

# Change to classification of MDMA and psilocybin to enable prescribing by authorised psychiatrists



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# Welcome

## Housekeeping

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- This webinar is being recorded
- Webinar will be made available in the upcoming weeks
- URL links will be broadcasted via the chat function
- Q&A session will occur after today's presentation
- Live poll – how did we go, let us know



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OR

**Dial:** 02 9338 2221 (+61-2-9338-2221 )

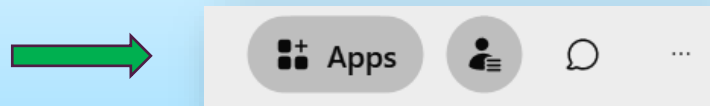
**Access code:** 2651 578 1167

# How to ask questions

## SLIDO

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### Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

### Slido QR

Scan the QR  
code to access  
separately from  
your mobile  
device





# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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## Change to classification of MDMA and psilocybin to enable prescribing by authorised psychiatrists



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# Psilocybin and MDMA with Drug-Assisted Psychotherapy



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Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

[tga.gov.au](https://www.tga.gov.au)

## To summarise..

- Growing number of randomised clinical trials supporting the efficacy of MDMA in the treatment of PTSD, and psilocybin in treatment resistant depression.
- There is potential benefit for these two cohorts of people in the community for whom other treatments are not effective, or a contraindicated, leaving them with few or no treatment options.

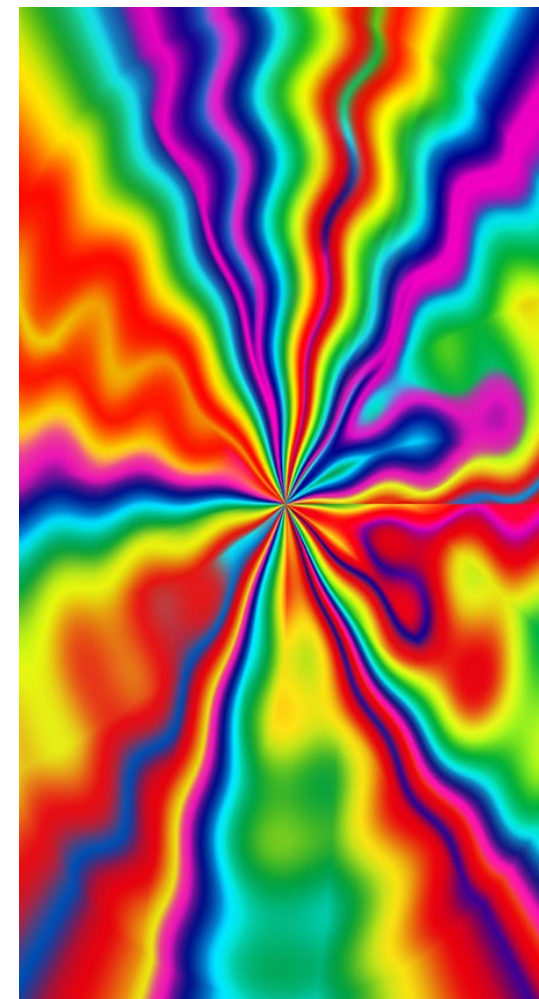


# Psychedelics

Psychedelics are a large group of natural, synthetic, and semisynthetic compounds with distinct pharmacological effects.

Psychedelic drugs manifest their effects on conscious experience that may include an altered sense of time and space, distorted perceptions of the environment, and dissociative symptoms.

A renewed sense of purpose and the loss of normal boundaries of the self, often described as “ego dissolution,” are also distinctive effects of these compounds.

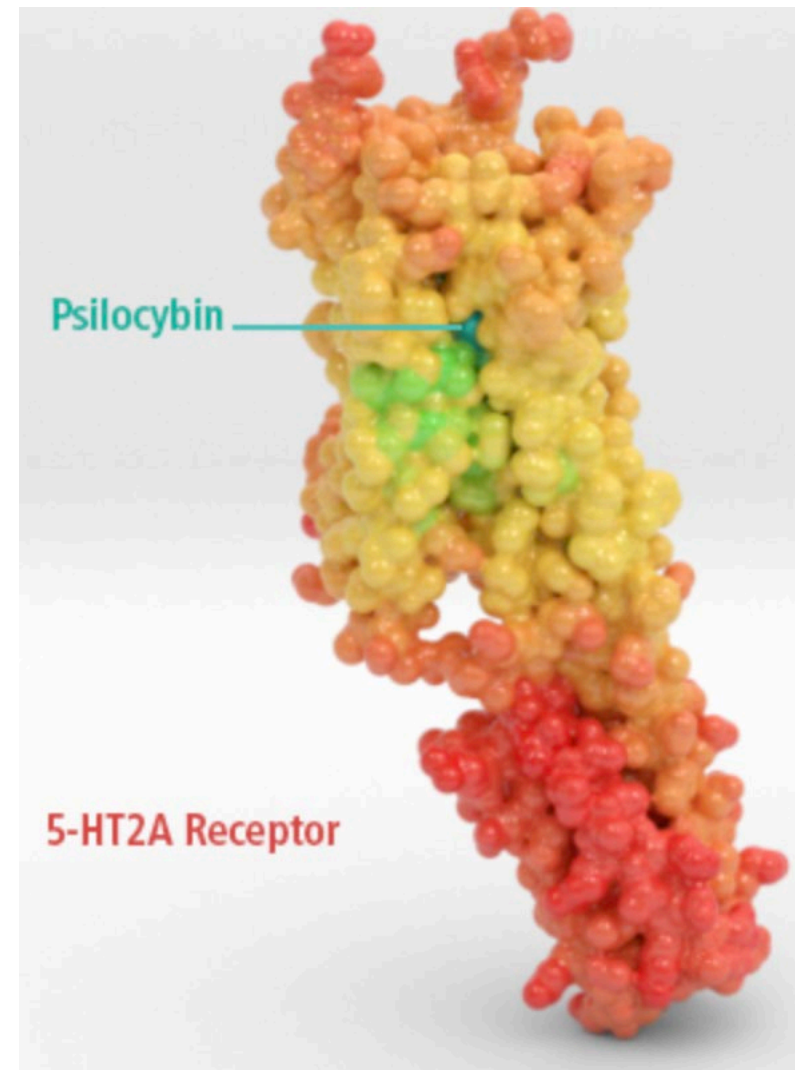




# Psychedelics

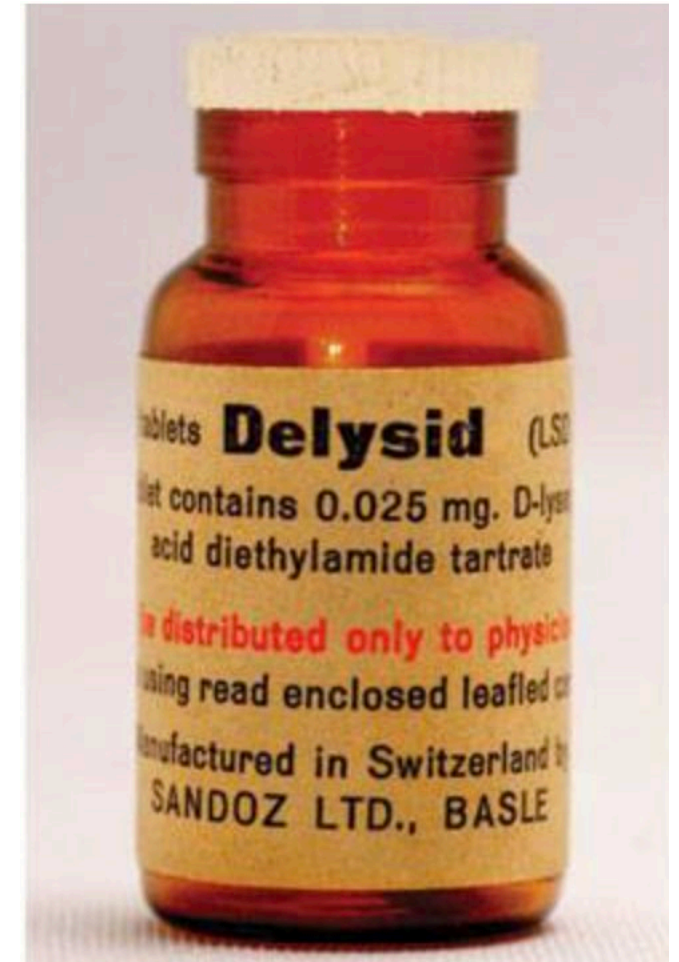
To date, the biological mechanisms underlying these complex psychoactive effects remain poorly understood.

The basic pharmacology of psychedelics includes activity at a number of receptors in the brain; serotonin (5HT) receptors, predominantly 5HT-2Ar, dopamine (D2) receptors, kappa opioid receptors, *N*-methyl-d-aspartate (NMDA)-receptor modulation, and monoamine transporters (serotonergic, dopaminergic, and noradrenergic)



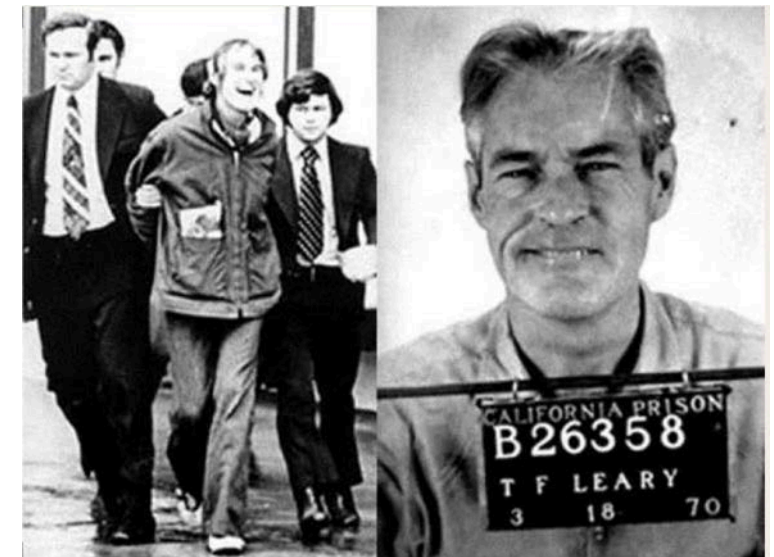
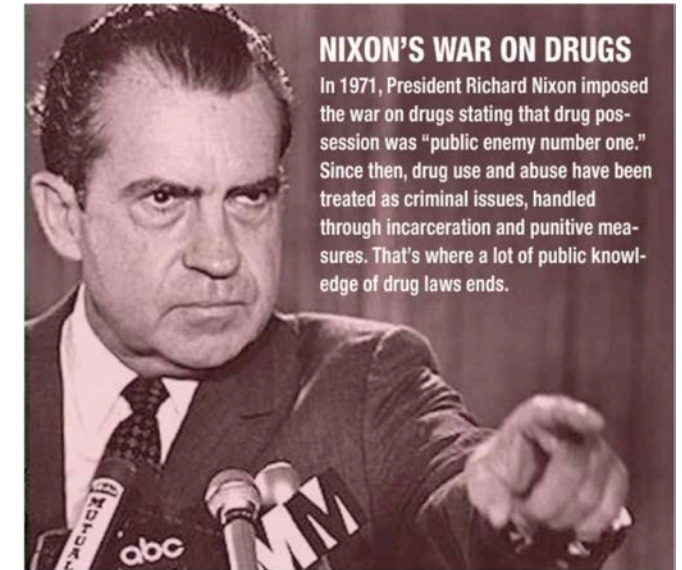
# Psychedelics and psychotherapy

- Psychadelics have been used in religious, shamanic, and spiritual ceremonies for millennia
- Psychedelic drugs were studied in a number of clinical trials in the 1950s and 1960s.
- LSD and psilocybin became more extensively used to facilitate progress in psychotherapy through self-reflection, ego dissolution, and access to unconscious material.
- These compounds were eventually marketed under brand names Delysid® (LSD) and Indocybin® (psilocybin) by Sandoz during the 1950s and 1960s



# Psychedelics and the 20<sup>th</sup> century

- Early studies suggested safety of these compounds even in medically complex patients,
- lack of rigorous scientific methodology and reports of adverse events limit the reliability of early findings on the safety of these compounds.
- Widespread use of psychedelics for non-medical purposes and careless experimentation with these drugs led to negative outcomes.
- their association with political activism and the counterculture movement of the 1960s resulted in stigma against these drugs which culminated with their criminalization as Schedule I drugs in the US and elsewhere by the Controlled Substance Act of 1970.



# The last decade – a resurgence of research



**MAPS**  
Public Benefit  
Corporation

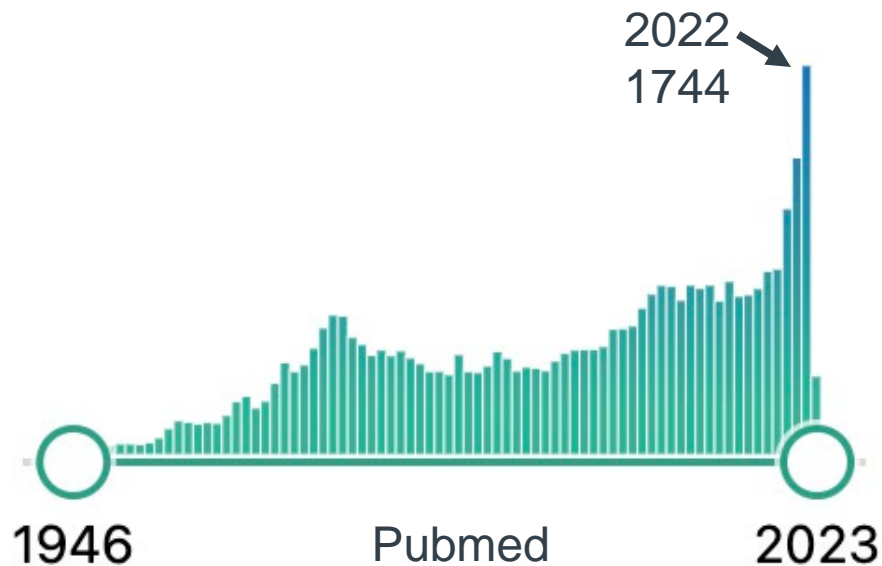


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Research  
Council



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Center for Psychedelic &  
Consciousness Research



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PSYCHEDELIC RESEARCH

Imperial College London



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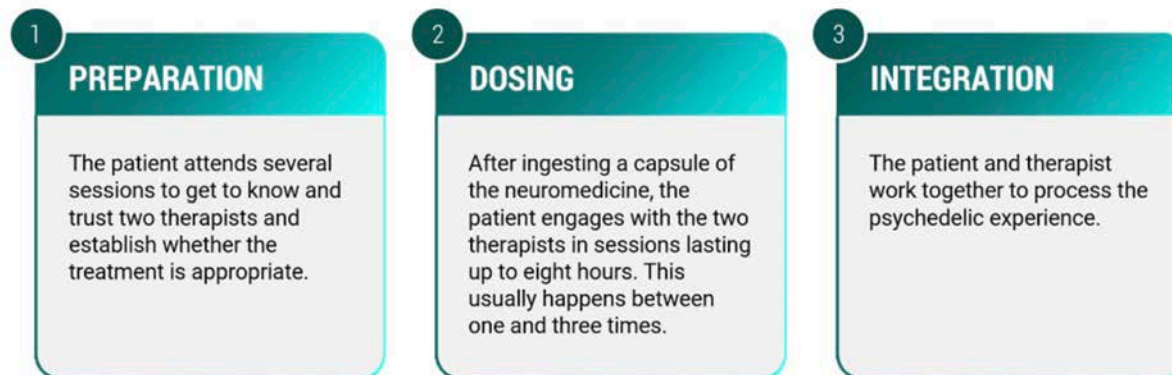




# Critical role of psychotherapy

Little is known about the intrapsychic processes and mechanisms by which psychedelic drugs are presumed to work in facilitating psychotherapy or general mental health.

It is believed that the therapeutic effect is a result of the interaction between the drug and the mindset of the patient (together often referred to as 'set'), the external conditions (often referred to as 'setting'), and the therapist(s) (Garcia-Romeu A, et al, *Int Rev Psychiatry* 2018).



# Inherent challenges in psychedelic clinical research

## Study design and implementation

- difficulty of ensuring adequate blinding (how to deliver a placebo?)
- overrepresentation in studies of participants who have previously used psychedelics
- uncertain patient selection, insufficient follow-up

## Interpretation

- testing not just one thing, but a combination of drug and psychotherapy

## Researchers and psychotherapy use

- raises concerns about bias and scientific integrity
- lead to the exploitation of research subjects, or promote biased reporting of results
- *excess enthusiasm* for psychedelics
- whether personal experience with psychedelics is necessary for those who provide psychedelic-assisted therapy

# Psilocybin – mechanism of action

Once ingested, metabolized to psilocin, a serotonin transporter inhibitor and 5-HT<sub>2A</sub> receptor partial agonist;

- it also binds to the 5-HT<sub>2C</sub>, 5-HT<sub>1A</sub>, and 5-HT<sub>1B</sub> receptors, with binding affinities in descending order.

When taken at high doses it can cause mild to profound changes in sensory perception, including synaesthesia, euphoria, sensory illusions, and auditory and visual hallucinations. These effects are dose dependent and last 8 to 10 hours.

Unpleasant effects can include feelings of a seemingly “unending experience,” as well as nausea, vomiting, and transient headaches.

**Use in clinical trials with assisted psychotherapy for a period of 8-10 hours, sometime 2-3 doses a week apart, in a controlled setting with trained therapists**



Author	Design.	N	Intervention	Outcomes
Roseman et al. 2018 Neuropharmacology Treatment resistant depression	Open label	$n = 20$	two separate dosing sessions with psilocybin. Psychological support. fMRI scans	<b>rapid and enduring improvements post psilocybin.</b> Amygdala hyperactivity on fMRI .
Carhart-Harris et al. 2016 Lancet Psychiatry treatment resistant depression	Open label	$n=12$	Psilocybin 10 mg, and 25 mg 2 weeks later. No comparison group	<b>depressive symptoms markedly reduced 1 week</b> (mean QIDS difference $-11.8$ , 95% CI $-9.15$ to $-14.35$ , $p = 0.002$ ,) and 3 months ( $-9.2$ , 95% CI $-5.69$ to $-12.71$ , $p = 0.003$ ) after high-dose treatment. Marked and sustained improvements in anxiety and anhedonia
Griffiths et al. 2016 J Psychopharmacology depression and anxiety in cancer	Randomized double-blind crossover	$n = 51$	Psilocybin 22 or 30 mg 70 kg vs Psilocybin, 1 or 3 mg/70 kg	<b>At 6-month follow-up, these changes were sustained, with about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety.</b>
Ross et al. 2016 J Psychopharmacology depression and anxiety in cancer	Randomized, double-blind, placebo-controlled, crossover trial	$n = 29$	Psilocybin 0.3 mg/kg vs Niacin	<b>At 6.5-month follow-up, enduring anxiolytic and anti-depressant effects (~ 60–80% of participants continued with clinically significant reductions in depression or anxiety)</b> , sustained benefits in existential distress and quality of life, as well as improved attitudes towards death.



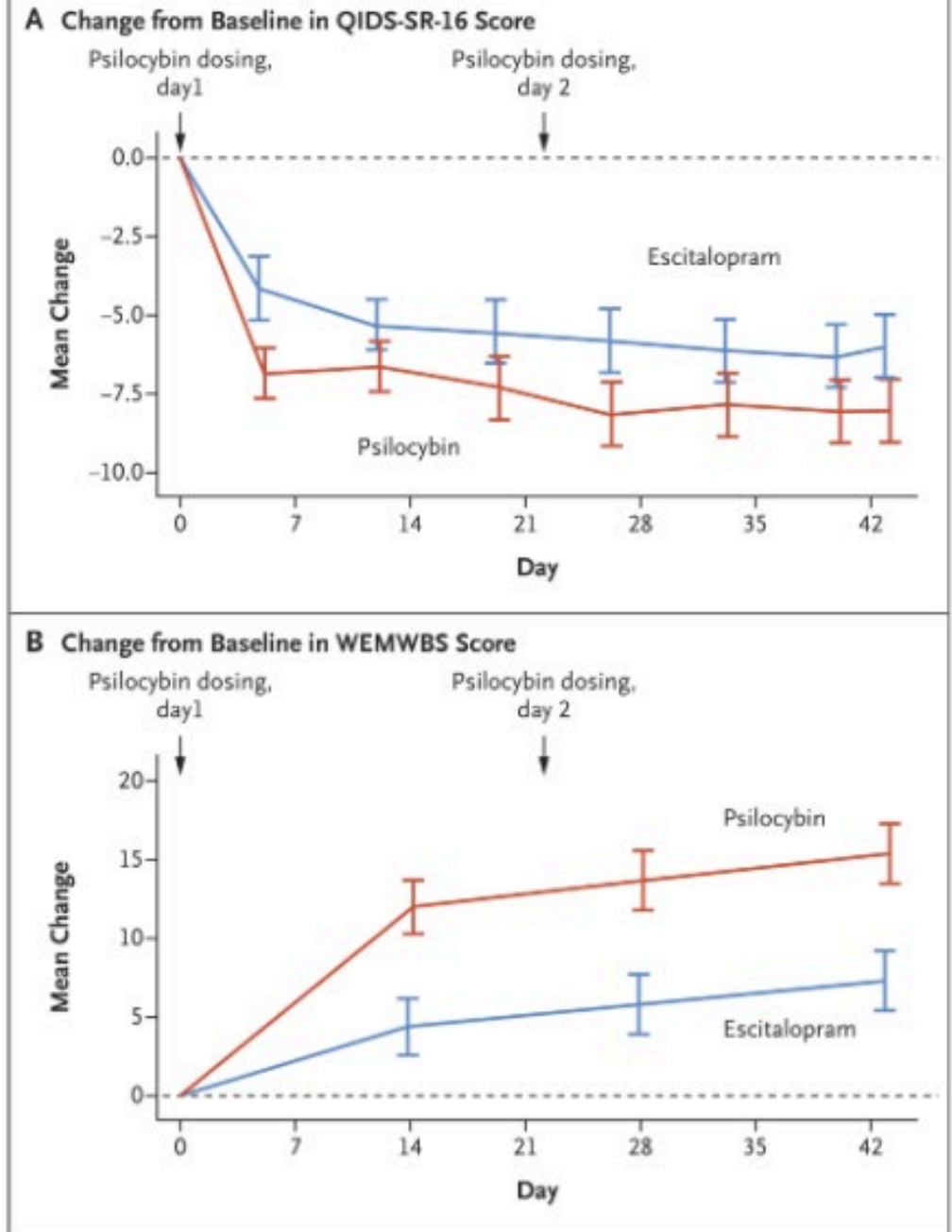
ORIGINAL ARTICLE

## Trial of Psilocybin versus Escitalopram for Depression

Robin Carhart-Harris, Ph.D., Bruna Giribaldi, B.Sc., Rosalind Watts, D.Clin.Psy.,  
Michelle Baker-Jones, B.A., Ashleigh Murphy-Beiner, M.Sc.,  
Roberta Murphy, M.D., Jonny Martell, M.D., Allan Blemings, M.Sc.,  
David Erritzoe, M.D., and David J. Nutt, M.D.

- Phase 2 double-blind RCT
- N=59, adults with moderate-severe major depressive disorder
- Psilocybin (2 x 25mg doses) +placebo
- Escitalopram + placebo (psilocybin 1mg)
- Change in QIDS-SR-16 depressive symptom at 6 weeks
- AE rate similar

No significant difference between psilocybin and escitalopram in QIDS-SR-16 score



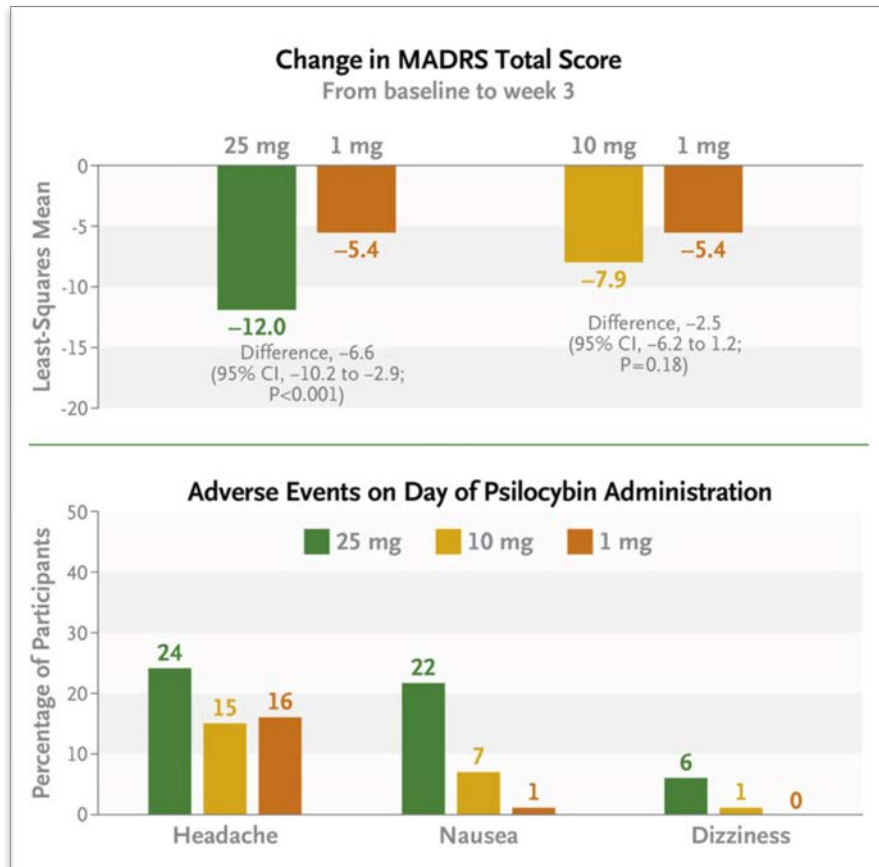
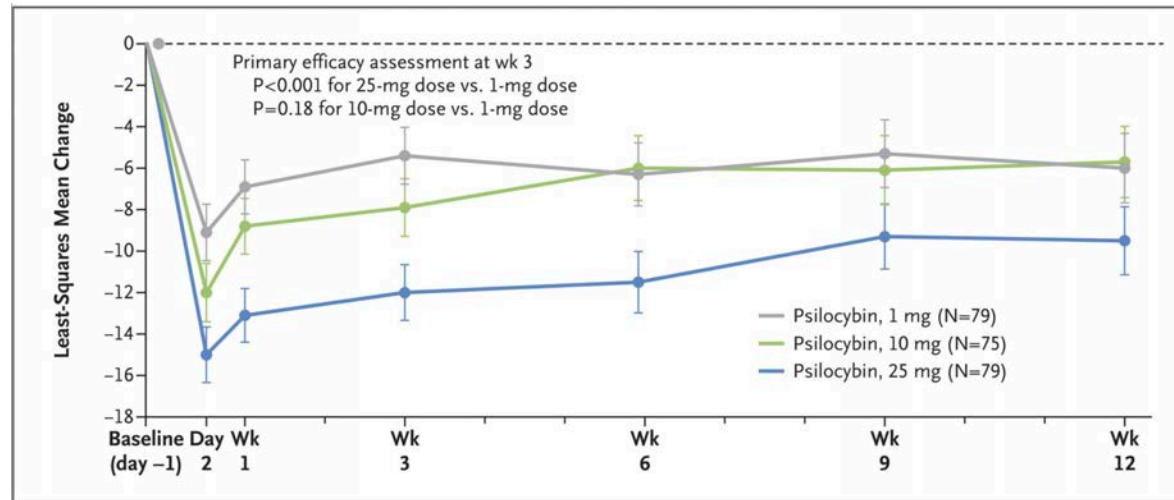
# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

NOVEMBER 3, 2022

VOL. 387 NO. 18

## Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression



MADRS (0-60), n=233

1mg, 10mg, 25mg dose with psychotherapy

Goodwin et al., NEJM 2022

# Risks – no psychosis in trial setting

While the acute presentation of a psilocybin-intoxicated individual closely resembles psychosis, hallucinogens such as psilocybin are not thought to precipitate a new psychotic illness but rather may unmask a psychotic disorder in those who are susceptible.

110 healthy study volunteers from 227 psilocybin administrations, researchers found no evidence of hallucinogen persisting perception disorder, prolonged psychosis, or other long-term impairment of functioning in any subjects.

Much of the research is from studies that screen participants for a history of psychiatric problems, regulate the dosage of the drug, and administer the drug in a controlled setting. These safeguards are intended to minimize the potential for adverse events.



Geyer MA, Vollenweider FX: **Trends Pharmacol Sci** 2008

Ross S, Peselow E: **Clin Neuropsychopharmacol** 2012

Studerus E, et al.: **J Psychopharmacol** 2011;

# Risks –

## psychosis in uncontrolled community setting

- online survey of almost 2,000 people who answered yes to the question of whether, after taking psilocybin mushrooms, they “ever had a psychologically difficult or challenging experience (i.e., a bad trip)—that is, have you experienced significant fear, anxiety, or distress or anything else that you found psychologically difficult,”

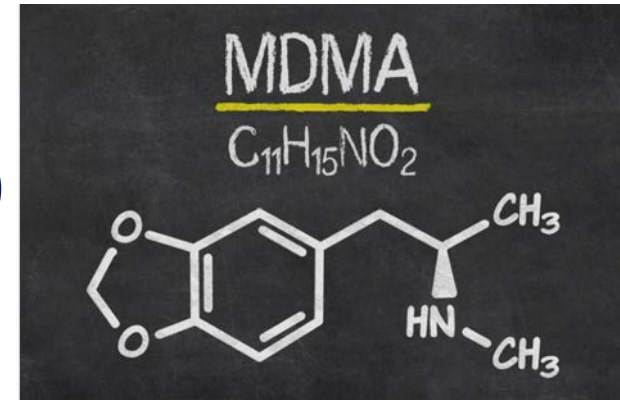
- 39% of respondents reported that the experience was one of the most challenging experiences of their lifetime.
- Twenty-four percent of participants reported psychological symptoms lasting 1 week or longer (i.e., fear, anxiety, depression, or paranoia),
- **10% reported persistent symptoms for more than 1 year, and**
- **7.6% sought professional help for psychological symptoms.**

Although this online survey is not rigorous enough to serve as a guide for clinical practice, it nevertheless points out potential concerns with the use of psychedelics in uncontrolled settings.



# MDMA

## (3,4-Methylenedioxymethamphetamine)



MDMA is a ring-substituted phenethylamine with structural similarities to amphetamine and mescaline.

**1912** MDMA was synthesized by Merck & Co. as a potential haemostatic agent.

**1976** psychotropic properties were recognized. Chemist Alexander Shulgin resynthesized MDMA, and the first published report characterizing the psychoactive effects of MDMA appeared in 1978.

- a new class of pharmacological agents, termed entactogens, with effects only partially overlapping those of psychostimulants and serotonergic hallucinogens

# MDMA use – the early years

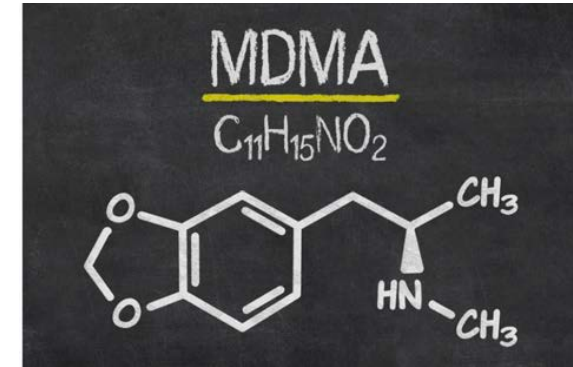
Early use by some psychotherapists to improve the outcome of psychotherapy sessions, with the goal of enhancing their patients' insights and understanding of their psychological problems, in the absence of any real evidence

MDMA was associated with feelings of emotional well-being and was described as “penicillin for the soul”.

These psychoactive properties led to use as a recreational drug.

In the early to mid-1980s, MDMA was illicitly synthesized and distributed under the street name Ecstasy and became popular for facilitating an altered emotional state at raves.

Because of concerns about abuse liability and neurotoxicity, the DEA emergently classified MDMA as a temporary Schedule I substance in 1985, and then permanently classified it as such in 1988.



# MDMA - effects and MOA

The effects of MDMA are believed to be mediated by a number of mechanisms

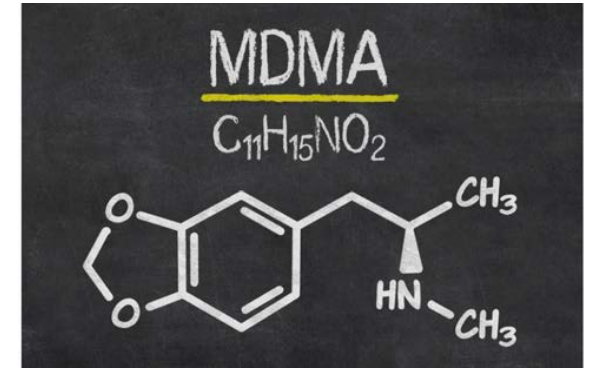
- monoamine release, serotonin and norepinephrine transporter reuptake inhibition, monoamine oxidase inhibition, partial agonism of serotonin receptors (5-HT<sub>2A</sub>, 5-HT<sub>1A</sub>, and 5-HT<sub>2C</sub> receptors),

## Studies with healthy volunteers

- easily controlled and reversible state of altered consciousness
- characterized by euphoria, empathy, well-being, insightfulness, extraversion, positive mood, gregariousness, feelings of authenticity, increased access to emotionally intense material, increased interpersonal trust, and compassion for oneself and others

## In the clinical population

- anxiety
- painful emotions such as grief, fear, and rage are not uncommon in participants with a diagnosis of PTSD



Author	Design.	N	Intervention	Outcome
Mithoefer et al. 2011 J Psychopharmacol.	RCT, DB	n=23	MDMA 125 mg plus optional 62.5 mg vs Placebo (lactose) plus psychotherapy	<b>Significant reduction in PTSD symptom</b> severity. mean change in CAPS at 2 months –53.7 MDMA – 20.5 placebo .
Mithoefer et al. 2018 Lancet Psychiatry	Ph 2 RCT, DB	n = 26	30 mg ( <i>n</i> = 7), 75 mg ( <i>n</i> = 7), or 125 mg ( <i>n</i> = 12) of MDMA plus psychotherapy	75 mg and 125 mg groups had <b>significantly greater decreases in PTSD symptom severity</b> (mean change CAPS-IV total scores of –58.3 [SD 9.8] and – 44.3 [28.7]; <i>p</i> = 0.001) than the 30 mg group (–11.4 [12.7]).
Ot'alora et al. 2018 J Psychopharmacol	Ph2 RCT	n = 28	active doses (100 and 125 mg) with a low dose (40 mg) of MDMA administered during eight-hour psychotherapy sessions.	active groups had the largest reduction in CAPS scores at the primary endpoint, with mean changes of –26.3 (29.5) for 125 mg, –24.4 (24.2) for 100 mg, and – 11.5 (21.2) for 40 mg. <b>PTSD symptoms remained lower than baseline at 12-month follow-up ( <i>p</i> &lt; 0.001) with 76% ( <i>n</i> = 25) not meeting PTSD criteria.</b>
Jerome et al. 2020 Psychopharmacology	longitudinal pooled analysis of six phase 2 trials	n=105	two to three active doses of MDMA (75–125 mg) during blinded or open-label psychotherapy sessions	significant reduction in CAPS-IV <i>p</i> < 0.0001), CAPS-IV scores continued to decrease to LTFU <i>p</i> < 0.05), <b>The number of participants who no longer met PTSD criteria increased from treatment exit (56.0%) to LTFU (67.0%).</b>



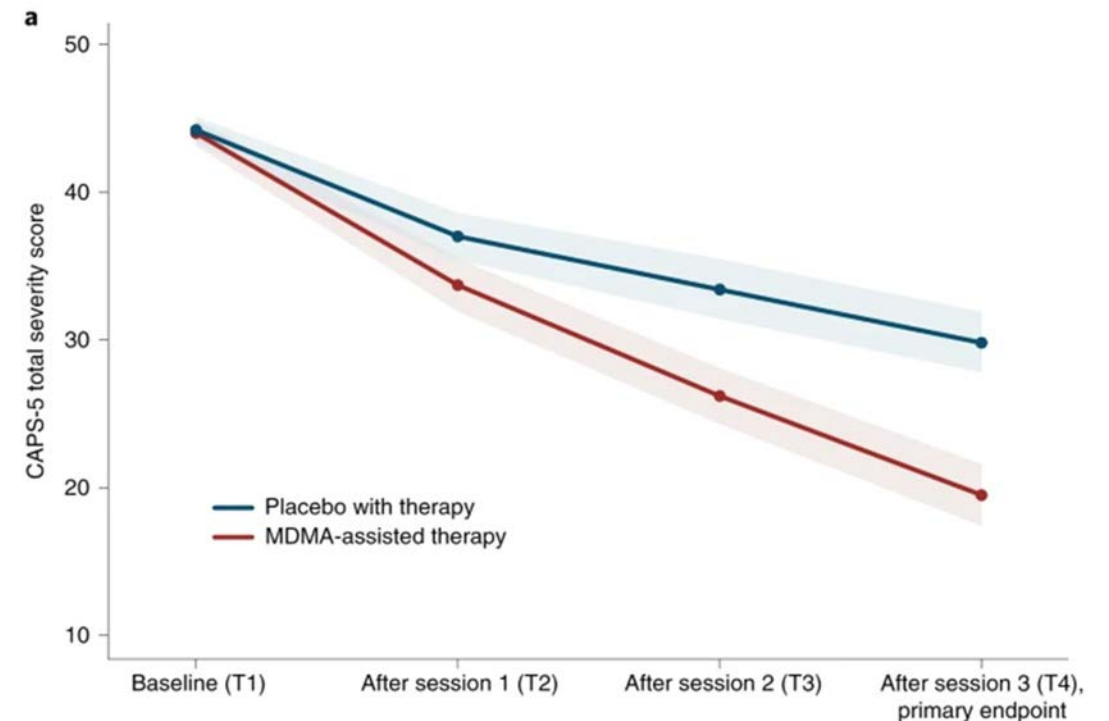


OPEN

# MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study

- n = 90
- Primary outcome; CAPS-5
- Secondary outcome; Sheehan Disability scale, BDI-II
- 3 prep and 9 integrative therapy sessions
- 3 doses MDMA
- Long term follow-up needed

**Fig. 2: Measures of MDMA efficacy in the MDMA-assisted therapy group and the placebo group.**



## Notable Advances 2021

Despite the continuous disruption caused by the COVID-19 pandemic, research in other areas carried on. Here is our selection of critical advances that have moved medicine forward in 2021.

### MENTAL HEALTH

## Psychiatry goes psychedelic

N. Engl. J. Med. **384**, 1402-1411 (2021)

Nat. Med. **27**, 1025-1033 (2021)



Nature Med  
December 2021

The New York Times

### *A Psychedelic Drug Passes a Big Test for PTSD Treatment*

A new study shows that MDMA, known as Ecstasy or Molly, can bring relief when paired with talk therapy to those with severe post-traumatic stress disorder.



NYT May 3 2021

# MDMA – abuse potential

There is research evidence of the abuse potential of MDMA in animals, albeit to a lesser degree than cocaine

(<https://www.drugabuse.gov/publications/drugfacts/mdma-ecstasy-molly>).

The prospective long-term follow-up study of individuals with PTSD who received MDMA (N=19) reported that no study participants developed a substance abuse problem (with any illicit drug) during the follow-up period of 7–17 months suggests that, at least in research settings, MDMA can be administered with minimal risk that patients will subsequently seek out and self-administer “street Ecstasy.”

However, further evaluation of MDMA’s long-term risks is needed.



## To summarise..

- Growing number of randomised clinical trials supporting the efficacy of MDMA in the treatment of PTSD, and psilocybin in treatment resistant depression.
- There is potential benefit for these two cohorts of people in the community for whom other treatments are not effective, or a contraindicated, leaving them with few or no treatment options.





# The TGA MDMA and Psilocybin scheduling decision –what does it mean?



Adjunct Professor John Skerritt

Head, Therapeutic Goods Administration  
Deputy Secretary, Health Products Regulation  
Australian Department of Health and Aged Care



# Purpose of today's presentation

- The TGA decision making process
- What the decision means
- Outline next steps for interested psychiatrist prescribers
- Don't forget clinical trials



# TGA is Australia's therapeutic goods regulator

- Provides a **national system of controls** and timely availability of therapeutic goods
- Prescription medicines are usually assessed for **quality, safety** and **efficacy** prior to TGA approval and market authorisation
- There are pathways for access to certain **unapproved products** which have not been assessed by TGA
  - Special Access Scheme (SAS), the Authorised Prescriber (AP) scheme and clinical trials
  - Unapproved medicines accessed through these pathways have not been evaluated by the TGA for safety, quality and efficacy



# Decision making process - over two years

- Original application
- Public submissions (over 13,000 submissions)
- Meeting of Advisory Committee on Medicines Scheduling
- Independent expert panel report – 15 Dec 2021
- Earlier decision (not to change scheduling) – 15 Dec 2021 and 21 Oct 2022
- Further public consultation (almost 7,000 submissions)
- Newer paper in literature on psilocybin for major depression – Nov 2022
- Final decision – 3 February 2023

*The Delegate changed their interim decisions because they were satisfied that sufficient controls on access to the substances as Schedule 8 drugs for particular purposes could be included*

*These controls are more restrictive than what was proposed in the application to the TGA but are consistent with the clinical evidence supporting the therapeutic use of the substances*



# What is medicines scheduling?

- **Scheduling determines the level of public access** to particular medicines and chemicals required to protect public health and safety
- While changes are generally adopted by default, **State and territory governments** decide whether or not to implement scheduling changes
- In some states and territories, it may also be an **offence to supply, use or possess psilocybin and MDMA due to state and territory drug laws** - even when they are in Schedule 8
  - It will be up to states and territories to decide if and when to make any changes to their legislation
- **Contact your state and territory health department** to clarify local legal requirements prior to submission of an application under the Authorised Prescriber scheme



# Schedule 8 vs Schedule 9

*Effective from 1 July 2023, the TGA made the decision to down schedule psilocybin and MDMA from Schedule 9 to Schedule 8 in the Poisons Standard when used under certain conditions.*

**For Both:** The substance is included in Schedule I or II of the UN Single Convention on Narcotic Drugs 1961 or in Schedule II or III of the UN Convention on Psychotropic Substances 1971.

**S8 factors:** The substance has an **established therapeutic value** but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.

**S9 factors:** The substance has **no currently established therapeutic value** and is likely to present a high risk of dependency, abuse, misuse or illicit use. A high level of control is required through prohibition of manufacture, possession, sale or use. The benefits of use are substantially outweighed by the risks.

Because of the interaction with state and territory regulation, this has restricted the supply of S9 substances to approved **clinical trial settings only**

# What changes after July 1 2023?

Rescheduling to Schedule 8 ('controlled drugs') of **psilocybin for treatment-resistant depression**, and **MDMA for post-traumatic stress disorder**

- authorisation to prescribe the substances for the above conditions restricted to registered psychiatrists who have obtained **approval from a Human Research Ethics Committee** and have also been authorised by the **TGA to be an Authorised Prescriber**
- possession of the substances without authority (e.g. legal prescription) will be illegal

## Note that

- The medicines will not be available for individual patients under the Special Access Scheme
- For other indications they remain as S9 prohibited substances (clinical trials only)
- It is not anticipated at this time that approval would be granted for protocols which enable the patient to be dispensed medicines containing these substances to take home

# Was Australia the first country in the world?

## Yes and No

Some **other countries** have already provided **psychedelics** under a small number of closely-supervised compassionate access schemes

But **potentially the first in the world** from a drug scheduling/enforcement to take the two substances in law from a prohibited drugs schedule into a controlled drug schedule for therapeutic purposes





# The Authorised Prescriber Scheme

Under the AP scheme, TGA grants a medical practitioner authority to prescribe a **specific unapproved medicine** for **particular indications** to a **class of patients** in their **immediate care**

To become an AP, a **medical practitioner must first obtain approval from a HREC** to prescribe the product under a protocol

Once a medical practitioner becomes an Authorised Prescriber, they must only report to the TGA the number of patients treated with the unapproved product twice yearly

There is **no application fee**

The screenshot shows the 'Authorised Prescriber Scheme - Application form' from the Australian Government Department of Health, Therapeutic Goods Administration. The form is titled 'Authorised Prescriber Scheme - Application form' and includes a 'TGA user only' box. It contains sections for 'Product details' and 'Prescribing medical practitioner details'. The 'Product details' section includes fields for 'Code Number', 'Trade name', 'Generic name', 'Indication for prescribing', 'Storage form', and 'Route of administration'. The 'Prescribing medical practitioner details' section includes fields for 'First name', 'Surname', 'MBA ID', 'MBA ID', 'Email', 'Phone', and 'Fax'. The 'Approving/endorsing body' section includes fields for 'Name of approving/endorsing committee of healthcare providers' and 'Name of endorsing specialist college (if applicable)'. The form also includes a 'TGA' logo and contact information for the Therapeutic Goods Administration.

# Prescriber eligibility under the decision

Prescribing of psilocybin and is limited to psychiatrists who are registered with the AHPRA with a **specialist registration in psychiatry** and completed a **Fellowship with the Royal Australian and New Zealand College of Psychiatrists**

**To prescribe** psychiatrists must:

- have obtained approval under Authorised Prescriber Scheme to use the substance for treating the conditions from a HREC that is registered with the NHMRC, and subsequently
- have sought and obtained authorisation by the TGA under the Authorised Prescriber Scheme to prescribe these substances for patients under their care.

Psychiatrists should also consider and discuss with their patients the suitability of medical treatment options that are TGA approved before seeking to prescribe psilocybin or MDMA

# How to become an Authorised Prescriber

**Step 1: Obtain approval to use the substances for treating these conditions from an HREC (that is registered with the NHMRC)**

**The HREC application** must contain details of the:

- Applying medical practitioner and training and experience of all staff involved in the treatment
- The 'unapproved' product details
- Clinical justification for the use of the product – this will be up to the HREC, but potentially include:
  - evidence its use that is appropriate, considering suitable alternatives
  - patient selection and exclusion
  - treatment protocol involving assessment and on-going management by the psychiatrist before and after administration of appropriately supervised single dosing of the patient in an appropriate setting
  - how the use of the substance will be combined with psychotherapy
  - safeguards to ensure the treatment does not cause harm



**Treatment protocols** are likely to be very similar to those used in Australia and internationally in clinical trials

**On trialled dosages and formulations**, more information can be found in:

The published study titled

Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression,<sup>1</sup> published in the New England Journal of Medicine on 3 Nov 2022.

The studies reviewed in Independent expert panel report on the TGA website titled

An evaluation of the therapeutic value, benefits and risks of methylenedioxymethamphetamine (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders







## Step 2: Complete an Authorised Prescriber application with the TGA

Applications can be submitted using the SAS & Authorised Prescriber Online System. A senior TGA medical practitioner reviews the application to confirm:

- Prescriber's clinical justification for their treatment regimen
- Governance over the treatment process
- Use of measures to protect patients, such as records of informed consent

The TGA will also expect that psychiatrists will have **considered all clinically appropriate medicine options** before applying to access a psilocybin or MDMA-containing product

An Authorised Prescriber is **only allowed to supply the product to specified patients under their immediate care** - not to other practitioners

- TGA may apply specific conditions on a case-by-case basis
- Authorised Prescribers are responsible for reporting adverse events
- Authorised Prescribers must provide supply reports on the number of new and total patients treated each 6 months

# Obtaining psilocybin and MDMA – Imports

To import products containing MDMA or psilocybin you will need an import licence and/or permit from the Office of Drug Control under the *Customs (Prohibited Imports) Regulations 1956*

- These are only granted where the use of the substance is permitted by the relevant state or territory

So that medicine for several patients can be imported in one shipment, TGA allows the substances to be imported and held prior to supply under the Authorised Prescriber scheme

- The medicine must be held under the direct control of the person principally responsible for importing the goods until the goods are authorised for supply under the AP scheme.
- Where the sponsor importing the medicine is someone other than an authorised prescriber, they must obtain a copy of the TGA approval letter from the prescriber before supplying the product to the prescriber.
- State and Territory Health Departments may require a pharmacy to hold the product securely until it is dispensed to the Authorised Prescriber for administration to the patient

TGA is considering arrangements that should be put in place to facilitate the lawful manufacture of MDMA and psilocybin in Australia and will provide further guidance later

# Obtaining psilocybin (and MDMA) – Domestic

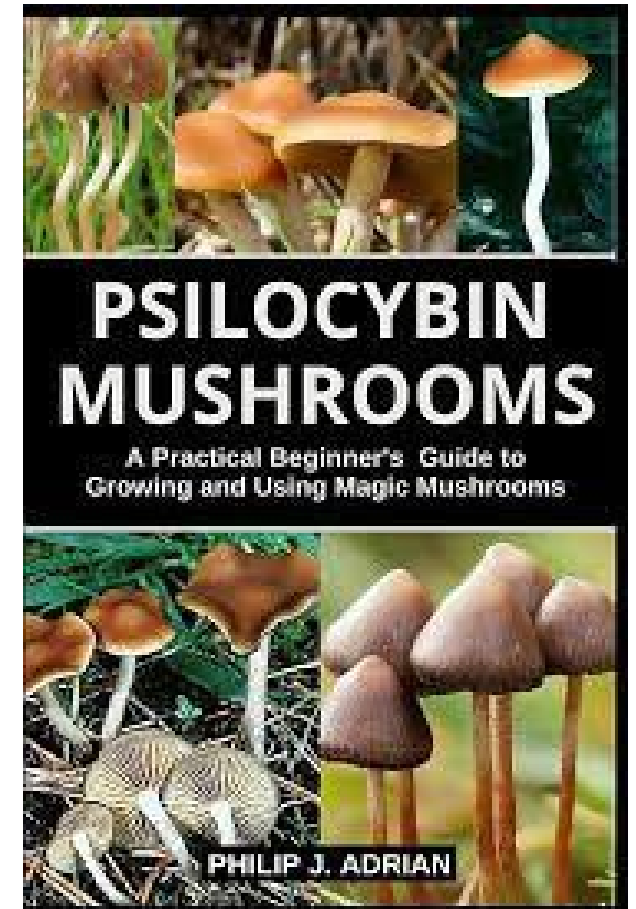
TGA is considering arrangements that should be put in place to facilitate the lawful manufacture of MDMA and psilocybin in Australia and **will provide further guidance later**

We recognise there are

- Some local organisations with state licences to cultivate psilocybin mushrooms
- Some clinical trials planned of mushroom products
- And some commercial excitement

But TGA would be **most unlikely to provide Authorised Prescriber application approval** for products **other than pharmaceutical grade psilocybin and MDMA**

- GMP manufacture strongly preferred
- Botanical crude products not currently in scope
- Compounded products discouraged



# Advertising controls

Prescription medicines and unapproved therapeutic goods such as MDMA or psilocybin are **prohibited by law from being advertised to the public**

**it is illegal** for Authorised Prescribers or healthcare facilities to indicate that they can prescribe and/or supply MDMA and/or psilocybin. But:

- MDMA and psilocybin may be advertised exclusively to health professionals provided there are means to prevent access to the advertisement by the public
- Information provided by a health practitioner to a patient during consultation or treatment is not subject to the advertising rules
- Presenting factual, balanced information about MDMA or psilocybin (e.g. at medical conferences) is unlikely to be considered advertising, but it depends on the context of the presentation



# **We need clinical trials to continue, especially for other indications - and the Schedule 9/CTN pathway enables this**

**TGA receives a notification**, and **the HREC reviews** the scientific validity of the trial design, risk versus harm, ethical acceptability, and approves the trial protocol and monitoring trial conduct.

**Substances being imported or used for the trial** still require TGA/ODC approval/ permit

## **Some current / approved Australian trials**

- Psilocybin – Treatment-resistant depression, Generalised Anxiety Disorder, Depression/ Anxiety in life-threatening illness, Substance use disorder, Motor symptoms in neurological disorders
- MDMA – Mood and anxiety in advanced cancer, PTSD, Obsessive compulsive disorders

## **Additional indications being trialled internationally** e.g. for psilocybin on [clinicaltrials.gov](https://clinicaltrials.gov)

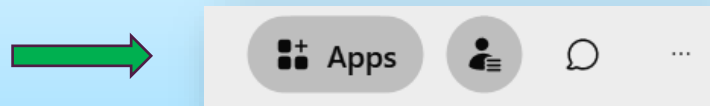
- Alcohol use disorder, cocaine use, tobacco addiction, smoking cessation
- Borderline personality disorder, Bipolar, Body dysmorphic disorder, suicidal ideation, autism spectrum disorder, binge eating, anorexia nervosa, obsessive compulsive disorder
- Parkinsons disease, early Alzheimers, migraine, chronic low back pain, fibromyalgia



# Question 'App' is now open

SLIDO

## Slido App



- Click on Apps+ icon
- Select "Slido"
- Open "Q&A" tab to ask questions
- Live Poll (use survey tab when prompted)

OR

## Slido QR

Scan the QR  
code to access  
separately from  
your mobile  
device



# Survey - Poll

## How did we go?

We'll be back with you in **1 minute**.

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A



**Anonymous or Open responses welcome**

# Questions

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**Adj Professor John Skerritt**

Head, Therapeutic Goods Administration  
Deputy Secretary, Health Products Regulation  
Department of Health and Aged Care



**Adj Professor Robyn Langham AM**

Chief Medical Adviser  
Health Products Regulation  
Department of Health and Aged Care



Q&A

# Website and link references

MDMA and psilocybin	<a href="https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin">https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin</a>
Medical-List-of-specialties--fields-and-related-titles-Registration-Standard	<a href="https://www.ahpra.gov.au/documents/default.aspx?record=WD10%2f106%5bv3%5d&amp;dbid=AP&amp;chksum=OU7zOxkohleqDQJe1bkVgQ%3d%3d">https://www.ahpra.gov.au/documents/default.aspx?record=WD10%2f106%5bv3%5d&amp;dbid=AP&amp;chksum=OU7zOxkohleqDQJe1bkVgQ%3d%3d</a>
Evaluation of the, benefits and risks of (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders.	<a href="https://www.tga.gov.au/sites/default/files/mmda-and-psilocybin-independent-expert-panel-review-final-report.pdf">https://www.tga.gov.au/sites/default/files/mmda-and-psilocybin-independent-expert-panel-review-final-report.pdf</a>
Authorised Prescriber Scheme	<a href="https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme">https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme</a>
The Royal Australian & New Zealand College of Psychiatrists	<a href="https://wwwThe.royalranzcp.org/home">https://wwwThe.royalranzcp.org/home</a>
Human Research Ethics Committees (HRECs)	<a href="https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees">https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees</a>
Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression	<a href="https://www.nejm.org/doi/full/10.1056/NEJMoa2206443">https://www.nejm.org/doi/full/10.1056/NEJMoa2206443</a>
Special Access Scheme (SAS) & Authorised Prescriber Scheme Online System	<a href="https://compliance.health.gov.au/sas/">https://compliance.health.gov.au/sas/</a>
Access to MDMA (3,4-methylenedioxy-methamphetamine) and psilocybin for therapeutic purposes – information for psychiatrist prescribers	<a href="https://www.tga.gov.au/resources/resource/guidance/access-mdma-34-methylenedioxy-methamphetamine-and-psilocybin-therapeutic-purposes-information-psychiatrist-prescribers">https://www.tga.gov.au/resources/resource/guidance/access-mdma-34-methylenedioxy-methamphetamine-and-psilocybin-therapeutic-purposes-information-psychiatrist-prescribers</a>
Re-scheduling of psilocybin and MDMA in the Poisons Standard: questions and answers	<a href="https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma/re-scheduling-psilocybin-and-mdma-poisons-standard-questions-and-answers">https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma/re-scheduling-psilocybin-and-mdma-poisons-standard-questions-and-answers</a>

# More information



TGA website <https://www.tga.gov.au>



TGA Facebook <https://www.facebook.com/TGAgovau/>



TGA Twitter <https://twitter.com/TGAgovau>



TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>





**Australian Government**

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**Department of Health and Aged Care**

Therapeutic Goods Administration