

The Medicines Scheduling Delegate of the Secretary
Commonwealth Department of Health

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

Dear Delegate

Comments on Proposals to down-schedule cannabidiol

I am writing to express my concerns about the public health implications in NSW of two proposals to be considered at the forthcoming meetings of the Advisory Committee on Medicines Scheduling, to remove restrictions on certain cannabidiol preparations so that they are available without prescription (Schedule 3), or even completely removed from the medicines schedules and available to consumers from any supplier who wishes to sell them.

Our view is that the current classification of cannabidiol as a Schedule 4 Prescription Only Medicine remains appropriate.

Cannabidiol meets the Scheduling Policy Framework's criteria for Schedule 4, notably, "1. *The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention.*" and "8. *The experience of the use of the substance under normal clinical conditions is limited.*"

Cannabidiol fails to meet the Schedule 3 criteria, notably "3. *The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.*"

Regarding the alternative proposal that cannabidiol be made an unscheduled medicine, it does not meet the *Scheduling Handbook* requirement "...able to be supplied, with reasonable safety, without any access to health professional advice", i.e. "the consumer is able to identify and self-manage the condition for which the medicine is intended without health professional input ... the risks to health from the medicine are small and can be managed with packaging and labelling ... the risk of inappropriate use and misuse is negligible".

I note there is no registered medicine containing cannabidiol. Thus any Schedule 3 preparation supplied would have no TGA-approved consumer product labelling or Consumer Medicines Information advising of the use, risks and precautions.

Cannabidiol's effects are little known. I note the TGA's *Guidance* documents state that there is limited evidence of benefit for cannabis medicines, that dose-response information for efficacy and toxicity is lacking, that there are no long term use data even in animal models.

The NSW Cannabis Medicines Advisory Service (CMAS) has assessed the TGA's recent review *Safety of low dose cannabidiol* and concluded there is limited, poor-quality evidence pertaining to the use of low dose cannabidiol overall. There are no clinical indications for which there is currently sufficient evidence to advise the prescribing of low dose cannabidiol outside of an experimental, patient-specific context. The TGA review specifically focuses on safety rather than efficacy. It does not directly suggest indications for which cannabidiol might be used, however all the conditions which are mentioned in the TGA review (chronic pain, nonspecific nausea and vomiting, anxiety, insomnia) require oversight by a medical practitioner.

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I am concerned about the potential promotion and marketing of cannabidiol preparations often for indications for which there is no evidence of efficacy. Some of this occurs illegally now. Down-scheduling would exacerbate this problem.

Cannabidiol has significant drug-drug interactions with a range of other medicines, and is expected to have other interactions which are as yet unknown.

NSW Ministry of Health inspectors have found that Cannabis medicines are often not labelled as legally required, and in some cases misleading as to the exact formulation. Down-scheduling of cannabidiol could facilitate further unauthorised use of preparations containing higher concentrations of more psychoactive cannabinoids such as tetrahydrocannabinol.

No other comparable country has approved cannabidiol to be supplied without prescription for therapeutic use.

Down-scheduling of cannabidiol would encourage use as first line treatment, contrary to the TGA's *Guidance* documents which state cannabis products "*should be considered only where conventional treatments have been appropriately tried and proven unsuccessful.*"

Thank you for your consideration of these reasons for retaining the existing Schedule 4 status of cannabidiol for therapeutic use. Should you require any further clarification about the NSW Ministry of Health's views on this matter, please contact Judith Mackson, Chief Pharmacist on 9424 5854 or email Judith.Mackson@health.nsw.gov.au.

Yours sincerely



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Chief Health Officer and Deputy Secretary
Population and Public Health

22 June 2020