



MIND MEDICINE
A U S T R A L I A

Media Alert: 10 March 2021

Mind Medicine Australia urges TGA to reverse its Interim Decision on scientific and humanitarian grounds

Mind Medicine Australia has just made its final submissions to the TGA opposing their interim decision NOT to reschedule psilocybin and MDMA as Controlled Medicines. The original rescheduling applications were lodged last July and supported by over 80 leading psychiatrists, psychologists, pharmacologists, researchers and other medical practitioners plus 30 leading scientists and clinicians from DrugScience UK.

Please see the final Submissions here: https://mindmedicineaustralia.org.au/wp-content/uploads/TGA-Interim-Submission-psilocybin-FINAL_040321.pdf

And https://mindmedicineaustralia.org.au/wp-content/uploads/TGA-Interim-Submission-MDMA-FINAL_040321.pdf

In commenting on the interim decisions, the Chairman of Mind Medicine Australia, Peter Hunt AM, said that, *“Under the rescheduling process we have now had the opportunity to address each of the reasons provided by the TGA in our final submissions. We recognise that part of the problem that the Delegate has faced are the views of risk-averse peak bodies that have not properly analysed the safety and efficacy of these therapies within a medically controlled environment. We deal directly with this failure in our Submission.”*

Executive Director Tania de Jong AM said: *“We hope that the Delegate will put aside the politics of 50 years ago which has caused so much mistrust and **focus on the data and science that will save lives.**”*

There is now plenty of evidence from over 150 overseas trials to show that **the use of medical grade GMP standard psilocybin and MDMA as part of psychotherapy** have an **established therapeutic value** as evidenced by the high remission rates for depression and PTSD after just 2-3 medicinal sessions in combination with psychotherapy. A comparison with other substances listed in Schedule 8 of the Poisons Standard indicates that this is the right schedule for the medical use of these substances in controlled medical environments. The fact that the treatments are available as part of expanded access schemes in a number of overseas countries, and the TGA has given a number of approvals already under Australia’s Special Access Scheme-B further supports these rescheduling submissions.

These medicines have also been shown to be extremely **safe when used in a medically controlled environment by trained professionals.**

At least 1 in 8 adults, 1 in 4 older adults and 1 in 30 children are on antidepressants currently. The relatively small remission rates from existing treatments is contributing to Australia’s devastating mental health statistics, which position Australia as second worst amongst all OECD nations, only ahead of Iceland. With mental illness accelerating



throughout the community as a result of the Covid-19 pandemic this makes the need for innovation even more urgent.

Peter Hunt said: *“Rescheduling the medical use of MDMA as part of therapy in medically controlled environments will not open “the flood gates” to the use of these therapies in Australia. The prescribing doctor will have to convince both the TGA and the relevant State/Territory Government that the needs of the particular patient warrant this therapy.”*

Tania de Jong said: *“Within those strictures we believe that **the choice to use this therapy should be between the treating doctor and the patient suffering from the treatment resistant condition.** Australians are suffering and dying, and this treatment finally offers an opportunity for true healing. Our community needs the TGA’s support.”*

Veteran and psychiatrist, Dr Stuart Saker from NSW, has received 12 SAS-B approvals from the TGA to treat seriously unwell patients with Psilocybin or MDMA assisted therapies depending on their specific condition. He said: *“All of these patients are Veterans and a number are suicidal. They deserve a chance to get better and rescheduling will enable me to administer these treatments before it’s too late.”*

The TGA will make its final decision on 22 April.

We thank the media for their ongoing support for creating positive change in Australia. This will help so many people suffering from debilitating mental illnesses in this country.

Please note the following are available for interview:

- **Peter Hunt AM (MMA Chair)**
- **Tania de Jong AM (MMA Executive Director)**
- **Dr Simon Longstaff AO**, Executive Director of The Ethics Centre (**MMA Director**)
- **The Hon. Andrew Robb AO (MMA Director)** - Board Director of MMA and former Trade Minister to Australia who has had treatment resistant depression for 43 years.
- **Chris Barrie AC** - Board Director of MMA and former Head of the Armed Forces who says these treatments are the only hope for Veterans suffering with PTSD.
- **Dr Jamie Rickcord** - who received the first SAS-B approval for a GP to treat a patient with psilocybin-assisted therapy in northern NSW.
- **Michael Raymond** - Veteran in Canberra who has healed through these treatments
- **Dr Stuart Saker** – Psychiatrist from NSW, currently a participant in the first Certificate in Psychedelic-Assisted Therapies

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