From: s22
To: SKERRITT, John
Subject: Invitation from s22 - A New Paradigm for Mental Health [SEC=No Protective Marking]
Date: Friday, 7 December 2018 2:50:22 PM
Attachments: Mind Medicine Australia VIP Launch Invitation.pdf

Dear Dr. Skerritt,

We would like to invite you to join us for the official launch of a new not-for-profit organisation, *Mind Medicine Australi*a. The launch will be held at 5:30pm on the evening of Wednesday, February 13th 2019 at the University of Melbourne. The launch will bring together a cross-section of Australian changemakers who are seeking better solutions to our growing mental health crisis. Please join us for the public lecture by the esteemed Professor David Nutt, Head of Neuropsychopharmacology, Imperial College London immediately followed by a private reception.

About us
Mind Medicine Australia (MMA) supports research and innovation in the treatment of mental health and psychological wellbeing through the use of psychedelic therapy. MMA is a charitable endeavour intended to serve as a nexus between academia, government, health practitioners, philanthropists and culture.

For more information please visit the MMA site at: www.mindmedicineaustralia.org

We look forward to welcoming you to this very special evening. Please RSVP to: admin@mindmedicineaustralia.org

Your early response would be appreciated as places are limited. Please see the attached invitation and below for more information.

Invitation to the Launch of Mind Medicine Australia

Did you know that one in two Australians will be affected by mental illness at some point in their lives?

Mind Medicine Australia imagines, with others, a world free of mental health disease. We support innovation in the treatment of mental health and the promotion of psychological wellbeing by acting as a nexus between academia, government, technology, philanthropy and culture.

To celebrate the launch of MMA, we invite you to join us for a public lecture followed by a private reception. The lecture will be delivered by Professor David Nutt of Imperial College, London, during which he will outline a new paradigm for promoting mental health. The public lecture will be followed by an exclusive launch event: an evening of stimulating conversation, champagne, and canapés - plus the chance to hear more from Professor Nutt and our team.

INTERNATIONAL KEYNOTE: PROFESSOR DAVID NUTT

Psychedelics: A New Paradigm for Mental Health
Renowned researcher and author, Professor David Nutt, is currently Head of

Neuropsychopharmacology at Imperial College London. Under the auspices of Professor Nutt, the Psychedelic Research Group at Imperial College is one of the world's foremost psychedelic research laboratories, publishing landmark research on psychedelic therapies and neuroimaging studies of the psychedelic state. Professor Nutt has also held many leadership positions in both UK and European academic, scientific and clinical organisations, including presidencies of: the European Brain Council, the British Neuroscience Association, the British Association of Psychopharmacology, the European College of Neuropsychopharmacology. He was previously Chair of the UK Advisory Council on the Misuse of Drugs.

Wednesday February 13, 2019

Public Lecture:
5:30 Arrival for 6pm start
Carrillo Gantner Theatre
Asia Sidney Myer Building
The University Of Melbourne

VIP Event:
7:15 - 8:30pm
Yasuko Hiraoka Myer Room (Room 106)
The University Of Melbourne
With champagne and canapes

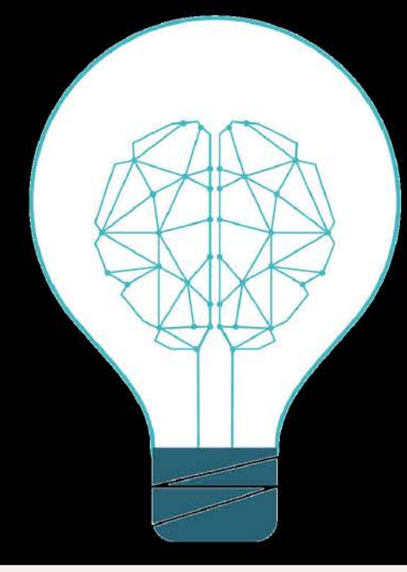
RSVP, as soon as possible, to: admin@mindmedicineaustralia.org

Best Wishes,

s22 [redacted]

s22 [redacted]
Mind Medicine Australia

Psychedelic Therap
A New Paradigm for Mental Health



MIND
Medicine Australia

"Psychedelics are to the mind what the microscope is for biology or the telescope is for astronomy." Dr. Stanislav Grof

Did you know that one in two Australians will be affected by mental illness at some point in their lives?

Wednesday, February 13 2019

Mind Medicine Australia is imagineering a world free of mental health disease. We support innovation in the treatment of mental health and psychological wellbeing by acting as a nexus between academia, government, technology, philanthropy and culture.To celebrate the launch of MMA, we are uniting the community of Australian changemakers in pursuit of better solutions to our growing mental health crisis.

First, in a **public lecture** you will hear of the emerging new paradigm of mental health presented by the esteemed Professor David Nutt of Imperial College, London. Then, in an exclusive **launch event,** enjoy an evening of stimulating conversation, champagne and canapés plus the chance to hear more from Professor Nutt and our team.

PUBLIC LECTURE

6 - 7:15pm (5:30 arrival)
Carrillo Gantner Theatre
Asia Sidney Myer Building
The University Of Melbourne

VIP EVENT

7:15 - 8:30pm
Yasuko Hiraoka Myer Room
(Room 106)
The University Of Melbourne
With champagne and canapes

RSVP ASAP as places are limited:
admin@mindmedicineaustralia.org

Join us in paving a new paradigm for the treatment of mental health in Australia!

and author, Professor David Nutt is currently Head of
logy at Imperial College London. Under the auspices of
ychedelic Research Group at Imperial College is one of
sychedelic research laboratories, publishing landmark
therapies and neuroimaging studies of the psychedelic
as also held many leadership positions in both UK and
entific and clinical organisations, including presidencies
ouncil, the British Neuroscience Association, the British
Psychopharmacology, the European College of
harmacology and was previously Chair of the
visory Council on the Misuse of Drugs.

PROFESSOR DAVID NUTT (UK)

From: s22
To: s22 @gmail.com"
Cc: GILL, Tony; Medicines Scheduling
Subject: RE: Acceptance of International clinical trial developments in the regulation drugs CRM:0007673 [SEC=OFFICIAL]
Date: Wednesday, 17 April 2019 11:03:47 AM
Attachments: image002.png
image001.png
image003.png

Hi s22

Thanks for your call this morning. I have just spoken with a member of the scheduling committee and they have sent me to this link on our website: https://www.tga.gov.au/form/application-amend-poisons-standard. It appears an application needs to be made to reschedule a product. Alternatively, unapproved Schedule 9 products may be accessed via the Special Access Scheme but please be aware that these products may be subject to individual state and territory legislation. For further information regarding the scheduling process please email medicines.scheduling@health.gov.au

Kind regards

s22
s22
s22 Experimental Products Section
Pharmacovigilance and Special Access Branch | Medicines Regulation Division
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: 136 Narrabundah Lane. Symonston, ACT
PO Box 100, Woden ACT 2606

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

Subject: Re: Acceptance of International clinical trial developments in the regulation drugs CRM:0007673 [SEC=OFFICIAL]

Hi s22

Thank you for providing these responses. I have a couple of questions about the TGA's process/conventions. Please note, s22 and understand the law and conventions. I am NOT seeking legal advice from the Scheduling Secretariat. I have already reviewed the information you reference and access to a regulatory consultant. But grateful for pointing out the links in your note. The substance of my enquiry in the first dot point goes to the practices and procedures of the TGA when dealing with substances under trial supervised by recognised overseas regulators. So, for example, if regulated trials of substances are being conducted at John Hopkins in the USA and the FDA approve the substance, how might the TGA act?

I have copied Mind Medicine Australia's s22 as we are very interested to know. s22 heads overseas in late April so I'd be pleased if we can have a quick chat. It might be better than email to provide you with context around our questions.

I wonder if we might be able to schedule a call for the week beginning 8 April?

Best regards

s22
(m) +s22

From: Medicines Scheduling <MedicinesScheduling@health.gov.au>
Date: Thursday, 21 March 2019 at 12:56
To: s22 [redacted] @gmail.com>
Subject: RE: Acceptance of International clinical trial developments in the regulation drugs CRM:0007673 [SEC=OFFICIAL]

Dear s22 [redacted]

Your email has been forwarded to the Medicines Scheduling Secretariat for response. Please accept our apologises for the delay in responding.

Please note that the Scheduling Secretariat is **unable to provide legal advice**. Advice on the legislative requirements can be sought from a regulatory consultant and a list of consultants is provided on the TGA website.

Further to your enquiry, please find the following information to your questions in turn:

- ***What process does the TGA go through for the approval, scheduling of an unapproved substance or the down-scheduling of substances for therapeutic purpose that have been the subject of fully regulated clinical trials in those places?***

  Please note that anyone can lodge an application to amend the Poisons Standard. There is no fee charged for lodging an application. Applicants may apply directly to the Scheduling Secretariat at medicines.scheduling@health.gov.au.

  According to subsection 52EAA(2) of the *Therapeutic Goods Act 1989* an application seeking to amend the Poisons Standard must:

  (a) be made in accordance with a form approved by the Secretary; and
  (b) set out the amendment sought; and
  (c) be delivered to an office of the Department specified in the form;

  As such an email, letter or petition is insufficient to initiate the process to amend the Poisons Standard and an application form must be completed. The application form and information on how to lodge an application can be found on the TGA website athttp://www.tga.gov.au/industry/scheduling-forms-poisons-standard-amend.htm.

  A scheduling application needs to be submitted and supported by sufficient evidence in order for the safety of the substance to be assessed. Information included in the application should:

  - include information on the identity (including physicochemical properties) of the substance.
  - include data relevant to addressing the potential toxicity of the substance. This may include an human health risk assessment or evaluation report.
  - include the proposed new or amended schedule entry.
  - address the relevant criteria outlined in the Scheduling Policy Framework (SPF)
  - address the 52E(1) criteria of the *Therapeutic Goods Act 1989* including:

    (a) the risks and benefits of the use of a substance;
    (b) the purposes for which a substance is to be used and the extent of use of a substance;
    (c) the toxicity of a substance;
    (d) the dosage, formulation, labelling, packaging and presentation of a substance;
    (e) the potential for abuse of a substance;
    (f) any other matters that the Secretary considers necessary to protect public health.

  Further information regarding the scheduling process including when and how matters

are referred to the Advisory Committees, information on the public consultation process and guidance for applicants, can be found on the webpage and in the Scheduling Handbook.

- ***What conventions/agreements might apply between the TGA – I have looked at the law and website in some detail in an effort to understand how the TGA might do this. However, I cannot see much on issue of international precedent in reclassifying a Schedule 9 substance (perhaps in a similar process to medicinal cannabis).***

Regarding International Conventions:

The Office of Drug Control (ODC) lists some of the applicable international conventions on their website. If you have an enquiry, you can contact the Office of Drug Control, Department of Health at https://www.odc.gov.au/contact-us. Also, the *Narcotic Drugs Act 1967* establishes a framework to both prevent abuse and diversion of controlled narcotics and to ensure the availability of such drugs for medical and research purposes, in accordance with the Single Convention on Narcotic Drugs, 1961 (the Single Convention), as in force from time to time. The Act provides for the control of drugs obtained from the opium poppy and the regulation of the manufacture of licit narcotics, such as morphine. With effect from October 2016, the Act was extended to include a regime for the regulation of cannabis cultivation and production in Australia, to enable a sustainable supply of safe medicinal cannabis products for therapeutic purposes and to benefit Australian patients in need (the 2016 Amendments). For more information, please email s22 [redacted] @health.gov.au.

Regarding Schedule 9:

Substances that are classified in Schedule 9 of the Poisons Standard are defined as follows:

> **Schedule 9:** Prohibited Substance – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

As previously mentioned, all scheduling decisions include consideration of a standard set of factors, to ensure that public health objectives are consistently met and the application of public health risk considerations is consistent within each Schedule. The factors for each schedule are set out in the Framework and relate back to the matters required to be taken into account by section 52E(1) of the *Therapeutic Goods Act 1989 (CTH)*. The **Scheduling factors for prohibited substances (Schedule 9)** are:

1. **The substance is included in either Schedule IV to the United Nations Single Convention on Narcotic Drugs, 1961 or in Schedule I to the United Nations Convention on Psychotropic Substances 1971.**

2. **The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use.**

    a. A high level of control is required through prohibition of

manufacture, possession, sale or use to prevent abuse, misuse or diversion into illicit activities.

b. The benefits of use are substantially outweighed by the risks, and dangers are such as to warrant limiting use to strictly controlled medical and scientific research.

c. Note: High risk substances which do not have risks of dependency, abuse, misuse or illicit use should be included in Schedule 10.

Schedule 9 does permit the use of such substances for prescribed purposes such as analysis, and medical or scientific research, including clinical trials, conducted with the approval of Commonwealth and/or State/Territory health authorities. Contact details for the Drugs and Poisons Units for each Australian State and Territory are available at: https://www.tga.gov.au/contacts-stateterritory-drugs-poisons-units.

- ***How the state and territory poisons advisory committees might be involved in the scheduling process***

Each State and Territory has its own laws that determine where consumers can buy a particular medicine or poison, and how it is to be packaged and labelled. However, State and Territory Governments classify the vast majority of medicines and poisons in accordance with the Poisons Standard (also known as the Standard for the Uniform Scheduling of Medicines and Poisons or (SUSMP) to achieve a uniform national approach to the scheduling of substances and uniform labelling and packaging requirements.

The Poisons Standard contains the decisions of the Secretary to the Department of Health, or a delegate, regarding the classification of medicines and poisons into Schedules.

The implementation of the Poisons Standard, as it affects access to and supply of medicines and poisons, is given legal effect through relevant State and Territory drugs, poisons and controlled substances legislation.

Again the contact details for the Drugs and Poisons Units for each Australian State and Territory are available at: https://www.tga.gov.au/contacts-stateterritory-drugs-poisons-units.

- ***What, if any, is the interaction between the World Health Organisation and Australian authorities?***

Since joining the WHO as a founding member in 1948, Australia has maintained a strong and active involvement in international health events and plays a significant part in shaping global health priorities. The Department of Health has a staff member based at the Australian Permanent Mission to the UN in Geneva to ensure regular and close engagement with the WHO.

Australia is a member of the WHO's Western Pacific Region and actively participates in Western Pacific Regional Committee meetings as well as broader WHO fora, including the World Health Assembly.

The Department of Health is responsible for payment of the Australian Government's assessed contribution to the WHO. This contribution enables us to retain membership of the WHO, to vote in the World Health Assembly, to

participate in technical forums, and to shape regional and global health priorities. Our engagement with the WHO serves to maintain Australia's position as a significant leader in the global health arena.

While the Department of Health is responsible for Australia's engagement with the WHO, the WHO also engages with a number of other government agencies and research institutes within Australia through their collaborating centres. These relationships are directly managed by the WHO.

Key involvement of the Australian Government with the WHO in recent years, include:

- EB Member 2004-2007, 2012-2015, and 2018-2021
- Host of 68th Regional Committee for the Western Pacific in Brisbane in October 2017;
- Co-chair Open-Ended Intergovernmental Meeting and Governance Reform 2016;
- CMO Chair of MERS IHR Emergency Committee 2013-2015 and member of Ebola IHR Emergency Committee 2014-2015;
- Chairman of the WHO Executive Board (EB) in 2013-2014;
- Chair of the WHO Intergovernmental Meeting on Pandemic Influenza Preparedness 2007-2009;
- Presidency of the 60th WHA in 2007;
- Chair of the WHO Programme, Budget and Administration Committee 2005-2007; and
- Vice Chair of the EB from 2005-2006.

- ***I am also looking for what I don't know.***

  SME Assist is a dedicated service that TGA offers to help small to medium enterprises (SMEs), researchers, start-ups and those unfamiliar with regulation. The SME assist page on the TGA website has various guidance articles, interactive decision tools, and where you can go for more help.

We trust the above information will be of assistance to you. The Scheduling Secretariat recommends that you seek the advice of a regulatory consultant to understand your legal obligations to adhere to Australian regulatory standards for medicines and chemicals scheduling.

Kind regards,

s22

The Chemicals and Medicines Scheduling Secretariat Team

Scheduling & Committee Support

Regulatory Engagement & Planning Branch | Regulatory Practice and Support Division
Health Products Regulation Group
Australian Government Department of Health
T: 1800 020 653 | E: chemicals.scheduling@health.gov.au and medicines.scheduling@health.gov.au
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

---------- Original Message ----------
From: s22 @gmail.com;
Received: 8/02/2019 1:27 PM

To: TGA Info (info@tga.gov.au);
Subject: Acceptance of International clinical trial developments in the regulation drugs [SEC=No Protective Marking]

Good Afternoon
I am a s22 of Mind Medicine Australia, a charitable organisation that is encouraging clinical research and education into the use of psychedelics to treat depression in various parts of the Australian community: https://mindmedicineaustralia.org. This development will hopefully help bring Australia up to speed with research conducted at Imperial College in the UK and John Hopkins in the USA in terms of palliative care and post traumatic stress disorders.
Part of the investigation involves us understanding the regulatory approval framework for the international rescheduling of substances in this case. I imagine it will be similar to developments with medicinal cannabis although there are some treaty differences.
I'll be grateful if you could provide me with information on how the TGA might accept clinical trial developments through the US FDA or UK/NZ authorities in administering the scheduling of substances. I am also interested in:

- what process does the TGA do through for the approval, scheduling of an unapproved substance or the down-scheduling of substances for therapeutic purpose that have been the subject of fully regulated clinical trials in those places?
- what conventions/agreements might apply between the TGA – I have looked at the law and website in some detail in an effort to understand how the TGA might do this. However, I cannot see much on issue of international precedent in reclassifying a Schedule 9 substance (perhaps in a similar process to medicinal cannabis)
- How the state and territory poisons advisory committees might be involved in the scheduling process
- What, if any, is the interaction is between the World Health Organisation and Australian authorities?

I am also looking for what I don't know. I appreciate this is a wide ranging query but would greatly appreciate the TGA's guidance on this. I haven't been able to find anything in law, treaties or on the TGA website.
I am aware that the TGA's International Engagement Strategy 2016-2020 is to recognise the work done overseas with the TGA as the final arbiter for scheduling and ARTG decisions. By way of background s22 so understand the general legal framework.
I will be in New Zealand until the 22nd of February and would be happy to speak with relevant people in the TGA directly on return to Sydney.
I look forward to hearing from you.
Best wishes
s22
(m) +s22

From: s22
To: SKERRITT, John
Cc: s22
Subject: TGA as promised - partnership proposal: Major International Medical Summit on Mental Illness 2020 [SEC=No Protective Marking]
Date: Friday, 13 March 2020 12:48:02 PM
Attachments: image001.png
image002.png
International Psychedelic Therapies Summit 2020 MMA - brief outline as at 10 February 2020.docx
Mind Medicine Australia Global Summit for Mental Illness Partnership Proposal - Feb 20 2020.pdf

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Dear John

Wonderful and inspiring to meet you. We are delighted to invite **TGA** to be a partner for this important global Summit. Hope to confirm soon and answer any of your questions. I am on s22 s22 .

Creative Innovation, Creative Universe and Mind Medicine Australia are producing a **major International Summit on Psychedelic-Assisted Therapies in the treatment of Mental Illness**. The Summit will be held at the Sofitel Melbourne from **18-19 November 2020**. We will need significant focus and collaboration to meet the enormous **mental health challenge** we are facing across our communities and our nation. This is an outstanding opportunity to **educate and reward key leaders and other partners and stakeholders**. You may also wish to provide **scholarships for emerging leaders** to participate in this ground-breaking global Summit.

The Summit will bring together clinicians, scientists, academics, mental and public health professionals, philanthropists, Government, law and policy makers, business, industry, investors, philanthropists and other interested stakeholders. The event will feature a rich 2-day program targeted specifically to **medical, scientific, research, allied health, legal, philanthropic and Government leaders** and emerging talent, with a mixture of international and national keynotes, master classes, hot spots, panel conversations and a gala dinner.

The Summit will be preceded by a 2 day therapist information workshop on **16-17 November 2020** led by **Professor** s22 (who developed the first academically accredited professional certificate training program for therapists for psychedelic assisted therapy in the US at the California Institute of Integral Studies) leading Psychotherapist and s22 s22 and Clinical Psychologist with the psilocybin trials at s22

We already have a range of leading international speakers committed for the 2-day summit including **Professor** s22 s22 at Imperial College London and lead advisor on the current s22 Phase 3 Trials on psilocybin assisted therapy for treatment resistant depression, **Dr** s22 psychiatrist, researcher and writer and currently leading the s22 trials on using MDMA therapy for alcohol dependence, **Dr** s22 s22 , Imperial College London, s22 s22 s22 s22 at Duke University, s22 s22 , s22 at the National Geographic Society and **Associate Professor** s22 s22 at Johns Hopkins University School of Medicine with a focus on psychedelic research for the treatment of mental illness, s22 s22 of Eleusis, **Dr** s22 s22 of

The Ethics Centre, **Professor** s22 s22 at St Vincent's Hospital and University of Melbourne and **Professor** s22 s22 and s22 s22 (See above).

We are attaching a proposal document for you. We would be delighted to welcome your organisation as one of our key partners. There are a range of partnership options for your consideration. We look forward to hearing from you and discussing which option is of greatest value for your organization. St Vincents has already confirmed a major partnership, Johns Hopkins University and Imperial College are also confirmed and a number of other organisations are showing keen interest.

There are a number of synergies and potential benefits from collaborating with us. You may also wish to engage these global leaders to speak/consult with your organisation and stakeholders during their time in Australia. Key themes and other information and partnership benefits are outlined in the attached document.

We'd be grateful if you would let me know what further information you need to confirm partnership of the 2020 Summit. We'd like to finalise key partners as soon as possible to give you the most leverage possible in the lead up.

We look forward to hearing from you soon re this and other collaboration opportunities.

Warmest love and gratitude

s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

MIND MEDICINE AUSTRALIA

From:	s22
To:	Medicines Scheduling
Cc:	s22
Subject:	Rescheduling Application for Psilocybin (spelt in the Poisons Standard with an "e" as Psilocybine) from Schedule 9 to Schedule 8. [SEC=No Protective Marking]
Date:	Tuesday, 14 July 2020 3:58:30 PM
Attachments:	ATT00001.htm Mind Medicine Australia Psilocybin Rescheduling S9 to S8 14 July 2020 FINAL.pdf ATT00002.htm

To: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

We have pleasure in lodging an Application to reschedule Psilocybin (spelt as Psilocybine in the Poisons Standard) from Schedule 9 to Schedule 8.

Accordingly we are attaching;

1. The completed Application Form which follows the prescribed form on the TGA website;

2. Appendix A which contains letters from Experts supporting the Rescheduling Application; and

3. A link to Appendix B which contains copies of papers referenced in the Application (A USB stick containing Appendix B has also been express posted to you): https://www.dropbox.com/s/0u1gwtog6y4o0ba/Mind%20Medicine%20Australia%20Psilocybin%20Rescheduling%20S9%20to%20S8%2014%20July%202020_Appendix%20B.pdf?dl=0

The Auspost Express Post tracking number for Appendix B is: 00 01045 28225 40060 60991

Could you please acknowledge receipt of this email and let us know if you require any further information.

Yours Faithfully

From: s22
To: Medicines Scheduling
Cc: s22
Subject: Fwd: Mind Medicine Australia Rescheduling Application - MDMA [SEC=No Protective Marking]
Date: Wednesday, 15 July 2020 4:53:47 PM
Attachments: ATT00001.htm
Mind Medicine Australia MDMA Rescheduling S9 to S8 15 July 2020 FINAL.pdf
ATT00002.htm

To: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

We have pleasure in lodging an Application to reschedule **N,a-Dimethyl-3,4 (methylenedioxy) Phenylethylamine (MDMA)** from Schedule 9 to Schedule 8 of the Poisons Standard.

Accordingly we are enclosing;

1. The completed Application Form which follows the prescribed form on the TGA website; and

2. Appendix A which contains letters from Experts supporting the Rescheduling Application.

A USB stick containing Appendix B (which contains copies of all of the papers referenced in the Application) has been express posted to you because it is too large to email.

The Auspost Express Post tracking number for Appendix B is: 00 01045 28225 10060 60990

Could you please acknowledge receipt of this email (and in due course the Express Post Parcel) and let us know if you require any further information.

Yours Faithfully

From: TGA Info
To: Medicines Scheduling
Subject: FW: Attention s22 [SEC=No Protective Marking] [SEC=OFFICIAL] CCEMS:07850000293
Date: Tuesday, 21 July 2020 1:45:30 PM
Attachments: image002.png
image001.png

Good afternoon

Please ensure that any internal correspondence, including this forwarding email, is deleted prior to sending the response.

Please find attached an email from - s22 @mindmedicineaustralia.org - for your follow up and response. If your area is not the appropriate area to respond to this email please let us know.

If you are responding directly to an external enquiry, you are responsible for ensuring that the TGA customer service standards are met.

If your area does not have access to a generic email address, the RAS can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.

If you have any questions about this email please contact s22 on s22 .

Kind regards

s22

Regulatory Assistance Service
Regulatory Guidance, Assistance and SME Section

Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

---------- Original Message ----------
From: s22

Received: Thu Jul 16 2020 11:24:35 GMT+1000 (AUS Eastern Standard Time)
To: TGA Info; info-Queue ;
Subject: Attention s22 [SEC=No Protective Marking]

Dear s22

Thanks again for your time over the phone today.

I was hoping you might be able to assist me with sourcing any information regarding the:

- Public consultation associated with the rescheduling of medicinal cannabis related compounds **from schedule 9**.

If there was no public consultation, or alternative process, would you mind providing me with information on how and why medicinal cannabis and its related compounds were rescheduled from schedule 9 to its current classifications.

Thanks again,

s22
s22
m: +s22
e: s22 @mindmedicineaustralia.org
Mind Medicine International
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: s22
To: Medicines Scheduling
Subject: Re: Scheduling application [SEC=OFFICIAL]
Date: Thursday, 23 July 2020 6:34 07 PM
Attachments: image001.png
image002.png
Importance: High

Dear s22

Thank you very much for confirming this to me

With best wishes

s22
s22
Mind Medicine Australia
s22
s22 @gmail com
www mindmedicineaustralia org

On 23 Jul 2020, at 2:51 pm, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:

Dear s22
Apologies for the delayed response.
I can confirm the Secretariat has received the Appendix B references for both application.
Best regards,

s22
The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health gov.au and chemicals scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga gov.au

<image001 gif>

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 20 July 2020 11:47 AM
To: Medicines Scheduling <Medicines.Scheduling@health gov.au>
Subject: Re: Scheduling application [SEC=OFFICIAL]

Dear s22
Thanks for confirming this Have you received the Appendix B refs for both applications?
With both wishes

s22
E: s22 @mindmedicineaustralia.org
P: +s22
www.mindmedicineaustralia.org

On 20 Jul 2020, at 9:52 am, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:

Dear s22
Just confirming the Secretariat has received the Appendix B references that were sent via express post.
Kind regards,

s22
The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health gov.au and chemicals scheduling@health.gov.au

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606
www.tga gov.au

From: Medicines Scheduling
To: s22
Cc: Medicines Scheduling
Subject: RE: MDMA Scheduling application [SEC=OFFICIAL]
Date: Tuesday, 18 August 2020 12:53:51 PM

Many thanks s22

Apologises. A typographical error on my part.

The amended Schedule 9 entry will be as you have identified, i.e. '... **except** when in Schedule 8'.

Best regards,

s22

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 17 August 2020 7:27 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22
s22 @mindmedicineaustralia.org>
Subject: Re: MDMA Scheduling application [SEC=OFFICIAL]
Importance: High

Dear s22

Thanks for your email. My only comment is that shouldn't the reference below "**except** when in Schedule 9" be a reference to "except when in Schedule 8"?

Please advise.

Thanks for your help with this.

With best wishes

s22

E: s22 @mindmedicineaustralia.org
P: +s22
www.mindmedicineaustralia.org

On 17 Aug 2020, at 4:27 pm, Medicines Scheduling

<Medicines.Scheduling@health.gov.au> wrote:

Dear s22

For the MDMA application, the pre-meeting public notice for MDMA will include the following amended Schedule 9 wording and Index entry in addition to the new proposed Schedule 8 wording:

Schedule 9 – Amend Entry
N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA) **except** when in Schedule 9.

Index- Amend Entry

N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE
cross reference: 3,4-METHYLENEDIOXY-N-α-DIMETHYLPHENYLETHYLAMINE, MDMA

Schedule 9
Schedule 8

If you have any objections, I would be grateful if you could advise me by **COB 12pm Tuesday 18 August 2020**.

Kind regards,

s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health.gov.au and chemicals.scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image005.gif>

should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: s22
To: Medicines Scheduling
Subject: Re: Rescheduling Application for Psilocybin [SEC=OFFICIAL]
Date: Monday, 17 August 2020 7:27:29 PM
Attachments: image001.png
image002.png

Dear s22

Thanks I have just responded

With best wishes

s22
Mind Medicine Australia
s22
s22 @gmail.com
www mindmedicineaustralia org

On 17 Aug 2020, at 4:30 pm, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:

Dear s22
Thank you for confirming the same for MDMA.
However, I have sent through another email regarding MDMA just to confirm the up-date entry as we need it for our records.
Best regards,
s22

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 17 August 2020 4:10 PM
To: Medicines Scheduling <Medicines.Scheduling@health gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org>
Subject: Re: Rescheduling Application for Psilocybin [SEC=OFFICIAL]

Dear s22
It's a pleasure The same will also apply to our MDMA rescheduling submission ie the rescheduling that we are seeking is only for the treatment of medical conditions
With best wishes

s22
Mind Medicine Australia
s22
s22 @gmail com
www mindmedicineaustralia org

<image001 png><image002 png>
On 17 Aug 2020, at 3:58 pm, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:
Dear s22
Many thanks for confirming the details of the scheduling proposal.
Best regards,
s22

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 17 August 2020 3:02 PM
To: Medicines Scheduling <Medicines.Scheduling@health gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org>
Subject: Re: Rescheduling Application for Psilocybin [SEC=OFFICIAL]
Importance: High

Dear s22
Thank you for your email I apologise for any ambiguity We are only seeking the down - scheduling of psilocybin for the treatment of medical conditions The way that you have expressed this below is therefore correct, I repeat it here for completeness;

Schedule 9 – Amend entry
PSILOCYBIN **except** when included in Schedule 8
Index – Amend Entry
PSILOCYBINE
Schedule 9
Schedule 8

Thank you for your help with this.
With best wishes

s22
Chair
Mind Medicine Australia
s22
s22 @gmail com

www mindmedicineaustralia org

<image001 png><image002 png>
On 17 Aug 2020, at 1:51 pm, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:
Dear s22
I am with regards the application to down schedule psilocybin from Schedule 9 to Schedule 8.
Based on the information provided in your application it is unclear whether the intent of the application is that only psilocybin for the treatment of medical conditions is down-scheduled?
If this is the case, the current Schedule 9 and Index entries would require amendment and the pre-meeting public notice would include the following information under the proposed scheduling:

Schedule 9 – Amend entry
PSILOCYBIN **except** when included in Schedule 8
Index – Amend Entry
PSILOCYBINE
Schedule 9
Schedule 8

I would be grateful if you could confirm if the above is an acceptable amendment to the scheduling proposed or if the application intent is to delete the existing Schedule 9 entry by**12pm Tuesday 18 August 2020.**
Kind regards,

s22
The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health gov.au and chemicals scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www tga gov au

<image005 gif>

From: TGA Info
To: Medicines Scheduling
Subject: FW: Att. s22 [SEC=No Protective Marking] [SEC=OFFICIAL] CCEMS:07410000584
Date: Thursday, 27 August 2020 11:35:51 AM
Attachments: image003.gif
image002.png
image001.png

Good morning

Please ensure that any internal correspondence, including this forwarding email, is deleted prior to sending the response.

Please find attached an email from - s22 @mindmedicineaustralia.org - for your follow up and response. If your area is not the appropriate area to respond to this email please let us know.

If you are responding directly to an external enquiry, you are responsible for ensuring that the TGA customer service standards are met.

If your area does not have access to a generic email address, the RAS can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.

If you have any questions about this email please contact s22 on s22 .

Kind regards

s22

Regulatory Assistance Service
Regulatory Guidance, Assistance and SME Section

Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

---------- Original Message ----------
From: s22

Received: Wed Aug 26 2020 14:17:37 GMT+1000 (Australian Eastern Standard Time)
To: info@tga.gov.au; info@tga.gov.au; info-Queue ;
Cc: s22 @gmail.com;
Subject: Att. s22 [SEC=No Protective Marking]

Dear s22

Thank you again kindly for your time today. If you could pass on my enquiry to the medicines scheduling team as discussed just now over the phone and ensure a response is received, that would be greatly appreciated.

Referencing the document "Consultation: Proposed amendments to the Poisons Standard – ACCS, ACMS and joint ACCS/ACMS meetings, November 2020 ; 26 August 2020"

I'm writing to alert the medicines scheduling team to 3 points of concern we have identified within the document issued today.

- Firstly, the 'y' in psylocybin (psilocybin) under point 1 – Australian regulations – page 25.
- Secondly, I would like to enquire as to why the section here, is only partially highlighted in red:

- **Schedule 8 – New Entry**
  PSILOCYBIN for use in the treatment of medical conditions:

a. In preparation for oral use as part of psychotherapy under the authorisation of a treating psychiatrist or specialist addiction physician in a medically controlled environment;
b. Manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or

c. Imported or manufactured in Australia as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
d. In therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989.*

Index – Amend Entry
PSILOCYBINE
Schedule 9

Schedule 8

Whereas the exact same excerpt, from MDMA, is wholly highlighted? See below.

Schedule 8 – New Entry
N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA) for use in the treatment of medical conditions:

a) In preparation for oral use under the authorisation of a treating psychiatrist or addiction specialist physician in a medically controlled environment;
b) Manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
c) Imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
d) In therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989.*

Index- Amend Entry
N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE
cross reference: 3,4-METHYLENEDIOXY-N-α-DIMETHYLPHENYLETHYLAMINE, MDMA
Schedule 9
Schedule 8

- Finally, why, in these same sections, item C in schedule 8 – New Entry (1.6 MDMA); or manufactured in Australia' is omitted? It is mentioned, as highlighted, in the same section under 1.5 Psilocybin. We advise the highlighted excerpt should be included in section C of *both* psilocybin and MDMA.

Thank you again for your assistance, I look forward to receiving a response shortly.
Warmly,

s22 [redacted]

Zoom Drop in - Wednesday's 12:00-1:00pm : s22 [redacted]
m: +s22 [redacted]
e: s22 [redacted] @mindmedicineinternational.org
Mind Medicine International
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineinternational.org

signature_2120714277

From: s22
To: Medicines Scheduling
Subject: Re: MDMA Scheduling proposal [SEC=OFFICIAL]
Date: Thursday, 17 September 2020 1:23:19 PM
Attachments: image001.png
image002.png

That's great Thanks s22

Best

s22

s22
Mind Medicine Australia
s22
s22 @gmail.com
www.mindmedicineaustralia.org

On 17 Sep 2020, at 10:42 am, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:

Dear s22
Just confirming that the pre-meeting public notice for November has been up-dated.
Kind regards,
s22

From: s22 @mindmedicineaustralia org>
Sent: Tuesday, 15 September 2020 3:58 PM
To: Medicines Scheduling <Medicines Scheduling@health.gov au>
Cc: s22 @mindmedicineaustralia.org>
Subject: Re: MDMA Scheduling proposal [SEC=OFFICIAL]
Importance: High

Dear s22
I am very sorry that I missed this Unfortunately your email went into my span emails and I didn't pick it up
Yes I can confirm that your approach below is correct Thank you for your help with this
With best wishes

s22
E: s22 @mindmedicineaustralia.org
P: s22
www.mindmedicineaustralia.org

On 1 Sep 2020, at 2:39 pm, Medicines Scheduling <Medicines Scheduling@health gov au> wrote:
Dear s22
The pre-meeting public notice for MDMA indicates that the proposed new Schedule 8 entry is as follows:
Schedule 8- New Entry
MDMA for use in the treatment of medical conditions:
a) In preparation for oral use under the authorisation of a treating psychiatrist or addiction specialist physician in a medically controlled environment
b) Manufactured in accordance with the Narcotic Drugs Act 1967; and/or
c) Imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or
d) In therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989
As per our telephone discussion, the wording at 'c)' should be consistent with the equivalent wording in the propose new Schedule 8 entry for Psilocybin, i e.:
'Imported **or manufactured in Australia** as therapeutic goods, or for use in therapeutic goods for supply in accordance the Therapeutic Goods Act 1989; and/or'.
As the wording in the public notice is consistent with the application can you please confirm that the proposed new entry should be:
Schedule 8- New Entry
MDMA for use in the treatment of medical conditions:
a) In preparation for oral use under the authorisation of a treating psychiatrist or addiction specialist physician in a medically controlled environment
b) Manufactured in accordance with the Narcotic Drugs Act 1967; and/or
c) Imported **or manufactured in Australia** as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or
d) In therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989.
If this correct, I will request that the public notice be up-dated.
Kind regards,
s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health.gov.au and chemicals.scheduling@health.gov au

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22
To: Medicines Scheduling
Subject: Re: Att medicines scheduling [SEC=OFFICIAL]
Date: Thursday, 1 October 2020 1:46:07 PM
Attachments: image001.png
image002.png
image003.gif
image004.gif
image005.png
image006.png
image007.gif

Thanks kindly,

s22
Zoom Drop in - Wednesday's 12:00-1:00pm s22
m: +s22
e: s22 @mindmedicineinternational.org
Mind Medicine International
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineinternational.org

signature_1304065982

From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Date: Thursday, 1 October 2020 at 1:33 pm
To: s22 @mindmedicineaustralia.org>
Subject: RE: Att medicines scheduling [SEC=OFFICIAL]

Dear s22
Yes I can confirm that we have received the submission from Dr s22 .
Kind regards,

s22
The Chemicals and Medicines Scheduling Secretariat Team

Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health.gov.au and chemicals.scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 29 September 2020 10:34 AM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: TGA Info <info@tga.gov.au>
Subject: Att medicines scheduling

Hi Medicines Scheduling and s22
We were hoping to receive a confirmation that this submission had been received in relation to the rescheduling of psilocybin and MDMA. It was emailed to you yesterday at 5:30pm -ish.
Thank you,

s22
Zoom Drop in - Wednesday's 12:00-1:00pm : s22
m: +s22
e: s22 @mindmedicineinternational.org
Mind Medicine International
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineinternational.org

signature_524240012

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Please consider the environment before printing this email

s22
Psychiatrist, Child and Adolescent specialist
s22

Submission of support for psilocybin and MDMA

I have worked as a doctor and psychiatrist in a wide variety of settings with a very broad age range of patients suffering from a wide variety of mental illness for 20 years. I currently enjoy a permanent position within s22 specialising in child and youth mental health and also work in my private practice where I see people of all ages.

Throughout my career I have taken a keen interested in both medication and longer-term therapeutic approaches. Both clearly have their place. During the 20 years of my practice, there have been no significant breakthroughs in mental health treatment. Therapeutic approaches *have* evolved and incorporate more mindfulness, meditation and Eastern influences that have helped many. The importance of physical health has also been recognized. Unfortunately despite the above changes, the mental health of Australians is worsening. There are multiple reasons for this but, tellingly, there have been no advances in the *biological* treatment of mental health conditions during my career. The statistics grimly bear witness to this lack of improvement. Australia's suicide rate is an unambiguous indication of people's untreated distress. Any deep consideration of this is profoundly unsettling. If you have not lost someone you know to suicide then be very thankful because if you have, you suddenly understand the terrible way it tilts the world askew. It is a profoundly difficult and uncomfortable idea to confront. And every single day over 8 Australians kill themselves.

This stagnation in the field leads me to the results of past and proceeding trials of psilocybin that have come to my attention over the past two years. I should start by saying my initial reaction to both psilocybin and MDMA research was negative and was influenced by the association of these substances with recreational use in certain subcultures. I dismissed the use of these powerful, mind-altering substances in a clinical setting as irresponsible. I probably can't escape having a science teacher for a mother

however (herself raised by a medical researcher) – whose memorable sayings not only include *"you can either be sceptical or you can be stupid"* but also *"everyone is always in danger of not finding out anything other than what they already know"*. She said this in one way or another just last week in fact. Not only that, I began to have patients or friends spontaneously asking what I knew about this emerging research area.

Upon reading the history of psychedelics (psilocybin and MDMA included) and listening to scientists and psychiatrists that I respected speaking about these substances (initially s22 , s22 , s22 , s22 , s22), I began to place my prejudices to one side and look more objectively at the emerging current research into Psychedelic Assisted Psychotherapy (PAP). I was struck by the innovation of a treatment that simultaneously focussed on both mind and brain. I was impressed by the caution being shown by researchers and the quality of the institutions that were taking the lead. The safety and side effect profile of both substances, *given a well-selected population group and the proper clinical environment*, was extremely reassuring, as was the evidence that they are not addictive (which does not mean they cannot be abused – as can many medications). Most surprisingly I found the efficacy with respect to treatment resistant depression, anxiety and PTSD absolutely remarkable.

I believe psilocybin and MDMA have a role, perhaps an extremely important one, in the treatment of psychiatric illnesses. I am convinced that there is now enough accumulated evidence to allow treating psychiatrists to use either of them as a legitimate augmenting agent for some of their patients. *Because these medications are powerful consciousness altering agents and have indications for therapeutic use in a particularly vulnerable patient population it is vitally important they are used in a highly supervised way with carefully selected patients* (as it has been done in research studies overseas). I do believe there should be some basic requirements with respect to use within a medical context. I see preparatory appointments and debriefing appointments as an essential component for therapeutic benefit. And I see two-person supervision and/or routine video monitoring during the period of alteration of consciousness as essential for patient safety. These medications obviously also need to be kept very securely and monitored very rigorously,

which is the point of the TGA controls that are already established with a wide variety of other important medical compounds.

As I have read and discussed psilocybin and MDMA with colleagues in Australia and overseas, I have made my way from initial dismissal, to scepticism, to a far more positive position with respect to their potential, and to now seeing the current level of restrictions on research and use as overly restrictive. I have in fact moved to now believe that to ***not*** support this line of investigation further would be unethical. To ignore treatments with such obvious potential would be to neglect my longest-suffering patients, many of whom have trialled dozens of medications and therapies without significant improvement in their levels of distress or functioning. In fact there have been hundreds of patients I have known through my career that the current mental health system and treatments have not been able to help in any meaningful way. If there are ***safe*** options that ***could*** change these patients' trajectory, I want to have the option to respectfully and carefully offer that to them. Having witnessed first-hand the long-term burden of chronic mental illness (not only to patients but to children, families and the entire health care system), I see this new paradigm of treatment options as being potentially life-altering for some patients and potentially enormously cost effective for the health system (compared to the current paradigm). It would be profoundly disappointing to see Australia lag behind other countries that have started to recognise the benefits of these medications and who are boldly but safely acting on this recognition.

From: GILL, Tony
To: [redacted] ; Medicines Scheduling
Subject: FW: Links provided by Mind Medicine on recent trials of MDMA and psilocybin [SEC=OFFICIAL]
Date: Wednesday, 23 December 2020 1:44:56 PM
Attachments: image011.png
image012.png
image013.gif

FYI

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Wednesday, 23 December 2020 1:33 PM
To: GILL, Tony <Tony.Gill@health.gov.au>; COOK, Jane <Jane.Cook@health.gov.au>; [redacted]@health.gov.au>
Subject: Links provided by Mind Medicine on recent trials of MDMA and psilocybin [SEC=OFFICIAL]

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: [redacted].com.au>
Sent: Wednesday, 23 December 2020 1:02 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: [redacted]@gmail.com>
Subject: Some links as promised

Dear John
Excellent to speak as always.
Here are some relevant links as promised:
OREGON legalises psilocybin for mental health
https://www.scientificamerican.com/article/psilocybin-treatment-for-mental-health-gets-legal-framework/
CANADA
https://www.vice.com/en/article/4adw4w/canada-is-allowing-people-with-depression-to-do-psychedelic-mushrooms
https://edition.cnn.com/2020/08/06/world/canada-psychedelic-mushrooms-cancer-therapy-trnd/index.html
https://nowtoronto.com/news/health-care-professionals-okayed-to-use-magic-mushrooms-for-training-in-psilocybin-therapy
Trial comparing SSRIs to psilocybin at Imperial College – completing over next 2-3 months
https://clinicaltrials.gov/ct2/show/NCT03429075
https://www.theguardian.com/commentisfree/2020/jun/08/psychedelic-drugs-treat-depression
Information on:
https://mindmedicineaustralia.org.au/certificate-in-psychedelic-assisted-therapies-cpat/
We wish you every happiness in this coming year.
[redacted]

Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

From: s22
To: Medicines Scheduling
Cc: s22
Subject: URGENT
Date: Tuesday, 2 February 2021 10:26:11 AM
Attachments: image001.png
image002.png
image003.gif

Hi Medicines Scheduling,
Would you be able to tell me what exact time tomorrow the decisions on the rescheduling of this round of medicines is released? Specifically psilocybin and MDMA.
Additionally, are the reasons for the decision released at the same time or at a different time?
Thanks in advance,

s22

Zoom Drop in - Wednesday's 12:00-1:00pm : s22
m: +s22
e: s22 @mindmedicineinternational.org
Mind Medicine International
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineinternational.org

signature_928951209

From: REBERA, Avi
To: s22
Cc: Medicines Scheduling; s22 ; s22
Subject: RE: Interim scheduling decisions [SEC=OFFICIAL]
Date: Wednesday, 10 February 2021 11:21:43 PM
Attachments: image001.png
image002.png
image003.png
image004.gif

Thanks s22
Cheers
Avi
Avi Rebera
Assistant Secretary
Regulatory Engagement, Education & Planning Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health
T: + 61 2 6289 2247 | M: +s22 | E: avi.rebera@health.gov.au
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Wednesday, 10 February 2021 5:33 PM
To: REBERA, Avi
Cc: Medicines Scheduling ; s22 ; s22
Subject: RE: Interim scheduling decisions [SEC=OFFICIAL]

Hi Avi
Please find attached the brief for tomorrow's afternoon meeting with Mind Medicine Australia.
Please let me know if you have any queries or require additional information.
Regards
s22

From: REBERA, Avi <Avi.Rebera@health.gov.au>
Sent: Wednesday, 10 February 2021 8:39 AM
To: s22 @health.gov.au>; s22
s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: Interim scheduling decisions [SEC=OFFICIAL]

Hi s22 – please see below email and attachments for the meeting tomorrow.
Could someone please provide me with a short brief for the meeting including highlighting if there is anything new in this email to their original submission. 2 pages will be sufficient.
Can you please also let me know who from the team will be attending.
Please call me if you have any questions.
Thanks.
Avi
Avi Rebera
Assistant Secretary
Regulatory Engagement, Education & Planning Branch

Regulatory Practice & Support Division | Health Products Regulation Group

Australian Government Department of Health
T: + 61 2 6289 2247 | M: s22 | E: avi.rebera@health.gov.au
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 .com.au>
Sent: Tuesday, 9 February 2021 11:36 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>
Cc: s22 @mtaust.com>; s22 .com.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>; s22 s22 @gmail.com>
Subject: RE: Interim scheduling decisions [SEC=OFFICIAL]

Dear Avi and team

We look forward to discussing the Interim Decision with you on Thursday.

A few important matters include the reliance on the RANZCP Clinical Memorandum and the views of PRISM, wrongly referred to in the Interim Decisions as a peak body (which it clearly is not).

By way of background we are attaching:

1. **RANZCP Clinical Memorandum**: There are no Authors named and no disclosure around peer review, who reviewed it and their connections to pharma companies
2. **Critique of that Memorandum** authored by nine academics confirming that it contains many false, misleading and prejudicial statements. Numerous psychiatrists have spoken publicly about its lack of veracity and prejudicial language, and the fact that it is preventing them from treating very unwell and potentially suicidal patients (including many Veterans) through their SAS-B approvals. The Clinical Memorandum and the RANZCP's position is not a reliable basis for rejecting the application.
3. **An article in The Conversation** by the two key Directors of PRISM. This was **annotated by MMA** to show their lack of understanding of critical aspects of rescheduling and a range of **governance issues** surrounding their charity. It contained a significant number of errors, misleading statements and lack of disclosure.
4. We'd also like to direct you to the **Certificate in Psychedelic-Assisted Therapies** through this link https://cpat.mindmedicineaustralia.org/ Please note the calibre of the Teaching Faculty which is 'best of breed' world standard.
5. The joint venture announcement between Emyria Ltd (A medical clinic group with representation around Australia) and MMA relating to the **development of protocols, standard operating practices and a registry. These are all now well advanced.**
6. **MMA's most recent presentation** on these treatments. We would draw your attention specifically to pages 9-17 which illustrate the calibre of our Board, Ambassadors and Advisory Panel members. You will see that MMA has much stronger credentials in terms of understanding these treatments because of our world class advisors and team than any other institution or organisation in Australia or the Asia-Pacific region.

Could you also please look at the **Appendices to our Original Applications which contain letters from global experts and list a large number of other experts both from Australia and overseas who support these applications.**

We very much look forward to discussing the Interim Decision and what we need to do in our

upcoming Submission to ensure the Delegate and the Advisory Panel are properly briefed.
Kind regards
s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

From: REBERA, Avi <Avi.Rebera@health.gov.au>
Sent: Monday, 8 February 2021 2:39 PM
To: s22 .com.au>
Cc: s22 @mtaust.com>; s22 .com.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>; s22 s22 @gmail.com>
Subject: RE: Interim scheduling decisions [SEC=OFFICIAL]
Hi s22 Certainly happy to get any background material ahead of the meeting.
Likewise looking forward to talking on Thursday.
Cheers
Avi
Avi Rebera
Assistant Secretary
Regulatory Engagement, Education & Planning Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health
T: + 61 2 6289 2247 | M: s22 | E: avi.rebera@health.gov.au
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 .com.au>

Sent: Monday, 8 February 2021 2:35 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>
Cc: s22 @mtaust.com>; s22 .com.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>; s22 s22 @gmail.com>
Subject: RE: Interim scheduling decisions [SEC=OFFICIAL]

Thanks Avi
We look forward to speaking with you and team on Thursday. Would it be helpful to send some background info prior?
Kindest s22

From: REBERA, Avi <Avi.Rebera@health.gov.au>
Sent: Monday, 8 February 2021 10:29 AM
To: s22 .com.au>
Cc: s22 @mtaust.com>; s22 .com.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>
Subject: FW: Interim scheduling decisions [SEC=OFFICIAL]

Hi s22
Hope you had a good weekend.
Following on from John's email below, I have responsibility for the scheduling secretariat and happy to catch up and discuss the decision and process.
Please let me know some available times and I can organise the necessary people from TGA to attend.
If it's easier, s22 can contact s22 (in my office) to set a time. s22 number is s22
I look forward to catching up.
Regards
Avi

Avi Rebera
Assistant Secretary
Regulatory Engagement, Education & Planning Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health
T: + 61 2 6289 2247 | M: +s22 | E: avi.rebera@health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Sunday, 7 February 2021 3:32 PM
To: s22 .com.au>
Cc: s22 @mtaust.com>; s22 .com.au>; s22 s22 @health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>
Subject: Interim scheduling decisions [SEC=OFFICIAL]

s22
Thanks for your note. I wasn't involved in the interim decision so I think you would learn a lot more about the decision and process for final decisions by talking with the head of the scheduling secretariat. If you would like I can arrange for a teleconference with them to be set up at a

mutually convenient time.
Please advise.
Regards
John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 .com.au>
Sent: Sunday, 7 February 2021 2:04 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @mtaust.com>; s22 .com.au>; s22 s22 @health.gov.au>
Subject: RE: quick call with s22 and I pre-xmas [SEC=OFFICIAL]

Dear John
We hope all is well.
We were disappointed and surprised by the Interim Decision because the reasons given don't seem to be very convincing and there appears to be some confusion. Could we please arrange a time to speak with you to discuss the Interim Decision over the next few days. We will find this very valuable as we prepare our final submission.
s22 will help organise a time.
Kindest regards

s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org



From: SKERRITT, John <John.Skerritt@health.gov.au>

Sent: Sunday, 13 December 2020 6:04 PM
To: s22 .com.au>
Cc: s22 @mtaust.com>; s22 .com.au>; s22 s22 @health.gov.au>
Subject: RE: quick call with s22 and I pre-xmas [SEC=OFFICIAL]

OK, this coming week is totally full but some spots in the diary early the following week

Regards

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 .com.au>
Sent: Thursday, 10 December 2020 3:09 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @mtaust.com>; s22 .com.au>
Subject: quick call with s22 and I pre-xmas

Dear John

How are you after this crazy year?!

s22 and I would like to have a quick convo with you prior to Xmas. What days and times would suit? s22 will send you some poss times now.

Warm regards

s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Medicines Scheduling
To: s22 Medicines Scheduling
Cc: s22
Subject: RE: Submission Inquiry - Urgent [SEC=OFFICIAL]
Date: Tuesday, 16 February 2021 3:35:40 PM
Attachments: image004.png
image006.png
image001.png

Dear s22

Thank you for your enquiry. Public consultation periods on proposed changes to the Poisons Standard, both pre- and post-meeting of the Advisory Committees, are open to all members of the public regardless of whether they have previously made a submission or not.

Kind regards

s22

Regulatory Scientist - Scheduling and Committee Support

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 16 February 2021 2:46 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 @gmail.com>; s22 @mindmedicineaustralia.org>
Subject: Submission Inquiry - Urgent
Importance: High

Dear Medicines Scheduling Unit,

We hope you're all keeping well.

We're wondering whether there are any restrictions on who can make a public submission for the most recent public submissions opening on interim decisions?

See here : https://consultations.health.gov.au/tga/november_2020_interim/

We were under the impression that only those who made a submission in the first round, could make submissions in the second round. Could you confirm or deny this please.

Please feel free to respond via email or phone call, my number is below.

We look forward to hearing from you shortly,

s22

Zoom Drop in - Wednesday's 12:00-1:00pm : s22

m: +s22

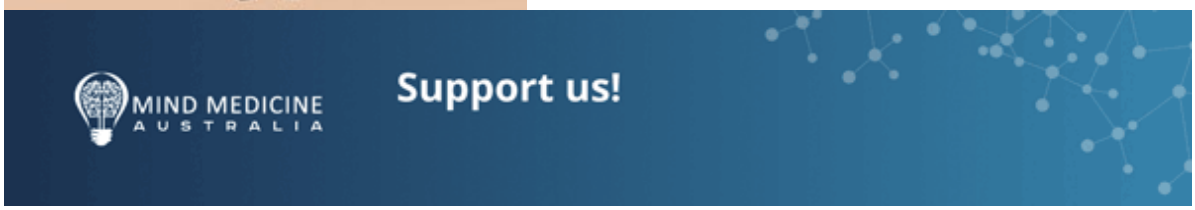
e: s22 @mindmedicineinternational.org

Mind Medicine International

Level 1 | 10 Dorcas St, Southbank

www.mindmedicineinternational.org

MIND MEDICINE INTERNATIONAL



From: s22
To: Medicines Scheduling
Cc: s22
Subject: Submission in relation to the Delegate"s interim decision on Psilocybin as part of therapy (spelt in the Poisons Standard with an "e" as Psilocybine) from Mind Medicine Australia (the original applicant)
Date: Thursday, 4 March 2021 1:56:33 PM
Attachments: image001.jpg
TGA Interim Submission psilocybin FINAL_040321.pdf

Dear Sir/Madam,

We have pleasure in lodging a Submission opposing the Delegate's Interim Decision not to reschedule Psilocybin (spelt as Psilocybine in the Poisons Standard from Schedule 9 to Schedule 8. We are the Applicant in relation to this rescheduling submission.

Accordingly, we are attaching;

1. The completed submission by Mind Medicine Australia to be considered;
2. A link to the papers referred to in Appendix G (A USB stick containing the full reference papers has also been express posted to you): https://www.dropbox.com/sh/wcam96rulr6kahh/AABYA3zzLzftcIO469WH89cga?dl=0

The Auspost Express Post tracking number for the Appendices is: 604 39971120 097
Could you please acknowledge receipt of this email and let us know if you require any further information.

Yours Faithfully

s22
Mind Medicine Australia

From: Medicines Scheduling
To: s22 @mindmedicineaustralia.org
Subject: RE: Submission in relation to the Delegate"s interim decision on MDMA as part of therapy (N,a-Dimethyl-3,4 (methylenedioxy) Phenylethylamine) from Mind Medicine Australia (the original applicant) [SEC=OFFICIAL]
Date: Wednesday, 10 March 2021 10:57:51 AM

Dear s22

We have now received the Appendix G papers, for both psilocybin and MDMA, that you sent us by mail.

Kind regards,

s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health.gov.au and chemicals.scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: Medicines Scheduling
Sent: Thursday, 4 March 2021 4:04 PM
To: s22 @mindmedicineaustralia.org>
Subject: RE: Submission in relation to the Delegate's interim decision on MDMA as part of therapy (N,a-Dimethyl-3,4 (methylenedioxy) Phenylethylamine) from Mind Medicine Australia (the original applicant) [SEC=OFFICIAL]

Dear s22

Thank you for your submission regarding the interim decision on MDMA. Your response, and all other submissions received by the deadline, will be considered by the Delegate in making their final decision.

Note that we cannot access the files linked in your email, but we will advise you when we receive the USB stick that you have sent us.

The submissions received in response to the interim consultation, along with the final decision, will be published on the TGA website in April 2021. To assist us in the processing of your privacy information, please complete the public submission cover sheet and submit via return email (medicines.scheduling@health.gov.au) at your earliest convenience. Otherwise, we will not be able to publish your submission on our website.

Kind regards,

s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Engagement, Education and Planning Branch

Phone: 1800 020 653
Email: medicines.scheduling@health.gov.au and chemicals.scheduling@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Thursday, 4 March 2021 2:06 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 @gmail.com>; s22 @mindmedicineaustralia.org>; s22 s22 .com.au>
Subject: Submission in relation to the Delegate's interim decision on MDMA as part of therapy (N,a-Dimethyl-3,4 (methylenedioxy) Phenylethylamine) from Mind Medicine Australia (the original applicant)

Dear Sir/Madam,

We have pleasure in lodging a Submission opposing the Delegate's Interim Decision not to reschedule N,a-Dimethyl-3,4 (methylenedioxy) Phenylethylamine (MDMA) from Schedule 9 to Schedule 8.
We are the Applicant in relation to this rescheduling submission.

Accordingly, we are attaching;

The completed submission by Mind Medicine Australia to be considered;

A link to the papers referred to in Appendix G (A USB stick containing the full reference papers has also been express posted to you): https://www.dropbox.com/sh/z3emgv110ybejoy/AAA48Tf23YpganqoIg8etVo_a?dl=0

The Auspost Express Post tracking number for the Appendices is: 604 39971117 097

Could you please acknowledge receipt of this email and let us know if you require any further information.

Yours Faithfully

s22 [redacted]

s22 [redacted]
Mind Medicine Australia

From: s22
To: s22
Cc: s22 ; Medicines Scheduling
Subject: FW: Global Drugs Survey and Other Matters [SEC=OFFICIAL]
Date: Thursday, 11 March 2021 3:54:31 PM
Attachments: image001.png
image002.png
s22 supports psychedelic therapy 7 Mar 21.docx

FYI

From: s22 @gmail.com s22 @gmail.com>
Sent: Thursday, 11 March 2021 2:59 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>
Cc: SKERRITT, John <John.Skerritt@health.gov.au>; s22
s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org>
Subject: Global Drugs Survey and Other Matters

Hi Avi and s22

You have probably seen this article that appeared in Sunday's Canberra Times. One of the things that the Article refers to is the recently released international drugs survey data which demonstrates the trend towards people with mental illness self- medicating with psychedelics because they can't access these treatments through the medical system - https://www.canberratimes.com.au/story/7155638/canberra-should-be-first-to-introduce-psychedelic-therapy-says-greens-mp/. This is not something that we want to see because of the risks involved (medicine purity, outside of a medically controlled environment and untrained therapists) but we believe that more and more desperate people will do this if they can't access these treatments on a case by case basis through our medical system.

There was also an article on today's ABC's 0nline portal that can be found here - https://www.abc.net.au/news/2021-03-11/andrew-robb-advocates-for-psychedelic-therapy/13230944. We are again seeing the s22 making statements without first doing the work to understand these therapies. As you will see the s22 s22 , talks about these substances being addictive in a medically controlled environment which is nonsense as are his comments about safety and efficacy and these therapies not being legitimately available overseas.

I hope this is helpful

With Best Wishes

s22

m: +s22
e: s22 @mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: s22
To: GILL, Tony; Medicines Scheduling
Subject: FW: Urgent: Letter from s22 AM to Adjunct Professor John Skerritt March 22 2021 [SEC=OFFICIAL]
Date: Monday, 22 March 2021 8:41:15 AM
Attachments: Letter from s22 AM to Adjunct Professor John Skerritt March 22 2021.pdf

FYI

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Sunday, 21 March 2021 9:20 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Subject: FW: Urgent: Letter from s22 AM to Adjunct Professor John Skerritt March 22 2021 [SEC=OFFICIAL]

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Sunday, 21 March 2021 7:47 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org
Subject: Urgent: Letter from s22 AM to Adjunct Professor John Skerritt March 22 2021

Dear John

s22 and I very much appreciated the time that you gave to us last Thursday. Please find letter attached which follows up on that call.

With best wishes

s22

m: s22
e: s22 **@mindmedicineaustralia.org**
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

MIND MEDICINE AUSTRALIA

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health
Canberra, ACT

March 21, 2021

Dear John

Rescheduling of medicinal use of MDMA and Psilocybin as part of Psychotherapy

Thank you for making time available to us last Thursday to discuss the above. We remain concerned that the TGA and the Delegate are placing a higher standard on the proposed rescheduling of the medicinal use of MDMA and psilocybin as part of psychotherapy in medically controlled environments than that which is warranted by the TGA's Rescheduling Policy Guidelines. We also remain concerned that the quality of reasoning in the Interim Decisions suggests that the Delegate didn't carefully read our original applications and may therefore not properly consider our current Submissions in relation to the Interim Decisions.

During our discussion we mentioned that current treatments (primarily SSRI's and psychotherapy) didn't work for many patients with treatment resistant depression and treatment resistant PTSD and that these pharmaceuticals were addictive and often had nasty side effects. See the views of leading Australian research psychiatrist, Professor Paul Fitzgerald here: https://medium.com/@pbfitzgerald/the-challenges-of-depression-treatment-in-2020-abd74269764

Australia is now in the unsatisfactory position that, pre-Covid, 1 in 8 Australians were on SSRIs (up 95% over 15 years) including I in 4 older Australians and 1 in 30 young Australians (including children as young as four). Yet despite this massive growth in the use of these medications Australia's mental health statistics continue to get worse.

According to the TGA website the scheduling in the Poisons Standard is all about *"…the level of regulatory control over the availability of the medicine…required to protect public health and safety"* and *"…the risk of harm and level of access control required to protect consumers".* This is then viewed in the context of the factors set out in Section 52E of the Therapeutic Goods Act.

In our original applications we not only listed a large number of studies which confirmed the safety and established therapeutic value of these substances, we also supported this analysis with letters of confirmation from leading experts in these therapies from around the World. We also had named support from a large number of other psychiatrists,

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psychologists, pharmacologists, researchers and other scientists. Finally, we offered to put the TGA in direct contact with world-leading experts so that it could verify our views.

In our recent Submissions we have responded in detail to each factor listed by both the ACMS and the Delegate as support for the Interim Decisions and added new information including:

1. The results of a new clinical trial conducted at Imperial College London comparing psilocybin assisted therapy with a leading SSRI which showed that psilocybin as part of psychotherapy was much more effective and associated with significantly less adverse effects than the SSRI combined with psychotherapy (whilst the results are confidential until publication we have forwarded, on a confidential basis, a summary to Mr Avi Reberra of your Medicines Rescheduling Unit provided by lead researcher Professor s22 of Imperial College London);
2. The results of a Phase 3 clinical trial provided to us by the sponsor, MAPS, which confirms that MDMA assisted psychotherapy for PTSD is much more effective than the placebo (psychotherapy without MDMA) and also considerably safer. Whilst these results are also confidential until publication, we have been authorised by MAPS to provide the full paper to the TGA on a confidential basis (we will email this to Mr Avi Reberra at the Medicines Rescheduling Unit on Monday).
3. The results of a new study of the safety and tolerability of MDMA assisted psychotherapy in patients with alcohol use disorder which showed that MDMA was well tolerated by participants with no unexpected adverse events and outstanding detox results.
4. The existence of expanded access schemes and exemptions in the US, Canada, Israel and Switzerland which allow medical practitioners to apply for patient-by-patient approvals and (unlike Australia) give them the ability to actually implement these therapies. Psilocybin asssisted psychotherapy is also legally available in Holland.
5. The minimal nature of diversion risk in terms of illegal access for recreational purposes (these medicines in synthetic medical grade form are far more expensive then accessing these substances from either the black market where they are readily obtainable or in the case of psilocybin by simply picking the mushrooms in the wild); tried and tested Schedule 8 controls; and the fact that unlike most other psychiatric medicines the patient will never be able to take the medicines home).
6. The infrastructure being sponsored by Mind Medicine Australia to ensure that these medicine-assisted therapies can be safely and effectively conducted in medically controlled environments including World's best practice training, protocols, standard operating procedures, data registries and training manuals.

In our discussion you mentioned the fact that both the Royal Australian and New Zealand College of Psychiatrists and the AMA had opposed our rescheduling applications. This is despite the fact that rescheduling was supported by 98% of submissions

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lodged with the TGA of which over half came from medical professionals. Unfortunately, it is readily apparent from the RANZCP and AMA submissions that neither organisation has done the work necessary to form a considered view about these therapies (see Section 3.2.3 and Section 3.4 of our Submissions) and despite attempts by us neither party has shown any interest in being briefed by World leading experts (which we have offered to arrange). Hubris, bias and vested interests are palpable.

We would in particular draw your attention to Table 5 in Section 3.4 of our Submissions which sets out in summary form the key mistakes highlighted by a group of 9 researchers that were made by RANZCP in its May 2020 Clinical Memorandum on the Therapeutic Use of Psychedelic Substances (the full critique is set out in Appendix C of our Submissions) . It seems to us that to be respected and relied upon as a peak body RANZCP needs to do the hard work required to properly understand the use of these therapies in a medically controlled environment which they have patently failed to do.

Australians with treatment resistant depression and treatment resistant PTSD should not be left to suffer (and some will die) because of the demonstrable hubris of these organisations.

We would also draw to your specific attention to Table 7 in Section 3.4 of each of our Submissions which contains a letter from Professor s22 (s22 s22 at Imperial College London and one of the leading experts in the World on the medical use of these substances as part of psychotherapy) that the Critique by the Researchers of the RANZCP clinical memorandum was impressive ("*The authors have given a comprehensive overview of the issues and the considerable amount of data that now exists to support the use of these medicines").*

Professor s22 goes on to say that the safety data is strong, and that "*There is outstanding evidence of the neuroscience behind the therapeutic effects of these medicines"* and that "*Overall it seems to me that the TGA's Interim Decision is significantly biased towards historical misinformation regarding the potential harms of these medicines when used in non-medical settings…When used in medical settings their safety will easily be within that of other psychiatric medicines and probably safer than most because they are given just once or twice ….. Taken in totality I can see no good reason why psilocybin and MDMA should not be moved into Schedule 8 of the Poisons Standard…".*

In concluding, we just want to say this. Current psychiatric medicines have been shown to be ineffective for a large number of Australians suffering from Depression and/or PTSD and psychotherapy has large drop-out and relapse rates and can be equally ineffective. ***These are debilitating diseases***. We have medicines (MDMA and Psilocybin) available to psychiatrists at the Federal level to use as part of psychotherapy for treatment resistant depression and treatment resistant PTSD (and a significant number of

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approvals for their use have already been given by the TGA), but which are being prohibited at the State and Territory level whilst these medicines wrongly remain as Schedule 9 substances.

On any objective assessment these medicines when used as part of psychotherapy in medically controlled environments fit the Schedule 8 criteria and should be rescheduled. ***Just think what this would mean for so many Australians***. But decisions are being impacted by unconscious bias and prejudice at both the Federal and State levels. As a matter of urgency, it's critical to so many Australians and their families that the TGA and the Delegate stand above all of this and show leadership in objectively analysing the facts.

Rescheduling to Schedule 8 is not going to open the floodgates and will nicely compliment the recent decision by Minister Hunt to provide funding for further research in this area. A psychiatrist wishing to offer this treatment to a treatment resistant patient will still require specific approvals on a patient-by-patient basis at both the Federal and State/Territory levels. However, rescheduling will be a critical part of a journey which can broaden the treatment paradigm in Australia and offer real hope to so many suffering (and in some cases suicidal) Australians.

We appeal to you to make sure that everyone involved in the decision-making process is properly briefed, understands the severity of Australia's mental health crisis, is open to discussions with overseas experts and is alerted to the risks of unconscious bias and prejudice.

Yours sincerely

s22 [redacted]

s22 [redacted]

Mob s22 [redacted]

1/10 Dorcas St
South Melbourne,

3006, VIC

hello@mindmedicineaustralia.org

From: s22
To: GILL, Tony
Cc: Medicines Scheduling; s22
Subject: FW: MAPS PHASE 3 TRIAL; EFFICACY AND SAFETY OF MDMA ASSISTED PSYCHOTHERAPY - PRIVATE AND CONFIDENTIAL [SEC=OFFICIAL]
Date: Thursday, 25 March 2021 10:01:00 AM
Attachments: MAPP1.NM.Manuscript.Revision.2021.03.02.pdf
image001.png
image002.png
image003.gif
image004.png

Dear Tony,
Further information for MDMA attached, noting that the consultation period has finished for this substance.
I have included s22 comments (from Mind Medicines Australia).

s22
s22 – Scheduling & Committee Support

Regulatory Practice, Engagement, Education and Support Division | Health Products Regulation Group
Regulatory Engagement & Planning Branch
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: Symonston
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 22 March 2021 6:02 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>
Cc: s22 @health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org
Subject: MAPS PHASE 3 TRIAL; EFFICACY AND SAFETY OF MDMA ASSISTED PSYCHOTHERAPY - PRIVATE AND CONFIDENTIAL

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Avi
You will recall that in Section 4 of our MDMA Rescheduling Submission in response to the Delegate's interim decision we mentioned that MAPS had just completed a randomised double-blind placebo-controlled multi-site Phase 3 Clinical Trial in relation to the use of MDMA as part of psychotherapy for the treatment of PTSD required by the FDA as part of the medicine registration process. We mentioned that "*the results were expected to be robustly significant with a large effect size and show an excellent safety record*". See page 29 of our Submission.
Mr s22, the Multidisciplinary Association of Psychedelic Studies ("MAPS"), has now given us the full paper describing the trial results which has been accepted for publication in Nature Medicine. Mr s22 has given us permission to share this paper with the TGA and the Delegate ***on a strictly confidential basis during this pre-publication phase***.

As you will see key take outs from the paper include:

- The trial included those with common comorbidities including dissociation, a history of alcohol and substance abuse disorders and childhood trauma.
- Participants (n=90) were randomised with 1:1 allocation after psychiatric medicine washout. Trial size was agreed with the FDA as being statistically significant because of the large effect sizes seen in the Phase 2 trials. Both groups received preparatory and integrative sessions.
- The mean duration of PTSD of participants in the group taking MDMA as part of therapy was 14.6 years and 11.6 years in the placebo group taking therapy.
- Changes in PTSD symptoms (Clinician-Administered PTSD scale (CAPS-5), primary endpoint) and functional impairment (Sheehan Disability Scale or SDS, secondary endpoint were measured) were analysed.
- Adverse events and suicidality were tracked throughout the study.
- MDMA assisted psychotherapy induced robust attenuation in CAPS-5 Total Severity Score compared to placebo and significantly reduced the SDS total score.
- MDMA ***did not*** induce adverse effects of abuse potential, suicidality or QT prolongation in contrast to the placebo group (which really highlights the challenges of unaided psychotherapy in terms of retriggering the patient).
- MDMA assisted therapy was equally effective in participants with comorbidities that are often associated with treatment resistance.
- **The conclusions were that "..not only is MDMA-assisted therapy highly efficacious in individuals suffering from severe PTSD but MDMA treatment is safe and well-tolerated, even with comorbidities",** that ***"Importantly, there were no major safety issues reported within the MDMA arm of the study"*** and that ***"Not only is MDMA-assisted therapy efficacious in individuals suffering from severe PTSD but it may also provide improved patient safety" .*** This is consistent with the results of the Phase 2 trials.

The paper also notes that "*We will soon be confronted with the potentially enormous economic and social repercussions of PTSD, exacerbated by the Covid-19 pandemic. Overwhelmingly high rates of psychological and mental health impairment will be with us for years to come and will impart a considerable emotional and economic burden. Novel PTSD therapeutics are desperately needed, especially for those for whom comorbidities confer treatment resistance".*

There are always arguments that can be made for more clinical trials with any psychiatric medicines (including SSRI's) but the question here is whether MDMA as part of therapy meets the Schedule 8 criteria. This trial represents clear evidence that it does. PTSD is a common and debilitating condition with immeasurable social and economic cost and, as mentioned in our submission, currently treatments lead to remissions in less than 10% of those seeking treatment.

I am more than happy to set up a conference call with MAPS to discuss the study results in more detail if that would be helpful.

With best wishes

s22 [redacted]

s22 [redacted] Mind Medicine Australia

Mobile s22 [redacted]

From: s22
To: TGA Committees Inbox
Cc: Medicines Scheduling; s22
Subject: RE: Presentation to the Committee on Medicines Scheduling - Psilocybin and MDMA assisted therapies - 23 June 2021 [SEC=OFFICIAL]
Date: Monday, 10 May 2021 3:59:29 PM
Attachments: image001.png
image004.png
image005.gif
image006.png
image007.png
image008.png

They are a 'something else'. They are **presenting** at the request of the applicant. They should only be able to be in the meeting during their allocated time to present. (4-5pm) Happy to discuss further.

s22
s22 – Scheduling & Committee Support

Regulatory Practice, Engagement, Education and Support Division | Health Products Regulation Group
Regulatory Engagement & Planning Branch
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: Symonston
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: TGA Committees Inbox <Committees@health.gov.au>
Sent: Monday, 10 May 2021 3:47 PM
To: s22 @health.gov.au>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 s22 @health.gov.au>
Subject: FW: Presentation to the Committee on Medicines Scheduling - Psilocybin and MDMA assisted therapies - 23 June 2021 [SEC=OFFICIAL]

Hi s22
Could you please indicate if the below invitees are to be special advisors, observer's, or something else?
Thanks,
s22

From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Friday, 7 May 2021 2:56 PM
To: TGA Committees Inbox <Committees@health.gov.au>
Subject: FW: Presentation to the Committee on Medicines Scheduling - Psilocybin and MDMA assisted therapies - 23 June 2021 [SEC=OFFICIAL]

Hi team,
Can we please add Prof s22 and Dr s22 to the invitee list (if not already done)
I'll chase up email contacts for them and pass them on
Thanks
s22

From: s22 @health.gov.au>
Sent: Tuesday, 27 April 2021 8:51 AM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: Presentation to the Committee on Medicines Scheduling - Psilocybin and MDMA assisted therapies - 23 June 2021 [SEC=OFFICIAL]

Hi team,

Please ensure that this time is set aside for MMA presentation in the June meeting agenda. We will need to provide MMA with presentation, webex details etc closer to the time.

Cheers,

s22

From: s22 @mindmedicineaustralia.org>
Sent: Thursday, 22 April 2021 12:53 PM
To: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>
Cc: SKERRITT, John <John.Skerritt@health.gov.au>; s22 s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org>; s22 s22 @mindmedicineaustralia.org>
Subject: Presentation to the Committee on Medicines Scheduling - Psilocybin and MDMA assisted therapies - 23 June 2021

Hi Avi and s22

We have confirmed Professor s22 and Dr s22 for the presentation to the Committee on Medicines Scheduling (and I assume the independent reviewer) by video conference for the **4-5 pm 23 June 2021** timeslot AEST that Adjunct Professor John Skerritt said was available in his email to me of 9 April below. I tried for the previous day but unfortunately Dr s22 was unavailable on that day.

As you will see from the attached CVs, Professor s22 s22 at Imperial College London – one of the main centres of excellence for these therapies in the World) and Dr s22 (a practicing UK Psychiatrist and Researcher at Imperial College London) both have extensive experience with analysing the safety and therapeutic value of the use of psilocybin and MDMA as part of therapy in medically controlled environments. In particular, Professor s22 was directly involved in the recent psilocybin assisted therapy trial at Imperial College London comparing a leading SSRI with psilocybin assisted therapy and Dr s22 was the Principal Investigator and Senior Research Fellow of the recent Bristol – Imperial College MDMA assisted therapy trial for alcohol abuse. Dr s22 is also a therapist and medical lead in the current Compass Pathways Psilocybin for Depression Phase 2 Clinical Trial and an Approved MDMA MAPS trained Psychotherapist. They have both written extensively on the utility of MDMA and psilocybin assisted therapies for the treatment of key classes of mental illness.

I look forward to receiving more details of the meeting format in due course so that I can make sure that Professor s22 and Dr s22 are properly briefed and address particular issues which you would like them to focus on.

With best wishes

s22

From: REBERA, Avi <Avi.Rebera@health.gov.au>
Sent: Wednesday, 14 April 2021 7:59 AM
To: s22 @mindmedicineaustralia.org>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>
Cc: s22 @mindmedicineaustralia.org>
Subject: RE: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

Hi s22
We will check with the chair and committee members and let you know.
Cheers
Avi

Avi Rebera
Assistant Secretary
Regulatory Engagement, Education & Planning Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health
T: + 61 2 6289 2247 | M: +s22 | E: avi.rebera@health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 13 April 2021 10:34 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22 @health.gov.au>
Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 s22 @mindmedicineaustralia.org>
Subject: RE: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

John
Before I see whether this can work is there any chance of starting at 8am Canberra time to make this more palatable and, if so, which day would work?
With best wishes
s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Tuesday, 13 April 2021 10:02 PM
To: s22 @mindmedicineaustralia.org>; s22 s22 @health.gov.au>
Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 s22 @mindmedicineaustralia.org>
Subject: RE: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

s22
Still in the office so will respond. We could go with first thing – 9 am Cbr time – but then this

makes it midnight for the UK and 7 pm for Baltimore.
Is this preferred ?
Welcome to the world of trying to engage UK and US at once – Im up to midnight many nights in videoconferences with them.
John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 13 April 2021 9:58 PM
To: s22 @health.gov.au>
Cc: SKERRITT, John <John.Skerritt@health.gov.au>; REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @mindmedicineaustralia.org>; s22 s22 @mindmedicineaustralia.org>
Subject: FW: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

Dear s22
Further to Adjunct Professor John Skerritt's email below we have confirmed that Professor s22 s22 is available to lead the presentation on either of the dates and times suggested. We will be back in touch very shortly to confirm the date (noting your preference) as soon as other members of the presentation team from the UK have confirmed availability.
Unfortunately, the time suggested will make it very challenging for people such as Professor s22 from Johns Hopkins University in Baltimore to join the meeting given the 14 hour time difference (ie the suggested start time will be 2am his time).
I'll be back in touch shortly.
With Best Wishes

s22
m: s22
e: s22 **@mindmedicineaustralia.org**
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 12 April 2021 1:39 PM
To: 'SKERRITT, John' <John.Skerritt@health.gov.au>
Cc: 'REBERA, Avi' <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; 'VINE, Ruth' <Ruth.VINE@health.gov.au>; 'brendan.murphy@health.gov.au' <brendan.murphy@health.gov.au>; s22 @andrewrobb.com.au>; s22 s22 @mindmedicineaustralia.org>
Subject: RE: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

Dear John

Thank you for your email below. My email was long, but I felt that there were important issues to deal with about a rescheduling process the outcome of which is enormously important to an increasing number of people in this country. It's critical that the final decision accurately reflects all of the available data and expertise.

You are quite right about the complexity of Australia's dual Federal State regulatory system which adversely effects the ability of experienced medical practitioners to access these unregistered medicines as part of therapy in medically controlled environments for their clients suffering from key treatment resistant mental illnesses . On the one hand we have an enormous number of people suffering from treatment resistant depression, PTSD and substance abuse who are not being well served by currently available treatments. On the other hand, we have an opaque and dated dual system across Australia which can be challenging to navigate.

The point that I tried to make in my email is that the States and Territories around Australia are largely "hiding behind" the TGA's scheduling of these substances (when used as part of therapy in controlled medical environments) as prohibited substances in Schedule 9 of the Poisons Standard. If the Delegate reschedules the medicinal use of these substances to Schedule 8 of the Poisons Standard, then these same States and Territories will have to develop their own access policies and will be directly accountable for whatever they do. We have been in contact with many of the State and Territory regulators and they have confirmed this.

We believe that in every State and Territory of Australia permits will still be required at the State/Territory level if the medicines are rescheduled at the Commonwealth level to Schedule 8 but at least this means that we can focus on educating these State/Territory regulators. This is because a Schedule 8 listing means that these regulators will have to make decisions and we can appeal any decisions that we believe aren't properly based on available data.

Thank you for clarifying whether the minutes of the meeting exist.

The only comment I made in my letter about the wording of "established therapeutic value" was that it was not a scientific phase. Therefore, a certain amount of judgment is required and there is a higher risk of unconscious bias. I agreed with your comment in Senate Estimates that the phase was *"a funny term that the committee and the delegate have to use".* But I also accept that the phase is currently in the Scheduling Policy framework. The point that I was trying to make in Section 15 of my letter was that because established therapeutic value wasn't a

scientific phrase, we believed that "*some guidance can be given by reference to other substances in Schedule 8 (and lower schedules*)". We also dealt with this in detail in our Submissions opposing the Interim Decisions.

I also agree that the UN Convention on Psychotropic Substances is included in the Scheduling Policy Framework but as I pointed out in Section 17 of my letter it would be strange (and indeed deeply disturbing) if the Delegate didn't recognise both the express exemptions in the Convention (which must be implicit in the Scheduling Guidelines) and the competing convention (the UN Convention on Economic, Social and Cultural Rights) that specifically provides for rights that Australians have to *"the enjoyment of the highest attainable standard of physical and mental health"*. This interpretive approach is also consistent with the fact that a number of other substances covered by the UN Convention on Psychotropic Substances and the UN Convention on Narcotic Drugs (both mentioned in the Scheduling Policy Framework) have been rescheduled by the TGA from Schedule 9 to lower schedules in the past (again dealt with at length in our Submissions).

I was very concerned by your assertion that I have quoted you as saying that these medicines "*should not be rescheduled*". I try to be very careful with the use of words and I have never said that. What I did say in my letter was that your comments on the ABC that *"What we don't have…. Is the complete package of evidence that shows that they [medicinal psilocybin and medicinal MDMA] were safe and effective…….. There's some really promising early data… we've got to wait until we've got the overwhelming evidence that these products are safe and effective"* didn't reflect the tests for rescheduling. I also made the point in my letter that your comments and those of the Secretary, Dr Brendan Murphy, at Senate Estimates could be interpreted as "leading" the Delegate to come to a negative conclusion. I am sure that this wasn't the intent, but it clearly risks having that effect.

Can you please give me the source of the alleged quote because I am equally concerned about this.

We are delighted to have the opportunity for international experts to present directly to "*either departmental staff, the delegate or the Advisory Committee on Medicines Scheduling*" and I will liaise with Dr s22 on this. Please note that given the opaqueness of the rescheduling process and the importance of this decision to so many suffering Australians we would hope that the actual decisionmaker (the Delegate) and his or her formal advisers (the Advisory Committee on Medicines Rescheduling) will be part of that call so that they have the chance to directly listen to and question these experts

Lastly, I did want to say how appreciative we are that we are able to have such a direct, constructive and helpful conversation with you on this matter.

With best wishes

s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Friday, 9 April 2021 3:19 PM
To: s22 @mindmedicineaustralia.org>
Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; VINE, Ruth <Ruth.VINE@health.gov.au>; MURPHY, Brendan <Brendan.Murphy@health.gov.au>
Subject: Mind Medicine Australia - Comments made in Senate Estimates [SEC=OFFICIAL]

Dear s22

I think there is little value in attempting to rebut each of the issues you have raised in your long letter of 5 April, but did want to clarify a few things:

The regulation of psychoactive drugs is not only a complex scientific matter, as you have identified, it is also a complex regulatory matter. The complexity arises not just, for example in the case of psilocybin, from its present inclusion in schedule 9 of the Poisons Standard and the present state and territory regulation of such substances. It also arises because each state and territory has sovereign jurisdiction over the laws which would give effect to scheduling decisions. I believe from experience with other scheduling decisions that it is not unlikely that even if the TGA delegate decided to reschedule the substances, some states and territories may decide not to reschedule them.

In the case of Victoria, for example, its legislation presently prescribes psilocybin as a drug of dependence. Should psilocybin be down-scheduled it would maintain its status as a drug of dependence and become a schedule 8 poison. At least one policy issue which we anticipate the Victorian Government may want to consider is whether psilocybin would appropriately be prescribed as a special schedule 8 poison for which a special schedule 8 permit would be required by health practitioners to authorise lawful dealings with it. Other states and territories are also likely to want to consider implications including any impact on access. This is not just a hypothetical situation. For example, until recently even though cannabidiol preparations had been down-scheduled to S4 (standard prescription only status) a separate scheme of permits was required in Queensland. In a number of states specific additional requirements exist for schedule 8 cannabis products too.

Yes, there was confusion in my mind about whether there were separate committee minutes to the summary of the committee discussion that in the last few years have been routinely included in the Delegates interim decision. I have now learnt that separate Minutes are still prepared. My confusion relates to the fact that I do not see, clear, nor get a copy of these Minutes in the normal course of events.

Whether or not you like the wording of “established therapeutic value” it is the term enshrined in the Scheduling policy framework which must be considered by the delegate. Similarly the status of the substance in the UN Convention on Psychotropic substances is similarly included in the Scheduling policy framework.

I am most concerned that you have quoted me as saying that these medicines “should not be rescheduled” – I have never said this and would find it offensive if you quoted me as saying same.

You have also sought an opportunity for certain international experts to present directly to either departmental staff, the delegate or the Advisory Committee on Medicines Scheduling. **The Scheduling Secretariat have confirmed that time is available for the group to present by Webex or similar from 4-5 pm (AEST) on either 22 June 2021 (preferred by the Committee) or 23 June 2021 for your presentation to the Committee.**

If possible I will participate in that call but as I have mentioned before I cannot, and will not, attempt to direct the decision making delegate. Please contact s22 [redacted] directly to confirm the date.

Regards

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Monday, 5 April 2021 10:45 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; VINE, Ruth <Ruth.VINE@health.gov.au>; MURPHY, Brendan <Brendan.Murphy@health.gov.au>
Subject: Comments made in Senate Estimates

Dear John

I have attached a letter to you about issues relevant to our applications to reschedule psilocybin and MDMA as part of therapy in medically controlled environments that arose from the Senate Estimates appearances of Dr Brendan Murphy and yourself on 24th March 2021.

I have become increasingly concerned about misinformation and the apparent lack of regard for all the information that we have provided to the TGA in our rescheduling applications and recent submissions against the Delegate's Interim Orders. It's not apparent to me that officials have really sought to understand the evidence available on the safety and established therapeutic value of MDMA and psilocybin as part of therapy.

I am also becoming increasingly concerned about the probity of the rescheduling process and the capacity of the Delegate to make an objective decision.

I have copied this email to Professor Ruth Vine because her position on the proposed rescheduling was mentioned on two occasions by Dr Brendan Murphy in his statements to the Senators as well to Dr Brendan Murphy and to Mr Avi Rebera and s22 (given their involvement in this process).

I hope that you will find the letter constructive and a sincere attempt to make sure that the Delegate is able (if this is still possible given the public statements already made) to objectively consider all of the available evidence that clearly supports the rescheduling of these medicines on the terms proposed. I would also encourage you and your colleagues (including Professor Ruth Vine and ideally Dr Brendan Murphy as well) to participate in conference calls that I can organise with recognised world leaders in this field who believe (as stated in our submissions and original applications) that these therapies are safe when used in medically controlled environments by trained professionals and that the medicines when used in this way have an established therapeutic value.

There are too many Australians suffering from treatment resistant depression and treatment resistant PTSD to get this rescheduling decision wrong.

I would very much like to talk this through with you and your colleagues in a considered way and will make myself available at a time of your choosing this week.

With best wishes

s22

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MIND MEDICINE AUSTRALIA

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulatory Group
Department of Health
Australian Government
Canberra, ACT

5 April 2021

Dear John

Senate Estimates Appearance: Wednesday 24th March 2021

I read with interest the transcripts of the recent Senate Estimates Committee held on 24th March 2021 that dealt with:

(i) a number of the major mental health issues that we have in Australia including suicide rates, the adverse effects of mental health drugs on the physical health and wellbeing of consumers and the lack of any material and impactful treatment innovation in Australia in relation to mental health for decades; and

(ii) the current rescheduling process in relation to psilocybin as part of therapy for treatment resistant depression and MDMA as part of therapy for treatment resistant PTSD.

I thought that it might be helpful if I made some observations about the comments that were made by both you and by the Secretary, Dr Brendan Murphy to the Senators at Senate Estimates.

1. **The assertion that the evidence for these medicines (psilocybin and MDMA as part of therapy) is still emerging.**

This is actually true of many psychiatric medicines used today. Antidepressants are used extensively in Australia (an estimated 1 in 8 Australians are on antidepressants including 1 in 4 older people and 1 in 30 younger people) and yet the trial evidence for the efficacy of antidepressants is not strong and the fact that they can have significant side effects is well documented. A good article describing the low treatment effectiveness of antidepressants from leading Australian psychiatrist, Professor Paul Fitzgerald, can be found here: https://medium.com/@pbfitzgerald/the-challenges-of-depression-treatment-in-2020-abd74269764

The reality is that MAPS has completed the first of two Phase 3 trials agreed with the FDA using MDMA as part of therapy for treatment resistant PTSD with superior results (discussed under 2 below) and psilocybin as part of therapy for depression has been investigated in a large number of trials over the last 15 years (as well as before prohibition in the 1950s and 1960s) again with superior results. It's also noteworthy that trials don't have to be as large

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to be statistically relevant when the effect size is high (as it is with psilocybin and MDMA when used as part of therapy).

Dr Murphy expressed the view that there wasn't a strong evidence base yet for the use of psilocybin for depression. This directly contradicts the views of leading researchers from around the World, such as Professor s22 and Dr s22, both from Imperial College London; Professor s22 from Johns Hopkins University in the United States and from leading Australian neuropharmacologist, Professor s22 s22 from Monash University. Letters from each of these experts are set out in each of our submissions opposing the Interim Decisions and in our earlier applications.

You should also note that our rescheduling applications were supported by a large number of Australian psychiatrists who attested to the safety and efficacy of these medicines when used as part of therapy.

2. **<u>The assertion that the data is based on relatively small studies.</u>**

There have now been over 75 clinical trials for the use of MDMA as part of therapy and over 40 clinical trials for the use of psilocybin as part of therapy. Altogether around 3,500 patients have been involved in MDMA trials and more than 2,000 patients have been involved in psilocybin trials. Throughout these trials a number of matters have become clear: high remission rates have been achieved for treatment resistant depression and for treatment resistant PTSD, there have been minimal adverse side effects (in contrast to many other psychiatric medicines) and high levels of patient safety have been recorded. Indeed, adverse events have been minimal and easily corrected.

The results of the latest trials have become available after the Interim Decision was announced by the TGA on the 3rd February 2021. We have given these trial results to the TGA on a confidential basis until publication later this month. The results involve:

- A MAPS Phase 3 trial using MDMA as part of therapy for treatment resistant PTSD involving 90 trial participants (a level regarded as statistically significant by the FDA and even more so given the large effect size shown). The results showed strong efficacy and safety and lower suicidal ideation amongst participants with treatment resistant PTSD than the placebo with the same therapy (I have forwarded the full results to Mr Avi Rebera at the TGA's Medicines Rescheduling Unit).
- A trial at Imperial College London with 59 trial participants comparing psilocybin-assisted therapy for major depressive disorder with a leading SSRI (escitalopram) in which the results in terms of efficacy and side effects strongly favoured psilocybin assisted therapy (I have forwarded these results to Mr Avi Rebera at the TGA).

These are two important trials and we would ask you to make sure that the recent trial results which we sent to Mr Avi Reberra are drawn to the attention of Dr Murphy, the Chief

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Psychiatrist Dr Ruth Vine and to the Delegate. As mentioned above, these results are statistically significant, particular given the large effect size shown (which is consistent with earlier trials).

3. **The comment about these treatments being available in a number of overseas jurisdictions.**

The overseas jurisdictions where the medicines can legally be accessed as part of therapy include the US, Canada (using psilocybin for end-of-life distress), Switzerland, Israel, Holland (for psilocybin) and a number of Central and South American countries. There is a significant point to consider here as to why Australians with treatment resistant depression and treatment resistant PTSD are being denied similar access when the treating psychiatrist believes that these treatments are appropriate, informed patient consent has been given, the safety record is very strong and the treatments are to occur in medically controlled environments. Ironically, the TGA are granting SAS-B approvals but the scheduling of the medicines in Schedule 9 is preventing these approvals from being implemented.

As Senator Dean Smith commented at Senate Estimates "*…because my point here is that perhaps Australia's approach is too narrow when it comes to treatments*?"

4. **The comment that people are already experimenting with the use of psychedelics for medical purposes.**

As mentioned in our submission, there is a steeply rising risk that more and more Australians suffering from treatment resistant conditions will seek to access these therapies illegally through underground therapists given the ease with which these medicines can be accessed on the Black Market. The problem here is a complete lack of quality control and regulation. This risk will be minimised if the medicines are rescheduled to Schedule 8 and brought into our medical system.

An insight into what is happening globally can be gained from the recently published Global Drug Survey (www.globaldrugsurvey.com/GDS2020), which showed a strongly rising trend in the use of psilocybin and MDMA for therapeutic purposes (with a sample size of 6,500 people). The report notes that "*Without appropriate training, screening and preparatory sessions, people with pre-existing mental health conditions may be exposed to greater risks of harm when using these substances in unregulated settings".* Interestingly, even in these unregulated settings, without proper screening, dosing supervision and integration being provided to support people suffering from mental illness, 52% found the treatment "*very helpful, things got much better*" and a further 34% found the treatments "*quite helpful, things got a bit better*".

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MIND MEDICINE AUSTRALIA

5. **The Length of Time Trials Take.**

This relates to a discussion between Senator Siewert and Dr Murphy. As you would know very well, the trial process is extremely time consuming and expensive, and trials of the type envisaged typically take at least 2-3 years (and up to a suggested 5 years in the Government's recent funding announcement). This process is ***not*** remarkably quick as suggested by Dr Murphy and during that time many more Australians will suffer from treatment resistant conditions and a number will commit suicide. As discussed below, there is plenty of evidence from overseas trials that these medicines when used as part of therapy are safe and have an established therapeutic value when used by trained professionals in medically controlled environments.

As mentioned in 1. above there is always a benefit in having more data but there is more than enough data today to justify rescheduling.

6. ***The comment from Dr Murphy that there "is a wide diversity of views among his [Dr Murphy's] fellow clinicians in this country about the utility and the level of evidence".***

One of the problems in Australia that is becoming apparent to us is that a number of clinicians give views without doing the hard analytical work to justify those views. This is highlighted by the many misleading and incorrect statements in the RANZCP **Clinical Memorandum on the therapeutic use of psychedelic substances (May 2020)** which we comment on in detail in Sections 3.2.3 and 3.4 of our Submissions on the Interim Decision. The reality, as referred to above, is that leading researchers from around the World are attesting to the evidence supporting both the safety and efficacy of these therapies.

We have also offered on several occasions to set up conference calls for the RANZCP, the TGA and the Delegate with World leading researchers in these medicinal therapies (such as Professor s22 , Dr s22 and Professor s22). However (and surprisingly to us given the immense suffering of so many Australians and the lack of effective treatment options) these offers have never been taken up.

7. **The rescheduling requirement of Established Therapeutic Value.**

We deal with this at length in our submissions to the TGA in relation to the Interim Decision. In our view there is demonstrable evidence that this requirement has been met and this is confirmed by a significant amount of trial data and the views of the leading experts mentioned in Section 1 above.

You pointed out to the Senators that "*the advisory committee was very divided on the advice that it gave on this".* We would hope that the latest trial data referred to in Section 2

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above would be helpful to both the TGA and the Delegate to demonstrate that the "Established Therapeutic Value" criteria had now been clearly met.

8. **Your comment that "*You don't have to reschedule things from [Schedule] 9 to 8 for them to be available to patients in therapy".***

This statement is not correct because our legal advice confirms that, even with an approval from the TGA under Special Access Scheme B, it would be illegal to use these therapies in all States and Territories of Australia (other than Victoria if a permit is obtained). This would change if the use of these medicines as part of therapy were rescheduled to Schedule 8 of the Poisons Standard because all States then have permit processes that can be used by the treating psychiatrist.

9. **Your Reference to Professor s22 , one of the World's leading neuropsychopharmacologists.**

Professor s22 has been very clear in his letter to the TGA appearing in Table 7 of Section 3.4 of each of our Submissions (and also as a signatory to the Drug Science letter extracted in Table 3 of Section 3.2.1 of both Submissions) that both MDMA and psilocybin when used as part of therapy are safe and have an established therapeutic value. Dr s22 (also from Imperial College London) and leading neuropharmacologist Professor s22 have also said the same thing (see Table 3 in Section 3.2.1 of both Submissions) and Professor s22 has said this in relation to psilocybin-assisted therapy, which is the medicine that he focuses on in his research (also in Table 3). The recent trial results referred to in Section 2 strongly reinforce this point.

As mentioned above, we have offered on several occasions to arrange a conference call for the Delegate and representatives of the TGA with each of these individuals but so far this offer has not been taken up.

We believe that it would be a really bad process outcome if the views of certain people in Australia, without expertise in this area (including RANZCP as evidenced by all of the mistakes and misleading statements in its Clinical Memorandum), were accepted against the clear advice of World recognised experts.

10. **Your comments on access through the Special Access Scheme and the position of States and Territories.**

As mentioned above, our legal advice indicates that only Victoria has a permit scheme, which will enable psychiatrists to access these treatments for their patients whilst the use of

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these medicines as part of therapy remains in Schedule 9. There are no patient access gateways in the other States and Territories unless these medicines are moved to Schedule 8.

The Victorian Government to date has refused to give a permit under its legislative provisions (despite its power to do so) because of the Schedule 9 scheduling of these medicines. They also rely on the RANZCP Clinical Memorandum, despite the fact that it is littered with mistakes and misleading statements. Again, rescheduling to Schedule 8 would change all of this.

According to our legal advice, your comment to the Senators that access would be denied in some States irrespective of whether the medicines are Schedule 8 or Schedule 9 is not correct. Our advice is that rescheduling to Schedule 8 will open permit pathways in all States and Territories of Australia.

Your comment that *"In Victoria. …there are already a number of psychiatrists …who are currently prescribing these medicines for people with either PTSD or major treatment resistant depression"* is not correct as no permits have been issued in that State ***because*** of the Schedule 9 listing of these medicines (see above).

There are a significant number of psychiatrists that have to date applied and gained approvals through the TGA under the Special Access Scheme to access these medicines as part of therapy. They clearly believe that these medicines when used in this way have an established therapeutic value. This view is shared by all of the other psychiatrists that supported our submissions.

It should be a big issue for the TGA and the Delegate to knowingly stand in the way of psychiatrists and their patients who believe that these treatments could lead to remissions in patients with treatment resistant conditions (some of whom will have suicidal ideation) by not rescheduling the medicines for therapeutic use. This is highlighted by all of the safety and efficacy data laid out in our submissions.

11. **Your comment that "*if the Delegate does reschedule it to [Schedule] 8, it is not that this will be automatically available in every jurisdiction the next day*".**

This is very true but rescheduling to Schedule 8 will lead to each State and Territory developing its own policy in relation to psychiatrists accessing these medicines. This is a good thing because it forces Health Departments around Australia to look at the data and the science. At the moment these Health Departments can simply hide behind your Schedule 9 listing of these substances.

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12. **<u>Your comment that if the final decision announced on April 22nd is not in favour of rescheduling these medicines "*someone could reapply the next day [to reschedule them]…So it is not as if we can't do anything for another year, even if the FDA trial results were fantastic".*</u>**

Relative to antidepressants the FDA trial results in relation to MDMA assisted therapy and the Imperial College results comparing psilocybin-assisted therapy with a leading SSRI (escitalopram) are fantastic!

However, as you are aware, whilst technically a person could reapply to have these medicines rescheduled the next day, the process would take over a year for that application to be considered. According to the TGA website the next lodgement deadline for a rescheduling application is 16th July 2021 and that would lead to a final decision in April 2022 and an effective date for any rescheduling in June 2022.

Why would the Delegate and the TGA put people who are suffering (with some having suicidal ideation) through another year of uncertainty when all the evidence shows that these medicines are safe to use as part of therapy in medically controlled environments and are achieving high remission rates?

I accept that a positive final decision on rescheduling later this month will not lead to a large use of these therapies in the short term because State and Territory Governments will need time to develop Schedule 8 permit policies for the use of these medicines as part of therapy in their jurisdictions. However, it will start the process and give patients around Australia with treatment resistant conditions the **hope** of a new therapy with much higher remission rates and much lower adverse side effects than existing therapies.

13. **<u>Comments about the Minutes of the ACMS Meeting.</u>**

There seems to be some confusion about whether these Minutes actually exist. We have been told that they do exist, whereas you were equivocal in your comments to the Senators (indicating initially that you thought they did exist and later indicating that they might not exist). It would be an extraordinary failure of due process if the analysis of a Committee meeting to decide on such an important rescheduling did not have minutes to capture the competing arguments and the data relied upon.

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14. **Your comment that most of the Special Access Scheme approvals to date "*will have been in Victoria".***

This is not correct because nearly all of the approvals to date have come from practitioners for patients in NSW. We have already had confirmation from senior officials at the NSW Department of Health that a permit process would be available if these medicines as part of therapy were moved to Schedule 8, and that if this occurred they would move quickly to develop an appropriate policy for dealing with permit applications.

15. **Your comment that Established Therapeutic Value is *"a funny term that the committee and the delegate have to use".***

We agree with this statement because established therapeutic value is not a scientific phrase. As a result, we believe some guidance can be given by reference to other substances in Schedule 8 (and lower schedules). We analysed this in detail in our submissions and demonstrated that there is much less evidence supporting the efficacy of a number of other substances in Schedule 8 and indeed Schedule 4 (and whether they have an established therapeutic value) than there is for psilocybin and MDMA when used as part of therapy.

16. **Your comment that the "*…eventual end point*" potentially being these medicines becoming registered medicines for use with PTSD and treatment resistant depression".**

We agree and believe that this will happen at some time in the future. But the whole purpose of the Special Access Scheme is to give doctors and their patient's access to unregistered medicines. The question is whether they should be moved to Schedule 8 because they have an established therapeutic value. For the reasons given above and in our submissions we believe that the evidence shows that they clearly do.

17. **Your comment that it was questionable whether the UN Convention on Psychotropic Substances *"was an absolute blocker to it [the medicines as part of therapy] being moved to Schedule 8".***

I would hope we have moved beyond this argument, both because there is an explicit exemption in this convention for medical use and a competing convention (the UN International Convention on Economic, Social and Cultural Rights) that explicitly provides for rights to "*the enjoyment of the highest attainable standard of physical and mental health".*

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It would truly be ironic if the TGA and the Australian Government relied on such a poor interpretation of the UN Convention on Psychotropic Substances to block rescheduling when Expanded Access and Compassionate Use Schemes are being used in the US, Switzerland and Israel and an exemption approach is being used for psilocybin in Canada; when the State of Oregon in the USA has legalised the medical use of psilocybin as part of therapy and more States in the USA are looking to follow a similar path; and where the use of psilocybin had been legalised in Holland.

This argument is also contradicted by the TGA's own actions in rescheduling a number of other substances covered by UN conventions in the past (see Section 6.1 of each of our submissions),

At the end of the day, as per the UN International Convention on Economic, Social and Cultural Rights, Australia has an obligation to look after the mental health of its people and it is currently failing to do this with the many people suffering from treatment resistant depression and treatment resistant PTSD.

<u>Our Concern that the Rescheduling Process being applied to these Medicines is Flawed.</u>

I have already made the point to Mr Avi Rebera and s22 [redacted] that we are concerned that the Delegate didn't appear to have actually read our rescheduling applications before making the Interim Decisions. This was highlighted in my mind when the Delegate didn't make any reference in the Interim Decisions to the fact that our applications were supported by some of the leading experts in the World. In addition, whilst the Delegate did mention that 98% (in the case of psilocybin) and 97% (in the case of MDMA) of the public submissions received by the TGA supported our proposed rescheduling of these medicines when used as part of therapy the Delegate failed to mention that over half of these supporting submissions came from Health Sector experts.

Since that time I have become even more concerned about the rescheduling process. We have offered on a number of occasions to connect the TGA with World leading experts to discuss their views that these medicines as part of therapy had an established therapeutic value but there has been no take up of these offers to date. Given the suffering of so many Australians (with some committing suicide) and the high remission rates being achieved by these therapies in numerous overseas trials the rescheduling decisions are of the utmost importance. Yet no interest is shown in connecting with these experts and reliance instead is given on a flawed clinical memorandum published by the RANZCP (which RANZCP are not prepared to acknowledge).

As I understand it, the Delegate works for the Department of Health, which would mean that both you and Dr Murphy are his or her superiors. Yet we have you coming out publicly a few weeks ago on the ABC saying that, in relation to rescheduling, "*What we don't have*

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….is the complete package of evidence that shows they are safe and effective….there's some really promising early data…..we've got to wait until we've got the overwhelming evidence that these products are safe and effective". As we discussed with you when we spoke, these comments don't reflect the tests for rescheduling.

At Senate Estimates we now also have Dr Murphy saying that "*the evidence…is still emerging, some of the studies from overseas are quite promising but they're relatively small…I've certainly been briefed by our Deputy Chief Medical Officer in Mental Health, Professor Vine, and her view accords with mine that it is an area of significant interest, with some very interesting data in PTSD …[but in relation to depression] I think it would be fair to say that there is not a strong evidence base yet. There are some exciting small-scale studies, and we need more and better data…we need to invest in more and better clinical research and get big ticket studies and prove the benefit one way or the other…As you say, the college has not been convinced, and there are others, like Professor Vine, and I would take the view that we don't know, that it's a space where we need more and better data …Not yet convinced, particularly about the breadth of the efficacy… If the therapy is administered in a safe and careful environment. There are risks to these treatments as well…I'm not yet convinced about the breadth or the scope of their efficacy, so we need more data on that. It may be that they have a role. In the context of PTSD...I think the data looks a bit stronger. In the context of depression…there's just not enough data that would make me, Professor Vine and others …convinced. We're certainly not opposed, but I think we need more data".*

So my question on process is this. **How can the Delegate (who remains unidentified) remain objective when his superiors (as well as the Chief Psychiatrist) are basically saying that the medicines as part of therapy shouldn't be rescheduled, where reliance is placed on a flawed clinical memorandum published by RANZCP and where the Delegate shows no interest in being briefed by World leading experts on the safety and efficacy of these medicinal therapies?**

This letter was far longer than I had intended but the comments of both Dr Murphy and yourself warranted, I believe, a detailed response from us. Too many Australians are suffering from treatment resistant mental illnesses and the current system of medical interventions is failing them. Many of these people are desperate and looking to their Government to provide them access within the medical system to psilocybin and MDMA assisted therapies, which have been clearly shown to have high levels of safety, minimal side effects and high remission rates in medically controlled environments.

Rescheduling to Schedule 8 is critical to these patients and their medical practitioners. The time to do this is now as the infrastructure is being built at World's best practice levels (see Section 5.8 of each of our submissions).

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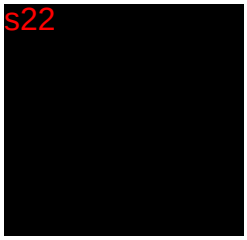
Doing nothing carries far greater risks with more and more desperate people suffering from these treatment resistant conditions being forced to seek these medicinal therapies illegally from underground therapists.

I look forward to your reply and would be keen to have a conversation about this with you and your colleagues later in the week. Could you please suggest a suitable time?

I'd also be grateful if you could forward a copy of this letter to both the Delegate and Dr Murphy.

Yours sincerely



Mind Medicine Australia
Mob s22

Cc. Mr Avi Rebera and s22 from the Medicines Rescheduling Unit.

Professor Ruth Vine, Chief Psychiatrist.

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From: Medicines Scheduling
To: s22
Cc: Medicines Scheduling
Subject: Re: Questions regarding a proposal CCEMS:07850001129 [SEC=OFFICIAL]
Date: Wednesday, 16 June 2021 9:57:10 AM
Attachments: image002.png

Dear s22

Thank you for your enquiry, which has been forwarded to the Medicines Scheduling Secretariat for response.

By way of background, scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules in the Poisons Standard according to the risk of harm and the level of access control required to protect public health and safety. The implementation of the Poisons Standard, as it affects access to and supply of medicines and poisons, is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.

The Poisons Standard is available online at https://www.tga.gov.au/scheduling-medicines-poisons.

With regards to psychedelics, you may be aware that a proposal to down-schedule psilocybin and MDMA from Schedule 9 (Prohibited Substance) to Schedule 8 (Controlled Substance) is currently being considered by the TGA decision maker (delegate). If approved, this would allow the substances to be administered by medical practitioners in controlled settings for the treatment of certain conditions. Two public consultation periods on the proposals were held in September 2020 and February 2021. In April 2021, the delegate decided to seek further advice in relation to psilocybin and MDMA, including an independent expert review, and to seek further advice from the Advisory Committee on Medicines Scheduling following this review. A final decision regarding the scheduling of these substances will be made at the completion of this process.

It should be noted that implementation of the Poisons Standard is the responsibility of states and territories, through their own legislation. The states and territories can, and sometimes do, implement additional controls and conditions on certain substances.

More information on applying to amend the Poisons Standard, including the application form, can be found on the TGA website.

Kind regards

s22

The Chemicals and Medicines Scheduling Secretariat Team

Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch

Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

---------- Original Message ----------
From: s22 <s22 >;
Received: Thu May 20 2021 21:35:21 GMT+1000 (Australian Eastern Standard Time)
To: info@tga.gov.au <info@tga.gov.au>; info-Queue <info@tga.gov.au>;
Subject: Questions regarding a proposal

Hello,

I'm writing a proposal to the therapeutic goods administration regarding the scheduling of hallucinogens such as LSD and Psylocibin. I'm doing a school project about these psychedelics and found that there were very few studies done surrounding their potential therapeutic properties.

How would I address the TGA? Also, who would I email the proposal to?

Kind Regards,

s22

From: s22
To: Medicines Scheduling; s22
Subject: RE: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]
Date: Wednesday, 23 June 2021 1:35:52 PM
Attachments: image002.png
image003.png
image004.png

Dear s22
Thank you for confirming this.
With best wishes

s22
m: +s22
e s22 mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org


From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Wednesday, 23 June 2021 9:36 AM
To: s22 @mindmedicineaustralia.org>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: RE: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Good morning s22
Thank you for your email. In preparation for the presentation this afternoon:

- Invites have been extended to all ACMS members, interested parties within the TGA, as well as the presenters and attendees in your previous email;
- ACMS members have been forwarded the biographies of the presenters previously sent to the Secretariat;
- Slides from the presentation have been circulated to ACMS members.

Kind regards

s22
The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au
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From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 22 June 2021 5:21 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: Fwd: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Hi s22
Just checking you received the email below.
Best
s22

s22
Mob s22

Begin forwarded message:

From: s22 @mindmedicineaustralia.org>
Date: 3 June 2021 at 6:55:04 pm AEST
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>,
s22 @mindmedicineaustralia.org
Cc: TGA Committees Inbox <Committees@health.gov.au>
Subject: RE: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Dear s22
Thank you for your email.
Just checking that the attendees that you have from our side are;
s22
Professor s22
Dr s22
Professor s22
Dr s22
We have asked Professor s22 and Dr s22 to present for about 20 – 25 minutes in total on the scientific understanding of how the medicines work, safety and efficacy (with a particular focus on whether they each have an established therapeutic value when used as part of psychotherapy). Professor s22 and psychiatrist Dr s22 will then briefly comment on the presentation from an Australian perspective. We are planning for about 30 minutes to be available for questions.
We will make sure we the presentation slides to you at least 2 days in advance of the meeting.
Thank you for your help with this.

With best wishes

s22

m: +s22

e s22 mindmedicineaustralia.org

Mind Medicine Australia

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From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Thursday, 3 June 2021 5:13 PM
To: s22 @mindmedicineaustralia.org; s22 @mindmedicineaustralia.org>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>; TGA Committees Inbox <Committees@health.gov.au>
Subject: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Dear s22 and s22

I am writing to provide you with an update in preparation for the 23 June Advisory Committee on Medicines Scheduling meeting.

The meeting will run from 4 – 5 pm AEST via WebEx. The TGA Committee team will provide the webex meeting details and information through a meeting invitation shortly.

In terms of the logistics on the day, we are happy to provide assistance where we can, in particular:

- We will run any PowerPoint presentations – If you would like a PowerPoint presentation to accompany the speakers, please provide the presentation(s) to committees@health.gov.au at least 2 days before the meeting.
- Formal agenda – it is recommended that sufficient time for questions following the speakers is built into your allocated time

If you have any questions, please do not hesitate to contact me.

Kind regards

s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia

T: s22 | E: medicines.scheduling@health.gov.au
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http://www.mailguard.com.au/mg

Report this message as spam

From: s22
To: Medicines Scheduling
Cc: s22 VINE, Ruth; SKERRITT, John; s22 ; s22 ; s22 @gmail.com; s22 @monash.edu; s22 @mindmedicineaustralia.org
Subject: RE: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]
Date: Tuesday, 15 June 2021 1:50:16 PM
Attachments: image002.png
image003.png

Dear s22

That's excellent. Thank you for your help with this.

With best wishes

s22

From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Tuesday, 15 June 2021 1:34 PM
To: s22 .com.au>
Cc: s22 @health.gov.au>; VINE, Ruth <Ruth.VINE@health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 @imperial.ac.uk>; s22 s22 @gmail.com>; s22 @gmail.com; s22 @monash.edu; s22 @mindmedicineaustralia.org
Subject: FW: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Dear s22

I can confirm that we have now circulated the papers which you provided last night amongst the Advisory Committee on Medicines Scheduling members.

Kind regards

s22
s22 **uling Secretariat Team**
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 .com.au>
Sent: Monday, 14 June 2021 10:36 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; VINE, Ruth <Ruth.VINE@health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>; s22 s22 @imperial.ac.uk>; s22 @gmail.com>; s22 @gmail.com;

s22 @monash.edu; s22 @mindmedicineaustralia.org

Subject: 23 June Advisory Committee on Medicines Scheduling meeting [SEC=OFFICIAL]

Dear s22

Having spoken with Professor s22 we believe that it would be very helpful if the Members of the Advisory Committee on Medicines Scheduling were sent the attached papers for background reading ahead of the meeting of the Committee on the 23rd June 2021. The first four papers report on the latest trial results with psilocybin assisted psychotherapy and MDMA assisted psychotherapy. These trial results were published after the interim decision was released by the Delegate on the 3rd February 2021. They therefore represent new information for consideration by the Committee. The 3 other papers attached will also provide Committee members with much of the latest research thinking about the safety and efficacy of these therapies.

The attachments are briefly described below.

1. **For MDMA assisted psychotherapy**

(i) Article in Nature Medicine dated 31 May 2021 reporting on the findings of a randomised, double-blind, placebo-controlled , multi-site Phase 3 trial to test the efficacy and safety of MDMA assisted psychotherapy for the treatment of patients with severe PTSD. As you will see, using MDMA as part of psychotherapy was found to induce significant and robust attenuation in CAPS-5 scores compared with the placebo and to significantly decrease the Sheehan Disability Scale total score which measures functional impairment. The authors concluded that *"These data indicate that, compared with manualised therapy with inactive placebo, MDMA-assisted therapy is highly efficacious in individuals with severe PTSD, and treatment is safe and well-tolerated, even in those with co-morbidities".*

(ii) Commentary in Nature Medicine on the Phase 3 trial from Professor s22 (s22 s22, Imperial College, London) and Professor s22 (s22 s22, University of Chicago). As you will see, the authors conclude that "*the phase 3 study ….replicates the high efficacy seen in Phase 2 trials for PTSD, with a similar tolerability profile…..What is remarkable about MDMA therapy is large clinical effects are produced by just 2 or 3 doses, given a few weeks apart in a structured psychotherapy program. This represents a very novel type of pharmacological intervention, very different from any available in psychiatry today…… The new evidence …supports the efficacy and safety of MDMA after just a few exposures at a relatively modest dose, without signs of tolerance or dependence …. MDMA treatment gives hope and excitement in a field in which outcomes have been historically very poor."*

(iii) Article in the Journal of Psychotherapy (February 2021) which details the results of the first study of safety and tolerability of MDMA assisted psychotherapy in patients with Alcohol Use Disorder. The study showed that MDMA was well tolerated by all participants with no unexpected adverse events and that psychosocial functioning improved across all participants. At 9 months post detox the average units of alcohol consumption of participants were 18.7 units per week compared with 130.6 units per week before the detox.

2. **For Psilocybin assisted psychotherapy**

(i) Article in the New England Journal dated April 15, 2021 reporting on the results of a Phase 2 trial comparing psilocybin assisted psychotherapy with a leading SSRI (escitalopram) plus psychotherapy over a 6 week period. Whilst the antidepressant effects of both approaches using the QIDS-SR -16 self- reporting questionnaire were broadly the same remission rates were far higher in the psilocybin group (at 57%) than they were in the escitalopram group (at 28%). Other secondary outcomes also favoured psilocybin including incidence of side effects and suicidal ideation.

(ii) An Article published in Cell last year in which World leading researchers at the Centre for Psychedelic Research at Imperial College London (including Professor s22 and Dr. s22) examine the importance of psychedelic -assisted therapy to psychiatry. Key take-outs relate to **the lack of innovation in mental health treatments** (*"Research leading to the discovery of new pharmacological treatments for psychiatric disorders has been painfully slow. With a few exceptions …..current medicines are derivatives of drugs discovered in the 1950's through serendipity and refined through pharmacological modification. For these reasons, most major pharmaceutical companies have retreated from researching brain targets, threatening to halt a progression in research knowledge and possibly inducing the same sort of dark age that antibiotic research has found itself in");* **the history of psychedelic research** *(*widely researched in the 1950's and 1960's and *"considered to achieve major breakthrough treatments by many psychiatrists"* but then banned "*when it became recreationally used by young people"* with research subsequently recommencing decades later and showing that "*its [psilocybin's] effects on patients suffering from depression were remarkable ….positioning it as one of the most powerful therapeutics for treatment-resistant depression*"); **its medical use as part of psychotherapy for a wide range of mental illnesses** (which share internalising disorders); **the understanding of how the medicine works in the brain** (*"Psychedelics likely work by deregulating activity in systems and circuits that encode these behaviours* [ie internalising disorders, including negative thinking and rumination)[allowing them to recalibrate as the acute effects of the drugs subside"); the **therapeutic mechanism of action** (through agonism of the 5-HT2A receptors) and **the need for rescheduling** (*"Overall, it seems the best way forward to fostering research and therapeutic application is to press for a rescheduling of psychedelics with proven therapeutic utility, especially psilocybin"*).

(iii) An article in JAMA Psychiatry (July 29 2020) by Professor s22 and Dr s22 s22 developing some of the same themes discussed in the Cell article

(iv) A draft paper that has recently been submitted to the Journal of Psychopharmacology by several leading researchers including Professor s22 examining the evidence base for alleged potential harms of the classic psychedelics such as psilocybin. The paper concludes that medical risks are minimal and that many – albeit not all – of the persistent negative perceptions of psychological risks are unsupported by the scientific evidence and that the majority of reported adverse effects are not observed in a regulated and/or medical context. Note that the Tables and Appendices for this paper are in a separate document attached.

I have also copied this email to Dr Ruth Vine given her interest in this subject.

I would be very grateful if you could confirm when these papers have been circulated to Members of the Advisory Committee on Medicines Scheduling so that I can brief the presenters about the level of knowledge that can be assumed for the meeing.

Thank you for your help with this.

With best wishes

s22 [redacted]
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Psychedelic-Assisted Therapy review for TGA
Clinical And Mechanistic Evidence plus safety data

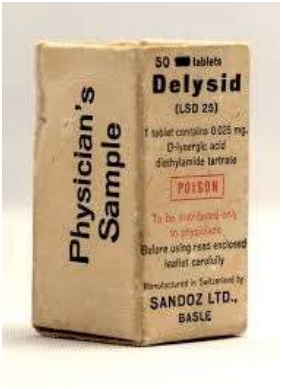
June 23rd 2021

s22 [redacted]

Imperial College London

Clinical research on LSD in the 1950s and 1960s

- Hundreds of psychiatrists worldwide
- 140 NIH grants
- 1000 clinical papers
- 40,000 patients
- 40 books
- 6 International conferences



Results were overwhelmingly positive, describing safe and effective treatments.

(Masters and Houston, 1971)

Adverse effects - Pooled analyses of 1960s data

- **44 psychiatrists, 5000 subjects and 25,000 drug sessions:**
  Rate of psychosis: 0.2%
  Rate of suicide of 0.04%
  (Cohen S. (1960) LSD: side effects and complications. Journal of Nervous and Mental Disorders 130: 30-40)

- **700 psychedelic drug sessions:**
  One case of prolonged psychosis
  (Chandler Al. & Hartman Ma. (1960) LSD-25 as a Facilitating Agent in Psychotherapy. *AMA Arch Gen Psychiatry*; 2(3):286-299)

- **350 patients over four years of outpatient treatments:**
  One attempted suicide
  (Ling TM, Buckman J (1963) The Treatment of Anxiety with Lysergic Acid and Methylphenidate. Practitioner 191: 201-4)

- **Review of 20 years of psychedelic therapy in the UK, 4000 patients and 50,000 psychedelic drug-assisted sessions.**
  Two completed suicides
  Thirty-seven patients with a prolonged psychosis
  (Malleson, N. (1971) 'Acute Adverse Reactions to LSD in clinical and experimental use in the UK.' Br J Psychiatry. 18(543): 229-30)

"Treatment with LSD is not without acute adverse reactions, but given adequate psychiatric supervision and proper conditions for its administration, the incidence of such reactions is not great,"

6 LSD trials in alcoholism

Review

Psychopharm

Lysergic acid diethylamide (LSD) for alcoholism: meta-analysis of randomized controlled trials

Teri S Krebs[1,2] and Pål-Ørjan Johansen[1,2]

Journal of Psychopharmacology
000(0) 1–9
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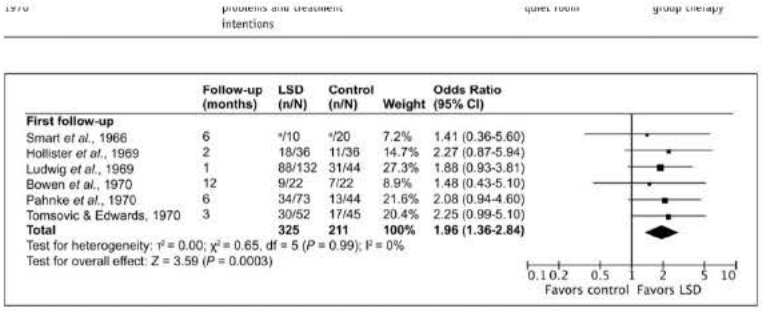
DOI: 10.1177/0269881112439253
jop.sagepub.com
SAGE

Abstract

Assessments of lysergic acid diethylamide (LSD) in the treatment of alcoholism have not been based on quantitative meta-analysis. Hence, we performed a meta-analysis of randomized controlled trials in order to evaluate the clinical efficacy of LSD in the treatment of alcoholism. Two reviewers independently extracted the data, pooling the effects using odds ratios (ORs) by a generic inverse variance, random effects model. We identified six eligible trials, including 536 participants. There was evidence for a beneficial effect of LSD on alcohol misuse (OR, 1.96; 95% CI, 1.36–2.84; $p = 0.0003$). Between-trial heterogeneity for the treatment effects was negligible ($I^2 = 0\%$). Secondary outcomes, risk of bias and limitations are discussed. A single dose of LSD, in the context of various alcoholism treatment programs, is associated with a decrease in alcohol misuse.

Keywords

Alcoholism, alcohol-related disorders, hallucinogens, meta-analysis, psychedelics, substance-related disorders



	Follow-up (months)	LSD (n/N)	Control (n/N)	Weight	Odds Ratio (95% CI)
First follow-up					
Smart *et al.*, 1966	6	*/10	*/20	7.2%	1.41 (0.36-5.60)
Hollister *et al.*, 1969	2	18/36	11/36	14.7%	2.27 (0.87-5.94)
Ludwig *et al.*, 1969	1	88/132	31/44	27.3%	1.88 (0.93-3.81)
Bowen *et al.*, 1970	12	9/22	7/22	8.9%	1.48 (0.43-5.10)
Pahnke *et al.*, 1970	6	34/73	13/44	21.6%	2.08 (0.94-4.60)
Tomsovic & Edwards, 1970	3	30/52	17/45	20.4%	2.25 (0.99-5.10)
Total		**325**	**211**	**100%**	**1.96 (1.36-2.84)**

Test for heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.65$, df = 5 ($P = 0.99$); $I^2 = 0\%$
Test for overall effect: $Z = 3.59$ ($P = 0.0003$)

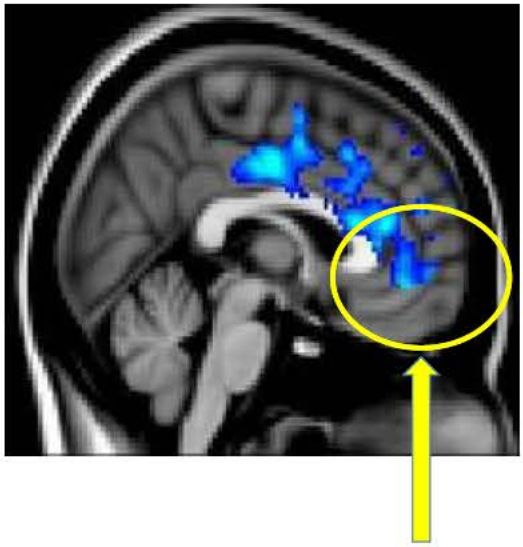
0.1 0.2 0.5 1 2 5 10
Favors control Favors LSD

Figure 2. Improvement on alcohol misuse at the first available follow-up after LSD versus control treatments.
*Continuous outcome data.

Effect size > = all current therapies

Resurrecting Psilocybin as a treatment from brain imaging - attenuated mPFC activity

Psilocybin 25mg p.o. attenuates activity in the brain region linked to depression
Carhart-Harris PNAS 2012

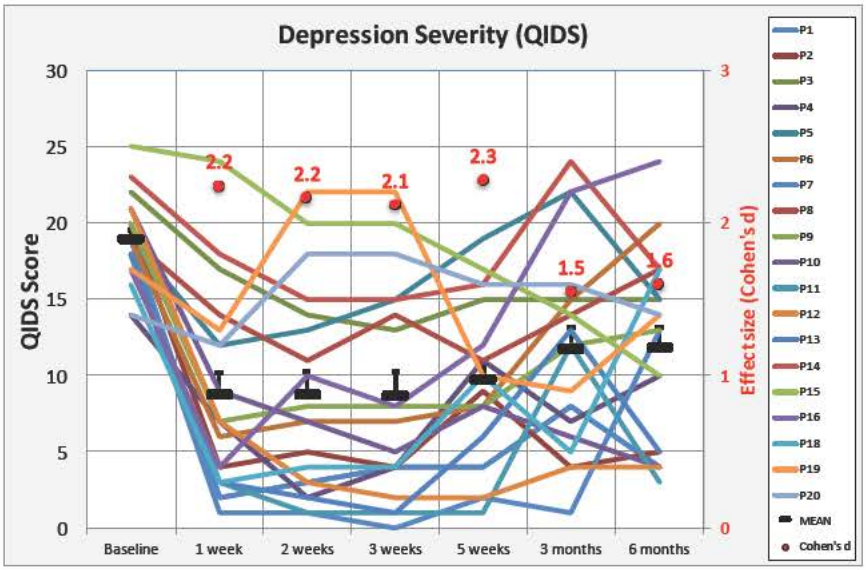


fMRI BOLD image

As do treatments for depression:

SSRIs	Kennedy et al. 01
CBT	Goldapple et al. 04
Sleep deprivation	Gillin et al. 01
ECT	Bonne et al. 96
Placebo	Mayberg et al. 02
Deep brain stimulation	Mayberg et al. 05
Ketamine	Deakin et al. 08

Psilocybin for resistant depression - UK MRC trial



Carhart-Harris Nutt et al Psychopharmacology, 2017

All treatment – resistant

Failed at least 2 antidepressant medicines and CBT

Patient quotes

It was like when you defrag the hard drive on your computer, I experienced blocks going into place, things being rearranged in my mind

My mind works differently [now]. I ruminate much less, and my thoughts feel ordered, contextualized. Rumination was like thoughts out of context, out of time; now my thoughts feel like they make sense, with context and logical flow. (P11)

"My outlook has changed significantly. I'm more aware now that it's pointless to get wrapped up in endless negativity. I feel as if I've seen a much clearer picture." P5

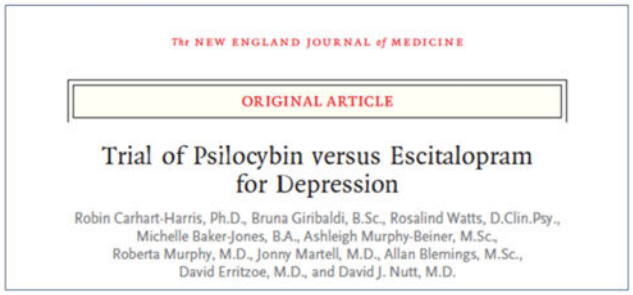
Watts et al Journal of Humanistic Psychology 2017, Vol. 57(5) 520

Most participants for whom it was effective (really out of 17) described a mental Reset, reboot, their mind being reconfigured. Many of them used these terms.

Some quotes. And where I give quotes I'll give an example of that theme happening during the session, and then how that theme looks 6 months down the line.

So here, P11 talking about his mind being reset during the experience, and then his experience of his mind still feeling kind of optimised, improved 6 months later: freeflowing, more orderly, ruminating less. Less stuck

Comparative trial v SSRIs

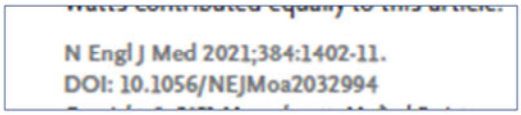


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trial of Psilocybin versus Escitalopram for Depression

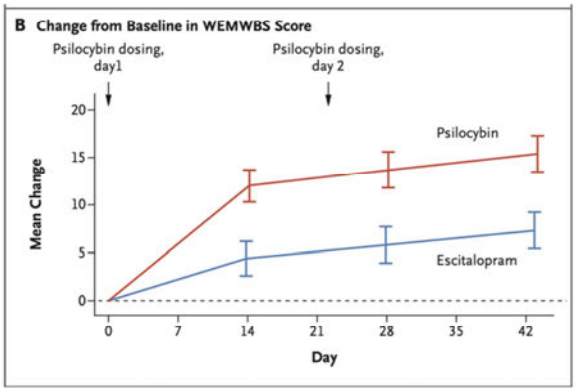
Robin Carhart-Harris, Ph.D., Bruna Giribaldi, B.Sc., Rosalind Watts, D.Clin.Psy., Michelle Baker-Jones, B.A., Ashleigh Murphy-Beiner, M.Sc., Roberta Murphy, M.D., Jonny Martell, M.D., Allan Blemings, M.Sc., David Erritzoe, M.D., and David J. Nutt, M.D.



N Engl J Med 2021;384:1402-11.
DOI: 10.1056/NEJMoa2032994

- 30 in each group
- Escitalopram – two 1mg doses psilocybin plus scitalopram10-20 mg for 6 weeks
- Psilocybin – two 25mg doses 3 weeks apart + placebo tabs
- Mood and other measures up to 6 weeks

Faster onset



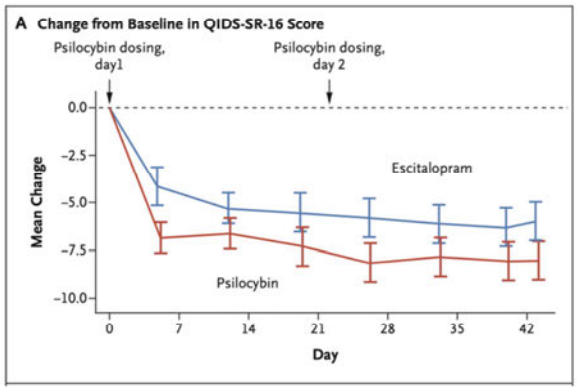
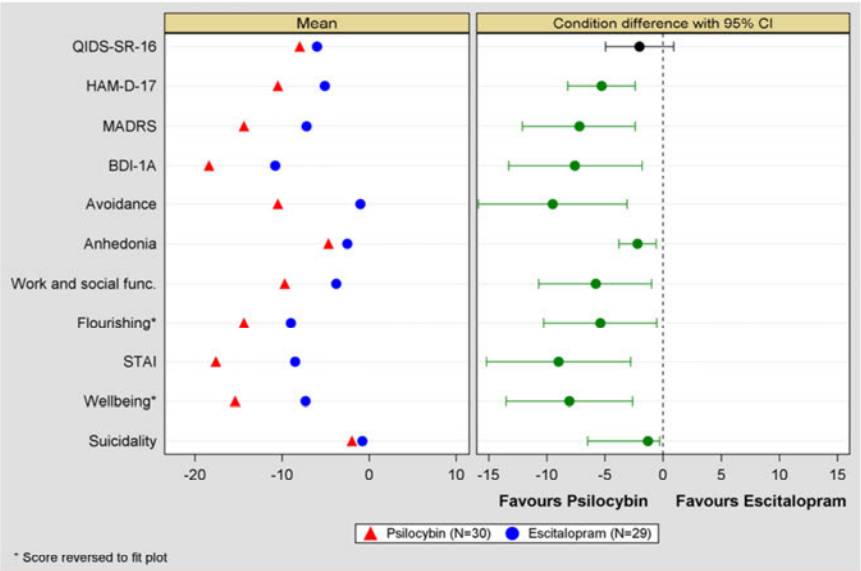


Figure 1.
Main paper

Efficacy: Green = >95% confident of difference



+ Remission rates psilocybin > twice that of escitalopram on all 4 mood scales

Side effects

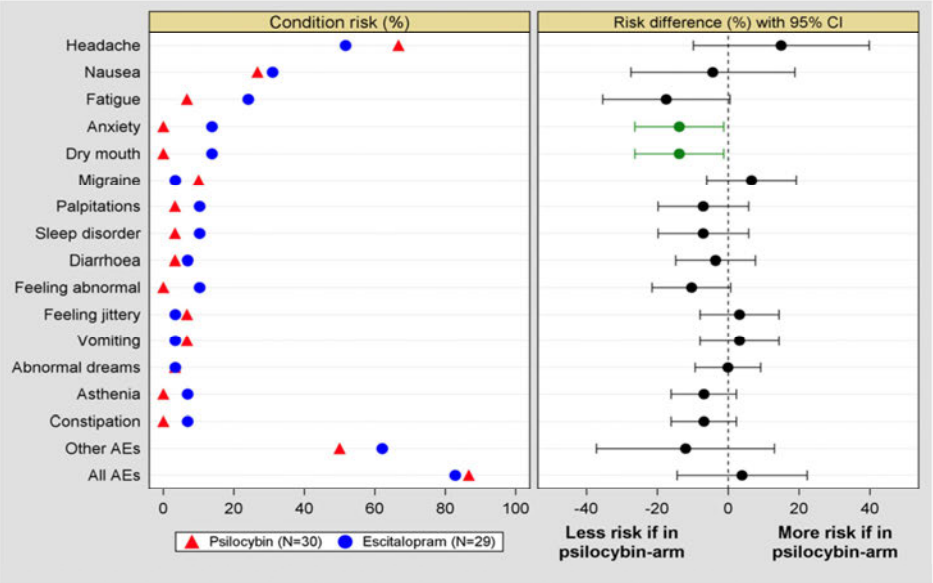
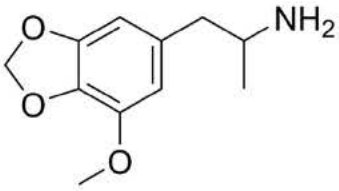


Figure S6. Supplementary appendix

Other trials with psilocybin - all positive

- End of life anxiety and depression – 2 double-blind RCTs:
  - Griffiths - Johns Hopkins and
  - Ross - NYU
- Depression – Griffiths - Johns Hopkins – comparison with no-treatment
- Smoking quitting - Johnson - Johns Hopkins - open trial
- Alcoholism – Bogenschutz - New Mexico – open trial
- Many others now underway including dose finding in resistant depression [COMPASSPathways] plus in anorexia, OCD, pain syndromes

3,4 Methylenedioxymethamphetamine (MDMA)



INSECURE Attachment

Self Narrative:

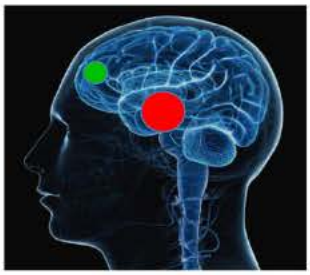
"I'm a bad person"
"I cannot achieve"
"I am unlovable"

World Narrative:

"Trust no one"
"The world is dangerous"
"People will hurt me"

- Synthetic phenethylamine
- Short acting (4-6 hours)
- Less perceptually disturbing than classical psychedelics
- Almost always pleasurable / well tolerated
- Safe in therapeutic applications
- Access to painful traumatic memories
- Enhances empathy
- **Selectively inhibits the fear response whilst leaving the other faculties intact**

Trauma and attachment disruption significant cause of treatment-resistant PTSD and addictions:



The Prefrontal Cortex versus The Amygdala

History of MDMA Timeline

1912 — MDMA first synthesized and patented by the German chemical company Merck.

1953 — The US army experiments with MDMA , possibly as a truth serum

1967 — Shulgin introduced to MDMA by a graduate student.

1977 — Shulgin introduces MDMA to Leo Zeff, psychotherapist. Who introduces the drug to hundreds of West coast therapists. Called Adam .

1980 — MDMA discussed at the ARUPA meetings at Esalen in the early to mid-80s.

By 1979, a small non-clinical market had developed for the drug "Ecstasy", a street name chosen over the more appropriate "Empathy". Mass manufacture and distribution for therapeutic application by the "Boston Group" in the early 1980s. Reports of Ecstasy appear in nightclubs in Dallas – "more popular than cocaine"

1983 — Case series studies are published by George Greer.

1985 - 1986 — DEA puts MDMA into Schedule 1. US psychotherapists challenge DEA. Judge rules Schedule 3 (Class C). DEA over-rules Judge & places MDMA permanently in Schedule 1 – disallowing research.
MAPS is formed by Rick Doblin

1987 — Ecstasy appears in UK and Ibiza and by 1990 rave has gone mainstream.

1988 — MAPS fund animal toxicity studies & human safety studies at Stanford University and Johns Hopkins University.

1998 - 1993 — Relaxation of laws in Switzerland for 5 years. Small research group formed, using MDMA psychotherapy.

1996 — FDA-approves double-blind, placebo-controlled Phase I dose-response safety study of MDMA by Charles Grob.

2004 — First MAPS-sponsored Phase 2 clinical trial of MDMA-PTSD (Mithoefers) approved by the FDA.

2009 — In the UK [redacted] is sacked for concluding to ACMD that MDMA be placed into Class B and be researched.

2010 — Mithoefer publishes MAPS-sponsored first RCT for MDMA Therapy

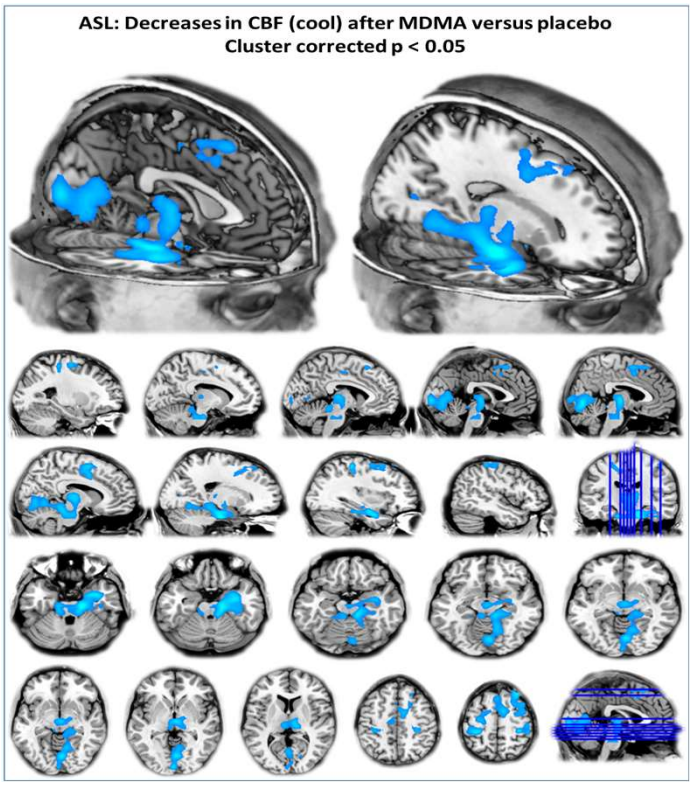
2015 — UK s first MDMA Study (and world s first addictions) begins

2017 — FDA grants Breakthrough Therapy status, for MDMA in USA

2021 — MAPS publishes Phase 2 MDMA-PTSD study data and starts Phase 3 studies in USA, Canada, & Europe Israel.
UK BIMA study published.

2023? — Current proposed date for FDA and EMA license approval of MDMA-PTSD

MDMA: Action in the brain:		MDMA: Effects
Action at serotonin receptors: **(POSITIVE MOOD + CREATIVE THINKING)**	5-HT_{1A} 5-HT_{1B}	• ↓ depression • ↓ anxiety • ↓fear (at the amygdala) • ↓ aggression and defensiveness • ↑ self-confidence
	5-HT_{2A}	• Alterations in perception of meaning
Increased Dopamine and Noradrenaline: **(STIMULATION)**		• ↑ level of alertness • ↑ arousal • ↑ conscious registration of external stimuli
Increased alpha-receptor activity: **(RELAXATION)**		• ↑ calmness and relaxation
At the hypothalamus: **(EMPATHY / BONDING)**		• Release of oxytocin



MDMA reduces brain blood flow in the stress circuit

hippocampus and amygdala
→ ability to cope with emotional memories during therapy

Carhart-Harris et al Biological Psychiatry 2015

MAPS PHASE 2 CONCLUSIONS

6 Phase 2 studies

More than 2/3 no longer met criteria for PTSD at the end of treatment

5 Sites (US, Switzerland, Canada & Israel)

N=103

Chronic PTSD, had prior treatment

Pre-post Effect Size:

Post 2 Sessions = 1.4

Post 3 Sessions = 1.9

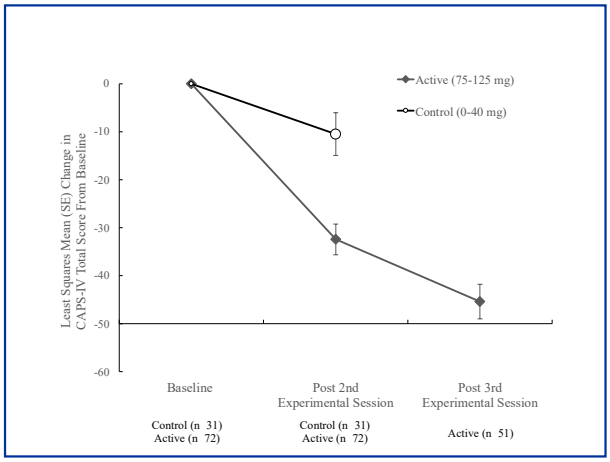
Control-subtracted Effect Size:

Post 2 Sessions = 0.8

Post 3 Sessions = 0.9

POOLED PHASE 2 DATA

CAPS-IV total score least squared mean estimates at endpoints



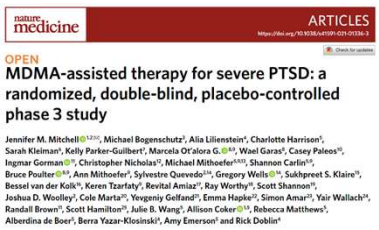
Mithoefer, M.C., Feduccia, A A., Jerome, L. et al. Psychopharmacology (2019). https://doi.org/10.1007/s00213-019-05249-5

MAPS PHASE 3 PROGRAMME

- 14 FDA Phase 3 Site Locations:
  - 11 in US,
  - 2 in Canada
  - 1 in Israel
- Chronic PTSD ≧ 6 months; Severe PTSD required for randomization
- Both groups receive identical therapy (42 hrs) per Treatment Manual with fidelity ratings & clinical supervision
- Observer-Blinded, Independent Rater Pool for DSM-5 diagnoses & Outcome Assessments with bias minimization
- First Phase 3 (Pivotal) Study Completed, second one underway
- Expanded Access / compassionate use approved in US and Israel
- 9 European locations for Phase 2 “Lead-in” studies and Phase 3 trial

MAPS PHASE 3 PIVOTAL STUDY CONCLUSIONS

- Largest PTSD study (N=90)
- ☑ Statistically very persuasive (p<0.0001) with confirmatory Phase 2 evidence, Large effect size
- ☑ Functional Impairment also improved per modified SDS (p=0.0116)
- ☑ No site-to-site variability across 15 centers in U.S. (N=77), Canada (N=9), Israel (N=5)
- ☑ No serious safety signals of MDMA emerged, long-term follow-up study in progress (1-2 years later)
- ☑ MDMA did not increase suicide risk in PTSD Study vs. therapy with Placebo



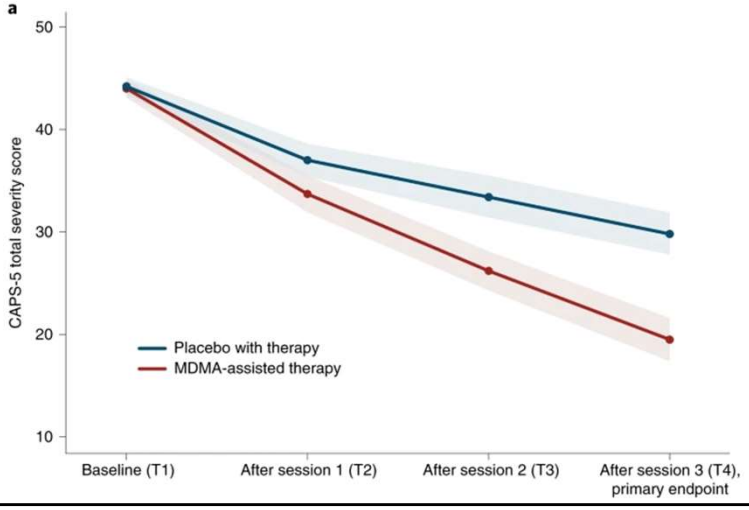
nature medicine ARTICLES

OPEN

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

Jennifer M. Mitchell, Michael Bogenschutz, Alia Lilienstein, Charlotte Harrison, Sarah Kleiman, Kelly Parker-Guilbert, Marcela Ot'alora G., Wael Garas, Casey Paleos, Ingmar Gorman, Christopher Nicholas, Michael Mithoefer, Shannon Carlin, Bruce Poulter, Ann Mithoefer, Sylvestre Quevedo, Gregory Wells, Sukhpreet S. Klaire, Bessel van der Kolk, Keren Tzarfaty, Revital Amiaz, Ray Worthy, Scott Shannon, Joshua D. Woolley, Cole Marta, Yevgeniy Gelfand, Emma Hapke, Simon Amar, Yair Wallach, Randall Brown, Scott Hamilton, Julie B. Wang, Allison Coker, Rebecca Matthews, Alberdina de Boer, Berra Yazar-Klosinski, Amy Emerson and Rick Doblin

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



- Improvement in Sleep Quality
- Posttraumatic Growth: positive changes in self-perception, interpersonal relationships, or philosophy of life, correlates with improvement in PTSD, durable at 12+ months follow-up
- Durable reduction in Alcohol use
- Increase in Openness

Ponte et al. in press; Gorman et al. 2020; Wagner et al. 2013; Jerome et al. 2020

4 dropouts in MDMA group:
2 COVID-related, 1 AE (depressed mood), 1 early efficacy

7 dropouts in Placebo group:
2 COVID-related, 2 SAEs, 2 AEs (insomnia, anxiety), 1 choice

MAPS STUDIES POOLED TREATMENT-EMERGENT ADVERSE EVENTS

Adverse Drug Reaction (>7%)	MDMA (N=46)	Placebo (N=44)	Adverse Drug Reaction (>7%)	MDMA (N=46)	Placebo (N=44)
Muscle tightness	63%	11%	BP increased	11%	-
Decreased appetite	52%	11%	Feeling jittery	11%	-
Nausea	30%	11%	Chest pain (non-cardiac)	11%	2%
Hyperhidrosis	20%	2%	Dry Mouth	11%	4%
Feeling cold	20%	7%	Vision Blurred	9%	2%
Restlessness	15%	-	Pollakiuria	9%	2%
Mydriasis	15%	-	Intrusive Thoughts	9%	-
Dizziness (postural)	13%	4%	Vomiting	9%	-
Bruxism	13%	2%	Stress	9%	-
Nystagmus	13%	-	Musculoskeletal Pain	9%	-

Sympathomimetic effects:

- +13-19mmHg SBP
- +11-19 bpm pulse

Adverse Events of Special Interest:

- Suicidality
  7% MDMA vs. 11% placebo
- Cardiovascular
  - 0% MDMA vs. 2% placebo
- Abuse potential
  - 0% MDMA vs. 0% placebo

Future MAPS-Sponsored MDMA-Assisted Psychotherapy studies

- Ongoing study of healthy subjects via the MDMA therapist training program, with plans for additional studies of MDMA therapy for race-based trauma and transgendered people as well.
- MAPS is undertaking a plan to make MDMA-assisted therapy into a Food and Drug Administration (FDA)-approved prescription treatment by 2023. For-profit pharmaceutical companies are not interested in developing MDMA into a medicine because the patent for MDMA has expired.
- Further MAPS studies completed or under development:
  - Reduction in social anxiety after MDMA-assisted therapy with Autistic Adults: RCT pilot study (Danforth et al 2018). Psychopharmacology.
  - MDMA+CBT Conjoint Therapy Study (Monson et al 2020) European Journal of Psychopharmacology
  - Open-label multisite Phase 2 safety and feasibility study of MDMA-assisted therapy for Eating Disorders
  - MDMA-assisted Therapy in People With Anxiety Related to Advanced Stage Cancer (John H. Halpern, MD, Mclean Hospital, USA)

The Bristol-Imperial MDMA-Alcoholism ('BIMA') Study

- World's first addictions study with MDMA therapy
- **Open-Label** Safety and Tolerability
- 8-week course of psychotherapy
- Alcoholics recruited from local drugs service
- n=14
- Male-Female MDMA co-therapist pair
- Two MDMA Sessions
- 125mg + 62.5mg MDMA
- Overnight stay

Original Paper

First study of safety and tolerability of 3,4-methylenedioxymethamphetamine-assisted psychotherapy in patients with alcohol use disorder

Ben Sessa[1], Laurie Higbed[1], Steve O'Brien[1], Claire Durant[1], Chloe Sakal[2], Daniel Titheradge[3], Tim M Williams[4], Anna Rose-Morris[4], Elsa Brew-Girard[4], Sam Burrows[4], Chantelle Wiseman[4], Sue Wilson[1], James Rickard[5] and David J Nutt[1,2]

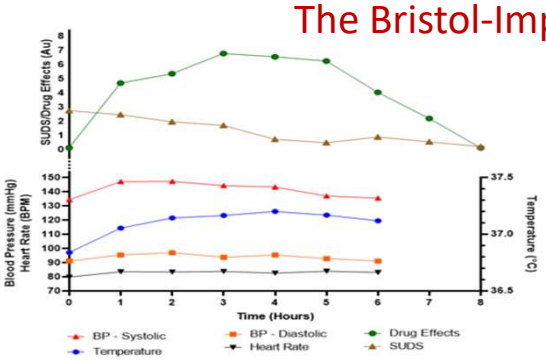
Psychopharm

Journal of Psychopharmacology 1–8

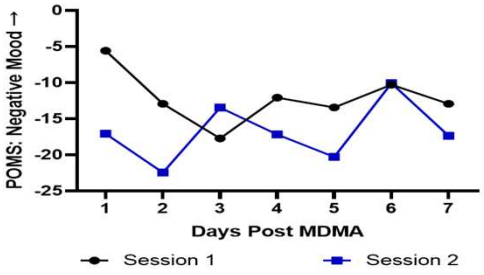
DOI: 10.1177/0269881121991792
journals.sagepub.com/home/jop
SAGE

2-weeks pre-detox	**Screening, consent and eligibility interview**	
Alcohol Detox	Seven to Ten Days, carried out by local Community Alcohol Detox Team. Followed by baseline assessments.	
1 week post detox	Session 1	60-minute therapy session.
2 weeks post detox	Session 2	60-minute therapy session
3 weeks post detox	**Session 3**	**MDMA-assisted therapy session 1 (~6-8 hours)**
	Session 4	Next day follow-up session (60 min) then daily phone calls 4 days.
4 weeks post detox	Session 5	60-minute therapy session
5 weeks post detox	Session 6	60-minute therapy session
6 weeks post detox	**Session 7**	**MDMA-assisted therapy session 1 (~6-8hours)**
	Session 8	Next day follow-up session (60 min) then daily phone calls 4 days.
7 weeks post detox	Session 9	60-minute therapy session
8 weeks post detox	Session 10	60-minute therapy session
3 months post detox	Face-to-face Follow-up interview	
6 months post detox	Face-to-face Follow-up interview	
9 months post detox	Face-to-face Follow-up interview	

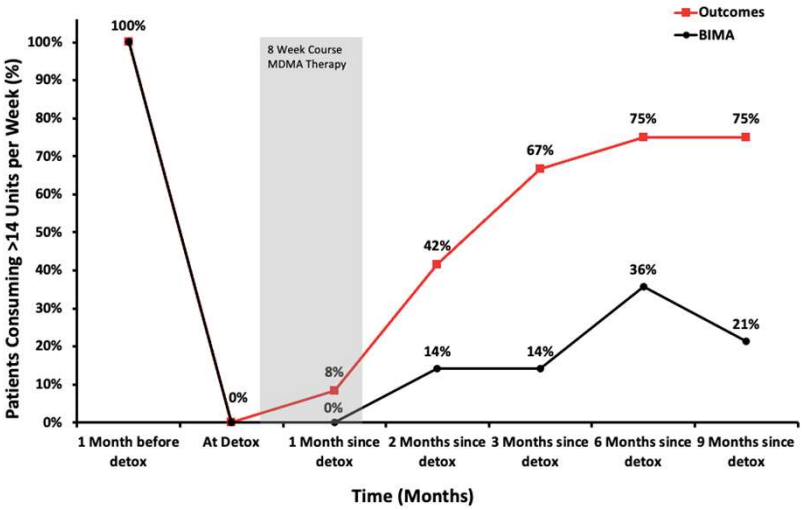
The Bristol-Imperial MDMA-Alcoholism ('BIMA') Study



Physiological monitoring of **BP, HR and Temp** during the 8-hour MDMA sessions
(Average scores across all 26 MDMA sessions)



Profile of Mood States (POMS) carried out by daily telephone calls for 7-days after each MDMA session (Average scores across 26 MDMA sessions)



Comparison of MDMA Therapy against Treatment As Usual for Alcohol Use Disorder

Next Steps for MDMA-AUD studies

- Phase 2b RCT to test efficacy of MDMA-assisted psychotherapy for the treatment of Harmful Drinking AUD (Awakn Life Sciences)
- Aiming for FDA/EMA approval of MDMA-assisted Psychotherapy for the treatment of AUD

From: SKERRITT, John
To: s22
Cc: REBERA, Avi; s22 s22 @mindmedicineaustralia.org; s22 @mindmedicineaustralia.org
Subject: RE: The Minutes of the ACMS Meeting on 4 November concerning Psilocybin and MDMA [SEC=OFFICIAL]
Date: Tuesday, 22 June 2021 9:58:40 AM

---

s22

Thanks for your letter.

I don't plan to respond in any length to the detailed comments that you have made on individual statements in the minutes, given this is a committee that none of the addresses on this email are members of.

In brief

- Of course we maintain a record of attendance at all Advisory Committee meetings
- The Minutes reflect the overall view of the meeting; they do no state that any decision was or was not unanimous
- The Minutes reflect what those members present at the meeting discussed. If they chose not to discuss use of substances in medically controlled environments versus recreational use in detail that is their prerogative.
- Similarly the range of statements on pages 3 and 4 of your letter quoted reflect the discussion at the meeting. IT is not for non-members or a secretariat to the committee to edit out or change particular statements if they reflected the view of the committee.
- The Delegates statement in the interim decision, and her/his decisions reflect wider issues. The Delegate takes advice from a wider range of sources than just the Committee. Therefore it is totally irrelevant that PRISM is mentioned in the Delegates interim decision but not in the ACMS Minutes.
- Again, it is not relevant whether or not you or I agree with the statement "a large proportion of the population have mental health conditions….". This is a statement in Minutes from the meeting of the committee. Similarly, the Committee chose not to assess the impact of "not bringing these therapies into our medical system".

Finally, I am certain that the Delegate has carefully reviewed the additional documents submitted, including the results of recent published studies.

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 .com.au>
Sent: Monday, 21 June 2021 11:30 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>

Cc: REBERA, Avi <Avi.Rebera@health.gov.au>; s22 @health.gov.au>; s22 @mindmedicineaustralia.org; s22 @mindmedicineaustralia.org
Subject: The Minutes of the ACMS Meeting on 4 November concerning Psilocybin and MDMA

Dear John

We have now had the chance to review the Minutes of the meeting of the Advisory Committee on Medicines Scheduling held on the 4th November 2021 which you referred to in Senate Estimates relating to to scheduling of the medical use of psilocybin and MDMA as part of therapy for the treatment of key mental illnesses.

I thought that it would be helpful if I raised some specific issues that we have with the Minutes which relate to the process that the Committee followed and which I believe are serious. I have done this in the attached letter.

I am available to discuss the contents of the letter with you at your convenience and look forward to hearing from you shortly.

Your Sincerely

s22

m: s22
e: s22 **@mindmedicineaustralia.org**
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

MIND MEDICINE AUSTRALIA

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulatory Group
Department of Health
Australian Government
Canberra, ACT

21 June 2021

Dear John

Minutes of the Meeting of the Advisory Committee on Medicines Scheduling held on 4 November 2020 to consider the proposed rescheduling of Psilocybin and MDMA as part of therapy in medically controlled environments

Thank you for arranging for Professor s22, Dr s22 Professor s22 s22 and Dr s22 to present as experts to the Advisory Committee on Medicines Scheduling on June 23rd 2021. The context of the meeting is to discuss whether the medicinal use of medical grade MDMA and medical grade psilocybin as part of psychotherapy each meet the requirements for a Schedule 8 medicine under the Poisons Standard**.** Our rescheduling applications were specifically restricted to these medicines only being used in medically controlled environments and being prescribed by a psychiatrist or specialist addiction physician. All other uses would remain in Schedule 9.

I have asked each of the experts to comment specifically on the key scheduling factors set out in Section 52E of the Therapeutic Goods Act and the Australian Health Minister's Advisory Council Guidelines. This includes the risks and benefits of the use of each substance as part of psychotherapy in medically controlled environments; the safety, toxicity and potential for abuse when used in this manner; and importantly whether each substance has an established therapeutic value when used in this manner. For completeness, I have also asked these experts to comment on whether there is any evidence that these substances, when used in this manner, can cause dependence and give rise to a high propensity for misuse.

In the context of Australia's worsening mental health environment and the inadequacy of current treatments for many Australians, we are conscious of the fact that the final advice which the Committee will give to the Delegate will be incredibly important to a substantial number of people suffering from treatment resistant depression, post-traumatic stress disorder and the trauma associated with many life-threatening addictions.

We have now had the opportunity to review the Minutes of the Advisory Committee's meeting held on 4 November 2020.

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Many of the arguments used by the Delegate in its Interim Decisions announced on 3rd February 2021 are reflected in the Minutes and we have addressed these arguments in detail in our Submissions to the Delegate dated 4th March 2021 opposing the Interim Decisions. We have also commented further about these arguments and the process being used in my letter to you of 5th April 2021. I would encourage you and your colleagues (including the Delegate, the Secretary of the Department of Health and the Chief Psychiatrist) as well as all of the members of the Committee to take the time to read our documents carefully.

In this context I thought that it would be helpful if I raised some specific issues relating to the Minutes which we weren't able to adequately cover in the above documents simply because, when they were prepared, we hadn't seen the Minutes. These additional issues (listed below) all relate to process.

1. **<u>There is no mention in the Minutes of which members of the Committee were actually present at the Meeting</u>**

Listing the participants in a meeting is usually regarded as an essential feature of the taking of Minutes.

2. **<u>Your Comments on the Meeting in Senate Estimates aren't contained in the Minutes.</u>**

In your comments to Senate Estimates on 24th March 2021 you advised the Senators that "*the advisory committee was very divided on the advice that it gave on this".* However, there is no mention of this division of views in the Minutes or the competing arguments. The Minutes are simply presented as if the views of Committee members were unanimous (when clearly according to your statements they were not). This is not helpful to readers of the Minutes and prevents readers from understanding the basis of the competing views.

3. **<u>The Lack of Differentiation in the Minutes between the Medical Use of these Substances in Medically Controlled Environments by Trained Professionals and their Recreational Use.</u>**

As you will understand, there are many examples of substances that are legally prescribed by medical practitioners for their patients but are illegal if used outside the medical system. Cannabis and morphine (an analogue of which is heroin) are two obvious examples. Yet the Minutes make it clear that the Committee did not carefully make this differentiation in its deliberations. This is particularly relevant, given that we made it clear in our rescheduling applications that the rescheduling that we were seeking was restricted to these medicines being prescribed as part of psychotherapy by psychiatrists or specialist addiction physicians,

and used only in medically controlled environments. In other words, the patient would never be able to take these substances home.

Some examples of this apparent confusion in the Minutes are:

- ***"It's potential for misuse is significant and at present, the benefits of use are substantially outweighed by the risks"***. This statement appears in both the psilocybin and the MDMA Minutes. The benefits of use in the way envisaged in our applications is that a person suffering from treatment resistant depression and/or treatment resistant PTSD (some of whom are potentially suicidal) are given the chance to get well. The safety data in trials to date are extraordinarily good, so the risks referred to must relate primarily to diversion risks into the recreational area. However, this ignores the fact that both psilocybin and MDMA (the latter in the street form of Ecstasy) are readily available in Australia at low prices through the Black Market (and in the case of psilocybin simply by picking the mushrooms which grow freely in many parts of Australia). Schedule 8 medicines are not only much that more expensive to purchase but they will be held in the medical system under strict controls. Why a Health Professional would risk losing his or her practicing certificate to fraudulently divert medicines held under strict controls which are readily available at much lower prices on the Black Market does deserve an explanation from the Committee.

- ***"The potential adverse effects, particularly relating to multi-drug toxicity, are unknown"*** *(*Psilocybin Minutes). The medical protocols require patients to list the current medications that they are on, such as antidepressants. The referring doctor will also list the medications that the patient is on in his or her referral. Contraindications for these therapies are known. The Committee's statement is far more relevant to recreational usage, but even there the use of psilocybin has been shown to be one of the safest recreational drugs currently in use in Australia - https://journals.sagepub.com/doi/abs/10.1177/0269881119841569. We believe that the Committee should be asked to examine these issues in more detail to justify the position that it took at its November meeting.

- *"**The Committee also raised that it was unclear as to whether MDMA is addictive, noting that it affects many of the neurotransmitter systems in the brain that are targeted by other addictive drugs and some studies report symptoms of addiction in users"*** *(*MDMA Minutes). All the trial results (including the recent Phase 3 results) clealy show that the use of MDMA as part of therapy (a maximum of three doses over a period of 2-3 months) is not addictive. Therefore the studies that are referred to (which aren't listed by the Committee in the Minutes) must presumably refer to the recreational use of Ecstasy which is not relevant to this rescheduling.

- **"*Members note that prolonged, even intermittent, use [of MDMA] can result in sleep disturbances, difficulties with concentration, depression, heart disease, impulsivity and decreased cognitive function. It can also reduce the ability to perceive and predict motion and can therefore result in accidents*"** (MDMA minutes). This paragraph is incongruent because we made it clear in our rescheduling applications that we weren't proposing the prolonged use of MDMA. At most, only 3 sessions with the medicines will occur as part of therapy over a two-to-three-month period. One of the reasons that this therapy occurs in controlled medical environments is to avoid accidents (the patient doesn't leave the medical establishment until after the effects of the medicine have worn off), and good medical practice will normally require the patient to be taken home by a family member or friend (this is exactly what happens with many day surgical procedures).

- ***"MDMA is subject to significant use in the Australian community resulting in harms including deaths"*** (MDMA Minutes). This statement is completely irrelevant to the medical use of MDMA in controlled medical environments and could be applied equally to a wide range of medicines in use today which are improperly and/or recreationally used.

- ***"Long-term use can result in sleep disturbances, depression, difficulties with concentration, heart disease, impulsivity and decreased cognitive function"*** (MDMA Minutes). Whilst the Committee hasn't linked this statement to any studies, it is entirely irrelevant to the medicinal use of MDMA as part of therapy which involves at most 2-3 controlled sessions with the medicine occurring as part of therapy over a relatively short period of 2-3 months.

- ***"MDMA can reduce the ability to perceive and predict motion and can therefore result in accidents"*** **(**MDMA Minutes). As mentioned above the therapy will occur only in medically controlled environments under the supervision of trained therapists. As with all medical procedures, the safety of the patient will be paramount.

- **"*It is not clear whether MDMA causes dependence*"** (MDMA Minutes). See comments above. As mentioned, we are talking about a maximum of 2-3 sessions with the medicines as part of therapy over a period of 2 – 3 months with all sessions occurring in medically controlled environments. There is absolutely no evidence that the use of MDMA in this way can cause dependence.

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4. **The Lack of any Reference in the Minutes to PRISM**

The absence of any reference to PRISM in the Committee Meeting Minutes is surprising given the way that the Delegate positively referred to the views of PRISM in each of the Delegate's Interim Decisions and described PRISM as a "peak body" alongside RANZCP and the AMA. PRISM clearly is not a peak body. As we mention in section 6.12 of our MDMA Submission (and Section 6.12 of our Psilocybin Submission), PRISM represents no members, sets no standards, has yet to lead or complete a single trial and had net expenses in the year to 30 June 2020 of $48,015 (of which $10,000 went to Entheogenesis Australia which has a major focus on the recreational use and preservation of plant-based medicines including psychedelics). Furthermore, two of PRISM's directors are on the Board of Entheogenesis Australia and a third director has a close involvement with Entheogenesis Australia's objectives.

The obvious point from a due process perspective is this. How did the Delegate form the view that PRISM was a peak body without advice to that effect from the Committee, and not realise the implications of its close association with Entheogenesis Australia? And secondly, if the Committee did advise the Delegate that PRISM was a peak body, why doesn't this appear in the Minutes?

5. **The Statement that "*A large proportion of the population have mental health conditions, but relatively few have conditions which are refractory to existing available treatments*"**

This statement appears in both the Psilocybin Minutes and the MDMA Minutes.

The Statement is extraordinary on a number of levels because it completely ignores the fact that:

i) For people suffering from treatment resistant conditions the emphasis of our mental health system is on managing mental illness (a palliative approach) rather than curing people (a curative approach).

ii) Less than 10% of people with PTSD gain remission from existing treatments and response rates from existing treatments are estimated to be as low as 30%.

iii) Only about 30-35% of people suffering from depression experience remission from pharmacotherapy and/or psychotherapy.

iv) According to Government figures, pre-Covid 1 in 8 Australians were on antidepressants and yet the effect size of antidepressants has been shown to be small (and not much better than a placebo). See the recent article in the Lancet accessed through this link - https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(20)30036-5/fulltext.

v) Relapse rates when people come off conventional therapies are estimated to be as high as 80%.

vi) There is evidence that the use of antidepressants may increase suicidality rates and there is clear evidence that antidepressants can give nasty side effects and cause difficult withdrawal symptoms.

vii) The Federal Government's own publicly stated policy to reduce the high suicide rate that we have in Australia and particularly amongst ADF veterans and First Responders (the terrible mental health experienced by many ADF Veterans will be highlighted even more by the forthcoming Royal Commission into Veteran Suicides.)

viii) The almost complete lack of effective treatment innovation in the sector for decades.

Whilst the exactness of the above percentages can be debated the orders of magnitude seem right and each of the percentages quoted has been the subject of serious research. Together they highlight the failure of current treatments for a large number of depression and trauma sufferers in Australia. For the Committee to argue that "*relatively few have conditions which can't be managed by existing available treatments*" is a truly extraordinary statement. At best the statement shows that the Committee wasn't properly briefed about the mental health crisis in Australia and the lack of treatment effectiveness for many Australians before providing its advice.

It's also noteworthy in this context that:

i) No apparent analysis was done by the Committee on the accuracy of the RANZCP Clinical Memorandum or the AMA Submission (see the analysis in Sections 3.2.3, 3.4 and 6.12 of our MDMA Submission and Sections 3.2.3, 3.4 and 6.16 of our Psilocybin Submission) despite a significant reliance by the Committee on both as part of its advice to the Delegate.

ii) The Committee's statement in the Minutes that "*…few [of the submissions received] were from practising psychiatrists"* was demonstrably wrong (see the large number of supporting psychiatrists listed in Section 3.2.1 of both of our Submissions).

6. <u>The Absence of Any Analysis of the Impact of Not Bringing these Medicinal Therapies into our Medical System.</u>

The Minutes don't reflect any discussion by the Committee of the risks that people suffering from depression or trauma incur when they seek to access these therapies illegally, simply because they are not provided through our medical system. When people suffering from these mental illnesses do this out of desperation there are no Government sanctioned controls over the purity of the substances being used, the accuracy of dosage levels or the

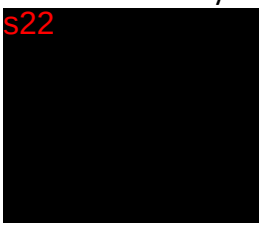
expertise of the treating therapists. As the media coverage of the effectiveness and safety of these therapies increases (as it is currently doing), more and more Australians suffering from these mental illnesses are likely to seek to access these therapies illegally if they are not brought into our medical system. Apparently, the Committee (according to the Minutes) didn't conduct any risk based analysis of this issue.

Since the Committee met in November 2020 three important trials have published their results. These are the MAPS Phase 3 results for MDMA assisted therapy for PTSD, the results of the Imperial College trials comparing psilocybin assisted therapy with Escitalopram (a leading SSRI) and the use of MDMA assisted therapy for severe alcohol addiction associated with trauma. All of these trials confirm the results of previous trials, namely that MDMA and psilocybin can be used as part of therapy safely and effectively to treat both depression and trauma. The Experts listed at the start of this letter will brief the Committee on these results.

Rescheduling the medical use of psilocybin and MDMA as part of therapy in medically controlled environments to Schedule 8 of the Poisons Standard will not open the "flood gates" to the use of these therapies in Australia. The prescribing doctor will still have to convince both the TGA and the relevant State/Territory Government where the treatment is to occur that the needs of the particular patient warrant access to this medicinal therapy

I am available to discuss the contents of this letter with you at your convenience and look forward to hearing from you shortly.

Yours Sincerely



Mind Medicine Australia Limited
Mob s22

From: s22
To: SKERRITT, John
Cc: s22
Subject: as discussed today
Date: Monday, 2 August 2021 6:10:04 PM
Attachments: image001.png
image002.png

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear John
Good to speak with you as always. We look forward to your presentation at our Summit in November for which we've sold over 500 tickets so far in spite of the pandemic. Have you checked out the website lately? https://summit.mindmedicineaustralia.org/

As mentioned, we have been becoming increasingly concerned by the delays on this decision. We are in the worst mental health crisis Australia has ever had and it's getting worse by the day.

As discussed, since the interim decision, we've had further trial results (with decent sized cohorts lead by leading researchers) which further confirm the safety and efficacy of these therapies.

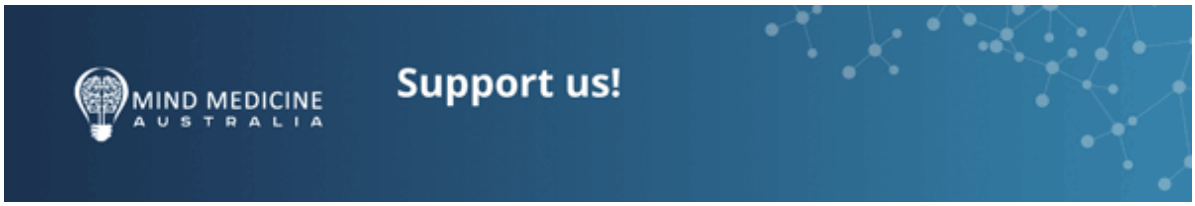
We get contacted daily by people who are suffering from treatment resistant mental illnesses, their doctors and the media asking us what is happening with the TGA. These delays are getting to the stage where they are simply cruel.

John, we need some patient-focused leadership from the TGA here. As you know better than most, treatment resistant mental illness causes terrible suffering. Were these any other substances they would have been rescheduled now and you fully understand that rescheduling will not open the floodgates in any case. Any delay has to be based on bias and prejudice and we all need to be better than that. There are simply too many lives at stake.

Kindest good wishes

s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

MIND MEDICINE
AUSTRALIA



From: s22
To: s22
Cc: s22@mindmedicineaustralia.org; Medicines Scheduling; s22; NOYEN, Benjamin
Subject: Re: Independent review of the therapeutic use of psilocybin and MDMA [SEC=OFFICIAL]
Date: Thursday, 30 September 2021 2:54:13 PM
Attachments: image001.png
image002.png
image003.gif
image004.png

HI s22

Thanks for letting me know. I very much appreciate that.

With best wishes

s22

> On 30 Sep 2021, at 14:21, s22@health.gov.au> wrote:
>
> Good afternoon s22
> I am pleased to advise that the Independenthivs22 Expert Panel report on the therapeutic value, benefits and risks of psilocybin and MDMA has been published on the TGA website.
> The report will be considered by the Advisory Committee on Medicines Scheduling (ACMS) at its meeting on 3 November 2021 and we anticipate the final decision will be made in the first week of December.
> Kind regards,
> s22
> s22
> s22 – Scheduling and Committee Support Section
> <image001.png>
>
> Regulatory Practice and Support Division | Health Products Regulation Group
> Regulatory Engagement, Education and Planning Branch
> Australian Government Department of Health
> T: s22 | M: s22 | E: s22@health.gov.au
> Location: Symonston GH
> PO Box 100, Woden ACT 2606, Australia
> <image002.png>
> <image003.gif>
> <image004.png>
>
> *The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our*

respects to them and their cultures, and to elders both past and present.

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http://www.mailguard.com.au/mg

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From: s22
To: s22
Cc: Medicines Scheduling; s22 ; NOYEN, Benjamin; s22 @mindmedicineaustralia.org; s22 @mindmedicineaustralia.org
Subject: RE: Independent review of the therapeutic use of psilocybin and MDMA [SEC=OFFICIAL]
Date: Friday, 1 October 2021 12:42:49 PM
Attachments: image005.png
image006.png
image007.png
image008.png
image009.gif
image010.png
TGA Releases the Independent Panel_011021.pdf

Hi s22

We released an announcement on our website earlier today about the Independent Panel Report which is attached for your information. As you will see we have commented positively about the Panel's approach.

Just wanted to keep you informed.

With best wishes

s22

m: +s22
e: s22 @mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: s22 @health.gov.au>

Sent: Thursday, 30 September 2021 2:21 PM
To: s22 @mindmedicineaustralia.org
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 s22 @Health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Subject: Independent review of the therapeutic use of psilocybin and MDMA [SEC=OFFICIAL]

Good afternoon s22

I am pleased to advise that the Independent Expert Panel report on the therapeutic value, benefits and risks of psilocybin and MDMA has been published on the TGA website.

The report will be considered by the Advisory Committee on Medicines Scheduling (ACMS) at its meeting on 3 November 2021 and we anticipate the final decision will be made in the first week of December.

Kind regards,

s22
s22
s22 – Scheduling and Committee Support Section
Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
T: s22 | M: s22 | E: s22 @health.gov.au
Location: Symonston GH
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

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http://www.mailguard.com.au/mg

Report this message as spam

From: s22
To: Medicines Scheduling
Subject: RE: Final decision on the scheduling of psilocybin and MDMA [SEC=OFFICIAL]
Date: Friday, 10 December 2021 3:46:47 PM
Attachments: image002.png
image003.png
image004.gif
image005.png

Thank you so much for your prompt reply. It would have been prudent to have published this update on your website. Can you do this?
I have been checking the following pages religiously:

1. https://www.tga.gov.au/public-notices-about-scheduling
2. https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin
3. https://www.tga.gov.au/scheduling-delegates-final-decisions

I have subscribed to the SMP mailing list meantime.
Have a wonderful weekend,

s22
s22
o: +s22
m: +s22
e: s22@mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Friday, 10 December 2021 3:34 PM
To: s22 @mindmedicineaustralia.org>

Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: Final decision on the scheduling of psilocybin and MDMA [SEC=OFFICIAL]

Dear s22

Thank you for your enquiry. Due to the importance of this decision, the publishing date has been slightly delayed to allow the Delegate to carefully consider all material provided regarding the scheduling of psilocybin and MDMA.

It is anticipated that the final decision will be published by the end of December. For same-day notifications of scheduling decisions, you may wish to subscribe to the SMP email list.

Kind regards

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: Medicines Scheduling
To: s22 @mindmedicineaustralia.org"
Cc: Medicines Scheduling; s22 @mindmedicineaustralia.org"
Subject: Delegates final decisions with respect to MDMA and psilocybin [SEC=UNOFFICIAL]
Date: Wednesday, 15 December 2021 1:27:28 PM
Attachments: image001.png

Dear Mind Medicines Australia,

Thank you for your applications proposing amendments to the scheduling of MDMA and psilocybin in the Poisons Standard.

On 3 November 2021, the Advisory Committee for Medicines and Scheduling (ACMS) considered your applications, along with the Independent Expert Report and the submissions received from the public prior to the meeting.

The decision maker (delegate) has now made a final decision in relation to your application, having considered your applications, their interim decision, the Independent Expert Report, all submissions and the further advice from the ACMS. The delegate's final decision is to affirm their interim decision and not amend the Poisons Standard in relation to MDMA and psilocybin.

The notice of the final decision will shortly (today) be published on the TGA website and will be available via the Scheduling delegate's final decisions page. The notice includes the reasons for the delegate's final decision. In brief, considering the factors specified in paragraph 52E(1)(a) of the *Therapeutic Goods Act 1989* and the Scheduling Policy Framework, the delegate was of the view that the risks of down-scheduling these substances outweighed the benefits and the current scheduling of MDMA and psilocybin in Schedule 9 remains appropriate. In particular, the delegate's view was that therapeutic value has not been established for either substance, the use of which only in a highly controlled clinical trial environment is warranted given the safety risks.

The delegate agrees with the view of the ACMS that further data and evidence are required in order to justify down-scheduling MDMA or psilocybin at this time. Pending the outcome of further clinical research, the scheduling of MDMA and psilocybin could be reconsidered in future applications.

The potential benefit of MDMA in treatment of PTSD and psilocybin in TRD determined from already-completed clinical trials was noted by the delegate and the final decision does not affect current access to MDMA or psilocybin for use in a clinical trial setting. Schedule 9 substances can be accessed for clinical trials in all Australian States and Territories to obtain further evidence which could inform future applications for down-scheduling of MDMA and psilocybin.

Thank you for your application and we wish to acknowledge and commend your commitment to mental health research and therapies.

Kind regards

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au

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From: s22
To: Medicines Scheduling
Cc: s22 .com.au); s22
Subject: RE: Rescheduling Application for Psilocybin (spelt in the Poisons Standard with an "e" as Psilocybine) from Mind Medicine Australia [SEC=OFFICIAL]
Date: Friday, 4 March 2022 2:27:54 PM
Attachments: image001.png
image002.png
image003.png
image004.jpg
image005.gif

Dear s22

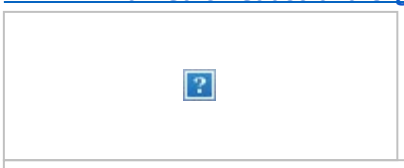
Thank you for your confirmation.

Our second application in relation to MDMA assisted psychotherapy will be with you shortly.

With best wishes

s22

m: +s22
e: s22 @mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org



From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Friday, 4 March 2022 9:46 AM
To: s22 @mindmedicineaustralia.org>; Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 .com.au>; s22 .com.au) s22 .com.au>

Subject: RE: Rescheduling Application for Psilocybin (spelt in the Poisons Standard with an "e" as Psilocybine) from Mind Medicine Australia [SEC=OFFICIAL]

Dear s22

Please accept this response as acknowledgement of your application for an amendment to the Poisons Standard. Your application has been logged and will be considered by the Delegate and at the next meeting of the appropriate Advisory Committee on Scheduling.

For email updates regarding the progress of your application, please subscribe to the SMP mailing list at https://www.tga.gov.au/smp-email-list.

Kind regards

s22
The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement, Education and Planning Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @mindmedicineaustralia.org>
Sent: Thursday, 3 March 2022 5:04 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 .com.au) s22 .com.au>; s22 .com.au) s22 .com.au>
Subject: TRIM: Rescheduling Application for Psilocybin (spelt in the Poisons Standard with an "e" as Psilocybine) from Mind Medicine Australia

Dear Sir/Madam,

We have pleasure in lodging an Application to reschedule Psilocybin (spelt as Psilocybine in the Poisons Standard) by retaining psilocybine in Schedule 9 but also having a Schedule 8 entry for restrictive medical use with Appendix D and Appendix F controls.

Accordingly we are attaching;

1. The completed Application Form which follows the prescribed form on the TGA website;
2. A link to the papers referenced in the Bibliography (A USB stick containing these has also been express posted to you: https://www.dropbox.com/sh/kh7ediq84uhq1x5/AACO5AkpViQho4TF8kzd8j5sa?dl=0

The Auspost Express Post tracking number for the papers referenced in the Bibliography is: 02 01000 38292 70060 30993

Could you please acknowledge receipt of this email and let us know if you require any further information.

Yours Faithfully

s22 [redacted]

s22 [redacted]

Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

Report this message as spam

From: s22
To: NOYEN, Benjamin; Medicines Scheduling
Subject: RE: Key dates as your have requested [SEC=OFFICIAL]
Date: Wednesday, 20 April 2022 8:17:26 AM
Attachments: image001.png
image002.png
image003.gif
image004.png
image005.png
image006.png

Hi Ben,
The timetable is still as stated on our website at https://www.tga.gov.au/scheduling-committees-meeting-dates-and-decisions-timeframes. We anticipate publishing the public notice in April and thus the public submission deadline will be in May. Only once the public notice is published will we know the precise public submission deadline and I do not wish to commit to a date before that.
Please let me know if you need something further.
s22

From: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Sent: Tuesday, 19 April 2022 8:33 PM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: Key dates as your have requested [SEC=UNOFFICIAL]
Appreciate some advice please re the timetable?
Ben.

Ben Noyen
Assistant Secretary
Regulatory Engagement Branch

Health Products Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health
☏ +61 2 6289 7214 | 💻: benjamin.noyen@health.gov.au
📫 PO Box 100, Woden, ACT, 2606

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From: s22 .com.au>
Sent: Tuesday, 19 April 2022 8:09 PM
To: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org
Subject: RE: Key dates as your have requested [SEC=UNOFFICIAL]

Dear Ben

Thanks for your email. Yes we will put the information summary together.

Can you also advise when our applications will go onto the TGA website and the detailed timetable published.

Best

s22

s22 [redacted]
m: +s22 [redacted]
e: s22 [redacted] @mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Sent: Tuesday, 19 April 2022 7:42 PM
To: s22 [redacted] .com.au>
Subject: FW: Key dates as your have requested [SEC=UNOFFICIAL]

Dear s22 [redacted]

Thank you for your email and request to arrange a delegation of mental health experts to meet with the Advisory Committee on Medicine Scheduling (ACMS). Your request has been considered in consultation with other senior officials of the TGA and with the Chair of the ACMS.

It's unusual for applicants or delegations supporting an application to meet or present to the ACMS, although I appreciate this opportunity was afforded to you previously. The application process is designed to obtain the necessary information to enable the ACMS and delegate to appropriately consider an application. Therefore, the previous presentation to the ACMS, independent expert panel literature review on MDMA and Psilocybin, information supporting the previous and new application is considered sufficient to enable an informed decision to be made.

As an alternative, you may wish to provide me with a brief overview of key additional information that you believe will support your application. I will personally ensure the ACMS is provided with the submission in addition to materials that support the new application.

Kind regards,

Ben.

Ben Noyen
Assistant Secretary
Regulatory Engagement Branch

Health Products Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health
☎ +61 2 6289 7214 | 💻: benjamin.noyen@health.gov.au
📫 PO Box 100, Woden, ACT, 2606

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From: s22 .com.au>
Sent: Tuesday, 12 April 2022 11:39 AM
To: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Cc: s22 @mindmedicineaustralia.org>; s22 s22 @mindmedicineaustralia.org) s22 @mindmedicineaustralia.org>
Subject: Re: Key dates as your have requested [SEC=UNOFFICIAL]

Hi Ben

Thanks. Good to talk with you.

Yes these are the broad dates currently on your website but the actual detailed timeline starts when the TGA publishes our applications on its website and announces actual dates. For example the public submission period will have to end sometime in May for you to give adequate notice and a 4 week submission period.

I would also like to discuss with you finding a time when a small delegation of mental health specialists which we put together can meet with the Medicines Scheduling Advisory Committee (and ideally the Delegate) to discuss our applications. The mental health crisis in Australia continues to get worth and a large number of sufferers are treatment resistant (ie current treatments don't work for them). This cause immense suffering and in some cases suicidal ideation and suicidal. It's apparent that few people on the Committee actually have any expertise in mental health and the weaknesses of psychiatric medicines and therapeutic treatments. Our delegation will include recognised experts in this space.

I am sure that the members of the Committee will benefit from this and it will lead to more informed advice being given.

I look forward to hearing from you.

With best wishes

s22

Mob s22

On 12 Apr 2022, at 11:19 am, NOYEN, Benjamin <Benjamin.Noyen@health.gov.au> wrote:

Hi s22

As requested key dates are as follows:

- Public consultations on proposed amendments to the Poisons Standard for psilocybin and MDMA will be held in April 2022.
- Advisory Committee meeting will be held 21-23 June 2022.
- Interim decisions and subsequent public consultations are due to be published in September 2022.
- Final decisions are anticipated to be published in November 2022.

Ben.

Ben Noyen
Assistant Secretary
Regulatory Engagement Branch

Health Products Regulation Group | Therapeutic Goods Administration
Australian Government Department of Health
☏ +61 2 6289 7214 | 💻: benjamin.noyen@health.gov.au
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From: s22
To: Medicines Scheduling
Cc: s22 .com.au); s22
Subject: RE: ACMS and ACCS 2022 meeting dates and decisions timeframes [SEC=OFFICIAL]
Date: Wednesday, 20 April 2022 1:06:20 PM
Attachments: image002.png
image003.png
image004.gif
image001.png

Thank you for the update s22
We look forward to seeing the notice published before the end of April.
Warm regards

s22
o: +s22
m: +s22
e: s22@mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

From: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Sent: Wednesday, 20 April 2022 1:04 PM
To: s22 @mindmedicineaustralia.org>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: RE: ACMS and ACCS 2022 meeting dates and decisions timeframes [SEC=OFFICIAL]

Dear s22
The timetable is still as stated on our website at https://www.tga.gov.au/scheduling-committees-

meeting-dates-and-decisions-timeframes. We anticipate publishing the public notice before the end of April and thus the public submission deadline will be in May (the public consultation period remains open for a minimum of 20 days). Only once the public notice is published will we know the precise public submission deadline.

Please let us know if we can assist with anything further.

Kind regards,

s22

The Chemicals and Medicines Scheduling Secretariat Team
Scheduling and Committee Support Section
Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Engagement Branch
Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
T: s22 | E: medicines.scheduling@health.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 19 April 2022 11:20 AM
To: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: ACMS and ACCS 2022 meeting dates and decisions timeframes

Dear Sir/Madam

Hope you're well.

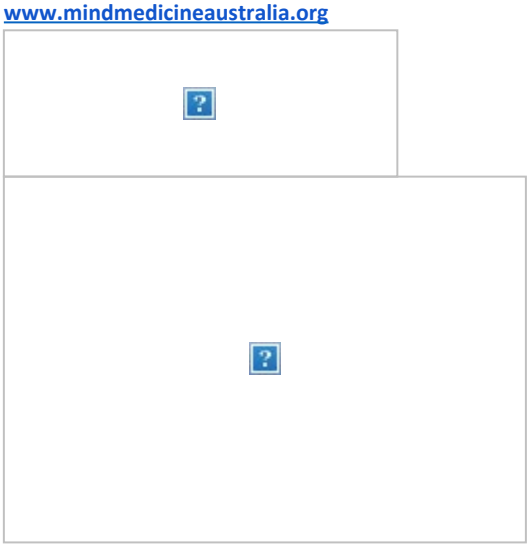
Can you please provide clarification for when public notice of proposed changes to scheduling and invitation to comment will open psilocybin and MDMA?

The TGA website: https://www.tga.gov.au/scheduling-committees-meeting-dates-and-decisions-timeframes states "April 2022."

Thank you in advance

s22

o: +s22
m: +s22
e s22@mindmedicineaustralia.org
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org



From: Medicines Scheduling
Bcc: s22 @mindmedicineaustralia.org; s22 [redacted]
Subject: Consultation: Invitation to comment on proposed amendments to the Poisons Standard [SEC=OFFICIAL]
Date: Tuesday, 3 May 2022 4:14:00 PM

As an identified potential stakeholder, you have received this email regarding proposed amendments to the Poisons Standard to be considered at the June 2022 meetings of the Advisory Committees on Medicines and Chemicals Scheduling. Due to technical faults the automated list server notice is currently unavailable. We apologise for any inconvenience.

Consultation: Invitation to comment on proposed amendments to the Poisons Standard being referred to the June 2022 meetings of the ACMS, ACCS and Joint ACCS/ACMS

Submissions on any of the substances to be considered at the June meetings of the ACMS, ACCS, and Joint ACMS-ACCS should be provided through our consultation hub.

Public consultation on proposed amendments to the Poisons Standard

The TGA invites public submissions on proposals to amend the Poisons Standard, referred by the delegates of the Secretary to the Department of Health, to the June meetings of the Advisory Committee on Medicines Scheduling, the Advisory Committee on Chemicals Scheduling (ACCS), and the Joint sitting of the Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS/ACCS).

Read the pre-meeting proposals

The closing date for public submissions on these matters is **27 May 2022**.

If you have difficulty accessing the consultation hub or uploading your submission, please contact medicines.scheduling@health.gov.au.

More information regarding the Poisons Standard is available on the TGA website.

==========

Medicines and Chemicals Scheduling Secretariat contact details:

Email: Medicines.Scheduling@health.gov.au

Telephone: 1800 020 653

==========
====

Unsubscribe from the scheduling email list.

From: s22
To: NOYEN, Benjamin
Cc: SKERRITT, John; s22 ; s22 ; s22 ; s22
Subject: Rescheduling Applications - Forthcoming Meeting of the ACMS - TIME SENSITIVE
Date: Friday, 10 June 2022 8:31:24 PM
Attachments: Letter to TGA_100622 - final .pdf
Appendices to TGA Letter June 22.pdf

Dear Ben

In our last conversation you indicated that the TGA would, in principle, be prepared to send out any further information that we had to the members of the Advisory Committee on Medicines Scheduling in preparation for their meeting later this month. .

I have therefore prepared a letter with attachments which endeavours to provide further relevant information. This is obviously a critical decision from the perspective of so many “at risk” patients suffering from treatment resistant Depression and treatment resistant PTSD. Thank you for your assistance with this.

Please let me know if you have any queries.

With best wishes

s22

MIND MEDICINE AUSTRALIA

10 June 2022

The Committee Members
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Canberra ACT

Dear Committee Members

Applications to Reschedule the Medical Use of MDMA and Psilocybin as Part of Psychotherapy for Treatment Resistant Depression and Treatment Resistant Post-Traumatic Stress Disorder

The Delegate's Final Decision rejecting our previous rescheduling applications was released by the TGA in December 2021. Whilst we were obviously disappointed by the decision, the Delegate's detailed published reasons did enable us to understand the particular matters that concerned the Delegate. As a result, we were able to directly respond to those concerns in our current applications.

Given the importance of the present applications to people suffering from treatment resistant Depression and treatment resistant Post-Traumatic Stress Disorder (**PTSD**) we have endeavoured to bring together a number of the key issues in this letter which we believe the Committee should consider in giving advice to the Delegate.

1. THE DELEGATE'S DECISION-MAKING FRAMEWORK

Section 52E of the Therapeutic Goods Act, the Scheduling Handbook (2019) and the Scheduling Policy Framework (2017) all make it clear that a rescheduling decision is based on a risk benefit analysis where the provision to medical practitioners and their patients of appropriate therapeutic management options is weighed against the objective of public health risk reduction. The framework emphasises both objective assessment of the factors and a "best fit" within the prescribed schedules. The framework also emphasises the importance of giving due consideration to public submissions which are an integral part of the Delegate's decision-making process.

We believe there are four key contextual factors which the Delegate (and therefore the Advisory Committee on Medicines Scheduling - ACMS) have to take into account in making a decision on our rescheduling applications.

MIND MEDICINE AUSTRALIA

1. THE 4 CONTEXTUAL FACTORS

1.1. Factor No 1 – The Lack of Effective Mental Illness Treatments for Many Australians

Australia is in the midst of an increasing mental health crisis. According to the Productivity Commission, even before the current Covid pandemic, 1 in 5 Australians had a chronic mental illness. After two years of dealing with the pandemic all the evidence indicates that the numbers are now significantly worse. Just as sobering is the fact that, according to Commonwealth Health Department figures, 1 in 8 Australians (pre-pandemic) were on antidepressants including 1 in 4 older people.

Whilst these statistics are bad, they are considerably worse for ADF Veterans and First Responders. **These are people that have provided enormous service to our Nation**. ADF Veterans have a one in two chance of suffering from a mental illness and much higher comorbidities, with suicidal ideation estimated to be ten times that of the general population.

Equally sobering is the fact that, in contrast to nearly all other areas of medicine, there has been minimal innovation in treatments for mental illness in over 50 years. The net result of all of this is that, for many Australians suffering from mental illness, our health system is palliative rather than curative in nature. The system does not have the treatment options to help more Australians go into remission and therefore to get out of the mental health system. **This is a massive systematic failure.**

With current treatments for Depression, only 35% of sufferers experience remission from pharmacotherapy (primarily antidepressants) and/or psychotherapy. Whilst a further 35% are estimated to show some response this does not mean that these patients get well. Relapse rates can be as high as 80% when treatments stop, and pharmaceuticals can give patients nasty and debilitating side effects.

The position for people who suffer from post-traumatic stress disorder (PTSD) is even worse than this. Remission rates for PTSD are estimated to be less than 10%. Whilst response rates are higher (up to 50%), response is all about management rather than cure. As with Depression relapse rates are high when treatments stop.

The residual group in each case (around 30% of Sufferers with Depression and 50% of Sufferers with PTSD) are described by the Health System as “treatment resistant”. The current system of treatment modalities doesn’t help them in any substantive way, and they are left to suffer. For those in this category life can be excruciatingly hard. For some the level of suffering becomes too much and this can lead to suicidal ideation. For a smaller number suicidality will lead to suicide.

We know that there have been many public submissions in response to our rescheduling applications because we have had an enormous number of people accessing the ‘TGA’ Section of our website during the public submission period which has just closed. There were over 50,000 visits which is more than 10 times the number that accessed this section of our website during the public submissions period for our first rescheduling applications. Whilst we have only been copied with some of these submissions, many of them highlight the challenges and suffering faced by people with treatment resistant conditions.

One example of a person suffering from treatment resistant depression is given in the attached submission made by **Mr.** s22 on behalf of his wife s22 – see ***Appendix A***. Please take the time to review this submission to understand both the level of s22 suffering, the devoted care given by her husband and the number of pharmaceuticals that s22 is being given in an attempt to alleviate her depression.

All governments around Australia have policy platforms aimed at reducing levels of mental illness and suicide. This properly recognises the enormous amount of pain and suffering within our communities. However, we believe that substantive reductions will be impossible without innovation in mental illness treatments which reduce the proportion of sufferers categorised as treatment resistant.

1.2. Factor No 2 – The Nature of the Rescheduling Decision

The rescheduling of a substance to Schedule 8 of the Poisons Standard is not dependent on whether that substance has been registered on the Australian Register of Therapeutic Goods (**ARTG**). Therefore, by definition, the standards of evidence that apply to the registration of a medicine on the **ARTG** are not the same standards that apply to the rescheduling of an unregistered medicine into Schedule 8 of the Poisons Standard. The use of unregistered Schedule 8 medicines comes under the TGA's much more restrictive Special Access Scheme which specifically recognises that some people are treatment resistant and "at risk", and that therefore they deserve a compassionate approach which properly recognises this.

As mentioned above, the rescheduling decision is a "best fit" approach considering the matters set out in *Section 52E of the Therapeutic Good Act, the Scheduling Policy Framework and the Scheduling Handbook* and in particular the need for adequate treatment options within the context of public safety.

In considering the various scheduling factors the Delegate and Committee members also have an additional burden of responsibility to come to the right decision. This is because (according to the Scheduling Handbook at page 6) scheduling decisions are *legislative* in nature and therefore can't be reviewed by the Commonwealth's Administrative Appeals Tribunal or by the Federal Court. In other words, the normal protections around due process have been removed from the scheduling decision.

1.3. Factor No 3 – The Importance of a Clear Ethical Framework

It is an obvious statement that Government decisions need to be made within an ethical framework that works within the specific legal framework. The ethical dimensions are specifically dealt with in a submission to the TGA made by **Dr** s22, the s22 s22 of the **Ethics Centre** and Australia's leading ethicist. This submission is attached as **Appendix B.** In Dr s22 words:

"In Summary: *the alleviation of human suffering cannot always await the attainment of perfect knowledge. The greater the suffering, the greater the requirement to apply a test of sufficiency. Or, perhaps to sharpen the point – there is a prima facie ethical obligation to alleviate avoidable suffering. That obligation can only be set aside in the face of compelling evidence that the means available to relieve suffering would cause more harm than the suffering itself. The*

current evidence does not support such a conclusion when it comes to the clinical use of MDMA and psilocybin."

1.4. Factor Number 4 – The Rescheduling Decision Has to be Viewed Against the Restrictive Nature of our Rescheduling Proposals and in the Context of Human Suffering

Our rescheduling proposals are very restrictive. We have added these restrictions in direct response to the issues raised by the Delegate, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and the Australian Medical Association (AMA) in relation to our first applications and the views expressed by the Australian Psychological Society in its recent Clinical Memorandum.

Key Elements of MMA's Restrictive Rescheduling Proposal

- As an unregistered medicine, the treating psychiatrist will only be able to prescribe pharmaceutical grade psilocybin or pharmaceutical grade MDMA as a Schedule 8 controlled medicine as part of psychotherapy if the psychiatrist first obtains approval from the TGA under its Special Access Scheme to use these substances as part of psychotherapy. **To obtain such an approval, the psychiatrist will have to demonstrate to the TGA that the patient is treatment resistant and 'at risk'**
- The treating psychiatrist will need to have received specific training in the use of this form of medicine assisted psychotherapy
- The psychiatrist's patient diagnosis and treatment plan will have to be confirmed by two other psychiatrists
- The substances used will have to be pharmaceutical grade and at GMP standard
- The treatment will only be allowed to take place in medically controlled environments (a hospital or medical clinic as occurs with Esketamine) – the patient will ***never*** be allowed to take the medicines home
- Two therapists will be with the patient at all times during the session with the medicine and (for abundant caution) a doctor will be available at all times (despite the fact that these medicines have been shown to be safe when used in this way)
- The State or Territory Government where the treatment is to occur will also need to approve the proposed treatment for the specified patient under its own Schedule 8 permit procedures

Importantly, all other uses of psilocybin and MDMA will remain in Schedule 9.

Importantly, rescheduling on the basis proposed will still leave power to give or withhold approval on an individual basis with the Commonwealth Government and the relevant State or Territory Government where the treatment is proposed to occur. This is because the psychiatrist involved (with the prescribing psychiatrist's diagnosis and treatment plan supported by two other psychiatrists) will need to apply to both the TGA for approval under the TGA's Special Access Scheme and to the relevant State or Territory Government for a Schedule 8 permit for each individual patient treatment.

Importantly, the restrictive terms of our proposed rescheduling applications are actually more conservative that a proposal set out by leading psychiatrists and psychologists in an article in RANZCP's own journal (*"Medicinal psychedelics for mental health and addiction: Advancing research of an emerging paradigm" by Daniel Perkins et al*, *the Australian and New Zealand Journal of Psychiatry 2021* – see **Appendix C** attached).

It's also important to note that both the RANZCP and the AMA have on occasions been overly conservative in their views about a number of relatively new modalities in psychiatry (such as the use of medical cannabis and transcranial magnetic stimulation). Whilst their views are important, they need to be weighed against all of the factors set out in our rescheduling applications (particularly in relation to safety and efficacy and the compassionate nature of the TGA's Special Access Scheme).

2. APPLYING THE RESCHEDULING FRAMEWORK AND THE KEY CONTEXTUAL FACTORS TO OUR RESCHEDULING APPLICATIONS

2.1. Protection of Public Health

This is one of the core requirements of the rescheduling framework and is specifically mentioned in Section 52E(1)(f) of the Therapeutic Goods Act. In our applications we deal with this matter in detail.

2.2. Safety of Treatment

All of the evidence to date shows that psilocybin and MDMA is safe to use in a medically controlled environment (see detailed comments in our Applications). In the context of the current applications three psychiatrists will have to confirm both the patient's diagnosis and treatment plan, the prescribing psychiatrist will have to have received specific training in these therapies and two therapists will have to be in the medicine dosing room with the patient at all times. These requirements are actually significantly more restrictive than the protocols used in the clinical trials that the Delegate refers to in the Delegate's Final Decision of last December.

The safety of these medicines when used in this context are highlighted by Professor s22 s22 at Imperial College London and Professors s22 s22 and s22 (the s22 of the Neuromedicines Discovery Centre at Monash University's Faculty of Pharmaceutical Sciences). Professor s22 is one of the World's leading researchers in these medicinal therapies and Professor s22 is the s22 at Monash University (ranked No 1 in the World), a Fellow of the Australian Academy of Science and Australia's leading Neuropsychopharmacologist.

See the Submissions from Professors s22, s22 and s22 s22 set out in Appendices D, E, F and G.

2.3. Translation Risk

This is dealt with in detail in our Applications. Translation risk applies to all medicines that move from the trial stage into clinical practice. To argue that Australian psychiatrists are incapable of properly managing these risks as part of a clinical team in a medically controlled environment where the patient can't take the medicines home is, in our view, inconsistent with both the high standards of clinical practice provided by our psychiatrists and the disciplined clinical environment in which they operate. A review of existing Schedule 8 medicines will indicate that far more dangerous and addictive medicines than MDMA and psilocybin are already in Schedule 8 (examples are given in Section 2.4 below).

Furthermore, as described in our Applications, protocols are easily available from recent trials and the Mind Medicine Institute and its global Faculty (https://www.mindmedicineinstitute.org.au/) is already training clinicians in the application of these therapies at World's Best Practice (see the comments supporting this from Professor s22 extracted in our Applications).

Finally, the Delegate in the Final Decision makes the point that "…*it is unclear to me how [psilocybin/MDMA] would be dispensed/supplied to a practitioner were it to be down-scheduled and an optimal therapeutic dose has not yet been established."*

We deal with the proposed secure medical psilocybin and MDMA supply lines for these substances in detail in our Applications and these are no different than those which are so effectively used with other more dangerous Schedule 8 controlled medicines. There is an existing secured pathway for Schedule 8 medicines which is understood by practitioners. In terms of optimal therapeutic dose, the same point could be made of many Schedule 8 medicines and it can definitely be made in relation to antidepressants and many other existing psychiatric medicines. The key point which we believe should be compelling is that we do have dosing levels from trials which showed high efficacy and safety results and we do know toxicity levels (see details in our Applications).

2.4. Diversion Risk

We also deal with this alleged risk at length in our Applications. In Schedule 8 there are already far more dangerous and addictive medicines than psilocybin and MDMA (eg medicinal cocaine, morphine, fentanyl, oxyiodene, methadone and dexamphetamines). The point we want to emphasise here is that our medical system already has controls in place to safeguard Schedule 8 medicines and to minimise diversion risk.

The Australia Institute and **Fearless** (a leading Australian Charity providing care to people suffering from PTSD chaired by the ex head of the Australian Defence Force, s22 s22 lodged a joint submission with the TGA making it clear that, in their view, diversion risk was negligible. They based this view both on existing controls and the fact that these substances are readily available in Australia through the Black Market and at prices much lower than the pharmaceutical grade costs of these medicines applicable for therapeutic treatments through our medical system. The Joint Submission from the Australia Institute and Fearless is set out in **Appendix H.**

2.5. The Need for More Research

The argument used by the Delegate in its Final Decision that more research is needed or that the mechanism of action is poorly understood is not consistent with normal practice and the safety and efficacy shown in overseas trials in the context of an unregistered medicine. The reality is that more research is perfectly consistent with rescheduling these medicines on the limited basis proposed.

We would go even further than this. Most psychiatric medicines (whether registered or unregistered) warrant further research and the mechanism of action for virtually all of them is poorly understood.

In the context of the proposed rescheduling to Schedule 8 these medicines when used as part of therapy have more trial evidence than many existing Schedule 8 unregistered medicines and stronger safety profiles and effect sizes. Certainly, more research is required but there is more than enough safety and efficacy data to support rescheduling these substances as unregistered medicines to Schedule 8 of the Poisons Standard.

2.6. Other Public Safety Matters to Consider

In our Applications, we comment on the availability of expanded access schemes in relation to these medicinal therapies in the US, Canada, Israel and Switzerland. Clearly the Governments and Health Authorities in those countries have formed the view that the balance between compassionately providing highly prospective treatments to alleviate suffering outweighs any public health concerns. In the Netherlands psilocybin assisted therapies are legal and a number of clinical groups offer these treatments. The obvious question here is why “at risk” Australians suffering from treatment resistant conditions should be denied access to these therapies in a controlled manner in this country when they are available in other Western countries with health systems comparable to Australia.

The other factor relevant here is that psilocybin and MDMA are ***not*** new medicines. MDMA was first invented by a pharmaceutical company over 100 years ago. Up until MDMA’s prohibition in the mid-1980s (prohibition was part of the War on Drugs and had nothing to do with medical merit) over **500,000** doses of MDMA were used legally and safely by practitioners across 20 years. In addition, at last count, **1,799** research participants have safely taken MDMA in clinical or research studies and MDMA assisted therapy has come through its first of two Phase 3 trials with flying colours.

Psilocybin use has a history going back into pre-history, was first synthesised by a pharmaceutical company 70 years ago, was used extensively in clinical practice and clinical trials in the late 1950s and 1960s and has completed Phase 2b trials with positive safety and efficacy results.

At last count there have been 94 MDMA trials and 73 psilocybin trials since trials recommenced in the late 1990s. There is therefore plenty of evidence of safe use, efficacy and contraindications within the context of scheduling as unregistered medicines. These are

not ‘new’ medicines, a lot is known about them and, by definition, treatment resistant patients are not being helped by existing treatments.

This brings me to my final point under public safety. At the moment treatment resistant patients who want to access these therapies have to either go underground in Australia or travel overseas. There is a thriving Black Market for these substances in Australia. The problem with accessing these therapies through the underground market is two-fold:

1. Whilst there are no doubt experienced and well intentioned therapists working with these therapies outside of the medical system, the treatments are (by definition) unregulated. This means that dosing levels, purity of medicines and the level of expertise of treating therapists are unmonitored by regulatory authorities, This is potentially dangerous to public health.
2. The system is forcing otherwise law-abiding Australians to act illegally or go overseas (if they can afford it) for treatment simply because of the pain and suffering that they are forced to endure and which is caused by the treatment resistant nature of their mental illness.

2.7. Established Therapeutic Value

We deal with this at length in our Applications in relation to both psilocybin and MDMA when used as part of therapy. In particular I refer you to:

1. The submissions made by **Professor** s22 [redacted] s22 [redacted] at Imperial College London and one of the leading researchers in this field internationally. In his submission Professor s22 confirms ***in unequivocal language*** that in his view the science and data support the fact that these substances, when used as part psychotherapy for the treatment of Depression and PTSD, ***have an established therapeutic value*** (i.e. they meet the necessary safety and efficacy tests for the rescheduling of these substances as unregistered medicines).

2. The submissions made by **Professor** s22 [redacted] and **Professor** s22 [redacted] s22 [redacted] from the Faculty of Pharmaceutical Sciences at Monash University, which also state ***in unequivocal language*** that ***the test of established therapeutic value*** has been met for these substances***.*** As previously mentioned Professor s22 [redacted] is not only the s22 [redacted] of the Faculty of Pharmaceutical Sciences at Monash University (ranked No 1 in the World) but he is also a Fellow of the prestigious Australian Academy of Science and Australia’s leading neuropsychopharmacologist.

2.8. The UN Convention on Psychotropic Substances

Whilst both MDMA and psilocybin are in Schedule 1 of the UN Convention on Psychotropic Substances its quite clear from previous decisions of the Delegate that this does not of itself prevent a rescheduling of a medicine to Schedule 8. This is because:

1. The Convention itself contains a specific exemption for limited medical use approved by Government (this is exactly what the TGA's Special Access Scheme is designed to do in conjunction with Schedule 8 of the Poisons Standard); and

2. The TGA has rescheduled substances in the past in exactly these circumstances.

Other countries comparable to Australia (e.g. the US, Canada, Switzerland and Israel) also use the exemption in the Convention to support the right of medical practitioners to apply for access to these medicinal therapies for their treatment resistant patients. In addition, there are highly relevant UN Conventions to which Australia is a signatory which support access in these limited circumstances (e.g. the UN Convention on Economic, Social and Cultural Rights which provides in Article 12 that people have the rights to "*the enjoyment of the highest standards of physical and mental health"*).

Finally, the Rescheduling Policy Framework makes it clear that the Delegate and the ACMS should take a "best fit" approach. Given the restrictions set out in our Applications, the supporting safety and efficacy evidence in relation to MDMA and psilocybin as unregistered medicines, the rescheduling precedents, the exemption to the Convention, the existence of other competing conventions and the amount of suffering in our communities, the argument that MDMA and psilocybin when used as part of psychotherapy for "at risk" patients with treatment resistant conditions does not fit the requirements of Schedule 8 of the Poisons Standard would be incredibly harsh.

3. CONCLUSION

We believe that there are compelling grounds to reschedule the therapeutic use of MDMA and Psilocybin as part of psychotherapy to Schedule 8 of the Poisons Standard on the highly restrictive basis envisaged by our applications. All other uses of these substances will remain in Schedule 9. The nature of the restrictions will not "open the flood gates" to the medical use of these substances and will not endanger public safety. Rescheduling on the basis envisaged will be an act of compassion to those people suffering from treatment resistant conditions who are "at risk" and will require Commonwealth and State Government approvals on a case-by-case basis at every stage of the process.

Of course, we are very happy and prepared to make leading experts available to deal with any residual issues that you may have.

Yours sincerely

Mind Medicine Australia
Mob s22

From: s22
To: SKERRITT, John; s22
Cc: s22 .com.au; s22
Subject: RE: quick call re RANZCP presentation meeting with Prof s22 [SEC=OFFICIAL]
Date: Tuesday, 23 August 2022 4:11:37 PM
Attachments: image001.png
image002.png
image003.png

Ok thanks we will lock that in thx John

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Tuesday, 23 August 2022 2:14 PM
To: s22 .com.au>; s22
s22 @health.gov.au>
Cc: s22 com.au; s22 @mindmedicineaustralia.org>
Subject: RE: quick call re RANZCP presentation meeting with Prof s22 [SEC=OFFICIAL]

Monday

Sent from Workspace ONE Boxer

On 23 August 2022 at 2:06:41 pm AEST, s22 .com.au> wrote:

>
>
> Thanks John
> For now let's lock both 10:30-12:30pm Monday and the 4pm Tuesday:)
> When do you think you can get the largest audience?
> All best s22
>
> ---
>
> **From:** SKERRITT, John <John.Skerritt@health.gov.au>
> **Sent:** Tuesday, 23 August 2022 12:44 PM
> **To:** s22 .com.au>; s22
> s22 @health.gov.au>
> **Cc:** s22 .com.au; s22 @mindmedicineaustralia.org>
> **Subject:** RE: quick call re RANZCP presentation meeting with Prof s22
> [SEC=OFFICIAL]
>
> 4-5 pm only – rest of day already fully booked
>
> **Adjunct Prof John Skerritt** FTSE FIPAA (Vic)

Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: s22 .com.au>
Sent: Tuesday, 23 August 2022 12:30 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22
s22 @health.gov.au>
Cc: s22 .com.au; s22 @mindmedicineaustralia.org>
Subject: RE: quick call re RANZCP presentation meeting with Prof s22
[SEC=OFFICIAL]

Please could you also advise re avail times on the Tuesday John…warmly s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Tuesday, 23 August 2022 7:51 AM
To: s22 .com.au>; s22
s22 @health.gov.au>
Cc: s22 .com.au; s22 @mindmedicineaustralia.org>
Subject: RE: quick call re RANZCP presentation meeting with Prof s22
[SEC=OFFICIAL]

I cant do lunch but have blocked off 1030-1230 at this stage on 21 Nov.

If he would like to give a seminar say from 1030-1130 I can book our conference room and we will invite staff to attend from 1030-1130; then from 1130-1230 he could meet with a smaller group of our senior staff.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
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F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: s22 .com.au>
Sent: Monday, 22 August 2022 10:40 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22
s22 @health.gov.au>
Cc: s22 .com.au; s22 @mindmedicineaustralia.org>
Subject: RE: quick call re RANZCP presentation meeting with Prof s22
[SEC=OFFICIAL]

Thank you John
We will check the flights – please do reserve the second half of the morning…can you do lunchtime?
Can you please organise a larger group for Prof s22 to present to as he is brilliant and he will provide education to the broader group?
All best s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Monday, 22 August 2022 8:40 PM
To: s22 .com.au>; s22
s22 @health.gov.au>
Cc: s22 .com.au; s22 @mindmedicineaustralia.org>
Subject: RE: quick call re RANZCP presentation meeting with Prof s22
[SEC=OFFICIAL]

s22

I could meet with Prof s22 on the Monday morning – even three months out my diary is full on the Monday afternoon and all Tuesday.

Unfortunately we don't have any committees meeting on those two days.

Regards

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA
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F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: s22 .com.au>
Sent: Monday, 22 August 2022 7:16 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 .com.au; s22 @mindmedicineaustralia.org>
Subject: quick call re RANZCP presentation meeting with Prof s22

Dear John
How are you? Hope all is well with you in these chaotic times.
We are delighted to let you know that we will be bringing Professor s22 to Australia in November. https://www.imperial.ac.uk/people/d.nutt

He will be meeting with and presenting to key Federal and State Ministers and other peak bodies. He will be in Canberra from 21-22 November.
Please could you advise potential dates and times that would suit for Prof s22 to come and present to you and key colleagues from your senior leadership and key committees and other stakeholders.
Looking forward to hearing from you shortly.
Kind regards

Warm good wishes

s22
Mind Medicine Australia
s22
s22 .com.au
www.mindmedicineaustralia.org

MIND MEDICINE AUSTRALIA

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[SEC=OFFICIAL]

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From: SKERRITT, John
To: s22 ; s22 ; s22 s22 (gmail); s22 ; s22 ; s22 s22
Cc: s22
Subject: RE: Professor s22 TGA presentation information Re: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]
Date: Thursday, 13 October 2022 11:26:42 AM
Attachments: image002.png
image003.png
image004.png
image006.png

OK, we have set aside 1030 to 1130 for his seminar for a group likely to be of two dozen staff and then 1130-12 noon for a meeting with a smaller group.

We cant go past 12 because of other commitments.

Our location is 27 Scherger Drive, Fairbairn ACT – if you ask at reception/ security for my EA s22 she will sign you in.

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Thursday, 13 October 2022 10:52 AM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22 s22 .com.au>; s22 @imperial.ac.uk>; s22 (gmail) s22 @gmail.com>; s22 .com.au>; s22 s22 @mindmedicineaustralia.org>
Subject: Professor s22 TGA presentation information Re: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]

Dear John,

Professor s22 Keynote topic for his Australian tour is ***'Psychedelic-Assisted Therapies: History, Neuroscience and Myths'*** .

Your smaller group presentation will offer you and your colleagues an opportunity to also hear directly from the esteemed Professor s22 about his work in the area of neuroscience and psychedelics, including an update on current global research . There will also be the opportunity for questions and interaction.

Professor s22 (UK) is s22 at Imperial College, London and s22 of the European Brain Council, to Australia. Professor s22 is both a psychiatrist and a neuropsychopharmacologist. He is one of the leading researchers in the World in the use of psychedelic assisted therapies for the treatment of key mental illnesses and is s22 of the World leading Centre for Psychedelic Research at Imperial College.

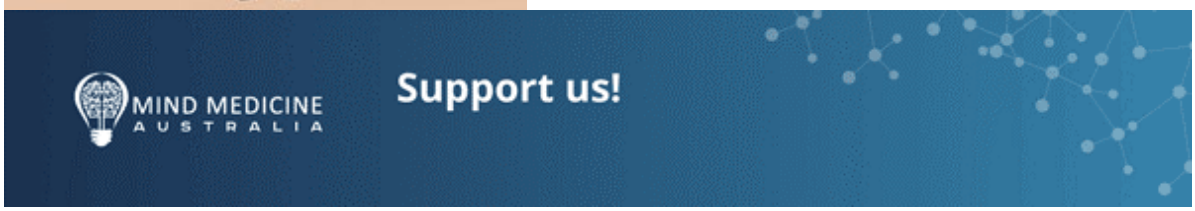
I do hope this information helps to promote this important meeting to your colleagues .

Please let me know if you need more information and see full tour information here.

Kindest regards,
s22

s22
o: +s22
e: s22 @mindmedicineaustralia.org
Working Hours:
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank
www.mindmedicineaustralia.org

MIND MEDICINE AUSTRALIA



From: "SKERRITT, John" <John.Skerritt@health.gov.au>
Date: Thursday, 13 October 2022 at 7:32 am

To: s22 .com.au>, s22 @imperial.ac.uk>, s22 (gmail)" s22 @gmail.com>, s22 s22 .com.au>, s22 @mindmedicineaustralia.org>, s22 @mindmedicineaustralia.org>
Subject: RE: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]

I haven't yet promoted Prof s22 presentation to colleagues – what is the title of his talk ?

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: s22 .com.au>
Sent: Wednesday, 12 October 2022 11:08 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22 @imperial.ac.uk>; s22 s22 @gmail.com>; s22 .com.au>; s22 s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org
Subject: RE: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]

He is dear John
We are just having a problem with our calendar. Will fix it now. He is very much looking forward to presenting and meeting with you all. Could you please advise how many of your colleagues and committee members approx. will be in attendance?
Kind good wishes
s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Wednesday, 12 October 2022 7:24 PM
To: s22 .com.au>; s22 @imperial.ac.uk>; s22 s22 @gmail.com>; s22 .com.au>; s22 s22 @mindmedicineaustralia.org>; s22 @mindmedicineaustralia.org
Subject: RE: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]

I thought that he was coming to TGA in person ?

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

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F: 02 6203 1265

Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

-----Original Appointment-----
From: s22 .com.au>
Sent: Wednesday, 12 October 2022 6:15 PM
To: s22 ; SKERRITT, John; s22 ; s22 ; s22 ; s22 @mindmedicineaustralia.org
Subject: Presentation by Prof s22 to TGA and meeting with John Skerritt and others
When: Monday, 21 November 2022 10:30 AM-12:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: ADDRESS TBC

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Meeting ID: 442 943 304 741
Passcode: m8Afzg
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From: s22
To: Medicines Scheduling
Subject: Psilocybin schedule 8
Date: Tuesday, 28 February 2023 12:45:58 PM

Hi,

I was part way through writing an application for the rescheduling of psilocin to schedule 8 and thought I might reach out first to confirm a full submission is necessary. It appears Mind Medicine Australia's original application covers all the relevant information. I assume not rescheduling psilocin was an oversight. For Psilocybin containing mushrooms to be used as a source of psilocybin the psilocin must also be updated to schedule 8.

Mind Medicine Australia's original application: https://mindmedicineaustralia.org.au/tga/

Psilocybe containing mushrooms contain a variety of tryptamines including but not limited to:
- psilocybin (3-[2-(dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate)
- baeocystin (3-[2-(methylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate)
- norbaeocystin (3-[2-aminoethyl]-1H-indol-4-yl dihydrogen phosphate)
- aeruginascin (3-[2-(trimethylammonio)ethyl]-1H-indol-4-yl hydrogen phosphate)
- psilocin (4-hydroxy-N,N-dimethyltryptamine)
- norpsilocin (4-hydroxy-N-methyltryptamine)

I would also ask you consider rescheduling any other tryptamines, lysergamides, phenylethylamines and amphetamines that are currently schedule 9 to schedule 8. If necessary I will make formal applications for psilocin, dmt, det and lsd.

Thanks,
s22

From: s22
To: NOYEN, Benjamin
Cc: SKERRITT, John
Subject: State of Canadian Psychedelic Law 2023 Report
Date: Tuesday, 20 December 2022 12:43:23 PM
Attachments: 2023+State+of+Canadian+Psychedelic+Law.pdf

Hi Ben

This legal report on the position of psychedelic therapies in Canada was forwarded to me. It's a good summary which I thought would interest you. Interesting how the Canadians and the Americans are leading the way on this.

Best

s22

s22
Mob s22

From: s22
To: SKERRITT, John
Cc: NOYEN, Benjamin; s22 (gmail); s22 ; s22
Subject: Feedback from State Governments
Date: Wednesday, 30 November 2022 12:06:19 PM
Attachments: ATT00001.png
ATT00002.png
ATT00003.gif
BAC-CO-32542 Signed Response to Mind Medicine Australia.pdf

Dear John

I thought the attached letter from the Victorian Department of Health would interest you. It's illustrative of the feedback we get from other State and Territory Governments. The decision rests with the Delegate and they will automatically adjust any changes to their own Schedules based on the Delegate's decision.

Professor s22 and I had a good meeting with the s22 of the Royal Australian and New Zealand College of Psychiatrists yesterday, Associate Professor s22 . Associate Professor s22 expressed support for the need for real world evidence and the concept of an independent registry that we put forward in our submission. When I took Associate Professor s22 through the overwhelming support that we had received for rescheduling on the limited basis proposed (including from Health Sector Experts and Researchers) he also seemed genuinely surprised that the view of the RANZCP would apparently be taken as such an enormous counterweight to this.

If you are able to arrange the presentation that I mentioned in my last email with the ACMS/Delegate from experts Professor s22 , Professor s22 and leading Australian psychiatrists we would be very happy (and indeed encourage) Associate Professor s22 to also be there.

I look forward to hearing from you.

With best wishes

s22

Mind Medicine Australia

s22

o:
e: s22 **@mindmedicineaustralia.org**
Working Hours:
Mind Medicine Australia
Level 5 | 468 St Kilda Rd, Melbourne
www.mindmedicineaustralia.org

Department of Health

50 Lonsdale Street
Melbourne Victoria 3000
Telephone 1300 650 172
GPO Box 4057
Melbourne Victoria 3001
www.health.vic.gov.au
DX 210081

BAC-CO-32542

s22
Mind Medicine Australia
1/10 Dorcas Street
South Melbourne VIC 3006
s22 .com.au

Dear s22 and s22

Thank you for your email of 21 November 2022 addressed to the Hon Gabrielle Williams MP, Minister for Mental Health regarding access to psilocybin and MDMA. Your letter has been referred to me for my consideration and response.

As noted in your email, the Therapeutic Goods Administration (TGA) is the national body responsible for the scheduling of medicines and poisons. The Advisory Committee on Medicines Scheduling makes recommendations to the Scheduling Delegate of the TGA, however the decision to reschedule MDMA and psilocybin lies with the Scheduling Delegate.

Victoria will automatically adopt any changes to the schedules in the Commonwealth Poisons Standard.

Thank you again for taking the time to write to Minister Williams about this matter.

Yours sincerely

s22

s22 , Medicines and Poisons Regulation
Regulatory, Risk, Integrity and Legal

25 / 11 / 2022

VICTORIA State Government

From: s22
To: SKERRITT, John
Subject: Accepted: Discuss Final Decision of the Delegate and the Special Access Scheme [SEC=OFFICIAL]

From: s22
To: s22
Cc: SKERRITT, John; s22 ; s22 ; COOK, Jane; WISEMAN, Michael
Subject: Re: Final Decision of the Delegate and the Special Access Scheme [SEC=OFFICIAL]
Date: Monday, 14 February 2022 1:20:00 PM
Attachments: image001.png
image002.png
image003.png
image001.png
image002.png
image003.png
image001.png
image002.png

Hi s22

Thank you for coming back to me on this. The problem with your approach is that it means that the Commonwealth Government through the TGA is not showing leadership on this issue. We already have a dysfunctional Federal State system of government in this country and this will make it worse. Let me give this some thought and get back to you.

With best wishes

s22
Mob s22

On 14 Feb 2022, at 8:55 am, s22 @health.gov.au> wrote:

Hi s22

In order to reduce confusion, we have changed our approach slightly and now request doctors confirm they have state or territory approval prior to review of SAS B applications. Inconsistency has led to confusion in the past, and as John has pointed out, approval is rather redundant without the ability to actually get the goods through state and territory legislation.

Kind regards

s22
s22
Experimental Products Section
International Regulatory Branch
Medicines Regulation Division
Health Products Regulation

Australian Government Department of Health

PO Box 100 Woden ACT 2606 AUSTRALIA

[SEC=OFFICIAL]

On 13 Feb 2022 9:51 pm, s22 .com.au> wrote:
REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi John
Thanks for your reply. Friday at 3pm works well. Shall I call you at that time on your mobile ?
We have not been encouraging doctors to make use of SAS-B until we get some traction at the State/Territory level or the medicines as part of therapy get rescheduled. Having said that we can't stop doctors applying and the fact that SAS-B is available is important. The levels of treatment resistant mental illness are getting significantly worse.
Yes, I realise that you are not the decision maker or on the Advisory Panel but would appreciate some guidance about our next application.
With best wishes

s22
m: +s22
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From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Saturday, 12 February 2022 2:30 PM
To: s22 @mindmedicineaustralia.org>
Cc: s22 @health.gov.au>; WISEMAN, Michael <Michael.Wiseman@health.gov.au>; COOK, Jane <Jane.Cook@health.gov.au>; s22 s22 @health.gov.au>
Subject: FW: Final Decision of the Delegate and the Special Access Scheme [SEC=OFFICIAL]
s22
Thanks – happy to meet although my diary is totally full until late Friday afternoon. I could do 3 pm Friday afternoon if that suits. I do need to remind you that I am not the decision maker nor on the advisory committee so if you don't feel that it's a good use of your time in meeting with me I perfectly understand.
My colleagues can jump in and correct me if I have my facts wrong, but the SAS scheme is still available for s9 substances – there has been no change to the regulations.
However it's a waste of our time – and more importantly the applicant's time if they put in an application to us, we provide an SAS authorisation and it either is not legal for the relevant state or territory to provide access under SAS or for whatever reason the state or territory have indicated that they are unwilling to approve these applicants. So my understanding is that my team have been advising applicants that they need to get some sort of assurance from a state or territory that they would allow supply first – otherwise its just a waste of everyone's time.
Regards
John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
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From: s22 .com.au>
Sent: Friday, 11 February 2022 11:59 AM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @mindmedicineaustralia.org>
Subject: Final Decision of the Delegate and the Special Access Scheme

Dear John

I hope you are well.

We are obviously disappointed by the Delegate's Final Decision but it did give us valuable insights about what the Delegate has accepted and what still concerns the Delegate. We are preparing new applications for the early March submission date which are designed to specifically address these concerns.

Would you be available in the next week or so for a short discussion on all of this?

On another matter we had a call from a doctor yesterday who had referred her patient with treatment resistant PTSD to a psychiatrist. The psychiatrist had in turn – after full discussion with the patient and the patient's informed consent – applied to the TGA for Special Access Scheme approval for MDMA assisted therapy. The psychiatrist was then going to apply for a permit from the State Government. The psychiatrist found to his dismay that the TGA had changed its SAS-B application form and when he called the relevant department at the TGA was told that the special access scheme was no longer available for Schedule 9 substances.

My reaction when told this was that it had to be a mistake or confused communications because such a stance would be even more restrictive that the UN Convention on Psychotropic Substances. It would also mean that Australia compared badly with Canada where Health Canada has just varied its Special Access Scheme to enable doctors to apply for approval for MDMA and Psilocybin assisted therapy and had already given a number of regulatory exemptions to enable such therapies to occur.

Could you please advise me on this.

With best wishes

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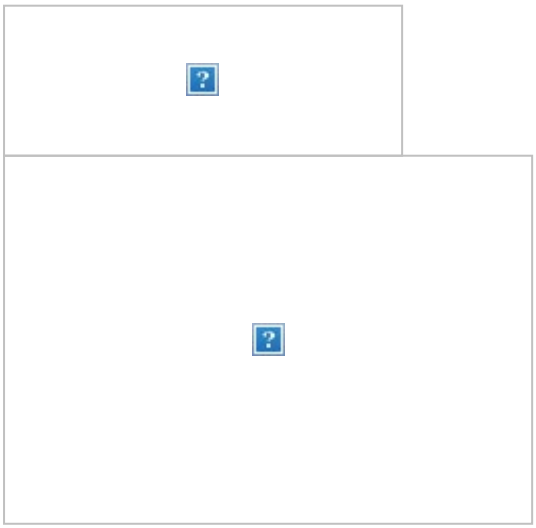

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From: s22
To: SKERRITT, John
Cc: NOYEN, Benjamin; VINE, Ruth; s22 @mindmedicineaustralia.org); s22
Subject: RE: Results of COMPASS Pathways"s Phase 2b Psilocybin Trial and Announcement by Monash of New Centre of Excellence in Psychedelic Therapies
Date: Thursday, 11 November 2021 5:53:56 PM
Attachments: image001.png
image002.png
PhaseIIbdata_20211109_sent.pdf

Dear John

We now have the Compass Pathways presentation on the results for your information.

Best

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From: s22
Sent: Wednesday, 10 November 2021 1:27 PM
To: John Skerritt <john.skerritt@health.gov.au>
Cc: Ben Noyen <benjamin.noyen@health.gov.au>; ruth.vine@health.gov.au; s22 s22 @mindmedicineaustralia.org) s22 @mindmedicineaustralia.org>; s22 s22 @mindmedicineaustralia.org>
Subject: Results of COMPASS Pathways's Phase 2b Psilocybin Trial and Announcement by Monash of New Centre of Excellence in Psychedelic Therapies

Dear John

Two pieces of big news.

Firstly the Compass Phase 2b results for Psilocybin assisted therapy for treatment resistant depression came out overnight and they are very positive. See below. I don't see how it's possible to argue that psilocybin when used as part of therapy in medically controlled environments doesn't satisfy the therapeutic value test of Schedule 8.

Secondly Monash University has just announced the establishment of its new Neuromedicines Discovery Centre to focus on psychedelic assisted therapies. Both Melbourne University and the

Florey Institute have come in as collaborators. See attachment below. We brought this initiative to Monash and have been working closely with them on this initiative for the last 18 months. All very exciting.

With best wishes

s22 [redacted]

Mind Medicine Australia

Mob s22 [redacted]

View this email in your browser

COMPASS Pathways Shares Positive Phase 2b Topline Results

Just a few days after we published our Special Issue in anticipation of the event, COMPASS Pathways has shared topline results from its COMP360 psilocybin-assisted therapy trial.

Read the Press Release Here

The results of the 233 person trial are positive, finding that a 25mg dose of the company's synthetic psilocybin demonstrates a statistically significant and clinically relevant reduction in depression symptom severity.

This response is, according to the company, "rapid and durable."

At least twice the number of patients in the 25mg group demonstrated response to the therapy and remission from their treatment-resistant depression at weeks 3 and 12 compared with the 1mg group.

Speaking to Bloomberg, CEO George Goldsmith said, “A high dose of psilocybin works immediately, the day after, for a large number of people, and continues to work.”

The 10mg group failed to demonstrate a statistically significant treatment difference.

In terms of safety and tolerability, 12 patients reported serious adverse events. These treatment-emergent adverse events included suicidal behaviour, intentional self-injury and suicidal ideation: all of which are - regrettably - common in treatment-

resistant depression patients. However, these events were common in the 25mg group than the 10mg or 1mg groups.

Goldsmith suggested that some of the most concerning adverse events were among non-responders, who were perhaps despairing at the therapy's inability to help them (especially in the context of such hype and promise).

COMPASS now expects to commence its Phase 3 programme in 2022. If successful in this even larger study, it could seek approval as early as 2024.

In a presentation on the results, the company stated that it would continue expanding its pipeline of indications beyond TRD and PTSD.

CMPS stock is down nearly 24% at the time of writing, while ATAI is down around 13%. Other psychedelics companies are also down at open, with MNMD and CYBN down around 10% and 6% respectively.

From: s22
To: NOYEN, Benjamin
Cc: s22 ; SKERRITT, John; s22 ; s22 .com.au; s22 @mindmedicineaustralia.org; s22 @mindmedicineaustralia.org
Subject: Letter to the Advisory Committee on Medicines Scheduling
Date: Thursday, 14 October 2021 1:20:43 PM
Attachments: image001.png
image002.png
Letter to TGA_141021 Final.pdf
Appendix A TGA Letter 141021.pdf

Dear Ben

As discussed, we have put together a letter to update the Advisory Committee on Medicines Scheduling on recent developments that relate to our psilocybin and MDMA rescheduling applications.

In our submissions lodged in early March in response to the Delegate's interim decision we dealt with each one of the Delegate's arguments in a lot of detail within the framework of the scheduling requirements. The attached letter focuses on developments since that time. There is also a link in the letter to a recent webinar given by Professor s22 on the current state of knowledge of both the depressed or traumatised brain, the pharmacology of psilocybin and MDMA and a working comparison with the way SSRIs are believed to work. We hope that this will provide useful background for the Committee's deliberations.

Please let me know if there is any more information that you would find useful. The forthcoming decision is obviously very important to so many people.

With best wishes

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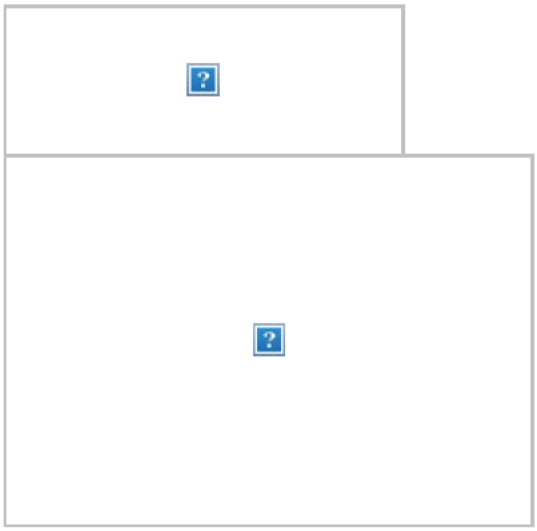

MIND MEDICINE AUSTRALIA

The Secretary
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Australian Government
Canberra, ACT

14th October 2021

Dear Sir/Madam

Applications for Rescheduling of Psilocybin and MDMA for use as part of Psychotherapy in Medically Controlled Environments from Schedule 9 to Schedule 8 of the Poisons Standard

We are conscious that the Advisory Committee on Medicines Scheduling will be meeting on the 3rd November 2021 to consider its advice to the Delegate in relation to the Delegate's Final Decision on the above applications which we lodged with the TGA in July 2020. The Committee's advice and the Delegate's Final Decision are incredibly important to the large (and increasing) number of people in Australia suffering from treatment resistant depression and treatment resistant post-traumatic stress disorder ("PTSD") and to their families. These people are not getting well and often experience significant side effects from current treatments. Many have dropped out of the mental health system in despair and some commit suicide.

Given the importance of the decision, we thought that it would be helpful if we raised a few critical matters for consideration by the Committee. These are in addition to the detailed submissions which we lodged with the TGA in early March in response to the Delegate's Interim Order.

1. **The Current Understanding of the Neuroscience behind the way MDMA and Psilocybin work as part of Psychotherapy in the Human Brain**

Professor s22 , the Head of Neuropsychopharmacology at Imperial College London and one of the World's leading experts in this field, gave a short 36-minute lecture on this subject at a Mind Medicine Australia event last week. Please follow the link to this lecture at https://youtu.be/KgoU0bsnyXw. We would encourage members of the Committee and the Delegate to watch Professor s22 presentation as part of their preparation for the Committee meeting as it gives very valuable background to the current state of knowledge of both the depressed or traumatised brain, the pharmacology of psilocybin and MDMA and a mechanistic explanation of how both these substances and SSRIs work.

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2. **<u>The Independent Panel Evaluation of the Therapeutic Value, Benefits and Risks of MDMA and Psilocybin for the Treatment of Mental, Behavioural or Development Disorders (September 2001).</u>**

We are grateful for the TGA's decision to appoint the independent panel of experts and for the quality of the work done by these experts. We believe that the evaluation of the Panel supports our analysis that MDMA and Psilocybin when used as part of psychotherapy each satisfy the Schedule 8 requirements for safety and established therapeutic value. ***As detailed in Section 6 below, we believe that the findings of the Panel clearly show that a Schedule 9 listing is an inappropriate listing for these substances when they are used in this way.***

Key take-outs from the Independent Panel's literature-based review are:

- **The conditions that have been explored for potential therapeutic efficacy with MDMA and psilocybin are serious.** For instance, "*a significant proportion of people living with PTSD or depression and anxiety in the face of serious illness do not obtain adequate relief from existing therapeutic strategies…many people are not helped by any [current] interventions and the social and economic costs are high for unresolved and lifelong PTSD. More effective treatments are needed. Similarly, many people with major depression do not achieve full or lasting recovery and* existing approaches *can increase side effects".*
- **That there were statistically significant differences for MDMA (when used as part of psychotherapy) in comparison with inactive or active controls.** The panel considered the standardised mean difference of the results evidenced "a strong effect size" in terms of treatment outcomes.
- **MDMA was well tolerated by participants in all studies.**
- **Statistically significant results were achieved for psilocybin in most studies.** In all but one of the psilocybin studies reviewed "*there was a statistically significant difference between psilocybin and active placebo and …psilocybin remained as effective as the antidepressant escitalopram"* (Note that this comment appears to understate the positive difference associated with psilocybin – see comments from Professor s22 [redacted] below)
- **Psilocybin was well tolerated in all studies**.

The Panel also emphasised the importance (as Mind Medicine Australia does) of these *"… medicines [being] administered in closely clinically supervised settings and with intensive professional support".*

Notwithstanding the high quality of the Panel's Report, the Principal Investigator of the latest psilocybin assisted therapy trial comparing psilocybin with escitalopram as part of psychotherapy, Professor s22 [redacted], believes that there is a critical error in the Panel's Report:

"However, I believe there may be an error in the calculation of the comparative effects of psilocybin and escitalopram in fig 8 of the Review which significantly

understates the depression scores and therefore the remission and response rates for psilocybin used in the Imperial College Trial and reported in the New England Journal earlier this year – see https://mindmedicineaustralia.org.au/wp-content/uploads/Carhart-Harris-2021-Psilocybin-vs-SSRIs.pdf.
The Expert Panel Review reports that there were lower remission rates for psilocybin than escitalopram in this trial, but in fact the remission results were significantly higher for psilocybin on both the self and doctor reported outcomes as shown underlined in the table below taken from the journal article."

(See Professor s22 Letter to the TGA attached to this Letter as Appendix A)

In relation to the trial sizes of the MDMA studies that the Panel reviewed, we would also respectfully argue that the Panel didn't take into account the fact that the size of the MAPS Phase 3 trial was determined in consultation with the FDA ***as being statistically relevant and of an appropriate size for a Phase 3 study***. The Panel also doesn't appear to have correlated effect size to trial size (normally the higher the effect size, the smaller the trial needs to be to satisfy statistically relevant criteria).

In each of our Submissions in response to the Delegate's Interim Orders we comment directly on trial size and the large number of trials that have occurred to date.

3. Key International Research Developments since the Delegate's Interim Decision was Announced in February 2021.

There are three key trial developments that have occurred since the Delegate published the Interim Decisions in February 2021.

3.1 The publication of the results of the first MAPS sponsored Phase 3 MDMA Assisted Psychotherapy Trial conducted in the US, Canada and Israel.

These results were published in the Nature Medicine Journal "MDMA-assisted therapy for severe PTSD; a randomised, double-blind, placebo-controlled phase 3 study" by Mitchell et al in June 2021 – Please see:
https://www.nature.com/articles/s41591-021-01336-3

Key findings of the Study were:

- PTSD presents a major public health problem for which currently available treatments are only modestly effective (*MMA Note: In Australia remission rates using current treatments are estimated to be as low as 5 -10% of patients).*
- The patients in the trial not only had severe PTSD but many also suffered from common co-morbidities such as dissociation, depression, substance use disorders and childhood trauma.

- Importantly, the protocol and statistical analysis plan behind the study was developed in conjunction with the FDA.
- The mean duration of PTSD diagnosis of participants in the MDMA study group was 14.8 years.
- The MDMA therapy led to significant and robust attenuation in CAPS-5 scores compared with placebo. The mean change in CAPS-5 scores of participants completing treatment was -24.4 (s.d. 11.6) in the MDMA group and -13.9 (s.d 11.5) in the placebo group and the effect size was near double commonly used pharmaceutical first-line treatments.
- MDMA was equally effective in participants with comorbidities that are often associated with treatment resistance.
- At the primary study endpoint (18 weeks after baseline), 67% of the participants in the MDMA group were in remission compared to 32% of those in the placebo group. It should be noted that in the 6 pooled Phase 2 trials remission rates for the MDMA group increased still further at the 12-month follow up.
- 88% of participants in the MDMA group experienced statistically significant improvements.
- Importantly there were no major safety issues reported in the MDMA arm of the study. MDMA did not induce adverse events of abuse potential, suicidality, or QT prolongation. Averse events were typically transient and mild to moderate in severity. In fact, adverse events (including suicidality) were significantly higher in the placebo group. According to the authors the *"… data suggests that MDMA has an equivalent, if not better, safety profile compared with that of first line SSRIs for the treatment of PTSD."*
- The authors of the study concluded that "…*compared with manualised therapy with inactive placebo, MDMA-assisted therapy is highly efficacious in individuals with severe PTSD, and treatment is safe and well-tolerated, even in those with comorbidities"*
- The authors speculated that the pharmaceutical properties of MDMA "…*may produce a "window of tolerance" in which participants are able to revisit and process traumatic content without becoming overwhelmed or encumbered by hyperarousal and dissociated symptoms. MDMA-assisted therapy may facilitate recall of negative or threatening memories with greater self-compassion, and less PTSD related shame and anger……Indeed, clinicians have suggested that MDMA may catalyse therapeutic processing by allowing patients to stay emotionally engaged while revisiting traumatic experiences without becoming overwhelmed".*

3.2 The Publication of the Imperial College London Results of a Phase 2 Trial Directly Comparing Psilocybin with a Leading SSRI (Escitalopram) when used as part of Psychotherapy

These results were published in the New England Journal "Trial Results for Psilocybin versus Escitalopram for Depression" by Carhart-Harris et al in April 2021 – Please see: https://mindmedicineaustralia.org.au/wp-content/uploads/Carhart-Harris-2021-Psilocybin-vs-SSRIs.pdf

Key findings of the Study were:

- Major depressive disorder effects a significant part of the general population, impairs patient lives and is costly to society. SSRIs are first-line treatments but take several weeks to work and in some patients do not induce a response (*MMA note: in Australia remission rates from SSRIs are estimated to be as low as 30-35% and relapse rates when treatments stop are estimated to be as high as 80%*).
- The mean age of the patients in the trial was 41 years and the average depression duration of participants was 22 years in the psilocybin group and 15 years in the escitalopram group.
- Using the QIDS-SR-16 change in depression scores at week 6 as the primary measure, the trial did not show a significant difference in antidepressant effects between psilocybin and escitalopram. However, secondary measures used generally favoured the psilocybin group and remission results were twice as high for psilocybin on both the self and doctor reported outcomes (See Professor s22 [redacted] explanation in Appendix A).
- No serious adverse events were observed in either trial group. The percentage of patients who had increased anxiety and dry mouth was actually higher in the escitalopram group than in the psilocybin group. The most common adverse events in the psilocybin group typically occurred within 24 hours after the medicine session and the most common was headache.
- When cued to report on specific emotional and side-effect related phenomena, patients in the psilocybin group reported greater perceived improvements in the ability to cry and feel compassion and pleasure and reported feeling less drowsy than in the escitalopram group.

It should be noted that in our rescheduling application psilocybin (as an unregistered medicine) as part of psychotherapy will only be available under the TGA's Special Access Scheme for treatment resistant patients. In other words, where the first line treatment (usually an SSRI) has failed.

3.3 The Publication of the Bristol University Imperial College London Results of the First Study of Safety and Tolerability of MDMA-Assisted Therapy for Patients with Alcohol Use Disorder.

The results were published in the Journal of Psychopharmacology "First Study of Safety and Tolerability of MDMA assisted psychotherapy for alcohol use disorder" by Ben Sessa et al in February 2021 – Please see:
https://journals.sagepub.com/doi/10.1177/0269881121991792

Whilst a relatively small trial with 14 patients with severe alcohol disorder, the study again confirmed that MDMA treatment was well tolerated by all participants with no unexpected adverse effects being observed and with very positive outcomes achieved in terms of consumption of alcohol at the 9 months follow up.

Alcohol use disorder is a very challenging social problem in Australia, with current treatments having high relapse rates.

It should be noted that all recent trials reinforce the results of previous trials (as well as experience before prohibition) that found that both medical grade MDMA and medical grade Psilocybin, when used as part of psychotherapy, were well tolerated by patients with minimal adverse effects and with strong treatment outcomes.

4. The Conservative Nature of Our Rescheduling Application

Under our rescheduling applications, we limit prescribing rights for the use of psilocybin and MDMA as part of psychotherapy to psychiatrists and specialist addiction physicians, with the medicines only being taken in medically controlled environments.

In practice the use of these therapies will be even more constrained because the psychiatrist or specialist addiction physician will have to get specific approval for the treatment of a particular patient from both the TGA under Special Access Scheme-B and the State or Territory Government's Health Department in the jurisdiction where the treatment is to occur. As part of the approval process the psychiatrist or specialist addiction physician will have to show, to the satisfaction of these authorities, that the patient is treatment resistant to first line treatments.

5. Importance of Properly Trained Professionals and the Need for Appropriate Protocols, Standard Operating Procedures and Training Manuals

We cover these requirements in detail in our submissions in response to the Delegate's Interim Decisions (please see pages 49-52 and Appendices I and J of our Psilocybin Submission dated 4 March 2021 and pages 48-50 and Appendices I and J of our MDMA Submission dated 3 March 2021).

In summary, psychiatrists, GPs, psychologists and psychotherapists and other medical professionals in Australia have already been (and continue to be) trained in these therapies at World's Best Practice standards. In addition, we have arranged for Protocols, Standard Operating Procedures and Training Manuals for these therapies to be developed by experienced clinicians using overseas best practice as adjusted for Australian conditions.

6. Satisfaction of the Scheduling Requirements

Our original applications dated July 2020, our Submissions in relation to the Delegate's Interim Orders and the recent TGA sponsored Panel's Evaluation all clearly demonstrate that the medical use of MDMA and psilocybin in controlled

medical environments ***does not*** fit into the requirements for a Schedule 9 prohibited substance.

We discuss this at length in Section 6.1 of both of our Submissions in relation to the Delegate's Interim Orders.

Schedule I of the United Nations Single Convention on Psychotropic Drugs contains an important exemption: namely the Government of a signatory State can authorise the limited use of such a substance for medical purposes by duly authorised persons in medical establishments specifically approved by that Government. This is exactly what happens when a psychiatrist or specialist addiction physician seeks the approval of the TGA for the use of an unregistered medicine under Special Access Scheme–B.

In addition (as we outline in our Submissions), Australia has rescheduled several substances for medical purposes from Schedule 9 to Schedule 8 of the Poisons Standard that were either in Schedule 1 of the UN Convention of Psychotropic Substances 1971 or Schedule IV of the UN Convention on Narcotics Drugs 1961. Our nearest neighbour, New Zealand, has already reclassified the use of MDMA as part of psychotherapy to our equivalent of Schedule 8.

Australia also needs to observe another important UN Convention called the International Convention on Economic, Social and Cultural Rights. Article 12 provides for rights to *"the enjoyment of the highest attainable standard of ...mental health".* For people with treatment resistant depression, PTSD, or substance abuse we believe that the evidence shows that compliance with this Convention strongly supports the proposed rescheduling.

The other limb of Schedule 9 requires the substance to have *"…no currently established therapeutic value"* and to be *"… likely to present a high risk of dependency, abuse, misuse and illicit activities".*

All of the evidence in our applications and submissions as well as the Independent Panel Evaluation supports both safety and established therapeutic value of medical grade MDMA and medical grade psilocybin when these substances are used as part of psychotherapy in medically controlled environments.

The evidence also shows that these substances, when used in this way, ***are not*** likely to present a high risk of dependency, abuse, misuse or illicit use.

Importantly under the terms of the proposed rescheduling the patients will never be allowed to take the medicines home. Like any Schedule 8 medicine, the medicines will also be subject to Schedule 8 controls relating to the transportation and safeguarding of these substances in medically controlled environments.

Whilst these substances when used as medicine could be argued to better fit the requirements of Schedule 4 of the Poisons Standard (where the much stronger

psychedelic Ibogaine has been placed), we applied for a Schedule 8 listing because of the tighter controls normally associated with that Schedule.

7. Risks to the Community of Not Rescheduling these Substances

In our submissions in response to the Delegate's Interim Decisions, we highlight the very real risks to the community of not rescheduling these substances for use in medically controlled environments as part of psychotherapy (See Section 5.8 of our MDMA and Psilocybin Submissions).

Members of the community are becoming increasingly aware that current treatments don't help a large number of patients, and that psilocybin and MDMA assisted therapies are showing outstanding results in overseas trials (both in terms of safety and efficacy). Unlawful access to these substances is relatively easy and cheap in Australia. After all, psilocybin mushrooms are plentiful and grow in the wild in many parts of Australia and what purports to be MDMA – but often is not – is easily accessible and cheap to obtain on the Black Market.

Retaining these substances in Schedule 9 of the Poisons Standard (which doesn't allow for State and Territory based approvals for use to be obtained by medical specialists) is therefore likely to lead to more and more patients seeking to access these treatments from underground therapists via the Black Market. This is dangerous because there are no legal protections in place, no minimum training standards and no supervision of the therapists involved. Given the level of desperation in the Australian community, it will be impossible for Governments around Australia to prevent this.

8. Final Comments

In conclusion we would like to say this. Australia is in the midst of a terrible mental health crisis with enormous associated suffering, self-harm and suicide. Our mental health statistics have worsened significantly during the Covid-19 pandemic. The first-line pharmaceuticals currently being used don't work (or don't work well enough) for a large number of people suffering from depression, PTSD and substance abuse and can also have nasty side effects. Unsupported psychotherapy is time consuming and expensive, does not work for a majority of patients and has high relapse rates when treatment stops. Where treatments fail a patient's joy in life can be severely compromised. Tragically, for some this will lead to suicidal ideation and suicide.

Rescheduling of these substances as part of psychotherapy in medically controlled environments is warranted by the evidence. A Schedule 8 listing will **not** open the flood gates in Australia because of the tight Schedule 8 requirements and the necessity of obtaining Government approvals **on a patient-by-patient basis** at both the Federal and State levels.

However, a Schedule 8 listing will offer treatment resistant patients the possibility of receiving a treatment that has been shown to be safe and lead to high remission rates in overseas trials. In a sector which has experienced minimal innovation for nearly 50 years this will finally offer real hope to patients with treatment resistant conditions.

Yours faithfully,

s22 [redacted]

Imperial College London

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The Secretary
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
Australian Goverenment
Canberra, ACT.

10th October 2021

Expert Panel Review for the TGA on the Therapeutic Value, Benefits and Risks of MDMA and Psilocybin for the Treatment of Mental, Behavioural or Developmental Disorders

Dear Sir/Madam

Thank you for publishing the Expert Panel's impressive review of the literature in relation to the above.

However, I believe there may be an error in the calculation of the comparative effects of psilocybin and escitalopram in fig 8 of the Review which significantly understates the depression scores and therefore the remission and response rates for psilocybin used in the Imperial College Trial and reported in the New England Journal earlier this year – see https://mindmedicineaustralia.org.au/wp-content/uploads/Carhart-Harris-2021-Psilocybin-vs-SSRIs.pdf The Expert Panel Review reports that there were lower remission rates for psilocybin than escitalopram in this trial but in fact the remission results were significantly higher for psilocybin on both the self and doctor reported outcomes as shown underlined in the table below taken from the journal article.

Response & remission rates

Outcomes	Unadjusted (observed)		Adjusted (model)		
	Psilocybin	Escitalopram	Psilocybin (n=30)	Escitalopram (n=29)	Difference (95% CI)
QIDS-SR-16 (change at 1 week)	-6.5 (4.7) (n=30)	-4.7 (4.4) (n=25)	-6.9 [-8.5 to -5.2]	-4.1 [-5.9 to -2.4]	-2.7 [-5.2 to -0.3]
QIDS-SR-16 (change at 6 weeks)	-7.7 (6.1) (n=30)	-6.4 (5.5) (n=29)	-8.0 [-10.1 to -6.0]	-6.0 [-8.1 to -3.9]	-2.0 [-5.0 to 0.9]
QIDS-SR-16 (change at 6 weeks) - PP Set	-8.5 (5.5) (n=26)	-6.0 (5.4) (n=24)	-8.5 [-10.5 to -6.4]	-6.2 [-8.2 to -4.1]	-2.3 [-5.2 to 0.6]
QIDS-SR-14 (change from pre to post DD1)	-5.3 (4.4) (n=27)	-3.1 (5.3) (n=27)	-5.7 [-7.5 to -3.9]	-2.8 [-4.6 to -1.0]	-3.0 [-5.5 to -0.4]
QIDS-SR-14 (change from pre to post DD2)	-1.4 (5.0) (n=28)	-2.0 (4.0) (n=24)	-1.7 [-3.2 to -0.2]	-1.6 [-3.2 to 0.0]	-0.1 [-2.3 to 2.1]
QIDS-SR-16 1 week responder - (%)	18 (60.0%)	6 (24.0%)	58.5%	25.0%	33.5% (8.3 to 58.7%)
QIDS-SR-16 6 weeks responder - (%)	21 (70.0%)	14 (48.3%)	70.2%	48.0%	22.3% [-2.9 to 47.5%]
QIDS-SR-16 1 week remitter - (%)	10 (33.3%)	2 (8.0%)	22.7%	5.2%	17.5% [-0.4 to 35.5%]
QIDS-SR-16 6 weeks remitter - (%)	18 (60.0%)	8 (27.6%)	57.1%	29.1%	28.1% [2.3 to 53.8%]
BDI-1A (change at 2 weeks)	-17 [-22 to -11] (n=29)	-7 [-11 to -2] (n=27)	-16.0 [-19.1 to -13.0]	-8.9 [-12.1 to -5.9]	-7.2 [-11.6 to -2.5]
BDI-1A (change at 6 weeks)	-21 [-27 to -12] (n=30)	-14 [-19 to -4] (n=29)	-18.4 [-22.6 to -13.8]	-10.8 [-14.3 to -7.3]	-7.6 [-13.3 to -1.8]
BDI-1A 2 weeks responder - (%)	62.1%	22.2%	63.4%	20.3%	43.1% [18.8 to 67.4%]
BDI-1A 6 weeks responder - (%)	76.7%	41.4%	76.7%	41.4%	35.3% [11.8 to 58.7%]
BDI-1A 2 weeks remitter - (%)	51.7%	18.5%	52.6%	14.8%	37.8% [13.4 to 62.2%]
BDI-1A 6 weeks remitter - (%)	56.7%	20.7%	57.9%	18.4%	39.5% [15.7 to 63.3%]
HAM-D-17 (change at 6 weeks)	-10.8 (5.8) (n=28)	-4.9 (6.0) (n=29)	-10.5 [-12.5 to -8.4]	-5.1 [-7.2 to -3.1]	-5.3 [-8.2 to -2.4]
HAM-D-17 6 weeks responder - (%)	75.0%	24.1%	74.6%	23.9%	50.8% [27.9 to 73.6%]
HAM-D-17 6 weeks remitter - (%)	50.0%	10.3%	49.3%	10.3%	39.0% [17.3 to 60.7%]
MADRS (change at 6 weeks)	-14.6 (9.4) (n=28)	-7.0 (9.2) (n=29)	-14.4 [-17.9 to -11.0]	-7.2 [-10.6 to -3.8]	-7.2 [-12.1 to -2.4]
MADRS 6 weeks responder - (%)	67.9%	20.7%	68.1%	20.4%	47.7 % [24.9 to 70.5%]
MADRS 6 weeks remitter - (%)	28.6%	6.9%	28.8%	6.5%	22.3% [3.1 to 41.4%]

Figure S1. Supplementary appendix

Could I ask you to raise this directly with the writers of the Review so that the Report can be corrected and with the Advisory Committee on Medicines Scheduling who I understand are considering this matter in early November? As the PI of this trial I am very happy to answer any questions that the TGA or members of the Committee may have.

Yours faithfully

s22 [redacted]

Prof s22 [redacted]

From: s22
To: s22
Cc: SKERRITT, John; s22 @mindmedicineaustralia.org
Subject: Panel Evaluation of Psilocybin and MDMA
Date: Tuesday, 12 October 2021 4:34:38 PM
Attachments: image001.png
image002.png
TGA letter oct 2021.doc

Dear s22

I wanted to thank the TGA for organising the independent panel evaluation of psilocybin and MDMA as part of psychotherapy in relation to our rescheduling applications. The members have approached the task in an independent and professional manner.

We have asked Professor s22 to review the Panel's evaluation and his letter to the TGA is attached. As you will see from Professor s22 letter, he was the s22 of the Imperial College London trial comparing the safety and efficacy of psilocybin with a leading SSRI (Escitalopram).

Whilst Professor s22 notes the impressive nature of the review, he also believes that there may be an error in the Panel's calculation of the comparative effects of psilocybin and escitalopram which significantly understates the depression scores and therefore the remission and response rates for psilocybin used in the Trial. As noted by Professor s22 *"The Expert Panel reports that there were lower remission rates for psilocybin than escitalopram in this trial but in fact the remission results were significantly higher for psilocybin on both the self and doctor reported outcomes"* (see the table that he extracts from the journal article in the attached letter).

Professor s22 has asked if you could raise this issue directly with the Panel members so that the Report can be corrected and with the Advisory Committee on Medicines Scheduling who will be considering our applications on 3rd November 2021. As you will see from the attached letter, Professor s22 (copied here) is available to

answer any questions that the TGA or Panel members may have.

Your sincerely

s22 [redacted]

m: +s22 [redacted]

e: s22 [redacted] @mindmedicineaustralia.org

Mind Medicine Australia

Level 1 | 10 Dorcas St, Southbank

www.mindmedicineaustralia.org

From: s22

To: s22 SKERRITT, John s22 ; s22 ; s22 ; s22@mindmedicineaustralia.org

Subject: Presentation by Prof s22 to TGA and meeting with John Skerritt and others

---

From: SKERRITT, John on behalf of s22
To: s22 ; s22 SKERRITT, John; s22 ; s22 ; s22 ; s22@mindmedicineaustralia.org
Subject: FW: Presentation by Prof s22 to TGA and meeting with John Skerritt and others [SEC=OFFICIAL]

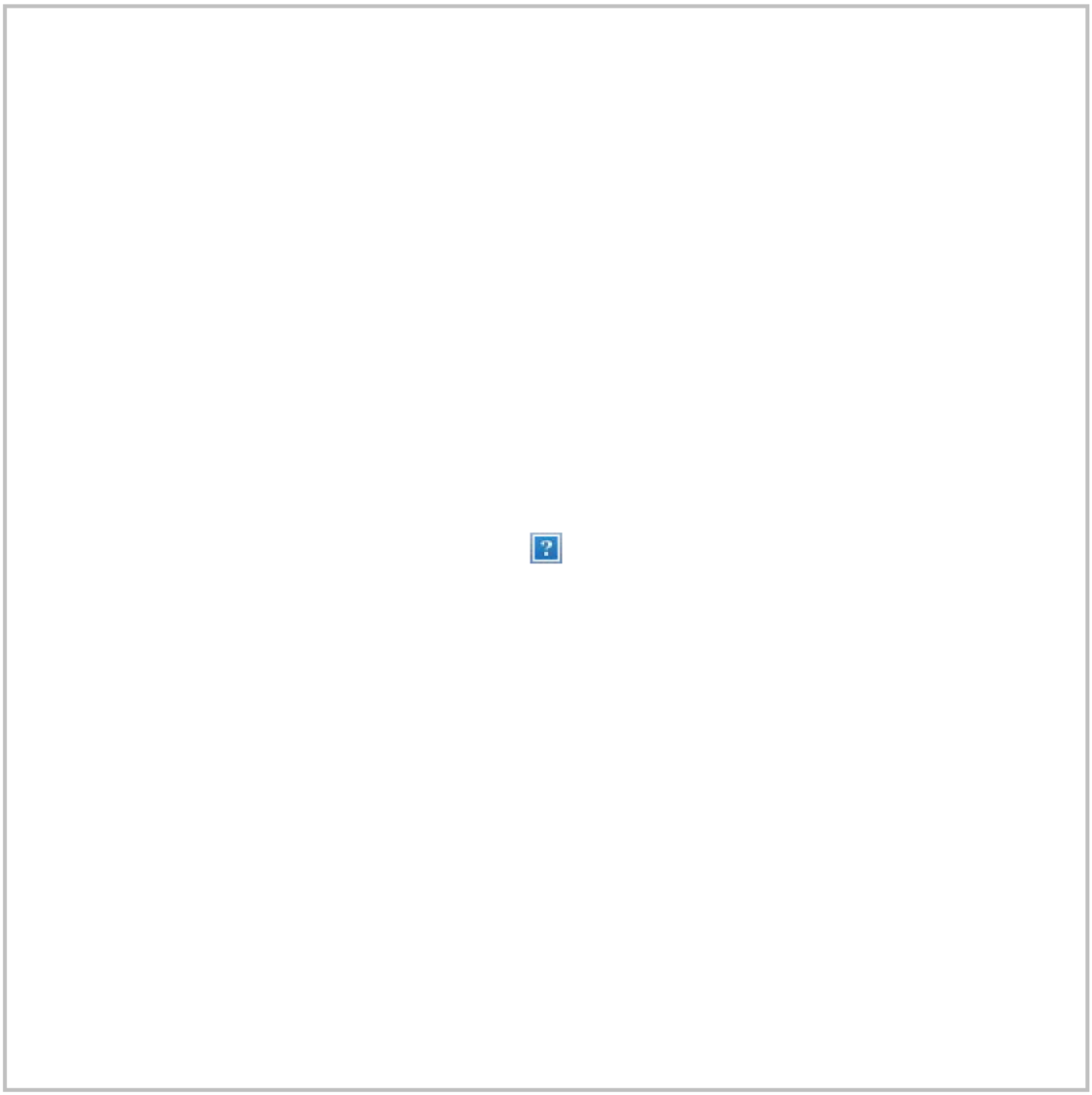
---

s22 – have you booked the main downstairs meeting room ?

-----Original Appointment-----
From: s22 .com.au <mailto s22 .com.au> >
Sent: Wednesday, 31 August 2022 3:13 PM
To: s22 ; s22 ; SKERRITT, John; s22 ; s22 ; s22 s22 @mindmedicineaustralia.org
<mailto s22 mindmedicineaustralia.org>
Subject: Presentation by Prof s22 to TGA and meeting with John Skerritt and others
When: Monday, 21 November 2022 10:30 AM-12:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: TGA - John to advise address and room and guest names please

From: Mind Medicine Australia
To: SKERRITT, John
Subject: John, you're invited to our Virtual Psychedelic Medicine Summit
Date: Wednesday, 1 September 2021 12:50:22 PM

Share Tweet Forward



Dear John,

We're happy to report some good news in amongst the doom and gloom…

Our inaugural **International Summit on Psychedelic Therapies for Mental Illness and 2-day Introductory Workshop** is going ahead this year and will now be *fully virtual.* **As the saying goes, 'The show must go on'!**

This means you will still be able to attend this incredible event, learn from the world's leading experts in psychedelic medicine, and connect with your peers regardless of what is happening with lockdowns, border closures and the suspension of international travel.

MMA will **democratise** and **decentralise** access to **world-class education** through transcending the limitations of geography and border restrictions, and use cutting-edge technologies to increase access around the world to this

ground-breaking ONLINE Summit.

Our commitment is to:

- Bring you education from world leaders in the field of psychedelic medicine and human consciousness to increase your knowledge and skills
- Prepare you to lead the way forward through the biggest innovation in mental health treatment in decades
- Increase accessibility to this global event for remote and regional areas
- Increase international and interstate participation and attendance
- Eliminate travel and accommodation costs
- Provide value-added benefits for all delegates through the wonders of interactive technology and the generosity of an increasing array of Supplier Partners

We understand that many of you attend the summit to connect with like-minded peers and foster personal and professional relationships.

In order to facilitate that connection and camaraderie, we will also be holding live online meet-ups in the weeks before and after the event so you can get to know other attendees.

You will retain ***lifetime*** access to these groups and we will endeavour to facilitate in person meet-ups as the country reopens.

You can learn more about the Summit and sign-up here >>

We know that many people were unable to attend due to being unable to take time off work or bear the costs of travel and accommodation so we are glad to completely eliminate those for you.

If you are unable to attend all of the sessions live, we are also providing recordings of the entire summit to attendees, and special gift bags will be mailed directly to your address.

By transitioning to fully virtual, we have been able to confirm and secure even more of the best thought leaders and experts from around the world in this field.

We are thrilled to let you know this means all of our international speakers are able to share their wisdom, and we have just confirmed that leading

psychologist and therapist trainer **Dr.** s22 [redacted] **(USA)** of Johns Hopkins University School of Medicine **and Esalen Faculty Member Dr.** s22 [redacted] **(USA)** will join our stellar line-up!

Read more about the speakers HERE and book your tickets today

John, if you're as fascinated by the potential of these therapies as we are, this event is going to provide a much-needed boost of inspiration and education on how we can deliver breakthrough innovation in the field of mental health.

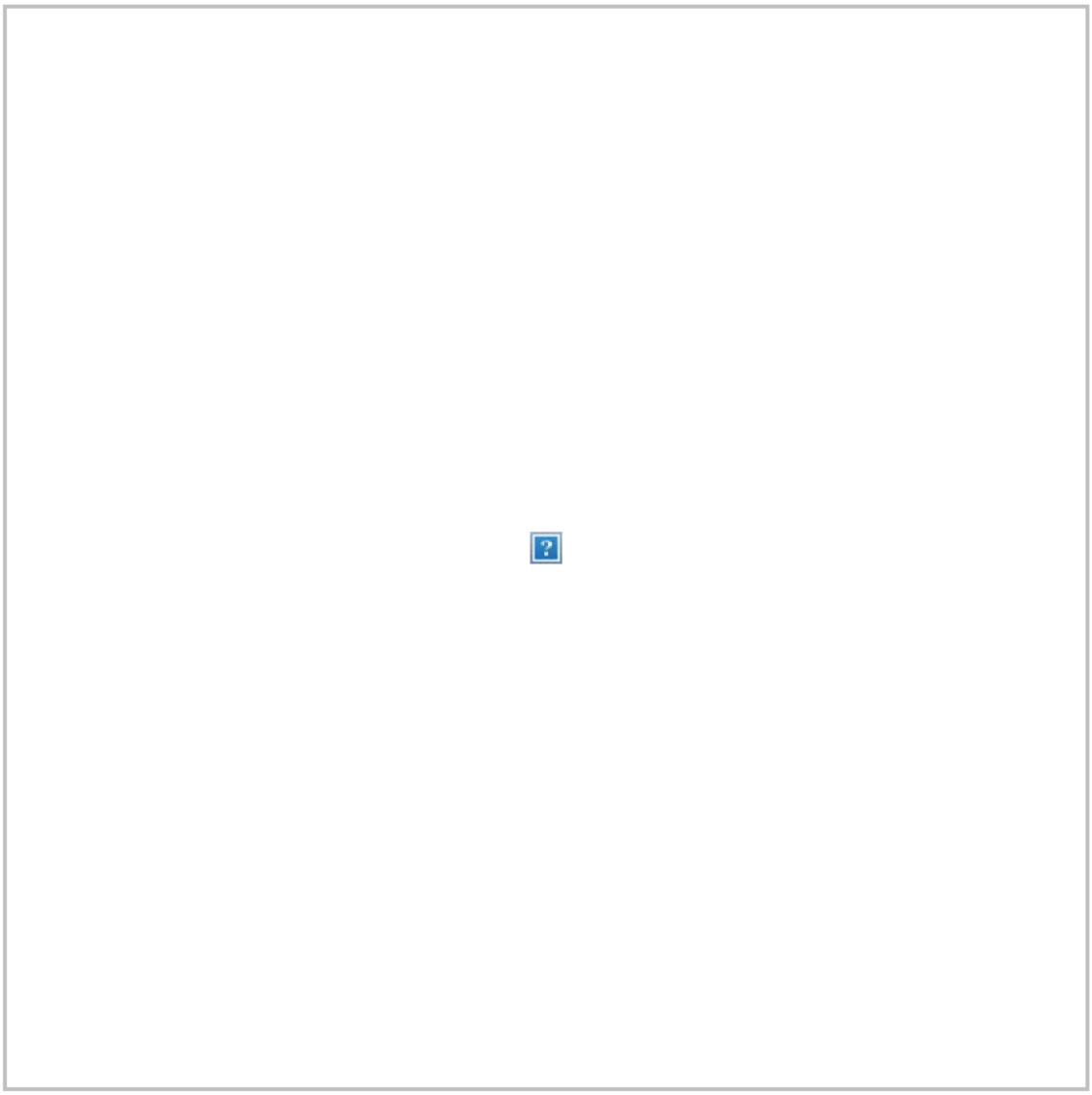
We believe the trauma created by the pandemic will lead to years of increased demand on the mental health system, and psychedelic-assisted therapy will be instrumental in providing the best possible healing outcomes for patients in need.

Please register for the Summit and Workshop using the link below, and if you have any questions please hit reply to this email.

Register here

Thank you for your support and flexibility in supporting this cause. Please rest assured we will be pulling out all stops so that we can deliver an inspiring, educational experience. We look forward to your participation. Together we can lead the world through this shadow pandemic and reduce suffering and suicide.

Warmly,
The Mind Medicine Australia Team



Mind Medicine Australia is delighted to announce the launch of a new online course, ***The Fundamentals of Psychedelic-Assisted Therapy for Mental Health***. This course will help people **understand the foundations of psychedelic-assisted therapy** and the application of their use in the treatment of chronic mental illness.

You can learn more and sign up here >>

We've brought on **Dr.** s22 and s22, the heads of our CPAT program to help you understand the **history, science and future of psychedelic medicines**.

This course is open to anyone with an interest in the topic.

The course will begin on Wednesday September 15th 2021.

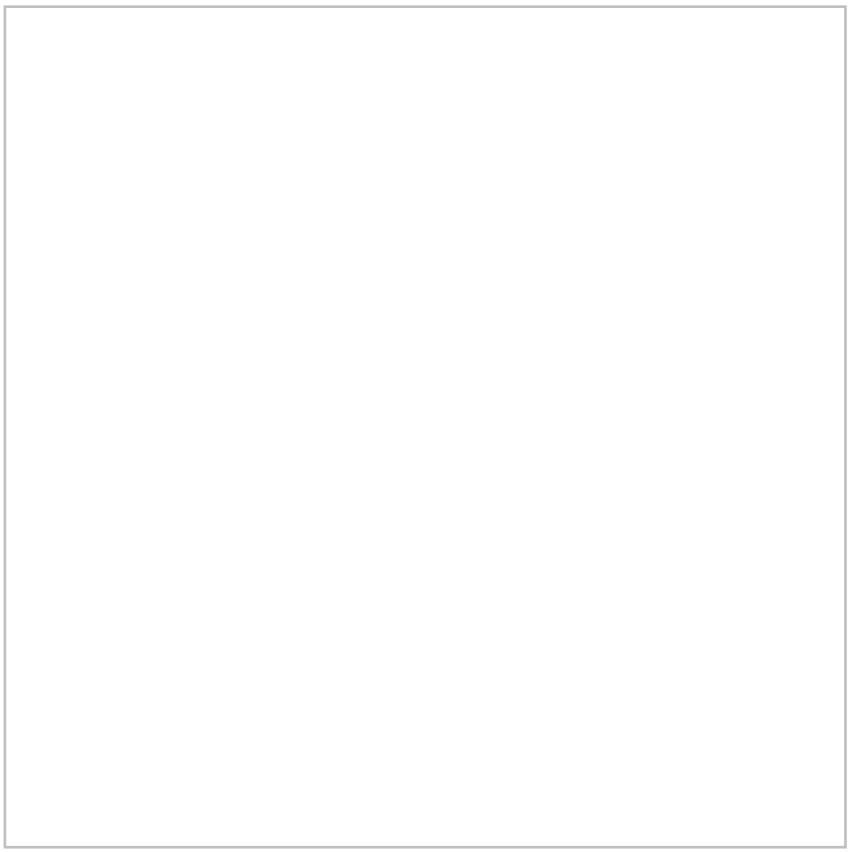
One of our core strategic pillars is to educate the public on psychedelic medicines, so on this page you'll also find a **FREE** presentation about the **5 Myths Stopping Australians getting access to these treatments**.

If there was ever a need for a breakthrough therapy to treat mental illness, it is right now, and we need people like you to educate yourselves and help advocate for fair access to these treatments.

You can see what the program will cover here:

Psychedelic Fundamentals Overview >>

Enrol Now



Our Chapters are a place for community gathering and sharing in relation to psychedelic science and medicine. By joining a Chapter, you will be helping to reduce the stigma and enhance the public understanding of the risks and beneficial uses of psychedelic-assisted therapies for treatment of a range of illnesses.

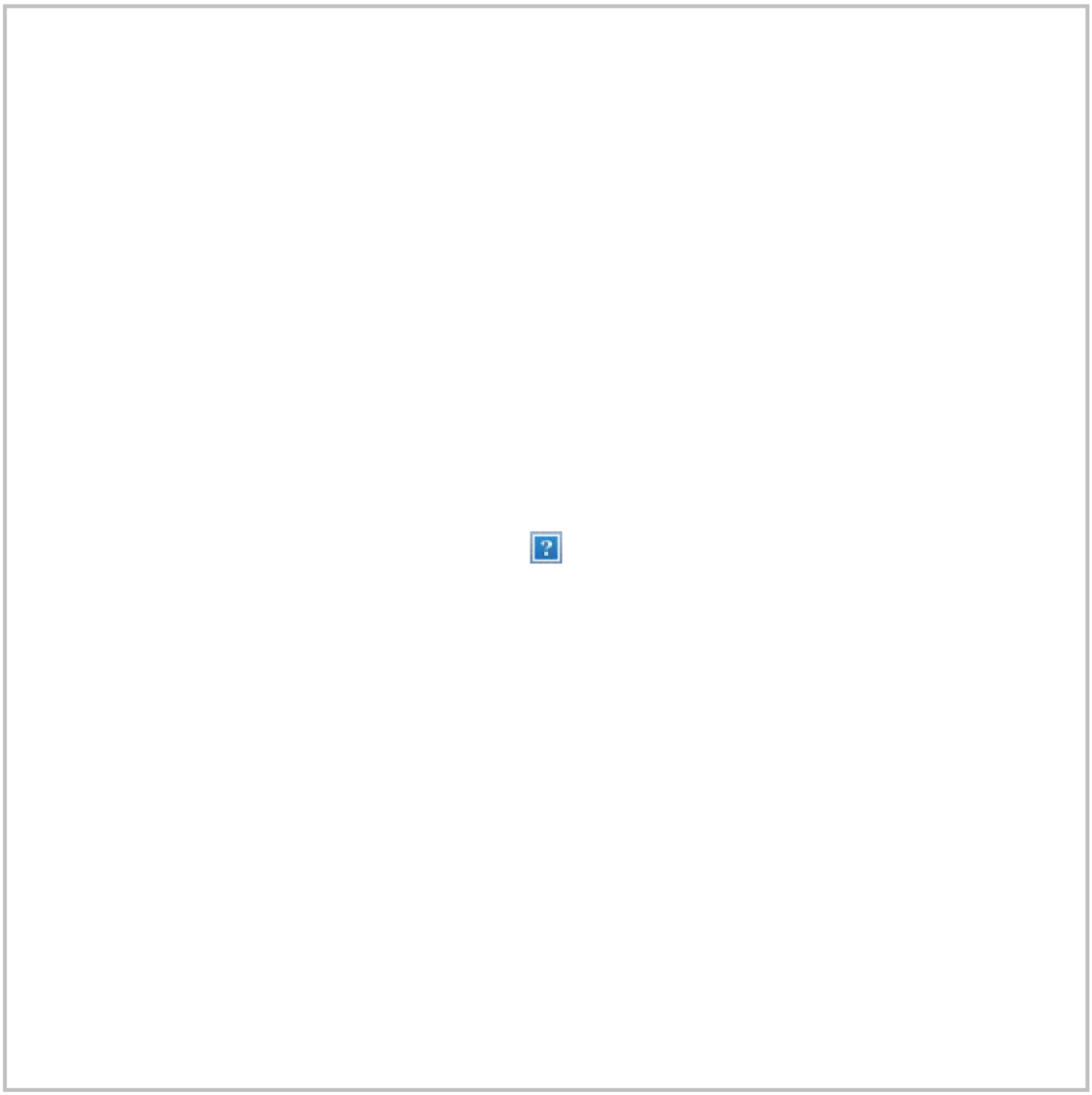
Join our community today

Despite national lockdowns, we have been very busy holding a range of virtual events. Many of these events were pivoted at the last minute to an online format with great success.

These events help us to reconnect, educate and engage. They provide an opportunity to hear about psychedelic-assisted psychotherapies for mental illness broadly, what Mind Medicine Australia is doing to create the eco-system for these treatments here in Australia and how you can help.

Our chapters have now grown to **over 30 nationally** and **thousands of engaged members**.

Join your local chapter here >>

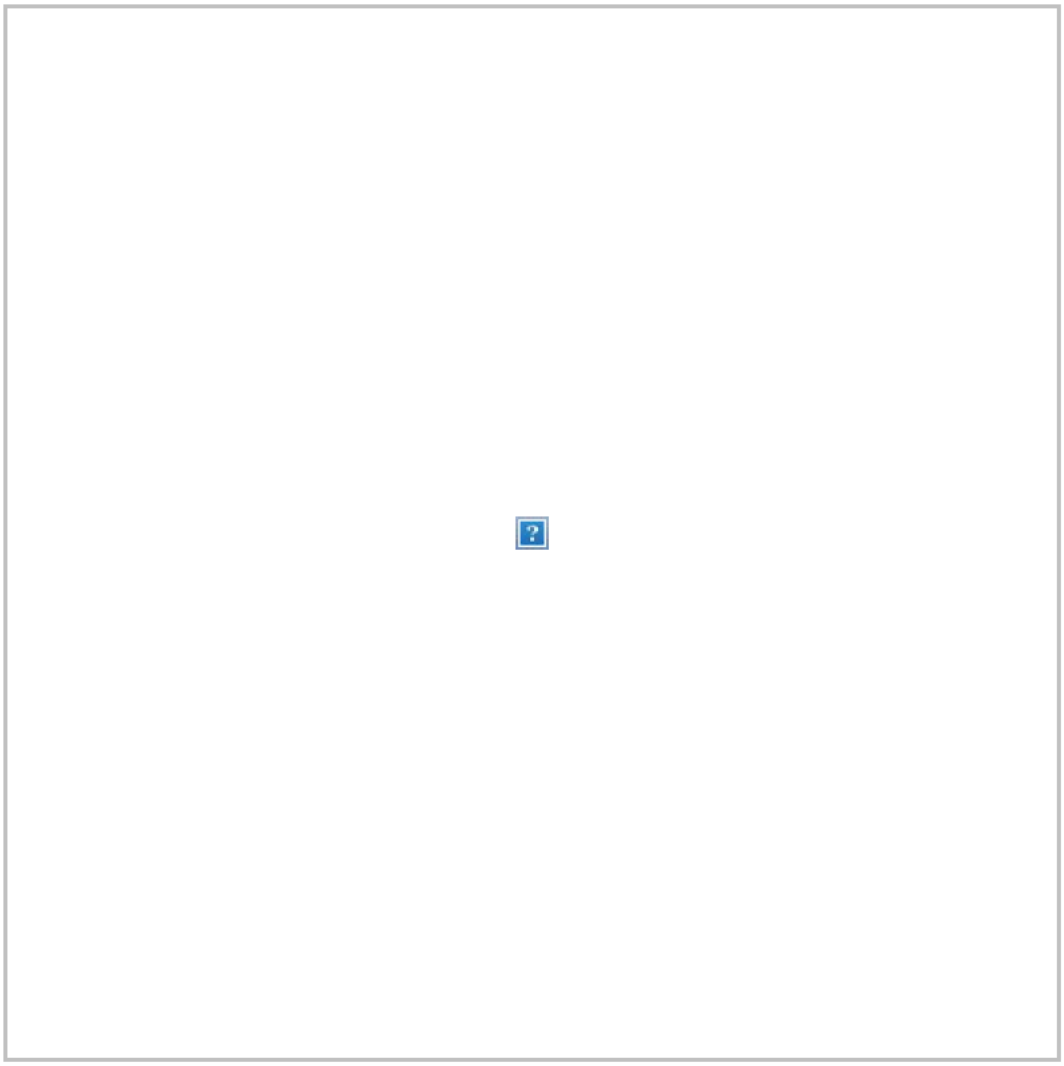


INTAKES 3 AND 4 FILLING FAST

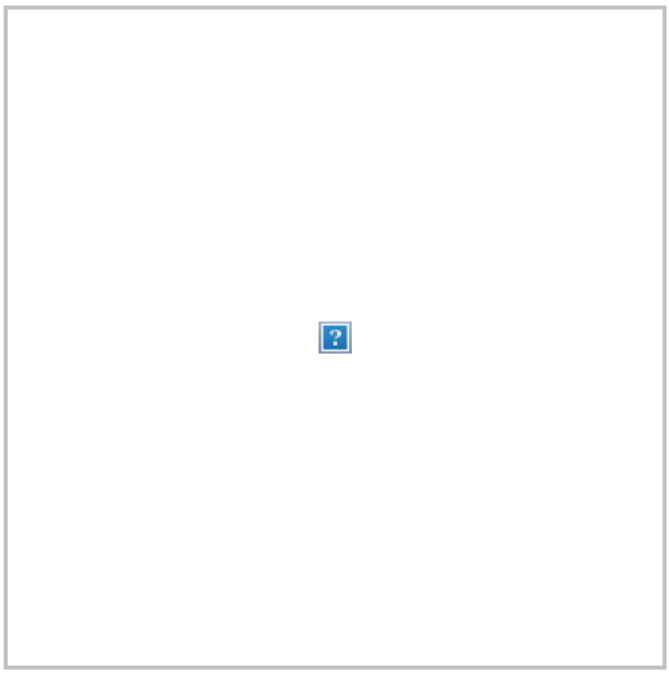
The initial cohort of the **Certificate in Psychedelic-Assisted Therapies** have just completed their course with the world class Faculty. The feedback has been outstanding. This course will give qualified clinicians the additional skills and awareness they need in order to safely and successfully facilitate psychedelic-assisted therapies. Applications are now open for further intakes:

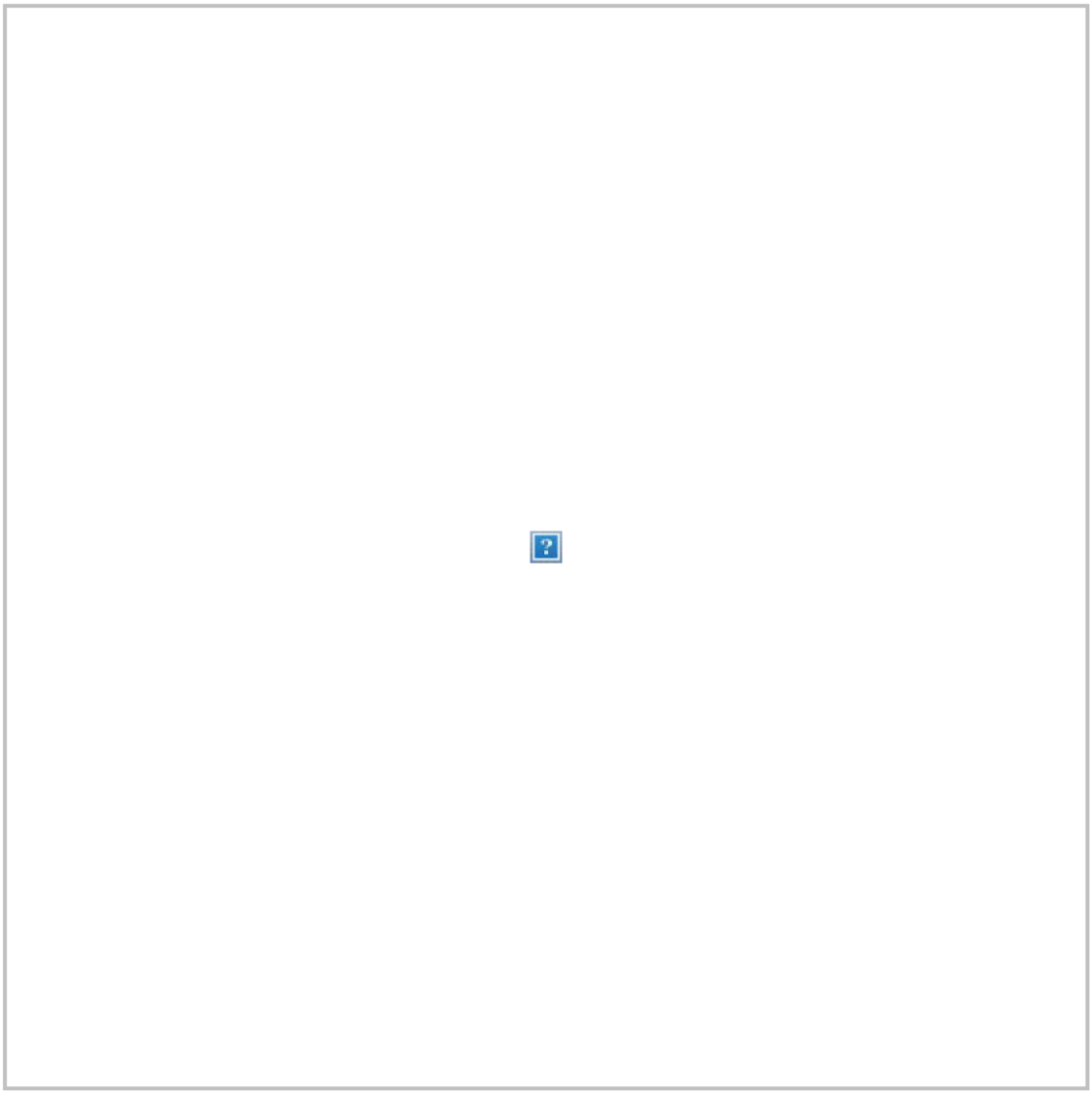
1. **Course 3: 22 January to 30 May 2022 (Applications filling fast)**
2. **Course 4: 23 July to 29 October 2022**

Please see upcoming intake dates HERE and enrol today.



Enrol today





Mind Medicine Australia, the Australian charity paving the way in psychedelic-assisted therapy, continues its **free online Webinar Series in 2021** for the Australian public. **World-leading experts** are brought straight into your living room for further discussion about the ground-breaking opportunity psychedelic-assisted therapies offer us in times when the mental health security of our communities is under increasing pressure.

This series will cover:

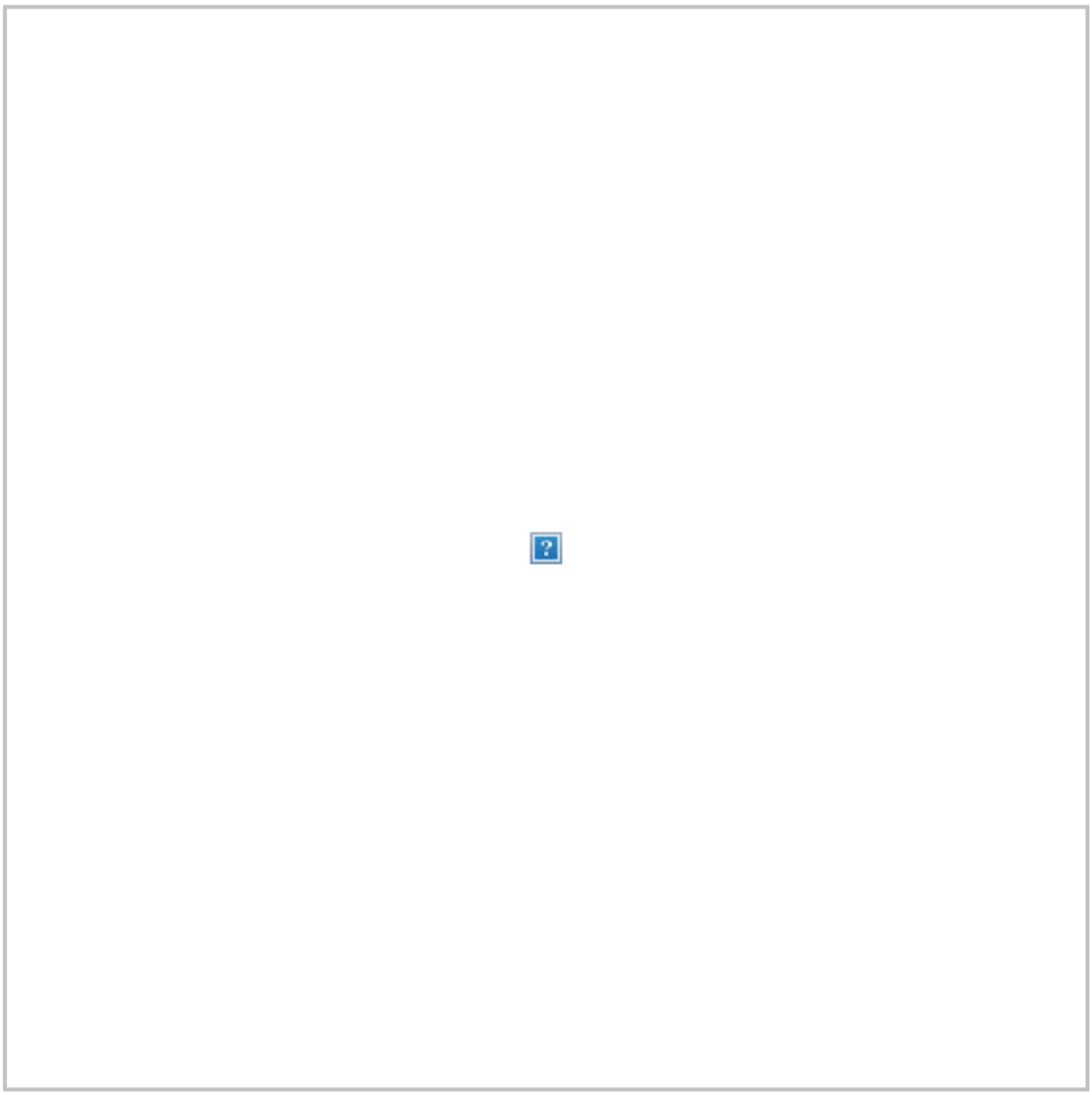
1. **Wednesday 1st September** 12:00 pm – 1:15 pm (AEST) |Bridging Indigenous Wisdom and Western Psychotherapy - s22 **(USA)**
2. **Wednesday 6th October** 7:30 pm - 8:45 pm (AEDT) | How neuroscience put psychedelics back into psychiatry - **Professor** s22 **UK)**
3. **Wednesday 20th October** 1:00 pm (AEDT) | The Relationship between Sex & Psychedelics: Connection to Self & Other - s22

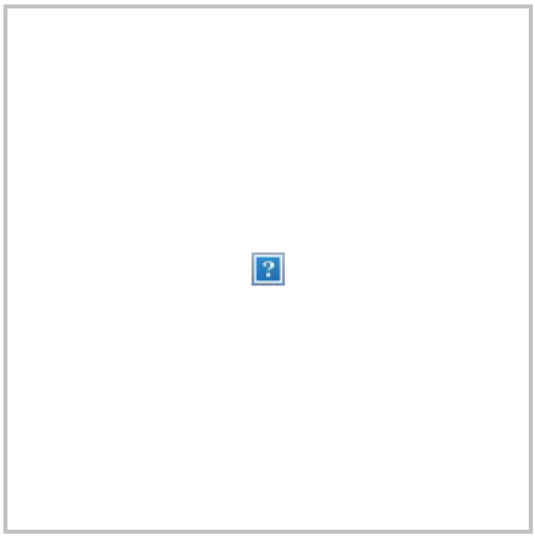
(USA)

and more to be announced...

Whilst our webinars are free of charge, we strongly encourage you to make a donation and support our important mission of making these therapies available through our medical system. This can be done at the time of reserving your ticket. Please share these events with your networks.

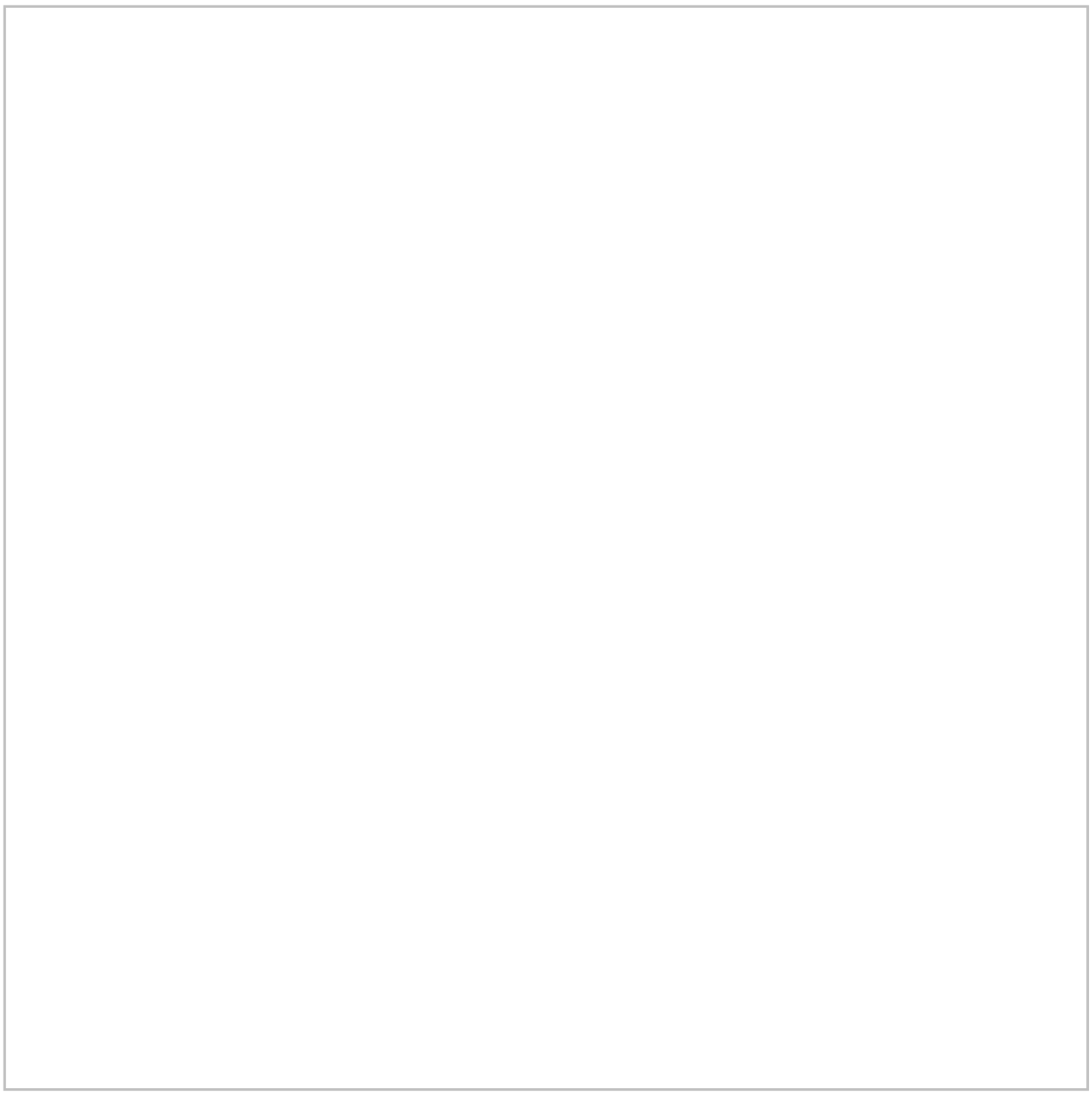
Find out more and register here





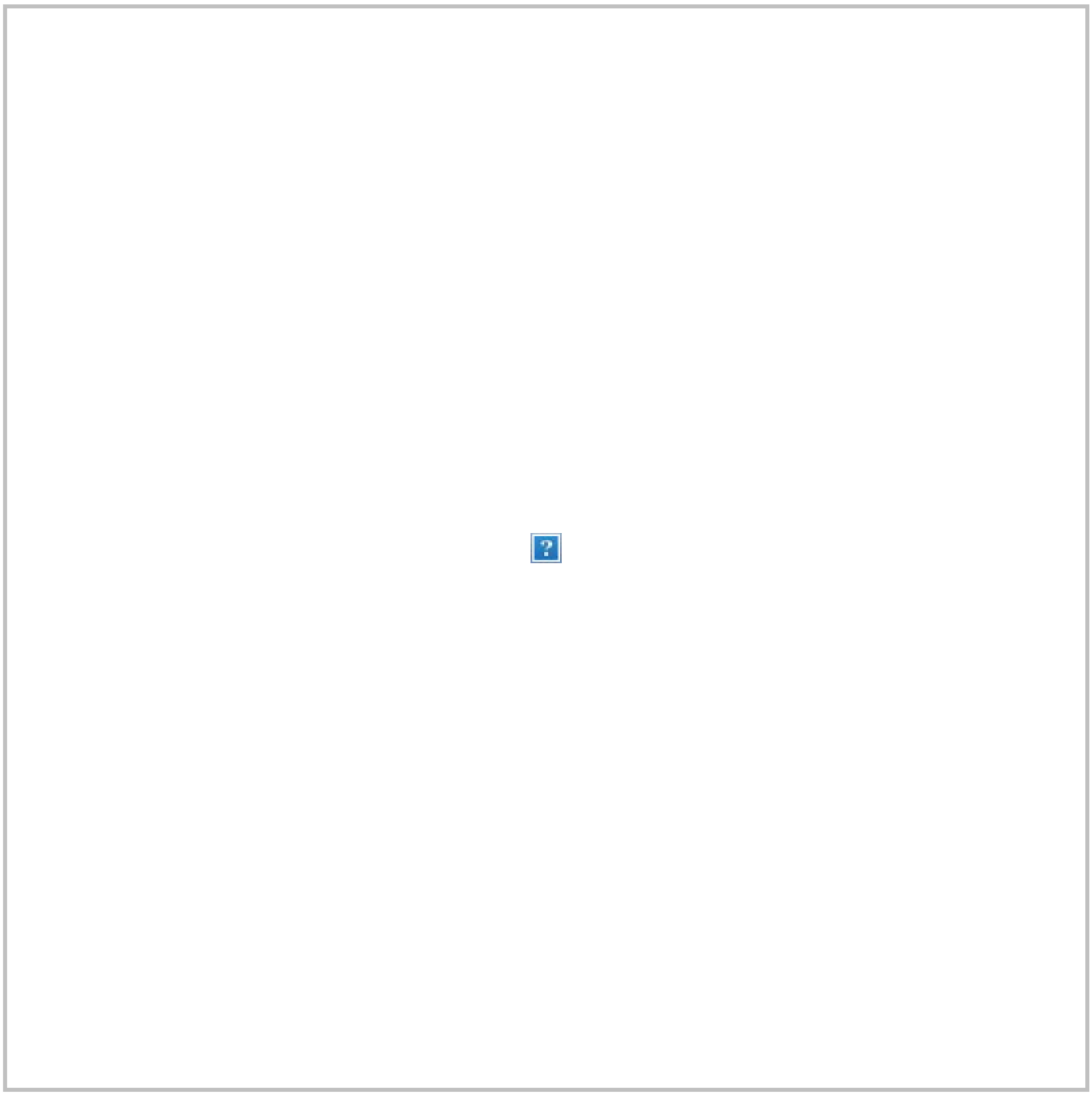
Share Tweet Forward

We would love you to share this with your friends or followers, and come back to us with your questions, ideas and comments.

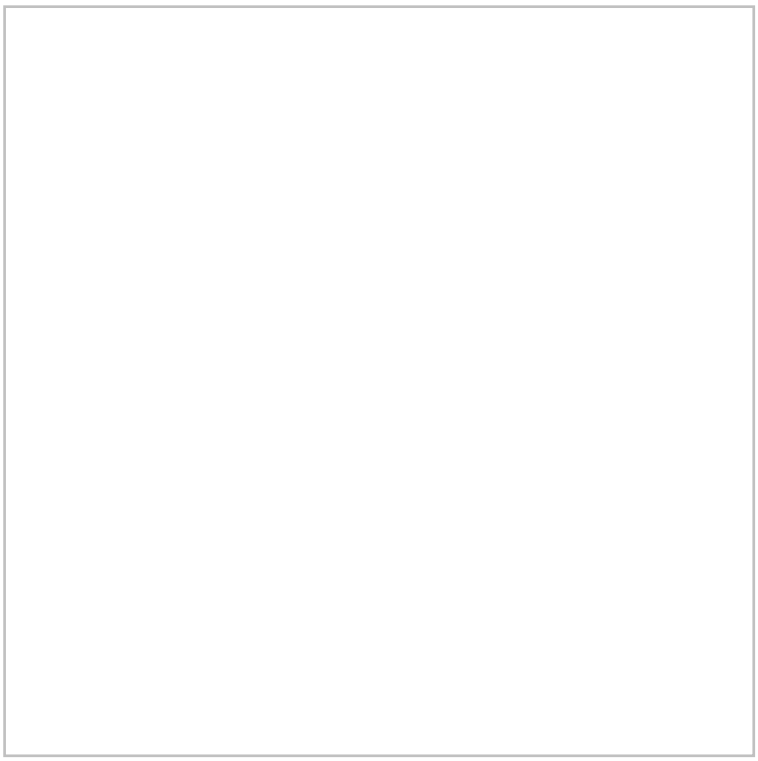


New York University end-of-life study participant: "*…everyone deserved to have this experience… that if everyone did, no one could ever do harm to another again … wars would be impossible to wage.*"

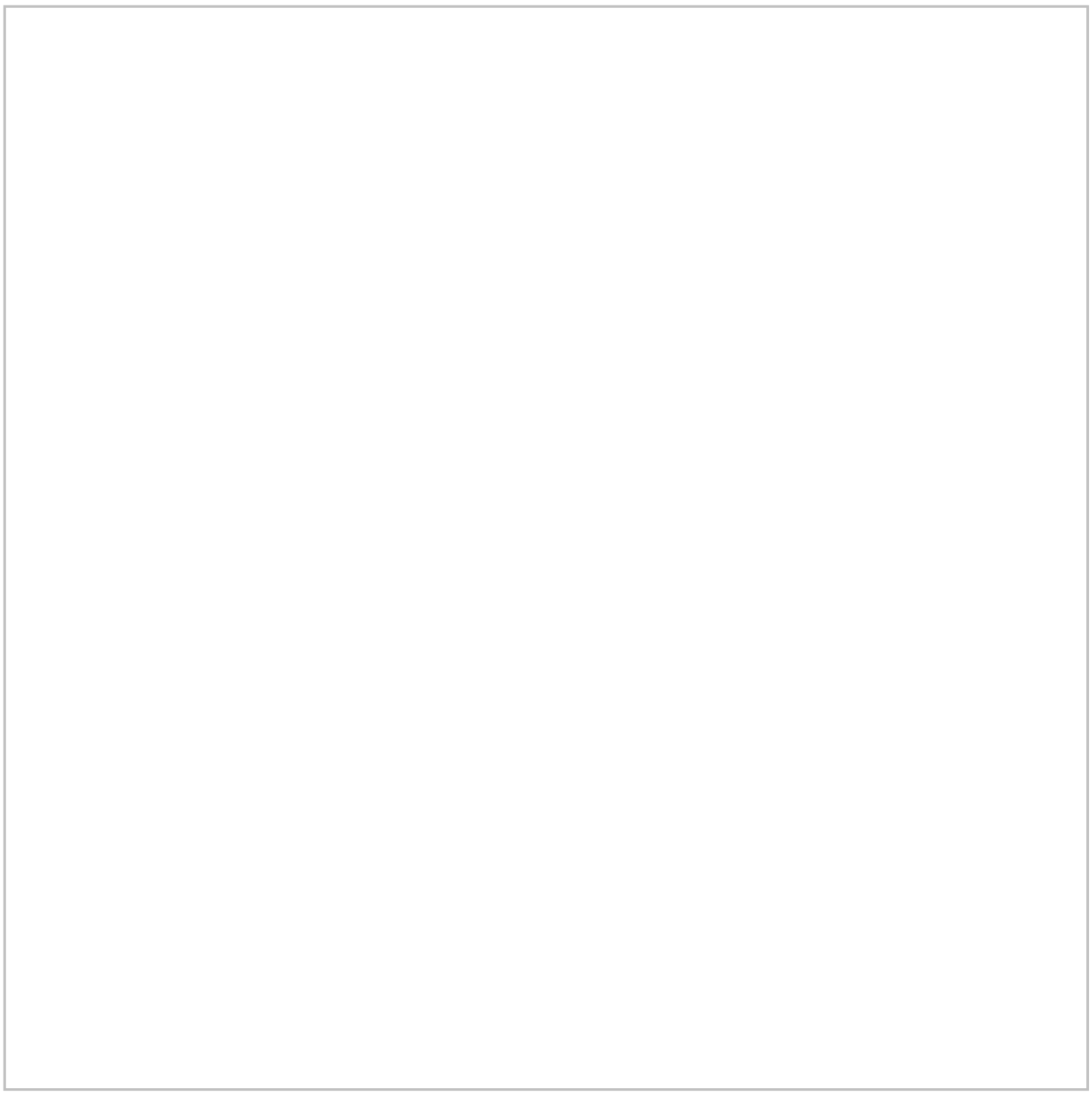
Read more inspirational testimonials here



By donating to Mind Medicine Australia, you will be helping us to accelerate the availability and best practice of medicine-assisted psychotherapy in Australia. We are a small organisation doing big things – we need your support.



Please make a tax-deductible donation



- Spread the word to your friends, colleagues and networks about the potential of Psychedelic-Assisted Therapies.
- Share our 2-minute Animation about psychedelic-assisted therapy far and wide!
- Download important documents about the state of mental health in Australia and Mind Medicine Australia HERE including our 2-page Mind Medicine Australia fact sheet and our Frequently Asked Questions.
- Keep up to date with the latest news about Psychedelic Medicine by accessing information from Mind Medicine's website and subscribing to our regular newsletter, click HERE and scroll down to subscribe.
- See the progress we have made in Mind Medicine Australia's Annual Review: 'Our First Two Years Review 2019-2021'.
- Register for and attend our Global webinar series.
- Donate to Mind Medicine Australia to support Psychedelic Research, Public Education and Therapist Training programs.
- Join our Chapters and advocacy network around Australia and NZ.

Reach out to your local politicians and MPs. Here is a link with more details on how to contact senators and members of parliament.
- Submit your application for our Certificate in Psychedelic-Assisted Therapies.
- Contact our national Psychological Support Service for psychological and integration support.
- Register your interest for our upcoming Introductory Workshop in Psychedelic-Assisted Therapies.
- Register for and attend our Global Summit on Psychedelic Therapies for Treatment of Mental Illness.
- Purchase one of our fashionable branded shirts and show your support.
- Volunteer to work with Mind Medicine Australia. We are a small organisation doing big things. If you feel you have the skills and time to lend us a hand…please get in touch.

About us

More about Mind Medicine Australia and psychedelic-assisted therapy:

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 caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients.

Unlike current treatments such as anti-depressants, which only manage the illness and can have nasty side effects, psilocybin and MDMA assisted therapies have been scientifically proven to be a safe and effective cure for anxiety, depression, end-of-life stress, addictions and PTSD after just a short treatment program. These medicines are also currently being researched for dementia, eating disorders, OCD and a number of other conditions. Both medicines have been granted Breakthrough Therapy Status by the FDA in the USA to fast-track their approval. This designation is only given to medicines which may prove to be vastly superior to existing treatments.

At Mind Medicine Australia we are dedicated to helping the now global

movement to spread this awareness and ensure these medicines are available via the medical system. Please watch and share our 2 minute animation to find out why psychedelic-assisted psychotherapy needs to be available to those who are suffering.

The recent pandemic has exacerbated Australia's mental health epidemic and these treatments have the potential to cure millions of people who are suffering.

Email

Facebook Twitter Website YouTube Instagram Email

Our mailing address is:
hello@mindmedicineaustralia.org

Mind Medicine Australia
Dimension 5, Level 1/10 Dorcas St,
Southbank, VIC, 3006, AUSTRALIA.

From: s22
To: SKERRITT, John
Cc: s22 .com.au)
Subject: WHOOPS: Correction to dates: 19-20th November 2021 | Please see below
Date: Tuesday, 7 September 2021 1:55:47 PM
Attachments: Mind-Medicine-Australia-Summit-2021-Speakers-John-Skerritt-07092021.jpg
1. International Psychedelic Therapies Summit 2021 MMA - Brief Outline 07092021.docx
3. Mind-Medicine-Australia-Summit-Poster-07092021.png
4. Mind-Medicine-Australia-Summit-2021-1000x1000-Instagram-26082021.jpg
5. Mind-Medicine-Australia-Summit-2021-300x450-26082021.jpg
6. Mind-Medicine-Australia-Summit-2021-450x300-26082021.jpg
7. Mind-Medicine-Australia-Summit-2021-728x90-26082021.jpg
8. Mind-Medicine-Australia-Summit-2021-1200x630-Facebook-26082021.jpg
9. Mind-Medicine-Australia-Summit-2021-1200x675-Twitter-26082021.jpg
10. Mind-Medicine-Australia-Summit-2021-1200x1000-26082021.jpg
11. Mind-Medicine-Australia-Summit-2021-1400x173-26082021.jpg
12. Mind Medicine Australia Logo.png
Copy for websites EDMs and Social Media posts for Speakers - Mind Medicine Australia International Summit-01092021.docx

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Dear John,

We are delighted to have you presenting and helping to spread the word about the inaugural **Mind Medicine Australia International Summit on Psychedelic Therapies for Mental Health** taking place ONLINE from **19-20 November 2021** preceded by the 2-day introductory workshop. We will be in touch soon regarding the exact timing and details of your session. We have attached marketing collateral including a personal graphic for you to share far and wide across your networks.

Here is the website link: https://summit.mindmedicineaustralia.org/

10% discount for event access

As a 2021 Summit speaker, you have access to our special 10% off discount code for event tickets for your networks. You can access this offer for your own business/organisation and you are also welcome to extend this offer to your networks as part of your promotion of the event. Your special 10% off discount code is 'MMA2021' and you and your networks can use it on the website when purchasing event packages.

Help us spread the word!

As you're aware, Summit supporters play an important role in helping to spread the word about the event via their networks.

Please could you promote the event to your networks, providing them with the exclusive 10% discount opportunity for ticket purchases. We have also included various social media graphics, including a personal graphic for you and extra content for sharing.

These pieces of marketing collateral can also be downloaded from this link:
https://www.dropbox.com/sh/lnc5xvgno12s2zj/AABz5kxwN8zIPkqrPLweqHRza?dl=0

Finally, here is our **new 2 minute video** about the use of safe and effective psychedelic-assisted treatments for mental illness in Australia. **We invite you to share with your friends, databases and followers.**

Are you following Mind Medicine Australia?

Don't forget to follow us!

Twitter: @MindMedicineAU and hashtag: #MMA2021

Facebook: https://www.facebook.com/mindmedicineau/

LinkedIn: https://www.linkedin.com/company/mind-medicine-australia/

INSTA: https://www.instagram.com/mindmedicine.au/

That's a wrap!

Looking forward to collaborating with you and welcoming you, your team, community and stakeholders to be part of this important future-shaping event! Together we can build a collective action plan to help create a healthier future and improve millions of lives.

If you need any further support, please don't hesitate to get in touch.

s22

International soprano, speaker, social entrepreneur

s22

M: s22

P: s22

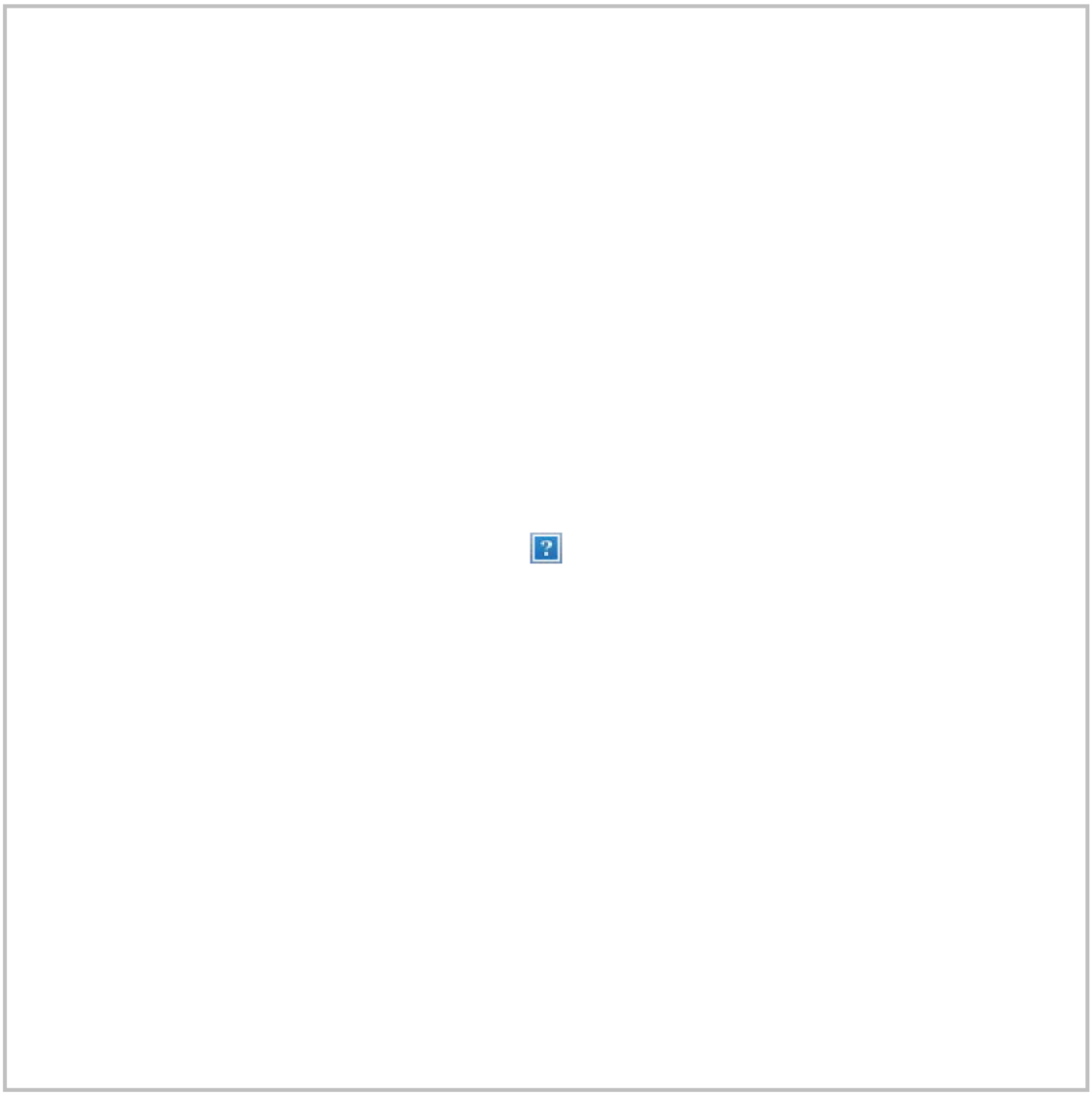
E: s22 @creativeuniverse.com.au

www.creativeuniverse.com.au

www.s22 .com

From: Mind Medicine Australia
To: SKERRITT, John
Subject: John, MMA International Psychedelic Medicine Summit - Program Released!
Date: Thursday, 14 October 2021 1:35:12 PM

Share Tweet Forward



John,

We've got just 5 weeks to go until our **International Summit on Psychedelic Treatments for Mental Illness** and have just released the program:

Please click here to see the 2-day program >>

This is the most important event in Psychedelic Medicine in the Southern Hemisphere. Given the recent findings from the TGA's Independent Review, the world has their eyes on Australia and what we are doing.

This is an incredibly exciting time to be part of this movement and be on the leading edge of this breakthrough treatment for mental health.

As far as what specifically the Summit will cover, you will be learning about:

- The neuroscience of new treatments with **Professor** s22 **(UK)**

- What can psychedelics teach us about the deeper causes of depression, anxiety and addiction with s22 **(UK)**
- MDMA-Assisted Psychotherapy for the Treatment of Alcohol Use Disorder with **Dr** s22 **(UK)**
- How psychedelics can help us get to the root cause of addiction, trauma and depression with **Dr** s22 **(USA)** from MAPS and others…
- The brain and therapeutic mechanisms of classic psychedelics with **Professor** s22 **(USA)**
- Creating the Future: What the Psychedelic Industry Will Look Like 5 Years Out with some of the leading for-profits from North America
- Psychedelics and Eating Disorders with **Dr** s22 **(USA)**
- From Depression to Addiction: An Overview of the Therapeutic Trials of Psilocybin at Johns Hopkins University with **Professor** s22 **(USA)**
- Expanded states of consciousness for healing and growth with s22 s22 **(Canada)**
- Indigenous wisdom and the art of shamanic healing with **Dr.** s22 **(Canada)**
- Myth, magic and psychotherapy in a changing world with **Dr.** s22 s22 **(USA)**
- End of life depression and anxiety treatment with psilocybin with **Dr** s22 s22 **(USA)**, **Dr.** s22 **(USA)** and s22 **(USA)**
- The Future of Psychedelics in Australia with key regulator **John Skerrit** from the **TGA**, The Head of The Ethics Centre **Dr** s22 and MMA Founders s22 and s22
- And much more…

See the program and book your tickets here >>

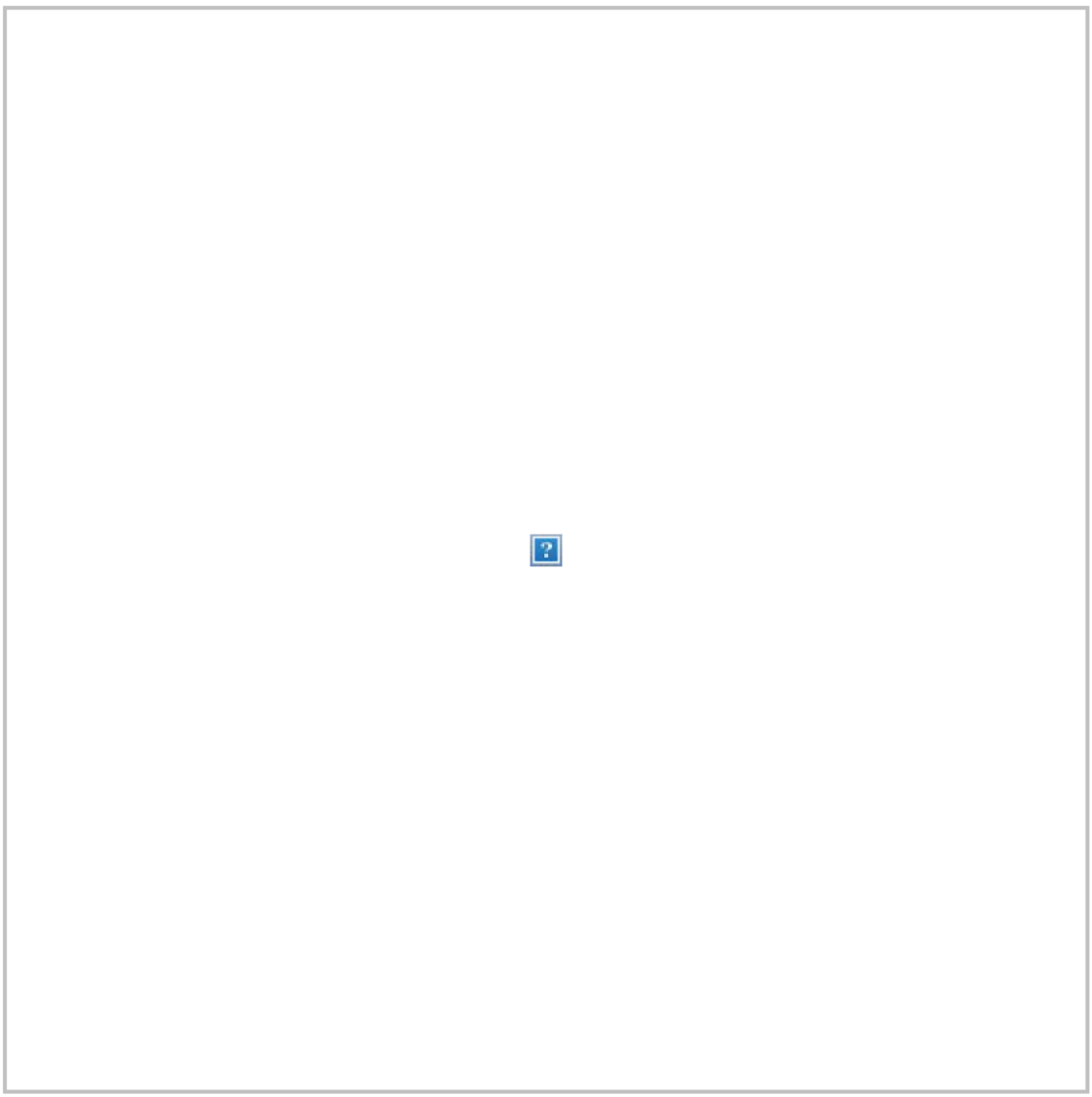
If you book Platinum or Gold/Silver tickets, you will also receive special gift bags from our sponsors, and be invited to intimate Hot Spot conversations with one or more of our international keynote speakers.

There's only a few weeks left to get your tickets, and we would hate you to forget and miss out. We'd be sad to see forget and miss out.

Hurry! Please book today >>

John, years from now you will look back at this event as one of the most important milestones in the evolution of the mental health industry.

After five decades of censorship, the psychedelic renaissance is back in motion and we would love you to help us lead the charge.



Please join us here.

We have also engaged leading psychologist and therapist trainer **Dr.** s22 s22 **(USA)** of Johns Hopkins University School of Medicine to help **facilitate** our **2-day Introductory Workshop on Psychedelic-Assisted Therapies on 17 and 18 November with** s22 **and Dr.** s22 s22

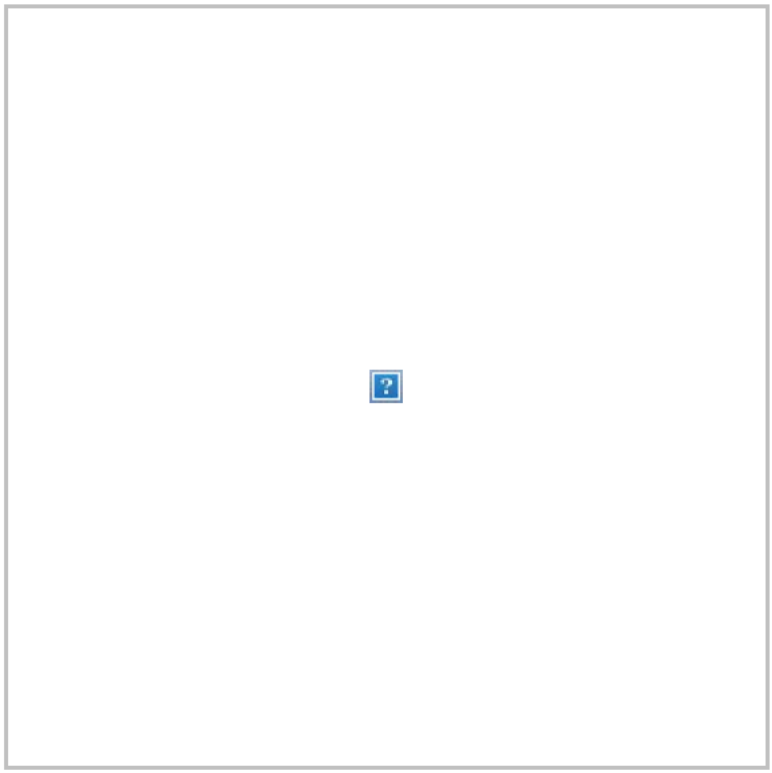
DON'T MISS OUT! PLEASE BOOK YOUR TICKETS TODAY.

You will learn more from the global leaders in this field including **Dr.** s22

s22 **(USA)**, **Professor** s22 **(UK)**, **Dr.** s22 **(Canada)**, **Professor** s22 **(UK)** and so many others, and even experience intimate group sessions with them!

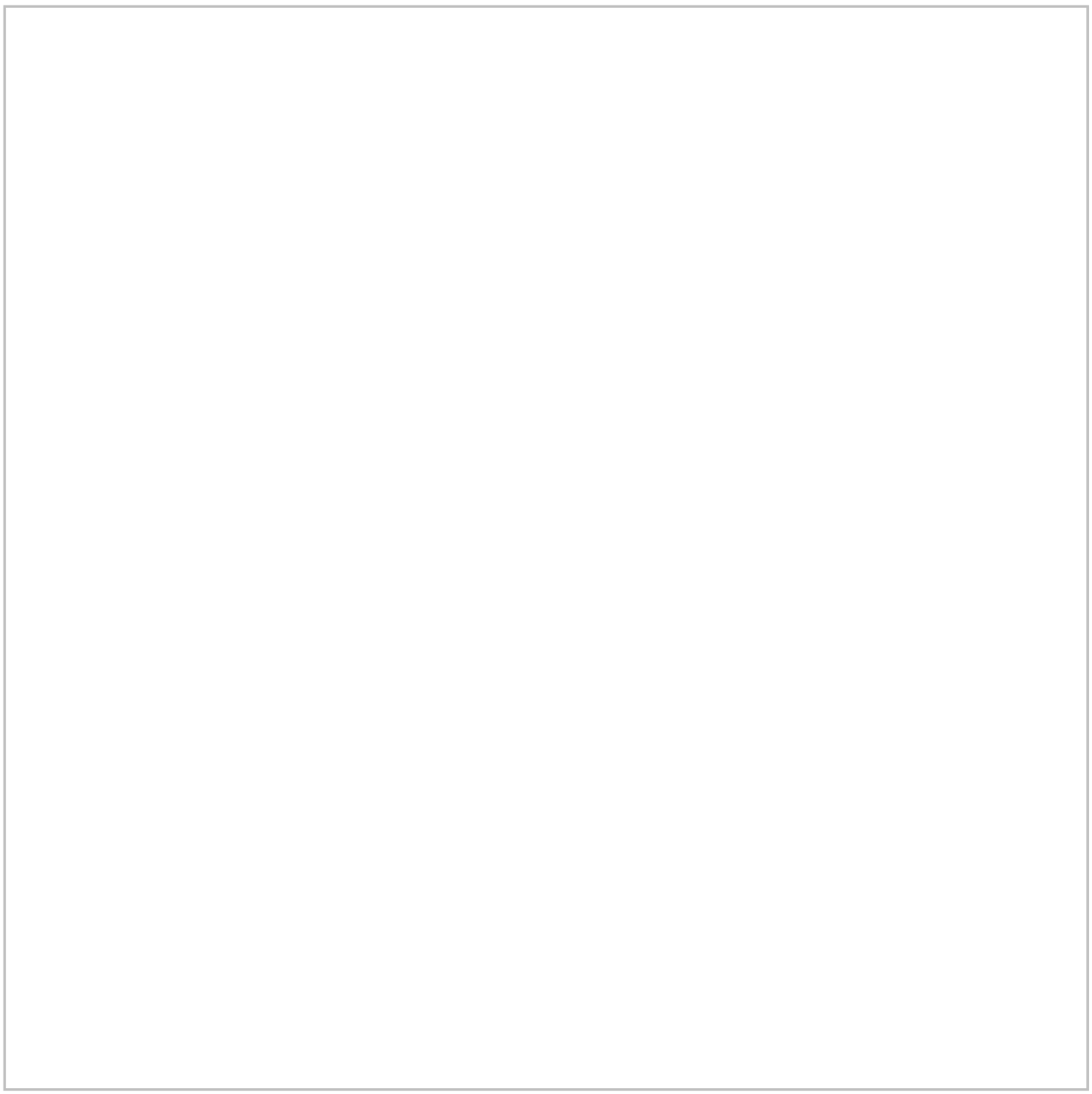
BOOK YOUR TICKETS TODAY

Warmly,
The Mind Medicine Australia Team



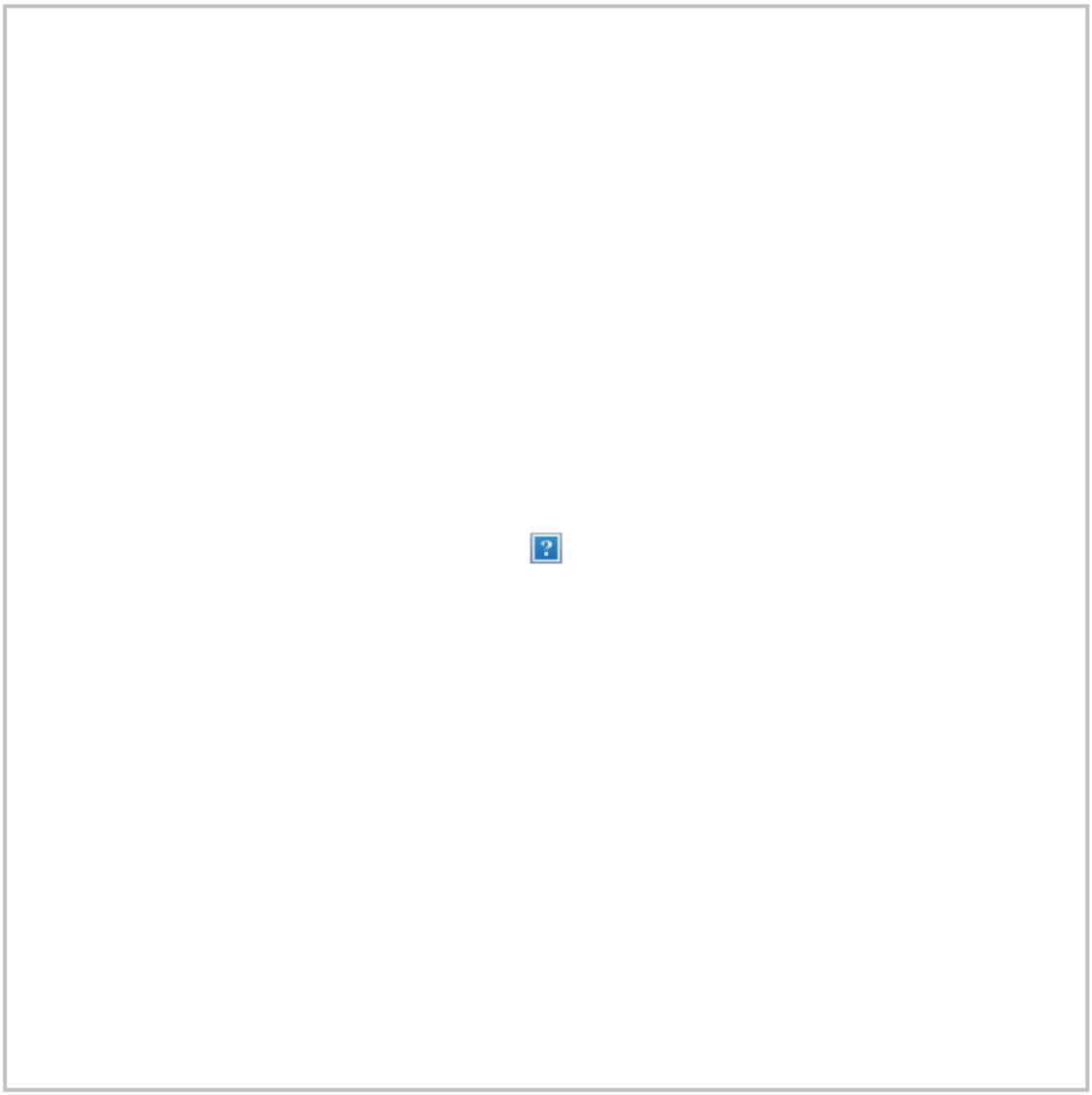
Mind Medicine Australia (**MMA**) and **Integrated Psychology and Medicine** (**IPM**) are delighted to announce the establishment of a new training, education and clinical services organisation called **Mind Medicine Training and Education** (**MMTE**).

Read the press release here



Mind Medicine Australia, is thrilled to announce that s22 **(USA)** has joined our world class Advisory Panel.

Our Advisory Panel is made up of over 70 national and international experts. They play an important role by providing guidance and new insights into the important work that we do.



Hamilton Morris (USA)

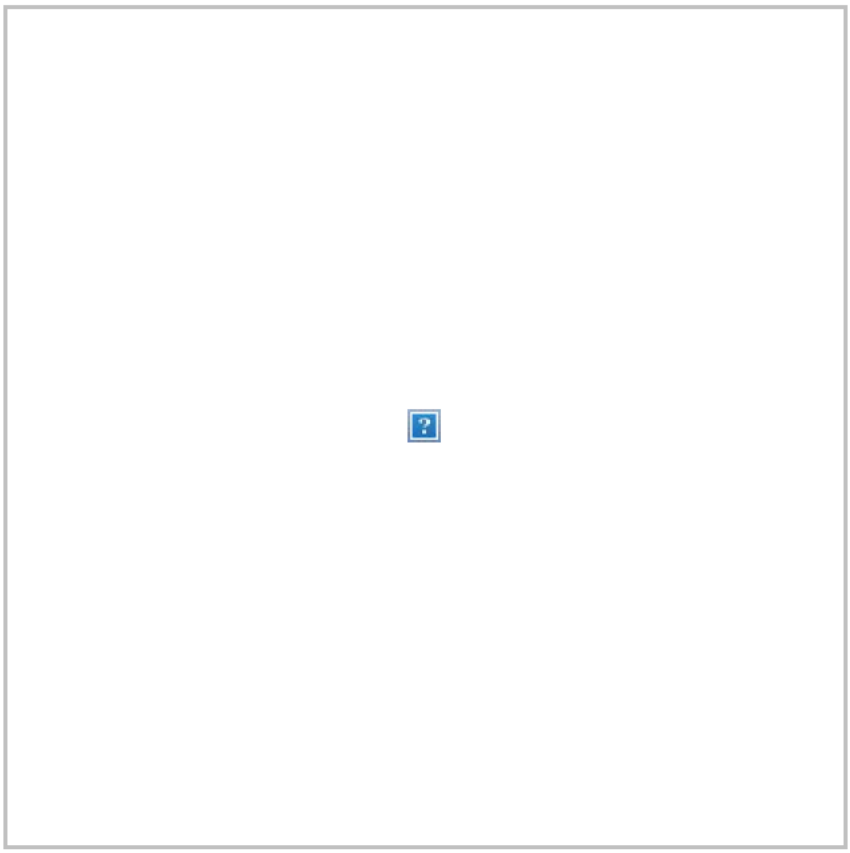
s22 is a chemist, filmmaker, and science journalist. He uses an interdisciplinary approach combining anthropology and chemistry in the study of psychoactive plants, fungi, chemicals, and the cultures that surrounds them in more than thirty countries. s22 is the director of the award winning documentary series s22 in which he explores the chemistry and traditions surrounding psychoactive drugs.

Please join us for an exclusive webinar:

1. **Wednesday 20th October** 1:00 pm (AEDT) | The Relationship between Sex & Psychedelics: Connection to Self & Other - s22 **(USA) and** s22 **(Canada)**

Get your FREE ticket today

Whilst our webinars are free of charge, we strongly encourage you to make a donation and support our important mission of making these therapies available through our medical system. This can be done at the time of reserving your ticket. Please share these events with your networks.



Our Chapters are a place for community gathering and sharing in relation to psychedelic science and medicine. By joining a Chapter, you will be helping to build local awareness through a range of events and share the incredible data and science of psychedelic-assisted therapies for the treatment of a range of illnesses.

Join our community today

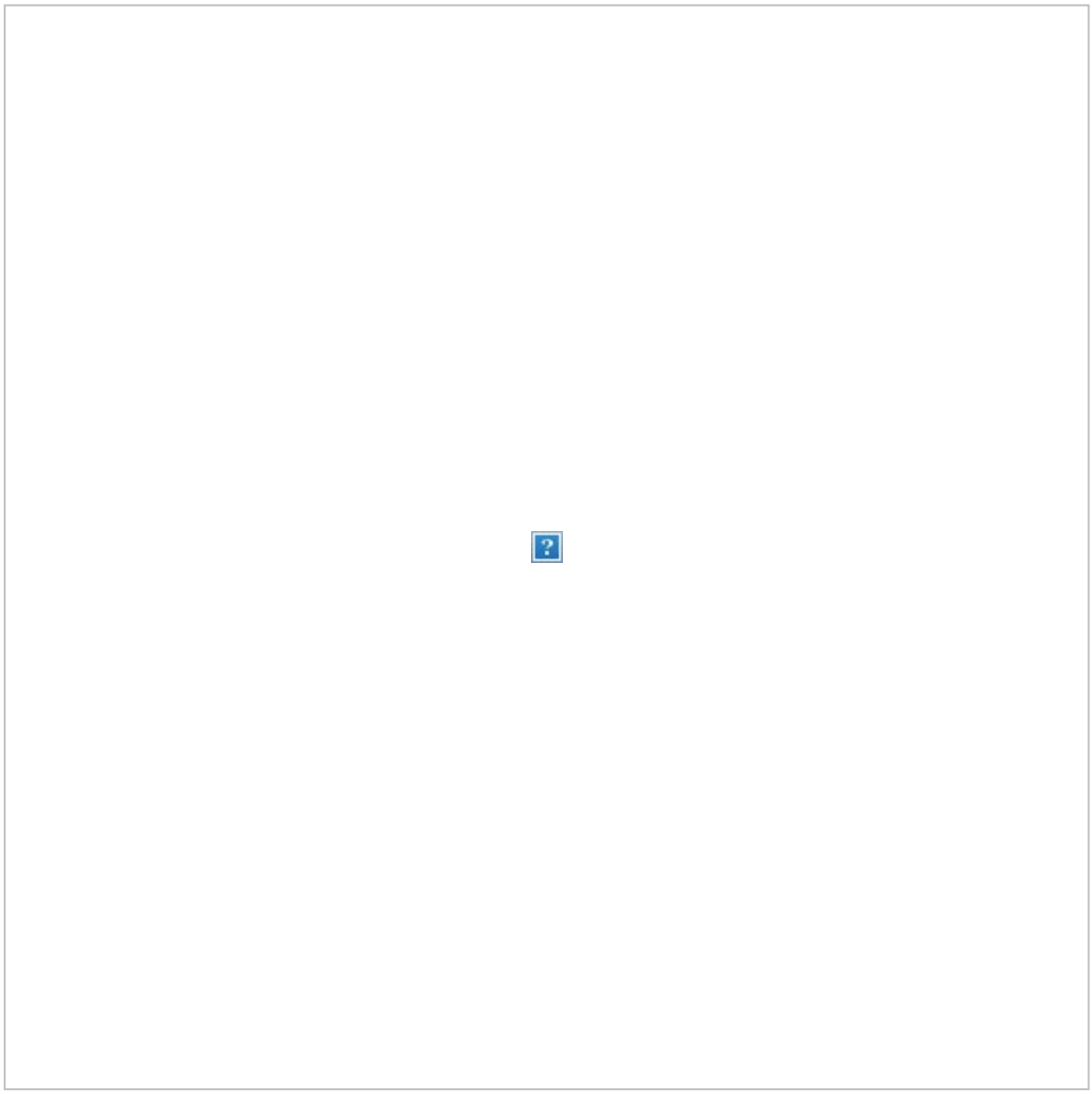
Despite national lockdowns, we have been very busy holding a range of virtual events. Many of these events were pivoted at the last minute to an online format with great success.

These events help us to reconnect, educate and engage. They provide an opportunity to hear about psychedelic-assisted psychotherapies for mental illness broadly, what Mind Medicine Australia is doing to create the eco-system

for these treatments here in Australia and how you can help.

Our chapters have now grown to **over 30 nationally** and **thousands of engaged members**.

Join your local chapter here >>



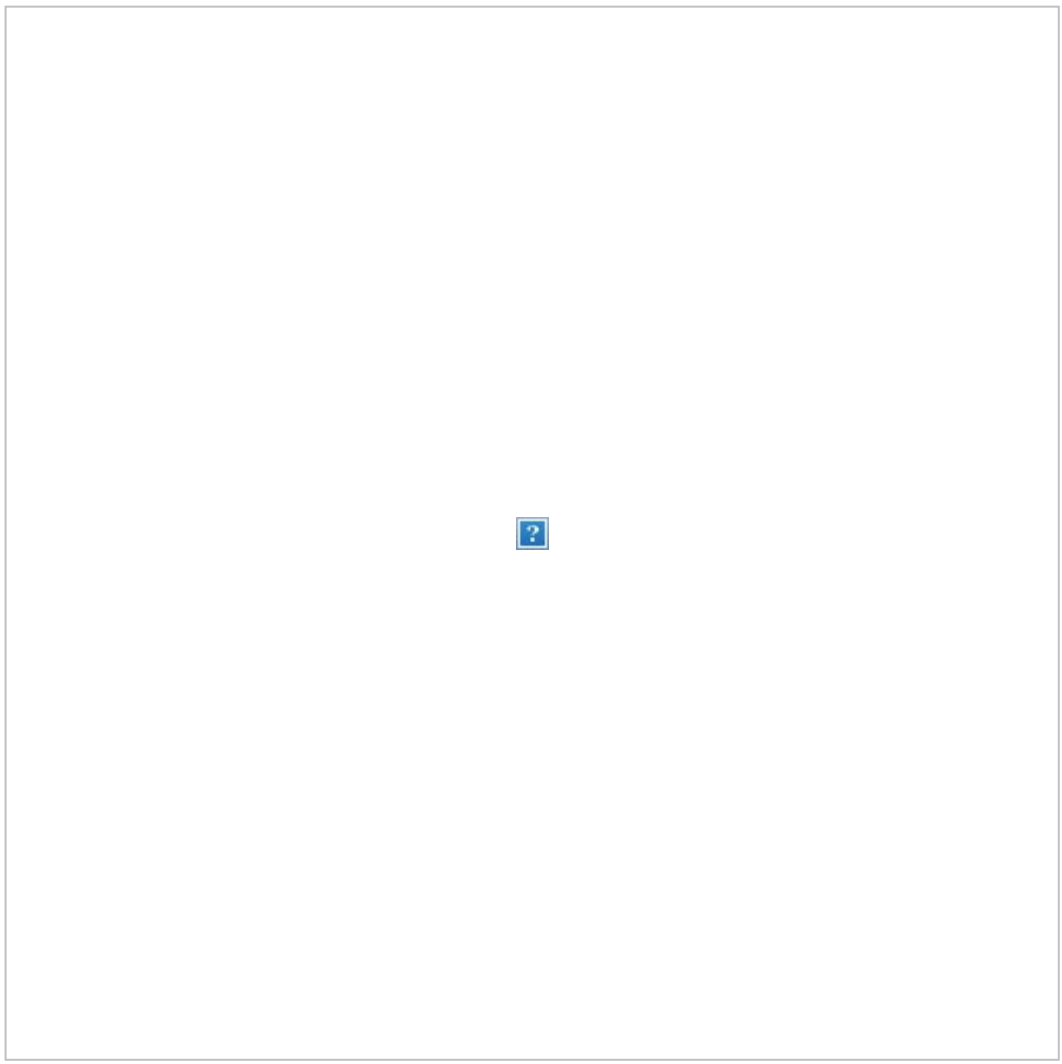
INTAKES 3 AND 4 FILLING FAST

The initial cohort of the **Certificate in Psychedelic-Assisted Therapies** have just completed their course with the world class Faculty. The feedback has been outstanding. This course will give qualified clinicians the additional skills and awareness they need in order to safely and successfully facilitate psychedelic-assisted therapies. Applications are now open for further intakes:

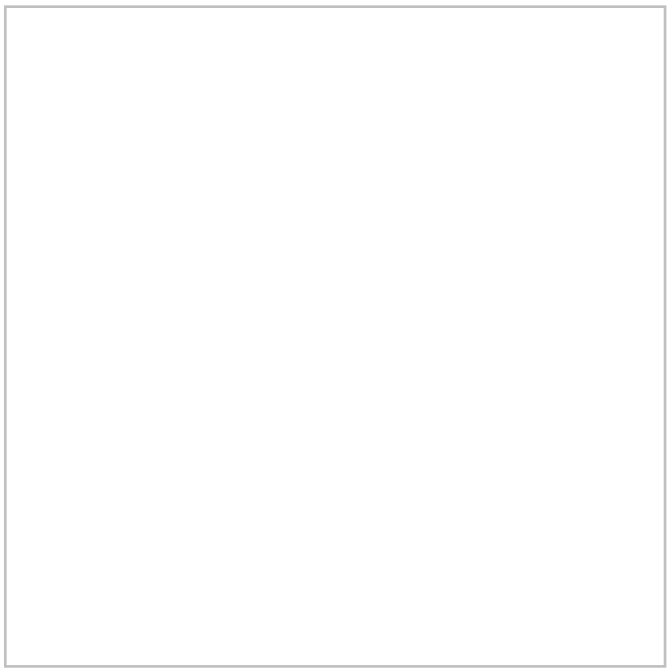
1. **Course 3 & 4:** Sunday 13 February - Sunday 19 June 2022 **(Applications filling fast)**

2. **Course 5 & 6:** Sunday 17 July – Sunday 13 November 2022

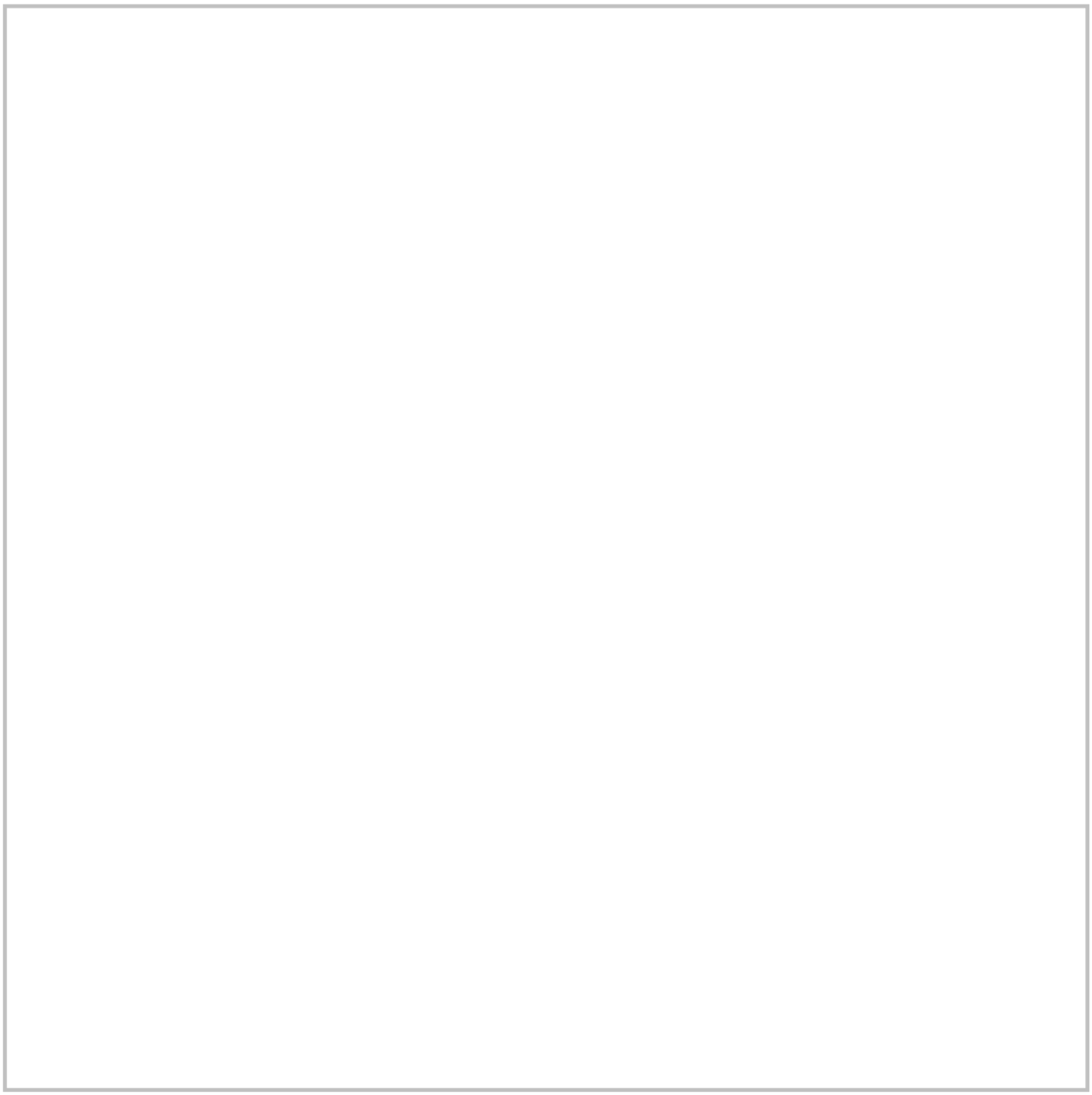
Please see upcoming intake dates HERE and enrol today.

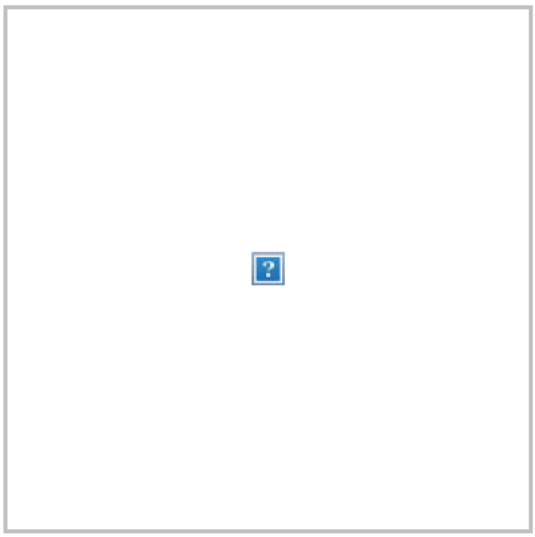


Enrol today

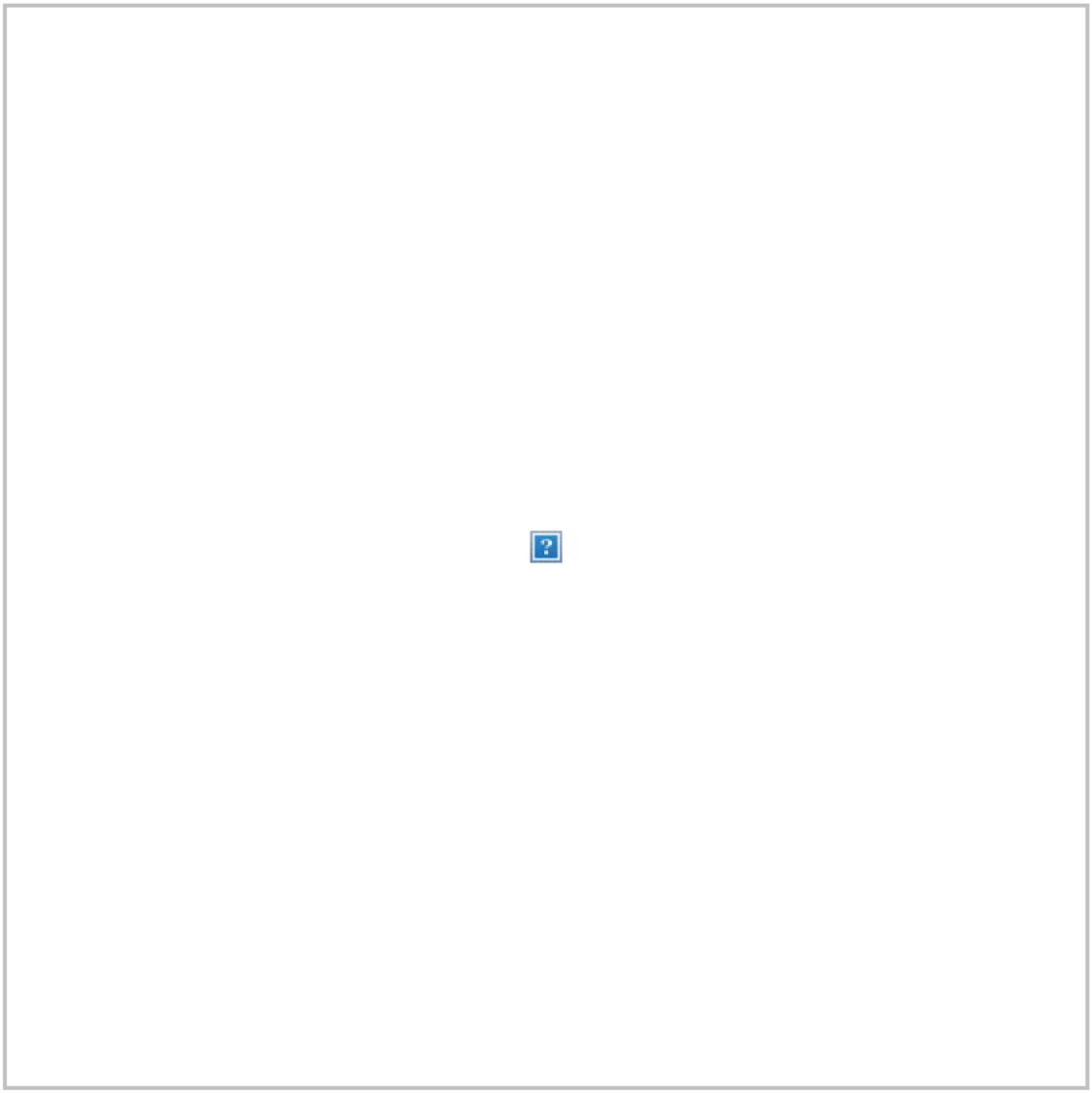


Find out more and register here



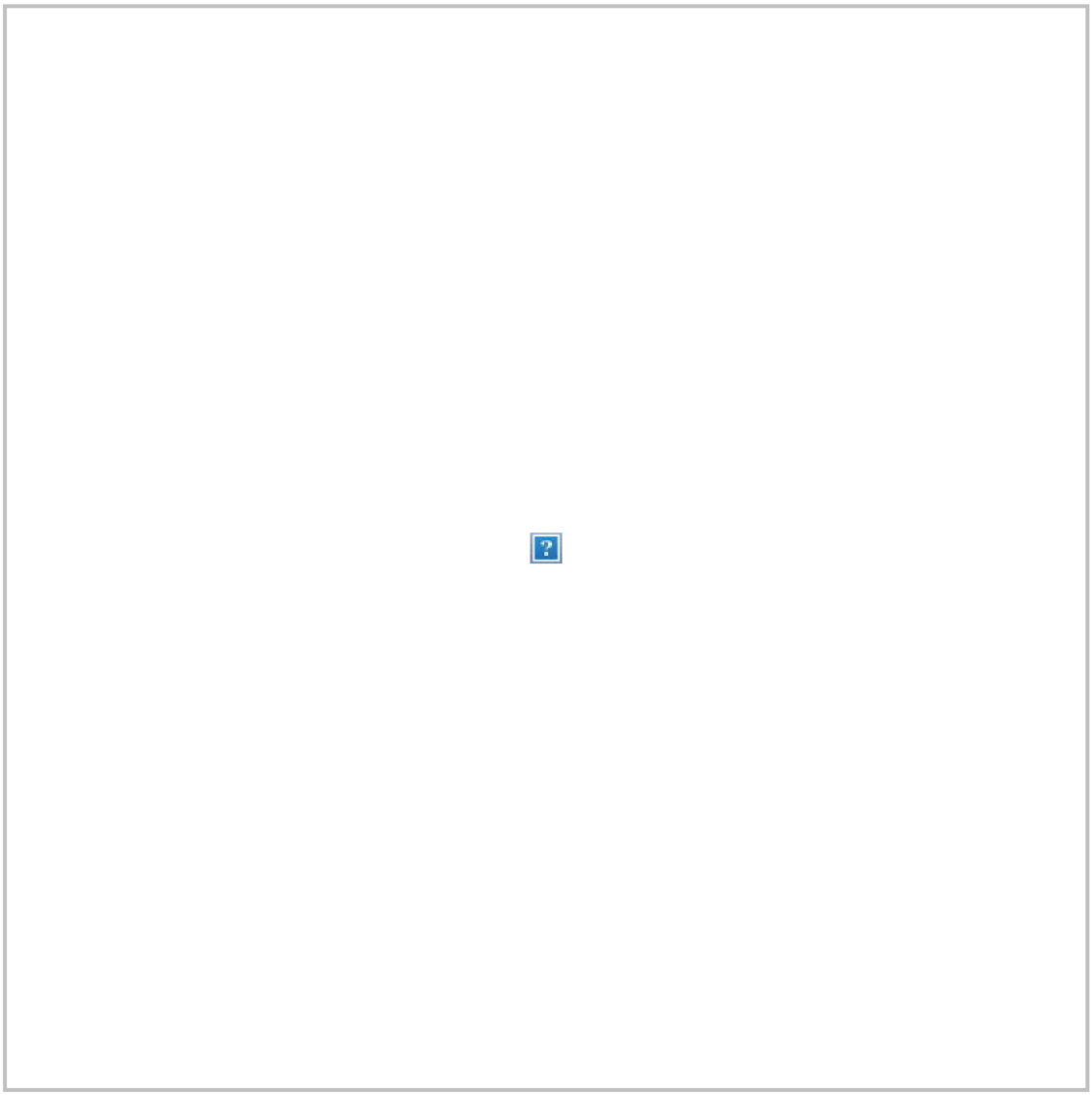


We would love you to share this with your friends or followers, and come back to us with your questions, ideas and comments.

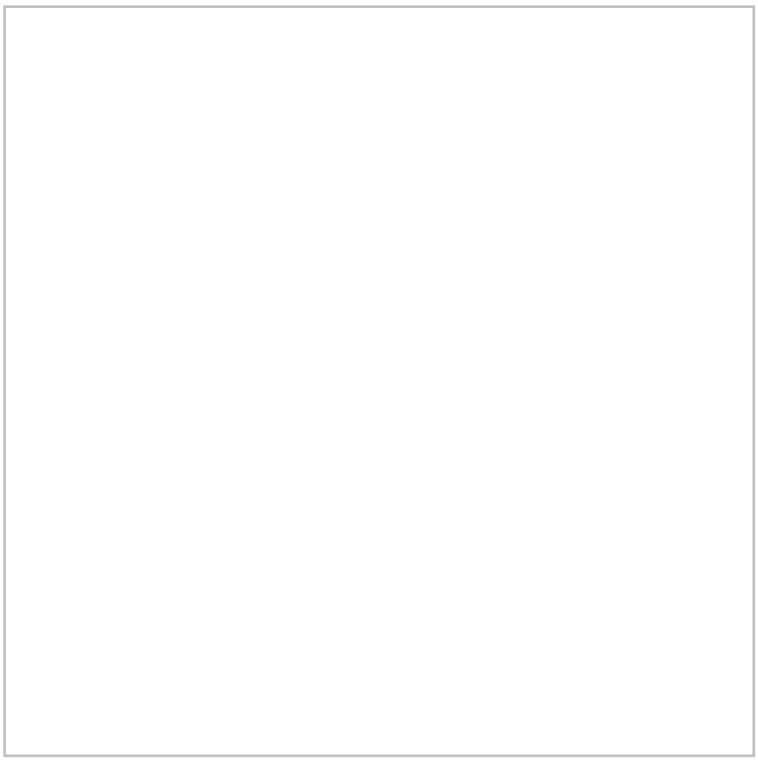


New York University end-of-life study participant: "*…everyone deserved to have this experience… that if everyone did, no one could ever do harm to another again … wars would be impossible to wage.*"

Read more inspirational testimonials here



By donating to Mind Medicine Australia, you will be helping us to accelerate the availability and best practice of medicine-assisted psychotherapy in Australia. We are a small organisation doing big things – we need your support.



Please make a tax-deductible donation

- Spread the word to your friends, colleagues and networks about the potential of Psychedelic-Assisted Therapies.
- Share our 2-minute Animation about psychedelic-assisted therapy far and wide!
- Download important documents about the state of mental health in Australia and Mind Medicine Australia HERE including our 2-page Mind Medicine Australia fact sheet and our Frequently Asked Questions.
- Keep up to date with the latest news about Psychedelic Medicine by accessing information from Mind Medicine's website and subscribing to our regular newsletter, click HERE and scroll down to subscribe.
- See the progress we have made in Mind Medicine Australia's Annual Review: 'Our First Two Years Review 2019-2021'.
- Register for and attend our Global webinar series.
- Donate to Mind Medicine Australia to support Psychedelic Research, Public Education and Therapist Training programs.
- Join our Chapters and advocacy network around Australia and NZ.

Reach out to your local politicians and MPs. Here is a link with more details on how to contact senators and members of parliament.
- Submit your application for our Certificate in Psychedelic-Assisted Therapies.
- Contact our national Psychological Support Service for psychological and integration support.
- Register your interest for our upcoming Introductory Workshop in Psychedelic-Assisted Therapies.
- Register for and attend our Global Summit on Psychedelic Therapies for Treatment of Mental Illness.
- Purchase one of our fashionable branded shirts and show your support.
- Volunteer to work with Mind Medicine Australia. We are a small organisation doing big things. If you feel you have the skills and time to lend us a hand…please get in touch.

About us

More about Mind Medicine Australia and psychedelic-assisted therapy:

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 caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients.

Unlike current treatments such as anti-depressants, which only manage the illness and can have nasty side effects, psilocybin and MDMA assisted therapies have been scientifically proven to be a safe and effective cure for anxiety, depression, end-of-life stress, addictions and PTSD after just a short treatment program. These medicines are also currently being researched for dementia, eating disorders, OCD and a number of other conditions. Both medicines have been granted Breakthrough Therapy Status by the FDA in the USA to fast-track their approval. This designation is only given to medicines which may prove to be vastly superior to existing treatments.

At Mind Medicine Australia we are dedicated to helping the now global

movement to spread this awareness and ensure these medicines are available via the medical system. Please watch and share our 2 minute animation to find out why psychedelic-assisted psychotherapy needs to be available to those who are suffering.

The recent pandemic has exacerbated Australia's mental health epidemic and these treatments have the potential to cure millions of people who are suffering.

From: SKERRITT, John
To: s22
Cc: s22 .com.au)
Subject: RE: PROMOTIONAL PACK TO SHARE - International Summit on Psychedelic Therapies for Mental Illness 2021, Melbourne [SEC=OFFICIAL]
Date: Tuesday, 7 September 2021 10:49:00 AM

Can you please correct the promotional materials where it says Health Products Regulation Group (TGA) by removing the reference to TGA

The two are not equivalent

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: s22 @mindmedicineaustralia.org>
Sent: Tuesday, 7 September 2021 10:43 AM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 .com.au) s22 .com.au>
Subject: PROMOTIONAL PACK TO SHARE - International Summit on Psychedelic Therapies for Mental Illness 2021, Melbourne

Dear John,

We are delighted to have you presenting and helping to spread the word about the inaugural **Mind Medicine Australia International Summit on Psychedelic Therapies for Mental Health** taking place ONLINE from 17-18 November 2021 preceded by the 2-day introductory workshop. We will be in touch soon regarding the exact timing and details of your session. We have attached marketing collateral including a personal graphic for you to share far and wide across your networks.

Here is the website link: https://summit.mindmedicineaustralia.org/

10% discount for event access

As a 2021 Summit speaker, you have access to our special 10% off discount code for event tickets for your networks. You can access this offer for your own business/organisation and you are also welcome to extend this offer to your networks as part of your promotion of the event. Your special 10% off discount code is 'MMA2021' and you and your networks can use it on the website when purchasing event packages.

Help us spread the word!

As you're aware, Summit supporters play an important role in helping to spread the word about the event via their networks.

Please could you promote the event to your networks, providing them with the exclusive 10% discount opportunity for ticket purchases. We have also included various social media graphics, including a personal graphic for you and extra content for sharing.

These pieces of marketing collateral can also be downloaded from this link:
https://www.dropbox.com/sh/lnc5xvgno12s2zj/AABz5kxwN8zIPkqrPLweqHRza?dl=0

Finally, here is our **new 2 minute video** about the use of safe and effective psychedelic-assisted treatments for mental illness in Australia. **We invite you to share with your friends, databases and followers.**

Are you following Mind Medicine Australia?

Don't forget to follow us!

Twitter: @MindMedicineAU and hashtag: #MMA2021

Facebook: https://www.facebook.com/mindmedicineau/

LinkedIn: https://www.linkedin.com/company/mind-medicine-australia/

INSTA: https://www.instagram.com/mindmedicine.au/

That's a wrap!

Looking forward to collaborating with you and welcoming you, your team, community and stakeholders to be part of this important future-shaping event! Together we can build a collective action plan to help create a healthier future and improve millions of lives.

If you need any further support, please don't hesitate to get in touch.

s22

International soprano, speaker, social entrepreneur

s22

M: s22

P: s22

E: s22 @creativeuniverse.com.au

www.creativeuniverse.com.au

www.s22 .com