Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Personal Importation Scheme

Personal importation scheme

Last updated:
18 March 2015

Individuals can legally import most therapeutic goods for personal use under the Personal Importation Scheme.

Personal importation occurs when:

- an individual arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier or family/friend; and
- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

It is important to note that such therapeutic goods may not be approved for supply in Australia; this means there are no guarantees about their safety or quality.

Because safety and quality cannot be guaranteed do not order medicines, including dietary supplements and herbal preparations, over the Internet unless:

- You know exactly what is in the preparation; and
- You have checked the legal requirements for importation and use in Australia.

Personal Importation Scheme

Under the Personal Importation Scheme you may import a **3 month supply** at the one time (at the maximum dose recommended by the manufacturer) of unapproved therapeutic goods into Australia without any approval required by the TGA provided that:

- the goods are for your own treatment or the treatment of your immediate family; and
- you do not supply (sell or give) the medicine to any other person; and
- where possible, you keep the medicines or medical devices in their original packaging with any dispensing labels intact; and
- the goods are not restricted under Australian Customs controls or quarantine rules and the goods do not contain a controlled substance (https://www.tga.gov.au/node/875060); and
- the goods are not injections that contain material of human or animal origin (except insulin); and
- the total quantity of the goods imported within a 12 month period does not exceed 15 months supply of the goods (for medicines, at the maximum dose recommended by the manufacturer); and
- if the goods are medicines in Schedule 4 or 8 of the Poisons Standard (https://www.tga.gov.au/node/5340) a prescription from an Australian-registered medical practitioner is held for the medicines.

You cannot import more than a **3 month supply** at the one time under the personal importation scheme. If you wish to bring **more than 3 months supply** at the one time into Australia, an **Australian-registered** doctor will first need to apply to the TGA for Special Access Scheme (https://www.tga.gov.au/node/3244) approval.

Customs

Each country has its own controls regarding the import of particular substances. Countries, which are signatories to international drug treaties, will generally have similar requirements for narcotic and psychotropic substances. However, there can be a vast difference in the way in which anabolic/androgenic steroids are regulated.

The substances listed below are not controlled substances in some countries (e.g. USA) and are widely available in dietary supplement preparations in those countries.

- DHEA (Dehydroepiandrosterone)
- Norandrostenedione
- Ephedra (ma huang)
- Ephedrine

However, under the Customs legislation in Australia, these substances are classified as either anabolic steroids or precursors and are prohibited imports unless an import permit has been obtained.

To establish if the goods are subject to the Customs controls you need to know what ingredients are in the product. You can check whether these ingredients are controlled substances which require import licences/permits (https://www.tga.gov.au/node/537070).

Anyone ordering herbal or dietary supplements from the USA should check that the product does not contain a controlled substance. Where such preparations are identified by Customs as prohibited imports, the goods will be seized. Import permits cannot be issued retrospectively and the goods may be destroyed by Customs.

Quarantine

Quarantine clearance may be required prior to the import of any material of biological origin (human, animal, plant or bacterial ingredients). You should contact the Department of Agriculture and Water Resources (http://www.agriculture.gov.au/biosecurity) to see if an import permit is required.

To import or export substances containing parts of animals and plants listed as endangered species you will require a permit issued under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act). Further information can be obtained from the Department of the Environment website (http://www.environment.gov.au/biodiversity/wildlife-trade).

Topics:

Import and export (https://www.tga.gov.au/how-we-regulate/import-and-export)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Personal Importation Scheme

Comparing
20/02/2024 - 9:41am (https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme) s 22
Light edits

21/06/2022 - 10:29am (https://www.tga.gov.au/node/287211/revisions/348159/view) PJOoNEkkpQAOViqT

Layout
Visual Inline (https://www.tga.gov.au/node/287211/revisions/view/348159/518656/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/287211/revisions/view/348159/518656/visual_inline?view_mode=full)

Personal ~~importation scheme~~Importation Scheme

Individuals can legally import most therapeutic goods for personal use under the Personal Importation Scheme.

Last updated:
~~18 March 2015~~30 January 2023

~~**Individuals can legally import most therapeutic goods for personal use under the Personal Importation Scheme.**~~
On this page

Personal importation occurs when both:

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- the goods are to be used by that individual or ~~a member of his/her~~ immediate family member and are not sold or supplied to any other person.

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- ~~the goods are for your own treatment or the treatment of your immediate family; and~~
- The goods are for your own treatment or the treatment of your immediate family that you are travelling with (such as a parent travelling with their child's medicine).
- ~~you~~You do not ~~supply (~~sell or give~~)~~ the medicine to any other person~~; and,~~
- ~~where~~Where possible, you keep the medicines or medical devices in their original packaging with any dispensing labels intact~~; and,~~
- ~~the~~The goods are not restricted under Australian Customs controls or quarantine rules, and the goods do not contain a ~~controlled substance (https://www.tga.gov.au/node/875060)~~controlled substance (https://www.tga.gov.au/node/287879)~~; and,~~
- ~~the goods are not injections that contain material of human or animal origin (except insulin); and~~
- ~~the~~The total quantity of the goods imported within a 12-month period does not exceed 15~~-months~~-month's supply of the goods (for medicines, at the maximum dose recommended by the manufacturer)~~; and,~~
- ~~if~~If the goods are medicines in Schedule 4 or 8 of ~~the~~ the Poisons Standard (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons_standard_susmp)~~Poisons Standard (https://www.tga.gov.au/node/5340)~~, (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons-standard-susmp) a prescription from an Australian-registered medical practitioner is held for the medicines.

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Each country has its own controls regarding the import of particular substances. Countries~~, which~~ that are signatories to international drug treaties; will generally have similar requirements for narcotic and psychotropic substances. However, there can be a vast difference in the way in which anabolic~~/~~ and androgenic steroids are regulated.

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To establish if the goods are subject to ~~the Customs~~customs controls, you need to know what ingredients are in the product. You can check whether these ingredients are ~~controlled substances which require import licences/permits (https://www.tga.gov.au/node/537070)~~Controlled substances that require import licences or permits (https://www.tga.gov.au/node/287879).

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Quarantine clearance may be required prior to the import of any material of biological origin (human, animal, plant or bacterial ingredients). You should contact the Department of Agriculture and Water Resources (http://www.agriculture.gov.au/biosecurity) to see if an import permit is required.

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~~**Topics:**~~
~~import and export~~ (https://www.tga.gov.au/how-we-regulate/import-and-export)

Unapproved therapeutic goods (https://www.tga.gov.au/products/unapproved-therapeutic-goods)

Access unapproved products (consumers) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-unapproved-products-consumers)

Prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)

Supply an unapproved therapeutic good (sponsors) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors)

Clinical trials (https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials)

Personal importation scheme (https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme)

Medicinal cannabis hub (https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub)

Vaping hub (https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub)

MDMA and Psilocybin hub (https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin-hub)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Personal Importation Scheme

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Last updated:
30 January 2023

On this page

Personal Importation Scheme (#scheme)
Customs (#customs)
Quarantine (#quarantine)

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Revisions for *Things to consider before undergoing procedures involving dermal fillers*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)		○	*Current revision*
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**

Revision	Operations
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	Revert
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26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	Revert
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	Revert
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	Revert

Compare selected revisions

Australian Government
Department of Health
Therapeutic Goods Administration

Things to consider before undergoing procedures involving dermal fillers

Non-surgical enhancements using cosmetic injections, such as dermal fillers, are becoming increasingly popular in Australia. Dermal fillers are materials injected under the skin to reduce the appearance of facial wrinkles or lines, and can also be used to enhance facial contours by adding volume to cheeks and lips and to improve the appearance of scars. Increasing interest in these types of procedures has prompted a reminder about the associated risks, the presence of counterfeit products and the conversations you should be having during your consultation.

Did you know?

- Dermal fillers are prescription-only products.
- Injecting dermal fillers is a medical procedure that can only be undertaken under the supervision of an authorised prescriber such as a medical doctor.
- Neither the brand of product or substance used in cosmetic injections can be advertised to the public. Brands should be discussed in consultations to make sure good quality products are used.
- Only products approved by the TGA should be used.
- Risks are not only associated with the product. If the person who performs a cosmetic procedure lacks adequate qualification, knowledge or experience, this can cause significant adverse events.

Are you aware of the risks associated with cosmetic injections?

Questions to ask during your consultation

There are questions you can ask during your consultation with the prescriber which will help you make an educated decision on whether or not to go ahead.

Question 1: Who will be performing my procedure?

Make sure the person performing the procedure is either the prescriber or a nurse under a prescriber's supervision. The national register maintained by the Australian Health Practitioner Regulation Agency (AHPRA) lists all persons who are registered with the Medical and Nursing Boards of Australia and can be freely searched on the AHPRA website (www.ahpra.gov.au).

Injecting a filler into the wrong area of the face may have serious consequences

Question 2: How much experience do you have in this type of procedure?

Anyone that performs a cosmetic injection must have extensive knowledge of facial anatomy, as well as the required training and experience.

Injecting a filler into the wrong area of the face may have serious consequences, including blindness or even death.

Question 3: What product will you be using? Is it approved by the TGA?

Due to legislation and regulations governing the advertising of therapeutic goods, product information such as the brand name and substances cannot be advertised. This information is only available if you ask.

Identifying the name of the product will allow you to search the Australian Register of Therapeutic Goods (ARTG) on the TGA website, to make sure we have approved that product for your procedure. The prescriber should know whether the product being used is approved.

Question 4: What are the risks associated with this procedure and what level of aftercare will you provide?

As with any procedure, there are associated risks that the prescriber should explain to you. But it is also important to make sure you will be supported after the procedure if you experience any side effects.

What to look out for

Counterfeit dermal filler products imported from overseas exist and should be avoided. These can be difficult to identify. The best way to avoid them is to only ever source prescription products from a medical professional who is registered in Australia.

Be aware of heavily advertised and discounted procedures. Ask the right questions to make sure you're comparing 'like with like' when researching clinics/doctors.

It is important to ensure you will be supported after the procedure if you experience any side effects

To report side effects as a result of a dermal filler product or a suspected counterfeit product, speak with your doctor or visit **www.tga.gov.au/reporting-problems**

If you require further information, you can contact us on **1800 020 653** or email **info@tga.gov.au**

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Things to consider before undergoing procedures involving dermal fillers

Fact sheet

Published:
22 August 2019

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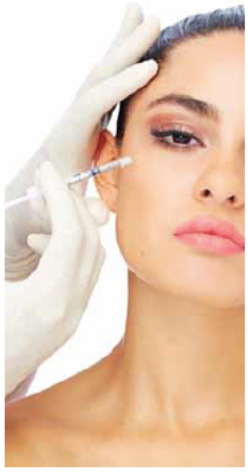

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To report side effects as a result of a dermal filler product or a suspected counterfeit product, speak with your doctor or visit Reporting problems (https://www.tga.gov.au/node/287456)

If you require further information, you can contact us on **1800 020 653** or **email** info@tga.gov.au

Translated resources

- Things to consider before undergoing procedures involving dermal fillers - Chinese simplified (pdf,515kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-simplified.pdf)
- Things to consider before undergoing procedures involving dermal fillers - Chinese traditional (pdf, 538kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-traditional.pdf)
- Things to consider before undergoing procedures involving dermal fillers - Korean (pdf,509kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-korean.pdf)
- Things to consider before undergoing procedures involving dermal fillers - Vietnamese (pdf,458kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-vietnamese.pdf)

Supporting documents

things-consider-undergoing-procedures-involving-dermal-fillers.jpg (https://www.tga.gov.au/media/9470)
syringes-blue.png (https://www.tga.gov.au/media/9472)

Things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-korean.pdf) [PDF, 508.93 KB]

Things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-vietnamese.pdf) [PDF, 457.75 KB]

Things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-traditional.pdf) [PDF, 537.25 KB]

Things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-simplified.pdf) [PDF, 514.57 KB]

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers.pdf) [564.75 KB]

Topics:

Prescription medicines (https://www.tga.gov.au/products/medicines/prescription-medicines)

Related content

Cosmetic injections checklist (https://www.tga.gov.au/news/news/cosmetic-injections-checklist)

22 August 2019 | News

Considering cosmetic injections? Complete this checklist first

Be alert when considering cosmetic injections (https://www.tga.gov.au/news/media-releases/be-alert-when-considering-cosmetic-injections)

23 July 2019 | Media releases

Risks associated with cosmetic injections can be related to both the product and the experience of the person performing the procedure

Three questions to ask natural health practitioners about testing services (https://www.tga.gov.au/news/news/three-questions-ask-natural-health-practitioners-about-testing-services)

2 April 2019 | News

Do your research before consenting to live blood analysis, electrodermal testing and other related tests

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods

Previous change (https://www.tga.gov.au/node/349154/revisions/view/435017/435100/visual_inline)

Comparing
27/03/2024 - 5:04pm (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)
s 22
updated guidance - 1253, s 22 .
21/02/2023 - 1:23pm (https://www.tga.gov.au/node/349154/revisions/435100/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/349154/revisions/view/435100/559287/visual_inline) -

View mode
Full content (https://www.tg

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods

Last updated:
27 March 2024

Special Access Scheme (SAS) guidance (https://www.tga.gov.au/sites/default/files/2024-03/special-access-scheme-sas-guidance.pdf) [PDF, 500.87 KB]

Special Access Scheme (SAS) guidance (https://www.tga.gov.au/sites/default/files/2024-03/special-access-scheme-sas-guidance.docx) [Word, 470.76 KB]

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

If you are a medical practitioner wanting to prescribe an 'unapproved' therapeutic good to multiple patients (a class of patients) on an ongoing basis you should consider becoming an Authorised Prescriber (https://www.tga.gov.au/node/288268).

The guidance replaces all previous guidance about the SAS. If you have any feedback or want more information please contact the SAS team.

Contents

- About this guidance
- Overview of the SAS
  - ~~When the SAS can be used~~
  - ~~When the SAS is not appropriate~~
  - ~~Who can be the prescribing health practitioner~~
  - ~~Who can submit the SAS notification or application~~
  - ~~Which pathway to use~~

- ~~What products can be supplied~~
- Before prescribing an 'unapproved' therapeutic good
  - ~~Consider ARTG treatments~~
  - ~~Consider risks of treatment~~
  - ~~Check the unapproved good is available~~
  - ~~Determine the appropriate SAS pathway~~
  - ~~Adhere to good medical practice and other codes of conduct~~
  - ~~Obtain informed consent~~
  - ~~Check state and territory requirements~~
- Submitting the SAS notification or application
  - ~~Notification and application forms~~
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Version	Description of change	Author	Effective date
V1.0	Original publication	International Regulatory Branch and Regulatory Guidance team	January 2023
V2.0	Minor updates relating to the SAS & AP online system	Business Improvement and Compliance Section, International Regulatory Branch	March 2024

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods

Last updated:
27 March 2024

Special Access Scheme (SAS) guidance (https://www.tga.gov.au/sites/default/files/2024-03/special-access-scheme-sas-guidance.pdf) [PDF, 500.87 KB]

Special Access Scheme (SAS) guidance (https://www.tga.gov.au/sites/default/files/2024-03/special-access-scheme-sas-guidance.docx) [Word, 470.76 KB]

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

If you are a medical practitioner wanting to prescribe an 'unapproved' therapeutic good to multiple patients (a class of patients) on an ongoing basis you should consider becoming an Authorised Prescriber (https://www.tga.gov.au/node/288268).

The guidance replaces all previous guidance about the SAS. If you have any feedback or want more information please contact the SAS team.

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- Before prescribing an 'unapproved' therapeutic good

- Submitting the SAS notification or application
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Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS)

Guidance for health practitioners accessing unapproved therapeutic goods

Version 2.0, March 2024

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About this guidance

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

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

The guidance replaces all previous guidance about the SAS. If you have any feedback or want more information please contact the SAS team.

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

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

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

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

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

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

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

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

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

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

Overview of the SAS

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

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

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

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

Health practitioners are expected to have trialled or considered treatment options that are included in the ARTG and are available for supply in Australia prior to considering accessing an 'unapproved' therapeutic good for their patient. 'Unapproved' therapeutic goods have undergone little or no evaluation for quality, safety, efficacy or performance by the TGA.

The TGA has a responsibility to maintain a balance between ensuring individuals have timely access to important new therapies and maintaining the broader community interest that therapeutic goods are evaluated for quality, safety, efficacy and performance.

When the SAS can be used

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

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

When the SAS is not appropriate

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

Off label use

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

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

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

Extemporaneous compounding

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

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

Schedule 9 and 10 products

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

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

Medicine shortages section 19A approvals

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

Clinical trials

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

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

Other research purposes, demonstration or sample items

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

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

Who can be the prescribing health practitioner

Only appropriate Australian-registered health practitioners can prescribe therapeutic goods under the SAS. The type of health practitioner depends on which SAS pathway is used. Refer to Which pathway to use for details. Generally, applications from health practitioners with non-practising, limited, student, provisional (requiring supervised practice) or conditions placed on their registration will not be considered.

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

- the appropriate knowledge of the condition being treated and the 'unapproved product'

  AND

- the intended use of the product is within their scope of practice.

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

Definition of registered health practitioner

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

Who can submit the SAS notification or application

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

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

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

Health practitioners acting on behalf of the prescriber

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

- have regard to the appropriate clinical order from the prescribing health practitioner (such as a prescription or medication chart entry)

- ensure you understand the clinical context in which the therapeutic good will be used
- include the **full name** and **AHPRA number** of the prescribing health practitioner **on the form**.

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

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

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

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

Which pathway to use

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

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

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

Table 1 – Key features of each SAS pathway

Key features	SAS Category A	SAS Category B	SAS Category C
Type of registered health practitioner			
Medical practitioner	Yes	Yes	Yes
Other health practitioner (as defined in the therapeutic goods legislation)	No	Yes	Yes
Type of goods			
Specified list of goods available	No	No	Yes
Medicinal cannabis	Yes (Products must be imported individually via the Office of Drug Control (ODC))	Yes	No
Schedule 8 goods	Yes	Yes	No

Key features	SAS Category A	SAS Category B	SAS Category C
Schedule 9 goods (only where state and territory legislation also permits use)	No	Yes (Only with evidence of state/territory agreement of use)	No
Schedule 10 goods	No	No	No
Notification or application form	Notification (Within 28 days after prescribing)	Application (Before prescribing)	Notification (Within 28 days after prescribing)
Decision letter	No	Yes	No

SAS Category A – notification for a seriously ill patient

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

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

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

Definition of a 'seriously ill patient'

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

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

For medical devices a Category A patient is defined as:

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

SAS Category B – application for all other patients or products

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

- a patient that does not fit the Category A definition

- products that are not authorised for supply under the Category C pathway.

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

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

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

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

Who can prescribe under SAS Category B

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

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

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

SAS Category C – notification for products with established history

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

The lists of therapeutic goods, indications and type of health practitioners who are authorised to access the goods are referred to as 'rules' and are included legislative instruments. There are separate legislative instruments for medicines, medical devices and biologicals available at Special Access Scheme rules.

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

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

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

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 for:

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

SAS Category B pathway

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

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

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

SAS Category C pathway

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

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

Before prescribing an ‘unapproved’ therapeutic good

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

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

Consider ARTG treatments

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

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

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

Consider risks of treatment

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

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

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

Check the unapproved good is available

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

Determine the appropriate SAS pathway

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

Adhere to good medical practice and other codes of conduct

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

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

Obtain informed consent

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

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

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

Informed consent should include an adequate knowledge of:

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

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

- that the therapeutic good is not currently in the ARTG and may not have been evaluated for quality, safety, efficacy or performance by the TGA
  - including the possible benefits of treatment and any known risks and side effects and that unknown risks and side effects are possible
- of any alternative approved treatments that are available in Australia.

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

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

Check state and territory requirements

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

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

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

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

Submitting the SAS notification or application

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

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

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

Read more about the SAS and AP Online System.

What to do if you have problems

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

Information needed for the notification or application

SAS Category A – notification for a seriously ill patient

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

Patient

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

Product

For medicines and biologicals:

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

For medical devices:

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

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

Prescriber and submitter

- Full name.
- AHPRA registration number (prescriber must be a medical practitioner and submitter must be a health practitioner).
- Contact details (email address is preferred).

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

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

SAS Category B - application for other patients

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

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

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

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

Patient

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

Clinical justification

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

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

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

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

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

Product

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

Prescriber and submitter

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

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

SAS Category C – notification for established products

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

Patient

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

Product

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

Prescriber and submitter

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

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

What to expect once the form is submitted

Timeframes for processing and Submission status

SAS Category A and C

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

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

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

SAS Category B

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

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

Medicinal cannabis

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

How the TGA Delegate makes a SAS Category B decision

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

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

- Applications must be made in an approved form. The application should be accompanied by information relating to the 'goods' as required by the delegate and as specified on the relevant application form (see TGA application process above).
- Approvals may only be granted to a health practitioner as defined in the legislation and are subject to the conditions specified in the approval.
- The Delegate, after having considered the application, must notify the applicant of the decision on the application within 28 days of making the decision (or of a decision not to grant approval and the reasons for this decision).

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

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

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

Appealing SAS Category B decisions

Decisions made under the SAS Category B application pathway are reviewable initial decisions under section 60 of the *Therapeutic Goods Act 1989* (The Act). Under section 60, a person whose interests are affected by a reviewable initial decision can seek to have the initial decision

reconsidered. A request for reconsideration of the initial decision must be made to the Minister within 90 days after the notice is given to the person.

Conditions of approval under SAS Category B

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

The standard conditions are:

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

How long notifications and approvals are valid

SAS Category A

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

SAS Category B

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

SAS Category C

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

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

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

Obtaining unapproved therapeutic goods

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

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

Products from Australian sponsors

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

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

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

Products imported from overseas

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

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

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

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

Sponsor requirements

In order to lawfully supply a good under the SAS, the sponsor of the good must be satisfied that the good is in fact to be used under the SAS.

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

Cost to patients

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

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

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

Reporting and record keeping

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

Report adverse events and defects

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

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

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

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

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

Adverse event reporting timelines

Health practitioner reporting timelines are outlined below.

Table 2. Adverse event reporting timelines

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

Record keeping and retention of documents

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

TGA requests for patient information

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

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

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

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

Privacy of information held by the TGA

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

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

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

TGA release of information to other agencies

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

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

Freedom of information

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

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

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

Making a complaint

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

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	International Regulatory Branch and Regulatory Guidance team	January 2023
V2.0	Minor updates relating to the SAS & AP online system	Business Improvement and Compliance Section, International Regulatory Branch	March 2024

Therapeutic Goods Administration

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Reference/Publication #

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors

Previous change (https://www.tga.gov.au/node/349155/revisions/view/435018/435087/visual_inline)

Comparing
07/12/2023 - 7:47am (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-and-authorised-prescriber-pathway-guidance-sponsors)
s 22
updated guidance to include the Authorised Prescriber Pathway - 984, s 22
21/02/2023 - 12:39pm (https://www.tga.gov.au/node/349155/revisions/435087/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/349155/revisions/view/435087/559288/visual_inline) -

View mode
Full content (https://www.tg

Special Access Scheme ~~(SAS)~~and Authorised Prescriber Pathway: Guidance for Sponsors

~~Last updated~~:
7 December 2023

This guidance is to assist sponsors (https://www.tga.gov.au/node/287245) understand their requirements when supplying 'unapproved' therapeutic goods under the Special Access Scheme (SAS) and Authorised Prescriber (AP) Pathway.

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

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023-12/special-access-scheme-authorised-prescriber-pathway-guidance.pdf) [PDF, 410.7 KB]

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023-12/special-access-scheme-authorised-prescriber-pathway-guidance.docx) [Word, 390.33 KB]

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~~**Special Access Scheme (SAS): Guidance for Sponsors**~~ (https://www.tga.gov.au/sites/default/files/2023-02/special-access-scheme-sas-guidance-sponsors.pdf) ~~[PDF, 472.15 KB]~~

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Revisions for *Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors*

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Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
07/12/2023 - 7:47am by s 22 [redacted] updated guidance to include the Authorised Prescriber Pathway - 984, s 22 [redacted]. (Published)		○	*Current revision*
07/12/2023 - 7:47am by s 22 [redacted] updated guidance to include the Authorised Prescriber Pathway - 984, s 22 [redacted]. (Published)	○		**Revert**
22/03/2023 - 10:07am by s 22 [redacted] (Published)	○	○	**Revert**
21/03/2023 - 4:20pm by s 22 [redacted] (Published)	○	○	**Revert**

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20/02/2023 5:06pm by s 22 (Draft)	○	○	Revert
20/02/2023 - 4:12pm by s 22 (Draft)	○	○	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors

Last updated:
7 December 2023

This guidance is to assist sponsors (https://www.tga.gov.au/node/287245) understand their requirements when supplying 'unapproved' therapeutic goods under the Special Access Scheme (SAS) and Authorised Prescriber (AP) Pathway.

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

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023 12/special access scheme authorised prescriber pathway guidance.pdf) [PDF, 410.7 KB]

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023 12/special access scheme authorised prescriber pathway guidance.docx) [Word, 390.33 KB]

Contents

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors

Special Access Scheme (SAS): Guidance for Sponsors

This guidance is to assist sponsors (https://www.tga.gov.au/node/287245) 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.

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Supporting documents

Special Access Scheme (SAS): Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023-02/special-access-scheme-sas-guidance-sponsors.pdf) [PDF, 472.15 KB]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme: Guidance for health practitioners and sponsors

Next change (https://www.tga.gov.au/node/289228/revisions/view/435066/435126/visual_inline)

Comparing
21/02/2023 - 10:09am (https://www.tga.gov.au/node/289228/revisions/435066/view) s 22
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Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)
Special Access Scheme: Guidance for health practitioners and sponsors (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-guidance-health-practitioners-and-sponsors)

Special Access Scheme: Guidance for health practitioners and sponsors

Version 1.1, September 2017

Last updated:
5 January 2018

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) (https://www.tga.gov.au/node/4049)~~Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/287250)) 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 (https://www.tga.gov.au/node/4049)~~ARTG (https://www.tga.gov.au/node/287250) 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:

✓ All 'approved' therapeutic goods (those registered, listed or included on the ARTG) have been considered and found clinically unsuitable	
✓ The specific unapproved good you intend to access is NOT ○ substantially similar to any good on the ARTG OR ○ if substantially similar, the approved therapeutic good is NOT currently marketed ('available') in Australia	**Consider SAS Access**

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 (https://www.legislation.gov.au/Details/F2017L01301)
    - **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01305)
    - **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01303)

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.	✓ (preferred)	✓	✓
Available for all other patients	✗	✓	✓
Who can apply			
Medical practitioners can apply	✓	✓	✓
Other health care practitioners can apply	✗	✓	✓ (as per lists above)
Other health practitioners can submit on behalf of the prescribing health practitioner	✓	✓	✓
Type of goods			
Specified list of goods available	✗	✗	✓
Can be used to access Schedule 8 goods	✓	✓	✗
Can be used to access Schedule 9 goods	✗	✓	✗
Can be used to access Schedule 10 goods	✓	✓	✗
Timing of approval			
Requires TGA approval prior to supply	✗	✓	✗
Requires notification or approval letter to be sent to sponsor to authorise supply	✓	✓	✗

Requires notification to be sent to TGA within 28 days of supply	✓	✗	✓

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 (https://www.tga.gov.au/node/4049)~~Register (https://www.tga.gov.au/node/287250).

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 (http://www.pbs.gov.au/pbs/home) or phone 1800 020 613.

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

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 (https://www.tga.gov.au/node/3988)~~Personal Importation Scheme (https://www.tga.gov.au/node/287211) to import therapeutic goods from overseas.

Supporting documents

red-arrow-right.png (https://www.tga.gov.au/media/7971)

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf) [333.87 KB]

Revisions for *Special Access Scheme: Guidance for health practitioners and sponsors*

Revisions

Home

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
21/02/2023 - 6:53pm by s 22 [redacted] Setting up redirects to SAS and AP landing page (Unpublished)		○	*Current revision*
21/02/2023 - 6:53pm by s 22 [redacted] Setting up redirects to SAS and AP landing page (Unpublished)	○		**Revert**
21/02/2023 - 10:09am by s 22 [redacted] (Unpublished)	○	○	**Revert**
01/09/2022 - 12:04pm by s 22 [redacted] (Published)	○	○	**Revert**

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21/06/2022 - 10:33am by PJOoNEkkpQAOViqT (Published)	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme: Guidance for health practitioners and sponsors

Special Access Scheme: Guidance for health practitioners and sponsors

Version 1.1, September 2017

Last updated:
5 January 2018

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) (https://www.tga.gov.au/node/4049)) 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

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Therapeutic goods are required to be evaluated for quality, safety and efficacy and included in the ARTG (https://www.tga.gov.au/node/4049) 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:

✔ All 'approved' therapeutic goods (those registered, listed or included on the ARTG) have been considered and found clinically unsuitable	⇨
✔ The specific unapproved good you intend to access is NOT ○ substantially similar to any good on the ARTG OR ○ if substantially similar, the approved therapeutic good is NOT currently marketed ('available') in Australia	⇨

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 (https://www.legislation.gov.au/Details/F2017L01301)
    - **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01305)
    - **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01303)

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**	**Categor notifica**
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.	✓ (preferred)	✓	✓
Available for all other patients	✗	✓	✓
Who can apply			
Medical practitioners can apply	✓	✓	✓
Other health care practitioners can apply	✗	✓	✓ (as pe abo
Other health practitioners can submit on behalf of the prescribing health practitioner	✓	✓	✓

Category type Application/ notification	Category A notification	Category B application	Categor notifica
Type of goods			
Specified list of goods available	✗	✗	✓
Can be used to access Schedule 8 goods	✓	✓	✗
Can be used to access Schedule 9 goods	✗	✓	✗
Can be used to access Schedule 10 goods	✓	✓	✗
Timing of approval			
Requires TGA approval prior to supply	✗	✓	✗
Requires notification or approval letter to be sent to sponsor to authorise supply	✓	✓	✗
Requires notification to be sent to TGA within 28 days of supply	✓	✗	✓

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 (https://www.tga.gov.au/node/4049).

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 (http://www.pbs.gov.au/pbs/home) or phone 1800 020 613.

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

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 (https://www.tga.gov.au/node/3988) to import therapeutic goods from overseas.

Supporting documents

red-arrow-right.png (https://www.tga.gov.au/media/7971)

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf) [333.87 KB]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Special Access Scheme

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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).

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✔ All 'approved' therapeutic goods (those registered, listed or included on the ARTG) have been considered and found clinically unsuitable	⇨
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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 (https://www.legislation.gov.au/Details/F2017L01301)
    - **Medical Devices**: Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01305)
    - **Biologicals**: Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules September 2017 (https://www.legislation.gov.au/Details/F2017L01303)

Overview of the SAS pathways

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

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Medical practitioners can apply	✓	✓	✓
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Category type Application/ notification	Category A notification	Category B application	Categor notifica
Type of goods			
Specified list of goods available	✗	✗	✓
Can be used to access Schedule 8 goods	✓	✓	✗
Can be used to access Schedule 9 goods	✗	✓	✗
Can be used to access Schedule 10 goods	✓	✓	✗
Timing of approval			
Requires TGA approval prior to supply	✗	✓	✗
Requires notification or approval letter to be sent to sponsor to authorise supply	✓	✓	✗
Requires notification to be sent to TGA within 28 days of supply	✓	✗	✓

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 (https://www.tga.gov.au/node/4049).

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 (http://www.pbs.gov.au/pbs/home) or phone 1800 020 613.

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

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 (https://www.tga.gov.au/node/3988) to import therapeutic goods from overseas.

Supporting documents

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme

Next change (https://www.tga.gov.au/node/288269/revisions/view/435071/435122/visual_inline)

Comparing
21/02/2023 - 10:27am (https://www.tga.gov.au/node/288269/revisions/435071/view) s 22
21/06/2022 - 10:31am (https://www.tga.gov.au/node/288269/revisions/349217/view) PJOoNEkkpQAOViqT

Layout
Visual Inline (https://www.tga.gov.au/node/288269/revisions/view/349217/435071/visual_inline)

View mode
Full content (https://www.tga.gov.au/r

Special Access Scheme

Last updated:
~~28 March~~22 November 2022

~~On this page~~

The Special Access Scheme (SAS) allows certain health practitioners to access ~~therapeutic goods (https://www.tga.gov.au/node/3970)~~therapeutic goods (https://www.tga.gov.au/node/287205) (such as medicines, medical devices or biologicals) that are not included in the ~~Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/4049)~~Australian Register of Therapeutic Goods (ARTG) () for a single patient. Therapeutic goods that are not included in the ARTG (and are not otherwise exempt from being in the ARTG) are described by us as 'unapproved'.

Medical practitioners that wish to access an 'unapproved' therapeutic good for a class of patients rather than an individual should visit the ~~Authorised Prescribers (https://www.tga.gov.au/node/3243)~~Authorised Prescribers (https://www.tga.gov.au/node/288268) web page.

If you are seeking to access medicinal cannabis products, please go to the ~~Access to medicinal cannabis products (https://www.tga.gov.au/node/732375)~~Access to medicinal cannabis products (https://www.tga.gov.au/node/288164) web page.

SAS Online System

Submitting an application or notification through the ~~SAS Online System (https://www.tga.gov.au/node/850660)~~SAS Online System (https://www.tga.gov.au/node/287775) will reduce processing times.

~~SAS Online System~~ (https://compliance.health.gov.au/sas/)

Submission by a health practitioner

SAS applications and notifications can only be submitted by certain registered health practitioners. Individual patients should discuss the suitability of using an 'unapproved' therapeutic good with a health practitioner.

'Unapproved' therapeutic goods have not been evaluated by us for quality, safety, efficacy or performance. Therefore, the prescribing health practitioner must consider the available evidence to support the use of the 'unapproved' product and any potential risks for the individual patient.

The ~~responsibilities of the prescribing health practitioner (/node/758721#resp)~~responsibilities of the prescribing health practitioner (/node/286058#resp) include adhering to relevant standards of good medical practice and obtaining informed consent. The prescribing health practitioner also accepts responsibility for the use of an 'unapproved' therapeutic good and any associated adverse reactions.

SAS pathways

There are three SAS pathways available to access 'unapproved' therapeutic goods. The prescribing health practitioner is responsible for deciding which pathway is most suitable for their patient.

Open all (https://www.tga.gov.auvoid(0)) | Close all (https://www.tga.gov.auvoid(0))

You will not receive acknowledgement from us when you make a SAS Category A or Category C notification. These notification pathways do not require approval from the TGA.

SAS category A: notification for a patient defined as seriously ill

Category A is a **notification** pathway that may be accessed by a prescribing medical practitioner or by a health practitioner on behalf of a prescribing medical practitioner.

Category A patients are defined as being seriously ill if:

- For medicines and biologicals, they have 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, they have 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.

A completed Category A form must be sent to the TGA:

- within 28 days after the medicine or biological is given to the person; or
- within 28 days after the use of the exempt medical device.

Substances in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by State or Territory law) cannot be accessed through SAS Category A.

SAS category B: application pathway

Category B is an application pathway that can be accessed by health practitioners (usually medical or dental practitioners) if the patient does not fit the Category A definition and if the therapeutic good is not authorised for supply under the SAS Category C notification pathway.

Category B applications must be approved by TGA before the 'unapproved' product may be supplied to the patient:

- The application must be completed in full and include three patient identifiers, the patient diagnosis and indication, product details and prescriber details.
- The application requires a clinical justification for the use of the product, which should summarise:
  - Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance.
  - An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Supporting evidence may be requested by the TGA for some novel indications.

In some instances, evidence of specialist support from a practitioner with appropriate expertise may also be requested.

SAS category C: notification of use of specified therapeutic goods

Category C is a notification pathway that allows certain types of health practitioners to supply therapeutic goods that are deemed to have an established history of use. These goods are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications.

A completed Category C form must be sent to the TGA within 28 days of the therapeutic goods being supplied.

There are separate lists for medicines, medical devices and biologicals. See the lists at ~~Special Access Scheme rules (https://www.tga.gov.au/node/758892)~~Special Access Scheme rules (https://www.tga.gov.au/node/287656).

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Guidance and FAQs

- ~~SAS guidance for use of online system (https://www.tga.gov.au/node/850658)~~SAS guidance for use of online system (https://www.tga.gov.au/node/289618)
  Users of the SAS online system should refer to the user guidance which provides information on the system's features and functionality.
- ~~SAS online system quick reference guide: medicinal cannabis (https://www.tga.gov.au/node/942666)~~SAS online system quick reference guide: medicinal cannabis (https://www.tga.gov.au/node/289693)
  A quick guide for submitting SAS applications for medicinal cannabis products using the online system
- ~~SAS guidance tool for access to unapproved therapeutic goods (https://www.tga.gov.au/node/758694)~~SAS guidance tool for access to unapproved therapeutic goods (https://www.tga.gov.au/node/287650)
  As a compliance aid, the guidance tool assists health practitioners in determining the most appropriate pathway (if any) to access unapproved therapeutic goods
- ~~SAS guidance for health practitioners and sponsors (https://www.tga.gov.au/node/4036)~~SAS guidance for health practitioners and sponsors (https://www.tga.gov.au/node/289228)
  Guidance for health practitioners and sponsors outlining the various access pathways and their regulatory obligations when accessing and supplying unapproved therapeutic goods
- ~~Access to medicinal cannabis products (https://www.tga.gov.au/node/769199)~~Access to medicinal cannabis products (https://www.tga.gov.au/node/137873)
  Information relevant to accessing unapproved medicinal cannabis products
- ~~SAS frequently asked questions (https://www.tga.gov.au/node/736644)~~SAS frequently asked questions (https://www.tga.gov.au/node/287625)
  Questions and answers for consumers, health practitioners and sponsors relating to the SAS
- ~~Access to unapproved therapeutic goods (https://www.tga.gov.au/node/4030)~~Access to unapproved therapeutic goods (https://www.tga.gov.au/node/287240)

Forms

The ~~SAS Online System (https://www.tga.gov.au/node/850660)~~SAS Online System (https://www.tga.gov.au/node/287775) is the preferred method of submission to reduce processing times for applicants. For commonly requested products, the timeframe between receipt of an online application by the TGA until a response is sent to the applicant, is typically 2 to 3 working days. This timeframe may be extended for products not previously requested under the SAS or where further information is required from the applicant.

Access the SAS Online System (https://compliance.health.gov.au/sas/)

Paper forms

Paper forms are available for use in exceptional circumstances, such as where the health practitioner is unable to access the SAS Online System.

Paper forms must be processed manually by our staff. Therefore, you must allow sufficient time (at least 2-7 business days) for paper applications to be processed.

Email forms to SAS@health.gov.au (preferred method) or fax to 02 6203 1105. **Note:** For email attachments, we prefer PDF and Microsoft Word documents.

To assist in timely processing, please ensure your submission is:

- Legible (typed submissions preferred)
- On the most current version of the form
- Completed in full with signature and date (provide **3 patient identifiers** as well as the treating health practitioner's name and AHPRA number. A clinical justification is also required for all Category B applications)

Please ensure each form is sent as a separate document.

~~How to access a pdf or Word document~~ (https://www.tga.gov.au/accessing-documents-website)

Paper version of SAS forms

~~Category A~~

- ~~SAS Category A form (pdf,158kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form-01.pdf)

- ~~SAS Category A form (docx,129kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form.docx)

~~**Category B**~~

- ~~SAS Category B form (pdf,165kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form-2020-10-06.pdf)
- ~~SAS Category B form (docx,129kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form.docx)

~~**Category C**~~

- ~~SAS Category C form (pdf,256kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.pdf)
- ~~SAS Category C form (docx,146kb)~~ (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.docx)

~~**Sponsor reporting obligations under the *Therapeutic Goods Regulations 1990* (reg 47B)**~~

~~Sponsors (importers/manufacturers) are reminded that they must report to the TGA every six months in relation to unapproved therapeutic goods supplied under the SAS and Authorised Prescriber (AP) schemes.~~

~~Regulation 47B of the *Therapeutic Goods Regulations 1990* outlines the requirement for the sponsor (importer) to submit six-monthly supply reports to the TGA listing the product (brand name) details and quantities supplied in Australia in the relevant period. 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.~~

- ~~Six monthly report - supply of unapproved therapeutic goods by a sponsor (pdf,87kb)~~ (https://www.tga.gov.au/sites/default/files/six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor.pdf)
- ~~Six monthly report - supply of unapproved therapeutic goods by a sponsor (docx,142kb)~~ (https://www.tga.gov.au/sites/default/files/six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor.docx)

~~Reports must be provided by email to eps@health.gov.au~~

Category A

- SAS Category A form (pdf,158kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form-01.pdf)
- SAS Category A form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form.docx)

Category B

- SAS Category B form (pdf,165kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form-2020-10-06.pdf)
- SAS Category B form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form.docx)

Category C

- SAS Category C form (pdf,256kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.pdf)
- SAS Category C form (docx,146kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.docx)

Contact details for enquiries about the Special Access Scheme

If your enquiry is not about the SAS, see: ~~Contact the TGA (https://www.tga.gov.au/node/3859)~~Contact the TGA (https://www.tga.gov.au/node/287148)

~~Email:~~~~SAS@health.gov.au~~

~~Phone~~Email:

- ~~1800 020 653~~
- ~~+61 2 6289 4632~~
- SAS@health.gov.au - general therapeutic good SAS enquiries
- medicinal.cannabis@health.gov.au - medicinal cannabis SAS enquiries

~~Fax~~Phone: ~~+61 2 6203 1105~~1800 020 653

Post: SAS, ~~Pharmacovigilance and Special Access~~International Regulatory Branch, ~~Therapeutic Goods Administration~~TGA, PO Box 100, ~~Woden~~Canberra ACT ~~2606, Australia~~

~~Street address (for deliveries):~~ ~~Therapeutic Goods Administration, 136 Narrabundah Lane, Symonston ACT 2609,~~2601 Australia

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Document 179

Revisions for *Special Access Scheme*

Revisions

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Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
21/02/2023 - 6:38pm by s 22 Setting up redirects to SAS and AP landing page (Unpublished)		○	*Current revision*
21/02/2023 - 6:38pm by s 22 Setting up redirects to SAS and AP landing page (Unpublished)	○		**Revert**
21/02/2023 - 5:16pm by s 22 Setting up redirects to SAS and AP landing page (Unpublished)	○	○	**Revert**
21/02/2023 - 10:27am by s 22 (Unpublished)	○	○	**Revert**
12/01/2023 - 1:23pm by s 22 Amending broken link to ARTG in first paragraph. (Published)	○	○	**Revert**

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Revision	Operations
22/11/2022 11:38am by s 22 [13992] updates to contact details s 22 (Published)	Revert
30/09/2022 - 2:26pm by s 22 added TOC, removed PDF download instructions, took forms out of accordion, fixed heading structure in Forms section, removed icons from contact information (Published)	Revert
30/09/2022 2:24pm by s 22 (Draft)	Revert
30/09/2022 - 2:14pm by s 22 (Draft)	Revert
30/09/2022 - 2:10pm by s 22 removed 'how to download a PDF' (Draft)	Revert
29/08/2022 - 10:43am by s 22 (Published)	Revert
11/08/2022 - 3:41pm by s 22 [13439] removed sponsor section from forms - s 22 (Published)	Revert
25/07/2022 - 9:09am by s 22 (Published)	Revert
21/06/2022 - 10:31am by PJOoNEkkpQAOViqT (Published)	Revert

Page not found

Revision	Operations
21/06/2022 10:31am by PJOoNEkkpQAOViqT (Published)	Revert
21/06/2022 - 10:31am by PJOoNEkkpQAOViqT (Published)	Revert

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Last updated:
28 March 2022

The Special Access Scheme (SAS) allows certain health practitioners to access therapeutic goods (https://www.tga.gov.au/node/3970) (such as medicines, medical devices or biologicals) that are not included in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/4049) for a single patient. Therapeutic goods that are not included in the ARTG (and are not otherwise exempt from being in the ARTG) are described by us as 'unapproved'.

Medical practitioners that wish to access an 'unapproved' therapeutic good for a class of patients rather than an individual should visit the Authorised Prescribers (https://www.tga.gov.au/node/3243) web page.

If you are seeking to access medicinal cannabis products, please go to the Access to medicinal cannabis products (https://www.tga.gov.au/node/732375) web page.

SAS Online System

Submitting an application or notification through the SAS Online System (https://www.tga.gov.au/node/850660) will reduce processing times.

SAS Online System (https://compliance.health.gov.au/sas/)

Submission by a health practitioner

SAS applications and notifications can only be submitted by certain registered health practitioners. Individual patients should discuss the suitability of using an 'unapproved' therapeutic good with a health practitioner.

'Unapproved' therapeutic goods have not been evaluated by us for quality, safety, efficacy or performance. Therefore, the prescribing health practitioner must consider the available evidence to support the use of the 'unapproved' product and any potential risks for the individual patient.

The responsibilities of the prescribing health practitioner (/node/758721#resp) include adhering to relevant standards of good medical practice and obtaining informed consent. The prescribing health practitioner also accepts responsibility for the use of an 'unapproved' therapeutic good and any associated adverse reactions.

SAS pathways

Open all (#) | Close all (#)

There are three SAS pathways available to access 'unapproved' therapeutic goods. The prescribing health practitioner is responsible for deciding which pathway is most suitable for their patient.

You will not receive acknowledgement from us when you make a SAS Category A or Category C notification. These notification pathways do not require approval from the TGA.

SAS category A: notification for a patient defined as seriously ill

Category A is a **notification** pathway that may be accessed by a prescribing medical practitioner or by a health practitioner on behalf of a prescribing medical practitioner.

Category A patients are defined as being seriously ill if:

- For medicines and biologicals, they have 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, they have 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.

A completed Category A form must be sent to the TGA:

- within 28 days after the medicine or biological is given to the person; or
- within 28 days after the use of the exempt medical device.

Substances in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by State or Territory law) cannot be accessed through SAS Category A.

SAS category B: application pathway

Category B is an application pathway that can be accessed by health practitioners (usually medical or dental practitioners) if the patient does not fit the Category A definition and if the therapeutic good is not authorised for supply under the SAS Category C notification pathway.

Category B applications must be approved by TGA before the 'unapproved' product may be supplied to the patient:

- The application must be completed in full and include three patient identifiers, the patient diagnosis and indication, product details and prescriber details.
- The application requires a clinical justification for the use of the product, which should summarise:
    - Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance.
    - An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Supporting evidence may be requested by the TGA for some novel indications.

In some instances, evidence of specialist support from a practitioner with appropriate expertise may also be requested.

SAS category C: notification of use of specified therapeutic goods

Category C is a notification pathway that allows certain types of health practitioners to supply therapeutic goods that are deemed to have an established history of use. These goods are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications.

A completed Category C form must be sent to the TGA within 28 days of the therapeutic goods being supplied.

There are separate lists for medicines, medical devices and biologicals. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/758892).

Guidance and FAQs

- SAS guidance for use of online system (https://www.tga.gov.au/node/850658)
  Users of the SAS online system should refer to the user guidance which provides information on the system's features and functionality.
- SAS online system quick reference guide: medicinal cannabis (https://www.tga.gov.au/node/942666)
  A quick guide for submitting SAS applications for medicinal cannabis products using the online system
- SAS guidance tool for access to unapproved therapeutic goods (https://www.tga.gov.au/node/758694)
  As a compliance aid, the guidance tool assists health practitioners in determining the most appropriate pathway (if any) to access unapproved therapeutic goods
- SAS guidance for health practitioners and sponsors (https://www.tga.gov.au/node/4036)
  Guidance for health practitioners and sponsors outlining the various access pathways and their regulatory obligations when accessing and supplying unapproved therapeutic goods
- Access to medicinal cannabis products (https://www.tga.gov.au/node/769199)
  Information relevant to accessing unapproved medicinal cannabis products
- SAS frequently asked questions (https://www.tga.gov.au/node/736644)
  Questions and answers for consumers, health practitioners and sponsors relating to the SAS
- Access to unapproved therapeutic goods (https://www.tga.gov.au/node/4030)

Forms

The SAS Online System (https://www.tga.gov.au/node/850660) is the preferred method of submission to reduce processing times for applicants. For commonly requested products, the timeframe between receipt of an online application by the TGA until a response is sent to the applicant, is typically 2 to 3 working days. This timeframe may be extended for products not previously requested under the SAS or where further information is required from the applicant.

SAS Online System (https://compliance.health.gov.au/sas/)

Paper forms are available for use in exceptional circumstances, such as where the health practitioner is unable to access the SAS Online System.

Paper forms must be processed manually by our staff. Therefore, you must allow sufficient time (at least 2 7 business days) for paper applications to be processed.

Email forms to SAS@health.gov.au (preferred method) or fax to 02 6203 1105. **Note:** For email attachments, we prefer PDF and Microsoft Word documents.

To assist in timely processing, please ensure your submission is:

- Legible (typed submissions preferred)
- On the most current version of the form
- Completed in full with signature and date (provide **3 patient identifiers** as well as the treating health practitioner's name and AHPRA number. A clinical justification is also required for all Category B applications)

Please ensure each form is sent as a separate document.

How to access a pdf or Word document (https://www.tga.gov.au/accessing-documents-website)

SAS forms

Category A

- SAS Category A form (pdf,158kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form-01.pdf)
- SAS Category A form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form.docx)

Category B

- SAS Category B form (pdf,165kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form-2020-10-06.pdf)
- SAS Category B form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form.docx)

Category C

- SAS Category C form (pdf,256kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.pdf)

- SAS Category C form (docx,146kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form-01.docx)

Sponsor reporting obligations under the *Therapeutic Goods Regulations 1990* (reg 47B)

Sponsors (importers/manufacturers) are reminded that they must report to the TGA every six months in relation to unapproved therapeutic goods supplied under the SAS and Authorised Prescriber (AP) schemes.
Regulation 47B of the *Therapeutic Goods Regulations 1990* outlines the requirement for the sponsor (importer) to submit six-monthly supply reports to the TGA listing the product (brand name) details and quantities supplied in Australia in the relevant period. 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.

- Six monthly report - supply of unapproved therapeutic goods by a sponsor (pdf,87kb) (https://www.tga.gov.au/sites/default/files/six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor.pdf)
- Six monthly report - supply of unapproved therapeutic goods by a sponsor (docx,142kb) (https://www.tga.gov.au/sites/default/files/six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor.docx)

Reports must be provided by email to eps@health.gov.au

Contact details for enquiries about the Special Access Scheme

If your enquiry is not about the SAS, see: Contact the TGA (https://www.tga.gov.au/node/3859)

Email: SAS@health.gov.au

Phone:

- 1800 020 653
- +61 2 6289 4632

Fax: +61 2 6203 1105

Post: SAS, Pharmacovigilance and Special Access Branch, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606, Australia

Street address (for deliveries): Therapeutic Goods Administration, 136 Narrabundah Lane, Symonston ACT 2609, Australia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme

Special Access Scheme

Last updated:
22 November 2022

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SAS Online System (#sas)

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Forms (#forms)

Contact details for enquiries about the Special Access Scheme (#contacts)

The Special Access Scheme (SAS) allows certain health practitioners to access therapeutic goods (https://www.tga.gov.au/node/287205) (such as medicines, medical devices or biologicals) that are not included in the Australian Register of Therapeutic Goods (ARTG) () for a single patient. Therapeutic goods that are not included in the ARTG (and are not otherwise exempt from being in the ARTG) are described by us as 'unapproved'.

Medical practitioners that wish to access an 'unapproved' therapeutic good for a class of patients rather than an individual should visit the Authorised Prescribers (https://www.tga.gov.au/node/288268) web page.

If you are seeking to access medicinal cannabis products, please go to the Access to medicinal cannabis products (https://www.tga.gov.au/node/288164) web page.

SAS Online System

Submitting an application or notification through the SAS Online System (https://www.tga.gov.au/node/287775) will reduce processing times.

Access the SAS Online System (https://compliance.health.gov.au/sas/)

Submission by a health practitioner

SAS applications and notifications can only be submitted by certain registered health practitioners. Individual patients should discuss the suitability of using an 'unapproved' therapeutic good with a health practitioner.

'Unapproved' therapeutic goods have not been evaluated by us for quality, safety, efficacy or performance. Therefore, the prescribing health practitioner must consider the available evidence to support the use of the 'unapproved' product and any potential risks for the individual patient.

The responsibilities of the prescribing health practitioner (/node/286058#resp) include adhering to relevant standards of good medical practice and obtaining informed consent. The prescribing health practitioner also accepts responsibility for the use of an 'unapproved' therapeutic good and any associated adverse reactions.

SAS pathways

Open all (#) | Close all (#)

There are three SAS pathways available to access 'unapproved' therapeutic goods. The prescribing health practitioner is responsible for deciding which pathway is most suitable for their patient.

You will not receive acknowledgement from us when you make a SAS Category A or Category C notification. These notification pathways do not require approval from the TGA.

SAS category A: notification for a patient defined as seriously ill

Category A is a **notification** pathway that may be accessed by a prescribing medical practitioner or by a health practitioner on behalf of a prescribing medical practitioner.

Category A patients are defined as being seriously ill if:

- For medicines and biologicals, they have 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, they have 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.

A completed Category A form must be sent to the TGA:

- within 28 days after the medicine or biological is given to the person; or
- within 28 days after the use of the exempt medical device.

Substances in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by State or Territory law) cannot be accessed through SAS Category A.

SAS category B: application pathway

Category B is an application pathway that can be accessed by health practitioners (usually medical or dental practitioners) if the patient does not fit the Category A definition and if the therapeutic good is not authorised for supply under the SAS Category C notification pathway.

Category B applications must be approved by TGA before the 'unapproved' product may be supplied to the patient:

- The application must be completed in full and include three patient identifiers, the patient diagnosis and indication, product details and prescriber details.
- The application requires a clinical justification for the use of the product, which should summarise:
    - Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance.
    - An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Supporting evidence may be requested by the TGA for some novel indications.

In some instances, evidence of specialist support from a practitioner with appropriate expertise may also be requested.

SAS category C: notification of use of specified therapeutic goods

Category C is a notification pathway that allows certain types of health practitioners to supply therapeutic goods that are deemed to have an established history of use. These goods are specified in a list along with their indications and the type of health practitioner authorised to supply these products for the respective indications.

A completed Category C form must be sent to the TGA within 28 days of the therapeutic goods being supplied.

There are separate lists for medicines, medical devices and biologicals. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/287656).

Guidance and FAQs

- SAS guidance for use of online system (https://www.tga.gov.au/node/289618)
  Users of the SAS online system should refer to the user guidance which provides information on the system's features and functionality.
- SAS online system quick reference guide: medicinal cannabis (https://www.tga.gov.au/node/289693)
  A quick guide for submitting SAS applications for medicinal cannabis products using the online system
- SAS guidance tool for access to unapproved therapeutic goods (https://www.tga.gov.au/node/287650)
  As a compliance aid, the guidance tool assists health practitioners in determining the most appropriate pathway (if any) to access unapproved therapeutic goods
- SAS guidance for health practitioners and sponsors (https://www.tga.gov.au/node/289228)
  Guidance for health practitioners and sponsors outlining the various access pathways and their regulatory obligations when accessing and supplying unapproved therapeutic goods
- Access to medicinal cannabis products (https://www.tga.gov.au/node/137873)
  Information relevant to accessing unapproved medicinal cannabis products
- SAS frequently asked questions (https://www.tga.gov.au/node/287625)
  Questions and answers for consumers, health practitioners and sponsors relating to the SAS
- Access to unapproved therapeutic goods (https://www.tga.gov.au/node/287240)

Forms

The SAS Online System (https://www.tga.gov.au/node/287775) is the preferred method of submission to reduce processing times for applicants. For commonly requested products, the timeframe between receipt of an online application by the TGA until a response is sent to the applicant, is typically 2 to 3 working days. This timeframe may be extended for products not previously requested under the SAS or where further information is required from the applicant.

Access the SAS Online System (https://compliance.health.gov.au/sas/)

Paper forms

Paper forms are available for use in exceptional circumstances, such as where the health practitioner is unable to access the SAS Online System.

Paper forms must be processed manually by our staff. Therefore, you must allow sufficient time (at least 2 7 business days) for paper applications to be processed.

Email forms to SAS@health.gov.au (preferred method) or fax to 02 6203 1105. **Note:** For email attachments, we prefer PDF and Microsoft Word documents.

To assist in timely processing, please ensure your submission is:

- Legible (typed submissions preferred)
- On the most current version of the form
- Completed in full with signature and date (provide **3 patient identifiers** as well as the treating health practitioner's name and AHPRA number. A clinical justification is also required for all Category B applications)

Please ensure each form is sent as a separate document.

Paper version of SAS forms

Category A

- SAS Category A form (pdf,158kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form-01.pdf)

- SAS Category A form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-a-form.docx)

Category B

- SAS Category B form (pdf,165kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form-2020-10-06.pdf)
- SAS Category B form (docx,129kb) (https://www.tga.gov.au/sites/default/files/special-access-scheme-category-b-form.docx)

Category C

- SAS Category C form (pdf,256kb) (https://www.tga.gov.au/sites/default/files/special_access_scheme_category_c_form_01.pdf)
- SAS Category C form (docx,146kb) (https://www.tga.gov.au/sites/default/files/special_access_scheme_category_c_form_01.docx)

Contact details for enquiries about the Special Access Scheme

If your enquiry is not about the SAS, see: Contact the TGA (https://www.tga.gov.au/node/287148)

Email:

- SAS@health.gov.au - general therapeutic good SAS enquiries
- medicinal.cannabis@health.gov.au - medicinal cannabis SAS enquiries

Phone: 1800 020 653

Post: SAS, International Regulatory Branch, TGA, PO Box 100, Canberra ACT 2601 Australia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) Category C lists

Special Access Scheme (SAS) Category C lists

Check the lists of unapproved products you can prescribe under SAS Category C.

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

If the product you want to use is on the list and conditions are met, you can prescribe immediately under SAS Category C.

You must notify us within 28 days of use of the unapproved product.

To notify us, submit the form in the online system.

SAS and AP online system (https://compliance.health.gov.au/sas/)

You must meet all listed criteria to prescribe a product. This includes:

- dosage form
- route of administration
- indication
- practitioner type.

There are separate lists for medicines, biologicals and medical devices.

Read more about unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0).

Medicines

Search: **Show** 10 **entries**

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hyopkalemia	Medical Practitioner	M160
Betaxolol 0.25% (preservative free), Eye drops, Opthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bismuth subcitrate, Tablet, Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126
Ciclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. (dry eye syndrome)	Medical Practitioner	M12

Showing 1 to 10 of 138 entries

Biologicals

Search: **Show** 10 **entries**

Product name, active ingredient, route of administration	Indication	Practitioner type	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical Practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17

Showing 1 to 10 of 31 entries

Medical devices

Search: **Show** 10 **entries**

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
14/16 Taper Femoral Heads – Oxinium, Smith & Nephew (Catalogue no: 71342280 to 71342368)	Revision hip arthroplasty	Orthopaedic Surgeon	D28
Aequalis PerForm Plus Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D29
Aequalis PerForm Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D30
AltiVate Reverse Shoulder system- DJO Global	For arthroplasty of the shoulder	Orthopaedic Surgeon	D49
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	General Surgeon	D6
BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Obstetrics and Gynaecology Specialist	D2
BlastGen (Product No: 1205)	Embryo transfer	Obstetrics and Gynaecology Specialist	D10
CelGro Type I/III collagen scaffold, Orthocell	Articular cartilage repair: Collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint	Orthopaedic Surgeon	D32
CelGro Type I/III collagen scaffold, Orthocell	Augmentation of rotator cuff tendon repair	Orthopaedic Surgeon	D33
CollaCote Dressing	For haemostasis	Dental Practitioner	D7

Showing 1 to 10 of 44 entries

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors

Next change (https://www.tga.gov.au/node/349155/revisions/view/506136/559288/visual_inline)

Comparing
07/12/2023 - 7:47am (https://www.tga.gov.au/node/349155/revisions/506136/view) s 22
updated guidance to include the Authorised Prescriber Pathway - 984, s 22 .
20/02/2023 - 4:12pm (https://www.tga.gov.au/node/349155/revisions/435014/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/349155/revisions/view/435014/506136/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/349155/revisions/view/435014/506136/visual_inline?view_mode=full)

Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)
Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-and-authorised-prescriber-pathway-guidance-sponsors)

Special Access Scheme ~~(SAS)~~and Authorised Prescriber Pathway: Guidance for Sponsors

~~Last updated:~~
7 December 2023

This guidance is to assist sponsors (https://www.tga.gov.au/node/287245) understand their requirements when supplying 'unapproved' therapeutic goods under the Special Access Scheme (SAS) and Authorised Prescriber (AP) Pathway.

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

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023-12/special-access-scheme-authorised-prescriber-pathway-guidance.pdf) [PDF, 410.7 KB]

Special Access Scheme and Authorised Prescriber Pathway: Guidance for Sponsors (https://www.tga.gov.au/sites/default/files/2023-12/special-access-scheme-authorised-prescriber-pathway-guidance.docx) [Word, 390.33 KB]

Contents

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  - ~~When the SAS is not appropriate~~
  - ~~SAS pathways~~
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- Introduction
- Sponsor requirements
  - ~~Ensure legal supply~~
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    - ~~Advertising 'unapproved' therapeutic goods~~
  - ~~Submit six-monthly supply reports~~
  - ~~Report adverse events and defects~~
  - ~~Comply with other legislative requirements~~
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  - ~~Include the product in the ARTG for long-term supply~~
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- Advertising 'unapproved' therapeutic goods
- Include in the ARTG for long term supply
- Australian manufacturing requirements
  - ~~Medicines and biologicals~~
  - ~~Medical devices~~
- Overseas manufacture
- ~~Labelling and packaging~~

Document 184

Revisions for *Special Access Scheme (SAS) Category C lists*

Revisions

Home › › Special Access Scheme (SAS) Category C lists

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
01/07/2024 - 3:26pm by s 22 medicines table updated (Published)		○	*Current revision*
15/01/2024 - 2:08pm by s 22 WEB-1067 – s 22 (Published)	○		**Revert**
03/08/2023 - 2:53pm by s 22 (Published)	○	○	**Revert**
17/07/2023 - 12:49pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 12:45pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 12:45pm by s 22 (Published)	○	○	**Revert**
20/02/2023 - 1:59pm by s 22 updated feedback link (Draft)	○	○	**Revert**
20/02/2023 - 1:51pm by s 22 Updated 'SAS and AP online system' link to 'primary call to action' style (Draft)	○	○	**Revert**
15/02/2023 - 4:43pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 3:59pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:08pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:05pm by s 22 (Draft)	○	○	**Revert**

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) Category C lists

Special Access Scheme (SAS) Category C lists

Check the lists of unapproved products you can access under SAS Category C.

Last updated:
15 January 2024

On this page

Medicines (#medicines)
Biologicals (#biologicals)
Medical devices (#medical-devices)

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

If the product you want to use is on the list and conditions are met, you can access immediately under SAS Category C.

You must notify us within 28 days of use of the unapproved product.

To notify us, submit the form in the online system.

SAS and AP online system (https://compliance.health.gov.au/sas/)

You must meet all listed criteria to prescribe a product. This includes:

- dosage form
- route of administration
- indication
- practitioner type.

There are separate lists for medicines, biologicals and medical devices.

Read more about unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0).

Medicines

Search: **Show** 10 **entries**

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hyopkalemia	Medical Practitioner	M160
Betaxolol 0.25% (preservative free), Eye drops, Opthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bismuth subcitrate, Tablet, Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126
Ciclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. (dry eye syndrome)	Medical Practitioner	M12

Showing 1 to 10 of 139 entries

first (#) previous (#) **1 (#)** 2 (#) 3 (#) 4 (#) 5 (#) ... (#) 14 (#) next (#) last (#)

Biologicals

Search: **Show** 10 **entries**

Product name, active ingredient, route of administration	Indication	Practitioner type	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical Practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17

Showing 1 to 10 of 31 entries

« first (#) ‹ previous (#) **1 (#)** 2 (#) 3 (#) 4 (#) next › (#) last » (#)

Medical devices

Search: **Show** 10 **entries**

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
14/16 Taper Femoral Heads – Oxinium, Smith & Nephew (Catalogue no: 71342280 to 71342368)	Revision hip arthroplasty	Orthopaedic Surgeon	D28
Aequalis PerForm Plus Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D29
Aequalis PerForm Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D30
AltiVate Reverse Shoulder system- DJO Global	For arthroplasty of the shoulder	Orthopaedic Surgeon	D49
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	General Surgeon	D6
BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Obstetrics and Gynaecology Specialist	D2
BlastGen (Product No: 1205)	Embryo transfer	Obstetrics and Gynaecology Specialist	D10

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
CelGro Type I/III collagen scaffold, Orthocell	Articular cartilage repair: Collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint	Orthopaedic Surgeon	D32
CelGro Type I/III collagen scaffold, Orthocell	Augmentation of rotator cuff tendon repair	Orthopaedic Surgeon	D33
CollaCote Dressing	For haemostasis	Dental Practitioner	D7

Showing 1 to 10 of 44 entries

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Previous change (https://www.tga.gov.au/node/337903/revisions/view/435079/435091/visual_inline) Next change (https://www.tga.gov.au/node/337903/revisions/view/472340/472857/visual_inline)

Comparing

02/03/2023 - 11:51am (https://www.tga.gov.au/node/337903/revisions/472340/view) s 22

21/02/2023 - 12:43pm (https://www.tga.gov.au/node/337903/revisions/435091/view) s 22

Layout

Visual Inline (https://www.tga.gov.au/node/337903/revisions/view/435091/472340/visual_inline) -

View mode

Full content (https://www.tga.gov.au/r

Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)

Unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0)

Unapproved products for individual patients (Special Access Scheme)

You can apply to prescribe unapproved products to individual patients through the Special Access Scheme (SAS).

On this page

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

How you prescribe an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A– medical practitioners only)
- product and your practitioner type is on our established history of use list (Category C)

In these cases you can prescribe immediately. You must notify us within 28 days.

If ~~not,~~ you ~~can~~aren't eligible to apply through categories A or C, use the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to prescribe medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

You must register an account to apply using the online system.

Use the SAS and AP Online System

SAS and AP Online System ()

Register an account

1. Go to the SAS and AP Online System.
2. Select Register now.
3. Follow the prompts.

Submit the form

1. Go to the SAS and AP Online System.

2. Select the SAS Dashboard.
3. Select New SAS submission.
4. Fill in and submit the form.

To find out more read the SAS online system guidance (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-online-system-guidance).

Patient is seriously ill (Category A)

You can prescribe an unapproved therapeutic good for an individual patient who is seriously ill.

You must be a medical practitioner to use Category A.

A health practitioner can submit the form on your behalf. For example, a pharmacist.

Medicines and biologicals

To prescribe medicines or biologicals under Category A, your patient must be
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.

Medical devices

To prescribe medical devices under Category A, your patient must be
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.

If your patient is not 'seriously ill'

If your patient does not fit the 'seriously ill' definition, consider prescribing under categories C or B.

Find out other ways to access unapproved therapeutic goods (https://www.tga.gov.au/node/240).

Notify us (Category A)

If your patient is seriously ill, you can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient's medical record. As it is a notification system, you will not receive an approval letter.

The prescriber must be a medical practitioner. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Product is on our established history of use list (Category C)

We have deemed some unapproved therapeutic goods to have an established history of use.

These goods are recorded in the SAS Category C lists.

You can prescribe unapproved products on the lists.

Whether you can prescribe a product depends on your profession and the patient's medical condition. These requirements are recorded in the list.

Check the list of products with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Notify us (Category C)

You can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient's medical record. As it is a notification system, you will not receive an approval letter.

A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Application pathway (Category B)

You can prescribe unapproved products through the application pathway (Category B):

- ~~If your patient is not seriously ill (Category A)~~
- ~~products are not on the established history of use list (Category C).~~

You should do this if you can't apply through categories A or C.

You can't prescribe immediately. You must apply and wait for an approval letter.

Another health practitioner such as a pharmacist can submit the form on your behalf.

Medical and other health practitioners can apply to prescribe unapproved products through this pathway.

What you can prescribe depends upon your scope of practice, qualifications, condition being treated and state and territory requirements.

If you don't have experience with a product or condition, you must get a letter of support from an appropriate specialist.

Clinical justification

You must provide brief clinical justification that supports the use of the product for the medical condition.

Your brief clinical justification should summarise relevant past treatments and procedures trialled or considered.

You should give reasons why products in the Australian Register of Therapeutic Goods (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg) may not be an appropriate treatment.

Summarise the expected clinical benefits versus the potential risks.

How to apply (Category B)

To apply to prescribe an unapproved product under Category B, submit the form in the online system.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

How your application is assessed

Your application will be processed in 2 to 5 days.

It may take longer if we need to ask you for more information.

It will be assessed by an officer of the Therapeutic Goods Administration. The officer will be a registered medical practitioner or pharmacist.

Decisions are made on a case-by-case basis.

Obtain unapproved products

As the prescriber, it is your responsibility to source the product.

You can do this in conjunction with the dispensing pharmacy.

If you can't source a product, contact someone experienced with importing unapproved products. For example:

- a hospital pharmacy
- wholesalers
- sponsors.

We give health practitioners approval to access unapproved products.

We don't arrange the supply of therapeutic goods.

Report adverse events and product defects

You are responsible for reporting adverse events or defects from the use of unapproved products you've prescribed.

You must report any suspected adverse events or defects within 15 days of learning of them.

Report a problem or side effect (https://www.tga.gov.au/safety/reporting-problems)

Guidance document

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)

Frequently asked questions (FAQ)

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What is an unapproved therapeutic good?

In general, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg), which is regulated by the Therapeutic Goods Administration (TGA).

All other therapeutic goods not included in the ARTG are considered 'unapproved' medicines. Importantly, unapproved medicines have not been assessed by the TGA with regards to safety, quality, and effectiveness.

Which pathway should I use?

The TGA has developed an interactive accessing unapproved therapeutic goods tool (https://www.tga.gov.au/accessing-unapproved-therapeutic-goods-tool) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

Potentially any unapproved therapeutic good can be supplied through the SAS Category A and B pathways, with the exception that the SAS Category A pathway cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products. See the SAS Category C list (https://www.tga.gov.au/node/337968).

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

I am having issues with logging into my online system account, how do I get help?

In order for the Special Access Section to assist with all portal enquiries, please send an email with the below information to sas@health.gov.au:

- full first and last name
- AHPRA number
- username
- email address linked to the account
- screenshot of the issue.

The team will review the issue you are having and respond within 3 business days.

When do SAS approvals or notifications expire?

The SAS Category A notification will remain valid as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by the TGA delegate as long as the conditions of approval are upheld.

The SAS Category C notification will remain valid as long as supply of the unapproved good continues to meet the conditions specified in the SAS Category C list (https://www.tga.gov.au/node/337968), except for medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, which a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- an outline of the patient's symptoms and/or diagnosis
- details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- an appraisal of the expected clinical benefits versus the potential risks of the proposed treatment.

How should I submit my SAS application and notifications?

The preferred pathway of submission is via the SAS and AP Online System (https://compliance.health.gov.au/sas/).

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email sas@health.gov.au with your request.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements for lawful supply of an unapproved good. These requirements can be product specific, and may be checked with contacts for state/territory medicines & poisons regulation units (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/scheduling/contacts-stateterritory-medicines-poisons-regulation-units).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the SAS Category C list (https://www.tga.gov.au/node/337968).

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/controlled-substances/list) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Downloadable forms

You can apply using a downloadable PDF form in exceptional circumstances.

For example, if you are unable to access the online system.

Downloadable forms for exceptional circumstances

Information entered into the form must be typed, not handwritten.

Your application will be processed within 7 days. We won't process your application if information is missing or it is not legible.

To submit the form, email it as a PDF or Microsoft Word document to sas@health.gov.au

Category A

- SAS Category A form (pdf,158kb) ()
- SAS Category A form (docx,129kb) ()

Category B

- SAS Category B form (pdf,165kb) ()
- SAS Category B form (docx,129kb) ()

Category C

- SAS Category C form (pdf,256kb) ()
- SAS Category C form (docx,146kb) ()

Contact us

To find out more email sas@health.gov.au

Medicinal cannabis

For questions related to medicinal cannabis email medicinal.cannabis@health.gov.au

Document 187

Revisions for *Unapproved products for individual patients (Special Access Scheme)*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
17/07/2023 - 12:15pm by s 22 [redacted] Content moved to Service content type /node/375799 (Unpublished)		○	*Current revision*
02/03/2023 - 11:51am by s 22 [redacted] (Published)	○		**Revert**
02/03/2023 - 11:51am by s 22 [redacted] (Published)	○	○	**Revert**
21/02/2023 - 3:15pm by s 22 [redacted] Copy of the revision from *Tue, 2023-02-21 14:52*. (Published)	○	○	**Revert**
21/02/2023 - 3:15pm by s 22 [redacted] (Published)	○	○	**Revert**

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Revision			Operations
21/02/2023 2:52pm by s 22 (Published)	○	○	Revert
21/02/2023 - 12:43pm by s 22 (Published)	○	○	Revert
21/02/2023 11:11am by s 22 (Draft)	○	○	Revert
21/02/2023 - 10:16am by s 22 (Draft)	○	○	Revert
20/02/2023 - 3:00pm by s 22 (Draft)	○	○	Revert
20/02/2023 - 2:48pm by s 22 (Draft)	○	○	Revert
20/02/2023 - 2:28pm by s 22 (Draft)	○	○	Revert
15/02/2023 - 4:35pm by s 22 (Draft)	○	○	Revert
15/02/2023 - 4:33pm by s 22 (Draft)	○	○	Revert
15/02/2023 - 3:59pm by s 22 (Draft)	○	○	Revert

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Revision	Operations
15/02/2023 12:27pm by s 22 (Draft)	Revert
15/02/2023 - 12:26pm by s 22 (Draft)	Revert
15/02/2023 12:22pm by s 22 (Draft)	Revert
15/02/2023 - 12:03pm by s 22 (Draft)	Revert
16/12/2022 - 2:28pm by s 22 (Draft)	Revert
16/12/2022 - 2:25pm by s 22 (Draft)	Revert
16/12/2022 - 2:20pm by s 22 (Draft)	Revert
16/12/2022 - 2:12pm by s 22 (Draft)	Revert
16/12/2022 - 1:54pm by s 22 (Draft)	Revert
16/12/2022 - 1:51pm by s 22 (Draft)	Revert

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Revision	Operations
16/12/2022 1:49pm by s 22 (Draft)	Revert
16/12/2022 - 1:46pm by s 22 (Draft)	Revert
16/12/2022 1:37pm by s 22 (Draft)	Revert
16/12/2022 - 1:25pm by s 22 (Draft)	Revert
16/12/2022 - 11:42am by s 22 (Draft)	Revert
16/12/2022 - 11:33am by s 22 (Draft)	Revert
16/12/2022 - 11:22am by s 22 (Draft)	Revert
16/12/2022 - 11:21am by s 22 (Draft)	Revert
16/12/2022 - 11:18am by s 22 (Draft)	Revert
16/12/2022 - 11:03am by s 22 (Draft)	Revert

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Revision			Operations
16/12/2022 10:59am by s 22 (Draft)	○	○	Revert
14/12/2022 - 3:43pm by s 22 (Draft)	○	○	Revert
14/12/2022 3:42pm by s 22 (Draft)	○	○	Revert
14/12/2022 - 3:38pm by s 22 (Draft)	○	○	Revert
14/12/2022 - 2:29pm by s 22 (Draft)	○	○	Revert
14/12/2022 - 1:56pm by s 22 (Draft)	○	○	Revert
14/12/2022 - 1:47pm by s 22 (Draft)	○	○	Revert
14/12/2022 - 1:30pm by s 22 (Draft)	○	○	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Unapproved products for individual patients (Special Access Scheme)

You can apply to prescribe unapproved products to individual patients through the Special Access Scheme (SAS).

On this page

Patient is seriously ill (Category A) (#patient-is-seriously-ill-category-a)

Patient is seriously ill (Category A) (#patient-is-seriously-ill-category-a)

Product is on our established history of use list (Category C) (#product-is-on-our-established-history-of-use-list-category-c)

Application pathway (Category B) (#application-pathway-category-b)

Obtain unapproved products (#obtain-unapproved-products)

Report adverse events and product defects (#report-adverse-events-and-product-defects)

Guidance document (#guidance-document)

Frequently asked questions (FAQ) (#frequently-asked-questions-faq)

Downloadable forms (#downloadable-forms)

Contact us (#contact-us)

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

How you prescribe an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A)
- product is on our established history of use list (Category C)

In these cases you can prescribe immediately. You must notify us within 28 days.

If not, you can apply through the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to prescribe medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

You must register an account to apply using the online system.

Use the SAS and AP Online System

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Register an account

1. Go to the SAS and AP Online System.
2. Select Register now.
3. Follow the prompts.

Submit the form

1. Go to the SAS and AP Online System.
2. Select the SAS Dashboard.
3. Select New SAS submission.
4. Fill in and submit the form.

To find out more read the SAS online system guidance (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-online-system-guidance).

Patient is seriously ill (Category A)

You can prescribe an unapproved therapeutic good for an individual patient who is seriously ill.

You must be a medical practitioner to use Category A.

A health practitioner can submit the form on your behalf. For example, a pharmacist.

Medicines and biologicals

To prescribe medicines or biologicals under Category A, your patient must be **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.**

Medical devices

To prescribe medical devices under Category A, your patient must be **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.**

If your patient is not 'seriously ill'

If your patient does not fit the 'seriously ill' definition, consider prescribing under categories C or B.

Find out other ways to access unapproved therapeutic goods (https://www.tga.gov.au/node/240).

Notify us (Category A)

If your patient is seriously ill, you can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient's medical record. As it is a notification system, you will not receive an approval letter.

The prescriber must be a medical practitioner. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Product is on our established history of use list (Category C)

We have deemed some unapproved therapeutic goods to have an established history of use.

These goods are recorded in the SAS Category C lists.

You can prescribe unapproved products on the lists.

Whether you can prescribe a product depends on your profession and the patient's medical condition. These requirements are recorded in the list.

Check the list of products with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Notify us (Category C)

You can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient’s medical record. As it is a notification system, you will not receive an approval letter.

A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Application pathway (Category B)

You can prescribe unapproved products through the application pathway (Category B):

- If your patient is not seriously ill (Category A)
- products are not on the established history of use list (Category C).

You can’t prescribe immediately. You must apply and wait for an approval letter.

Another health practitioner such as a pharmacist can submit the form on your behalf.

Medical and other health practitioners can apply to prescribe unapproved products through this pathway.

What you can prescribe depends upon your scope of practice, qualifications, condition being treated and state and territory requirements.

If you don't have experience with a product or condition, you must get a letter of support from an appropriate specialist.

Clinical justification

You must provide brief clinical justification that supports the use of the product for the medical condition.

Your brief clinical justification should summarise relevant past treatments and procedures trialled or considered.

You should give reasons why products in the Australian Register of Therapeutic Goods (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg) may not be an appropriate treatment.

Summarise the expected clinical benefits versus the potential risks.

How to apply (Category B)

To apply to prescribe an unapproved product under Category B, submit the form in the online system.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

How your application is assessed

Your application will be processed in 2 to 5 days.

It may take longer if we need to ask you for more information.

It will be assessed by an officer of the Therapeutic Goods Administration. The officer will be a registered medical practitioner or pharmacist.

Decisions are made on a case-by-case basis.

Obtain unapproved products

As the prescriber, it is your responsibility to source the product.

You can do this in conjunction with the dispensing pharmacy.

If you can't source a product, contact someone experienced with importing unapproved products. For example:

- a hospital pharmacy
- wholesalers
- sponsors.

We give health practitioners approval to access unapproved products.

We don't arrange the supply of therapeutic goods.

Report adverse events and product defects

You are responsible for reporting adverse events or defects from the use of unapproved products you've prescribed.

You must report any suspected adverse events or defects within 15 days of learning of them.

Report a problem or side effect (https://www.tga.gov.au/safety/reporting-problems)

Guidance document

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)

Frequently asked questions (FAQ)

Open all (#) | Close all (#)

What is an unapproved therapeutic good?

In general, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg), which is regulated by the Therapeutic Goods Administration (TGA).

All other therapeutic goods not included in the ARTG are considered 'unapproved' medicines. Importantly, unapproved medicines have not been assessed by the TGA with regards to safety, quality, and effectiveness.

Which pathway should I use?

The TGA has developed an interactive accessing unapproved therapeutic goods tool (https://www.tga.gov.au/accessing-unapproved-therapeutic-goods-tool) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

Potentially any unapproved therapeutic good can be supplied through the SAS Category A and B pathways, with the exception that the SAS Category A pathway cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products. See the SAS Category C list (https://www.tga.gov.au/node/337968).

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

I am having issues with logging into my online system account, how do I get help?

In order for the Special Access Section to assist with all portal enquiries, please send an email with the below information to sas@health.gov.au:

- full first and last name
- AHPRA number
- username
- email address linked to the account
- screenshot of the issue.

The team will review the issue you are having and respond within 3 business days.

When do SAS approvals or notifications expire?

The SAS Category A notification will remain valid as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by the TGA delegate as long as the conditions of approval are upheld.

The SAS Category C notification will remain valid as long as supply of the unapproved good continues to meet the conditions specified in the SAS Category C list (https://www.tga.gov.au/node/337968), except for medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, which a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- an outline of the patient's symptoms and/or diagnosis
- details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- an appraisal of the expected clinical benefits versus the potential risks of the proposed treatment.

How should I submit my SAS application and notifications?

The preferred pathway of submission is via the SAS and AP Online System (https://compliance.health.gov.au/sas/).

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email sas@health.gov.au with your request.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements for lawful supply of an unapproved good. These requirements can be product specific, and may be checked with contacts for state/territory medicines & poisons regulation units (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/scheduling/contacts-stateterritory-medicines-poisons-regulation-units).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the SAS Category C list (https://www.tga.gov.au/node/337968).

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/controlled-substances/list) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Downloadable forms

You can apply using a downloadable PDF form in exceptional circumstances.

For example, if you are unable to access the online system.

Downloadable forms for exceptional circumstances

Information entered into the form must be typed, not handwritten.

Your application will be processed within 7 days. We won't process your application if information is missing or it is not legible.

To submit the form, email it as a PDF or Microsoft Word document to sas@health.gov.au

Category A

- SAS Category A form (pdf,158kb) ()
- SAS Category A form (docx,129kb) ()

Category B

- SAS Category B form (pdf,165kb) ()
- SAS Category B form (docx,129kb) ()

Category C

- SAS Category C form (pdf,256kb) ()
- SAS Category C form (docx,146kb) ()

Contact us

To find out more email sas@health.gov.au

Medicinal cannabis

For questions related to medicinal cannabis email medicinal.cannabis@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Unapproved products for individual patients (Special Access Scheme)

You can apply to prescribe unapproved products to individual patients through the Special Access Scheme (SAS).

On this page

Patient is seriously ill (Category A) (#patient-is-seriously-ill-category-a)

Product is on our established history of use list (Category C) (#product-is-on-our-established-history-of-use-list-category-c)

Application pathway (Category B) (#application-pathway-category-b)

Obtain unapproved products (#obtain-unapproved-products)

Report adverse events and product defects (#report-adverse-events-and-product-defects)

Guidance document (#guidance-document)

Frequently asked questions (FAQ) (#frequently-asked-questions-faq)

Downloadable forms (#downloadable-forms)

Contact us (#contact-us)

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

How you prescribe an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A – medical practitioners only)
- product and your practitioner type is on our established history of use list (Category C)

In these cases you can prescribe immediately. You must notify us within 28 days.

If you aren't eligible to apply through categories A or C, use the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to prescribe medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

You must register an account to apply using the online system.

Use the SAS and AP Online System

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Register an account

1. Go to the SAS and AP Online System.
2. Select Register now.
3. Follow the prompts.

Submit the form

1. Go to the SAS and AP Online System.
2. Select the SAS Dashboard.
3. Select New SAS submission.
4. Fill in and submit the form.

To find out more read the SAS online system guidance (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-online-system-guidance).

Patient is seriously ill (Category A)

You can prescribe an unapproved therapeutic good for an individual patient who is seriously ill.

You must be a medical practitioner to use Category A.

A health practitioner can submit the form on your behalf. For example, a pharmacist.

Medicines and biologicals

To prescribe medicines or biologicals under Category A, your patient must be **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.**

Medical devices

To prescribe medical devices under Category A, your patient must be **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.**

If your patient is not 'seriously ill'

If your patient does not fit the 'seriously ill' definition, consider prescribing under categories C or B.

Find out other ways to access unapproved therapeutic goods (https://www.tga.gov.au/node/240).

Notify us (Category A)

If your patient is seriously ill, you can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient's medical record. As it is a notification system, you will not receive an approval letter.

The prescriber must be a medical practitioner. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Product is on our established history of use list (Category C)

We have deemed some unapproved therapeutic goods to have an established history of use.

These goods are recorded in the SAS Category C lists.

You can prescribe unapproved products on the lists.

Whether you can prescribe a product depends on your profession and the patient's medical condition. These requirements are recorded in the list.

Check the list of products with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Notify us (Category C)

You can prescribe the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A copy of the form must be kept with the patient's medical record. As it is a notification system, you will not receive an approval letter.

A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Application pathway (Category B)

You can prescribe unapproved products through the application pathway (Category B):

You should do this if you can't apply through categories A or C.

You can’t prescribe immediately. You must apply and wait for an approval letter.

Another health practitioner such as a pharmacist can submit the form on your behalf.

Medical and other health practitioners can apply to prescribe unapproved products through this pathway.

What you can prescribe depends upon your scope of practice, qualifications, condition being treated and state and territory requirements.

If you don't have experience with a product or condition, you must get a letter of support from an appropriate specialist.

Clinical justification

You must provide brief clinical justification that supports the use of the product for the medical condition.

Your brief clinical justification should summarise relevant past treatments and procedures trialled or considered.

You should give reasons why products in the Australian Register of Therapeutic Goods (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg) may not be an appropriate treatment.

Summarise the expected clinical benefits versus the potential risks.

How to apply (Category B)

To apply to prescribe an unapproved product under Category B, submit the form in the online system.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

How your application is assessed

Your application will be processed in 2 to 5 days.

It may take longer if we need to ask you for more information.

It will be assessed by an officer of the Therapeutic Goods Administration. The officer will be a registered medical practitioner or pharmacist.

Decisions are made on a case-by-case basis.

Obtain unapproved products

As the prescriber, it is your responsibility to source the product.

You can do this in conjunction with the dispensing pharmacy.

If you can't source a product, contact someone experienced with importing unapproved products. For example:

- a hospital pharmacy
- wholesalers
- sponsors.

We give health practitioners approval to access unapproved products.

We don't arrange the supply of therapeutic goods.

Report adverse events and product defects

You are responsible for reporting adverse events or defects from the use of unapproved products you've prescribed.

You must report any suspected adverse events or defects within 15 days of learning of them.

Report a problem or side effect (https://www.tga.gov.au/safety/reporting-problems)

Guidance document

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)

Frequently asked questions (FAQ)

Open all (#) | Close all (#)

What is an unapproved therapeutic good?

In general, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg), which is regulated by the Therapeutic Goods Administration (TGA).

All other therapeutic goods not included in the ARTG are considered 'unapproved' medicines. Importantly, unapproved medicines have not been assessed by the TGA with regards to safety, quality, and effectiveness.

Which pathway should I use?

The TGA has developed an interactive accessing unapproved therapeutic goods tool (https://www.tga.gov.au/accessing-unapproved-therapeutic-goods-tool) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

Potentially any unapproved therapeutic good can be supplied through the SAS Category A and B pathways, with the exception that the SAS Category A pathway cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products. See the SAS Category C list (https://www.tga.gov.au/node/337968).

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

I am having issues with logging into my online system account, how do I get help?

In order for the Special Access Section to assist with all portal enquiries, please send an email with the below information to sas@health.gov.au:

- full first and last name
- AHPRA number
- username
- email address linked to the account
- screenshot of the issue.

The team will review the issue you are having and respond within 3 business days.

When do SAS approvals or notifications expire?

The SAS Category A notification will remain valid as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by the TGA delegate as long as the conditions of approval are upheld.

The SAS Category C notification will remain valid as long as supply of the unapproved good continues to meet the conditions specified in the SAS Category C list (https://www.tga.gov.au/node/337968), except for medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, which a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- an outline of the patient's symptoms and/or diagnosis
- details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- an appraisal of the expected clinical benefits versus the potential risks of the proposed treatment.

How should I submit my SAS application and notifications?

The preferred pathway of submission is via the SAS and AP Online System (https://compliance.health.gov.au/sas/).

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email sas@health.gov.au with your request.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements for lawful supply of an unapproved good. These requirements can be product specific, and may be checked with contacts for state/territory medicines & poisons regulation units (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/scheduling/contacts-stateterritory-medicines-poisons-regulation-units).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the SAS Category C list (https://www.tga.gov.au/node/337968).

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/controlled-substances/list) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Downloadable forms

You can apply using a downloadable PDF form in exceptional circumstances.

For example, if you are unable to access the online system.

Downloadable forms for exceptional circumstances

Information entered into the form must be typed, not handwritten.

Your application will be processed within 7 days. We won't process your application if information is missing or it is not legible.

To submit the form, email it as a PDF or Microsoft Word document to sas@health.gov.au

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Category B

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Category C

- SAS Category C form (pdf,256kb) ()
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Contact us

To find out more email sas@health.gov.au

Medicinal cannabis

For questions related to medicinal cannabis email medicinal.cannabis@health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Previous change (https://www.tga.gov.au/node/348992/revisions/view/435012/435089/visual_inline) Next change (https://www.tga.gov.au/node/348992/revisions/view/472346/472855/visual_inline)

Comparing

26/06/2023 - 11:29am (https://www.tga.gov.au/node/348992/revisions/472346/view) s 22
removed link to feedback as it is closed

21/02/2023 - 12:41pm (https://www.tga.gov.au/node/348992/revisions/435089/view) s 22

Layout Visual Inline (https://www.tga.gov.au/node/348992/revisions/view/435089/472346/visual_inline) **View mode** Full content (https://www.tga.gov.au/r

Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)

Special Access Scheme (SAS) and Authorised Prescriber (AP) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/special-access-scheme-sas-and-authorised-prescriber-ap)

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Health practitioners can prescribe unapproved products under SAS or as an Authorised Prescriber.

~~We are updating our content for unapproved therapeutic goods. Please give your feedback~~ (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting)~~.~~

Generally, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg).

This must be done before they can be legally supplied, imported to or exported from Australia.

Products not included in the ARTG are referred to as unapproved therapeutic goods.

If conditions are met, health practitioners can prescribe unapproved therapeutic goods.

If you supply, import or export an unapproved therapeutic good, you are the sponsor for that product.

(https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)
Prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)
(https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)

You can access unapproved goods through the Special Access Scheme or as an Authorised Prescriber

(https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors)
Supply an unapproved therapeutic good (sponsors) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors)
(https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors)

Find out the requirements to supply unapproved therapeutic goods in Australia, including through the Special Access Scheme or Authorised Prescriber scheme.

Clinical trials

Read more about how unapproved products can be supplied through clinical trials (https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials).

Individual patients

If you are a patient, talk to your health practitioner. Individual patients can't apply for access to unapproved therapeutic goods.

Individuals can legally import goods for personal use, not supply, under the Personal Importation Scheme (https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme).

Document 191

Revisions for *Special Access Scheme (SAS) and Authorised Prescriber (AP)*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
17/07/2023 - 12:09pm by s 22 [redacted] Unpublished and redirected to node/337901 (Unpublished)	○	○	*Current revision*
26/06/2023 - 11:29am by s 22 [redacted] removed link to feedback as it is closed (Published)		○	**Revert**
26/06/2023 - 11:29am by s 22 [redacted] removed link to feedback as it is closed (Published)	○	○	**Revert**
24/05/2023 - 2:39pm by s 22 [redacted] meta fix (Published)	○	○	**Revert**
24/05/2023 - 2:29pm by s 22 [redacted] meta fixes (Published)	○	○	**Revert**

Document 191

Revision	Operations
24/05/2023 1:40pm by s 22 meta updated (Published)	Revert
22/02/2023 - 2:18pm by s 22 (Published)	Revert
21/02/2023 12:41pm by s 22 (Published)	Revert
20/02/2023 - 3:33pm by s 22 (Draft)	Revert
20/02/2023 - 3:26pm by s 22 (Draft)	Revert
15/02/2023 - 4:30pm by s 22 (Draft)	Revert
15/02/2023 - 3:58pm by s 22 (Draft)	Revert
15/02/2023 - 3:47pm by s 22 (Draft)	Revert
15/02/2023 - 1:14pm by s 22 (Draft)	Revert
15/02/2023 - 12:52pm by s 22 (Draft)	Revert

Document 191

Revision	Operations
15/02/2023 11:47am by s 22 (Draft)	Revert
15/02/2023 - 11:47am by s 22 (Published)	Revert
15/02/2023 10:58am by s 22 (Draft)	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Health practitioners can prescribe unapproved products under SAS or as an Authorised Prescriber.

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

Generally, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg).

This must be done before they can be legally supplied, imported to or exported from Australia.

Products not included in the ARTG are referred to as unapproved therapeutic goods.

If conditions are met, health practitioners can prescribe unapproved therapeutic goods.

If you supply, import or export an unapproved therapeutic good, you are the sponsor for that product.

Prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)

You can access unapproved goods through the Special Access Scheme or as an Authorised Prescriber

Supply an unapproved therapeutic good (sponsors) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors)

Find out the requirements to supply unapproved therapeutic goods in Australia, including through the Special Access Scheme or Authorised Prescriber scheme.

Clinical trials

Read more about how unapproved products can be supplied through clinical trials (https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials).

Individual patients

If you are a patient, talk to your health practitioner. Individual patients can't apply for access to unapproved therapeutic goods.

Individuals can legally import goods for personal use, not supply, under the Personal Importation Scheme (https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme).

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Special Access Scheme (SAS) and Authorised Prescriber (AP)

Health practitioners can prescribe unapproved products under SAS or as an Authorised Prescriber.

Generally, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg).

This must be done before they can be legally supplied, imported to or exported from Australia.

Products not included in the ARTG are referred to as unapproved therapeutic goods.

If conditions are met, health practitioners can prescribe unapproved therapeutic goods.

If you supply, import or export an unapproved therapeutic good, you are the sponsor for that product.

Prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)

You can access unapproved goods through the Special Access Scheme or as an Authorised Prescriber

Supply an unapproved therapeutic good (sponsors) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapprove

d-therapeutic-good-sponsors)

Find out the requirements to supply unapproved therapeutic goods in Australia, including through the Special Access Scheme or Authorised Prescriber scheme.

Clinical trials

Read more about how unapproved products can be supplied through clinical trials (https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials).

Individual patients

If you are a patient, talk to your health practitioner. Individual patients can't apply for access to unapproved therapeutic goods.

Individuals can legally import goods for personal use, not supply, under the Personal Importation Scheme (https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme).

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Next change (https://www.tga.gov.au/node/375799/revisions/view/520629/561959/visual_inline)

Comparing
27/03/2024 - 5:53pm (https://www.tga.gov.au/node/375799/revisions/520629/view) s 22
WEB-1253 PETERS, Nimali
13/07/2023 - 6:01pm (https://www.tga.gov.au/node/375799/revisions/472717/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/375799/revisions/view/472717/520629/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/375799/revisions/view/472717/520629/visual_inline?view_mode=full)

Unapproved products for individual patients (Special Access Scheme)

You can apply to ~~prescribe~~access unapproved products ~~to~~for individual patients through the Special Access Scheme (SAS).

On this page

We are updating our content for unapproved therapeutic goods. Please give ~~your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting)~~your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

How you ~~prescribe~~access an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A – medical practitioners only)
- product and your practitioner type is on our established history of use list (Category C)

In these cases you can ~~prescribe~~access the unapproved product immediately. You must notify us within 28 days.

If you aren't eligible to apply through categories A or C, use the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to ~~prescribe~~access medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

To access an unapproved product for an individual patient you must use the Special Access Scheme (SAS) and Authorised Prescriber (AP) Online System. You must register an account to do so.

SAP and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Before you apply

Read about what you need to do before you apply ~~using~~to prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners).

Patient is seriously ill (Category A)

You can access an unapproved therapeutic good for an individual patient who is seriously ill.

You must be a medical practitioner to use Category A.

A health practitioner can submit the form on your behalf. For example, a pharmacist.

Medicines and biologicals

To access medicines or biologicals under Category A, your patient must be
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.

Medical devices

To access medical devices under Category A, your patient must be
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.

If your patient is not 'seriously ill'

If your patient does not fit the 'seriously ill' definition, consider applying under category B or notifying us under category C.

Find out other ways to access unapproved therapeutic goods (https://www.tga.gov.au/node/240).

Notify us (Category A)

If your patient is seriously ill, you can access the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

The prescriber must be a medical practitioner. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Product is on our established history of use list (Category C)

We have deemed some unapproved therapeutic goods to have an established history of use.

These goods are recorded in the SAS Category C lists.

You can access unapproved products on the lists.

Whether you can access a product depends on your profession and the patient's medical condition. These requirements are recorded in the list.

Check the list of products with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Notify us (Category C)

You can access the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Application pathway (Category B)

You can apply to access unapproved products through the application pathway (Category B):

You should do this if you can't access the unapproved product through categories A or C.

You must apply and wait for an approval letter.

Another health practitioner such as a pharmacist can submit the form on your behalf.

Medical and other health practitioners can apply to access unapproved products through this pathway.

What you can prescribe depends upon your scope of practice, qualifications, condition being treated and state and territory requirements.

If you don't have experience with a product or condition, you must get a letter of support from an appropriate specialist.

Clinical justification

You must provide brief clinical justification that supports the use of the product for the medical condition.

Your brief clinical justification should summarise relevant past treatments and procedures trialled or considered.

You should give reasons why products in the Australian Register of Therapeutic Goods (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg) may not be an appropriate treatment.

Summarise the expected clinical benefits versus the potential risks.

How to apply (Category B)

To apply to access an unapproved product under Category B, submit the form in the online system.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

How your application is assessed

Your application will be processed in 2 to 5 days.

It may take longer if we need to ask you for more information.

It will be assessed by an officer of the Therapeutic Goods Administration. The officer will be a registered medical practitioner or pharmacist.

Decisions are made on a case-by-case basis.

Obtain unapproved products

As the prescriber, it is your responsibility to source the product.

You can do this in conjunction with the dispensing pharmacy.

If you can't source a product, contact someone experienced with importing unapproved products. For example:

- a hospital pharmacy
- wholesalers
- sponsors.

We give health practitioners approval to access unapproved products.

We don't arrange the supply of therapeutic goods.

Report adverse events and product defects

You are responsible for reporting adverse events or defects from the use of unapproved products you've prescribed.

You must report any suspected adverse events or defects within 15 days of learning of them.

Report a problem or side effect (https://www.tga.gov.au/safety/reporting-problems)

Guidance document

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods (https://www.tga.gov.au/resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)

Frequently asked questions (FAQ)

Open All Close All

What is an unapproved therapeutic good?

In general, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg), which is regulated by the Therapeutic Goods Administration (TGA).

All other therapeutic goods not included in the ARTG are considered 'unapproved' medicines. Importantly, unapproved medicines have not been assessed by the TGA with regards to safety, quality, and effectiveness.

Which pathway should I use?

The TGA has developed an interactive accessing unapproved therapeutic goods tool (https://www.tga.gov.au/accessing-unapproved-therapeutic-goods-tool) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

Potentially any unapproved therapeutic good can be supplied through the SAS Category A and B pathways, with the exception that the SAS Category A pathway cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products. See the SAS Category C list (https://www.tga.gov.au/node/337968).

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

I am having issues with logging into my online system account, how do I get help?

In order for the Special Access Section to assist with all online system enquiries, please send an email with the below information to SAS.Support@Health.gov.au:

- full first and last name
- AHPRA number
- username
- email address linked to the account
- screenshot of the issue.

The team will review the issue you are having and respond within 3 business days.

When do SAS approvals or notifications expire?

The SAS Category A notification will remain valid as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by the TGA delegate as long as the conditions of approval are upheld.

The SAS Category C notification will remain valid as long as supply of the unapproved good continues to meet the conditions specified in the SAS Category C list (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists), except for medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, which a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- an outline of the patient's symptoms and/or diagnosis
- details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- an appraisal of the expected clinical benefits versus the potential risks of the proposed treatment.

How should I submit my SAS application and notifications?

Submissions must be made via the SAS and AP Online System ().

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email sas@health.gov.au with your request.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements for lawful supply of an unapproved good. These requirements can be product specific, and may be checked with contacts for state/territory medicines & poisons regulation units (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/scheduling/contacts-stateterritory-medicines-poisons-regulation-units).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the SAS Category C list (https://www.tga.gov.au/node/337968).

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances () is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (). For further information please email dcs@health.gov.au

Contact us

To find out more email sas@health.gov.au

Medicinal cannabis

For questions related to medicinal cannabis email medicinal.cannabis@health.gov.au

Prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners)

SAS and AP Online System Information (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme)

Unapproved products for multiple patients (Authorised Prescriber) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-multiple-patients-authorised-prescriber)

List of therapeutic goods with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use)

Submit Special Access Scheme (SAS) applications and notifications through the SAS and AP Online System

Online form

Revisions for *Unapproved products for individual patients (Special Access Scheme)*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
13/08/2024 - 9:48am by s 22 1635 - s 22 - s 22 (Published)	○		*Current revision*
27/03/2024 - 5:53pm by s 22 WEB 1253 s 22 (Published)	○	○	**Revert**
27/03/2024 - 8:35am by s 22 Small typo fix (Draft)	○	○	**Revert**
26/03/2024 - 4:07pm by s 22 WEB-1253 s 22 (Draft)	○	○	**Revert**
21/11/2023 - 2:06pm by s 22 added product type tag. (Published)	○	○	**Revert**
03/08/2023 - 4:20pm by s 22 (Published)	○	○	**Revert**
03/08/2023 - 2:56pm by s 22 (Published)	○	○	**Revert**
03/08/2023 - 2:34pm by s 22 (Published)	○	○	**Revert**
03/08/2023 - 2:33pm by s 22 (Published)	○	○	**Revert**
03/08/2023 - 2:24pm by s 22 (Published)	○	○	**Revert**
03/08/2023 - 2:23pm by s 22 (Published)	○	○	**Revert**
02/08/2023 - 11:43am by s 22 (Published)	○	○	**Revert**
17/07/2023 - 3:11pm by s 22 (Published)	○	○	**Revert**

Revision			Operations
17/07/2023 12:45pm by s 22 (Published)	○	○	Revert
17/07/2023 - 12:42pm by s 22 (Published)	○	○	Revert
17/07/2023 - 12:14pm by s 22 added in menu, published (Published)	○	○	Revert
14/07/2023 - 2:24pm by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:37am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:32am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:30am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:28am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:27am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:25am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:22am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:22am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:20am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:18am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:09am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:08am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:06am by s 22 (Draft)	○	○	Revert

Revision			Operations
14/07/2023 10:04am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:03am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:01am by s 22 (Draft)	○	○	Revert
14/07/2023 - 10:00am by s 22 (Draft)	○	○	Revert
13/07/2023 - 6:01pm by s 22 (Draft)	◯		Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Unapproved products for individual patients (Special Access Scheme)

You can apply to prescribe unapproved products to individual patients through the Special Access Scheme (SAS).

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

How you prescribe an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A – medical practitioners only)
- product and your practitioner type is on our established history of use list (Category C)

In these cases you can prescribe immediately. You must notify us within 28 days.

If you aren't eligible to apply through categories A or C, use the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to prescribe medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

You must register an account to apply using the online system.

Submit Special Access Scheme (SAS) applications and notifications through the SAS and AP Online System

Online form

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unapproved products for individual patients (Special Access Scheme)

Unapproved products for individual patients (Special Access Scheme)

You can apply to access unapproved products for individual patients through the Special Access Scheme (SAS).

On this page

Before you apply (#before-you-apply)
Patient is seriously ill (Category A) (#patient-is-seriously-ill-category-a)
Product is on our established history of use list (Category C) (#product-is-on-our-established-history-of-use-list-category-c)
Application pathway (Category B) (#application-pathway-category-b)
Obtain unapproved products (#obtain-unapproved-products)
Report adverse events and product defects (#report-adverse-events-and-product-defects)
Guidance document (#guidance-document)
Frequently asked questions (FAQ) (#frequently-asked-questions-faq)
Contact us (#contact-us)

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

How you access an unapproved product for an individual patient depends on if the:

- patient is seriously ill (Category A – medical practitioners only)
- product and your practitioner type is on our established history of use list (Category C)

In these cases you can access the unapproved product immediately. You must notify us within 28 days.

If you aren't eligible to apply through categories A or C, use the application pathway (Category B). You must apply and wait for approval before prescribing.

If you want to access medicinal cannabis, it is generally faster to do so through the application pathway (Category B).

To access an unapproved product for an individual patient you must use the Special Access Scheme (SAS) and Authorised Prescriber (AP) Online System. You must register an account to do so.

SAP and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Before you apply

Read about what you need to do before you apply to prescribe an unapproved therapeutic good (health practitioners) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners).

Patient is seriously ill (Category A)

You can access an unapproved therapeutic good for an individual patient who is seriously ill.

You must be a medical practitioner to use Category A.

A health practitioner can submit the form on your behalf. For example, a pharmacist.

Medicines and biologicals

To access medicines or biologicals under Category A, your patient must be
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.

Medical devices

To access medical devices under Category A, your patient must be
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.

If your patient is not 'seriously ill'

If your patient does not fit the 'seriously ill' definition, consider applying under category B or notifying us under category C.

Find out other ways to access unapproved therapeutic goods (https://www.tga.gov.au/node/240).

Notify us (Category A)

If your patient is seriously ill, you can access the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

The prescriber must be a medical practitioner. A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Product is on our established history of use list (Category C)

We have deemed some unapproved therapeutic goods to have an established history of use.

These goods are recorded in the SAS Category C lists.

You can access unapproved products on the lists.

Whether you can access a product depends on your profession and the patient's medical condition. These requirements are recorded in the list.

Check the list of products with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Notify us (Category C)

You can access the unapproved product immediately.

You must submit a form to notify us within 28 days of use of the unapproved product. You can fill in and submit the form in the online system.

A health practitioner such as a pharmacist can submit the form on behalf of the prescriber.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

Application pathway (Category B)

You can apply to access unapproved products through the application pathway (Category B):

You should do this if you can't access the unapproved product through categories A or C.

You must apply and wait for an approval letter.

Another health practitioner such as a pharmacist can submit the form on your behalf.

Medical and other health practitioners can apply to access unapproved products through this pathway.

What you can prescribe depends upon your scope of practice, qualifications, condition being treated and state and territory requirements.

If you don't have experience with a product or condition, you must get a letter of support from an appropriate specialist.

Clinical justification

You must provide brief clinical justification that supports the use of the product for the medical condition.

Your brief clinical justification should summarise relevant past treatments and procedures trialled or considered.

You should give reasons why products in the Australian Register of Therapeutic Goods (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg) may not be an appropriate treatment.

Summarise the expected clinical benefits versus the potential risks.

How to apply (Category B)

To apply to access an unapproved product under Category B, submit the form in the online system.

SAS and AP Online System (https://compliance.health.gov.au/sas/)

Read more about the SAS and AP Online System. (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/sas-and-ap-online-system-information)

How your application is assessed

Your application will be processed in 2 to 5 days.

It may take longer if we need to ask you for more information.

It will be assessed by an officer of the Therapeutic Goods Administration. The officer will be a registered medical practitioner or pharmacist.

Decisions are made on a case-by-case basis.

Obtain unapproved products

As the prescriber, it is your responsibility to source the product.

You can do this in conjunction with the dispensing pharmacy.

If you can't source a product, contact someone experienced with importing unapproved products. For example:

- a hospital pharmacy
- wholesalers
- sponsors.

We give health practitioners approval to access unapproved products.

We don't arrange the supply of therapeutic goods.

Report adverse events and product defects

You are responsible for reporting adverse events or defects from the use of unapproved products you've prescribed.

You must report any suspected adverse events or defects within 15 days of learning of them.

Report a problem or side effect (https://www.tga.gov.au/safety/reporting-problems)

Guidance document

Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods (https://www.tga.gov.au_resources/resource/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods)

Frequently asked questions (FAQ)

Open All | Close All

What is an unapproved therapeutic good?

In general, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg), which is regulated by the Therapeutic Goods Administration (TGA).

All other therapeutic goods not included in the ARTG are considered 'unapproved' medicines. Importantly, unapproved medicines have not been assessed by the TGA with regards to safety, quality, and effectiveness.

Which pathway should I use?

The TGA has developed an interactive accessing unapproved therapeutic goods tool (https://www.tga.gov.au/accessing-unapproved-therapeutic-goods-tool) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

Potentially any unapproved therapeutic good can be supplied through the SAS Category A and B pathways, with the exception that the SAS Category A pathway cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products. See the SAS Category C list (https://www.tga.gov.au/node/337968).

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

I am having issues with logging into my online system account, how do I get help?

In order for the Special Access Section to assist with all online system enquiries, please send an email with the below information to SAS.Support@Health.gov.au:

- full first and last name
- AHPRA number
- username
- email address linked to the account
- screenshot of the issue.

The team will review the issue you are having and respond within 3 business days.

When do SAS approvals or notifications expire?

The SAS Category A notification will remain valid as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by the TGA delegate as long as the conditions of approval are upheld.

The SAS Category C notification will remain valid as long as supply of the unapproved good continues to meet the conditions specified in the SAS Category C list (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists), except for medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, which a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- an outline of the patient's symptoms and/or diagnosis
- details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- an appraisal of the expected clinical benefits versus the potential risks of the proposed treatment.

How should I submit my SAS application and notifications?

Submissions must be made via the SAS and AP Online System ().

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email sas@health.gov.au with your request.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements for lawful supply of an unapproved good. These requirements can be product specific, and may be checked with contacts for state/territory medicines & poisons regulation units (https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/scheduling/contacts-stateterritory-medicines-poisons-regulation-units).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the SAS Category C list (https://www.tga.gov.au/node/337968).

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances () is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (). For further information please email dcs@health.gov.au

Contact us

To find out more email sas@health.gov.au

Medicinal cannabis

For questions related to medicinal cannabis email medicinal.cannabis@health.gov.au

Submit Special Access Scheme (SAS) applications and notifications through the SAS and AP Online System

Online form

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme: frequently asked questions

Comparing
21/02/2023 - 10:32am (https://www.tga.gov.au/special-access-scheme-frequently-asked-questions) s 22
21/06/2022 - 10:29am (https://www.tga.gov.au/node/287625/revisions/348573/view) PJOoNEkkpQAOViqT

Layout
Visual Inline (https://www.tga.gov.au/node/287625/revisions/view/348573/472330/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/287625/revisions/view/348573/472330/visual_inline?view_mode=full)

Special Access Scheme: frequently asked questions

Last updated:
20 April 2021

The Special Access Scheme (SAS) refers to arrangements which provide for the importation and/or supply of an unapproved therapeutic good (i.e. those not included on the Australian Register of Therapeutic Goods (ARTG)) for a single patient, on a case-by-case basis.

Consumers

Open all (https://www.tga.gov.auvoid(0)) | Close all (https://www.tga.gov.auvoid(0))

Can I write and submit my own SAS application or notification?

An application or notification form must be completed by an appropriate health practitioner as they must be able to justify on medical grounds why their patient requires the unapproved therapeutic good.

The prescribing health practitioner (e.g., doctor) is best placed to determine the needs of the patient, including whether or not treatment with a particular unapproved therapeutic good is required. It is expected that, in accordance with good medical practice, a prescribing health practitioner will educate themselves with all available relevant information relating to an unapproved therapeutic good before using it.

It is also important to note that a prescribing health practitioner has the right to decline to prescribe an unapproved therapeutic good if they believe there is either insufficient clinical justification or no evidence to support the use of that particular product.

Does it cost to submit a SAS application or notification?

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

Are therapeutic goods accessed through the SAS available at a reduced cost or for free?

The monetary cost of a therapeutic good is set by the sponsor of the goods and/or the pharmacy through which the goods are accessed (if applicable). Unapproved therapeutic goods are also not eligible to be subsidised under the Pharmaceutical Benefits Scheme (PBS). The TGA does not consider the monetary cost of the goods when making a decision under the SAS.

In some circumstances, a sponsor of a therapeutic good may choose to provide the good on a 'compassionate basis' (compassionate supply). In these scenarios the product may attract no fee or be available at a reduced cost to the patient. Please note, this decision is made at the discretion of the sponsor.

A cheaper version of my current medication is available overseas. Can the SAS be used to allow access to this product?

Applications which give monetary reasons as a means of supporting the application will not be considered. The applicant must provide a clinical justification for the therapeutic good and its use, including reasons why the ARTG registered product available in Australia is not appropriate for their patient

In certain circumstances, patients may wish to use the ~~Personal Importation Scheme (https://www.tga.gov.au/node/5247)~~Personal Importation Scheme (https://www.tga.gov.au/node/282893) to import medicines from overseas.

Health practitioners

What is the difference between the Special Access Scheme Category A, Category B and Category C pathways?

- Category A is a **notification pathway** which can be accessed by a prescribing medical practitioner or a health practitioner 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 Category C. An approval letter from TGA is required before the good may be accessed. Approvals for medicines accessed through this pathway are typically only issued to medical and dental practitioners.
- 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. See the lists at ~~Special Access Scheme rules (https://www.tga.gov.au/node/758892)~~Special Access Scheme rules (https://www.tga.gov.au/node/287656).

The TGA has developed an ~~interactive decision tool (https://www.tga.gov.au/node/758694)~~interactive decision tool (https://www.tga.gov.au/node/287650) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

For the SAS Category A and B there is no 'list' of products available. Any unapproved therapeutic good can potentially be supplied through these two schemes with one exception for SAS Category A. SAS Category A cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products under this access pathway. See the lists at ~~Special Access Scheme rules (https://www.tga.gov.au/node/758892)~~Special Access Scheme rules (https://www.tga.gov.au/node/287656).

Who can apply for access to therapeutic goods via the SAS pathways?

Applications and notifications made under the SAS pathways are completed and submitted by registered health practitioners, preferably the prescribing health practitioner, who is best placed to determine the needs of the patient, including whether or not treatment with a particular product is required. It is expected that, in accordance with good medical practice, a health practitioner will educate themselves with all relevant and available information about a therapeutic good before using it.

If a patient asks to be treated with a particular unapproved therapeutic good, a health practitioner has the right to refuse to apply to obtain the product if they believe there is either insufficient clinical justification or evidence to support the use of the therapeutic good.

What is the process for submitting a Category A notification form?

The prescribing health practitioner or another health practitioner acting on their behalf (e.g. a pharmacist) can supply therapeutic goods to seriously ill patients who meet the Category A definition, without the approval of the TGA as long as the health practitioner provides the TGA with a completed Category A notification form. A copy of the completed Category A form must be sent to TGA within 28 days of the medicine or biological being given to the person or within 28 days after the use of the exempt medical device.

The SAS Category A is a notification pathway only, and as such, the TGA does not send out a letter of approval or acknowledgment on receipt of the completed notification form.

The health practitioner is also required to send a copy of the completed Category A form to the supplier of the therapeutic good. This provides the supplier with the legal authority to supply the therapeutic good.

What is the process for submitting a Category B application form?

The prescribing health practitioner or someone acting on their behalf can submit an application to the TGA to gain access to an unapproved therapeutic good for a patient that does not fit the Category A definition. Approval of an application to supply a product is required from a delegate in the TGA. Approval by the TGA is given on a patient-by-patient basis to reflect the needs of different patients. Applications can be made by lodging a completed ~~Category B application form (/node/3244#forms)~~Category B application form (/node/288269#forms) with the TGA).

Further information on the application process can be found in the ~~Special Access Scheme Guidance for health practitioners and sponsors (https://www.tga.gov.au/node/4036)~~Special Access Scheme Guidance for health practitioners and sponsors (https://www.tga.gov.au/node/289228).

For commonly requested products, the timeframe between receipt of an application by the TGA until provision of a response to the applicant, is typically 2 to 3 working days. Applications for products not previously requested under the SAS may take longer.

Paper forms must be processed manually by our staff. Therefore, the prescriber must allow sufficient time (at least 2-7 business days) for paper applications to be processed.

If there is an urgent medical need for access to a therapeutic good, on the top of your application please write: 'URGENT'.

For a limited number of products a phone approval can be given where there is an urgent medical need. This provision is generally only available during advertised TGA shut down periods (e.g. the Christmas holiday period)

What is the process for submitting a Category C notification form?

The prescribing health practitioner or a health practitioner (eg. Pharmacist) acting on their behalf needs to complete and submit the SAS Category C form following the supply of the unapproved therapeutic good via the SAS Category C pathway. The form does not need to be completed before the good is supplied and is not required to supply the good.

The reason this pathway is referred to as a *notification* pathway is that health practitioners supplying the unapproved therapeutic good are required to notify the TGA within 28 days of supplying the good.

On our website, the TGA has made available a ~~notification form (/node/3244#forms)~~notification form (/node/288269#forms) that health practitioners must complete and provide within this specified period.

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

When do SAS approvals or notifications expire?

The SAS Category A notification form is valid indefinitely as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by a delegate in the TGA. Category B approvals remain valid as long as the conditions of approval are upheld.

The SAS Category C notification form is also valid indefinitely, unless the substance is captured by the Customs (Prohibited Imports) Regulations 1956. For medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved medicinal cannabis product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- An outline of the patient's symptoms and/or diagnosis
- Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Where should a completed SAS form be sent?

It is preferred that forms are sent via email, as single attachments, to SAS@health.gov.au. If you do not have access to email, you may fax the form to 02 6203 1105. Posting of the hardcopies is not required.

If you have filled out the application incorrectly or require an amendment to an existing application or approval letter, the applicant should contact SAS@health.gov.au or phone 02 6289 4632 to discuss.

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email SAS@health.gov.au with your request.

Please note that a copy of the form should be kept by the applicant prior to submitting the form to the TGA.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good merely because the TGA has given an approval or authority to supply the product. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements that need to be met before the product can be supplied lawfully. These requirements can be product specific and applicants need to check these with their ~~State/Territory health department (https://www.tga.gov.au/node/4448)~~State/Territory health department (https://www.tga.gov.au/node/287386).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the lists at ~~Special Access Scheme rules (https://www.tga.gov.au/node/758892)~~Special Access Scheme rules (https://www.tga.gov.au/node/287656) .

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/ws-lps-index) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Sponsors

Is an exemption under the SAS required to use an unapproved product as a demonstration or sample item (i.e. not for human therapeutic use)?

Item 3 of Schedule 5 of the *Therapeutic Goods Regulations 1990 (https://www.legislation.gov.au/Series/F1996B00406)* states that the following goods are exempt from Part 3-2 of the Act:

Samples of therapeutic goods imported, exported, manufactured, or supplied for:

a. submission to a regulatory authority; or

b. subjection to developmental or quality control procedures; or

c. examination, demonstration or display; or

d. subjection to analysis or laboratory testing procedures;

e. but not for supply for therapeutic use in humans.

Therefore, if importing therapeutic goods for research purposes only (not for supply for therapeutic use in humans), SAS exemption is not required.

Can therapeutic goods be brought into Australia for commercial supply under the SAS?

The SAS is a mechanism by which individual patients can access an unapproved therapeutic good through their health practitioner. Therapeutic goods intended for commercial supply in Australia are required to undergo an evaluation for quality safety and efficacy prior to being allowed on the market. The various mechanisms for supply of unapproved products are intended to be only temporary measures for supply, pending general marketing approval of the product.

The TGA has a responsibility to encourage at all times the use of approved (evaluated) products in Australian patients.

For the SAS Category C notification pathway, where can sponsors find products deemed to have an established history of use?

The therapeutic goods, indications and health practitioners that are authorised to supply these goods for the particular indication are included in a legislative instrument.

There are separate legislative instruments for medicines, medical devices and biologicals, respectively. These legislative instruments are publically accessible so sponsors can check to see if any of their products are included on them. See the lists at ~~Special Access Scheme rules (https://www.tga.gov.au/node/758892)~~Special Access Scheme rules (https://www.tga.gov.au/node/287656) .

Inclusion of a product in any of these legislative instruments acts as the authorisation to supply.

Sponsors are 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 one of the instruments.

Can sponsors apply to have unapproved goods added or removed from the legislative instrument?

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. For example, if TGA believed there were significant safety concerns with the good it would be removed from the instrument; and any further supply of the product would need approval via the existing Category B (application) pathway.

Is a SAS submission required for 'off-label' use of a therapeutic good?

Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, supplied in, and exported from Australia. Therapeutic goods are included in the ARTG with specific indication(s) or intended purpose(s). 'Off-label use' generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in the ARTG entry.

The TGA is not responsible for regulating health professionals or clinical practice. 'Off-label use' is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent from their patient. Therefore, no exemption, approval or authorisation is required from the TGA to allow the off-label use of a product.

In exceptional circumstances, a Special Access Scheme (SAS) submission may be required for off-label use of a medicine or biological. For example, this may occur in situations where the prescriber has directly contacted the sponsor to request access to the product for their patient through a compassionate supply arrangement. In these circumstances, the sponsor may request an SAS notification or approval to ensure legal supply of the product under the therapeutic goods legislation.

However, the TGA does not have the authority to grant an SAS Category B approval for a medical device included in the ARTG. Therefore, the SAS Category B pathway cannot be used to obtain supply of any medical device included in the ARTG, regardless of the proposed use of the device.

Revisions for *Special Access Scheme: frequently asked questions*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
21/02/2023 - 10:32am by s 22 (Unpublished)		○	*Current revision*
21/02/2023 - 10:32am by s 22 (Unpublished)	○		**Revert**
26/08/2022 - 3:29pm by s 22 (Published)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme: frequently asked questions

Special Access Scheme: frequently asked questions

Last updated:
20 April 2021

The Special Access Scheme (SAS) refers to arrangements which provide for the importation and/or supply of an unapproved therapeutic good (i.e. those not included on the Australian Register of Therapeutic Goods (ARTG)) for a single patient, on a case-by-case basis.

Consumers

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Can I write and submit my own SAS application or notification?

An application or notification form must be completed by an appropriate health practitioner as they must be able to justify on medical grounds why their patient requires the unapproved therapeutic good.

The prescribing health practitioner (e.g., doctor) is best placed to determine the needs of the patient, including whether or not treatment with a particular unapproved therapeutic good is required. It is expected that, in accordance with good medical practice, a prescribing health practitioner will educate themselves with all available relevant information relating to an unapproved therapeutic good before using it.

It is also important to note that a prescribing health practitioner has the right to decline to prescribe an unapproved therapeutic good if they believe there is either insufficient clinical justification or no evidence to support the use of that particular product.

Does it cost to submit a SAS application or notification?

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

Are therapeutic goods accessed through the SAS available at a reduced cost or for free?

The monetary cost of a therapeutic good is set by the sponsor of the goods and/or the pharmacy through which the goods are accessed (if applicable). Unapproved therapeutic goods are also not eligible to be subsidised under the Pharmaceutical Benefits Scheme (PBS). The TGA does not consider the monetary cost of the goods when making a decision under the SAS.

In some circumstances, a sponsor of a therapeutic good may choose to provide the good on a 'compassionate basis' (compassionate supply). In these scenarios the product may attract no fee or be available at a reduced cost to the patient. Please note, this decision is made at the discretion of the sponsor.

A cheaper version of my current medication is available overseas. Can the SAS be used to allow access to this product?

Applications which give monetary reasons as a means of supporting the application will not be considered. The applicant must provide a clinical justification for the therapeutic good and its use, including reasons why the ARTG registered product available in Australia is not appropriate for their patient

In certain circumstances, patients may wish to use the Personal Importation Scheme (https://www.tga.gov.au/node/5247) to import medicines from overseas.

Health practitioners

What is the difference between the Special Access Scheme Category A, Category B and Category C pathways?

- Category A is a **notification pathway** which can be accessed by a prescribing medical practitioner or a health practitioner 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 Category C. An approval letter from TGA is required before the good may be accessed. Approvals for medicines accessed through this pathway are typically only issued to medical and dental practitioners.
- 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. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/758892).

The TGA has developed an interactive decision tool (https://www.tga.gov.au/node/758694) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

For the SAS Category A and B there is no 'list' of products available. Any unapproved therapeutic good can potentially be supplied through these two schemes with one exception for SAS Category A. SAS Category A cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products under this access pathway. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/758892).

Who can apply for access to therapeutic goods via the SAS pathways?

Applications and notifications made under the SAS pathways are completed and submitted by registered health practitioners, preferably the prescribing health practitioner, who is best placed to determine the needs of the patient, including whether or not treatment with a particular product is required. It is expected that, in accordance with good medical practice, a health practitioner will educate themselves with all relevant and available information about a therapeutic good before using it.

If a patient asks to be treated with a particular unapproved therapeutic good, a health practitioner has the right to refuse to apply to obtain the product if they believe there is either insufficient clinical justification or evidence to support the use of the therapeutic good.

What is the process for submitting a Category A notification form?

The prescribing health practitioner or another health practitioner acting on their behalf (e.g. a pharmacist) can supply therapeutic goods to seriously ill patients who meet the Category A definition, without the approval of the TGA as long as the health practitioner provides the TGA with a completed Category A notification form. A copy of the completed Category A form must be sent to TGA within 28 days of the medicine or biological being given to the person or within 28 days after the use of the exempt medical device.

The SAS Category A is a notification pathway only, and as such, the TGA does not send out a letter of approval or acknowledgment on receipt of the completed notification form.

The health practitioner is also required to send a copy of the completed Category A form to the supplier of the therapeutic good. This provides the supplier with the legal authority to supply the therapeutic good.

What is the process for submitting a Category B application form?

The prescribing health practitioner or someone acting on their behalf can submit an application to the TGA to gain access to an unapproved therapeutic good for a patient that does not fit the Category A definition. Approval of an application to supply a product is required from a delegate in the TGA. Approval by the TGA is given on a patient-by-patient basis to reflect the needs of different patients. Applications can be made by lodging a completed Category B application form (/node/3244#forms) with the TGA).

Further information on the application process can be found in the Special Access Scheme Guidance for health practitioners and sponsors (https://www.tga.gov.au/node/4036).

For commonly requested products, the timeframe between receipt of an application by the TGA until provision of a response to the applicant, is typically 2 to 3 working days. Applications for products not previously requested under the SAS may take longer.

Paper forms must be processed manually by our staff. Therefore, the prescriber must allow sufficient time (at least 2-7 business days) for paper applications to be processed.

If there is an urgent medical need for access to a therapeutic good, on the top of your application please write: 'URGENT'.

For a limited number of products a phone approval can be given where there is an urgent medical need. This provision is generally only available during advertised TGA shut down periods (e.g. the Christmas holiday period)

What is the process for submitting a Category C notification form?

The prescribing health practitioner or a health practitioner (eg. Pharmacist) acting on their behalf needs to complete and submit the SAS Category C form following the supply of the unapproved therapeutic good via the SAS Category C pathway. The form does not need to be completed before the good is supplied and is not required to supply the good.

The reason this pathway is referred to as a *notification* pathway is that health practitioners supplying the unapproved therapeutic good are required to notify the TGA within 28 days of supplying the good.

On our website, the TGA has made available a notification form (/node/3244#forms) that health practitioners must complete and provide within this specified period.

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

When do SAS approvals or notifications expire?

The SAS Category A notification form is valid indefinitely as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by a delegate in the TGA. Category B approvals remain valid as long as the conditions of approval are upheld.

The SAS Category C notification form is also valid indefinitely, unless the substance is captured by the Customs (Prohibited Imports) Regulations 1956. For medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved medicinal cannabis product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- An outline of the patient's symptoms and/or diagnosis
- Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Where should a completed SAS form be sent?

It is preferred that forms are sent via email, as single attachments, to SAS@health.gov.au. If you do not have access to email, you may fax the form to 02 6203 1105. Posting of the hardcopies is not required.

If you have filled out the application incorrectly or require an amendment to an existing application or approval letter, the applicant should contact SAS@health.gov.au or phone 02 6289 4632 to discuss.

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email SAS@health.gov.au with your request.

Please note that a copy of the form should be kept by the applicant prior to submitting the form to the TGA.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good merely because the TGA has given an approval or authority to supply the product. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements that need to be met before the product can be supplied lawfully. These requirements can be product specific and applicants need to check these with their State/Territory health department (https://www.tga.gov.au/node/4448).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/758892) .

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/ws-lps-index) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Sponsors

Is an exemption under the SAS required to use an unapproved product as a demonstration or sample item (i.e. not for human therapeutic use)?

Item 3 of Schedule 5 of the *Therapeutic Goods Regulations 1990 (https://www.legislation.gov.au/Series/F1996B00406)* states that the following goods are exempt from Part 3-2 of the Act:

Samples of therapeutic goods imported, exported, manufactured, or supplied for:

a. submission to a regulatory authority; or

b. subjection to developmental or quality control procedures; or

c. examination, demonstration or display; or

d. subjection to analysis or laboratory testing procedures;

e. but not for supply for therapeutic use in humans.

Therefore, if importing therapeutic goods for research purposes only (not for supply for therapeutic use in humans), SAS exemption is not required.

Can therapeutic goods be brought into Australia for commercial supply under the SAS?

The SAS is a mechanism by which individual patients can access an unapproved therapeutic good through their health practitioner. Therapeutic goods intended for commercial supply in Australia are required to undergo an evaluation for quality safety and efficacy prior to being allowed on the market. The various mechanisms for supply of unapproved products are intended to be only temporary measures for supply, pending general marketing approval of the product.

The TGA has a responsibility to encourage at all times the use of approved (evaluated) products in Australian patients.

For the SAS Category C notification pathway, where can sponsors find products deemed to have an established history of use?

The therapeutic goods, indications and health practitioners that are authorised to supply these goods for the particular indication are included in a legislative instrument.

There are separate legislative instruments for medicines, medical devices and biologicals, respectively. These legislative instruments are publically accessible so sponsors can check to see if any of their products are included on them. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/758892) .

Inclusion of a product in any of these legislative instruments acts as the authorisation to supply.

Sponsors are 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 one of the instruments.

Can sponsors apply to have unapproved goods added or removed from the legislative instrument?

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. For example, if TGA believed there were significant safety concerns with the good it would be removed from the instrument; and any further supply of the product would need approval via the existing Category B (application) pathway.

Is a SAS submission required for 'off-label' use of a therapeutic good?

Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, supplied in, and exported from Australia. Therapeutic goods are included in the ARTG with specific indication(s) or intended purpose(s). 'Off-label use' generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in the ARTG entry.

The TGA is not responsible for regulating health professionals or clinical practice. 'Off-label use' is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent from their patient. Therefore, no exemption, approval or authorisation is required from the TGA to allow the off-label use of a product.

In exceptional circumstances, a Special Access Scheme (SAS) submission may be required for off-label use of a medicine or biological. For example, this may occur in situations where the prescriber has directly contacted the sponsor to request access to the product for their patient through a compassionate supply arrangement. In these circumstances, the sponsor may request an SAS notification or approval to ensure legal supply of the product under the therapeutic goods legislation.

However, the TGA does not have the authority to grant an SAS Category B approval for a medical device included in the ARTG. Therefore, the SAS Category B pathway cannot be used to obtain supply of any medical device included in the ARTG, regardless of the proposed use of the device.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme: frequently asked questions

Special Access Scheme: frequently asked questions

Last updated:
20 April 2021

The Special Access Scheme (SAS) refers to arrangements which provide for the importation and/or supply of an unapproved therapeutic good (i.e. those not included on the Australian Register of Therapeutic Goods (ARTG)) for a single patient, on a case-by-case basis.

Consumers

Open all (#) | Close all (#)

Can I write and submit my own SAS application or notification?

An application or notification form must be completed by an appropriate health practitioner as they must be able to justify on medical grounds why their patient requires the unapproved therapeutic good.

The prescribing health practitioner (e.g., doctor) is best placed to determine the needs of the patient, including whether or not treatment with a particular unapproved therapeutic good is required. It is expected that, in accordance with good medical practice, a prescribing health practitioner will educate themselves with all available relevant information relating to an unapproved therapeutic good before using it.

It is also important to note that a prescribing health practitioner has the right to decline to prescribe an unapproved therapeutic good if they believe there is either insufficient clinical justification or no evidence to support the use of that particular product.

Does it cost to submit a SAS application or notification?

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

Are therapeutic goods accessed through the SAS available at a reduced cost or for free?

The monetary cost of a therapeutic good is set by the sponsor of the goods and/or the pharmacy through which the goods are accessed (if applicable). Unapproved therapeutic goods are also not eligible to be subsidised under the Pharmaceutical Benefits Scheme (PBS). The TGA does not consider the monetary cost of the goods when making a decision under the SAS.

In some circumstances, a sponsor of a therapeutic good may choose to provide the good on a 'compassionate basis' (compassionate supply). In these scenarios the product may attract no fee or be available at a reduced cost to the patient. Please note, this decision is made at the discretion of the sponsor.

A cheaper version of my current medication is available overseas. Can the SAS be used to allow access to this product?

Applications which give monetary reasons as a means of supporting the application will not be considered. The applicant must provide a clinical justification for the therapeutic good and its use, including reasons why the ARTG registered product available in Australia is not appropriate for their patient

In certain circumstances, patients may wish to use the Personal Importation Scheme (https://www.tga.gov.au/node/282893) to import medicines from overseas.

Health practitioners

What is the difference between the Special Access Scheme Category A, Category B and Category C pathways?

- Category A is a **notification pathway** which can be accessed by a prescribing medical practitioner or a health practitioner 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 Category C. An approval letter from TGA is required before the good may be accessed. Approvals for medicines accessed through this pathway are typically only issued to medical and dental practitioners.

- 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. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/287656).

The TGA has developed an interactive decision tool (https://www.tga.gov.au/node/287650) to assist health practitioners to determine the most appropriate pathway (if any) to access an unapproved therapeutic good.

Which therapeutic goods are available through the SAS?

For the SAS Category A and B there is no 'list' of products available. Any unapproved therapeutic good can potentially be supplied through these two schemes with one exception for SAS Category A. SAS Category A cannot be used to access drugs of abuse in Schedule 9 of the Poisons Standard where the manufacture, possession, sale or use is prohibited by State or Territory law.

For SAS Category C, there is a list available that specifies the medicines, biologicals and medical devices, their indications and the type of health practitioner authorised to supply these products under this access pathway. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/287656).

Who can apply for access to therapeutic goods via the SAS pathways?

Applications and notifications made under the SAS pathways are completed and submitted by registered health practitioners, preferably the prescribing health practitioner, who is best placed to determine the needs of the patient, including whether or not treatment with a particular product is required. It is expected that, in accordance with good medical practice, a health practitioner will educate themselves with all relevant and available information about a therapeutic good before using it.

If a patient asks to be treated with a particular unapproved therapeutic good, a health practitioner has the right to refuse to apply to obtain the product if they believe there is either insufficient clinical justification or evidence to support the use of the therapeutic good.

What is the process for submitting a Category A notification form?

The prescribing health practitioner or another health practitioner acting on their behalf (e.g. a pharmacist) can supply therapeutic goods to seriously ill patients who meet the Category A definition, without the approval of the TGA as long as the health practitioner provides the TGA with a completed Category A notification form. A copy of the

completed Category A form must be sent to TGA within 28 days of the medicine or biological being given to the person or within 28 days after the use of the exempt medical device.

The SAS Category A is a notification pathway only, and as such, the TGA does not send out a letter of approval or acknowledgment on receipt of the completed notification form.

The health practitioner is also required to send a copy of the completed Category A form to the supplier of the therapeutic good. This provides the supplier with the legal authority to supply the therapeutic good.

What is the process for submitting a Category B application form?

The prescribing health practitioner or someone acting on their behalf can submit an application to the TGA to gain access to an unapproved therapeutic good for a patient that does not fit the Category A definition. Approval of an application to supply a product is required from a delegate in the TGA. Approval by the TGA is given on a patient-by-patient basis to reflect the needs of different patients. Applications can be made by lodging a completed Category B application form (/node/288269#forms) with the TGA).

Further information on the application process can be found in the Special Access Scheme Guidance for health practitioners and sponsors (https://www.tga.gov.au/node/289228).

For commonly requested products, the timeframe between receipt of an application by the TGA until provision of a response to the applicant, is typically 2 to 3 working days. Applications for products not previously requested under the SAS may take longer.

Paper forms must be processed manually by our staff. Therefore, the prescriber must allow sufficient time (at least 2-7 business days) for paper applications to be processed.

If there is an urgent medical need for access to a therapeutic good, on the top of your application please write: 'URGENT'.

For a limited number of products a phone approval can be given where there is an urgent medical need. This provision is generally only available during advertised TGA shut down periods (e.g. the Christmas holiday period)

What is the process for submitting a Category C notification form?

The prescribing health practitioner or a health practitioner (eg. Pharmacist) acting on their behalf needs to complete and submit the SAS Category C form following the supply of the unapproved therapeutic good via the SAS Category C pathway. The form does not

need to be completed before the good is supplied and is not required to supply the good.

The reason this pathway is referred to as a *notification* pathway is that health practitioners supplying the unapproved therapeutic good are required to notify the TGA within 28 days of supplying the good.

On our website, the TGA has made available a notification form (/node/288269#forms) that health practitioners must complete and provide within this specified period.

Can health practitioners apply to have unapproved goods added or removed from the SAS Category C legislative instrument?

Health practitioners cannot apply to the TGA to have therapeutic goods included or removed from the legislative instruments.

The TGA will regularly review unapproved therapeutic goods and make changes to add or remove products from the Category C legislative instruments as appropriate. For example, if TGA believed there were significant safety concerns with a therapeutic good it may be removed from the instrument and any further supply of the product would need approval via the existing Category B pathway.

When do SAS approvals or notifications expire?

The SAS Category A notification form is valid indefinitely as long as the patient continues to meet the Category A definition.

The SAS Category B approval is valid for the period of time specified on the approval letter signed by a delegate in the TGA. Category B approvals remain valid as long as the conditions of approval are upheld.

The SAS Category C notification form is also valid indefinitely, unless the substance is captured by the Customs (Prohibited Imports) Regulations 1956. For medicines containing substances captured by the Customs (Prohibited Imports) Regulations 1956, a new Category C notification form will need to be submitted if further quantities are required.

What clinical justification is required for a SAS Category B application for an unapproved therapeutic good?

When applying to access an unapproved medicinal cannabis product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification. The justification should include the seriousness of the patient's condition, consideration for the use of medicines that are included in the ARTG and the potential risks and benefits of using the proposed unapproved medicine.

The clinical justification may be succinct and should summarise:

- An outline of the patient's symptoms and/or diagnosis
- Details of relevant past treatments and procedures trialled or considered, including reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance
- An appraisal of the expected clinical benefits versus the potential risks of the proposed treatment

Where should a completed SAS form be sent?

It is preferred that forms are sent via email, as single attachments, to SAS@health.gov.au. If you do not have access to email, you may fax the form to 02 6203 1105. Posting of the hardcopies is not required.

If you have filled out the application incorrectly or require an amendment to an existing application or approval letter, the applicant should contact SAS@health.gov.au or phone 02 6289 4632 to discuss.

Can copies be provided of previous SAS application submitted to TGA?

Requests for original application forms submitted to TGA will be considered on a case-by-case basis and will only be provided to the health practitioner whose details are provided on the form. Please email SAS@health.gov.au with your request.

Please note that a copy of the form should be kept by the applicant prior to submitting the form to the TGA.

Does a completed SAS Category A notification form, Category B approval letter or authorisation through SAS Category C automatically grant access to a therapeutic good?

Sponsors are under no obligation to supply an unapproved therapeutic good merely because the TGA has given an approval or authority to supply the product. Before considering accessing unapproved therapeutic goods or submitting an application to the TGA, health practitioners should check with the sponsor of the goods to confirm that they will supply the product.

In addition, TGA approval does not override any State or Territory requirements that need to be met before the product can be supplied lawfully. These requirements can be product specific and applicants need to check these with their State/Territory health department (https://www.tga.gov.au/node/287386).

How do I get the product once the TGA has given approval/authorisation?

The TGA does not supply any therapeutic goods.

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution such as a hospital, supply of a medicine may be arranged through the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a Category A patient, the completed Category A form acts as the authorisation. For Category B, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. For Category C, the inclusion of a product in the legislative instruments acts as the authorisation. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/287656) .

A completed notification form is not required to authorise supply of products through SAS Category C, however a completed notification form must be submitted to the TGA no later than 28 days after the product has been supplied.

If the product is not available from an Australian sponsor, the requesting health practitioner will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances (https://www.odc.gov.au/ws-lps-index) is available on the Office of Drug Control website.

If the product is a prohibited import, a permit or licence (or both) may be required. Permits and licences are administered by the Office of Drug Control (https://www.odc.gov.au/). For further information please email dcs@health.gov.au

Sponsors

Is an exemption under the SAS required to use an unapproved product as a demonstration or sample item (i.e. not for human therapeutic use)?

Item 3 of Schedule 5 of the *Therapeutic Goods Regulations 1990 (https://www.legislation.gov.au/Series/F1996B00406)* states that the following goods are exempt from Part 3-2 of the Act:

Samples of therapeutic goods imported, exported, manufactured, or supplied for:

a. submission to a regulatory authority; or
b. subjection to developmental or quality control procedures; or
c. examination, demonstration or display; or
d. subjection to analysis or laboratory testing procedures;
e. but not for supply for therapeutic use in humans.

Therefore, if importing therapeutic goods for research purposes only (not for supply for therapeutic use in humans), SAS exemption is not required.

Can therapeutic goods be brought into Australia for commercial supply under the SAS?

The SAS is a mechanism by which individual patients can access an unapproved therapeutic good through their health practitioner. Therapeutic goods intended for commercial supply in Australia are required to undergo an evaluation for quality safety and efficacy prior to being allowed on the market. The various mechanisms for supply of unapproved products are intended to be only temporary measures for supply, pending general marketing approval of the product.

The TGA has a responsibility to encourage at all times the use of approved (evaluated) products in Australian patients.

For the SAS Category C notification pathway, where can sponsors find products deemed to have an established history of use?

The therapeutic goods, indications and health practitioners that are authorised to supply these goods for the particular indication are included in a legislative instrument.

There are separate legislative instruments for medicines, medical devices and biologicals, respectively. These legislative instruments are publically accessible so sponsors can check to see if any of their products are included on them. See the lists at Special Access Scheme rules (https://www.tga.gov.au/node/287656) .

Inclusion of a product in any of these legislative instruments acts as the authorisation to supply.

Sponsors are 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 one of the instruments.

Can sponsors apply to have unapproved goods added or removed from the legislative instrument?

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. For example, if TGA believed there were significant safety concerns with the good it would be removed from the instrument; and any further supply of the product would need approval via the existing Category B (application) pathway.

Is a SAS submission required for 'off-label' use of a therapeutic good?

Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, supplied in, and exported from Australia. Therapeutic goods are included in the ARTG with specific indication(s) or intended purpose(s). 'Off-label use' generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in the ARTG entry.

The TGA is not responsible for regulating health professionals or clinical practice. 'Off-label use' is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent from their patient. Therefore, no exemption, approval or authorisation is required from the TGA to allow the off-label use of a product.

In exceptional circumstances, a Special Access Scheme (SAS) submission may be required for off-label use of a medicine or biological. For example, this may occur in situations where the prescriber has directly contacted the sponsor to request access to the product for their patient through a compassionate supply arrangement. In these circumstances, the sponsor may request an SAS notification or approval to ensure legal supply of the product under the therapeutic goods legislation.

However, the TGA does not have the authority to grant an SAS Category B approval for a medical device included in the ARTG. Therefore, the SAS Category B pathway cannot be used to obtain supply of any medical device included in the ARTG, regardless of the proposed use of the device.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Lists of products with an established history of use

Next change (https://www.tga.gov.au/node/337991/revisions/view/474739/549365/visual_inline)

Comparing
03/08/2023 - 2:54pm (https://www.tga.gov.au/node/337991/revisions/474739/view) s 22
16/12/2022 - 11:27am (https://www.tga.gov.au/node/337991/revisions/422317/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/337991/revisions/view/422317/474739/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/337991/revisions/view/422317/474739/visual_inline?view_mode=full)

Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)

~~List~~Lists of ~~therapeutic goods~~products with an established history of use

If an unapproved product you want to use is listed here, and conditions are met, you can access it.

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://tgaau.qualtrics.com/ife/form/SV_57rDaBiJKfJL3UQ).

Medical and health practitioners can access unapproved products with an established history of use.

These products are recorded in lists. The list you should use depends on if you:

- use the Special Access Scheme (Category C) OR
- become an Authorised Prescriber.

Special Access Scheme (SAS) Category C lists (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Authorised Prescriber established history of use lists (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/authorised-prescriber-established-history-use-lists)

You must meet all the listed criteria to access the product.

If conditions are met, you can access a SAS Category C list product immediately.

To find out more read how to prescribe an unapproved therapeutic good (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners).

How products are listed

Unapproved products are listed if we deem them to have an established history of use.

We can do this if there are no significant safety concerns associated with a product for at least 3 years.

This is an internal process. You can't apply to have a product listed.

Revisions for *Lists of products with an established history of use*

Revisions

Home ›

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
13/06/2024 - 3:55pm by s 22 product type updated to Unapproved therapeutic goods, Unapproved therapeutic goods removed from topic (Published)	○		*Current revision*
03/08/2023 - 2:54pm by s 22 (Published)	○		**Revert**
17/07/2023 - 12:49pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 3:12pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 3:12pm by s 22 (Published)	○	○	**Revert**
15/02/2023 - 4:40pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 4:39pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 4:38pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 3:59pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:04pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:01pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:00pm by s 22 (Published)	○	○	**Revert**
15/02/2023 - 12:59pm by s 22 (Unpublished)	○	○	**Revert**

Revision	Operations
15/02/2023 12:58pm by s 22 (Unpublished)	Revert
15/02/2023 - 12:51pm by s 22 (Unpublished)	Revert
05/01/2023 - 10:59am by s 22 (Unpublished)	Revert
04/01/2023 - 3:50pm by s 22 (Unpublished)	Revert
04/01/2023 - 1:31pm by s 22 (Unpublished)	Revert
04/01/2023 - 1:30pm by s 22 (Published)	Revert
04/01/2023 - 1:29pm by s 22 (Draft)	Revert
04/01/2023 - 1:26pm by s 22 (Draft)	Revert
04/01/2023 - 1:14pm by s 22 (Draft)	Revert
04/01/2023 - 1:12pm by s 22 (Draft)	Revert
20/12/2022 - 2:39am by s 22 (Draft)	Revert
20/12/2022 - 2:32am by s 22 (Draft)	Revert
20/12/2022 - 2:26am by s 22 (Draft)	Revert
20/12/2022 - 2:21am by s 22 (Draft)	Revert
20/12/2022 - 2:19am by s 22 (Draft)	Revert
20/12/2022 - 2:13am by s 22 (Draft)	Revert
20/12/2022 - 2:11am by s 22 (Draft)	Revert

Revision	Operations
20/12/2022 2:08am by s 22 (Draft)	○ ○ Revert
19/12/2022 - 12:44pm by s 22 (Draft)	○ ○ Revert
16/12/2022 - 11:32am by s 22 (Draft)	○ ○ Revert
16/12/2022 - 11:27am by s 22 (Draft)	○ ○ Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Lists of products with an established history of use

Lists of products with an established history of use

If an unapproved product you want to use is listed here, and conditions are met, you can access it.

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

Medical and health practitioners can access unapproved products with an established history of use.

These products are recorded in lists. The list you should use depends on if you:

- use the Special Access Scheme (Category C) OR
- become an Authorised Prescriber.

Special Access Scheme (SAS) Category C lists (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

Authorised Prescriber established history of use lists (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/authorised-prescriber-established-history-use-lists)

You must meet all the listed criteria to access the product.

If conditions are met, you can access a SAS Category C list product immediately.

To find out more read how to prescribe an unapproved therapeutic good (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners).

How products are listed

Unapproved products are listed if we deem them to have an established history of use.

We can do this if there are no significant safety concerns associated with a product for at least 3 years.

This is an internal process. You can't apply to have a product listed.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Lists of products with an established history of use

List of therapeutic goods with an established history of use

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) Category C lists

Comparing
01/07/2024 - 3:26pm (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)
s 22
medicines table updated
15/02/2023 - 1:05pm (https://www.tga.gov.au/node/349012/revisions/434692/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/349012/revisions/view/434692/551283/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/349012/revisions/view/434692/551283/visual_inline?view_mode=full)

Special Access Scheme (SAS) Category C lists

Check the lists of unapproved products you can ~~prescribe~~access under SAS Category C.

~~Last updated~~:
15 January 2024

~~On this page~~

We are updating our content for unapproved therapeutic goods. Please give ~~your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting)~~your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

If the product you want to use is on the list and conditions are met, you can ~~prescribe~~access immediately under SAS Category C.

You must notify us within 28 days of use of the unapproved product.

To notify us, submit the form in the online system.

SAS and AP online system (https://compliance.health.gov.au/sas/)

You must meet all listed criteria to prescribe a product. This includes:

- dosage form
- route of administration
- indication
- practitioner type.

There are separate lists for medicines, biologicals and medical devices.

Read more about unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0).

Medicines

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
~~Riboflavin, 0.1% in sodium chloride, Eye drops, Ophthalmic~~	~~Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus.~~	~~Medical Practitioner~~	~~M10~~
~~Levomepromazine, Tablet, Oral~~	~~Treatment of nausea and vomiting~~	~~Medical Practitioner~~	~~M100~~
~~Levomepromazine, Tablet, Oral~~	~~Treatment of agitation~~	~~Medical Practitioner~~	~~M101~~
~~Levomepromazine, Injection, Subcutaneous~~	~~Treatment of nausea and vomiting~~	~~Medical Practitioner~~	~~M102~~
~~Levomepromazine, Injection, Subcutaneous~~	~~Treatment of agitation~~	~~Medical Practitioner~~	~~M103~~
~~Mexiletine, Tablet, Oral~~	~~Treatment of ventricular arrhythmia~~	~~Medical Practitioner~~	~~M105~~
~~Mexiletine, Tablet, Oral~~	~~Treatment of myotonic disorders~~	~~Medical Practitioner~~	~~M106~~
~~Mexiletine, Capsule, Oral~~	~~Treatment of ventricular arrhythmia~~	~~Medical Practitioner~~	~~M107~~
~~Mexiletine, Capsule, Oral~~	~~Treatment of myotonic disorders~~	~~Medical Practitioner~~	~~M108~~
~~Moxifloxacin 0.5%, Eye drops, Ophthalmic~~	~~Treatment of refractory bacterial conjunctivitis~~	~~Medical Practitioner~~	~~M109~~
~~Flunarizine, Tablet, Oral~~	~~Treatment of vestibular disorders~~	~~Medical Practitioner~~	~~M11~~
~~Nadolol, Tablet, Oral~~	~~Treatment of ventricular tachycardia~~	~~Medical Practitioner~~	~~M110~~
~~Nadolol, Tablet, Oral~~	~~Treatment of long QT Syndrome~~	~~Medical Practitioner~~	~~M111~~
~~Natamycin 5%, Eye drops, Ophthalmic~~	~~Treatment of refractory fungal blepharitis, conjunctivitis or keratitis~~	~~Medical Practitioner~~	~~M112~~
~~Sodium benzoate, Tablet, Oral~~	~~Treatment of urea cycle disorders~~	~~Medical Practitioner~~	~~M113~~
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hypokalemia	Medical Practitioner	M160
~~Tizanidine~~Betaxolol 0.25% (preservative free), ~~Capsule~~Eye drops, ~~Oral~~Opthalmic	Treatment of ~~spasticity~~elevated intraocular pressure where other treatments ~~have failed~~are inappropriate	Medical Practitioner	~~M114~~M92
~~Tizanidine, Tablet, Oral~~	~~Treatment of spasticity where other treatments have failed~~	~~Medical Practitioner~~	~~M115~~
~~Deflazacort, Tablet, Oral~~	~~Treatment of Duchenne muscular dystrophy~~	~~Medical Practitioner~~	~~M116~~
~~Ripasudil 0.4%, Eye drops, Ophthalmic~~	~~Treatment of refractory corneal oedema~~	~~Medical Practitioner~~	~~M117~~

~~Ripasudil 0.4%, Eye drops, Ophthalmic~~	~~Treatment of refractory glaucoma~~	~~Medical Practitioner~~	~~M118~~
~~Tacrolimus 0.03%, Ointment, Topical~~	~~Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children~~	~~Medical Practitioner~~	~~M119~~
Bismuth subcitrate, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126
Ciclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. (dry eye syndrome)	Medical Practitioner	M12
~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Treatment of non-infectious uveitis~~	~~Medical Practitioner~~	~~M120~~
~~F-18 myocardial perfusion trace (18F flurpiridaz), Injection, Intravenous~~	~~Myocardial perfusion study~~	~~Medical Practitioner~~	~~M121~~
~~F-18 NaF (sodium fluoride), Injection, Intravenous~~	~~Bone study~~	~~Medical Practitioner~~	~~M122~~
~~Gallium-68 (Ga-68) Galligas, Aerosol, Inhalation~~	~~Lung ventilation study~~	~~Medical Practitioner~~	~~M123~~
~~Gallium-68 (Ga-68) - MAA, Injection, Intravenous~~	~~Lung perfusion study~~	~~Medical Practitioner~~	~~M124~~
~~Carbidopa, Tablet, Oral~~	~~Premedication for F-18 DOPA imaging~~	~~Medical Practitioner~~	~~M126~~
Cinnarizine, Tablet, Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)	Medical Practitioner	M13
Clobetasol propionate 0.05%, Cream, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M94
Clobetasol propionate 0.05%, Lotion, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M95
Clobetasol propionate 0.05%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M96
Clofazimine, Capsule, Oral	Treatment of drug resistant tuberculosis	Medical Practitioner	M127
Clofazimine, Capsule, Oral	Treatment of non-tuberculosis mycobacterial infections	Medical Practitioner	M128
Clofazimine, Capsule, Oral	Treatment of other infections as recommended by an infectious diseases specialist	Medical Practitioner	M129
~~Cinnarizine, Tablet, Oral~~	~~Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)~~	~~Medical Practitioner~~	~~M13~~
Clofazimine, Capsule, Oral	Treatment of Leprosy	Medical Practitioner	M31
Clofazimine, Capsule, Oral	Treatment of granulomatous cheilitis	Medical Practitioner	M32
Clofazimine, Capsule, Oral	Treatment of Melkersson Rosenthal Syndrome	Medical Practitioner	M33
Clofazimine, Capsule, Oral	Treatment of confirmed mycobacterium avium paratuberculosis in immunocompromised patients recommended by an infectious disease specialist	Medical Practitioner	M34
Clofazimine, Capsule, Oral	Treatment of erythema nodosum leprosum	Medical Practitioner	M35
Colecalciferol, Capsule, Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner	M26
Colecalciferol, Injection, Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner	M27
Cyclopentolate 0.2% & phenylephrine 1% Eye drops, Ophthalmic	Production of mydriasis	Medical Practitioner	M20
Deflazacort, Tablet, Oral	Treatment of Duchenne muscular dystrophy	Medical Practitioner	M116
Dehydrated ethanol (alcohol) 96% - 100%, Ampoule, Topical	Treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)	Medical Practitioner	M36
Dexamethasone (preservative free), Eye drops, Ophthalmic	Treatment of inflammatory conditions of the eye that are non-infected and steroid responsive in patients sensitive to preservative-containing formulations	Medical Practitioner	M130
Diazoxide, Capsule, Oral	Treatment of hypoglycaemia	Medical Practitioner	M40
Diazoxide, Capsule, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M41
Diazoxide, Capsule, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M42
Diazoxide, Capsule, Oral	Treatment of insulinoma	Medical Practitioner	M43
Diazoxide, Suspension, Oral	Treatment of hypoglycaemia	Medical Practitioner	M44
Diazoxide, Suspension, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M45
Diazoxide, Suspension, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M46
Diazoxide, Suspension, Oral	Treatment of insulinoma	Medical Practitioner	M47
Diazoxide, Tablet, Oral	Treatment of hypoglycaemia	Medical Practitioner	M48
Diazoxide, Tablet, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M49
Diazoxide, Tablet, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M50
Diazoxide, Tablet, Oral	Treatment of insulinoma	Medical Practitioner	M51
Diflunisal, Tablet, Oral	Treatment of amyloidosis	Medical Practitioner	M97
Dimethyl sulfoxide (DMSO), Solution, Intravesical	Symptomatic relief of interstitial cystitis	Medical Practitioner	M52
Disulfiram, Tablet, Oral	Deterrent to alcohol consumption	Medical practitioner	M152
Doxycycline, Injection, Intralesional	Sclerotherapy of lymphatic malformations	Medical Practitioner	M131
F-18 DCFPyl (PSMA), Injection, Intravenous	Prostate cancer imaging study	Medical Practitioner	M132
~~Flunarizine, Capsule, Oral~~	~~Prophylactic treatment of migraine~~	~~Medical Practitioner~~	~~M133~~
F-18 myocardial perfusion trace (18F flurpiridaz), Injection, Intravenous	Myocardial perfusion study	Medical Practitioner	M121
F-18 NaF (sodium fluoride), Injection, Intravenous	Bone study	Medical Practitioner	M122
Flunarizine, ~~Tablet~~Capsule, Oral	Prophylactic treatment of migraine	Medical Practitioner	~~M134~~M133
~~Gallium-68 prostate specific membrane antigen (PSMA), Injection, Intravenous~~	~~Prostate cancer imaging study~~	~~Medical Practitioner~~	~~M135~~
~~Levofloxacin, Tablet, Oral~~	~~Treatment of drug resistant tuberculosis~~	~~Medical Practitioner~~	~~M136~~
~~Neomycin, Tablet, Oral~~	~~Sepsis prevention for colorectal operation~~	~~Medical Practitioner~~	~~M137~~
~~Riboflavin, 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC), Eye drops, Ophthalmic~~	~~Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus~~	~~Medical Practitioner~~	~~M138~~
~~Riboflavin, 0.22% in sodium chloride, Eye drops, Ophthalmic~~	~~Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus~~	~~Medical Practitioner~~	~~M139~~
~~Hypertonic sodium chloride, 5%, Eye drops, Ophthalmic~~	~~Temporary relief of corneal oedema (hypertonicity)~~	~~Medical Practitioner~~	~~M14~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of *trichomonas vaginalis* infections of the genito-urinary tract in female and male patients~~	~~Medical Practitioner~~	~~M140~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of giardiasis~~	~~Medical Practitioner~~	~~M141~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of amoebic dysentery~~	~~Medical Practitioner~~	~~M142~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of amoebic liver abscess~~	~~Medical Practitioner~~	~~M143~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of acute giardiasis in children~~	~~Medical Practitioner~~	~~M144~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of acute amoebic dysentery in children~~	~~Medical Practitioner~~	~~M145~~
~~Tinidazole, Tablet, Oral~~	~~Treatment of amoebic liver disease in children~~	~~Medical Practitioner~~	~~M146~~
~~Tinidazole, Tablet, Oral~~	~~Prevention of infection at the surgical site~~	~~Medical Practitioner~~	~~M147~~

~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Treatment of diabetic macular oedema~~	~~Medical Practitioner~~	~~M148~~
~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Treatment of cystoid macular oedema secondary to retinal vein occlusion~~	~~Medical Practitioner~~	~~M149~~
Flunarizine, Capsule, Oral	Treatment of vestibular disorders	Medical Practitioner	M53
Flunarizine, Tablet, Oral	Treatment of vestibular disorders	Medical Practitioner	M11
Flunarizine, Tablet, Oral	Prophylactic treatment of migraine	Medical Practitioner	M134
Furazolidone, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M23
Gallium-68 (Ga-68) = MAA, Injection, Intravenous	Lung perfusion study	Medical Practitioner	M124
Gallium-68 (Ga-68) Galligas, Aerosol, Inhalation	Lung ventilation study	Medical Practitioner	M123
Ganciclovir, Gel, Ophthalmic	Treatment of cytomegalovirus	Medical Practitioner	M162
Glycopyrronium bromide, Tablet, Oral	Treatment of excessive salivation in patients with neurological conditions	Medical Practitioner	M25
Hyoscine hydrobromide, Patch, Transdermal	Treatment of excessive salivation	Medical Practitioner	M56
Hypertonic sodium chloride, 5% Eye ointment, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner	M15
~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Treatment of uveitic macular oedema~~	~~Medical Practitioner~~	~~M150~~
~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Treatment of post-operative macular oedema (cataract surgery)~~	~~Medical Practitioner~~	~~M151~~
~~Disulfiram, Tablet, Oral~~	~~Deterrent to alcohol consumption~~	~~Medical practitioner~~	~~M152~~
Hypertonic sodium chloride, 5%, Eye drops, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner	M14
Iloprost, Injection, Intravenous infusion	Treatment of patients with severe disabling Raynaud's phenomenon	Medical practitioner	M153
Iloprost, Injection, Intravenous infusion	Treatment of peripheral ischaemia	Medical practitioner	M154
Indigo Carmine, Injection, Intravenous	For intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures	Medical Practitioner	M57
Indocyanine green dye, Injection, Intravenous	For intra-operative diagnostic use	Medical Practitioner	M58
Interferon Alpha-2b, Eye drops, Ophthalmic	Treatment of ocular surface squamous neoplasia	Medical practitioner	M155
Ketotifen, Tablet, Oral	Treatment of allergic conditions	Medical Practitioner	M59
Levofloxacin, Tablet, Oral	Treatment of drug resistant tuberculosis	Medical Practitioner	M136
Levofloxacin, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M99
Levomepromazine, Injection, Subcutaneous	Treatment of nausea and vomiting	Medical Practitioner	M102
Levomepromazine, Injection, Subcutaneous	Treatment of agitation	Medical Practitioner	M103
Levomepromazine, Tablet, Oral	Treatment of nausea and vomiting	Medical Practitioner	M100
Levomepromazine, Tablet, Oral	Treatment of agitation	Medical Practitioner	M101
Lifitegrast, Eye drops, Ophthalmic	Treatment of dry eye disease	Medical practitioner	M156
~~Progesterone, Injection, Subcutaneous~~	~~Treatment of progesterone deficiency~~	~~Medical practitioner~~	~~M157~~
~~Progesterone in oil, Injection, Intramuscular~~	~~Treatment of progesterone deficiency~~	~~Medical practitioner~~	~~M158~~
~~Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA) I&S, Injection, Intravenous~~	~~Prostate cancer imaging study~~	~~Medical practitioner~~	~~M159~~
~~Buspirone, Tablet, Oral~~	~~Treatment of generalised anxiety disorders~~	~~Medical Practitioner~~	~~M17~~
~~Allergens – multiple, various (including control solutions), Drops, Skin prick~~	~~Confirmation of suspected allergic reactions~~	~~Medical Practitioner~~	~~M19~~
~~Triamcinolone acetonide, Suspension for Injection, Ophthalmic~~	~~Visualisation during vitrectomy~~	~~Medical Practitioner~~	~~M2~~
~~Cyclopentolate, 0.2%, & phenylephrine, 1%, Eye drops, Ophthalmic~~	~~Production of mydriasis.~~	~~Medical Practitioner~~	~~M20~~
~~Verteporfin Powder for injection, Intravenous infusion~~	~~Photosensitisation for photodynamic therapy~~	~~Medical Practitioner~~	~~M21~~
~~Pyrazinamide, Tablet, Oral~~	~~Treatment of tuberculosis~~	~~Medical Practitioner~~	~~M22~~
~~Furazolidone, Tablet, Oral~~	~~Treatment of resistant *Helicobacter Pylori* infection~~	~~Medical Practitioner~~	~~M23~~
~~Glycopyrronium bromide, Tablet, Oral~~	~~Treatment of excessive salivation in patients with neurological conditions~~	~~Medical Practitioner~~	~~M25~~
~~Colecalciferol, Capsule, Oral~~	~~Treatment of severe vitamin D deficiency and prevention of osteoporosis~~	~~Medical Practitioner~~	~~M26~~
~~Colecalciferol, Injection, Intramuscular~~	~~Treatment of severe vitamin D deficiency and prevention of osteoporosis~~	~~Medical Practitioner~~	~~M27~~
~~Allergens – multiple, various (including control solutions), Drops, Intradermal~~	~~Confirmation of suspected allergic reactions~~	~~Medical Practitioner~~	~~M28~~
~~Calcitriol, Liquid, Oral~~	~~Prevention of hypophosphatemic rickets in children~~	~~Medical Practitioner~~	~~M29~~
Melatonin, ~~Syrup~~Capsule, Oral	Treatment of sleep disorders	Medical Practitioner	~~M3~~M6
~~Calcitriol, Liquid, Oral~~	~~Treatment of hypoparathyroidism (with severe hypocalcaemia)~~	~~Medical Practitioner~~	~~M30~~
~~Clofazimine, Capsule, Oral~~	~~Treatment of Leprosy~~	~~Medical Practitioner~~	~~M31~~
~~Clofazimine, Capsule, Oral~~	~~Treatment of granulomatous cheilitis~~	~~Medical Practitioner~~	~~M32~~
~~Clofazimine, Capsule, Oral~~	~~Treatment of Melkersson Rosenthal Syndrome~~	~~Medical Practitioner~~	~~M33~~
~~Clofazimine, Capsule, Oral~~	~~Treatment of confirmed *Mycobacterium avium* paratuberculosis in immunocompromised patients recommended by an infectious disease specialist~~	~~Medical Practitioner~~	~~M34~~
~~Clofazimine, Capsule, Oral~~	~~Treatment of erythema nodosum leprosum~~	~~Medical Practitioner~~	~~M35~~
~~Dehydrated ethanol (alcohol) 96% - 100%, Ampoule, Topical~~	~~Treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)~~	~~Medical Practitioner~~	~~M36~~
~~Diazoxide, Capsule, Oral~~	~~Treatment of hypoglycaemia~~	~~Medical Practitioner~~	~~M40~~
~~Diazoxide, Capsule, Oral~~	~~Treatment of hyperinsulinaemia~~	~~Medical Practitioner~~	~~M41~~
~~Diazoxide, Capsule, Oral~~	~~Treatment of Beckwith-Weiderman Syndrome~~	~~Medical Practitioner~~	~~M42~~
~~Diazoxide, Capsule, Oral~~	~~Treatment of insulinoma~~	~~Medical Practitioner~~	~~M43~~
~~Diazoxide, Suspension, Oral~~	~~Treatment of hypoglycaemia~~	~~Medical Practitioner~~	~~M44~~
~~Diazoxide, Suspension, Oral~~	~~Treatment of hyperinsulinaemia~~	~~Medical Practitioner~~	~~M45~~
~~Diazoxide, Suspension, Oral~~	~~Treatment of Beckwith-Weiderman Syndrome~~	~~Medical Practitioner~~	~~M46~~
~~Diazoxide, Suspension, Oral~~	~~Treatment of insulinoma~~	~~Medical Practitioner~~	~~M47~~
~~Diazoxide, Tablet, Oral~~	~~Treatment of hypoglycaemia~~	~~Medical Practitioner~~	~~M48~~
~~Diazoxide, Tablet, Oral~~	~~Treatment of hyperinsulinaemia~~	~~Medical Practitioner~~	~~M49~~
Melatonin, Immediate Release Tablet, Oral	Treatment of sleep disorders	Medical Practitioner	M5
~~Diazoxide, Tablet, Oral~~	~~Treatment of Beckwith-Weiderman Syndrome~~	~~Medical Practitioner~~	~~M50~~
~~Diazoxide, Tablet, Oral~~	~~Treatment of insulinoma~~	~~Medical Practitioner~~	~~M51~~
~~Dimethyl sulfoxide (DMSO), Solution, Intravesical~~	~~Symptomatic relief of interstitial cystitis~~	~~Medical Practitioner~~	~~M52~~
~~Flunarizine, Capsule, Oral~~	~~Treatment of vestibular disorders~~	~~Medical Practitioner~~	~~M53~~
~~Hyoscine hydrobromide, Patch, Transdermal~~	~~Treatment of excessive salivation~~	~~Medical Practitioner~~	~~M56~~
~~Indigo Carmine, Injection, Intravenous~~	~~For intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures~~	~~Medical Practitioner~~	~~M57~~
~~Indocyanine green dye, Injection, Intravenous~~	~~For intra-operative diagnostic use~~	~~Medical Practitioner~~	~~M58~~

~~Ketotifen, Tablet, Oral~~	~~Treatment of allergic conditions~~	~~Medical Practitioner~~	~~M59~~
Melatonin, Lozenge, Oral	Treatment of sleep disorders	Medical Practitioner	M62
Melatonin, ~~Capsule~~Syrup, Oral	Treatment of sleep disorders	Medical Practitioner	~~M6~~M3
~~Melatonin, Lozenge, Oral~~	~~Treatment of sleep disorders~~	~~Medical Practitioner~~	~~M62~~
Metolazone, Tablet, Oral	Treatment of fluid overload	Medical Practitioner	M163
Mexiletine, Capsule, Oral	Treatment of ventricular arrhythmia	Medical Practitioner	M107
Mexiletine, Capsule, Oral	Treatment of myotonic disorders	Medical Practitioner	M108
Mexiletine, Tablet, Oral	Treatment of ventricular arrhythmia	Medical Practitioner	M105
Mexiletine, Tablet, Oral	Treatment of myotonic disorders	Medical Practitioner	M106
Moxifloxacin 0.5%, Eye drops, Ophthalmic	Treatment of refractory bacterial conjunctivitis	Medical Practitioner	M109
Nadolol, Tablet, Oral	Treatment of ventricular tachycardia	Medical Practitioner	M110
Nadolol, Tablet, Oral	Treatment of Long QT Syndrome	Medical Practitioner	M111
Natamycin 5%, Eye drops, Ophthalmic	Treatment of refractory fungal blepharitis, conjunctivitis or keratitis	Medical Practitioner	M112
Neomycin, Tablet, Oral	Sepsis prevention for colorectal operation	Medical Practitioner	M137
Nicotine/zero nicotine therapeutic vaping goods (incl substances, kits, and goods in vaping packs), solid/liquid, inhalation	smoking cessation or management of nicotine dependence in patients 16 years and older	Medical Practitioner, Nurse Practitioner	M164
Nitazoxanide, Suspension, Oral	Treatment of giardiasis	Medical Practitioner	M64
Nitazoxanide, Suspension, Oral	Treatment of cryptosporidiosis	Medical Practitioner	M65
Nitazoxanide, Suspension, Oral	Treatment of blastocystis	Medical Practitioner	M66
~~Nitazoxanide, Tablet, Oral~~	~~Treatment of giardiasis~~	~~Medical Practitioner~~	~~M67~~
Nitazoxanide, Tablet, Oral	Treatment of giardiasis	Medical Practitioner	M67
Nitazoxanide, Tablet, Oral	Treatment of cryptosporidiosis	Medical Practitioner	M68
~~Nitazoxanide, Tablet, Oral~~	~~Treatment of blastocystis~~	~~Medical Practitioner~~	~~M69~~
~~Bismuth subcitrate, Tablet, Oral~~	~~Treatment of resistant *Helicobacter Pylori* infection~~	~~Medical Practitioner~~	~~M7~~
~~Paromomycin, Capsule, Oral~~	~~Antiprotozoal treatment of *Blastocystis hominis*~~	~~Medical Practitioner~~	~~M70~~
~~Paromomycin, Capsule, Oral~~	~~Antiprotozoal treatment of *Dientomoeba fragilis*~~	~~Medical Practitioner~~	~~M71~~
~~Paromomycin, Capsule, Oral~~	~~Antiprotozoal treatment of *Entamoeba histolytica*~~	~~Medical Practitioner~~	~~M72~~
Nitazoxanide, Tablet, Oral	Treatment of blastocystis	Medical Practitioner	M69
Paromomycin, Capsule, Oral	Antiprotozoal treatment of Dientomoeba fragilis	Medical Practitioner	M71
Paromomycin, Capsule, Oral	Antiprotozoal treatment of Entamoeba histolytica	Medical Practitioner	M72
Paromomycin, Capsule, Oral	Antiprotozoal treatment of parasite infection	Medical Practitioner	M73
Paromomycin, Capsule, Oral	Antiprotozoal treatment of ~~parasite infection~~Blastocystis hominis	Medical Practitioner	~~M73~~M70
Pimozide, Tablet, Oral	Treatment of schizophrenia	Medical Practitioner	M74
Pimozide, Tablet, Oral	Treatment of chronic psychosis	Medical Practitioner	M75
Pimozide, Tablet, Oral	Treatment of Tourette syndrome	Medical Practitioner	M76
Pristinamycin, Tablet, Oral	Treatment of confirmed methicillin-resistant ~~*Staphylococcus aureus*~~Staphylococcus aureus and vancomycin-resistant ~~*enterococci*~~ enterococci infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis.	Medical Practitioner	M77
Pristinamycin, Tablet, Oral	Treatment of refractory or resistant ~~*mycoplasma genitalium*~~mycoplasma genitalium infections	Medical Practitioner	M78
Pristinamycin, Tablet, Oral	Treatment of other infections as prescribed by an infectious disease specialist	Medical Practitioner	M79
~~Tetracycline, Capsule, Oral~~	~~Treatment of resistant *Helicobacter Pylori* infection~~	~~Medical Practitioner~~	~~M8~~
Progesterone in oil, Injection, Intramuscular	Treatment of progesterone deficiency	Medical practitioner	M158
Progesterone, Injection, Subcutaneous	Treatment of progesterone deficiency	Medical practitioner	M157
Pyrazinamide, Tablet, Oral	Treatment of tuberculosis	Medical Practitioner	M22
Riboflavin, 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC), Eye drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus	Medical Practitioner	M138
Riboflavin, 0.1% in 20% dextran, Eye drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.	Medical Practitioner	M9
Riboflavin, 0.1% in sodium chloride, Eye drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus.	Medical Practitioner	M10
Riboflavin, 0.22% in sodium chloride, Eye drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus	Medical Practitioner	M139
Ripasudil 0.4%, Eye drops, Ophthalmic	Treatment of refractory corneal oedema	Medical Practitioner	M117
Ripasudil 0.4%, Eye drops, Ophthalmic	Treatment of refractory glaucoma	Medical Practitioner	M118
Sodium benzoate, Tablet, Oral	Treatment of urea cycle disorders	Medical Practitioner	M113
Tacrolimus 0.03%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children	Medical Practitioner	M119
Tacrolimus 0.1%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults	Medical Practitioner	M87
~~Tetracycline, Tablet, Oral~~	~~Treatment of resistant *Helicobacter Pylori* infection~~	~~Medical Practitioner~~	~~M88~~
Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S, Injection, Intravenous	Prostate cancer imaging study	Medical practitioner	M159
Tetracycline, Capsule, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M8
Tetracycline, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M88
Tick-borne Encephalitis Vaccine, Injection, Intramuscular	Prevention of tick-borne encephalitis	Medical Practitioner	M89
~~Riboflavin, 0.1% in 20% dextran, Eye drops, Ophthalmic~~	~~Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.~~	~~Medical Practitioner~~	~~M9~~
~~Yttrium-90 (Y-90) Citrate, Injection, Intraarticular~~	~~Radiosynovectomy treatment~~	~~Medical Practitioner~~	~~M90~~
Tinidazole, Tablet, Oral	Treatment of trichomonas vaginalis infections of the genito-urinary tract in female and male patients	Medical Practitioner	M140
Tinidazole, Tablet, Oral	Treatment of giardiasis	Medical Practitioner	M141
Tinidazole, Tablet, Oral	Treatment of amoebic dysentery	Medical Practitioner	M142
Tinidazole, Tablet, Oral	Treatment of amoebic liver abscess	Medical Practitioner	M143
Tinidazole, Tablet, Oral	Treatment of acute giardiasis in children	Medical Practitioner	M144
Tinidazole, Tablet, Oral	Treatment of acute amoebic dysentery in children	Medical Practitioner	M145
Tinidazole, Tablet, Oral	Treatment of amoebic liver disease in children	Medical Practitioner	M146
Tinidazole, Tablet, Oral	Prevention of infection at the surgical site	Medical Practitioner	M147
Tizanidine, Capsule, Oral	Treatment of spasticity where other treatments have failed	Medical Practitioner	M114
~~Betaxolol 0.25% (preservative free)~~Tizanidine, ~~Eye drops~~Tablet, ~~Opthalmic~~Oral	Treatment of ~~elevated intraocular pressure~~spasticity where other treatments ~~are inappropriate~~have failed	Medical Practitioner	~~M92~~M115
~~Clobetasol propionate 0.05%, Cream, Topical~~	~~Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed~~	~~Medical Practitioner~~	~~M94~~

~~Clobetasol propionate 0.05%, Lotion, Topical~~	~~Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed~~	~~Medical Practitioner~~	~~M95~~
~~Clobetasol propionate 0.05%, Ointment, Topical~~	~~Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed~~	~~Medical Practitioner~~	~~M96~~
~~Diflunisal, Tablet, Oral~~	~~Treatment of amyloidosis~~	~~Medical Practitioner~~	~~M97~~
~~Levofloxacin, Tablet, Oral~~	~~Treatment of resistant *Helicobacter Pylori* infection~~	~~Medical Practitioner~~	~~M99~~
~~Amiloride, Tablet, Oral~~	~~Treatment of hyopkalemia~~	~~Medical Practitioner~~	~~M160~~
~~Gallium-68 prostate specific membrane antigen (PSMA), Injection, Intravenous~~	~~PET CT gallium 68 PSMA (prostate specific membrane antigen) whole body uptake study~~	~~Medical Practitioner~~	~~M161~~
~~Ganciclovir, Gel, Ophthalmic~~	~~Treatment of cytomegalovirus~~	~~Medical Practitioner~~	~~M162~~
~~Metolazone, Tablet, Oral~~	~~Treatment of fluid overload~~	~~Medical Practitioner~~	~~M163~~
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Treatment of non-infectious uveitis	Medical Practitioner	M120
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Treatment of diabetic macular oedema	Medical Practitioner	M148
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Treatment of cystoid macular oedema secondary to retinal vein occlusion	Medical Practitioner	M149
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Treatment of uveitic macular oedema	Medical Practitioner	M150
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Treatment of post-operative macular oedema (cataract surgery)	Medical Practitioner	M151
Triamcinolone acetonide, Suspension for injection, Ophthalmic	Visualisation during vitrectomy	Medical Practitioner	M2
Verteporfin Powder for injection, Intravenous infusion	Photosensitisation for photodynamic therapy	Medical Practitioner	M21
Yttrium-90 (Y-90) Citrate, Injection, Intraarticular	Radiosynovectomy treatment	Medical Practitioner	M90

Biologicals

Product name, active ingredient, route of administration	Indication	Practitioner type	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical Practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Bone augmentation around implants	Dental Practitioner	B18
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Bony defects	Dental Practitioner	B19
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Composite grafting	Dental Practitioner	B20
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Filling of periodontal defects	Dental Practitioner	B21
MinerOss Cancellous (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B37
MinerOss Cancellous (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B38
MinerOss Cancellous (human bone allograft), Intra-oral graft	Bony defects	Dental Practitioner	B39
MinerOss Cortical (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B40
MinerOss Cortical (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B41
MinerOss Cortical (human bone allograft), Intra-oral graft	Bony defects	Dental Practitioner	B42
MinerOss Cortical and Cancellous (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B53
MinerOss Cortical and Cancellous (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B54
MinerOss Cortical and Cancellous (human bone allograft), Intra-oral graft	Bony defects	Dental Practitioner	B55
Ortho-ATI (tenocytes), cell suspension	Treatment of chronic lateral epicondylitis or gluteal tendinopathy (> 6 months) with or without partial tendon tear, that is not responsive to conservative treatment."	Orthopaedic Surgeon	B56
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B46
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B47
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Bony defects	Dental Practitioner	B48
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B49
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B50
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Bony defects	Dental Practitioner	B51
Tutoplast Pericardium (sterilised human tissue allograft), Topical	Soft tissue graft	Medical Practitioner	B29

Medical devices

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
14/16 Taper Femoral Heads – Oxinium, Smith & Nephew (Catalogue no: 71342280 to 71342368)	Revision hip arthroplasty	Orthopaedic Surgeon	D28
Aequalis PerForm Plus Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D29
Aequalis PerForm Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D30
AltiVate Reverse Shoulder system- DJO Global	For arthroplasty of the shoulder	Orthopaedic Surgeon	D49
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	General Surgeon	D6

BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Obstetrics and Gynaecology Specialist	D2
BlastGen (Product No: 1205)	Embryo transfer	Obstetrics and Gynaecology Specialist	D10
CelGro Type I/III collagen scaffold, Orthocell	Articular cartilage repair: Collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint	Orthopaedic Surgeon	D32
CelGro Type I/III collagen scaffold, Orthocell	Augmentation of rotator cuff tendon repair	Orthopaedic Surgeon	D33
CollaCote Dressing	For haemostasis	Dental Practitioner	D7
CollaCote Dressing	To protect the wound surface during dental procedures	Dental Practitioner	D24
CollaPlug Absorbable Collagen Wound Dressing	For haemostasis	Dental Practitioner	D8
CollaPlug Absorbable Collagen Wound Dressing	To protect the wound surface during dental procedures	Dental Practitioner	D25
CollaTape Absorbable Collagen	For haemostasis	Dental Practitioner	D9
CollaTape Absorbable Collagen	To protect the wound surface during dental procedures	Dental Practitioner	D26
Duraloc Acetabular Cup System – Hip Insert/Liner – Johnson & Johnson t/a DePuy Synthes	Revision hip arthroplasty	Orthopaedic Surgeon	D50
EmbryoGen V2 (Product No: 1204)	Culture of human embryos until the 2-8 cell stage	Obstetrics and Gynaecology Specialist	D3
EmbryoGen V2 (Product No: 1204)	Embryo transfer at day 2 or 3	Obstetrics and Gynaecology Specialist	D11
EmbryoGen & BlastGen (Product No: 1206)	Culture of embryos until the 2-8 cell stage (Embryogen) and culture of embryos from the 4-8 cell stage through to the blastocyst stage (Blastgen)	Obstetrics and Gynaecology Specialist	D4
EmbryoGen & BlastGen (Product No: 1206)	Embryo transfer	Obstetrics and Gynaecology Specialist	D12
EmbryoGen (Product No: 1203)	Fertilisation and culture until the 2-8 cell stage	Obstetrics and Gynaecology Specialist	D5
EmbryoGen (Product No: 1203)	Embryo transfer at day 2 or 3	Obstetrics and Gynaecology Specialist	D13
Endotine Forehead	For use in subperiosteal browplasty surgery	Plastic Surgeon	D14
Endotine Midface	For use in subperiosteal midface suspension surgery	Plastic Surgeon	D15
GM508 CultActive	For investigation of fertilization failure after previous ICSI-cycles	Obstetrics and Gynaecology Specialist	D16
Ilex Skin Protectant	For use on a variety of dermal wounds and stomal irritations as a topical skin barrier	Medical Practitioner; Nurse Practitioner	D17
Insall/Burstein II Modular Knee System - Posterior Stabilised Tibial Articular Surface, Zimmer Biomet (Catalogue no: 00522003101 to 00522003506)	Revision knee arthroplasty	Orthopaedic Surgeon	D35
Jupiter Sternal Protection Device	For use following median sternotomy incisions to add a protective layer over the entire cut surfaces of the sternal bone	Cardiothoracic Surgeon	D18
MG II Total Knee System - Tibial Articular Surface, Zimmer Biomet (Catalogue no: 00511002309 to 00511005323)	Revision knee arthroplasty	Orthopaedic Surgeon	D38
M/G Unicompartmental Knee System - Tibial Articulating Surface, Zimmer Biomet (Catalogue no: 00578804008 to 00578808014)	Revision knee arthroplasty	Orthopaedic Surgeon	D39
Natural Knee II System – Durasul PE Congruent Tibial Insert, Zimmer Biomet (Catalogue no: 620108809 to 620110916)	Revision knee arthroplasty	Orthopaedic Surgeon	D40
NexGen Complete Knee Solution – Cruciate Retaining (CR) Articular Surface, Zimmer Biomet (Catalogue no: 00597002009 to 00597005020)	Revision knee arthroplasty	Orthopaedic Surgeon	D41
NexGen Complete Knee Solution Legacy PS - Articular Surface, Zimmer Biomet (Catalogue no: 5996-020-09 to 00-5996-022-23 AND 00-5996-030-09 to 00-5996-051-20)	Revision knee arthroplasty	Orthopaedic Surgeon	D42
NexGen Complete Knee Solution Mobile Bearing Knee System - Articular Surface, Zimmer Biomet (Catalogue no: 00594203109 to 00594207217)	Revision knee arthroplasty	Orthopaedic Surgeon	D43
NexGen Complete Knee Solution – Posterior Stabilized (PS) Articular Surface, Zimmer Biomet (Catalogue no: 00598202010 to 00598205123)	Revision knee arthroplasty	Orthopaedic Surgeon	D44
Omnifit Crossfire Series II Cup Insert, Stryker Orthopaedics (Catalogue no: 2041C2240 to 2041C3274)	Revision hip arthroplasty	Orthopaedic Surgeon	D45
Primetech Piezo Micro Manipulator and microinjection pipettes	In vitro fertilisation	Obstetrics and Gynaecology Specialist	D51
Pro Osteon® Bone Graft Substitute 200R	For use as a bone graft substitute only for bony voids or gaps that are not intrinsic to the stability of the bony structure	Medical Practitioner; Dental Practitioner	D20
Pro Osteon® Bone Graft Substitute 500R	For use as a bone graft substitute only for voids or gaps that are not intrinsic to the stability of the bony structure	Medical Practitioner	D21
Quintip Individual Skin Test System	For allergy skin testing using puncture to apply the test extract	Medical Practitioner	D22
Reflection Ceramic Acetabular System - Reflection Biolox Forte Ceramic Acetabular Liner, Smith & Nephew (Catalogue no: 71338146 to 71338456)	Revision hip arthroplasty	Orthopaedic Surgeon	D46
Regeneten Bioinductive Implant – Bone Anchors with Anthroscopic Delivery System	Rotator cuff surgery	Orthopaedic Surgeon	D52
SeleXys Hip System – Inlay Bionit2 - Mathys Orthopaedics (Catalogue no: 55462803 to 55463612)	Revision hip arthroplasty	Orthopaedic Surgeon	D47
Trilogy AB Alternate Bearing Shell Insert, Zimmer Biomet (Catalogue no: 00640502601 to 00640503206 AND 00641502802 to 00641503206)	Revision hip arthroplasty	Orthopaedic Surgeon	D48

List of therapeutic goods with an established history of use (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use)

Authorised Prescriber established history of use list (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/authorised-prescriber-established-history-use-lists)

Special Access Scheme (SAS) Category C lists (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/special-access-scheme-sas-category-c-lists)

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Revisions for *Special Access Scheme (SAS) Category C lists*

Revisions

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Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
01/07/2024 - 3:26pm by s 22 medicines table updated (Published)		○	*Current revision*
15/01/2024 - 2:08pm by s 22 WEB-1067 – s 22 (Published)	○		**Revert**
03/08/2023 - 2:53pm by s 22 (Published)	○	○	**Revert**
17/07/2023 - 12:49pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 12:45pm by s 22 (Published)	○	○	**Revert**
21/02/2023 - 12:45pm by s 22 (Published)	○	○	**Revert**
20/02/2023 - 1:59pm by s 22 updated feedback link (Draft)	○	○	**Revert**
20/02/2023 - 1:51pm by s 22 Updated 'SAS and AP online system' link to 'primary call to action' style (Draft)	○	○	**Revert**
15/02/2023 - 4:43pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 3:59pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:08pm by s 22 (Draft)	○	○	**Revert**
15/02/2023 - 1:05pm by s 22 (Draft)	○	○	**Revert**

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Special Access Scheme (SAS) Category C lists

Special Access Scheme (SAS) Category C lists

Check the lists of unapproved products you can access under SAS Category C.

Last updated:
15 January 2024

On this page

Medicines (#medicines)
Biologicals (#biologicals)
Medical devices (#medical-devices)

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://tgaau.qualtrics.com/jfe/form/SV_57rDaBiJKfJL3UO).

If the product you want to use is on the list and conditions are met, you can access immediately under SAS Category C.

You must notify us within 28 days of use of the unapproved product.

To notify us, submit the form in the online system.

SAS and AP online system (https://compliance.health.gov.au/sas/)

You must meet all listed criteria to prescribe a product. This includes:

- dosage form
- route of administration
- indication
- practitioner type.

There are separate lists for medicines, biologicals and medical devices.

Read more about unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0).

Medicines

Search: **Show** 10 **entries**

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hyopkalemia	Medical Practitioner	M160
Betaxolol 0.25% (preservative free), Eye drops, Opthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bismuth subcitrate, Tablet, Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126
Ciclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. (dry eye syndrome)	Medical Practitioner	M12

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Biologicals

Search: **Show** 10 **entries**

Product name, active ingredient, route of administration	Indication	Practitioner type	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical Practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17

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Medical devices

Search: **Show** 10 **entries**

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
14/16 Taper Femoral Heads – Oxinium, Smith & Nephew (Catalogue no: 71342280 to 71342368)	Revision hip arthroplasty	Orthopaedic Surgeon	D28
Aequalis PerForm Plus Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D29
Aequalis PerForm Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D30
AltiVate Reverse Shoulder system- DJO Global	For arthroplasty of the shoulder	Orthopaedic Surgeon	D49
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	General Surgeon	D6
BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Obstetrics and Gynaecology Specialist	D2
BlastGen (Product No: 1205)	Embryo transfer	Obstetrics and Gynaecology Specialist	D10

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
CelGro Type I/III collagen scaffold, Orthocell	Articular cartilage repair: Collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint	Orthopaedic Surgeon	D32
CelGro Type I/III collagen scaffold, Orthocell	Augmentation of rotator cuff tendon repair	Orthopaedic Surgeon	D33
CollaCote Dressing	For haemostasis	Dental Practitioner	D7

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Therapeutic Goods Administration

Special Access Scheme (SAS) Category C lists

Special Access Scheme (SAS) Category C lists

Check the lists of unapproved products you can prescribe under SAS Category C.

We are updating our content for unapproved therapeutic goods. Please give your feedback (https://www.tga.gov.au/resources/resource/forms/website-feedback-or-error-reporting).

If the product you want to use is on the list and conditions are met, you can prescribe immediately under SAS Category C.

You must notify us within 28 days of use of the unapproved product.

To notify us, submit the form in the online system.

SAS and AP online system (https://compliance.health.gov.au/sas/)

You must meet all listed criteria to prescribe a product. This includes:

- dosage form
- route of administration
- indication
- practitioner type.

There are separate lists for medicines, biologicals and medical devices.

Read more about unapproved products for individual patients (Special Access Scheme) (https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme-0).

Medicines

Search: **Show** 10 **entries**

Active ingredient, dosage form, route of administration	Indication	Practitioner type	Code
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Amiloride, Tablet, Oral	Treatment of hyopkalemia	Medical Practitioner	M160
Betaxolol 0.25% (preservative free), Eye drops, Opthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bismuth subcitrate, Tablet, Oral	Treatment of resistant *Helicobacter Pylori* infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Carbidopa, Tablet, Oral	Premedication for F-18 DOPA imaging	Medical Practitioner	M126
Ciclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. (dry eye syndrome)	Medical Practitioner	M12

Showing 1 to 10 of 138 entries

Biologicals

Search: **Show** 10 **entries**

Product name, active ingredient, route of administration	Indication	Practitioner type	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical Practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17

Showing 1 to 10 of 31 entries

Medical devices

Search: **Show** 10 **entries**

Product name, manufacturer name, description (including manufacturer's intended purpose and any variant details)	Purpose	Practitioner type	Code
14/16 Taper Femoral Heads – Oxinium, Smith & Nephew (Catalogue no: 71342280 to 71342368)	Revision hip arthroplasty	Orthopaedic Surgeon	D28
Aequalis PerForm Plus Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D29
Aequalis PerForm Reversed Glenoid, Wright Medical	For arthroplasty of the shoulder	Orthopaedic Surgeon	D30
AltiVate Reverse Shoulder system- DJO Global	For arthroplasty of the shoulder	Orthopaedic Surgeon	D49
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	General Surgeon	D6
BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Obstetrics and Gynaecology Specialist	D2
BlastGen (Product No: 1205)	Embryo transfer	Obstetrics and Gynaecology Specialist	D10
CelGro Type I/III collagen scaffold, Orthocell	Articular cartilage repair: Collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint	Orthopaedic Surgeon	D32
CelGro Type I/III collagen scaffold, Orthocell	Augmentation of rotator cuff tendon repair	Orthopaedic Surgeon	D33
CollaCote Dressing	For haemostasis	Dental Practitioner	D7

Showing 1 to 10 of 44 entries

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections – tips to help you make an informed decision

Comparing
30/01/2024 - 12:49pm (https://www.tga.gov.au/resources/resource/guidance/cosmetic-injections-tips-help-you-make-informed-decision) s 22
21/06/2022 - 10:33am (https://www.tga.gov.au/node/289459/revisions/350407/view) PJOoNEkkpQAOViqT

Layout
Visual Inline (https://www.tga.gov.au/node/289459/revisions/view/350407/558930/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/289459/revisions/view/350407/558930/visual_inline?view_mode=full)

Cosmetic injections – tips to help you make an informed decision

~~**Guidance**~~

If you are considering a cosmetic injection, use this information to carefully research both the products and the health practitioners involved.

Last updated:
23 July 2019

Cosmetic injections are medical procedures that involve injecting a substance under your skin to change an aspect of your appearance (e.g. reducing the appearance of wrinkles or lines on your face). If used incorrectly, the substances in these injections could cause skin damage, blindness or even death.

If you are considering a cosmetic injection, use this information to carefully research both the products and the health practitioners involved.

Attend a consultation

The products used in cosmetic injections require a prescription from a registered medical practitioner. The doctor authorising the administration of the injection must consult with you and fully explain the procedure before the treatment goes ahead. This consultation should always occur face-to-face, either in person or via video conference.

Make a list of your questions or concerns and bring these along to your consultation. You should be provided with enough information for you to make an informed decision, including possible risks and complications. Your informed consent in writing should be obtained before the procedure goes ahead. Make sure to give yourself time to think about all that is involved before agreeing to anything. See our fact sheet '~~things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/node/840574)~~things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/node/151126)', for tips on questions to ask during a consultation.

Check that the clinic is operating legally

A legal requirement is for cosmetic injection clinics to be licenced. However, illegal procedures often take place in various locations including beauty clinics, residential homes and hotel rooms, including airports.

To find out if the clinic is licenced, contact the local council or territory government in the area the clinic is located.

Check the registration status of the health practitioners involved

You should check that both the doctor who prescribes the cosmetic injection product and the health practitioner who administers the injection are registered. The register of practitioners can be searched on the Australian Health Practitioner Regulation Agency's (AHPRA) (https://www.ahpra.gov.au/) website.

The Medical Board of Australia's (https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx) guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures, outline the requirements for medical practitioners prescribing and administering cosmetic injection products.

In limited cases, nurse practitioners and dentists may prescribe cosmetic injection products. The Dental Board of Australia (https://www.dentalboard.gov.au/Codes-Guidelines/FAQ/botulinum-toxin-and-dermal-fillers.aspx) has published a fact sheet outlining expectations of dentists performing cosmetic injections. The Nursing and Midwifery Board of Australia (https://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Position-Statements/nurses-and-cosmetic-procedures.aspx) has also issued a position statement outlining expectations of nurses working in the area of cosmetic procedures. Cosmetic registered nurses administering cosmetic injections must be supervised by a doctor.

Reputable, registered health practitioners are less likely to be involved in the illegal importation and/or use of dangerous counterfeit products. You can avoid these products by ensuring you are prescribed a product that has been approved by the TGA.

Check that the health practitioners involved are suitably experienced

Your registered health practitioner must have the appropriate knowledge and training.

Ask your registered health practitioner how much experience they have with this type of procedure. They must also ensure that anyone else involved in the procedure is suitably qualified and experienced.

Research the risks

As with all medical procedures, there is a degree of risk associated with cosmetic injections. Cosmetic injections into the wrong area of the face may result in serious consequences. While less severe side-effects such skin redness, acne and swelling can occur, some of the more serious risks include:

- permanent blindness, which can occur when the filler is injected into any part of the facial artery and is not limited to procedures involving the eye area
- discolouration and death of skin tissue following dermal fillers being injected incorrectly; and
- the presence of counterfeit cosmetic injectables on the Australian market. There is no knowing what these are made of and should be avoided.

Your registered health practitioner is also responsible for providing aftercare. You should be provided with written instructions and advice on what follow-up will be provided and what to do if you experience unexpected side effects.

Research the products

Ask about the products that are going to be used in your procedure. As legislation prevents the advertising of product and brand names, you will need to ask for this information.

Substances used in cosmetic injections are regulated as Schedule 4 medicines, and can only be accessed with a valid prescription. This means products purchased without a prescription, such as those from overseas, may be counterfeit and dangerous.

The ~~Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/4049)~~Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/287250) lists all of the products that can be legally supplied in Australia. Search the ARTG to ensure that the product used in your procedure is registered.

Avoid counterfeit products

Some clinics have been involved in the illegal importation and use of dangerous counterfeit products. Cheaper products imported from overseas can be difficult to identify and may pose health risks.

Do your research and ensure that your registered health practitioner is prescribing a product that is included on the ARTG (see above). If it sounds too good to be true, it often is!

Report any unexpected side effects

As with most medical procedures, there will be a range of side effects that are considered normal for cosmetic injections. These side effects should be explained to you and may include redness and swelling of the skin.

It is important for health practitioners to report unexpected side effects to the TGA. You can also report problems experienced as a result of a cosmetic injection ~~directly to the TGA (https://www.tga.gov.au/node/4578)~~directly to the TGA (https://www.tga.gov.au/node/287456).

Report illegal or questionable practices

The TGA oversees the regulation of therapeutic goods used in Australia, whether produced in Australia or elsewhere. The TGA implements a range of enforcement remedies to address illegal supply of unapproved therapeutic goods, including seizing and destroying illegal medicines and medical devices, and criminal or civil court proceedings, which can result in substantial fines or imprisonment.

You should ~~report illegal or questionable practices (https://www.tga.gov.au/node/5529)~~report illegal or questionable practices (https://www.tga.gov.au/node/282892), including suspected counterfeit medicines and medical devices, to the TGA. Also ~~advertising complaints (https://compliance.tga.gov.au/advertising_complaint/)~~advertising complaints (https://compliance.health.gov.au/ac-report/) can be made online.

Topics:

Alert/Advisory (https://www.tga.gov.au/topics/alertadvisory)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections – tips to help you make an informed decision

Guidance

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Last updated:
23 July 2019

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Your registered health practitioner must have the appropriate knowledge and training.

Ask your registered health practitioner how much experience they have with this type of procedure. They must also ensure that anyone else involved in the procedure is suitably qualified and experienced.

Research the risks

As with all medical procedures, there is a degree of risk associated with cosmetic injections. Cosmetic injections into the wrong area of the face may result in serious consequences. While less severe side-effects such skin redness, acne and swelling can occur, some of the more serious risks include:

- permanent blindness, which can occur when the filler is injected into any part of the facial artery and is not limited to procedures involving the eye area
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Topics:

Alert/Advisory (https://www.tga.gov.au/topics/alertadvisory)

Revisions for *Cosmetic injections – tips to help you make an informed decision*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
30/01/2024 - 12:49pm by s 22 (Published)		○	*Current revision*
30/01/2024 - 12:49pm by s 22 (Published)	○		**Revert**
23/05/2023 - 4:49pm by s 22 fixed 'advertising complaints' link (Published)	○	○	**Revert**
21/06/2022 - 10:33am by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**
21/06/2022 - 10:33am by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**
21/06/2022 - 10:33am by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections – tips to help you make an informed decision

Cosmetic injections – tips to help you make an informed decision

Last updated:
23 July 2019

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It is important for health practitioners to report unexpected side effects to the TGA. You can also report problems experienced as a result of a cosmetic injection directly to the TGA (https://www.tga.gov.au/node/4578).

Report illegal or questionable practices

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Topics:

Alert/Advisory (https://www.tga.gov.au/topics/alertadvisory)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections

Next change (https://www.tga.gov.au/node/287869/revisions/view/511057/550077/visual_inline)

Comparing
09/01/2024 - 12:32pm (https://www.tga.gov.au/node/287869/revisions/511057/view) s 22
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Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node) Cosmetic injections (https://www.tga.gov.au/products/medical-devices/cosmetic-injections)

Cosmetic injections

Information on cosmetic injections so you can make an informed decision about your procedure.

Last updated:
22 August 2019

Cosmetic injections are medical procedures that involve injecting a substance under your skin to change an aspect of your appearance. For example, reducing the appearance of wrinkles or wrinkles on your face, or putting filler into your lips to make them fuller. If used incorrectly, the substances in these injections could cause skin damage, blindness or even death.

The information provided on this website is designed to support, not replace, the relationship that exists between a patient and a health practitioner. We have provided this information to help the public make informed decisions about whether or not to get cosmetic injections.

If you are considering a cosmetic injection, use this information carefully to research both the products and health practitioners involved:

- Understand all the risks that are associated with cosmetic injections so you can ~~make an informed decision about your procedure (https://www.tga.gov.au/node/874801)~~make an informed decision about your procedure (https://www.tga.gov.au/node/289459).
- ~~Beware of home-based beauty services (https://www.tga.gov.au/node/711346)~~Beware of home-based beauty services (https://www.tga.gov.au/node/151118). Individuals offering cheaper, home-based services may be using imported products which have not been approved for supply in Australia.
- Always attend a consultation before you commit to any cosmetic procedure, and make sure the person performing your procedure is suitably qualified and experienced.
- ~~Report illegal or questionable practices (https://www.tga.gov.au/node/5529)~~Report illegal or questionable practices (https://www.tga.gov.au/node/282892) to us for investigation.
- ~~Report any unexpected side effects (https://www.tga.gov.au/node/4578)~~Report any unexpected side effects (https://www.tga.gov.au/node/287456).

Resources

~~Cosmetic injections checklist~~ (https://www.tga.gov.au/node/874442)

~~Things to consider before undergoing procedures involving dermal fillers (fact sheet)~~ (https://www.tga.gov.au/node/840574)

~~Beware of 'home based' beauty services~~ (https://www.tga.gov.au/node/711346)

~~Counterfeit medicines and medical devices~~ (https://www.tga.gov.au/node/3989)

~~Cosmetic injectables: things to know before the procedure (video)~~ (https://www.youtube.com/watch?list=PLbha5HB_rfeBlfYodtx83Y4UqupI-QAsH&v=CDAMOYhUx0A)

~~Understanding the risks of cosmetic injectables (video)~~ (https://www.youtube.com/watch?v=hMNDCJ2ipYo&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=14&t=0s)

~~How to get help when a procedure has gone wrong (video)~~ (https://www.youtube.com/watch?v=HknqxKAhK8g&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=7&t=0s)

~~Cosmetic treatments: injectables~~ (https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/cosmetic-treatments-injectables)

~~Know your consumer rights before you consider a beauty treatment or cosmetic procedure (pdf,57kb)~~ (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0011/386786/FT_Beauty_Checklist_DL_LoRes.pdf)

~~Beauty and cosmetic services~~ (https://www.fairtrading.nsw.gov.au/buying-products-and-services/buying-services/beauty-services)

- Cosmetic injections checklist (https://www.tga.gov.au/node/151130)
- Things to consider before undergoing procedures involving dermal fillers (fact sheet) (https://www.tga.gov.au/node/151126)
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- Counterfeit medicines and medical devices (https://www.tga.gov.au/node/287212)
- Cosmetic injectables: things to know before the procedure (video) (https://www.youtube.com/watch?list=PLbha5HB_rfeBlfYodtx83Y4UqupI-QAsH&v=CDAMOYhUx0A)
- Understanding the risks of cosmetic injectables (video) (https://www.youtube.com/watch?v=hMNDCJ2ipYo&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=14&t=0s)
- How to get help when a procedure has gone wrong (video) (https://www.youtube.com/watch?v=HknqxKAhK8g&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=7&t=0s)
- Cosmetic treatments: injectables (https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/cosmetic-treatments-injectables)
- Know your consumer rights before you consider a beauty treatment or cosmetic procedure (pdf,57kb) (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0011/386786/FT_Beauty_Checklist_DL_LoRes.pdf)
- Beauty and cosmetic services (https://www.fairtrading.nsw.gov.au/buying-products-and-services/buying-services/beauty-services)

Translated resources

Mandarin

~~Cosmetic injectables: things to know before the procedure (video)~~ (https://www.youtube.com/watch?v=3vi2Z0_NIrw&feature=youtu.be)

- Cosmetic injectables: things to know before the procedure (video) (https://www.youtube.com/watch?v=3vi2Z0_NIrw&feature=youtu.be)

Chinese simplified

~~Cosmetic injections checklist (pdf,453)~~ (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-simplified.pdf)

~~Things to consider before undergoing procedures involving dermal fillers (pdf,515kb)~~ (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-simplified.pdf)

~~Understanding the risks of cosmetic injectables (subtitled video)~~ (https://www.youtube.com/watch?v=WzTRdLObb4w&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=10&t=0s)

~~How to get help when a procedure has gone wrong (subtitled video)~~ (https://www.youtube.com/watch?v=6DDOUEEI2o4&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=9&t=0s)

~~Know your consumer rights before you consider a beauty treatment or cosmetic procedure (pdf,182kb)~~ (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0011/392735/3.ChineseS_FT_Beauty_Checklist_pink-LR.pdf)

~~Beauty and cosmetic services (pdf,363kb)~~ (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0010/392707/2.ChineseS_Beauty_Consumer_0718.pdf)

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~~Understanding the risks of cosmetic injectables (subtitled video)~~ (https://www.youtube.com/watch?v=ihcxcaNp7M0&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=12&t=0s)

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Various languages

~~Top Tips for Safe Health Care~~ (http://healthtranslations.vic.gov.au/bhcv2/bhcht.nsf/PresentDetail?Open&s=Top tips for safe health care: what you need to know for yourself, your family or someone you care for) ~~is a valuable resource, available in a variety of translations, including English, Simplified Chinese, Traditional Chinese, Korean and Vietnamese.~~

- Top Tips for Safe Health Care (http://healthtranslations.vic.gov.au/bhcv2/bhcht.nsf/PresentDetail?Open&s=Top tips for safe health care: what you need to know for yourself, your family or someone you care for) is a valuable resource, available in a variety of translations, including English, Simplified Chinese, Traditional Chinese, Korean and Vietnamese.

Topics:

Medical devices safety (https://www.tga.gov.au/topics/medical-devices-safety)

Medical devices (https://www.tga.gov.au/products/medical-devices)

Breast implant hub (https://www.tga.gov.au/products/medical-devices/breast-implant-hub)

Cosmetic injections (https://www.tga.gov.au/products/medical-devices/cosmetic-injections)

Find information about a medical device (https://www.tga.gov.au/products/medical-devices/find-information-about-medical-device)

IVD medical devices regulation basics (https://www.tga.gov.au/products/medical-devices/vitro-diagnostic-ivd-medical-devices)

List of ventilators, CPAP, and BiPAP devices unaffected by foam material (https://www.tga.gov.au/products/medical-devices/list-ventilators-cpap-and-bipap-devices-unaffected-foam-material)

Medical devices overview (https://www.tga.gov.au/products/medical-devices/medical-devices-overview)

Medical devices regulation basics (https://www.tga.gov.au/products/medical-devices/medical-devices-regulation-basics)

Metal-on-metal hip replacement implants (https://www.tga.gov.au/products/medical-devices/metal-metal-hip-replacement-implants-hub)

Types of medical devices (https://www.tga.gov.au/products/medical-devices/specific-types-medical-devices)

Urogynaecological (transvaginal) surgical mesh hub (https://www.tga.gov.au/products/medical-devices/urogynaecological-transvaginal-surgical-mesh-hub)

Revisions for *Cosmetic injections*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
21/06/2024 - 11:33am by s 22 [redacted] medical device topic removed, medical device product type added (Published)	○		*Current revision*
09/01/2024 - 12:32pm by s 22 [redacted] (Published)	○		**Revert**
12/08/2022 - 9:21am by s 22 [redacted] (Published)	○	○	**Revert**
12/08/2022 - 9:21am by s 22 [redacted] (Published)	○	○	**Revert**
12/08/2022 - 9:20am by s 22 [redacted] (Published)	○	○	**Revert**
05/08/2022 - 3:06pm by s 22 [redacted] (Published)	○	○	**Revert**
03/08/2022 - 12:48pm by s 22 [redacted] (Published)	○	○	**Revert**
02/08/2022 - 4:12pm by s 22 [redacted] (Published)	○	○	**Revert**
28/07/2022 - 1:02pm by s 22 [redacted] (Published)	○	○	**Revert**
28/07/2022 - 12:58pm by s 22 [redacted] (Published)	○	○	**Revert**
28/07/2022 - 12:57pm by s 22 [redacted] (Published)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**
21/06/2022 - 10:29am by PJOoNEkkpQAOViqT (Draft)	○	○	**Revert**

Revision			Operations
21/06/2022 10:29am by PJOoNEkkpQAOViqT (Draft)	◯	◯	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections

Cosmetic injections

Last updated:
22 August 2019

Cosmetic injections are medical procedures that involve injecting a substance under your skin to change an aspect of your appearance. For example, reducing the appearance of wrinkles or wrinkles on your face, or putting filler into your lips to make them fuller. If used incorrectly, the substances in these injections could cause skin damage, blindness or even death.

The information provided on this website is designed to support, not replace, the relationship that exists between a patient and a health practitioner. We have provided this information to help the public make informed decisions about whether or not to get cosmetic injections.

If you are considering a cosmetic injection, use this informat on carefully to research both the products and health practitioners involved:

- Understand all the risks that are associated with cosmetic injections so you can make an informed decision about your procedure (https://www.tga.gov.au/node/874801).
- Beware of home-based beauty services (https://www.tga.gov.au/node/711346). Individuals offering cheaper, home-based services may be using imported products which have not been approved for supply in Australia.
- Always attend a consultation before you commit to any cosmetic procedure, and make sure the person performing your procedure is suitably qualified and experienced.
- Report illegal or questionable practices (https://www.tga.gov.au/node/5529) to us for investigation.
- Report any unexpected side effects (https://www.tga.gov.au/node/4578).

Resources

Cosmetic injections checklist (https://www.tga.gov.au/node/874442)

Things to consider before undergoing procedures involving dermal fillers (fact sheet) (https://www.tga.gov.au/node/840574)

Beware of 'home based' beauty services (https://www.tga.gov.au/node/711346)

Counterfeit medicines and medical devices (https://www.tga.gov.au/node/3989)

Cosmetic injectables: things to know before the procedure (video) (https://www.youtube.com/watch?list=PLbha5HB_rfeBlfYodtx83Y4UqupI-QAsH&v=CDAMOYhUx0A)

Understanding the risks of cosmetic injectables (video) (https://www.youtube.com/watch?v=hMNDCJ2ipYo&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=14&t=0s)

How to get help when a procedure has gone wrong (video) (https://www.youtube.com/watch?v=HknqxKAhK8g&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=7&t=0s)

Cosmetic treatments: injectables (https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/cosmetic-treatments-injectables)

Know your consumer rights before you consider a beauty treatment or cosmetic procedure (pdf,57kb) (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0011/386786/FT_Beauty_Checklist_DL_LoRes.pdf)

Beauty and cosmetic services (https://www.fairtrading.nsw.gov.au/buying-products-and-services/buying-services/beauty-services)

Translated resources

Mandarin

Cosmetic injectables: things to know before the procedure (video) (https://www.youtube.com/watch?v=3vi2Z0_NIrw&feature=youtu.be)

Chinese simplified

Cosmetic injections checklist (pdf,453) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-simplified.pdf)

Things to consider before undergoing procedures involving dermal fillers (pdf,515kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-chinese-simplified.pdf)

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Chinese traditional

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Various languages

Top Tips for Safe Health Care (http://healthtranslations.vic.gov.au/bhcv2/bhcht.nsf/PresentDetail?Open&s=Top_tips_for_safe_health_care:_what_you_need_to_know_for_yourself,_your_family_or_someone_you_care_for_) is a valuable resource, available in a variety of translations, including English, Simplified Chinese, Traditional Chinese, Korean and Vietnamese.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections

Cosmetic injections

Information on cosmetic injections so you can make an informed decision about your procedure.

Last updated:
22 August 2019

Cosmetic injections are medical procedures that involve injecting a substance under your skin to change an aspect of your appearance. For example, reducing the appearance of wrinkles or wrinkles on your face, or putting filler into your lips to make them fuller. If used incorrectly, the substances in these injections could cause skin damage, blindness or even death.

The information provided on this website is designed to support, not replace, the relationship that exists between a patient and a health practitioner. We have provided this information to help the public make informed decisions about whether or not to get cosmetic injections.

If you are considering a cosmetic injection, use this informat on carefully to research both the products and health practitioners involved:

- Understand all the risks that are associated with cosmetic injections so you can make an informed decision about your procedure (https://www.tga.gov.au/node/289459).
- Beware of home-based beauty services (https://www.tga.gov.au/node/151118). Individuals offering cheaper, home-based services may be using imported products which have not been approved for supply in Australia.
- Always attend a consultation before you commit to any cosmetic procedure, and make sure the person performing your procedure is suitably qualified and experienced.
- Report illegal or questionable practices (https://www.tga.gov.au/node/282892) to us for investigation.
- Report any unexpected side effects (https://www.tga.gov.au/node/287456).

Resources

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- Things to consider before undergoing procedures involving dermal fillers (fact sheet) (https://www.tga.gov.au/node/151126)
- Beware of 'home based' beauty services (https://www.tga.gov.au/node/151118)
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- Things to consider before undergoing procedures involving dermal fillers (pdf,509kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-korean.pdf)
- Understanding the risks of cosmetic injectables (subtitled video) (https://www.youtube.com/watch?v=ihcxcaNp7M0&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=12&t=0s)
- How to get help when a procedure has gone wrong (subtitled video) (https://www.youtube.com/watch?v=kmYat9VjmtY&list=PLplfF3Uu2rPeRnER_x-pzrG-C13BSCT9v&index=8&t=3s)
- Know your consumer rights before you consider a beauty treatment or cosmetic procedure (pdf,110kb) (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0007/385702/3.Korean_FT_Beauty_Checklist_pink-LR.pdf)
- Beauty and cosmetic services (pdf,202kb) (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0005/392711/2.Korean_Beauty_Consumer_0718.pdf)

Vietnamese

- Cosmetic injections checklist (pdf,461kb) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-vietnamese.pdf)
- Things to consider before undergoing procedures involving dermal fillers (pdf,458kb) (https://www.tga.gov.au/sites/default/files/things-consider-undergoing-procedures-involving-dermal-fillers-vietnamese.pdf)
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- Beauty and cosmetic services (pdf,160kb) (https://www.fairtrading.nsw.gov.au/__data/assets/pdf_file/0008/392714/2.Vietnamese_Beauty_Consumer_0718.pdf)

Various languages

- Top Tips for Safe Health Care (http://healthtranslations.vic.gov.au/bhcv2/bhcht.nsf/PresentDetail?Open&s=Top_tips_for_safe_health_care:_what_you_need_to_know_for_yourself,_your_family_or_someone_you_care_for_) is a valuable resource, available in a variety of translations, including English, Simplified Chinese, Traditional Chinese, Korean and Vietnamese.

Topics:

Medical devices safety (https://www.tga.gov.au/topics/medical-devices-safety)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising health services and cosmetic injections: frequently asked questions and answers

Find answers to frequently asked questions about advertising cosmetic injection services and our guidelines.

Last updated:
22 May 2024

On this page

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General questions about referring to cosmetic injectables in advertising (#general-questions-about-referring-to-cosmetic-injectables-in-advertising)
FAQs about advertising specific products and treatments (#faqs-about-advertising-specific-products-and-treatments)
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About these Frequently Asked Questions (FAQs)

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Advertisers are encouraged to read our updated guidance on Advertising health services () for detailed information on how to advertise health services, including cosmetic injection services, without unlawfully advertising therapeutic goods.

This page provides advertisers with answers to frequently asked questions in relation to these products.

It is the responsibility of each advertiser to ensure their advertisement does not promote therapeutic goods in a way that is not compliant with the legislative requirements. To obtain advice specific to your circumstances you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant (). Please note, these consultants are not endorsed by us.

General questions about referring to cosmetic injectables in advertising

Why have guidelines for advertising cosmetic injections been updated?

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Detailed information on the background to these changes is provided in our media release Referring to cosmetic injectables in advertising ().

What has changed?

The legislation regarding cosmetic injectables has not changed. Most cosmetic injectables contain substances that are in Schedule 4 to the Poisons Standard () and, in accordance with the *Therapeutic Goods Act 1989* (the Act), cannot be advertised to the public.

We no longer expressly permit references to terms such as 'wrinkle reducing injections' or 'dermal fillers' where those terms would result in a reasonable consumer understanding the intention of the content is to promote the use or supply of a prescription-only medicine or good containing such as substance. This includes through acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to a specific prescription-only medicine or substance.

This does not apply to cosmetic injectables that do not contain any prescription-only substances.

Can you provide me with a list of acceptable terms for describing the cosmetic injection services I offer?

In line with the TGA customer service standards (), we do not give advice on specific issues, or advice specific to individual circumstances. Therefore, we cannot advise in specific terms what can be done by industry or provide a list of 'acceptable' or 'substitute' terms.

As outlined in our guidance on Advertising health services (), clinics should focus their advertising on the types of consultations available instead of referring to prescription-only medicines or substances used in the treatments they offer.

Advertisers must determine if the information they are disseminating would meet the Act's definition of 'advertise' in relation to therapeutic goods. In doing so, they should consider if the viewer would reasonably consider the intention of the information is to promote the use or supply of a therapeutic good.

How can I communicate treatment options with my patients?

Prescription-only medications carry higher risks than goods available for self-selection. It is important that all patients can make informed and accurate decisions about which cosmetic treatment is right for them.

The most credible information around whether a prescription-only medicine is right for a specific patient comes from a consultation between a patient and their appropriately trained and qualified health professional.

While the advertising of therapeutic goods is within the jurisdiction of the Act, it does not extend to the education of patients and clients, provided the information is non-promotional.

Additionally, information shared between a health practitioner and their patient during a private consultation or treatment, is not subject to the advertising rules for therapeutic goods.

Are phone consultations allowed with patients?

The regulation of health services, including telehealth (phone) consultations between a patient and their treating health practitioner, is not within our jurisdiction.

Additionally, information shared between a health practitioner and their patient during a private consultation or treatment, including through telehealth consultation, is not subject to the advertising rules for therapeutic goods.

How can I advertise my cosmetic injection service without advertising therapeutic goods?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. This would have to be considered in context as other information in the promotional material could make it clear to consumers that what is being offered (promoted) are prescription-only substances or goods that contain such substances.

Can non-medical staff at a clinic answer direct questions from patients or potential patents about which cosmetic injectables are offered at the clinic?

If information provided by non-medical staff would be reasonably taken by its audience to be intended to promote the use or supply of a prescription-only medicine or substance, the information is likely to be considered advertising.

Generally, solicited information (requested or asked for by a patient) is less likely to meet the legislative definition of 'advertise' than unsolicited information that is published or widely disseminated. Giving information necessary to answer a direct question (without providing additional information that could be taken to be intended to be promotional) is unlikely to be advertising. However, this will depend on what is communicated in the telephone conversation or in person.

Can I refer to cosmetic injectables in my client booking system?

Publicly available booking systems that draw consumers to a service on the basis that specific therapeutic goods are used in the delivery of the service are likely to be an advertisement for **therapeutic goods**. Where the advertisement also refers to prescription-only medicines or substances it would be unlawful. For example:

- providing a form or other facility from which the consumer self-selects from a list of treatments involving prescription-only medicines or substances
- providing price information for a prescription-only medicine or substance.

Whether the use of a prescription-only medicine or substance is appropriate for an individual should be discussed with a patient during consultation with an appropriately trained health practitioner. Such a consultation also allows the practitioner to discuss risks and contra-indications with their patient.

Is educational content about 'cosmetic injectables' or 'injectables' considered to be an advertisement?

Not all information released to the public about therapeutic goods is advertising. However, if the intention of the information (from the end viewer's point of view) is to promote the use or supply of a therapeutic good then we would likely consider it to be advertising and it must meet the legislative requirements as set out in the Act.

Whether or not information is an advertisement or not must be considered in context on a case-by-case basis. In general, the following types of information are unlikely to be considered advertising:

- information about the risks that may be associated with using cosmetic injectables
- information about training courses or training material for health care professionals.

Educational information for patients that is purely factual and balanced (communicates risks and benefits) and is non-promotional in nature is also unlikely to be considered advertising. Examples include 'before' and 'after' care instructions.

Why have surgeons and surgical procedures not been addressed in this change?

We regulate the advertising, manufacture, import, export and supply of therapeutic goods, which include medicines, medical devices and biologicals.

By contrast, the regulation of the promotion of health services is not within our jurisdiction.

The Australian Health Practitioner Regulation Agency (Ahpra) (https://www.ahpra.gov.au/) and the National Boards regulate health practitioners and their practices/services which encompasses surgeons and surgical cosmetic procedures.

Why has the cosmetic industry come under more scrutiny than other industries?

We have updated our guidance on Advertising health services, including cosmetic injection services, to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods. The legislation regarding cosmetic injectables has not changed.

Recently we have witnessed the widespread promotion of health services (including telehealth) which seeks to attract consumers on the basis that particular prescription-only medicines (for example 'weight loss injections', 'nicotine vaping products', or 'medicinal cannabis'), can be prescribed at, and in some cases supplied by, the health service.

We interpret that this type of advertising is an advertisement for a therapeutic good that refers to prescription-only medicines, which is unlawful. We were concerned to resolve any inconsistency in interpretation across all industry areas.

We have taken enforcement actions against entities across a number of industry areas for alleged unlawful advertising of prescription-only medicines. More information can be found at Compliance actions and outcomes (https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-actions-and-outcomes#infringement).

FAQs about advertising specific products and treatments

How can I find what substances are part of the Schedule 4 drugs list?

Information relating to how prescription-only substances are scheduled, along with a link to the current version, can be found on the Poisons Standard (the SUSMP) () webpage.

Can I advertise a bio-stimulator such as Sculptra?

Sculptra contains the substance Poly-L-lactic acid, which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Sculptra (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise REJURAN?

In Australia, Rejuran is regulated as a Class III medical device. Rejuran is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (does not contain a prescription-only or pharmacist only medicine) and is not prohibited from being advertised to the public.

Can I advertise polydioxanone (PDO) threads?

PDO threads are regulated as a Class III medical device. Polydioxanone is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (do not contain a prescription-only or pharmacist only medicine) and are not prohibited from being advertised to the public, provided the product is included in the Australian Register of Therapeutic Goods (ARTG) ().

Can I advertise Masseter treatment?

Advertisers cannot make any reference, directly or indirectly, in their advertisement to prescription-only substances or to the trade names of prescription-only goods. This includes acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to the specific good or substance.

If a reference to the 'Masseter treatment' is likely to be taken by the audience to be a reference to a prescription-only substance or good containing such as substance this would likely contravene the Act.

Please note that advertising a therapeutic good for an indication that has not been accepted in relation to the inclusion of the good on the register, for example advertising Botox for an off-label use, is also prohibited by the Act.

Can I advertise Profhilo?

Profhilo contains hyaluronic acid which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Profhilo (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise Platelet Rich Plasma (PRP), bio-remodellers and monothreads?

PRP, bio-remodellers and monothreads are outside the scope of these changes if they do not contain any substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard (i.e. do not contain a prescription-only or pharmacist only medicine).

It should be noted that the application of the legislative requirements around advertising PRP is complex – we encourage stakeholders to seek independent advice if necessary.

Can I advertise energy-based medical devices used in cosmetic procedures such as lasers, ultrasound and radio frequency devices?

In general, medical devices that do not contain substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard may be lawfully advertised to the public (subject to meeting applicable regulatory requirements which may include inclusion in the ARTG). Advertisements for these devices must comply with all applicable legislative requirements, including the Therapeutic Goods Advertising Code.

How can I explain to patients that we can assist with medical conditions such as migraines, hyperhidrosis, TMJ etc?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement. It is the advertiser's responsibility to focus on the service being provided at the practice and not the medicine being administered to treat the condition.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. For example, 'call our clinic for a consultation to discuss treatment options for migraines'.

Questions about specific types of advertising

Can I provide price lists for 'anti-wrinkle injections' and 'dermal fillers'?

The prohibition on advertising therapeutic goods containing prescription-only substances to the public applies to any 'statement, pictorial representation or design' that promotes the use or supply of the goods. Generally, stating a price in reference to a prescription-only cosmetic injectable (irrespective if it is total cost of treatment or cost per unit) is likely to be considered an advertisement for that product.

Under the advertising legislation price lists may be published for prescription medicines subject to strict requirements. These include price lists/pricing information:

- may only be published or disseminated by a retail pharmacy or agent acting on behalf of a retail pharmacy
- must contain no less than 25 medicines
- must be in alphabetical order and grouped into their specific scheduling.

It is unlikely that a cosmetic clinic would meet the definition of a retail pharmacy and therefore publication of price lists/pricing information (for prescription-only medicine or substance) by cosmetic injection services is likely to contravene the Act.

Can I place advertisements in the reception area?

Information shared between a health practitioner and their patient during a private consultation or treatment, is not subject to the advertising rules for therapeutic goods.

However, this is unlikely to extend to the displaying of advertisements in the reception area and therefore doing so is likely to contravene the Act.

Can I refer to cosmetic injectables to describe 'before and after' photos?

Advertisers are not prohibited from using 'before' and 'after' photos to advertise their health service. However, they must not, directly or indirectly, refer to prescription-only substances or goods containing such substances used in the delivery of that service.

Advertisers of cosmetic injection services have an obligation to comply with the legislative requirements for advertising therapeutic goods as well as any requirements governing the advertising of services, which are administered by Ahpra.

Where 'before and after' photos are used and it is apparent that the 'after' photo is due to the administration of a prescription-only cosmetic injectable, this is likely to amount to an advertisement for a therapeutic good that would contravene the Act.

Do I need to update old social media content that refers to cosmetic injectables?

Due to the nature of social media posts and their ready accessibility to consumers regardless of the date posted, all social media posts, historical and new, are required to comply with the requirements.

For more information about advertising on social media, please review our social media advertising guide () which should be read in conjunction with the guidance on advertising health services ().

Am I responsible for social media posts where a patient has referenced my clinic?

Business owners are responsible for the content of social media pages created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

Although it is up to the party responsible for the advertising to ensure compliance with the requirements, we recommend that businesses also provide corrective information if they become aware of misinformation from third parties on social media channels for which they are not responsible and endeavour to remove any identifying factors (such as hashtags).

Advertisers should ensure any corrective information also complies with the advertising requirements if it is used within an advertisement or is an advertisement in its own right.

For more information, please visit our social media advertising guide. ()

Can I refer to 'injectables' in my business name?

Consistent with guidance we have provided for other industries, advertisers that promote treatment services need to take care to ensure that they are not, in addition to promoting their services, also promoting prescription-only medicines or substances.

Whether a business name would be likely to result in a contravention of the Act must be considered in context on a case-by-case basis and depends on the surrounding information and materials that accompany the clinic or business name. As is always the case, the likely consumer take-out of any representation (including a business name) must be considered in its entirety.

In general, if a business name includes a reference to a prescription-only good (even generically using terms such as 'injector' or 'injectables') it is more likely that a consumer viewing the promotion of the service would consider that the service includes the use of these prescription-only goods. This includes references made directly or indirectly to prescription-only goods through references such as:

- a trade names
- an abbreviation or acronym
- a colloquial name.

Can suppliers of cosmetic injectables advertise to clinics?

The advertising of prescription-only cosmetic injectables directed exclusively to health professionals (and other persons mentioned in section 42AA of the Act) is not prohibited. This includes advertising directed to medical practitioners, nurses, purchasing officers and practice managers.

This reflects the position that the training and expertise of health professionals means they have the appropriate knowledge to critically evaluate information contained in advertisements. It also recognises that those who are responsible for purchasing therapeutic goods used by health professionals in a medical or dental practice or a hospital (such as practice managers and hospital purchasing officers) should not be prohibited, for pragmatic purposes, from viewing advertisements for prescription-only goods.

Allowing persons other than health professionals to view advertising intended for health professionals (or the other individuals mentioned in section 42AA of the Act) will generally be considered unlawful advertising to the public. Such advertising may disrupt the doctor/patient relationship and create an inappropriate demand for a good or encourage inappropriate self-diagnosis.

Businesses must ensure that information provided for health professionals is not in the public domain or publicly accessible. See advertising to health professionals (https://www.tga.gov.au/resources/resource/guidance/advertising-health-professionals#who) for more information.

Questions about compliance and enforcement

How long do I have to comply with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the new guidance. However, we understand that it will take time for industry to embed the changes into their business practices.

Future enforcement will be consistent with our approach to compliance management () and we will seek high levels of voluntary compliance by engaging and educating the industry in the first instance.

How will you monitor and enforce compliance with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the updated Advertising health services () guidance.

Any future compliance action we take will be consistent with our regulatory framework. This means it will be evidence-based and will adjust to respond to the nature and seriousness of the alleged non-compliance. For more information on the types of actions we may take, please see the Compliance and enforcement hub () on our website.

If you suspect non-compliance in relation to therapeutic goods, we encourage you to report illegal or questionable practices and suspected non-compliant advertising to us using our reporting portal (https://compliance.health.gov.au/ac-report/) form.

What are the consequences or penalties if you become aware a business or practitioner is non-compliant with the Act?

Further information on the types of enforcement actions we may take can be found on the Compliance actions () and outcomes page on our website.

We understand the clarifications will take time for industry to embed into their business practices and we will continue to assist industry to bring their advertising into compliance. Consistent with the our approach to compliance, we will seek high levels of voluntary compliance by engaging with and educating industry in the first instance.

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/2024-04/advertising-health-services-cosmetic-injections-faqs.pdf) [393.34 KB]

Topics:

Advertising (https://www.tga.gov.au/how-we-regulate/advertising) Cosmetics (https://www.tga.gov.au/topics/cosmetics)

Prescription medicines (https://www.tga.gov.au/products/medicines/prescription-medicines)

Regulatory compliance (https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/regulatory-compliance)

Therapeutic goods regulation (https://www.tga.gov.au/topics/therapeutic-goods-regulation)

Page history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section	April 2024
V2.0	Updated questions and answers following the webinar 'Advertising cosmetic injection health services compliant with therapeutic goods legislation' on 10 April 2024	Advertising and Compliance Education and Policy Section	May 2024

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising health services and cosmetic injections: frequently asked questions and answers

Next change (https://www.tga.gov.au/node/416427/revisions/view/546534/546535/visual_inline)

Comparing
22/05/2024 - 11:59am (https://www.tga.gov.au/node/416427/revisions/546534/view) s 22
08/04/2024 - 3:38pm (https://www.tga.gov.au/node/416427/revisions/521117/view) s 22

Layout
Visual Inline (https://www.tga.gov.au/node/416427/revisions/view/521117/546534/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/416427/revisions/view/521117/546534/visual_inline?view_mode=full)

Home (https://www.tga.gov.au/) (https://www.tga.gov.au/node)
Advertising health services and cosmetic injections: frequently asked questions and answers (https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/special-topic-pages/advertising-health-services-and-cosmetic-injections-frequently-asked-questions-and-answers)

~~Frequently~~Advertising health services and cosmetic injections: frequently asked questions and answers

Find answers to frequently asked questions about advertising cosmetic injection services and our guidelines.

~~Last updated~~:
22 May 2024

~~On this page~~

About these Frequently ~~asked questions and answers about advertising cosmetic injection services~~

Asked Questions (FAQs)

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General questions about referring to cosmetic injectables in advertising

~~Why has the TGA updated its guidelines for advertising cosmetic injections?~~

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~~How can I communicate treatment options with my patients?~~

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Prescription-only medications carry higher risks than goods available for self-selection. It is important that all patients can make informed and accurate decisions about which cosmetic treatment is right for them.

The most credible information around whether a prescription-only medicine is right for a specific patient comes from a consultation between a patient and their appropriately trained and qualified health professional.

While the advertising of therapeutic goods is within the jurisdiction of the Act, it does not extend to the education of patients and clients, provided the information is non-promotional.

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To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement.

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Can non-medical staff at a ~~**publicly**~~clinic answer direct questions from patients or potential patents about which cosmetic injectables are offered at the clinic?

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Generally, solicited information (requested or asked for by a patient) is less likely to meet the legislative definition of 'advertise' than unsolicited information that is published or widely disseminated. Giving information necessary to answer a direct question (without providing additional information that could be taken to be intended to be promotional) is unlikely to be advertising. However, this will depend on what is communicated in the telephone conversation or in person.

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Whether the use of a prescription-only medicine or substance is appropriate for an individual should be discussed with a patient during consultation with an appropriately trained health practitioner. Such a consultation also allows the practitioner to discuss risks and contra-indications with their patient.

~~**Is all information that refers to 'cosmetic injectables' or 'injectables' considered to be an advertisement?**~~Is educational content about 'cosmetic injectables' or 'injectables' considered to be an advertisement?

Not all information released to the public about therapeutic goods is advertising. However, if the intention of the information (from the end viewer's point of view) is to promote the use or supply of a therapeutic good then we would likely consider it to be advertising and it must meet the legislative requirements as set out in the Act.

Whether or not information is an advertisement or not must be considered in context on a case-by-case basis. In general, the following types of information are unlikely to be considered advertising:

- information about the risks that may be associated with using cosmetic injectables
- information about training courses or training material for health care professionals.

Educational information for patients that is purely factual and balanced (communicates risks and benefits) and is non-promotional in nature is also unlikely to be considered advertising. Examples include 'before' and 'after' care instructions.

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By contrast, the regulation of the promotion of health services is not within our jurisdiction.

The Australian Health Practitioner Regulation Agency (Ahpra) (https://www.ahpra.gov.au/) and the National Boards regulate health practitioners and their practices/services which encompasses surgeons and surgical cosmetic procedures.

Why has the cosmetic industry come under more scrutiny than other industries?

We have updated our guidance on Advertising health services, including cosmetic injection services, to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods. The legislation regarding cosmetic injectables has not changed.

Recently we have witnessed the widespread promotion of health services (including telehealth) which seeks to attract consumers on the basis that particular prescription-only medicines (for example 'weight loss injections', 'nicotine vaping products', or 'medicinal cannabis'), can be prescribed at, and in some cases supplied by, the health service.

We interpret that this type of advertising is an advertisement for a therapeutic good that refers to prescription-only medicines, which is unlawful. We were concerned to resolve any inconsistency in interpretation across all industry areas.

We have taken enforcement actions against entities across a number of industry areas for alleged unlawful advertising of prescription-only medicines. More information can be found at Compliance actions and outcomes (https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-actions-and-outcomes#infringement).

FAQs about advertising specific products and treatments

How can I find what substances are part of the Schedule 4 drugs list?

Information relating to how prescription-only substances are scheduled, along with a link to the current version, can be found on the Poisons Standard (the SUSMP) () webpage.

Can I advertise a bio-stimulator such as Sculptra?

~~**Can I advertise a bio-stimulator such as Sculptra?**~~

Sculptra contains the substance Poly-L-lactic acid, which is included in Schedule 4 to the Poisons Standard; and is prohibited from being advertised to the public. References to Sculptra (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

~~**Can I advertise REJURAN?**~~ Can I advertise REJURAN?

In Australia, Rejuran is regulated as a Class III medical device. Rejuran is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (does not contain a prescription-only or pharmacist only medicine) and is not prohibited from being advertised to the public.

~~**Can I advertise Masseter treatment?**~~ Can I advertise polydioxanone (PDO) threads?

PDO threads are regulated as a Class III medical device. Polydioxanone is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (do not contain a prescription-only or pharmacist only medicine) and are not prohibited from being advertised to the public, provided the product is included in the Australian Register of Therapeutic Goods (ARTG) ().

Can I advertise Masseter treatment?

Advertisers cannot make any reference, directly or indirectly, in their advertisement to prescription-only substances or to the trade names of prescription-only goods. This includes acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to the specific good or substance.

If a reference to the 'Masseter treatment' is likely to be taken by the audience to be a reference to a prescription-only substance or good containing such as substance~~, and the 'Masseter treatment' was being promoted,~~ this would likely contravene the Act.

Please note that advertising a therapeutic good for an indication that has not been accepted in relation to the inclusion of the good on the register, for example advertising Botox for an off-label use, is also prohibited by the Act.

~~Can I advertise Profhilo?~~ Can I advertise Profhilo?

Profhilo contains hyaluronic acid which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Profhilo (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

~~Can I advertise Platelet Rich Plasma (PRP), bio-remodellers and monothreads?~~Can I advertise Platelet Rich Plasma (PRP), bio-remodellers and monothreads?

PRP, bio-remodellers and monothreads are outside the scope of these changes if they do not contain any substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard (i.e. ~~does~~do not contain a prescription-only or pharmacist only medicine).

It should be noted that the application of the legislative requirements around advertising PRP is complex – ~~the TGA encourages~~we encourage stakeholders to seek independent advice if necessary.

Can I advertise energy-based medical devices used in cosmetic procedures such as lasers, ultrasound and radio frequency devices?

In general, medical devices that do not contain substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard may be lawfully advertised to the public (subject to meeting applicable regulatory requirements which may include inclusion in the ARTG). Advertisements for these devices must comply with all applicable legislative requirements, including the Therapeutic Goods Advertising Code.

How can I explain to patients that we can assist with medical conditions such as migraines, hyperhidrosis, TMJ etc?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement. It is the advertiser's responsibility to focus on the service being provided at the practice and not the medicine being administered to treat the condition.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. For example, 'call our clinic for a consultation to discuss treatment options for migraines'.

Questions about specific types of advertising

Can I provide price lists for 'anti-wrinkle injections' and 'dermal fillers'?

~~**Can I provide price lists for 'anti-wrinkle injections' and 'dermal fillers'?**~~

The prohibition on advertising therapeutic goods containing prescription-only substances to the public applies to any 'statement, pictorial representation or design' that promotes the use or supply of the goods. Generally, ~~prices are provided~~stating a price in reference to ~~promote goods and are~~a prescription-only cosmetic injectable (irrespective if it is total cost of treatment or cost per unit) is likely to be considered ~~a form of advertising~~an advertisement for that product.

~~**Can I refer to cosmetic injectables to describe 'before and after' photos?**~~Under the advertising legislation price lists may be published for prescription medicines subject to strict requirements. These include price lists/pricing information:

- may only be published or disseminated by a retail pharmacy or agent acting on behalf of a retail pharmacy
- must contain no less than 25 medicines
- must be in alphabetical order and grouped into their specific scheduling.

It is unlikely that a cosmetic clinic would meet the definition of a retail pharmacy and therefore publication of price lists/pricing information (for prescription-only medicine or substance) by cosmetic injection services is likely to contravene the Act.

Can I place advertisements in the reception area?

Information shared between a health practitioner and their patient during a private consultation or treatment is not subject to the advertising rules for therapeutic goods.

However, this is unlikely to extend to the displaying of advertisements in the reception area and therefore doing so is likely to contravene the Act.

Can I refer to cosmetic injectables to describe 'before and after' photos?

Advertisers are not prohibited from using 'before' and 'after' photos to advertise their health service. However, they must not, directly or indirectly, refer to prescription-only substances or goods containing such substances used in the delivery of that service.

~~If~~Advertisers of cosmetic injection services have an obligation to comply with the legislative requirements for advertising therapeutic goods as well as any requirements governing the advertising of services, which are administered by Ahpra.

Where 'before and after' photos are used and it is apparent ~~to the consumer~~ that the 'after' photo is due to the administration of a prescription-only ~~substance or good~~cosmetic injectable, this is likely to amount to an advertisement for a therapeutic good that would contravene the Act.

~~Do I need to update old social media content that refers to cosmetic injectables?~~

~~Businesses who use~~Do I need to update old social media content that refers to cosmetic injectables?

Due to the nature of social media posts and their ready accessibility to consumers regardless of the date posted, all social media posts, historical and new, are required to comply with the requirements.

For more information about advertising on social media, please review our social media advertising guide () which should be read in conjunction with the guidance on advertising health services ().

Am I responsible for social media posts where a patient has referenced my clinic?

Business owners are responsible for the content of ~~any materials~~social media pages created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

~~Due~~Although it is up to the ~~nature of social media posts and their ready accessibility~~party responsible for the advertising to ~~consumers regardless of the date posted, all social media posts, historical and new, are required to comply~~ensure compliance with the requirements, we recommend that businesses also provide corrective information if they become aware of misinformation from third parties on social media channels for which they are not responsible and endeavour to remove any identifying factors (such as hashtags).

Advertisers should ensure any corrective information also complies with the advertising requirements if it is used within an advertisement or is an advertisement in its own right.

For more information ~~about advertising on social media~~, please ~~review the TGA's~~visit our social media advertising guide. ()

~~which should be read~~Can I refer to 'injectables' in ~~conjunction with the guidance on~~ my business name?~~advertising health services~~ ();

~~Can I refer to 'injectables' in my business name?~~

Consistent with guidance ~~the TGA has~~we have provided for other industries, ~~businesses~~advertisers that promote treatment services need to take care to ensure that they are not, in addition to promoting their services, also promoting prescription-only ~~goods~~medicines or ~~goods containing such~~ substances.

Whether ~~or not a particular~~ business name would be likely to result in a contravention of the Act must be considered in context on a case-by-case basis and depends on the surrounding information and materials that accompany the clinic or business name. As is always the case, the likely consumer take-out of any representation (including a business name) must be considered in its entirety.

In general, if a business name includes a reference to a prescription-only good (even generically using terms such as 'injector' or 'injectables') it is more likely that a consumer viewing the promotion of the service would ~~reasonably~~ consider that the service includes the use of these prescription-only goods.

This includes references made directly or indirectly to prescription-only goods through references such as:

- a trade names
- an abbreviation or acronym
- a colloquial name.

Can suppliers of cosmetic injectables advertise to clinics?

The advertising of prescription-only cosmetic injectables directed exclusively to health professionals (and other persons mentioned in section 42AA of the Act) is not prohibited. This includes advertising directed to medical practitioners, nurses, purchasing officers and practice managers.

This reflects the position that the training and expertise of health professionals means they have the appropriate knowledge to critically evaluate information contained in advertisements. It also recognises that those who are responsible for purchasing therapeutic goods used by health professionals in a medical or dental practice or a hospital (such as practice managers and hospital purchasing officers) should not be prohibited, for pragmatic purposes, from viewing advertisements for prescription-only goods.

Allowing persons other than health professionals to view advertising intended for health professionals (or the other individuals mentioned in section 42AA of the Act) will generally be considered unlawful advertising to the public. Such advertising may disrupt the doctor/patient relationship and create an inappropriate demand for a good or encourage inappropriate self-diagnosis.

Businesses must ensure that information provided for health professionals is not in the public domain or publicly accessible. See advertising to health professionals (https://www.tga.gov.au/resources/resource/guidance/advertising-health-professionals#who) for more information.

Questions about ~~the TGA's approach to~~ compliance and enforcement

How long do I have to comply with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the new guidance. However, we understand that it will take time for industry to embed the changes into their business practices.

~~**How will the TGA monitor and enforce compliance with the updated guidance?** Future~~ enforcement will be consistent with our approach to

compliance management () and we will seek high levels of voluntary compliance by engaging and educating the industry in the first instance.

How will you monitor and enforce compliance with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the updated Advertising health services () guidance.

Any future compliance action we take will be consistent with our regulatory framework. This means it will be evidence-based and will adjust to respond to the nature and seriousness of the alleged non-compliance. For more information on the types of actions we may take, please see the Compliance and enforcement hub ()on ~~the TGA~~our website.

If you suspect non-compliance in relation to therapeutic goods, we encourage you to report illegal or questionable practices and suspected non-compliant advertising to us using our reporting portal (https://compliance.health.gov.au/ac-report/) form.

~~What are the consequences or penalties if the TGA becomes aware if a business or practitioner is non-compliant with the Act?~~What are the consequences or penalties if you become aware a business or practitioner is non-compliant with the Act?

Further information on the types of enforcement actions we may take can be found on the Compliance actions () and outcomes page on ~~the TGA~~our website.

~~The TGA understands~~We understand the clarifications will take time for industry to embed into their business practices and we will continue to assist industry to bring their advertising into compliance. Consistent with the ~~TGA's~~our approach to compliance, we will seek high levels of voluntary compliance by engaging with and educating industry in the first instance.

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/2024-04/advertising-health-services-cosmetic-injections-faqs.pdf) [393.34 KB]

Topics:

Advertising (https://www.tga.gov.au/how-we-regulate/advertising) | Cosmetics (https://www.tga.gov.au/topics/cosmetics) | Prescription medicines (https://www.tga.gov.au/products/medicines/prescription-medicines) | Regulatory compliance (https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/regulatory-compliance) | Therapeutic goods regulation (https://www.tga.gov.au/topics/therapeutic-goods-regulation)

Page history

Show all page updates (1)

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section	April 2024
V2.0	Updated questions and answers following the webinar 'Advertising cosmetic injection health services compliant with therapeutic goods legislation' on 10 April 2024	Advertising and Compliance Education and Policy Section	May 2024

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V1.0	Original publication	Advertising and Compliance Education and Policy Section	April 2024
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Special topic pages (https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/special-topic-pages)

Advertising health services and cosmetic injections: frequently asked questions and answers (https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/special-topic-pages/advertising-health-services-and-cosmetic-injections-frequently-asked-questions-and-answers)

Document 220

Revisions for *Advertising health services and cosmetic injections: frequently asked questions and answers*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
22/05/2024 - 12:36pm by s 22 [redacted] FAQs updated on page and doc - 1394 - s22 [redacted] (Published)	○		*Current revision*
22/05/2024 - 11:59am by s 22 [redacted] (Draft)		○	**Revert**
22/05/2024 - 11:51am by s 22 [redacted] (Draft)	○	○	**Revert**
22/05/2024 - 11:50am by s 22 [redacted] (Draft)	○	○	**Revert**
22/05/2024 - 11:48am by s 22 [redacted] (Draft)	○	○	**Revert**
22/05/2024 - 11:44am by s 22 [redacted] (Draft)	○	○	**Revert**
22/05/2024 - 11:42am by s 22 [redacted] (Draft)	○	○	**Revert**
21/05/2024 - 7:15pm by s 22 [redacted] (Draft)	○	○	**Revert**
21/05/2024 - 7:11pm by s 22 [redacted] (Draft)	○	○	**Revert**
21/05/2024 - 7:11pm by s 22 [redacted] (Draft)	○	○	**Revert**
08/04/2024 - 5:18pm by s22 [redacted] changed a few references from 'businesses' to 'advertisers' - s 22 [redacted]. (Published)	○	○	**Revert**
08/04/2024 - 5:11pm by s 22 [redacted] (Draft)	○	○	**Revert**
08/04/2024 - 5:05pm by s 22 [redacted] (Draft)	○	○	**Revert**

Revision			Operations
08/04/2024 5:04pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 4:53pm by s 22 shorten intro. (Published)	○	○	Revert
08/04/2024 - 4:40pm by s 22 1278 - s 22 . (Published)	○	○	Revert
08/04/2024 - 4:32pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 4:18pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 4:02pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 3:59pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 3:55pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 3:55pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 3:54pm by s 22 (Draft)	○	○	Revert
08/04/2024 - 3:38pm by s 22 (Draft)	○	○	Revert

Compare selected revisions

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising health services and cosmetic injections: frequently asked questions and answers

Frequently asked questions and answers about advertising cosmetic injection services

Frequently asked questions and answers about advertising cosmetic injection services

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Business are encouraged to read the updated TGA guidance on Advertising health services () for detailed information on how to advertise health services, including cosmetic injection services, without unlawfully advertising therapeutic goods.

This page provides consumers with answers to frequently asked questions in relation to these products.

It is the responsibility of each advertiser to ensure their advertisement does not promote therapeutic goods in a way that is not compliant with the legislative requirements. To obtain advice specific to your circumstances you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant (). Please note, these consultants are not endorsed by the TGA.

General questions about referring to cosmetic injectables in advertising

Why has the TGA updated its guidelines for advertising cosmetic injections?

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Detailed information on the background to these changes is provided in the TGA media release Referring to cosmetic injectables in advertising ().

What has changed?

The legislation regarding cosmetic injectables has not changed. Most cosmetic injectables contain substances that are in Schedule 4 to the Poisons Standard () and, in accordance with the *Therapeutic Goods Act 1989* (the Act), cannot be advertised to the public. The TGA no longer expressly permits references to terms such as 'wrinkle reducing injections' or 'dermal fillers' where those terms would result in a reasonable consumer understanding the intention of the content is to promote the use or supply of a prescription-only medicine or good containing such as substance. This includes through acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to a specific prescription-only medicine or substance.

This does not apply to cosmetic injectables that do not contain any prescription-only substances.

Can the TGA provide a list of acceptable terms that I can use to describe the cosmetic injection services I offer?

In line with the TGA customer service standards (), we do not give advice on specific issues, or advice specific to individual circumstances. Therefore, the TGA cannot advise in specific terms what can be done by industry or provide a list of acceptable terms.

Businesses must determine if the information they are disseminating would meet the Act's definition of 'advertise' in relation to therapeutic goods. In doing so, they should consider if the viewer would reasonably consider the intention of the information is to promote the use or supply of a therapeutic good.

How can I communicate treatment options with my patients?

Prescription-only medications carry higher risks than goods available for self-selection. It is important that all patients can make informed and accurate decisions about which cosmetic treatment is right for them.

The most credible information around whether a prescription medicine is right for a specific patient comes from a consultation between a patient and their appropriately trained and qualified health professional.

While the advertising of therapeutic goods is within the jurisdiction of the Act, it does not extend to the education of patients and clients, provided the information is non-promotional.

Additionally, information shared between a health practitioner and their patient during a private consultation or treatment, is not subject to the advertising rules for therapeutic goods.

How can I advertise my cosmetic injection service without advertising therapeutic goods?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. This would have to be considered in context as other information in the promotional material could make it clear to consumers that what is being offered (promoted) are prescription-only substances or goods that contain such substances.

Can I refer to cosmetic injectables in my client booking system?

If a publicly available booking system draws consumers to a service on the basis of that service offering specific therapeutic goods used in the delivery of the service, it is likely to be an advertisement for **therapeutic goods**. Where the advertisement also refers to prescription-only medicines or substances it would be unlawful. For example:

- providing a form or other facility from which the consumer self-selects from a list of treatments involving prescription only medicines or substances
- providing price information for a prescription only medicine or substance.

Whether the use of a prescription-only medicine or substance is appropriate for an individual should be discussed with a patient during consultation with an appropriately trained health practitioner. Such a consultation also allows the practitioner to discuss risks and contra-indications with their patient.

Is all information that refers to 'cosmetic injectables' or 'injectables' considered to be an advertisement?

Not all information released to the public about therapeutic goods is advertising. However, if the intention of the information (from the end viewer's point of view) is to promote the use or supply of a therapeutic good then we would likely consider it to be advertising and it must meet the legislative requirements as set out in the Act.

Whether or not information is an advertisement or not must be considered in context on a case-by-case basis. In general, the following types of information are unlikely to be considered advertising:

- information about the risks that may be associated with using cosmetic injectables
- information about training courses or training material for health care professionals.

FAQs about advertising specific products and treatments

Can I advertise a bio-stimulator such as Sculptra?

Sculptra contains the substance Poly-L-lactic acid, which is included in Schedule 4 to the Poisons Standard, and is prohibited from being advertised to the public. References to Sculptra (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise REJURAN?

In Australia, Rejuran is regulated as a Class III medical device. Rejuran is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (does not contain a prescription-only or pharmacist only medicine) and is not prohibited from being advertised to the public.

Can I advertise Masseter treatment?

Advertisers cannot make any reference, directly or indirectly, in their advertisement to prescription-only substances or to the trade names of prescription-only goods. This includes acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to the specific good or substance.

If a reference to the 'Masseter treatment' is likely to be taken by the audience to be a reference to a prescription-only substance or good containing such as substance, and the 'Masseter treatment' was being promoted, this would likely contravene the Act.

Please note that advertising a therapeutic good for an indication that has not been accepted in relation to the inclusion of the good on the register, for example advertising Botox for an off-label use, is also prohibited by the Act.

Can I advertise Profhilo?

Profhilo contains hyaluronic acid which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Profhilo (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise Platelet Rich Plasma (PRP), bio-remodellers and monothreads?

PRP, bio-remodellers and monothreads are outside the scope of these changes if they do not contain any substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard (i.e. does not contain a prescription-only or pharmacist only medicine).

It should be noted that the application of the legislative requirements around advertising PRP is complex – the TGA encourages stakeholders to seek independent advice if necessary.

Questions about specific types of advertising

Can I provide price lists for 'anti-wrinkle injections' and 'dermal fillers'?

The prohibition on advertising therapeutic goods containing prescription-only substances to the public applies to any 'statement, pictorial representation or design' that promotes the use or supply of the goods. Generally, prices are provided to promote goods and are considered a form of advertising.

Can I refer to cosmetic injectables to describe 'before and after' photos?

Advertisers are not prohibited from using 'before' and 'after' photos to advertise their health service. However, they must not, directly or indirectly, refer to prescription-only substances or goods containing such substances used in the delivery of that service.

If it is apparent to the consumer that the 'after' photo is due to the administration of a prescription-only substance or good, this is likely to amount to an advertisement for a therapeutic good that would contravene the Act.

Do I need to update old social media content that refers to cosmetic injectables?

Businesses who use social media are responsible for the content of any materials created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

Due to the nature of social media posts and their ready accessibility to consumers regardless of the date posted, all social media posts, historical and new, are required to comply with the requirements.

For more information about advertising on social media, please review the TGA's social media advertising guide () which should be read in conjunction with the guidance on advertising health services ().

Can I refer to 'injectables' in my business name?

Consistent with guidance the TGA has provided for other industries, businesses that promote treatment services need to take care to ensure that they are not, in addition to promoting their services, also promoting prescription-only goods or goods containing such substances.

Whether or not a particular business name would be likely to result in a contravention of the Act must be considered in context on a case-by-case basis. In general, if a business name includes a reference to a prescription-only good (even generically using terms such as 'injectables') it is likely that a consumer viewing the promotion of the service would reasonably consider that the service includes the use of these prescription-only goods.

This includes references made directly or indirectly to prescription-only goods through references such as:

- a trade names
- an abbreviation or acronym
- a colloquial name.

Questions about the TGA's approach to compliance and enforcement

How will the TGA monitor and enforce compliance with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the updated Advertising health services () guidance.

Any future compliance action we take will be consistent with our regulatory framework. This means it will be evidence-based and will adjust to respond to the nature and seriousness of the alleged non-compliance. For more information on the types of actions we may take, please see the Compliance and enforcement hub ()on the TGA website.

If you suspect non-compliance in relation to therapeutic goods, we encourage you to report illegal or questionable practices and suspected non-compliant advertising to us using our reporting portal (https://compliance.health.gov.au/ac-report/) form.

What are the consequences or penalties if the TGA becomes aware if a business or practitioner is non-compliant with the Act?

Further information on the types of enforcement actions we may take can be found on the Compliance actions () and outcomes page on the TGA website.

The TGA understands the clarifications will take time for industry to embed into their business practices and we will continue to assist industry to bring their advertising into compliance. Consistent with the TGA's approach to compliance, we will seek high levels of voluntary compliance by engaging with and educating industry in the first instance.

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections: beware of 'home based' beauty services

Comparing
01/02/2024 - 4:59pm (https://www.tga.gov.au/news/news/cosmetic-injections-beware-home-based-beauty-services) s 22
unpublished a part of remove old news project.

26/05/2022 - 10:13pm (https://www.tga.gov.au/node/151118/revisions/153051/view) PJOoNEkkpQAOViqT

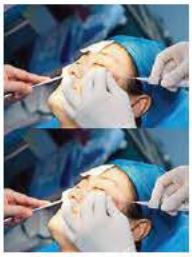
Layout
Visual Inline (https://www.tga.gov.au/node/151118/revisions/view/153051/517873/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/151118/revisions/view/153051/517873/visual_inline?view_mode=full)

Cosmetic injections: beware of 'home based' beauty services

Published:
19 November 2015

You should **always** see a qualified health professional for cosmetic anti-wrinkle injections. Make sure the service is provided in a safe and sterile environment.



The TGA has received reports of individuals offering these services from home-based beauty salons. These home based services may be using imported products which have not been approved for supply in Australia.

These products may contain harmful ingredients and usually do not meet the same standards of quality and safety as those approved by the TGA.

Approved cosmetic injections must be prescribed by a registered medical practitioner. The medical practitioner or someone they supervise must give the injection.

Approved cosmetic injections are labelled in English and have been evaluated for safety and quality.

All injections must be stored in a clean, sterile environment.

If you are going to have these injections, consider these questions:

- Did you receive an appropriate consultation by a qualified medical practitioner?
- Will the treatment be provided under the supervision of a medical practitioner?
- Has the product been evaluated by the TGA for safety and quality, and stored appropriately?
- If I suffer an adverse reaction or am not satisfied with the treatment, am I able to again consult with the medical practitioner who is supervising and taking responsibility for my treatment?

Don't sacrifice your health for cheaper treatments which may be offered by home-based beauty salons.

For information about cosmetic injections and their implications for your health, see the Better Health Channel (https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/cosmetic-treatments-injectables).

More information

Anti-wrinkle injections commonly contain botulinum toxin. Dermal filler injections are made up of hyaluronic acid.

These chemicals are dangerous to your health if used incorrectly and can cause infection.

Report suspected counterfeit medicine or devices

If you are concerned about counterfeit medicines or medical devices, or suspect you may have seen or bought counterfeit goods, you can report the matter to the TGA:

- **online:** ~~Report a perceived breach of the Therapeutic Goods Act or questionable practices relating to therapeutic products (https://www.tga.gov.au/node/5529)~~Report a perceived breach of the Therapeutic Goods Act or questionable practices relating to therapeutic products (https://www.tga.gov.au/node/282892)
- **by phone:** 1800 020 653
- **by email:** info@tga.gov.au
- ~~**in writing, via post to:**~~

  ~~Chief Investigator~~
  ~~Regulatory Compliance Unit~~
  ~~Therapeutic Goods Administration~~
  ~~PO Box 100~~
  ~~Woden ACT 2606~~
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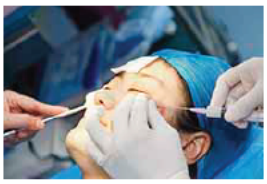
Topics:
Safety (https://www.tga.gov.au/safety/safety)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Cosmetic injections: beware of 'home based' beauty services

Published:
19 November 2015

You should **always** see a qualified health professional for cosmetic anti-wrinkle injections. Make sure the service is provided in a safe and sterile environment.



The TGA has received reports of individuals offering these services from home-based beauty salons. These home based services may be using imported products which have not been approved for supply in Australia.

These products may contain harmful ingredients and usually do not meet the same standards of quality and safety as those approved by the TGA.

Approved cosmetic injections must be prescribed by a registered medical practitioner. The medical practitioner or someone they supervise must give the injection.

Approved cosmetic injections are labelled in English and have been evaluated for safety and quality.

All injections must be stored in a clean, sterile environment.

If you are going to have these injections, consider these questions:

- Did you receive an appropriate consultation by a qualified medical practitioner?
- Will the treatment be provided under the supervision of a medical practitioner?
- Has the product been evaluated by the TGA for safety and quality, and stored appropriately?
- If I suffer an adverse reaction or am not satisfied with the treatment, am I able to again consult with the medical practitioner who is supervising and taking responsibility for my treatment?

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Topics:

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Revisions for *Cosmetic injections: beware of 'home based' beauty services*

Revisions

Home › › **Cosmetic injections: beware of 'home based' beauty services**

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Compare selected revisions

Revision			Operations
01/02/2024 - 4:59pm by [redacted] unpublished a part of remove old news project. (Unpublished)		○	*Current revision*
24/05/2023 - 4:52pm by [redacted] meta updated (Published)	○		Revert
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	Revert
26/05/2022 - 10:13pm by PJOoNEkkpQAOViqT (Published)	○	○	Revert
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Cosmetic injections checklist

Comparing
04/01/2024 - 1:05pm (https://www.tga.gov.au/news/news/cosmetic-injections-checklist) s 22
updated meta fields

26/05/2022 - 10:13pm (https://www.tga.gov.au/node/151130/revisions/153063/view) PJOoNEkkpQAOViqT

Layout
Visual Inline (https://www.tga.gov.au/node/151130/revisions/view/153063/510884/visual_inline)

View mode
Full content (https://www.tga.gov.au/node/151130/revisions/view/153063/510884/visual_inline?view_mode=full)

Cosmetic injections checklist

Published:
22 August 2019

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If you are considering a cosmetic injection, use this checklist to carefully research both the products and people involved.

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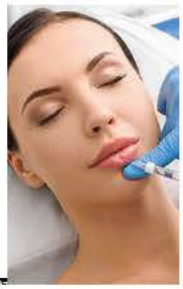
Complete this checklist first.



Decorative image

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Make a list of your questions or concerns and bring these along to your consultation. The prescriber should provide you with enough information for you to make an informed decision, including possible risks and complications. Your informed consent should be obtained before the procedure goes ahead.

Check the registration status of the people involved

You should check that both the prescriber of the cosmetic injection and the person who administers the injection are appropriately qualified. The register of qualified people can be freely searched on the Australian Health Practitioner Regulation Agency's (AHPRA) website.

The Medical Board of Australia's guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures outline the requirements for medical practitioners prescribing and administering cosmetic injection products.

Some nurses and dentists can prescribe cosmetic injection products. The Dental Board of Australia has published a fact sheet outlining expectations of dentists performing cosmetic injections. The Nursing and Midwifery Board of Australia has also issued a position statement outlining expectations of nurses working in the area of cosmetic procedures (see next page for links).

Check that the people involved are suitably experienced

Cosmetic injections into the wrong area of the face may result in serious consequences, including blindness or death. The person administrating the injection must have the appropriate knowledge and training.

Ask the person who will give the injection how much experience they have with this type of procedure. Also ensure that anyone else involved in the procedure is suitably qualified and experienced.

Research the risks

As with all medical procedures, there is a degree of risk associated with cosmetic injections. Your prescriber should explain the risks to you.

The person responsible for the procedure is also responsible for providing aftercare. You should be provided with written instructions and advice on what follow-up will be provided and what to do if you experience unexpected side effects.

Research the products

Ask about the products that are going to be used in your procedure. As legislation prevents the advertising of product and brand names, you will need to ask for this information.

The Australian Register of Therapeutic Goods (ARTG) lists all of the products that can be legally supplied in Australia. Search the ARTG to ensure that the product used in your procedure is registered.

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Some clinics have been involved in the illegal importation and use of dangerous counterfeit products. Cheaper products imported from overseas can be difficult to identify and may pose health risks.

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It is important for prescribers to report unexpected side effects to the TGA. You can also report problems experienced as a result of a cosmetic injection directly to the TGA.

Related links

Report a problem or side effect (https://www.tga.gov.au/node/4578)Report a problem or side effect (https://www.tga.gov.au/node/287456)

Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/4649)Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/287250)

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Translated resources

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Topics:
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Related content

(https://www.tga.gov.au/news/news/things-consider-undergoing-procedures-involving-dermal-fillers)
Things to consider before undergoing procedures involving dermal fillers (https://www.tga.gov.au/news/news/things-consider-undergoing-procedures-involving-dermal-fillers) (https://www.tga.gov.au/news/news/things-consider-undergoing-procedures-involving-dermal-fillers)
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Are you aware of the risks associated with cosmetic injections?

(https://www.tga.gov.au/news/news/three-questions-ask-natural-health-practitioners-about-testing-services)
Three questions to ask natural health practitioners about testing services (https://www.tga.gov.au/news/news/three-questions-ask-natural-health-practitioners-about-testing-services) (https://www.tga.gov.au/news/news/three-questions-ask-natural-health-practitioners-about-testing-services)
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(https://www.tga.gov.au/news/media-releases/be-alert-when-considering-cosmetic-injections)
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23 July 2019 | Media releases

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Published:
22 August 2019

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If you are considering a cosmetic injection, use this checklist to carefully research both the products and people involved.

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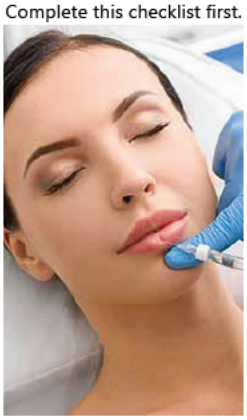

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The products used in cosmetic injections require a valid prescription from an authorised prescriber such as a medical doctor, dentist or nurse practitioner. The prescriber must consult with you and fully explain the procedure before it goes ahead. This consultation may occur face-to-face or via video conference.

Make a list of your questions or concerns and bring these along to your consultation. The prescriber should provide you with enough information for you to make an informed decision, including possible risks and complications. Your informed consent should be obtained before the procedure goes ahead.

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You should check that both the prescriber of the cosmetic injection and the person who administers the injection are appropriately qualified. The register of qualified people can be freely searched on the Australian Health Practitioner Regulation Agency's (AHPRA) website.

The Medical Board of Australia's guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures outline the requirements for medical practitioners prescribing and administering cosmetic injection products.

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Check that the people involved are suitably experienced

Cosmetic injections into the wrong area of the face may result in serious consequences, including blindness or death. The person administrating the injection must have the appropriate knowledge and training.

Ask the person who will give the injection how much experience they have with this type of procedure. Also ensure that anyone else involved in the procedure is suitably qualified and experienced.

Research the risks

As with all medical procedures, there is a degree of risk associated with cosmetic injections. Your prescriber should explain the risks to you.

The person responsible for the procedure is also responsible for providing aftercare. You should be provided with written instructions and advice on what follow-up will be provided and what to do if you experience unexpected side effects.

Research the products

Ask about the products that are going to be used in your procedure. As legislation prevents the advertising of product and brand names, you will need to ask for this information.

The Australian Register of Therapeutic Goods (ARTG) lists all of the products that can be legally supplied in Australia. Search the ARTG to ensure that the product used in your procedure is registered.

Avoid counterfeit products

Some clinics have been involved in the illegal importation and use of dangerous counterfeit products. Cheaper products imported from overseas can be difficult to identify and may pose health risks.

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Topics:

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Related content

Things to consider before undergoing procedures involving dermal fillers

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Be alert when considering cosmetic injections

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Revisions

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Related links

Report a problem or side effect (https://www.tga.gov.au/node/4578)

Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/4049)

Register of practitioners (https://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx)

Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures (https://www.medicalboard.gov.au/codes-guidelines-policies/cosmetic-medical-and-surgical-procedures-guidelines.aspx)

Fact sheet: The use of botulinum toxin and dermal fillers by dentists (https://www.dentalboard.gov.au/codes-guidelines/faq/botulinum-toxin-and-dermal-fillers.aspx)

Position statement on nurses and cosmetic procedures (https://www.nursingmidwiferyboard.gov.au/codes-guidelines-statements/position-statements/nurses-and-cosmetic-procedures.aspx)

If you require further information, you can contact us on 1800 020 653 or email info@tga.gov.au

Translated resources

- Cosmetic injections checklist - Chinese simplified (pdf,453kb) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-simplified.pdf)
- Cosmetic injections checklist - Chinese traditional (pdf,522b) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-traditional.pdf)
- Cosmetic injections checklist - Korean (pdf,510kb) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-korean.pdf)
- Cosmetic injections checklist - Vietnamese (pdf,461kb) (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-vietnamese.pdf)

Supporting documents

Cosmetic injections checklist - Korean (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-korean.pdf) [PDF, 509.5 KB]

Cosmetic injections checklist - Vietnamese (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-vietnamese.pdf) [PDF, 460.97 KB]

Cosmetic injections checklist - Chinese simplified (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-simplified.pdf) [PDF, 452.59 KB]

Cosmetic injections checklist - Chinese traditional (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist-chinese-traditional.pdf) [PDF, 551.47 KB]

Print version

Download PDF (https://www.tga.gov.au/sites/default/files/cosmetic-injections-checklist.pdf) [619.3 KB]

Topics:

Cosmetics (https://www.tga.gov.au/topics/cosmetics)

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Things to consider before undergoing procedures involving dermal fillers
(https://www.tga.gov.au/news/news/things-consider-undergoing-procedures-involving-dermal-fillers)
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Are you aware of the risks associated with cosmetic injections?

Three questions to ask natural health practitioners about testing services
(https://www.tga.gov.au/news/news/three-questions-ask-natural-health-practitioners-about-testing-services)
2 April 2019 | News

Do your research before consenting to live blood analysis, electrodermal testing and other related tests

Be alert when considering cosmetic injections
(https://www.tga.gov.au/news/media-releases/be-alert-when-considering-cosmetic-injections)
23 July 2019 | Media releases

Risks associated with cosmetic injections can be related to both the product and the experience of the person performing the procedure

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Be alert when considering cosmetic injections

Published:
23 July 2019

Be aware of the risks

It is very risky having cosmetic injectable procedures from unqualified operators. Even though treatments involving cosmetic injections have become commonplace, you should exercise due diligence and be aware of unregistered people practicing illegally.

It is important to understand that the risks associated with cosmetic injections can be related to both the product and the experience of the person performing the procedure. While less severe side-effects such skin redness, acne and swelling can occur, some of the more serious risks include:

- **permanent blindness**, which can occur when the filler is injected into any part of the facial artery and is not limited to procedures involving the eye area
- **discolouration and death of skin tissue**, following dermal fillers being injected incorrectly; and
- the presence of **counterfeit products** on the Australian market. There is no knowing what these are made of and should be avoided.

There is always an element of risk in medical procedures, however many of these can largely be avoided by researching and selecting a qualified, registered medical doctor with extensive experience and knowledge of the facial anatomy.

Report illegal or questionable practices

The TGA oversees the regulation of therapeutic goods used in Australia, whether produced in Australia or elsewhere. The TGA implements a range of enforcement remedies to address illegal supply of unapproved therapeutic goods, including seizing and destroying illegal medicines and medical devices, and criminal or civil court proceedings, which can result in substantial fines or imprisonment. Also, any person, including businesses, need to comply with the TGA requirements when advertising cosmetic injections (https://www.tga.gov.au/resources/resource/guidance/advertising-health-services).

You should report illegal or questionable practices (https://www.tga.gov.au/node/282892), including suspected counterfeit medicines and medical devices, to the TGA. And if you see an ad that breaks the rules, you can make an advertising complaint (https://compliance.tga.gov.au/advertising-complaint/) online.

More information

- Cosmetic injections (https://www.tga.gov.au/node/287869)
- 10 things to look for in medicine ads (https://www.tga.gov.au/node/282893)

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16/05/2023 - 12:51pm (https://www.tga.gov.au/news/media-releases/be-alert-when-considering-cosmetic-injections) s 22
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You should ~~report illegal or questionable practices (https://www.tga.gov.au/node/5529)~~report illegal or questionable practices (https://www.tga.gov.au/node/282892), including suspected counterfeit medicines and medical devices, to the TGA. And if you see an ad that breaks the rules, you can make an advertising complaint (https://compliance.tga.gov.au/advertising-complaint/) online.

More information

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- ~~10 things to look for in medicine ads (https://www.tga.gov.au/node/843493)~~10 things to look for in medicine ads (https://www.tga.gov.au/node/282893)

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Revisions for *Be alert when considering cosmetic injections*

Revisions

Revisions allow you to track differences between multiple versions of your content, and revert to older versions.

Revision			Operations
16/05/2023 - 12:51pm by s 22 (Published)		○	*Current revision*
21/06/2022 - 10:24am by PJOoNEkkpQAOViqT (Published)	○		**Revert**
21/06/2022 - 10:24am by PJOoNEkkpQAOViqT (Published)	○	○	**Revert**

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