

Australian Government

Department of Health Therapeutic Goods Administration

Authorised Prescriber user guidance

Special Access Scheme & Authorised Prescriber Scheme online system

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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, it is 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 <u>Special Access Scheme (SAS) Online System Guidance</u>.

For information regarding the Authorised Prescriber Scheme, please refer to the <u>Authorised</u> <u>Prescriber Scheme Guidance for Medical Practitioners, Human Research Ethics Committees,</u> <u>Specialist Colleges and Sponsors</u>.

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.

Terminology and definitions

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:

Australian Government Department of Health Therapeutic Goods Administration	TGA online			1
Welcome				
Step 1 Welcome	Step 2 User type	Step 3 User details	Step 4 Review	>
The Portal allows you to submit your AHPRA number below if yo	SAS applications if you are a health pra www.uld like to submit SAS application	actitioner and have a valid AHPRA number. Ple s.	ease indicate that you are a health practitio	ner and provide
Are you a health practitioner? * No O Yes				
Previous Next				

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:

Australian Government Department of Health Therapeutic Goods Administration TGA online	
Forgot password	
Username	
	Reset 🗲

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):

Hi Test Test,
A request was made to reset your password for the online system for the Special Access Scheme (SAS). Please follow this link to reset your password: https://apps.tga.gov.au/hortalaccounts/password/set/285550000/cf52f16a-7fc6-4a7b-aad7-f2b671005-e99.
The above link will expire in 24 hours.
Please contact the TGA if you believe there has been a mistake.

5. Enter your new password:

Reset password						
Password guide						
 Your new password must be different from your last 8 passwords. Your password cannot contain your account name or more than two consecutive characters of your full name. Your password must contain characters from the following four categories: English uppercase characters (A through Z) English lowercase characters (a through z) Numbers (0 through 9) Non-alphabetic characters (for example, !, \$, #, %) Your password must be a minimum of 10 characters. Your password can only be changed once per day. 						
New password						
Confirm new password						
	Reset 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:

Australian Grovernment Department of Health Trapendus Grouds Administration	💄 Jane Smith 🕶
Special Access Scheme O Dashboard My affiliated sites	Profile My invitations Change password
Dashboard	C ∙ Sign out
SAS submissions	

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.

Special Access Scheme & Authoris	ed Prescriber Scheme	O SAS Dashboard	My affiliated sites	O Authorised Prescriber Dashboard	
AS submissions					
					New SAS submission
Drafts Submitted Expire	ing 🖉 Expired				

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

Australian Government Department of Health Therapeutic Goods Administration				₽ K	
Special Access Scheme & Authorised Prescriber Scheme	🙆 SAS Dashboard	My affiliated sites	O Authorised Prescriber Dashboard		

Authorised Prescriber dashboard

							New AP ap	oplication
Sho	w 10 •	Search		Ownload	l receipt(s)	Download outcome lette	er(s) 🕑 Save li	st as CSV
Select	Product type	Product	Created date	Application number	<u>Status</u>	Decision date	Expiry date	Actions
0			02/11/2018		Draft			*
	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	31/10/2018	DAP18/0000138	Under TGA	Review		*
Prev	ious 1 Nez	ĸt					Showing 1 to 2	of 2 entries

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

										• New AP a	pplication
She	ow 10 🗸		Search				Download receip	ot(s) 🖲 D	ownload outcome l	etter(s) ④ Save	ist as CSV
Selec	Product t <u>type</u>	Product	RawCreatedDate ★	<u>Created</u> <u>date</u>	Application number	<u>Status</u>	RawDecisionDate	Decision date	RawExpiryDate	Expiry date	Actions
0	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	31/10/2018	DAP18/0000138	Under TGA Review			*			
Ο			02/11/2018		Draft			*			
Pre	vious 1	Next								Showing 1 to 2	2 of 2 entries

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?'.

New Authorised Prescriber application

Step 1 Step 2 Approval/end	orsement > Step 3 Product	Step 4 Summary
Prerequisites		
Is this a renewal? *		
® Yes © No		
Previous AP application reference number *		
Have you submitted all 6 monthly reports for the previous appr (It is a condition of your Authorised Prescriber approval that yo term of the authorisation. These reports must be supplied to th Your renewal application will not be considered until all outstar	' 'aval for this product? * u must provide TGA with a supply report for the preceding : e TGA within one calendar month after the reporting perior Iding reports have been submitted, please submit one com	ix month periods ending 30 june and 31 December throughout the 1, by 31 july and 31 january respectively.) pleted form per unapproved product per reporting period, using
the template to <u>authorised.prescribers@health.gov.au</u>		
© No		
Prescriber details		
Title	AHPRA number	
	MICD 1122430703	
First name	Practitioner type	
Doctor	Medical Practitioner	
Last name Doctor		
Application contact details		
Email 1 * Please enter the email address where the approval letter and or email you have registered your account with.	ther correspondence will be sent - this can be different to th	ie
Doctor@email.com		
Email 2 Optional secondary email address where the approval letter an	d other correspondence will also be sent.	
admin@email.com		
Phone * Including area code, for example 0262329000		
0262912345		

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.

Save and Next

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.

New Authorised Prescriber application

Step 1 Prescriber details Step 2 Approval/endorsement Step 3 Product Step 4 Summary
Human Research Ethics Committee (HREC) approval/specialist college endorsement
Look up the name of your approving HREC or endorsing specialist college *
٩
The name of your HREC or specialist college could not be found through the search tool
Date of approval or endorsement *
Indications * Please ensure that the indication below is exactly the same as the indications approved/endorsed by the HREC/Specialist College in their letter.
Class of patient Provide a description of type of patients to receive the treatment (diagnosis and specific attributes eg "thoracic aneurysm unsuitable for operative repair by open heart surgery").
Please upload your recent approval letter from a Human Research Ethics Committee (HREC) or endorsement letter from a specialist college *
Please note that attachments must be in DOC, DOCX or PDF format, and that the total file size of all attachments cannot exceed 17MB.
+ Select files (or drop files here)
You have not uploaded any attachments.

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.

New Authorised Prescriber application

Step 1 Prescriber details Step 2 Approval/endorsement Step 3 Product Step 4 Summary											
Human Research Ethics Committee (HREC) approval/specialist college endorsement											
Look up the name of your approving HREC or endorsing specialist college *											
٩											
The name of your HREC or specialist college could not be found through the search tool											
Date of approval or endorsement *											
Indications * Please ensure that the indication below is exactly the same as the indications approved/endorsed by the HREC/Specialist College in their letter.											
Class of patient Provide a description of type of patients to receive the treatment (diagnosis and specific attributes eg "thoracic aneurysm unsuitable for operative repair by open heart surgery").											
Please upload your recent approval letter from a Human Research Ethics Committee (HREC) or endorsement letter from a specialist college *											
Please note that attachments must be in DOC, DOCX or PDF format, and that the total file size of all attachments cannot exceed 17MB.											
+ Select files (or drop files here)											
You have not uploaded any attachments.											

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.

Prescribing sites *									
The location(s) where you intend to prescribe or administer this product; these must match the sites approved/endorsed by the HREC/specialist college in their letter									
				Add Existing site(s)	Add New site				
Site name	Office or Suite number	Address Line 1	Suburb	State	Postcode				
		There are no records to d	isplay.						
Previous Save and Next									

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.

specialist co	olle	ge *				, or chaore		ii oiii u
Please note that a	Ac	d existing site(s)					>	
You have not u						Search	٩	
	•	Site name	Office or Suite number	Address Line 1	Suburb	State	Postcode	
Prescribing		🖊 site		123 suite st	Canberra	ACT	2620	
resensing	•	site 2		123 Test St	Canberra	ACT	2620	
The location(s) w		site 3		123 plight st	Canberra	ACT	2620	
								Add New site
Site name								code
site) 🔽
site 2) 🗸
site 3		Selected Records						
	L	site X site 2					ŕ	

Step 3: Product

1. Select the type of unapproved therapeutic good:

New Authorised Prescriber application



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

The	era	pe	utic	good	type	*
<u> </u>						

- Medicine
 Biological
- Medical Device
- 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:

		Search Q
,	Name +	
è.	Adelmumet	
	Allergen	
	BCG vacone	
	Betamethasone	
	Buspirone	
	Onnarizine	
	Clofazimine daptone	
	Dibigatran	,
×.	1 2 3 2	

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:

Step 1 Prescriber details	Step 2 Approval/endorsement	Step 3 Product									
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 <i>Defore</i> utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.											
Therapeutic good type * [®] Medicine [©] Biological [©] Medical Device											
Medicine											
Please use the search below to make your proc	duct selection (including active ingredient and do	sage form).									
Active ingredient/product name											
The active ingredient(s)/product name I nee	d could not be found through the search tool										
Other active ingredient(s)/product name *											
Test active ingredient											

- 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.

Step 1 Prescriber details	*	Step 2 Approval/endorsement	~	Step 3 Product	Step 4 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 blologicals. It is recommended that you search all three therapeutic good types <i>before</i> utilising the free text function. If you use the free text function and categorise your product incorrectly, you will be asked to withdraw the application/notification and create a new submission.										
Therapeutic good type * Medicine Biological Medical Device										
Medicine										
Please use the search below to make you	r prod	uct selection (including active ingree	dlent and dosa	ge form).						
Active ingredient/product name *										
			٩							
The active ingredient(s)/product name	Ineed	could not be found through the se	arch tool							
Dosage form (eg. capsule, injection) * Select a single dosage form from the list. please complete this application, return t the 'Clone' option from the dropdown to required.	If appi to the D submit	roval for multiple dosage forms is re lashboard and click the Actions tab a new application for each dosage	equired, and select form							
_										
Product strength(s) * If your product contains multiple strengt 50mg/mL; 100mg/mL)	hs, plei	ase separate with a semi colon (Eg 1	2mg/mL;							
Trade name										
Sponsor/supplier										
L										
Provide supporting informa	tion									

Please upload any supporting information including product brochures. Please note that attachments must be in DOC, DOCX or PDE formatil and that the total file size of all attachments cannot exceed 17MB.

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).

Sponsor/supplier	
Provide supporting information	
Please upload any supporting information including product brochures. Please note that attachments must be in DOC, DOCX or PDF format, and that the total file size of all attachments cannot exceed 17MB.	
+ Select files or drop files here)	
Number of attachment(s): 1 (6.13MB) Act.pdf Delete	
Additional Information	
Previous Save and Next	

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 when 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 you 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 *								
	I have read and understood the privacy statement *								

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'

Authorised Prescriber dashboard

							New AP ap	plication
Show	v 10 v	Search		Ownload	receipt(s) 🕑 Downlo	ad outcome lette	er(s) 🕚 Save lis	st as CSV
Select	Product type	Product	Created date	Application number	<u>Status</u>	ecision date	Expiry date	Actions
	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	27/11/2018	DAP18/0000018	Under TGA Review			*
	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	27/11/2018	DAP18/0000017	Under TGA Review			*
	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	27/11/2018	DAP18/0000016	Under TGA Review			*
	Medicine	Adalimumab XS	26/11/2018		Draft			*
	Medicine	Medicine Adalimumab XS			Draft			*
Previo	pus <mark>1</mark> Ne	xt				J	Showing 1 to 5	of 5 entries

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.

Australian Government Department af Hodit Thempendic Goods Administration TGA online	≇ κ →
Special Access Scheme & Authorised Prescriber Scheme	SAS Dashboard My affiliated sites O Authorised Prescriber Dashboard

Authorised Prescriber dashboard

										◆ New AP a	pplication
Show	10 🗸		Search				Download receiption	ipt(s) 🕑 D	ownload outcome le	etter(s)	ist as CSV
Select	<u>Product</u> <u>type</u>	Product	<u>RawCreatedDate</u> ▲	<u>Created</u> <u>date</u>	Application number	<u>Status</u>	RawDecisionDate	Decision date	RawExpiryDate	Expiry date	Actions
0	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	31/10/2018	DAP18/0000138	Under TGA Review			*			
ο			02/11/2018		Draft			*			
Previo	ous 1	Next								Showing 1 to 2	2 of 2 entries

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:

Ŵ	Naga T	Testing	g site	YT	YY		01/02/1994	raj simha	Other ingredient	13/04/2018	TGA Approved
0	Ravi Si	te		GF	IYGG		13/06/1978	raj simha	BCG Vaccine	13/04/2018	Und View details
0	Naga T	Testing	g site	TR	FT		06/06/1978	raj mehtha	Buspirone	12/04/2018	TG/
Prev	ious	1	2	3	4	Next				Showing 1	to 10 of 33 entries 1 row selected

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:

	Australian Government Department of Health Therapeutic Goods Administration		≜ к -
Special Access Scheme & Authorised Prescriber Scheme Or SAS Dashboard My affiliated sites Or Authorised Prescriber Dashboard	Special Access Scheme & Authorised Prescriber Scheme	SAS Dashboard My affiliated sites O Authorised Prescriber Dashboard	

Authorised Prescriber dashboard

							New AP ap	plication
Show	v 10 •	Search		Ownload	l receipt(s)	load outcome lett	er(s) 🛞 Save li	st as CSV
Select	Product type	Product	Created date	Application number	<u>Status</u>	Decision date	Expiry date	Actions
0			02/11/2018		Draft			~
0	Medical Device	Equinoxe Superior Posterior Augment Prosthesis	31/10/2018	DAP18/0000138	Under TGA Review			~
Previo	pus 1 Ne	xt					Showing 1 to 2	of 2 entries

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:

🖍 Drafts	✓ Submitted	⊙ Expiring Ø Exp	ired					
Show	10 🗸	Search			Download receipt(s)) ④ Download ou	utcome letter(s)	Save list as CSV
Select	Product type	Product	Created date	Application number	Status	Decision date	Expiry date	Actions
	Medicine	Adalimumab XS	27/11/2018	MAP18/0000021	Under TGA Review			*
O	Medicine	Adalimumab XS	27/11/2018	MAP18/0000022	Under TGA Review			*

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: <u>info@tga.gov.au</u> Phone: 1800 020 653 Fax: 02 6203 1605 <u>https://www.tga.gov.au</u>

Reference/Publication #