Clear Form

CP07/16

Application for Authority to Prescribe and Supply a Cannabis-based Product

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.

Eligible applications are generally processed within 30 business days.

Section A: Medical Practitioner to be authorised

Name:

(first names) *(family name)*

Name of Practice:

Address:

Suburb/Town: **Postcode:**

This must be the premises where consultation or treatment of the patient is to take place

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

AHPRA Registration No:	**PBS Prescriber No:**

AHPRA Specialty:

☐ Medical Oncology ☐ Radiation Oncology ☐ Paediatric Oncology

☐ Haematology ☐ Paediatric Haematology ☐ Neurology ☐ Paediatric Neurology

☐ Palliative Medicine ☐ Pain Medicine ☐ Other specialty, *please specify* .....

1. Indicate below the circumstances of your application

☐ I will need to apply for approval under the Special Access Scheme ····▶ *Go to Question 3*

☐ I am an Authorised Prescriber under the Authorised Prescriber scheme ····▶ *Please attach TGA letter of approval*

☐ I will need to apply to become an Authorised Prescriber under the Authorised Prescriber scheme ····▶ *Please specify the name of the Human Research Ethics Committee where your application to become an Authorised Prescriber will be directed:*

.....

☐ A clinical trial is being conducted under the CTN or CTX scheme ····▶ *Please attach the protocol*

2. Please provide details of the ethics committee that has approved the use of the product

Note: The ethics committee must be a Human Research Ethics Committee that has been constituted in accordance with NHMRC Ethics Committee guidelines. The letter of approval must be attached.

Name of committee:

HREC approval number:

Products approved:

Indication:

Site:

Conditions:

Expiry date of the approval:

Trial No (for CTN/CTX only):

3. Will you be engaging an agent to import the product(s) on your behalf?

☐ N

☐ Y ····▶ *Please specify the business name and address of the agent* .....

.....

4. Will you be engaging an agent to transport the product(s) on your behalf?

☐ N

☐ Y ····▶ *Please specify the business name and address of the agent*

.....

5. Will you be dispensing the product(s) from your practice?

☐ N

☐ Y ····▶ *Please describe how the supply and storage of the product(s) will be managed*

.....

.....

.....

6. Will a pharmacy be dispensing and supplying the product(s)?

☐ N ····▶ *Go to Section C*

☐ Y

Section B: Pharmacy to be authorised

Pharmacy Name *(as appears of the NSW Register of Pharmacies)*: .....

Pharmacy Address *(as appears on NSW Register of Pharmacies)*:

Suburb/Town: **Postcode:**

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

Section C: 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:** ☐ M ☐ F

If a clinical trial under the CTN or CTX scheme ····▶ *Go to Section F*

Section D: Drug (product) details

Note: These details are specific to the patient in the application. Do not include quantities relating to any other patients.

8. Drug: .....

9. Product Name *(if applicable)*: .....

10. Indicate below which of the following you are attaching to the application:

- ☐ Certificate of Analysis *(Note: This must refer to the batch that is being imported for the patient)*
- ☐ Investigator's Brochure *(Note: This will be treated by the Ministry as commercial-in-confidence)*
- ☐ Product Information from another jurisdiction

11. Active constituents *(if applicable)*: .....

12. Specify the name and address of the manufacturer: .....

.....

13. Presentation: ☐ bud ☐ oral liquid ☐ spray ☐ other, *specify*: .....

14. Route of delivery: ☐ oral ☐ inhaled via vaporiser ☐ oromucosal ☐ other, *specify*: .....

15. Is there a medical device to be used in delivery?

- ☐ N
- ☐ Y ⋯▶ *Please specify*: .....

16. Specify the planned dosage regimen *(e.g. 2.5mg TDS PRN up to a maximum of 10mg PRN)*: .....

17. Specify the expected maximum daily dose *(e.g. 30 mg)*: .....

18. What quantity will be dispensed at any one time? *(Note that this is the quantity that the patient is expected to have in their possession at any one time)*: .....

19. Specify the amount that will be imported: ..... ☐ Not applicable

20. Specify expected duration of treatment *(Specify days, weeks or months, as applicable)*: .....

Section E: Clinical indication and use

21. Patient's diagnosis *(e.g. epilepsy)*: .....

22. Clinical indication for use *(e.g. severe seizures refractory to standard anti-epileptic drugs)*: .....

.....

23. Explain why you are prescribing the treatment, including efficacy and potential harms, and the scientific evidence to support the treatment

24. Explain how this drug will form part of the treatment plan for the patient, including any previous pharmacotherapy and/or non-pharmacotherapy

25. Describe the planned clinical review of the patient to monitor efficacy, harms and adherence

26. Describe the pre-defined, objective outcomes that need to be met to judge whether the treatment should be continued

Section F: Signature

I have explained the nature of treatment and the potential side effects with the patient and he/she has consented to the treatment.

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 a cannabis-based 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. For further advice or clarification please email pharmserv@doh.health.nsw.gov.au

Indicate below which attachments are included with the application:

- ☐ Evidence as an Authorised Prescriber under the Authorised Prescriber scheme (TGA letter of approval)
- ☐ Ethics committee letter of approval
- ☐ Clinical trial protocol
- ☐ Certificate of Analysis
- ☐ Investigator's Brochure
- ☐ Product Information from another jurisdiction

Fax completed form and supporting documentation to the Chief Pharmacist Unit: 02 9424 5860
Enquiries: Tel 02 9391 9944.