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>.

Medicinal cannabis products

Declaration of conformity with Therapeutic Goods Order (TGO) 93

Section 1: General information about this form

- This form is used to support applications for the supply of medicinal cannabis products in Australia pursuant to:
  - notifications under the Special Access Scheme (Category A)
  - approvals under the Special Access Scheme (Category B);
  - authorities under the Authorised Prescriber Scheme;
  - approvals under the Clinical Trial Exemption (CTX) Scheme; and
  - notifications under the Clinical Trial Notification (CTN) Scheme.
- Manufacturers of medicinal cannabis products are to complete this form and provide it to persons seeking access to medicinal cannabis products under the above schemes. Persons seeking access (including medical practitioners and clinical trial sponsors) are to submit the completed form to the Therapeutic Goods Administration (TGA) as part of the application or notification process.
- Manufacturers are required to complete this form prior to the supply of any new unapproved medicinal cannabis products in Australia, and also following any material change to medicinal cannabis products (including cannabis plants used in their manufacture) that were the subject of a previous declaration of conformity provided to the TGA where that change could have affected the quality of the products.
- Manufacturers are to:
  - provide the information requested in section 2 (manufacturer details) and section 3 (medicinal cannabis product details); and
  - declare that the medicinal cannabis products mentioned in section 3 conform with the requirements specified in the Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) by signing section 4 (declaration).
- The TGA may request that the manufacturer provide the raw material and finished product specifications at any time. The TGA will not disclose specifications to medical practitioners or any other persons, unless the disclosure is required or authorised by or under law or a court/tribunal order.
- There is a section at the end of the form that should be completed by a clinical trial sponsor if any of the products in section 3 of this form are intended to be supplied through a CTN or CTX.

Section 2: Manufacturer details

Manufacturer name:			
Postal address:			
Contact person:			
Position: (e.g. regulatory affairs officer, agent)			
Email address:			
Telephone number:		Fax number:	

Section 3: Medicinal cannabis product details

Examples of product information required

Name of product (trade name)	Formulation		Dosage form	Route of administration	Shelf-life (closed and open/in-use, if applicable)	Container type and material
	Ingredient(s) (including active ingredient(s) and excipient(s))	Concentration or proportion of ingredient(s) per dosage unit				
Example: XYZ THC/CBD Oral Solution	Example: THC CBD Grapeseed oil	Example: Each bottle contains: THC:CBD (1:1 ratio) 10mg/ml (THC) 10mg/ml (CBD) To 50 mL	Example: Solution	Example: Oral	Example: 2 years at 2-8°C (closed) 7 days at 25°C (open/in-use)	Example: glass bottle
Example: Smithtrade Indica dried cannabis bud (afghani)	Example: THC CBD	Example: Each bud contains: 22.4% (THC) <0.1% (CBD)	Example: Inhalation	Example: Inhaled		Example: LDPE bag
Example: MED CBD and hemp oil Capsules	Example: CBD and hemp oil	Example: Each capsule contains: 15mg (CBD) 375mg (hemp oil)	Example: Capsule	Example: Oral		Example: Al/Al blister pack in cardboard box

Enter the medicinal cannabis product details in the table below:

Name of product (trade name)	Formulation		Dosage form	Route of administration	Shelf-life[1] (closed and open/in-use, if applicable)	Container type and material
	Ingredient(s) (including active ingredient(s) and excipient(s))	Concentration or proportion of ingredient(s) per dosage unit				

Please attach additional pages if there are more than **four** medicinal cannabis products.

[1] The TGA expects the shelf life of the product to be established in accordance with the principles outlined in the relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) quality guidelines adopted by the TGA.

Section 4: Declaration

I **declare** that:

a. I am a person authorised to make this declaration on behalf of the manufacturer mentioned in section 2 of this form;

b. this form, and any attachments to this form, do not contain any information that is inaccurate, false or misleading; and

c. the products mentioned in section 3 of this form conform with the Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis).

I **understand** that giving inaccurate, false or misleading information, or omitting to give information regarding a material particular, is a serious offence.

Name of authorised person:			
Position/relationship to manufacturer: (if different from Section 2)			
Email address:			
Telephone number:		Fax number:	
Signature of authorised person:		Date:	

To be completed by a clinical trial sponsor if any of the products in section 3 of this form are intended to be supplied through a CTN or CTX.

Name of product	TGA Application No.	Protocol No.
Example: XYZ THC/CBD Oral Solution	Example: CT-2017-CTN-03000-1	Example: CBD-THC-1234_Study

Please include additional pages if there are more than **four** medicinal cannabis products that will be supplied through a CTN or CTX.