Authorised Prescriber Scheme

The Authorised Prescriber scheme allows authorised medical practitioners to access and legally supply a specified 'unapproved' therapeutic good (or class of 'unapproved' therapeutic goods) to a class of patients with a particular medical condition.

An Authorised Prescriber is allowed to supply the product directly to patients in their immediate care without requiring separate approval for individual patients. The product must not be supplied to other practitioners who prescribe or administer the product.

Clinicians who are applying to the TGA to become an 'Authorised Prescriber' for an unapproved device/drug must follow one of two pathways. The TGA has created a Guidance Tool to aid applicants in identifying the appropriate pathway for them.

Established History of Use Pathway

Where the medical practitioner is applying to become an Authorised Prescriber of medicines specified in subregulation 12B(1B) of the *Therapeutic Goods Regulations 1990*, that are considered to have an established history of use, the medical practitioner can apply directly to the TGA.

You do not need the endorsement of a Human Research Ethics Committee (HREC) if you are using this pathway.

A printable list of medicines with an established history of use can be found here.

Standard Pathway – TGA Authorised Prescriber (AP) Endorsement

Clinicians who are applying to the TGA to become an 'Authorised Prescriber' for an unapproved device/drug not included in subregulation 12B(1B) of the *Therapeutic Goods Regulations 1990* must obtain the endorsement of a HREC prior to making their application to the TGA.

The TGA has made a number of guidelines and resources available here, to assist clinicians in making an application to the TGA to become an authorised prescriber.

Role of the Human Research Ethics Committee

The HREC supplies the clinician with a letter endorsing the AP application, after assessing the safety of the product (in the context of the proposed use) and the patient information material.

To obtain a letter of endorsement from the SCGOPHCG HREC, the following information must be supplied by the deadline date for a HREC meeting:

- A copy of the TGA AP application and any attachments.

Note: A protocol for the use of the unapproved drug/device might be requested, if this information is not fully covered in the TGA application.

- A Patient Information Sheet/Consent Form that complies with the TGA AP requirements.

Note: See page 15 of "Authorised Prescriber Scheme" for the specific information that must be included and which the HREC will look for

A recommendation from the clinician about the appropriate frequency of usage, outcome and adverse event reporting to the HREC

The HREC office will email an endorsement letter to the clinician/s following approval. This can then be appended to the AP application for submission to the TGA.

The TGA does not inform the HREC when it has approved a clinician as an AP. As such, we request that the clinician forward a copy of the correspondence to the HREC for its records.

Annual Renewals

AP approvals are valid for 12 months (sometimes 24 months) and a new HREC endorsement letter is required for the TGA to roll-over existing approvals.

It is the responsibility of the clinician to:

- Inform the HREC of the impending expiration of an AP approval no later than 3 weeks prior to the expiration.
- Provide a brief annual report of usage and adverse event data, according to the conditions set out in the endorsement letter.

On receipt of the annual report, a renewal endorsement letter will be provided by the HREC Chairperson, or their delegate. If there is no important information arising from the usage and safety reports, this will not need to go to an HREC meeting.

This document can be made available in alternative formats on request.