



Proposed amendments to the Poisons Standard – Cannabidiol

Submission from Cancer Council Australia, May 2020

Cancer Council Australia makes this submission in opposition to two applications that propose amendments to the scheduling of cannabidiol (CBD) in the Poisons Standard. The applications are:

- CAS 13956-29-1 initiated by a private applicant to regulate CBD in the same way as complementary medicines; and
- CAS 13956-29-1 initiated by the Delegate of the Secretary of the Commonwealth Department of Health to down-schedule low dose CBD in therapeutic preparations to Schedule 3 (Pharmacist Only Medicine).

Both applications have been referred to the June 2020 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #25).

Analysis

Cancer Council Australia submits that the proposed amendments to the scheduling of CBD would not be in the interest of public health, following proper consideration of the relevant matters in s 52E(1) of the *Therapeutic Goods Act 1989* (Cth) ('the Act'). The current scheduling of CBD is appropriate and ought to be maintained.

This submission focuses on the matters in sections 52E(1)(a), (e) and (f) of the Act because these illustrate our concerns most clearly.

The risks and benefits of the use of a substance: s 52E(1)(a)

Existing published, peer-reviewed evidence does not support the therapeutic application of CBD in cancer care. There are currently no formal international or national guidelines for prescribing cannabis for the management of side effects of cancer or cancer treatments.

Cancer Council Australia's position statement on Medical Use of Cannabis (January 2020)¹, made jointly with the Clinical Oncology Society of Australia (COSA), notes that there is some limited evidence that medical cannabis and cannabinoids in controlled delivery may benefit cancer patients where conventional treatments have been unsuccessful in providing relief from nausea in chemotherapy patients, as an analgesic in patients experiencing pain, and as an appetite stimulant for patients experiencing weight loss.

Evidence from controlled clinical trials is required to evaluate the effectiveness and safety of CBD products for managing side effects of cancer or its treatment. No such products have been approved by the TGA for this purpose. In the event that CBD products were approved by the TGA for cancer care, the oversight of the patient's medical practitioner would be required. The current scheduling of CBD as Schedule 4 (Prescription Only Medicine) is therefore appropriate.

¹ Cancer Council Australia and Clinical Oncology Society of Australia. Medical use of cannabis. Updated January 2020. Available at: cancer.org.au/policy-and-advocacy/supportive-care-policy/cannabis-for-medical-purposes.html

The potential for abuse of a substance: s 52E(1)(e)

In our view, the risk that CBD will be abused through use in e-cigarette devices and other products is unacceptably high. Both applications propose weakening the scheduling of CBD, thereby increasing access and the strong probability that CBD will be used for non-therapeutic purposes or in unapproved ways. The delegate initiated application down-schedules CBD to Schedule 3, which removes the oversight of a medical practitioner and the protection that a legal prescription provides.

The growing international market for CBD e-liquids (also called CBD vape juice) signals a high risk that CBD products will be abused. Even without the psychoactive constituent of THC, there is strong demand for these commercial products. Numerous international websites offer to deliver CBD e-liquids to Australian customers.²

It is possible that people could attempt to use oral CBD tinctures in e-cigarette devices, or add flavouring and thinning agents to make the liquid more suitable.

Cancer Council Australia refers to the Cancer Australia statement on e-cigarettes³, which cites growing evidence of harms from e-cigarette use, including increased risk of respiratory disease, cardiovascular disease and carcinogenesis. There is currently insufficient evidence to support the use of e-cigarettes for smoking cessation, and none have been approved by the TGA for this purpose.

CBD oils, flavouring and thinning agents have not been proven safe to inhale directly to the lungs.

The 2019 outbreak of e-cigarette product use-associated lung injury (EVALI) in the United States gives further cause for serious concern about new additives to e-liquids. As of February 2020, a total of 2,807 cases had been reported with 68 deaths.⁴ Investigations found that THC-containing products played a major role in the outbreak, with vitamin E acetate strongly implicated. However, the Centers for Disease Control and Prevention (CDC) advises that the evidence is not sufficient to rule out the contribution of other chemicals. The CDC has warned people not to vape cannabis products.

In September 2019, the Australian Chief Medical Officer and State and Territory Chief Health Officers confirmed the governments' precautionary approach and stated that there is an emerging link between the use of e-cigarettes and lung disease.⁵

Any other matters that the Secretary considers necessary to protect public health s 52E(1)(f)

Cancer Council Australia wishes to draw attention to the involvement of both the tobacco and e-cigarette industries in the commercialisation of CBD products overseas. In order to protect public health, we submit that the Secretary should take into account the fact that scheduling decisions may empower and provide new markets for industries that have a fundamental conflict of interest and a disturbing record of inappropriate and irresponsible direct and indirect promotion.

By way of illustration, Altria (parent company of Philip Morris USA) has been granted 41 US patents for vaping devices suitable for cannabis and has invested heavily in Canadian cannabis enterprise Cronos and US e-cigarette company, Juul. The company uses Juul as a spin-off marketing

² Eg. www.mixologycbd.co.uk; vape-australia.com/cbd/cbd-vape-juice-in-australia/; vapejuicemaster.com;

³ Cancer Australia. Statement on e-cigarettes in Australia. February 2018. Available at: canceraustralia.gov.au/sites/default/files/statement_on_e-cigarettes_february_2018_0.pdf

⁴ Centers for Disease Control and Prevention (CDC). Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. Updated February 25, 2020. Available at: cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

⁵ Australian Government, Department of Health. E-cigarettes linked to severe lung disease. 13 September 2019. Available at: health.gov.au/news/e-cigarettes-linked-to-severe-lung-illness

opportunity for its brand of combustible cigarettes, Marlboro.⁶ There is strong evidence of tobacco and e-cigarette industry interest and involvement in cannabis.

Cancer Council Australia is concerned that the proposals to downschedule CBD would provide new promotional opportunities for e-cigarettes and CBD e-liquids in Australia. These have the potential to be very enticing to young people.

The availability and visibility of CBD products in Australian pharmacies would also contribute to normalising cannabis use. Co-use of cannabis and tobacco is common and has a synergistic effect, greatly increasing the risk of respiratory symptoms and chronic obstructive pulmonary disease (COPD).⁷ With respect to young people, there is a bidirectional gateway effect of cannabis and tobacco.

Conclusion

Given the current lack of strong evidence for clinical benefits, our concerns about the potential harms of down-scheduling CBD and the additional problems this would serve to create and promote, should be given considerable weight. Our analysis is that the relevant matters in s 52E(1) of the *Therapeutic Goods Act 1989* (Cth) do not support the exercise of power to amend the Poisons Standard in the ways proposed by either Applicant.

About Cancer Council Australia

Cancer Council Australia has been one of the most active nongovernment organisations in tobacco control since concerted efforts to work in a multi-sectorial capacity to reduce the health harms of tobacco use gathered momentum in the 1970s. This has included successful advocacy to phase out broadcast and print tobacco advertising and increase tobacco taxation, membership on intergovernmental and intersectoral bodies advising on tobacco control policies and the delivery of programs and services.

Around 20% of all cancer deaths and 16% of all cardiovascular disease deaths in Australia are attributed to smoking. While these are unacceptably high rates of mortality and exposure risk, they have nonetheless reduced significantly in recent years through the evidence-based interventions, supported by Australian governments and statutory health authorities, that have halved smoking prevalence over the past 25 years.

Advancing evidence-based tobacco control, and protecting the population from the risks of reforms that are not supported by the evidence, are fundamental to our mission. The (standing and co-opted) membership of our joint Tobacco Issues Committee includes some of Australia's leading academics and policy advisers on tobacco control and operates within a strict evidence-based framework, reporting to Cancer Council Australia's principal Public Health Committee.

⁶ Candice M. Bowling, Amy Y. Hafez & Stanton A. Glantz (2020): Public Health and Medicine's Need to Respond to Cannabis Commercialization in the United States: A Commentary. *Journal of Psychoactive Drugs*, DOI: 10.1080/02791072.2020.1761040

⁷ Tan W, Lo C, Jong A, Xing L, Fitzgerald, M, Vollmer, W. et al. Marijuana and chronic obstructive lung disease: a population-based study. *Canadian Medical Association Journal* 2009; 180(8):814-20. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665947/?tool=pubmed>