



MIND MEDICINE
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Media Release: 1 September 2020

Mind Medicine Australia Submits Australian-First Application for the Rescheduling of Psilocybin and MDMA

Mind Medicine Australia has submitted Australia's first applications to the Therapeutic Goods Administration (TGA) to reschedule Psilocybin and MDMA so that they can be more easily used as part of clinical therapies for the treatment of major classes of mental illness. The rescheduling would move these medicines from Schedule 9 of the Uniform Scheduling of Medicines and Poisons (which deals with Prohibited Substances) to Schedule 8 (which deals with **Controlled Medicines**).

The changes proposed by Mind Medicine Australia will not affect existing legal prohibitions on the recreational use or supply of these substances. **If successful, Australia will become the first country in the world to reschedule these substances for their therapeutic potential.**

The rescheduling will enable psychiatrists and specialist addiction physicians to more easily access these medicines to augment therapy for patients suffering from key mental illnesses such as depression, PTSD and for the depression and anxiety often associated with a terminal illness diagnosis (and hopefully in the future for substance abuse, OCD, anorexia and early stage dementia). It will also relieve a significant part of the regulatory burden associated with undertaking trials with these medicines in Australia.

Treatment innovation in Australia's mental health sector is desperately needed to reduce the burden of mental illness in this country. In November last year the Productivity Commission reported that 1 in 5 Australian currently had a chronic mental illness, a ratio that will almost certainly have deteriorated further with the bush fires earlier this year and the current COVID-19 pandemic. Suicides and self-harm are also increasing.

Mind Medicine Australia is encouraging people to lodge submissions with the TGA in support of our rescheduling submissions. The rescheduling of these medicines will help to expand the treatment paradigm for mental illnesses in this country and be a historic moment for all of us! Please see the rescheduling applications and a simple guideline document on how to make submissions here: <https://mindmedicineaustralia.org/tga/>

Key Dates

Wednesday the 26th August 2020 - TGA publishes notices seeking public submissions on the proposed rescheduling, closing **Monday the 28th September**. For further information on making a public submission please see [the TGA's invitation for public comment](#).

Wednesday the 3rd February 2021 - An interim decision will be published by the TGA and submissions will be invited on the interim decision from those parties who lodged submissions in the current period. This second round of submissions will close on Thursday the 4th March.



Thursday the 22 April 2021 - Publication of notice of the TGA's final decision.

According to Mind Medicine Australia's Chairman, **Peter Hunt AM**, **"A proactive approach to broadening the treatment options available for people who have a mental illness is desperately needed. The rescheduling of Psilocybin and MDMA will represent a giant-leap for innovation in mental healthcare, not only in Australia, but globally."**

Board member and Executive Director of the Ethics Centre, **Dr Simon Longstaff AO** says, **"We should not allow the prejudices of the past to deny relief in the present. If these medicines are safe and effective when applied in a clinical environment, as current research suggests, then Australian governments have an obligation to make them available."**

Tania de Jong AM, Executive Director, says, **"Unlike conventional treatments, which often require patients to endure years of daily medications and weekly support from a mental health professional, medicine-assisted psychotherapy using these medicines can be effective after just two to three clinically supervised sessions. The medicines are safe and non-addictive when administered within a medically-controlled environment."**

The development of Medicine-Assisted Therapies utilising Psilocybin and MDMA in Australia follows international research that has been so successful that the American Food and Drug Administration (FDA) has granted these medicines Breakthrough Therapy Designation which is only given to medicines that indicate significant superiority to existing medicines. The FDA has approved Expanded Access Schemes to allow people in need to undertake these therapies ahead of the conclusion of clinical trials and is expected to give full regulatory approval for these treatments in the US soon. These medicines are also being used in expanded access schemes in Switzerland and Israel and the use of Psilocybin-assisted therapy for end of life depression and anxiety has recently been approved in Canada.

In Australia the TGA has also given approval for the use of these therapies under Australia's Special Access Scheme-B. Mind Medicine Australia has information packs available for medical practitioners who would like to access this scheme for their patients.

Mind Medicine Australia is a registered charity (DGR-1 status) working to develop evidence-based and regulated psychedelic-assisted treatments for mental illness in Australia. Mind Medicine Australia is wholly focused on the clinical application of psychedelics, and provides a nexus between medical practitioners, academia, government, regulatory bodies, philanthropists and other partners. We support research, and develop therapist training, ethical guidelines, and educational material and events.

Mind Medicine Australia is focused specifically on the clinical application of psilocybin-assisted therapy and MDMA-assisted therapy for the treatment of mental illness.

We do not advocate for non-clinical use of psychedelics or any other prohibited substances,



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nor do we advocate for any change to the law with respect to non-clinical use.

Mind Medicine Australia's Board, Management team, Ambassadors, and Advisory Panel members consist of leading practitioners in the applied treatment of mental illness, psychedelic medical research, health strategy, ethics, and other relevant fields from both Australia and overseas.

Please visit mindmedicineaustralia.org for more information about our quest to introduce Medicine-Assisted Therapy to Australia: website www.mindmedicineaustralia.org.au

Please note the following are available for interview:

- The Hon. Andrew Robb AO
- Peter Hunt AM
- Tania de Jong AM
- Dr Simon Longstaff AO

For further information, or to arrange an interview, please contact Ilan Hayman ilan@mindmedicineaustralia.org or Tania de Jong tania@mindmedicineaustralia.org or 0411 459 999.