



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Special Access Scheme Portal

Information for Healthcare Professionals

## **Petra Bismire**

Director – Experimental Products Section  
Pharmacovigilance and Special Access Branch  
Medicine Regulation Division  
Therapeutic Goods Administration

11 March 2021



**TGA** Health Safety  
Regulation

# Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
  - Messages will only be visible to the moderator and speaker
  - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **‘Chat’** function
- Relevant links will be sent to you via the chat function box
- Live polls will be conducted throughout this event.



## Difficulties hearing from your computer?

Check your settings located under **“Audio & Video”** tab located top of your screen:

OR

**Dial:** +61-2-9338-2221    **Passcode:** 165 546 4851

# Topics for discussion

- What is changing?
- Walkthrough SAS Dashboard Changes
- Walkthrough AP Dashboard Changes
- Where to go for support
- Questions

# What is changing?

## 'Look and feel' and navigation

### SAS dashboard:

- The state specific forms for medicinal cannabis applications for NSW, ACT and VIC forms have been updated to comply with legislative changes. We have also removed the QLD form to reflect recent legislative change.

### AP dashboard:

- The process for applying for nicotine products has been streamlined to a single button application available from the AP dashboard landing page.
- Submission of six monthly patient data reports can now be done directly via the SAS & AP Online System instead of PDF form emailed to the TGA.



# Logging in to the SAS & AP online system

Welcome to the Regulatory and Compliance Portal.

## Services



Devices  
Compliance  
(PMR)



Special Access  
Scheme (SAS)

# Navigate across to correct dashboard

The screenshot shows the 'My profile' page on the SAS Dashboard. The page header includes the Australian Government logo and the text 'Regulatory and Compliance'. The navigation menu has five items: 'Home', 'SAS Home Page', 'SAS Dashboard' (which is highlighted with a blue underline), 'My affiliated sites', and 'Authorised Prescriber Reports'. The main content area is titled 'My profile' and contains a 'Personal Details' section. This section includes a question 'Are you a Health Practitioner' with radio buttons for 'No' (selected) and 'Yes'. Below this are four text input fields: 'Title \*' (with a search icon), 'First Name \*', 'Last Name \*', and 'Preferred Name'. A horizontal line is visible at the bottom of the page.

Australian Government  
Department of Health

## Regulatory and Compliance

Home SAS Home Page **SAS Dashboard** My affiliated sites Authorised Prescriber Reports

### My profile

Personal Details

Are you a Health Practitioner  
 No  Yes

Title \*

First Name \*

Last Name \*


Preferred Name





# Navigating through the portal


- The form has been categorised into different sections on the left hand side of the form.


## New SAS submission

 Prescriber details

 Product selection

 Product details

 Patient details

 Summary

### Share submission

You can make this submission visible to a Site you have an affiliation with once it is saved (select site below). Please note that sharing this submission with a Site may allow other affiliated users to view the information contained in this submission for the purpose of continuing patient care or supplying relevant goods.

You cannot specify a site to share this application as you are not currently associated with any site. [Go to the My Affiliated Sites page](#) to register a new site or request to join an existing one.

### Prescriber details

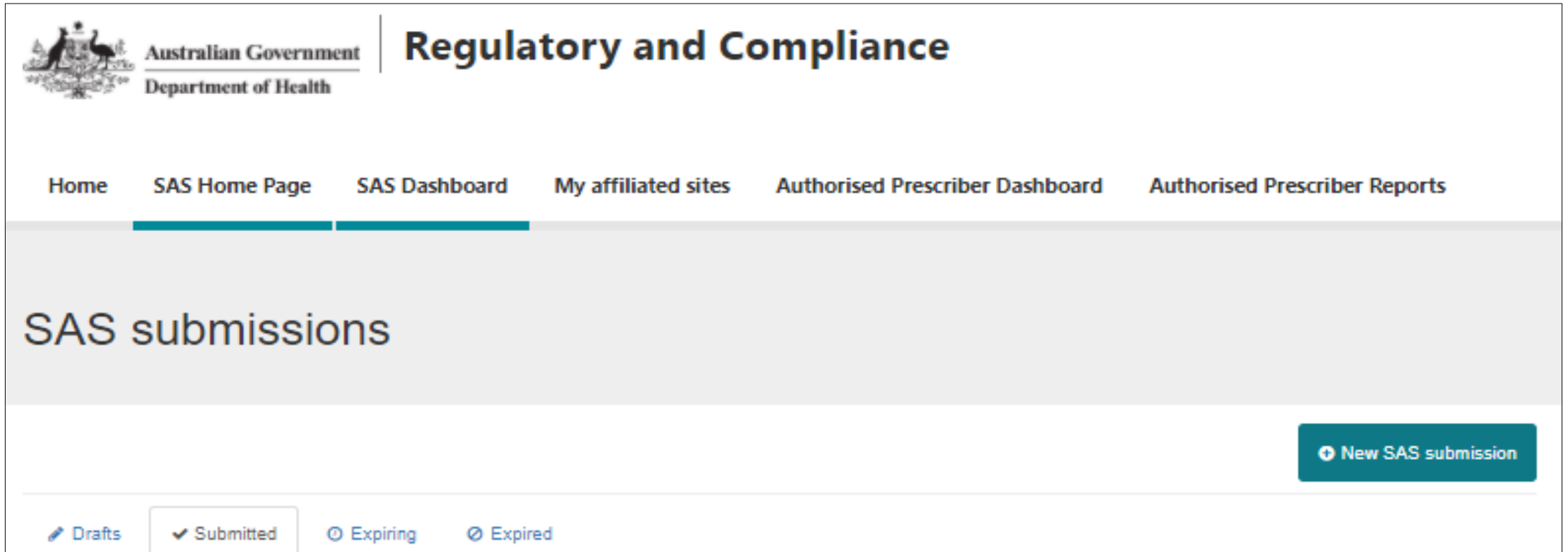
Are you the prescriber? \*

Yes

No

[Save and Next](#)

# Walkthrough SAS Dashboard Changes



The screenshot displays the 'Regulatory and Compliance' section of the Australian Government Department of Health website. The header includes the Australian Government logo and the text 'Regulatory and Compliance'. A navigation menu contains links for 'Home', 'SAS Home Page', 'SAS Dashboard', 'My affiliated sites', 'Authorised Prescriber Dashboard', and 'Authorised Prescriber Reports'. The 'SAS Dashboard' link is highlighted with a teal bar. Below the navigation, the main heading reads 'SAS submissions'. On the right side, there is a teal button labeled 'New SAS submission'. At the bottom, there are four filter tabs: 'Drafts', 'Submitted', 'Expiring', and 'Expired'. The 'Submitted' tab is currently selected and highlighted.



# NSW, ACT and VIC forms updated

- NSW, ACT and VIC forms have been updated to comply with legislative changes.
- QLD form has been removed. QLD approval is required only for those cases where the patient is considered drug dependent and you are seeking to treat them with a schedule 8 medicinal cannabis medicine. The request for Chief Executive approval can be found in the QLD health site.
- When you select the state, the form will be updated for the relevant state.

## New SAS submission

 **Prescriber details**  
 **Product selection**  
 **Product details**  
 **Patient details**  
 **Summary**

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

### Therapeutic Good Type \*

- Medicine
- Biological
- Medical Device

### Medicine

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

### Active ingredient(s) \*

ABCD Medicinal Cannabis 25mg/ml

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

### Dosage form \*

Oral Liquid

The dosage form I need could not be found through the search tool

### Indication \*

chronic pain

The indication I need could not be found through the search tool

### Do you need to notify or apply to a state or territory health department? \*

In answering 'yes' to this question, you will be asked to select which state or territory health department you would like to notify or apply to. Upon selection, you will be presented with additional data fields that are specific to the state or territory application or notification. You **do not** need to separately apply to or notify the state or territory health department once this information has been submitted via this system. If you are unsure, please contact the relevant state or territory health department to clarify before proceeding with this submission. Contact details for state and territory health departments may be found on our website. **Please note that the person submitting this must be the prescribing health practitioner.**

- Yes
- No, I have determined at the time of this submission that no State or Territory Health Department is required to be notified or applied to.

### Please indicate which state or territory health department should be notified or applied to \*

The ability to submit medicinal cannabis applications/notification to all state and territory health departments is not currently available via this online system. If your state or territory is not available, please leave this field blank and proceed with your SAS submission to the TGA. If you need to notify or apply to a state or territory, you will need to do this using the available paper forms located on their website.

### Do you need to notify or apply to a state or territory health department? \*

In answering 'yes' to this question, you will be asked to select which state or territory health department you would like to notify or apply to. Upon selection, you will be presented with additional data fields that are specific to the state or territory application or notification. You **do not** need to separately apply to or notify the state or territory health department once this information has been submitted via this system. If you are unsure, please contact the relevant state or territory health department to clarify before proceeding with this submission. Contact details for state and territory health departments may be found on our website. **Please note that the person submitting this must be the prescribing health practitioner.**

- Yes
- No, I have determined at the time of this submission that no State or Territory Health Department is required to be notified or applied to.

### Please indicate which state or territory health department should be notified or applied to \*

The ability to submit medicinal cannabis applications/notification to all state and territory health departments is not currently available via this online system. If your state or territory is not available, please leave this field blank and proceed with your SAS submission to the TGA. If you need to notify or apply to a state or territory, you will need to do this using the available paper forms located on their website.

# NSW form

- The form is updated to the NSW form with the relevant questions for NSW applications.

## New SAS submission



Prescriber details



Product selection



Product details



Patient details



Cannabis (NSW)



Summary

Application to NSW Health required \*

*Only complete this question if your patient belongs to any of the mentioned categories below. If neither response options apply, please reconsider your submission at the Product selection step or contact NSW Health for assistance.*

Is the patient drug dependant

- Yes  
 No

*A 'drug dependant person' means a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug within the meaning of the NSW Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug (Section 27 of the Poisons and Therapeutic Goods Act 1966).*

Is the patient aged under 16 years

- Yes  
 No

*For patients aged under 16 years, medical practitioners require an exemption under Section 175 (4A) of the Children and Young Persons (Care and Protection) Act 1998 before prescribing a S8 drug of addiction for more than 10 days in any period of 30 days, unless treatment is for cancer. The exemption is requested from the Secretary of Department of Communities and Justice by the Secretary of NSW Health.*

*Please note, as per NSW legislative requirements, NSW authority is not required to prescribe medicines included in Schedule 4 of the Poisons Standard.*

Additional patient details

First name \*

# NSW form (cont.)

## Additional patient details

First name \*

Last name \*

Alias first name(s)

Alias last name

Previous NSW Health authority number

Address line 1 \*

Address line 2

Suburb \*

State/territory \*

Postcode \*

## Additional prescriber details

Prescriber specialty \*

## Supporting Information

Do you have any recent specialist reports or additional information to support your application? \*

- Yes  
 No

## Privacy disclaimer

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The TGA is collecting personal information in this form in order to:

- Assess the application; and
- Contact the health practitioner and discuss the application where necessary.

For the purposes of assessing the application, information on patients and prescribers will be used by and disclosed between the TGA and NSW authorities with responsibility for therapeutic goods or medical practitioner conduct.







By submitting this form, I confirm that:

- The patient, or the patient's parent or guardian (if applicable), has given his or her consent that the patient's personal and health information will be collected and used for the purposes of this application and ensuring the lawful supply of the product in accordance with the Therapeutic Goods Act 1989;
- The patient, or the patient's parent or guardian (if applicable), has given his or her consent that the patient's personal and health information may be disclosed to NSW authorities with responsibilities for therapeutic goods and health practitioner conduct for the purposes of ensuring the lawful supply of the product in that State;
- I have notified the patient, or the patient's parent or guardian (if applicable), that their personal and health information may be disclosed by NSW to the Therapeutic Goods Administration; and
- I have and will comply with any applicable requirements of the Children and Young Persons (Care and Protection) Act 1998 and the Guardianship Act 1987(both of NSW).

Please note that the giving of false or misleading information is an offence under the Criminal Code Act 1995 and that penalties may be imposed.

# ACT form

- The form is updated to the ACT form with the relevant questions for ACT applications.

-  Prescriber details
-  Product selection
-  Product details
-  Patient details
-  Cannabis (ACT)
-  Summary

### Additional prescriber details

AHPRA specialty \*

### Additional patient details

Is the patient drug dependent \*

Yes  
 No

*Drug-dependent person, in relation to a controlled medicine or prohibited substance, means a person with a condition - (a) who, as a result of the administration of the medicine or substance, demonstrates, in relation to the person's use of the medicine or substance - (i) Impaired control; or (ii) Drug-seeking behaviour that suggests impaired control; and (b) who, as a result of the cessation of the administration of the medicine or substance, is likely to experience symptoms of mental or physical distress or disorder. ACT Medicines, Poisons and Therapeutic Goods Regulation 2008*

First name \*

Last name \*

Address line 1 \*

Address line 2

State/territory \*

Suburb \*

Postcode \*

### Prescriber declaration

By submitting this application,

- I understand that the issue of an approval does not indicate Chief Health Officer support or endorsement of a proposed treatment.
- My patient is aware that this product has not been registered by the Therapeutic Goods Administration and should be considered experimental.
- My patient is aware that driving after taking medicinal cannabis may result in a positive drug driving test.
- I declare I have discussed with the patient and they are aware that their personal information included in this form may be shared with relevant health practitioners and/or other State or Territory Government officials in order to protect public health and safety, including monitoring and evaluating the supply of the requested medicine(s) to themselves, and to ensure compliance with the Medicines, Poisons and Therapeutic Goods Act 2008. The patient has been informed further information about the extent and purpose for which their information may be used or disclosed may be obtained via the ACT Health website <https://health.act.gov.au/health-professionals/pharmaceutical-services/controlled-medicines/medical-cannabis>.



# VIC form

- The form is updated to the VIC form with the relevant questions for VIC applications.

The screenshot displays a web-based form for VIC applications. On the left, a vertical navigation menu includes: Prescriber details, Product selection, Product details, Patient details, Cannabis (VIC) (highlighted with a red box), and Summary. The main content area is titled 'Privacy disclaimer' and contains text regarding the collection and use of information under the Drugs, Poisons and Controlled Substances Act 1981 (Vic). Below this is a section for 'Additional patient details' with fields for Title, First name, Last name, Address line 1, Address line 2, Suburb, State/territory, and Postcode. To the right, a separate section titled 'Additional prescriber details' includes a 'Prescriber qualifications' text area, a 'Supporting information' section with a question about specialist reports, and a 'Declaration' section with a statement of truth. At the bottom right, there are 'Previous' and 'Save and Next' buttons.

# Where to go for support

- **Online guidance documents** have been updated for:
  - SAS Dashboard - <https://www.tga.gov.au/form/special-access-scheme>
  - AP Dashboard - <https://www.tga.gov.au/form/authorised-prescribers>
- **Weekly online training sessions** where we will demonstrate the changes and answer any questions you may have. These sessions will be held on the following days:

Date	Time	Topic
Wednesday, 17 March	11:00-11:30am	SAS Dashboard
	11:30-12:00pm	AP Dashboard
Wednesday, 24 March	10:00-10:30am	SAS Dashboard
	10:30-11:00am	AP Dashboard
Wednesday, 31 March	10:00-10:30am	SAS Dashboard
	10:30-11:00am	AP Dashboard

If you're interested in attending these sessions, send an email to [eps@health.gov.au](mailto:eps@health.gov.au)

# SAS Portal Outage

The SAS portal will not be available from

**12:00pm Saturday, 13 March** until **8:00pm**

**Sunday, 14 March.**





Petra is currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

**LIVE POLL**

QUESTIONS

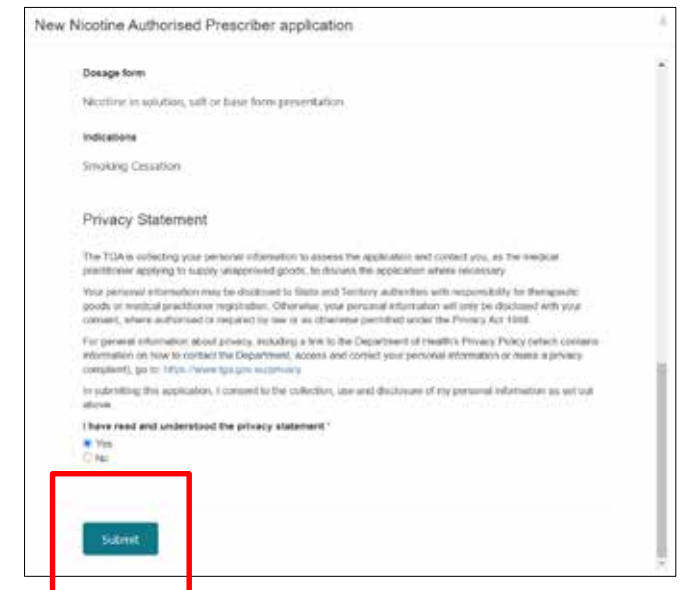
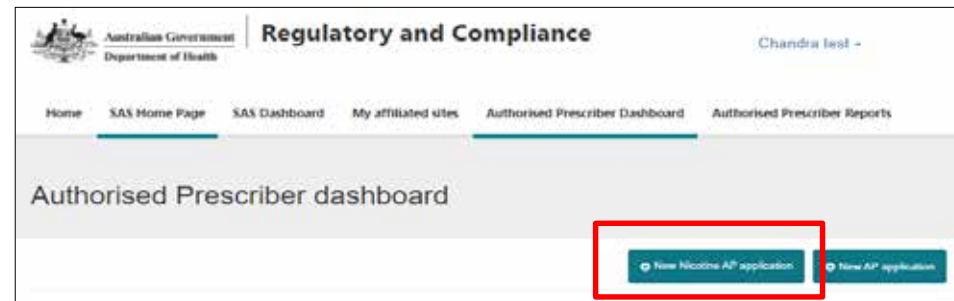


# Walkthrough AP dashboard changes

The screenshot displays the 'Regulatory and Compliance' dashboard. At the top left is the Australian Government logo and text: 'Australian Government Department of Health'. The main header is 'Regulatory and Compliance'. Below this is a navigation bar with tabs: 'Home', 'SAS Home Page', 'SAS Dashboard', 'My affiliated sites', 'Authorised Prescriber Dashboard', and 'Authorised Prescriber Reports'. The 'Authorised Prescriber Dashboard' tab is active. The main content area features the heading 'Authorised Prescriber dashboard'. At the bottom right, there are two teal buttons: 'New Nicotine AP application' and 'New AP application'.

# Applying for a new Nicotine AP application

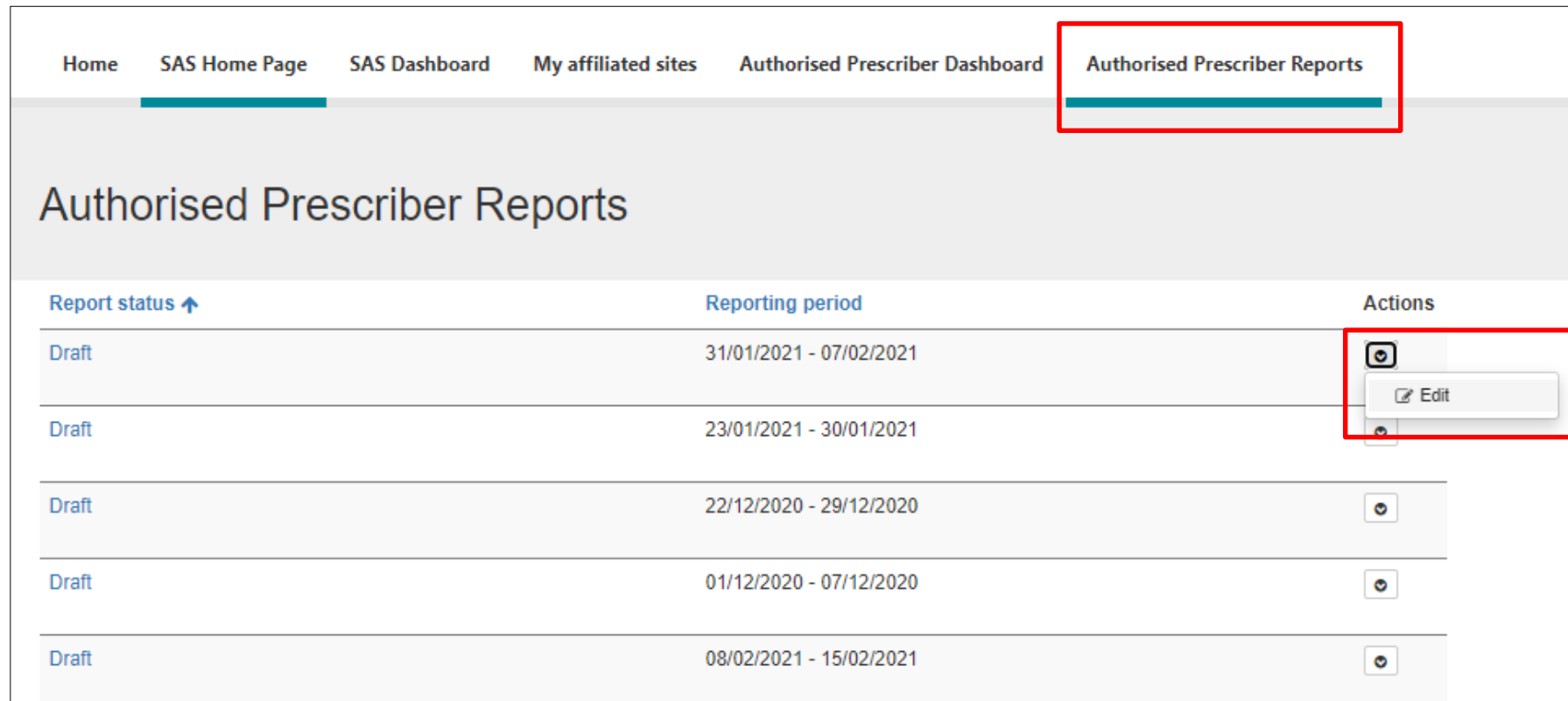
- The process for applying for Nicotine has been streamlined to a single button application on the AP dashboard.










The screenshot shows the 'New Nicotine Authorised Prescriber application' form. The form includes sections for 'Dosage form' (Nicotine in solution, salt or base form presentation), 'Indications' (Smoking Cessation), and a 'Privacy Statement'. The privacy statement text reads: 'The TGA is collecting your personal information to assess the application and contact you, as the medical practitioner applying to supply unapproved goods, in 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'. Below the privacy statement, there is a section 'I have read and understood the privacy statement' with radio buttons for 'Yes' (selected) and 'No'. A 'Submit' button is located at the bottom of the form and is highlighted with a red box.

# Six monthly patient data report

Submission of six monthly patient data reports can be done directly via the portal



Report status 	Reporting period	Actions
Draft	31/01/2021 - 07/02/2021	  Edit
Draft	23/01/2021 - 30/01/2021	
Draft	22/12/2020 - 29/12/2020	
Draft	01/12/2020 - 07/12/2020	
Draft	08/02/2021 - 15/02/2021	

Refer to the report for the current reporting period

# Six monthly patient data report


## Authorised Prescriber Report

**Prescriber Name**  
Jane Smit (MED0001198569)

**Reporting Period**  
31/01/2021 - 07/02/2021

**Outstanding Or Complete**  
Outstanding

**Report Status**  
Draft


Authorised Prescriber ↑	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices	Actions
MAP21-0000522	18F-DCFPyL (PSMA)	Injection			 Edit

**Privacy Statement Accepted**  
The TGA is collecting your personal information as part of your reporting obligations under regulation 47B(1)(b) of the Therapeutic Goods Regulations 1990. 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>.

Yes  
 No

Select 'Edit' against the product you want to enter the patient data

# Six monthly patient data report

 Edit

---

**Authorised Prescriber Application**  
MAP21-0000522

**Product Profile**  
18F-DCFPyL (PSMA)

**Product Presentation**  
Injection

**Number of New Patients**  
This number should include only patients initiated on this unapproved product under the AP scheme during this period

**Number of Prescription or Devices**  
For medicines, a prescription is considered as a single supply of an unapproved product. If repeats are provided, they should be considered as additional prescriptions for reporting purposes

Enter the number of new patients and prescription or devices



# Six monthly patient data report

## Privacy Statement Accepted

The TGA is collecting your personal information as part of your reporting obligations under regulation 47B(1)(b) of the Therapeutic Goods Regulations 1990. 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>.

- Yes
- No

Submit

Read and accept the privacy statement to submit your report.

# Where to go for support

- **Online guidance documents** have been updated for:
  - SAS Dashboard - <https://www.tga.gov.au/form/special-access-scheme>
  - AP Dashboard - <https://www.tga.gov.au/form/authorised-prescribers>
- **Weekly online training sessions** where we will demonstrate the changes and answer any questions you may have. These sessions will be held on the following days:

Date	Time	Topic
Wednesday, 17 March	11:00-11:30am	SAS Dashboard
	11:30-12:00pm	AP Dashboard
Wednesday, 24 March	10:00-10:30am	SAS Dashboard
	10:30-11:00am	AP Dashboard
Wednesday, 31 March	10:00-10:30am	SAS Dashboard
	10:30-11:00am	AP Dashboard

If you're interested in attending these sessions, send an email to [eps@health.gov.au](mailto:eps@health.gov.au)

QUESTIONS



# More information



TGA website [www.tga.gov.au](http://www.tga.gov.au)



TGA Facebook <https://www.facebook.com/TGAgovau/>



TGA Twitter <https://twitter.com/TGAgovau>



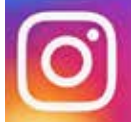
TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>





# Contact us

Experimental Products Section

[eps@health.gov.au](mailto:eps@health.gov.au)



**Australian Government**

---

**Department of Health**  
Therapeutic Goods Administration