Australian Government
Department of Health
Therapeutic Goods Administration

Medicinal cannabis – Changes to Special Access Scheme (SAS) and Authorised Prescriber applications

Information for health professionals

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TGA Health Safety Regulation

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Welcome

- This webinar is being recorded
- If you need to contact the moderator – please use the **'Chat'** function
- Slides will be made available on the TGA website
- Questions to the **panel** – please use the **Q&A** tool
  - Questions will be answered at the end of the presentation
- Relevant links will be sent to you via the chat function box
- Live poll after presentation – how did we go?.

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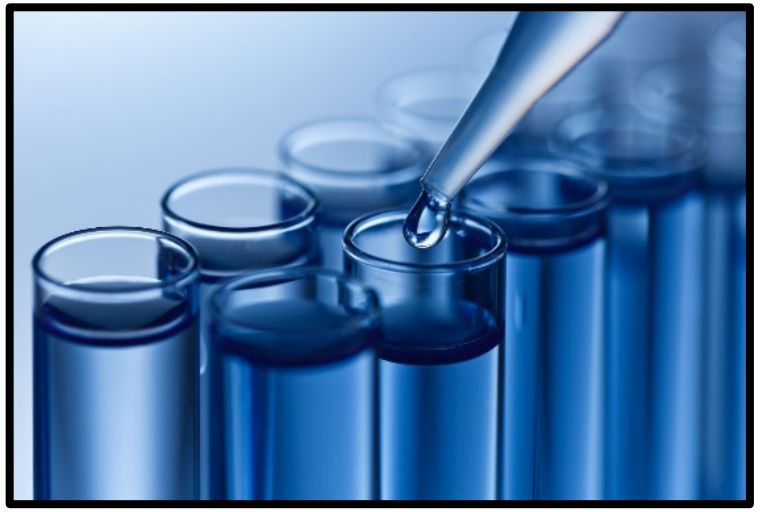
Today's session

- What's changed? The key points
- Active ingredient categories for Special Access Scheme and Authorised Prescriber applications
- Inclusion of certain medicinal cannabis medicines in the Authorised Prescriber "Established history of use' pathway.
- Why were the changes made?
- How will the changes affect current prescribing?
- Walkthrough of applying for access of an unapproved medicinal cannabis medicine via the SAS/AP Online System under SAS and AP 'established history of use' pathway.

What's changed

The key points

- ✓ From 22 November 2021, SAS and Authorised Prescriber submissions for unapproved medicinal cannabis products are made by active ingredient under a category based on cannabinoid content, rather than by brand (trade) name.
- ✓ Inclusion of certain medicinal cannabis products in the Authorised Prescriber Established History of Use pathway
- ✓ Publication of a list of medicinal cannabis products on the TGA website



SAS & Authorised Prescriber submissions by category of active ingredient

Why were the changes made?

- ✓ Reduction in administrative burden for prescribers who determine that an unapproved medicinal cannabis product is clinically suitable for their patient.
- ✓ Allow flexibility in brand substitution when needed, i.e. in the event of a product shortage or discontinuation.
- ✓ Facilitate improved patient access by enabling continuation of therapy in the event of a product discontinuation/shortage.

Active ingredient categories for medicinal cannabis products

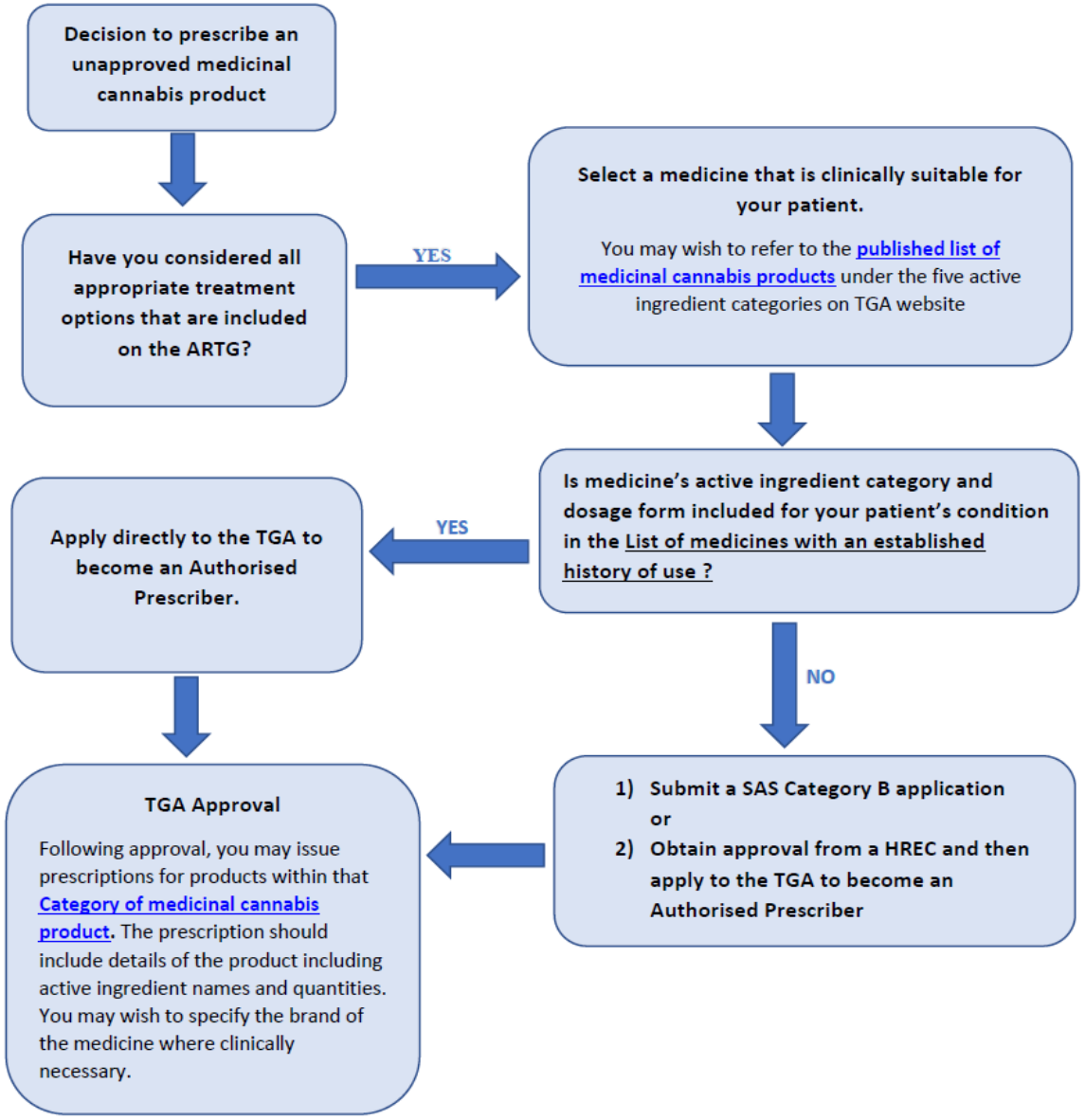
Category	Category description	Category requirements	CBD content by category
Category 1	CBD medicinal cannabis product (CBD ≥98%)	• Schedule 4 Prescription Only medicines as per the Poisons Standard • cannabidiol comprises 98% or more of the total cannabinoid content of the medicine • any cannabinoids, 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 • the medicine contains no other active ingredients	98% Category 1
Category 2	CBD dominant medicinal cannabis product (CBD ≥60% and <98%)	• Schedule 8 Controlled Drugs 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 of the medicine • the medicine contains no other active ingredients	60% Category 2
Category 3	Balanced medicinal cannabis product (CBD <60% and ≥40%)	• Schedule 8 Controlled Drugs 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 of the medicine • the medicine contains no other active ingredients	40% Category 3
Category 4	THC dominant Medicinal Cannabis Product (THC 60-98%)	• Schedule 8 Controlled Drugs 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 • the medicine contains no other active ingredients	2% Category 4
Category 5	THC medicinal cannabis product (THC >98%)	• Schedule 8 Controlled Drugs 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 • the medicine contains no other active ingredients	0% Category 5

Inclusion of certain medicinal cannabis medicines in the Authorised Prescriber "Established history of use" pathway.

Category	Category description	Dosage forms	Indications
Category 1	CBD medicinal cannabis product (CBD ≥98%)	Liquid, capsule	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients
Category 2	CBD dominant medicinal cannabis product (CBD ≥60% and <98%)	Liquid, capsule	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients
Category 3	Balanced medicinal cannabis product (CBD <60% and ≥40%)	Liquid, capsule	(a) treatment of refractory chronic pain in adult patients

How will the changes affect current prescribing?

Information for prescribers



Changes to TGA approval letters

AP letter

Schedule 1:

Details of authority granted under subsection 19(5) of the Therapeutic Goods Act 1989

Reference (MAP21-0000589)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
[redacted]	Authorised Prescriber Estab. Hx-Category 1-CBD medicinal cannabis product (CBD≥98%) - - Oral liquid CBD≥98% Percent Oral Liquid Oral	For the following indication(s): Refractory anxiety in adult patients	

SAS letter

Schedule 1

Reference: MB21-000[redacted]

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
[redacted] (12345679) Test Business Practice for Ayyaz 4 jennifer street Woden ACT 2900	*Medicine:* Category 1-CBD medicinal cannabis product (CBD≥98%) *Product description:* Capsule	*Patient initials:* RD *Patient gender:* Female *Patient DOB:* 12 Jun 1985	*Purpose:* anxiety *Dosage:* .

How will the changes affect current prescribing?

Information for prescribers and pharmacists

1. Consultation with patient

If 'unapproved' medicinal cannabis is deemed clinically appropriate for your patient, select a medicine that is clinically suitable for your patient's condition.

You may wish to refer to the **published list of medicinal cannabis products** under the five active ingredient categories on the TGA website.

2. TGA approval

The SAS/AP Online System is the preferred method of submission to reduce processing times.

As of 22 November 2021, you will be able to apply for an **active ingredient category instead of a specific product (trade name).**

3. Write a prescription for your patient

Write a prescription for your patient in accordance with relevant State and Territory legislation.

Generally, a script should include active ingredient name/s, strength, dosing amount and frequency, quantity of the medication and number of repeats (if applicable). You may wish to specify the brand of the medicine where clinically necessary.

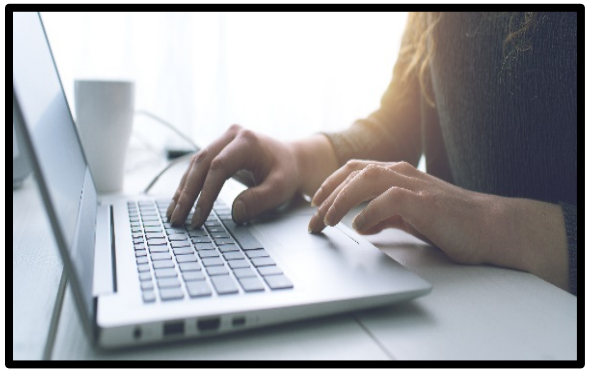
4. Pharmacy

Pharmacists should dispense the medicine in accordance with their relevant state and territory drugs and poisons (or equivalent) legislation.

Product unavailable from sponsor

How to apply

Special Access Scheme and Authorised Prescriber



- Applications are submitted through the SAS and Authorised Prescriber Online System (the System)
- Applications to both TGA and State or Territory Health Department can be submitted simultaneously for SAS B applications
- The online system can be accessed via this link: Special Access Scheme · Custom Portal (https://compliance.health.gov.au/sas)

Reporting side effects

- You are responsible for continually monitoring the use of the therapeutic good you supply under the SAS, AP and clinical trial pathway.
- The TGA has an important role in monitoring the safety of 'unapproved' products.
- The preferred reporting route is via the TGA website

Walkthrough of the SAS & Authorised Prescriber Online System

- Submitting an application to become an Authorised Prescriber for a medicinal cannabis medicine in the **Established history of use list**
- Submitting an application to become an Authorised Prescriber for a medicinal cannabis not included in the established history of use list – **Standard Pathway**
- Submitting a **SAS Category B** application for an unapproved medicinal cannabis product

Where to go for support

- **Webpages** have been updated:
  - Medicinal cannabis: Information for health professionals - Medicinal cannabis: Information for health professionals |
  - Medicinal cannabis: Information for sponsors and manufacturers - Medicinal cannabis: Information for sponsors and manufacturers |
- **Support tools** have been created:
  - Description of the active ingredient categories - Active ingredient categories for medicinal cannabis products |
  - List of medicinal cannabis products by category of active ingredient - Medicinal cannabis products by active ingredients |
  - Authorised Prescriber Scheme List of medicines with an established history of use
- **Guidance documents** have been updated:
  - Authorised Prescriber guidance document: Authorised Prescriber Scheme |
  - SAS Online System guidance - Special Access Scheme (SAS) online system guidance |
  - Authorised Prescribers Online System guidance- Authorised Prescriber Scheme online system guidance |

Petra is currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

LIVE POLL

QUESTIONS

To ask a question,
please use the
Q&A tool

Contact us

Experimental Products Section

medicinal.cannabis@health.gov.au

More information – Social media

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