Medicinal cannabis access pathways: FAQs for prescribers

1. Why does medicinal cannabis require AP or SAS approval?

The Therapeutic Goods Administration (TGA) is responsible for ensuring that the therapeutic goods available for supply in Australia are safe and fit for their intended purpose. The TGA also has a responsibility to encourage the use of medicines that are included in the Australian Register of Therapeutic Goods (ARTG), as these products have been evaluated to ensure they meet strict standards of safety, quality and effectiveness.[1]

Most medicinal cannabis products in Australia are unapproved therapeutic goods, not included on the ARTG. The TGA has not assessed them for safety, quality or effectiveness. The Authorised Prescriber (AP) Scheme and Special Access Scheme (SAS) provide pathways for access if you wish to prescribe an unapproved medicinal cannabis product for your patient.[2]

2. What should I consider before using the AP or SAS scheme to access an 'unapproved' therapeutic good for my patient?

Before prescribing an 'unapproved' therapeutic good, you must consider the following prerequisites:[3]

- Relevant 'approved' therapeutic goods (those registered, listed or included on the ARTG) have been trialled or considered and found clinically unsuitable.
- The specific 'unapproved' therapeutic good is NOT:
  - substantially similar to any product included on the ARTG, or
  - if substantially similar, the approved therapeutic good is NOT currently marketed ('available') for supply in Australia.

As the prescribing health practitioner, you are primarily responsible for the decision to use an 'unapproved' therapeutic good for the patient, noting you have appraised the particular circumstances of that patient. When prescribing unapproved therapeutic goods, you are required to adhere to the relevant standards of good medical practice. Good medical practice: a code of conduct for doctors in Australia is published by the Medical Board of Australia for registered medical practitioners. Other health practitioners should refer to their appropriate governing body for further information and guidance.[3]

The TGA cannot guarantee the quality, safety and effectiveness of unapproved products accessed via the AP or SAS pathways.[3]

3. What do I need to tell patients?

Before you consider prescribing an unapproved medicinal cannabis product, you should inform your patient:[3-5]

- that the product is not approved in Australia and (potentially) other countries
- that the quality, safety and efficacy have not been assessed by the TGA
- about the possible benefits of treatment
- about any known risks and side effects
- about available alternative treatments for their condition that use approved products.

Adequate knowledge of the condition being treated, the treatment options, the likelihood of recovery and long-term prognosis is necessary for your patient to be able to make an informed decision regarding treatment with an unapproved medicinal cannabis product.[3,5]

The use of unapproved medicinal cannabis products is considered experimental. You must obtain informed consent from the patient (or the patient's legal guardian) before applying to the TGA to access a medicinal cannabis product. Informed consent should be freely given by the patient (or their legal guardian) and obtained in line with good medical practice.[3,5]

It is best practice to:[4,5]

- obtain informed consent in writing unless there are good reasons to the contrary
- provide a copy of the informed consent form template to the Human Research Ethics Committee (HREC) or specialist college, if required
- keep the signed informed consent form on the patient's profile.

You should not submit informed consent forms to the TGA.[3,4]

4. How do I apply using the online system?

The SAS and AP online system is the preferred method of submission. This allows you to submit applications to both the TGA and the relevant state or territory health department (if required) at the same time. The TGA will send you a single correspondence containing both the TGA and state or territory decision letter within 48 hours (2 business days).[6]

You need to register an account to access the online system's dashboard to submit an AP or SAS application.

Table 1: Summary of AP and SAS applications via the online system[7,8]

Details	AP – established history of use pathway	AP – standard (HREC) pathway	SAS B application
Log in	▸ Log in to the online system ▸ Go to '*Authorised Prescriber Dashboard*' ▸ Click on '*+New AP application*'		▸ Log in to the online system ▸ Go to '*SAS Dashboard*' ▸ Click on '*+New SAS submission*'
Prescriber	▸ The prescriber details will be pre-populated from the account		
Product	▸ **Therapeutic Good Type:** select '*Medicine*' ▸ **Is the product:** select '*Included in the Established History of Use list*' ▸ **Active ingredient/ product name:** select *one of the three active ingredient categories* ▸ **Dosage form:** select '*oral liquid*' or '*capsule*'	▸ **Therapeutic Good Type:** select '*Medicine*' ▸ **Is the product:** select '*Any other product*' ▸ **Active ingredient/ product name:** select from *one of five active ingredient categories* ▸ **Dosage form:** select from available options ▸ **Additional information:** attach the relevant HREC documentation	**Product selection** ▸ **Therapeutic Good Type:** select '*Medicine*' ▸ **Active ingredient(s):** select from *one of five active ingredient categories* ▸ **Dosage form:** select from available options ▸ **Indication:** select from available options or enter free text ▸ **Do you need to notify or apply to a state or territory health department?** If '*YES*', choose the relevant state/ territory ▸ **Would you like to submit a category A notification?** Select '*No*' for a SAS B application **Product details** ▸ **Dosage and frequency:** prefilled with '*As per prescription*' ▸ **Expected duration of treatment:** SAS B approval is valid for 24 months ▸ **Intended date of supply:** enter as required
Approval/ endorsement	▸ **Indication:** enter free text (must be included in the Established History of Use list)	▸ **HREC/specialist college:** enter HREC or endorsing college details ▸ **Indications:** enter exactly as per HREC/specialist college letter	
Patient			▸ Enter **Patient details**, **Diagnosis(es)**, **Clinical justification**, **Consideration of other ARTG products** and **Intended monitoring details**
Summary	▸ Acknowledge that you have read and understood the privacy statement and consent and click '*Submit*' to send application to the TGA for review		

For more information:

- AP scheme online system guidance
- AP applications quick reference guide for medicinal cannabis
- SAS online system guidance
- SAS applications quick reference guide for medicinal cannabis

5. What is appropriate to write on a prescription?

You are responsible for providing prescriptions in accordance with relevant state and territory legislation, and the TGA approval. Prescriptions for medicinal cannabis products:[6]

- must include active ingredient name(s), strength, dosing amount and frequency
- must include quantity and number of repeats (if necessary)
- may include brand (trade) name if clinically necessary
- should include details regarding the preparation of the extemporaneously compounded product if relevant
- may include any other formulation details if clinically necessary.

6. Is brand substitution allowed?

AP and SAS applications for medicinal cannabis products are made by active ingredient rather than brand (trade) name. Each product falls under one of five categories based on cannabinoid content.[9]

You may wish to refer to the List of medicinal cannabis products by active ingredient category.

The medicinal cannabis prescribing pathway allows products to be switched within the approved active ingredient category and dosage form as the clinical need of your patient changes. You do not need to apply for a new approval each time.[10]

Flexibility in brand substitution is useful, such as in the event of a product shortage or discontinuation.[11]

You may indicate on the prescription that brand substitution is not permitted if you wish to order a specific brand.[12]

As for any other prescription, pharmacist decisions regarding brand substitution, or whether a new prescription is required, should be made in consultation with the prescriber and the patient.[12]

7. How do the changes affect my current approval for a brand (trade) name product?

SAS Category B and AP approvals received prior to November 2021 are valid for the duration specified on the approval letter. Approvals remain valid as long as the conditions of approval are upheld.[4,13]

If you wish to substitute for different brands or write prescriptions for different products, you can apply to become an AP for the active ingredient category with a new approval application. Alternatively, you may apply through the SAS Category B pathway for a category-based approval.[14]

All existing AP approvals require 6-monthly reporting data to be submitted to the TGA.[4] If you currently hold trade name-based approvals and category-based approvals, you are required to report on both. To avoid regulatory burden and duplication, you may wish to withdraw all trade name-based approvals in writing to: authorised.prescribers@health.gov.au.

8. Do I need to apply separately for various routes of administration, dosage forms or indications within the same category?

Applications are made for one category, for one dosage form, for a specific indication. If you wish to prescribe a product with a different route of administration, dosage form or indication within the same category, you will need to apply for a separate application.[7,8]

SAS B applications are made for one indication on a patient-by-patient basis. While there are no restrictions on the medical conditions for which you may apply, you need to have the appropriate knowledge on the condition being treated and the medicinal cannabis product you wish to prescribe. The TGA may request supporting evidence for some novel indications.[14]

Multiple indications may be approved for AP applications depending on the pathway used. Prescribers can apply for AP approval via the standard (HREC) pathway for more than one indication if the indications are exactly the same as the corresponding indications on the HREC approval letter or specialist college endorsement letter.[7]

9. How do I prescribe for paediatric patients?

If you are a medical practitioner, you can apply to become an AP of medicinal cannabis for a class of patients for a particular condition. This includes paediatric patients (aged 18 years and under). However, this class of patients must be listed on the HREC approval letter or specialist college endorsement. It must also be listed on the AP application.[7]

10. Can I prescribe an extemporaneously compounded product?

From 28 April 2022, you can only prescribe an extemporaneously compounded medicinal cannabis product based on approvals under either the AP or SAS pathway. You are required to make AP or SAS submissions on the basis of the active ingredient category of cannabinoid content and the dosage form of the final extemporaneously compounded product.[6]

11. Do I need to enrol in a certain course to be able to prescribe medicinal cannabis?

No. However, if you wish to apply to become an AP of medicinal cannabis products not included in the List of medicinal cannabis medicines with established history of use, you must obtain approval from a HREC or endorsement from a specialist college before applying to the TGA.[14]

12. As an AP, why do I need to report to the TGA every 6 months?

It is a legal requirement of the AP scheme that you provide reports on the number of patients treated, for each of your AP approvals, for the periods 1 January to 30 June and 1 July to 31 December. You must send reports within 1 month of each reporting period ending. A report is required even if you have not treated any patients in the relevant period.[4]

The two categories for reporting are:[4]

- number of new patients commenced on treatment
- number of total patients treated during this period (new patients plus patients continued on treatment).

The preferred reporting method is through the SAS and AP online system. Failure to comply with the conditions of the AP scheme may result in revocation of AP status.[4]

13. Can I apply for approval to prescribe in more than one category?

The TGA accepts SAS and AP submissions for medicinal cannabis products by active ingredient, rather than brand (trade) name. Each product falls under one of five categories based on cannabinoid content.[9]

You can potentially access any unapproved medicinal cannabis product under the SAS or AP scheme. Applications are made for one category, for one dosage form, for a specific indication. It is your responsibility to specify which product you wish to access.[5] If you wish to apply for approval to prescribe in more than one category, a separate application needs to be submitted for each category.

Further information

- Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE)
- Australian Prescriber: Medicinal cannabis
- NPS MedicineWise: Medicinal cannabis resources
- NSW Cannabis Medicines Advisory Service
- TGA: Guidance for the use of medicinal cannabis in Australia: Overview

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