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

Version 1.10, October 2024

Contents

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. Toreduce 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 OnlineSystem 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

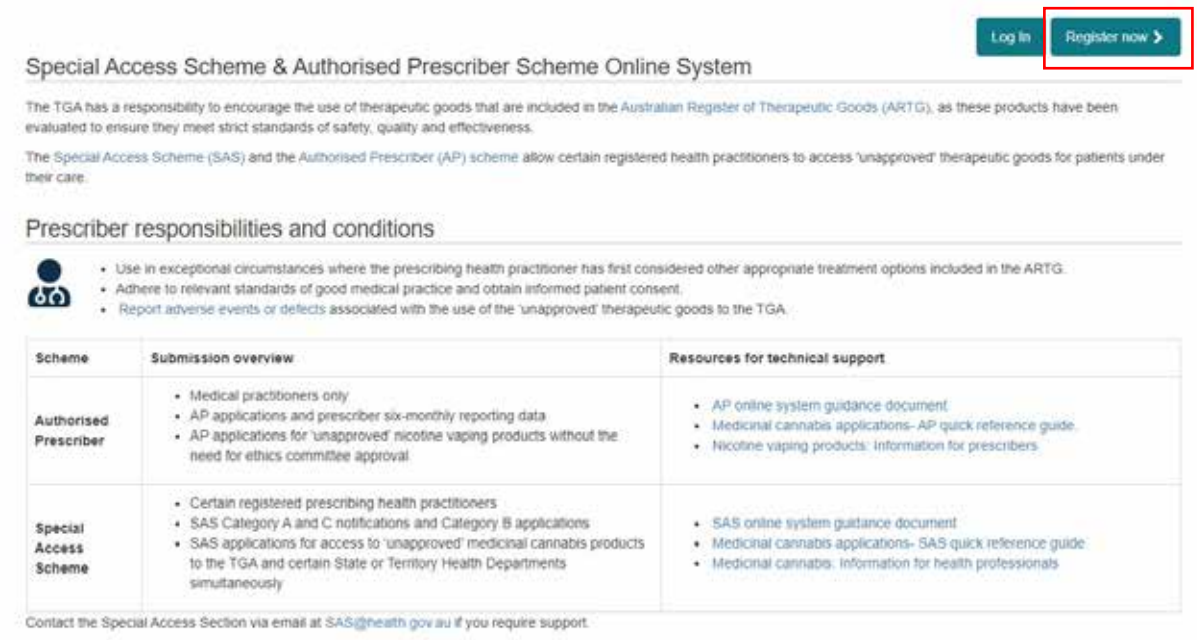
All users of the system are required to register a personal account. Users are required to provide the following information to successfully register an account:

- 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).

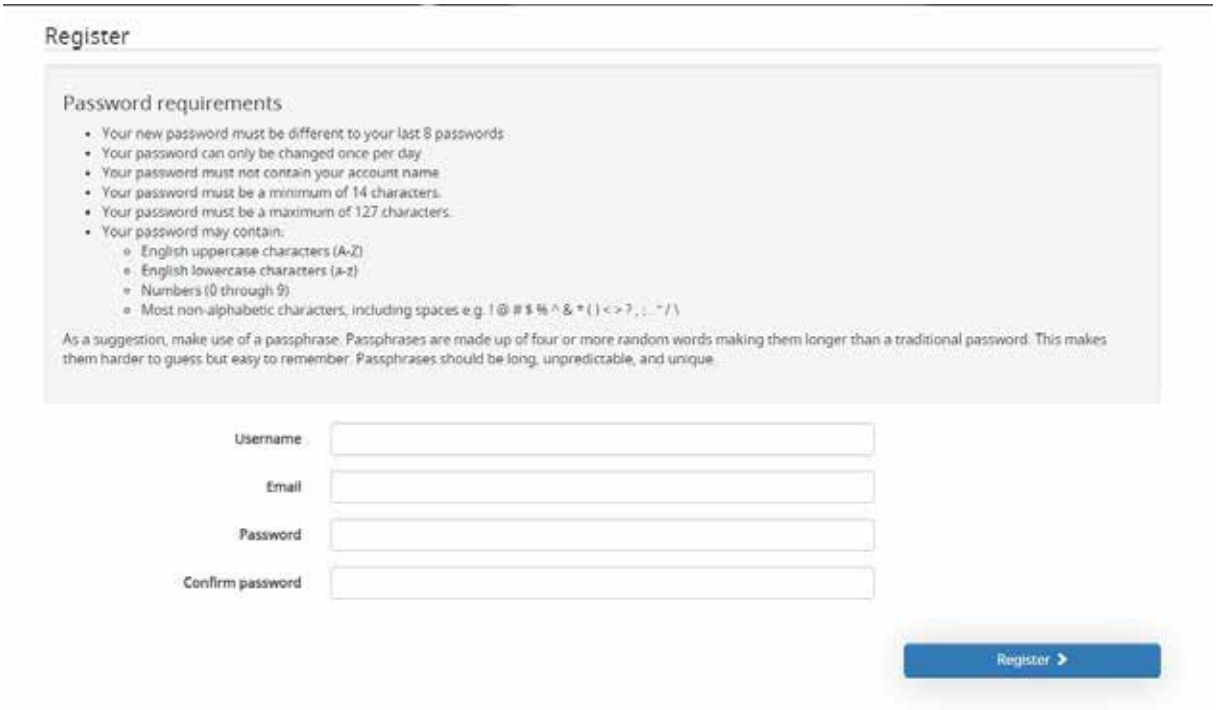
Note: users who have registered with other systems hosted by the TGA should login (rather than register) using the username and password to which they registered with the first TGA system.

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

2. Select Register Now



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



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

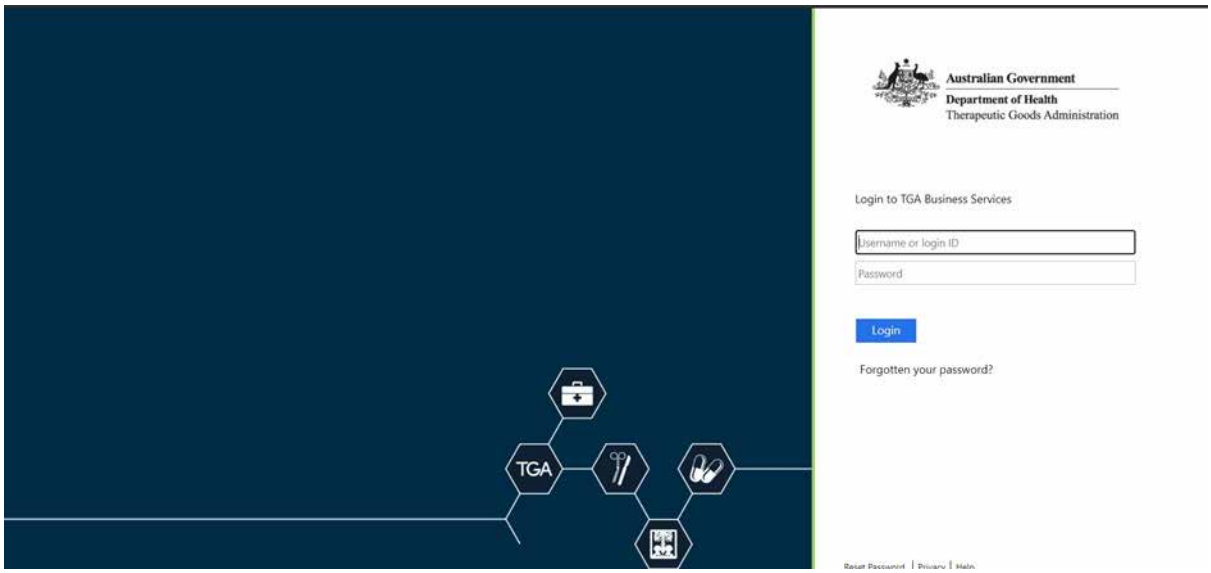
5. Click on the hyperlink in the email (note this link will expire in 24 hours after receiving this email):

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.dmz.development.tga.gov.au/portalaccounts/account/activate/af3f314c-716d-4470-88d2-c5f9d3b0ae14/288580002

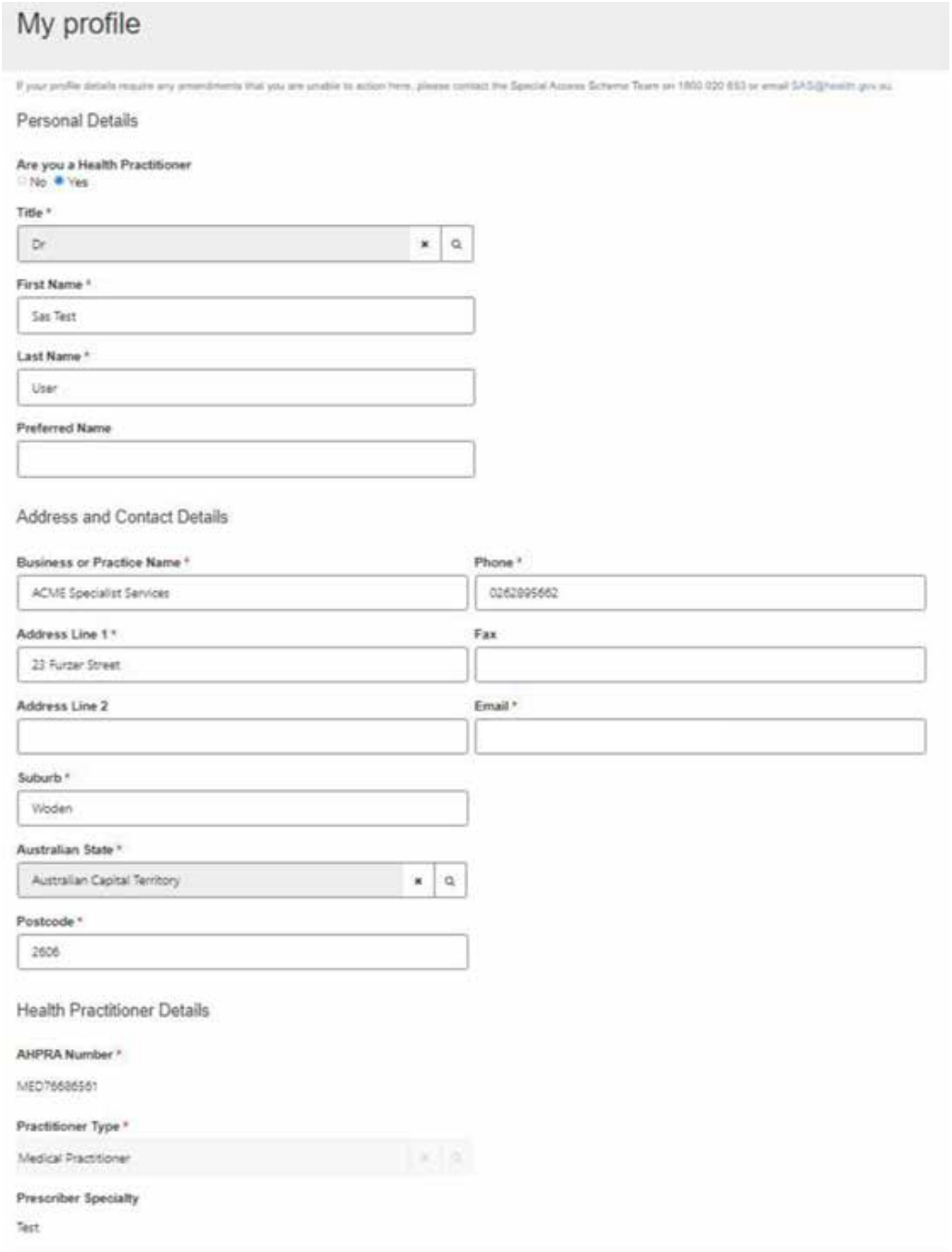
This link will expire in 24 hours.

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

6. Log in with your username and password:

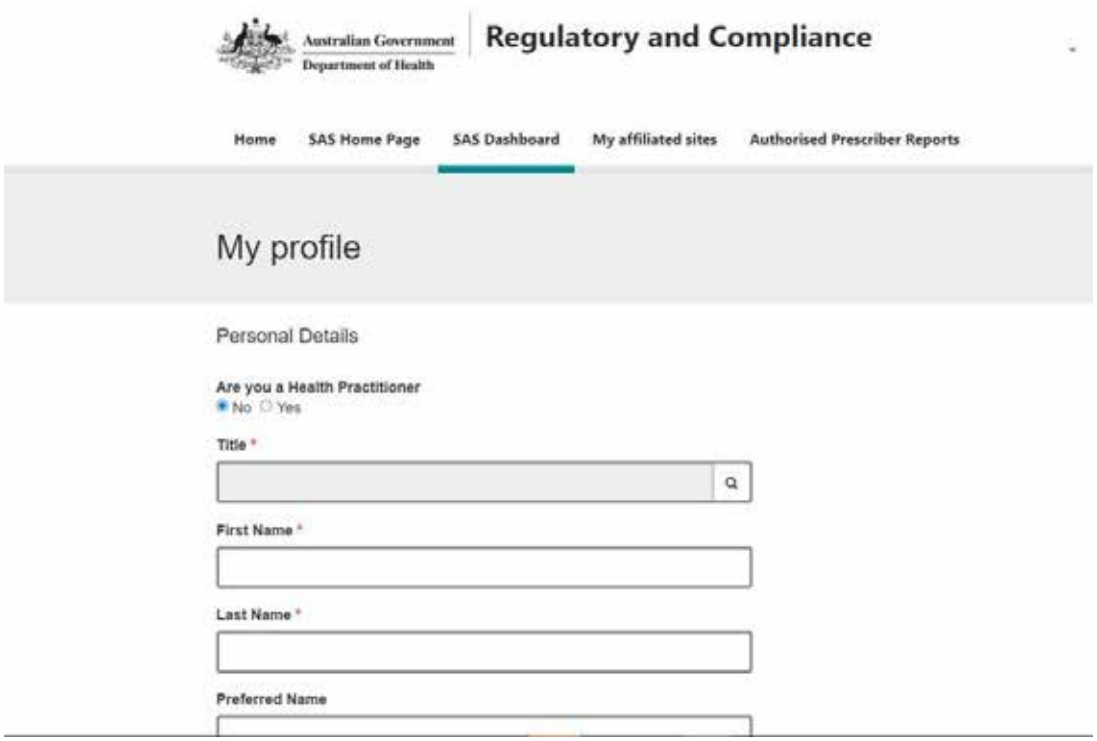


7. Complete your profile information. Your account registration is not finalised until you complete this step and you will not be able to submit applications/notifications.



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:



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

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

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

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

Non-health practitioners

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

Health practitioners

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

Non-health practitioners

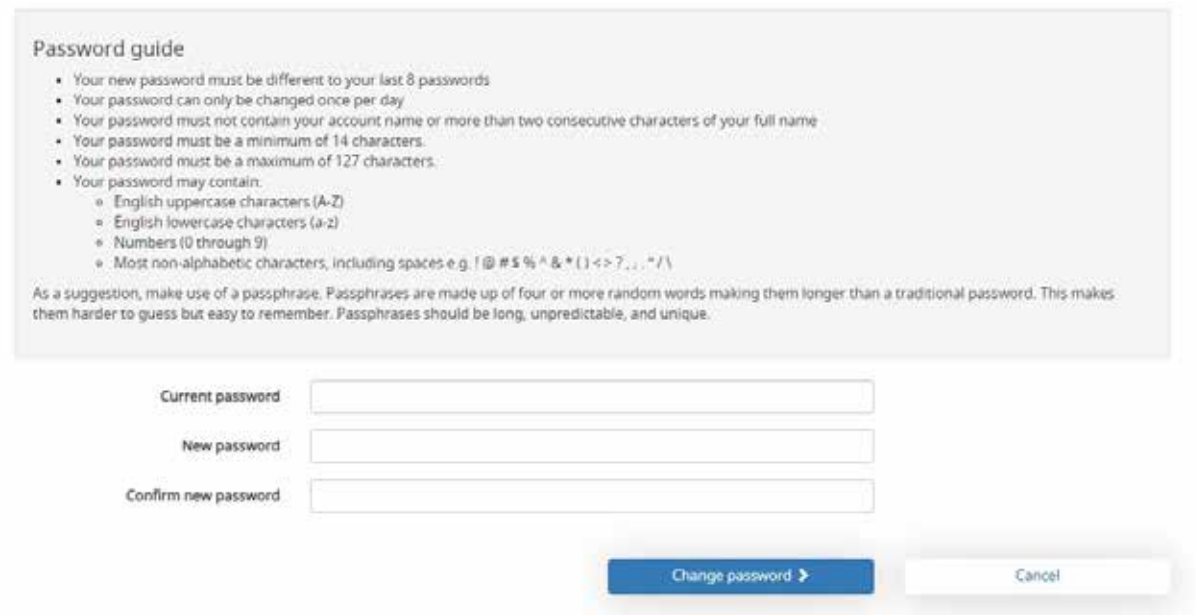
Do not have the ability to draft and submit SAS applications and notification to the TGA however may have oversight of applications and notifications being made by their affiliated site.

Change Password

Passwords will expire every 90 days. 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:

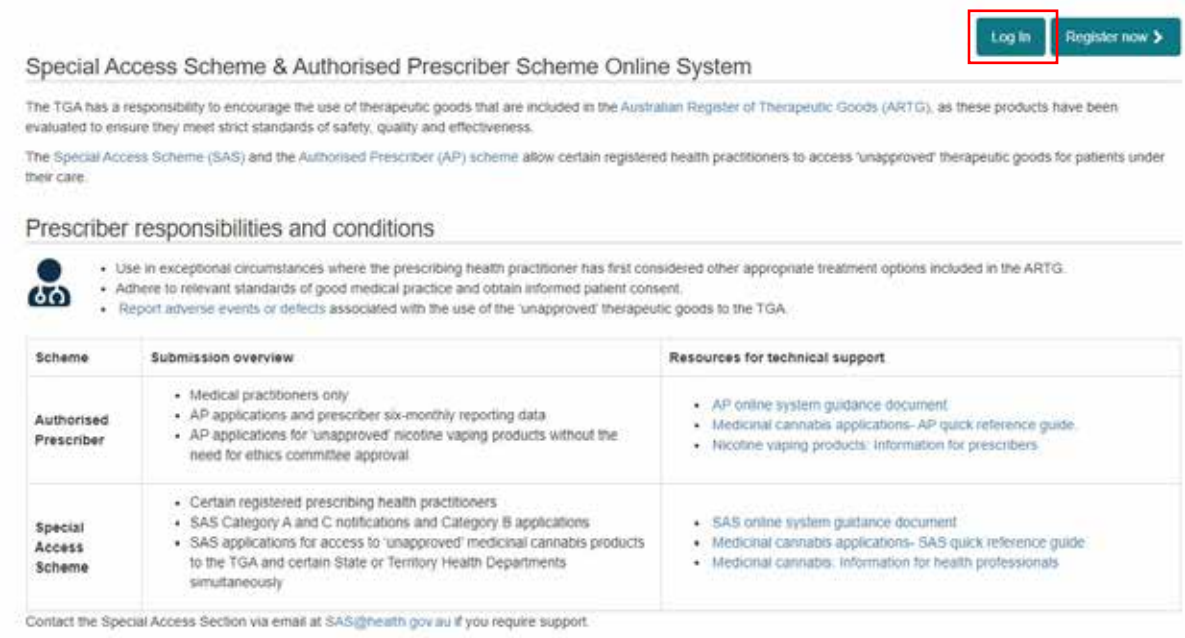


Note: Passwords cannot be reset or changed more than once in a 24 hour period.

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.

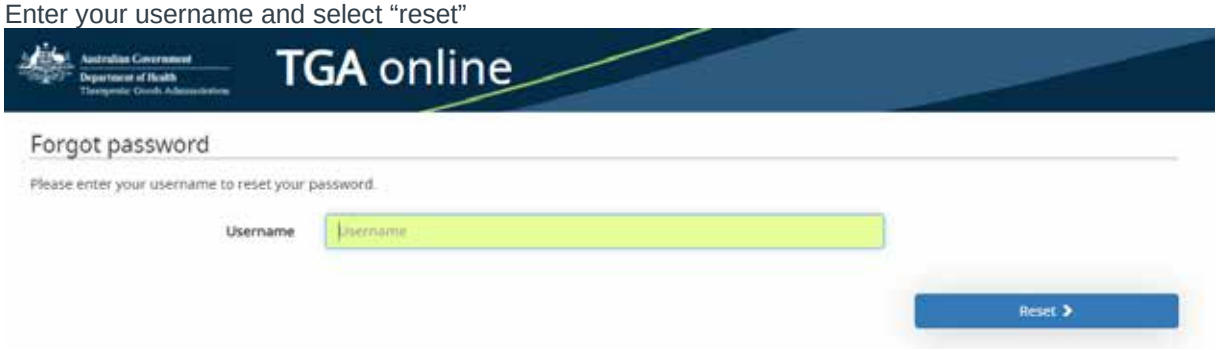
Forgotten your password

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

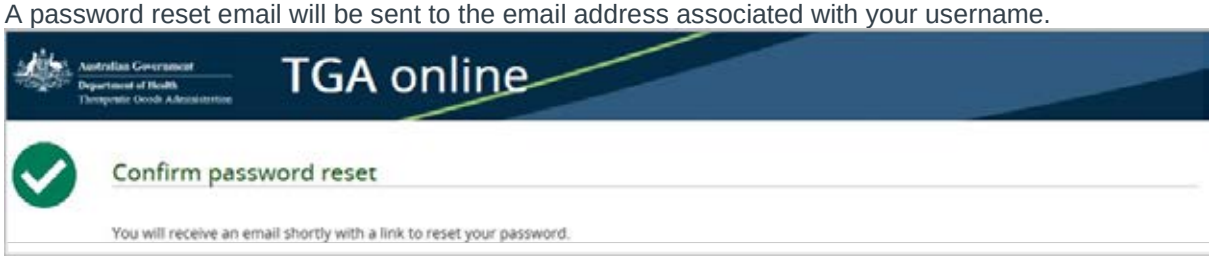


2. Select “Forgotten your password?”

3. Enter your username and select “reset”

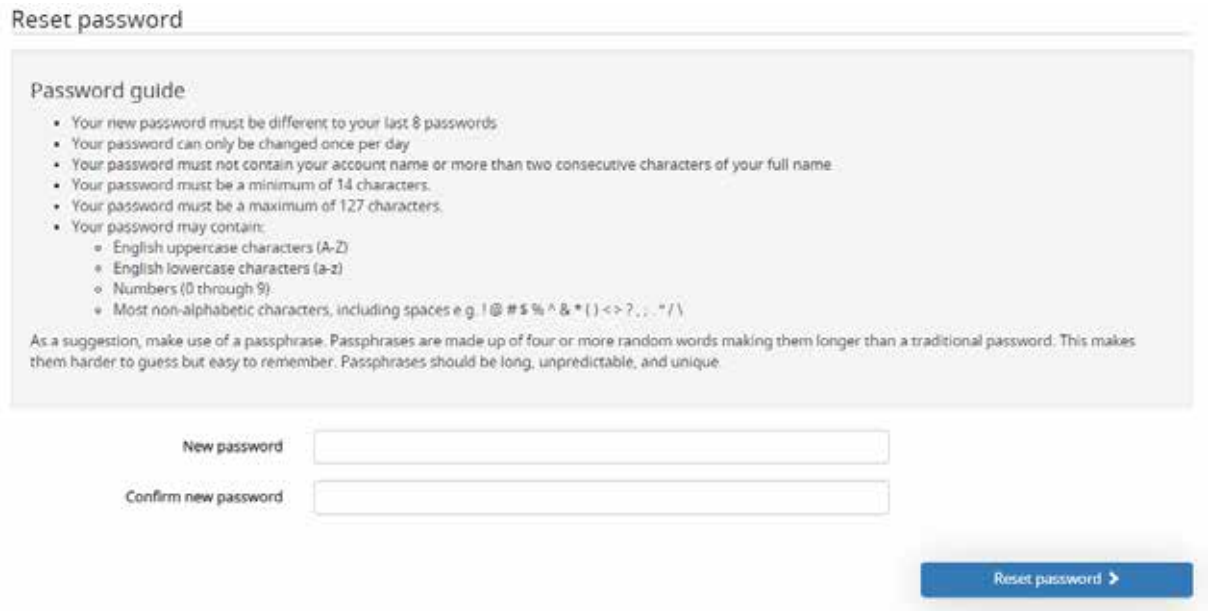


4. A password reset email will be sent to the email address associated with your username.



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

6. Enter your new password



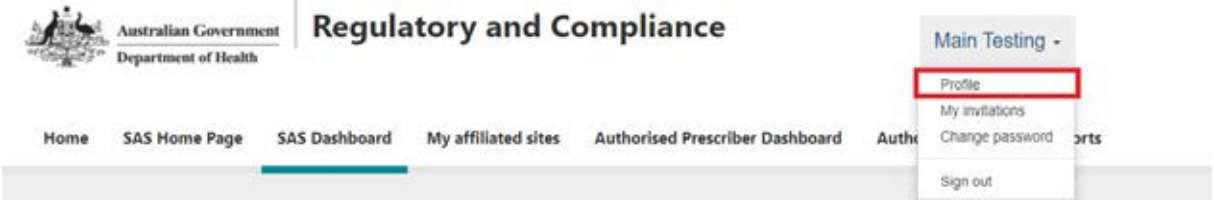
7.

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:



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:

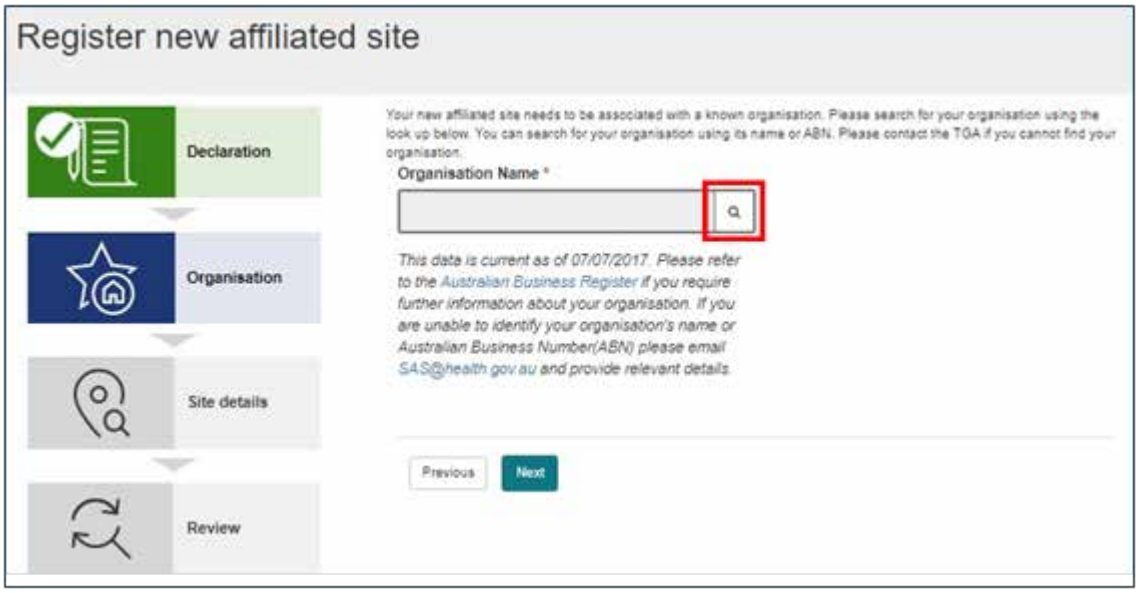
- Send invitations to affiliate with the Site via email.
- Accept or reject requests to affiliate with the Site.
- Edit the details of the affiliated Site (Site name, location information etc).
- Assign other users as Site Administrators (assuming they have successfully affiliated). To register a new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

1. Select the ‘My affiliated sites’ tab:

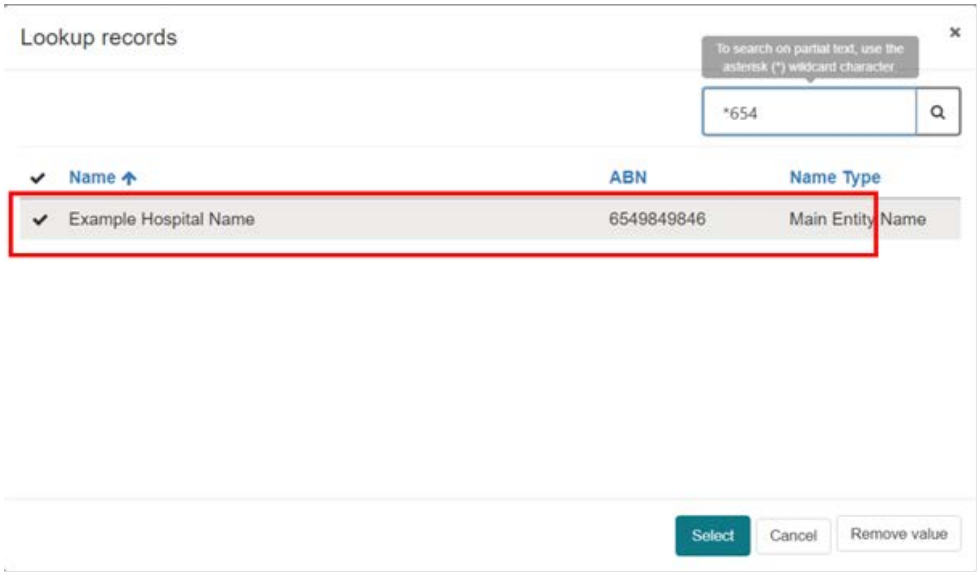
2. Select ‘Register a new site’:

3. Read and acknowledge the following declaration:

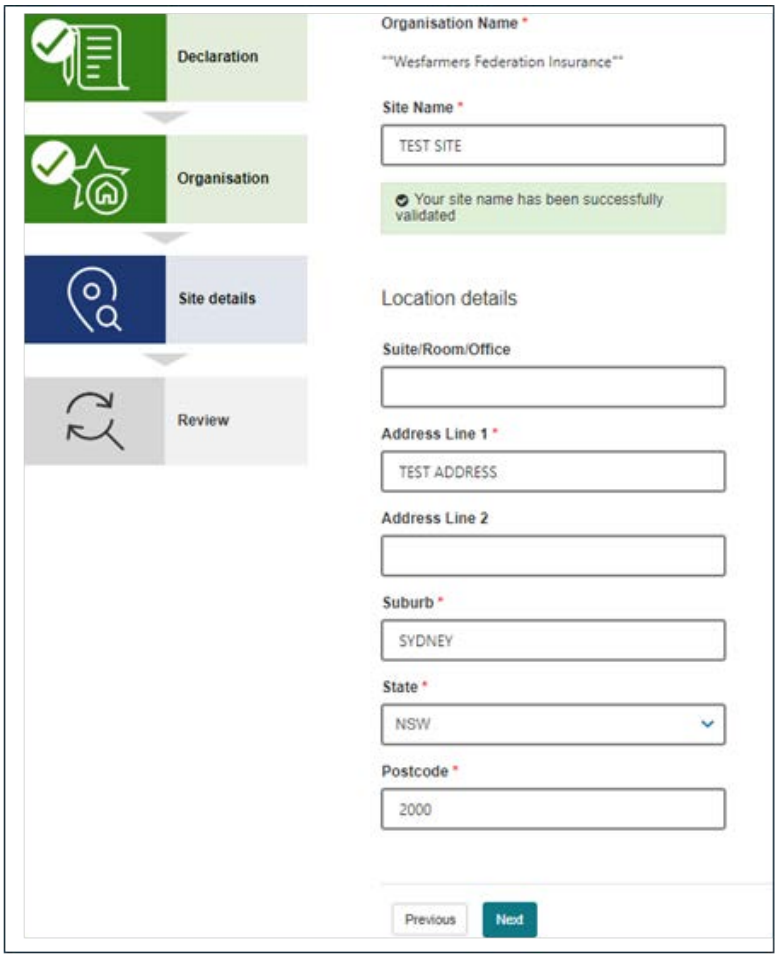
4. Select the lookup icon to search for the organisation you wish to register the Site against:



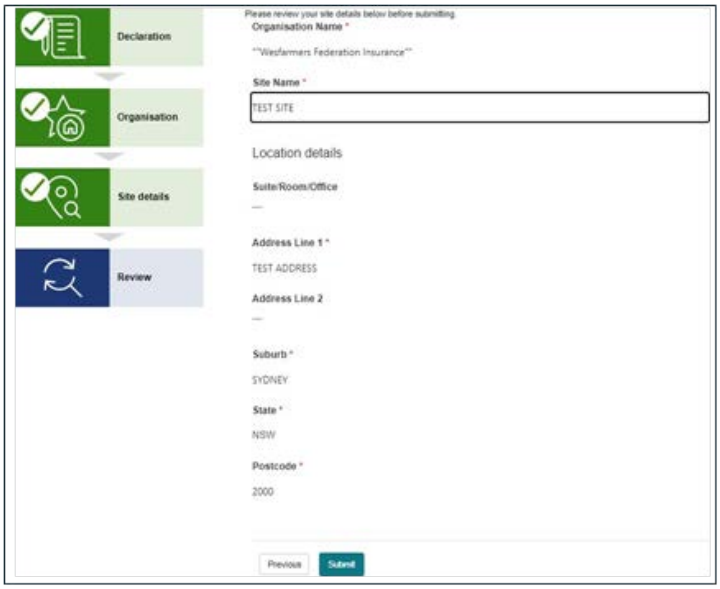
5. New organisations need to be added to the Online System. If your organisation is not available, please email SAS@health.gov.au with the Organisation Name and ABN so that it can be added to the look-up function. Once complete, this will allow users to then select that organisation and register an Affiliated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



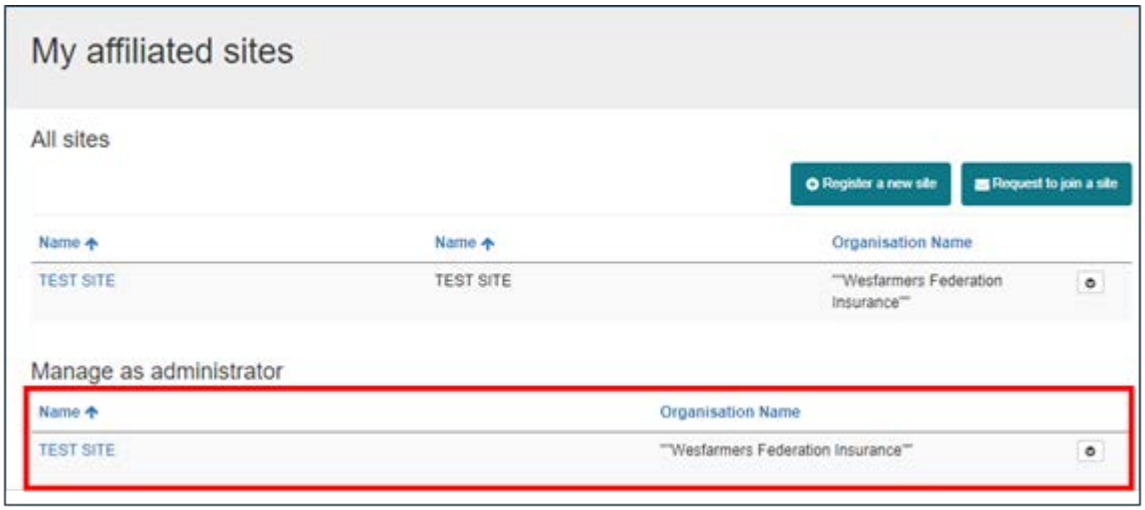
6. Once the organisation has been selected, provide the additional details associated with the Site you wish to register. It is important to note that the 'Site Name' is different from that of the organisation name. Multiple Sites may be registered under a single organisation (for example, a hospital 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.



7. Review the details before registering the Site:



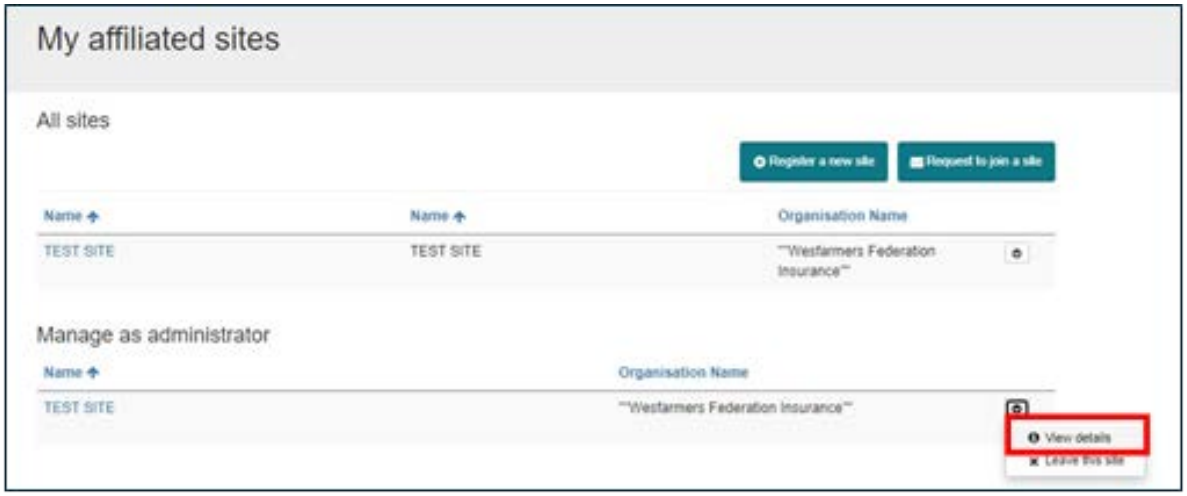
8. Once the Site has been registered, it will appear under the ‘My affiliated sites’ tab:



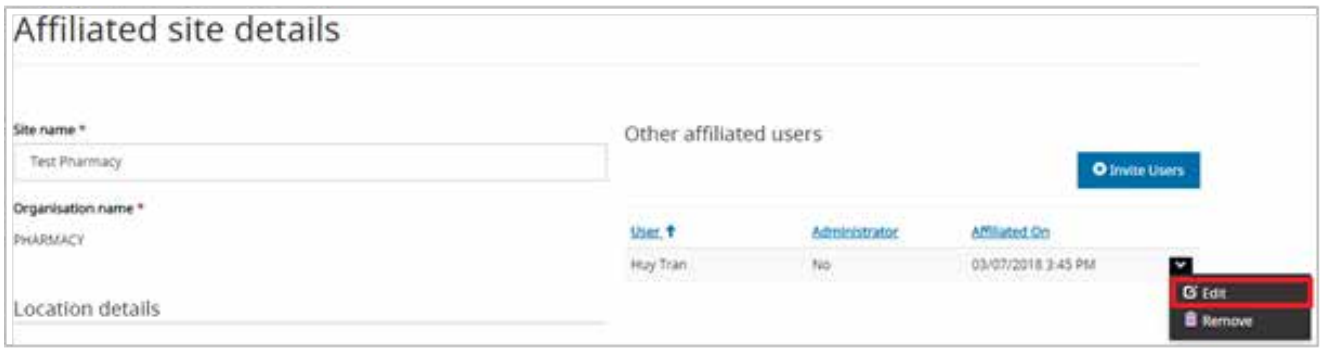
Adding a site administrator(s)

The role of a Site Administrator is automatically assigned to the user who first registers that site into the system. It is important to ensure that the user registering the site for the first time is an appropriate person as they will be granted rights to invite other users via email and 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.

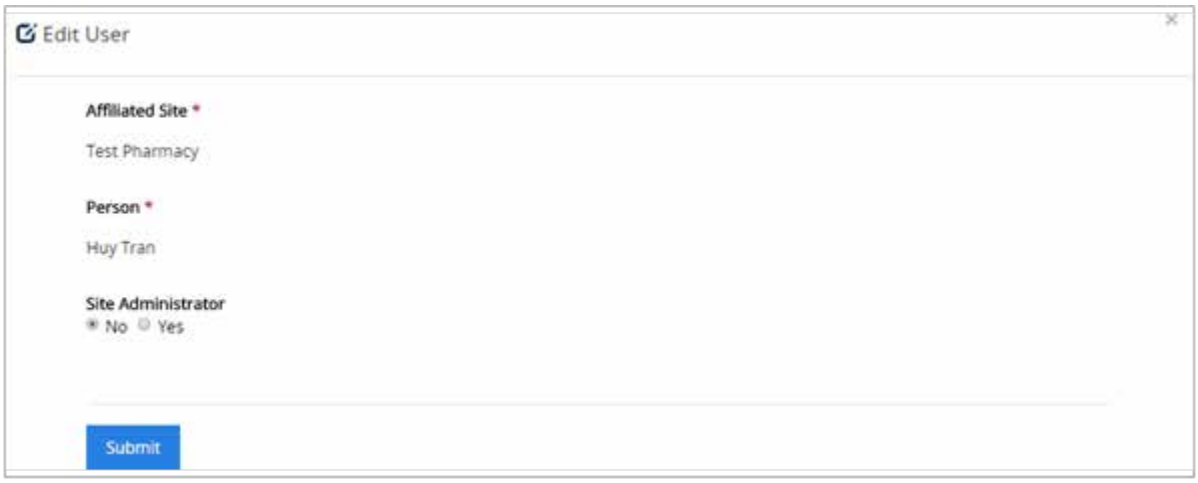
1. To invite another user to become an Administrator, select the ‘View details’ button on the site:



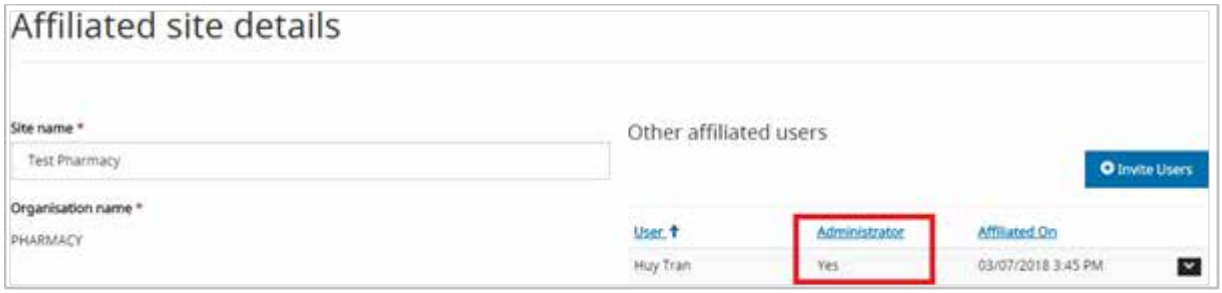
2. Select the user you wish to invite to become an Administrator and select the ‘Edit’ button:



3. Under ‘Site Administrator’, select ‘Yes’:

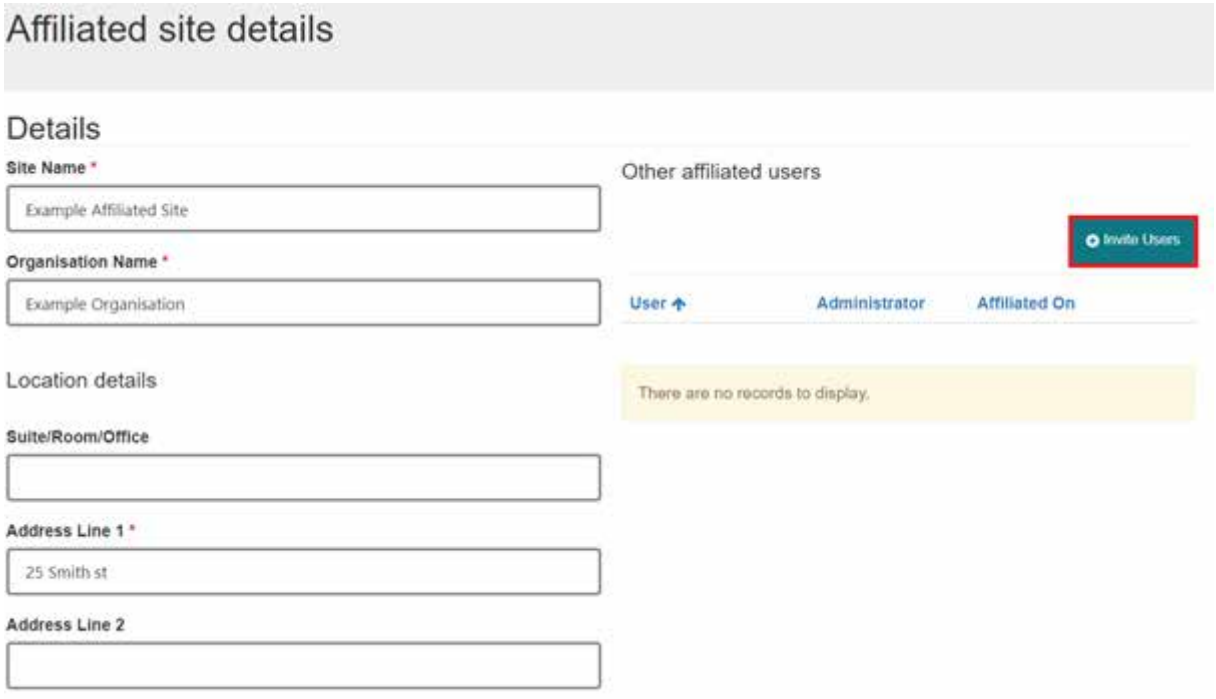


4. The user will now be listed as a Site Administrator:

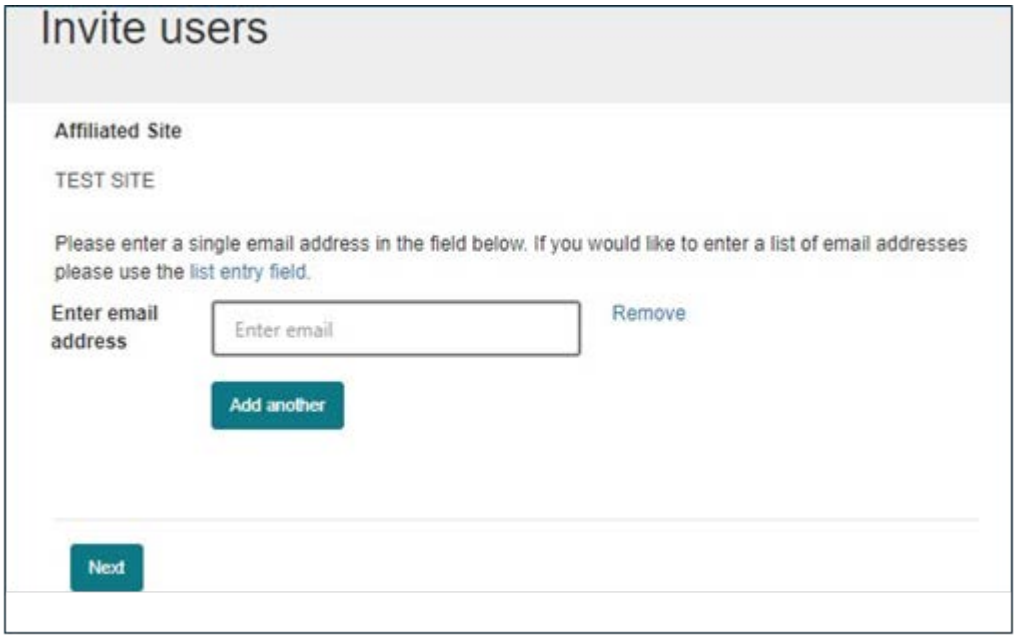


Sending invitations to affiliate

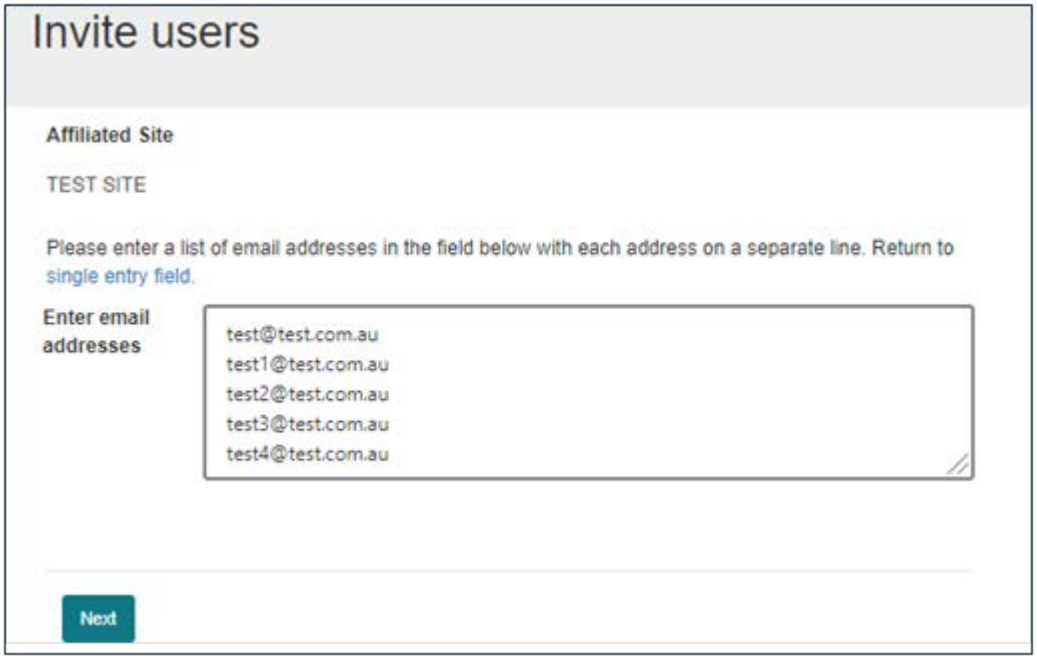
1. Site Administrators are able to invite others to affiliate with a site by clicking the ‘Invite Users’ button:



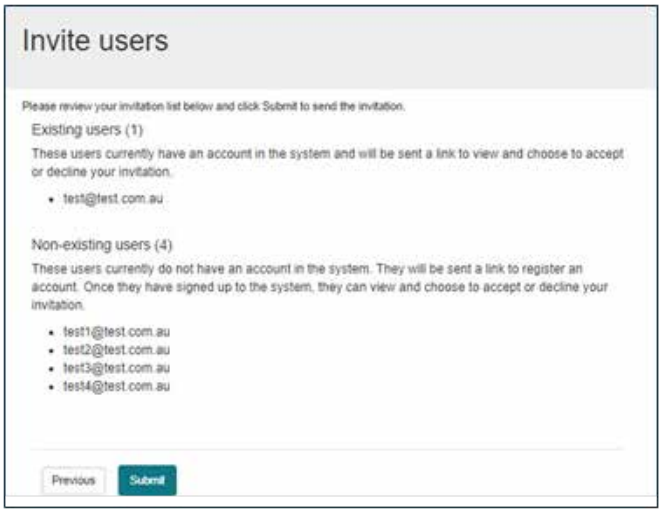
2. Invites to affiliate with the site will be sent via email. Email addresses can be entered individually:



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

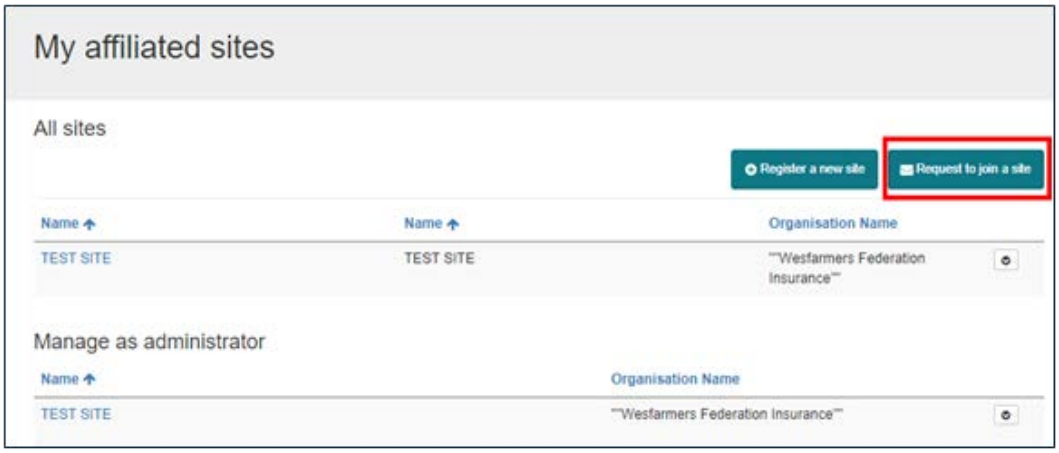


4. The system will identify those users who do not yet have a personal account registered in the system. In the below example, the4 email addresses are not registered in the system. Upon opening the email containing the invitation to affiliate with the site, the user will be required to register a personal account in the system. Once this has been registered, they will be presented with the option to accept or decline the invitation to affiliate:

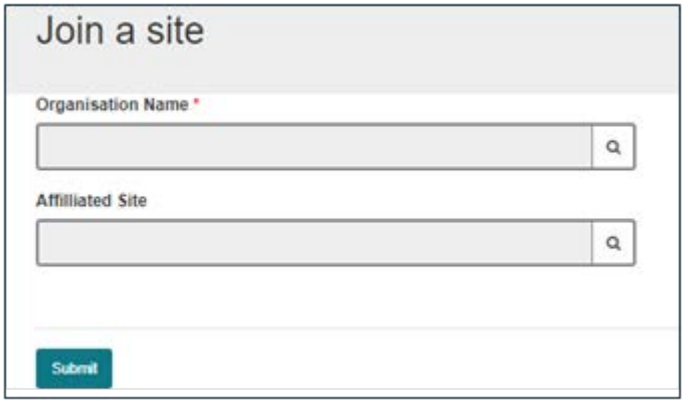


Requesting to affiliate with a site

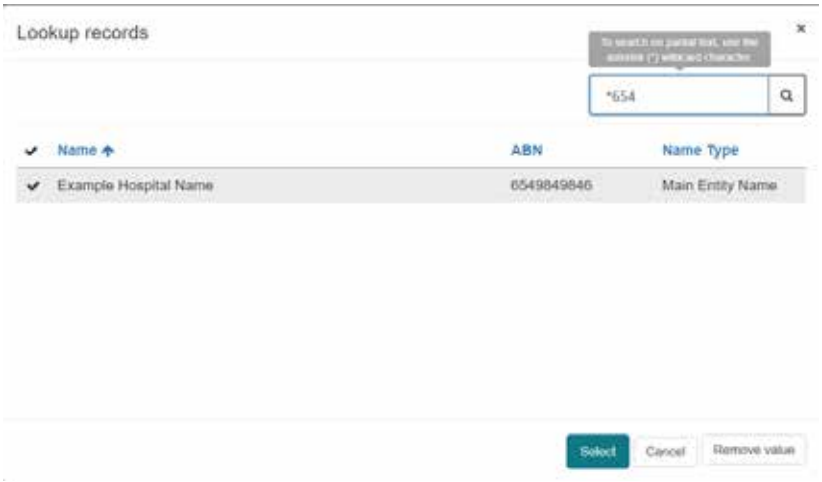
1. Once a site has been registered in the system, users may request to join a site (rather than having to be invited by a Site Administrator). Select 'Request to join a site':



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

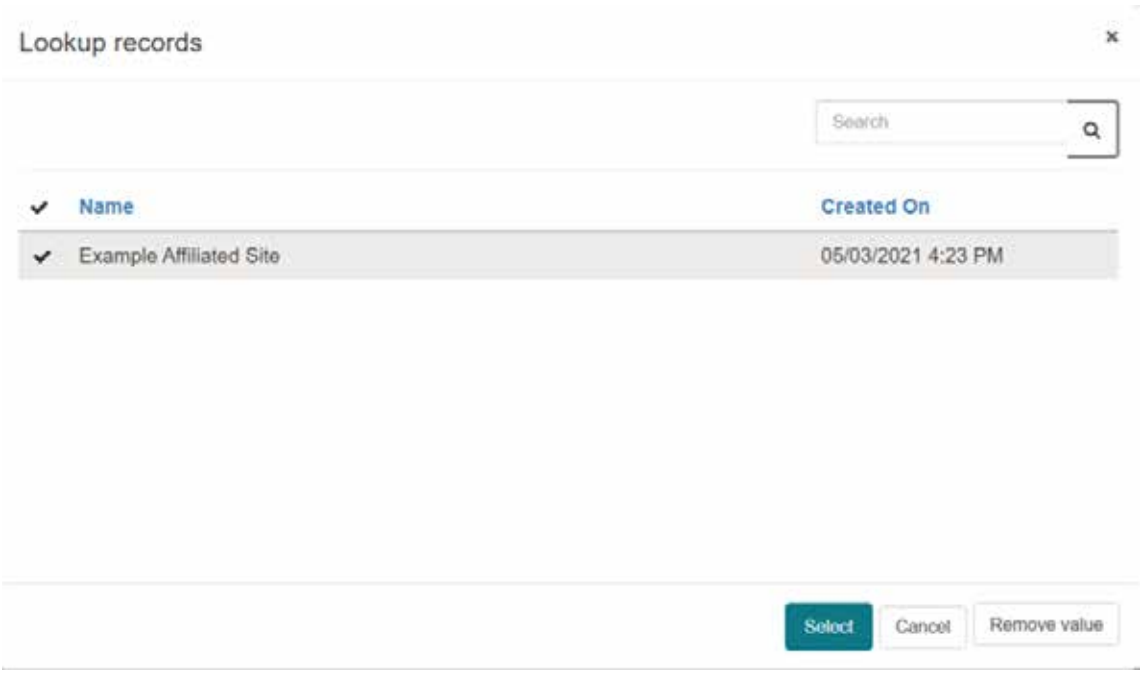


3. Search for the organisation by using the organisation name or ABN:



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:



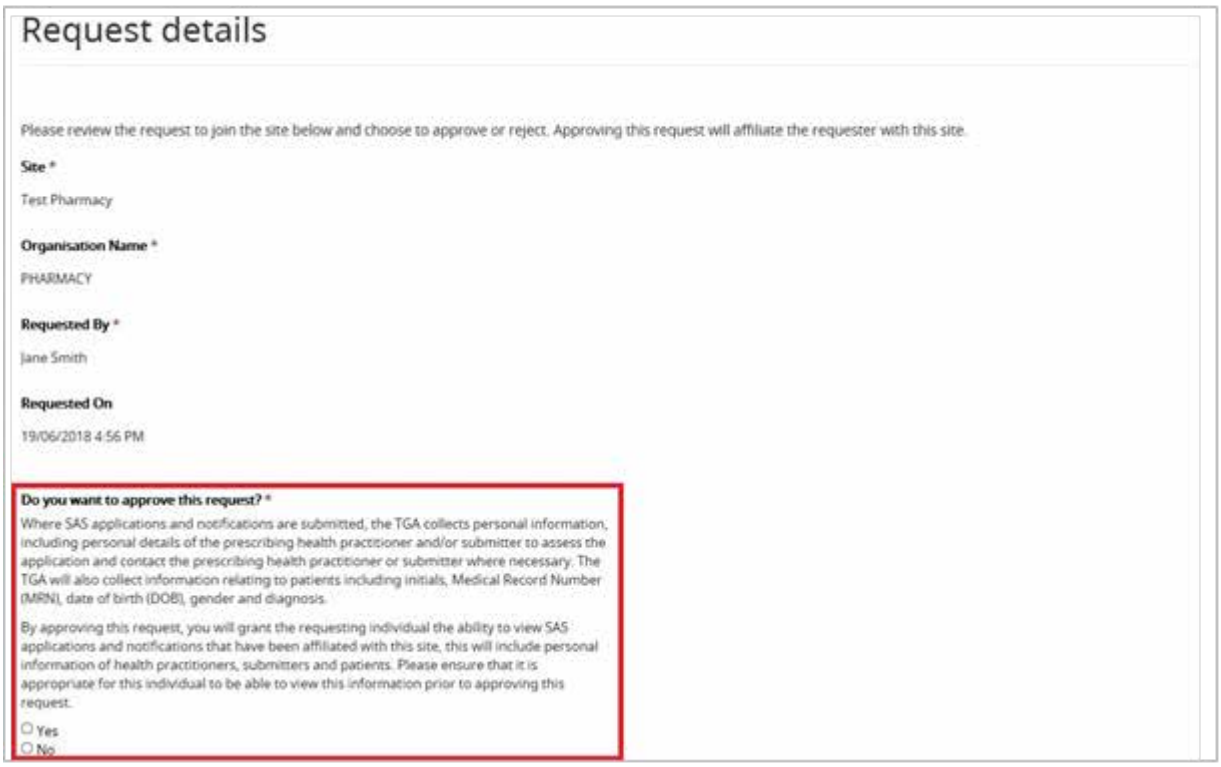
6. Once selected, a confirmation message will be presented and the request will be sent to the Administrator(s) or the site for review:

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:

2. Select 'View details':

3. 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:



SAS/AP validation search tool

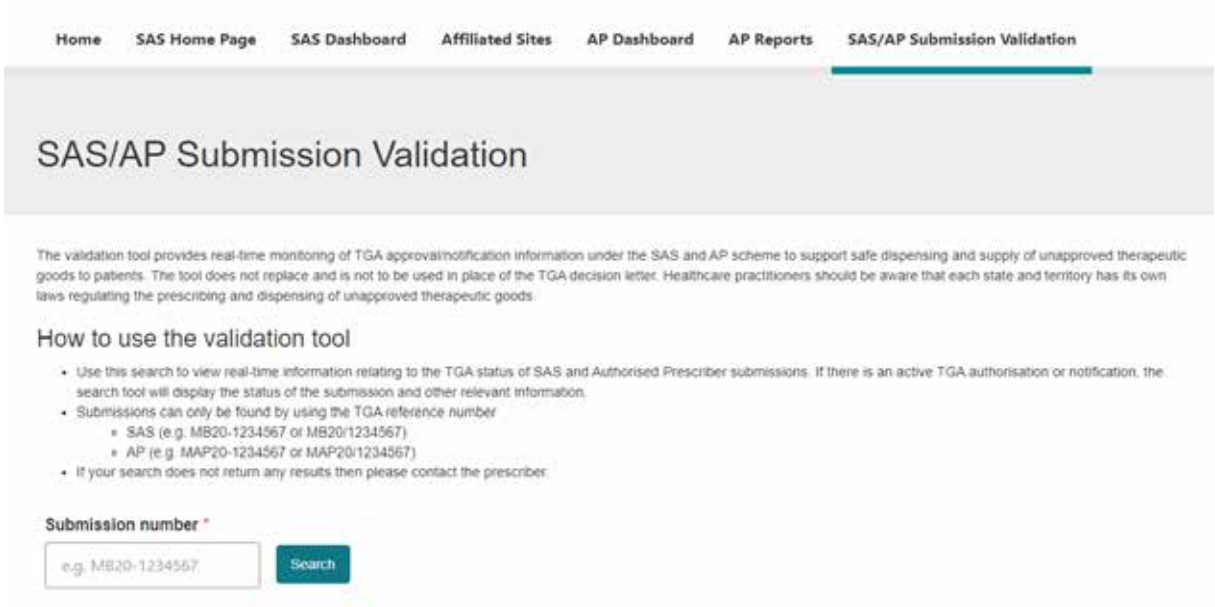
Health practitioners can use the SAS/AP submission validation search to view real-time information relating to the TGA status of SAS and AP submissions. If there is an active TGA authorisation or notification, the search tool will display the status of the submission and other relevant information.

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

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



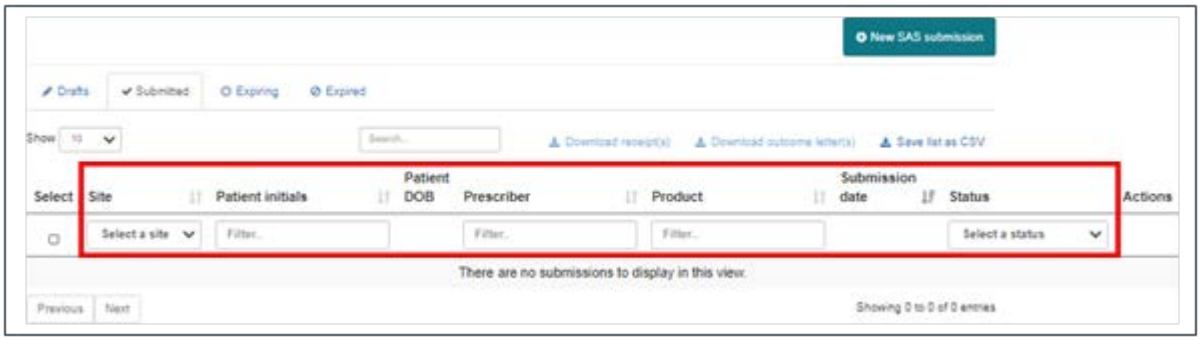
4. If the approval/notification is valid you will be shown the relevant details of the submission including its status. If the submission is no longer valid or does not exist, an error message will appear. In these cases, please contact the prescriber.

User dashboards

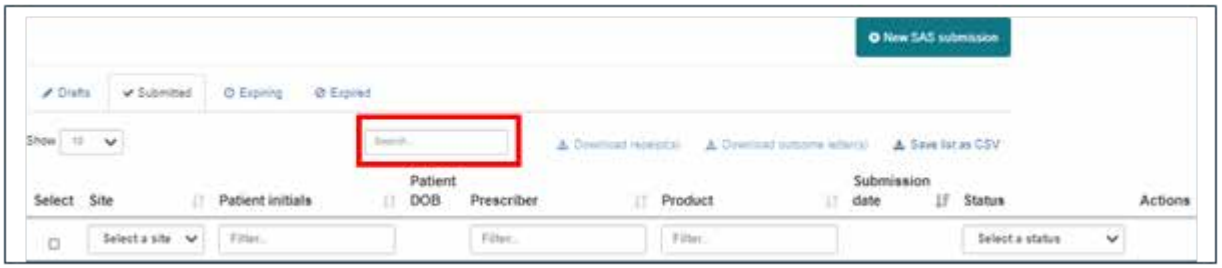
All users who have registered an account in the SAS & AP online system will have a personal dashboard that displays information specific to SAS applications and notifications they have drafted or submitted via the system. These dashboards differ between health practitioners and non-health practitioners.

Filtering dashboard information

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

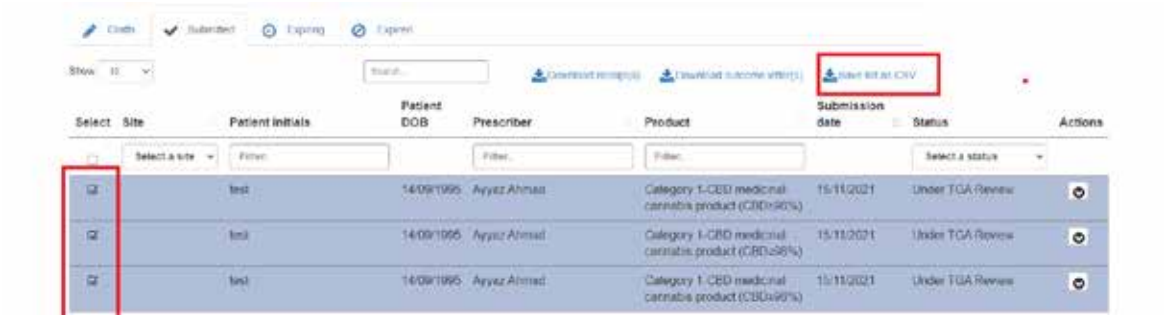


2. Users can also apply a uniform search across all available data fields by typing in the below text box:



Exporting submission data

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



Cloning submissions

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

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

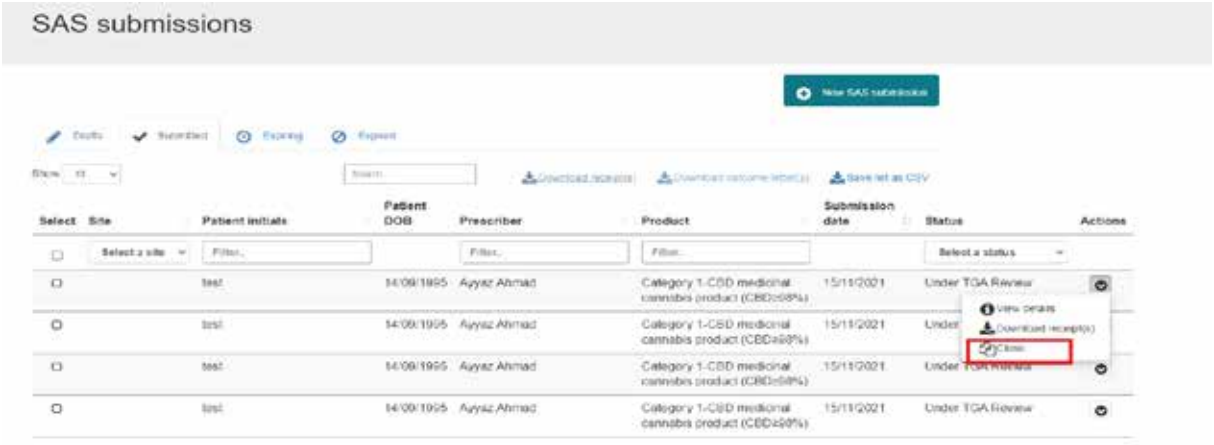
Please be aware that the following information will not be prepopulated into the new draft by the cloning function, and will need to be provided before submitting to the TGA:

1. Answer to whether the patient’s condition meets the SAS Category A definition (‘yes/no’)
2. Intended date of supply
3. Any attachments uploaded with the original submission

4. Answer to the privacy statement on the Summary step ('yes/no')

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

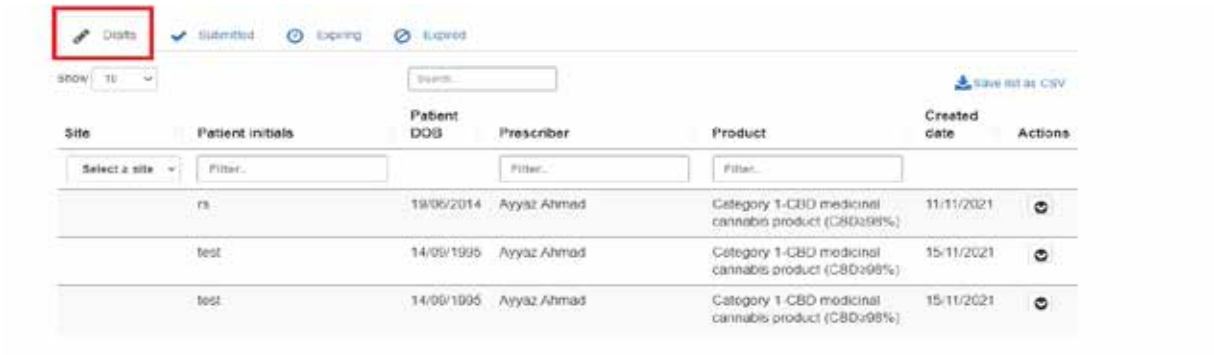
Identify the submission that needs to be cloned by filtering in the user dashboard; click the 'Actions' tab and select 'Clone' from the dropdown:



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.



Non-health practitioners

Dashboards for non-health practitioners will not include the 'Draft

Submissions' tab as they are unable to submit SAS applications or notification to the TGA as per the provisions of the Act and associated regulations.

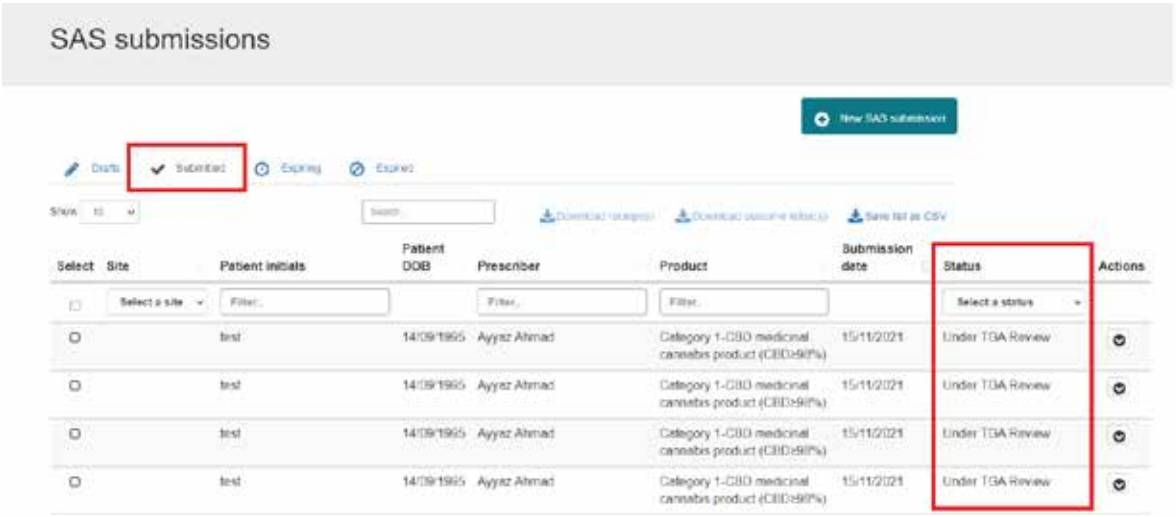
Saving as 'Draft'

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

Completed submissions

Status of completed submissions

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



A list of the status terminology can be found below:

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

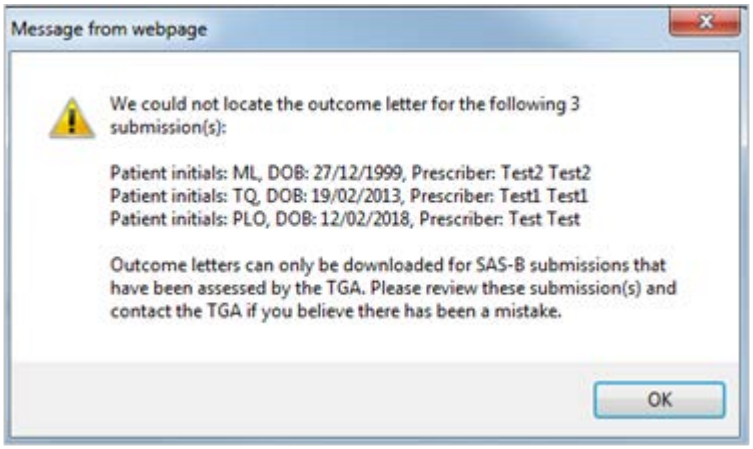
Downloading receipts and outcome letters

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

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

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.

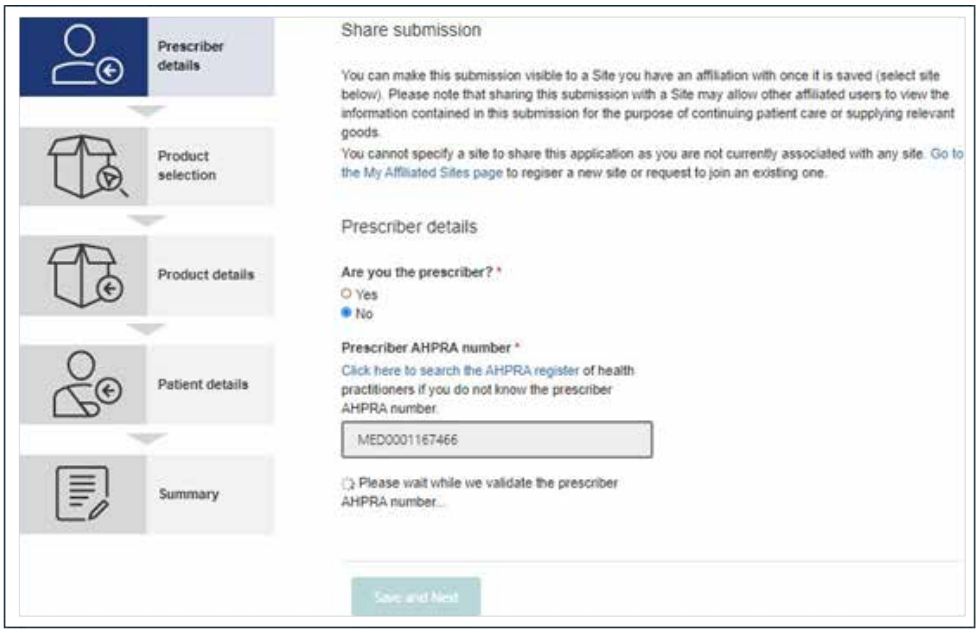
1. To complete a SAS application or notification and submit this to the TGA via the system, go to your dashboard and select 'New SAS submission':

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:

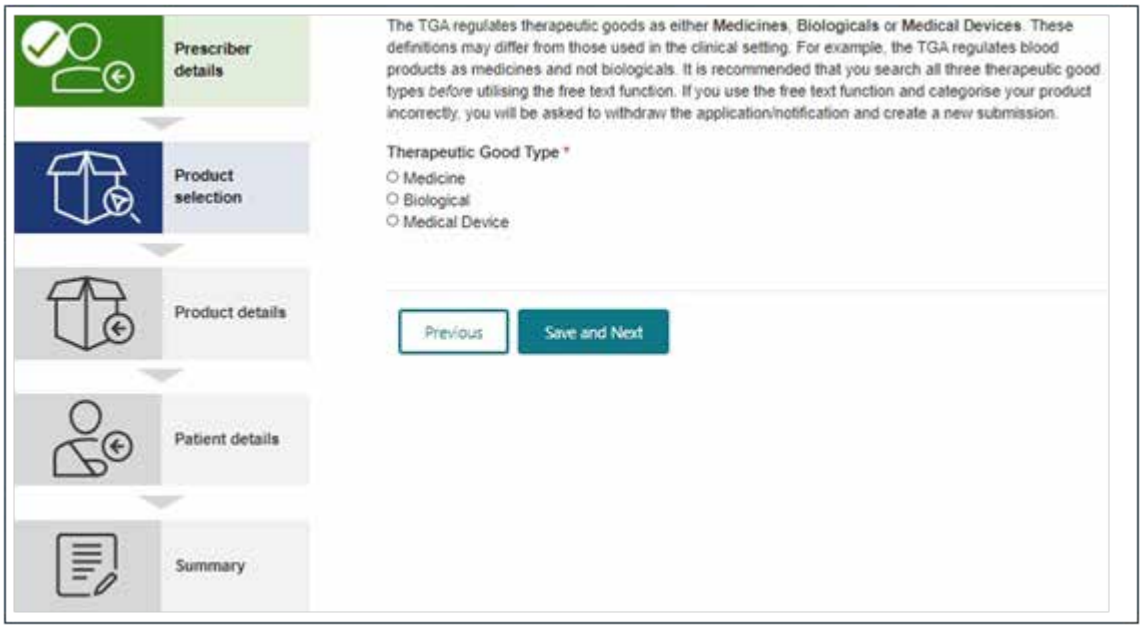
2. If you are not the prescriber, the user will be asked to provide the AHPRA registration number for the prescriber. The system will then search the TGA's internal database in attempts to identify whether a profile associated with that AHPRA registration number already exists. If not, the user will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

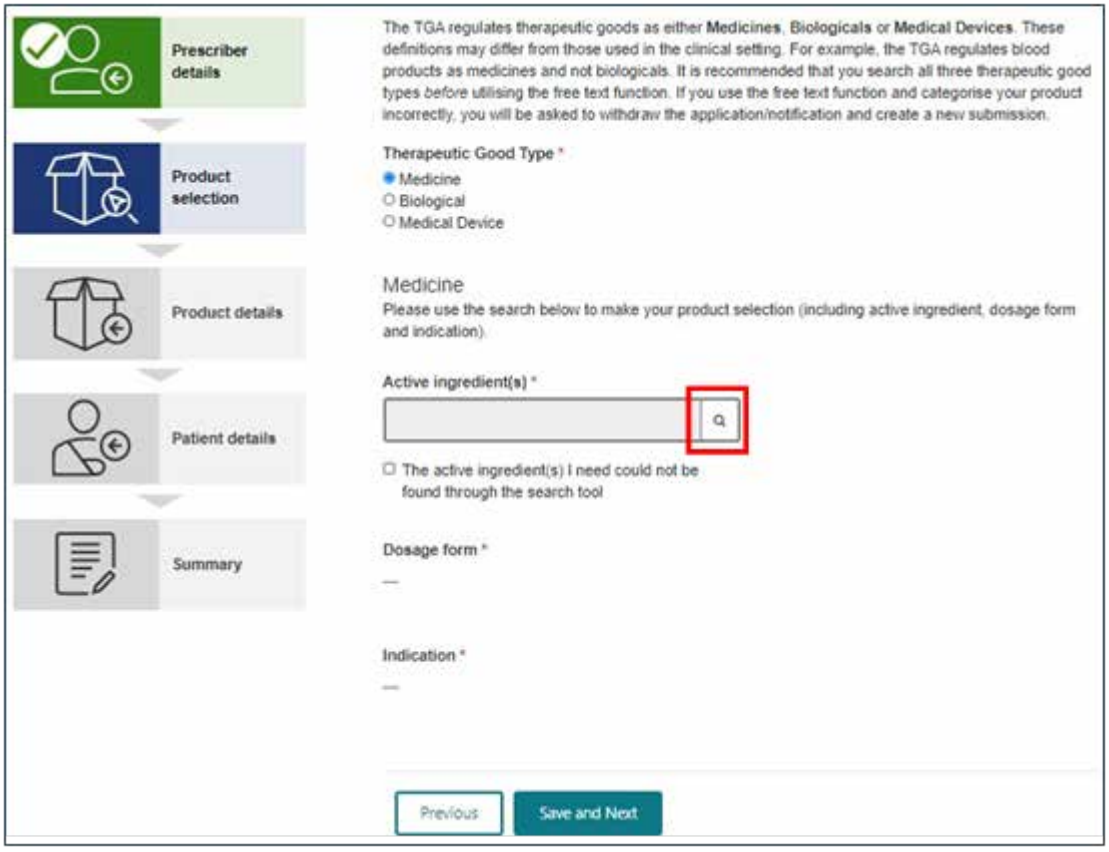


Step 2 – Product selection

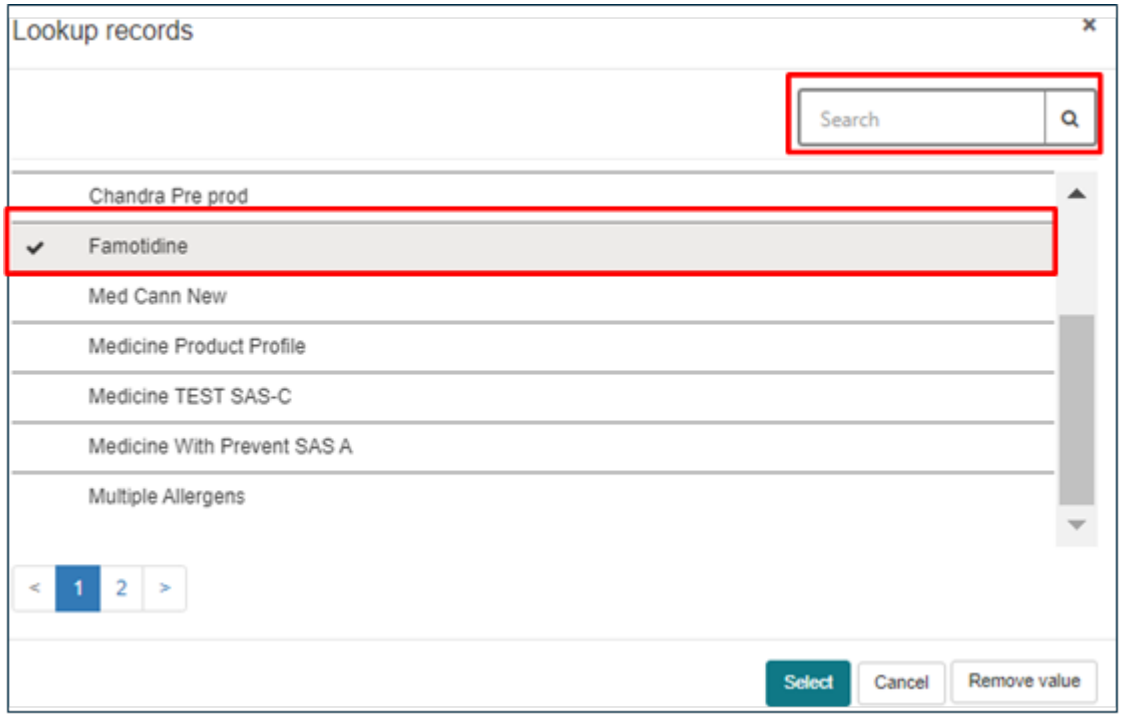
1. Select the type of unapproved therapeutic good for which access is being sought:



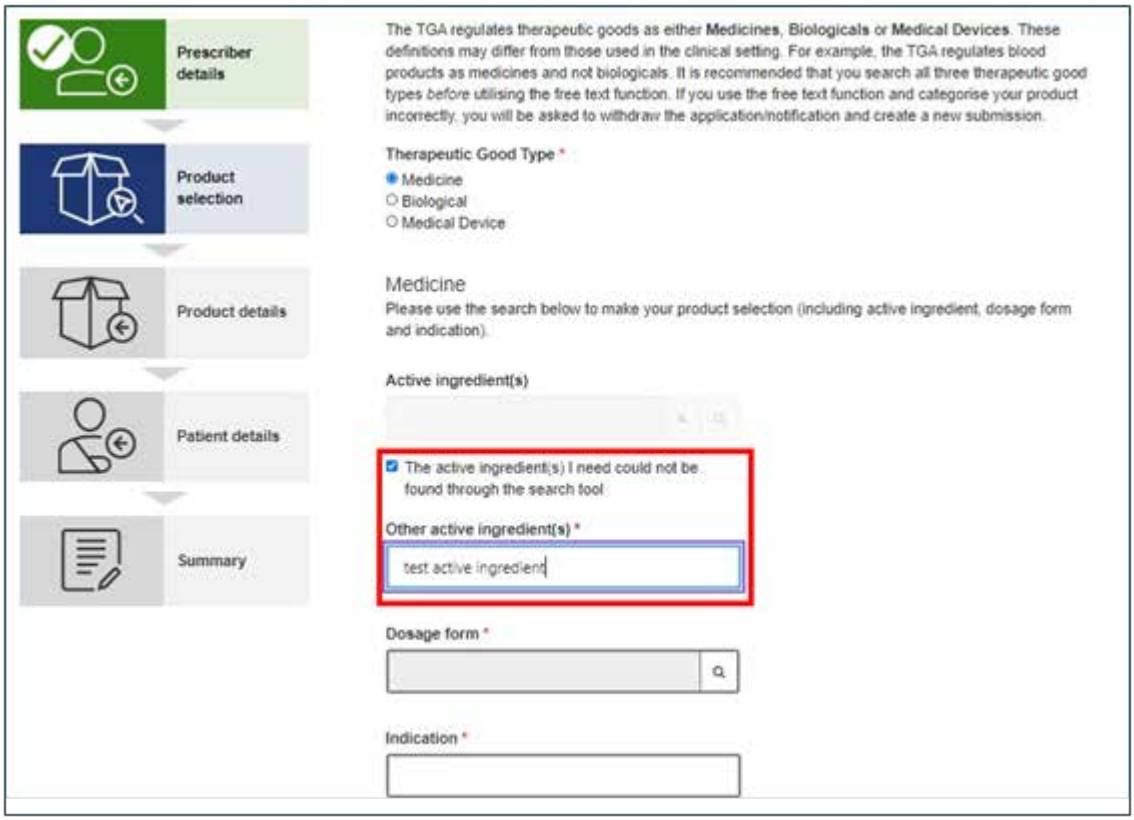
2. Upon selecting a type of therapeutic good, the user will be prompted to provide details of the product such as the active ingredient, dosage form and indication. A look-up function is available to search TGA's internal database of existing entries as shown below:



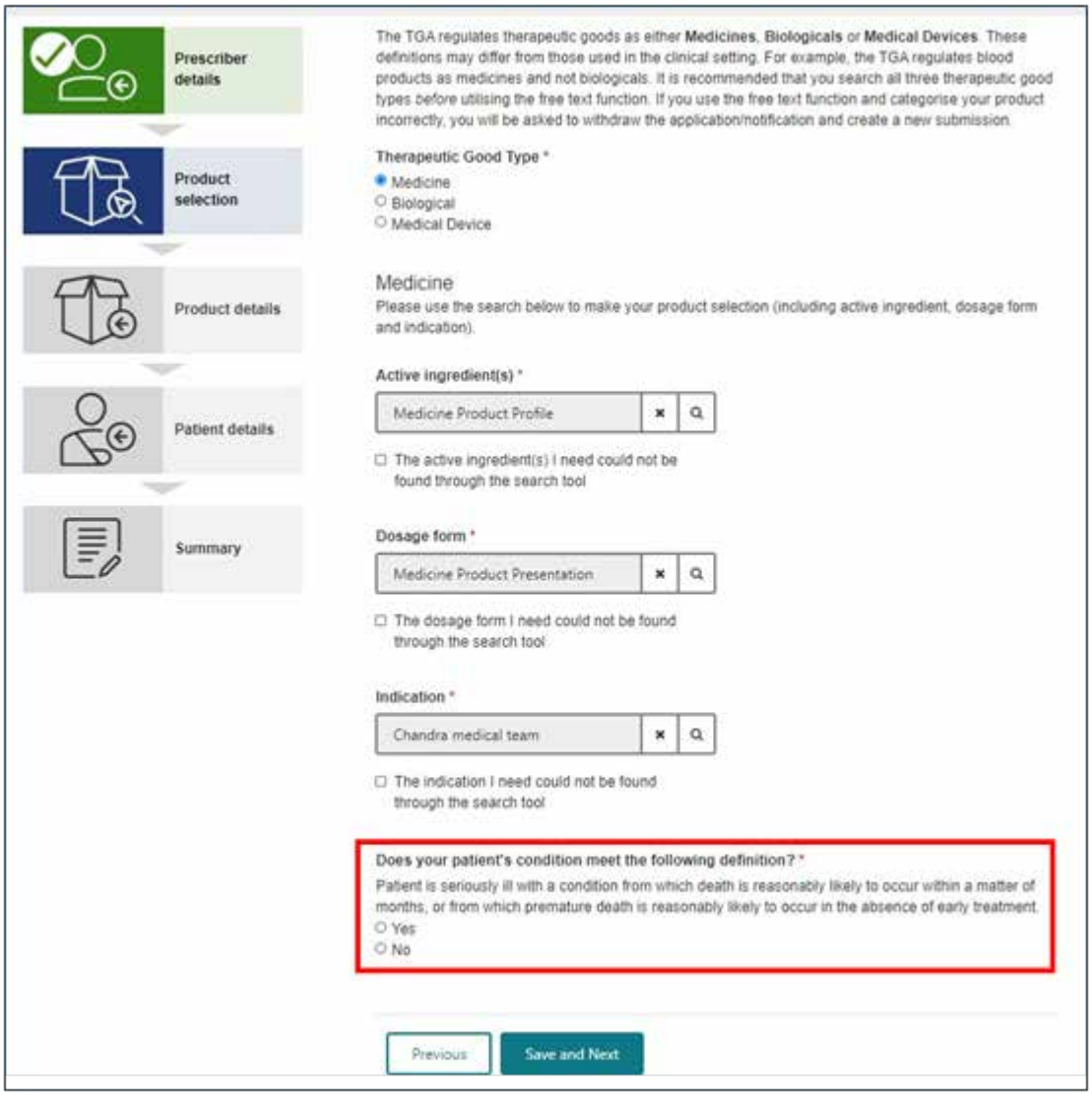
3. Use the search bar to identify the active ingredient. To search on partial text, use the asterisk (*) wildcard character:



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:

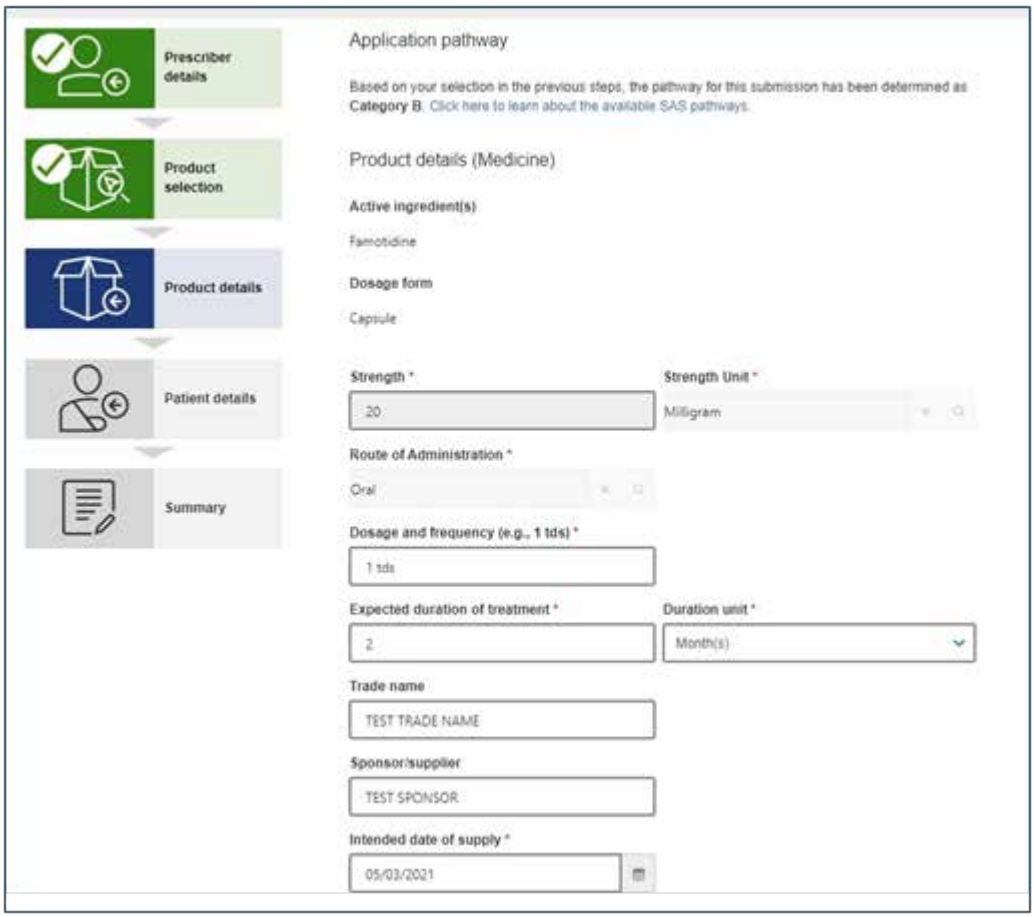


5. If the product and indication are not able to be supplied by way of notification under the SAS Category C pathway, the user is prompted to confirm whether the patient meets the definition of a SAS Category A patient. This question is only presented as an option where the prescriber for the submission 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:



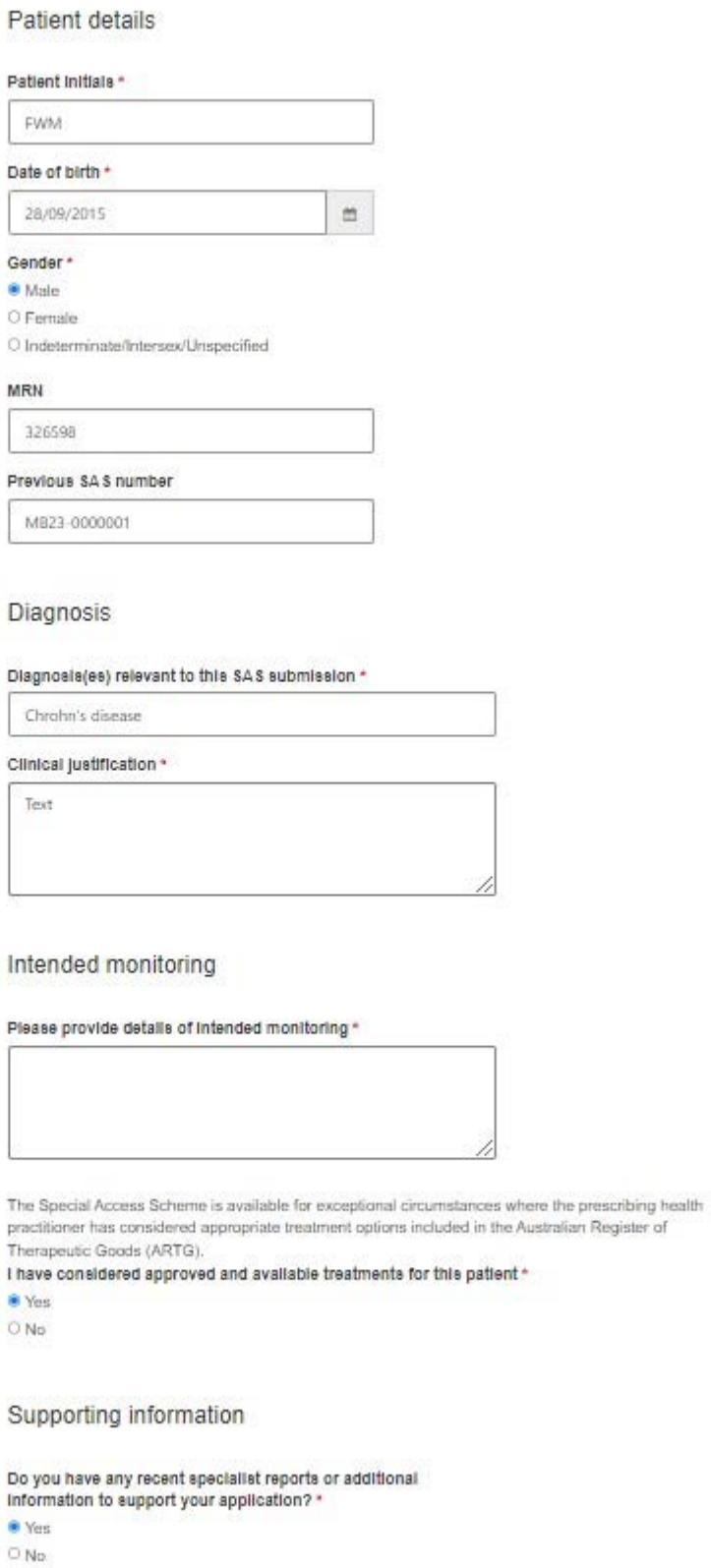
Step 3 – Product details

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



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

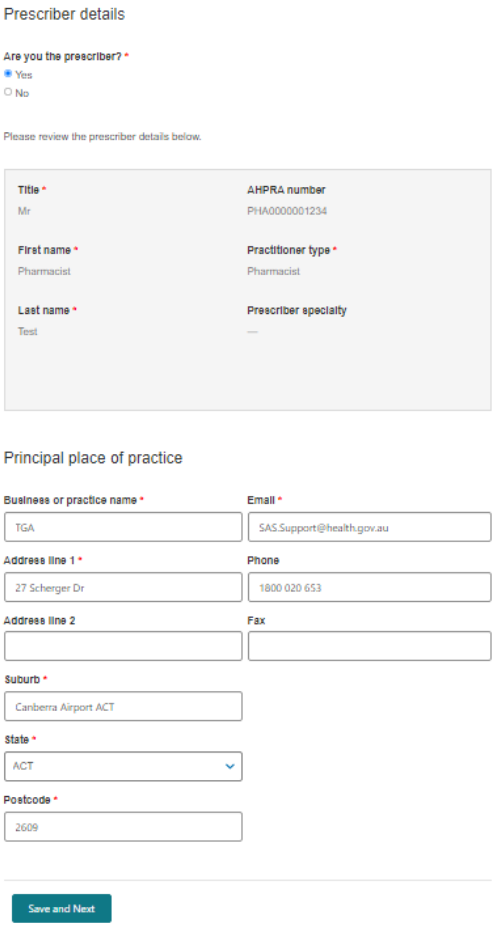
Submitting S3 products as a pharmacist

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':

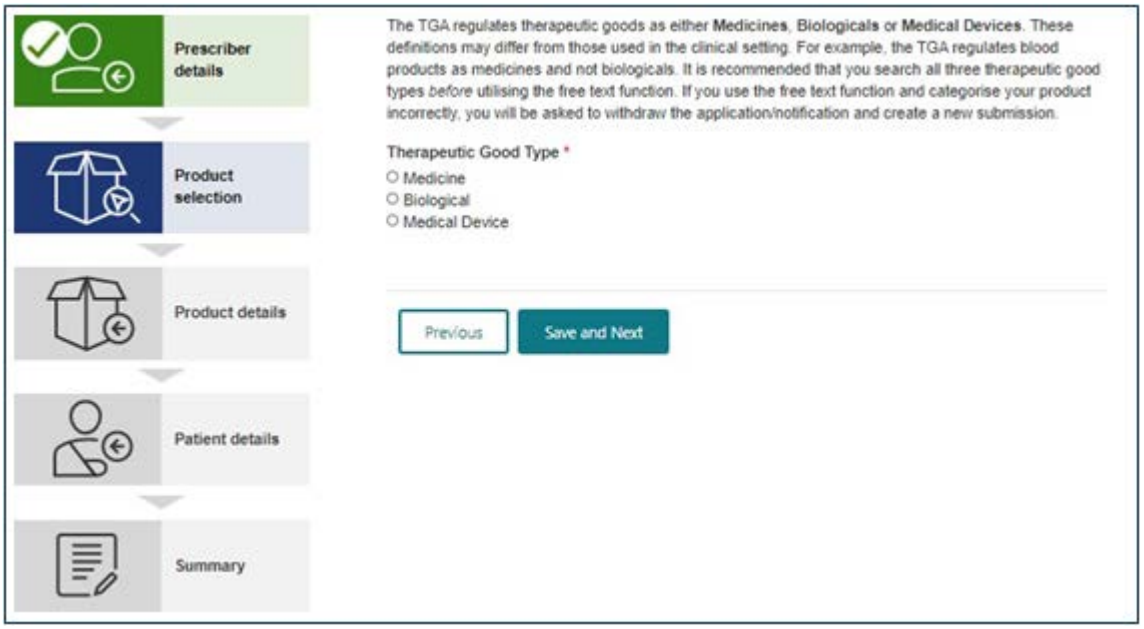
Step 1 – Prescriber details

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:

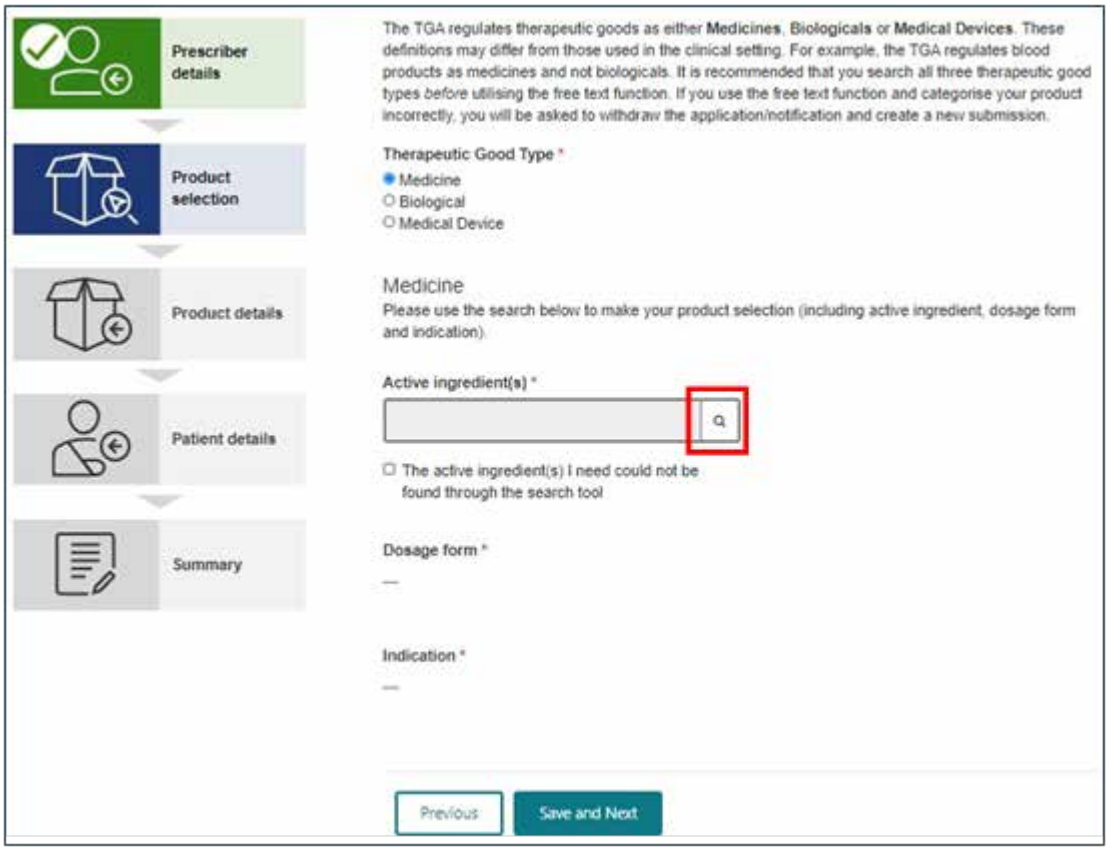


Step 2 – Product selection

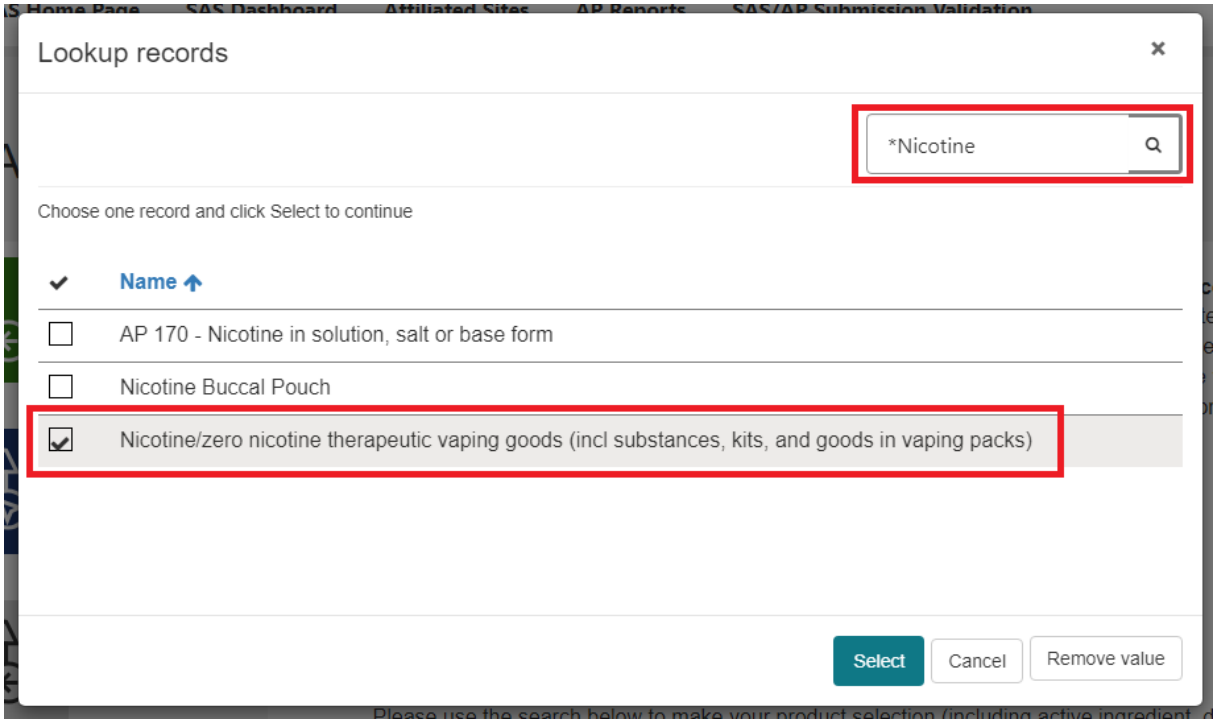
1. Select the type of unapproved therapeutic good for which access is being sought:



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:

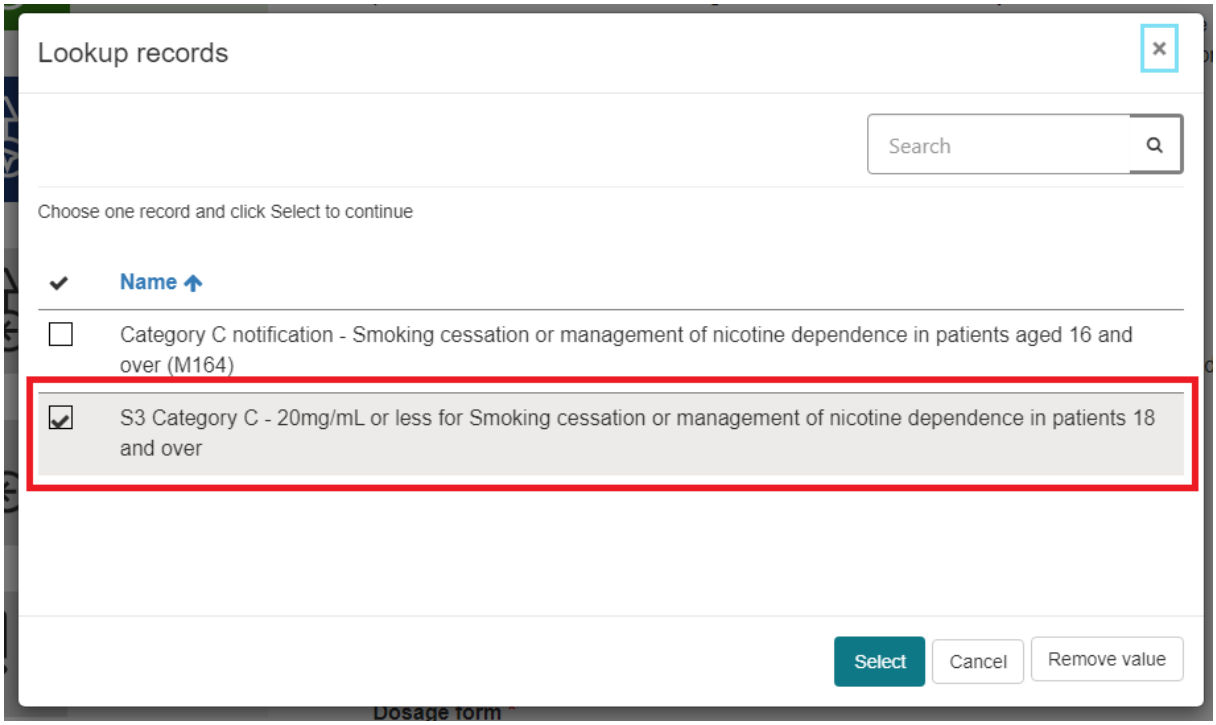


3. Use the search bar to identify the active ingredient. To search on partial text, use the asterisk (*) wildcard character:



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

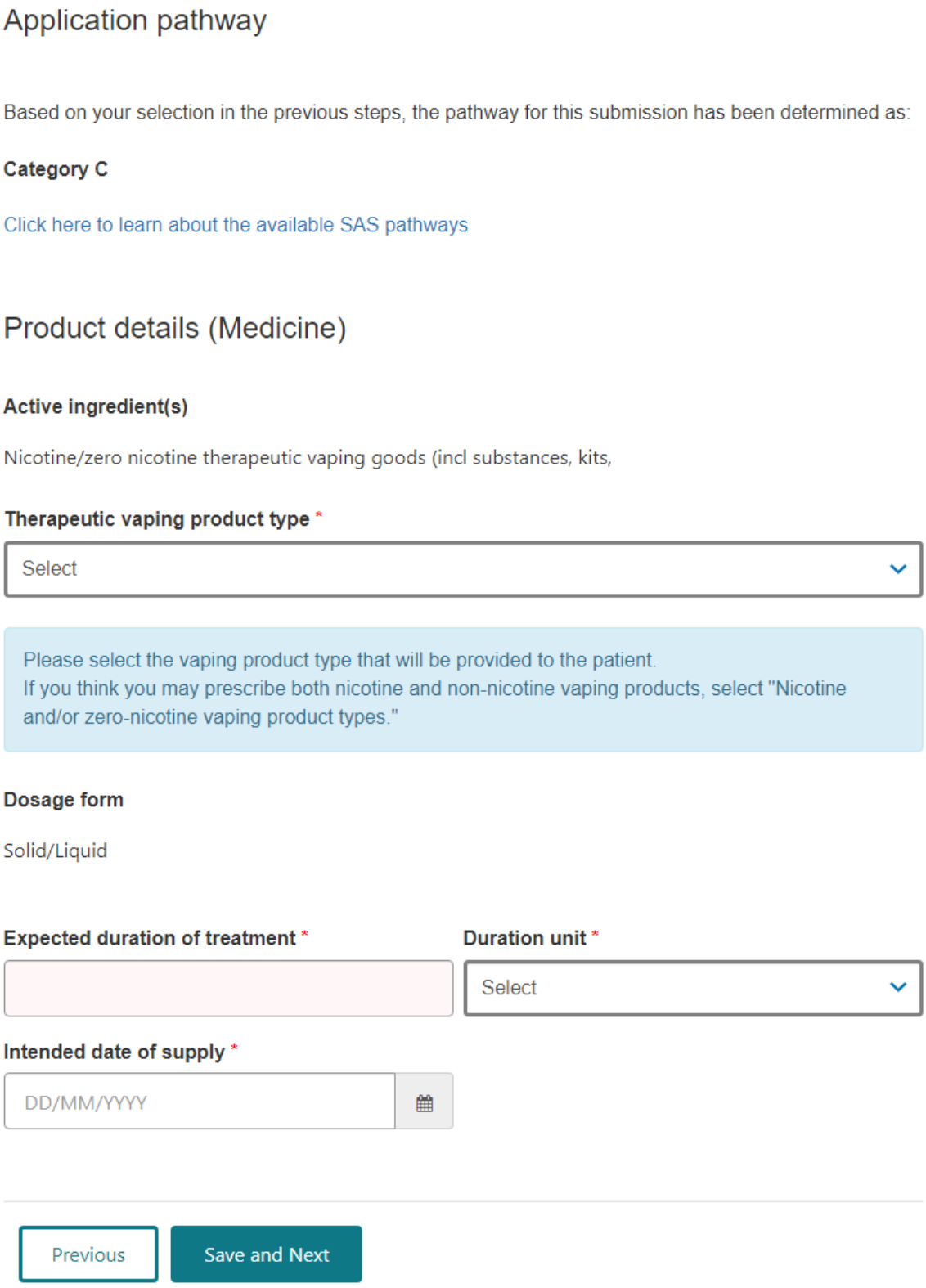
5. For Schedule 3 Products included in the SAS C list, type “S3” into the search bar and identify the indication that includes ‘Category C’ as part of the text. To search on partial text, use the asterisk (*) wildcard character (e.g. “*S3”):



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

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

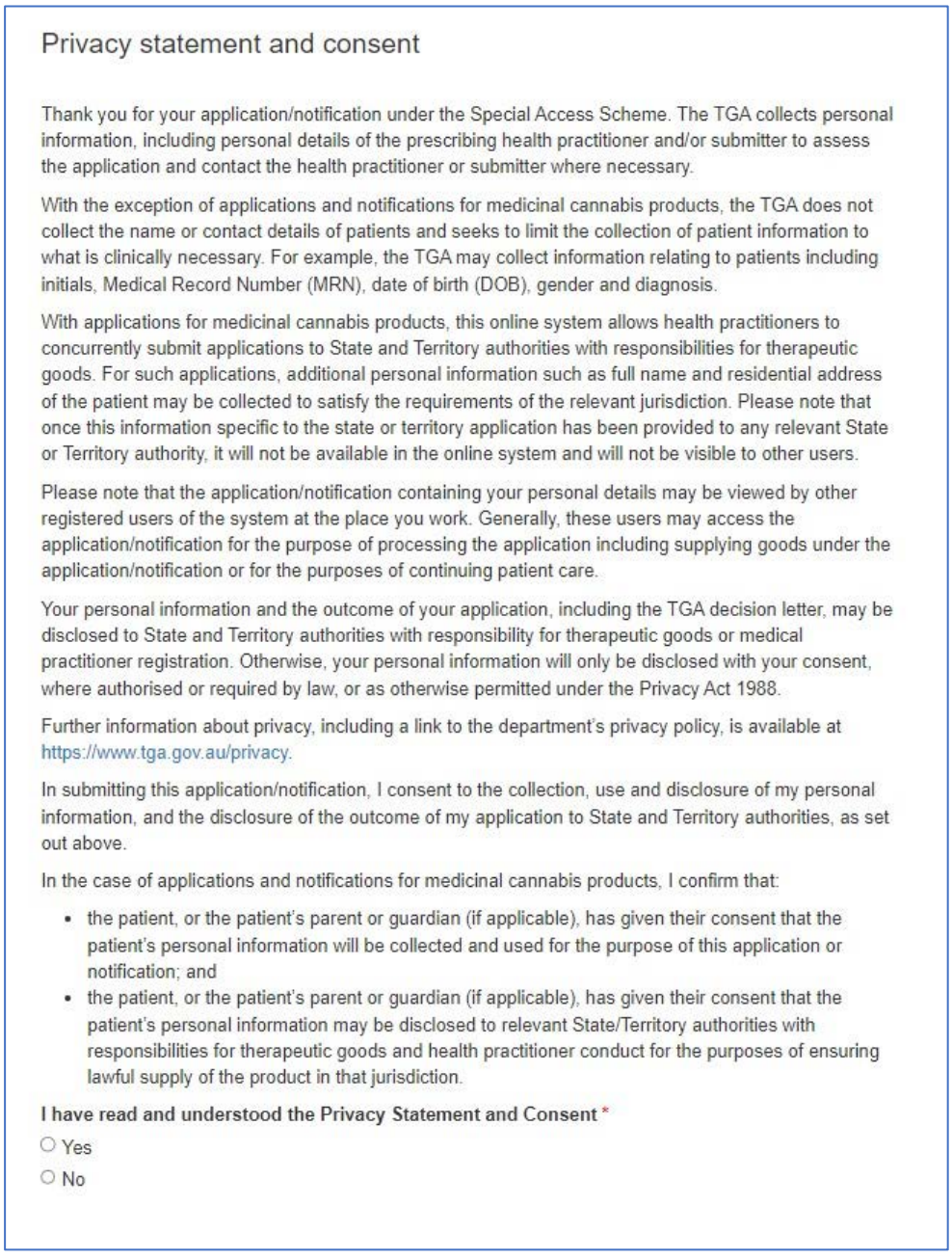


Step 4 – Patient details

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

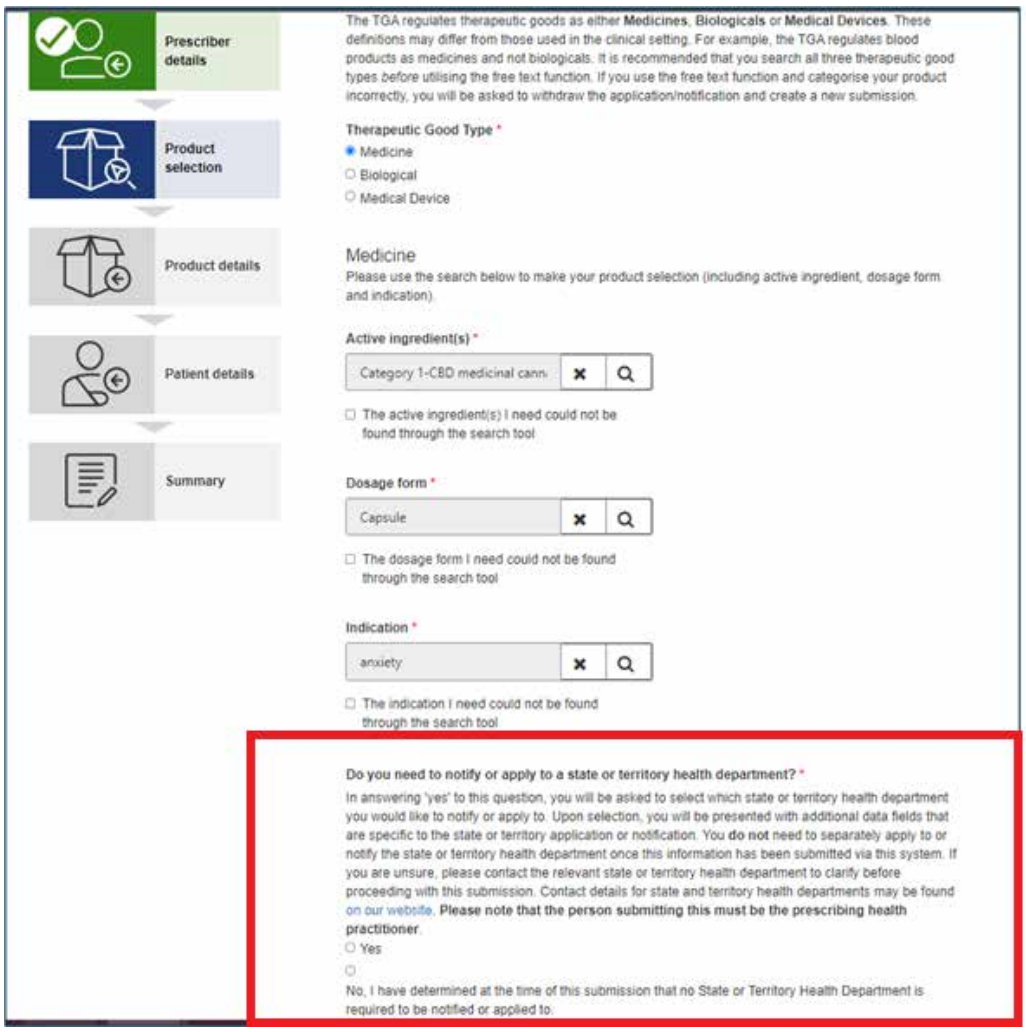
There are circumstances where the TGA's SAS & Authorised Prescriber Online System should not be used for medicinal cannabis submissions. These circumstances include:

- 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.

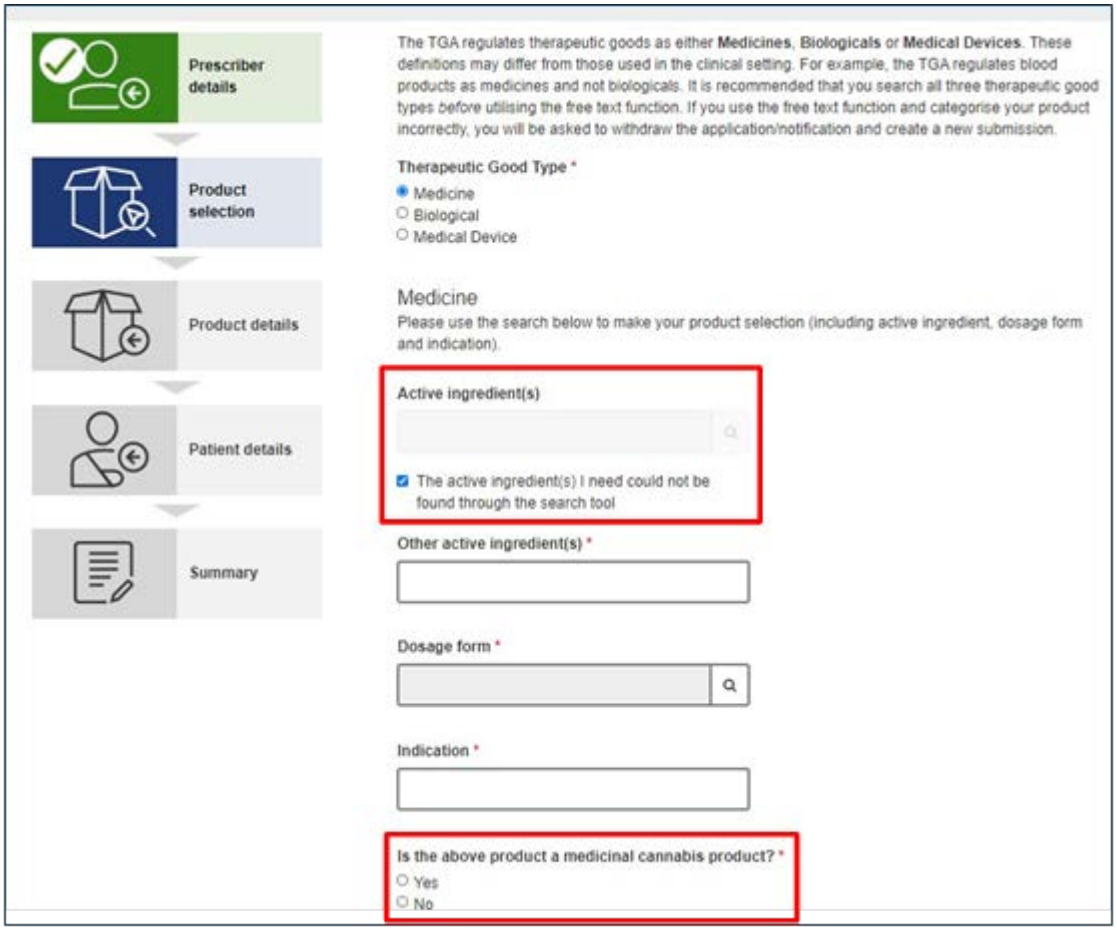
Notifying or applying to a state or territory health department via the system

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.

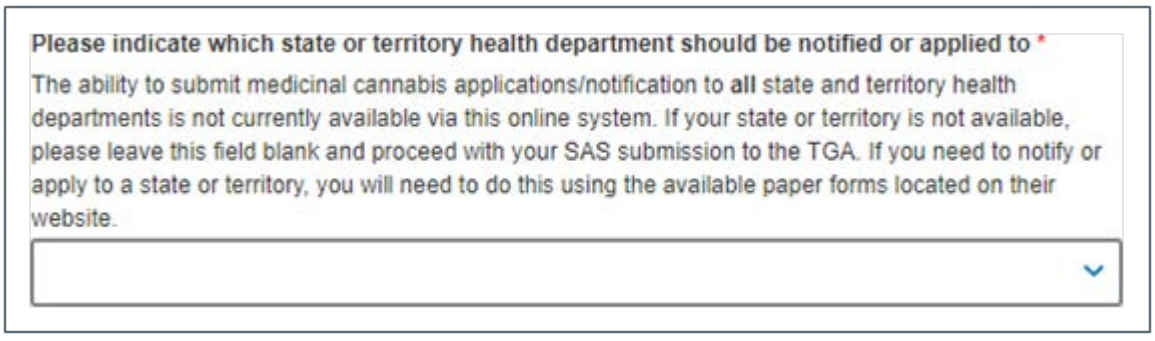
   In selecting a medicinal cannabis active ingredient category from the look-up function, the prescriber will then be prompted to select whether a State or Territory Health Department should also be notified or applied to as part of the submission. It is the responsibility of the prescribing healthcare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


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) *
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.

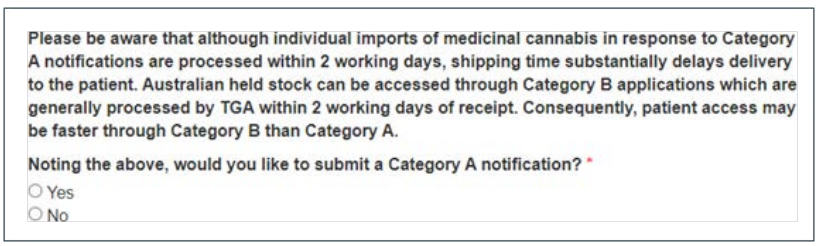
2. If the proposed active ingredient is unable to be selected via the look-up function, prescribers will have the ability to free-text details of the product. Upon entering free-text information, the prescriber will then be asked whether the product is a medicinal cannabis product as shown below:



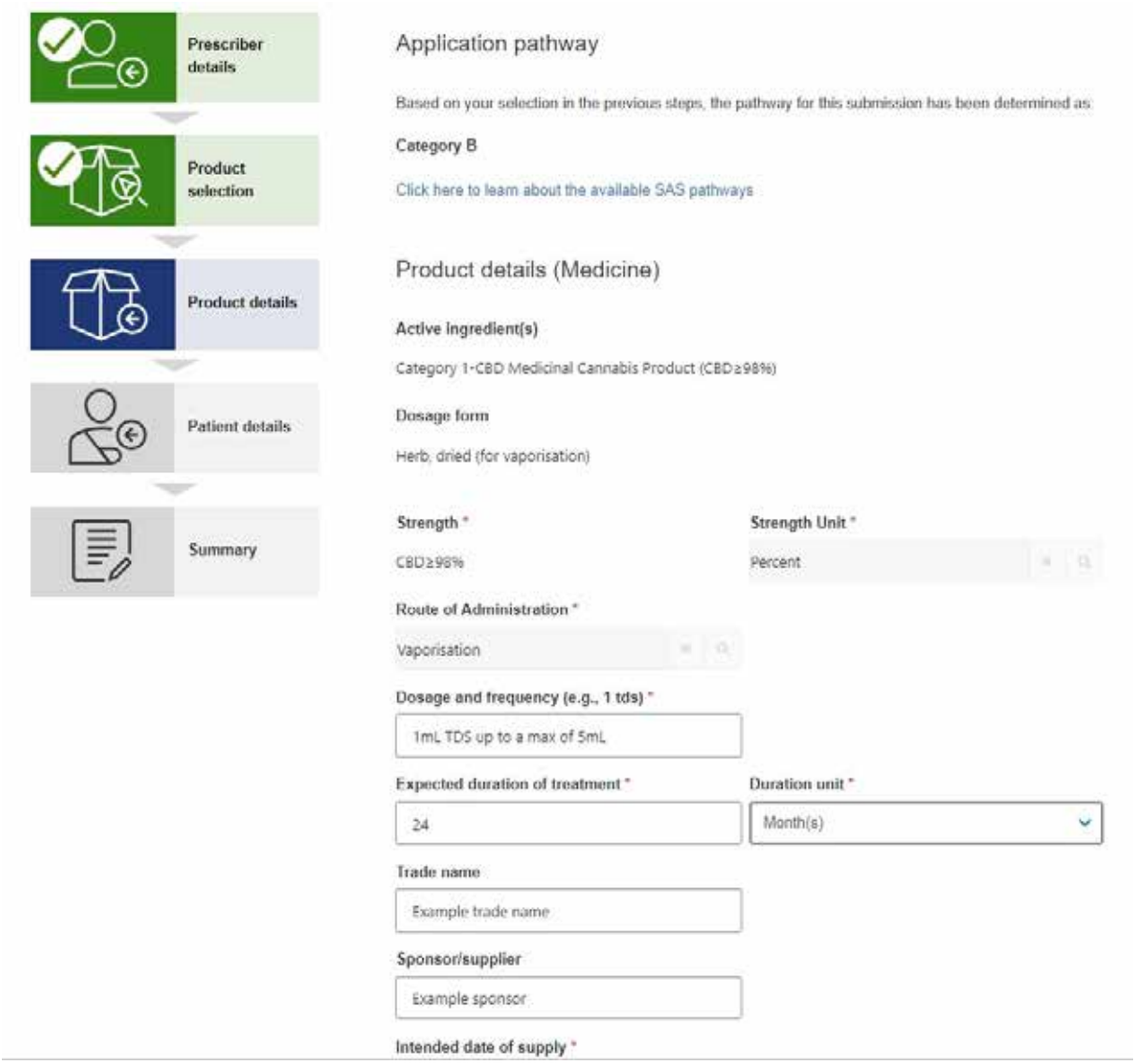
3. If 'Yes' is selected to the above question, the prescriber will be asked which State or Territory Health Department should receive the notification/application. If you need to notify or apply to a State or Territory Health Department not included in the system, you will need to contact the State or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



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



5. Enter the product details.



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

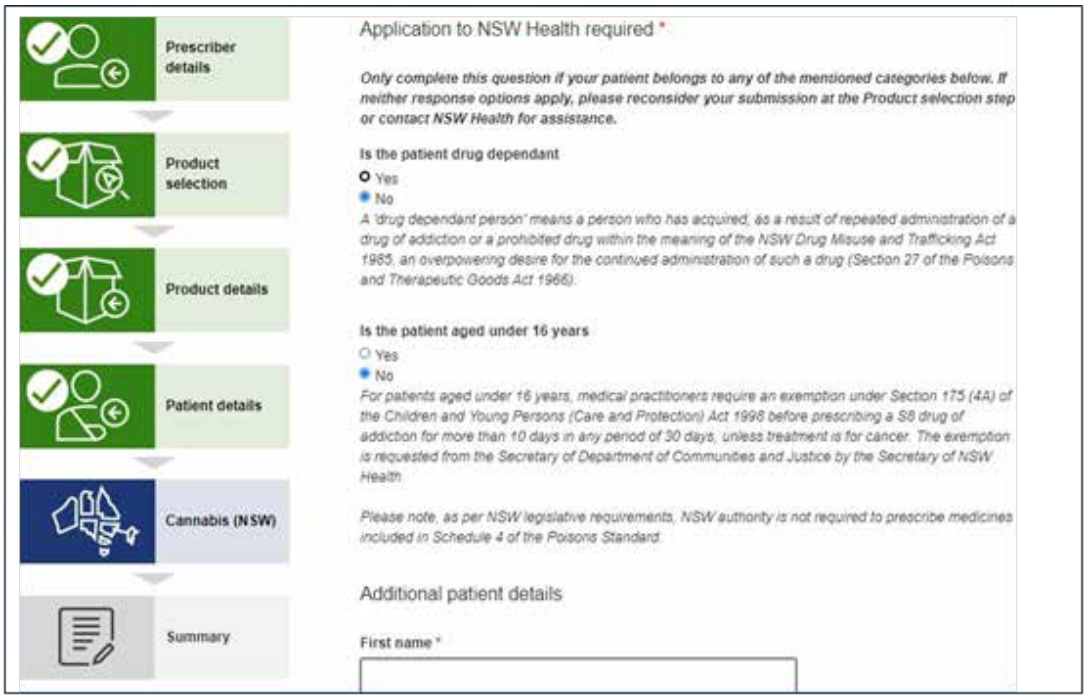
Add files

There are no folders or files to display.

Additional Information

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:



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 basedon 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

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