



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**AGREEMENT TO TREATMENT DIRECTIONS  
 AUTHORISATION OF PRESCRIBERS  
 UNDER SECTION 19(5) OR SECTION 41HC OF  
 THE THERAPEUTIC GOODS ACT 1989**

Unapproved product to be supplied: \_\_\_\_\_

Route of administration/dosage form: \_\_\_\_\_  
 (medicines only)

Indication / reason for prescribing: \_\_\_\_\_

Supplier's name and address \_\_\_\_\_

Name of endorsing Ethics Committee: \_\_\_\_\_

**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 section 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.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Medical Practitioner's name and address : \_\_\_\_\_  
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