



Media Alert: 1st October 2021

TGA moves one step closer to rescheduling MDMA and Psilocybin in Australia.

Yesterday, the TGA released the [Independent Review](https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin) that it had commissioned on the therapeutic value, benefits and risks of MDMA and psilocybin for the treatment of key mental health disorders. (<https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin>)

This follows [Mind Medicine Australia's \(MMA's\)](#) application to the TGA to reschedule these medicines from Schedule 9 of the Poisons Standard (prohibited substances) to Schedule 8 (controlled medicines). It should be emphasised that MMA's application for rescheduling of these medicines was restricted to treatments occurring only in medically controlled environments by trained professionals and prescribed by a psychiatrist or specialist addiction physician. It is **not** envisaged that patients will ever be allowed to take these substances away from the clinical environment.

Australia's mental health statistics are some of the worst in the World. According to the Productivity Commission 1 in 5 Australians had a mental illness even before the current pandemic which has significantly worsened mental health outcomes in this country. 1 in 8 Australians were on anti-depressants, including 1 in 4 older people and 1 in 30 younger people.

According to the Chairman of Mind Medicine Australia, Peter Hunt AM: *"These are truly terrible statistics and evidence the enormous amount of suffering in our society. One of our great problems is the minimal innovation in the sector now for decades, and treatment outcomes for many Australians are poor."*

Key take-outs from the Independent Panel's Review of the trials and literature are:

- **The conditions that have been explored for potential therapeutic efficacy with MDMA and psilocybin are serious.** For instance, *"a significant proportion of people living with PTSD or depression and anxiety in the face of serious illness do not obtain adequate relief from existing therapeutic strategies...many people are not helped by any [current] interventions and the social and economic costs are high for unresolved and lifelong PTSD. More effective treatments are needed. Similarly, many people with major depression do not achieve full or lasting recovery and existing approaches can increase side effects"*.
- **That there were statistically significant differences for MDMA (when used as part of psychotherapy) in comparison with inactive or active controls.** The panel considered the standardised mean difference of the results evidenced "a strong effect size" in terms of treatment outcomes.
- **MDMA was well tolerated by participants in all studies.**



- **Statistically significant results were achieved for psilocybin in most studies.** In all but one of the psilocybin studies reviewed *“there was a statistically significant difference between psilocybin and active placebo and ...psilocybin remained as effective as the antidepressant escitalopram”*
- **Psilocybin was well tolerated in all studies.**

The Panel emphasised the importance (as MMA does) of these *“... medicines [being] administered in closely clinically supervised settings and with intensive professional support”*. MMA is arranging for the Panel’s Report to be reviewed by its own experts and welcomes the way that the Panel has approached its review.

The Executive Director of MMA, Tania de Jong AM, commented that:

“Australia is at the crossroads. We know that current mental health treatments don’t work for many Australians and there is increasing suffering and suicides in our community. Our Health Practitioners desperately need new treatment options. We have a serious mental health emergency in Australia and people need some hope for healing.”

“Psilocybin assisted therapy (primarily for treatment resistant depression and end of life anxiety) and MDMA assisted therapy (primarily for treatment resistant post-traumatic stress disorder) have both shown remission outcomes of 60-80% in overseas trials after just two to three medicinal sessions in combination with a short course of psychotherapy. As the Panel has observed, these medicines are very safe and well tolerated by patients in a clinical environment.”

Peter Hunt concluded by saying that:

“We are very hopeful that these medicinal therapies will now be rescheduled as controlled medicines under the Poisons Standard. This will enable psychiatrists who are already getting approvals from the TGA, to treat seriously ill and suicidal patients under its Special Access Scheme on a case-by-case basis, to apply for individual permits from State and Territory Governments around Australia. What we need now is a nationally standardised approach for providing medical approvals to those who are suffering desperately.”

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Please note the following are available for interview:

- **Peter Hunt AM (MMA Chair)**
- **Tania de Jong AM (MMA Executive 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 (MMA Director)** - Board Director of MMA and former Head of the Armed Forces who says these treatments are the only hope for Veterans suffering with PTSD.

**For further information, or to arrange an interview, please contact Ilan Hayman ilan@mindmedicineaustralia.org or Tania de Jong AM tania@mindmedicineaustralia.org
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