



**MIND MEDICINE**  
A U S T R A L I A

**Media Alert: 17 March 2022 - for immediate release**

**It's Time to Introduce New Treatments for Mental Illness!**

**Mind Medicine Australia Lodges New Applications for the Restricted Medical use of MDMA and Psilocybin Assisted Therapies for Patients with Treatment Resistant Mental Illnesses**

Australia is experiencing a severe mental health epidemic, and this crisis is getting worse. Unfortunately, existing treatments only lead to remission for a minority of patients with depression and post-traumatic stress disorder and the psychiatric pharmaceuticals can cause dependence and nasty side effects for some patients.

It's estimated that only about 35% of patients with depression and less than 10% of patients with post-traumatic stress disorder go into remission with current treatments. Treatment outcomes have not improved for at least 50 years and the science behind many of the pharmaceuticals being used is over 50 years old. There has been minimal treatment innovation in the sector for decades.

Mental illness can cause enormous suffering and is at the heart of many entrenched social problems such as homelessness, domestic violence, and suicide. This comes at a massive social and economic cost to the Australian community. We desperately need to broaden the treatment paradigm for medical practitioners and their patients.

For this reason, [Mind Medicine Australia](http://www.mindmedicineaustralia.org) is again seeking to reschedule the medical use of psilocybin and MDMA as part of therapy from Schedule 9 (prohibited substances) to Schedule 8 (controlled medicines) of the Poisons Standard. The Poisons Standard is administered by the Therapeutic Goods Administration (TGA) in Canberra and then usually adopted by States and Territories around Australia under Australia's cooperative system of government.

These therapies have been shown to be safe and effective in overseas trials and lead to high remission rates. Trial results from the largest trials conducted to date were published last year and they confirmed the safety and high efficacy rates of these therapies.

According to the Chairman of Mind Medicine Australia, Peter Hunt AM:

*"We have carefully noted the issues raised by the Delegate of the Secretary of the Department of Health (Dr Brendan Murphy) in the TGA's decision not to amend the Poisons Standard for these therapies in December last year and we have responded to each of these issues in our new applications. In particular, we are applying for a much more restrictive rescheduling of these substances when used in conjunction with psychotherapy in medically controlled environments. We are also promoting the establishment of an independent registry to collate*



*valuable patient data (redacted) enabling translation of these treatments into the medical domain.”*

Under the terms of Mind Medicine Australia’s rescheduling proposal:

1. The medicines will only be able to be used in conjunction with psychotherapy in medically controlled environments under strict Schedule 8 controls. They will have to be administered by trained medical professionals. The patient will never be allowed to take these substances home.
2. The medicine will only be able to be prescribed by the treating psychiatrist if the psychiatrist first obtains approval from the TGA for the patient under the TGA’s Special Access Scheme. To do this the psychiatrist will have to demonstrate that the patient is “treatment resistant” and “at risk”.
3. The treating psychiatrist will need to have received specific training in the proposed use of this form of medicine assisted psychotherapy.
4. The treating psychiatrist’s diagnosis and treatment plan for the patient will need to be confirmed by two other psychiatrists.
5. Finally, the Health Department of the State or Territory where the treatment is to occur will also need to approve the proposed treatment for the proposed patient.

According to the Executive Director of Mind Medicine Australia, Tania de Jong AM:

*“We have deliberately made access to these therapies highly restrictive so that we can give the TGA and the Delegate comfort that these therapies will only be used safely and effectively in controlled environments and all risks can be properly managed. Existing treatments aren’t working for many patients who continue to suffer terribly as a result. Some may take their own lives in desperation. If we are serious about helping people with treatment resistant mental illness get well, we believe that it is incumbent on our regulators and politicians to make access to these therapies workable on the limited basis proposed.”*

In Australia the TGA has already given a number of approvals for the use of Psilocybin and MDMA assisted therapies for treatment resistant patients on a case-by-case basis under Australia’s Special Access Scheme.

Veteran and NSW based psychiatrist Dr Stuart Saker has received 12 such approvals to treat seriously unwell patients. All of these patients are Veterans. **They deserve a chance to get better.**

Most States of Australia still prohibit the use of these medicines under confusing recreational drug laws that were never designed for medically controlled therapies. These prohibitions should be urgently reviewed by both the Australian Government and the State and Territory Governments involved given the high levels of untreatable mental illness in our communities.

Mind Medicine Australia has published the applications that we have made to the TGA on our website – see <https://mindmedicineaustralia.org/tga/>



# MIND MEDICINE A U S T R A L I A

The TGA will be calling for public submissions in early April and we urge as many people and organisations as possible to lodge submissions in support of these applications. All safety and efficacy information about these treatments are set out in detail in the applications. We commend them to you.

**For further information, or to arrange an interview, please contact Ilan Hayman [ilan@mindmedicineaustralia.org](mailto:ilan@mindmedicineaustralia.org) or Tania de Jong AM [tania@mindmedicineaustralia.org](mailto:tania@mindmedicineaustralia.org).  
Phone: (03) 8679 6015 or 0411 459 999**

## **Interviewees include:**

- **Peter Hunt AM** - Chair, Mind Medicine Australia 0419 271 483
- **Tania de Jong AM** - Executive Director, Mind Medicine Australia 0411 45 9999
- **The Hon. Andrew Robb AO** - 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 Stuart Saker** - Veteran and Psychiatrist in NSW
- **Dr Eli Kotler** - Board Director of MMA and Addiction and Trauma Psychiatrist, and a graduate of the first intake of the Certificate in Psychedelic-Assisted Therapies
- **Michael Raymond** - Royal Australian Airforce Veteran and Mind Medicine Australia lived experience panel member and Veteran spokesperson

**About Us:** [www.mindmedicineaustralia.org](http://www.mindmedicineaustralia.org)

Mind Medicine Australia is an Australian registered charity (with DGR 1 status) seeking to develop the ecosystem in Australia through our medical system for the use of regulatory approved psychedelic assisted psychotherapy as treatment options available to our medical practitioners and their patients for key classes of mental illnesses such as depression and PTSD. MMA's focus is wholly clinical.