|  |  |  |  |
| --- | --- | --- | --- |
| Therapeutic Goods Administration |  | | |
|  | TGA use only |  |
|  |  |  |

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 medical practitioner and discuss the application where necessary. * The personal information of the medical 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)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Patient initials** | **Gender**  Male  Female  Intersex/Indeterminate/Unspecified | **DOB** | **MRN** (if applicable) | **Previous SAS No.** (if applicable) |
|  | **Diagnosis(es) or Medical Condition(s):** | | | | |
|  | **Indication:** | | | | |
|  | **Clinical justification for use of product:** (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)

|  |  |
| --- | --- |
| **Therapeutic good type** Medicine  Biological  Medical device | |
| Medicine/biological  |  |  | | --- | --- | | **Trade Name** (if known) | **Sponsor / Supplier** | | **Active ingredient(s)** | | | **Dosage form** (e.g. tablet) | **Strength** (e.g., 1 mg/ml) | | **Route of administration** (e.g., IV) | **Dose & frequency** (1 tds) | | **Quantity[[1]](#footnote-1) required for treatment or duration** | | | Medical device  |  |  | | --- | --- | | **Trade name** | | | **Product description (including variant[[2]](#footnote-2))** | | | **No of units** | **Sponsor / Supplier** | | **Proposed duration of treatment** | **Intended date of use** | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Treating health practitioner details  |  |  | | --- | --- | | **First name** | **Surname** | | **AHPRA ID** | **Health practitioner[[3]](#endnote-1) type** | | **Email** | **Speciality** | | **Fax** | **Phone** | | **Principle practice address** | | | Submitter details (if different)  |  |  | | --- | --- | | **Business or practice name** (e.g. Pharmacy name) | | | **First name** | **Surname** | | **Health practitioner type** | **Fax** | | **Email** | **Phone** | | **Preferred Contact:**  Treating health practitioner  Submitter | **Preferred contact method:**  Email  Fax  Phone | |

|  |  |
| --- | --- |
| **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** |

**Please send this form to the TGA only**

1. For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided [↑](#footnote-ref-1)
2. 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) [↑](#footnote-ref-2)
3. The health practitioner type is any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist ; podiatrist; psychologist. [↑](#endnote-ref-1)