Australian Government
Department of Health
Therapeutic Goods Administration

Access to medicinal cannabis products: questions and answers

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On this page: Consumers | Medical practitioners | Sponsors and manufacturers of medicinal cannabis products

- Click on the plus or minus icon next to the question to toggle the answer on or off or [Open all | Close all].
- If you want to print all questions & answers, you need to Open all before you print.

Consumers

What are medicinal cannabis products and what does it mean if they are 'unapproved'?

The term 'medicinal cannabis' describes a range of cannabis preparations intended for therapeutic use, including:

- pharmaceutical cannabis preparations, such as oil, tinctures and other extracts.
- Untreated cannabis (raw and dried cannabis)
- cannabis resin (hashish)natural and synthetic cannabinoids

All medicines imported into, supplied in and exported from Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) (//www.tga.gov.au/australian-register-therapeutic-goods), unless special conditions apply. Any medicine not on the ARTG is considered an 'unapproved therapeutic good'. Unapproved therapeutic goods can be accessed using one of the relevant access schemes administered by the TGA.

If a medicinal cannabis product is unapproved by the TGA, what should I expect the doctor to tell me about it?

Before a doctor considers prescribing an unapproved medicinal cannabis product, you should be informed of the following:

- that the product is not approved in Australia and (potentially) other countries
- the quality, safety and efficacy have not been assessed by the TGA
- the possible benefits of treatment and any risks and side effects that are known
- the possibility of unknown risks and late side effects
- any alternative treatments using approved products which are available.

This information, along with adequate knowledge of the condition, the treatment options, the likelihood of recovery and the long-term prognosis, is necessary to ensure that you (as either the patient or the patient's legal guardian) are able to make an informed decision regarding treatment.

Your doctor must get your informed consent before applying to the TGA to get access to an unapproved medicinal cannabis product. Informed consent should be freely given and obtained in line with good medical practice, and it should be in writing unless there are good reasons to the contrary.

Which medical conditions or diseases can medicinal cannabis products be used to treat?

The TGA will evaluate each application received from a medical practitioner to access unapproved medicinal cannabis products on a case by case basis taking into consideration the supporting evidence provided with the application.

The TGA is developing educational materials in conjunction with the states/territories for doctors to support them in determining whether prescribing medicinal cannabis products is appropriate and beneficial for the patient, as well as information on how to use the available access schemes.

Can any doctor apply to the TGA on my behalf to access unapproved medicinal cannabis products?

Your doctor must be approved by their state/territory health department before they can prescribe medicinal cannabis products in that jurisdiction.

Your doctor must also have appropriate qualifications and/or expertise for the proposed conditions for which the product being proposed would be used. If your doctor is not a specialist in the condition, then the TGA would expect a report from an appropriate specialist on the use

and suitability of the medicinal cannabis product for you for your particular condition to be included with the application.

Why does my doctor need to apply for approvals from both the Commonwealth and State/Territory government before I can gain access to medicinal cannabis?

Both the Commonwealth Government and state and territory governments have a role in the importing, supply and prescribing of medicinal cannabis products to patients.

The importing and supply of unapproved medicinal cannabis products is governed by the Commonwealth Government. When considering an application for a prescriber to access unapproved medicinal cannabis products, the Commonwealth will consider whether the prescriber has the appropriate expertise to prescribe the product and the suitability of the product to treat the patient's medical condition. The quality of the product proposed to be prescribed and the appropriateness of the manufacturing quality standards that have been applied to the product will also be considered.

Your state or territory government will also consider whether the medicinal cannabis product is being appropriately prescribed for the patient's condition as well as looking at the suitability of the individual prescriber and the particular patient. This will require a balance between managing increasing community interest in using medicinal cannabis products, with the risks and safety issues associated with the use of an unapproved product, including that for some patients these medicines may not work and may have side effects.

How long does it take to review my application to access medicinal cannabis that was submitted to the TGA by my doctor?

The approval time is generally under 5 working days once **all the relevant information** required by the TGA to assess the application is provided by your medical practitioner.

My doctor has applied to the TGA and has been given approval to supply a medicinal cannabis product to treat my condition. What if I still can't access it?

There can be many reasons why you may not be able to access an unapproved medicinal cannabis product, even after your doctor has received approval to supply it to you. While TGA approval is necessary, there are other factors that can affect availability and supply, such as:

- **securing a legal supply of the product:** The person or company that is responsible for supplying the product (the sponsor (//www.tga.gov.au/role-sponsor)), is under no obligation to supply your doctor with the unapproved medicinal cannabis product, even if your doctor has been given approval or authorisation to supply it. In these instances, your doctor should seek an alternative supply of the same product or an alternative product, noting that an alternative product may require them to submit a

new application to the TGA.

- **receiving the necessary approvals to prescribe the medicinal cannabis product under state/territory legislation:** Your doctor must be approved by their state/territory health department before they can prescribe medicinal cannabis products in their state/territory.

Is the medical cannabis product I am receiving quality controlled?

Yes, the TGA has established quality standards for medicinal cannabis products which companies that import, manufacture and supply medicinal cannabis products in Australia are required to meet.

Can I personally import medicinal cannabis products for treatment of myself or my family members?

Personal import of medicinal cannabis products containing controlled drugs (cannabis, dronabinol, nabilone or tetrahydrocannabinols) is prohibited. Access to these medicinal cannabis products would be subject to SAS (Category B) or Authorised Prescriber requirements, following an application for approval or authorisation by your doctor. Personal import of products that contain certain other types of medicinal cannabis is subject to import permit and any applicable state and territory requirements.

Medical practitioners

I have been approached by a patient and been asked to prescribe an unapproved medicinal cannabis product. Do I have an obligation to prescribe it?

The responsibility for prescribing an unapproved product rests with the prescriber. The prescriber and patient, patient's parents or guardian accept responsibility for any adverse consequence of therapy. You have the right to decline to prescribe an unapproved product if you believe there is either insufficient clinical justification to support the use of the product.

Which of the unapproved medicine access schemes cannot be used to access medicinal cannabis products?

There are other schemes that exempt certain therapeutic goods from the requirement for registration on the Australian Register of Therapeutic Goods (ARTG).

Medicinal cannabis products, which are not yet considered to be "established pharmaceuticals", require adequate level of regulatory oversight and safeguards to the public to ensure that high quality, safe and effective products are used in appropriate circumstances.

At the current time, the following pathways to access unapproved medicines are not considered

to provide this level of oversight and are therefore unavailable:

- Special Access Scheme (Category A)
- medicinal cannabis products that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person (except in public hospitals)
- medicinal cannabis products that are manufactured by a person under a contract between the person and a private hospital, public hospital in a state or territory or public institution ('contract manufacturing').

Note that the latter two options (products that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, and contract manufacturing of products) are permitted if the products have been approved or authorised through Special Access Scheme (Category B) or the Authorised Prescriber Scheme respectively.

Why is unapproved medicinal cannabis that is extemporaneously compounded in a public hospital exempt from the requirement for registration?

As public hospitals are operated by state and territory governments it is expected that the identification of patients, prescribers and products will be appropriately managed in the normal course of the hospital's operations.

Will the TGA only allow me to access finished product made from particular strains of medicinal cannabis?

No. The TGA will evaluate each application received under the Special Access Scheme (Category B) or the Authorised Prescriber Scheme for access to a specific medicinal cannabis product on the basis of the supporting evidence accompanied by the application and any other information that may be known to the Delegate of the Secretary.

Are there specific medical conditions for which the TGA will allow access to medicinal cannabis?

No. The TGA will evaluate each application received under the Special Access Scheme (Category B) or the Authorised Prescriber Scheme requesting access to a specific medicinal cannabis product on the basis of the supporting evidence accompanied by the application.

What level of clinical evidence is expected to support my application to access medicinal cannabis for my patient(s)?

The efficacy and safety data submitted in support of the application should be weighed against the seriousness of the condition.

Does the TGA publish a list of Authorised Prescribers?

For privacy reasons, the TGA does not publish a list of Authorised Prescribers who have been authorised to supply medicinal cannabis products under the *Therapeutic Goods Act 1989*.

The TGA has authorised my application to become an Authorised Prescriber but the state/territory has not granted me the necessary approval to treat a named patient with the product I have been authorised to supply. Can I still use the product on the named patient?

Authorisation from the TGA to import and supply a specific medicinal cannabis product to treat the class of patients as per the authorisation does not override any state/territory requirements.

What is the relevance of the form completed by the manufacturer and submitted to me declaring that the medicinal cannabis product conforms with the Standard for Medicinal Cannabis (TGO No. 93)?

Conformance with this standard provides an assurance to the medical practitioner that the product they intend to prescribe to their patient(s) meet a high standard of quality, consistent with is expected of a pharmaceutical grade product.

Am I required to complete the form declaring that the medicinal cannabis product conforms with the Standard for Medicinal Cannabis (TGO No. 93)?

No. The manufacturer should complete this form and submit it to the medical practitioner. It is therefore important for the medical practitioner to request that the manufacturer complete this form in a timely manner so that it is submitted as part of the SAS B or Authorised Prescriber application. A failure to submit this form will result in delays in processing the SAS B or Authorised Prescriber application.

Am I required to submit the form declaring that the medicinal cannabis product conforms to the Standard for Medicinal Cannabis (TGO No. 93) after this has been completed by the manufacturer?

Yes. The completed declaration form along with any attachments must be submitted with and will be considered as part of the SAS B or Authorised Prescriber application. The form will serve as evidence that the product intending to be supplied by the medical practitioner to their patient(s) meets the high standard of quality expected of a pharmaceutical grade product.

Does the TGA charge a fee to process my application to access medicinal cannabis products through the Special Access Scheme (Category B)/ Authorised Prescriber Scheme?

No.

I have obtained approval/authorisation to supply the unapproved medicinal cannabis product through the Special Access Scheme (Category B)/ Authorised Prescriber Scheme but the sponsor of the goods will not supply it.

A sponsor is under no obligation to supply an unapproved product merely because it has been approved or authorised under the Special Access Scheme (Category B) or the Authorised Prescriber Scheme respectively.

You are advised to contact the sponsor and ensure that they will agree to supply on receipt of the appropriate approval or authorisation before making an application to the TGA.

Sponsors and manufacturers of medicinal cannabis products

I am interested in obtaining general marketing status for my medicinal cannabis product(s). What is required for me to register my medicinal cannabis product on the ARTG?

The *Therapeutic Goods Act 1989* requires that medical products imported into, supplied in, or exported from Australia must be included on the Australian Register of Therapeutic Goods (ARTG). In order for a prescription medicine to be included on the ARTG, a sponsoring company is required to submit an application to the TGA. A submission to register a prescription medicine consists of:

- data that support the quality, safety and efficacy of the product for its intended use
- completed forms
- payment of fees.

More information on how to register a prescription medicine (//www.tga.gov.au/prescription-medicines-registration-process) can be found on the TGA website.

Am I able to advertise my unapproved medicinal cannabis product?

No. The advertising of prescription only medicines (including medicinal cannabis preparations) to the public is prohibited.

Prescription medicines not included on the Australian Register of Therapeutic Goods (ARTG) are considered unregistered therapeutic goods and therefore cannot be advertised in Australia to consumers or health professionals.

I am a pharmacist who currently extemporaneously prepares medicines and am currently exempt from the requirement to have a GMP licence. Does

extemporaneous compounding of medicinal cannabis products by a pharmacist require a manufacturing license?

Pharmacists working in a public hospital will not require a Good Manufacturing Practice (GMP) licence to extemporaneously compound medicinal cannabis products.

Pharmacists working in a private hospital; a pharmacy open to the public where the pharmacist practices; or on the premises of a dispensary conducted by a Friendly Society will require a GMP licence to extemporaneously compound medicinal cannabis products.

This GMP licence will only be required for extemporaneously compounded medicinal cannabis preparations. You will not be required to obtain a GMP licence for extemporaneous compounding of non-medicinal cannabis preparations. However manufacturing by a person under a contract between the person and a private hospital, public hospital in a state/territory or public institution ('contract manufacturing') is required to be done under a GMP licence.

Am I required to supply a medicinal cannabis product to a medical practitioner if he/she has obtained approval/authorisation to supply the product through the Special Access Scheme (Category B) or the Authorised Prescriber Scheme?

A sponsor is under no obligation to supply an unapproved product merely because it has been approved or authorised under the Special Access Scheme (Category B) or the Authorised Prescriber Scheme respectively.

Does the TGA have any quality standards for medicinal cannabis products that my product(s) need to conform to?

Yes. There are various standards that apply to medicinal cannabis products, including *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)*.

The TGA has published a guidance document (//www.tga.gov.au/conforming-tgo-93-standard-medicinal-cannabis) that provides a plain English explanation on how to apply the requirements set out in Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis), to assist sponsors in complying with their regulatory obligations.

Am I required to conduct all the tests specified in Schedule 1 of TGO 93 on every batch of cannabis plant used in the manufacture of my medicinal cannabis product(s)?

Reduced or rotational testing of the cannabis plant used in the manufacture of the product can be carried out provided that this is justified on good manufacturing practice (GMP) grounds. For example, a manufacturer may be able to justify reducing or not conducting pesticide testing if no pesticides are used in the cultivation of the cannabis plant. The manufacturer should ensure that the product, if tested by the TGA laboratories, will meet all the requirements of the standard.

Do these apply equally to imported and Australian manufactured products?

Yes

Will the TGA evaluate my raw material and finished product specifications to ensure these comply with the Standard for Medicinal Cannabis?

No. The manufacturer is required to review their raw material and finished product specifications against the requirements of the *Standard for Medicinal Cannabis* (TGO 93). If they are satisfied that their unapproved medicinal cannabis product(s) meet the requirements of the standard, they should complete the declaration form (//www.tga.gov.au/form/medicinal-cannabis-products) available on the TGA website to declare that their medicinal cannabis product(s) meets this standard.

Who do I need to submit this declaration form to?

The form is submitted to the medical practitioner in the case of SAS B and Authorised Prescriber applications, and to the Australian clinical trial sponsor in the case of Clinical Trial Notifications (CTN) and Clinical Trials Exemption (CTX) applications. The medical practitioner or clinical trial sponsor (as relevant) is required to submit this form as supportive documentation to the TGA with their application or notification, as applicable. For more information on where to find and how to submit the form, please see the Forms webpage (//www.tga.gov.au/form/medicinal-cannabis-products).

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