

Authorised prescriber applications

In accordance with the Therapeutic Goods Act (1989), when seeking Therapeutic Goods Administration (TGA) approval to become an authorised prescriber, practitioners must obtain *“endorsement from the HREC at the institution at which they practice”*. A full application is not required. Below is the list of items which must be addressed to assist the HREC in their consideration of requests. If approved, the HREC will provide a letter of endorsement in the format defined by the TGA. The HREC endorsement letter must be submitted with authorised prescriber applications to the TGA.

Please forward to the HREC a cover letter explaining your request, including (in the letter or as attachments):

- Your details (or those of the named prescriber), i.e. *“Suitability of the medical practitioner”* to prescribe and past experience (attach a copy of the prescriber’s CV)
- The indication for which the medication will be prescribed, and a clinical justification for its use
- Information about the medication and its bonafide use for x, including the route of administration and dosage form (attach an investigator brochure or equivalent if available)
- Safety of the product in relation to its proposed use, including information about its previous use in humans, adverse events, etc.
- How long you have been using the medication at [institution name], explaining previous access through SAS if any
- Patient information and consent forms
- Any other material to support your request