



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Authorised Prescriber (AP)

Special Access Scheme & Authorised Prescriber Scheme Online System guide

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Online system overview

The Special Access Scheme (SAS) & Authorised Prescriber (AP) Online System (SAS & AP online system) allows medical practitioners to submit AP applications. The SAS & AP Online System is designed to reduce administrative burden and provide medical practitioners additional reporting and management functions to assist in the management of their AP applications.

This document provides information on how to register an account and submit AP applications.

For six-monthly patient data reports via the SAS & AP Online System (the system) please see below document:

[Submitting six-monthly reports for Authorised Prescribers](#)

If you wish to access information regarding the submission of SAS applications and notifications via the online system, please refer to the [Special Access Scheme \(SAS\) Online System Guidance](#).

For information regarding the Authorised Prescriber Scheme, please refer to the [Authorised Prescriber Scheme Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors](#).

Terminology and definitions

Terminology	Definition
Account	Upon successful registration in the system, each user will have created an 'account' which is accessible using their credentials (username and password) selected as part of the registration process.
Outcome letter	The Approval or Rejection letter provided by the TGA in response to an Authorised Prescriber application.
Receipt	A copy of the AP application 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.

Features of the SAS & AP Online System

- Medical practitioners are required to register an account before they can begin drafting and submitting AP applications to the TGA.
- A searchable database of products (medicines, medical devices and biologicals) is available for users to select.
- Users have a dashboard within their account to:
 - Track the status of their application.
 - Search for previously submitted applications using parameters such as product, submission date and status (i.e. approved, rejected, withdrawn, completed).
 - Download a PDF copy of the application receipt.
 - Identify applications that are expiring or that have expired.

- Download a copy of the TGA Outcome letter.
- Clone (copy) previously submitted AP submissions.

Account management

Account registration

All users of the system are required to register a personal account. Unlike the Special Access Scheme Dashboard, **only medical practitioners are able to access the Authorised Prescriber Dashboard** and submit AP applications. As part of this registration process, 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; AHPRA registration number; and contact details (this will be used to populate the user's profile).
- **Step 6 must be completed to submit applications/notifications.**

Note: users who have registered with other systems hosted by the TGA may be able to login (rather than register) using the username and password *first* registered with the TGA system. **If this is unsuccessful, please register with a unique email address and username.**

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

The screenshot shows the top of the Regulatory and Compliance Portal. At the top left is the Australian Government logo with the text 'Australian Government Department of Health and Aged Care Therapeutic Goods Administration'. To the right is the heading 'Regulatory and Compliance'. Below this is a large grey banner with the text 'Welcome to the Regulatory and Compliance Portal.' Underneath is a section titled 'Services' with three icons: a syringe for 'Devices Compliance (PMR)', a briefcase for 'Advertising Compliance', and a key for 'Special Access Scheme (SAS)'. The 'Special Access Scheme (SAS)' icon is highlighted with a red border.

2. Select Register Now

Log In
Register now

Special Access Scheme & Authorised Prescriber Scheme Online System

The TGA has a responsibility to encourage the use of therapeutic goods that are included in the [Australian Register of Therapeutic Goods \(ARTG\)](#), as these products have been evaluated to ensure they meet strict standards of safety, quality and effectiveness.

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

Prescriber responsibilities and conditions

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

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

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

3. Provide a 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

Email

Password

Confirm password

Register >

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

Confirm registration

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

This link will expire in 24 hours.

- 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:

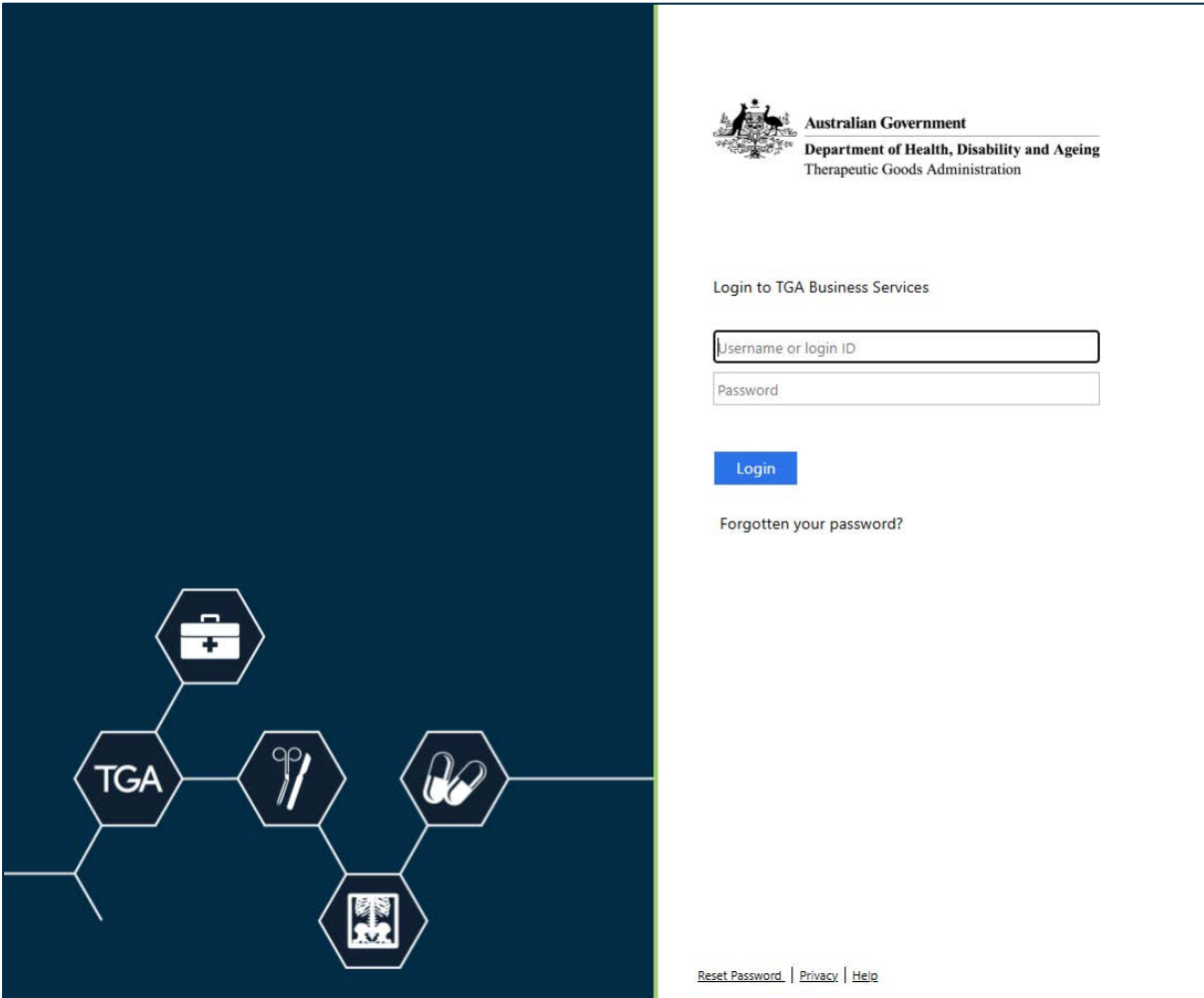
<https://apps.tga.gov.au/portalaccounts/account/activate/3a1a806c-9f3e-40dc-8e43-41cb8cb3b9ca/288580002>

This link will expire in 24 hours.

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

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

- Log in with your username and password



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

Login to TGA Business Services

Username or login ID

Password

Login

Forgotten your password?

Reset Password | Privacy | Help

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

My profile

Personal Details

Title *

First Name *

Last Name *

Preferred Name

Address and Contact Details

Business or Practice Name * **Phone ***

Address Line 1 * **Fax**

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

Suburb *

Australian State *

Postcode *

Health Practitioner Details

Do you have an AHPRA registration number? *
 No Yes

AHPRA Number *

✔ Your AHPRA number has been successfully validated

Practitioner Type *

Prescriber Specialty

Medical practitioners



Unlike the Special Access Scheme Dashboard, only medical practitioners are able to access the Authorised Prescriber Dashboard and submit AP applications.

Upon registration of an account, medical practitioners will have the ability to draft and submit AP applications to the TGA. In the account registration process, users will be presented with the following question to determine their health practitioner status.

Health Practitioner Details

Do you have an AHPRA registration number? *

No Yes

AHPRA Number *

Practitioner Type *

Prescriber Specialty


[Submit](#)

Medical 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).

Change password

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

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



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Therapeutic Goods Administration

Regulatory and Compliance

Example Account ▾

- Profile
- My invitations
- Change password
- Sign out

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

2. Enter your new password

Password guide

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

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

Current password

New password

Confirm new password

Change password >
Cancel

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

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

Forgotten your password

1. If you have forgotten your password, select "Log in".

Log In
Register now

Special Access Scheme & Authorised Prescriber Scheme Online System

The TGA has a responsibility to encourage the use of therapeutic goods that are included in the Australian Register of Therapeutic Goods (ARTG), as these products have been evaluated to ensure they meet strict standards of safety, quality and effectiveness.

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

Prescriber responsibilities and conditions

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

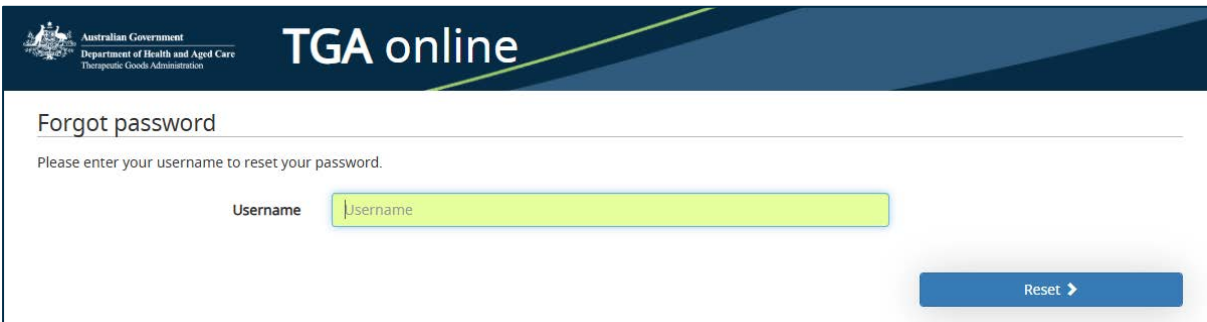
Scheme	Submission overview	Resources for technical support
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Special Access Scheme	<ul style="list-style-type: none"> Certain registered prescribing health practitioners SAS Category A and C notifications and Category B applications SAS applications 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

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

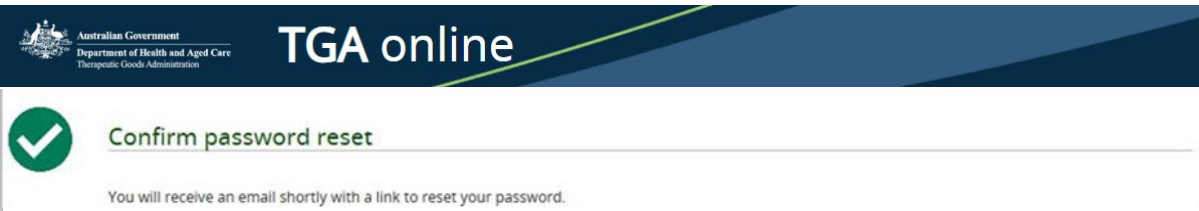
2. Select "Forgotten your password?".



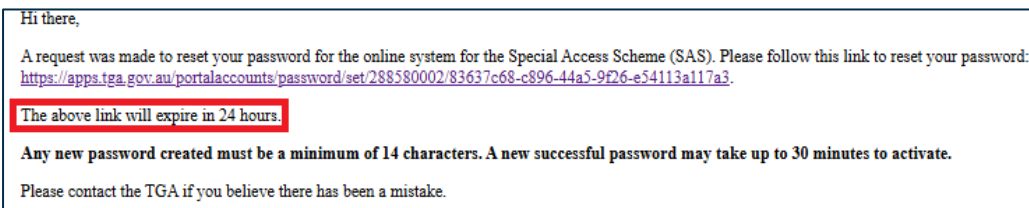
3. Enter your Username and select "Reset".



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



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



6. Enter your new password

Reset password

Password guide

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

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

New password

Confirm new password

[Reset password >](#)

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

If you are locked out of your account for 24 hours, please do not attempt to reset the password until after this time has lapsed otherwise the lockout period will be restarted. 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, contact details, adding or removing practicing locations etc.) by updating their user profile.

Regulatory and Compliance

Example Account ▾

- Profile
- My invitations
- Change password
- Sign out

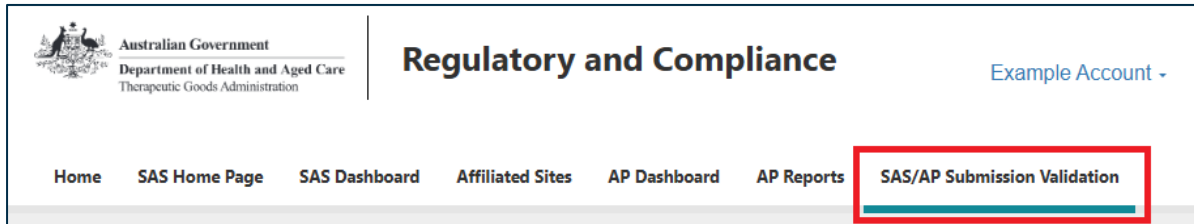
Home SAS Home Page SAS Dashboard Affiliated Sites AP Dashboard AP Reports SAS/AP Submissi

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'

The screenshot shows the 'SAS/AP Submission Validation' page. At the top, there is a navigation menu with the following items: Home, SAS Home Page, SAS Dashboard, Affiliated Sites, AP Dashboard, AP Reports, and SAS/AP Submission Validation. The 'SAS/AP Submission Validation' item is highlighted with a blue underline. Below the navigation menu is the title 'SAS/AP Submission Validation'. Underneath the title is a paragraph of text: '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.' Below this text is the heading 'How to use the validation tool' followed by a bulleted list of instructions:

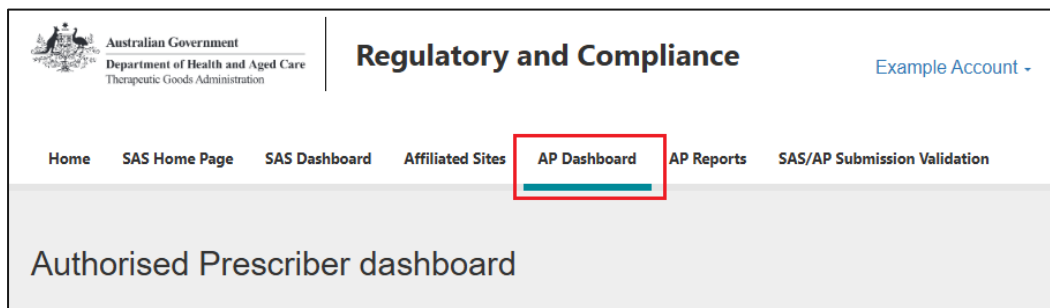
- Use this search to view real-time information relating to the TGA status of SAS and Authorised Prescriber submissions. If there is an active TGA authorisation or notification, the search tool will display the status of the submission and other relevant information.
- Submissions can only be found by using the TGA reference number
 - SAS (e.g. MB20-1234567 or MB20/1234567)
 - AP (e.g. MAP20-1234567 or MAP20/1234567)
- If your search does not return any results then please contact the prescriber.

Below the list is a form with the label 'Submission number *'. There is a text input field containing 'e.g. MB20-1234567' and a blue '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 dashboard

All users who have registered an account in the system will have a personal SAS dashboard displaying details of their SAS applications and notifications drafted or submitted via the system. This is the default landing page when you log into the system.



Authorised prescriber dashboard

Users who are registered as medical practitioners will have an additional dashboard called 'Authorised Prescriber Dashboard'. To view information specific to AP applications that have been drafted and submitted in the online system, users will need to select the AP Dashboard from the ribbon.

Once selected, the Authorised Prescriber dashboard will appear as below. Additional features of the dashboard are discussed further in the 'System Features' section:

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000791	Under TGA Review			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000790	TGA Rejected	02/06/2022		
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000789	Withdrawn			

Authorised prescriber reports

Users who are registered medical practitioners will have an additional dashboard called 'AP Reports'.

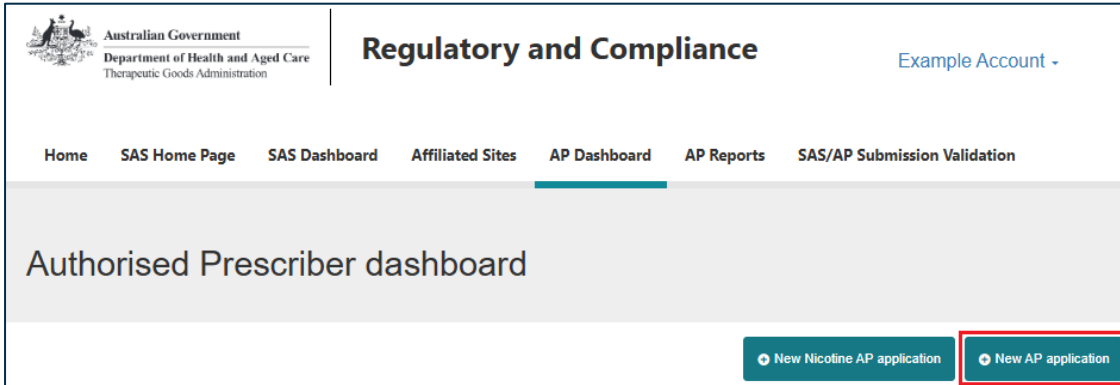
For further information on Authorised Prescriber Reports please see the document below:

[Submitting six-monthly reports for Authorised Prescribers](#)

Submitting AP applications

The online system guides medical practitioners to provide the correct information when seeking Authorised Prescriber approval.

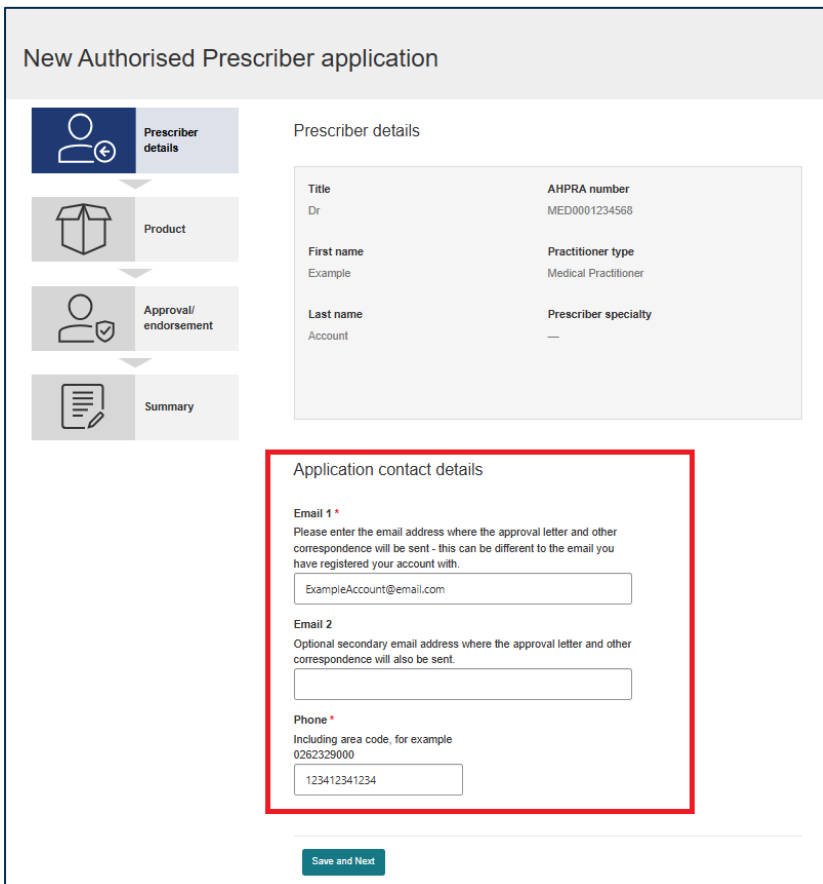
To start a new AP application, go to your AP dashboard and select 'New AP application':



Step 1: Prescriber details

The prescriber details will begin pre-populated from the details in your account. For instructions on how to update your account details, please refer to the 'Updating account information' section. Please provide a preferred contact email to which all correspondence regarding this application will be sent. Both 'Email 1' and 'phone number' are mandatory fields.

Confirm your details.



Step 2: Product

1. Select the type of unapproved therapeutic good.

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

Therapeutic Good Type *

Medicine

Biological

Medical Device

Previous **Save and Next**

2. When selecting the **Medicine** type of therapeutic good, the user will be prompted to select whether the product is included in the TGA's list of medicines with an established history of use as specified in subregulation 12B(1B) or 12B(1C) of the Therapeutic Goods Regulations 1990.

Please only select the unapproved good with an established history of use if the medicine/dosage form and indication is included in the above list. For all other unapproved goods please select 'Any other unapproved therapeutic good'.

3. The user must then select 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

Is the product *

Included in TGA's Established History of Use list

Any other product

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

Active ingredient/product name *

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

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

Lookup records x

Choose one record and click Select to continue

✓ **Name** ↑

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

- If you are unable to identify the required information via the look-up function, select the checkbox below the search field. This will allow users to manually enter details of the product. Please do not use the free text option for a medicinal cannabis product or a product listed in the 12B(1B) or 12B(1C) established history of use pathway. All these products have a profile in the online database.

Prescriber details

Product

Approval/endorsement

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

Is the product *

Included in TGA's Established History of Use List
 Any other product

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

Active ingredient/product name

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

Other active ingredient(s)/product name *

- The user is then prompted to provide details of dosage form, presentation or model number as well as details of the trade name and Sponsor if known. Please note that for medical devices, trade name and Sponsor/supplier details are mandatory. Product strength, trade name and sponsor/supplier details are not mandatory fields for medicinal cannabis.

- The user can upload or free text any additional information that may support their application. This can include but is not limited to Instructions for Use (IFU) or Product Information.

Medicine + Included in TGA's Established History of Use	All other applications												
<p>Product strength(s) * If your product contains multiple strengths, please separate with a semi colon (Eg 12mg/mL; 50mg/mL; 100mg/mL)</p> <input type="text"/>	<p>Product strength(s) * If your product contains multiple strengths, please separate with a semi colon (Eg 12mg/mL; 50mg/mL; 100mg/mL)</p> <input type="text"/>												
<p>Trade name</p> <input type="text"/>	<p>Trade name</p> <input type="text"/>												
<p>Sponsor/supplier</p> <input type="text"/>	<p>Sponsor/supplier</p> <input type="text"/>												
<p>Additional Information</p> <div style="border: 1px solid gray; height: 30px;"></div>	<p>Additional Information</p> <div style="border: 1px solid gray; height: 30px;"></div>												
<p>Please upload any supporting information including product brochures. Please note that attachments must be in DOC,DOCX or PDF format.</p> <p style="text-align: right;">Add files</p>	<p>Please upload any supporting information including product brochures. Please note that attachments must be in DOC,DOCX or PDF format.</p> <p style="text-align: right;">Add files</p>												
<table border="1"> <thead> <tr> <th>Name</th> <th>Modified</th> </tr> </thead> <tbody> <tr> <td>📧 Emails</td> <td>3 minutes ago</td> </tr> <tr> <td>📄 Example Document.pdf (3235 KB)</td> <td>less than a minute ago</td> </tr> </tbody> </table>	Name	Modified	📧 Emails	3 minutes ago	📄 Example Document.pdf (3235 KB)	less than a minute ago	<table border="1"> <thead> <tr> <th>Name</th> <th>Modified</th> </tr> </thead> <tbody> <tr> <td>📧 Emails</td> <td>3 minutes ago</td> </tr> <tr> <td>📄 Example Document.pdf (3235 KB)</td> <td>less than a minute ago</td> </tr> </tbody> </table>	Name	Modified	📧 Emails	3 minutes ago	📄 Example Document.pdf (3235 KB)	less than a minute ago
Name	Modified												
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Name	Modified												
📧 Emails	3 minutes ago												
📄 Example Document.pdf (3235 KB)	less than a minute ago												
<p>Previous Save and Next</p>	<p>Previous Save and Next</p>												

Step 3: Approval/endorsement

8. Complete the 'Indications' field exactly as per the corresponding indication in the List of medicines with an established history of use; the indication(s) endorsed by the HREC or Specialist College in their approval letter. This is mandatory information.

The screenshot shows a web form for the 'Approval/endorsement' step. On the left, a vertical progress bar has four items: 'Prescriber details' (green), 'Product' (green), 'Approval/endorsement' (blue, active), and 'Summary' (grey). The main content area is titled 'Indication *' and includes the instruction: 'Please ensure indication is included in the established history of use specified list'. Below this is a large text input field. At the bottom of the form, there are two buttons: 'Previous' and 'Save and Next'.

Step 4: ARTG product consideration

1. Confirm that you will consider appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG) before supplying an "unapproved" good via the Authorised Prescriber Pathway for your patient.

The screenshot shows a section titled 'ARTG product consideration'. It contains the following text: 'The Authorised Prescriber scheme is available for exceptional circumstances where the prescribing medical practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG)'. Below this is a red-bordered box containing the question: 'Please confirm that you will consider approved and available treatments for your patients before supplying an 'unapproved' good via the Authorised Prescriber scheme. *'. There are two radio button options: 'Yes' (selected) and 'No'.

Step 5: Summary

1. Acknowledge that you have read and understood the following disclaimer to submit the AP application to the TGA:

Privacy statement

The TGA is collecting your personal information to assess the application and contact you, as the medical practitioner applying to supply unapproved goods, to discuss the application where necessary.

Your personal information and the outcome of your application may be viewed by other registered health professionals (i.e pharmacists). Generally, these registered users may view application details for the purpose of ensuring lawful supply of unapproved therapeutic goods under a TGA authorisation or exemption to a patient with a valid prescription.

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.

For general information about privacy, including a link to the Department of Health and Aged Care's Privacy Policy (which contains information on how to contact the Department, access and correct your personal information or make a privacy complaint), go to: <https://www.tga.gov.au/privacy>.

In submitting this application, I consent to the collection, use and disclosure of my personal information, and the disclosure of the outcome of my application to State and Territory authorities, and other registered health professionals, as set out above.

I have read and understood the privacy statement *

Yes

No

Submitting nicotine AP application

The online system provides a streamlined application process for medical practitioners to apply to be an Authorised Prescriber for unapproved nicotine products. The system guides medical practitioners to provide the correct information when seeking Nicotine Authorised Prescriber approval.

Step 1: New nicotine authorised prescriber application

To start a new Nicotine AP application, go to your AP dashboard and select 'New Nicotine AP application'.

The screenshot shows the 'Regulatory and Compliance' dashboard for the Therapeutic Goods Administration. The page title is 'Regulatory and Compliance' and the user is logged in as 'Example Account'. The navigation menu includes: Home, SAS Home Page, SAS Dashboard, Affiliated Sites, AP Dashboard (highlighted), AP Reports, and SAS/AP Submission Validation. The main content area is titled 'Authorised Prescriber dashboard'. At the bottom right, there are two buttons: 'New Nicotine AP application' (highlighted with a red box) and 'New AP application'.

Step 2: Submit a nicotine authorised prescriber application

1. The system will prefill the dosage form and indication based on the list of medicines with an established history of use.
2. Read the consent to online publication of personal information section and select “Yes” or “No” for publishing the name of prescriber and practice details on the TGA website.

Consent to online publication of personal information

To assist patients, the TGA may wish to publish a list of approved Authorised Prescribers for nicotine vaping products. If this occurs and you wish for your name to be included in the list please provide your consent below.

I consent to the Therapeutic Goods Administration (TGA) being part of the Australian Government Department of Health and Aged Care, publishing on the TGA website:

- my name; and
- the name and address of the practice where I work,

for the purpose of identifying me as an Authorised Prescriber of the product associated with this application. *

Yes

No

- If the user selects “Yes” for publication of information on the TGA website, the system will generate additional fields to be completed.

Yes

No

Exact information to be published on TGA website
Please set out your personal information exactly as you would like it to appear on the website

My name *

Dr Example Account

- The user has the option of providing a physical address or an online address for publication.

Physical address only

Online address only

Practice name *

Example Practice

Practice address *

123 Example St, Example Suburb ACT 1111

State/Territory *

ACT ▼

Or

Physical address only
 Online address only

Practice name *

Example Business Practice

This must be the business name and not the website address

- 3. Confirm that you will consider appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG) before supplying an “unapproved” good via the Authorised Prescriber Pathway for your patient.

ARTG product consideration

The Authorised Prescriber scheme is available for exceptional circumstances where the prescribing medical practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG).

Please confirm that you will consider approved and available treatments for your patients before supplying an 'unapproved' good via the Authorised Prescriber scheme. *

Yes
 No

- 4. Read the privacy statement and select “Yes” if you are satisfied.
- 5. Submit your application by clicking “Submit”.

Privacy Statement

The TGA is collecting your personal information to assess the application and contact you, as the medical practitioner applying to supply unapproved goods, to discuss the application where necessary.

Your personal information and the outcome of your application may be viewed by other registered health professionals (i.e pharmacists). Generally, these registered users may view application details for the purpose of ensuring lawful supply of unapproved therapeutic goods under a TGA authorisation or exemption to a patient with a valid prescription.

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.

For general information about privacy, including a link to the Department of Health and Aged Care's Privacy Policy (which contains information on how to contact the Department, access and correct your personal information or make a privacy complaint), go to: <https://www.tga.gov.au/privacy>.

In submitting this application, I consent to the collection, use and disclosure of my personal information, and the disclosure of the outcome of my application to State and Territory authorities, and other registered health professionals, as set out above.

I have read and understood the privacy statement *

Yes
 No

Submit

Completed applications

Status of draft and completed applications

All AP applications drafted or submitted via the system will appear in the AP Dashboard and include the current 'status' of the application.

The screenshot shows the AP Dashboard interface. At the top right, there are two buttons: 'New Nicotine AP application' and 'New AP application'. Below these, there is a search bar and several utility links: 'Download receipt(s)', 'Download outcome letter(s)', and 'Save list as CSV'. The main table has columns for 'Select', 'Product', 'Product Presentation', 'Created date', 'Application number', 'Status', 'Decision date', 'Expiry date', and 'Actions'. A red box highlights the 'Status' column, which contains the following values for the listed applications: Draft, Under TGA Review, TGA Rejected, Withdrawn, and TGA Approved.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000791	Under TGA Review			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000790	TGA Rejected	02/06/2022		
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000789	Withdrawn			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000788	TGA Approved	02/06/2022	23/06/2025	

Status	Description
'TGA Approved'	Reflects TGA's approval of an AP application.
'TGA Rejected'	Reflects TGA's rejection of an AP application.
'Under TGA Review'	An AP application has been successfully submitted to the TGA, and a decision is pending or the TGA have received an application amendment and the application is being updated
'Withdrawn'	Reflects that an AP application that has been submitted via the system and subsequently withdrawn at the request of the applicant.
'Draft'	Reflects a preliminary version of an AP application that has not yet been submitted via the system.
'Expired'	AP applications are only valid for specific period of time. The application status will change to expired once it has reached It's expiry date and the approval will no longer be valid.

Downloading application receipts and outcome letters

Application receipts may be downloaded once an application is submitted. Outcome letters may be downloaded following a TGA decision. Application receipts and outcome letters may be downloaded for individual applications or for multiple applications at a time.

To download application receipts and outcome letters, select the applications you wish to download the documents for in the left-hand column. Then select the report you wish to generate, either 'Download receipt(s)' or 'Download outcome letter(s)'. These functions are shown in red below.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>								
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000791	Under TGA Review			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000790	TGA Rejected	02/06/2022		
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000789	Withdrawn			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000788	TGA Approved	02/06/2022	23/06/2022	

System features

Cloning applications

All AP submissions visible in a user’s dashboard 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 alternate dosage forms, etc.

When cloning a submission, previously entered information will be used to prepopulate a new draft AP application. 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. Any attachments uploaded to the original submission (including letter of approval/endorsement).
2. Answer to the privacy statement on the Summary step ('yes/no')

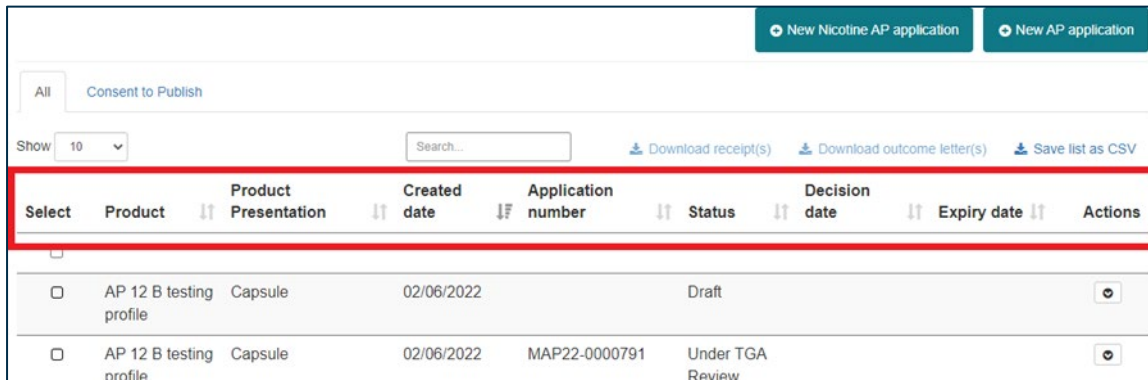
To clone an application, identify the submission that needs to be cloned by filtering in the user dashboard; click the 'Actions' tab and select 'Clone' from the dropdown.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>								
<input type="checkbox"/>	AP 12 B testing profile	Capsule	06/06/2022	MAP22-0000814	Under TGA Review			<ul style="list-style-type: none"> View details Download receipt Clone
<input type="checkbox"/>	AP 12 B testing profile	Capsule	06/06/2022	MAP22-0000813	Under TGA Review			

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

Filtering dashboard information

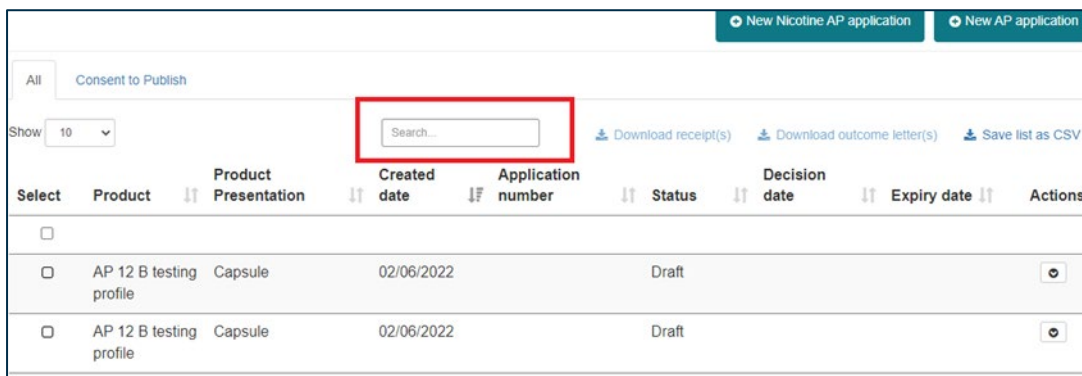
1. The dashboard allows users to search and filter submissions based on the fields shown below:



The screenshot shows the dashboard interface with a table of submissions. The table header is highlighted with a red border. The table contains two rows of data.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000791	Under TGA Review			

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

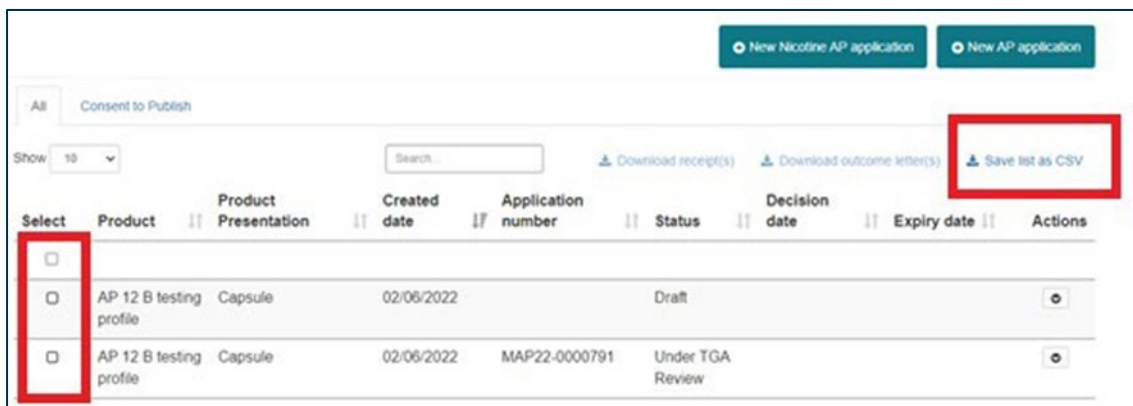


The screenshot shows the dashboard interface with the search box highlighted in red. The table below it contains two rows of data.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			

Exporting submission data

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



The screenshot shows the dashboard interface with the 'Save list as CSV' link and the first two rows of the table highlighted in red. The table contains two rows of data.

Select	Product	Product Presentation	Created date	Application number	Status	Decision date	Expiry date	Actions
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022		Draft			
<input type="checkbox"/>	AP 12 B testing profile	Capsule	02/06/2022	MAP22-0000791	Under TGA Review			

Managing applications where consent to publish has been provided

- On the dashboard there is a separate tab entitled 'Consent to Publish'. This displays applications where consent can be provided to have prescriber details published on the TGA website. If an application exists for an eligible product it will display in this view.

- Users can edit their response to the consent fields within the application by clicking 'Manage consent'.

Select	Product	Product Presentation	Created date	Application number	Status	Consent provided	Decision date	Expiry date	Actions
<input type="checkbox"/>	Nicotine in Solution (Salt or Base Form)	Solid / Liquid	11/10/2023	MAP23-0058094	Under TGA Review	Yes			View details, Download receipt, Manage Consent
<input type="checkbox"/>	Nicotine in Solution (Salt)	Solid / Liquid	06/09/2023	MAP23-0055723	TGA Cancelled	Yes			

- Update the necessary fields.

AP application number: MAP23-0058094 Submitted on: 11/10/2023 1:51 PM

Consent to online publication of personal information

I consent to the Therapeutic Goods Administration (TGA) being part of the Australian Government Department of Health and Aged Care, publishing on the TGA website:

- my name; and
- the name and address of the practice where I work,

for the purpose of identifying me as an Authorised Prescriber of the product associated with this application. *

Yes
 No

Exact information to be published on TGA website
 Please set out your personal information exactly as you would like it to appear on the website

My name *

*
 Physical address only
 Online address only

Practice name *

This must be the business name and not the website address

Submitting six monthly patient data

The online system guides medical practitioners to provide six monthly patient data.

For further information on Authorised Prescriber Reports Please see the document:

[Submitting six-monthly reports for Authorised Prescribers](#)

TGA contact details

Gather the following information before you ask for help with the SAS & 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)	
V1.1	Guidance updates based on system changes.	Experimental Products Section (EPS); Pharmacovigilance and Special Access Branch (PSAB)	22 April 2021
V1.2	Guidance updates based on new six-month reporting form	Experimental Products Section (EPS); International Regulatory Branch (IRB)	December 2021
V1.3	Guidance updated based on system changes.	Experimental Products Section (EPS); International Regulatory Branch (IRB)	March 2021
V.1.4	Guidance updated based on system changes.	Special Access Section (SAS); International Regulatory Branch (IRB)	June 2022
V1.5	Guidance updated based on system changes	Special Access Section (SAS); International Regulatory Branch (IRB)	October 2023
V1.6	Guidance updated based on system changes	Business Improvements and Compliance Section (BICS); International Regulatory Branch (IRB)	February 2024
V1.7	Guidance updated based on system changes	Business Improvements and Compliance Section (BICS); International Regulatory Branch (IRB)	March 2024
V1.8	Guidance updated for clarification	Business Improvements and Compliance Section (BICS); International Regulatory Branch (IRB)	July 2024
V2.0	Guidance updated based on system changes	Unapproved Medicines Access Section (UMAS); International Regulatory Branch (IRB)	May 2026

OFFICIAL

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Reference/Publication #