



This form, when completed, will be classified as 'For official use only'.  
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

# Special Access Scheme – Category B

### Important information

Email completed form to [SAS@health.gov.au](mailto:SAS@health.gov.au) (preferred) or fax to 02 6232 8112.

**The SAS Category B application form should be completed if guidance for use of an unapproved good will be met and the SAS Category A or SAS Category C pathways are not applicable.**

### Privacy information

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The TGA is collecting personal information in this form in order to:

- Assess the application.
- Contact the health practitioner and discuss the application where necessary.
- The personal information of the health practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration.

**Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form. Please complete the form clearly and in full. Applications cannot be assessed if the form is incomplete or illegible. PLEASE PRINT IN BLOCK LETTERS.**

## Patient details (minimum of 3 (three) identifiers required)

<b>Gender</b> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex/Indeterminate/Unspecified <input type="checkbox"/>	<b>Patient initials</b>	<b>DOB</b>	<b>MRN (if applicable)</b>	<b>Previous SAS No. (if applicable)</b>
<b>Diagnosis(es) or Medical Condition(s):</b>				
<b>Indication:</b>				
<b>Clinical justification for use of product:</b> (e.g. Include seriousness of condition, details of previous treatment including reasons why a therapeutic good currently listed on the ARTG cannot be used for the treatment of this patient in this circumstance)				

## Product details (attach efficacy and safety data to support proposed use of the product and details of intended monitoring)

<b>Therapeutic good type</b> Medicine <input type="checkbox"/> Biological <input type="checkbox"/> Medical device <input type="checkbox"/>																			
<b>Medicine/biological</b> <table border="1"> <tr> <td><b>Trade Name (if known)</b></td> <td><b>Sponsor / Supplier</b></td> </tr> <tr> <td colspan="2"><b>Active ingredient(s)</b></td> </tr> <tr> <td><b>Dosage form (e.g. tablet)</b></td> <td><b>Strength (e.g., 1 mg/ml)</b></td> </tr> <tr> <td><b>Route of administration (e.g., IV)</b></td> <td><b>Dose &amp; frequency (1 tds)</b></td> </tr> <tr> <td colspan="2"><b>Quantity<sup>1</sup> required for treatment or duration</b></td> </tr> </table>	<b>Trade Name (if known)</b>	<b>Sponsor / Supplier</b>	<b>Active ingredient(s)</b>		<b>Dosage form (e.g. tablet)</b>	<b>Strength (e.g., 1 mg/ml)</b>	<b>Route of administration (e.g., IV)</b>	<b>Dose &amp; frequency (1 tds)</b>	<b>Quantity<sup>1</sup> required for treatment or duration</b>		<b>Medical device</b> <table border="1"> <tr> <td colspan="2"><b>Trade name</b></td> </tr> <tr> <td colspan="2"><b>Product description (including variant<sup>2</sup>)</b></td> </tr> <tr> <td><b>No of units</b></td> <td><b>Sponsor / Supplier</b></td> </tr> <tr> <td><b>Proposed duration of treatment</b></td> <td><b>Intended date of use</b></td> </tr> </table>	<b>Trade name</b>		<b>Product description (including variant<sup>2</sup>)</b>		<b>No of units</b>	<b>Sponsor / Supplier</b>	<b>Proposed duration of treatment</b>	<b>Intended date of use</b>
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<sup>1</sup> For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided

<sup>2</sup> Variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device)

## Treating health practitioner details

First name	Surname
AHPRA ID	Health practitioner <sup>i</sup> type
Email	Speciality
Fax	Phone
Principal practice address	

## Submitter details (if different)

Business or practice name (e.g. Pharmacy name)	
First name	Surname
Health practitioner type	Fax
Email	Phone
<b>Preferred Contact:</b> <input type="checkbox"/> Treating health practitioner <input type="checkbox"/> Submitter	<b>Preferred contact method:</b> Email <input type="checkbox"/> Fax <input type="checkbox"/> Phone <input type="checkbox"/>

Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.

Submitter's signature	Date
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Please send this form to the TGA only

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<sup>i</sup> The health practitioner type for the **treating health practitioner** details above can be any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist; podiatrist; psychologist. **Other health practitioner types can be included as the submitter.**