

NIIM HREC: TGA AUTHORISED PRESCRIBER SCHEME APPLICATION APPROVAL POLICY

1. Policy Statement

The aim of this policy is to set out the principles by which the NIIM Human Research Ethics Committee (HREC) will receive and where appropriate approve applications from medical practitioners to access and prescribe unapproved therapeutic goods under the Therapeutic Goods Administration's (TGA's) Authorised Prescriber Scheme.

The related Procedures are the *NIIM HREC TGA Authorised Prescriber Scheme Application Approval Procedures*.

2. Application

This policy and its related procedures applies only to applications by medical practitioners wishing to apply under the TGA's Authorised Prescriber Scheme 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.

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.

HREC Human Research Ethics Committee

TGA Therapeutic Goods Administration

Unapproved Goods Therapeutic goods that are not listed on the Australian Register of Therapeutic Goods and therefore not approved by the TGA

4. Principles

4.1 The TGA's Authorised Prescriber Scheme provides a mechanism by which medical practitioners who become Authorised Prescribers can access and legally supply an unapproved therapeutic good or class of goods to appropriate patients.

4.2 Only medical practitioners can become Authorised Prescribers under the Therapeutic Goods Act 1989 and its related regulations. Other health practitioners are not eligible. However, these practitioners may be able to access unapproved therapeutic goods for individual patients under the TGA's Special Access Scheme.

4.3 The TGA provides final approval for a medical practitioner to be an Authorised Prescriber of unapproved therapeutic goods. The TGA's mechanism for approval includes approval or endorsement of a medical practitioner's application by a HREC or specialist college, *prior* to final approval by the TGA.

4.5 The TGA provides guidance to medical practitioners, HRECs, Specialist Colleges and Sponsors with respect to roles and responsibilities and processes to be followed by each party in relation to applications to become an Authorised Prescriber. These form the basis of the NIIM HREC's approval criteria and procedures for applications from medical practitioners to become Authorised Prescribers under the TGA's Authorised Prescriber Scheme.

5. Approval Criteria

5.1 Approval criteria is based on the requirements set out in the *TGA's Authorised Prescriber Scheme. Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors Version 3.0 (July 2017)* or any later version published by the TGA, and is set out in the NIIM HREC TGA Authorised Prescriber Scheme Application Approval Procedures.

6. Roles and Responsibilities of the HREC

6.1 The NIIM HREC 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.

6.2 The NIIM HREC will provide written communication to the medical practitioner on the outcome of the application in a timely manner.

6.3 The NIIM HREC will monitor the medical practitioner's use of the unapproved therapeutic goods via receipt of practitioner reports to the TGA to ensure continued approval is appropriate, in accordance with the related NIIM HREC TGA Authorised Prescriber Scheme Application Approval Procedures.

6.4 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.

6.5 The NIIM HREC has the right to revoke an Authorised Prescriber Approval if:

- A suitable alternative good becomes available and is entered on the Australian Register of Therapeutic Goods
- The HREC becomes aware of any significant concerns about the good's safety
- The HREC becomes aware of any significant concerns about the medical practitioner's prescribing practice in relation to the good
- The applicant fails to fulfil the requirements of approval as set out in the related Procedures
- The application does not meet any conditions that have been applied to the NIIM HREC's approval or the TGA's approval

7. Roles and Responsibilities of the Authorised Prescriber

7.1 A medical practitioner who wishes to apply to the NIIM HREC for approval as an Authorised Prescriber as part of the TGA Authorised Provider Scheme is required to follow the processes set out in the Procedures related to this policy.

7.2 A medical practitioner granted approval of his/her application to become an Authorised Prescriber of an approved good by the HREC and the TGA must abide by the requirements set out in the Procedures related to this Policy, and requirements set by the TGA. This includes:

- a. Remaining informed about changes to the benefits and risks of the good as they arise

- b. Considering the benefits and risks the unapproved good may offer each patient it is prescribed for
- c. Obtaining written informed consent from each patient before prescribing
- d. Arranging the supply of the goods directly through a sponsor or pharmacy
- e. Monitoring the patient during and after the use of the unapproved good
- f. Providing the TGA with a supply report every six months for the periods ending 30 June and 31 December, within one calendar month after the reporting period
- g. Informing the TGA and the NIIM HREC of any adverse events associated with the use of the good
- h. Complying with relevant State or Territory legislation governing the supply of therapeutic goods

8. Appeals against HREC Decisions

6.1 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. The NIIM Director will consider the appeal in accordance with the related Procedures.

6.2 Where an applicant remains dissatisfied with the decision of the NIIM Director, no further internal appeal process is available. Applicants may appeal to the Victorian Ombudsman (<https://www.ombudsman.vic.gov.au/Complaints>)

9. Approvals Summary

Policy/Procedure Code & Name	TGA Authorised Prescriber Scheme Application Approval Policy
This Version Number	1.0
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