



Australian Government

Department of Health
Therapeutic Goods Administration

Special access scheme

Most therapeutic goods are required to undergo an evaluation for quality safety and efficacy and be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

In recognition that there are circumstances where patients need access to therapeutic goods that are not on the ARTG, the TGA manages the Special Access Scheme (SAS) and [other programs](https://www.tga.gov.au/accessing-unapproved-products) ([//www.tga.gov.au/accessing-unapproved-products](https://www.tga.gov.au/accessing-unapproved-products)).

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About the special access scheme

The SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Patients are grouped into two categories under the scheme:

- Category A patients are defined as 'persons 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 patients are all other patients that do not fit the Category A definition.

With the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited by State or Territory law; any unapproved therapeutic good can potentially be supplied via the SAS.

- [Special access scheme applications](https://www.tga.gov.au/special-access-scheme-applications) ([//www.tga.gov.au/special-access-scheme-applications](https://www.tga.gov.au/special-access-scheme-applications))
Applications under the Special Access Scheme are made to the TGA by registered medical practitioners, preferably the treating doctor
- [Supply of unapproved therapeutic goods under the Special Access Scheme](https://www.tga.gov.au/supply-unapproved-therapeutic-goods-under-special-access-scheme) ([//www.tga.gov.au/supply-unapproved-therapeutic-goods-under-special-access-scheme](https://www.tga.gov.au/supply-unapproved-therapeutic-goods-under-special-access-scheme))
Applicants should check with the supplier to see if they are prepared to supply the product before making an application

- [Access to unapproved therapeutic goods - Special Access Scheme \(//www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme\)](https://www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme)

Describes how to obtain approval for the supply of an unapproved therapeutic good in Australia under the Special Access Scheme and how to obtain the product once approval for supply has been given

Special access scheme forms

Forms can be emailed to SAS@tga.gov.au (<mailto:SAS@tga.gov.au>) (preferred method) or faxed to 02 6232 8112. Note: Only PDF and Microsoft Word documents are acceptable as email attachments.

Please ensure each form is sent as a separate document.

These forms are available in both pdf and Microsoft Word formats. The pdf forms can be filled in and saved to your computer using Adobe Reader version 7 or later or any version of Adobe Acrobat Standard or Professional. If you have an earlier version of Adobe Reader you can fill in the form on-screen and print it out but you will not be able to save the completed form.

Category A patients

[SAS Category A form \(pdf,95kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-categorya-140901.pdf\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-categorya-140901.pdf)

[SAS Category A form \(Microsoft Word,136kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-categorya-140901.docx\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-categorya-140901.docx)

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

Category B patients

[SAS Category B form \(pdf,81kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-categoryb-140901.pdf\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-categoryb-140901.pdf)

[SAS Category B form \(Microsoft Word,138kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-categoryb-140901.docx\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-categoryb-140901.docx)

Consent to treatment and indemnity

Note: Do not send the 'Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma' to the TGA. This should be kept on the patient's file.

[SAS - Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma \(pdf,85kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-consent-140901.pdf\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-consent-140901.pdf)

[SAS - Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma \(Microsoft Word,130kb\) \(//www.tga.gov.au/sites/default/files/access-forms-sas-consent-140901.docx\)](https://www.tga.gov.au/sites/default/files/access-forms-sas-consent-140901.docx)

</default/files/access-forms-sas-consent-140901.docx>)

Importing controlled substances

- [Importing narcotic, psychotropic and precursor substances \(Special Access Scheme only\) \(form and guidance\) \(//www.tga.gov.au/importing-narcotic-psychotropic-and-precursor-substances-special-access-scheme-only\)](#)

Contact details for enquiries about the Special Access Scheme

If your enquiry is not about the special access scheme, see: [Contact the TGA \(//www.tga.gov.au/contact-tga\)](#)

Contact details

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| Email | SAS@tga.gov.au (mailto:SAS@tga.gov.au) |
| Phone | <ul style="list-style-type: none"> • 1800 020 653 • +61 2 6232 8644 |
| Fax | +61 2 6232 8112 |
| Postal address | The Medical Officer, 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 |

Category: Unapproved therapeutic goods

Tags: special access scheme

URL: <https://www.tga.gov.au/node/3244> ([//www.tga.gov.au/form/special-access-scheme](https://www.tga.gov.au/form/special-access-scheme))

