Australian Government
Department of Health
Therapeutic Goods Administration

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

# Special Access Scheme – Category B (Medicinal Cannabis NSW)

**Important information**

Please only submit this completed application form to medicinal.cannabis@health.gov.au (preferred) or fax to 02 6232 8112.

**Please note that this application form captures both the relevant requirements for the TGA SAS Category B application and the NSW Health authority application form.**

**You are not required to also provide a copy of this application form to NSW Health.**

**Privacy information**

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The TGA is collecting personal information in this form in order to:

- Assess the application.
- Contact the health practitioner and discuss the application where necessary.

**For the purposes of assessing the application, information on patients and prescribers will be used by and disclosed between the TGA and NSW authorities with responsibility for therapeutic goods or medical practitioner conduct.**

## Patient details

| | | | |
|---|---|---|---|
| **First name** | **Last Name** | **Also known as (alias)** (if applicable) | |
| **Patient Residential Address** | | **Suburb/Town** | **Postcode** |
| **Gender**<br>Male ☐ Female ☐ Intersex/Indeterminate/Unspecified ☐ | **DOB** | **Previous NSW Health Authority Number** (if applicable) | **Previous TGA SAS No.** (if applicable) |
| **Diagnosis(es):** | | | |
| **Indication(s):** | | | |
| **Clinical justification for use of product:**<br>(e.g. details of previous treatment including reasons why a therapeutic good currently included in the ARTG cannot be used in this circumstance) | | | |

## Medicinal cannabis product details

(please attach efficacy and safety data to support proposed use of the product and details of intended monitoring)

| | |
|---|---|
| **Trade Name** | **Sponsor / Supplier** |
| **Active ingredient(s)** | |
| **Dosage form** (e.g. solution, capsule etc) | **Strength** (e.g. 1 mg/mL) |
| **Route of administration** (e.g. oral, inhaled etc) | **Dose & frequency including maximum daily dose** |
| **Duration of treatment** | |

## Place of supply

| | | |
|---|---|---|
| **Name of Pharmacy** | | |
| **Address** | **Suburb/Town** | **Postcode** |

## Prescribing health practitioner details

| | |
|---|---|
| **First name** | **Surname** |
| **AHPRA ID** | **Health practitioner type** |
| **Email** | **Specialty**(if applicable) |
| **Fax** | **Phone** |
| **Principal practice name and address** | |

## Submitter details (if different)

| | |
|---|---|
| **Business or practice name** (e.g. Pharmacy name) | |
| **First name** | **Surname** |
| **Health practitioner type** | **Fax** |
| **Email** | **Phone** |
| **Preferred contact:**<br>☐ Prescribing health practitioner<br>☐ Submitter | **Preferred contact method:**<br>Email ☐ Fax ☐ Phone ☐ |



**By signing this form, I confirm that:**

- **The patient, or the patient's parent or guardian (if applicable), has given his or her consent that that the patient's personal and health information will be collected and used for the purposes of this application and ensuring the lawful supply of the product in accordance with the *Therapeutic Goods Act 1989*;**
- **The patient, or the patient's parent or guardian (if applicable), has given his or her consent that the patient's personal and health information may be disclosed to NSW authorities with responsibilities for therapeutic goods and health practitioner conduct for the purposes of ensuring the lawful supply of the product in that State;**
- **I have notified the patient, or the patient's parent or guardian (if applicable), that their personal and health information may be disclosed by NSW to the Therapeutic Goods Administration; and**
- **I have and will comply with any applicable requirements of the *Children and Young Persons (Care and Protection) Act 1998* and the *Guardianship Act 1987* (both of NSW).**

**Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.**

| | |
|---|---|
| **Prescriber's signature** | **Date** |

**Please send this form to the TGA only**