MIND MEDICINE AUSTRALIA

Allowing treatment-resistant PTSD and depression patients to be treated in the ACT under the TGA Special Access Scheme.

Summary

Mind Medicine Australia proposes changes to ACT legislation to allow medical practitioners to treat patients who have been approved under the Therapeutic Goods Administration's Special Access Scheme. This would allow treatment-resistant PTSD and treatment-resistant depression patients to receive MDMA assisted psychotherapy for the treatment of PTSD and psilocybin assisted psychotherapy for the treatment of depression.

Benefits

- MDMA and psilocybin assisted psychotherapy trials have shown results that are significantly better than existing treatments (both in terms of higher remission rates and much lower side effects). The treatments only require 2-3 sessions with the medicines as part of psychotherapy in medically controlled environments and have been shown to be safe and non-addictive when used in this way. Allowing such therapy is likely to dramatically change patients' lives and reduce suicides and the immense cost of mental ill health.
- Initially there would be a handful of practitioners treating a small number of treatment-resistant patients but this is likely to grow over times as good results are achieved. (Unfortunately the cost of therapy may be beyond many people due to the hours of therapy involved and the cost of medical MDMA and psilocybin.) However it would also be a measured and significant step that would put the ACT at the forefront of the emerging field of psychedelic assisted psychotherapy. It is consistent with the ACT being an educated electorate that looks at the facts.
- The TGA allows treatment-resistant patients to be treated under its Special Access Scheme on compassionate grounds. The TGA recognises the long term suffering of these patients, their 'all other options exhausted' nature and their serious risk of self-harm. **To argue against allowing this in the ACT, seems almost cruel and places you in disagreement with the TGA.** It also puts you in disagreement with the medical authorities of the US[1], Canada[2], Switzerland[3] and Israel[4] which have allowed similar access for treatment-resistant patients for similar reasons.
- **Nothing would take place that has not already been approved by the TGA.**

---

[1] MAPS (2020) *FDA Agrees to Expanded Access Program for MDMA-Assisted Therapy for PTSD*, https://maps.org/news/media/press-release-fda-agrees-to-expanded-access-program-for-mdma-assisted-psychotherapy-for-ptsd

[2] Government of Canada (2022) *Health Canada's Special Access Program,* https://www.canada.ca/en/health-canada/services/substance-use/controlled-illegal-drugs/magic-mushrooms.html#a9

[3] Schmid et al (2020) *Acute subjective effects in LSD- and MDMA-assisted psychotherapy,* Journal of Psychopharmacology, Vol. 35(4), pp. 362-374.

[4] Blum (2020) *How Israel has become an unexpected leader in medicinal psychedelics,* https://www.israel21c.org/how-israel-has-become-an-unexpected-leader-in-medicinal-psychedelics/

hello@mindmedicineaustralia.org
www.mindmedicineaustralia.org

Level 1/10 Dorcas St
Southbank Vic 3006
Australia

MIND MEDICINE
AUSTRALIA

Background

The US FDA has granted "Breakthrough Designation" status to MDMA and psilocybin assisted psychotherapy for the treatment of PTSD and depression respectively. This signifies that trials to date have shown results significantly better than existing treatments. Following this, the TGA has allowed medical practitioners to individually apply for the treatment for patients with treatment-resistant PTSD and depression under its Special Access Scheme – Category B. However whilst over 30 patients to date have received approvals for treatment from the TGA, the treatments haven't taken place because states and territories legislation (other than Victoria) refers to the Poisons Standard (Commonwealth legislation) where MDMA and psilocybin are classified as Schedule 9 - prohibited substances. This includes the ACT.

The TGA oversees the Poisons Standard where substances are scheduled based on perceived harm. Schedule 9 drugs are 'prohibited substances' and include heroin and ice which are much more addictive and harmful than MDMA and psilocybin.

Last year Mind Medicine Australia applied to the TGA to reclassify the medical use of MDMA and psilocybin as part of psychotherapy in controlled medical environments as Schedule 8 controlled medicines, the same as medicinal cannabis. The TGA declined the application. We note the contradiction between the TGA allowing SAS-B treatments but not changing the classification of MDMA and psilocybin so those treatments can take place.

In declining the application the TGA noted there is emerging evidence that supports the effectiveness of psychedelic therapy but more evidence is required. We note that while the evidence may not have led to mainstream approval of psychedelic therapy in other western countries, competent regulators in the USA, Canada, Switzerland and Israel (as well as the TGA) have judged there to be sufficient evidence to allow usage by treatment-resistant patients. In declining the application the TGA also cited the risk of diversion of the substances into black market. We believe this fear is unjustified, given MDMA and psilocybin are generally judged to amongst the least harmful of illicit drugs and are already easy and cheap to obtain (see Box 1 below).

(Given the increased evidence that has appeared on the effectiveness of MDMA and psilocybin-assisted therapy since the TGA made its decision on rescheduling last year, and also the unjustified risk of diversion, Mind Medicine plans to shortly lodge another application to downgrade MDMA and psilocybin when used as part of psychotherapy.)

Advice from Greg Barns QC indicates that the changes to ACT legislation required to allow SAS-B patients to treated in the ACT would be small and straightforward.

hello@mindmedicineaustralia.org
www.mindmedicineaustralia.org

Level 1/10 Dorcas St
Southbank Vic 3006
Australia

MIND MEDICINE AUSTRALIA

Box 1: The risk from diversion is insignificant

MDMA and psilocybin are already easy to obtain in Australia. MDMA in the form of ecstasy capsules was considered "easy or very easy to obtain" by 84% of ecstasy users in 2020 and 92% of users in 2019. Nationally, the price for a single MDMA tablet/capsule ranged between $10 and $30 in 2019-20 with the ACT having a similar price range.[5] Some 20 species of psilocybin grow naturally in Australia and it can be stored by drying indicating it is also easy and cheap to obtain.

If ACT treatment-resistant patients were to be treated, the hours of psychotherapy needed (15 and probably more per patient), the high cost of medical MDMA and psilocybin (some 5-15 times more expensive than the street market) would result in a small numbers of patients that would be treated.[6] The small number of patients would mean that any diversion that took place would be unnoticeable compared to the size of the black market. We guess that no more than 50 SAS-B MDMA-assisted psychotherapy patients would be treated annually in the ACT (there would probably be considerably fewer patients initially). That would require around 25 grams of MDMA.[7] Even if *all* that 25 grams were to be diverted, it would have little impact on the black market. The National Wastewater Monitoring Program estimated that *2.2 tonnes* of MDMA is consumed annually in Australia.[8]

The same factors that apply to MDMA apply to psilocybin implying the risk from diversion of medical psilocybin is also insignificant.

We also note under the current SAS-B scheme, MDMA- and psilocybin- assisted therapy would be prescribed and administered by psychiatrists. They enjoy high incomes and high social standing but face the serious risk of deregistration if diversion takes place under their responsibility, either intentionally or unintentionally. In contrast the rewards from allowing diversion to place are small given the MDMA and psilocybin markets are already very well supplied and prices are low. In summary the incentives to stop diversion are strong.

[5] Australian Criminal Intelligence Commission (2021) *Illicit Drug Data Report 2019-20*, p45-48, p187 *https://www.acic.gov.au/publications/illicit-drug-data-report*

[6] While Mind Medicine would like treatment to be available to all regardless of income, it is as better that some people get treated rather than no-one.

[7] Patients in the recent Phase 3 trial of MDMA-assisted therapy were given 480mg of medicinal MDMA across three sessions. Mitchell et al (2021*) MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study,* https://www.nature.com/articles/s41591-021-01336-3

[8] Australian Criminal Intelligence Commission, *Ninth wastewater report reveals Australians spend over $11.3 billion a year on drug*s, https://www.acic.gov.au/media-centre/media-releases-and-statements/ninth-wastewater-report-reveals-australians-spend-over-113-billion-year-drugs#:~:text=Australians%20spent%20an%20estimated%20%2411.3,aspects%20of%20illicit%20drug%20markets.

hello@mindmedicineaustralia.org
www.mindmedicineaustralia.org

Level 1/10 Dorcas St
Southbank Vic 3006
Australia