

Doctor education document: Government position papers and processes explained

Australia is a very conservative jurisdiction with a strong focus on safety. Consequently, regulations around unregistered medications are stringent and tight. Medicinal Cannabis is, in almost all situations, an unregistered medication. Because of the paucity of conclusive evidence either for or against Medicinal Cannabis there is an even higher level of regulation and oversight controlling access to the substance in Australia. To ensure that doctors considering prescribing Medicinal Cannabis have a balanced view of the government's and regulator's opinions and processes we have assembled the following document. It is important to note that as yet only "guidance" for doctors has been published, this should not be confused with "guidelines". We have included below some of the relevant government and regulatory publications on the topic from Federal and State levels, as well as a meta-analysis from the Canadian government:

- Upon review of evidence, the Australian Department of Health found that cannabinoids are less likely to be associated with severe adverse events than opiate medicines. They are generally regarded as having low acute toxicity, however concurrent use of other drugs may mask the effects of cannabis.
[http://www.health.gov.au/internet/ministers/publishing.nsf/Content/0A09D583048E3126CA2581FD008335D1/\\$File/17-12-22%20Hunt%20-%20Media%20Release%20-%20New%20comprehensive%20guidance%20on%20medicinal%20..pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/0A09D583048E3126CA2581FD008335D1/$File/17-12-22%20Hunt%20-%20Media%20Release%20-%20New%20comprehensive%20guidance%20on%20medicinal%20..pdf)
- TGO-93 is the standard set by the TGA for any Medicinal Cannabis product to achieve before it can be used in the Australia <https://www.tga.gov.au/sites/default/files/conforming-tgo-93-standard-medicinal-cannabis.pdf>
- The TGA has published the following guidance for patients and doctors on the prescribing and use of Medicinal Cannabis.
 - This link is to the general guidance page with information about the indications being treated: <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>
 - This is the link to the guidance for pharmacists and patients: <https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-patient-information>
- Childhood epilepsy. The attached link is a very balanced "guidance" (not "guidelines") for doctors, patients and families. In Australia, under very strict supervision and governance, there is an Authorised Prescriber Network of Paediatric Neurologists involved in an extended clinical trial. Most published clinical and pre-clinical data on efficacy in epilepsy is with CBD. Its role in treatment is as an adjuvant treatment to current treatment in drug resistant epilepsy where four or five other anti-epileptic drugs (AEDS) have not controlled the epilepsy. Note: there does not appear to be any information on the use of medicinal cannabis products being administered as 'rescue' therapy for status epilepticus. <https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-treatment-epilepsy-paediatric-and-young-adult-patients-australia>
- The Federal minister for Health has recently decided to authorise export of Medicinal Cannabis from Australia provided adequate supply is reserved to support Australian patients.
<http://www.greghunt.com.au/Home/LatestNews/tabid/133/ID/4461/Turnbull-Government-to-allow-medicinal-cannabis-exports.aspx>
- The Canadian government has produced a comprehensive meta-analysis showing the pros and cons of Medicinal Cannabis as a treatment option for Doctors however this includes "smoked" Cannabis and it is acknowledged that smoking is a separate risk https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/marihuana/info/cons-eng.pdf

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- The Australian Federal Minister for Health has proposed, and COAG has recommended, that all states reduce the barriers to access for Medicinal Cannabis in the same way as New South Wales has last March 2018
 - http://www.health.nsw.gov.au/news/Pages/20180302_00.aspx
 - https://www.coaghealthcouncil.gov.au/Portals/0/CHC%20Communique%20130418_corrected_1.pdf (page 2, bottom)
 - <http://a.msn.com/09/en-au/AAvPJEP?ocid=se>

The normal SAS Category B process is the appropriate form of application should any doctor consider it appropriate to trial a patient on Medicinal Cannabis. The steps are as follows:

1. Doctor decides Medicinal Cannabis may be appropriate and justified as a trial for a patient
2. Doctor fills in the clinical form <http://www.anspec.com.au/doctors.php> and saves.
3. Doctor may seek colleague or specialist advice as appropriate
4. Doctor fills in SAS B form for TGA application <http://www.anspec.com.au/doctors.php> and email to SAS@health.gov.au
5. Doctor fills in the state form online <http://www.anspec.com.au/doctors.php> and emails to the state email address on the form.
6. Doctor selects Brand and dosing for Medicinal Cannabis and includes this in the application
7. Doctor selects an appropriate participating Pharmacy and includes this in the application (currently in Queensland (only) this needs to be a pharmacy registered to handle medicinal cannabis. See the list at: https://www.health.qld.gov.au/_data/assets/pdf_file/0023/644018/medicinal-cannabis-management-plan.pdf)
8. To increase the possibility of an effective application fill in the Supporting clinical information form available on request.
9. 36 hours – response from TGA to the doctor
10. Doctor sends to the nominated pharmacy
11. Pharmacy orders nominated product from supplier
12. Supplier ships to pharmacy and pharmacy dispense to the patient
13. Pharmacy may then stock for the patient
14. Hospital pharmacy may stock for a trial

Doctor, pharmacy, supplier maintain copies of all paperwork for SAS B plus medicinal cannabis

At the COAG meeting in April 2018, state and territory governments agreed to adopt what Greg Hunt described as the “one-stop shop” devised by Canberra and NSW. Under this model, the doctor fills in forms online through a single TGA portal and receives letters from the TGA and their state department of health within 24-36 hours. This is expected to become the normal model for all states and territories in the coming months.

Further detail from Federal, State and Territory governments may be found through the links on the Anspec website <http://www.anspec.com.au/doctors.php> or directly from government websites.

For GPs the current position statement by the RACGP supports simplification of access to medicinal cannabis prescribing for GPs and patients and can be found at:

<https://www.racgp.org.au/download/Documents/Policies/Health%20systems/Regulatory-framework-for-medicinal-use-of-cannabis-products-.pdf>

END

This document has been developed by Anspec Pty. Ltd., for doctor education on access to medicinal cannabis only. We have used our best endeavours to ensure that it is accurate and current as at: 11 May 2018