

Access to medicinal cannabis in Victoria

Information for health practitioners

Is treatment with medicinal cannabis appropriate for my patient?

High quality evidence for the use of medicinal cannabis products remains limited, but it is evolving rapidly.

The Commonwealth Department of Health, in conjunction with state and territory governments, has released clinical guidance documents to assist health professionals in treating patients with medicinal cannabis products. A patient information document is also available.

These documents are available from:

<<https://www.tga.gov.au/access-medicinal-cannabis-products>>

It is the responsibility of the treating medical practitioner to assess available efficacy and safety data, and weigh this information against their patient's circumstances to determine whether treatment with medicinal cannabis is appropriate.

What medicinal cannabis products are available?

Medicinal cannabis products are quality assured, pharmaceutical products that vary in composition and routes of administration. The therapeutic effect of different products will depend on their THC/CBD composition. Before deciding which medicinal cannabis product to prescribe, available clinical evidence should be reviewed to determine the type of product most likely to produce positive outcomes for the patient.

Most medicinal cannabis products available in Australia have been imported, but local products are also available.

The Office of Drug Control (ODC) publishes an updated list of Australian importers and manufacturers of medicinal cannabis, which may assist in identifying products currently available

<<https://www.odc.gov.au/importers-and-manufacturers-medicinal-cannabis-products>>

The suppliers of these products may be contacted directly for further information.

Only one medicinal cannabis product has been registered on the Australian Register of Therapeutic Goods (ARTG). That product is Sativex® (nabiximols), which is approved for the indication of treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis.

How do I prescribe medicinal cannabis?

Prescribing medicinal cannabis products follows the same process as for all other pharmaceutical medicines, with processes dependent on (see also **Figure 1**):

1. How the product is scheduled within the Poisons Standard (SUSMP); and
2. Whether the product is registered on the ARTG.

As with any unapproved drug, accessing medicinal cannabis products not registered on the ARTG must be done via the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS) or Authorised Prescriber Scheme. Patients may also be able to access medicinal cannabis products as part of registered clinical trials. No Commonwealth (TGA) approvals are required for medicinal cannabis products that are registered on the ARTG.

Depending on the product, it may also be necessary to apply for a Schedule 8 treatment permit under the *Victorian Drugs, Poisons and Controlled Substances Act 1981*. Exceptions to requiring a Schedule 8 treatment permit apply if you are prescribing to a patient in hospital, aged care facilities, prisons, or receiving palliative care.

Victorian (Schedule 8) and Commonwealth (TGA) approvals required to prescribe medicinal cannabis products not listed on the ARTG can now be sought

together via the TGA's single online application < <https://sas.tga.gov.au/>>.

The Office of Medicinal Cannabis also has several resources to assist prescribers on its website < <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis>>.

Please note that if you are prescribing a medicinal cannabis product to a Victorian patient from interstate, different requirements may apply. Please contact your state health authority for more information.

How does the patient fill their prescription?

The patient can take the prescription for a medicinal cannabis product to any pharmacy. Dispensing of medicinal cannabis products follows the same process as for all other pharmaceutical medicines.

If the patient is prescribed an unregistered product, the pharmacy will need to provide the product supplier with a copy of the SAS or Authorised Prescriber approval letter when ordering the product.

How much does medicinal cannabis cost?

There are currently no medicinal cannabis products subsidised under the Pharmaceutical Benefits Scheme. Costs will vary depending upon products and dosages suitable for your patient's medical condition. As these products are not subsidised, the full cost must be funded by the patient. Information

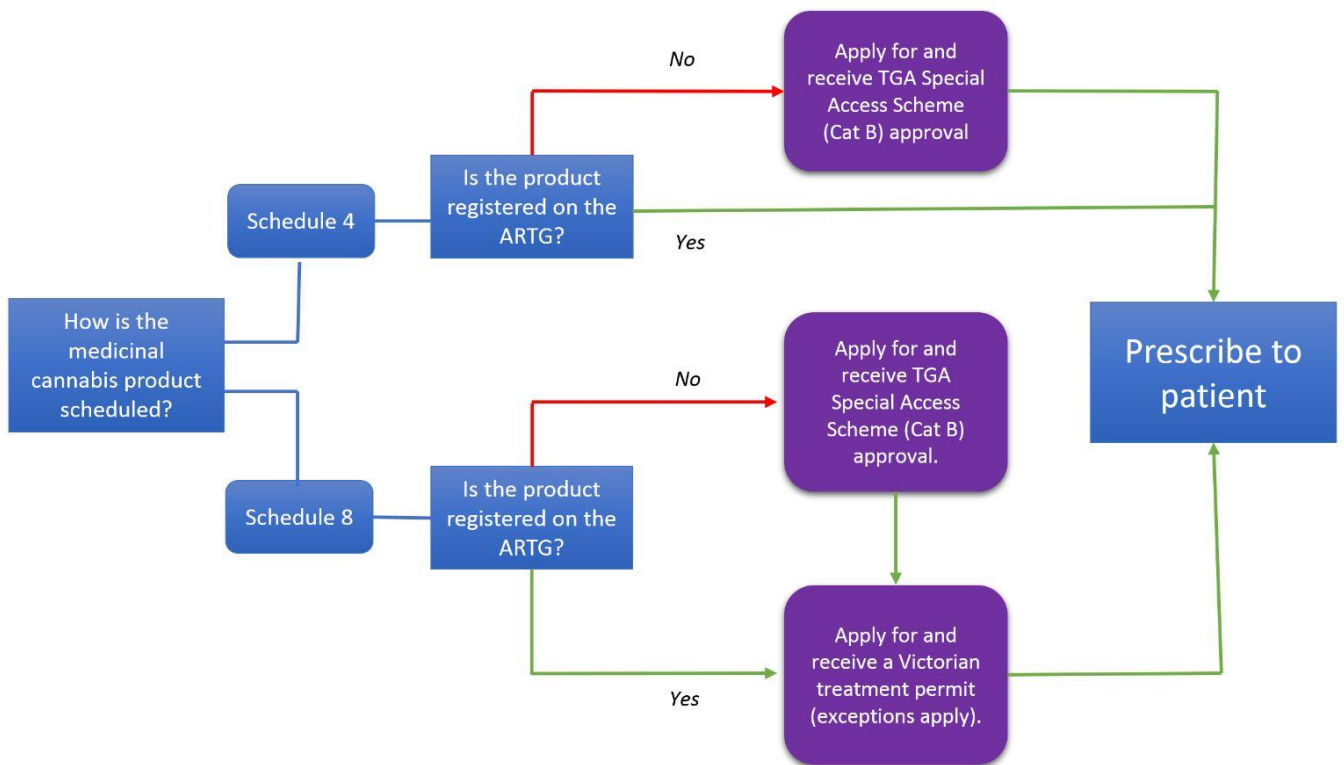
regarding the cost of products may be obtained from the suppliers listed on the ODC website.

Can my patient drive while taking medicinal cannabis?

As THC is known to have impairing effects, patients should be advised not to drive or operate machinery while taking products containing THC.

Furthermore, it is an offence to drive with any detectable amount of THC in a person's system in Victoria (even if from a legally prescribed product) and this may be detectable for a number of days after consumption. THC may also be detected by occupational/organisational drug testing programs.

Figure 1: Approval process for medicinal cannabis products in Victoria



Useful links

SAS Online Portal

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

Office of Medicinal Cannabis Victoria

<https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis>

Therapeutic Goods Administration – Medicinal cannabis

<https://www.tga.gov.au/access-medicinal-cannabis-products>

Office of Drug Control

<https://www.odc.gov.au/importers-and-manufacturers-medicinal-cannabis-products>

Drugs and Poisons Regulation – Treatment permits

<https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medical-practitioners-medicines-control/legislation-permits>

To receive this publication in an accessible format phone (03) 9096 7768 using the National Relay Service 13 36 77 if required, or email <medicinal.cannabis@dhhs.vic.gov.au>.

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Available at <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis>