Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Authorised Prescriber Scheme

Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors

Version 5.2, December 2022

Contents

About this guidance

This guidance is for medical practitioners, Human Research Ethics Committees (HRECs), specialist colleges and sponsors of 'unapproved' therapeutic goods and provides information about the:

- Authorised Prescriber scheme
- roles and responsibilities of HRECs, specialist colleges, Authorised Prescribers, sponsors and TGA in relation to the Authorised Prescriber scheme
- legal basis for supply of 'unapproved' therapeutic goods

This guidance also provides details about relevant amendments to the *Therapeutic Goods Regulations 1990* to streamline the application process for medicines considered to have an established history of use.

This document replaces previous guidance on this topic.

This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation.

You should seek your own independent legal advice to ensure that all of the legislative requirements are met.

Authorised Prescriber Scheme

Generally, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, supplied in, and exported from Australia. Therapeutic goods that are not included in the ARTG (described by us as 'unapproved' goods) cannot be lawfully supplied in Australia unless exempt, approved or authorised under the therapeutic goods legislation.

The therapeutic goods legislation provides a number of avenues that allow access to therapeutic goods that are not included in the ARTG. 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.

Changes to the Authorised Prescriber Scheme

Established history of use pathway On 24 July 2020, the Therapeutic Goods Administration (TGA) implemented a change to the Authorised Prescriber scheme to streamline the application process for medicines considered to have an established history of use in Australia.

This change removes the TGA requirement for Human Research Ethics Committee (HREC) approval or specialist college endorsement in circumstances where the medical practitioner is applying to become an Authorised Prescriber of medicines specified in subregulation 12B(1B) and 12B(1C) of the *Therapeutic Goods Regulations 1990*, that are considered to have an established history of use. This arrangement only applies where the medicine to be

prescribed, concentration (if any), dosage form, route of administration and indication match an entry in subregulation 12B(1B) or 12B(1C).

Subregulation 12B(1C) includes the addition of certain medicinal cannabis medicines to the 'Established history of use' pathway, by reference to active ingredient categories, dosage forms and indications.

A printable list of medicines with an established history of use is available on our website. HREC or institutional approval may still be required to use certain 'unapproved' therapeutic goods within an institution such as a hospital. Medical practitioners need to liaise with the relevant institution to confirm the institution's requirements.

For medicines accessed under the established history of use pathway, the approving Delegate may authorise supply for up to a five year period. However, the individual delegate assessing the application has discretion to apply any duration they assess is appropriate for the application.

No changes have been made to the application process for medical devices and biologicals. The duration of authorisation may be extended for medical devices (from one year to two years) and biologicals (from two years to five years) that are listed in the Special Access Scheme rules.

Who can become an Authorised Prescriber

Only medical practitioners can apply to become Authorised Prescribers under the *Therapeutic Goods Act 1989*. The therapeutic goods legislation defines a medical practitioner as 'a person who is registered, in a state or internal territory, as a medical practitioner'. In addition, the HREC (if applicable) and TGA Delegate must be assured that the medical practitioner has the qualifications and experience necessary to appropriately manage the medical condition and use the product.

To become an Authorised Prescriber, applicants must:

- be a medical practitioner with specialist registration or general registration with the Medical Board of Australia
  - 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 the proposed use of the product
- be able to best determine the needs of the patient
- be able to monitor the outcome of therapy.

The application should specify the medical practitioner's registration number in the national Register of practitioners on the Australian Health Practitioner Regulation Agency (AHPRA) website. 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

The TGA

The TGA administers the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations), and various Orders and Determinations, and regulates the quality, safety and efficacy of therapeutic goods as well as access to therapeutic goods that have not been approved for general use ('unapproved' therapeutic goods).

The TGA:

- encourages the use of products included in the ARTG
- 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

Medical practitioners

Medical practitioners who wish to apply to become Authorised Prescribers must:

- determine whether any suitable alternative therapeutic goods are included in the ARTG
- apply for approval from an HREC or endorsement from a specialist college (if applicable)
- submit an application to the TGA.

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 of the 'unapproved' for 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 the TGA with a six monthly report for the periods 1 January to 30 June and 1 July to 31 December. These reports must be supplied to TGA within one calendar month after the reporting period ends
- 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 (where applicable) 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

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[1]
- inform us of emerging safety concerns associated with the use of 'unapproved' goods that they supply

How to become an Authorised Prescriber

There are 2 pathways medical practitioners may use to apply to become an Authorised Prescriber, depending on the product to be prescribed:

1. Established history of use pathway
2. Standard pathway

Established history of use pathway

If the medicine, concentration (if any), dosage from, route of administration and indication match an entry in subregulation 12B(1B) or 12B(1C) of the *Therapeutic Goods Regulations 1990*, then HREC approval or specialist college endorsement is **not** required by the TGA. See a printable version on our website at list of medicines with an established history of use.

HREC or institutional approval may still be required to use certain 'unapproved' therapeutic goods within an institution such as a hospital. Medical practitioners need to liaise with the relevant institution to confirm the institutions requirements.

To become an Authorised Prescriber using the 'Established history of use pathway', a medical practitioner should follow these steps:

1. check if the product is included in the list of medicines with an established history of use (if not, refer to Standard pathway below)
2. complete an online (preferred) application using the SAS & Authorised Prescriber Online System to the TGA

- the following details are required:
    i. Medical practitioners name and contact details
    ii. Product details and indication or item code

Submission of applications via the online portal reduces processing times and users have a dashboard within their account where they can:

- Track the status of their application
- Search for previously submitted applications using parameters such as product, submission date and status (i.e. approved, rejected, withdrawn, completed)
- Download a PDF copy of the application receipt
- Identify applications that are expiring or that have expired
- Download a copy of the TGA decision letter. –
- Clone (copy) previously submitted AP submissions.

The online system also allows you to easily submit your AP six monthly report figures.

Further information on using the online portal system can be found in the Special Access Scheme & Authorised Prescriber Scheme Online system guidance document.

A 'paper form' is available on the Authorised Prescriber Webpage for exceptional circumstances.

3. The TGA will assess the application and provide further correspondence once reviewed.

To renew an application, an Authorised Prescriber will need to follow the above steps **and** ensure that all six monthly reports for the previous authorisation period have been provided to the TGA.

Standard pathway

To become an Authorised Prescriber of products that are not included in subregulation 12B(1B) or 12B(1C) of the *Therapeutic Goods Regulations 1990*, a medical practitioner should follow the 'Standard pathway' steps:

1. Submit an application to an HREC or a specialist college as outlined in 'Applying for HREC approval or specialist college endorsement' and receive approval
2. Complete an online (preferred) application using the SAS & Authorised Prescriber Online System to the TGA

Submission of applications via the online portal reduces processing times and users have a dashboard within their account where they can:

- Track the status of their application
- Search for previously submitted applications using parameters such as product, submission date and status (i.e. approved, rejected, withdrawn, completed)
- Download a PDF copy of the application receipt
- Identify applications that are expiring or that have expired
- Download a copy of the TGA decision letter. –
- Clone (copy) previously submitted AP submissions.

The online system also allows you to easily submit your AP six monthly report figures.

Further information on using the online portal system can be found in the Special Access Scheme & Authorised Prescriber Scheme Online system guidance document.

A 'paper' form is available on the Authorised Prescriber Webpage for exceptional circumstances.

3. Attach the HREC letter of approval or a letter of endorsement from a specialist college (where required), including a declaration that all necessary documentation has been reviewed

4. The TGA will assess the application and provide further correspondence once reviewed.

To renew an application, an Authorised Prescriber will need to follow the steps above **and** ensure that all six monthly reports for the previous authorisation period have been provided.

Where to find an HREC or specialist college

HRECs

In the therapeutic goods legislation, an ethics committee means a committee:

a. constituted and operating as an ethics committee in accordance with guidelines issued by the CEO of the National Health and Medical Research Council (NHMRC) as in force from time to time

   AND

b. which has notified its existence to the Australian Health Ethics Committee (AHEC) established under the *National Health and Medical Research Council Act 1992*

A list of registered ethics committees is available on the NHMRC website.

Specialist colleges

For 'unapproved' **medicines or biologicals** – if the medical practitioner is engaged in clinical practice outside a hospital and does not have access to an ethics committee, then 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.

For ‘unapproved’ **medical devices** – if the medical practitioner 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,

then the medical practitioner may seek endorsement from a specialist college that has expertise relevant to the treatment of the medical condition for which the authority is sought.

The therapeutic goods legislation defines ‘specialist’ as having the same meaning as in the *Health Insurance Act 1973*. This includes that the medical practitioner is a fellow of a ‘relevant organisation’ in relation to the specialty.

A list of these ‘relevant organisations’ are provided in Schedule 1 of the *Health Insurance Regulations 2018*. Therefore, the list of ‘relevant organisations’ are taken to be the ‘specialist colleges’ referred to for the purposes of the Authorised Prescriber scheme. Medical practitioners may only obtain specialist college endorsement from one of the ‘relevant organisations’.

Endorsement from a specialist society or other expert body **cannot** be accepted by the TGA. However, specialist colleges may choose seek advice from an expert body or specialist society when providing endorsement.

Applying for HREC approval or specialist college endorsement

The TGA does not provide a set template for HREC or specialist college applications. The medical practitioner’s application for HREC approval or specialist college endorsement (if required) must be made in writing and provide sufficient evidence to justify the use of the ‘unapproved’ product. An application for HREC or specialist college approval or endorsement must contain details of the:

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

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
  - 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

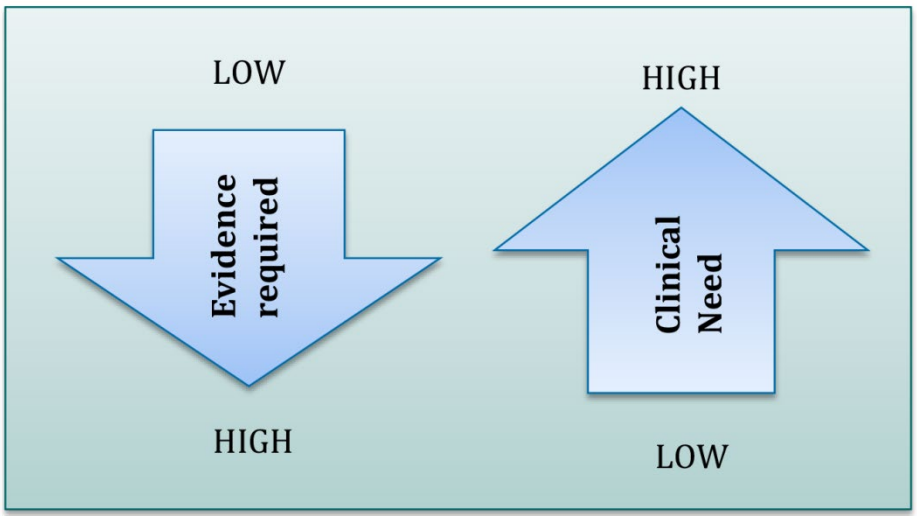
Evidence

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:

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.

The 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
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

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 **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

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 class of patients for a particular indication
- requirements for reporting
- any conditions applied to the approval
- the duration of approval

All approvals are subject to general conditions. The 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 (if applicable) 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.

Information for Medical Practitioners

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 the TGA has not 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
- provide a copy of your informed consent form template to the HREC or specialist college
- keep the signed informed consent form on the patient's file

Informed consent forms should **not** be submitted to the TGA.

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.

You should also prescribe the goods in accordance with the legislative requirements relevant to your state or territory. Obtaining the '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.

Six monthly reporting

It is a condition of the Authorised Prescriber scheme that medical practitioners provide supply reports on the number of patients treated for each of their Authorised Prescriber approvals for the periods 1 January to 30 June and 1 July to 31 December. We must receive these reports within one month of the reporting period ending. If no patients have been treated in the relevant period, this must also be reported.

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

Failure to comply with conditions of authorisation may result in the revocation of the Authorised Prescriber's status.

The preferred method of reporting is through the SAS & Authorised Prescriber Online System. Alternatively, there is a 'paper' form available on the Authorised Prescriber webpage for use in exceptional circumstances.

Information on using the online portal system to submit six monthly reports is found in the Special Access Scheme & Authorised Prescriber Scheme Online system guidance document.

Reporting adverse events and product defects

'Unapproved' therapeutic goods generally have not been evaluated for safety, quality and efficacy and could pose unknown risks. Authorised Prescribers are responsible for reporting adverse events or defects arising from the use of 'unapproved' therapeutic goods accessed under the Authorised Prescriber scheme.

If you become an Authorised Prescriber, you **must** report any suspected adverse events or product defects related to the 'unapproved' good to us 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.

The HREC, specialist college and 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 is available in the ARTG

If a suitable alternative good becomes available in the ARTG, you should stop using the 'unapproved' good.

If you want to continue using the 'unapproved' good you must submit a new Authorised Prescriber application to the TGA.

If applicable, you will need to submit a clinical justification to your evaluating HREC or specialist college to explain 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.

Review of medicines with an established history of use

The TGA will periodically review the 'unapproved' therapeutic goods included in subregulations 12B(1B) and 12B(1C) of the *Therapeutic Goods Regulations 1990* to determine if additional therapeutic goods or indications need to be added.

We will also remove certain therapeutic goods or indications from the list where necessary, for example, this may be where the products become registered in Australia or if a safety concern arises. These may be administrative or clinical decisions based on the ongoing monitoring of the scheme.

Sponsors and health practitioners **cannot** apply to the TGA to have goods included or removed from the list. At this time, only medicines have been included in the list.

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 for products not included in subregulation 12B(1B) or 12B(1C) of the *Therapeutic Goods Regulations 1990*.

Details of what should be reviewed are outlined in 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.

Clinical justification for the use of the goods

The TGA encourages the use of approved therapeutic goods that 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 provide:

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

You should consider whether the clinical justification is appropriate, with regard 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 or used?
  - 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.

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 6 month period
- report suspected adverse events to you within a specified timeframe

The medical practitioner must provide the TGA with a copy of the letter of approval or endorsement (where required) 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.

The letter of endorsement or approval should include the following details, which must match the information provided on the application form:

- a clear statement that approval or endorsement is being given for the purpose of the medical practitioner becoming an authorised prescriber
- the name of the medical practitioner who has gained approval or endorsement
- the unapproved therapeutic goods for which approval or endorsement has been given
  - Note, medicinal cannabis products are accepted under the following categories:
    - Schedule 4 medicinal cannabis products
    - Schedule 8 medicinal cannabis products

the letter must specify the dosage form, route of administration, indication and class of patient for endorsement.

An acceptable format for a category based HREC approval would be as follows:

Schedule 4 medicinal cannabis products:

Dosage Form:	Oral Liquid	Oils	Extracts	Tinctures	Wafers	Lozenges
Route of Administration:	Oral	Oral and/or Sublingual	Oral	Oral	Sublingual	Sublingual
Indication/s: (NB: Only list indications appropriate to that dosage form, route of administering and schedule of product)	1. e.g. Chronic Pain 2. e.g. Anxiety 3…… 4…… Etc.	1…… 2…… Etc.	1…… 2…… 3…… 4…… Etc.	1…… Etc.	1…… Etc.	1…… 2…… 3…… 4…… Etc.

Schedule 8 medicinal cannabis products:

Dosage Form:	Oral Liquid	Oils	Extracts	Tinctures	Wafers	Lozenges
Route of Administration:	Oral and/or vaporisation and/or inhalation	Oral and/or Sublingual and/or Inhalation	Oral	Oral	Sublingual	Sublingual
Indication/s:	1…… 2…… 3…… 4…… Etc.	1…… 2…… 3…… 4…… Etc.	1…… 2…… Etc.	1…… 2…… Etc.	1…… Etc.	1…… Etc.

Schedule 8 medicinal cannabis products:

Dosage Form:	Resins	Dried Flowers	Dried Herbs	Crystals
Route of Administration:	Inhalation	Inhalation and/or vaporisation	Inhalation and/or vaporisation	Inhalation and/or vaporisation
Indication/s:	1…… 2…… 3…… 4…… Etc.	1…… 2…… Etc.	1…… 2…… 3…… Etc.	1…… 2…… 3…… 4…… Etc.

- the sites at which use is covered by the approval or endorsement
- any conditions that have been applied to the approval or endorsement
- a declaration that all necessary documentation has been reviewed.
- The declaration that all necessary documentation has been reviewed may be either included in the letter or approval or endorsement, or as a separate document.

This letter should be signed by the chair of the approving ethics committee or an appropriate representative of the endorsing specialist college.

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 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 in the ARTG and authorised for supply in Australia
- you become aware of significant concerns about the good's safety

If you withdraw your approval or endorsement of a medical practitioner, inform the TGA of this decision.

Information for sponsors

Releasing 'unapproved' goods to medical practitioners

A sponsor should be satisfied that the prescriber holds a valid TGA approval letter before the release of an 'unapproved' good.

Reporting requirements

Sponsor reporting obligations under the *Therapeutic Goods Regulations 1990* (Regulation 47B).

Sponsors are reminded that they must report to the TGA every six months in relation to unapproved therapeutic goods supplied under the SAS and Authorised Prescriber schemes.

Regulation 47B of the *Therapeutic Goods Regulations 1990* outlines the requirement for the sponsor (importer) to submit six-monthly supply reports to the TGA listing the product (trade name) details and quantities supplied in Australia in the relevant period. Reporting periods are 1 January - 30 June (inclusive) and 1 July - 31 December (inclusive). Reports must be submitted within 1 month of the end of the relevant reporting period.

Sponsor six monthly reporting data for medicinal cannabis products are used to publish medicinal cannabis product details by active ingredient category. This list aims to support health care professionals in prescribing and supplying medicinal cannabis products therefore timely submission of six monthly reports is essential.

Please complete the below template and email the report to:

- SAS@health.gov.au - general therapeutic goods
- medicinal.cannabis@health.gov.au - medicinal cannabis products

The approved reporting form is available on the TGA website.

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.

However, sponsors are expected to report:

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

Advise the 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 Report a problem or side effect.

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 in the ARTG can be legally supplied in Australia.

Under section 19 of the Act, some medicines are exempt from inclusion in the ARTG. 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
  - if the medical practitioner wishes to apply for a medicine that is included in subregulation 12B(1B) or 12B(1C) of the Regulations, then ethics committee approval or specialist college endorsement is not required to be submitted to the TGA
  - the medical practitioner may prescribe an ‘unapproved’ therapeutic good only for patients with a life-threatening or otherwise serious illness or condition

  - 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
  - handling of the goods
  - monitoring of the supply of the goods
  - 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 patients
- 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
  - handling of the biological
  - monitoring and supply of the biological
  - 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 states:

  - 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
  - handling of devices of those kinds
  - monitoring of the supply of devices of those kinds
  - results of the supply of devices of those kinds

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

The TGA meets our privacy requirements under the Department of Health's Privacy Policy, the *Privacy Act 1988* and the *Freedom of Information Act 1982*.

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
V4.0	Updated to include guidance on regulatory amendment and application pathways Other minor updates to clarify list of HRECs, types of medical practitioners, specialist college definition, adverse event terminology, six monthly reporting	Pharmacovigilance and Special Access Branch and Regulatory Guidance Team	October 2020
V5.0	Review and addition of information relating to subregulation 12B(1C), six monthly reporting and use of the online portal	Experimental Products Section - International Regulatory Branch	November 2021
V5.1	Minor updates under reporting requirements in section 22. Link and email updates for sponsor reporting.	Experimental Products Section - International Regulatory Branch	February 2022
V5.2	Minor updates under reporting requirements. Link and email updates for sponsor reporting.	Special Access Section - International Regulatory Branch	December 2022

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Reference/Publication #