



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Special Access Scheme (SAS)

## Special Access Scheme & Authorised Prescriber Scheme Online System guidance

Version 1.2, April 2021

**TGA** Health Safety  
Regulation



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## Online System overview

The Special Access Scheme (SAS) & Authorised Prescriber (AP) scheme Online System (SAS & AP online system) is the preferred method of submission for SAS applications and notifications. The SAS & AP online 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 the [Special Access Scheme: Guidance for health practitioners and 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.

Terminology	Definition
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 Online System

- Users of the system are required to register an account before they are able to begin drafting and submitting online 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 where they are able 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, product, 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, prompting health practitioners to conduct a review of the patient's condition and resubmit SAS applications/notifications as required.
  - 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 new, 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).

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

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



## 2. Select Register Now

### Welcome

#### Special Access Scheme & Authorised Prescriber Scheme

Most therapeutic goods are required to undergo an evaluation for quality, safety and efficacy and be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. In recognition that there are circumstances where patients need access to therapeutic goods that are not included in the ARTG, the Therapeutic Goods Administration (TGA) manages the Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).





It is important to note that the prescribing health practitioner accepts responsibility for the use of an "unapproved" therapeutic good and any associated adverse reactions.

#### Medicinal Cannabis Submissions

On 13 April 2018, the Council of Australian Governments Health Ministers agreed to work together to streamline access to medicinal cannabis for Australian health practitioners. The announcement made, stated that prescribers of medicinal cannabis could provide the relevant information, through a single application process to fulfil both Commonwealth and jurisdictional requirements to enable access. The TGA will send a single correspondence containing both the TGA and relevant state or territory decision letter after respective evaluations have been completed within 48 hours (2 business days) of having received all the information required to make a decision.

Typically, prescribers of unapproved medicinal cannabis products were required to separately apply to the TGA and relevant State or Territory Health Department for authorisation.

Remember the following when using the SAS online system for medicinal cannabis applications:

-  You **must** be the prescribing health practitioner to submit an application for a medicinal cannabis product via the online system.
-  By using the SAS online system, prescribers will now be able to submit applications to the TGA and State or Territory Health Department simultaneously.
-  Currently most states and territories (except for Tasmania) can be applied to simultaneously via this online system.
-  If your state or territory is not available via the online system, you will need to apply separately to the TGA and the relevant State or Territory Health Department. Submitting your application via the online system will only satisfy TGA requirements.

[Log In](#)
[Register now >](#)

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

### Register

#### Password requirements

- Your new password must be different from your last 8 passwords.
- Your password cannot contain your account name or more than two consecutive characters of your full name.
- Your password must contain characters from the following four categories:
  - English uppercase characters (A through Z)
  - English lowercase characters (a through z)
  - Numbers (0 through 9)
  - Non-alphabetic characters (for example, !, \$, #, %)
- Your password must be a minimum of 10 characters.
- Your password can only be changed once per day.

Username

Email

Password

Confirm password

[Register >](#)

## 4. 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.



- Click on the hyperlink in the email (note this link will expire in 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.dmz.development.tga.gov.au/portalaccounts/account/activate/af3f314c-716d-4470-88d2-c5f9d3b0ae14/288580002>

This link will expire in 24 hours.

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

- Log in with your username and password:



Australian Government  
Department of Health  
Therapeutic Goods Administration

Login to TGA Business Services

Username or login ID

Password

Login

Forgotten your password?

Reset Password | Privacy | Help

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

## My profile

If your profile details require any amendments that you are unable to action here, please contact the Special Access Scheme Team on 1800 020 653 or email [SAS@health.gov.au](mailto:SAS@health.gov.au).

### Personal Details

Are you a Health Practitioner  
☐ No ☒ Yes

Title \*  
Dr

First Name \*  
Sas Test

Last Name \*  
User

Preferred Name

### Address and Contact Details

Business or Practice Name * ACME Specialist Services	Phone * 0262895662
Address Line 1 * 23 Furzer Street	Fax 
Address Line 2 	Email * <a href="mailto:Chandra.moramoudi@health.gov.au">Chandra.moramoudi@health.gov.au</a>
Suburb * Woden	
Australian State * Australian Capital Territory	
Postcode * 2606	

### Health Practitioner Details

AHPRA Number \*  
MED76086561

Practitioner Type \*  
Medical Practitioner

Prescriber Specialty  
Test

## 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:

Australian Government  
Department of Health

### Regulatory and Compliance

Home SAS Home Page **SAS Dashboard** My affiliated sites Authorised Prescriber Reports

## My profile

Personal Details

Are you a Health Practitioner  
☒ No ☐ Yes

Title \*

First Name \*

Last Name \*

Preferred Name

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.

## Password resets

Passwords will expire every 90 days. This is as per security requirements policy of the Department of Health.

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 username:

 A screenshot of the TGA online 'Forgot password' form. The header shows the Australian Government logo, Department of Health, and Therapeutic Goods Administration. The main header is 'TGA online'. Below this is a form titled 'Forgot password' with the instruction 'Please enter your username to reset your password.' There is a text input field labeled 'Username' and a 'Reset' button.

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



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



5. Enter your new password:

**Reset password**

**Password guide**

- Your new password must be different from your last 8 passwords.
- Your password cannot contain your account name or more than two consecutive characters of your full name.
- Your password must contain characters from the following four categories:
  - English uppercase characters (A through Z)
  - English lowercase characters (a through z)
  - Numbers (0 through 9)
  - Non-alphabetic characters (for example, !, \$, #, %)
- Your password must be a minimum of 10 characters.
- Your password can only be changed once per day.

New password

Confirm new password

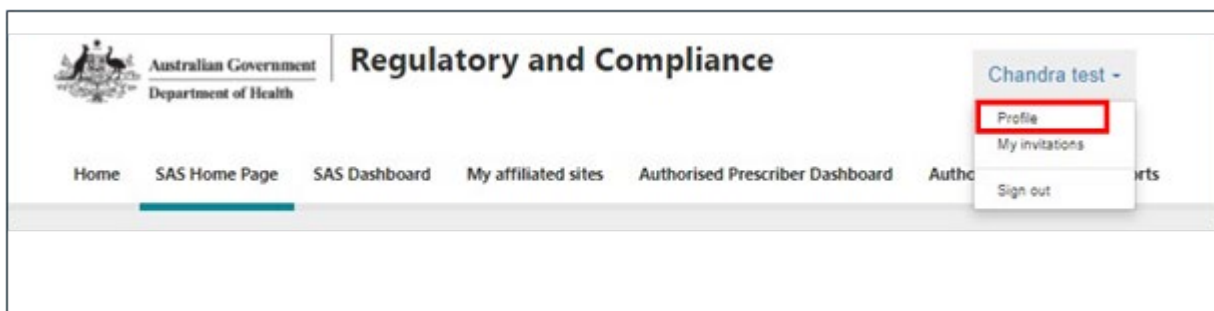
Reset password >

**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 time has lapsed otherwise the lockout period will be restart. 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:



# Affiliated sites

## Purpose

To enable better oversight and management of applications and notifications submitted via the 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 are able to 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 have the ability to:

- 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 'My affiliated sites' tab:



2. Select 'Register a new site':



3. Read and acknowledge the following declaration:

**Register new affiliated site**

**Declaration**

In registering a new Affiliated Site, I declare that:

- I have the authority to register this Affiliated Site; and
- The information I have provided is true and correct.
- I acknowledge that giving false or misleading information is a serious offence.

**I have read and understood the above declaration \***

☐ No ☒ Yes

**Next**

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

**Register new affiliated site**

**Declaration**

**Organisation**

**Site details**

**Review**

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](mailto:SAS@health.gov.au) and provide relevant details.*

**Previous** **Next**

5. New organisations need to be added to the Online System. If your organisation is not available, please email [psabsystems@health.gov.au](mailto:psabsystems@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

\*654

Q

✓ Name ↑	ABN	Name Type
✓ Example Hospital Name	6549849846	Main Entity Name

SelectCancelRemove value



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 multi-step registration process. On the left, a vertical navigation bar contains four steps: 'Declaration' (green icon of a document with a checkmark), 'Organisation' (green icon of a star and a house), 'Site details' (blue icon of a location pin), and 'Review' (grey icon of a circular arrow). The 'Site details' step is currently active. The main content area is titled 'Location details' and contains the following fields: 'Organisation Name \*' with the value '\*\*\*Wesfarmers Federation Insurance\*\*'; 'Site Name \*' with the value 'TEST SITE' and a green success message 'Your site name has been successfully validated'; 'Suite/Room/Office' (empty); 'Address Line 1 \*' with the value 'TEST ADDRESS'; 'Address Line 2' (empty); 'Suburb \*' with the value 'SYDNEY'; 'State \*' with a dropdown menu showing 'NSW'; and 'Postcode \*' with the value '2000'. At the bottom, there are 'Previous' and 'Next' buttons.

Step	Field	Value
Declaration	Organisation Name *	***Wesfarmers Federation Insurance**
	Site Name *	TEST SITE
	Your site name has been successfully validated	
	Location details	
Site details	Suite/Room/Office	
	Address Line 1 *	TEST ADDRESS
	Address Line 2	
	Suburb *	SYDNEY
	State *	NSW
	Postcode *	2000
	Previous Next	

7. Review the details before registering the Site:

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

Previous Submit

8. Once the Site has been registered, it will appear under the 'My affiliated sites' tab:

My affiliated sites		
All sites		
		<a href="#">Register a new site</a> <a href="#">Request to join a site</a>
Name ↑	Name ↑	Organisation Name
TEST SITE	TEST SITE	"Wesfarmers Federation Insurance"
Manage as administrator		
Name ↑	Organisation Name	
TEST SITE	"Wesfarmers Federation Insurance"	

## 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 also 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 are affiliated with that site to become Administrators.

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

The screenshot shows the 'My affiliated sites' page. It has a header 'My affiliated sites' and a sub-header 'All sites'. There are two buttons: 'Register a new site' and 'Request to join a site'. Below is a table with columns 'Name', 'Name', and 'Organisation Name'. The first row shows 'TEST SITE', 'TEST SITE', and 'Westfarmers Federation Insurance'. Below the table is a section 'Manage as administrator' with a table showing 'TEST SITE' and 'Westfarmers Federation Insurance'. A 'View details' button is highlighted with a red box in the bottom right corner of the table.

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

The screenshot shows the 'Affiliated site details' page. It has a header 'Affiliated site details'. On the left, there are fields for 'Site name' (Test Pharmacy), 'Organisation name' (PHARMACY), and 'Location details'. On the right, there is a section 'Other affiliated users' with a table. The table has columns 'User', 'Administrator', and 'Affiliated Co'. The first row shows 'Huy Tran', 'No', and '03/07/2018 3:45 PM'. An 'Invite Users' button is above the table. An 'Edit' button is highlighted with a red box in the bottom right corner of the table.

3. Under 'Site Administrator', select 'Yes':

The screenshot shows the 'Edit User' form. It has a header 'Edit User'. There are three sections: 'Affiliated Site' (Test Pharmacy), 'Person' (Huy Tran), and 'Site Administrator' (No Yes). A 'Submit' button is at the bottom.

4. The user will now be listed as a Site Administrator:

**Affiliated site details**

Site name \*  
Test Pharmacy

Organisation name \*  
PHARMACY

Other affiliated users

[Invite Users](#)

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

## Sending invitations to affiliate

1. Site Administrators are able to invite others to affiliate with a site by clicking the 'Invite Users' button:

**Affiliated site details**

**Details**

Site Name \*  
Example Affiliated Site

Organisation Name \*  
Example Organisation

Location details

Suite/Room/Office

Address Line 1 \*  
25 Smith st

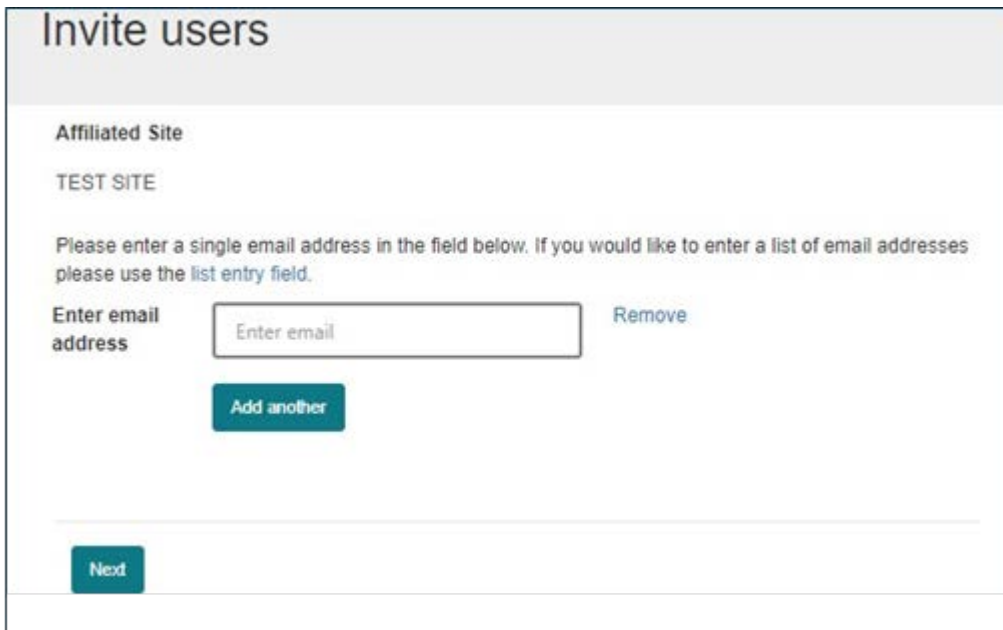
Address Line 2

Other affiliated users

[Invite Users](#)


User ↑	Administrator	Affiliated On
There are no records to display.		

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



The screenshot shows a web form titled "Invite users". Under the heading "Affiliated Site", the text "TEST SITE" is displayed. Below this, a message reads: "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](#)." There is a text input field labeled "Enter email" with a "Remove" link to its right. Below the input field is a teal button labeled "Add another". At the bottom left of the form is a teal button labeled "Next".

- 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 the same "Invite users" form. Under the heading "Affiliated Site", the text "TEST SITE" is displayed. Below this, a message reads: "Please enter a list of email addresses in the field below with each address on a separate line. Return to [single entry field](#)." There is a large text input field labeled "Enter email addresses" containing 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. 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 having to be 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

2. 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:

Lookup records

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

\*654

✓ Name ↑	ABN	Name Type
✓ Example Hospital Name	6549849846	Main Entity Name

Select Cancel Remove value

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:

Lookup records

Search

Q

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

Select

Cancel

Remove value

6. 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

1. 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.](#)

2. Select 'View details':

Join affiliated site requests

SAS Unit	Organisation Name	Requested By	Requested On	
<a href="#">Test Pharmacy</a>	PHARMACY	Jane Smith	19/06/2018 4:56 PM	<div> <div>View Details</div> </div>



- 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

## User dashboards

All users who have registered an account in the SAS 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

- Dashboards allow users to search and filter submissions based on the fields shown below:

New SAS submission

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

Show 10
Search...
[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...	Filter...	Filter...			Select a status	

There are no submissions to display in this view.

Previous
Next

Showing 0 to 0 of 0 entries

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

The screenshot shows the top section of the SAS dashboard. At the top right is a 'New SAS submission' button. Below it are tabs for 'Drafts', 'Submitted', 'Expiring', and 'Expired'. A 'Show' dropdown is set to '10'. A search bar with the placeholder text 'Search...' is highlighted with a red box. To the right of the search bar are three links: 'Download receipt(s)', 'Download outcome letter(s)', and 'Save list as CSV'. Below these are several filter boxes for 'Site', 'Patient initials', 'Patient DOB', 'Prescriber', 'Product', 'Submission date', and 'Status'. The 'Status' dropdown is set to 'Select a status'.

## Exporting submission data

- 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:

The screenshot shows the same SAS dashboard as above, but with the 'Save list as CSV' link highlighted with a red box. Below the search bar and filters, there is a table of submissions. The first column of the table is 'Select', which is also highlighted with a red box. The table has columns for 'Site', 'Patient initials', 'Patient DOB', 'Prescriber', 'Product', 'Submission date', 'Status', and 'Actions'. The table contains three rows of data:

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"/>	TSTMf		12/10/1980		Cannabis Profile	04/03/2021	Under TGA Review	
<input checked="" type="checkbox"/>	Test		10/10/1980		Medicine Product Profile	04/03/2021	Under TGA Review	
<input checked="" type="checkbox"/>	TSTM2		12/10/1980		Cannabis Profile	02/03/2021	Under TGA Review	

## 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:

- Answer to whether the patient's condition meets the SAS Category A definition ('yes/no')
- Intended date of supply
- Any attachments uploaded with the original submission
- 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:

Site	Patient initials	Patient DOB	Prescriber	Product	Created date	Actions
Select a site	Filter..		Filter..	Filter..		
				Medicine Product Profile	19/02/2021	
NSWM		10/10/1980		Cannabis Profile	19/02/2021	<ul style="list-style-type: none"> <li>View details</li> <li>Delete</li> <li>Clone</li> </ul>
NSWM		10/10/1980		Cannabis Profile		

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

Show10

Search...

Save list as CSV

Site	Patient initials	Patient DOB	Prescriber	Product	Created date	Actions
Select a site	Filter...		Filter...	Filter...		
				Medicine Product Profile	19/02/2021	
NSWM		10/10/1980		Cannabis Profile	19/02/2021	
NSWM		10/10/1980		Cannabis Profile	19/02/2021	

### 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.

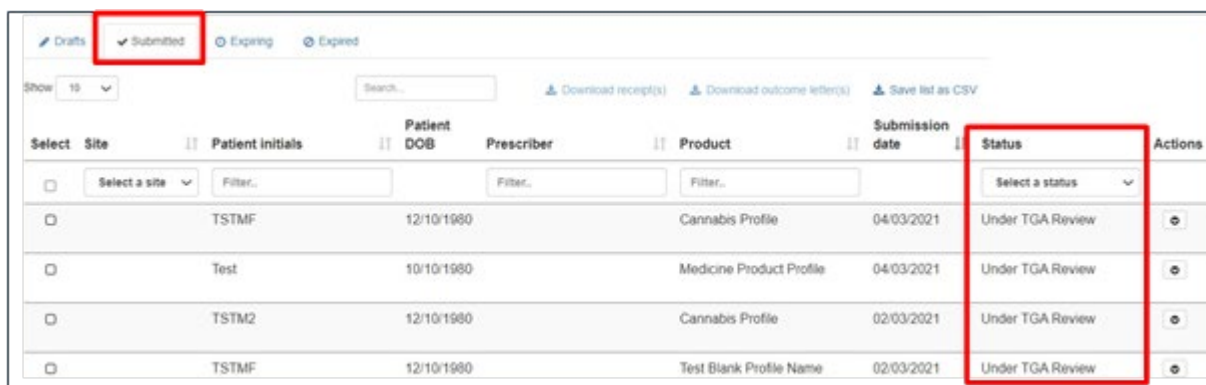
### Saving as 'Draft'

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'.



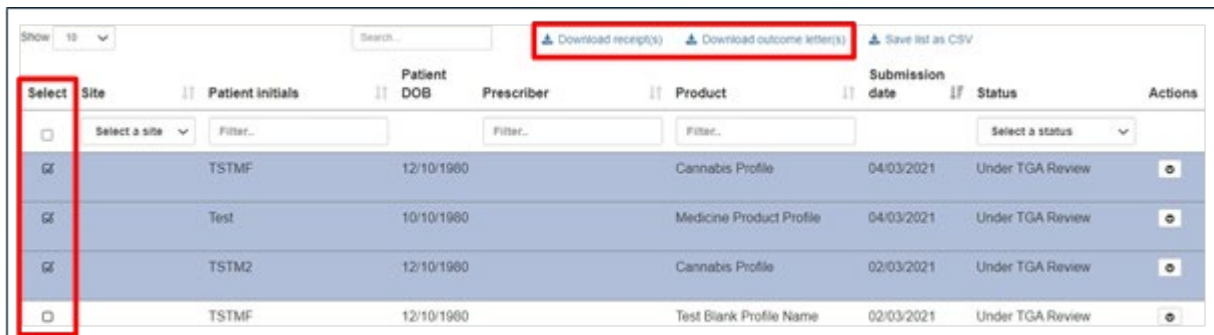
Select	Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
<input type="checkbox"/>	Select a site	Filter..		Filter..	Filter..		Select a status	
<input type="checkbox"/>		TSTMF	12/10/1980		Cannabis Profile	04/03/2021	Under TGA Review	
<input type="checkbox"/>		Test	10/10/1980		Medicine Product Profile	04/03/2021	Under TGA Review	
<input type="checkbox"/>		TSTM2	12/10/1980		Cannabis Profile	02/03/2021	Under TGA Review	
<input type="checkbox"/>		TSTMF	12/10/1980		Test Blank Profile Name	02/03/2021	Under TGA Review	

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.

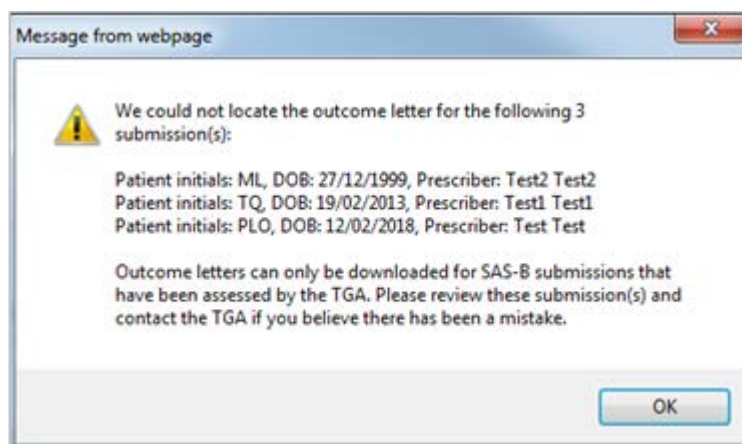
## Downloading receipts and outcome letters

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:



A message box will be presented when attempting to download outcome letters if:

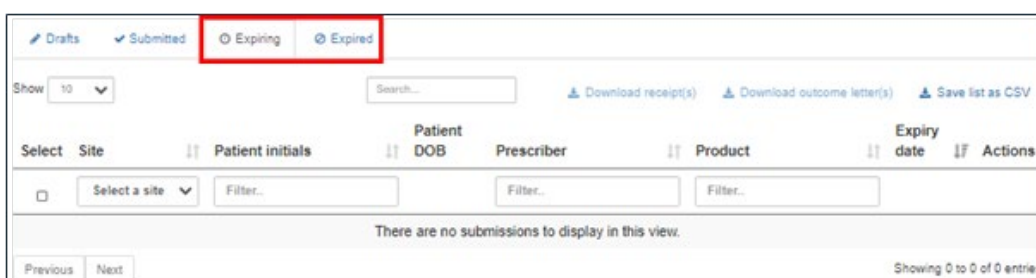
1. The user is attempting to download an outcome letter for a SAS Category A or SAS Category C notification (as outcome letters are only applicable to SAS Category B applications); and
2. The outcome letter for that SAS Category B application is not yet available.



## 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.



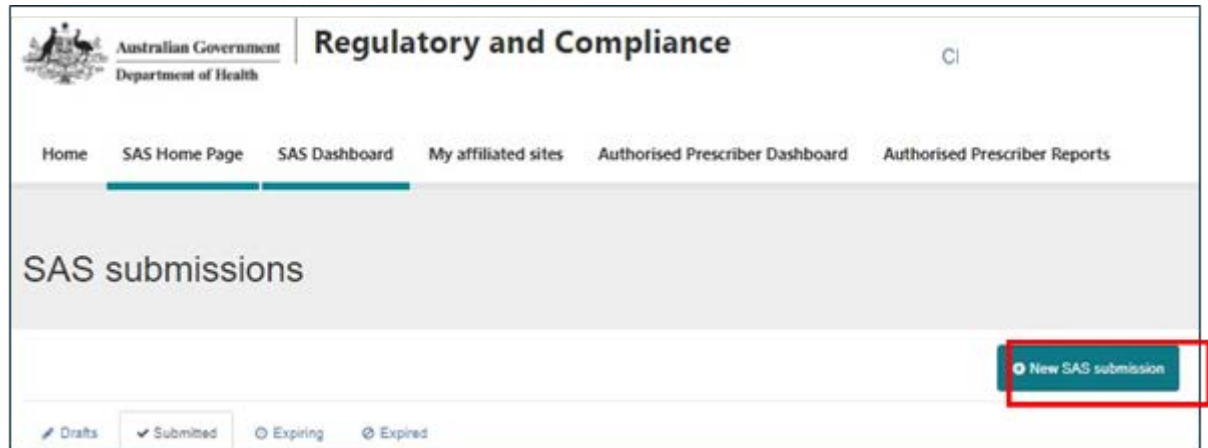
The purpose of displaying expiring and expired SAS applications and notifications in these tabs is to:

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

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

1. 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

Are you the prescriber? \*

☒ Yes

☐ No

Please review your health practitioner details below. If these appear incorrect, please update your user profile and then return to this form.

Title *	AHPRA number
Dr	MED143456465
First name *	Practitioner type *
Chandra	Nurse
Last name *	Prescriber specialty
test	---

Principal place of practice

Business or practice name *	Email *
ACHIE Specialist Services	sasprod04@example.com
Address line 1 *	Phone
23 Ronald Avenue	263895662
Address line 2	Fax
Suburb *	
wooden	
State *	
ACT	
Postcode *	
2606	

[Save and Next](#)



- 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.

You cannot specify a site to share this application as you are not currently associated with any site. [Go to the My Affiliated Sites page](#) to register a new site or request to join an existing one.

**Prescriber details**

Are you the prescriber? \*

☐ Yes

☒ No

**Prescriber AHPRA number \***

[Click here to search the AHPRA register of health practitioners if you do not know the prescriber AHPRA number.](#)

MED0001167466

Please wait while we validate the prescriber AHPRA number...

[Save and Next](#)

## 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

[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 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 \***

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

**Lookup records**

Chandra Pre prod

☒ Famotidine

Med Cann New

Medicine Product Profile

Medicine TEST SAS-C

Medicine With Prevent SAS A

Multiple Allergens

< 1 2 >

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

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 \***

5. 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:

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) \***

Medicine Product Profile

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

**Dosage form \***

Medicine Product Presentation

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

**Indication \***

Chandra medical team

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

**Does your patient's condition meet the following 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

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:

The screenshot shows the 'Step 3 – Product details' form. On the left is a vertical navigation menu with five items: 'Prescriber details' (green), 'Product selection' (green), 'Product details' (blue, currently selected), 'Patient details' (grey), and 'Summary' (grey). The main content area is titled 'Application pathway' and states: '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.](#)' Below this is the 'Product details (Medicine)' section. It includes fields for 'Active ingredient(s)' (Famotidine), 'Dosage form' (Capsule), 'Strength' (20), 'Strength Unit' (Milligram), 'Route of Administration' (Oral), 'Dosage and frequency (e.g., 1 tds)' (1 tds), 'Expected duration of treatment' (2), 'Duration unit' (Month(s)), 'Trade name' (TEST TRADE NAME), 'Sponsor/supplier' (TEST SPONSOR), and 'Intended date of supply' (05/03/2021).

Application pathway	
Based on your selection in the previous steps, the pathway for this submission has been determined as <b>Category B</b> . <a href="#">Click here to learn about the available SAS pathways.</a>	
Product details (Medicine)	
Active ingredient(s)	Famotidine
Dosage form	Capsule
Strength *	20
Strength Unit *	Milligram
Route of Administration *	Oral
Dosage and frequency (e.g., 1 tds) *	1 tds
Expected duration of treatment *	2
Duration unit *	Month(s)
Trade name	TEST TRADE NAME
Sponsor/supplier	TEST SPONSOR
Intended date of supply *	05/03/2021

## Step 4 – Patient details

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

The screenshot shows the 'Patient details' section of the SAS Online system. On the left is a vertical navigation menu with five items: 'Prescriber details' (green icon), 'Product selection' (green icon), 'Product details' (green icon), 'Patient details' (blue icon, currently selected), and 'Summary' (grey icon). The main content area is titled 'Patient details' and contains the following fields:

- Patient initials \***: Text input field containing 'FWM'.
- Date of birth \***: Date input field containing '28/09/2015'.
- Gender \***: Radio button options: ☒ Male, ☐ Female, ☐ Indeterminate/Intersex/Unspecified.
- MRN**: Text input field containing '326598'.
- Previous SAS number**: Text input field containing 'MB18/000001'.
- Diagnosis**:
  - Diagnosis(es) relevant to this SAS submission \***: Text input field containing 'Crohn's disease'.
  - Clinical justification \***: Text area containing 'Failed previous therapies and no alternative registered treatments for this age group available.'
- Supporting information**:
  - Do you have any recent specialist reports or additional information to support your application? \***: Radio button options: ☒ Yes, ☐ No.
  - Add files**: Button to upload supporting documents.
  - File list**: Table showing uploaded files.
 

Name	Modified
Act.pdf (734 KB)	less than a minute ago
  - Additional information**: Text area for further details.

At the bottom of the form are two buttons: 'Previous' and 'Save and Next'.

## Step 5 – Summary

1. 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 and/or submitter to assess the application and contact the health practitioner or submitter where necessary.

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. For example, the TGA may collect information relating to patients including initials, Medical Record Number (MRN), date of birth (DOB), gender and diagnosis.

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. Please note that 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 your personal details 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.

If you are a prescribing health practitioner, your name may be disclosed to State and Territory authorities with responsibility for therapeutic goods or health practitioner registration. Otherwise, and for all registered users, your personal information will only be disclosed with your consent, where authorised or required by law or as otherwise permitted under the Privacy Act 1988.

For general information about privacy, go to: <https://www.tga.gov.au/privacy>.

In submitting this application/notification, I consent to the collection, use and disclosure of my 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

Previous

Submit



## 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 [Access to medicinal cannabis products: using access schemes](#).

## When not to use the system to submit medicinal cannabis applications

There are circumstances where the TGA's SAS 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 [Access to medicinal cannabis products: using access schemes](#).

## 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.

Please note that medicinal cannabis products are listed via trade name rather than active ingredient (as displayed below).

In selecting a medicinal cannabis product 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.

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) \***

ABCD Medicinal Cannabis 25mg/ml

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

**Dosage form \***

Oral Liquid

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

**Indication \***

chronic pain

☐ 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 the proposed product is unable to be selected via the look-up function, prescribers will have the ability to free-text details of the product. Upon entering free-text information, the prescriber will then be asked whether the product is a medicinal cannabis product 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

**Other active ingredient(s) \***

**Dosage form \***

**Indication \***

**Is the above product a medicinal cannabis product? \***

☐ Yes

☐ No

3. 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.

4. 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


5. Enter the product details.


 Prescriber details

 Product selection

 Product details

 Patient details

 Cannabis (NSW)

 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)

ABCD Medicinal Cannabis 25mg/ml Oral Liquid (CBD 25mg/ml)

Dosage form

Oral Liquid

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 \*

## 6. Enter the patient details.

**Patient details**

**Patient initials \***

TS

**Date of birth \***

14/09/2005

**Gender \***

☒ Male  
☐ Female  
☐ Indeterminate/Intersex/Unspecified

**MRN**

326598

**Previous SAS number**

MB18/0000001

**Diagnosis**

**Diagnosis(es) relevant to this SAS submission \***

TEST DIAGNOSIS

Previous Save and Next

## 7. 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 dependent**

☐ 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 \***

8. 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*.
9. 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.
10. 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

Email	<b>Special Access Scheme:</b> <a href="mailto:SAS@health.gov.au">SAS@health.gov.au</a> <b>Medicinal Cannabis:</b> <a href="mailto:Medicinal.cannabis@health.gov.au">Medicinal.cannabis@health.gov.au</a>
Phone	<b>Special Access Scheme:</b> 1800 020 653; +61 2 6289 4632 <b>Medicinal Cannabis:</b> 1800 020 653; +61 2 (02) 6289 4631
Fax	<b>Special Access Scheme and Medicinal Cannabis:</b> +61 2 6203 1105

## 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

## **Therapeutic Goods Administration**

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Reference/Publication #