

Transition to paperless (digital) access for unapproved therapeutic goods

The TGA has recently announced that Special Access Scheme (SAS) and Authorised Prescriber (AP) submissions will be transitioning to a paperless model, and all applications must be submitted through the SAS & AP Online System.

The transition to the online system is staged as follows:

- Phase 1
 From 1 April 2024 the TGA will no longer accept paper-based submissions under the SAS Cat B pathway or Authorised Prescriber scheme
- Phase 2 From 1 July 2024 – the TGA will no longer accept paper-based submissions under the SAS Cat A and C pathway

All submissions made via the SAS & AP Online System need to be made by the prescribing health practitioner.

Note: In some scenarios another health practitioner (e.g. pharmacists) can act on the behalf of the prescriber, and complete the submission. However, for some medications such as medicinal cannabis only the prescriber is permitted to submit an online application.

Benefits of SAS & AP Online System

- Streamlines the SAS applications and notifications process, and reduces TGA processing times
- Allows you to track the status of an application (in the case of SAS Cat B)
- Identifies applications and notifications that are expiring or have expired
- Ability to clone (copy) previously submitted SAS submissions, avoiding the need to re-enter the same information
- Reduces paper waste

Site Affiliation

Site Affiliation is a function which enables better oversight and management of submitted applications and notifications between users who are affiliated under a Site (e.g. pharmacy within a hospital). Users affiliated under a Site can share applications and notifications with other users affiliated under the same Site, and identify submissions and access any relevant documentation (e.g. approval letters).

Example scenario: A prescriber is set up to be affiliated to the Pharmacy Site at their hospital. The prescriber charts an order for an SAS Cat B medication and submits an application via the SAS Online System. Pharmacy receives the chart order for the SAS Cat B medication and checks the SAS Online System to see if an application has been submitted by the prescriber. Pharmacy sees that the application has been approved by the TGA and proceeds with ordering and dispensing the SAS medication without delay.

Recommendations:

- If not already registered, prescribers can register to the SAS & AP Online System as follows:
 - 1. Visit: https://compliance.health.gov.au/sas/
 - 2. Click: Register now
 - 3. Enter a username, unique email and password



You will promptly receive an email with a link asking you to "Activate your SAS online system account" which navigates you to your profile to complete your login including AHPRA number, name and address.

- Please ensure you have set up Site Affiliation with Epic Pharmacy Murdoch to maximise the functions of the Online System and to streamline the ordering and dispensing process of prescribed unapproved medications.

Further information can be found on the TGA website:

<u>Transition to paperless (digital) access for unapproved therapeutic goods.</u>
<u>SAS & AP Online System guidance</u>

Please contact Epic Pharmacy Murdoch if you require more information on the new TGA SAS & AP Online System and submissions process.