



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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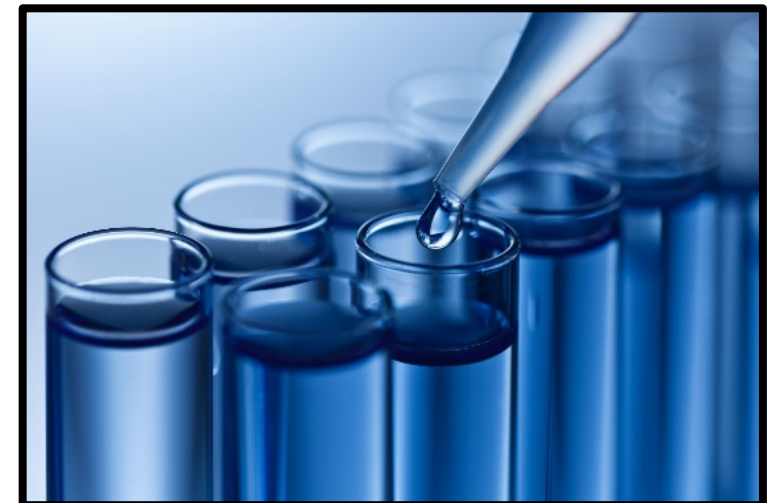
Today's session

- 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%)	<ul style="list-style-type: none"> 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%)	<ul style="list-style-type: none"> 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%)	<ul style="list-style-type: none"> 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%)	<ul style="list-style-type: none"> 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%)	<ul style="list-style-type: none"> 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

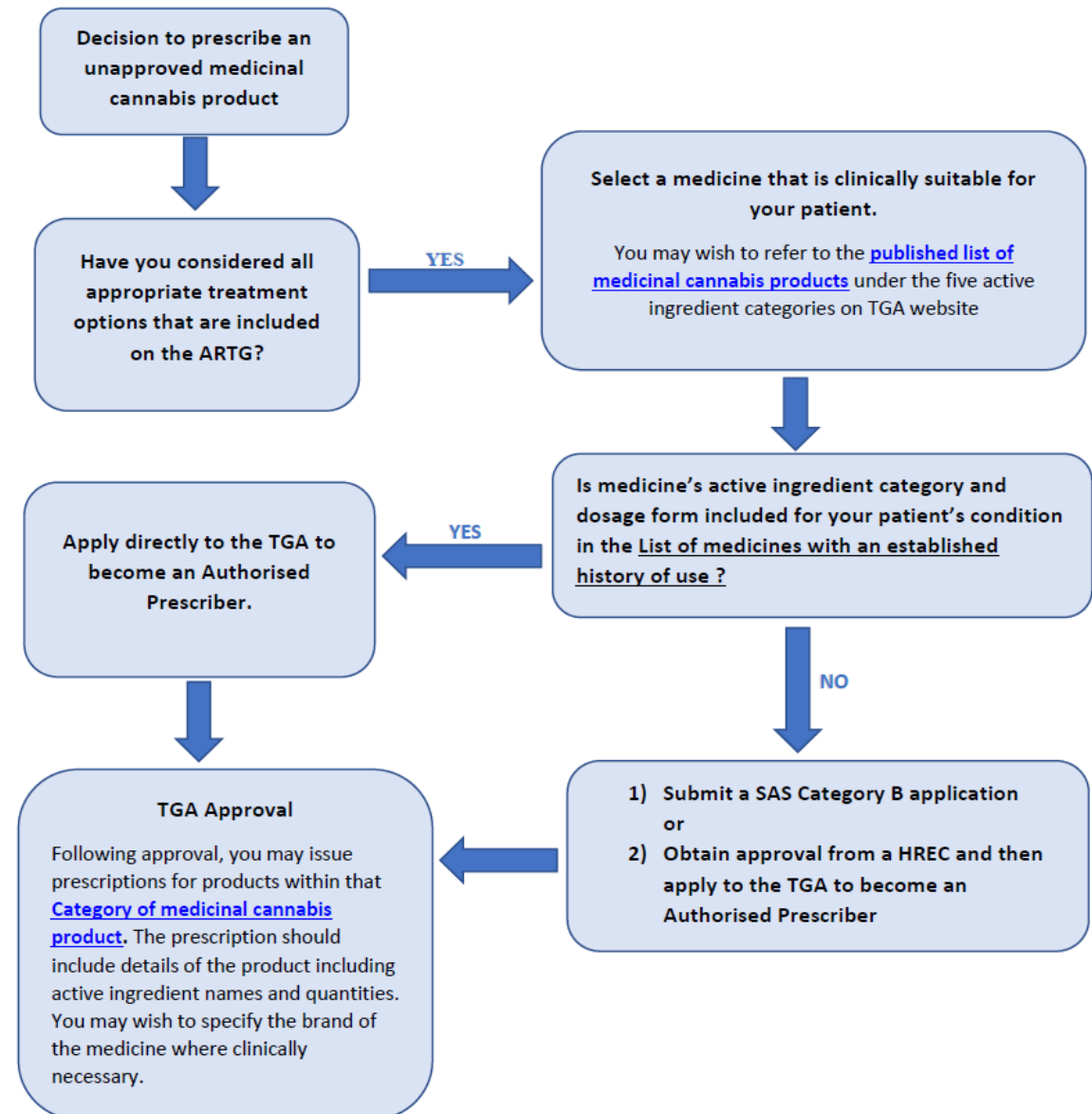
Inclusion of certain medicinal cannabis medicines in the Authorised Prescriber “Established history of use’ pathway.



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)
	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

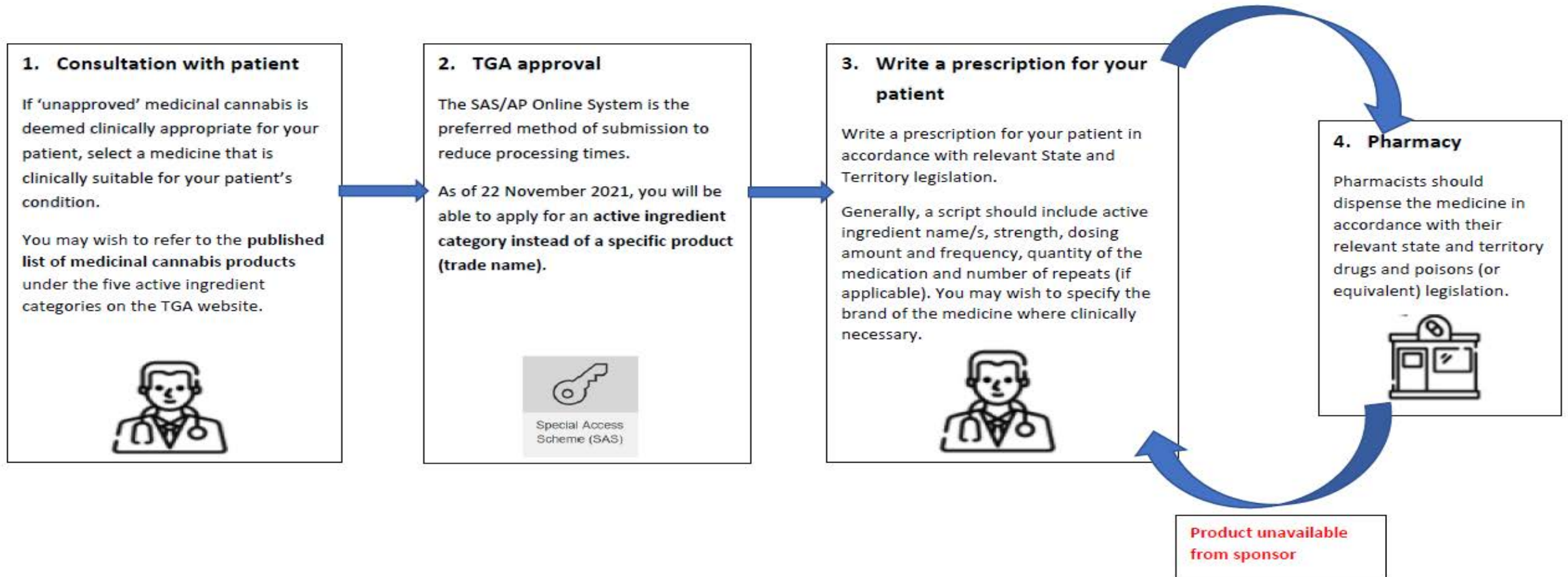
Schedule 1

Reference: MB21-000

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
 (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



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 \(https://compliance.health.gov.au/sas\)](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



More information – Social media

TGA
.gov.au

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	Facebook	https://www.facebook.com/TGAgovau/
	Twitter	https://twitter.com/TGAgovau
	YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
	Topic blogs	https://www.tga.gov.au/blogs/tga-topics
	LinkedIn	https://www.linkedin.com/company/therapeutic-goods-administration/
	Instagram	https://www.instagram.com/tgagovau/?hl=en

Contact us

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