Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS)

Guidance for health practitioners accessing unapproved therapeutic goods

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Contents

About this guidance

This guidance is to assist health practitioners understand their requirements when prescribing 'unapproved' therapeutic goods for an **individual patient** using the Special Access Scheme (SAS).

If you are a medical practitioner wanting to prescribe an 'unapproved' therapeutic good to multiple patients (a class of patients) on an ongoing basis you should consider becoming an Authorised Prescriber.

Health practitioners will be regarded as the product sponsor if they:

- import, or arrange to import, the product themselves directly from an overseas supplier, for supply to Australian consumers (e.g. order a product online rather than sourcing it from an Australian supplier)
- export or arrange to export the product from Australia (e.g. send it to a consumer overseas)
- extemporaneously compound or manufacture the product themselves.

If you are a **sponsor** or importer refer to Special Access Scheme – guidance for sponsors supplying 'unapproved' therapeutic goods through SAS.

This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation.

The therapeutic goods legislation details the legal requirements for supplying therapeutic goods, including 'unapproved' goods, in Australia.

The relevant Australian legislation for the SAS can be found in section 19 of the *Therapeutic Goods Act 1989* (the Act).

You should seek your own independent legal advice to ensure that all of the legislative requirements are met.

If you are a **patient**, please consult your health practitioner about the suitability of using an 'unapproved' therapeutic good and arranging access to an 'unapproved' therapeutic good on your behalf. Patients **cannot** apply to the TGA for access to 'unapproved' therapeutic goods through the SAS. Access can only be arranged through an Australian registered health practitioner.

For information about **medicinal cannabis products** refer to the Access to medicinal cannabis products web page.

For information relating to **therapeutic vapes** refer to the Vaping hub web page.

Overview of the SAS

Generally, therapeutic goods (medicines, biologicals and medical devices) must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully imported into, supplied in, or exported from Australia. Therapeutic goods that are not included in the ARTG are referred to as '**unapproved**' therapeutic goods.

Therapeutic goods include medicines, biologicals, and medical devices. Further information is available at What are 'therapeutic goods'?

The Therapeutic Goods Administration (TGA) encourages the use of therapeutic goods that are included in the ARTG. However, there are times when patients require therapeutic goods that are not included in the ARTG. The SAS allows Australian registered health practitioners to access an 'unapproved' therapeutic good for **an individual patient on a case-by-case basis**.

Other pathways to allow supply of 'unapproved' therapeutics goods can be found at Accessing 'unapproved' products.

Health practitioners are expected to have trialled or considered treatment options that are included in the ARTG and are available for supply in Australia prior to considering accessing an 'unapproved' therapeutic good for their patient. 'Unapproved' therapeutic goods have not been assessed for quality, safety, efficacy or performance by the TGA.

When the SAS can be used

The SAS can be used for individual patients when the prescriber reasonably believes that there are limited therapeutic options, having trialled or considered therapies included in the ARTG. This includes circumstances where:

- critically ill patients require urgent, early access to therapeutic goods not included in the ARTG including experimental and investigational therapeutic goods
- therapeutic goods are available overseas but not registered or supplied in Australia
- therapeutic goods have been initially provided to patients through a clinical trial, but the trial has ended
- there is a shortage of a registered medicine in Australia, or the product has been discontinued - the Medicine shortage reports database webpage provides information about shortages of reportable medicines in Australia, including those arising from the discontinuation of products.

When the SAS is not appropriate

The situations where SAS is not necessary or appropriate are described below.

Off label use

Therapeutic goods are included in the ARTG with specific indication(s) or intended purpose(s). 'Off-label use' generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in the ARTG entry.

Generally, a health professional does not require an exemption, approval or authorisation from the TGA in order to use a therapeutic good for off-label use. Off-label use is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent from their patient. The TGA is not responsible for regulating health professionals or clinical practice.

In exceptional circumstances, SAS may be required for off-label use of a **medicine or biological**. For example, in situations where the prescriber has directly contacted the sponsor to request the product for their patient through a compassionate supply arrangement. In these circumstances, the sponsor may request the relevant SAS notification or approval from the prescriber to ensure legal supply of the product under the therapeutic goods legislation. The SAS Category B pathway cannot be used to obtain supply of any medical device included in the ARTG, regardless of the proposed use of the device (including off-label use). The TGA does not have the authority to grant an SAS Category B approval for a **medical device** included in the ARTG.

Extemporaneous compounding

Generally, medicines that are extemporaneously compounded by a pharmacist for the treatment of a particular patient are exempt from the requirement to be included in the ARTG. The manufacture and supply of extemporaneously compounded products by a pharmacist, other than medicinal cannabis, **does not** require additional approval or exemption under the SAS.

Prior to extemporaneous compounding of therapeutic vapes, pharmacists must seek Section 41RC consent from the TGA. Obligations for sponsors would apply, in these circumstances, including, for example, mandatory reporting requirements.

Compounded vaping substances must comply with the product standards outlined in the Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO110) Order 2021. Further detailed information on the vaping goods standards is available in Guidance for TGO110 and related matters.

Different requirements apply to the extemporaneous compounding of medicinal cannabis products, and additional approval is required under SAS Category B or Authorised Prescriber pathways. Further information is available on the TGA website.

Schedule 9 and 10 products

Products containing substances included in Schedule 10 of Poisons Standard are prohibited for manufacture, possession, sale or use, and therefore SAS cannot be used to access products containing these substances.

Schedule 9 substances are prohibited for manufacture, possession, sale or use by law except when required for medical or scientific research, or for analytical, teaching or training purposes and approval should be sought by medical practitioners from State or Territory Health Authorities prior to submitting an application under the SAS.

Medicine shortages section 19A approvals

SAS should not be used when there is a current section 19A approval in place and stock is available for supply of an overseas medicine during a shortage.

Clinical trials

The TGA supports the use of clinical trials to collect information about the safety, efficacy (or performance) of therapeutic goods. The SAS should **not** be used by health practitioners for the purposes of conducting a clinical trial.

Health practitioners wanting to conduct a clinical trial (investigator-initiated trials) involving the use of an unapproved therapeutic good should consider the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) pathways, as appropriate.

Other research purposes, demonstration or sample items

Therapeutic goods for purposes such as quality control, examination, demonstration or display are exempt from the requirement to be included in the ARTG (provided they are not used for therapeutic use) and do not require additional approval or exemption under the SAS.

Further information about this exemption can be found in Item 1.3 of Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and Item 3 of Schedule 5 of the *Therapeutic Goods Regulations 1990*.

Who can be the prescribing health practitioner

Only appropriate Australian-registered health practitioners can prescribe therapeutic goods under the SAS. The type of health practitioner depends on which SAS pathway is used. Refer to Which pathway

to use for details. Generally, applications from health practitioners with non- practising, limited, student, provisional (requiring supervised practice) or conditions placed on their registration will not be considered.

There are generally no restrictions on the medical conditions a registered health practitioner may prescribe an 'unapproved' product for, provided the prescriber has:

- the appropriate knowledge of the condition being treated and the 'unapproved product' AND
- the intended use of the product is within their scope of practice.

However, in making an application under the Category B pathway, the prescribing health practitioner will need to supply sufficient clinical justification that supports the use of the product to treat the particular symptom or condition.

Definition of registered health practitioner

For the purposes of the SAS, an Australian *registered health practitioner* is a person who, under a law of a state or internal territory of Australia, is registered or licensed to practice in a health professions. The Australian Health Practitioner Regulation Agency (AHPRA) is responsible for regulating the registration of health practitioners in Australia.

Who can submit the SAS notification or application

An appropriate Australian registered health practitioner must complete and submit the SAS notification or application. Patients are **not able** to submit their own SAS applications or notifications.

Subject to Scheduling conditions, SAS forms can only be submitted by the prescribing health practitioner or another registered health practitioner acting on behalf of the prescriber.

Due to an agreement with States and Territory Health Departments, SAS submissions for **medicinal cannabis products,** should be made by the **prescribing health practitioner**.

Health practitioners acting on behalf of the prescriber

If you are a health practitioner submitting the SAS form on behalf of the prescriber, you must:

- have regard to the appropriate clinical order from the prescribing health practitioner (such as a prescription or medication chart entry)
- ensure you understand the clinical context in which the therapeutic good will be used
- include the **full name, contact email** and **AHPRA number** of the prescribing health practitioner **on the form**.

All related correspondence (such as requests for information, compliance education or decision letters) will be sent to both the prescribing health practitioner and the submitter.

Non-health practitioners, sponsors and patients are **not** able to draft or submit SAS forms.

However, non-health practitioner users can check the progress of **online** submissions made to the TGA in their user dashboards if they are made an 'affiliated' user.

Further information regarding the online SAS form can be found in the SAS Online System guidance.

Which pathway to use

There are three SAS pathways. The prescribing health practitioner is responsible for deciding which pathway is appropriate.

An interactive decision tool is available on our website to help health practitioners determine whether the SAS is appropriate and, if so, which pathway is the most suitable for accessing the unapproved product.

Which SAS pathway to use depends on the type of registered health practitioner, patient's status, and therapeutic good and its intended indication for use (see table 1 and 2 below).

Table 1 – Key features of each SAS pathway

Key features	SAS Category A	SAS Category B	SAS Category C
Type of registered health practitioner			
Medical practitioner	Yes	Yes	Yes
Other health practitioner (as defined in the therapeutic goods legislation)	No	Yes	Yes
Type of goods			
Specified list of goods available	No	No	Yes
Medicinal cannabis	Yes (Products must be imported individually via the Office of Drug Control (ODC))	Yes	No
Schedule 4 therapeutic vapes	No	Yes	Yes
Schedule 3 therapeutic vapes	No	No	Yes
Schedule 8 goods	Yes	Yes	No
Schedule 9 goods (only where state and territory legislation also permits use)	No	Yes (Only with evidence of state/territory agreement of use)	No
Schedule 10 goods	No	No	No

Key features	SAS Category A	SAS Category B	SAS Category C
Notification or application form	Notification (Within 28 days after prescribing)	Application (Before prescribing)	Notification [1] (Within 28 days after prescribing)
Decision letter	No	Yes	No

Table 2 – Access Pathways for Scheduled therapeutic vapes, subject to compliance with state and territory laws

Schedule	Health Practitioner Type	Patient age status	Pathway	Indication
Schedule 4 (vapes containing nicotine >20 mg/mL)	Medical Practitioner (MP) Nurse Practitioner	≥16 years	AP (MP only) SAS C	Smoking cessation or management of nicotine dependence
Schedule 4 (vapes containing nicotine >20 mg/mL)	Medical Practitioner Nurse Practitioner	<16 years	SAS B	
Schedule 3 (vapes containing nicotine 20 mg/mL or less)	Pharmacist[2]	≥18 years	SAS C	

SAS Category A – notification for a seriously ill patient

SAS Category A allows a prescribing **medical practitioner** to prescribe an 'unapproved' therapeutic good for an individual patient who is seriously ill (definition below). This is the **preferred pathway** for seriously ill patients.

This is a **notification pathway** – prior approval from the TGA is **not** required.

The prescribing medical practitioner or another health practitioner acting on their behalf (e.g. a pharmacist) must submit a completed Category A form to the TGA within 28 days of a medicine or biological being given to the person or within 28 days after the use of an exempt medical device. Failure to do so is an offence and carries a financial penalty.

Definition of a 'seriously ill patient'

For medicines and biologicals a Category A patient is defined as:

[1] To facilitate patient access while maintaining appropriate controls and protections, SAS C Schedule 3 therapeutic vape must be notified for each instance of supply.

[2] Subject to strict conditions, see - Pharmaceutical Society of Australia (psa.org.au) guidelines for pharmacists providing smoking cessation support.

- someone who is ‘seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment’.

For medical devices a Category A patient is defined as:

- someone ‘who is seriously ill with a condition that is reasonably likely to lead to the person’s death within less than a year or, without early treatment, to the person’s premature death’.

SAS Category B – application for all other patients or products

SAS Category B allows a registered health practitioner with relevant expertise to prescribe an ‘unapproved’ therapeutic good for:

- a patient that does not fit the Category A definition
- products that are not authorised for supply under the Category C pathway.

The treating health practitioner should have appropriate qualifications and/or expertise in the condition being treated and the proposed use of the product. Generally, Category B applications are made by medical practitioners or dentists but, depending on the product and state or territory requirements, another health practitioner may be more appropriate.

This is an **application pathway** - an approval letter **must be** obtained from the TGA before the product can be supplied to the patient.

The prescribing health practitioner or another health practitioner acting on their behalf (a pharmacist for example) must submit an application to the TGA. Category B applications must be approved by a TGA Delegate before the 'unapproved' product may be supplied to the patient.

Prescribing health practitioners who are not experienced in the use of the product or particular medical condition should include a supporting letter from an appropriate specialist supporting the use of the product for the patient’s condition.

Who can prescribe under SAS Category B

Health practitioners other than medical practitioners can potentially prescribe ‘unapproved’ therapeutic goods under the Category B pathway.

It is the responsibility of the treating health practitioner to determine that prescription and administration of the product is in accordance with their:

- scope of practice
- relevant professional standards
- state and territory legislation.

SAS Category C – notification for products with established history

Category C allows specified health practitioners to access ‘unapproved’ therapeutic goods from a list of products that have been deemed by the TGA to have an established history of use.

The lists of therapeutic goods, indications and type of health practitioners who are authorised to access the goods are referred to as ‘rules’ and are included in legislative instruments. There are

separate legislative instruments for medicines, medical devices and biologicals available at Special Access Scheme rules.

The Category C pathway cannot be used if the product, indication and/or type of health practitioners does not match those listed in the legislative instrument. The prescribing health practitioner is responsible for ensuring that the therapeutic goods are supplied to patients in accordance with the 'rules'.

This is a **notification pathway** – prior approval from the TGA is **not** required.

The prescribing health practitioner or another health practitioner acting on their behalf (such as a pharmacist) must submit a completed Category C form to the TGA within 28 days of the therapeutic good being supplied. Failure to do so is an offence and carries a financial penalty.

Under the new 'rules', from 1 October 2024, pharmacist may supply therapeutic vapes with a nicotine concentration of 20mg/mL or less for smoking cessation and the management of nicotine dependence (classified as Schedule 3 in the Poisons Standard) to patients 18 years or over **without a prescription** (subject to strict conditions and compliance with state and territory laws). Pharmacists are advised to submit a SAS C notification using the SAS/AP Online System for each supply under this 'rule'.

To supply a vape to a patient without a prescription, a pharmacist will need to be satisfied it is clinically appropriate and meet several other conditions.

Further guidance on professional obligation for pharmacist while providing services for smoking cessation or the management of nicotine dependence, see:

- Guidelines for pharmacists providing nicotine dependence support (psa.org.au)
- RACGP - Supporting smoking cessation: A guide for health professionals.

What products can be supplied

The choice of product is at the discretion of the prescribing practitioner or pharmacists in the case of Schedule 3 therapeutic vape supply.

Where possible, the product to be used should be manufactured in accordance with relevant principles of good manufacturing practice (GMP).

SAS Category A pathway

Any unapproved therapeutic good can potentially be supplied through SAS Category A, except for:

- products included in Schedule 9 and 10 of the Poisons Standard.
- Medicinal cannabis products supplied through SAS Category A must be imported by the medical practitioner on a patient-by-patient basis. Australian held stock can be accessed through Category B applications. Consequently, access is generally faster using the Category B pathway.

SAS Category B pathway

While any product may be applied for under the Category B pathway, there is no guarantee that the TGA will provide approval for the product. Under the Category B pathway, the applicant must provide clinical justification that supports the use of the particular product for the medical condition.

Schedule 10 substances are prohibited for manufacture, possession, sale or use, and therefore SAS cannot be used to access products containing these substances.

Schedule 9 substances are prohibited for manufacture, possession, sale or use by law except when required for medical or scientific research, or for analytical, teaching or training purposes and approval should be sought by medical practitioners from State or Territory Health Authorities prior to submitting an application under the Special Access Scheme.

SAS Category C pathway

The ‘unapproved’ therapeutic goods that can be accessed under SAS Category C are publicly available in the Special Access Scheme Category C Lists. There are separate lists for medicines, biologicals and medical devices. Sponsors of ‘unapproved’ therapeutic goods should regularly review the Special access scheme rules for changes.

Health practitioners may only source and supply Schedule 3 and Schedule 4 therapeutic vapes that are included on the TGA’s list of notified vapes . The sponsors have notified the TGA that these vapes comply with the relevant product requirements, including the requirements in TGO 110. The listed vapes may be lawfully imported, manufactured and supplied as unapproved therapeutic goods, subject to the regulatory requirements.

Refer to vapes: information for sponsors, importers and manufacturers for more information.

Sponsors **cannot** apply to the TGA to have goods included or removed from the Category C legislative instruments. The TGA regularly reviews the legislative instruments and makes changes to add or remove products as appropriate.

Before prescribing an ‘unapproved’ therapeutic good

Make sure you understand the requirements set out in this guidance before prescribing any ‘unapproved’ therapeutic good.

Prescribing health practitioners are best placed to determine the needs of their patients, including whether treatment with a particular ‘unapproved’ therapeutic good is required.

Consider ARTG treatments

Before prescribing an ‘unapproved’ therapeutic good, the prescribing health practitioner must ensure:

- relevant ‘approved’ therapeutic goods (those registered, listed or included in the ARTG) have been trialled or considered and found clinically unsuitable
- the specific ‘unapproved’ good is **not:**
  - substantially similar to any product included in the ARTG

    OR
  - if substantially similar, the approved therapeutic good is NOT currently available for supply in Australia

Consider risks of treatment

The prescribing health practitioner must also ensure they have considered the evidence to support the use of the 'unapproved' product and any potential risks for the individual patient before prescribing it.

‘Unapproved' therapeutic goods have undergone little or no evaluation by the TGA for quality, safety, efficacy or performance. The prescribing health practitioner takes responsibility for the use of an 'unapproved' therapeutic good and outcomes, including any associated adverse reactions.

The treating health practitioner has the right decline to prescribe an ‘unapproved’ therapeutic good if they believe there is insufficient clinical justification or evidence to support the use of the product, or both.

Check the unapproved good is available

The TGA administers the SAS but is not involved with the actual supply of unapproved goods. Before making an SAS submission, the health practitioner should check with the intended sponsor (or supplier) to ensure they are prepared to supply the product. Inability to source the product may require a change to the patient's treatment.

Determine the appropriate SAS pathway

The prescribing health practitioner is responsible for deciding which pathway is appropriate based on the type of registered health practitioner, patient's status and therapeutic good and its intended indication for use. Refer to Which pathway to use for details.

Adhere to good medical practice and other codes of conduct

Registered medical practitioners must operate in accordance with the principles outlined in the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia.

Other health practitioners should refer to their appropriate national health practitioner board for further information and guidance on the relevant codes of conduct and guidelines.

Obtain informed consent

The prescribing health practitioner is required to obtain informed consent from the patient or the patient's legal guardian prior to providing any treatment. Importantly, this is an accepted principle of good medical practice and of the codes of conduct for other health practitioners.

The patient or their guardian must be able to make an informed decision regarding treatment. Informed consent should be given freely, in writing (unless unable), and in line with good medical practice.

Informed consent, in relation to treatment or proposed treatment, means consent freely given by a person on the basis of information concerning the potential risks and benefits of the treatment that was sufficient information to allow the person to make an informed decision whether to consent to the treatment.

Informed consent should include an adequate knowledge of:

- the condition and its consequences
- treatment options
- the likelihood of recovery
- the long-term prognosis.

In relation to supplying 'unapproved' therapeutic goods, the TGA also expects that health practitioners will inform patients:

- that the therapeutic good is not currently in the ARTG and may not have been evaluated for quality, safety, efficacy or performance by the TGA

  - including the possible benefits of treatment and any known risks and side effects and that unknown risks and side effects are possible

- of any alternative approved treatments that are available in Australia.

Health practitioners need to ensure that consent is appropriately recorded in the patient's medical record. Informed consent documentation does not need to be sent to the TGA, it should be kept on the patient's file.

Standard informed consent forms may be created by prescribing health practitioners. The TGA **does not** provide a template for these forms.

Check state and territory requirements

SAS notification and approval do not override any state or territory requirements that need to be met before the product can be obtained, prescribed or administered lawfully. It is the responsibility of the prescribing health practitioner to ensure that the relevant state/territory requirements are met.

In addition to SAS notification/approval, a prescriber may also need to apply for approval or permission from the relevant state/territory health department to prescribe certain Scheduled medicines. Restrictions on supply and possession of Scheduled medicines are given legal effect through the relevant state and territory legislation. Therefore, you will need to contact the relevant state or territory drug & poisons regulation unit for any further information regarding the necessary approvals.

For unapproved medicinal cannabis products, the Special Access Scheme & Authorised Prescriber Online System allows prescribers in every state and territory to submit an application to the Commonwealth and the relevant state or territory health department (if required) simultaneously.

In addition, a valid **prescription or order** is necessary for a pharmacist to dispense medications included in Schedule 4 ('Prescription Only Medicine') and Schedule 8 ('Controlled Drug') of the Poisons Standard.

Each state and territory have tobacco/smoking product or e-cigarette control legislation that may apply to pharmacists seeking to dispense therapeutic vapes. Pharmacists must comply with the requirements in of their jurisdiction. Please contact your relevant state or territory health department for further information.

Submitting the SAS notification or application

There is no cost associated with submitting SAS notifications or applications to the TGA. The information needed and submission methods are outlined below.

SAS applications and notifications must be submitted via the SAS & AP Online System. Once registered, health practitioners can draft and submit SAS applications and notifications as well as download copies of completed notifications and approval letters.

For medicinal cannabis, the use of the online system qualifies applications for processing within **2 business days,** provided the form contains all information required to make a decision.

Read more about the SAS and AP Online System.

What to do if you have problems

- Password reset - email SAS.Support@health.gov.au

- For all other portal issues, email SAS.Support@health.gov.au with a screenshot of the issue, your full name, your username, AHPRA number, and email affiliated with your account.
- Application status - check in online system or contact medicincal.cannabis@health.gov.au for medicinal cannabis applications and sas@health.gov.au for all other applications.

Information needed for the notification or application

SAS Category A – notification for a seriously ill patient

The following details are required for a **valid** notification:

Patient

- **Three** patient identifiers (for example patient initials, gender, date of birth or medical record number).
- Patient diagnosis and indication/purpose (diagnosis is the medical condition and indication is reason for use). These may be the same. For example, diagnosis: Hepatitis C and indication: liver failure.

Product

For medicines and biologicals:

- trade name (if known)
- name of the sponsor/supplier
- active ingredient(s)
- strength
- dosage form/presentation
- route of administration
- dose and frequency
- expected duration and/or quantity[1] required for treatment

For medical devices:

- trade name
- product description (including any applicable model number/variant)
- name of supplier/sponsor/manufacturer
- number of units/quantity
- expected duration of treatment

[1] For substances captured by the *Customs (Prohibited Imports) Regulations 1956* the quantity must be provided

Prescriber and submitter

- Full name.
- AHPRA registration number (prescriber must be a medical practitioner and submitter must be a health practitioner).

- Contact details (email address is preferred).

To generate a Category A notification, you need to select 'yes' that the patient's condition meets the seriously ill definition in the **online form**.

The TGA may conduct compliance checks and request further information on the notification to ensure compliance with the scheme and that notifications are received within the correct timeframe (refer to Requests for Information).

SAS Category B - application for other patients

Category B applications are subject to a **regulatory review** by a Delegate of the Secretary of the Department of Health who is registered as a medical practitioner, dental practitioner or pharmacist. The review is **not** an evaluation of quality, safety, efficacy and performance of the 'unapproved' therapeutic good.

Decisions on Category B applications are made on a case-by-case basis in recognition of the individual circumstances and presentation of each patient. The major criteria for determining whether to grant approval to supply relate to the patient, the product and the prescriber.

Applications that give monetary reasons, convenience factors or using up excess stock as a means of supporting the application **will not** be considered.

The following information is required for a **valid** SAS B application.

Patient

- **Three** patient identifiers (for example patient initials, gender, date of birth or medical record number).
- Patient diagnosis and indication/purpose, including the seriousness of the patient's condition(s) (diagnosis is the medical condition and indication is reason for use). These may be the same. For example, diagnosis: Hepatitis C and indication: liver failure.

Clinical justification

- A **brief clinical justification** to support the use of the product for treatment of the particular patient, which should summarise:
  - **details of relevant past treatments and procedures trialled or considered**, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
  - **expected clinical benefits versus the potential risks** of the proposed treatment.

Repeat applications should include a brief summary of the outcome of the therapy (patient response) and whether any adverse effects were experienced.

For **product shortages**, the prescriber should clearly indicate that the registered product is unavailable at this time and that there are no other available treatment options included in the ARTG. For current medicine shortages, refer to our Medicines shortages hub.

For **compassionate supply** arrangements, the prescriber should clearly indicate that the sponsor has requested SAS approval for compassionate supply and brief details of the request (e.g. off-label indication, pediatric patient).

Where the product has been previously withdrawn from, or refused entry to, the Australian market because of safety concerns, we would expect that all conventional therapies have been trialled and failed, or resulted in unacceptable adverse events or defects.

Product

- For **medicines and biologicals** – include the trade name (if known), name of sponsor/supplier, active ingredient(s), strength, dosage form/presentation, route of administration, dose & frequency and expected duration and/or quantity[2] required for treatment.
- For **medical devices** – include the trade name, the product description (including any applicable model number/variant), name of supplier/manufacturer, number of units/quantity, intended date of use and expected duration of treatment.
- For **new or experimental products, new indications** that have not been accessed under the SAS previously – clinical evidence of efficacy (or device performance) and safety data may be necessary to support applications. This may include treatments undergoing clinical trials or use in new patient populations (such as paediatric patients). Attach a copy of the reference articles with the application.
  - This assists the TGA Delegate to identify the correct product and product presentation. In the case of a product still undergoing clinical trials, this information could instead be in the form of an instructional brochure for the investigational product.

Prescriber and submitter

- Full name
- AHPRA registration number (submitter and prescriber must be health practitioners)
- Contact details (Note that any correspondence and the decision letter will be sent to the email address provided on the form only)
- Attach a supporting letter from an appropriate specialist if necessary. For example, use of THC containing products in paediatric patients should be supported with a letter from a paediatrician or relevant specialist.

[2] For substances captured by the *Customs (Prohibited Imports) Regulations 1956* the quantity must be provided

SAS Category C – notification for established products

The following details are required for a **valid** notification:

Patient

- **Three** patient identifiers (such as patient initials, gender, date of birth or medical record number)
- Patient diagnosis and indication/purpose (diagnosis is the medical condition and indication is reason for use. These may be the same. E.g. *diagnosis: Hepatitis C and indication: liver failure*).

Product

- The product and indication must match an entry in the Special Access Scheme rules. Ensure you:
  - include the correct product type (medicine, medical device or biological); and
  - select the correct Category C indication and code number (online form).

Prescriber and submitter

- Full name
- AHPRA registration number (submitter must be a health practitioner and prescriber type must match that included in the Special Access Scheme rules)
- Contact details. (**email address** is preferred).

The TGA may conduct compliance checks and request further information on the notification to ensure compliance with the scheme and that notifications are received within the correct timeframe (see Requests for Information).

What to expect once the form is submitted

Timeframes for processing and Submission status

SAS Category A and C

For the notification pathways, the TGA does **not** send out a letter of approval.

Submission 'receipts' for SAS Category A or SAS Category C notifications can be downloaded via a user's dashboard.

This 'receipt' can be provided to sponsors/suppliers as proof that the product is prescribed for a Category A patient.

SAS Category B

The timeframe between receipt of an application by the TGA until provision of a response to the applicant, is typically 2 to 3 working days. This timeframe may be extended for products not previously requested under the SAS or where further information is required from the applicant.

The status of a Category B application can be checked using the online system.

Medicinal cannabis

When submitting a medicinal cannabis application, prescribers can simultaneously apply for TGA approval and where applicable a state or territory health department approval via the online system. These applications are reviewed within 2 business days of submission, provided there is no further information required.

How the TGA Delegate makes a SAS Category B decision

The TGA aims to facilitate access to therapeutic goods. The TGA Delegate may request further information from the applicant if required. The applicant should provide the requested information; if the applicant cannot provide the information requested, they should contact the TGA or, potentially, withdraw the application.

Category B applications must be approved by a Delegate of the Secretary of the Department of Health who is registered as a medical practitioner, dental practitioner or pharmacist. The decision made by a Delegate must consider the legislative requirements under section 19(1)(a) to 19(4) of the *Therapeutic Goods Act 1989* such as:

- Applications must be made in an approved form. The application should be accompanied by information relating to the 'goods' as required by the delegate and as specified on the relevant application form (see TGA application process above).
- Approvals may only be granted to a health practitioner as defined in the legislation and are subject to the conditions specified in the approval.

- The Delegate, after having considered the application, must notify the applicant of the decision on the application within 28 days of making the decision (or of a decision not to grant approval and the reasons for this decision).

Decisions regarding Special Access Scheme (SAS) Category B applications are made on a case-by-case basis. The major criteria for determining whether to approve an application relate to the needs of the patient, the status of the product and the expertise of the prescriber.

The TGA delegate considers whether the applicant has supplied enough information about the patient, product and prescriber to demonstrate that they have considered the 'unapproved' therapeutic good is the most suitable treatment for the particular patient.

There are no powers under the therapeutic goods legislation to allow the retrospective approval of products already supplied. Therefore, the TGA is unable to consider a SAS Category B application if the supply of the therapeutic good has already occurred.

Appealing SAS Category B decisions

Decisions made under the SAS Category B application pathway are reviewable initial decisions under section 60 of the *Therapeutic Goods Act 1989* (The Act). Under section 60, a person whose interests are affected by a reviewable initial decision can seek to have the initial decision reconsidered. A request for reconsideration of the initial decision must be made to the Minister within 90 days after the notice is given to the person.

Conditions of approval under SAS Category B

Approval will be subject to standard conditions. Further conditions or warnings may be imposed at the Delegate's discretion.

The standard conditions are:

- the 'unapproved' therapeutic good is only used in the manner described in the application
- the approval holder accepts responsibility for the outcome of the use of the 'unapproved' therapeutic good
- reporting of adverse events and defects that may arise during the course of supply of the 'unapproved' therapeutic good to the TGA
- the 'unapproved' therapeutic good is used within the context of fully informed consent.

How long notifications and approvals are valid

SAS Category A

The notification is valid indefinitely provided the patient continues to meet the Category A definition. However, if the health practitioner specifies an expected duration of treatment, a new notification form will need to be submitted if treatment is to continue after this duration.

SAS Category B

The approval is valid for the duration specified on the approval letter provided the conditions of approval are upheld.

SAS Category C

The notification is valid indefinitely, unless the substance is captured by the *Customs (Prohibited Imports) Regulations 1956.*

For medicines containing substances captured by the *Customs (Prohibited Imports) Regulations 1956*, a new Category C notification form will need to be submitted every time the goods are supplied to the patient to meet requirements of any import licence/permission.

To ensure monthly supply requirements under the new rules for Schedule 3 therapeutic vapes, pharmacists are required to notify on each instances of dispensing therapeutic vapes.

Refer to Pharmaceutical Society of Australia (PSA) guidance for further information.

A Category C notification would no longer be valid if the 'unapproved' therapeutic good is removed from the lists of Category C products.

Obtaining unapproved therapeutic goods

The SAS is reliant on the sponsor being able to supply the product in Australia and this is likely to depend on its stage of development and other considerations (such as cold-chain storage requirements, availability of logistics companies, and commercial decisions of pharmaceutical companies.

It is the responsibility of the prescriber, in conjunction with the dispensing pharmacy, to source the product. Inability to source the product may require a change to the patient's treatment.

Products from Australian sponsors

If the product is available from an Australian sponsor, the prescribing health practitioner or someone acting on their behalf (e.g. pharmacist) should contact the sponsor to organise supply. Within an institution such as hospital, supply may be arranged through the pharmacy department.

Ideally, arrangements should be made for delivery to a doctor or pharmacy to allow for labelling and any additional instructions.

A prescription is also required for dispensing Schedule 4 and Schedule 8 medicines.

Products imported from overseas

If the product is not available from an Australian sponsor, the product may need to be imported from an overseas source. This can be arranged by the doctor, pharmacist, hospital, patient or appropriate wholesaler/importer.

If you are unable to source a supplier, we recommend that you contact a hospital pharmacy, wholesaler or sponsor experienced with the importation of 'unapproved' therapeutic goods for further assistance. Note that the importer takes on the responsibilities of a sponsor.

For medicinal cannabis in particular, if both state/territory and TGA requirements are satisfied, then a pharmacy or hospital, can dispense the product. The medicinal cannabis products may already be available in Australia. The Office of Drug Control website provides a list of companies who have been licenced to import or manufacture medicinal cannabis in Australia. However, inclusion on this list does not guarantee stock availability. This is not an exclusive list of all licenced manufacturers/importers. Only manufacturers who have provided consent to publish information are included in this list. If the product is not available in Australia, refer to the Office of Drug Control (ODC) for further information on the requirements for importing a product from overseas.

The importer will also need to check if other relevant Commonwealth and state or territory import permissions and approvals are required **in addition** to the SAS notification or approval. These are further detailed in the Guidance for sponsors.

Sponsor requirements

In order to lawfully supply a good under the SAS, the sponsor of the good must be satisfied that the good is in fact to be used under the SAS. Sponsors responsibilities are detailed in the Guidance for sponsors.

A sponsor may request evidence confirming the use of the good will be under one of the SAS pathways. Sponsors may request a copy of the SAS Category A or C notification online system 'receipt', or SAS Category B approval letter, prior to supplying the goods.

Cost to patients

The Commonwealth does not subsidise the cost of 'unapproved' therapeutic goods through the Pharmaceutical Benefits Scheme (PBS). For more information on the PBS, visit Pharmaceutical Benefits Scheme or phone 1800 020 613.

The price charged for a therapeutic good that is not on the PBS (full cost or private) is determined by the supplier. In some circumstances and at their own discretion, a sponsor may provide a therapeutic good to a patient on a compassionate basis (referred to as compassionate supply) at reduced or no cost.

Health practitioners should contact the sponsor of the particular therapeutic good to determine whether the product can be supplied at reduced or no cost.

Reporting and record keeping

There are reporting and record keeping requirements that apply to all SAS pathways.

Report adverse events and defects

The TGA collects adverse event reports to monitor the safety of medicines and build a detailed profile of the safety of medicines supplied in Australia. The prescribing health practitioner is responsible for reporting adverse events or defects arising from the use of 'unapproved' therapeutic goods accessed under all three SAS pathways (Category A, B and C) to the TGA.

The Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia and the codes of conduct for other health practitioners also require the reporting of adverse events to the relevant authority, as necessary.

Details of any adverse events or defects associated with the use of the 'unapproved' therapeutic good must be reported to the TGA **within 15 calendar days after becoming aware of them**.

Sponsors of unapproved products may also impose reporting requirements on health practitioners. Refer to the Guidance for sponsors for information on adverse event reporting for sponsors.

Defects are issues that are suspected or confirmed to have arisen during manufacture, storage or handling that may have an impact on public health. For medical devices these may also involve defective components, performance failures, poor construction or design.

Adverse event reporting timelines

Health practitioner reporting timelines are outlined below.

Table 2. Adverse event reporting timelines

Report type	Who to report to	Reporting timeframe
All adverse events and defects associated with the used of the 'unapproved' therapeutic good	TGA and sponsor Report to TGA via the reporting a problem webpage	**≤ 15 calendar days** after the prescriber being made aware of the adverse event or defect

Record keeping and retention of documents

There are no specific requirements imposed by the TGA in relation to the retention of and period of retention for SAS documents. Medical record keeping requirements may be imposed by other legislation such as the Privacy Act and state and territory authorities. Archiving of patient documentation including SAS forms, patient consent forms and approval letters, are no different from other medical records. You should discuss record keeping requirements with the appropriate area in your hospital as well as the relevant state or territory health department.

TGA requests for patient information

To clarify the product's intended use or obtain information concerning patient diagnosis, the TGA may request certain information from the prescribing health practitioner referred to in a SAS submission including the:

- condition of the patient
- supply of the goods
- handling of the goods
- monitoring of the supply of the goods
- results of the supply of the goods.

Penalties can be applied under the therapeutic goods legislation if a health practitioner fails to comply with such a request.

Requests for information are made on a case-by-case basis. Depending on the nature of the information provided, we may assess compliance in relation to the use of the unapproved therapeutic good accessed through a particular pathway. We can also enforce compliance in a number of ways, from giving informal warnings through to applying penalties where there has been serious intentional noncompliance.

Privacy of information held by the TGA

The TGA obtains personal information (such as names and contact details) as part of the SAS notification and application process. Personal information is protected by law under the *Privacy Act 1988*, which contains the Australian Privacy Principles.

The TGA is part of the Australian Government Department of Health and is committed to protecting your privacy and personal information. The Department of Health's Privacy Policy contains information about how we comply with the *Privacy Act 1988*.

For further details about how the TGA uses personal information refer to Privacy.

TGA release of information to other agencies

Under the therapeutic goods legislation, the TGA is authorised to release information to state or territory bodies with functions relating to therapeutic goods or agencies responsible for the health practitioner registration (such as AHPRA). This allows states and territories to have information to take action on matters under their jurisdiction, such as medical or pharmacy practice.

How a doctor treats an individual in a particular clinical setting is a matter of medical practice. Medical practice is not governed by TGA but we do to an extent oversee the supply of the unapproved therapeutic good to ensure that the appropriate mechanism is used in the circumstances. For example, if we believe a medical practitioner is using the Category A provisions inappropriately, and the medical practitioner continues to do so, we may provide relevant information to the Medical Board of Australia.

Freedom of information

The TGA releases an Annual Performance Statistics Report that includes general data on access to 'unapproved' therapeutic goods. The Medicinal Cannabis Access Data Dashboard displays de-identified data on the number of unapproved medicinal cannabis products accessed through the SAS.

The *Freedom of Information Act 1982* (FOI Act) provides members of the public with the legal right of access to documents held by the Commonwealth Government and its agencies where that information is not publicly available. The FOI Act also requires that consultation occurs between the TGA and the owner of the information prior to release of that documentation.

Further information and application forms to make an FOI request are available on our Freedom of Information webpage or by emailing tga.foi@health.gov.au.

Making a complaint

A person or organisation may report a perceived breach or questionable practice involving the **use of an 'unapproved' therapeutic good** through the TGA website. The TGA does not regulate health professionals or clinical practice.

- Complaints regarding an individual health practitioner are matters for the AHPRA. Further information is available on the AHPRA website: www.ahpragov.au
- General complaints about healthcare services can also be directed to the Health Care Complaints Commission (or equivalent) in each state/territory.
- Consumer complaints about the cost of products or services can be directed to the Australian Competition and Consumer Commission.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	International Regulatory Branch and Regulatory Guidance team	January 2023
V2.0	Minor updates relating to the SAS & AP online system	Business Improvement and Compliance Section, International Regulatory Branch	March 2024
V3.0	Updates in relation to changes to regulation of vapes.	Special Access Section, International Regulatory Branch	October 2024

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Reference/Publication #