines

Privacy Statement: The information set out in this form is required by the NSW Ministry of Health for the issuance of an approval to prescribe or supply a Schedule 8 medicine as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. Information collected as part of the application process may be used and disclosed as part of assessing the application. Medicare numbers may be used for the purpose of patient identification. Practitioner information, and data regarding the number of patients for whom they hold approvals to prescribe or supply a Schedule 8 medicine , may also be used, and disclosed for policy and planning purposes. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety or where required or authorised by law. The application may not be processed if all information and all declarations requested on the form are not completed. For further information on privacy, visit http://www.health.nsw.gov.au/patients/privacy

☐ **I confirm that I have read and understood the information contained in 'Clinical Advice and Support' and the 'Privacy Statement'**

(This declaration is mandatory and must be completed)

Enquiries:

Please direct any enquiries to the Pharmaceutical Services Unit: Tel: **(02) 9424 5923** or email: MOH-CannabisMedicinesApplicationsNSW@health.nsw.gov.au

Submitting the application:

Fax completed form to the Pharmaceutical Services Unit: Fax: **(02) 9424 5860** or email to: MOH-CannabisMedicinesApplicationsNSW@health.nsw.gov.au

Processing Time:

Please allow up to **2 business days** for the processing of applications.

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SECTION A – PRESCRIBER DETAILS

Prescriber Name: (as displayed in AHPRA)

First Name (s): _____ Middle Name(s): _____

Family Name: _____

Name of Practice: _____

Address: _____ Suburb/town: _____

Postcode: _____ Telephone: _____ Fax: _____

Mobile: _____

Email: _____ (please note this email address will be used for all correspondence)

AHPRA Registration No.: _____ PBS Prescriber No.: _____

SECTION B – PATIENT DETAILS

Patient Name: (as shown on Medicare card)

First Name(s): _____ Middle Name(s): _____

Family Name: _____

Patient also known as: (if applicable)

First Name (s): _____ Middle Name(s): _____

Family Name: _____

Address: _____ Suburb/town: _____

Postcode: _____ Medicare number: (if applicable) _____ Ref no.: _____

DVA number: (if applicable) _____

DOB: _____ (dd/mm/yyyy) Sex: ☐ Male ☐ Female ☐ Another term

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SECTION C – PRE-QUESTIONS

1. IS THE PATIENT CURRENTLY ENROLLED ON THE OPIOID TREATMENT PROGRAM (OTP)?

☐ **No**. Go to **question 2**

☐ **Yes**. I am the authorised OTP prescriber. Go to **question 2**

☐ **Yes. I am NOT the authorised OTP prescriber.** Has the patient been reviewed by the authorised OTP prescriber and written agreement to the proposed treatment obtained?

- ☐ **Yes**. Go to **question 2**
- ☐ **No**. Contact the authorised OTP prescriber and obtain written agreement before submitting this application. **This application cannot proceed** and will not be considered until written agreement is obtained.

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2. DO YOU CONSIDER THIS PATIENT TO BE DRUG DEPENDENT?

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of:

(a) a drug of addiction, or

(b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985,

*an overpowering desire for the continued administration of such a drug (**section 27 of the Poisons and Therapeutic Goods Act 1966**).*

☐ **Yes.**

☐ **No.** Authority is NOT required for this patient at this time.

SECTION D – CANNABIS MEDICINE AUTHORISATION DETAILS

Unregistered cannabis medicines (specify):

Active ingredient: _____

Trade name: _____

ARTG registered cannabis medicine

☐ **Nabiximols**

Route of administration: _____ Maximum daily dose: _____ mg

☐ **Other** (specify): _____

Route of administration: _____ Maximum daily dose: _____ mg

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SECTION E – DECLARATION

☐ I confirm that the information I have provided in this application is true and complete to the best of my knowledge and where required, that I have sought a review and obtained written agreement from an appropriate medical specialist for the proposed treatment.

Signature: Print and Sign _____ Date: _____ (dd/mm/yyyy)