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Secretary to the Department of Health (Australia)
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14 May 2020

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

Dear Secretary,

We wish to put forward the following response to consultation around the scheduling of cannabidiol (both in proposal items 2.2 and 2.5 on the agenda for the June 2020 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling).

This submission relates to an aspect of the Schedule 4 entry of cannabidiol.

We believe that the current Schedule 4 entry for cannabidiol should be changed as follows (indicated by the strike-through text):

CANNABIDIOL in preparations ~~for therapeutic use~~ where:

- a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and
- b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.

Unlike almost every other entry within Schedule 4 of the Poisons Standard, the cannabidiol entry currently specifies that it must be “for therapeutic use”.

However, like many other substances listed in Schedule 4 of the Poisons Standard, cannabidiol is frequently required to be obtained for research and analysis.

When being used in research and analysis, it is not being used therapeutically. Even if the research/analysis is associated with a project that may have an ultimate therapeutic aim, the analytical work itself would be unlikely to be considered to be “therapeutic” (or at best, it’s ambiguous whether it could somehow be considered to be “for therapeutic use”).

Moreover, the research/analysis of cannabidiol may, in fact, not be for a definitive therapeutic aim (i.e. it may just be studying the chemical properties of the substance for reference).

If cannabidiol does not fulfil the Schedule 4 criteria (i.e. of being “for therapeutic use”), it would default to the Schedule 9 entry for cannabis.

This creates significant problems for organisations carrying out research and analysis, as there are significantly increased controls for the storage, movement and record keeping of Schedule 9 substances. These controls seem disproportionate to the risks of cannabidiol that otherwise fulfil the other criteria for the Schedule 4 entry of cannabidiol (i.e.

- a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and
- b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.)

Furthermore:

- Schedule 4 (as a general category) within the Poisons Standard is for substances that are classified as “prescription only medicines”. So, there is clearly no increased risk that an unauthorised member of the general public could somehow obtain Schedule 4 cannabidiol without a prescription (i.e. if the “for therapeutic use” criteria was removed from its criteria).
- Victorian Medicines and Poisons Regulation is putting forward this submission in response to collective feedback from numerous stakeholders over the past few years.
- It appears that the current agenda item for cannabidiol proposes circumstances where cannabidiol may, in fact, be removed from the Poisons Standard altogether (or be included in Schedule 3). If the Secretary is willing to consider such significant down-scheduling proposals, then it should at least be considered that cannabidiol does not necessarily have to be “for therapeutic use” to fulfil the Schedule 4 criteria.

We are not suggesting that cannabidiol become unscheduled or be down-scheduled. We are simply seeking clarity around the intent of when cannabidiol should be considered to be within Schedule 4.

We therefore recommend that the “for therapeutic use” criteria is removed from the Schedule 4 entry of cannabidiol.

Yours Sincerely,

[REDACTED]
[REDACTED]
Victorian Medicines and Poisons Regulation

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