

**NIIM HREC: TGA AUTHORISED PRESCRIBER SCHEME APPLICATION APPROVAL PROCEDURES**

**1. Procedures Statement**

The aim of these procedures is to set out the processes for applications to the NIIM Human Research Ethics Committee (HREC) under the Therapeutic Goods Administration’s (TGA’s) Authorised Prescriber Scheme Standard Pathway.

The related policy is the *TGA Authorised Prescriber Scheme Application Approval Policy.*

**2. Application of the Procedures**

These procedures and its related policy applies only to applications by medical practitioners wishing to apply under the TGA’s Authorised Prescriber Scheme Standard Pathway to be able to access and prescribe unapproved therapeutic goods (those not listed on the Australian Register of Therapeutic Goods). It does not apply to other kinds of healthcare practitioners who may wish to access unapproved therapeutic goods for individual patients- such individuals may be able to access such goods under the Special Access Scheme. Note that there are separate policy and procedures relating to the authorised prescriber process for psychedelic medicines. Note also that medical practitioners applying to become authorised prescribers under the TGA’s Authorised Prescriber Established History of Use Pathway do not need approval from a HREC.

**3. Definitions**

**ARTG** Australian Register of Therapeutic Goods

**Authorised Prescriber** Individual medical practitioner approved to use an unapproved therapeutic good under the TGA’s Authorised Prescriber Scheme.

**CPD** Continuing Professional Development

**HREC** Human Research Ethics Committee

**TGA** Therapeutic Goods Administration

**Unapproved Therapeutic Good** Therapeutic good that is not listed on the Australian Register of Therapeutic Goods and therefore not approved by the TGA

**4. Approval Criteria**

4.1 The applicant:

a. Must be currently registered as a medical practitioner under the Australian Health Practitioner Regulation Agency (AHPRA).

b. Must supply the required evidence in support of their qualifications, expertise and experience to use the unapproved good and to support the clinical justification for the use of the unapproved good. The sources of evidence for data to support the use of the unapproved good, in order of highest to lowest level of significance are:

* product information documents or the equivalent
* randomised controlled trials
* non-randomised controlled trials
* individual case studies
* consensus opinion of specialist colleges and societies

Note that the global regulatory status of an unapproved therapeutic good may affect the level of evidence required in an application. Applicants are advised to consult the TGA Authorised Prescriber Scheme Guidelines[[1]](#footnote-1) for further information.

c. Has the qualifications, knowledge, expertise and experience necessary to appropriately manage the medical condition and safely use the unapproved therapeutic good. Demonstration of expertise could include completion of a course or other training in the use of an unapproved therapeutic good.

d. Has access to the facilities needed to appropriately administer and monitor treatment

e. Can demonstrate how they will determine if the use of the unapproved therapeutic good is effective

f. Can demonstrate how they will advise patients on the following:

* that TGA has not have evaluated the unapproved therapeutic good’s safety, quality and efficacy
* of the possible benefits and risks of its use
* of the possibility that there may be unknown side effects
* of any alternative approved therapeutic goods

g. Can demonstrate how risks associated with the use of the unapproved therapeutic good will be managed including mechanisms for the detection, monitoring and reporting of potential adverse events

h. Undertakes to remain up to date in relation to knowledge about potential future approved goods that may be entered on the ARTG that could be used instead of the unapproved therapeutic good, and where a suitable alternative good becomes available on the ARTG, stop using the unapproved therapeutic good. Where there is a good reason to continue using the unapproved therapeutic good, the applicant undertakes to reapply for approval, submitting a clinical justification to the HREC on why you want to use the unapproved therapeutic good instead of the now approved good.

i. Undertakes to provide the HREC and TGA with regular reports as required by the TGA (detailed in Section 7)

j. Agrees to abide by any conditions set by the HREC and/or TGA in relation to approval to use the unapproved therapeutic good.

k. Completes the application form thoroughly and provide the required evidence set out in the application form.

4.2 In making a decision about an application, the HREC will take into consideration the following in relation to the level of evidence required to be submitted in an application:

* 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

**5. Applications**

5.1 The Application Form in **Appendix 1** should be completed by applicants. This information is in accordance with requirements set out in the *TGA’s Authorised Prescriber Scheme. Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors Version 5.2 (December 2022)1*or a later version where this exists. Applicants should read the TGA Guidelines prior to completing the application form.

5.2 Applicants are required to disclose:

a. whether they have applied to another HREC for Authorised Prescriber approval for an unapproved therapeutic good within the last 12 months and whether approval has been denied, and the grounds upon which this has been denied. Evidence submitted includes written communication from the other HREC to the applicant.

b. whether they have applied to the TGA for Authorised Prescriber approval for an unapproved therapeutic good and whether approval was denied, and the basis upon which it was denied.

5.3 The application form, supporting evidence, and application checklist should be submitted to the NIIM HREC at: aps@niim.com.au . On receipt of the application, an invoice will be raised and sent to the applicant for payment within 7 days.

5.4 Where supporting information has not been supplied, applications will not be considered.

5.5 Where an application is complete and complies with the HREC requirements, it is sent to the HREC Executive Committee for approval.

5.6 Approval letters are issued after HREC Executive Committee approval and the invoice has been paid.

**6. HREC Approval Process**

6.1 The NIIM HREC Executive Committee will evaluate a medical practitioner’s application to become an Authorised Prescriber under the TGA Authorised Prescriber Scheme and either approve it or not approve it at the next available meeting.

6.2 Decisions by the NIIM HREC Executive are ratified at the next meeting.

6.3 Initial HREC approval for Authorised Prescribers of medicinal cannabis is for 26 months and for Biological Therapies injectable nutrients is 24 months. Note that re-approval should be sought prior to expiration of the previous approval, in accordance with Section 8.

6.4 The NIIM HREC will communicate their decision within five (5) working days of the HREC meeting in writing, via email. The letter, signed by the Chair of the HREC, will form the evidence that the applicant is required to submit to the TGA to obtain final approval. The letter will state:

* The approved goods and dosage form
* Approved indication
* Approved class of patients
* Requirements for reporting
* The fact that this letter forms part of the TGA approvals process under the TGA’s Authorised Provider Scheme and that applicants are required to complete the TGA application process
* The fact that ongoing approval is contingent on submission of evidence of continuing professional development (CPD) in relation to the unapproved good eg. successful completion of an NIIM HREC-approved CPD course

6.5 Where the HREC decides not to approve an application, the letter will state:

* That authorisation has not been granted
* The reasons for the decision
* The process of appeal

6.6 Where the NIIM HREC decides not to approve an application, it will notify the TGA of its decision.

**7. Applicant Reports and Monitoring**

7.1 The NIIM HREC will monitor the medical practitioner’s use of the unapproved therapeutic goods(s) to ensure continued approval is appropriate.

7.2 As required by the TGA, medical practitioners granted authorised prescriber approval must submit a six monthly report to the TGA using the TGA periodic report template, in January and July of each year. Reports must be received by the TGA within one month of the reporting period ending. There are two categories to report:

• Number of new patients commenced on treatment or number of devices supplied

• Number of total patients treated during this period

If no patients have been treated in the relevant period, this must also be reported. Failure to comply with conditions of authorisation may result in the revocation of the Authorised Prescriber's status. TGA 6 monthly reports are generally completed online via the SAS & Authorised Prescriber Online System. Further information about submission of 6 monthly reports can be found at the Authorised Prescriber Special Access Scheme & Authorised Prescriber Scheme Online system guidance Version 1.4 (June 2022) or later versions when they become available. This is available at: <https://www.tga.gov.au/sites/default/files/authorised-prescriber-scheme-online-system-guidance.pdf>

7.3 Medical practitioners are also required to submit a 6 monthly report using the NIIM HREC 6 monthly report template. This template can be found at: <https://niim.com.au/research/niim-human-research-ethics-committee/tga-authorised-prescriber-scheme-applications-including-medicinal-cannabis>

7.3 As required by the TGA1, the medical practitioner must submit reports of any suspected adverse events and product defects within 15 calendar days of learning of it. You are also required to report any fatal or life threatening adverse drug reactions to the TGA within 7 calendar days after becoming aware of the information and follow up with a complete report if necessary within 8 additional calendar days. A copy should also be submitted to the NIIM HREC within these time periods.

7.4 The NIIM HREC will consider any new information available to determine whether continuing approval of a medical practitioner’s application to be an Authorised Prescriber is warranted.

**8. Applicant Re-Approval**

8.1 Approval as an Authorised Prescriber is valid for 26 months only. Applicants who have gained approval from the NIIM HREC must apply for re-approval of their Authorised Prescriber status. This should be done at least 2 months prior to the expiry date. As part of this process, applicants must provide evidence of completion of continuing professional development (CPE) in relation to the unapproved therapeutic good. Refer to the NIIM HREC website for application forms: (<https://niim.com.au/research/niim-human-research-ethics-committee/tga-authorised-prescriber-scheme-applications-including-medicinal-cannabis> )

8.2 The NIIM HREC will take into account evidence supplied in the 6 monthly reports in granting (or not) re-approval.

8.3 The NIIM HREC will consider any new information available to determine whether re-approval of a medical practitioner’s application to be an Authorised Prescriber is warranted.

8.4 In addition to the requirements for 12 monthly re-approval, at any time where a suitable therapeutic good becomes available on the ARTG, the TGA advises that the medical practitioner should stop using the unapproved therapeutic good. At the time that the medical practitioner becomes aware of an approved alternative available on the ARTG, and he/she believes there is good reason to continue using the unapproved therapeutic good, the medical practitioner is required to submit a clinical justification to the NIIM HREC as to why he/she should be able to continue using the unapproved therapeutic good. This application should be made in writing to the HREC. The HREC will consider all evidence supplied and follow the processes set out in Section 6. Following re-approval by the HREC, the applicant must then submit a letter from the NIIM HREC as part of a new application to become an Authorised Prescriber.

**9. Revoking Authorisation**

9.1 The NIIM HREC may revoke an Authorised Prescriber approval if:

* A suitable alternative therapeutic good becomes available and is entered on the Australian Register of Therapeutic Goods
* The HREC becomes aware of any significant concerns about the unapproved therapeutic good’s safety
* The HREC becomes aware of any significant concerns about the medical practitioner’s prescribing practice in relation to the unapproved therapeutic good
* The applicant fails to provide 6 monthly reports to the HREC
* The applicant fails to supply evidence in relation to Applicant Re-approval (Section 8)
* The application does not meet any conditions that have been applied to the NIIM HREC’s approval or the TGA’s approval

**10. Appeals against HREC Decisions**

10.1 Applicants who are dissatisfied with a HREC decision in relation to an Authorised Prescriber application may appeal in writing to the NIIM Director. The applicant must detail reasons why he/she is appealing the decision.

10.2 The NIIM Director or their delegate will consider the evidence provided by the HREC and the applicant’s rationale for appeal.

10.3 The NIIM Director or their delegate will decide to either uphold the appeal or reject the appeal.

10.4 The outcome of the decision will be communicated to the applicant within 10 working days of receipt of their written appeal.

10.5 No further internal appeal process is available. Where an applicant remains dissatisfied with the decision, they may appeal to the relevant state and territory Ombudsman.

**11. Approvals Summary**

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| Policy/Procedure Code & Name | TGA Authorised Prescriber Scheme Application Approval Procedures |
| This Version Number  | 2.0 |
| Date of Original Version | 5 December 2017 |
| Approving Authority | NIIM HREC |
| Approval Date | 6 June 2023 |
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| Contact Officer | NIIM HREC Chairperson |

1. <https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme> [accessed 18.05.2023] [↑](#footnote-ref-1)