Australian Government
Department of Health
Therapeutic Goods Administration

Authorised Prescriber user guidance

Special Access Scheme & Authorised Prescriber Scheme online system

Version 1.0, November 2018

TGA Health Safety Regulation

Contents

Online system overview

This document provides information on how register an account and submit Authorised Prescriber (AP) applications via the Special Access Scheme & Authorised Prescriber Online System.

In July 2018, the Therapeutic Goods Administration (TGA) implemented an online system (the system) to enable the electronic submission and management of Special Access Scheme (SAS) applications and notifications to the TGA. In November 2018, the system was expanded and renamed to allow the electronic submission of AP applications by medical practitioners.

The expansion of the system is expected to reduce administrative burden and provide medical practitioners (users) with additional reporting functions to assist in the management of their AP applications.

It is important to note that while use of the system to submit AP applications is encouraged, itis not mandatory and the TGA will still accept paper forms. The TGA are planning to transition away from paper forms and move towards the submission of all AP applications via the online system from 1 July 2019.

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 Authorised Prescriber online system

- Users of the system will be required to register an account before they can begin drafting and submitting online AP applications to the TGA.
- Users can draft and submit AP applications to the TGA by navigating through an interactive workflow which contains a series of questions (further details provided under the 'Submitting Authorised Prescriber Applications via the Special Access Scheme & Authorised Prescriber Online System' section).
- A searchable database of products (medicines, medical devices and biologicals) will be available for users to select. This will assist the user to accurately provide the required information and reduce the need for the TGA to seek further clarification regarding the identity of the product.
- Users will also have a dashboard within their account where they will be able 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 Online System, **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:

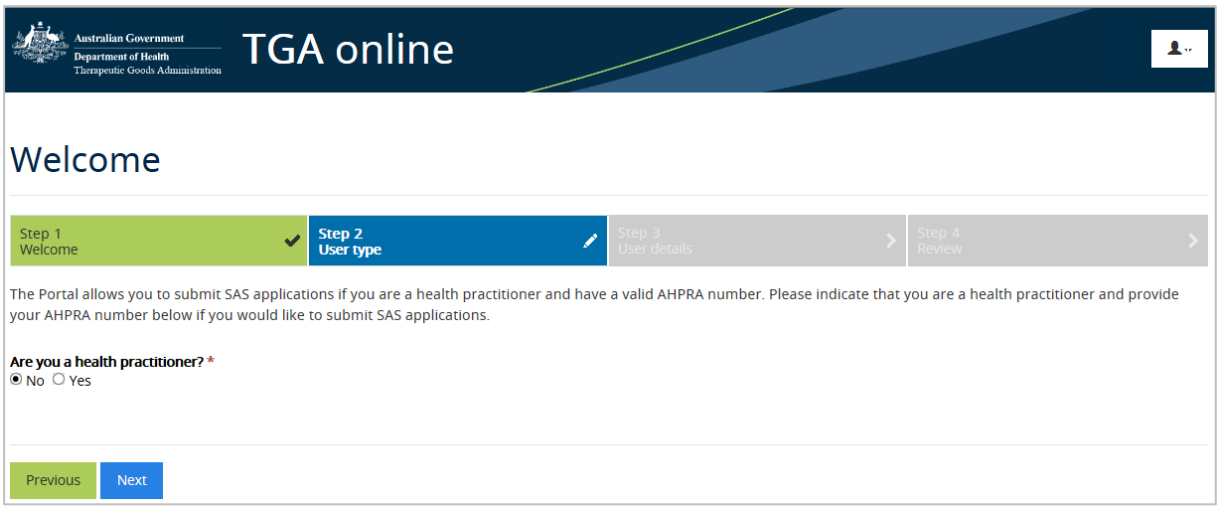
- A new, unique username; password; email address (for the purposes of account registration).
- Personal information such as full name; health practitioner type; AHPRA registration number; and contact details (this will be used to populate the user's profile).

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.

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:

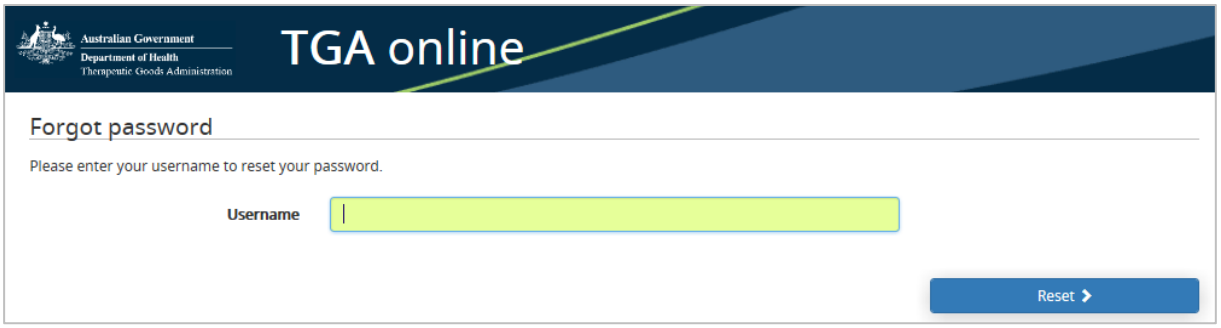


Medical practitioners registering an account in the system will be asked to provide their AHPRA registration number. The AHPRA registration number should be entered exactly as it appears in the AHPRA public register, including the three letter prefix (i.e. MED1234567890).

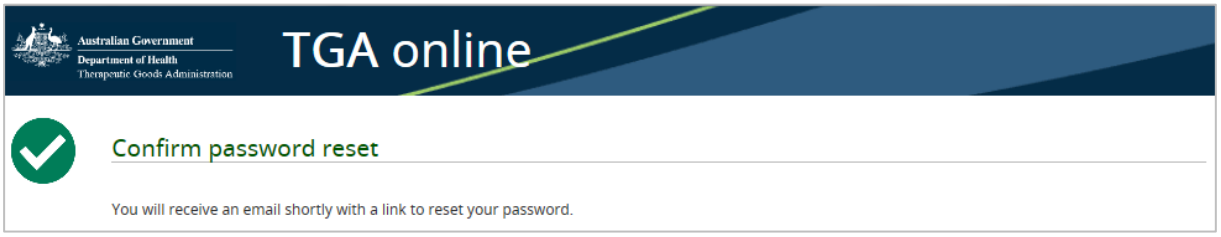
Password resets

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

2. Enter your username:

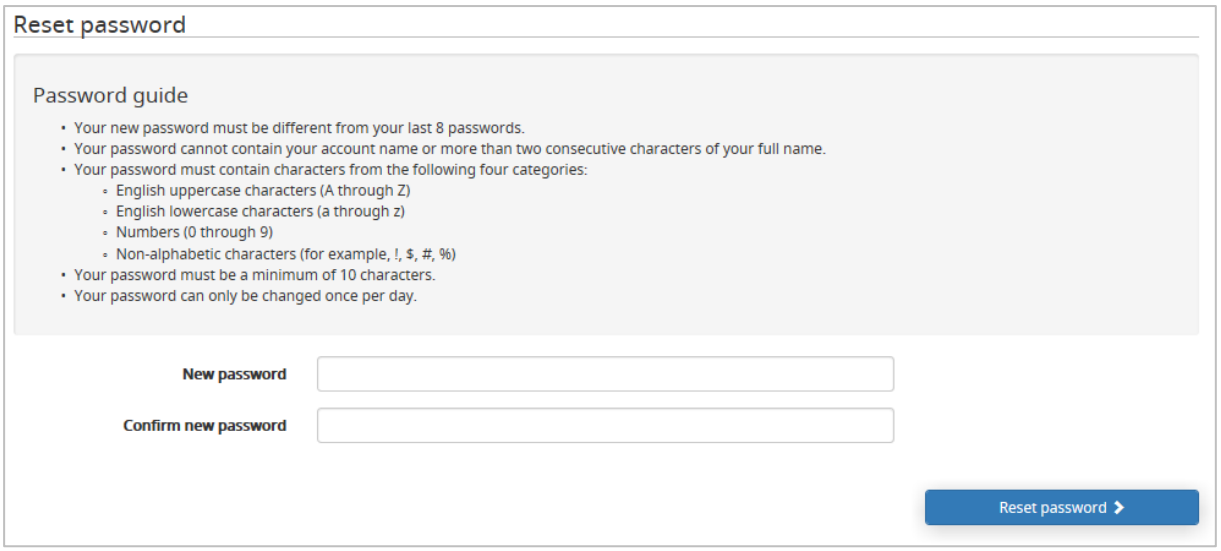


3. A password reset email will be sent to the email address associated with your username:



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

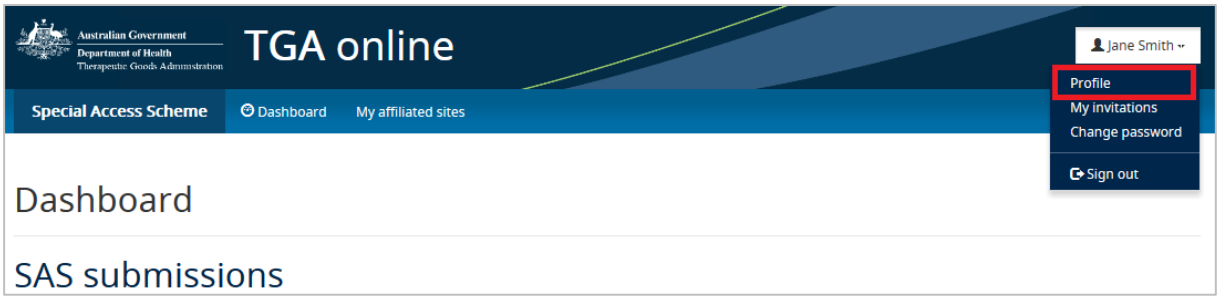
5. Enter your new password:



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

Updating account information

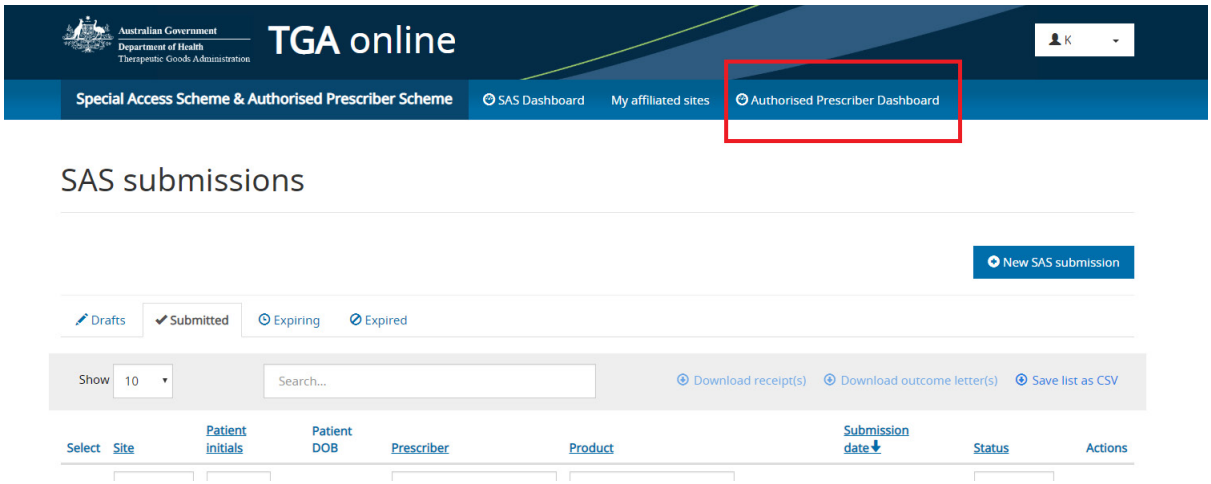
Once an account has been registered in the system, users will be able to update the information associated with their account (such as name, contact details, adding or removing practicing locations etc.) by updating their user profile:



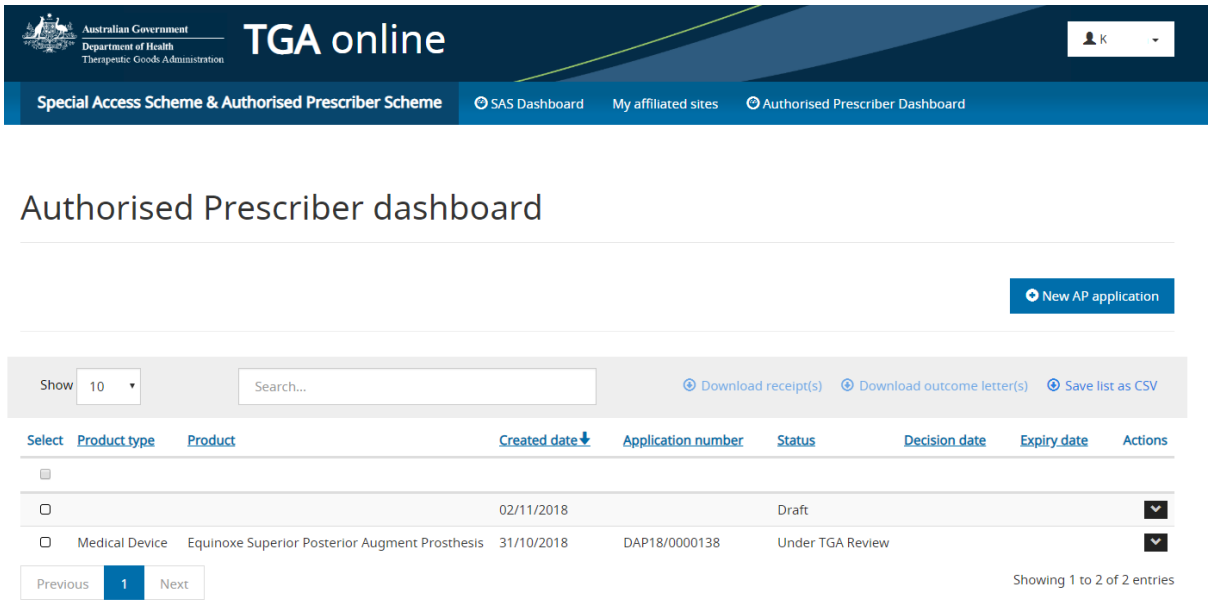
User dashboard

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.

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.



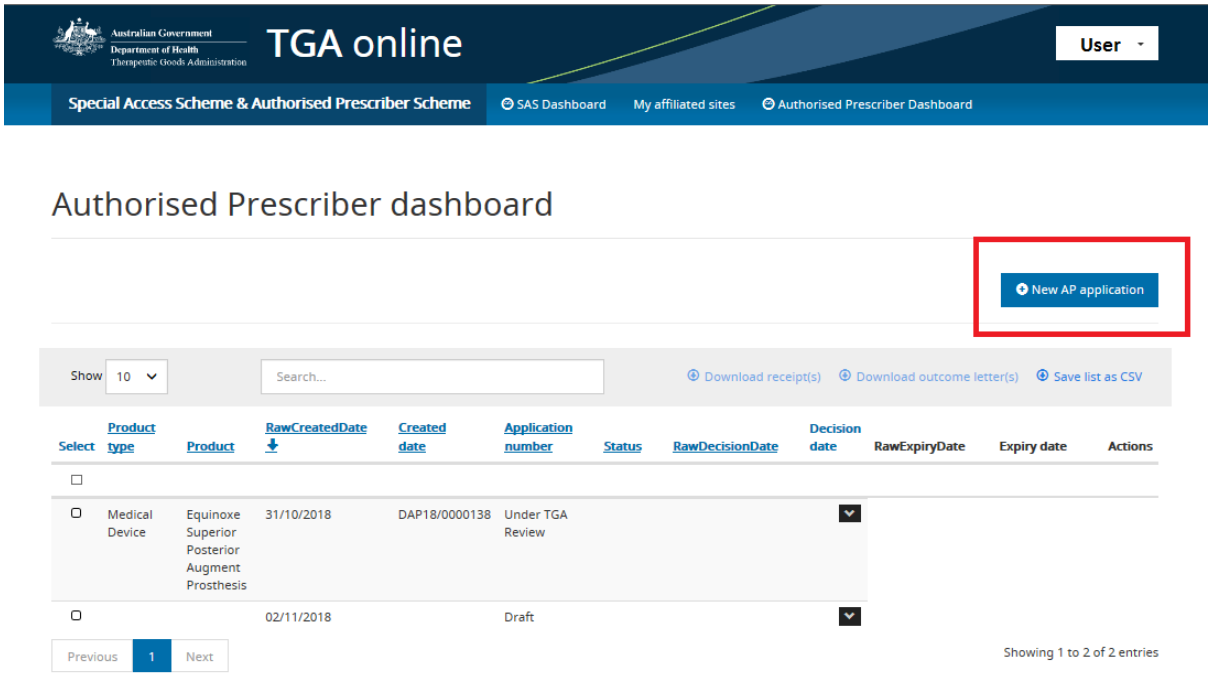
Once selected, the Authorised Prescriber dashboard will appear as below. Additional features of the dashboard are discussed further in the 'System Features' section:



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

1. Select 'Yes' or 'No' to the question 'Is this a renewal?'

Renewal application

AP application for a particular product which the user has an expiring or expired approval.

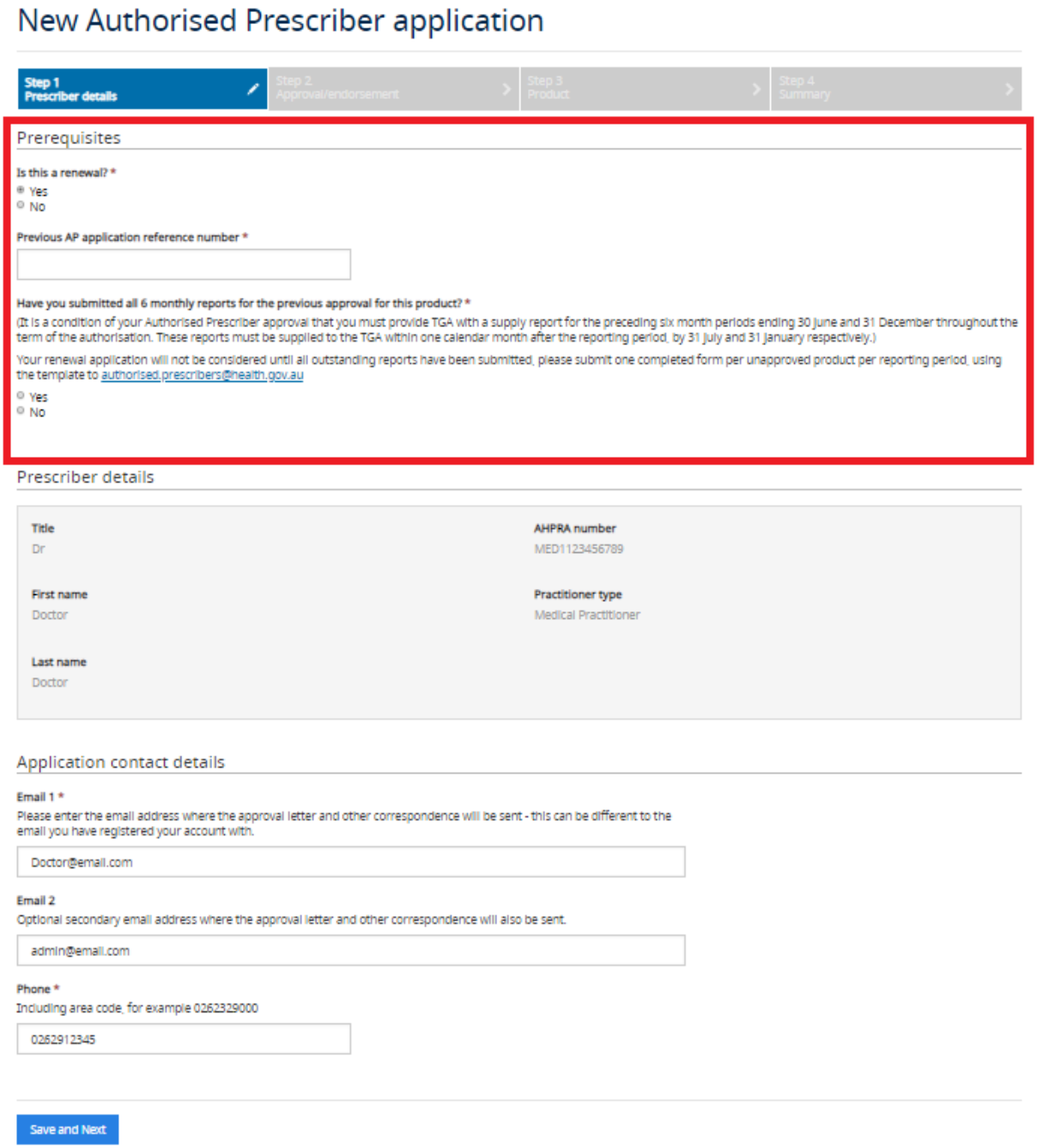
New application

AP application for a particular product which the user has not received approval in the past.

By selecting 'No' the user is declaring that this is a new application for which an expiring or expired AP approval does not exist.

By selecting 'Yes' you are taken through the additional workflow which requests previous AP approval number, and will require you to declare whether you have submitted all the required supply reports (in accordance with the conditions of your previous approval).

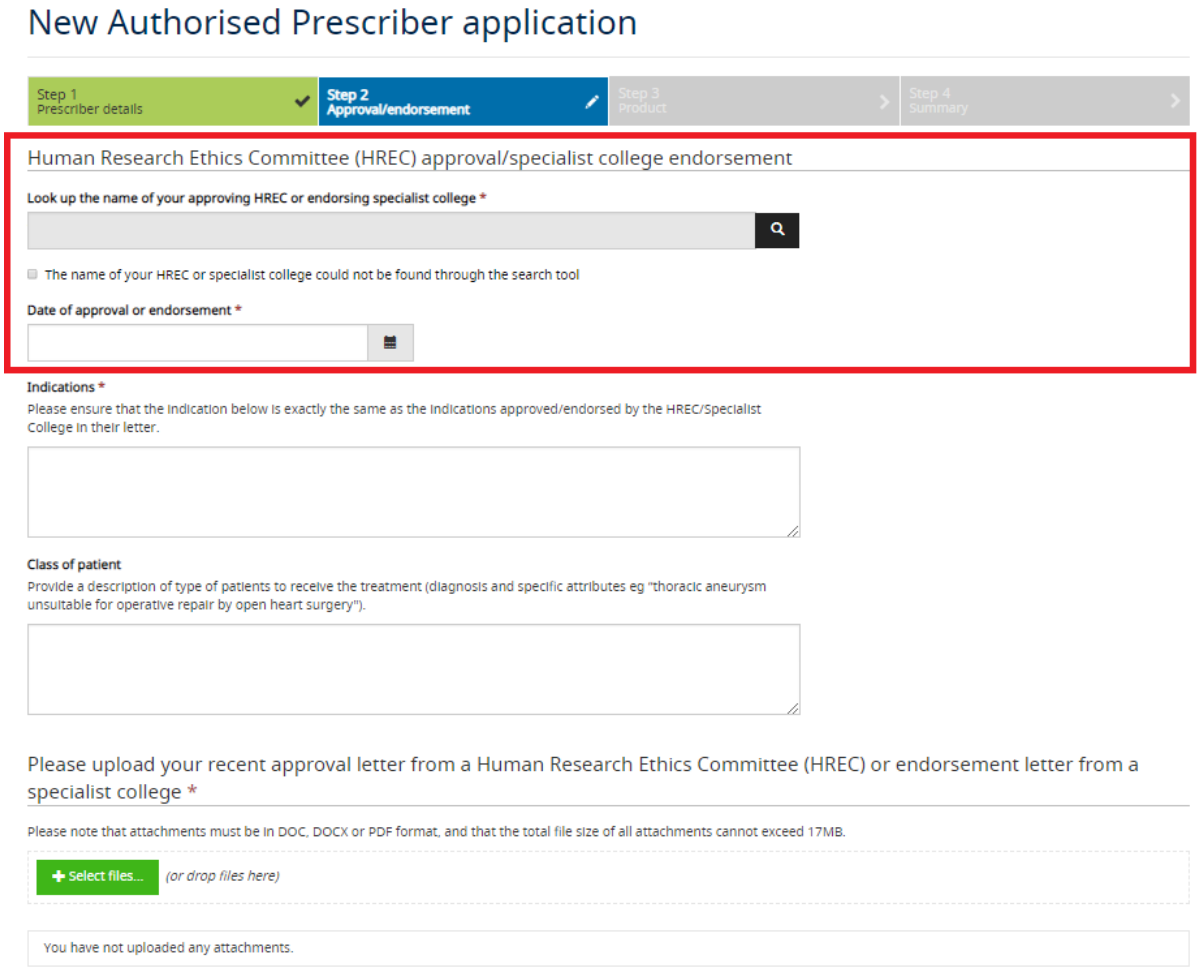
Please note, renewal applications will not be considered until all required reports have been submitted to the TGA, and you will not be able to progress to the next section of the application until you answer 'Yes' to the question 'Have you submitted all 6 monthly reports for the previous approval for this product?'.



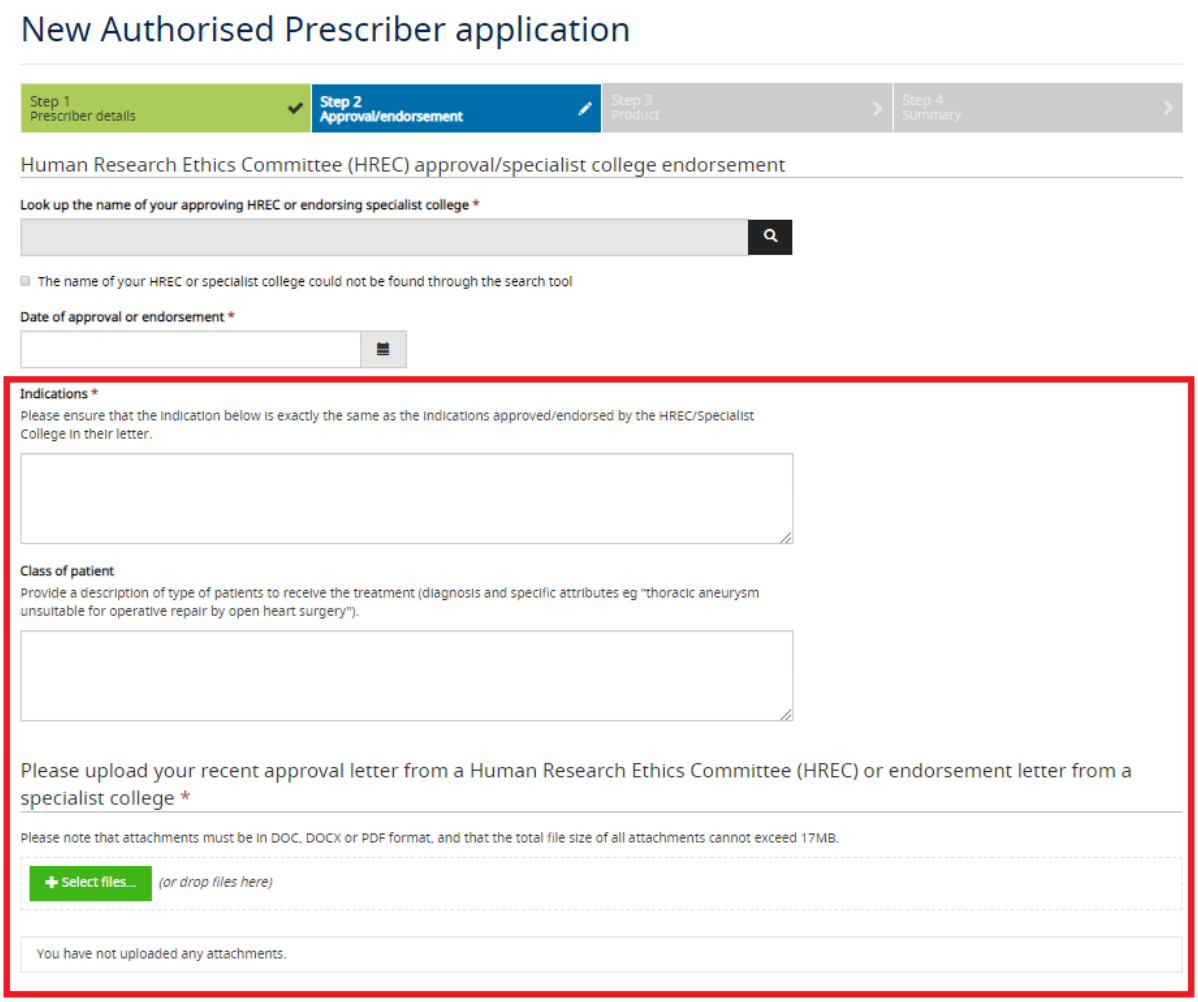
2. The prescriber details are prepopulated from the details in your account. For instructions on how to update your account details, please refer to the 'Updating account information' section. As it is understood that medical practitioners may practice from multiple locations and may use different email addresses, you are asked to 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: Approval/endorsement

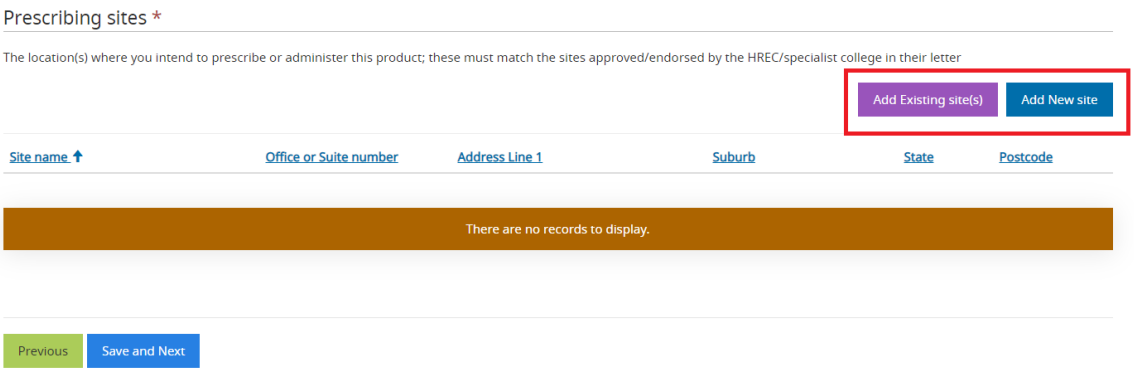
1. Select the name of the Approving HREC or Endorsing Specialist College using the look-up function. This look-up function searches TGA's internal database of existing HREC and Specialist College entries. If name of the required HREC or Specialist College cannot be found in the look-up, tick 'The name of your HREC or specialist college could not be found through the search tool' and the HREC or Specialist College can be manually entered.



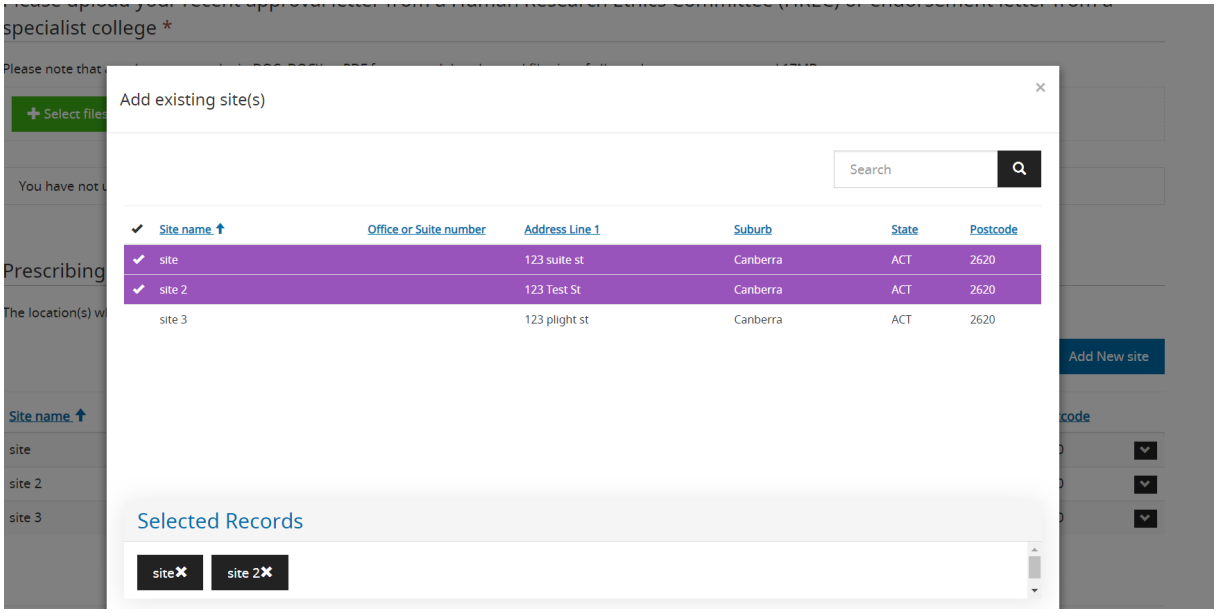
2. Complete the 'Indications' and 'Class of patient' sections based on the information in the HREC/Specialist College approval/endorsement letter. The indication should be written as it appears in the approval/endorsement letter from the HREC/Specialist College (this is mandatory information). The approval/endorsement letter should also be uploaded at this step.



3. Add the site/s that the unapproved therapeutic good will be used or prescribed. The sites included in this section should match those in the endorsement/approval letter.

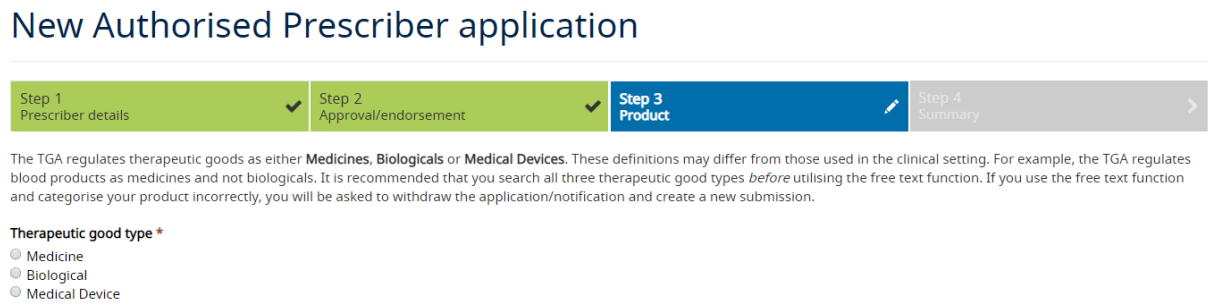


4. A look up function is available by selecting 'Add existing site(s)' which enables the user to select sites that they have entered into the online system in the past.

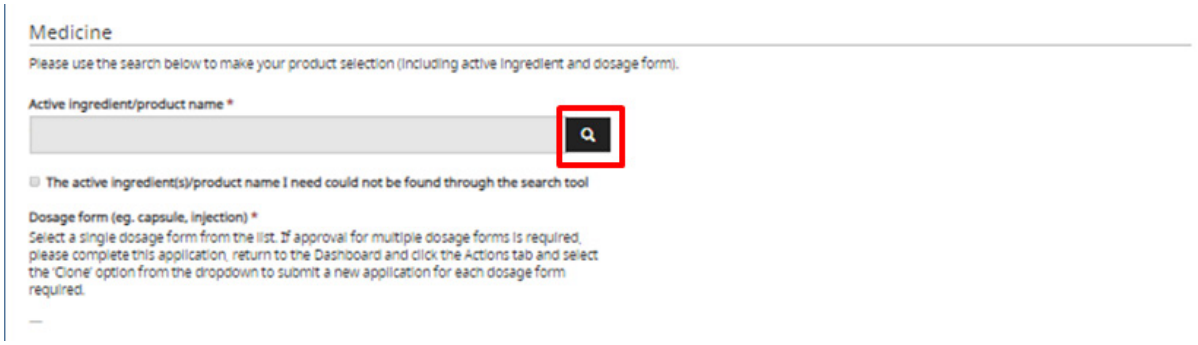


Step 3: Product

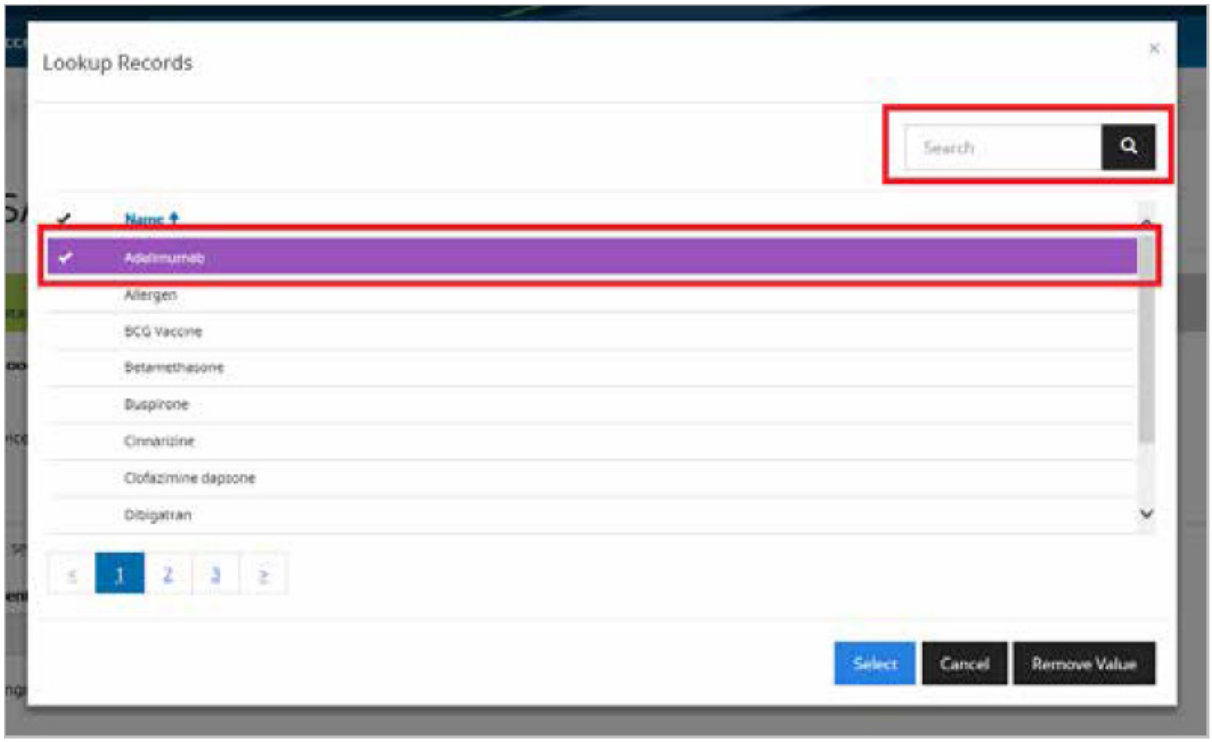
1. Select the type of unapproved therapeutic good:



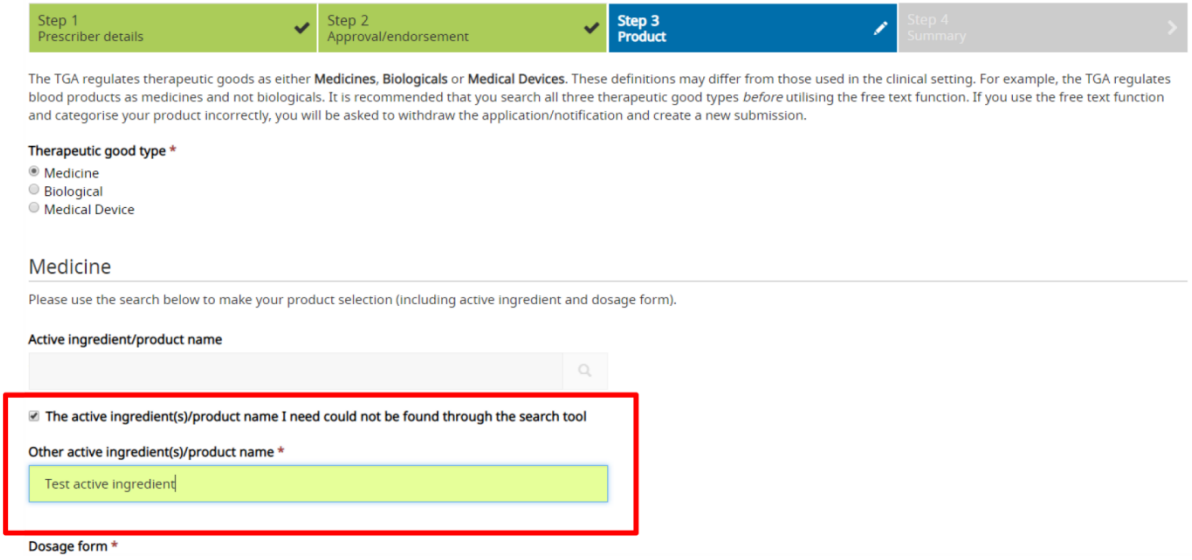
2. Upon selecting type of therapeutic good, the user will be prompted to provide details of the product such as the active ingredient, dosage form and indication. A look-up function is available to search TGA's internal database of existing entries as shown below:



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

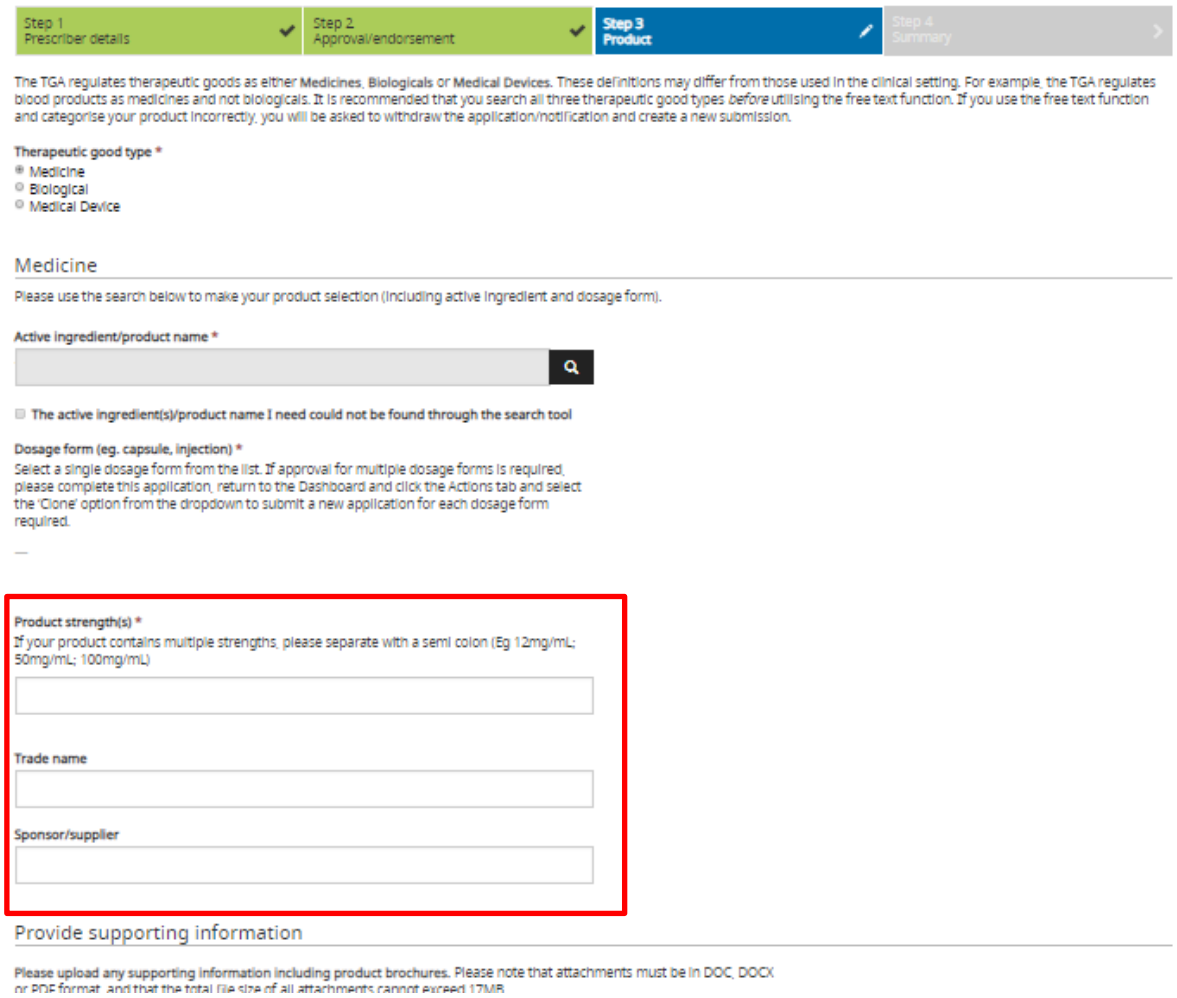


4. If you are unable to identify the required information via the look-up function, select the check-box below the search field. This will allow users to manually enter details of the product:

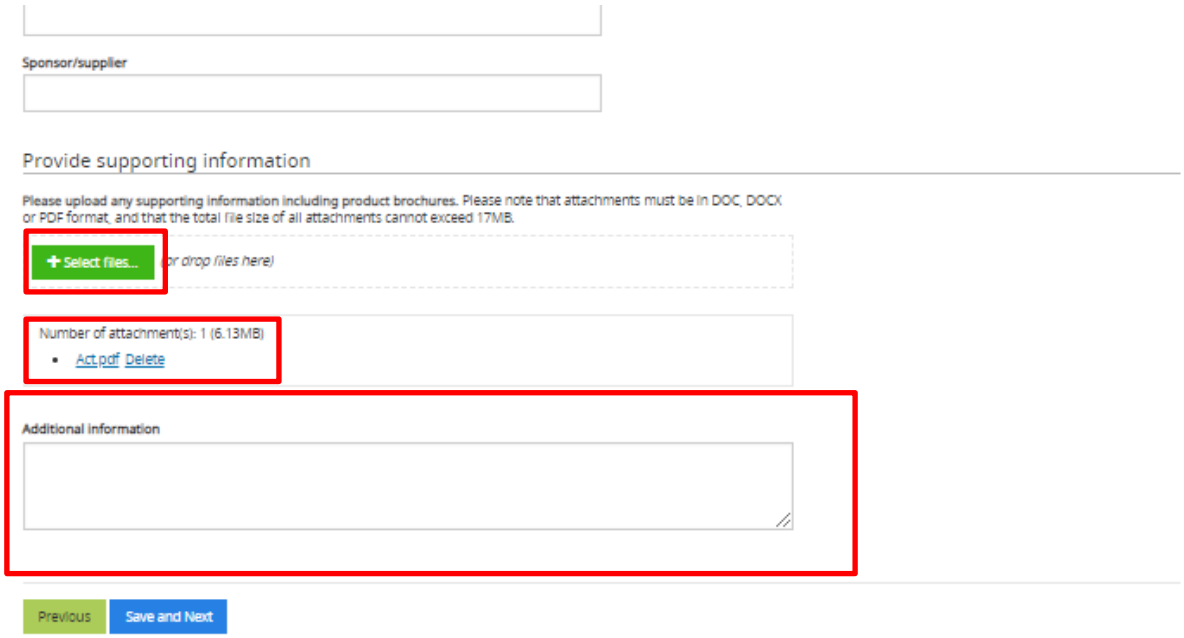


5. The user is then prompted to provide details of dosage form, presentation or model number as well as details of the trade name and Sponsor if known. Please note that for medical devices, trade name and Sponsor/supplier details are mandatory.

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.

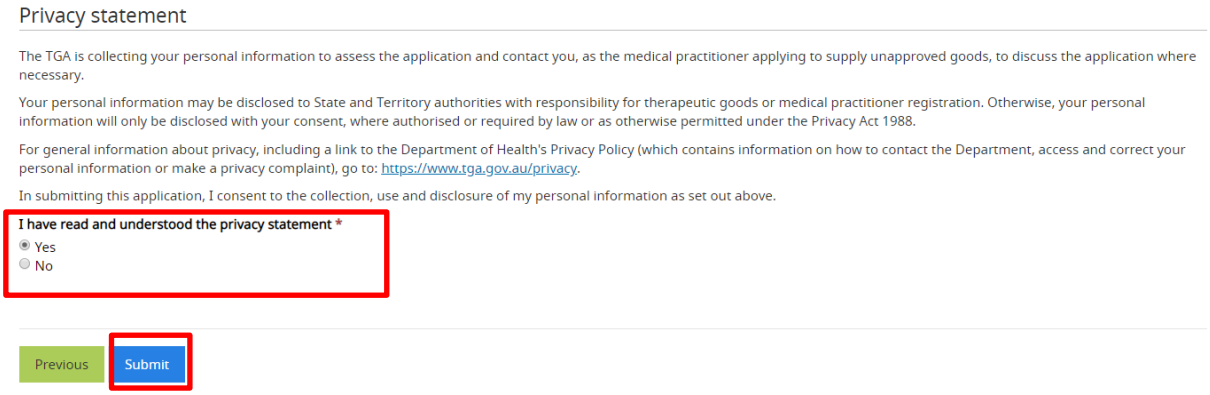


6. The user is able to upload or free-text any additional information that may support their application. This can include, but is not limited to Instructions for Use (IFU) or Product Information. The HREC/Specialist College approval/endorsement letter will also appear here (previously uploaded in Step 2).



Step 4: Summary

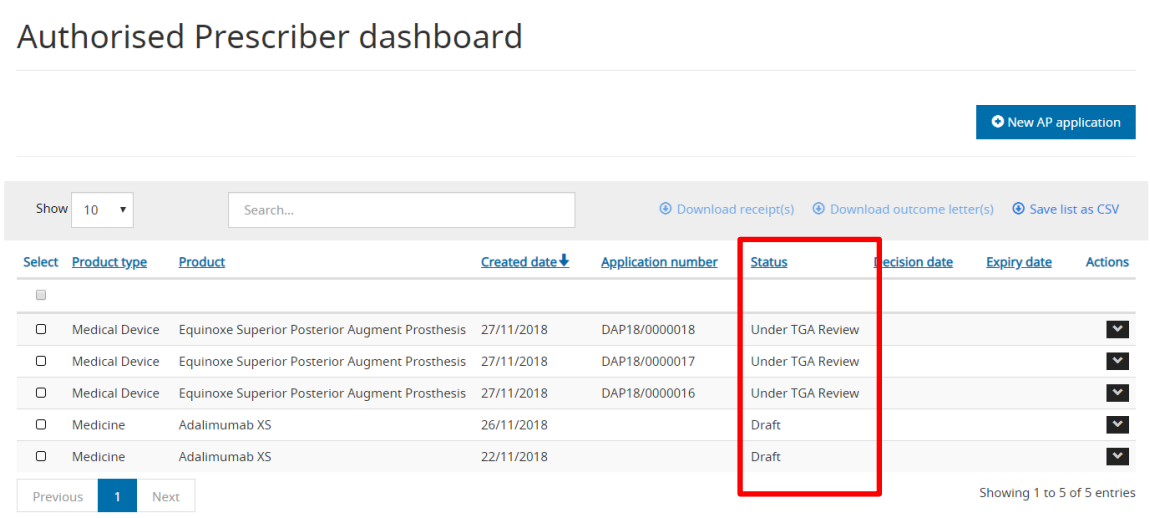
1. Acknowledge that you have read and understood the following disclaimer to submit the AP application to the TGA:



Completed Applications

Status of draft and completed applications

All AP applications drafted in or submitted via the system will appear in the AP Dashboard. Each entry will be accompanied by a 'status'



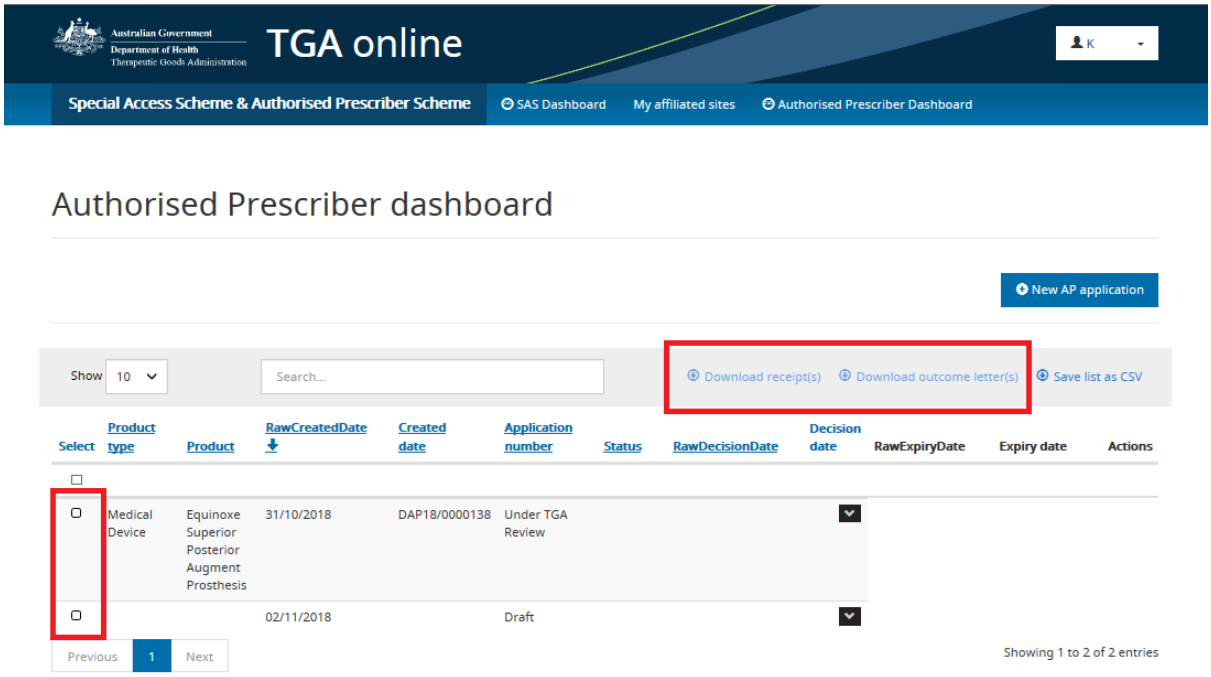
Status	Description
"TGA Approved"	Reflects TGA's approval of an AP application.
"TGA Rejected"	Reflects TGA's rejection of an AP application.
"Under TGA Review"	An AP application has been successfully submitted to the TGA, for which the TGA is yet to make a decision.

Status	Description
"Withdrawn"	Reflects that an AP application that has been submitted via the system and subsequently withdrawn at the request of the applicant.

Downloading application receipts and outcome letters

You will be able to download application receipts once an application is submitted and the outcome letters once the TGA has made a decision on the application. This can be done for single applications or for multiple applications at a time.

To download either application receipts or 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.

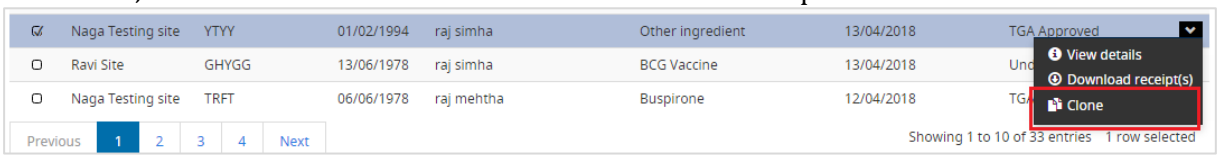
When cloning a submission, previously entered information will be used to prepopulate a new draft AP application. It is the responsibility of the submitter to review the information copied into the cloned submission to ensure that the correct information is provided to the TGA.

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")

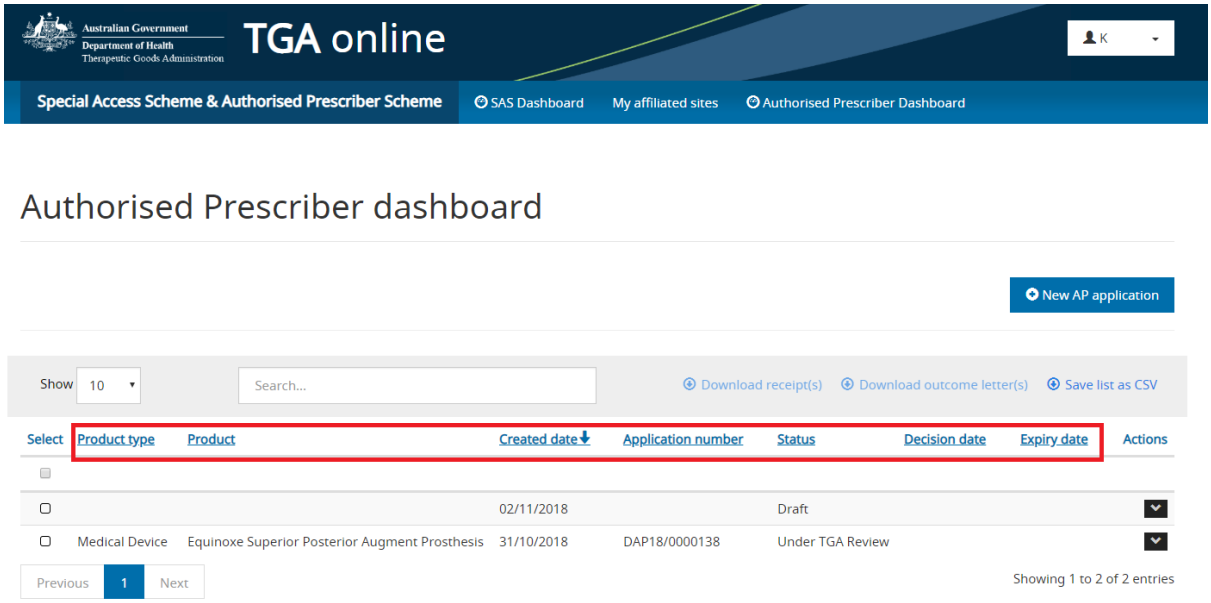
To clone an application, identify the submission that needs to be cloned by filtering in the user dashboard; click the 'Actions' tab and select 'Clone' from the dropdown:



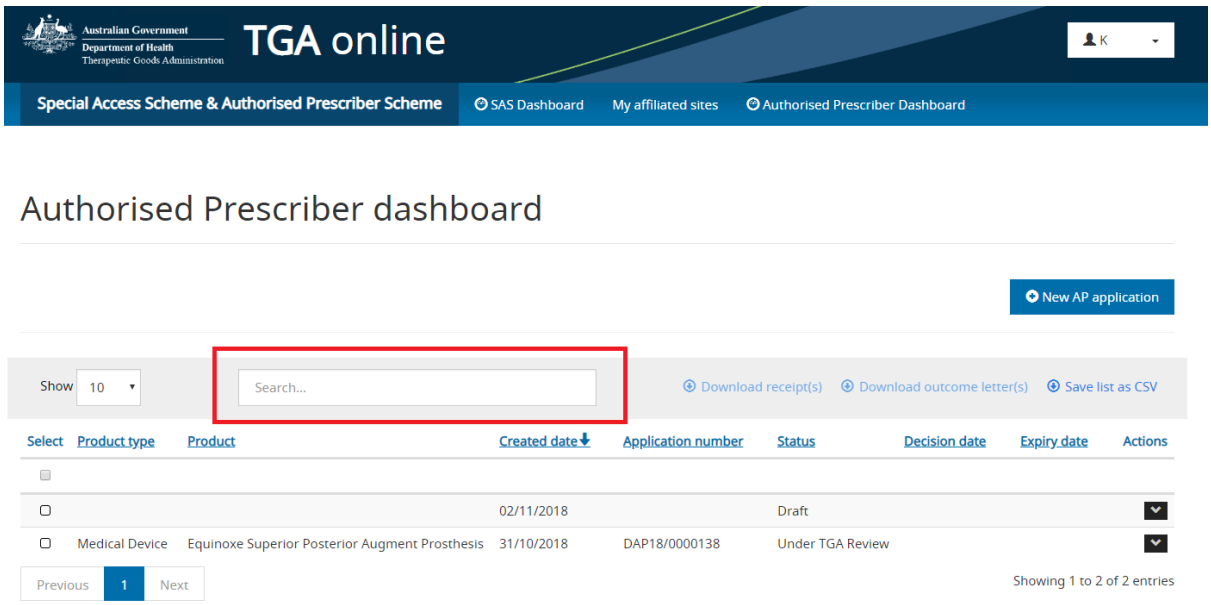
Navigate through the workflow and provide/update any relevant information specific to the new AP application before submitting to the TGA.

Filtering dashboard information

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

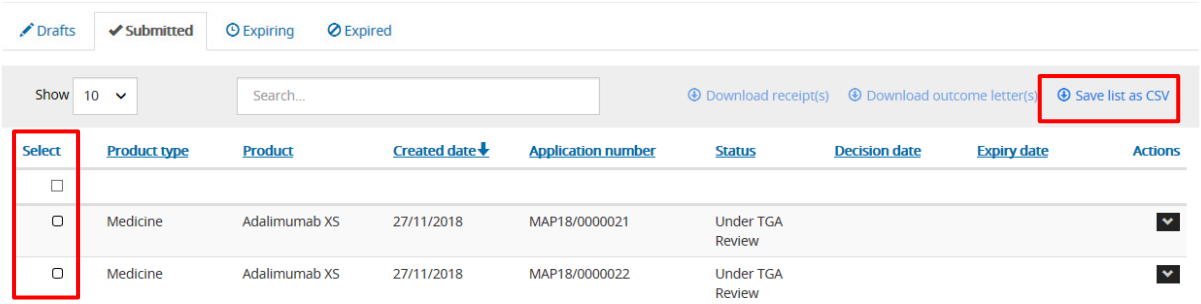


2. Users can also apply a uniform search across all available data fields by typing in the 'search' box:



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:



TGA contact details

Email	authorised.prescribers@health.gov.au
Phone	+61 2 6232 8911

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Experimental Products Section (EPS); Pharmacovigilance and Special Access Branch (PSAB)	29 November 2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #