

Australia moves one step closer to allowing greater access to CBD

14 September 2020

Further to our [Insight of 4 May 2020](#), after a review of a substantial number of public submissions, the Delegate of the Secretary of the Department of Health (**Delegate**) has issued an interim decision in respect of a private scheduling application and a Delegate-initiated amendment concerning the regulation of cannabidiol (**CBD**) in Australia. Given the significant overlap, both proposals were considered jointly and the Delegate has issued the following interim decisions:

- Private scheduling application – an interim decision not to:
 - amend the current Poisons Standard to exclude CBD from scheduling; and
 - allow its general sale; and
- Delegate initiated amendment – an interim decision to down schedule CBD to permit greater access via a new Schedule 3 (**S3**) entry in the Poisons Standard in accordance with:
 - specific requirements to be added to S3; and
 - supply requirements to be added to Appendix M to enable CBD to be provided by a pharmacist provided that the medicine has been entered on the Australian Register of Therapeutic Goods.

The Delegate initiated amendment would require various amendments and new entries in the Poisons Standard including the addition of CBD to S3 of the Poisons Standard as being a pharmacist-only medicine in respect of oral, oral mucosal and sublingual formulations preparations permitted for therapeutic use when:

- the CBD is either plant-derived or, when synthetic, only contains the (-) CBD enantiomer;
- the maximum recommended daily dose is 60mg or less of CBD;
- in packs containing not more than 30 days' supply;
- CBD comprises 98% or more of the total cannabinoid content of the preparation;
- 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;
- packed in blister or strip packaging or in a container fitted with a child-resistant closure; and
- for adults aged 18 and over.

In addition, a new entry in the Poison Standard (Appendix F, Part 3) would be required for CBD when included in S3 that products contain the following warning statements:

- 67 “do not use if pregnant or likely to become pregnant”; and

- 111 “do not use if breastfeeding or plan to breastfeed”.

Submissions regarding the interim decision close on 13 October 2020. More information can be found [here](#). For further information relating to the interim decision or 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 1027

E cate.sendall@addisons.com

Tim Clarke | Special Counsel

D +61 2 8915 1001

E tim.clarke@addisons.com

Level 12, 60 Carrington Street, Sydney, NSW 2000, Australia

addisons.com | [LinkedIn](#)



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

Liability limited by a scheme approved under Professional Standards Legislation