

Attachment 1

TREATMENT DIRECTIONS FOR AUTHORISATION UNDER SECTION 19 (5)

- The product may be prescribed only for patients under the authorised medical practitioner's immediate care.
- The authorised practitioner will obtain informed consent from each patient (or guardian) in relation to the proposed use of the unregistered drug, and in this context, the patient must be informed that the product is **not registered** in Australia.
- The product is not registered for use in Australia. The Therapeutic Goods Administration (TGA) cannot vouch for the quality, safety or efficacy of an unregistered drug, therefore, the use of this product must be regarded as experimental.
- The giving of an authority under subsection 19(5) 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 Secretary of the Department of Health and Aged Care may give notice of revocation of this authorisation at any time. This approval is valid until revoked or until this or a similar product is registered in Australia, whichever is the earlier. This condition is imposed in part because to do otherwise would remove any incentive for a sponsor to register such a product in Australia. If you have any interest in the continuing supply, long term, you should ensure that a sponsor is seeking registration of the product in Australia.
- The authorised practitioner will report any suspected adverse reaction to the product to the TGA, preferably using the blue "Report of Suspected Adverse Drug Reaction" pre-paid mailer card that is distributed with the Pharmaceutical Benefits Book.
- The authorised prescriber will submit, every three months, a report of the number of patients for whom the drug has been prescribed, the quantity prescribed for each of those patients and an indication of whether or not prescribing is continuing for each individual patient.
- The authorised practitioner must continue to have an appropriate endorsement in order to continue to supply the drug.

This means that the authorised prescriber must be a medical practitioner engaged in clinical practice at a hospital and having the endorsement of the ethics committee of the hospital for the purpose of supply of the drug or a medical practitioner endorsed by a relevant specialist medical college or specialist medical society for the purpose of supply of the drug, as required by Regulation 12B(1) of the Therapeutic Goods Regulations.

- The authorised practitioner will comply with all relevant State/Territory requirements.
- The authorised practitioner will instruct the patient or patient's agent to return any unused product to a pharmacy.