Australian Government
Department of Health
Therapeutic Goods Administration

Authorised Prescriber (AP) Applications - Quick Reference Guide

Medicinal cannabis

Version 1.1, June 2022

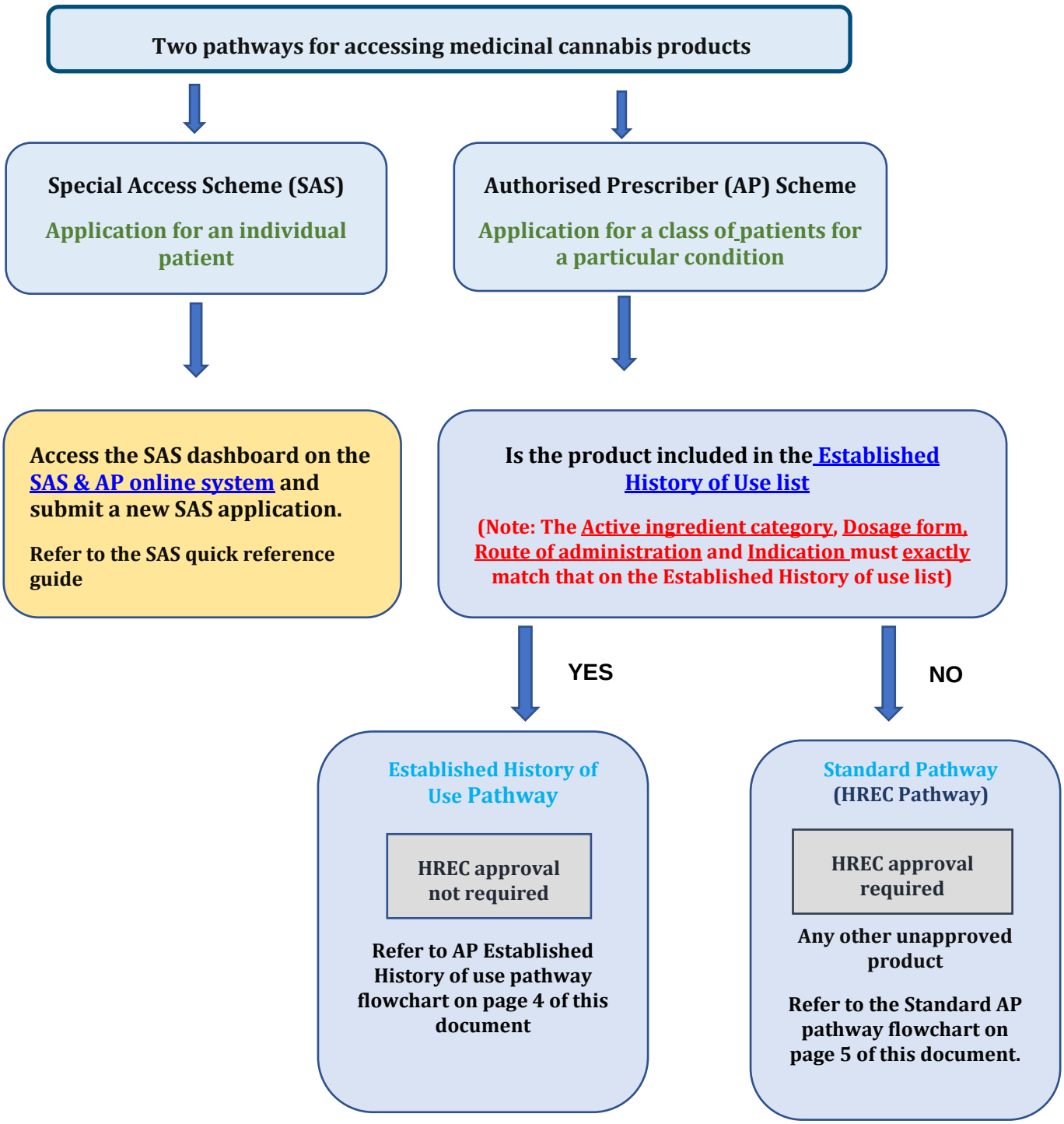
TGA Health Safety Regulation

Introduction

The Authorised Prescriber (AP) quick reference guide is a tool to assist medical practitioners in using the Special Access Scheme (SAS) and AP online system to submit AP applications to access an unapproved medicinal cannabis product.

This guide is to be read in conjunction with the Authorised Prescriber Scheme online system guidance document available on the TGA website.

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



Established History of use pathway

Log-in to the SAS & AP online system, go to **'Authorised Prescriber Dashboard'** and click on

'+New AP application'

Prescriber details

The prescriber details will be pre-populated from the account information.

Note: The contact details can be amended before continuing.

Product

- **Therapeutic Good Type –** Select **Medicine**
- **Is the product –** Select **Included in the TGA's Established History of Use list**
- **Active ingredient/product name -** Select one of the **three AP active ingredient categories**

- **Dosage form – Select oral liquid or capsule**

Note: Product Strength, Trade name, Sponsor/supplier details & Additional information sections are non-mandatory fields.

Approval/ endorsement

Indication

This is a free text section. Please type the indication for which you are seeking approval.

Note: The indication must be included in the established history of use specified list for the selected product category.

Summary

ARTG product consideration- Select Yes or NO

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

Standard Pathway (HREC Pathway)

On SAS & AP online system, go to **'Authorised Prescriber Dashboard'** and click on

'+New AP application'

The prescriber details will be pre-populated from the account information.

Note: The contact details can be amended before continuing.

- **Therapeutic Good Type –** Select **Medicine**
- **Is the product –** Select **Any other product**
- **Active ingredient/product name –** select from one of the five **active ingredient categories**

- **Dosage form –** Select from the available options
- **Additional Information-** Attach the relevant Human Research Ethics Committee (HREC) documentation.

Note: Product Strength, Trade name and Sponsor/supplier details are non-mandatory fields.

- **Human Research Ethics Committee (HREC) approval/Specialist College-**Enter the HREC or endorsing college details
- **Indications-** Enter indication(s) exactly as the corresponding indication approved/endorsed by the HREC/Specialist College in their letter**.**

ARTG product consideration- Select Yes or NO

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

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 #