Unapproved Therapeutic Goods

Medicinal Cannabis Consultation, Practitioner Obligations and Patient Understanding

Kristy Tomas
Director
Medicinal Cannabis
Regulatory Reforms Section

Deborah Greenbaum
Assistant Director
Medicinal Cannabis
Regulatory Reforms Section

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Purpose of session

1. Explain the purpose and key findings of the medicinal cannabis consultation
2. Identify gaps in patient understanding and communication opportunities
3. Describe what ‘unapproved therapeutic goods’ are and the available access pathways
4. Understand practitioner obligations when prescribing or supplying unapproved therapeutic goods

Medicinal Cannabis Consultation

Deborah Greenbaum
Assistant director
Medicinal Cannabis Regulatory Reforms Section

Review of unapproved medicinal cannabis products

Why did we consult?

Multiple stakeholders raised concerns about:

1. **Safety risks with THC-containing unapproved medicinal cannabis products**
2. **Large number of patients prescribed medicinal cannabis via the unapproved therapeutic goods pathways (SAS and AP scheme)**
3. Growing ‘product specific’ telehealth and direct-to-consumer businesses prescribing through vertically integrated business models.

TGA is addressing the **first 2 issues**

Submissions received

Gathered input on knowledge, experience, and observations on unapproved medicinal cannabis products in Australia

Stakeholders	Submissions	Percentage of total submissions
Consumers/patients, carers or personal interest	615	78.24%
Registered healthcare professionals	70	8.91%
Sponsors or industry associations	43	5.47%
Special interest groups	24	3.05%
Healthcare professional associations or colleges	12	1.53%
Academics	12	1.53%
Commonwealth or State & Territory Departments	10	1.27%
Total	**786**	100%

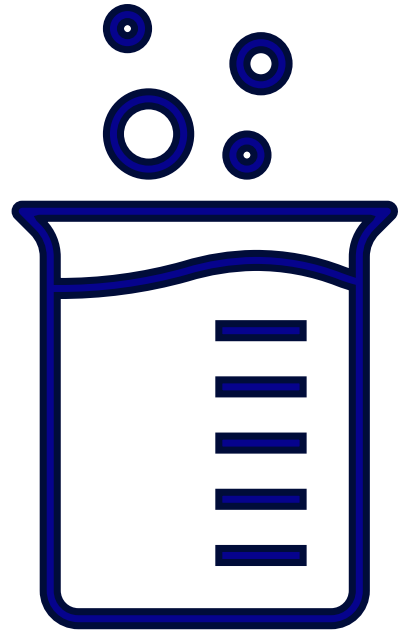
What we heard…

Unapproved status of medicinal cannabis products

- Consumers/patients are unaware that most medicinal cannabis products are **unapproved** and **not assessed** by the TGA for quality, safety or efficacy.

- Access pathways via SAS/AP are no longer fit for purpose.
  - **product volume**
  - **insufficient oversight**
  - **intent of these access mechanisms not appropriate for medicinal cannabis products**.

What we heard…



Safety

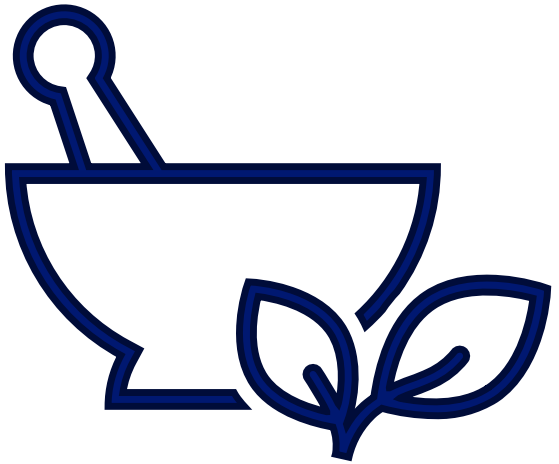
THC concentration limits

- Some did not support setting an upper limit for THC, as ‘safe’ concentrations vary depending on patient group, clinical situation and dosage form.
- Other stakeholders proposed varying ‘safe’ upper limits for THC concentrations based on harm minimisation.
- Many submissions noted that high potency THC products can increase risks of developing psychosis and cannabis use disorder.

CBD and other cannabinoids

- Most stakeholders consider CBD to be well tolerated although some submissions highlighted the potential for adverse events and drug-drug interactions.
- Although CBD was viewed as having a more favourable safety profile compared to THC, stakeholders emphasised the limited availability of high-quality safety and efficacy data.
- Many also noted the current lack of evidence for the use of other cannabinoids.

What we heard…

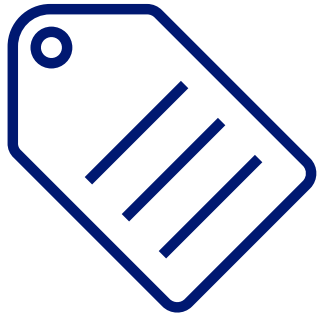


Safety concerns with certain dosage forms/routes of administration

- Stakeholders raised safety risks across all dosage forms, but most concerns related to dried herb (smoking/vaping) and concentrated extracts (for vaping).
- Many highlighted accidental ingestion risk by children of pastilles/gummies due to similar appearance to confectionary and snack food.
- Safety concerns were raised with inhalation (vaping and smoking) of medicinal cannabis as a route of administration.

What we heard…

Product quality and labelling



Greater enforcement of quality standards & labelling requirements:

- Strong stakeholder support for medicinal cannabis products where the quality has been assured.
- Strong support from industry for consistent application and enforcement of quality standards for both domestic and imported products.
- Calls to establish device-specific quality standards.
- Stakeholders would like to introduce:
  - plain packaging
  - standardisation of THC/CBD descriptors
  - mandatory warning statements
  - transparency of registration status
  - Product Information documents
  - child-resistant closures
  - restrictions to inappropriate brand names and packaging.

What we heard…

At risk patient population groups

Paediatric patients

- Strong support for restricting access to THC-containing products, particularly those for inhalation.
- Support for specialist oversight, with calls to consider increasing the age limit from 18 to 25 years due to brain development.

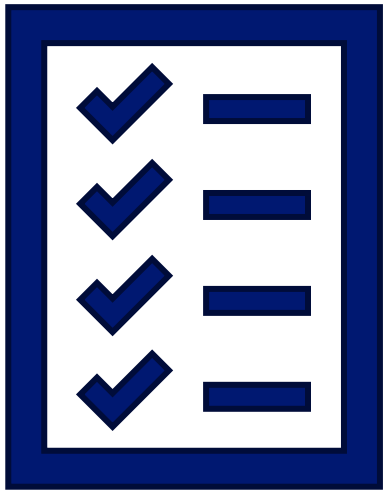
Use in pregnancy or breastfeeding

- Calls to prohibit or restrict access to medicinal cannabis products for those who are pregnant or breastfeeding due to lack of safety evidence.

Other at-risk groups

- Strong caution was recommended for use in patients with a history of mental health conditions, addiction/substance use disorder, cardiovascular issues, the elderly or cognitive impairment.

What we heard…



Scheduling

CBD and other cannabinoids

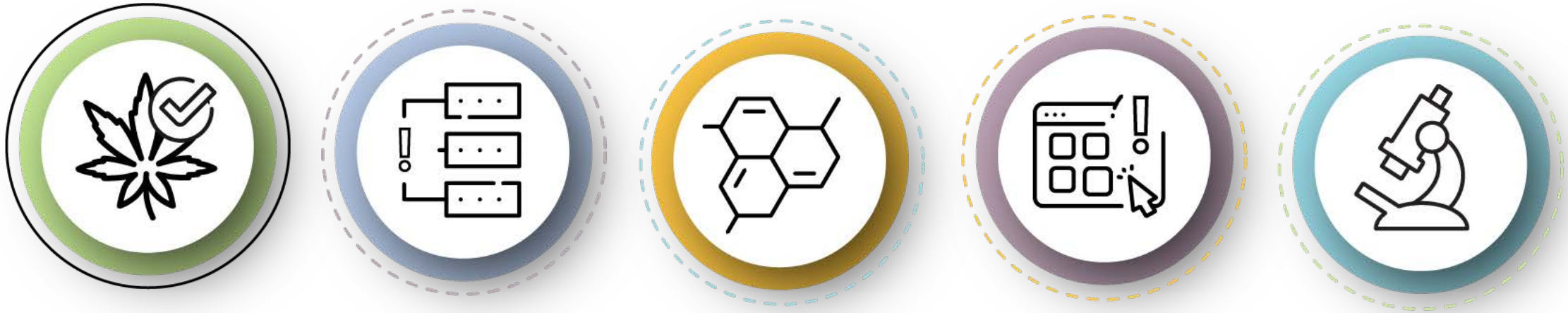
- Some calls for consideration to down-schedule CBD.
- Suggestions for other cannabinoids to have their own entry in the Poisons Standard e.g. CBN (cannabinol), CBG (cannabigerol) and THCV (tetrahydrocannabivarin).

THC

- Strong calls to include limits on THC potency, recognising there are differences based on dosage formas.
- Introduction of restrictions to specialists-only prescribing for certain patient population groups and for high THC concentration products.

Next Steps

While we continue to analyse and consider much needed and supported longer term regulatory reforms, we have identified actions to be undertaken in the short to medium term to reduce potential harm to patients.



Next Steps – the action plan

Short term:

public awareness

Communication activities to raise awareness

Medium term:

risk mitigation

Consider current scheduling arrangements

Long term:

regulatory reform

Regulatory reform options co-developed with stakeholders and recommendations to be considered by government

Practitioner Obligations

Kristy Tomas
Director
Medicinal Cannabis Regulatory Reforms Section

What this session is (and isn't)

☑	☒
Education and clarification	Clinical advice
Regulatory obligations and risks	Endorsement or criticism of prescribing decisions
Patient safety focus	

Key message

If you take one thing away…

Most medicinal cannabis products accessed in Australia are unapproved medicines and have not been assessed by the Therapeutic Goods Administration (TGA) for safety, quality or efficacy.

Role of the TGA

High-level overview

- Regulates therapeutic goods under the Therapeutic Goods Act 1989
- Assesses products for inclusion in the Australian Register of Therapeutic Goods
- Administers legal access pathways for unapproved therapeutic goods
- Does **not** regulate clinical practice

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

The Medicine Access Toolbox

ARTG registration

Approved goods
- Assessed for quality, safety and efficacy

Unapproved goods
- Have **not** been assessed for quality, safety and efficacy

Special Access Scheme

A **B** **C**

Authorised Prescriber

Standard **Reg 12B(1B) & 12B(1C)**

Personal importation

Section 19A

Clinical trials

Extemporaneous compounding

Where medicinal cannabis fits

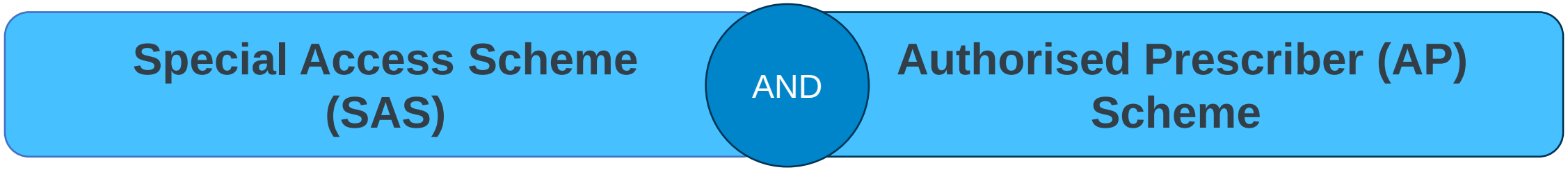
Most medicinal cannabis products are unapproved

- Only 2 medicinal cannabis products are included in the ARTG.
- Majority of products are supplied via:
    - Special Access Scheme (SAS)
    - Authorised Prescriber (AP) Scheme
- These pathways enable access (**not approval**)

Common misconceptions we see/hear

- ‘The TGA approved my application, so the product is approved’
- ‘It’s widely prescribed, so it must be assessed’
- ‘Responsibility sits with the sponsor and/or regulator’

What really happens



Special Access Scheme – three possible pathways

Allows access to unapproved therapeutic goods for an individual patient

Category A

Notification pathway accessed by a medical practitioner for a patient who is "**seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment**."

Category B

Application pathway that can be accessed by a health practitioner for a patient that does not fit the Category A definition and where the unapproved therapeutic good is not authorised for supply under the Category C pathway. An approval letter from the TGA is required before the product can be supplied to the patient.

Category C

Notification pathway that allows specified health practitioners to supply unapproved therapeutic goods from a list of products deemed to have an established history of use. This list is reviewed and updated annually.

Special Access Scheme Category C (medicines)

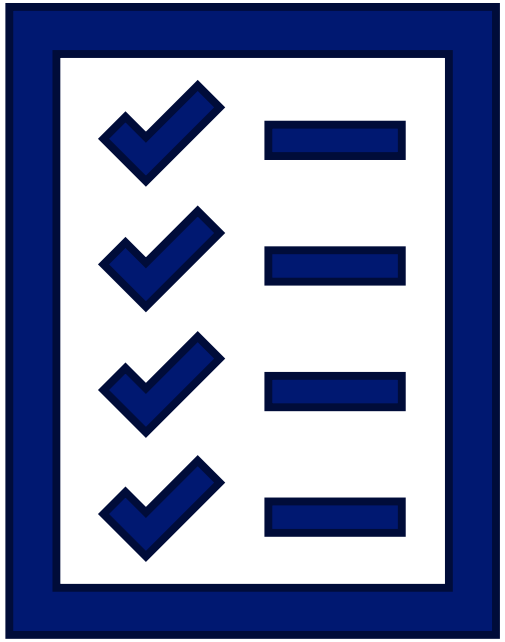
Medicines

Search: Show 10 entries

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hypokalemia	Medical Practitioner	M160
Betaxolol 0.25% (preservative free), Eye drops, Opthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bismuth subcitrate, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M7
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126

Special Access Scheme Category B pathway

- Provides a legal access pathway for a health practitioner to access an unapproved therapeutic good for an individual patient.
- The TGA does not conduct an in-depth clinical assessment.
- The major criteria for determining whether to approve supply of the good relate to the patient, the medicine and the prescriber.
- Approvals are specific for an active ingredient (or active ingredient category for medicinal cannabis).
- The TGA often does not have oversight of the actual product being accessed.



Special Access Scheme (SAS)

Single patient access per application/notification

The SAS pathways:

Category A – Medical practitioners who wish to immediately supply a product for a seriously ill patient

Category C – Certain health practitioners can immediately supply products that have been deemed to have an established history of use by the TGA

Not available for medicinal cannabis

Category A and C are notification pathways.
The TGA must be notified within 28 days of supply to the patient.

Category B – For Health practitioners who are unable supply the product through the Category A or C pathway. Approval required **before** supply.

Generally, approvals are for 2 years

Notifications and approvals are specific to patient, prescriber, product and indication

Authorised Prescriber Scheme – two possible pathways

- Allows medical practitioners access to unapproved therapeutic goods for a class of patients with a particular medical condition.
- An authorised prescriber can supply the product directly to a patient under their immediate care without requiring separate approval for individual patients.

Established history of use pathway

- 12B(1B) – Unapproved therapeutic goods with an established history of use for the indication listed
- 12B(1C) – Unapproved medicinal cannabis products/indications with an established history of use

Standard pathway (HREC pathway)

- All other unapproved therapeutic goods (including medicinal cannabis)
- Requires HREC approval of Specialist college letter of endorsement

Authorised Prescriber Scheme established history of use

Authorised Prescriber established history of use products

Search:

Show 10 entries

Active ingredient	Dosage form	Route of administration	Indication	Code
Allergens – multiple, various (including control solutions)	Drops	Skin prick	Confirmation of suspected allergic reactions	AP3
Allergens— multiple, various (including control solutions)	Drops	Intradermal	Confirmation of suspected allergic reactions	AP2
Amiloride	Tablet	Oral	Treatment of hypokalemia	AP158
Argipressin	Injection	Intravenous	To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines	AP147
Argipressin	Injection	Intravenous	Treatment of uterine fibroids	AP157

Medicinal cannabis products

Search:

Show 10 entries

Active ingredient category and circumstances	Dosage form	Route of administration	Indication	Code
Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%) Circumstances: • a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and • b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and • c) the medicine contains no other active ingredients	capsule	oral	Treatment of refractory anxiety in adult patients	AP138
Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)	liquid	oral	Treatment of refractory sleep	AP166

Authorised Prescriber (AP) Scheme

Multiple patient access per application

The AP pathways:

Established history of use pathway - Medicines that can be accessed through this pathway are specified in Sub regulation 12B(1B) and 12B(1C) of the Therapeutic Goods Regulations 1990.

Standard pathway - Human Research Ethics Committee (HREC) or Specialist College Endorsement is required before applying to the TGA.

Generally, approvals are between 2 to 5 years.

Approvals are specific to prescriber, product and indication.

Where responsibility lies

- The TGA administers pathways to allow access to unapproved therapeutic goods in certain situations

However,

- Medicolegal responsibility sits with the prescribing health practitioner

Relevant to both SAS & AP pathways.

Prescriber responsibilities

- The applicant must have considered appropriate treatment options included in the ARTG prior to applying to access unapproved goods.
- They should provide appropriate clinical justification (not based on cost or convenience).
- The prescriber takes on responsibility for outcomes (including adverse events) of the treatment and is responsible for obtaining informed patient consent.
- Adverse event reporting.
- The TGA is not involved in actual supply arrangements.

Detailed guidance on '**Meeting your professional responsibilities**' is provided by AHPRA and the National Boards

AP reporting requirements

Regulation 47B of the Therapeutic Goods Regulations

01 January to 30 June and 01 July to 31 December (reports must be received within 1 month of the reporting period ending).

Prescribers must report for all their AP approvals:

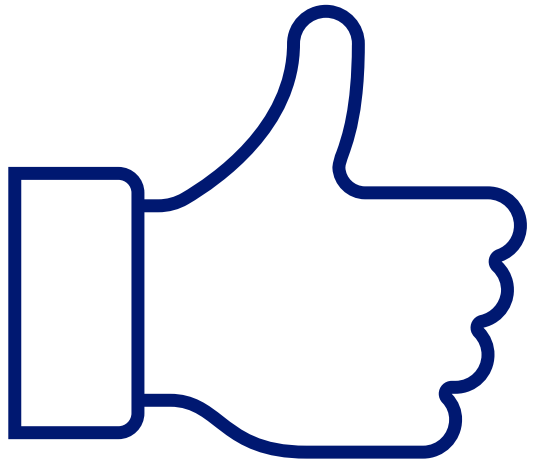
- Patients commenced use of the unapproved product in the six-month period and
- Total number of patients on the treatment in the reporting period.

Informed patient consent

Heightened importance for unapproved goods

Informed consent should be documented and include clear discussion with the patient about:

- the medicinal cannabis product being unapproved and not included on the ARTG.
- the limited evidence for safety and efficacy and any potential risks and adverse events.
- potential drug interactions with other medicines the patient is taking.
- alternative treatment options, including products on the ARTG.
- any financial costs, access arrangements, and implications of ongoing treatment.
- the patient's ability to ask questions and withdraw consent at any time.

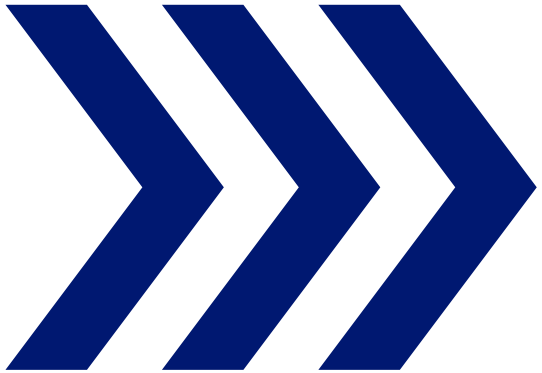


What patients should understand

- What is meant by ‘unapproved’
  - i.e. The product has not been evaluated by the TGA for quality, safety, or efficacy **even with SAS or AP approval in place**
  - Evidence may be limited or evolving
- Alternative approved therapies have been considered

Key takeaways for practice

- Most medicinal cannabis products accessed in Australia are unapproved therapeutic goods
- Access ≠ Approval
- Clinical and legal responsibility sits with the prescriber
- Clear patient understanding and informed consent are critical



Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration