This information has been adapted from the TGA website: https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme

Please note: To access an unapproved therapeutic good for a single patient, go to the Special Access Scheme web page.

For medicinal cannabis information, go to the Access to medicinal cannabis web page.

Authorised prescriber – Applying for HREC endorsement

Please follow the guidance in this document and submit your written application for HREC endorsement to SESLHD-RSO@health.nsw.gov.au. Please include 'Authorised Prescriber – application for HREC endorsement' in the subject line.

In your submission, please include the status of any application that has been made via the SESLHD New Intervention Assessment Process (NIAP), if applicable.

A medical practitioner's application for HREC endorsement must be made in writing and provide sufficient evidence to justify the use of the 'unapproved' product. An application for HREC endorsement must contain details of the:

- medical practitioner applying for Authorised Prescriber status
- 'unapproved' good
- clinical justification for the use of the good.

When an HREC assesses your application, they will consider the following factors to determine what level of evidence is required:

- whether other treatments registered on the ARTG are available and suitable for the intended class of patients
- the seriousness of the medical condition
- the global regulatory status of the therapeutic good
- the relevant experience and qualifications of the applicant

Medical practitioner details

The medical practitioner's details to include are:

- name
- contact details (postal address, phone number, fax number and email)
- details of their qualifications, specialty, training and experience

  Note: generally, applications from medical practitioners with non-practising, limited, student, provisional registration (requiring supervised practice), or conditions placed on their registration will not be considered for the Authorised Prescriber scheme

- have the training and expertise appropriate for the condition being treated and/or the proposed use of the product
- a description of how they propose to use the goods
- details of the site(s) at which the goods will be used

The application should also provide evidence that the medical practitioner has:

- the qualifications and experience necessary to appropriately manage the medical condition and use the product
- access to the facilities needed to appropriately administer and monitor treatment.

Generally, medical practitioners will have to demonstrate a higher level of experience and training to be approved as Authorised Prescribers of therapeutic goods that:

- are indicated for highly specialised medical conditions
- have significant safety risks
- require specialised monitoring
- require specialised administration or handling

‘Unapproved’ therapeutic good description and evidence

The application should contain evidence of the ‘unapproved’ therapeutic good’s suitability for the intended indication that supports the clinical justification the medical practitioner has provided.

The application should include the following details of the ‘unapproved’ good.

Description

For ‘unapproved’ medicines:

- active ingredient
- strength/concentration
- dosage form
- sponsor
- whether the good is approved for the indication by an overseas regulatory body

For ‘unapproved’ biologicals:

- name of biological
- sponsor
- whether the good is approved for the indication by an overseas regulatory body

For ‘unapproved’ medical devices:

- name of the medical device
- sponsor
- whether the good is approved for this indication by an overseas regulatory body

Use and monitoring

The application should detail:

- the dosage range (where applicable)
- the route of administration or type of sample for IVDs
- the duration of treatment
- how the medical practitioner will determine if the use is effective
- how the medical practitioner will determine whether an adverse event has occurred
- what monitoring is required, how it will be done, and the interval and duration of monitoring

Efficacy and safety

The application must contain information on:

- the ‘unapproved’ good’s efficacy and expected benefits
- any known/expected adverse effects, risks and safety issues
- related toxicology

Evidence

The application should contain appropriate sources of evidence to support the use of the ‘unapproved’ good. The sources of evidence for data, with the highest level of significance first, in decreasing order are:

- product information documents (of equivalent) (if the good is approved by an overseas regulator)
- randomised controlled trials
- non-randomised controlled trials
- individual case studies
- consensus opinion of specialist colleges and societies

Less serious conditions require stronger evidence than more serious medical conditions.

Global regulatory status

The global regulatory status of the 'unapproved' good may affect the level of evidence required in the application.

Clinical justification for the use of the goods

The TGA encourages the use of approved therapeutic goods as these have been assessed for safety, quality and efficacy. The clinical justification for use of an 'unapproved' good should provide sufficient evidence to demonstrate that this use is appropriate, considering the availability of any approved goods that may be suitable alternatives.

The clinical justification should contain information on the:

- indication for which the good will be used
- seriousness of the condition
- expected benefits of the proposed treatment versus its potential risks.

It should also address the circumstances where there are approved treatments for the same indication, specifically:

- have they been attempted or used?
- will they be attempted prior to supplying the 'unapproved' good?
- why are they inappropriate?
- why is the proposed 'unapproved' good a more appropriate option than any approved available alternative?
- how the risk associated with the use of an 'unapproved' good will be managed
  - the monitoring that will be undertaken
  - the process of investigating and reporting adverse events

The following are <u>not acceptable justifications</u> for the use of an 'unapproved' good:

- that the 'unapproved' good is less expensive than any suitable approved treatment
- personal preference for an 'unapproved' good