



21 May 2020

Advisory Committee on Medicines Scheduling (ACMS)
Therapeutic Goods Administration

By email: medicines.scheduling@health.gov.au

Re: Amendments to the Poisons Standard (Medicines/Chemicals)

1. We are pleased to make this confidential submission to the Therapeutic Goods Administration (TGA) on behalf of Cronos Australia Ltd (**Cronos Australia**).
2. By way of background, Cronos Australia is a public company limited by shares that is incorporated and domiciled in Victoria, and listed on the Australian Securities Exchange (**ASX**).
3. Cronos Australia, via one of its wholly-owned subsidiaries Cronos Australia - Operations Pty Ltd, has secured the necessary licences from the Office of Drug Control (**ODC**) to cultivate, produce, manufacture, research, import and export medicinal cannabis in Australia. Currently, the focus of Cronos Australia's business is the supply of medicinal cannabis products (including CBD-only products) to patients in Australia.
4. Cronos Australia is a member of the Medicinal Cannabis Industry Association (**MCIA**) and has contributed to the submission made by the MCIA.
5. The TGA is undertaking consultation for both a delegate-initiated proposal (**Delegate Proposal**) and a private submission (**Private Submission**) to amend the scheduling for cannabidiol.

Delegate Proposal

6. Cronos Australia is supportive of any changes to the schedules that will facilitate patient access to CBD products in a timely and safe manner.
7. Cronos Australia supports the down-scheduling of CBD in light of increasing evidence of its safety profile, however, has some reservations in relation to specific details of the Delegate Proposal as it relates to low dosage thresholds.
8. Cronos Australia is concerned that the current proposal will not deliver the desired outcomes. This is due to the lack of evidence around the therapeutic value of low dosage CBD products. Without evidence or justification of the therapeutic benefit, the proposal as outlined is unlikely to result in any products coming to market as it will be

almost impossible for manufacturers to demonstrate efficacy. Thus, while the proposal is a positive direction, it may not result in improved outcomes for patients or the industry.

9. Cronos Australia advocates an alternative approach - to reschedule CBD to schedule 3 without any dosage thresholds. This should result in product efficacy, application and safety being addressed through the product registration process. This approach would ensure that products available had evidential therapeutic value for the patient, whilst at the same time providing commercial incentive for industry to invest in such products.
10. In the event that CBD is re-scheduled to Schedule 3, Cronos Australia would also advocate for CBD to be included in Appendix H of the Poisons Standard.

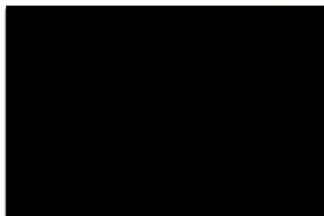
Private Submission

11. Cronos Australia does not support the Private Submission in its current form.
12. Notwithstanding the above, Cronos Australia is an advocate for the de-scheduling of CBD from the Poisons Standard.
13. Cronos Australia supports the position adopted in a number of Western countries that preparations containing predominantly CBD with not more than 0.2% THC should not be placed under a drug control framework. Cronos Australia notes that this position has also been propagated by the World Health Organisation's Expert Committee on Drug Dependence (ECDD) regarding cannabis and cannabis related substances.
14. Cronos Australia believes that the potential benefits of removing plant-derived CBD from the Poisons Standard, and instead regulating it as other herbal medicine, is that this will substantially increase its access, and reduce costs to the patient. It will also facilitate the growth of a local of a CBD product manufacturing and supply industry.

Cronos Australia is keen to work with the TGA with a view to reducing patient barriers to CBD products in one form or another.

Please feel free to contact me if you have any queries in relation to our submission.

Yours sincerely,



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[Redacted]

Cronos Australia Ltd