

How to apply to be an Authorised Prescriber of a drug (under Section 19(5) of the Therapeutic Goods Act)

- Obtain Drug Usage Committee approval (if the drug/form not already approved for use in the hospital).
- Obtain endorsement from an Ethics Committee:
 - Write to the RCH Human Research Ethics Committee asking to be endorsed as an Authorised Prescriber including:
 - drug and dose form
 - disease to be treated/ indication for use
 - justification for use of the medicine and why a product registered in Australia cannot be used.
- Write to the Therapeutic Goods Administration including the following:
 - Address to:
 - The Medical Officer, SAS
Drug Safety and Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
 - Include in the letter:
 - disease to be treated.
 - an outline of the seriousness of the condition, and, if other approved treatments are available, justification for the use of the unapproved product in preference to those treatments.
 - for unapproved medicines - active ingredient, trade name, dose form, supplier.
 - dosage, route of administration, duration of treatment, details of proposed monitoring.
 - efficacy and safety data sufficient to support the proposed use of the product. A copy of the reference articles from which the data have been obtained should be included.
 - name, postal address, phone number, fax number of prescriber.
 - Attach a completed and signed Agreement to Treatment Directions Form <http://www.tga.gov.au/docs/pdf/unapproved/apagree.pdf>
 - Attach copy of the endorsement letter from Ethics Committee

Further information can be obtained at:

<http://www.tga.gov.au/hp/apglance.htm>

<http://www.tga.gov.au/docs/html/authpres.htm>