From: [redacted]
To: Medicines Scheduling
Subject: Proposed Amendments to the poison standard (medicines/chemicals) [SEC=No Protective Marking]
Date: Friday, 22 May 2020 5:19:51 PM
Attachments: public-submission-cover-sheet.pdf

Greetings.

The World Health Organisation (WHO) have already conducted a critical review into CBD.
It seems peculiar right now for Australia to conduct our own review into low dose CBD products without following the already known desires of the UN when it comes to CBD scheduling and definitions.
I note that when the media got hold of the UNs decision regarding CBD, the TGA released a press release and claimed they had already
mirrored the UN decision on CBD earlier, by making it an S4. This is not the case since an S4 listing is clearly not removing a substance or product from the schedules.
Neither now is creating an S3 for a lower dose product.

I urge you for example to look up the value of the non- medical CBD market in the USA vs the medical market. The FDA commissioner stated that it would be a fools errand to try and ban CBD.
As a result I do not fully agree with the two proposed amendments.

The TGA proposed amendment is suitable for a medical product as an S3 but it does not go far enough in that it does not also exempt CBD products from scheduling altogether, for example as mentioned by the UN for cosmetic and dietary uses.
The WHO and the UN have stated that it wants to allow CBD to be prescribed as medicines as well as CBD be removed from scheduling altogether to
allow for cosmetic and dietary use. This will not be a trafficable substance and our laws should not pretend that it is.

The way this proposal is worded right now, these products that have now been reviewed as safe, will continue to sit in schedule 9 in which case would give the states and territories of Australia the impression that they are highly dangerous products and should involve severe criminal penalties.
This type of scenario where citizens of Australia can be harassed, prosecuted, charged with fines and perhaps even spend time in prison and have a criminal record precluding them from work, all just for possession or consumption of a CBD products (of which both the WHO and UN have decided are safe enough for complete de-sheduling) should absolutely not be tolerated here.
This scenario should be shocking to the conscience of all whom are involved in this process.
This is a major side effect of poorly constructed scheduling work in that it will no doubt affect people inappropriately.

The ECCD had finalised their decision and recommended CBD not to be scheduled.
The report produced clarified the position on CBD and importantly provided the following definition.

“The committee recommended that a footnote be added to schedule 1 of the 1961 Single Convention on Narcotic Drugs to read:
Preparations containing predominately cannabidiol and not more than 0.2% of delta-9-tetrahydrocannabinol are not under international control.”
I note that this definition is well known as this definition has been displayed and linked around the proposals.

This shows that a suitable definition has already been considered and has been formed for countries to consider and insert into legislation.
The TGA proposed definition is limiting in that it requires a further and costly step in the manufacturing process which drives the cost of the medicine up higher and also limits the potential suppliers.
There is no reason to believe that this will address the access or cost issues which were purported to drive the proposal.

The 98/2 definition only serves to eliminate cheaper produced and arguably more affective plant extracts from being directly used in products since the pathway to create CBDA in plants involves some production of THCA in the realm of just over 23 to 1 parts CBDA to THCA and not 98 to 1 like an isolate.
At low doses of 60mg CBD per day this would amount to less than 2.6 mg of THC being consumed, but even less being absorbed since absorption is only around 8 percent.
This diluted plant extract product fits within the UN definition for both THC and CBD concentrations and so has been assessed as safe already.

The UN is also planning to remove cannabis extracts and tinctures from the schedules because their position in schedule 1 causes confusion for member parties
and may lead to member parties prohibiting CBD products based on this entry of extracts and tinctures. This has been recommended as changes to the UN schedules in the 61 treaty.

The private citizen proposal has seemed to mix up the TGAs definition (98) with the UNs (0.2%). This needs to change before it is approved.

To change these now would save a lot of time and problems for all involved.

I propose that the TGAs proposal be approved but adjusted to widen the product definition to allow not only CBD isolates to be available as medicines and also the private citizens proposal be altered so that:

“preparations containing predominately cannabidiol and not more than 0.2% of delta -9-tetrahyrdacannabinol are
exempt from schedules altogether.

If consideration is required on amounts made available then it would be possible to cap these cosmetic and dietary products similarly at 1800mg of CBD per product.

The TGA CBD definition should be changed to say “ Preparations containing predominately cannabidiol with a maximum of 1800mg cannabidiol and not more than 0.2% of delta-9-

tetrahydracannabinol.”

These products should be allowed to be manufactured from both isolate and plant extracts as long as they fit within the definitions.

Thank you.

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