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www.csiro.au

36 Gardiner Rd, Clayton VICTORIA, Australia
Postal Address; Bag 10, Clayton South VICTORIA 3169, Australia
T +61-3-9545 2560 • **ABN** 41 687 119 230

4th May 2020

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

I refer specifically to the proposed rescheduling of **cannabidiol** (CBD).

- Overall, I am strongly in favour of the proposed changes, as they take account of the fact that CBD is widely accepted to have a much lower potential to cause harm relative to other current Schedule 8 poisons such as, for example, tetrahydrocannabinol (THC). It should therefore not be subject to the same onerous and expensive compliance requirements. The proposed changes should be of significant financial benefit to manufacturers, distributors and prescribers of CBD-containing therapeutics and significantly reduce the cost to patients of these locally produced and distributed medicines.

- I have a suggested wording change:

  In the Schedule 4 Amended entry:

  b. "cannabidiol is a synthetic or semi-synthetic copy of the molecule" should be changed to

  "**cannabidiol is synthetically or semi-synthetically derived**"

  The use of the term "copy of the molecule" implies that synthetic or semi-synthetic CBD is somehow different from the naturally derived compound, whereas it is identical. In addition, the use of the term "molecule" when referring to a chemical is inappropriate, as a molecule is the smallest indivisible part of a sample of a chemical and is so small that it can only be poorly visualised with the most powerful of microscopes. A chemical or compound consists of an enormous number of identical molecules. It is simpler and more accurate to simply refer the name of the chemical, in this case cannabidiol, rather than an individual molecule.

- As a medicinal chemistry researcher, however, I am most interested in having naturally-derived CBD and cannabis that contains very low levels of THC (ie < 0.2%), that is used for research purposes and not therapeutic purposes, be removed from Schedule 9. I would like to confirm that this is the intention of the combination of;

  The existing Schedule 9 entry for cannabis:

  "CANNABIS (.....), except
  a. when separately specified in these Schedules;"

  and

  the Schedule 4 Amended entry:

  "CANNABIDIOL in preparations for therapeutic use where:"
  .....

"**except** when cannabidiol comprises 98 per cent or more of the total cannabinoid content and the tetrahydrocannabinol (THC) content is less than or equal to 0.2 per cent of the total cannabinoid content of the preparation."

This change takes cannabidiol in preparations for therapeutic use, that have very low levels of THC, out of the SUSMP entirely, which is a positive step. But does it also take cannabidiol-containing substances that have very low levels of THC, but not intended for therapeutic use out of the SUSMP? If not, then I request that the following additional exception be placed in the Schedule 9 entry for CANNABIS:

"d. **except** when the total cannabinoid content of the cannabis comprises 98 per cent or more cannabidiol and the tetrahydrocannabinol (THC) content is less than or equal to 0.2 per cent of the total cannabinoid content"

The development of therapeutics typically goes through an extensive research phase where isolates, formulations and prototype products are generated for the purpose of optimising their physical and pre-clinical properties, and many samples are produced that are not themselves intended for therapeutic use. Currently high CBD, very low THC (<0.2 %) cannabis and related products of this type, ie not intended for therapeutic use, fall under Schedule 9 and hence are subject to very onerous and expensive Schedule 9 compliance requirements. In addition, a Federal Office of Drug Control Manufacture License and associated permits are required in order to undertake such product development activities. If the type of exemption described in "d." above is not embodied by the planned changes, then local developers and manufacturers of high CBD, low THC therapeutics will be greatly disadvantaged over imported products where the R&D has been undertaken overseas. In addition, the development of new therapeutics based on CBD will generally be hindered, as input from high quality Australian chemical and medical science research will continue to be limited by the current onerous and financially demanding restrictions.

Yours sincerely,