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 <http://www.tga.gov.au/about/tga-information-to.htm>.

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 <http://www.tga.gov.au/about/website-privacy.htm>.
- 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;
  - the product may be prescribed only for patients in an Authorised Prescriber's immediate care; and
  - an Authorised Prescriber must continue to have an appropriate endorsement in order to supply the product.
  - This means that the Authorised Prescriber must be a medical practitioner engaged in clinical practice in a hospital and who has been given approval by the ethics committee of the hospital to supply the unapproved product, or a medical practitioner treating patients outside a hospital setting and who does not have access to an ethics committee that could approve the supply and has obtained endorsement

from a specialist college that has an established expertise relevant to the use of the unapproved product.

– the Therapeutic Goods Administration may give notice of revocation of this authorisation at any time and that any authorisation would be valid only until revoked or until the specified product or a similar product is approved in Australia, whichever is the earlier.

I agree 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;

· 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	