Australian Government
Department of Health
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>.

Authorised prescriber scheme

Application form

Privacy information

For general privacy information, including a link to the Department of Health's Privacy Policy (which contains information on how to contact the Department, access and correct your personal information or make a privacy complaint), please go to <https://www.tga.gov.au/privacy>.

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

- Assess the application; and
- Contact you, as the medical practitioner applying to supply the unapproved goods, to discuss the application where necessary.

Your personal information may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration.

Details of unapproved product: (please do not provide patient information)

Name of unapproved product:	
Route of administration:	
Indication / reason for prescribing:	
Supplier's name and address:	
Name of approving/endorsing ethics committee/specialist college:	

Please tick:
(Please note that applications cannot be processed without applicable approval/endorsement)

☐ I have attached the most recent letter from the approving ethics committee or endorsing specialist college.

☐ I have attached a declaration from the ethics committee or specialist college that all necessary documentation has been reviewed and is appropriate.

I understand that:

- the product is not approved for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unapproved product, and that its use is regarded as experimental;
- the giving of an authority under subsection 19(5) or sections 32CM or 41HC does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person;
- that in order to be given such an authority, I must be either:
  - a medical practitioner engaged in clinical practice in a hospital and have approval from the ethics committee of the hospital to supply and or use the unapproved product, or
  - a medical practitioner treating patients outside a hospital setting and without access to an ethics committee that could approve the supply who has obtained endorsement from a specialist college that has an established expertise relevant to the use of the unapproved product.

I agree to:

- the collection of my personal information for the purposes set out above.
- obtain from each patient (or guardian) informed consent in relation to the proposed use of the unapproved product, and in this context, inform the patient that the product is not approved in Australia; OR inform the requesting doctor that the in vitro diagnostic medical device used to perform the test is not approved in Australia;
- the product only being prescribed for patients in my immediate care;
- the product only to being used in accordance with the treatment directions (being the protocol or product information or instructions for use provided with the application);
- continuing to have an appropriate approval or endorsement in order to supply and or use the product;
- report any suspected adverse events to the TGA, the sponsor and either the approving Ethics Committee or endorsing specialist college (if this is condition of authorisation); and
- comply with all relevant State/Territory legislation.

Name of prescribing doctor:	
Postal address:	
Fax number:	
Phone number:	
Email address:	

Signature:		Date:	