Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Special Access Scheme and Authorised Prescriber Pathway

## Guidance for Sponsors

Version 1.2, November 2023

# Contents

# About this guidance

This guidance is to assist sponsors understand their regulatory obligations when supplying 'unapproved' therapeutic goods under the Special Access Scheme (SAS) and Authorised Prescriber (AP) Pathway

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 the legislative requirements are met.

# Introduction

## Role of a sponsor

A sponsor is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

A full definition is provided in Chapter 1 Section 3 of the *Therapeutic Goods Act 1989- external site*.

The sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia.

For information on the role and responsibilities of a sponsor, as well as information on how to apply for an entry on the ARTG, please refer to the Industry section of our website.

## Overview of the SAS and AP scheme

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 Special Access Scheme (SAS) allows Australian-registered health practitioners to access an 'unapproved' therapeutic good for an **individual patient on a case-by-case basis.**

The Authorised Prescriber (AP) pathway allows an Australian registered medical practitioner to access an 'unapproved' therapeutic goods for a class of patients **under their immediate care without requiring separate approval for individual patients.**

Further information on the pathways can be found on the TGA website.

## What products can be supplied under the SAS and AP scheme

The choice of product accessed under the SAS Category A and B scheme and the AP scheme is at the discretion of the medical practitioner after consideration of all available ARTG listed products.

Unapproved products that can be accessed under the SAS Category C or AP established history of use pathway are publicly available on the list of products with an established history of use TGA webpage. Sponsors cannot apply to the TGA to have goods included or removed from the legislative instruments. The TGA regularly reviews the legislative instruments and makes changes to add or remove products as appropriate.

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 to the TGA.

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

# Sponsor requirements

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 or AP scheme.

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

  - Supply through the SAS and AP pathway is done in accordance with a valid authority or exemption

- 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.

## Ensuring 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 or AP pathway.

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

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); and

kept in a warehouse or a properly secured area under the control of the sponsor; and supplied in accordance with a relevant notification, approval, or authorisation under the approved pathways.

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 at 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.

## Comply with other legislative requirements

- Make sure you comply with other relevant Australian and state and territory legislative requirements.
- SAS and AP authorisations 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

## 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 ncs@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.**

## 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 medicinal.cannabis@health.gov.au for medicinal cannabis products or SAS@health.gov.au for all other products.
- Reporting periods are 1-January – 30th June (inclusive) and 1 July - 31 December (inclusive). Reports must be submitted within 1 month of the end of the relevant reporting period.
- Sponsor six monthly reporting data for medicinal cannabis products are used to publish medicinal cannabis product details by active ingredient category. This list aims to support health care professionals in prescribing and supplying medicinal cannabis products therefore timely submission of six-monthly reports is essential.

# 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 TGA advertising hub for further information. The TGA has also published guidance on advertising exclusively to health professionals

## 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.

We encourage sponsors to report all adverse events and product defects to us. This helps us to monitor the safety of all therapeutic goods.

**Sponsors are expected to report:**

- fatal or life-threatening adverse reactions to us early - ideally **within 7 calendar days** of becoming aware of them and then follow up with a more complete report within the **next 8 calendar days**
- other serious and unexpected adverse reactions - **within 15 calendar days** and advise the TGA if you think any of these may have already been reported to us

There are various ways to report adverse events and product defects, which can be found on our website at Report a problem or side effect.

Adverse events and defects for biologicals can be reported using the same mechanism that currently exists for medicine.

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 and the TGA.

### 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.

## Include 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.

## Australian manufacturing requirements

### Quality Standards

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

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.

### 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)

There are no legislative requirements for 'unapproved' therapeutic goods supplied under the SAS and Authorised Prescriber scheme 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.

Medicinal cannabis products must comply with the labelling standards below:

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

Nicotine vaping products must comply with the labelling standards below:

- Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021.

## 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 special access 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

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

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 or Authorised Prescriber scheme, 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 and AP pathway from an overseas manufacturer should be manufactured in accordance with the relevant code of GMP in order to ensure the quality of the product.

Please note, new requirements will apply to medicinal cannabis products available for supply in Australia from 1 July 2023. Overseas manufacturing of medicinal cannabis must occur on sites that comply with one of the Good Manufacturing Practice (GMP) standards and the Australian sponsor (the importer) of the medicinal cannabis product must hold evidence of GMP compliance in accordance with section 13 of the TGO 93.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | International Regulatory Branch and Regulatory Guidance team | February 2023 |
| V.1.1 | Clarification regarding labelling requirements for medicinal cannabis and nicotine vaping products.<br>Clarification regarding oversees manufacturing requirements for medicinal cannabis products | International Regulatory Branch | March 2023 |
| V.1.2 | Clarification regarding sponsor reporting requirements | International Regulatory Branch | November 2023 |

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