Clear Form

NSW GOVERNMENT

CM 09/19

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

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 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), or
- a child aged under 16 years

To make an application to NSW Health to prescribe an unregistered medicine under the **Special Access Scheme (SAS)**, use the Therapeutic Goods Administration's SAS online system at https://www.tga.gov.au/special-access-scheme-and-authorised-prescriber-online-system.

To make an application directly to NSW Health, complete this fillable PDF form (https://www.health.nsw.gov.au/pharmaceutical/cannabismedicines/Pages/how-to-apply.aspx) electronically using a computer. If completing the form by hand, please use BLOCK LETTERS and ensure that all details are legible.

Applications to prescribe or supply a Schedule 8 cannabis medicine for a clinical trial are to be made using the form Application for Authority to Prescribe and Supply a Substance for the Purpose of Human Research.

Eligible applications are generally processed within 2 business days of receiving all required information.

Section A: Prescriber

Prescriber name:

(first names) *(family name)*

Name of practice/hospital/facility:

Address:

Suburb/Town: **Postcode:**

Telephone:	**Fax:**	**Email:**

AHPRA registration no:

AHPRA specialty/field: ☐ General Practice ☐ Palliative Medicine ☐ Pain Medicine ☐ Physician-Neurology ☐ Physician-Medical Oncology ☐ Rehabilitation Medicine ☐ General registration (no specialty) ☐ Other specialty, *please specify* .....

Section B: Patient details

Patient name:

(first names) *(family name)*

Also known as *(if applicable)*:

(first names) *(family name)*

Patient residential address:

Suburb/Town: **Postcode:**

Patient date of birth: ___ ___ ___ ___ ___ ___ **Sex:** ☐ Male ☐ Female

Do you consider this patient to be drug dependent? ☐ Y ☐ N

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of a drug of addiction or 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*).

Diagnosis(es):

Clinical indication(s):

Patient Family Name

Clinical justification for use of product (Include information about the patient's current treatment and medications prescribed)**:**

Section C: Product

Tick one box only: ☐ cannabis ☐ nabiximols ☐ dronabinol ☐ nabilone

Trade name	
Sponsor/Supplier	
Active ingredient(s) *State the full name of each active ingredient, e.g. tetrahydrocannabinol and cannabidiol*	
Dosage form *(e.g. oil, spray, solution)*	
Strength *(e.g. 1mg/mL)*	
Route of administration *(e.g. oral, oromucosal, inhalation)*	
Dose and frequency	
Duration of treatment	

Section D: Approval under the *Therapeutic Goods Act 1989* (Commonwealth approval)

Approval under the Commonwealth Therapeutic Goods Act 1989 (Authorised Prescriber Scheme or Special Access Scheme) for an unregistered medicine is required to prescribe or supply an unregistered medicine

Indicate the status of your approval to prescribe and supply an unregistered product under Commonwealth law

☐ **Not applicable** - product is registered (e.g. Sativex)

☐ **Authorised Prescriber Scheme** - I have been approved to treat the clinical indications listed in Section B and a copy of my approval is attached

☐ **Special Access Scheme A** - I have notified the TGA

☐ **Special Access Scheme B** - I have submitted an application to the TGA

For SAS applications, if you have used the TGA's online system, do not submit this application to NSW Health

Section E: Declaration

I have explained the following to the patient:

- **where the product is an unregistered medicine, that it has not been assessed for safety or efficacy by the TGA**
- **the nature of the treatment and potential harms, and the patient has consented to the treatment**
- **that if a product contains 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)*

I confirm that the information I have provided in this application is true, accurate and complete to the best of my knowledge.

Signed:..... Date: __ __ __ __ __ __ __ __

Privacy Statement: The collection, use and disclosure of the information provided on this form will be in accordance with privacy laws. The information collected may be disclosed to other health practitioners when necessary to facilitate coordination of treatment and patient safety. In addition, personal health information may be disclosed where required by law or where otherwise lawfully authorised. NSW Health may provide any or all of the contents of this application and information provided with it to law enforcement agencies and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure laws and regulations are being complied with. For further information on privacy visit http://www.health.nsw.gov.au/patients/privacy. For advice or clarification please email MOH-PharmaceuticalServices@health.nsw.gov.au

For assistance contact the Pharmaceutical Regulatory Unit during business hours on (02) 9391 9944
Email completed form and other required documents to: MOH-CannabisMedicinesApplicationsNSW@health.nsw.gov.au