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>.

Agreement to treatment directions authorisation of prescribers under section 19(5), 32CM or section 41HC of the *Therapeutic Goods Act 1989*

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.

Name of unapproved product:	
Route of administration:	
Indication / reason for prescribing:	
Supplier's name and address:	
Name of endorsing Ethics Committee/College:	

Please tick:

(Please note that applications cannot be processed without both applicable endorsement and clinical justification)

☐ I have attached the most recent letter from the endorsing Ethics Committee or College.

☐ I have attached clinical justification for the use of this product.

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 without access to an ethics committee that could approve the supply and have obtained endorsement from a specialist college that has an established expertise relevant to the use of the unapproved product.

I agree to:

- to 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 can only be prescribed for patients in my immediate care;
- the product is only to be used in accordance with the treatment directions being the protocol or product information or instructions for use provided with the application;
- that I must continue to have an appropriate endorsement in order to supply and or use the product;
- to report any suspected adverse reactions to the TGA, the sponsor and the endorsing Ethics Committee; and
- comply with all relevant State/Territory legislation.

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

Signature:		Date:	