

TGA approves low-dose cannabidiol (CBD) for supply over-the-counter

21 December 2020

On 15 December 2020, the Therapeutic Goods Administration (**TGA**) announced that certain low dose cannabidiol (**CBD**) preparations would be down-scheduled from Schedule 4 (Prescription Medicine) to Schedule 3 (Pharmacist Only Medicine) of the Poisons Standard.¹ This means that low-dose CBD products, containing up to a maximum of 150 mg/day, for use in adults will be permitted to be supplied over-the-counter by pharmacists without a prescription. CBD products will only be permitted to be supplied over-the-counter if they are approved by the TGA, are included on the Australian Register of Therapeutic Goods (**ARTG**) and comply with specific packaging and dosage requirements under the Poisons Standard.

This decision follows a public review conducted by the TGA in early 2020 which indicated that the use of CBD in low doses would be unlikely to result in serious adverse health consequences. This decision also increases the previously proposed maximum daily dose limit from 60 mg/day to 150 mg/day. For more information on the public review or the interim decision regarding the scheduling of CBD products, see our previous Insights of [4 May 2020](#) and [14 September 2020](#).

Companies who wish to sponsor the registration of low-dose CBD may now apply to the TGA for inclusion of Schedule 3 CBD products on the ARTG. For more information relating to this decision or the regulation of CBD in Australia, please contact us.

Jamie Nettleton | Partner

D +61 2 8915 1030

E jamie.nettleton@addisons.com

Cate Sendall | Special Counsel

D +61 2 8915 1028

E sarah.best@addisons.com

Tim Clarke | Special Counsel

D +61 2 8915 1001

E laura.hartley@addisons.com

Brodie Campbell | Solicitor

D +61 2 8915 1143

E brodie.campbell@addisons.com

¹ See Therapeutic Goods Administration, '[Notice of final decision to amend \(or not amend\) the current Poisons Standard – cannabidiol](#)' (15 December 2020).



Level 12, 60 Carrington Street
Sydney NSW 2000 Australia

ABN 55 365 334 124
Telephone +61 2 8915 1000

mail@addisons.com
www.addisons.com

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