



Media Release: 12th January 2020

Mind Medicine Australia Anticipates Interim Decision Regarding Australia's First Applications to Reschedule Psilocybin and MDMA for Medical Use as Part of Therapy for Key Mental Illnesses to be Announced on February 3

Mind Medicine Australia awaits the Therapeutic Goods Administration's (TGA) interim decision on the rescheduling of psilocybin and MDMA to be used as part of clinical therapy for the treatment of major classes of mental illness. If approved, this would reclassify the medicines from Schedule 9 (Prohibited Substance) of the Standard for the Uniform Scheduling of Medicines and Poisons, to Schedule 8 (Controlled Medicine) for medical purposes.

The changes proposed by Mind Medicine Australia will not have any effect on the existing legal prohibitions on the recreational use or supply of these substances. A decision in favour of rescheduling will enable Australia to become a global leader in mental healthcare innovation.

Since Mind Medicine Australia has submitted its rescheduling applications to the TGA in July 2020, further developments with psychedelic-assisted therapies from around the world highlight the continuing positive momentum:

- The Multidisciplinary Association for Psychedelic Studies (MAPS), sponsor of the current phase 3 trials in the US, has announced that there is a 90% or greater probability of obtaining statistically significant outcomes in the treatment of PTSD with MDMA-assisted psychotherapy. MAPS have also released an economic study showing that there should be substantial cost savings associated with psychedelic assisted therapies.
- Health Canada has granted approval for psilocybin-assisted therapy to be used on a case-by-case basis to relieve patients suffering from the anxiety and depression associated with a terminal illness;
- The German government has approved a phase 2B study on psilocybin for treatment-resistant depression and is providing millions of Euros to the project;
- The state of Oregon (USA) has legalised psilocybin for medical therapeutic use;
- Expanded access schemes for psilocybin and MDMA assisted therapies continue to be available for patients and their doctors in the United States, Switzerland, Israel and Australia;
- The for-profit sector and investor interest around the world, focused on the development and application of these therapies for the treatment of key classes of



mental illness, has continued to rapidly expand with the potential size of the market estimated to be around \$US15-20B with growth forecasted up to \$US200B over the coming years. There are now over 50 for profit companies working on developing these therapies in the United States and Europe compared to just one such company 2 years ago.

- Compass Pathways, the largest for-profit company developing psychedelic-assisted therapies, with a market capitalisation of US\$1.62 billion, has just announced the establishment of a Centre of Excellence in Psychedelic-Assisted Therapies in the United States in collaboration with The Sheppard Pratt Institute for Advanced Diagnostics and Therapeutics.
- Imperial College, London will shortly be announcing the first trial that directly compares the efficacy of antidepressants and psilocybin-assisted therapies. The strong expectation is that psychedelic-assisted therapies will be shown to be much more effective and without the nasty side effects that can be associated with antidepressants.

The rescheduling will enable psychiatrists and specialist addiction physicians to more easily access these medicines to improve treatment outcomes for patients suffering from key mental illnesses such as depression, PTSD, and for depression and anxiety associated with a terminal illness diagnosis (and potentially in 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 June 2020 the Australian Productivity Commission reported that approximately 1 in 5 Australians experience a mental illness each year, a ratio that has only been worsened by the stress experienced by many Australians due to COVID-19. Deaths by suicide and self-harm are also increasing.

The rescheduling of these medicines – which have been shown to be safe and highly effective in clinical environments in overseas trials - will help to expand the treatment paradigm for mental illnesses in this country and be a historic moment for all of us!

Key Dates

- **Wednesday 3 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 relation to the rescheduling applications in September 2020.
- **Thursday 4 March 2021** - Final date for second round submissions.
- **Thursday 22 April 2021** - Publication of notice of the TGA's final decision.



MIND MEDICINE A U S T R A L I A

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 as part of therapy in medically controlled environments would be a giant-leap forward for results - orientated innovation in mental healthcare."*

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, Mind Medicine Australia's 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 can be effective after just two to three clinically supervised sessions with these medicines. All the research indicates that 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 may have significant superiority to existing medicines.

In Australia the TGA has given approval for the use of these therapies on a case-by-case basis under Australia's Special Access Scheme-B. Whilst Victoria has a permit system which applies to these medicines, many other States of Australia still prohibit their use under antiquated recreational drug laws that were never designed for medically controlled therapies. These prohibitions should be urgently reviewed by the State Governments in question given the high levels of untreatable mental illness and suicides in our communities.

Mind Medicine Australia is a registered charity (DGR-1 status) working to develop the ecosystem in Australia to enable these therapies to be safely used by skilled practitioners in medically controlled environments to assist patients with treatment resistant depression, treatment resistant PTSD, substance abuse and a number of other major classes of mental illness. The remission rates in overseas trials to date have been very high.

Mind Medicine Australia is wholly focused on the clinical application of psychedelic medicines, 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'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, pharmacology, law and other relevant fields from both Australia and overseas.



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Please visit our website for more information about the critical need to introduce Medicine-Assisted Therapies to Australia as early as practically possible: website www.mindmedicineaustralia.org.au

Please note the following are available for interview:

- Peter Hunt AM (Chair)
- Tania de Jong AM (Executive Director)
- The Hon. Andrew Robb AO (Director)
- Dr Simon Longstaff AO (Director)

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