
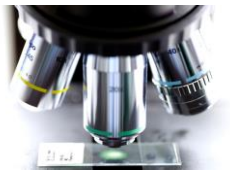


Member Alert

Consumer access to CBD in Australia is changing. Two Consultations on down-scheduling Cannabidiol now open for public comment.

Dear Member,

In the space of a week, two similar but different proposals to down-schedule Cannabidiol in Australia have been published for consultation, one by a private applicant, and one by the TGA. Due to a recent Senate Inquiry on this matter recommending that the TGA consult with the public on reducing barriers to accessing medicinal cannabis, and the 2019 recommendation by the World Health Organisation ('WHO') that preparations containing predominantly CBD with not more than 0.2% THC should not be placed under international drug control, **we are confident this re-Scheduling will result in increased consumer access to cannabidiol products**.

Research has found that the cannabis plant produces between 80 and 100 cannabinoids (including both cannabidiol or 'CBD' and delta-9-tetrahydrocannabinol or psychoactive 'THC') and about 300 non-cannabinoid chemicals. Both of these proposals provide that the preparations total cannabinoid content would be required to be 98% or more of cannabidiol (CBD), as recommended by the WHO.

The consultation process including the public responses and safety considerations will influence the final outcome of how consumers and industry will be able to access and market CBD. CMA will be providing a submission, and encourages all interested businesses and individuals to make a submission such that the Joint ACMS/ACCS and the TGA are aware of the level of public interest and response. CMA will provide more information to members prior before the submission deadline to consider as a part of a response.

How the down-scheduling process operates

The public submissions to the two related proposals will be considered by the Joint Meeting of the Advisory Committees on Medicines & Chemicals Scheduling. The joint Committee makes a recommendation to the TGA Delegate of the Secretary, who then makes an "interim decision" subject to a second round of public consultation, followed by the final decision to amend (or not amend) the Poisons Standard. The decision becomes published in law several months later.

Anticipated timeframe:

Public submission deadline (proposal)	**22 May 2020**
Joint Committee Meeting:	23-25 June 2020
Public notice/consultation of interim decision	9 September 2020
Public submission deadline (interim decision)	**13 October 2020**
Public notice of final decision	25 November 2020
Poison Standard (effective date in law)	**1 February 2021**

PO Box 450 Mawson ACT 2607 | Tel: +61 (0)2 6260 4022 | Website: www.cmaustralia.org.au

Comparable proposals for consumer access to CBD (other than Prescription medicines or higher)

	TGA Proposal	Private Applicant Proposal
Level of consumer access	Pharmacist Only (Schedule 3) – Consumers must obtain the medicine directly from a pharmacist to ensure some health care practitioner oversight.	Public access (unscheduled) Consumers would be able to purchase the preparation across the counter from any retailer or from any health care professional.
Regulatory level	S3 medicines must be "registered" / AUST R medicines, which are subject to a full safety, quality, and efficacy evaluation of the clinical evidence by the TGA before market entry. More serious therapeutic indications can be approved.	Unscheduled preparations for therapeutic use are eligible to become listed or registered medicines (AUST L / L(A) or AUST R) - if the substance were to be approved as suitable for use in listed medicines. AUST L medicines only use lower level 'permissible indications'.
CBD as % of all cannabinoids	98% cannabidiol or more of the total cannabinoid content	98% cannabidiol or more of the total cannabinoid content
Other content	Any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.	Contains less than or equal to 0.2 per cent tetrahydrocannabinol (THC).
Cannabidiol source	• Plant derived; or • Synthetic, if it only contains the (-) CBD enantiomer	• Whole plant cannabis product or distillate or isolate *Note: synthetic or semi-synthetic CBD proposed as prescription only.*
Maximum recommended daily dose	**60mg** (or less)	-
Pack size	**30 days** supply	- (however concept supported)
Age requirement	**Adults** 18 years or older	-
More information	The full proposal contains: • Applicant's reasons • Domestic regulation • International regulation	The full proposal contains: • Applicant's reasons • Domestic regulation • International regulation

How to respond to the proposals

As these consultations are very closely related, the due date for both cannabidiol consultations has been harmonised to the close of business **22 May 2020**. A submission must:

- be accompanied by a completed TGA Consultation submission coversheet
- be submitted by closing date to medicines.scheduling@health.gov.au and include in the subject line 'Proposed Amendments to the Poisons Standard (Medicines/Chemicals)'.

Submissions should:

- Include whether or not you support the amendment/s (and suggested specific alterations).
- Be succinct to key points relevant to the proposed amendments.
- May include an assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
- Address any other relevant matters in section 52E of the *Therapeutic Goods Act 1989*:
  - risks and benefits of the use of a substance;
  - purposes for which a substance is to be used and the extent of use of a substance;
  - toxicity of a substance;
  - dosage, formulation, labelling, packaging and presentation of a substance;
  - potential for abuse of a substance;
  - any other matters that the Secretary considers necessary to protect public health.
  -

Resources – More about this process

- The TGA April 2020 safety review of cannabidiol
- The cannabidiol Scheduling consultation (proposal by private applicant)
- The cannabidiol Scheduling consultation (proposal by the TGA)
- The Senate Inquiry Report and List of Recommendations
- WHO 2019 recommendation to down-regulate cannabidiol
- WHO 2018 Critical Review Report on Cannabidiol

Resources – More about cannabidiol

- American Botanical Council Analysis of Medicinal Cannabis Industry
- Alcohol & Drug Foundation Fact Sheet on Medicinal Cannabis
- European Monitoring Centre for Drugs and Drug Addiction - Medical use of cannabis and cannabinoids – Policymaking
- The Market Herald (AU) - Inside the multi-billion dollar CBD market
- Pharmacology and toxicology information on CBD by FSANZ
- Cannabidiol: A Review of Its Safety for Human Consumption by Centre for Medicinal Cannabis Research.