Clear Form

UC 10/19

Application for Authority to Prescribe and Supply an Unregistered or (Pharmacy) Extemporaneously-Compounded Schedule 8 Product for Human Therapeutic Use

This form is available online in PDF format (http://www.health.nsw.gov.au/pharmaceutical) and should be filled in electronically using a computer. If completing the form by hand, please use BLOCK LETTERS and ensure that all details are legible.

The application form is to be used for:

- unregistered Schedule 8 medicines other than cannabis medicines
- any extemporaneously-compounded Schedule 8 products

Eligible applications are generally processed within 30 business days. Further information in support of the application may be requested.

Section A: Prescriber details

Prescriber name:

(first names) *(family name)*

Name of practice:

Address:

Suburb/Town: **Postcode:**

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

AHPRA registration no:	**PBS prescriber no:**

AHPRA specialty/field:

☐ Pain Medicine ☐ Addiction Medicine ☐ Psychiatry
☐ Rheumatology ☐ Palliative Medicine ☐ General Practice ☐ Paediatrics
☐ Neurology ☐ 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).*

Do you have any of the following concerns?

☐ past/current IV drug use ☐ drug seeking ☐ unsanctioned dosage escalation
☐ illicit drug use ☐ doctor shopping ☐ medical dependence
☐ diversion ☐ drug misuse ☐ lost prescriptions/medication
☐ longer period of use than intended or appropriate

☐ no concerns

Patient Family Name

Section C: Product details

Schedule 8 substance/s:

Is this a proprietary product being imported from overseas?

☐ Y ····▶ *Please attach TGA Special Access Scheme approval*

☐ N ····▶ *If the product is to be pharmacy compounded the prescriber is advised to seek evidence from the pharmacist that the quality and stability of the formulation is in accordance with the guidelines on compounding medicines published by the Pharmacy Board of Australia.*

Form *(e.g. capsule, troche, lozenge, injection, cream, gel, mixture, spray)*:

Maximum daily dose of the Schedule 8 substance/s: mg

Quantity/volume to be prescribed (as specified on the prescription):

Specify the appropriate measurement – gram, mg or mL

Expected duration of treatment *(Specify days, weeks or months, as applicable)*:

Section D: Clinical indication and use

Patient's diagnosis:

Clinical indication for use:

Is the patient's condition an ARTG approved indication for use of the Schedule 8 substance(s) contained in the product?

Note: Therapeutic goods entered in the Australian Register of Therapeutic Goods (ARTG) can be lawfully supplied in Australia. The ARTG holds information on product name and formulation details, as well as sponsor and manufacturer details.

☐ Y

☐ N ····▶ *Please attach a second opinion supporting the treatment from a relevant specialist, if available.*

Describe the evidence of efficacy for the product in the treatment of the patient's condition. Provide details of published citations, where available.

Patient Family Name

Explain why ARTG products are unsuitable and how this product will form part of the patient's management plan. Include details of pharmacological and non-pharmacological treatments that have previously been trialled.

Section E: Attachments

Indicate the attachments provided with this application (tick all that apply):

☐ TGA Special Access Scheme approval (Section C)
☐ Second opinion supporting the treatment from a relevant specialist (Section D)

Section F: Signature

I have explained the following to the patient:

- **the product (as an unregistered medicine) has not been assessed for safety or efficacy by the TGA**
- **the nature of treatment and potential harms, and the patient has consented to the treatment**
- **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 information set out in this form is required by the Ministry of Health for the issuance of an authority to prescribe an unregistered Schedule 8 product as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety, and may be disclosed to other State and Commonwealth jurisdictions to facilitate consideration of treatment approvals. Personal information will not be disclosed for any other purpose without prior consent, except where required by law or where otherwise lawfully authorised to do so. The application may not be processed if all information requested on the form is not completed. For further information on privacy visit http://www.health.nsw.gov.au/patients/privacy.

Fax completed form and supporting documentation to the Pharmaceutical Regulatory Unit: 02 9424 5889
Enquiries: Tel 02 9424 5923 or email MOH-S8Auth@health.nsw.gov.au
Allow up to 7 business days for the processing of applications.