



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Special Access Scheme (SAS)

Special Access Scheme & Authorised Prescriber Scheme Online System User Guide

Version 2.0, May 2026

OFFICIAL

OFFICIAL

Copyright

© Commonwealth of Australia 2026

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Online system overview _____	5
Terminology and definitions _____	5
Features of the SAS & authorised prescriber online system _____	6
Account management _____	7
Account registration _____	7
Health practitioners _____	11
Non-health practitioners _____	12
Change Password _____	12
Updating account information _____	15
Affiliated sites _____	16
Purpose _____	16
Site registration _____	16
Adding a site administrator(s) _____	19
Sending invitations to affiliate _____	20
Requesting to affiliate with a site _____	22
Approving or rejecting a request to affiliate with a site _____	24
SAS/AP validation search tool _____	25
User dashboards _____	25
Filtering dashboard information _____	26
Exporting submission data _____	26
Cloning submissions _____	26
Draft submissions _____	27
Completed submissions _____	28
Status of completed submissions _____	28
Downloading receipts and outcome letters _____	29
Expiring and expired submissions _____	29
Submitting SAS applications and notifications _____	30
Step 1 – Prescriber details _____	31

Step 2 – Product selection	32
Step 3 – Product details	36
Step 4 – Patient details	37
Step 5 – Summary	38
Submitting S3 products as a pharmacist	39
Medicinal cannabis submissions	45
When not to use the system to submit medicinal cannabis applications	45
Notifying or applying to a state or territory health department via the system	45
TGA contact details	49

Online system overview

The Special Access Scheme (SAS) & Authorised Prescriber (AP) Online System (the system) allows Health Practitioners to submit SAS applications and notifications. The system is designed to reduce administrative burden and provide health practitioners and organisations such as hospitals with additional reporting and management functions to assist in the management of their SAS applications and notifications.

This document provides users of the system with guidance about how to use the system. To reduce processing times, healthcare practitioners are strongly encouraged to submit submissions through the online system.

If you wish to access information regarding the submission of Authorised Prescriber applications via the online system, please refer to the [Authorised Prescriber Scheme Online System User Guidance](#).

For information regarding the Special Access Scheme, please refer to:

[Special Access Scheme: Guidance for health practitioners](#)

[Special Access Scheme: Guidance for sponsors](#)

Terminology and definitions

Terminology	Definition
Account	Upon successful registration in the system, each user will have created an 'account' which is accessible using their credentials (username and password) selected as part of the registration process.
Affiliation	Where a user has successfully been accepted by a Site Administrator to affiliate with a site providing ability to 1) share submissions with the site; and 2) view submissions shared with the site by other users in their dashboard.
Affiliated Site	Creation of a site of practice within the system (such as a hospital or pharmacy department) to which system users may affiliate (by way of request or invitation from a Site Administrator). Once users become affiliated, they will then have the ability to share submissions with that site.
Outcome letter	The Approval or Rejection letter provided by the TGA in response to SAS Category B applications.
Receipt	A copy of the SAS Category A or SAS Category C notification form which can be downloaded via a user's dashboard.
Request for Information (RFI)	The process by which the TGA requests additional information to be provided by the user after submission of an application.
Share	Upon being affiliated with a site, a user has the option to make the SAS submission visible to other users who are also affiliated with that site. Sharing submissions will result in other users of the affiliated site to see that submission in their dashboard.
Site Administrator	A system user who initially registered a site. The user will have the ability to invite other users to affiliate with that site, accept/reject requests to affiliate with that site; remove a system user's affiliations from that site, and invite other affiliated users to become Site Administrators.

Features of the SAS & authorised prescriber online system

- Registered health practitioners are required to register an account before they can begin drafting and submitting SAS applications and notifications to the TGA.

The system allows [health practitioners](#) to submit on behalf of the prescribing health practitioner. However, medicinal cannabis submissions must be made by the prescribing health practitioner.

- Users have a dashboard within their account to:
 - Track the status of their application (in the case of SAS Category B).
 - Search previously submitted applications and notifications for reporting purposes using parameters such as patient details, therapeutic good, prescriber, submission date and status (i.e. approved, rejected, withdrawn, completed).
 - Download a PDF copy of the application or notification to be saved locally.
 - Identify applications and notifications that are expiring (i.e. duration of supply is running out) or that have expired
 - Download a copy of the TGA decision letter in the case of SAS Category B applications.
 - Clone (copy) previously submitted SAS submissions.

Account management

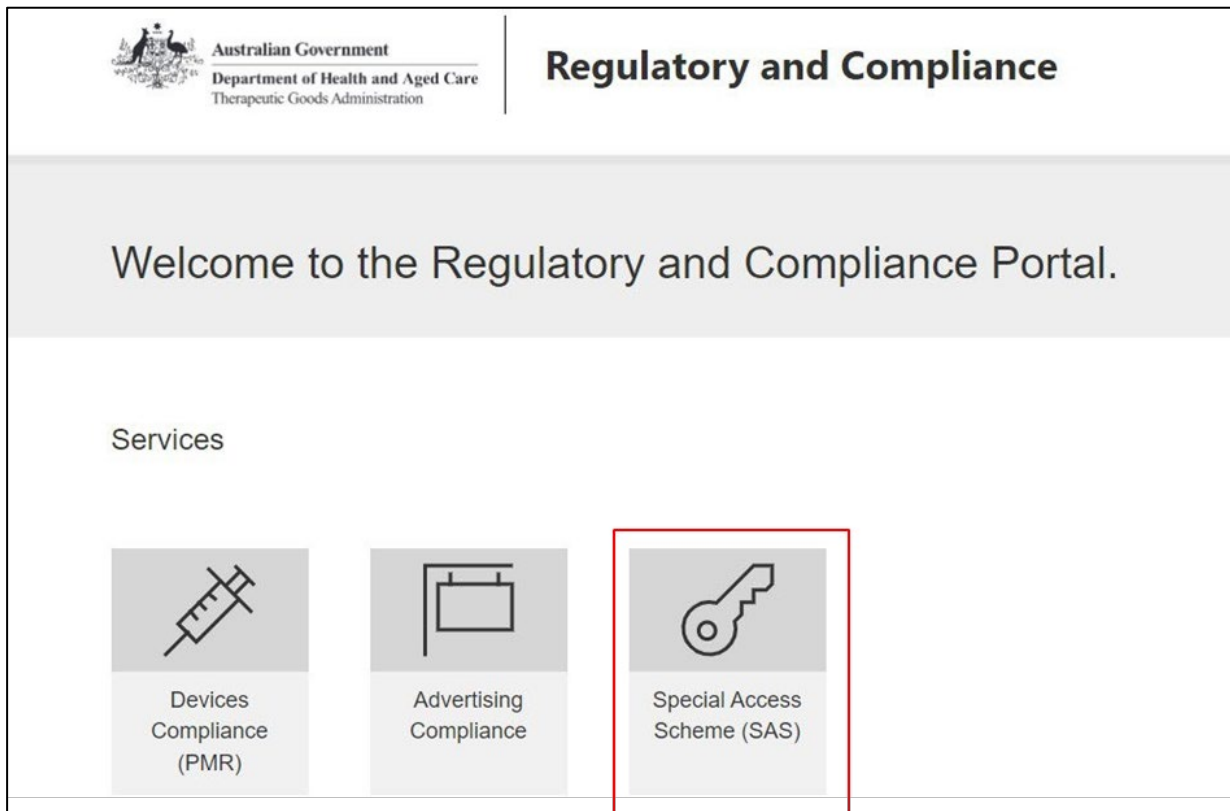
Account registration

All users of the system are required to register a personal account. Users are required to provide the following information to successfully register an account:

- A unique username; password; email address (for the purposes of account registration).
- Personal information such as full name; health practitioner type (if applicable); contact details (this will be used to populate the user's profile).
- **Step 6 must be completed to submit applications/notifications.**

Note: users who have registered with other systems hosted by the TGA should attempt to login (rather than register) using the username and password to which they registered with the first TGA system.

1. To register a personal account, select Special Access Scheme (SAS) from the [Regulatory and Compliance Portal home page](#)



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Regulatory and Compliance

Welcome to the Regulatory and Compliance Portal.

Services

- Devices Compliance (PMR)
- Advertising Compliance
- Special Access Scheme (SAS)**

2. Select 'Register Now'.

Log In Register now

Special Access Scheme & Authorised Prescriber Scheme Online System

The TGA has a responsibility to encourage the use of therapeutic goods 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.

The [Special Access Scheme \(SAS\)](#) and the [Authorised Prescriber \(AP\) scheme](#) allow certain registered health practitioners to access 'unapproved' therapeutic goods for patients under their care.

Prescriber responsibilities and conditions

- Use in exceptional circumstances where the prescribing health practitioner has first considered other appropriate treatment options included in the ARTG.
- Adhere to relevant standards of good medical practice and obtain informed patient consent.
- [Report adverse events or defects](#) associated with the use of the 'unapproved' therapeutic goods to the TGA.

Scheme	Submission overview	Resources for technical support
Authorised Prescriber	<ul style="list-style-type: none"> Medical practitioners only AP applications and prescriber six-monthly reporting data AP applications for 'unapproved' nicotine vaping products without the need for ethics committee approval 	<ul style="list-style-type: none"> AP online system guidance document Medicinal cannabis applications - AP quick reference guide Nicotine vaping products: Information for prescribers
Special Access Scheme	<ul style="list-style-type: none"> Certain registered prescribing health practitioners SAS Category A and C notifications and Category B applications SAS applications for access to 'unapproved' medicinal cannabis products to the TGA and certain State or Territory Health Departments simultaneously 	<ul style="list-style-type: none"> SAS online system guidance document Medicinal cannabis applications - SAS quick reference guide Medicinal cannabis: Information for health professionals

If you require support please send an email to SAS@health.gov.au.

3. Provide a unique username; password; email address (for the purposes of account registration).

Register

Password requirements

- Your new password must be different to your last 8 passwords
- Your password can only be changed once per day
- Your password must not contain your account name
- Your password must be a minimum of 14 characters.
- Your password must be a maximum of 127 characters.
- Your password may contain:
 - English uppercase characters (A-Z)
 - English lowercase characters (a-z)
 - Numbers (0 through 9)
 - Most non-alphabetic characters, including spaces e.g. ! @ # \$ % ^ & * () < > ? , ; : " ' / \

As a suggestion, make use of a passphrase. Passphrases are made up of four or more random words making them longer than a traditional password. This makes them harder to guess but easy to remember. Passphrases should be long, unpredictable, and unique.

Username

Email

Password

Confirm password

Register >

A registration confirmation email will be sent to your nominated email address.

Confirm registration

You will receive an email shortly with a link to confirm your registration.

This link will expire in 24 hours.

- 4. Click on the hyperlink in the email (note this link will expire 24 hours after receiving this email).

Thank you for registering an account with the online system for the Special Access Scheme (SAS). To complete your registration you need to activate your account. Please click on this link to activate your account:

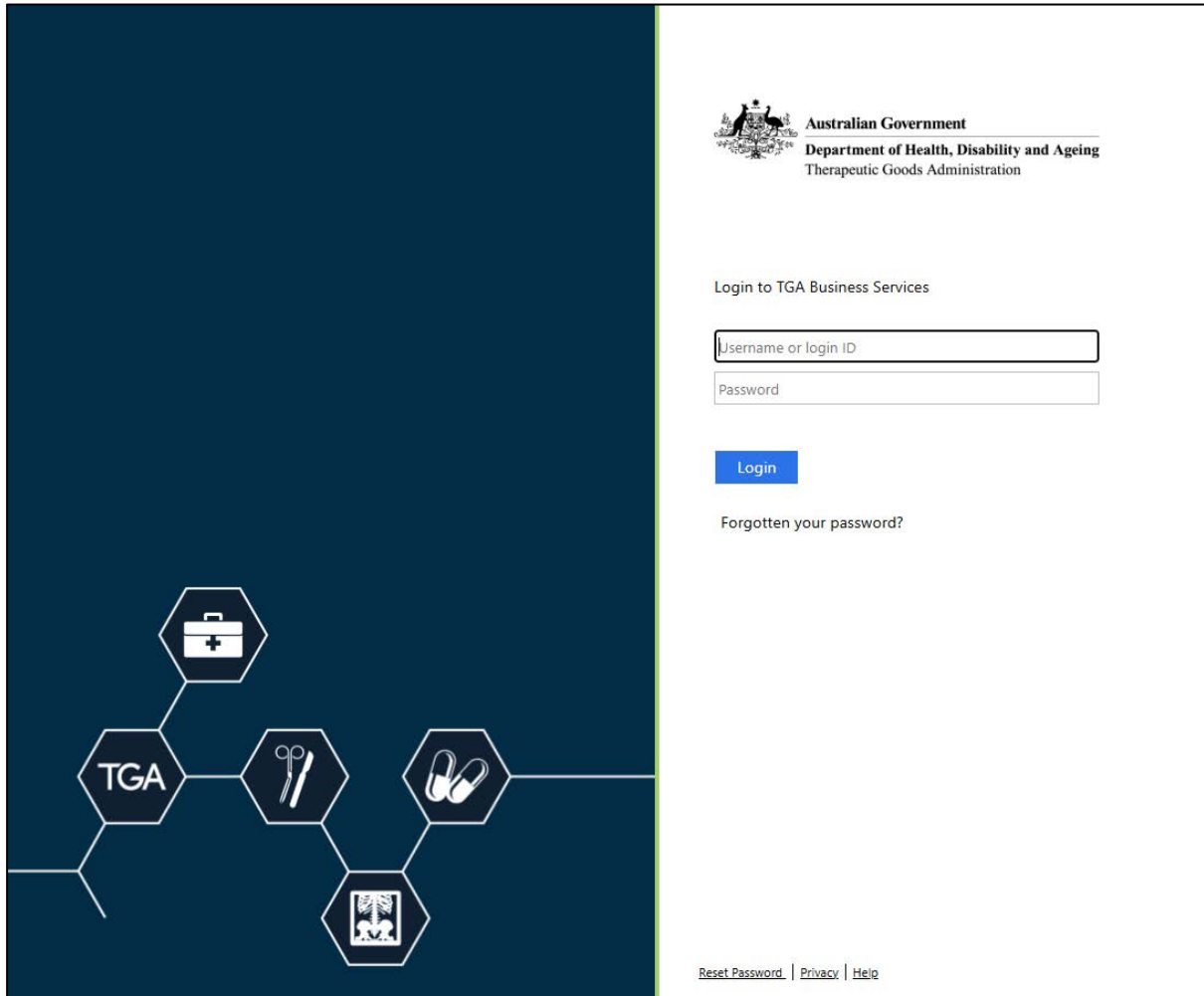
<https://apps.tga.gov.au/portalaccounts/account/activate/3a1a806c-9f3e-40dc-8e43-41cb8cb3b9ca/288580002>

This link will expire in 24 hours.

Any new password created must be a minimum of 14 characters.

Please contact the TGA if you believe there has been a mistake.

- 5. Log in with your username and password.



- 6. Complete your profile's information. Your account registration is not finalised until you complete this step, and you will not be able to submit applications/notifications.

My profile

Personal Details

Title *

First Name *

Last Name *

Preferred Name

Address and Contact Details

Business or Practice Name * **Phone ***

Address Line 1 * **Fax**

Address Line 2 **Email *** ExampleEmail@email.com

Suburb *

Australian State *

Postcode *

Health Practitioner Details

Do you have an AHPRA registration number? *
 No Yes

AHPRA Number *

 Your AHPRA number has been successfully validated

Practitioner Type *

Prescriber Specialty

Health practitioners

Upon registration of an account, health practitioners will have the ability to draft and submit SAS applications and notifications to the TGA. In the account registration process, users will be presented with the following question to determine their health practitioner status. If you have incorrectly responded to these questions, Contact SAS.Support@health.gov.au as they cannot be updated from your profile.

Health Practitioner Details

Do you have an AHPRA registration number? *

No Yes

AHPRA Number *

Practitioner Type *

Prescriber Specialty

Health practitioners registering an account in the system will be asked to provide their AHPRA registration number. The AHPRA registration number should be entered exactly as it appears in the AHPRA public register, including the three-letter prefix (i.e. MED1234567890).

Note: Those health practitioners able to submit SAS applications and notifications to the TGA are defined in the *Therapeutic Goods Act 1989*. This definition is as follows:

“**Health practitioner** means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

- Aboriginal and Torres Strait Islander health practice
- dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist)
- medical
- medical radiation practice
- nursing
- midwifery
- occupational therapy
- optometry
- pharmacy
- physiotherapy

- podiatry
- psychology”

Non-health practitioners

Upon registration of an account, non-health practitioners will not be able to draft or submit applications to the TGA. This is in accordance with the relevant provisions of the *Therapeutic Goods Act 1989* (the Act) and associated regulations relevant to the SAS. However, non-health practitioner users will be able to affiliate with a site to view the progress of submissions made to the TGA in their user dashboards (see [‘Affiliated Sites’](#) section for further information).



Health practitioners

Have the ability to draft and submit SAS applications and notifications to the TGA, including the submission of applications and notifications on behalf of prescribing health practitioners.

Non-health practitioners

Do not have the ability to draft and submit SAS applications and notification to the TGA however may have oversight of applications and notifications being made by their affiliated site.

Change Password

Passwords will expire every 90 days as per the security requirements policy of the Department of Health, Disability and Aged Care.

1. Select the ‘Change password’ option from the dropdown menu in your user profile. Alternatively, this can also be done when attempting to login to the system.



2. Enter your new password.

Password guide

- Your new password must be different to your last 8 passwords
- Your password can only be changed once per day
- Your password must not contain your account name or more than two consecutive characters of your full name
- Your password must be a minimum of 14 characters.
- Your password must be a maximum of 127 characters.
- Your password may contain:
 - English uppercase characters (A-Z)
 - English lowercase characters (a-z)
 - Numbers (0 through 9)
 - Most non-alphabetic characters, including spaces e.g. !@#\$%^&*()<>?.,;:~"/\

As a suggestion, make use of a passphrase. Passphrases are made up of four or more random words making them longer than a traditional password. This makes them harder to guess but easy to remember. Passphrases should be long, unpredictable, and unique.

Current password

New password

Confirm new password

Change password >
Cancel

Note: Passwords cannot be reset or changed more than once in a 24-hour period.

If you are locked out of your account for 24 hours, please do not attempt to reset the password until after the time has lapsed otherwise the lockout period will be reset. Once the lockout has lapsed follow the steps to reset your password.

Forgotten your password

1. If you have forgotten your password, select “log in”.

Log In
Register now

Special Access Scheme & Authorised Prescriber Scheme Online System

The TGA has a responsibility to encourage the use of therapeutic goods 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.

The [Special Access Scheme \(SAS\)](#) and the [Authorised Prescriber \(AP\) scheme](#) allow certain registered health practitioners to access 'unapproved' therapeutic goods for patients under their care.

Prescriber responsibilities and conditions

- Use in exceptional circumstances where the prescribing health practitioner has first considered other appropriate treatment options included in the ARTG.
- Adhere to relevant standards of good medical practice and obtain informed patient consent.
- Report adverse events or defects associated with the use of the 'unapproved' therapeutic goods to the TGA.

Scheme	Submission overview	Resources for technical support
Authorised Prescriber	<ul style="list-style-type: none"> Medical practitioners only AP applications and prescriber six-monthly reporting data AP applications for 'unapproved' nicotine vaping products without the need for ethics committee approval 	<ul style="list-style-type: none"> AP online system guidance document Medicinal cannabis applications - AP quick reference guide. Nicotine vaping products: Information for prescribers
Special Access Scheme	<ul style="list-style-type: none"> Certain registered prescribing health practitioners SAS Category A and C notifications and Category B applications SAS applications for access to 'unapproved' medicinal cannabis products to the TGA and certain State or Territory Health Departments simultaneously 	<ul style="list-style-type: none"> SAS online system guidance document Medicinal cannabis applications - SAS quick reference guide Medicinal cannabis: Information for health professionals

If you require support please send an email to SAS@health.gov.au.

2. Select "Forgotten your password?".

3. Enter your username and select "Reset".

4. A password reset email will be sent to the email address associated with your username.

5. Click on the hyperlink provided to reset your password (note this link will expire in 24 hours after receiving this email).

Hi there,

A request was made to reset your password for the online system for the Special Access Scheme (SAS). Please follow this link to reset your password:
<https://apps.tga.gov.au/portalaccounts/password/set/288580002/83637c68-c896-44a5-9f26-e54113a117a3>.

The above link will expire in 24 hours.

Any new password created must be a minimum of 14 characters. A new successful password may take up to 30 minutes to activate.

Please contact the TGA if you believe there has been a mistake.

6. Enter your new password.

Reset password

Password guide

- Your new password must be different to your last 8 passwords
- Your password can only be changed once per day
- Your password must not contain your account name or more than two consecutive characters of your full name
- Your password must be a minimum of 14 characters.
- Your password must be a maximum of 127 characters.
- Your password may contain:
 - English uppercase characters (A-Z)
 - English lowercase characters (a-z)
 - Numbers (0 through 9)
 - Most non-alphabetic characters, including spaces e.g. ! @ # \$ % ^ & * () < > ? , ; . " ' / \

As a suggestion, make use of a passphrase. Passphrases are made up of four or more random words making them longer than a traditional password. This makes them harder to guess but easy to remember. Passphrases should be long, unpredictable, and unique.

New password

Confirm new password

Reset password >

Note: Passwords cannot be reset or changed more than once in a 24-hour period.

If you are locked out of your account for 24 hours, please do not attempt to reset the password until after the 24 hour lockout time has lapsed otherwise the lockout period will be reset. Once the lockout has lapsed follow the steps to reset your password.

Updating account information

Once an account has been registered in the system, users will be able to update the information associated with their account (such as name and contact details) by updating their user profile.

If your health practitioner details (AHPRA Number, Prescriber Specialty, or Practitioner Type) need changing, please reach out to SAS.Support@Health.gov.au

Regulatory and Compliance

Example Account -

- Profile
- My invitations
- Change password
- Sign out

Home SAS Home Page SAS Dashboard Affiliated Sites AP Dashboard AP Reports SAS/AP Submissi

Affiliated sites

Purpose

To enable better oversight and management of applications and notifications submitted via SAS, the system allows users to share applications and notifications with other users who are affiliated under a Site (such as those working at a particular hospital or pharmacy). In sharing applications and notifications with a particular Site, other affiliated users can then identify those submissions and access any documentation that may be relevant to the procurement of the good (such as copies of approval letters).

Site registration

Any user may register a Site in the system. It is important to note that the user who registers a Site will automatically become the Site Administrator. Site Administrators can:

- Send invitations to affiliate with the Site via email.
- Accept or reject requests to affiliate with the Site.
- Edit the details of the affiliated Site (Site name, location information etc).
- Assign other users as Site Administrators (assuming they have successfully affiliated). To register a new site in the system, follow the below instructions:

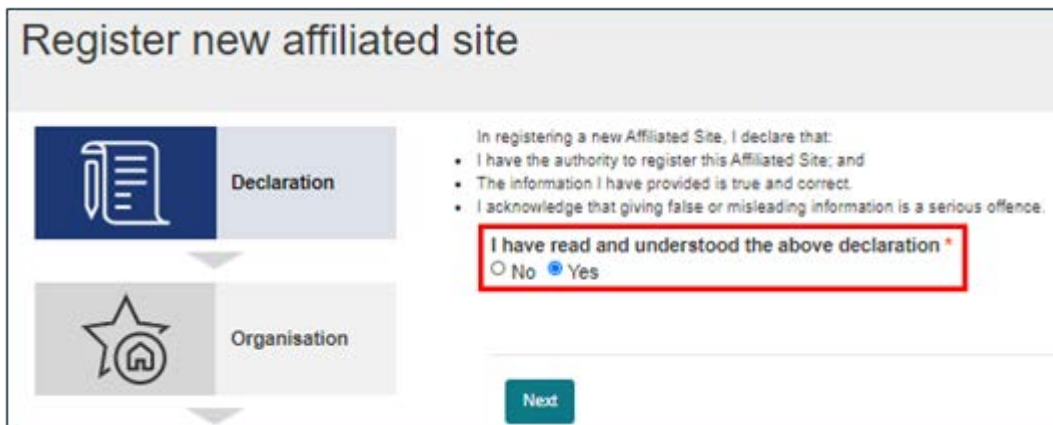
1. Select the 'Affiliated Sites' tab.



2. Select 'Register a new site'.



3. Read and acknowledge the following declaration.



- 4. Select the lookup icon to search for the organisation you wish to register the Site against.

Register new affiliated site

Your new affiliated site needs to be associated with a known organisation. Please search for your organisation using the look up below. You can search for your organisation using its name or ABN. Please contact the TGA if you cannot find your organisation.

Organisation Name *

This data is current as of 07/07/2017. Please refer to the Australian Business Register if you require further information about your organisation. If you are unable to identify your organisation's name or Australian Business Number(ABN) please email SAS@health.gov.au and provide relevant details.

- 5. New organisations need to be added to the Online System. If your organisation is not available, please email SAS@health.gov.au with the Organisation Name and ABN so that it can be added to the look-up function. Once complete, this will allow users to then select that organisation and register an Affiliated Site(s).

Lookup records

To search on partial text, use the asterisk (*) wildcard character

<input checked="" type="checkbox"/> Name ↑	ABN	Name Type
<input checked="" type="checkbox"/> Example Hospital Name	6549849846	Main Entity Name

- 6. Once the organisation has been selected, provide the additional details associated with the Site you wish to register. It is important to note that the 'Site Name' is different from that of the organisation name. Multiple Sites may be registered under a single organisation (for example, a hospital may wish to register individual departments under the single organisation, resulting in various Sites). Once the Site name has been entered, the system will validate the uniqueness of the name to ensure no other Sites exist that also use that name.

The screenshot shows a registration form with a sidebar on the left containing four steps: Declaration, Organisation, Site details, and Review. The 'Site details' step is currently active. The main content area contains the following fields and information:

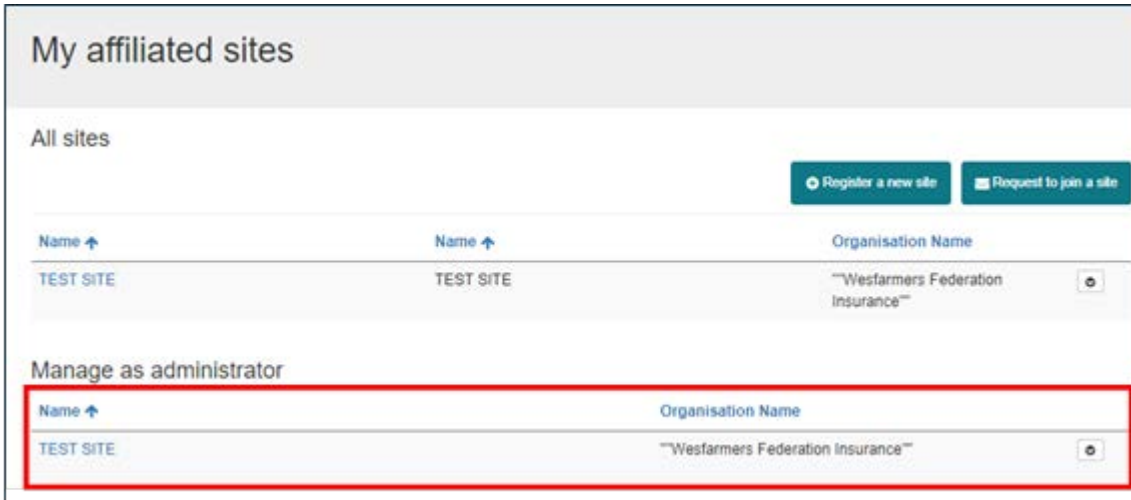
- Organisation Name ***: ""Wesfarmers Federation Insurance""
- Site Name ***: TEST SITE
- Validation Message**: Your site name has been successfully validated
- Location details**
 - Suite/Room/Office**: (empty field)
 - Address Line 1 ***: TEST ADDRESS
 - Address Line 2**: (empty field)
 - Suburb ***: SYDNEY
 - State ***: NSW (dropdown menu)
 - Postcode ***: 2000
- Navigation**: Previous (disabled), Next (active)

- 7. Review the details before registering the Site.

The screenshot shows the same registration form as in step 6, but now in the 'Review' step. The sidebar highlights the 'Review' step. The main content area displays the following information:

- Message**: Please review your site details below before submitting
- Organisation Name ***: ""Wesfarmers Federation Insurance""
- Site Name ***: TEST SITE
- Location details**
 - Suite/Room/Office**: -
 - Address Line 1 ***: TEST ADDRESS
 - Address Line 2**: -
 - Suburb ***: SYDNEY
 - State ***: NSW
 - Postcode ***: 2000
- Navigation**: Previous (disabled), Submit (active)

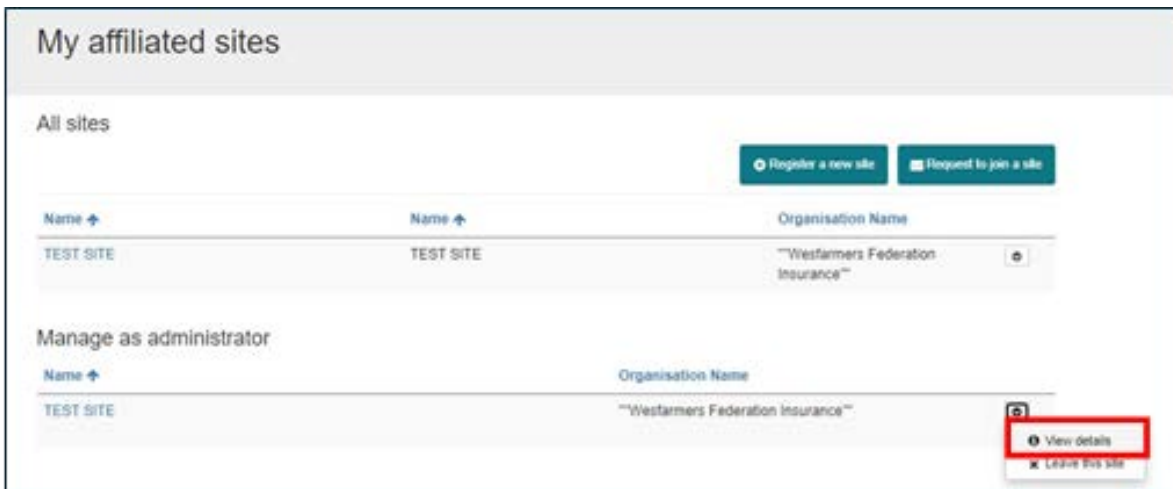
8. Once the Site has been registered, it will appear under the 'Affiliated Sites' tab.



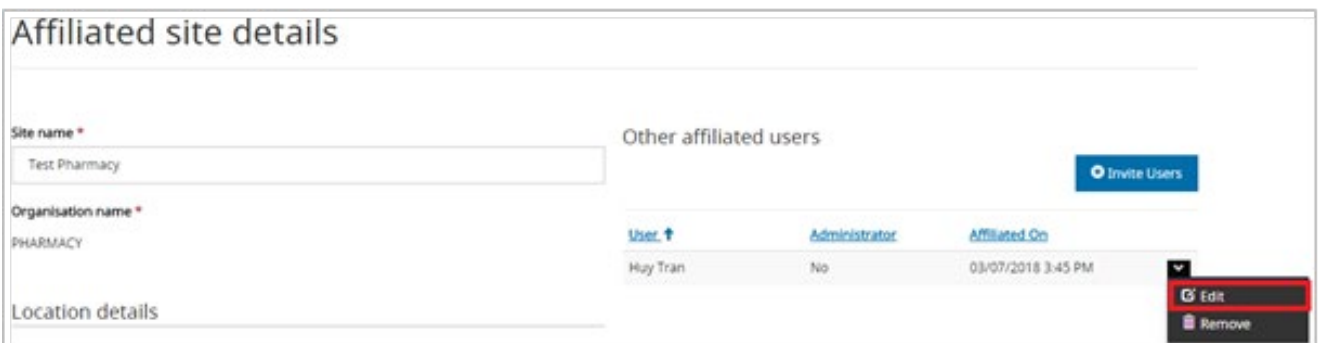
Adding a site administrator(s)

The role of a Site Administrator is automatically assigned to the user who first registers that site into the system. It is important to ensure that the user registering the site for the first time is an appropriate person as they will be granted rights to invite other users via email and approve or reject any requests made by users to affiliate with the site (explained below). Users who are affiliated with a site have visibility of all SAS applications and notifications shared with that site. Site Administrators may invite other users who of their site to become additional Administrators.

1. To invite another user to become an Administrator, select the 'View details' button on the site.



2. Select the user you wish to invite to become an Administrator and select the 'Edit' button.



- Under 'Site Administrator', select 'Yes'.

- The user will now be listed as a Site Administrator.

User	Administrator	Affiliated On
Huy Tran	Yes	03/07/2018 3:45 PM

Sending invitations to affiliate

- Site Administrators can invite others to affiliate with a site by clicking the 'Invite Users' button.

- 2. Invites to affiliate with the site will be sent via email. Email addresses can be entered individually.

The screenshot shows a form titled "Invite users" with a header "Affiliated Site" and the text "TEST SITE". Below this, there is a message: "Please enter a single email address in the field below. If you would like to enter a list of email addresses please use the list entry field." The form contains a label "Enter email address" next to a text input field with the placeholder "Enter email". To the right of the input field is a "Remove" link. Below the input field is a teal button labeled "Add another". At the bottom left of the form is a teal button labeled "Next".

- 3. Or email addresses can be entered in bulk (each email address will need to be on a new line as shown below).

The screenshot shows a form titled "Invite users" with a header "Affiliated Site" and the text "TEST SITE". Below this, there is a message: "Please enter a list of email addresses in the field below with each address on a separate line. Return to single entry field." The form contains a label "Enter email addresses" next to a text area. The text area contains a list of five email addresses: "test@test.com.au", "test1@test.com.au", "test2@test.com.au", "test3@test.com.au", and "test4@test.com.au". At the bottom left of the form is a teal button labeled "Next".

- The system will identify those users who do not yet have a personal account registered in the system. In the below example, the 4 email addresses are not registered in the system. Upon opening the email containing the invitation to affiliate with the site, the user will be required to register a personal account in the system first. Once this has been registered, they will be presented with the option to accept or decline the invitation to affiliate.

Invite users

Please review your invitation list below and click Submit to send the invitation.

Existing users (1)
These users currently have an account in the system and will be sent a link to view and choose to accept or decline your invitation.

- test@test.com.au

Non-existing users (4)
These users currently do not have an account in the system. They will be sent a link to register an account. Once they have signed up to the system, they can view and choose to accept or decline your invitation.

- test1@test.com.au
- test2@test.com.au
- test3@test.com.au
- test4@test.com.au

Previous Submit

Requesting to affiliate with a site

- Once a site has been registered in the system, users may request to join a site (rather than being invited by a Site Administrator). Select 'Request to join a site'.

My affiliated sites

All sites

Register a new site Request to join a site

Name ↑	Name ↑	Organisation Name
TEST SITE	TEST SITE	Wesfarmers Federation Insurance

Manage as administrator

Name ↑	Organisation Name
TEST SITE	Wesfarmers Federation Insurance

- Select the look-up icon to search for the organisation to which the site is registered under.

Join a site

Organisation Name *

Affiliated Site

Submit

- 3. Search for the organisation by using the organisation name or ABN.

Name	ABN	Name Type
Example Hospital Name	6549849846	Main Entity Name

- 4. Once an organisation has been selected, users will be able to search all the sites registered under that organisation. Select the look-up icon to search through the registered sites.

Join a site

Organisation Name *
Example Hospital Name

Affiliated Site

Submit

- 5. In the below example, only a single site has been registered against that organisation. Where multiple sites have been registered (such as different hospital departments), identify and select the desired site.

Name	Created On
Example Affiliated Site	05/03/2021 4:23 PM

- Once selected, a confirmation message will be presented, and the request will be sent to the Administrator(s) or the site for review.

Join a site

Your request to join this site has been successfully submitted. The relevant Site Administrator(s) have been notified and will be reviewing this request. You will be notified once your request has been actioned.
[Click here to return to your list of affiliated sites](#)

Approving or rejecting a request to affiliate with a site

- Site Administrators will be notified in their user dashboard when a request to affiliate with a site has been made. Site Administrators can review this request by clicking the link provided.

Manage as administrator

There are 1 request(s) to join an affiliated site you manage. [Click here to review and action them.](#)

- Select 'View details'.

Join affiliated site requests

SAS Unit ↑	Organisation Name	Requested By	Requested On ↑
Test Pharmacy	PHARMACY	Jane Smith	19/06/2018 4:56 PM

[View Details](#)

- Site Administrators should ensure that the user requesting to affiliate is appropriate to view the information that is contained in submissions that will be viewable upon accepting the request.

Request details

Please review the request to join the site below and choose to approve or reject. Approving this request will affiliate the requester with this site.

Site *

Test Pharmacy

Organisation Name *

PHARMACY

Requested By *

Jane Smith

Requested On

19/06/2018 4:56 PM

Do you want to approve this request? *

Where SAS applications and notifications are submitted, the TGA collects personal information, including personal details of the prescribing health practitioner and/or submitter to assess the application and contact the prescribing health practitioner or submitter where necessary. The TGA will also collect information relating to patients including initials, Medical Record Number (MRN), date of birth (DOB), gender and diagnosis.

By approving this request, you will grant the requesting individual the ability to view SAS applications and notifications that have been affiliated with this site, this will include personal information of health practitioners, submitters and patients. Please ensure that it is appropriate for this individual to be able to view this information prior to approving this request.

- Yes
 No

SAS/AP validation search tool

Health practitioners can use the SAS/AP submission validation search to view real-time information relating to the TGA status of SAS and AP submissions. If there is an active TGA authorisation or notification, the search tool will display the status of the submission and other relevant information.

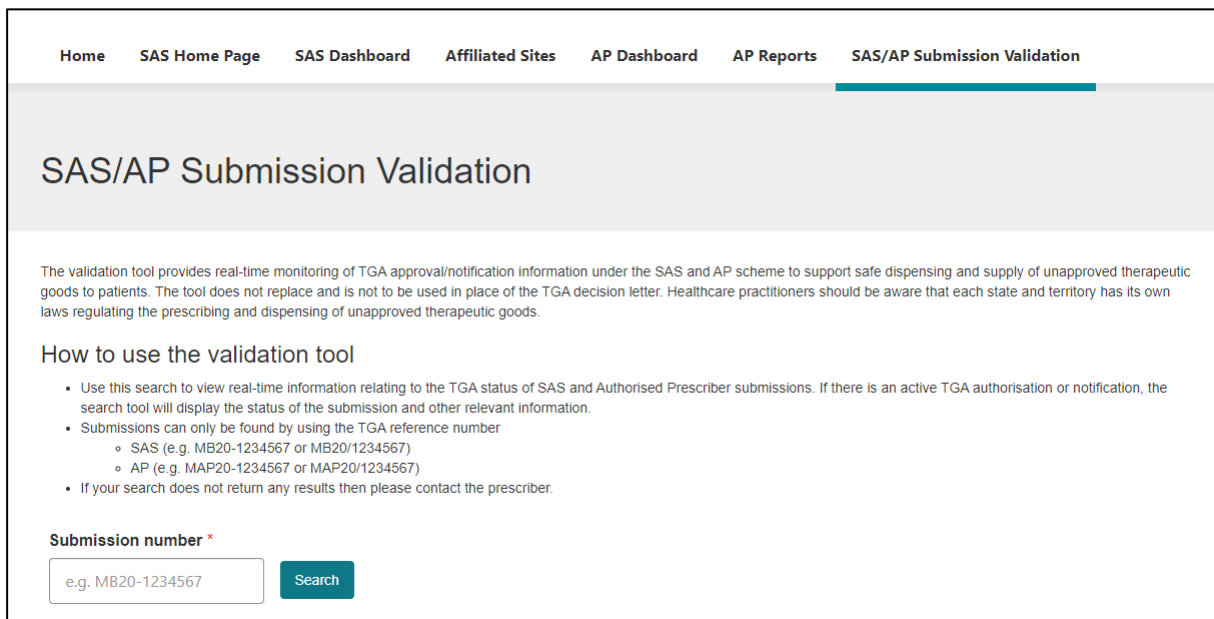
If the search does not return any results, then the prescriber should be contacted.

To access the validation tool:

1. Open SAS & AP online system, login at the top right-hand corner.
2. Click the 'SAS/AP Submission Validation' tab on the right-hand side



1. Enter the submission number provided by the prescriber and click 'Search'.



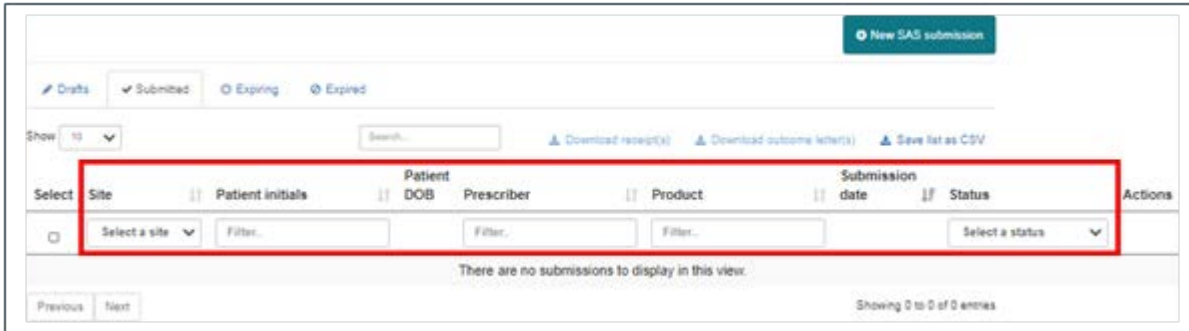
3. If the approval/notification is valid you will be shown the relevant details of the submission including its status. If the submission is no longer valid or does not exist, an error message will appear. In these cases, please contact the prescriber.

User dashboards

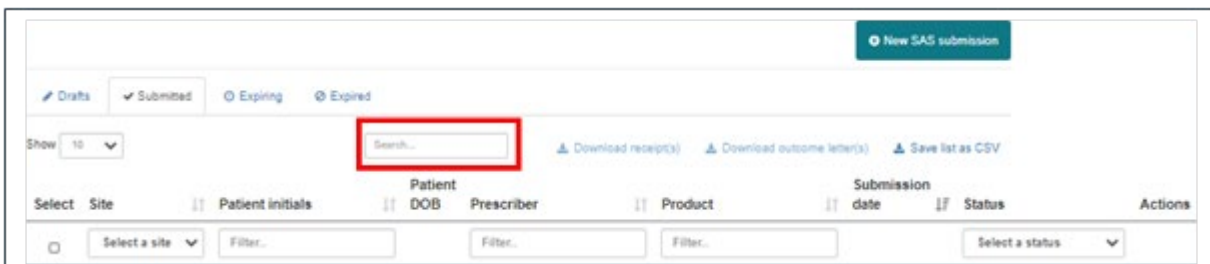
All users who have registered an account in the SAS & AP online system will have a personal dashboard that displays information specific to SAS applications and notifications they have drafted or submitted via the system. These dashboards differ between health practitioners and non-health practitioners.

Filtering dashboard information

1. Dashboards allow users to search and filter submissions based on the fields shown below.

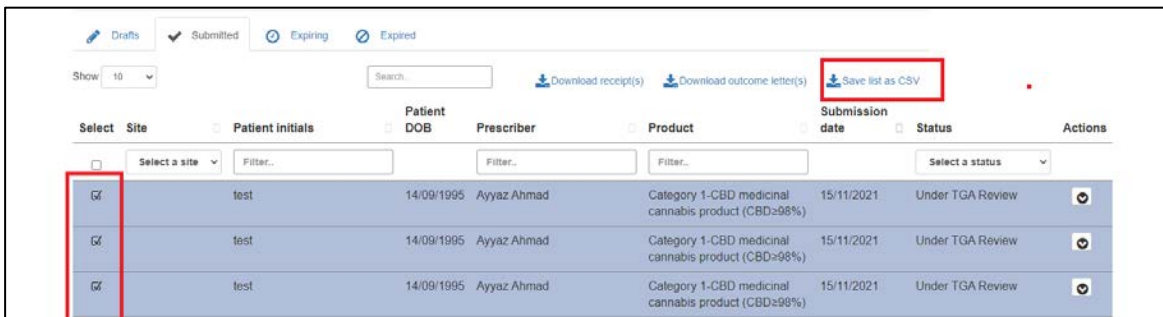


2. Users can also apply a uniform search across all available data fields by typing in the below text box.



Exporting submission data

1. Selection of submissions and selecting the 'Save list as CSV' link will download a local .csv copy of the available data fields contained in the dashboard for those selected submissions as shown below.



Cloning submissions

All SAS submissions visible in a user’s dashboard, including those submissions shared by another user via an Affiliated Site, can be cloned. The purpose of this function is to reduce the administrative burden of re-entering identical information into renewal submissions, or submissions for frequently used unapproved goods.

Upon cloning a submission, previously entered information will be used to prepopulate a new draft SAS submission. It is the responsibility of the submitter to review the information copied into the cloned submission to ensure that the correct information is provided to the TGA.

Please be aware that the following information will not be prepopulated into the new draft by the cloning function, and will need to be provided before submitting to the TGA:

1. Answer to whether the patient’s condition meets the SAS Category A definition (‘yes/no’)

2. Intended date of supply
3. Any attachments uploaded with the original submission
4. Answer to the privacy statement on the Summary step ('yes/no')

Note: Information specific to State or Territory Health Department for medicinal cannabis submissions will not be copied into the new draft submission. This information will need to be provided in Step 5 before submitting.

Identify the submission that needs to be cloned by filtering in the user dashboard; click the 'Actions' tab and select 'Clone' from the dropdown.

SAS submissions

[New SAS submission](#)

[Drafts](#) [Submitted](#) [Expiring](#) [Expired](#)

Show 10 [Download receipt\(s\)](#) [Download outcome letter\(s\)](#) [Save list as CSV](#)

Select	Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
<input type="checkbox"/>	Select a site	Filter..		Example A	Filter..		Select a status	
<input type="checkbox"/>	Symonston	TES	11/02/2000	Example Account	Tebipenem	11/02/2026	TGA Cancelled	<ul style="list-style-type: none"> View details Download receipt(s) Clone

Previous 1 Next Showing 1 to 1 of 1 entries

Navigate through the workflow and provide/update any relevant information specific to the new SAS application or notification before submitting to the TGA.

Draft submissions

Draft submissions are saved when a user has entered information as part of a new SAS application or notification but has not yet submitted this to the TGA. A draft submission saves information already entered into the application or notification which can then be accessed from the dashboard for completion at a later date. Draft submissions appear under the 'Drafts' tab of the dashboard. No information is displayed in the 'submitted date' field.

[Drafts](#) [Submitted](#) [Expiring](#) [Expired](#)

Show 10 [Save list as CSV](#)

Site	Patient initials	Patient DOB	Prescriber	Product	Created date	Actions
Select a site	Filter..		Example A	Filter..		
Symonston	Te	11/02/2000	Example Account	Testosterone	11/02/2026	
			Example Account	Test	16/02/2026	



Non-health practitioners

Dashboards for non-health practitioners will not include the 'Draft Submissions' tab as they are unable to submit SAS applications or notification to the TGA as per the provisions of the Act and associated regulations.

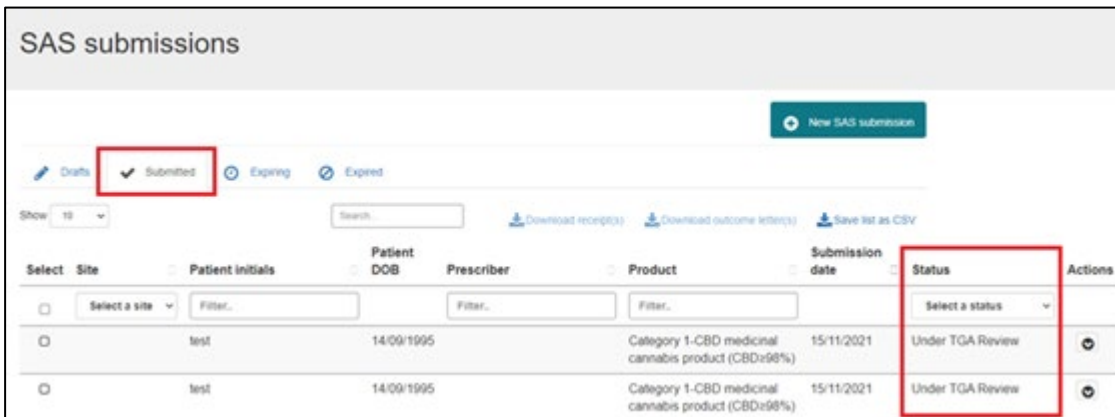
Saving as 'Draft'

The system does not include a 'save as draft' button to be selected. A draft submission is saved automatically when a user 1) closes their browser prior to submitting; or 2) navigates to another part of the system outside of the workflow.

Completed submissions

Status of completed submissions

All SAS applications and notifications that have been submitted via the system will appear under the 'submitted tab' and will each be accompanied by a 'status'.

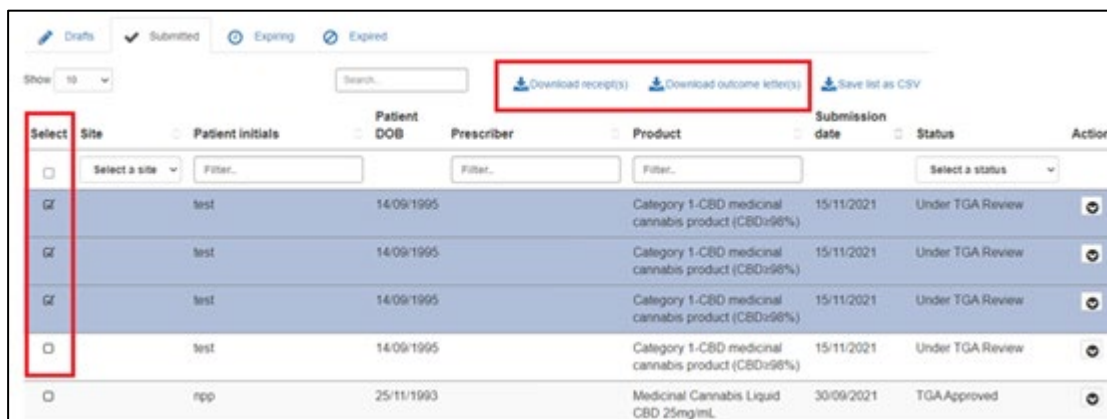


A list of the status terminology can be found below.

Status	Description
"TGA Approved"	Reflects TGA's approval of a SAS Category B (SASB) application.
"TGA Completed"	Completion of a compliant SAS Category A (SASA) or SAS Category C (SASC) notification.
"TGA Non-compliant"	Completion of a SASA or SASC notification where 1) the notification was submitted greater than 28 days after supply; or 2) an incorrect type of health practitioner has supplied the good.
"TGA Rejected"	Reflects TGA's rejection of a SASB application.
"Under TGA Investigation"	When a SASA or SASC notification has been submitted and the TGA is investigating the compliance of the notification with the SASA regulatory requirements or SASC Rules.
"Under TGA Review"	Completion of a successful SASB application to the TGA to which a decision is yet to be made on that application.
"TGA Withdrawn"	Reflects the status of a SASB application that has been submitted via the system and subsequently withdrawn at the request of the applicant.

Downloading receipts and outcome letters

Users will have the ability to download receipts and outcome letters provided by the TGA through their dashboard. This can be done on a single submission basis or a bulk download by selecting the submissions of interest as shown below.

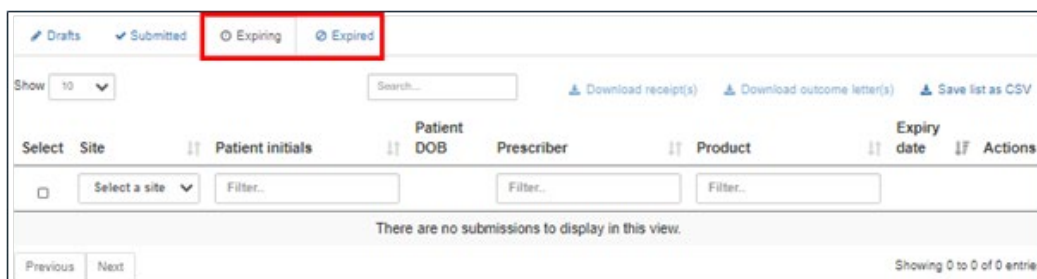


Select	Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
<input type="checkbox"/>	Select a site	Filter..	Filter..	Filter..			Select a status	
<input checked="" type="checkbox"/>		test	14/09/1995		Category 1-CBD medicinal cannabis product (CBD:98%)	15/11/2021	Under TGA Review	
<input checked="" type="checkbox"/>		test	14/09/1995		Category 1-CBD medicinal cannabis product (CBD:98%)	15/11/2021	Under TGA Review	
<input checked="" type="checkbox"/>		test	14/09/1995		Category 1-CBD medicinal cannabis product (CBD:98%)	15/11/2021	Under TGA Review	
<input type="checkbox"/>		test	14/09/1995		Category 1-CBD medicinal cannabis product (CBD:98%)	15/11/2021	Under TGA Review	
<input type="checkbox"/>		rpp	25/11/1993		Medicinal Cannabis Liquid CBD 25mg/mL	30/09/2021	TGA Approved	

Expiring and expired submissions

The terms 'expiring and 'expired' are made in reference to the duration of supply remaining on a SAS application or notification:

- **Expiring** means there are less than 14 calendar days remaining on the duration of supply of the SAS application/notification.
- **Expired** means that the duration of supply approved/notified under the SAS has been exceeded.



Select	Site	Patient initials	Patient DOB	Prescriber	Product	Expiry date	Actions
<input type="checkbox"/>	Select a site	Filter..	Filter..	Filter..			
There are no submissions to display in this view.							
Previous							Next
Showing 0 to 0 of 0 entries							

The purpose of displaying expiring and expired SAS applications and notifications in these tabs is to:

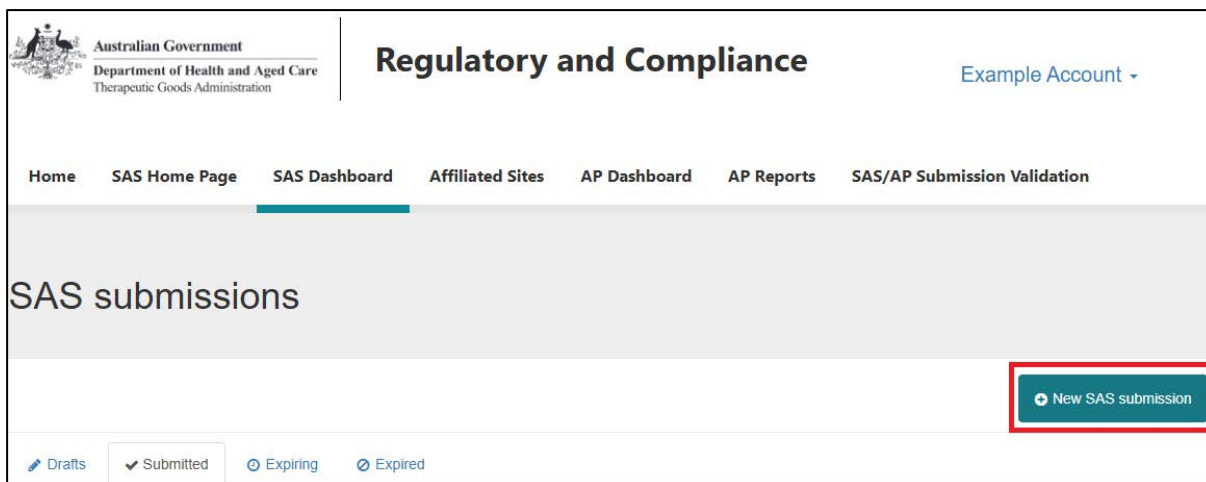
1. Prompt health practitioners to conduct a review of the patient's condition post-treatment.
2. Ensure continuation of patient care by accessing unapproved therapeutic goods under the SAS should the patient require further treatment.
3. If supply of the unapproved therapeutic good is still required after the expiry date, a new SAS application/notification should be made for that patient.

Submitting SAS applications and notifications

Pharmacists submitting SAS notification/applications for S3 unapproved therapeutic goods please see the submitting S3 Products as a Pharmacist section below.

The online system has been designed to guide health practitioners down the correct SAS pathway when seeking access to unapproved therapeutic goods.

To complete a SAS application or notification and submit this to the TGA via the system, go to your dashboard and select 'New SAS submission'.



Step 1 – Prescriber details

1. If submitting as the prescriber, the details will be automatically populated from the account which was registered through the system, as shown below. Note that contact details may be amended prior to continuing.

Prescriber details

Pharmacists intending to submit a Schedule 3 product submission please select Yes to Are you the prescriber?

Are you the prescriber? *

Yes

No

Please review the prescriber details below.

Title *	AHPRA number
Dr	MED0001234568
First name *	Practitioner type *
Example	Medical Practitioner
Last name *	Prescriber speciality
Account	—

Principal place of practice

Business or practice name *	Email *
<input type="text" value="Example Practice"/>	<input type="text" value="ExampleAccount@email.com"/>
Address line 1 *	Phone
<input type="text" value="123 Example St"/>	<input type="text" value="123412341234"/>
Address line 2	Fax
<input type="text"/>	<input type="text"/>
Suburb *	
<input type="text" value="Example Suburb"/>	
State *	
<input style="border-bottom: none; border-right: none; border-left: none; border-top: none; text-align: right; padding-right: 5px; width: 100%;" type="text" value="ACT"/>	▼
Postcode *	
<input type="text" value="1111"/>	

- If you are not the prescriber, the user will be asked to provide the AHPRA registration number for the prescriber. The system will then search the TGA's internal database in attempts to identify whether a profile associated with that AHPRA registration number already exists. If not, the user will be required to provide the prescriber's information before proceeding with the submission.

Note: The validation of this AHPRA ID does not refer to the AHPRA registry.

Share submission

You can make this submission visible to a Site you have an affiliation with once it is saved (select site below). Please note that sharing this submission with a Site may allow other affiliated users to view the information contained in this submission for the purpose of continuing patient care or supplying relevant goods.

Prescriber details
Specify a new prescriber below and click OK, or click Cancel to continue using the current prescriber details.

Pharmacists intending to submit a Schedule 3 product submission please select Yes to Are you the prescriber?

Are you the prescriber? *

Yes No

Prescriber AHPRA number *

New prescriber details
Please provide the health practitioner details associated with the AHPRA number MED1234567999. [Click here to visit the AHPRA website to search for this AHPRA number.](#)

Title *	AHPRA number
<input type="text" value="Select"/>	<input type="text" value="MED1234567999"/>
First name *	Practitioner type *
<input type="text"/>	<input type="text" value="Select"/>
Last name *	Prescriber specialty
<input type="text"/>	<input type="text"/>

Step 2 – Product selection

- Select the type of unapproved therapeutic good for which access is being sought.

The TGA regulates therapeutic goods as either Medicines, Biologicals or Medical Devices. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types before utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine
 Biological
 Medical Device

- Upon selecting a type of therapeutic good, the user will be prompted to provide details of the product such as the active ingredient, dosage form and indication. A look-up function is available to search TGA's internal database of existing entries as shown below.

The TGA regulates therapeutic goods as either Medicines, Biologicals or Medical Devices. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types before utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

- Medicine
- Biological
- Medical Device

Medicine
Please use the search below to make your product selection (including active ingredient, dosage form and indication).

Active ingredient(s) *

The active ingredient(s) I need could not be found through the search tool

Dosage form *
—

Indication *
—

- Use the search bar to identify the active ingredient. To search on partial text, use the asterisk (*) wildcard character.


Lookup records ×


Choose one record and click Select to continue


✓ **Name ↑**


- Candida Albicans Skin Test Antigen
- Dihydrotestosterone
- Estriol/Oestradiol/Testosterone
- Test Product**


4. If you are unable to identify the required information via the look-up function, select the checkbox below the search field. This will allow users to provide a free-text entry to support the submission.


Prescriber details


Product selection


Product details


Patient details


Summary

The TGA regulates therapeutic goods as either **Medicines**, **Biologicals** or **Medical Devices**. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types *before* utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine
 Biological
 Medical Device

Medicine
 Please use the search below to make your product selection (including active ingredient, dosage form and indication).

Active ingredient(s)

The active ingredient(s) I need could not be found through the search tool


Other active ingredient(s) *

Dosage form *


Indication *

- If the product and indication are not able to be supplied by way of notification under the SAS Category C pathway, the user is prompted to confirm whether the patient meets the definition of a SAS Category A patient. This question is only presented as an option where the prescriber for the submission is a medical practitioner. The answer to the below determines whether the submission is processed as a SAS Category A notification or SAS Category B application.


New SAS submission




Prescriber details




Product selection



Product details



Patient details



Summary

The TGA regulates therapeutic goods as either **Medicines**, **Biologicals** or **Medical Devices**. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types *before* utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine

Biological

Medical Device

Medicine

Please use the search below to make your product selection (including active ingredient, dosage form and indication).

Active ingredient(s) *

Product x Q

The active ingredient(s) I need could not be found through the search tool

Dosage form *

Dosage x Q

The dosage form I need could not be found through the search tool

Indication *

Indication x Q

The indication I need could not be found through the search tool

If a product is on the TGA's established history of use [list](#) the indication will state 'Category C Notification'. Select this indication to submit a Category C notification. As this is a notification pathway you will not receive a TGA approval letter.

The prescriber's practitioner type must be the same as what is listed on the TGA's established history of use list.

[Click here to learn about the available SAS pathways](#)

Does your patient's condition meet the following Category A definition? *

Patient 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.

Yes

No

If you select 'Yes' your submission will be processed as a **Category A notification**. As this is a notification pathway you will not receive a TGA approval letter.

If you select 'No' it will be processed as a **Category B application**.

The prescriber must be a medical practitioner to use Category A.

[Click here to learn about the available SAS pathways](#)

Your pathway has been determined as:

Category B

This is an application pathway to be used when you can't access an unapproved product through categories A or C. You must apply and wait for an approval letter.

You must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the ARTG are not suitable for treatment of the patient.

This pathway was determined based on the product and indication/purpose you selected and/or your response to the question 'Does your patient's condition meet the following Category A definition?'. To change the pathway, change the product or your response to the above question.

[Click here to learn about the available SAS pathways](#)

Previous

Save and Next

Step 3 – Product details

For SAS Category B applications, additional data fields specific to the product are required to be completed as shown below.

Prescriber details

Product selection

Product details

Patient details

Summary

Application pathway

Based on your selection in the previous steps, the pathway for this submission has been determined as:

Category B

[Click here to learn about the available SAS pathways](#)

Product details (Medicine)

Active ingredient(s)

Test Product

Dosage form

Dosage

Strength *

Strength Unit *

Route of Administration *

Dosage and frequency (e.g., 1 tds) *

Expected duration of treatment *

Duration unit *

Trade name

Sponsor/supplier

Intended date of supply *

Step 4 – Patient details

Complete the patient details section and attach any supporting information via the upload function.

Prescriber details

Product selection

Product details

Patient details

Summary

Patient details

Patient initials *

Date of birth *

Gender *

Male
 Female
 Indeterminate/Intersex/Unspecified

MRN

Previous SA \$ number

Diagnosis

Diagnosis(es) relevant to this SA \$ submission *

Clinical justification *

The Special Access Scheme is available for exceptional circumstances where the prescribing health practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG).

I have considered approved and available treatments for this patient *

Yes
 No

Supporting information

Do you have any recent specialist reports or additional information to support your application? *

Yes
 No

[Add files](#)

Name ↑	Modified
📧 Emails	about 2 hours ago

Additional information

Step 5 – Summary

Acknowledge that you have read and understood the following disclaimer to submit the SAS application or notification to the TGA.

Privacy statement and consent

Thank you for your application/notification under the Special Access Scheme. The TGA collects personal information, including personal details of the prescribing health practitioner, the person submitting the application/notification, and personal information about the patient, to assess the application and contact the health practitioner or submitter where necessary. In relation to SAS C notifications, certain types of personal information about prescribers and patients are required by law to be provided to the TGA by prescribers.

With the exception of applications and notifications for medicinal cannabis products, the TGA does not collect the name or contact details of patients and seeks to limit the collection of patient information to what is clinically necessary. Personal information about patients that is collected consists of the patient's initials, Medical Record Number (MRN) (if provided), date of birth (DOB), gender, diagnosis and indications for which the medicine is prescribed. You must inform your patient that the TGA collects this information before submitting your application/notification.

With applications for medicinal cannabis products, this online system allows health practitioners to concurrently submit applications to State and Territory authorities with responsibilities for therapeutic goods. For such applications, additional personal information such as full name and residential address of the patient may be collected to satisfy the requirements of the relevant jurisdiction. Once this information specific to the state or territory application has been provided to any relevant State or Territory authority, it will not be available in the online system and will not be visible to other users.

Please note that the application/notification containing personal information about you and your patient may be viewed by other registered users of the system at the place you work. Generally, these users may access the application/notification for the purpose of processing the application including supplying goods under the application/notification or for the purposes of continuing patient care.

Your personal information, the personal information of patients referred to above, and the outcome of your application/notification may also be viewed by other registered health professionals (e.g. pharmacists) that have access to this portal and to the applicable application/notification number. Generally, these registered users may view application/notification details for the purpose of ensuring lawful supply of unapproved therapeutic goods under a TGA authorisation or exemption to a patient with a valid prescription.

The personal information you provide about you and your patient and the outcome of your application, including the TGA decision letter, may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration. Otherwise, the personal information you provide will only be disclosed with your consent, where authorised or required by law, or as otherwise permitted under the Privacy Act 1988.

Further information about privacy, including a link to the department's privacy policy, is available at <https://www.tga.gov.au/privacy>.

In submitting this application/notification, I:

- consent to the collection, use and disclosure of my personal information, and the disclosure of the outcome of my application to State and Territory authorities, and other registered health professionals, as set out above;
- confirm that my patient consents to the collection and disclosure of their personal information as set out above.

In the case of applications and notifications for medicinal cannabis products, I confirm that:

- the patient, or the patient's parent or guardian (if applicable), has given their consent that the patient's personal information will be collected and used for the purpose of this application or notification; and
- the patient, or the patient's parent or guardian (if applicable), has given their consent that the patient's personal information may be disclosed to relevant State/Territory authorities with responsibilities for therapeutic goods and health practitioner conduct for the purposes of ensuring lawful supply of the product in that jurisdiction.

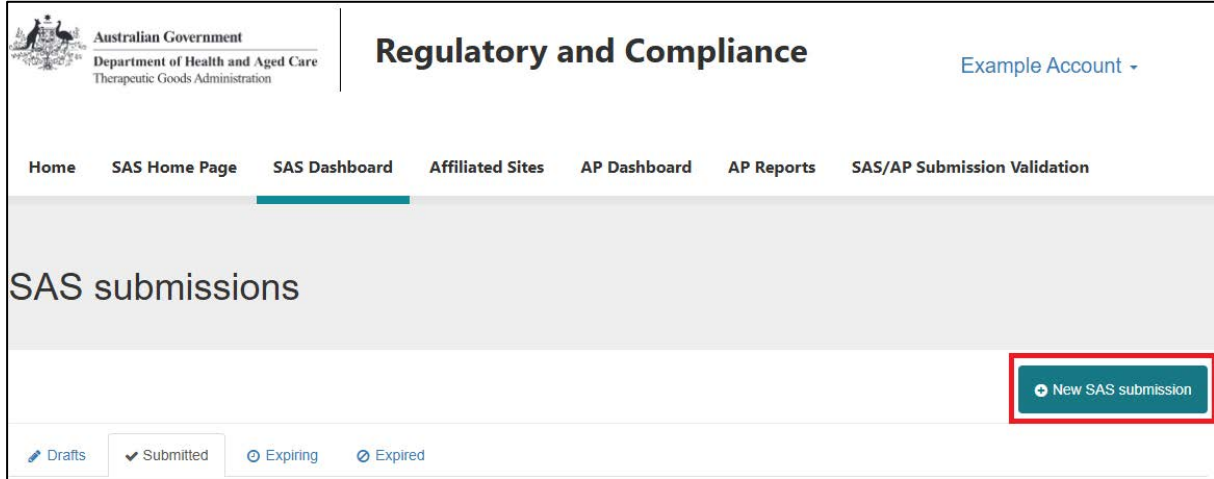
I have read and understood the Privacy Statement and Consent *

- Yes
 No

Submitting S3 products as a pharmacist

S3 submissions can be made through the same SAS submission process as all other unapproved goods. Some additional steps are required to ensure submissions are correctly received by the TGA.

To complete a SAS application or notification and submit this to the TGA via the system, go to your dashboard and select 'New SAS submission'.



Step 1 – Prescriber details

Select the 'Yes' option for 'Are you the prescriber', the details will be automatically populated from the account, which was registered through the system, as shown below.

Note that contact details may be amended prior to continuing.

Prescriber details

Pharmacists intending to submit a Schedule 3 product submission please select 'Yes to Are you the prescriber?'

Are you the prescriber? *

Yes

No

Please review the prescriber details below.

Title * Dr	AHPRA number MED0001234568
First name * Example	Practitioner type * Medical Practitioner
Last name * Account	Prescriber specialty —

Principal place of practice

Business or practice name * Example Practice **Email *** ExampleAccount@email.com

Address line 1 * 123 Example St **Phone** 123412341234

Address line 2 **Fax**

Suburb * Example Suburb

State * ACT

Postcode * 1111

Step 2 – Product selection

1. Select the type of unapproved therapeutic good for which access is being sought.

The TGA regulates therapeutic goods as either **Medicines**, **Biologicals** or **Medical Devices**. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types before utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine
 Biological
 Medical Device

Previous Save and Next

2. Upon selecting a type of therapeutic good, the user will be prompted to provide details of the product such as the active ingredient, dosage form and indication. A look-up function is available to search TGA’s internal database of existing active ingredients, their dosage forms, and indications, as shown below.

The TGA regulates therapeutic goods as either **Medicines**, **Biologicals** or **Medical Devices**. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types before utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine
 Biological
 Medical Device

Medicine
 Please use the search below to make your product selection (including active ingredient, dosage form and indication).

Active ingredient(s) *

The active ingredient(s) I need could not be found through the search tool

Dosage form *
 —

Indication *
 —

Previous Save and Next

Step 3 – Product details

For S3 notifications, additional data fields specific to the product are required to be completed as shown below.

Application pathway

Based on your selection in the previous steps, the pathway for this submission has been determined as:

Category C

[Click here to learn about the available SAS pathways](#)

Product details (Medicine)

Active ingredient(s)

Nicotine/zero nicotine therapeutic vaping goods (incl substances, kits,

Therapeutic vaping product type *

Please select the vaping product type that will be provided to the patient. If you think you may prescribe both nicotine and non-nicotine vaping products, select "Nicotine and/or zero-nicotine vaping product types."

Dosage form

Solid/Liquid

Expected duration of treatment *

Duration unit *

Intended date of supply *


 


Previous


Save and Next


Step 4 – Patient details


Complete the patient details section and attach any supporting information via the upload function.


Prescriber details


Product selection


Product details


Patient details


Summary

Patient details

Patient initials *

Date of birth *

Gender *

Male

Female

Indeterminate/Intersex/Unspecified

MRN

Previous SAS number

Diagnosis

Diagnosis(es) relevant to this SAS submission *

The Special Access Scheme is available for exceptional circumstances where the prescribing health practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG).

I have considered approved and available treatments for this patient *

Yes

No

Supporting information

Do you have any recent specialist reports or additional information to support your application? *

Yes

No

Add files

Name ↑	Modified
<div style="display: flex; align-items: center;"> <div style="width: 20px; height: 20px; background-color: #4285F4; margin-right: 5px;"></div> Emails </div>	21/04/2026 9:57 AM

Additional Information

Previous
Save and Next

Step 5 – Summary

Acknowledge that you have read and understood the following disclaimer to submit the SAS application or notification to the TGA.

Privacy statement and consent

Thank you for your application/notification under the Special Access Scheme. The TGA collects personal information, including personal details of the prescribing health practitioner, the person submitting the application/notification, and personal information about the patient, to assess the application and contact the health practitioner or submitter where necessary. In relation to SAS C notifications, certain types of personal information about prescribers and patients are required by law to be provided to the TGA by prescribers.

With the exception of applications and notifications for medicinal cannabis products, the TGA does not collect the name or contact details of patients and seeks to limit the collection of patient information to what is clinically necessary. Personal information about patients that is collected consists of the patient's initials, Medical Record Number (MRN) (if provided), date of birth (DOB), gender, diagnosis and indications for which the medicine is prescribed. You must inform your patient that the TGA collects this information before submitting your application/notification.

With applications for medicinal cannabis products, this online system allows health practitioners to concurrently submit applications to State and Territory authorities with responsibilities for therapeutic goods. For such applications, additional personal information such as full name and residential address of the patient may be collected to satisfy the requirements of the relevant jurisdiction. Once this information specific to the state or territory application has been provided to any relevant State or Territory authority, it will not be available in the online system and will not be visible to other users.

Please note that the application/notification containing personal information about you and your patient may be viewed by other registered users of the system at the place you work. Generally, these users may access the application/notification for the purpose of processing the application including supplying goods under the application/notification or for the purposes of continuing patient care.

Your personal information, the personal information of patients referred to above, and the outcome of your application/notification may also be viewed by other registered health professionals (e.g. pharmacists) that have access to this portal and to the applicable application/notification number. Generally, these registered users may view application/notification details for the purpose of ensuring lawful supply of unapproved therapeutic goods under a TGA authorisation or exemption to a patient with a valid prescription.

The personal information you provide about you and your patient and the outcome of your application, including the TGA decision letter, may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration. Otherwise, the personal information you provide will only be disclosed with your consent, where authorised or required by law, or as otherwise permitted under the Privacy Act 1988.

Further information about privacy, including a link to the department's privacy policy, is available at <https://www.tga.gov.au/privacy>.

In submitting this application/notification, I:

- consent to the collection, use and disclosure of my personal information, and the disclosure of the outcome of my application to State and Territory authorities, and other registered health professionals, as set out above;
- confirm that my patient consents to the collection and disclosure of their personal information as set out above.

In the case of applications and notifications for medicinal cannabis products, I confirm that:

- the patient, or the patient's parent or guardian (if applicable), has given their consent that the patient's personal information will be collected and used for the purpose of this application or notification; and
- the patient, or the patient's parent or guardian (if applicable), has given their consent that the patient's personal information may be disclosed to relevant State/Territory authorities with responsibilities for therapeutic goods and health practitioner conduct for the purposes of ensuring lawful supply of the product in that jurisdiction.

I have read and understood the Privacy Statement and Consent *

- Yes
 No

Medicinal cannabis submissions

In April 2018, the Commonwealth and State and Territory Health Departments announced a collaborative approach to streamline access to unapproved medicinal cannabis products for Australian health practitioners through a 'single-in' application process where medical practitioners can notify or apply to both the Commonwealth and the relevant State or Territory Health Department (where applicable) to prescribe and supply medicinal cannabis products via a single application. Historically, prescribers of unapproved medicinal cannabis products had been required to separately apply/notify the TGA and the State or Territory Health Department (where applicable) for approval/authorisation to supply these products.

Note that only one state or territory can be applied to for a single application. In instances where multiple state/territory authorisations are required, the additional authorisation will need to be sought directly from the State or Territory Health Department. Contact details are available on the TGA webpage [contacts for State/Territory medicines & poisons regulation units](#)

When not to use the system to submit medicinal cannabis applications

There are circumstances where the TGA's SAS & Authorised Prescriber Online System should not be used for medicinal cannabis submissions. These circumstances include:

- Where the prescriber of the unapproved therapeutic good is not the prescribing health practitioner.
- Where the prescriber is in possession of a current TGA approval and the notification/application only relates to the state or territory. A notification or application in these circumstances should be made directly to the relevant State or Territory Health Department. Contact details are available on the TGA webpage [contacts for State/Territory medicines & poisons regulation units](#)

Notifying or applying to a state or territory health department via the system

1. Upon selecting 'medicine' as the therapeutic good type, the prescriber will be prompted to provide details of the medicinal cannabis product such as the active ingredient. A look-up function is available to search TGA's internal database of existing entries.

The screenshot displays the 'Product selection' step of the application process. On the left, a vertical navigation menu shows five steps: 'Prescriber details', 'Product selection' (current step), 'Product details', 'Patient details', and 'Summary'. The main content area includes a warning about TGA definitions, a radio button selection for 'Therapeutic Good Type' (with 'Medicine' selected), and a text input field for 'Active ingredient(s)'. A red box highlights the search icon in the input field. Below the input field, there is a checkbox for 'The active ingredient(s) I need could not be found through the search tool'. At the bottom, there are 'Previous' and 'Save and Next' buttons.

Lookup records ✕

<input type="checkbox"/>	AP Estab. Hx-Category 2: CBD dominant medicinal cannabis product (CBD≥60% and <98%)
<input type="checkbox"/>	AP Estab. Hx-Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
<input type="checkbox"/>	Category 1: CBD medicinal cannabis product (CBD≥98%)
<input type="checkbox"/>	Category 2: CBD dominant medicinal cannabis product (CBD≥60% and < 98%)
<input type="checkbox"/>	Category 3: Balanced medicinal cannabis product (CBD ≥ 40% and < 60%)
<input type="checkbox"/>	Category 4: THC/other cannabinoid dominant medicinal cannabis product (CBD ≥2% and <40%)
<input type="checkbox"/>	Category 5: THC/other cannabinoid medicinal cannabis product (CBD <2%)

In selecting a medicinal cannabis active ingredient category from the look-up function, the prescriber will then be prompted to select whether a State or Territory Health Department should also be notified or applied to as part of the submission. It is the responsibility of the prescribing healthcare practitioner to know the legislative requirements of the jurisdiction(s) in which they are practising.

- Prescriber details
- Product selection
- Product details
- Patient details
- Summary

The TGA regulates therapeutic goods as either Medicines, Biologicals or Medical Devices. These definitions may differ from those used in the clinical setting. For example, the TGA regulates blood products as medicines and not biologicals. It is recommended that you search all three therapeutic good types before utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.

Therapeutic Good Type *

Medicine
 Biological
 Medical Device

Medicine

Please use the search below to make your product selection (including active ingredient, dosage form and indication).

Active ingredient(s) *

The active ingredient(s) I need could not be found through the search tool

Dosage form *

The dosage form I need could not be found through the search tool

Indication *

The indication I need could not be found through the search tool

Do you need to notify or apply to a state or territory health department? *

In answering 'yes' to this question, you will be asked to select which state or territory health department you would like to notify or apply to. Upon selection, you will be presented with additional data fields that are specific to the state or territory application or notification. You do not need to separately apply to or notify the state or territory health department once this information has been submitted via this system. If you are unsure, please contact the relevant state or territory health department to clarify before proceeding with this submission. Contact details for state and territory health departments may be found on our [website](#). **Please note that the person submitting this must be the prescribing health practitioner.**

Yes
 No, I have determined at the time of this submission that no State or Territory Health Department is required to be notified or applied to.

2. If 'Yes' is selected to the above question, the prescriber will be asked which State or Territory Health Department should receive the notification/application. If you need to notify or apply to a State or Territory Health Department not included in the system, you will need to contact the State or Territory Health Department directly.

Please indicate which state or territory health department should be notified or applied to *

The ability to submit medicinal cannabis applications/notification to all state and territory health departments is not currently available via this online system. If your state or territory is not available, please leave this field blank and proceed with your SAS submission to the TGA. If you need to notify or apply to a state or territory, you will need to do this using the available paper forms located on their website.

3. Determine what SAS form type (Category A or Category B) should be submitted to the TGA.

Please be aware that although individual imports of medicinal cannabis in response to Category A notifications are processed within 2 working days, shipping time substantially delays delivery to the patient. Australian held stock can be accessed through Category B applications which are generally processed by TGA within 2 working days of receipt. Consequently, patient access may be faster through Category B than Category A.

Noting the above, would you like to submit a Category A notification? *

Yes

No

4. Enter the product details.

Prescriber details

Product selection

Product details

Patient details

Summary

Application pathway

Based on your selection in the previous steps, the pathway for this submission has been determined as:

Category B

[Click here to learn about the available SAS pathways](#)

Product details (Medicine)

Active ingredient(s)

Category 1: CBD medicinal cannabis product (CBD≥98%)

Dosage form

Capsule

Strength *

CBD≥98%

Strength Unit *

Percent ✕ 🔍

Route of Administration *

Oral ✕ 🔍

Dosage and frequency (e.g., 1 tds) *

As per prescription

Expected duration of treatment *

24

Duration unit *

Month(s) ▼

Trade name


Example


Sponsor/supplier


Example


Intended date of supply *


5. Enter the patient details.


Prescriber details


Product selection


Product details


Patient details


Summary

Patient details

Patient initials *

Date of birth *

Gender *

Male

Female

Indeterminate/Intersex/Unspecified

MRN

Previous SAS number

Diagnosis

Diagnosis(es) relevant to this SAS submission *

Clinical justification *

Example

Intended monitoring

Please provide details of intended monitoring *

Example

The Special Access Scheme is available for exceptional circumstances where the prescribing health practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG).

I have considered approved and available treatments for this patient *

Yes

No

Supporting information

Do you have any recent specialist reports or additional information to support your application? *

Yes

No

6. When a State or Territory Health Department has been selected, an additional step will be included in the system containing the data fields relevant to the state or territory application process.

Application to NSW Health required *

Only complete this question if your patient belongs to any of the mentioned categories below. If neither response options apply, please reconsider your submission at the Product selection step or contact NSW Health for assistance.

Is the patient drug dependant

Yes
 No

A 'drug dependant person' means a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug within the meaning of the NSW Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug (Section 27 of the Poisons and Therapeutic Goods Act 1966).

Is the patient aged under 16 years

Yes
 No

For patients aged under 16 years, medical practitioners require an exemption under Section 175 (4A) of the Children and Young Persons (Care and Protection) Act 1998 before prescribing a S8 drug of addiction for more than 10 days in any period of 30 days, unless treatment is for cancer. The exemption is requested from the Secretary of Department of Communities and Justice by the Secretary of NSW Health.

Please note, as per NSW legislative requirements, NSW authority is not required to prescribe medicines included in Schedule 4 of the Poisons Standard.

Additional patient details

First name *

7. Once all the information requested in the system has been completed as part of the submission, the prescriber will then submit the application/notification. In submitting the application/notification via the system, both the TGA and selected State or Territory Health Department will concurrently receive the application information. This means that prescribers *do not need to then separately notify or apply to the relevant State or Territory Health Department*.
8. The TGA and relevant State or Territory Health Department will each conduct their own evaluation processes on the information submitted via the system. It is important to note that as part of these evaluation processes, the TGA and State or Territory Health Department may contact the prescriber seeking further information in support of the application.
9. The prescriber will receive a single email from the TGA containing both the TGA and state or territory outcome letters within 48 hours (2 business days) of having received all information required to evaluate the application.

TGA contact details

Gather the following information before you ask for help with the SAS and AP Online System:

- description or screenshot of error
- submitting practitioner's name
- username for SAS and AP Online System
- email address used for SAS and AP Online System
- [AHPRA](#) number
- web browser used (for example Chrome or Edge)
- SAS/AP reference number (if applicable).

To get help email the above information to SAS.Support@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication.	Experimental Products Section (EPS); Pharmacovigilance and Special Access Branch (PSAB)	31 July 2018
V1.1	Guidance updates based on system changes.	Experimental Products Section (EPS); Pharmacovigilance and Special Access Branch (PSAB)	28 September 2018
V1.2	Guidance updates based on system changes.	Experimental Products Section (EPS); Pharmacovigilance and Special Access Branch (PSAB)	22 April 2021
V1.3	Guidance updates based on system changes.	Experimental Products Section (EPS); International Regulatory Branch (IRB)	14 December 2021
V1.4	Guidance updates based on system changes.	Experimental Products Section (EPS); International Regulatory Branch (IRB)	03 February 2022
V1.5	Guidance updated based on system changes.	Experimental Products Section (EPS); International Regulatory Branch (IRB)	21 March 2022
V1.6	Guidance updated based on system changes.	Special Access Section (SAS); International Regulatory Branch (IRB)	06 June 2022
V1.7	Guidance updated based on system changes	Special Access Section (SAS); International Regulatory Branch (IRB)	11 October 2023
V1.8	Guidance updated based on system changes	Business Improvements and Compliance Section (BICS); International Regulatory Branch (IRB)	February 2024

Version	Description of change	Author	Effective date
V1.9	Guidance updated based on changes to SAS and AP online system.	Business Improvements and Compliance Section; International Regulatory Branch.	March 2024
V1.10	Updated title to User Guide and updated content based on system changes	Business Improvement and Compliance Section (BICS); International Regulatory Branch (IRB)	1 October 2024
V2.0	Guidance updated based on system changes	Unapproved Medicines Access Section (UMAS); International Regulatory Branch (IRB)	May 2026

OFFICIAL

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #

OFFICIAL