Australian Government
Department of Health
Therapeutic Goods Administration

Legislative framework and Commonwealth access schemes relevant to supply of medicinal cannabis

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TGA Health Safety Regulation

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Covering

- Legislative framework
- Current scheduling of Cannabis and THC for human therapeutic use in certain circumstances.
- TGA access pathways
- Interfaces with states and territories

Legislative framework

Commonwealth

- Therapeutic Goods Act
  - Scheduling
  - Access
  - Manufacturing
- Narcotic Drugs Act
  - Cultivation
  - Manufacture
- Customs (Prohibited Imports) Regulations
  - Importation

State/Territory

- Drugs and poisons regulation
- Specific medicinal cannabis legislation

Current scheduling of cannabis etc.

As of 1 June 2015

- Schedule 4 had added
  - CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.

Current scheduling of cannabis etc.

As of 1 November 2016

- Schedule 8 had added

  CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) **when prepared or packed for human therapeutic use**, when:

  a) cultivated or produced, or in products manufactured, **in accordance with the *Narcotic Drugs Act 1967***; and/or

  b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

  c) **imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*;** and/or

  d) **in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,**

  except when:

  i) **it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990** applies; or ……..

Current scheduling of cannabis etc.

As of 1 November 2016

- Schedule 8 **also** had added
  - # TETRAHYDROCANNABINOLS when extracted from cannabis for **human therapeutic use**, when:

  a) included in products **manufactured in accordance with the *Narcotic Drugs Act 1967***; and/or

  b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

  c) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989,*

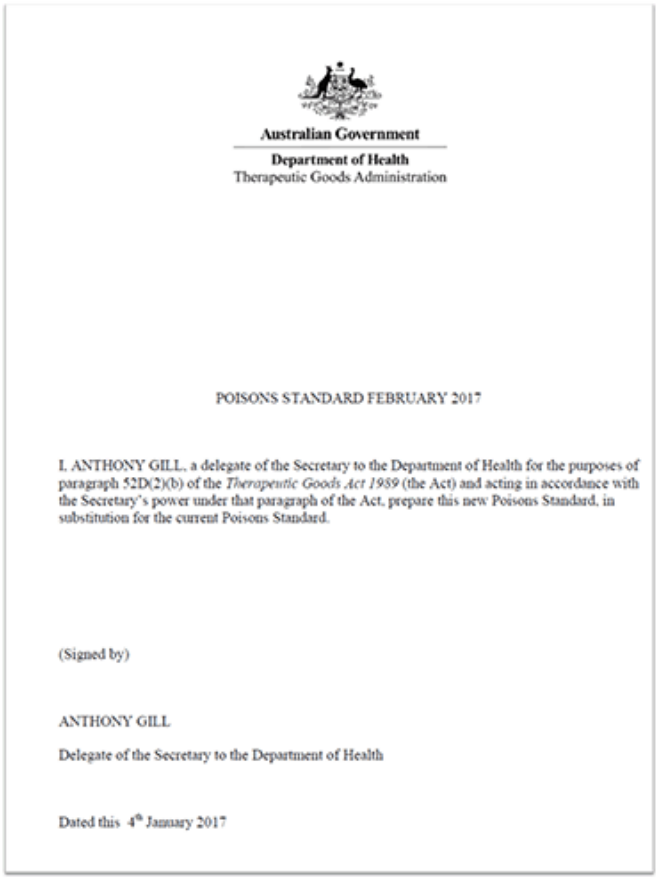
  except when:

  i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or …….

Current scheduling of cannabis etc.

As of 1 November 2016 also added were

- New Appendix D Item 1 entries for Cannabis and Tetrahydrocannabinols substances such that when S8 will only be available from or on the prescription or order of a medical practitioner authorised by states and territories, and
- New Appendix K entries for Cannabis and Tetrahydrocannabinols (substances to be labelled with a warning regarding their sedation potential)



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POISONS STANDARD FEBRUARY 2017

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health for the purposes of paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989* (the Act) and acting in accordance with the Secretary's power under that paragraph of the Act, prepare this new Poisons Standard, in substitution for the current Poisons Standard.

(Signed by)

ANTHONY GILL

Delegate of the Secretary to the Department of Health

Dated this 4th January 2017

Implications of current scheduling

- Cannabidiol
  - Schedule 4
  - Requirement for state approvals in QLD and TAS, and VIC in certain circumstances
- Schedule 8 Cannabis and THCs
  - Require state/territory S8 and/or medicinal cannabis approvals as applicable

Access history relating to *Therapeutic Goods Act 1989*

Prior to 1 November 2016 access was restricted as:

- S9 substances are **Prohibited Substance** – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.
- TGA legislation does not allow products containing S9 substances to be accessed through SAS Category A.
- States and territories had various abilities to approved S9 containing products to be used, if at all.

Access related history

Narcotic Drugs Act 1967 amendments passed in Commonwealth Parliament and in place from 29 February 2016 allowed cultivation, production and manufacture involving cannabis in order to deliver medicinal cannabis products.

Amendments had restrictions on how supply was allowed to occur such that could only be:

i. supplied for the purposes of use in a clinical trial that is, or is likely to be, approved under the *Therapeutic Goods Act 1989* or notified to the Secretary under that Act; or

ii. otherwise supplied in accordance with an **approval or authority** under the *Therapeutic Goods Act 1989*

Access under TG legislation

Amended 1 November 2016

- Therapeutic Good Regulations were amended as of 1 November 2016 to align with Narcotic Drugs Act amendments as scheduling had changed
- Amendments removed use of SAS Category A for '*medicines that contain a substance covered by any of the following entries in the Poisons Standard:*
  - *(a) the entry for cannabidiol in Schedule 4;*
  - *(b) the entry for cannabis in Schedule 8;*
  - *(c) the entry for dronabinol in Schedule 8;*
  - *(d) the entry for nabilone in Schedule 8;*
  - *(e) the entry for nabiximols in Schedule 8;*
  - *(f) the entry for tetrahydrocannabinols in Schedule 8;*
  - ***(g) an entry in Schedule 9.' Note this was no change***

Access under TG legislation

Amended 1 November 2016

Amendments also tightened access in line with scheduling and removed ability to use some of the exemptions in Schedules 5 and 5A of Therapeutic Goods Regulations:

- Personal importation of goods
  - Can not be used if contain a substance of a kind covered by any of the following entries in Schedule 8 to the Poisons Standard:
    I. cannabis;
    II. dronabinol;
    III. nabilone;
    IV. tetrahydrocannabinols;
- Extemporaneous compounding – cannot use exemption for not being on the ARTG aligned with that for SAS Category A

Current access allowed under TG legislation

- Access under TG legislation is allowed, if approved, via:
  - Clinical trials
  - SAS Category B
  - Authorised Prescriber

- Access to medicinal cannabis products
  - No ARTG product available (SATIVEX® is approved but Australian product is not being supplied)
  - All need to be imported and then requirements of the Customs (Prohibited Imports) Regulations 1956 apply – administered by Office of Drug Control in Department.

Details of SAS and AP access

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Access assistance for doctors

Access to medicinal cannabis products in Australia

Resource for doctors

Step 1 — Doctor has consultation with patient

Prescribing considerations

- Is a medicinal cannabis product appropriate for my patient?
- Do I have the appropriate expertise/qualifications? Should I consider specialist involvement?
- Review evidence for potential products in the context of the patient's condition.
- Use this information to guide specific product selection.

Depending on the circumstances, you may need to seek approval/authorisation from the TGA, your state/territory health department and/or the ODC before you can prescribe, access or arrange importation of medicinal cannabis products.

Seeking approval/authorisation for a specific medicinal cannabis product

a) Gather product details – trade name, formulation, dosage form, route of administration, dose and product specifications.

b) Follow steps 2A and 2B then:

1) if imported stock is already in Australia or Australian manufactured stock is available, follow Step 3A.
2) if stock must be imported into Australia, follow Step 3B. ***

For further information, see the TGA's Access to medicinal cannabis products webpage.

For assistance call 1800 020 653 (or 02 6232 8866) or email medicinal.cannabis@health.gov.au

Step 2A — TGA access schemes

For individual patients:

Special Access Scheme Category B (SAS B)
Complete application – SAS B form (include supporting evidence, product details).
Submit paperwork to the TGA.
*Timeframe: Max. 6 working days**

For a class of patients:

Authorised Prescriber (AP)
Complete application – Agreement to Treatment Directions form, treatment protocol (include supporting evidence, product details), HREC/College endorsement.
Submit paperwork to TGA.
*Timeframe: Max. 10 working days**

* Timing dependent on applications containing all necessary information.

Step 2B — Check your state/territory requirements

Rules relating to medicinal cannabis products may vary between states and territories.

Contact your state/territory health department to confirm requirements (contact details below).

Obtain prescribing approval if required (may not be required if schedule 4, for example cannabidiol entry)

Timeframe: Max. 20 working days

! — Import licence and permit (from the ODC)

*** If intending to import product from overseas (Step 3B):

- Check import licence status of importer.
  - If no licence is held, importer must apply for a licence from the ODC. (Max. 30 working days)
- Import permit is a later step – issued on a case by case basis after TGA and state/territory approval.

Step 3A — If stock available in Australia

Pharmacist or medical practitioner:

- Contact supplier.
- Provide supplier SAS B approval or AP authorisation and state/territory approval if required.
- Supplier releases product.

Step 3B — If product must be imported

Pharmacist or medical practitioner:

- Determine importer.
  - Importer must hold an ODC licence. ***
- Send SAS B approval/AP authorisation and state/territory approval to importer.

Importer:

- Importer applies to ODC for an import permit (per shipment).
  Timeframe: Max. 20 working days
- Liaise with overseas supplier.
- Exporter supplies product.
- Importation of product.
- Supply of product.

PATIENT ACCESS

https://www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes

Criteria for SAS Category B and Authorised Prescriber

The criteria used by delegates in deciding whether to approve supply through Authorised Prescriber or SAS Cat B in the current guidance documents on AP and SAS are:

- The patient/patients
- The product
- The prescriber

Note that this information is required for all SAS B or Authorised Prescriber applications for any unapproved medicine or device.

Authorised Prescribers

To be an Authorised Prescriber the medical practitioner must have:

- the training and expertise appropriate for the condition being treated and the proposed use of the product;
- the Authorised Prescriber must be able to best determine the needs of the patient; and
- to monitor the outcome of therapy.

Patient criteria

Patient details

- Patient information
- Diagnosis and what is the indication being treated by the unapproved product

Clinical Justification - this should include an outline of:

- The seriousness of the condition; and
- Details of past treatment - If other approved treatments are available, the applicant will need to justify the use of the unapproved product in preference to those treatments.
- It is important for the justification to balance the availability of approved therapies against the seriousness of the patient's medical condition and to include an appraisal of the expected benefits from the use of the unapproved product.

Product details

- Trade name
- Active ingredients
- Dosage Form e.g. capsule
- Route of administration
- Name of the sponsor
- Schedule in SUSMP
- Declaration of conformity with the *Standard for Medicinal Cannabis* (TGO 93)
- Ancillary dosing aids (if applicable)

Product details contd.

Administration details:

- Dosage
- Route or method of administration
- Duration of treatment

Monitoring Details:

- Efficacy of the treatment
- Adverse events/reactions

Efficacy/safety data:

- Human studies to demonstrate efficacy and safety data sufficient to support the proposed use of the actual product being requested, including dosage and route of administration
- Level of evidence required will depend on the seriousness of the condition

Prescriber Details

- Doctor with qualifications and/or expertise appropriate to the condition being treated and the proposed use of the product
- If the prescriber is not a specialist then TGA would expect a specialist report from the appropriate specialist on suitability of the product requested for the patient
- Information that the prescriber is either approved or is applying for approval to prescribe medicinal cannabis by the State/Territory in which he/she practices or where the patient resides
- Ethics Committee/Specialist College endorsement for Authorised Prescriber applications.
- Agreement to Treatment Directions for Authorised Prescriber applications

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Interface with States and Territories

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S8 Medicinal Cannabis Products

State / Territory	Specialists	GPs	Process
ACT	Yes	Yes with specialist support	Specific process
QLD – patient class (similar to TGA's AP)	Yes	No	Specific process
QLD – single patient (similar to TGA's SASB)	Yes	Yes	Specific process
NSW	Yes	Yes with specialist support	Specific process
VIC – Eligible patient – Currently children with intractable epilepsy (under Vic legislation)	Yes	Initial application must be made by specialist then GP can help prescribe ongoing treatment	Specific process
VIC – Exceptional circumstances (under Vic legislation)	Yes	Yes	Specific process
VIC – General Schedule 8 (imported or non VIC manufacture)	Yes	Yes	Standard S8 process
TAS	Yes	No	Specific process
SA standard	Yes	Yes with specialist support	Standard S8 process
WA – notification (similar to TGA's AP)	Yes	Initial application must be made by specialist then GP can help prescribe ongoing treatment	Specific process
WA - authorisation (similar to TGA's SASB)	Yes	Yes with specialist support	Specific process
NT	Yes	Initial application must be made by specialist then GP can help prescribe ongoing treatment	Standard S8 process

State/Territory prescribers – S4 products

State / Territory	Specialists	GPs	Process
QLD – patient class	Yes	Not eligible for this pathway	Specific process
QLD – single patient	Yes	Yes	Specific process
TAS	Yes	Not eligible to prescribe	Specific process
VIC – Eligible patient – Currently children with intractable epilepsy (under Vic legislation)	Yes	Initial application must be made by specialist then GP can help prescribe ongoing treatment	Specific process
VIC – Exceptional circumstances (under Vic legislation)	Yes	Yes	Specific process

Assistance for Doctors re SAS B and AP

Medicinal Cannabis Section at TGA

- call 1800 220 007 (or 02 6232 8866), or
- Access to medicinal cannabis products - https://www.tga.gov.au/access-medicinal-cannabis-products
- Access to medicinal cannabis products: steps to using access schemes - https://www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes
- email to: medicinal.cannabis@health.gov.au

Questions?

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