



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Authorised Prescriber Scheme

## Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors

Version 3.0, July 2017

**TGA** Health Safety  
Regulation

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## Authorised Prescriber Scheme

Therapeutic goods not included on the Australian Register of Therapeutic Goods (ARTG) cannot legally be supplied unless TGA grants an exemption. The Authorised Prescriber Scheme allows medical practitioners who become Authorised Prescribers to access and legally supply an unapproved therapeutic good or class of goods to appropriate patients.

On 1 July 2017, Therapeutic Goods Administration (TGA) implemented a change to the application process of Authorised Prescriber Scheme to streamline access to unapproved therapeutic goods. This change removed the requirement for a medical practitioner to resubmit their clinical justification to the TGA as this is required to be submitted to and be evaluated by a Human Research Ethics Committee (HREC) or specialist college. The duration of approval may now also be extended for therapeutic goods which are deemed to have an established history of use - from one year to two years for medical devices and from two years to five years for medicines and biologicals, at the discretion of the Delegate who makes the decision.

Goods and their indications/uses listed on in the following legislative instruments are deemed to have an established history of use:

- **Medicines:** [Therapeutic Goods \(Authorised Supply of Specified Medicines\) Rules 2017](#)
- **Medical Devices:** [Therapeutic Goods \(Authorised Supply of Specified Medical Devices\) Rules 2017](#)
- **Biologicals:** [Therapeutic Goods \(Authorised Supply of Specified Biologicals\) Rules 2017](#)

Goods other than those listed in the instruments above or the same goods used for different indications/uses will be considered on an individual basis at the discretion of the Delegate.

This guidance:

- provides an overview of the Authorised Prescriber Scheme
- describes the roles and responsibilities of HRECs, specialist colleges, Authorised Prescribers, sponsors and TGA
- outlines the legal basis for supply

This document replaces previous guidance on this topic.

## Who can become an Authorised Prescriber

Medical practitioners can become Authorised Prescribers under the [Therapeutic Goods Act 1989](#) and its associated regulations.

Other health practitioners, including dentists, are not eligible to become Authorised Prescribers. These practitioners may be able to access unapproved therapeutic goods for individual patients under the [Special Access Scheme](#).

## Roles and responsibilities

### Medical practitioners

[Medical practitioners](#) who wish to become Authorised Prescribers must:

- determine whether any suitable alternative marketed goods are available on the ARTG
- [apply](#) to an HREC for approval
- [provide](#) the HREC with complete and accurate information in support of the application
- In circumstances where the medical practitioner seeking to become an Authorised Prescriber of unapproved **medicines or biologicals** does not have access to an ethics committee, the medical practitioner may obtain endorsement from a specialist college that has expertise relevant to the treatment of the medical condition for which authority is sought.
- In circumstances where the medical practitioner seeking to become an Authorised Prescriber of unapproved **medical devices** does not have access to an ethics committee that:
  - has the expertise relating to the use of the unapproved good; or
  - conducts its activities in the geographical area where the approval is sought

the medical practitioner may seek endorsement from a specialist college that has expertise relevant to the treatment of the medical condition.

Medical practitioners who become Authorised Prescribers must:

- remain informed about changes to the benefits and risks of the good as they arise
- consider the potential benefits and risks the unapproved good may offer each patient it is prescribed for
- obtain written [informed consent](#) from each patient before prescribing
- arrange [supply](#) of the goods directly through a sponsor or pharmacy
- monitor the patient during and after use of the unapproved good
- provide TGA with a [supply report](#) every six months for the periods ending 30 June and 31 December. These reports must be supplied to TGA within one calendar month after the reporting period
- [inform us of adverse events associated with use of the good](#)
- meet any conditions the TGA, HREC or specialist college applies to the approval or endorsement
- comply with relevant State or Territory legislation governing the supply of therapeutic goods. Approval as an Authorised Prescriber does not override State or Territory legislation

## HRECs and specialist colleges

HRECs and specialist colleges:

- [evaluate](#) a medical practitioner's submission and, if appropriate, approve or endorse it
- if [the application is approved or endorsed](#), provide the medical practitioner with a letter declaring they have reviewed all necessary documentation and clearly stating this approval or endorsement
- monitor the medical practitioner's use of the unapproved goods to ensure continued endorsement is appropriate. Examples of monitoring that have been undertaken by HRECs and specialist college have included the requirement for medical practitioner to submit to them:
  - reports outlining the number of patients who have been treated
  - adverse event or product defect reports.
- consider any new information available to determine whether it would be appropriate to continue the endorsement or approval

## TGA

TGA:

- encourages the use of approved, fully evaluated products
- determines whether there are emerging safety concerns that would make approval or endorsement inappropriate
- determines whether the requirements for authorisation as an Authorised Prescriber have been met

## Sponsors of unapproved therapeutic goods

[Sponsors](#):

- must obtain a copy of the TGA approval letter from the medical practitioner before supplying the unapproved good to the medical practitioner
- supply the unapproved good, at their discretion
- monitor the use of the goods, [report adverse events and product defects](#) and record the balance of benefits and risks
- provide TGA with [six-monthly reports](#) on the supply of unapproved goods<sup>1</sup>
- inform us of emerging safety concerns associated with the use of unapproved goods that they supply

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<sup>1</sup> As per the requirements of Section 47(B)(1)(c)(iii) of the Therapeutic Goods Regulations 1990

## Information for Medical Practitioners

### How medical practitioners become Authorised Prescribers

To become an Authorised Prescriber, a medical practitioner:

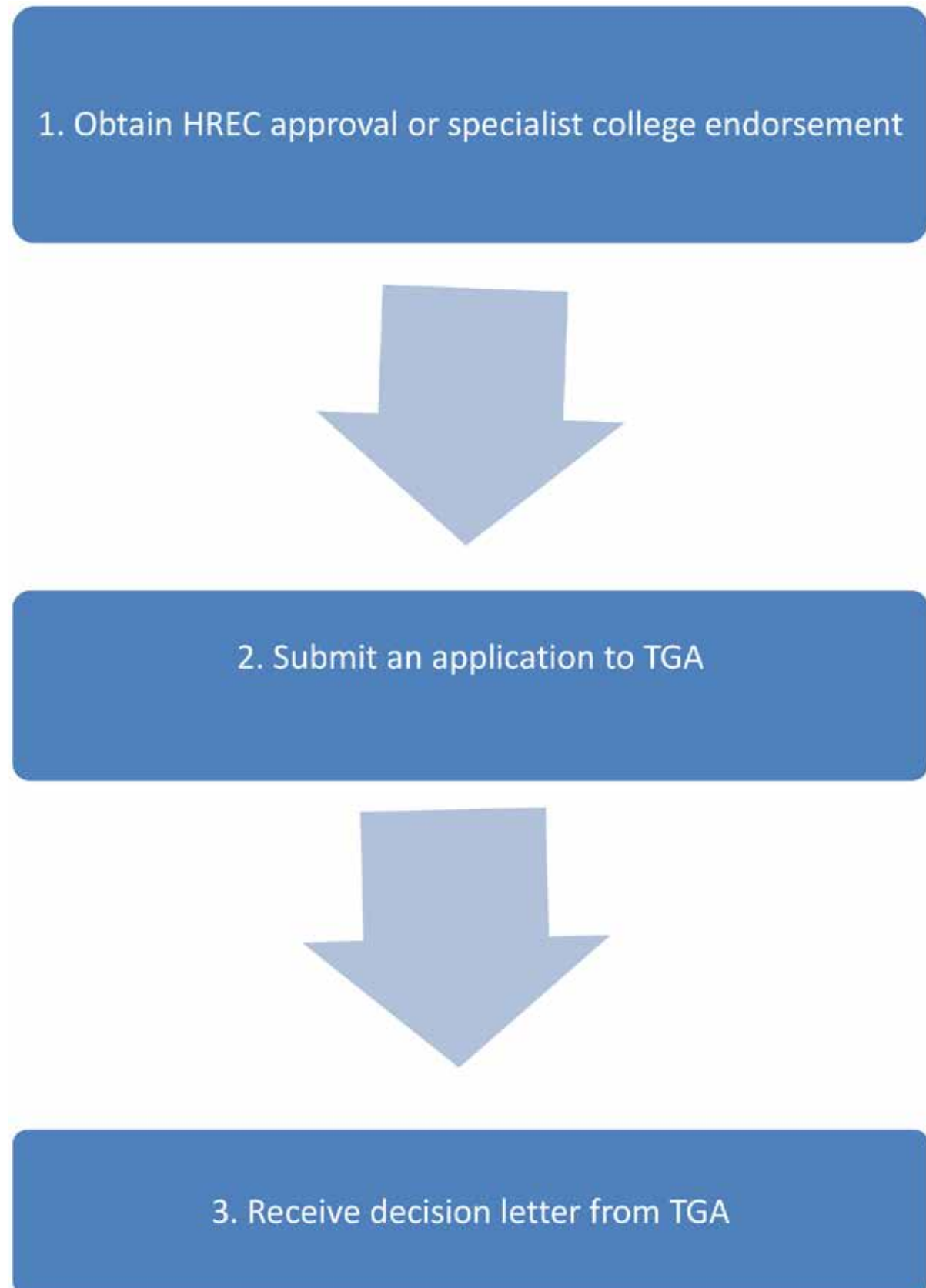
- submits an application to an HREC (or a specialist college, if appropriate) with
  - an appropriate clinical justification
  - informed consent form template
- receives approval from an HREC or endorsement from a specialist college.

Once the medical practitioner has HREC approval or specialist college endorsement, they submit an application to the TGA with:

- the letter of approval from the HREC or letter of endorsement from the specialist college, which contains a declaration that all necessary documentation has been properly evaluated
- a completed [Authorised Prescriber scheme application form](#)

The TGA will assess the application and make a decision.

**Figure 1: How medical practitioners become Authorised Prescribers**





## Preparing a submission for an HREC or specialist college

If you are a medical practitioner wanting to apply to TGA for Authorised Prescriber status, your application will need to be approved by a Human Research Ethics Committee (HREC) or endorsed by a specialist college.

## Applying for HREC or specialist college approval or endorsement

The medical practitioner's application for HREC approval or specialist college endorsement must provide sufficient evidence to justify the use of the unapproved product. The application will contain details of the:

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

### The prescriber

The medical practitioner's application will provide:

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

### The unapproved good

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

The application will include the following details of the unapproved good.

## Description

For unapproved **medicines**:

- trade name
- active ingredient
- strength/concentration
- dosage form
- sponsor
- whether the good is approved for the indication in another jurisdiction

For unapproved **biologicals**:

- name of biological
- sponsor
- whether the good is approved for the indication in another jurisdiction

For unapproved **medical devices**:

- name of the medical device
- sponsor
- whether the good is approved for this indication in another jurisdiction

## 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

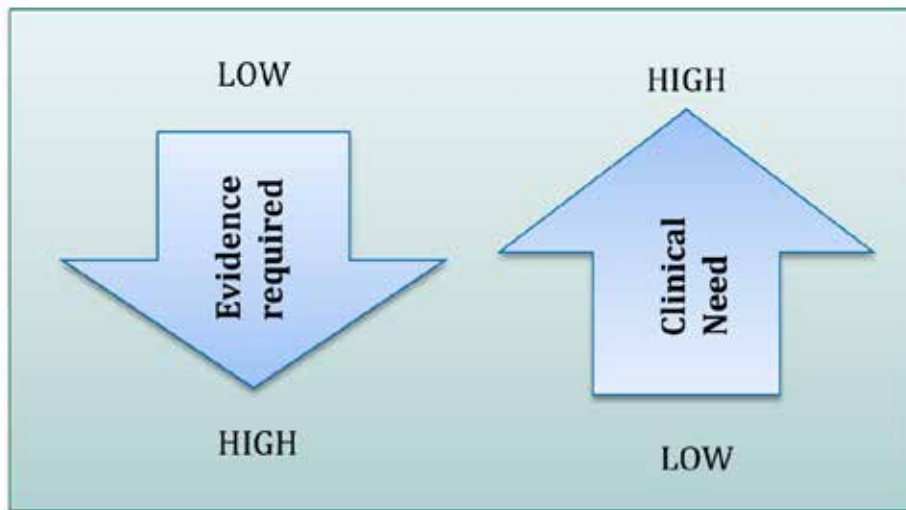
## Evidence

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:

**Figure 2: Evidence requirements and the seriousness of the medical condition**



## Global regulatory status

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

This table describes differences in global regulatory status and the effect that status may have on the level of evidence required.

This information in Figure 3 is provided as a guide only.

**Figure 3: Effect of global regulatory status**

Regulatory status	Possible effect on the level of extra evidence required to be submitted to a HREC or specialist college
Goods which are not approved in Australia, but are approved for the indication and the conditions of use in countries with a regulatory standard comparable to Australia	Decreased

Regulatory status	Possible effect on the level of extra evidence required to be submitted to a HREC or specialist college
Goods previously approved by the TGA which have been withdrawn for non-safety reasons	Decreased
Goods which are not approved in Australia, but are approved in countries with regulatory standards that are not comparable to Australia	Increased
Goods that have not been approved anywhere for the indication and are still undergoing clinical trials	Increased
Goods previously approved by the TGA which have been withdrawn for safety reasons	Increased
Goods that have not been granted registration in Australian for safety reasons	Increased



When an HREC or specialist college assesses your application, they should 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

You may wish to contact the HREC or specialist college before you submit your application to ensure you submit the necessary evidence.

## Clinical justification for the use of the goods

TGA encourages the use of approved therapeutic goods as these have been assessed for safety, quality and efficacy. The clinical justification for use of the 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
- the seriousness of the condition
- the 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?
- 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 not acceptable justifications 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

## **Informed consent**

The use of unapproved goods is considered experimental. The Authorised Prescriber must obtain the informed consent of each patient for whom they prescribe the unapproved good.

The Authorised Prescriber must advise patients:

- that TGA has not have evaluated the unapproved 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 goods

It is best practice to obtain informed consent in writing using a standard form. The medical practitioner will provide the template of the informed consent form they intend to use with their application to the HREC or specialist college. This should not be submitted to the TGA, but should be kept on the patients file. If the unapproved good is, however, derived from biological tissues including blood or plasma, the medical practitioner must obtain informed consent using the [form](#) available on the TGA website.

## **Applying to TGA**

Once you have the approval of an HREC or endorsement by a specialist college, you can apply to TGA to become an Authorised Prescriber. Your application must include:

- the HREC letter of approval or a letter of endorsement from a specialist college, including a declaration that all necessary documentation has been reviewed
- a completed application form. Ensure the indication listed on this form is the indication approved by the HREC or specialist college

Submit your application to us by:

- email (preferred) to [EPS@health.gov.au](mailto:EPS@health.gov.au)
- fax to 02 6232 8112
- post to:

Medicines Shortages Section  
Pharmacovigilance and Special Access Branch  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
Australia

## TGA decision

### Applications that we authorise

If we approve your application, we will send you an approval letter. The letter will state the:

- approved goods and dosage form
- approved indication
- approved class of patients
- requirements for reporting
- any conditions applied to the approval
- approved sites of practice

It will also state the period for which the approval will be valid.

All approvals are subject to general conditions. TGA may also apply specific conditions on a case-by-case basis. You must meet these conditions to retain your approval. The approving HREC or endorsing specialist college may also apply conditions to your approval.

Once you have been authorised to be an Authorised Prescriber of an unapproved good, you may prescribe that good to patients in your care.

### Applications that we do not authorise

If we do not authorise your application, we will send you a letter stating:

- that an authorisation has not been granted
- the reasons for the decision
- the contact details of the delegate who made the decision, if you wish to discuss the decision
- the process if you want to appeal the decision

You should inform the HREC or specialist college which approved or endorsed your application of our response and provide them with a copy of the decision letter.

If we do not authorise your application to become an Authorised Prescriber, you may submit a new application addressing the reasons for rejection.

## Appeals mechanisms

### Informal appeals

If you wish to appeal a TGA decision, and before you make a formal appeal, you should contact the delegate who evaluated your submission to discuss the matter informally.

### Formal appeals

If you disagree with the outcome of an informal appeal, you can make a formal appeal:

- [under section 60 of the \*Therapeutic Goods Act 1989\*](#)
- [to the Administrative Appeals Tribunal \(AAT\)](#)

You must have attempted to appeal a decision under section 60 of the *Therapeutic Goods Act 1989* before lodging an appeal with the AAT.

## Obtaining unapproved goods

As an Authorised Prescriber, you are responsible for obtaining the unapproved good. You can do this by contacting the sponsor of the good to arrange supply; however, the sponsor is not legally obligated to supply the good. You can also ask a pharmacy or supplier to arrange supply of the unapproved good.

You must give the sponsor a copy of your TGA approval letter. This authorises them to legally supply the good for use.

You must also consider whether the good is controlled under the *Customs (Prohibited Import) Regulations 1956* and the *Customs (Prohibited Export) Regulations 1958*, and, if the good is controlled, obtain a permit to import it from the [Office of Drug Control](#).

Access to medicinal cannabis may have additional requirements. For further information, refer to the TGA web page discussing [Access to medicinal cannabis products: steps to using access scheme](#).

If you are supplying the goods in a hospital, you might need any hospital drugs and therapeutics committees to approve the use and funding of these goods within the institution.

Unapproved therapeutic goods are not subsidised under the Pharmaceutical Benefits Scheme (PBS), so you should consider the cost that will be incurred.

## Prescribing and using the unapproved good

In prescribing the unapproved good for a patient, you are responsible for considering the benefits and risks that apply for the patient. As unapproved goods have not been evaluated by the TGA, you should remain informed of changes to the benefits and risks as they arise.

Prescribe the goods in accordance with the legislative requirements relevant to your State or Territory.

## Periodic reporting

You will receive a periodic report template with the letter of approval. You must report to us every six months (for the periods ending 30 June and 31 December) how many patients you treated with the unapproved good during that six-month period. You must send this to us within one month after the reporting period. If you treated no patients during that time, you must also report this.

## Reporting adverse events and product defects

Unapproved therapeutic goods generally have not been evaluated for safety, quality and efficacy and could pose unknown risks. When you become an Authorised Prescriber you must report any adverse event or product defect related to the unapproved good to us within 15 calendar days of learning of it.

The HREC, specialist college and/or the good's sponsor may also require you to provide them with adverse event reports.

There are various ways to report adverse events and product defects, which can be found on our website at [Reporting adverse events](#).

## Revoking authorisation

TGA can revoke your Authorised Prescriber status if:

- the HREC or specialist college withdraws their approval or endorsement of your status
- you do not meet the conditions we apply to your approval
- a suitable alternative good becomes available and is entered on the ARTG
- we become aware of any significant concerns about a good's safety

If a suitable alternative good becomes available on the ARTG, you should stop using the unapproved good. If there is a good reason to continue using the unapproved good you must reapply. You will need to submit a clinical justification to your evaluating HREC or specialist college on why you want to use the unapproved good instead of the now approved good. The HREC or specialist college will consider this and decide whether continued approval or endorsement is appropriate in light of any available approved good that has been thoroughly evaluated for safety, quality and efficacy. You must then resubmit this approval or endorsement to the TGA in a new application to become an Authorised prescriber.



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## Information for HRECs and specialist colleges

HRECs and specialist colleges provide the initial assessment of a medical practitioner's application to become an Authorised Prescriber. Details of what should be reviewed are outlined above under [Applying for HREC or specialist college approval or endorsement](#). By undertaking this assessment, you are determining that the use of the product is suitable for the proposed indication and that the medical practitioner has the appropriate expertise or qualifications for the proposed use of the product. The medical practitioner is ultimately responsible for determining whether it is appropriate to prescribe the unapproved goods for each patient that they treat.

HRECs and specialist colleges can approve or endorse a medical practitioner's application for Authorised Prescriber status. As an HREC or specialist college, you need to determine what level of evidence is appropriate to support an application based on a number of factors, including those described below under Clinical justification for the use of the goods.

Specialist colleges may decide to develop a protocol by which they will evaluate a medical practitioner's submission. Potential protocols include:

- establishing clinical justification through the use of a clinical practice guideline which you will require the medical practitioner to follow
- seeking advice from a specialist society which you will consider in your assessment

The medical practitioner may want to discuss their application with you before they submit it, to determine what level of evidence you will require.

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

### Clinical justification for the use of the goods

TGA encourages the use of approved therapeutic goods which have been assessed for safety, quality and efficacy. You need to evaluate the clinical justification the medical practitioner provides to determine whether the use of the unapproved good is appropriate, considering the availability of any approved goods.

The medical practitioner must supply you with:

- details of the indication for which the good will be used
- a clinical justification for its use

Consider whether the clinical justification is appropriate with regards to:

- the seriousness of the condition
- expected benefits of the proposed treatment versus the potential risks
- approved treatments for the same indication:
  - have they been attempted?
  - why are they inappropriate?
  - will they be attempted prior to prescribing the unapproved good?
  - why is the proposed unapproved good a more appropriate treatment?
- 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 not justifications for the use of an unapproved good:

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

## Providing approval or endorsement

If you support the medical practitioner's application, provide the medical practitioner with an approval letter if you are a HREC or a letter of endorsement if you are a specialist college. This letter must declare that you have reviewed all the necessary documentation.

The letter of approval must be personally signed by the chair of the HREC. Specialist colleges must determine who the most appropriate person to sign the letter of endorsement and declaration is.

You may apply conditions to the approval or endorsement. If the medical practitioner does not meet these conditions, you may revoke your approval or endorsement. Past conditions have included requirements to:

- provide regular reports on how the unapproved good is used, such as the periodic report the medical practitioner submits to the TGA, which outlines the number of patients that have been treated in a six month period
- report suspected adverse events to you within a specified timeframe

The medical practitioner must provide us with a copy of the letter of approval or endorsement so we can determine if it is appropriate to approve them as an Authorised Prescriber. They will also supply these documents to the unapproved good's sponsor, thereby authorising them to supply the goods.

## Applications not approved or endorsed

If you do not approve or endorse an application, provide the medical practitioner with the reason for your decision in writing.

## Withdrawal of approval or endorsement

You may withdraw your approval or endorsement of a medical practitioner if it is no longer appropriate. This could include, but is not limited to circumstances where:

- the medical practitioner has not met the conditions that you have applied to their approval or endorsement
- you become aware that the medical practitioner is using the unapproved good inappropriately
- a suitable alternative good becomes available on the ARTG
- you become aware of significant concerns about the good's safety

If you withdraw your approval or endorsement of a medical practitioner, [inform us](#) of this decision.

## Information for Sponsors

### Releasing unapproved goods to medical practitioners

You must obtain a copy of the TGA approval letter from the medical practitioner before the release of the unapproved good.

### Reporting of supply to TGA

You must report to us ever six months the quantity of the unapproved good that you have supplied during that six-month period under the Authorised Prescriber scheme. It is preferred that this information be provided to us via [email](#).

### Reporting adverse events and product defects

We encourage sponsors to report all adverse events and product defects to us. This helps us to monitor the safety of all therapeutic goods.

Sponsors are encouraged to report:

- fatal or life-threatening outcomes to us early (ideally within seven calendar days of becoming aware of them) and then follow up with a more complete report (ideally within the next eight calendar days)
- other serious and unexpected adverse within 15 calendar days (advise TGA if you think any of these may have already been reported to us)

Advise TGA as soon as possible of any information that could affect the risk-benefit assessment of the product or situations in which the product should be used.

There are various ways to report adverse events and product defects, which can be found on our website at [Reporting problems](#).

## Legal basis of the Scheme

Therapeutic goods in Australia are regulated under the [Therapeutic Goods Act 1989](#) (the Act), the [Therapeutic Goods Regulations 1990](#) (the Regulations) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Medical Devices Regulations). Under the Act, only goods entered on the ARTG can be legally supplied in Australia.

Under section 19 of the Act, some medicines are exempt from inclusion on the ARTG prior to supply. Similarly, some biologicals and medical devices are also exempt under subsection 32CM and chapter 4, parts 4–7 of the Act respectively. These provisions allow for the Authorised Prescriber scheme.

## Medicines

The following clauses relate to the Authorised Prescriber Scheme and access to unapproved medicines:

- subsection 19(5) of the Act provides that a specific medical practitioner may be authorised to supply a medicine to a specified class or classes of patient
- regulation 12B of the Regulations relate to medicines and provide that:
  - you must be a medical practitioner and have approval from an appropriate ethics committee to become an Authorised Prescriber
  - if the medical practitioner does not have access to an appropriate ethics committee, they may seek endorsement from a specialist college with relevant expertise
  - the medical practitioner may prescribe an unapproved therapeutic good only for patients with a life-threatening or serious illness
  - the medical practitioner must meet any conditions applied to their approval as an Authorised Prescriber.
- subsection 31B(3) of the Act provides that a medical practitioner who has been approved under subsection 19(5) may be notified in writing that they must provide information on matters including:
  - the supply of the goods
  - the handling of the goods
  - the monitoring of the supply of the goods
  - the results of the supply of the goods.

## Biologicals

The following clauses relate to the Authorised Prescriber Scheme and access to unapproved biologicals:

- subsection 32CM(1) of the Act provides that a specific medical practitioner may be authorised to supply a biological to a specified class or classes of patient
- regulation 12C of the Regulations relate to biologicals and provides that:
  - you must be a medical practitioner and have approval from an appropriate ethics committee to become an Authorised Prescriber

- if the medical practitioner does not have access to an appropriate ethics committee, they may seek endorsement from a specialist college with relevant expertise
  - the medical practitioner may prescribe an unapproved therapeutic good only for patients with a life-threatening or serious illness
  - the medical practitioner must meet any conditions applied to their approval as an Authorised Prescriber
- subsection 32JG(3) of the Act provides that a medical practitioner who has been approved under subsection 32CM(1) may be notified in writing that they must provide information on matters including:
    - the supply of the biological
    - the handling of the biological
    - the monitoring and supply of the biological
    - the results of the supply of the biological

## Medical devices

The following clauses relate to access to unapproved medical devices and the Authorised Prescriber Scheme:

- subsection 41HC of the Act states that, subject to the requirements of the Medical Devices Regulations, a specific medical practitioner may be authorised to supply specific kinds of medical devices to a specified class of patient. Conditions may be applied to this authority
- regulation 7.6 of the Medical Device Regulations state:
  - you must be a medical practitioner approved by an appropriate ethics committee to become an Authorised Prescriber
  - if the medical practitioner does not have access to an appropriate ethics committee, they may seek endorsement from a specialist college with relevant expertise
  - the class of patients for which the medical practitioner may prescribe an unapproved therapeutic good must have a life-threatening or serious illness or condition
- regulation 7.7 of the Medical Device Regulations states the medical practitioner must meet any conditions applied to your approval as an Authorised Prescriber
- subsection 41JF(1) of the Act provides that a medical practitioner who has been approved under subsection 41HC may be notified in writing that they must provide information on matters including:
  - the supply of devices of those kinds
  - the handling of devices of those kinds
  - the monitoring of the supply of devices of those kinds
  - the results of the supply of devices of those kinds

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## Prohibition of promoting unapproved therapeutic goods

The Act provides (at Section 22(6) for medicines and biologicals and section 41MM for medical devices) that a person must not publicly claim they can supply unapproved therapeutic goods.

## Information and privacy

TGA meets our privacy requirements under the [Department of Health's Privacy Policy](#), the [Privacy Act 1988](#) (Cth; especially section 61) and the [Freedom of Information Act 1982](#).



### **Serious illnesses and conditions**

Serious illnesses and conditions are those which are generally accepted to require diagnosis, treatment or supervision from a suitably qualified health professional.

## Version history

Version	Description of change	Author	Effective date
V2.0	Access to Unapproved Therapeutic Goods (Authorised Prescriber Scheme)	TGA	October 2004
V3.0	New title New material aligned with MMDR Review recommendations Restructured	Pharmacovigilance and Special Access Branch and Regulatory Guidance Team	July 2017

## **Therapeutic Goods Administration**

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<https://www.tga.gov.au>

Reference/Publication #