



## Media Alert: 7 February 2023 – Melbourne, Australia

### [Next Steps for Psychedelic Assisted Therapies in Australia following the TGA's Rescheduling Announcement for the Medical Use of Psilocybin and MDMA](#)

The Therapeutic Goods Administration (TGA) has just announced that the medical use of MDMA and Psilocybin will be rescheduled from Schedule 9 (Poisons Standard) to Schedule 8 (Controlled Substance) on a restricted basis.

This means that from July 1 2023 psychiatrists who become authorised prescribers for this purpose will soon be able to prescribe these substances as part of therapy for patients with treatment-resistant depression (psilocybin) and treatment resistant post-traumatic stress disorder (MDMA).

The TGA's decision to reschedule these substances for medical purposes on a restrictive basis is the culmination of Mind Medicine Australia's (MMA) applications lodged in March 2022 and our objections to the interim decisions lodged in November 2022. The decision recognises the enormous number of Australians who lodged their submissions in support and the fact that treatment resistant patients aren't benefitting from currently available treatments. Australia can be very proud of the fact that we are the first nation in the World to reschedule these medicines for medical purposes and Australia is now an innovative leader in the treatment of mental illness.

You can read the TGA's full announcement and the Delegate's Final Decision here - <https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists>

MMA is receiving hundreds of enquiries about the way this program is likely to work in practice, as well as enormous interest in medicine supplies, clinician training and costs to patients.

#### **Real World Evidence**

The rescheduling decision will lead to Real World Evidence being received from psychiatrists about the progress of their patients both during and after these treatments. We believe that it is very important that appropriate data is collected, analysed and published. This will add to the body of knowledge provide by the randomised control trials being done by COMPASS Pathways and Usona with psilocybin and the Phase 3 trials in PTSD recently completed by MAPS with MDMA.



### **Measuring Outcomes**

Mind Medicine Australia believes that an integral part of these treatments should be the collection of outcome data reporting on the clinical value of these treatments. We envisage that this will be done using standard questionnaires and ratings from both the patient and the doctor. Under this approach an independent expert academic statistics group will oversee curation, analysis, reporting and publication of this data. This will be in addition to the TGA's reporting back requirements.

### **Supply of Psilocybin and MDMA**

Mind Medicine Australia is arranging for these medicines to be supplied through licensed pharmacists holding Schedule 8 permits. The supply chain will be tightly controlled at all times in strict accordance with Australian and State/Territory regulatory requirements.

### **Therapist Training**

Since 2021 Mind Medicine Australia has trained 240 psychiatrists, psychologists, psychotherapists, GPs, physicians, addiction specialists, mental health nurses, social workers and occupational therapists through its [Certificate in Psychedelic-Assisted Therapies \(CPAT\)](#). This training was recently described by Professor David Nutt as the "world's leading CPAT training" on ABC Radio National and features a world class international Faculty. Many graduates have [described the course](#) as life-changing and the most outstanding professional development program they have completed. The course is also recognised by graduates' professional colleges and associations through Continuing Professional Development (CPD) credits. It is important to note that psychedelic-assisted therapies require a multidisciplinary team approach, so that whilst psychiatrists will be screening patients and prescribing treatments where suitable, the actual treatments are likely to be supervised by a range of therapists.

Mind Medicine Australia will shortly be making an exciting announcement about its [Certificate in Psychedelic-Assisted Therapies](#) and launching dates for 2023 intakes.

### **Supporting those who cannot afford treatments**

Mind Medicine Australia will be setting up a special fund to receive donations from large to small philanthropists, and hopefully governments around Australia, to support those who cannot afford the full costs of treatments. We welcome donations here: <https://mindmedicineaustralia.org.au/donate/>

This initiative is designed to help to bridge the funding gap before funds from Health Funds and from the Australian Government's Medical Benefits Scheme become available to patients in the future. The economic case for this and the need to reduce human suffering is overwhelming.



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

In commenting on the decision and the way forward for Australia, Professor David Nutt, Head of Neuropsychopharmacology at Imperial College, said: *“I am delighted that Australia is continuing to lead the way in psychedelic treatment research after the earlier AMRC research grant initiative. This new scheduling decision gives hope to the many tens thousands of patients with depression and PTSD for whom current treatments fail. The data collection plan will provide Real World Evidence of the value of these treatments that is likely to change medical practice around the world. I am working hard to ensure the UK catches up with Australia!”*

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Mind Medicine Australia is Australia’s leading not-for-profit organisation working on the use of medicinal psilocybin and MDMA-assisted therapies to treat a range of mental illnesses. Mind Medicine Australia exists to help alleviate the suffering and suicides caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients.

Visit: <https://mindmedicineaustralia.org/>

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- Professor Nutt is also available for interviews on request.