Fact Sheet

Medicinal Cannabis Products

Cannabis for human therapeutic use is regulated as a medicine in Australia. The term 'medicinal cannabis products' covers a range of cannabis preparations intended for therapeutic use, including pharmaceutical cannabis preparations, such as oils, tinctures and other extracts.

Some examples of medicinal cannabis products that may be available through approved suppliers in Australia are listed below. Products must be legally produced and manufactured to appropriate quality standards. Commonwealth approval to supply, and where necessary import a medicinal cannabis product is granted by the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC).

Product	Australian Medicines	South Australia ¹	Commonwealth ²
	Schedule/Registration		
Dronabinol (Marinol®,	Schedule 8. Unregistered	An authority issued under	TGA Special Access
Syndros®, US FDA	synthetic/analogue cannabinoid	section 18A of the	Scheme or Authorised
approved medicine)	products.	Controlled Substances Act	Prescriber Scheme or
Nabilone (Cesamet®, US		1984 may be required.1	Clinical Trials Schemes.
FDA approved medicine)			
Tablet/capsule form.			
Nabiximols (Sativex®)	Schedule 8. The only registered	An authority issued under	Registered on the
Oral spray form.	cannabinoid product in Australia	section 18A of the	ARTG – approved
	- for symptom improvement in	Controlled Substances Act	product.
	multiple sclerosis.	1984 may be required.1	
Cannabidiol in preparations for	Schedule 4. Unregistered	A section 18A authority is	TGA Special Access
therapeutic use where	cannabidiol products.	not required for Schedule	Scheme or Authorised
cannabidiol comprises 98 per	Refer to the Poisons Standard	4 medicines.	Prescriber or clinical
cent or more of the total	for detail on Schedule 4 listing.		trials schemes.
cannabinoid content of the			
preparation.			
Medicinal cannabis products	Schedule 8. Unregistered	An authority issued under	TGA Special Access
containing	cannabinoid products derived	section 18A of the	Scheme or Authorised
tetrahydrocannabinol,	from the cannabis plant.	Controlled Substances Act	Prescriber Scheme or
cannabidiol and other	Refer to the Poisons Standard	1984 may be required.1	clinical trials schemes.
cannabinoids in varying	for detail on Schedule 8 listing.		
strengths and forms available			
through approved suppliers.			

¹ A section 18A authority to prescribe a Schedule 8 controlled drug (drug of dependence) is required after two months of treatment (or before commencing treatment where the person is already prescribed another Schedule 8 drug for a period exceeding two months), or before commencing treatment for any person the medical practitioner reasonably believes to be dependent on drugs.

A section 18A authority is not required for patients:

- > aged 70 years or older
- Notified Palliative Care Patients

For more information

Medicines and Technology Programs Department of Health and Wellbeing SA Health

www.sahealth.sa.gov.au/medicinalcannabis

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²A single application to satisfy both SA and Commonwealth requirements can be made via the <u>TGA SAS Online system</u>.