

# Australian Government to consider amending the way in which Cannabidiol is regulated

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## Submissions close 22 May 2020

While there has been great interest in the supply of Cannabidiol (**CBD**) in Australia, especially from overseas companies, the supply of CBD has been very tightly controlled in Australia. However, this may be changing. The Therapeutic Goods Administration (**TGA**) recently announced in April 2020 that it was inviting public submissions regarding two proposals to amend the scheduling of CBD in the Poisons Standard. The proposals, if accepted, would permit CBD to be available for purchase without a prescription.

Currently, CBD is classified in the Poisons Schedule as:

- a prohibited substance (Schedule 9);
- a controlled drug (Schedule 8), and
- a prescription-only medicine (Schedule 4),

meaning that the manufacture, supply, distribution and possession of CBD is heavily restricted.

The Department of Health's proposed amendment of the Poisons Standard would result in CBD being added to Schedule 3 of the Poisons Standard, being a pharmacist only medicine permitted for therapeutic use when:

- (a) the CBD is either plant-derived or, when synthetic, only contains the (-) CBD enantiomer;
- (b) the maximum recommended daily dose is 60mg or less of CBD;
- (c) in packs containing not more than 30 days' supply;
- (d) CBD comprises 98% or more of the total cannabinoid content of the preparation;
- (e) any cannabinoids, other than CBD, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation; and
- (f) for adults aged 18 and over.

In making this proposal, the Department of Health relied on the available evidence that CBD's safety and tolerability was acceptable at the proposed dose. The proposal provides that any negative risks associated with the regulation of CBD in this manner could be adequately managed through limiting the amount of CBD able to be sold and the inclusion of appropriate warning labels on the product.

The other proposal, which was put forward by a private applicant, if accepted, would result in CBD's entry in Schedule 4 of the Poisons Standard being amended to remove plant-derived CBD, which would then be

dealt with in the same way that herbal medicines and complementary medicines are currently regulated. This proposal would make access easier than the Department of Health's proposal.

Both proposals would result in CBD's regulation in Australia aligning more closely with other markets, including the USA and UK.

Submissions regarding the proposals close on **22 May 2020**. An interim decision concerning the proposals is expected in September 2020 following which will be a further opportunity for submissions. More information can be found [here](#).<sup>1</sup> For further information relating to these proposals or CBD in Australia, please contact us.

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<sup>1</sup> Department of Health, Therapeutic Goods Administration, *Consultation: Proposed amendments to the Poisons Standard – Joint ACMS/ACCS meetings, June 2020* < <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-acmsaccs-meetings-june-2020#how>>.



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