



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Special Access Scheme (SAS)

Special Access Scheme & Authorised Prescriber Scheme Online System User Guide

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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.

Terminology	Definition
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 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, 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, 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.



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

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

Contact the Special Access Section via email at SAS@health.gov.au if you require support.

3. Provide a new, 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:	<input type="text"/>
Email:	<input type="text"/>
Password:	<input type="password"/>
Confirm password:	<input type="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.

5. 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.dmx.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.

6. Log in with your username and password:



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.

Personal Details

Are you a Health Practitioner
 No Yes

Title *

 * Q

First Name *

Last Name *

Preferred Name:

Address and Contact Details

Business or Practice Name *

 * Phone

Phone *

0262095662

Address Line 1 *

 * Fax

Fax

Address Line 2

 * Email

Email *

Suburb *

Australian State *

 * Q

Postcode *

Health Practitioner Details

AHPRA Number *

MED76636561

Practitioner Type *

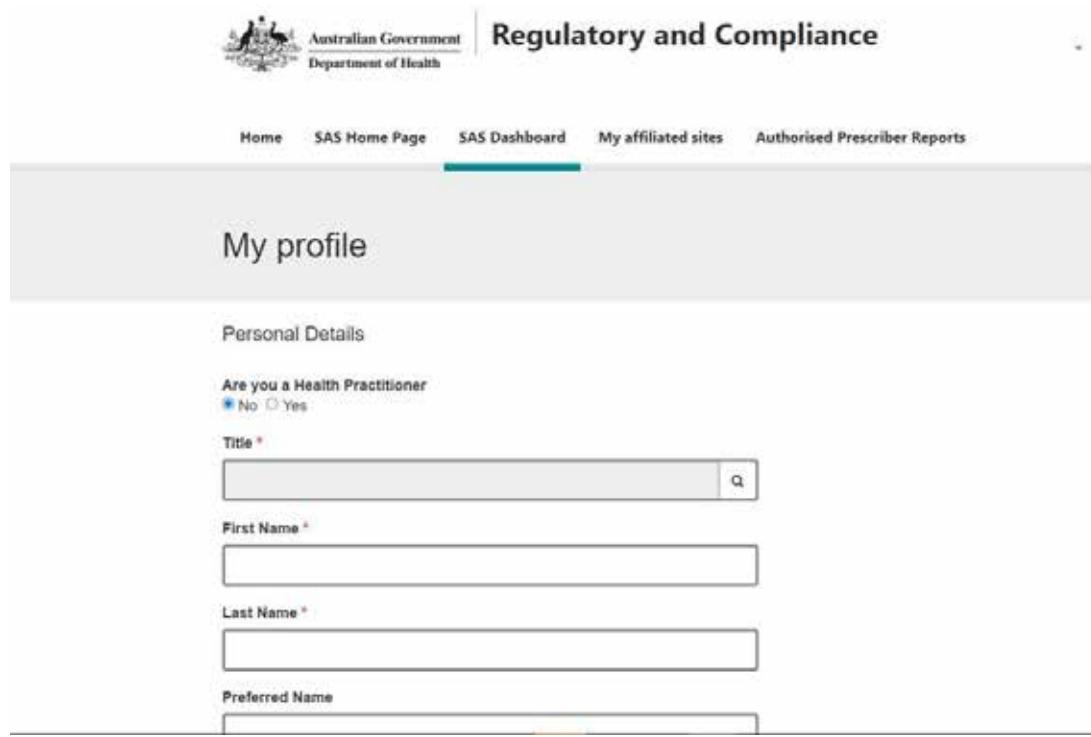
 * Q

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:



The screenshot shows the TGA SAS Online System interface. At the top, there is a logo for the Australian Government Department of Health. The main navigation bar includes links for Home, SAS Home Page, SAS Dashboard (which is underlined in blue), My affiliated sites, and Authorised Prescriber Reports. Below the navigation, a section titled 'My profile' is visible. Under 'Personal Details', there is a question 'Are you a Health Practitioner' with radio buttons for 'No' (selected) and 'Yes'. There are four input fields for 'Title', 'First Name', 'Last Name', and 'Preferred Name', each with a small search icon to the right.

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 prosthodontist 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. 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 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	<input type="text"/>
New password	<input type="text"/>
Confirm new password	<input type="text"/>

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 restart. 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”

Special Access Scheme & Authorised Prescriber Scheme Online System

Log in ➔
[Register now ➔](#)

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.
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- Report adverse events or defects associated with the use of the ‘unapproved’ therapeutic goods to the TGA.

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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

Contact the Special Access Section via email at SAS@health.gov.au if you require support.

2. Select “Forgotten your password?”



Login to TGA Business Services

Username or login ID

Password

Login

Forgotten your password?

3. Enter your username and select “reset”

The TGA online login page. It features the Australian Government Department of Health Therapeutic Goods Administration logo and the text "TGA online". Below the logo is a "Forgot password" link. A text input field is labeled "Username" and is highlighted with a green glow. A blue "Reset" button is located to the right of the input field.

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

The TGA online password reset confirmation page. It features the Australian Government Department of Health Therapeutic Goods Administration logo and the text "TGA online". A green checkmark icon is followed by the text "Confirm password reset". Below this, a message states "You will receive an email shortly with a link to reset your password."

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

Hi Test Test,

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/portal/accounts/password/set/288580000/cf52>

The above link will expire in 24 hours.

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 ➔

7.

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:

The screenshot shows the SAS Dashboard with the 'Regulatory and Compliance' section active. A user profile dropdown menu is open, showing options: 'Profile' (which is highlighted with a red box), 'My invitations', 'Change password', and 'Sign out'. The 'Profile' option is the current selection.

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:

- Select the 'My affiliated sites' tab:



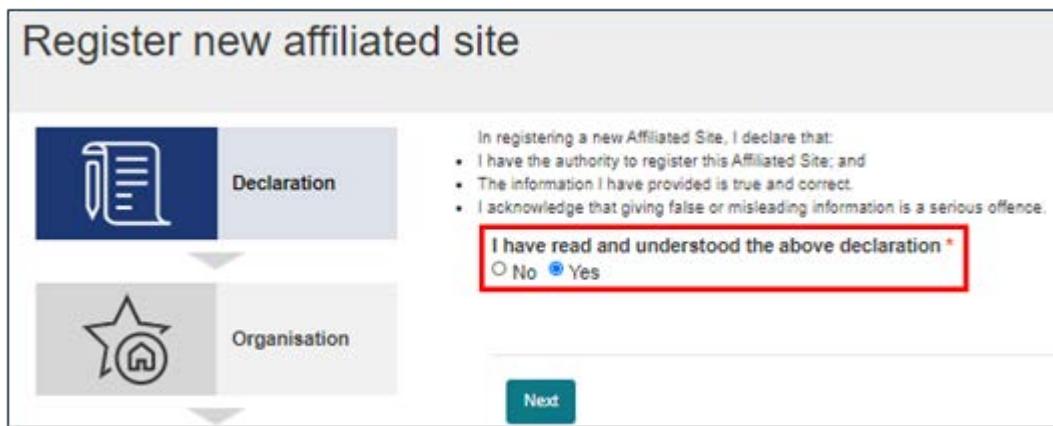
The screenshot shows the SAS dashboard with the following layout:
 - Top left: Australian Government Department of Health logo.
 - Top center: 'Regulatory and Compliance' text.
 - Top right: 'Chandra test -'.
 - Navigation bar: Home, SAS Home Page, SAS Dashboard, **My affiliated sites** (highlighted with a red box), Authorised Prescriber Dashboard, Authorised Prescriber Reports.
 - Main content area: 'My affiliated sites' tab is active.

- Select 'Register a new site':



The screenshot shows the 'My affiliated sites' page with the following layout:
 - Top left: 'My affiliated sites' tab.
 - Top right: 'Chandra test -'.
 - Main content area: 'All sites' section with a 'Register a new site' button highlighted with a red box.

- Read and acknowledge the following declaration:



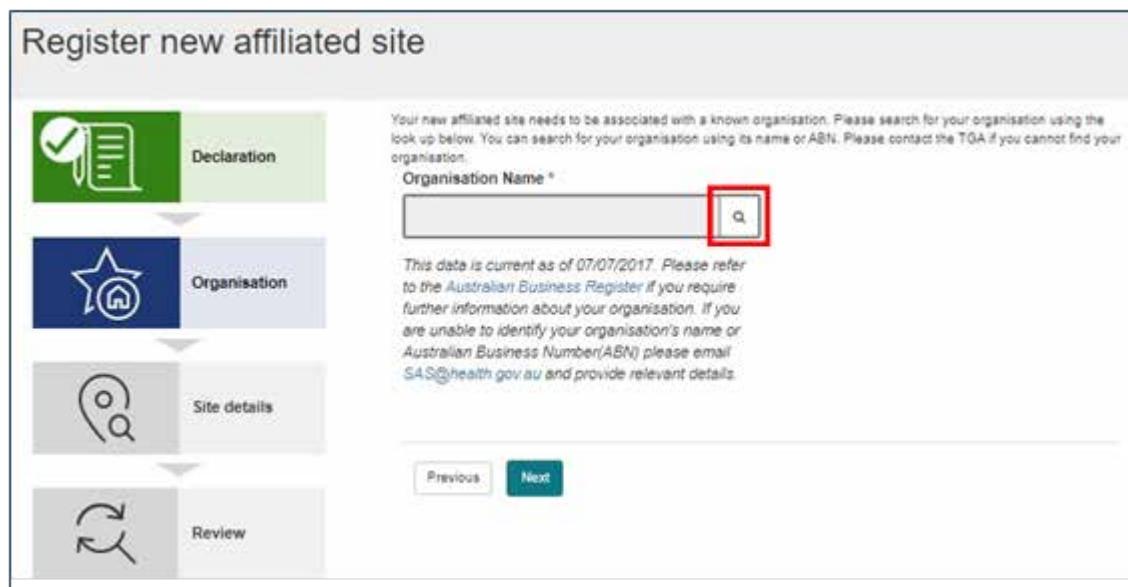
The screenshot shows the 'Register new affiliated site' declaration page with the following layout:
 - Top left: 'Declaration' section with a document icon.
 - Top right: 'Organisation' section with a star icon.
 - Declaration text: 'In registering a new Affiliated Site, I declare that:

- 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 *' with a 'Yes' radio button selected.
 - Bottom right: 'Next' button.

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.

Previous

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

	ABN	Name Type
▼ 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.

Organisation Name *Wesfarmers Federation Insurance

Site Name *TEST SITE

Your site name has been successfully validated

Location 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

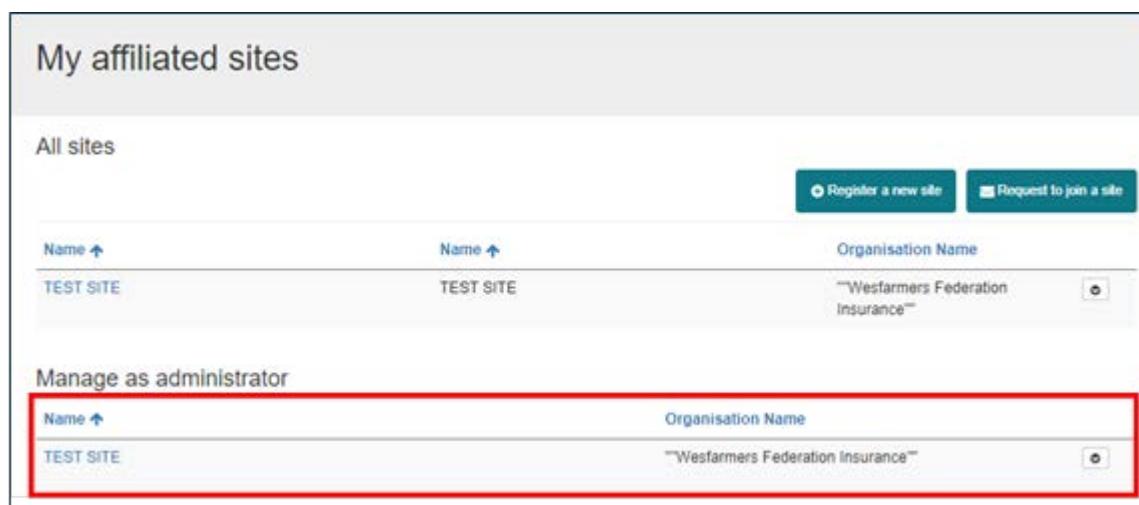
Suburb *SYDNEY

State *NSW

Postcode *2000

Previous Submit

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



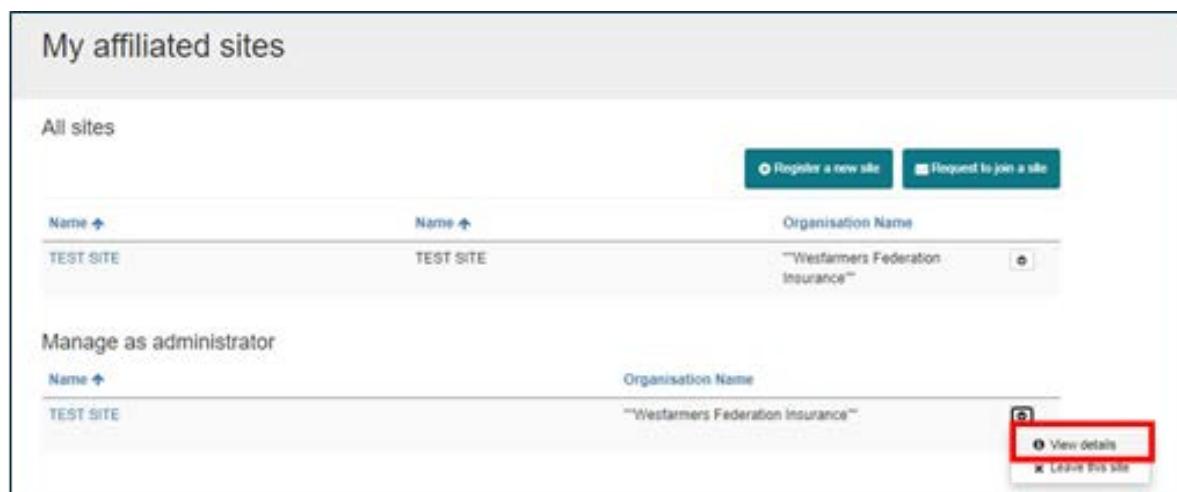
The screenshot shows the 'My affiliated sites' page with a single registered site. The site is named 'TEST SITE' and is associated with the organization 'Westfarmers Federation Insurance'. There are buttons for 'Register a new site' and 'Request to join a site'. A red box highlights the 'Manage as administrator' section, which shows the same site information with an additional 'Edit' button.

Name	Name	Organisation Name
TEST SITE	TEST SITE	“Westfarmers 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.

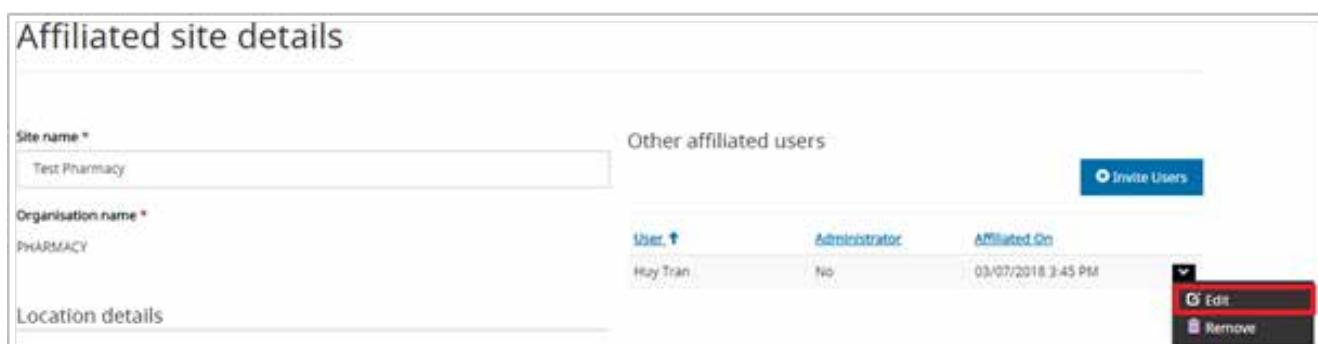
- To invite another user to become an Administrator, select the 'View details' button on the site:



The screenshot shows the 'My affiliated sites' page with a single registered site. The site is named 'TEST SITE' and is associated with the organization 'Westfarmers Federation Insurance'. The 'Manage as administrator' section shows the same site information. A red box highlights the 'View details' button, which is located next to the 'Edit' button. The 'View details' button is highlighted with a red box.

Name	Name	Organisation Name
TEST SITE	TEST SITE	“Westfarmers Federation Insurance”

- 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 includes fields for 'Site name' (Test Pharmacy), 'Organisation name' (PHARMACY), and 'Location details'. On the right, there is a table for 'Other affiliated users' with one row for 'Huy Tran'. The 'Edit' button for this user is highlighted with a red box. The 'Edit' and 'Remove' buttons in the bottom right corner of the table are also highlighted with red boxes.

User	Administrator	Affiliated On
Huy Tran	No	03/07/2018 3:45 PM

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

 Edit User X

Affiliated Site *
Test Pharmacy

Person *
Huy Tran

Site Administrator
* No Yes

Submit

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

Affiliated site details

Site name *

Other affiliated users

[Invite Users](#)

Organisation name *

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	Other affiliated users
Organisation Name *	Example Organisation	User ↑ Administrator Affiliated On <div style="border: 2px solid red; padding: 2px; margin-top: 10px;">Invite Users</div>
Location details <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">There are no records to display.</div>		
Suite/Room/Office <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"></div>		
Address Line 1 * <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">25 Smith st</div>		
Address Line 2 <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"></div>		

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

Invite users

Affiliated Site
TEST SITE

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](#).

Enter email address Remove

[Add another](#)

[Next](#)

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

Invite users

Affiliated Site
TEST SITE

Please enter a list of email addresses in the field below with each address on a separate line. Return to [single entry field](#).

Enter email addresses

[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.

- test1@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

Name	Name	Organisation Name
TEST SITE	TEST SITE	“Wesfarmers Federation Insurance”

Request to join a site

[Register a new site](#) [Request to join a site](#)

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:

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:

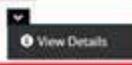
Manage as administrator

 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



- 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.

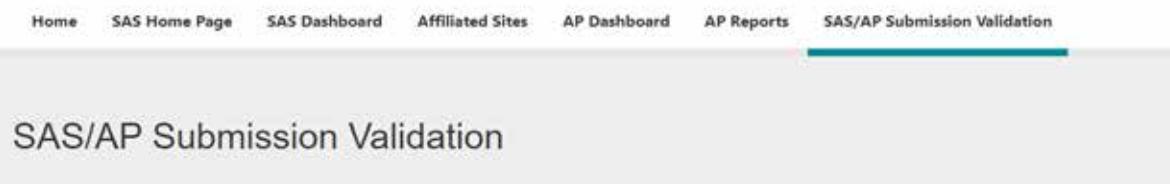
To access the validation tool:

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



The screenshot shows the 'Regulatory and Compliance' dashboard. At the top, there is a logo for the Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration. Below the logo, a navigation bar includes links for Home, SAS Home Page, SAS Dashboard, Affiliated Sites, AP Dashboard, AP Reports, and SAS/AP Submission Validation. The 'SAS/AP Submission Validation' link is highlighted with a red box.

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



The screenshot shows the 'SAS/AP Submission Validation' page. At the top, the title 'SAS/AP Submission Validation' is displayed. Below the title, a note states: 'The validation tool provides real-time monitoring of TGA approval/notification information under the SAS and AP scheme to support safe dispensing and supply of unapproved therapeutic goods to patients. The tool does not replace and is not to be used in place of the TGA decision letter. Healthcare practitioners should be aware that each state and territory has its own laws regulating the prescribing and dispensing of unapproved therapeutic goods.' Under this note, there is a section titled 'How to use the validation tool' with a list of instructions. At the bottom of the page is a search form with a text input field containing 'e.g. MB20-1234567' and a 'Search' button.

4. 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:

The screenshot shows a search bar with the placeholder 'Search...' and a 'Save list as CSV' button. Below the search bar is a table header with columns: Select, Site, Patient initials, DOB, Prescriber, Product, Submission date, Status, and Actions. The 'Actions' column contains a dropdown menu. The table body is empty, displaying the message 'There are no submissions to display in this view.'

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

The screenshot shows the same dashboard as above, but with a red box highlighting the 'Search...' input field. The rest of the interface, including the table header and body, is identical to the first screenshot.

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:

The screenshot shows the dashboard with three submissions selected, indicated by a red box around the checkboxes in the 'Actions' column. The 'Save list as CSV' button is highlighted with a red box. The table body contains three rows of submission data.

Select	Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
<input checked="" type="checkbox"/>	test	14/09/1995	Aryez Ahmed	Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/>	test	14/09/1995	Aryez Ahmed	Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/>	test	14/09/1995	Aryez Ahmed	Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>	

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:

Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	Under TGA Review	<input type="button" value="View details"/>
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	Under TGA Review	<input type="button" value="Download receipt(s)"/>
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	Under TGA Review	<input type="button" value="Clone"/>
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	Under TGA Review	<input type="button" value="View details"/>

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.

Site	Patient initials	Patient DOB	Prescriber	Product	Created date	Actions
test		19/06/2014	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	11/11/2021	<input type="button" value="View details"/>
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	<input type="button" value="View details"/>
test		14/09/1995	Ayyaz Ahmad	Category 1-CBD medicinal cannabis product (CBD>50%)	15/11/2021	<input type="button" value="View details"/>

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.

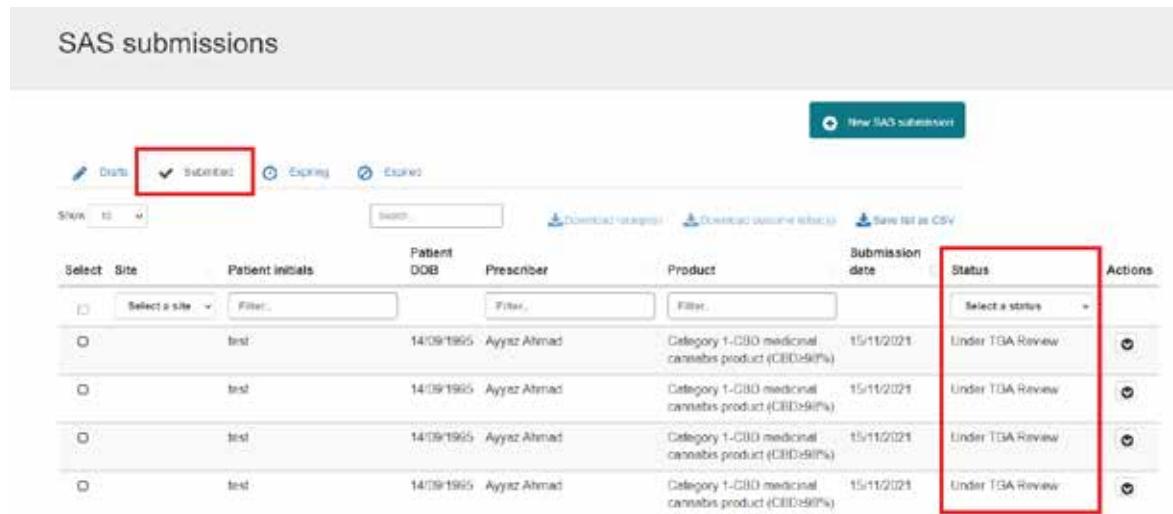
Saving as 'Draft'

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'.



The screenshot shows a table of SAS submissions. The columns are: Select, Site, Patient initials, Patient DOB, Prescriber, Product, Submission date, Status, and Actions. The 'Status' column for all four entries is highlighted with a red box. The 'Submitted' status is also highlighted with a red box in the top navigation bar.

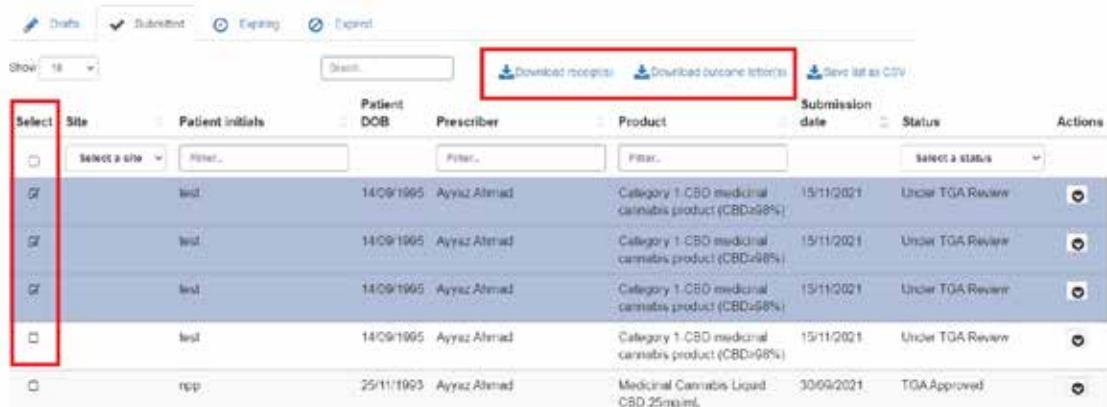
Select	Site	Patient initials	Patient DOB	Prescriber	Product	Submission date	Status	Actions
<input type="checkbox"/>	Select a site	Filter...	Filter...	Filter...	Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>
<input type="checkbox"/>	test	14/09/1995	Ayyaz Ahmad		Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>
<input type="checkbox"/>	test	14/09/1995	Ayyaz Ahmad		Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>
<input type="checkbox"/>	test	14/09/1995	Ayyaz Ahmad		Category 1-CBD medicinal cannabis product (CBD>90%)	15/11/2021	Under TGA Review	<input checked="" type="checkbox"/>

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

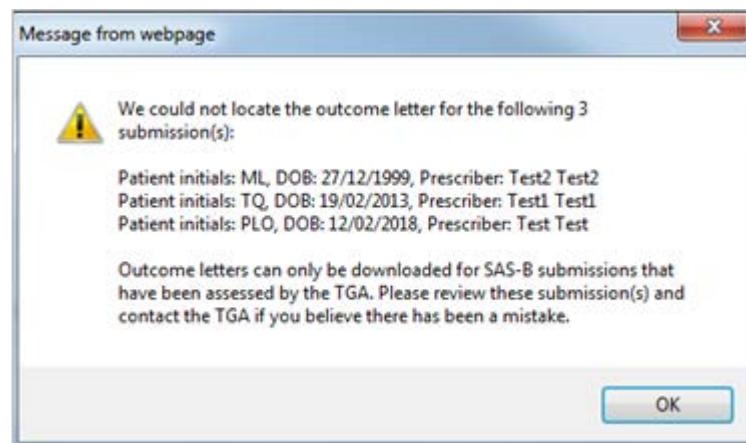
Users will have the ability to download receipts and outcome letters provided by the TGA through their dashboard. This can be done on a single submission basis or a bulk download by selecting the submissions of interest as shown below:



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

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

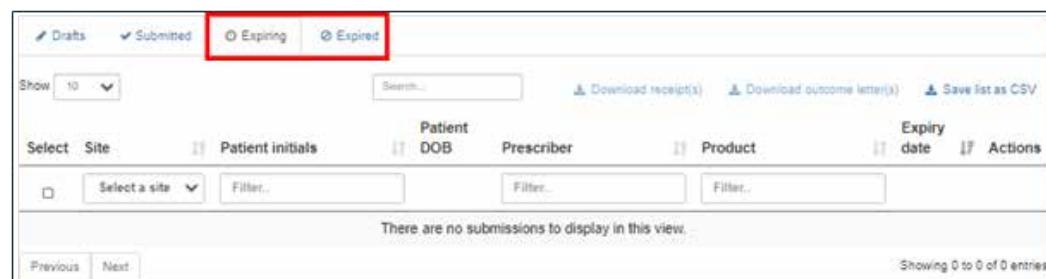
1. The user is attempting to download an outcome letter for a SAS Category A or SAS Category C notification (as outcome letters are only applicable to SAS Category B applications); and
2. The outcome letter for that SAS Category B application is not yet available.



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.



Select	Site	Patient initials	Patient DOB	Prescriber	Product	Expiry date	Actions
There are no submissions to display in this view.							
Showing 0 to 0 of 0 entries							

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

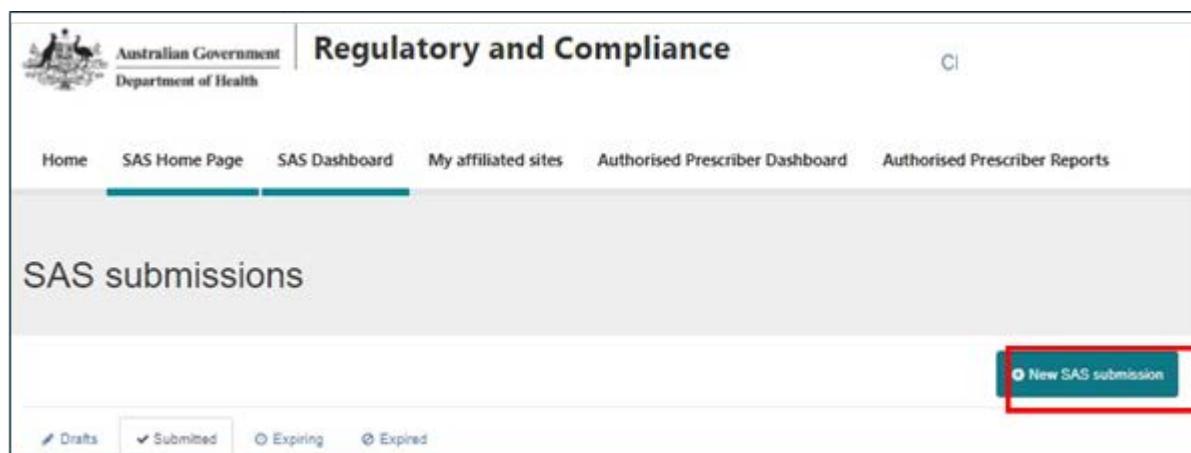
1. Prompt health practitioners to conduct a review of the patient's condition post-treatment.
2. Ensure continuation of patient care by accessing unapproved therapeutic goods under the SAS should the patient require further treatment.
3. If supply of the unapproved therapeutic good is still required 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.

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':



The screenshot shows the 'Regulatory and Compliance' section of the SAS submissions dashboard. At the top, there is a logo for the Australian Government Department of Health. Below the logo, there is a navigation bar with links for 'Home', 'SAS Home Page', 'SAS Dashboard', 'My affiliated sites', 'Authorised Prescriber Dashboard', and 'Authorised Prescriber Reports'. The 'SAS Dashboard' link is underlined, indicating it is the active page. The main content area is titled 'SAS submissions'. At the bottom of this area, there are four filter buttons: 'Drafts' (with a draft icon), 'Submitted' (with a checkmark icon), 'Expiring' (with an exclamation mark icon), and 'Expired' (with a crossed-out circle icon). To the right of these filters, there is a green button with white text that says 'New SAS submission'. This button is highlighted with a red rectangular box.

Step 1 – Prescriber details

- 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	MED14345678
First name *	Practitioner type *
Chandra	Name
Last name *	Prescriber specialty
Net	—

Principal place of practice

Business or practice name *	Email *
ACME Specialist Services	seccorespro04@evarmore.com
Address line 1 *	Phone
23 Ronald Avenue	243289462
Address line 2	Fax
Suburb *	
Woden	
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.

Prescriber details

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

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

The screenshot shows a vertical flow of five steps: Prescriber details, Product selection, Product details, Patient details, and Summary. Each step has a corresponding icon on the left and a label on the right. The Product selection step is currently active, showing a list of therapeutic good types: Medicine (selected), Biological, and Medical Device. A note at the top right explains that the TGA regulates therapeutic goods as Medicines, Biologicals, or Medical Devices, and that these definitions may differ from those used in the clinical setting. Buttons for 'Previous' and 'Save and Next' are visible at the bottom of the Product selection step.

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 screenshot shows the Product selection step expanded to show the Medicine section. The section title 'Medicine' is bolded. Below it is a note: 'Please use the search below to make your product selection (including active ingredient, dosage form and indication)'. A search input field with a magnifying glass icon is highlighted with a red box. Below the input field is a checkbox: 'The active ingredient(s) I need could not be found through the search tool'. The other steps in the flow (Prescriber details, Product details, Patient details, Summary) are visible on the left.

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

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:

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:

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 *

Chandira 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:

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)
Famotidine

Dosage form
Capsule

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

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



Patient details

Patient Initials *
FWM

Date of birth *
28/09/2015

Gender *
 Male
 Female
 Indeterminate/Intersex/Unspecified

MRN
326598

Previous SAS number
MB23-0000001

Diagnosis

Diagnose(es) relevant to this SAS submission *
Crohn's disease

Clinical justification *
Text

Intended monitoring

Please provide details of intended monitoring *

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

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.

Your personal information 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, 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.

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, 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.

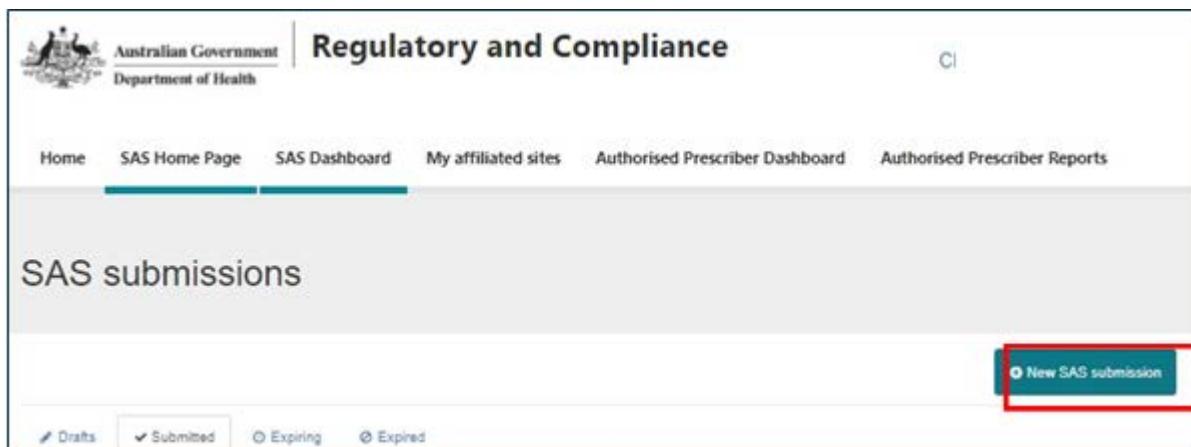
I have read and understood the Privacy Statement and Consent *

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.

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':



The screenshot shows the SAS dashboard with the following navigation menu:

- Home
- SAS Home Page
- SAS Dashboard (highlighted)
- My affiliated sites
- Authorised Prescriber Dashboard
- Authorised Prescriber Reports

Below the menu, the 'SAS submissions' section is displayed. At the bottom of this section is a teal button labeled 'New SAS submission', which is highlighted with a red box.

Filter options at the bottom of the 'SAS submissions' section include: Drafts, Submitted, Expiring, and Expired.

Step 1 – Prescriber details

1. 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

Are you the prescriber? *

Yes

No

Please review the prescriber details below.

Title *	AHPRA number
Mr	PHA0000001234
First name *	Practitioner type *
Pharmacist	Pharmacist
Last name *	Prescriber specialty
Test	—

Principal place of practice

Business or practice name *	Email *
TGA	SAS.Support@health.gov.au
Address line 1 *	Phone
27 Scherzer Dr	1800 020 653
Address line 2	Fax
Suburb *	
Canberra Airport ACT	
State *	
ACT	
Postcode *	
2609	

[Save and Next](#)

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

Product details

Patient details

Summary

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) *

q

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

Dosage form *

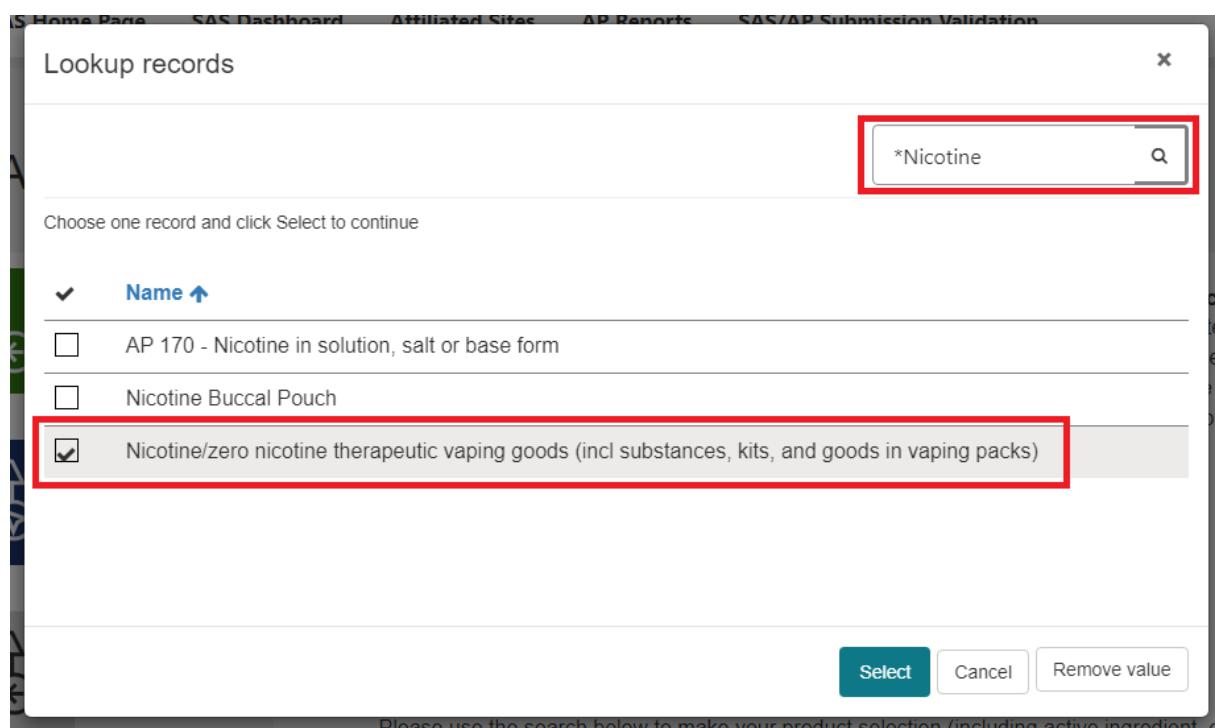
—

Indication *

—

Previous **Save and Next**

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



Lookup records

*Nicotine

Choose one record and click Select to continue

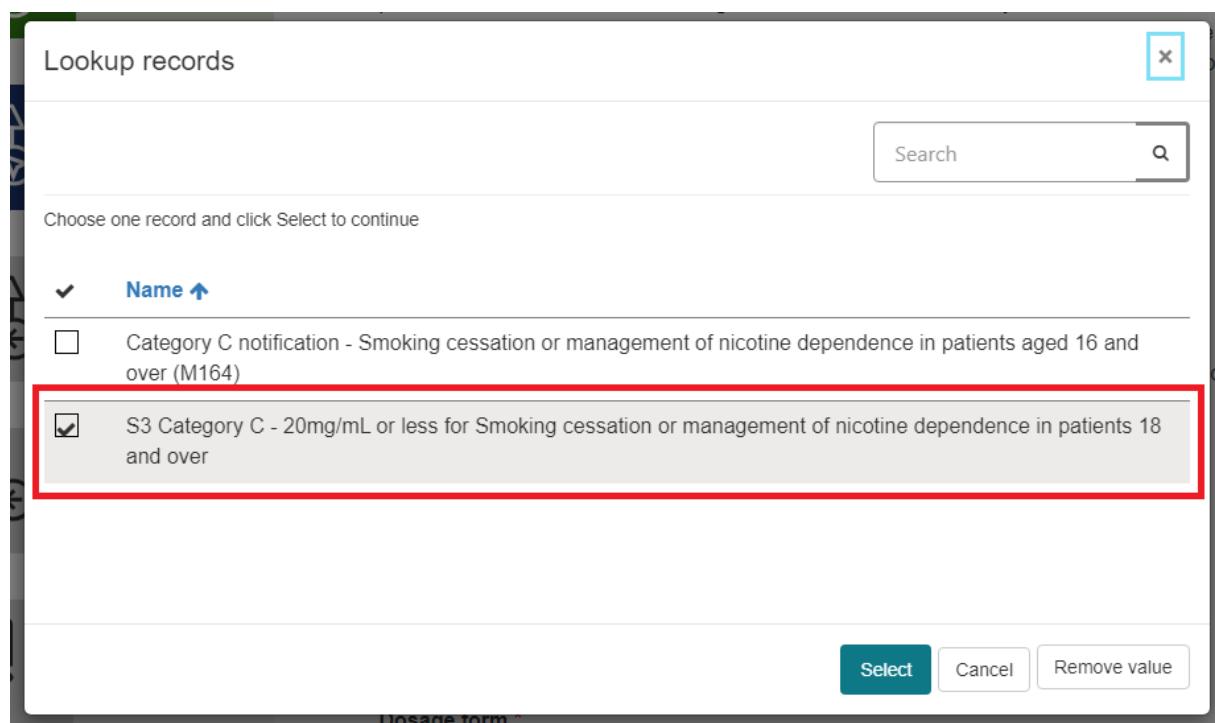
✓ Name ↑

- AP 170 - Nicotine in solution, salt or base form
- Nicotine Buccal Pouch
- Nicotine/zero nicotine therapeutic vaping goods (incl substances, kits, and goods in vaping packs)

Select Cancel Remove value

4. Use the search bar to identify the dosage form. To search on partial text, use the asterisk (*) wildcard character.

5. For Schedule 3 Products included in the [SAS C list](#), type “S3” into the search bar and identify the indication that includes ‘Category C’ as part of the text. To search on partial text, use the asterisk (*) wildcard character (e.g. “*S3”):



Lookup records

Search

Choose one record and click Select to continue

✓ Name ↑

- Category C notification - Smoking cessation or management of nicotine dependence in patients aged 16 and over (M164)
- S3 Category C - 20mg/mL or less for Smoking cessation or management of nicotine dependence in patients 18 and over

Select Cancel Remove value

Note: If the indication you select does not begin with “S3” then the prescriber listed in step 1 should not be a pharmacist.

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 *

Select



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 *

Select

Intended date of supply *

 DD/MM/YYYY

Previous

Save and Next

Step 4 – Patient details

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

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.

Your personal information 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, 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.

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, 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 [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 & 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 [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.

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.

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) *

Category 1-CBD medicinal cann.

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

Dosage form *

Capsule

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

Indication *

anxiety

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 active ingredient 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.

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
Herb, dried (for vaporisation)

Strength * **Strength Unit ***

Route of Administration *
Vaporisation

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 *
14/09/85

Gender *
 Male
 Female
 Indeterminate/Intersex/Unspecified

MRN
326598

Previous SAS number
MB19/0000001

Diagnosis

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

Clinical justification *

Intended monitoring

Please provide details of intended monitoring *

Have you considered other ARTG Products? *
 Yes
 No

Supporting information

Do you have any recent specialist reports or additional information to support your application? *
 Yes
 No

There are no folders or files to display.

Additional Information

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:

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

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

Therapeutic Goods Administration

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<https://www.tga.gov.au>

Reference/Publication #