Australian Government
Department of Health
Therapeutic Goods Administration

Special Access Scheme

Guidance for health practitioners and sponsors

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TGA Health Safety Regulation

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This guidance is for health practitioners and sponsors involved in providing patients with access to unapproved therapeutic goods (goods which are not entered in the Australian Register of Therapeutic Goods (ARTG)) through the Special Access Scheme (SAS). It outlines the various access pathways and the regulatory obligations when accessing and supplying unapproved therapeutic goods.

Individual patients cannot apply for access to unapproved therapeutic goods through the SAS. If you are a patient, please consult your health practitioner about the suitability of using an unapproved therapeutic good and the process involved in applying for access to an unapproved therapeutic good on your behalf.

Special Access Scheme

Therapeutic goods are required to be evaluated for quality, safety and efficacy and included in the ARTG before they can be supplied in Australia.

Where patients need access to therapeutic goods that are not on the ARTG, the TGA administers the SAS and other programs that provide access to therapeutic goods that are not included in the ARTG.

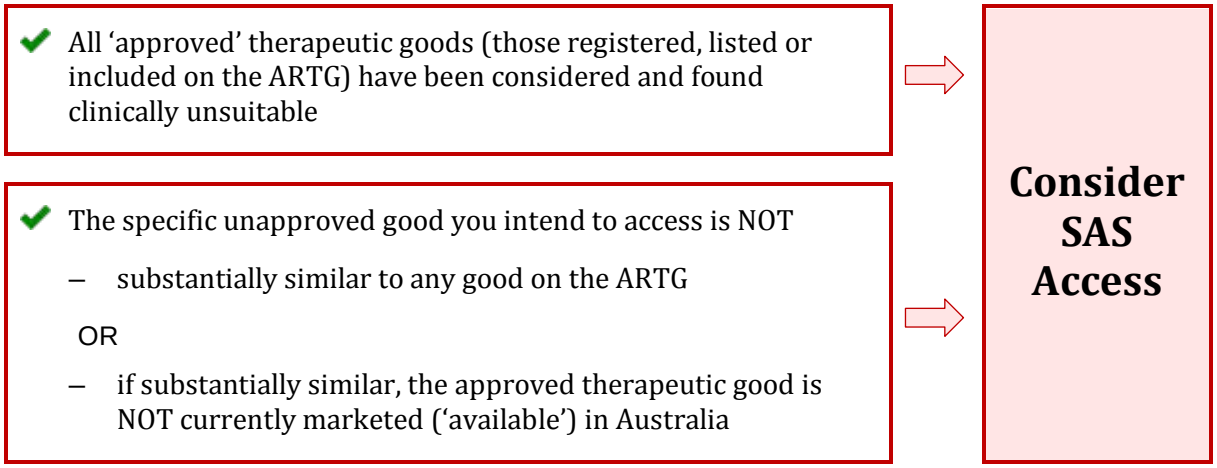
The SAS provides for the import and supply of an unapproved therapeutic good to a single patient on a case-by-case basis.

It is expected that the prescribing health practitioner will have considered all appropriate treatment options that are included on the ARTG and available in Australia, prior to considering accessing an unapproved good under the SAS for their patient(s).

The pathways available to access unapproved therapeutic goods through 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 CTN or CTX pathways, as appropriate.

The regulatory controls placed on clinical trials conducted through the CTN and CTX pathways provide sufficient assurance that high quality, credible data that contribute to the answering of specific scientific questions is collected, while also protecting the rights, safety and well-being of clinical trial participants.

The following infographic describes prerequisites that the treating health practitioner must consider PRIOR to attempting to access any unapproved good via the SAS:



SAS pathways

Under the SAS, health practitioner can access unapproved therapeutic goods through a number of pathways:

- Category A is a **notification pathway** which can be accessed by health practitioners on behalf of a prescribing medical practitioner for patients who are 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.
- Category B is an **application pathway** which can be accessed by health practitioners for patients that do not fit the Category A definition and where the unapproved good is not

deemed to have an established history of use and cannot therefore be accessed through SAS Category C. An approval letter from the TGA is required before the good may be accessed.

- Category C is a **notification pathway** which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products for their respective indications. There is a separate list for medicines, medical devices and biologicals, as follows:
  - **Medicines**: Therapeutic Goods (Authorised Supply of Specified Medicines) Rules September 2017
  - **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017
  - **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017

Overview of the SAS pathways

The table below indicates the key features of each SAS pathway.

Category type Application/notification	Category A notification	Category B application	Category C notification
Patient type			
Available for patients seriously ill with a condition from which death is reasonably likely to occur within a couple of months or from which premature death is likely to occur in the absence of treatment.	ü (preferred)	ü	ü
Available for all otherpatients	×	ü	ü
Who can apply			
Medical practitioners can apply	ü	ü	ü
Other health practitioners can apply	×	ü	ü (as per lists above)
Other health practitioners can submit	ü	ü	ü
Type of goods			
Specified list of goods available	×	×	ü
Can be used to access Schedule 8 goods	ü	ü	×
Can be used to access Schedule 9 goods	×	ü	×
Can be used to access Schedule 10 goods	ü	ü	×

Category type Application/notification	Category A notification	Category B application	Category C notification
Timing of approval			
Requires TGA approval prior to supply	×	ü	×
Requires notification or approval letter to be sent to sponsor to authorise supply	ü	ü	×
Requires notification to be sent to TGA within 28 days of supply	ü	×	ü

Therapeutic goods accessible through the SAS

Any unapproved therapeutic good can potentially be supplied via the appropriate SAS pathway.

The SAS allows individual patients access to unapproved therapeutic goods in circumstances including where:

- critically ill patients require urgent, early access to therapeutic goods including experimental and investigational therapeutic goods
- therapeutic goods have been withdrawn from the Australian market for commercial or other reasons
- therapeutic goods are initially provided to patients through a clinical trial while a marketing application is being considered
- therapeutic goods are available overseas but not marketed in Australia

An unapproved good is a good which is not registered, listed or included in the Register.

Costs associated with the SAS

There is no cost associated with applications or notifications to TGA to access or supply unapproved therapeutic goods through the SAS.

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.

In some circumstances and at their own discretion, a sponsor may provide therapeutic good to a patient on a compassionate basis (referred to as compassionate supply) at reduced or no cost.

The TGA will not consider applications which cite monetary reasons as justification for supply of the unapproved good. The applicant must provide a clinical justification for the use of the good, including why any product on the ARTG and available in Australia is not appropriate for their patient.

In certain circumstances, patients may utilise the Personal Importation Scheme to import therapeutic goods from overseas.

Information for health practitioners

TGA is currently developing an integrated online system that will allow treating health practitioners or those acting on their behalf, such as pharmacists, to submit SAS notifications and applications and AP applications online.

The online system is scheduled for release mid-2018.

Please join our subscriber list for updates.

Supplying an unapproved therapeutic good

Health practitioners who are considering treating a patient with an unapproved therapeutic good need to acknowledge that it has not been evaluated for quality, safety or efficacy and it has not been approved by the TGA. The TGA cannot guarantee the quality, safety or efficacy of an unapproved product.

The prescribing health practitioner is best placed to determine the needs of the patient, including whether or not treatment with a particular unapproved good is required. Health practitioners are expected to be up to date with all relevant and available information about the unapproved good before choosing to prescribe it for their patient. The treating health practitioner has the right decline to prescribe an unapproved product if they believe there is either insufficient clinical justification or no evidence to support the use of the product, or both.

If another health practitioner is submitting a SAS form on behalf of the prescribing health practitioner, they must have regard to the appropriate clinical order (such as a prescription or medication chart entry) from the prescribing health practitioner and that they understand the clinical context in which the good will be used.

The submitting health practitioner should also note, in the case of SAS Category B, correspondence regarding the application will also be sent to the prescribing health practitioner.

Responsibilities of prescribing practitioners

Prescribing practitioners are responsible for:

- determining if the patient they are treating is a Category A patient;
- determining the most appropriate pathway for accessing the unapproved therapeutic good and meeting any rules or conditions of the selected pathway applicable to that health practitioner;
- ensuring the patient has given informed consent prior to treatment (see Obtaining informed consent);
- adhering to relevant standards of good medical practice (see Good medical practice);
- monitoring the use of the unapproved goods in treating the patient and reporting any adverse events or defects to the TGA and to the sponsor of the good (see Reporting adverse events and defects) and

- ensuring compliance with relevant state or territory legislation governing the supply of therapeutic goods within the particular state or territory (SAS approval or notification does not override state or territory law).

A health practitioner other than the prescribing health practitioner who submits the SAS forms on behalf of the prescribing practitioner must ensure that they have a valid order (such as a prescription or medication chart entry) for the unapproved good and that they understand the clinical context in which the good will be used.

In allowing another appropriate health practitioner to submit these forms on behalf of the prescribing health practitioner, the TGA recognises that there are other controls imposed in jurisdictional legislation around the prescribing, dispensing, storage, possession and supply of scheduled substances which provide additional assurance to the treating health practitioner that the supply of the physical good to the patient will occur in an appropriate and legal manner. To provide further assurance, in the case of SAS Category B application, the TGA also sends all related correspondence (such as requests for information or decision letters) to both the submitter and the prescribing health practitioner. This process provides a further opportunity for the prescribing health practitioner to verify that the request for supply of the unapproved good is appropriate.

Good medical practice

Health practitioners are expected to adhere to the relevant standards of 'good medical practice' in the treatment of their patients.

Good medical practice generally refers to a series of standards that relevant healthcare practitioners should adhere to when treating patients. These standards are generally patient-centred (where the term 'patient' also includes appropriate parties who are acting on behalf of the patient) and set out what standards of ethical and professional conduct are expected by the health practitioner's professional peers and the community.

For examples, registered medical practitioners must operate in accordance with the principles outlined in the document published by the Medical Board of Australia titled Good Medical Practice: A Code of Conduct for Doctors in Australia.

Other health practitioners should refer to their appropriate health practitioner governing body for further information and guidance.

Obtaining informed consent

The prescribing health practitioner is required to obtain informed consent from the patient or the patient's legal guardian. 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

Patients should be specifically informed:

- that the therapeutic good is not approved in Australia
- of the possible benefits of treatment and any known risks and side effects
- that unknown risks and late side effects are possible
- of any alternative treatments using approved products which are available

Further information can be found in National Health and Medical Research Council (NHMRC) does provide General Guidelines for Medical Practitioners on Providing Information to Patients.

TGA has provided a sample consent form on the website for 'products derived from biological tissues including human blood or plasma' however this form is guidance only and does not need to be sent to the TGA. If the form is utilised, it should be kept on the patient's file.

Health practitioners need to ensure that consent is appropriately recorded in the patient's medical record.

Reporting adverse events and defects

The TGA prioritises reports of issues that may:

- have adverse health consequences for consumers as a result of public access to dangerous or inappropriate goods; or
- affect confidence in our regulatory processes or contribute to a loss of confidence in therapeutic goods in Australia.

The TGA takes a risk-based approach to complaints consistent with how we regulate therapeutic goods. We take action based on the likely risk associated with adverse events and defects. We value all information we receive about potential adverse events and defects and regularly adjust our prioritisation strategies in response to new information or trends.

The prescribing health practitioner is primarily responsible for reporting adverse events or defects arising from the use of unapproved therapeutic goods accessed under the SAS. The prescribing health practitioner must report the details of any adverse events or defects to TGA and the sponsor within 15 calendar days of becoming aware of them. These reporting requirements apply equally to products accessed under all of the SAS pathways.

There are multiple ways in which adverse events and defects can be reported to the TGA (see Reporting mechanisms).

Sponsors of unapproved products may also impose reporting requirements upon treating health practitioners.

Defects, in relation to therapeutic goods, are taken to be 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.

Accessing unapproved products

Arrangements for access to unapproved products vary according to the:

- type of health practitioner prescribing the good (i.e. a medical or other health practitioner) e.g. The SAS Category A pathway is only available to a medical practitioner or a health practitioner acting on behalf of a medical practitioner while the SAS Category B and C pathways may also be available to other health practitioners
- patient's status (e.g. whether the patient meets the Category A definition)
- type of therapeutic good and its intended indication for use (i.e. a Category B or Category C)

For the purposes of the SAS pathways, a *health practitioner* includes any of the following persons who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

- medical practitioner
- ATSI health practitioner
- dentist
- radiographer
- nurse
- midwife
- occupational therapist
- optometrist
- pharmacist
- podiatrist
- psychologist

TGA has developed an interactive decision tool to help health practitioners determine whether the SAS is appropriate and, if so, which pathway is the most suitable for accessing the unapproved product. You can access this interactive decision tool on our website.

If you are a medical practitioner, and you wish to supply a particular unapproved good to multiple patients (a class of patients) on an ongoing basis, you should consider becoming an Authorised prescriber rather than using the SAS (which is for individual patients).

For more information on access to medicinal cannabis products please refer to Access to Medicinal Cannabis: steps to using access schemes.

Category A

Health practitioners other than the prescribing medical practitioner are able to complete and submit a Category A form on behalf of the prescribing medical practitioner to gain access to unapproved therapeutic goods through the Category A pathway.

Category A patients

For medicines and biologicals:

- a Category A patient is defined as 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'.

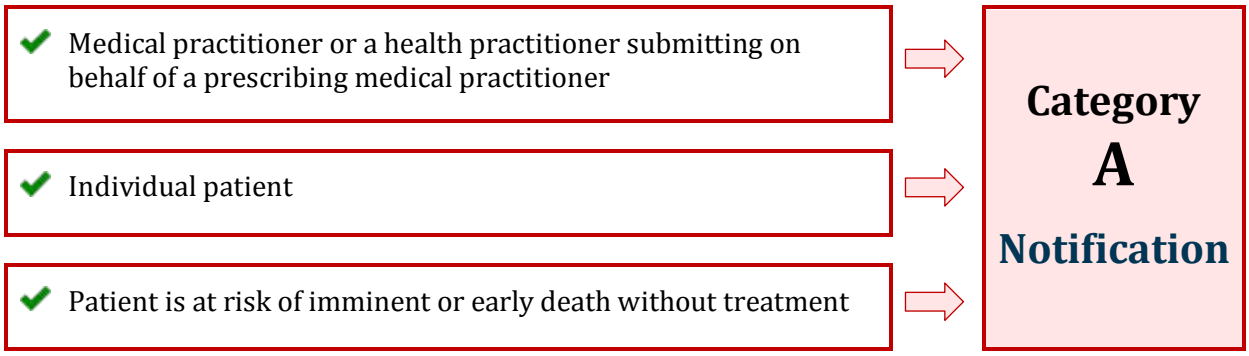
For medical devices:

- 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'.

It is up to the individual prescribing medical practitioner to assess their patient and determine whether they fit the criteria for notification under Category A. TGA may request further information on the notification to ensure compliance with the scheme (see Requests for Information).

Health practitioners treating Category A patients can potentially access any unapproved therapeutic good with the exception of products containing substances listed in Schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP or Poisons Standard)

Figure 1: When can Category A pathway be used?



Notification process

Medical practitioners or a health practitioner submitting on behalf of a prescribing medical practitioner need to complete and submit the SAS Category A form available on our website to the supplier in order to arrange supply of an unapproved good for a Category A patient. The completed form provides the sponsor with the legal authority to supply the product.

In completing the SAS Category A form the submitting health practitioner must ensure that they:

- have determined the patient is a Category A patient;
- have obtained the informed consent of the patient or their guardian to the use of the product; and
- will prescribe the product in accordance with good medical practice.

As a Category A patient's medical status is serious, prior approval is not required before the unapproved products can be accessed.

A copy of the completed Category A form must be sent to us – for medicines and biologicals: within 28 days of the medicine or biological being given to the person; for medical devices: within 28 days after the use of the exempt device. Failure to do so is an offence and carries a financial penalty.

A copy should also be kept with the patient's medical record.

Download the SAS Category A notification form from the TGA website.

Category B

The Category B application pathway allows an appropriate health practitioner to apply to treat a patient with an unapproved therapeutic good and where it is not available through the Category C pathway and does not meet the Category A criteria.

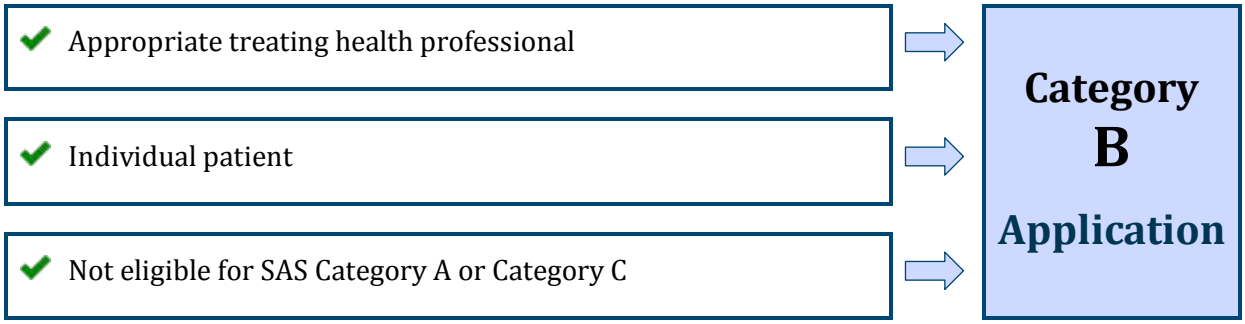
Generally, goods that are not eligible for supply via the SAS Category C pathway, are deemed to be of higher risk and require evaluation by a TGA delegate prior to their supply and use. Decisions are made on a patient-by-patient basis in line with their various needs. The major criteria for determining whether to approve supply of the good relate to the patient, the product and the prescriber.

In considering whether to grant approval, the delegate will generally consider the quality of the information provided in relation to each of the criteria. Practitioners should address each of the criteria and supply the information requested. Applicants can also provide any other information they consider important.

The delegate will consider each of the criteria and will not approve supply of the good unless all are met.

Download the SAS Category B application form from the TGA website.

Figure 2: Category B requirements



Criteria one – the patient

The application should contain adequate clinical justification for the product's use, including an outline of the seriousness of the condition being treated.

The practitioner needs to supply general information about the individual patient (e.g. initials, date of birth and gender) and clinical information about the patient's diagnosis and, more specifically, the indication(s) the product will be used to treat or manage.

The clinical justification should include:

- an outline of the seriousness of the patient's condition;
- details of any relevant past treatment, including procedures if applicable;
- a justification for the use of the unapproved product over the approved treatments, if applicable; and
- an appraisal of the expected clinical benefits versus the potential risks of use.

The justification needs to balance the availability of approved therapies against the seriousness of the patient's condition and include an appraisal as well as safety and efficacy data.

The applicant may attach additional information in support of their application. This could range from evidence from published randomised controlled trials to evidence from published non-randomised trials and case reports, to consensus opinion. The level of evidence required will depend on the seriousness of the condition (see How TGA makes a decision).

Criteria two – the product

The application should indicate how the product is to be used and include an appraisal of the quality, efficacy and safety of the product's proposed use. TGA recommends that, where possible, the product to be used is manufactured in accordance with appropriate good manufacturing practice (GMP).

Details of the product's use should include:

- for medicines and biologicals- the trade name (if known), name of sponsor/supplier, active ingredient(s), strength, dosage form, route of administration, dose & frequency and duration and/or quantity[1] required for treatment. and
- for medical devices- the trade name, the product description (including any applicable variant information), name of supplier/manufacturer, number of units, intended date of use and proposed duration of treatment.

The applicant should also provide details of how they will determine both the outcome of the treatment and the occurrence and severity of any adverse event. This could include clinical, biochemical, haematological and/or immunological monitoring. Appropriate references could range from evidence from published randomised controlled trials through evidence from published non-randomised trials and case reports, to consensus opinion. The level of evidence required will depend on the seriousness of the condition (see How TGA makes a decision under SAS Category B).

Monitoring should occur throughout treatment and, in some cases, it may be appropriate to continue monitoring for some time after.

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

Criteria three – the health practitioner (prescriber)

The application to access an unapproved therapeutic good via the Category B pathway can be made by a prescribing health practitioner with appropriate qualifications and/or expertise in the condition being treated and the proposed use of the product. Applications can also be made be another health practitioner on behalf of theprescribing health practitioner, provided that they have regard to the appropriate clinical order (such as a prescription or medication chart entry) from the treating health practitioner and that they understand the clinical context in which the good will be used.

Where a general practitioner or other prescribing health practitioner who is not experienced in the use of the good or in the particular medical condition chooses to apply, they may consider including a supporting letter or similar documentation from an appropriate specialist supporting the use of the product for the patient's condition.

Generally applications are made by medical practitioners but, depending on the product, another health practitioner may be more appropriate (e.g. a dentist, for a dental product) or may apply on behalf of the treating medical practitioner.

See Prescribing an unapproved therapeutic good for more information about the role and responsibilities of the prescribing health practitioner.

How TGA makes a decision under SAS Category B

The following scenario is a guide only. It does not cover all possibilities but provides a general indication of how the complex issues impacting a decision may be balanced.

There is a hierarchy of evidence of efficacy or performance and safety relating to:

- the product;
- the patient (seriousness of the patient's condition); and
- the health practitioner applicant's qualifications or expertise.

How these hierarchies interact will affect the decision made.

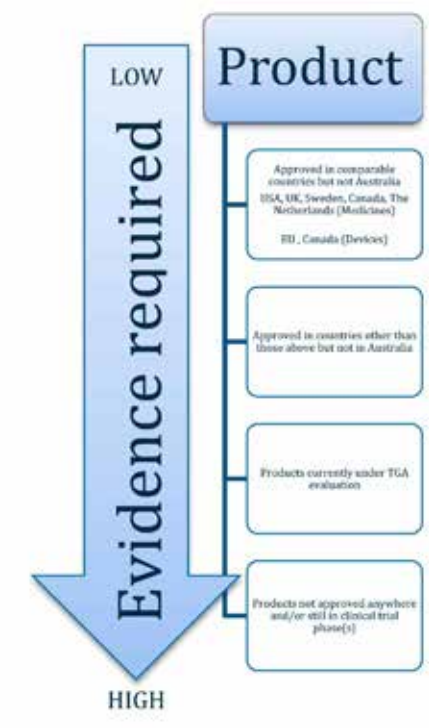
The Product

Unapproved products can be further classified according to the level of evidence that is available of their safety and efficacy (Figure 3).

Evidence can range from:

- published randomised controlled trials (highest level of evidence);
- published non-randomised trials;
- individual case reports; or
- consensus opinion of specialist colleges and societies (lowest level of evidence).

Figure 3: Evidence required according to the unapproved product



The Patient's Clinical Need

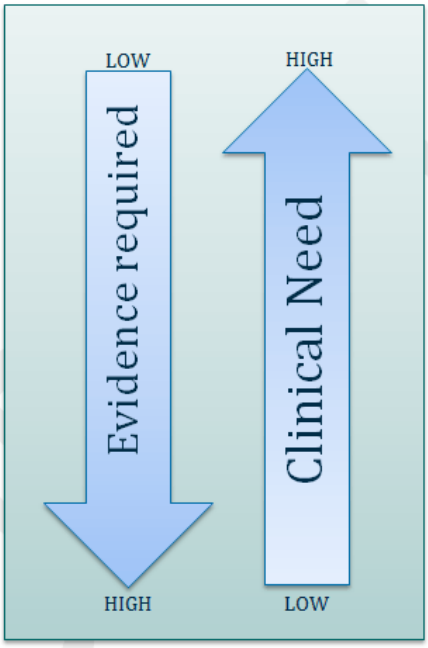
The efficacy and safety data submitted in support of the product's use should be weighed against the seriousness of the patient's condition. The clinical justification should always address the risk-benefit balance of using the proposed therapy.

As a general approach, the less serious the clinical need, the higher the degree of evidence expected to support the use of the product (Figure 4). For example, a product that has been approved in a country with a regulatory system comparable to Australia's is more likely to be considered for supply under the SAS for a condition for which it has been approved in those countries. However, if the only evidence of safety and efficacy available is that from published case reports, it is unlikely that use of the product would be considered for anything other than the most serious conditions. In these situations the prescriber needs to demonstrate, as part of the clinical justification, that other conventional therapies are unlikely to control the condition.

The extent to which the clinical justification should address the use of available approved therapies will depend on the seriousness of the patient's condition and how much is known about the product. Generally, the less serious the clinical need, the greater the need to demonstrate that other available therapies are clinically inappropriate.

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 tried and failed, or were accompanied by unacceptable adverse events or defects

Figure 4: Evidence required according to patient's clinical need



Repeat applications

If a health practitioner submits a SAS application for the same product, patient and indication(s)—that is, a repeat application—they are expected to provide with that application the results of previous monitoring, including measures of patient response and safety parameters.

The TGA delegate's responsibilities

The TGA delegate:

- has a responsibility to encourage, at all times, the use of approved, fully evaluated products. To do otherwise would remove the incentive for a sponsor to seek registration of the unapproved product or for other sponsors to seek registration of alternative products for treatment of the indication
- is responsible for undertaking a limited search for information, but processing times will be reduced if the applicant supplies all relevant information about the patient and the product to be used in their initial application
- may be aware of information the applicant is not aware of (e.g. the status of a product overseas, or whether it is being evaluated by TGA, through general or internal TGA knowledge or previous applications). If TGA has evaluated another product and approved it for treatment of an indication, a higher level of evidence is required to support an application to use an unapproved product for that indication instead of the new product, particularly if the product contains the same active ingredient or active ingredients in the same therapeutic class.

Approval of an application to supply a medical device that is a variation on a previous model or that duplicates the intended performance of an approved medical device requires a very high level of evidence. The associated clinical justification should discuss why the approved product cannot be used to treat the patient and should be based on medical reasons rather than on cost or convenience.

If a health practitioner has an interest in the continued long-term supply of a particular product, they should strongly encourage the sponsor to apply to register the product in Australia.

Appealing decisions

The TGA aims to facilitate access to therapeutic goods, and a decision to reject the application is not generally the delegate's first option. The TGA delegate may request further information from the applicant. 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.

Where the application is insufficient and no additional information is provided, the delegate may reject the application. They will provide reasons for their rejection.

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

Approval, if granted, will almost always be subject to certain conditions placed on the applicant and, in some cases, the sponsor.

The types of conditions imposed involve:

- Reporting of adverse events and defects that may arise during the course of supply of the unapproved therapeutic good to the TGA.
- The use of the unapproved therapeutic good within the context of fully informed consent.

These are legislative requirements that applicants must take into account when supplying the unapproved good. If an applicant cannot or is not willing to meet any of the conditions, they may wish to reconsider using the unapproved product to treat their patient.

Category C

The government accepted the *Expert Review of Medicines and Medical Devices Regulation* recommendation to enable faster patient access to unapproved therapeutic goods that are deemed to have an established history of use by not requiring that these goods be approved by the TGA before they can be accessed.

An unapproved therapeutic good is deemed to have an established history of use if:

- The TGA determines the goods have an established history of use within Australia or overseas for a given indication or intended purpose; and
- there have been no significant safety concerns associated with the good over a 3-year period.

The Category C is a notification pathway allows certain unapproved therapeutic goods that are deemed to have an established history of use to be supplied to an individual patient or class of patients without TGA approval.

Under this pathway, health practitioners may be authorised to supply certain unapproved therapeutic goods for a particular indication. The therapeutic goods, indications and health practitioners who are authorised to supply these goods for the particular indication are referred to as "rules" and will be included in a legislative instrument. There will be a separate legislative instrument for medicines, medical devices and biologicals.

The inclusion of a product in the following legislative instruments acts as the authorisation for these products to be supplied:

- **Medicines**: Therapeutic Goods (Authorised Supply of Specified Medicines) Rules September 2017
- **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017
- **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017

The authorised health practitioner must have obtained the informed consent of the patient or their guardian to the use of the product, agree to prescribe the product in accordance with good medical practice and report adverse events and product defects to the TGA.

Goods listed in the legislative instrument for medicines, medical devices and biologicals may, from time to time, appear to be similar to goods which are currently listed, registered or included on the ARTG.

The goods on the instrument that can be supplied via the SAS Category C pathway must vary in a material way from goods on the ARTG[2] and be used in a patient (or classes of patients) only in circumstances where the use of any alternative goods on the ARTG would not be clinically appropriate.

It is important to note that goods which are included in the instruments are not to be used in preference to ARTG goods where these are available and their use would be appropriate for a particular patient (or class of patients).

Notification process

Theprescribing health practitioner or someone acting on their behalf (e.g. pharmacist) needs to complete and submit the SAS Category C form available on our website **after the unapproved therapeutic good has been supplied** through the SAS Category C pathway. The form does not need to be completed before the good is supplied or to effect the supply of the product.

Prior approval is not required before unapproved therapeutic goods used in accordance with the "rules" of the legislative instruments can be accessed. However, a copy of the completed Category C form must be sent to the TGA within 28 days of the therapeutic goods being supplied. Failure to do so is an offence and carries a financial penalty.

A copy of the completed form should also be kept with the patient's medical record.

It is the notifying prescriber's responsibility to ensure they meet the legislative and regulatory requirements associated with the SAS Category C pathway.

[2] except in cases where an ARTG good is not currently being supplied in Australia where a similar product may be included on the relevant instrument.

Supplying unapproved therapeutic goods in a manner that is not in accordance with the "rules" of the legislative instruments such as using a product on the instrument for an indication different to that on the instrument may constitute an offence and attract penalties.

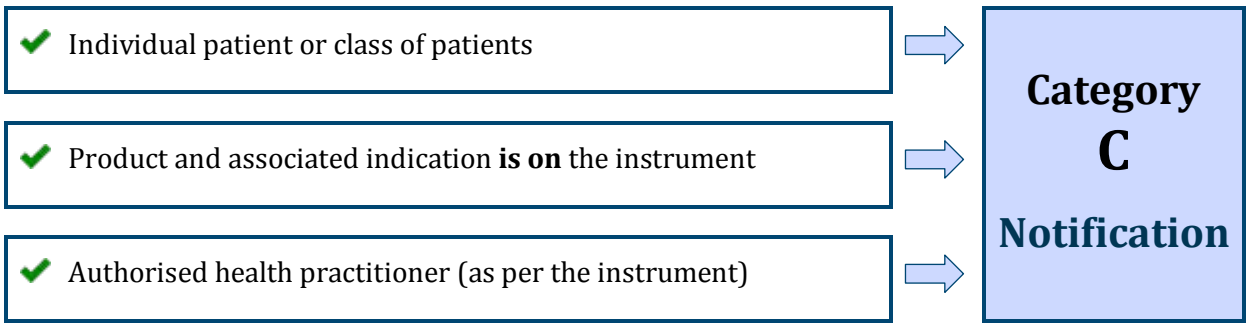
Download the SAS Category C form from the TGA website.

Review of the 'rules' by TGA

The TGA will periodically review the unapproved therapeutic goods accessed through the various SAS pathways to determine if additional goods or indications to existing goods need to be added to the instruments. We will also remove certain therapeutic goods or indications associated with particular goods from the relevant instrument where necessary, for example if these become registered in Australia or no longer meet the above criteria (i.e. if a safety concern arises).

Sponsors and health practitioners cannot apply to TGA to have goods included or removed from the legislative instruments.

Figure 5: When can the Category C pathway be used?



Using the Category C form

- The form is completed by an appropriate health practitioner (the submitter) and submitted to TGA. The submission may be done on behalf of the treating health practitioner (e.g. a pharmacist may submit the form on behalf of a medical practitioner) or the treating health practitioner may complete and submit the form themselves (thus also acting as the submitter). In either case, only a single signature - from the person submitting the form (the submitter) - is required.
- To reduce administrative burden while also enhancing compliance, the paper form requests a code to be used in place of describing the good and the conditions of supply. The codes, which match the entries on the legislative instruments, are located on the back of the form.

  An **example** is given below:

Code	Active ingredient(s), Dosage Form, Release mechanism, Route of administration	Indication	Authorised health practitioner
M4	*Melatonin, modified release tablet, oral*	*Treatment of sleep disorders*	*Medical Practitioner*

- If the unapproved good, indication, and health practitioner do not all match an entry for a code on the back of the form, this pathway cannot be used. You may potentially still be able to access this good for the particular indication through one or more of the existing unapproved therapeutic goods schemes, including: SAS Category A, SAS Category B (application) or the Authorised Prescriber Scheme.

Requests for information

To clarify the product's intended use or obtain information concerning patient diagnosis, the TGA has powers under the Act to request certain information from the prescribing health practitioner referred to in a Category A notification, Category B application or Category C notification including:

- the condition of the patient (Category A only)
- the supply of the goods
- the handling of the goods
- the monitoring of the supply of the goods
- the 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.

Release of information

Under the therapeutic goods legislation, the TGA is authorised to release information to state or territory bodies with functions relating to therapeutic goods or which are responsible for the health practitioner registration (e.g. the Australian Health Practitioner Regulation Agency, or AHPRA).

How a doctor prescribes a treatment for 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 information concerning such use to the Medical Board of Australia.

Obtaining unapproved goods

The TGA does not supply therapeutic goods. Before notifying or applying to TGA under the SAS, applicants should check with the intended sponsor (or supplier) to ensure they are prepared to supply the product.

Suppliers are under no obligation to supply an unapproved product regardless of whether the TGA has approved or authorised the use of the product or received a notification under the SAS.

The TGA approval does not override any state or territory requirements that need to be met before the product can be obtained, prescribed or administered lawfully. Such requirements can be product-specific and applicants need to check these with their state or territory health department.

If the product is available from an Australian supplier, 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.

If the product is not available from an Australian supplier, the health practitioner will need to find an overseas source. The product can then be imported from that overseas supplier by a doctor, pharmacist, hospital, patient or licensed importer.

When importing an unapproved therapeutic good, the health practitioner will need to check whether it is controlled under Customs (Prohibited Import) Regulations. In this case, it cannot be imported without an import permit. A full list of controlled substances is available on the Office of Drug Control website. Import licences and permits are issued by the Office of Drug Control.

Information for sponsors

Suppliers are under no obligation to supply an unapproved product regardless of whether the TGA has approved or authorised the use of the product or received a notification under the SAS.

Responsibilities of sponsors

Supply reports

Under the Therapeutic Goods Regulations 1990 (The Regulations) (regulation 47B), the sponsor is required to provide us with six-monthly reports detailing each kind of therapeutic good supplied, the number of times supplied to a health practitioner and the quantity supplied by the sponsor during the period to which the report relates.

If you, as the sponsor, anticipate a need for long-term supply of the product, you should consider submitting a registration application.

Reporting adverse events and defects

You are responsible for continually monitoring the use of the therapeutic good you supply under the SAS, reporting the types of adverse reactions and effects described below and any defects, and recording the balance of its benefit and risk. Ideally, the use of an unapproved medicine, biological or medical device should be the subject of treatment protocols that are issued by yourself, with clear requirements for the treating health practitioner to report any adverse outcomes to yourself.

Sponsors of products supplied under the SAS are also required to rapidly advise TGA of any information that has bearing on the benefit-risk assessment of the product—particularly any information that change how the product is used under the SAS.

As part of the evaluation dossier and overall development of a medicine, biological or medical device, sponsors should continually monitor and record the product's safety and assess the risk-benefit of its use.

We expect sponsors to report all suspected unexpected serious adverse reactions (for medicines and biologicals), unanticipated serious adverse device effects (for medical devices) and any defects that affect unapproved therapeutic goods supplied in Australia to TGA. This helps us to monitor the safety of all therapeutic goods.

Suspected unexpected serious adverse reactions are defined as an adverse reaction that is both serious and unexpected.

An unanticipated serious adverse device effect is defined as a serious adverse device effect which by its nature, incidence, severity or outcome is both serious and unanticipated.

These should be reported in accordance with the following timelines:

- For fatal or life-threatening outcomes, these should be reported to us within seven calendar days of first knowledge (initial report) and then follow up with a more complete report within eight additional calendar days

- All other serious and unexpected/unanticipated adverse reactions/effects and any defects should be reported within 15 calendar days

There are multiple ways in which adverse events and defects can be reported to the TGA (see Reporting mechanisms).

Supply of products

SAS Category A

A completed notification form from the prescribing medical practitioner or a health practitioner acting on behalf of the prescribing medical practitioner is required to be submitted to the sponsor before the sponsor can legally supply the product.

SAS Category B

An approval letter from TGA is required to be submitted to the sponsor before the sponsor can legally supply the product.

SAS Category C

The inclusion of a product in the following legislative instruments acts as the authorisation for these products to be supplied:

- **Medicines**: Therapeutic Goods (Authorised Supply of Specified Medicines) Rules September 2017
- **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017
- **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017

The sponsor is not legally required to be in receipt of the notification form from an authorised health practitioner before they can supply an unapproved therapeutic good that is included in lists of products that are deemed to have an established history of use. The health practitioner needs to submit the notification form only to TGA, and can do so after the goods have been supplied to the patient.

It is the responsibility of the health practitioner to ensure that the therapeutic goods are supplied to patients in accordance with the 'rules' of the instrument. This means that the goods must only be supplied for the indications and by the health practitioner(s) who have been authorised to supply these goods.

The legislative instruments are publically available so that sponsors can check to see if any of their products are affected.

Unapproved therapeutic goods that are not included on any of the legislative instruments; or are included but need to be accessed for an indication or by a health practitioner that is not on the instrument may potentially still be supplied to health practitioners provided that supply occurs lawfully through one or more of the existing unapproved therapeutic goods schemes, including: SAS Category A, SAS Category B application or Authorised Prescriber.

Sponsors cannot apply to the TGA to have goods included or removed from the legislative instruments. The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products as appropriate. Sponsors may wish to subscriber to the email

subscriber list which will be utilised by TGA to notify of any changes to the current SAS processes including changes to the goods that can be notified via SAS Category C.

Reporting mechanisms – adverse events and defects

Reports for adverse events and defects can be made:

- online via the TGA website Report a problem section (preferred) (adverse events and defects for all types of therapeutic goods)
- via email to info@health.gov.au or adr.reports@health.gov.au (adverse events and defects for medicines and biologicals only)
- via the blue card (adverse events for medicines and biologicals only) reporting form which can be downloaded from the TGA website and mailed, faxed or emailed to TGA (details on web page above)

Please note that adverse events and defects for biologicals can be reported using the same mechanisms that currently exist for medicines.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch and Regulatory Guidance team	July 2017
V1.1	To clarify the requirements in relation to the types of adverse events and effects that should be reported and the time period within which this should be done.	Pharmacovigilance and Special Access Branch	September 2017

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Reference/Publication #