



Promoting Illicit Drug Prevention Initiatives Nationally

21 March 2021

Advisory Committee on Medicines Scheduling &
Medicinal Cannabis Team | Medicine Shortages Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear TGA representatives

Drug Free Australia is the peak drug prevention organisation in Australia, and we are very cognisant of the fact that the 2019 National Drug Strategy Household Survey found that 80% of Australians did not give their approval to the recreational use of cannabis. Given that 96%-99% of Australians do not give their approval to the regular use of heroin, ice, speed, cocaine and ecstasy, we think it a reasonable extrapolation that Australians do not want increased illicit drug use but rather want less.

To that end we have some questions regarding the Federal administration of medicinal cannabis, where the 2016 legislation came with the promise to treat it with the same strictures applied to any other medication here in Australia.

Drug Free Australia has given evidence to a number of Federal and State Parliamentary Inquiries that recreational cannabis users in the US most commonly use the ruse of 'pain' to legally access medical cannabis in those states where recreational use of cannabis has not been legalised, but where medical cannabis is available. 90-94% of medical cannabis patients in various US states access medical cannabis for chronic pain.

When profiles for regular chronic pain patients are compared to the profiles of US medical cannabis patients they are sharply different. A majority of chronic pain patients are women mostly in their 80s while men are in their 60s. Medical cannabis chronic pain patients are 75% men with an average 32 years of age, mostly having commenced cannabis use as teenagers (we would be happy to send this evidence to you on request seeing as we can't link to this evidence). A Canadian [study](#) found that over 80% of medical cannabis patients were also recreational users. This suggests that medical cannabis for most is just a legalised form of recreational use accessed by ruse. Doctors, of course, cannot objectively verify chronic pain, relying on a patient's subjective descriptions. It appears that the majority of Australian applications to the TGA for access to medical cannabis are for pain, raising questions as to whether large numbers of Australians are using the same ruse here for 'legalised' use.

We have ask the TGA to forgive Drug Free Australia for trying to ensure that our medical cannabis legislation is not being abused with similar motives to those in the US. This leads us to seek information from the TGA to get an understanding of what has been happening since 2016 with approvals for medicinal cannabis. We have signaled that we do understand how difficult the role of the TGA is when it comes to approvals for conditions outside the normal indications for which cannabis has been deemed fit. Compassion demands flexibility – that we do understand, yet we are keen to get an understanding on how the TGA seeks to avoid the US scenario where medical cannabis is a ruse covering for recreational use by prescription.

This raises various questions. We have reviewed the current Approval Schedules on your website to inform these questions. We have asked for your best thoughts and explanation of processes in place when addressing these questions.

Questions

1. A 2018 [review](#) in the online medical journal 'Pain', reviewed 104 studies comprising around 10,000 medical cannabis patients and concluded that cannabis is not adequate for chronic pain, only effective for a 30% reduction in pain. They suggested that for chronic pain cannabis could only be an adjunct to opiates. Yet another 2019 [study](#) found that cannabis does not reduce opiate levels for chronic pain. 62% of the prescriptions the TGA approves are for chronic pain. We also note that the [UK](#) does not recommend chronic pain as eligible for a medical cannabis prescription.

Will the TGA be reviewing the medical literature and make any changes to provide more checks on chronic pain prescriptions as a result?

2. There are many prescriptions that are TGA approved for anxiety, and yet the world's most authoritative [review](#) by the US National Institutes of Health in 2017 found no weight of evidence supporting the effectiveness of cannabis for anxiety.

How has the TGA determined that anxiety should be approved?

3. There are frequent TGA approvals for depression, yet the world's most authoritative [review](#) finds no effectiveness of cannabis for depression.

On what basis does the TGA approve applications for depression?

4. The same [review](#) finds no effectiveness for epilepsy, even though we know that it has some effectiveness with childhood epilepsy-like conditions. We note that Epidiolex was [approved](#) for patients 2 year of age and older in September 2020.

On what basis does the TGA approve cannabis for adult epilepsy?

5. The same [review](#) finds no weight of evidence that cannabis improves irritable bowel syndrome, yet applications are frequently approved.

On what basis does the TGA approve applications for irritable bowel syndrome?

6. There are approvals for PTSD but [studies](#) show that cannabis makes the symptoms worse.

On what basis does the TGA approve cannabis for PTSD?

7. A very recent [study](#) found cannabis causal in cases of autism in the US.

Given that it is being prescribed for autism in Australia, and the world's most authoritative [review](#) gives no evidence for the effectiveness of cannabis for autism, will the TGA be reviewing approvals for autism?

Will the TGA be seeking information on whether a patient seeking approval for medical cannabis is currently pregnant?

8. We understand that there will be many rarer conditions where doctors may want to try cannabis as a last resort, given there are no studies to guide them.

Does the TGA put any reporting mechanisms in place to build a knowledge base around the effectiveness of cannabis with these rarer unstudied conditions?

9. We have read that cannabis leaf is being imported for use by medical cannabis patients, yet the Hon Sussan Ley MP made public commitments that medical cannabis would be treated as any other medicine by the TGA.

Does the TGA have a role in approving the mode of administration of medical cannabis as it relates to raw cannabis leaf versus a pharmaceutical preparation, or is this only a State issue? If it is a TGA determination, on what grounds is cannabis leaf approved?

Again, Drug Free Australia would like to get an understanding of how the TGA tries to balance compassion, with some need for accountability in an area where the use of medical cannabis covers for legalised recreational use.

We very much appreciate the level of accountability the TGA has shown us in the past, and we thank you for considering these questions.

Sincere regards

**Major Brian Watters AO
President
Drug Free Australia**