Australian Government

Department of Health

Deputy Secretary

Ms Gail Wiseman
General Manager
Australian Medicinal Cannabis Association

Email – info@ausmca.org

Dear Ms Wiseman

Changes to sponsors' obligations regarding medicinal cannabis

I writing to inform you of some important changes to medicinal cannabis sponsor obligations. These will reduce regulatory burden for industry and prescribers and take effect from **22 November**:

- removal of the requirement to submit TGO 93 declaration forms to the TGA for products;
- streamlining sponsor six monthly reporting obligations by introducing a new form;
- allowing submission of TGA applications by active ingredient, rather than trade name; and
- publishing a list of medicinal cannabis products on the TGA website.

Further detail on the changes is outlined below. We will also be hosting a webinar on 22 November to answer any questions. Should you wish to attend, please register your interest at Medicinal cannabis - Changes to sponsor requirements for supplying unapproved medicinal cannabis products in Australia.

Removal of requirement to submit the TGO93 declaration form

You will no longer be required to submit product declarations of conformity with the *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (TGO 93).

However, as a sponsor of medicinal cannabis products, you continue to be legally responsible for ensuring that your products comply with the TGO 93, and all other relevant orders. Any breach is subject to a range of regulatory compliance actions, including civil and criminal penalties under sections 14 and 14A of the *Therapeutic Goods Act 1989.*

A larger number of products will be selected for targeted laboratory testing and other compliance assessment as part of our TGO 93 compliance audits. This includes testing for consistency with claims of the stated content of active cannabinoid ingredients, and for the presence of toxins and impurities.

Sponsor six monthly reporting

As part of your ongoing sponsor responsibilities, you are reminded of your six monthly reporting obligations under Regulation 47B of the *Therapeutic Goods Regulation 1990*.

To streamline this requirement a sponsor six monthly report form is included as an attachment to this letter. Please refer to https://www.tga.gov.au/medicinal-cannabis-information-sponsors-and-manufacturers for further guidance in submitting your six monthly report.

Prescribing by active ingredient

To reduce regulatory burden for prescribers, from 22 November 2021, the TGA will accept SAS and Authorised Prescriber submissions for unapproved medicinal cannabis products by active ingredient, rather than by trade name.

Unapproved medicinal cannabis products will be categorised by proportion of cannabinoid content:

Category	Description	Requirements
Category 1	CBD medicinal cannabis product **(CBD ≥98%)**	• Schedule 4 Prescription Only medicine as per the Poisons Standard; • cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; • any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and • the medicine contains no other active ingredients
Category 2	CBD dominant medicinal cannabis product **(CBD ≥60% and <98%)**	• Schedule 8 Controlled Drug as per the Poisons Standard; • cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content; and • the medicine contains no other active ingredients
Category 3	Balanced medicinal cannabis product **(CBD <60% and ≥40%)**	• Schedule 8 Controlled Drug as per the Poisons Standard; • cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content; and • the medicine contains no other active ingredients
Category 4	THC dominant medicinal cannabis product **(THC 60-98%)**	• Schedule 8 Controlled Drug as per the Poisons Standard; • other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise 60% or more and 98% or less of the total cannabinoid content of the medicine; • cannabidiol derived from cannabis comprises 2% or more and less than 40% of the total cannabinoid content of the medicine; and • the medicine contains no other active ingredients

Category 5	THC medicinal cannabis product **(THC >98%)**	• Schedule 8 Controlled Drug as per the Poisons Standard; • cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise more than 98% of the total cannabinoid content of the medicine; • cannabidiol comprises less than 2% less of the total cannabinoid content of the medicine; and • the medicine contains no other active ingredients

Published list of products by category on the TGA website

To assist prescribers and pharmacists with medicinal cannabis prescribing, we will publish a list of products by trade name and their corresponding category of active ingredient. Sponsor details will also be included.

To have your products included in this list initially, please return the attached form by email to medicinal.cannabis@health.gov.au by 17 November 2021. The list will then be updated on a six monthly cycle, based on product data collected from sponsor six monthly reports.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

15 November 2021

Attachment A: Sponsor six monthly report form

Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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>.

Six monthly report – supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the *Therapeutic Goods Regulations 1990*

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	
Address	
Email address	
Phone number	
Name and position of authorised person	

Reporting period for the six months

(Select the period for which this report applies and complete the year)

☐ 1 January – 30 June 20__

OR

☐ 1 July – 31 December 20__

Signature		Date	

Therapeutic goods supplied to health practitioners

Active ingredient/s* (name and strength) or device name	**Trade name**	**Category of cannabinoid content (medicinal cannabis products only)****	**Dosage form*** (where applicable)	**Quantity per dosage unit** (where applicable)	**Quantity of units supplied by pathway** (Not applicable to nicotine vaping products)			
					Special access scheme	**Authorised prescriber**	**Clinical trials**	**Total**

Please attach additional pages as required

* Refer to TGA approved terminology where available

** Categories of medicinal cannabis products are available at Medicinal cannabis: Information for health professionals | Therapeutic Goods Administration (TGA):

- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
- Category 4: THC dominant Medicinal Cannabis Product (THC 60-98%)
- Category 5: THC medicinal cannabis product (THC >98%)

Attachment B: Form to publish product details on the TGA webpage

List of products

Section 1: General information about this form

This form is used in the context of seeking information regarding your unapproved medicinal cannabis product(s) for publication on the TGA website to assist prescribers and pharmacists with medicinal cannabis prescribing under the five active ingredient categories*.

Section 2: Medicinal cannabis product details

Sponsor name	**Active ingredient category* (1-5)**	**Product trade name**	**Concentration or proportion of active ingredient(s) as it appears on the product label** Example: 10mg/mL THC and 10mg/mL CBD	**Dosage form**** Please note you are required to use TGA approved terminology.

***Categories of medicinal cannabis products (further description in letter):**

- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (<60% and ≥40% CBD)
- Category 4: THC dominant Medicinal Cannabis Product (60-98% THC)
- Category 5: THC medicinal cannabis product (>98% THC)

****TGA approved dosage form terminology:**

- Capsule
- Tablet
- Tablet, chewable
- Oral liquid
- Herb (dried)
- Spray, solution
- Topical
- Inhalation, pressurised (Metered Dose Preparation)
- Lozenge
- Patch, dermal
- Pastille
- Wafer