



Australian Government
Department of Health
Therapeutic Goods Administration

Special Access Scheme (SAS) Applications - Quick Reference Guide

Medicinal cannabis

Version 1.1, June 2022

TGA Health Safety
Regulation



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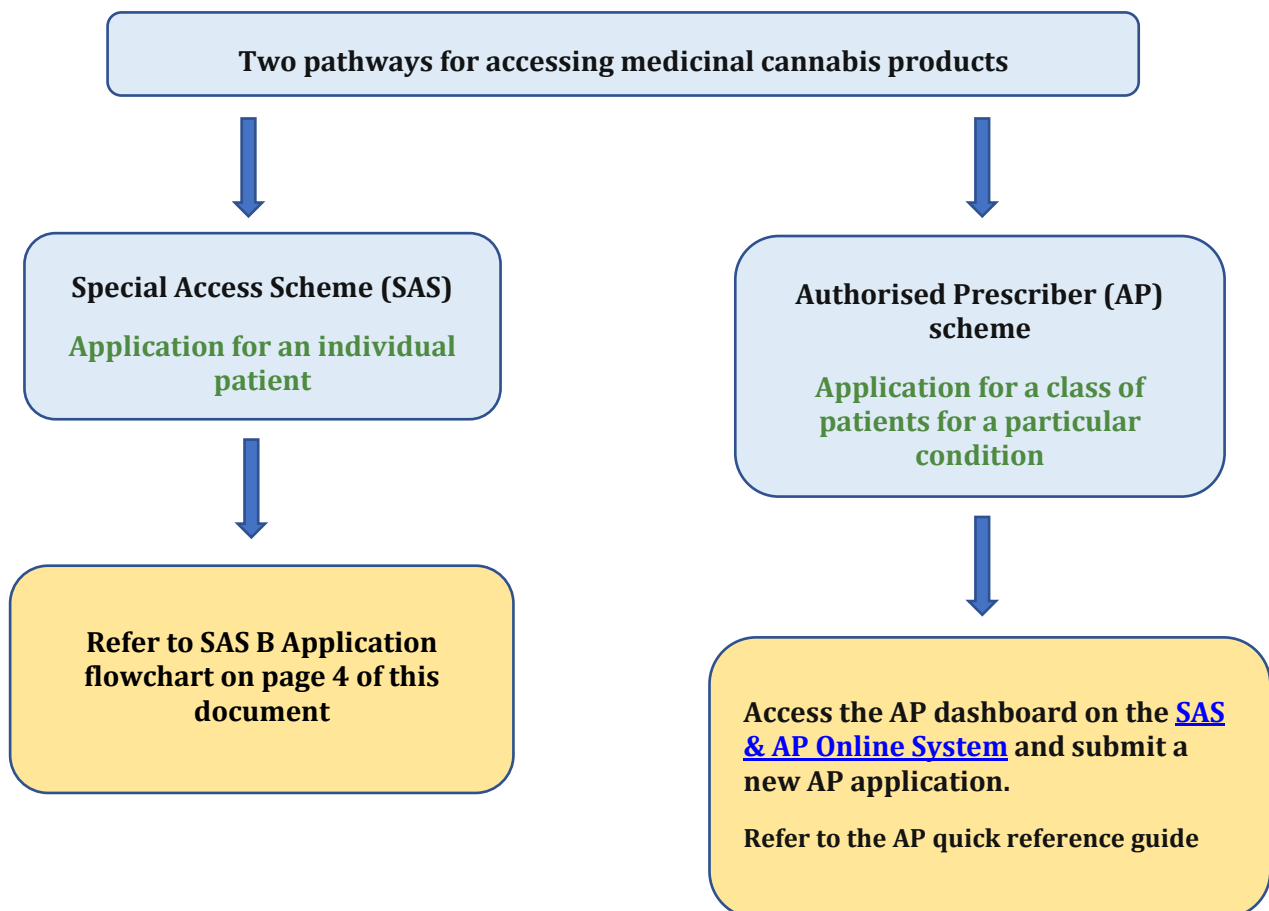
Introduction

The Special Access Scheme (SAS) quick reference guide is a tool to assist health professionals in using the SAS and Authorised Prescriber (AP) online system to submit SAS B applications to access unapproved medicinal cannabis products for their patients.

This guide is to be read in conjunction with the [Special Access Scheme \(SAS\) online system guidance](#) document available on the TGA website.

From 22 November 2021, SAS applications for medicinal cannabis products are only accepted by **active ingredient category** rather than by trade names. For general information on access pathways available for medicinal cannabis, refer to '[Accessing medicinal cannabis for a patient](#)' on the TGA website.

To support health professionals in prescribing and supplying medicinal cannabis products, TGA has published a [list of available medicinal cannabis products](#) by active ingredient. Sponsor details are also included to facilitate patient access.



Special Access Scheme (SAS) B Applications

Log in to the [SAS & AP online system](#), go to 'SAS Dashboard' and click on '+New SAS submission'

The prescriber details will be pre-populated from the account if you are the prescriber.

Note: The contact details can be amended before continuing.

Therapeutic Good Type – Select *Medicine*

Active ingredient(s) – select from one of the [five medicinal cannabis product categories](#)

- Category 1-CBD medicinal cannabis product (CBD≥98%)
- Category 2-CBD dominant medicinal cannabis product (CBD≥60% and less than 98%)
- Category 3-Balanced medicinal cannabis product (CBD less than 60% and ≥40%)
- Category 4-THC dominant medicinal cannabis product (THC 60-98%)
- Category 5-THC medicinal cannabis product (THC greater than 98%)

Dosage form – Select from the options available.

Indication – Select from the options available. If the required indication is not available, there is a free text option.

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.

Dosage and Frequency – Prefilled with 'As per prescription'. This field is editable if necessary.

Expected duration of treatment – SAS B approval for a medicinal cannabis product is valid for 24 months.

Intended date of supply – Enter as required.

Note: Trade name & Sponsor/supplier are non-mandatory fields.

Enter **Patient details, Diagnosis(es), Clinical justification and Intended monitoring details**. There is also an option to attach any additional supporting information in this section.

Have you considered other ARTG Products? Select Yes or NO

Acknowledge that you have read and understood the privacy statement and consent and click on 'submit' to send the application to TGA for review.

Prescriber details

Product selection

Product details

Patient details

Summary

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	International Regulatory Branch	March 2022
V1.1	Guidance updated based on system changes.	Special Access Section (SAS); International Regulatory Branch (IRB)	June 2022

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Reference/Publication #