Australian Government
Department of Health
Therapeutic Goods Administration

Special Access Scheme (SAS)

Guidance for Sponsors

Version 1.0, February 2023

TGA Health Safety Regulation

Contents

About this guidance

This guidance is to assist sponsors understand their requirements when supplying 'unapproved' therapeutic goods under the Special Access Scheme (SAS).

If you have any feedback or want more information, please contact the SAS team

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.

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

If you are a health practitioner wanting to prescribe an 'unapproved' therapeutic good for an individual patient, refer to Special Access Scheme – guidance for health practitioners accessing 'unapproved' therapeutic goods through SAS.

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.

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

For information relating to nicotine vaping products refer to the Nicotine e-cigarettes web page.

Overview of the SAS

Generally, therapeutic goods (such as 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.

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.

When the SAS can be used

The SAS allows Australian-registered health practitioners to access 'unapproved' therapeutic goods for an **individual patient** on a case-by-case basis in 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 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 in Australia or the product has been discontinued. The Medicines Shortages Information Initiative webpage provides information about shortages of medicines in Australia, including those arising from the discontinuation of products.

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

The SAS allows access to 'unapproved' therapeutic goods for use in humans only.

Veterinary medicines are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

When the SAS is not appropriate

The SAS should not be used when:

- product is in the ARTG and available for supply in Australia, including for off-label use
- medicines (other than medicinal cannabis) are extemporaneously compounded by a pharmacist for the treatment of a particular patient. Further information is available on the TGA website.
- there is a current section 19A approval in place for supply of an overseas medicine during a shortage and stock is available.

- conducting a clinical trial to collect safety and efficacy (or performance) data. If you want to conduct a clinical trial (investigator-initiated trials) involving the use of an unapproved therapeutic good you should consider the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) pathways.

More information is available in Special Access Scheme – Guidance for health practitioners.

SAS pathways

There are three SAS pathways. The prescribing health practitioner is responsible for deciding which pathway is appropriate and submitting the appropriate notification or application to the TGA.

Sponsors and patients are **not able** to submit SAS applications or notifications. An appropriate registered health practitioner must make the SAS notification or application on behalf of their patient. Refer to Special Access Scheme – guidance for health professionals for more information about who can prescribe under the SAS.

SAS Category A – notification for a seriously ill patient

SAS Category A allows a prescribing **medical practitioner** to access an 'unapproved' therapeutic good for an individual patient who is seriously ill.

This is a **notification pathway** – prior approval from the TGA is **not** required. The prescribing health practitioner must send a completed Category A notification form to the TGA within 28 days after the 'unapproved' product is obtained for patient.

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'.

SAS Category B – application for all other patients and products

SAS Category B allows a prescribing health practitioner to access an 'unapproved' therapeutic good for a patient that does not fit the Category A definition and where the product is not authorised for supply under the Category C pathway.

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

SAS Category C – notification for established products

SAS Category C allows specified health practitioners to supply 'unapproved' therapeutic goods from a list of products that have been deemed by the TGA as having an established history of use in specified circumstances.

This is a **notification pathway** – prior approval from the TGA is **not** required. The prescribing health practitioner must send a completed Category C form to the TGA within 28 days after the supply of the 'unapproved' product.

The lists of products, indications and type of health practitioner authorised to supply the products are available at Special Access Scheme Category C Lists. There are separate lists for medicines, biologicals and medical devices.

What products can be supplied

The choice of product is at the discretion of the medical practitioner.

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:

- 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 **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.

Sponsor requirements

Under SAS, the sponsor is considered to be the Australian person or company who does one of the following:

- imports 'unapproved' therapeutic goods into Australia
- manufactures 'unapproved' therapeutic goods for supply in Australia or elsewhere

- arranges for another party to import, export or manufacture 'unapproved' therapeutic goods.

Sponsors 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 cannot give any assurance regarding the quality, safety or efficacy of an 'unapproved' product. All parties involved in the supply of 'unapproved' therapeutic goods need to recognise that the practice may carry medico-legal risk, and in the case of a company, there may be implications for the company's indemnity.

Sponsors who choose to supply 'unapproved' therapeutic goods must take on the following responsibilities:

- Ensuring legal supply of any 'unapproved' products under the therapeutic goods legislation, including
  - Submitting six monthly supply reports to the TGA
  - Reporting adverse events and defects to the TGA
- Complying with other legislative requirements including:
  - import restrictions of other agencies as required under other Commonwealth legislation
  - state and territory requirements relating to importation, storage, wholesaling and distribution
  - ensuring products comply with applicable standards/orders and GMP requirements
- Applying to include the product in the ARTG if considering long-term supply.

Ensure legal supply

Before supplying an 'unapproved' therapeutic good for any reason, make sure you understand the requirements set out in this guidance. The therapeutic goods legislation details the legal requirements for supplying therapeutic goods in Australia.

Generally, it is unlawful for a sponsor to supply a therapeutic good that is not included in the ARTG, however there are some exceptions, such as supply under the SAS.

It is the sponsor's responsibility to ensure that the good is exempt or approved (as relevant) under the SAS and obtain confirmation that the requirements for the relevant SAS pathway are satisfied. For example, prior to supplying a good under the SAS, a sponsor may require a purchaser to provide documentation confirming that:

- a good for use under the SAS A pathway is to be given to a person that is a Category A patient in circumstances where;
  - informed consent is obtained from the person or their guardian;
  - a statement in relation to the person is completed by a medical practitioner (or health practitioner acting on behalf of the medical practitioner) in the form approved by the Secretary; and
  - the good is dispensed on the prescription of a medical practitioner in accordance with good medical practice.
- a good for use under the SAS B pathway is approved for supply under section 19(1)(a) of the Act; or

- a good for use under the SAS C pathway is to be used in accordance with the requirements of the SAS C Rules.

Importing and holding stock prior to supply

In some cases, therapeutic goods can be imported into Australia and held prior to supply under the SAS and without being included the ARTG.

Item 1 of Schedule 5A of the *Therapeutic Goods Regulations 1990* and item 2.1 of Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* exempt therapeutic goods imported into Australia for use under SAS where the goods are:

- held under the direct control of the sponsor (importer)
- kept in a warehouse or a properly secured area under the control of the sponsor, and
- supplied in accordance with a relevant SAS notification, approval or authorisation

The sponsor is also required to keep records relating to the source and supply of the goods and give those records to the TGA on request.

Separate requirements apply to medicines needed for dispensing for SAS A patients. Item 1B of Schedule 5A of the *Therapeutic Goods Regulations 1990* allows for the importation of therapeutic goods needed for patients who are seriously ill with a condition from which premature death is reasonably likely to occur in the absence of early treatment, where they are kept:

- in a warehouse or a properly secured area under the control of the sponsor, or
- at a hospital or other healthcare facility after being delivered to the hospital or facility by, or on behalf of, the sponsor, and
- supplied in accordance with such a prescription.

Medicinal cannabis and nicotine vaping products

Some specific exemptions apply to medicinal cannabis and nicotine vaping products.

Information about distribution arrangements specific to medicinal cannabis is available in the Importation, manufacture and supply of unapproved medicinal cannabis products

Separate requirements apply to nicotine vaping products to allow wholesaling supply to pharmacies. Refer to Nicotine vaping products: Information for sponsors, wholesalers and manufacturers for details.

Advertising ‘unapproved’ therapeutic goods

It can be a criminal offence or a civil contravention to advertise therapeutic goods that are:

- not included in the ARTG and an exemption or exclusion does not apply
- included in Schedules 3, 4, or 8 of the current Poisons Standard.

Advertisement of unapproved goods is considered to be a breach of sections:

- 42DL(1)(12) of the *Therapeutic Goods Act 1989* (the Act)) (criminal)
- 42DLB(3)(9) of the Act (civil).

Refer to the Regulation of therapeutic advertising in Australia for further information. The TGA has also published guidance on advertising exclusively to health professionals.

Submit six-monthly supply reports

Sponsors are required to submit six-monthly supply reports to the TGA (under Regulation 47B(1)(c) of the *Therapeutic Goods Regulations 1990*).

Six monthly supply reports must be submitted:

- in the form titled Six monthly report - supply of unapproved therapeutic goods by a sponsor and
- emailed as an attachment to SAS@health.gov.au
- for medicinal cannabis products email medicinal.cannabis@health.gov.au

Reporting periods are 1 January - 30 June (inclusive) and 1 July - 31 December (inclusive). Reports must be submitted within 1 month of the end of the relevant reporting period.

Report adverse events and defects

Sponsors are responsible for continually monitoring and recording product safety. All adverse events should be collected and collated in a safety database for ongoing assessment of benefit and risk.

Sponsors must report all suspected unexpected serious adverse reactions (for medicines and biologicals), unanticipated serious adverse device effects (for medical devices) and any defects related to 'unapproved' therapeutic goods supplied in Australia to the TGA.

The use of an 'unapproved' therapeutic good should be the subject of treatment protocols that are issued by the sponsor, with clear requirements for the treating health practitioner to report any adverse outcomes to the sponsor.

Suspected unexpected serious adverse reactions are adverse reactions that are serious and unexpected.

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

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.

Timeframes for reporting

Timeframes for reporting requirements can be found on the TGA website.

Other adverse event reports

Individual Case Safety Report (ICSR) from overseas patients and Developmental Safety Update Reports (DSURs) do not need to be routinely submitted to the TGA for the purposes of the SAS unless requested.

Comply with other legislative requirements

Make sure you comply with other relevant Australian and state and territory legislative requirements.

Additional import restrictions

Additional restrictions can be placed on the import of therapeutic goods by other agencies:

- an import declaration may be required from the Australian Border Force
- a licence and/or permit may be required to import substances controlled under *Customs (Prohibited Imports) Regulations 1956*. A full list of controlled substances is available on the Office of Drug Control website. Please contact dcs@health.gov.au for further information.
- permission may be required prior to importing any material of biological origin (human, animal, plant or microbial). Check the Biosecurity Import Conditions system (BICON) to determine if the product you want to import needs an import permit.
- permission may be required prior to importing endangered species and genetically modified organisms

Contact the exporting country to ensure you meet their importation requirements.

State and territory requirements

SAS notifications or approvals do not override state and territory requirements for provisions such as storage, handling and use of scheduled medicines. For details on relevant state or territory legislation contact the health department in your state or territory.

Include the product in the ARTG for long term supply

The TGA has a responsibility to encourage the use of products included in the ARTG. Sponsors should review the information at Overview of supplying therapeutic goods in Australia to find out how to include a product in the ARTG.

Quality standards

Sponsors should be aware that certain Australian quality standards ('orders') apply to 'unapproved' therapeutic goods accessed under the SAS.

Sponsors are responsible for ensuring compliance with all applicable standards, including the Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018.

Medicinal cannabis products sponsors need to ensure the product complies with the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017.

For nicotine vaping products sponsors need to make sure the product complies with the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*.

Refer to the current Therapeutic Goods Orders on the TGA website to confirm requirements.

Civil and criminal penalties may apply where these requirements are not met. Non-compliance with a standard is also grounds for recalling a medicine from the market.

Australian manufacturing requirements

Manufacture of a good that is not included in the ARTG

Generally, a therapeutic good must be included in the ARTG before it can be lawfully manufactured, unless the good is exempt or otherwise approved or authorised under the Act.

The sponsor for an unapproved good is responsible for ensuring that an exemption, approval or authorisation under one of the SAS pathways is in place relating to the therapeutic goods.

The manufacturer is the sponsor if the manufacture occurs without a request from another entity such as a hospital.

If another entity, such as a health facility, requests the manufacture of the unapproved good, then the health facility will be the sponsor.

Requirement to hold a manufacturing licence

Australian manufacturers of therapeutic goods, including 'unapproved' therapeutic goods, must hold a manufacturing licence that specifically authorises the manufacture of unapproved goods unless the goods or the person manufacturing the goods are exempt (see below)or a conformity assessment certificate (with certain exceptions).

'Unapproved' therapeutic goods must also be manufactured according to the Therapeutic Goods (Manufacturing Principles) Determinations, which require therapeutic good manufacturers to demonstrate that manufacturing practices comply with procedures and requirements in the PIC/S Guide to good manufacturing Practice (GMP). There are different codes of GMP depending on the type of therapeutic good:

- Medicines and biologicals that comprise or contain live animal cells, tissues or organs (PIC/S Guide to Good Manufacturing Practice for Medicinal Products)
- Human blood, blood components, haematopoietic progenitor cells (HPCs) and biologicals that comprise, contain or are derived from human cells and tissues (The Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products). Further information on manufacturing blood and blood components is available at Manufacturing blood and blood components | Therapeutic Goods Administration (TGA)

A different system, known as conformity assessment, is used to ensure that medical devices are of high quality.

Additional information about manufacturing therapeutic goods is available on our website. Labelling is also considered a manufacturing step under the *Therapeutic Goods Act 1989*.

We have also published specific guidance on medicinal cannabis manufacture separate to this guidance.

Medicines and biologicals

Australian facilities manufacturing medicines or biologicals must hold a manufacturing licence issued by the TGA, that specifically authorises the manufacture of unapproved goods. .

This requirement applies to products manufactured in Australia for supply under the SAS, except under the following circumstances:

- pharmacists who manufacture goods in a pharmacy where pharmacy is open to the public and the goods are supplied from those premises (other than by wholesale) to individual patients (item 2, Schedule 8 of the *Therapeutic Goods Regulations 1990*)
- pharmacists employed by a public hospital or public institution who manufacture goods for supply to patients in hospitals/public institutions in the same state or territory (item 3, Schedule 8 of the *Therapeutic Goods Regulations 1990*)
- a person who applies supplementary labelling to a manufactured product, where the supplementary label contains only a name and address, the registration or listing number of goods, or the biological number of a biological as specified (item 5, Schedule 8 of the *Therapeutic Goods Regulations 1990*).

Medical devices

Manufacturers of all medical devices (including IVD medical devices) manufactured and/or supplied in Australia should ensure that they have appropriate:

- conformity assessment procedures to ensure that a medical device complies with the Essential Principles set out in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- documentation demonstrating compliance of the device with the Essential Principles.

For further information refer to Manufacturing medical devices and IVDs.

Overseas manufacture

The TGA uses internationally harmonised manufacturing standards to allow manufacturers to operate in an international environment.

For medicines intended to be included in the ARTG that involve an overseas manufacturer, GMP clearance or certification may be required for each of the overseas manufacturing sites as evidence of an acceptable standard of GMP.

Products that are not included in the ARTG and supplied under the SAS from an overseas manufacturer should be manufactured in accordance with the relevant code of GMP in order to ensure the quality of the product.

Labelling and packaging

Medicines included in the ARTG must comply with the labelling standards below:

- Therapeutic Goods Order No. 91 - *Standard for labels of prescription and related medicines* (TGO 91)
- Therapeutic Goods Order No. 92 - *Standard for labels of non-prescription medicines* (TGO 92)

- Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017.

There are no legislative requirements for 'unapproved' therapeutic goods supplied under the SAS to adhere to TGO 91 and 92. However, TGO 91 and 92 seek to prevent selection and/or administration errors and accidental ingestion. Therefore, these standards should be used by sponsors wherever possible.

Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017 applies to any medicine that is labelled or packaged in a way that states or implies to a consumer or purchaser that the product, as presented, is child-resistant.

The Poisons Standard includes labelling and packaging requirements that are enforced through relevant state and territory drugs, poisons and controlled substances legislation. Contact the relevant state/territory drugs and poisons unit for further information. Labels also need to adhere to Commonwealth advertising requirements for therapeutic goods.

Products that are approved for use overseas should already comply with the labelling requirements of the country of origin. However, for non-English labels, the sponsor needs to:

- over-label in English

  OR

- provide health care professionals with instructions in English clarifying any unclear information that may lead to medication errors.

It is also recommended, where possible, to include wording to demonstrate that the product is not included in the ARTG and is not available for general supply.

Version history

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Therapeutic Goods Administration

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