Authorised Prescriber
Special Access Scheme & Authorised Prescriber Scheme Online system guidance

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Contents

Online system overview _________________________ 4
Terminology and definitions ______________________ 4
Features of the SAS & AP Online System___________ 5
Account management _____________________________ 5
  Account registration________________________________________ 5
  Medical practitioners _________________________________________ 10
  Change password ____________________________________________ 10
  Forgotten your Password ______________________________________ 11
  Updating account information ________________________________ 13
User dashboard ____________________________________________ 13
  Authorised prescriber dashboard______________________________ 14
  Authorised prescriber reports_______________________________ 14
Submitting AP applications ___________________________ 15
  Step 1: Prescriber details____________________________________ 16
  Step 2: Product _____________________________________________ 16
  Step 3: Approval/endorsement __________________________________________ 20
  Step 4: Summary ____________________________________________ 20
Submitting nicotine AP application______________________ 21
  Step 1: New nicotine authorised prescriber application__________ 21
  Step 2: Submit a nicotine authorised prescriber application ______ 22
Completed applications ________________________________ 24
  Status of draft and completed applications ____________________ 24
  Downloading application receipts and outcome letters _________ 24
System features _____________________________________________ 25
  Cloning applications________________________________________ 25
Filtering dashboard information ____________________________ 26
  Exporting submission data ____________________________________ 27
  Managing applications where consent to publish has been provided 27
Submitting six monthly patient data _____________________ 28
Online system overview

The Special Access Scheme (SAS) & Authorised Prescriber (AP) Online System (SAS & AP online system) is the preferred method of submission for 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 and six monthly patient data reports via the SAS & AP Online System (the system). To reduce processing times, prescribers are strongly encouraged to submit applications through the system.

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

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account</td>
<td>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.</td>
</tr>
<tr>
<td>Outcome letter</td>
<td>The Approval or Rejection letter provided by the TGA in response to an Authorised Prescriber application.</td>
</tr>
<tr>
<td>Receipt</td>
<td>A copy of the AP application form which can be downloaded via a user’s dashboard.</td>
</tr>
<tr>
<td>Request for Information (RFI)</td>
<td>The process by which the TGA requests additional information to be provided by the user after submission of an application.</td>
</tr>
</tbody>
</table>
Features of the SAS & AP Online System

- Users of the system are required to register an account before they can begin drafting and submitting online 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 decision 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).

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).

<table>
<thead>
<tr>
<th>Register</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Password requirements</strong></td>
</tr>
<tr>
<td>• Your new password must be different from your last 8 passwords.</td>
</tr>
<tr>
<td>• Your password cannot contain your account name or more than two consecutive characters of your full name.</td>
</tr>
<tr>
<td>• Your password must contain characters from the following four categories:</td>
</tr>
<tr>
<td>1. English uppercase characters (A through Z)</td>
</tr>
<tr>
<td>2. English lowercase characters (a through z)</td>
</tr>
<tr>
<td>3. Numbers (0 through 9)</td>
</tr>
<tr>
<td>4. Non-alphabetic characters for example, (!, #, %)</td>
</tr>
<tr>
<td>• Your password must be a minimum of 14 characters.</td>
</tr>
<tr>
<td>• Your password can only be changed once per day.</td>
</tr>
</tbody>
</table>

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-c5f0d3b0ae14/288580002

   **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.
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:

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. 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:

![Change password form]

**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?”

![Login to TGA Business Services](image)

3. Enter your username and select “reset”

![TGA online](image)

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

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

![Hyperlink to reset password]

6. Enter your new password

![Password input fields]

**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, contact details, adding or removing practicing locations etc.) by updating their user profile:

![User profile update interface]

**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'. In order to view information specific to AP applications that have been drafted and submitted in the online system, users will need to select the Authorised Prescriber 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:

Authorised prescriber reports

Users who are registered medical practitioners will have an additional dashboard called 'Authorised Prescriber Reports'. Users can submit six monthly patient data directly into the reports available by selecting the Authorised Prescriber Reports from the ribbon.
Once selected, the Authorised Prescriber reports will appear as below with the draft report for each reporting period.

![Authorised Prescriber reports](image)

### 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’:

![Authorised Prescriber dashboard](image)
Step 1: Prescriber details

1. Confirm your details.

The prescriber details are 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.

Step 2: Product

1. Select the type of unapproved therapeutic good.
2. After selecting the 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'

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

![Search bar screenshot]

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 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 of these products have a profile in the online database.

![Manual entry screenshot]
5. 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.

6. The user is able to 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.
Step 3: Approval/endorsement

1. 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 the approval letter. This is mandatory information.

![Diagram showing the 'Indications' field with a dropdown menu labeled 'Please ensure indication is included in the established history of use specified list.'](image)

Step 4: 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 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'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 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’.
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.

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

- The user has the option of providing a physical address or an online address for publication.
3. Read the privacy statement and select “Yes” if you are satisfied.
4. Submit your application by clicking “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.

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>'TGA Approved'</td>
<td>Reflects TGA's approval of an AP application.</td>
</tr>
<tr>
<td>'TGA Rejected'</td>
<td>Reflects TGA's rejection of an AP application.</td>
</tr>
<tr>
<td>'Under TGA Review'</td>
<td>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</td>
</tr>
<tr>
<td>'withdrawn'</td>
<td>Reflects that an AP application that has been submitted via the system and subsequently withdrawn at the request of the applicant.</td>
</tr>
<tr>
<td>‘Draft’</td>
<td>Reflects a preliminary version of an AP application that has not yet been submitted via the system.</td>
</tr>
</tbody>
</table>

## 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.

### 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:

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

![Authorised Prescriber dashboard]

**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:

![Exporting submission data]

**Managing applications where consent to publish has been provided**

1. 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.

![Managing applications where consent to publish has been provided]
2. Users have the ability to edit their response to the consent fields within the application by clicking ‘Manage consent’

3. Update the necessary fields

Submitting six monthly patient data

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

1. Go to the ‘Authorised Prescriber Reports’ to submit your six monthly patient data.
2. Refer to the report for the current reporting period and select ‘Edit’.

3. To enter your patient data, select ‘Edit’ against the appropriate AP approval number/product.
4. Enter the ‘Number of new patients commenced on treatment or number of devices supplied’ during the six month period and the total ‘Number of patients treated during this period’. Note: Total patients is new patients plus patients who have been continued on treatment.

5. Select ‘Yes’ once you have read the privacy statement and click ‘Submit’.

TGA contact details

<table>
<thead>
<tr>
<th>Email</th>
<th><a href="mailto:authorised.prescribers@health.gov.au">authorised.prescribers@health.gov.au</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>1800 020 653</td>
</tr>
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</table>
## Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Original publication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V1.1</td>
<td>Guidance updates based on system changes.</td>
<td></td>
<td>22 April 2021</td>
</tr>
<tr>
<td>V1.2</td>
<td>Guidance updates based on new six-month reporting form</td>
<td></td>
<td>December 2021</td>
</tr>
<tr>
<td>V1.3</td>
<td>Guidance updated based on system changes.</td>
<td></td>
<td>March 2021</td>
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