Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Transition to paperless (digital) access for unapproved therapeutic goods through the Special Access Scheme and Authorised Prescriber scheme

Communique

Version 1.0, February 2024

Contents

1. Purpose 4
2. Transition timeline 4
3. Background 4
3.1 Improvements to the system 5
3.2 Current SAS and AP scheme utilisation data 6
3.3 Guidance and resources 7
4. Why are we transitioning to a digital model? 8
4.1 Broader digital transformation 8
4.2 Quality assurance 8
4.3 Increasing compliance activities 8
5. Communicating and managing changes 8

1. Purpose

The Therapeutic Goods Administration (TGA) wishes to advise the transition to a paperless model for Special Access Scheme (SAS) and Authorised Prescriber (AP) submissions. From 1 July 2024 the TGA will only accept submissions via the SAS/AP Online System (the System).

The digitalisation of the SAS and AP framework has enabled simpler and more secure interactions between the TGA and healthcare practitioners to apply, notify and manage submissions under SAS and AP frameworks. Since the launch of the System in 2018, the TGA has recorded a substantial uptake of its use by healthcare practitioners. To date, over 26,000 users are registered to use the System.

The TGA intends to implement a staged approach to allow digital submissions only under the SAS and AP scheme from 1 July 2024. Paper and emailed submissions will not be accepted after the period.

2. Transition timeline

The timeline noted below aims to provide healthcare practitioners and organisations currently submitting paper-based notifications with sufficient time to register to use the System.

The TGA believes that a gradual transition allows all stakeholders the opportunity to plan and develop internal processes in response to the proposed changes.

Proposed transition timeline:

Phase 1

- The TGA will no longer accept paper-based submissions (i.e. faxed, emailed submissions) under the SAS Category B pathway or Authorised Prescriber scheme from **1 April 2024**.

Phase 2

- The TGA will no longer accept paper-based submissions (i.e. faxed, emailed submissions) under the SAS Category A and C pathway from **1 July 2024**.

3. Background

The SAS provides for the import and/or supply of a therapeutic good to an individual patient in circumstances where that good is not included in the Australian Register of Therapeutic Goods (ARTG). The AP scheme provides for the authorisation of a medical practitioner to supply specified therapeutic goods or a specified class of therapeutic goods (where that good is not included in the ARTG) to the class(es) of patients specified in the AP authority.

In March 2015, the Expert Panel conducting the Review of Medicines and Medical Devices Regulation (MMDR Review) made recommendations aimed at streamlining the TGA's processes and improving timely access by Australian consumers to medicines and medical devices.

The MMDR Review recommended improving the TGA processes for unapproved therapeutic goods by establishing an integrated, online system to manage notifications, approvals and reporting requirements.

On 15 September 2016, the Australian Government released its Response to the Review of Medicines and Medical Devices Regulation, committing to the development of an online system to streamline access to medicines and medical devices not currently in the ARTG, and enabling better monitoring of the use of these products.

In July 2018, the TGA launched an online system for SAS applications and notifications and AP applications to enable improvements to the pathways for access to unapproved therapeutic goods with the intent of moving all submissions online by 1 July 2019.

Stakeholder feedback at the time indicated that the TGA system was still in its infancy, haltering plans to move SAS and AP submissions solely online.

3.1 Improvements to the system

In 2021, the TGA committed to a phased enhancement approach to improve the reliability and the user experience of the system, investing over $1.65 million over five phases of work.

Between 2021 and 2024, the investment into the system has seen significant improvements, delivering more reliable infrastructure and better services for stakeholders and ultimately uplifting the performance, usability, and accessibility of the System for users.

The TGA also undertook a User Discovery Project in 2022 to better understand the current experience of stakeholders as well their needs, behaviours, ways of working and ecosystems. The findings of the project have supported significant design solutions and improvements and continues to inform future system enhancements planned for 2024.

The key system design solutions and improvements have included:

- **Improvements to the user registration process**

The user registration process has been enhanced to help address concerns raised by users, who identified the registration process as complex and difficult to follow. A more efficient system, with clear guidance and support has been developed to help users create and manage their account. These changes have been made in line with the Department of Health and Aged Care's ICT security policies ensuring secure and safe delivery of the service.

- **Streamlined navigation of the online application process**

The TGA regularly reviews the SAS and AP online submission process, ensuring that it is intuitive and accessible. Since 2021 the forms have been updated to address issues raised and recommendations made by users. Where possible the forms have been streamlined, removing requests for redundant information, providing clearer guidance information, and fixing pain-points and navigational problems.

- **Improvements to the internal application management system**

Multiple improvements have been made to the internal workflow to ensure internal efficiencies in processing and assessing SAS and AP submissions. These changes have enabled redistribution of the TGA workforce, increasing the focus on compliance activities and business improvement projects.

- **Streamlined therapeutic vape submission process.**

Medical practitioners can use the therapeutic vape 'quick form' to become Authorised Prescribers of the therapeutic good. The form contains pre-populated active ingredient, indication and dosage form information, allowing medical practitioners to submit the application form within minutes. Additional improvements were made to the system to support the reforms to the regulation of vapes.

- **Inclusion of an Authorised Prescriber six monthly patient data reporting functionality**

Authorised Prescribers can seamlessly manage and submit patient reporting data through a dedicated dashboard. This functionality eases the administrative burden of AP patient data reporting obligations. New online reports are automatically generated at the commencement of each reporting period for individual Authorised Prescribers to complete.

- **Ability for pharmacists to check the validity of SAS/AP notifications and application approvals issued by the TGA prior to dispensing an unapproved product to a patient.**

This functionality had been requested by a number of peak medical organisations, including the Royal Australian College of General Practitioners (RACGP). Pharmacists can now access the submission validation search to validate the application and notification status and details in real-time.

- **Unapproved therapeutic goods hub on TGA website**

Guidance and information on the TGA Website on how to access unapproved therapeutic goods is now more accessible to stakeholders. A clear navigational structure and intuitive pathways have been designed to ensure information is logically displayed and easy to find. Content has been updated, using language and labelling that is meaningful to the target audience. The look and feel of the pages have been modernised and duplicate and out-of-date content has been archived.

The TGA is committed to continuing to uplift the System's usability and accessibility. Further discovery work is currently underway to review the affiliated site functionality, with the intention of improving how information is shared amongst system users within an organisation.

Key deliverables for the enhancement work in the 2024 will support:

- Strengthening of the system security by automatically validating health practitioner registration status against the Australian Health practitioner Regulation Agency (AHPRA) data registry and safeguarding against fraudulent account creation.

- Analysis of how best to redesign the way health practitioners and organisations (i.e. hospital pharmacy departments) can manage and share applications and notifications within their organisation.

- The TGA will continue to review and seek feedback about the online system and unapproved therapeutic good pathways. Where possible, enhancements will be investigated to ensure the system is as efficient and user-friendly as possible.

3.2 Current SAS and AP scheme utilisation data

The number of healthcare practitioners utilising the SAS and AP scheme has increased exponentially in the past five years, with the increase in the use of medicinal cannabis and nicotine vaping products among Australian patients.

In 2019, there were 111,664 submissions made via the SAS to access unapproved therapeutic goods compared to 264,286 in 2023. This is a percentage increase of 137%. Similarly, in 2019 the TGA approved 1,201 applications under the AP scheme, compared to 16,471 in 2023. This is an increase of 1,271%. With the increase in the utilisation of the SAS and AP schemes, stakeholders have benefited significantly from the modernisation and digital optimisation of the framework. In 2023 the TGA received 236,587 submissions via the online system. This accounts for 84% of all submissions received in the calendar year.

However, the TGA continues to receive applications and notifications by fax, post and email. As shown in **Figure 1**, 44,170 submissions (16%) in 2023 were received via fax, post or email.

As depicted in **Figure 2**, data analysis of these submissions shows that 85% of these submissions were notifications under the SAS Category A and C pathways. The majority of these SAS Category A and C notifications are received from tertiary hospitals.

The TGA acknowledges that paper-based methods of submission of SAS Category A and C notifications are embedded into long standing hospital pharmacy practices.

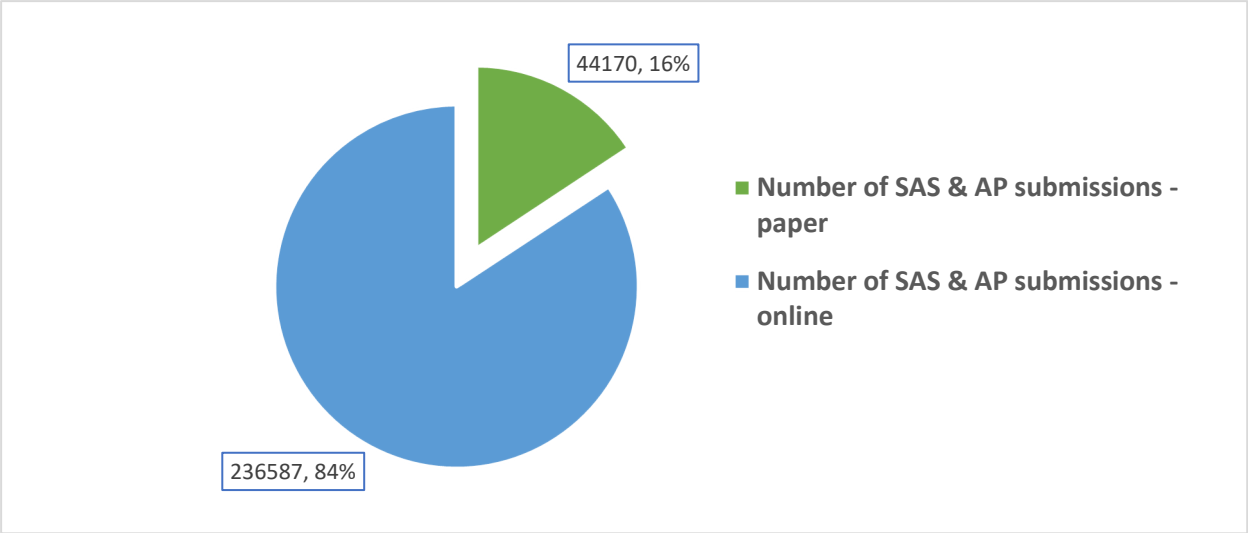

Figure 1: Analysis of submissions received via paper-based methods vs online (2023)

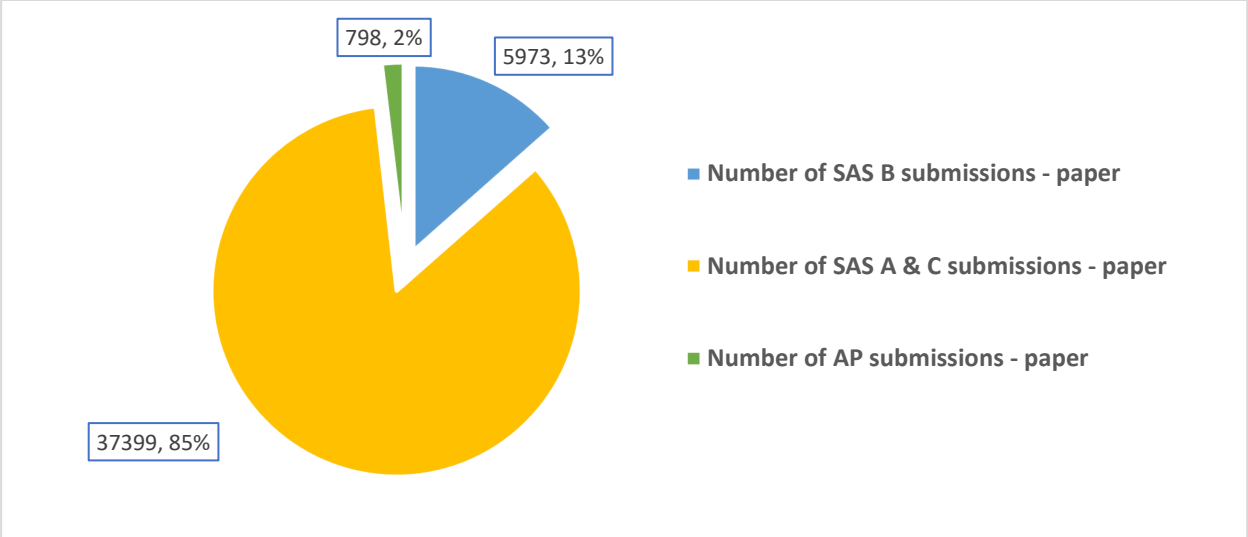

Figure 2: Breakdown of the source pathway of paper-based submissions (2023)

3.3 Guidance and resources

The TGA has developed extensive guidance on the TGA website to assist health practitioners in using the online system, as well as publishing clear and concise information about how unapproved therapeutic goods are accessed and supplied in Australia.

4. Why are we transitioning to a digital model?

4.1 Broader digital transformation

Since 2021, the TGA has embarked on a transformation designed to modernise its service delivery and improve the outcomes and experiences of stakeholders who interact with the TGA. As part of this process, several barriers and obstacles experienced by our stakeholders when interacting with the TGA have been identified, including outdated information systems, poor information and guidance. Improvements to the System is one key initiative of the TGA's broader digital transformation, delivering reduced regulatory burden and improved access to unapproved therapeutic goods for health professionals and consumers, ensuring better health and wellbeing for all Australians.

4.2 Quality assurance

The System is designed to provide greater versatility to healthcare practitioners who want the flexibility to make a submission request from any location. The System is designed to work across multiple platforms, including via computer, laptop, iPad, tablet, or smart phone.

The move to an online only model will ensure healthcare practitioners have access to a secure platform with built in quality assurance checks to minimise transcription errors and potential misuse of the system. The system also enables healthcare practitioners with real-time access to their applications and notifications and submission data.

4.3 Increasing compliance activities

Removal of the avenue for submission via email, fax and post will drastically reduce the burden on the TGA's administrative staff responsible for manual data entry tasks. This will allow the TGA to redistribute its workforce, increasing our focus on compliance activities. Due to the improvements to the system since 2021, this transition has already commenced as the number of paper submissions is reducing each year.

The TGA is continuing to develop a compliance framework for unapproved goods to provide:

- The capability within the TGA to work on future improvements to how unapproved goods are accessed in line with legislation, regulation and policies;
- An increase in education campaigns to support compliance;
- Capacity to identify and monitor potential compliance breaches; and
- A proactive approach, allowing the TGA to be at the forefront of identifying issues.

5. Communicating and managing changes

The TGA recognises that the changes to the submission process must be clearly communicated to the users of the schemes.

The TGA has already commenced targeted communication via email with certain high-volume users of the AP scheme and SAS Category B scheme to inform the proposed move to digital submissions.

The TGA will also be engaging with high volume users of the SAS Category A and C pathways who submit via fax, email or post. In particular, communication will include tertiary hospitals and individual healthcare providers to support them through the transition to a digital submission model.

If you require assistance in your transition to using the System, the TGA can coordinate a time that suits for a team member to contact you directly to discuss.

Please email BICS@health.gov.au for further information.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Business Improvement and Compliance Section, International Regulatory Branch	February 2024

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 #D23-2950777