

The House of Representatives Standing Committee on Health, Aged Care and Sport:

Inquiry into the approval processes for new drugs and novel medical technologies in Australia

Submission by Mind Medicine Australia 7th October 2020

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Contents

Submission summary

Australia is facing a mental health crisis and traditional treatment options are not working for many Australians. What is already a poor state of mental health in Australia will deteriorate even further as a result of the COVID-19 pandemic. New treatment options are urgently required if we are to successfully address this epidemic.

Psychedelic-assisted psychotherapy represents a breakthrough treatment for mental illness - It involves giving patients small, controlled doses of medical psilocybin or medical MDMA, in 2–3 closely supervised therapy sessions, lasting 6-8 hours per session and conducted in a fully supervised clinical setting. The combination of these medicines as part of day-long therapy sessions, represents a new interface between medicine and novel therapies for the treatment of mental illness.

Mind Medicine Australia (MMA) is a registered charity registered DGR 1 charity founded by Tania de Jong AM and Peter Hunt AM. We exist to help alleviate the suffering caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients.

Psychiatrists working with MMA have already received approvals from the Therapeutic Goods Administration (TGA) at the Commonwealth level to use these therapies under the Special Access Scheme. In July 2020, MMA applied to the TGA to have medicinal psilocybin¹ and medicinal MDMA rescheduled from Schedule 9 ("prohibited substance") to Schedule 8 ("controlled medicine") of the Poisons Standard to assist in providing more straightforward regulatory pathways for psychiatrists and specialist addiction physicians to use these medicines as part of therapy under State legislation.

Psychedelic-assisted psychotherapy represents one of the very few scalable breakthroughs, that we have seen in decades, to improve mental health outcomes. To accelerate Australians, with major mental illnesses, gaining access to these breakthrough medicinal therapies, we recommend the following:

- Recommendation 1: The Commonwealth Government should establish a Steering Group to advise all levels of Government on the application of psychedelic-assisted psychotherapy.
- Recommendation 2: Medical practitioners applying under Special Access Schemes for permission to administer controlled medicines to patients should be able to use a single approval process for the Commonwealth and State/Territory in which the treatment is to occur (as is the case with medicinal cannabis).
- **Recommendation 3:** Australia should establish a "Centre of Excellence" for Emerging Mental Health Therapies, through which we will have the opportunity to become a world leader in the research and application of psychoactive medicines as part of therapy for the treatment of major classes of mental illness.

Psychedelic-assisted psychotherapy represents a new paradigm in the treatment of major classes of mental illness. We would welcome the opportunity to appear before the Committee to explain how this new treatment innovation can deliver vastly improved mental health outcomes for the millions of Australians who are suffering from depression, post-traumatic stress disorder, anxiety disorder, anorexia, obsessive compulsive disorder, substance abuse and related illnesses.

¹ The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) spells psilocybine with an 'e' on the end. All the literature spells psilocybin without an 'e' on the end. For the purposes of this document psilocybin will be spelt without an 'e' on the end.

Australia's mental health crisis

Australia is experiencing an accelerating mental health crisis. These were the statistics prior to the COVID-19 pandemic.

- 1 in 5 Australians are currently suffering a mental illness and 1 in 2 will experience a serious mental illness in their lifetimes.²
- 1 in 8 Australians are on antidepressants, including 1 in 4 older adults.³ Children as young as twelve are being prescribed psychiatric drugs.⁴
- In Australia, from 2008–09 to 2017–18, the proportion of Australians aged 0 to 27 using antidepressants grew from about 2.9% to 4.8%, with 101,174 children (under 18) being prescribed antidepressants in 2017-18⁵
- The use of antidepressants across Australia is up by 95% over the last 15 years, yet mental health statistics continue to worsen and suicide rates continue to rise.⁶
- Sadly, for Australians between 15 and 24 years of age, suicide is the leading cause of death.⁷ Self-harm in young people has increased by 33% in Victoria in July and August.⁸
- According to the Productivity Commission, the total cost of mental illness and suicide to the Australian economy is approximately \$180 billion per year.⁹

Current treatment options for mental illness are not working for Many Australians:

- In many cases, support is simply not available. Less than 50% of Australians with a mental illness will access mental health services in a given 12-month period. 10
- For those who do access services, outcomes are often far from satisfactory and treatment remains inadequate. Current medicines, such as antidepressants, require a daily dose and frequently have significant and nasty side effects, with only 20% of patients experiencing remission and relapse common when daily dosing stops.¹¹ Others are left with no viable treatment.
- Currently, when psychotherapy is used, in combination with antidepressants, remission rates can be up to 35% at best.¹²

² Australian Bureau of Statistics. National Survey of Mental Health and Wellbeing: A Summary of Results. 4326.0. Canberra: ABS, 2008.

³ Australian Institute of Health and Welfare. "Mental health-related prescriptions." In *Mental health services: In brief 2018*. Canberra: AIHW, 2018.

⁴ "An open letter to the premier of Victoria", *The Australian*, online article, https://origin.go.theaustralian.com.au/wp-content/uploads/2020/09/AN-OPEN-LETTER-TO-THE-PREMIER-OF-VICTORIA.pdf

⁵Whitely, M., Raven, M. and Jureidini, J. "Antidepressant Prescribing and Suicide/Self-harm by Young Australians: Regulatory Warnings, Contradictory Advice, and Long-Term Trends." *Frontiers of Psychiatry* (June 2020). https://doi.org/10.3389/fpsyt.2020.00478

 $^{^{6}}$ KPMG. "Suicide rates grow up to 40 percent without better prevention." September 10, 2019.

 $^{^{7}}$ Australian Health Economics Society. "The Cost of Youth Suicide in Australia." April 4, 2018.

⁸ Clayton, R. "Statistics show increase in children presenting to hospitals after self-harming", *ABC News*, 8 August 2020.

⁹ Kinchin, I. and Doran, C. "The Cost of Youth Suicide in Australia." *International Journal of Environmental Research and Public Health* 15, no. 4 (2018): 672. https://doi.org/10.3390/ijerph15040672. https://doi.org/10.1071/AH13142.

¹⁰ Whiteford H. A., Buckingham W. J., Harris M. G., Burgess P.M., Pirkis J. E., Barendregt J. J. and Hall W. D. 2014. "Estimating treatment rates for mental disorders in Australia." *Australian Health Review* 38(1):80–5 https://doi.org/10.1071/AH13142.

¹¹Cipriani, A., Furukawa, T., Salanit, G. et al. "Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis." *Lancet* 391 (2018): 1357–66. https://doi:10.1016/0140-6736(17)32802-7.

Mueller, T. I., Leon, A. C., Keller, M. B et al. "Recurrence after recovery from major depressive during 15 years of observational follow-up." *American Journal of Psychiatry* 156, no. 7 (1999): 1000–1006. https://doi:10.1176/ajp.156.7.1000.

 Additionally, psychotherapy can require a weekly commitment over an extended period of time, leading to significant costs that many people cannot afford.¹³

COVID-19 will cause mental health outcomes to deteriorate further:

- The Mind and Brain Centre recently announced that the COVID-19 crisis could lead to a 25% jump in the suicide rate if unemployment reaches 11%.¹⁴
- Lifeline has reported up to a 130% increase in calls associated with COVID-19 related distress,¹⁵ with Beyond Blue reporting that calls in June were up 47% from the same time last year.¹⁶

These statistics cannot do justice to the heartache, suffering and community damage that mental illness is currently having on our society. In the absence of effective treatment options, Australia's mental health system is being crippled by accelerating levels of mental illness.

Psychedelic-assisted psychotherapy is a breakthrough treatment

Psychedelic-assisted psychotherapy represents a breakthrough for the treatment of mental illness.

The treatment combines a short program of psychotherapy with 2 to 3 doses of either medical psilocybin or medical MDMA, administered in a controlled clinical environment. Importantly the patient will never be allowed to take these substances home. The use of psychedelic medicines, as well as day-long therapy sessions, represents a new interface between medicines and novel therapies.

This treatment is currently being tested in many countries:

- Over 120 trials have been conducted globally, at major clinical centres in the USA and Europe.
 Major universities with research and clinical programs include Harvard, Johns Hopkins, UCLA,
 NYU, Yale, Imperial College London, Kings College London, Oxford, Cambridge, Bristol, Basel,
 New Mexico and Autonoma de Barcelona.
- In Australia, a clinical trial using psilocybin-assisted therapy is underway at St. Vincent's Hospital, Melbourne for patients experiencing end-of-life anxiety and depression due to a terminal diagnosis.

This treatment approach has demonstrated remarkable promise in treating a range of mental illnesses, including depression, anxiety, addiction and trauma with trials underway for dementia, anorexia and other eating disorders, OCD and cluster headaches.

The US Federal Drug Administration (FDA) has granted psilocybin and MDMA-assisted therapies "breakthrough therapy status", due to their likely superiority over existing treatments and safety record. This status has allowed for fast track approval, upon completion of phase 3 trials, as early as 2021 for medicinal MDMA and 2023 for medicinal psilocybin.

¹³ Kamenov, K., Twomey, C., Cabello, M., Prina, A. and Ayuso-Mateos, J. "The efficacy of psychotherapy, pharmacotherapy and their combination on functioning and quality of life in depression: a meta-analysis." *Psychological Medicine* 47, no. 3 (2017): 414–425. https://doi.org/10.1017/S0033291716002774

¹⁴ Reiner, V. "Modelling shows path to suicide prevention in covid-recovery", *University of Sydney*, May 13, 2020.

¹⁵ Jervis-Bardy, D. "Spike in emergency interventions amid COVID-19 crisis: Lifeline." *The Canberra Times*, last modified July 31, 2020.

 $^{^{16}}$ Jacks, T. "Record calls to mental health services during second lockdown." The Age, July 10, 2020.

The results are unparalleled compared to existing medicines:

- Medicinal psilocybin-assisted psychotherapy and medicinal MDMA-assisted psychotherapy has demonstrated ongoing remission in between 60-80% of cases.¹⁷
- These therapies are comparable to decades of therapy, in just a few sittings.¹⁸

In addition, several countries such as Israel, Switzerland, the USA are using Compassionate or Expanded Access Schemes (similar to Australia's "Special Access Scheme") to expedite access to these therapies for patients who are not benefiting from current treatments and Health Canada is giving exemptions for the use of medicinal psilocybin for patients suffering from anxiety and depression associated with a terminal diagnosis.

This approach is best summarised by research published in *Frontiers in Pharmacology* and *Frontiers in Psychiatry* in 2018^2 regarding effect sizes among the most effective treatments for mental illness using Cohen's = d scale where 0.2 = "small"; 0.5 = "medium"; 0.8 = "large" - treatment benefit:

- Antidepressants for depression have effect sizes of around d = 0.3.
- By comparison, in the Phase 2 trials MDMA-assisted psychotherapy for PTSD had much higher effect sizes of d = 1.17-1.24.
- Psilocybin-assisted psychotherapy for depression had even higher effect sizes of d = 2.0–3.1.^{19,20}

Put simply, psychedelic-assisted psychotherapy has proven much more effective at treating depression and PTSD than traditional antidepressant medications. And the results can be achieved in only 2–3 dosed sessions, in contrast to conventional treatments that usually require daily medications and/or weekly psychotherapy over extended timeframes – often for years.

Medicinal psilocybin and medicinal MDMA have a strong safety record when used in a medically controlled environment and the medicines themselves are non-addictive.

We are not advocating a "free-for-all" or "over the counter" use of these substances. These medicines would only be supplied to and administered by, specially trained and registered clinicians on prescription of a psychiatrist or specialist addiction physician in a supervised clinical setting. Patients will never be allowed to take these medicines home.

The process of bringing psychedelic-assisted psychotherapy to Australians

For psychedelic-assisted psychotherapy to be available to Australians, approval is required at both the Commonwealth and State/Territory levels.

Commonwealth approvals:

Psychiatrists working with MMA have already received approvals at the Commonwealth level for the use of these therapies under Special Access Scheme-B.

¹⁷ Watts, R., Day, C., Krzanowski, J., Nutt, D. and Carhart-Harris, R. "Patients' Accounts of Increased 'Connectedness' and 'Acceptance' After Psilocybin for Treatment-Resistant Depression." *Journal of Humanistic Psychology* 57 no. 5 (2017): 520–564. https://doi.org/10.1177/0022167817709585.

^{18 &}quot;The Project: Psychedelic Science", The Project – Network 10, 9 April 2018.

¹⁹ Schenberg, E. E. S. "Psychedelic-Assisted Psychotherapy: A Paradigm Shift in Psychiatric Research and Development." *Frontiers in Pharmacology* 9 (2018): 733. https://doi.org/10.3389/fphar.2018.00733

²⁰ Hengartner, M. P., & Plöderl, M. (2018). "Statistically significant antidepressant-placebo differences on subjective symptom-rating scales do not prove that antidepressants work: Effect size and method bias matter." *Frontiers in psychiatry* 9 (2018): 517.

In July 2020, MMA applied to the Therapeutics Goods Administration (TGA) to have two psychoactive substances, medicinal psilocybin and medicinal MDMA, reclassified from Schedule 9 ("prohibited substance") to Schedule 8 ("controlled medicine") of the Poisons Standard. Psilocybin is used in conjunction with therapy to treat depression and medicinal MDMA is used with therapy to treat PTSD. This rescheduling will greatly improve the accessibility of these therapies at the State and Territory Level. An amendment would also need to occur to the Commonwealth Narcotic Drugs Act 1967 to allow for the local manufacture of synthetic medicinal psilocybin and MDMA, which would further improve accessibility by reducing cost and improving the availability of these substances in Australia.

State/Territory approvals:

MMA is currently in discussions with the Departments of Health and relevant ministers in a number of Australian jurisdictions. What is clear from these discussions is that there is no uniform process across States and Territories for the approval of new medicines or therapies such as this. Each State and Territory has its own unique approval processes and timeframes differ considerably.

Whilst recognising that healthcare is primarily a State/Territory responsibility, we see merit in establishing a national Steering Group, with representation from all levels of government, leading Australian clinicians and other relevant parties. Its role would be to seek advice from leading researchers and clinicians from around the world with specific expertise in the application and safety of psychedelic-assisted psychotherapies and provide a single "national view" on this treatment approach. The Steering Committee would make recommendations to Government about the benefits and safety of psychedelic-assisted psychotherapies, cost effectiveness, treatment protocols, required medical training and preferred legal implementation framework and rollout strategies.

This single national approach would avoid the same work needing to be replicated in each State and Territory and would accelerate the access to psychedelic-assisted psychotherapy for Australians suffering from major classes of mental illness.

Recommendation 1: The Commonwealth Government should establish a Steering Group to advise all levels of government on the application of psychedelic-assisted psychotherapy. Forming a single national view as to how psychedelic-assisted psychotherapy should be managed and implemented will accelerate the uptake of this breakthrough treatment for mental illness.

Access to these therapies across Australia should require only a single approval from the TGA

We recommend that the Commonwealth and State/Territory approvals be done via a single point of contact (as is the case with medicinal cannabis). This method is preferable to having to seek approvals from both the Commonwealth and the relevant State/Territory in which the treatment is to occur.

Recommendation 2: Medical practitioners applying under Special Access Scheme approvals for permission to administer these medicines to patients as part of therapy should use a single approval process at the Commonwealth level (as is the case with medicinal cannabis).

Making Australia a world-leader in psychedelic medicines

Although clinical trials have been conducted to date in numerous universities and research centres in North America, Europe and Israel, there are currently only three "centres of excellence" in the world for research into psychedelic-assisted psychotherapy – Imperial College London, Johns Hopkins and Berkeley in the USA.

Australia has a major opportunity to establish a "centre of excellence" serving the Asia-Pacific Region, to maximise and extend our understanding of psychedelic-assisted and other emerging mental health psychotherapies. The Centre would be established with an affiliation to a major Australian University or universities. Amongst other things, it would focus on:

- Research into the practical use of psychedelic-assisted psychotherapies in areas such as depression, PTSD, early stage dementia, anorexia nervosa, chronic pain, treatment of addiction and potentially bipolar disorder and related diseases including mechanistic studies.
- The development of local trials and participation in global multi-site trials.
- Establishment of an agricultural base in Australia for the supply of medical grade psilocybin and the agricultural precursor to MDMA.
- The development of secure medicinal MDMA and medicinal psilocybin manufacturing capabilities and/or sources of supply and manufacturing expertise for the supply of GMP certified pharmaceutical grade medicines to domestic and international markets.
- The education of health professionals and medical schools around Australia.

We envisage that the "Centre of Excellence" would be funded jointly by philanthropists and State and Federal Governments, with financial and in-kind support from the university(s) involved.

Recommendation 3: Australia should establish a "Centre of Excellence" in Emerging Mental Health Therapies, through which we will have the opportunity to become a world-leader in the research and application of psychoactive medicines for the treatment of mental illness.

Appendix 1: About Mind Medicine Australia

Mind Medicine Australia (MMA) is a registered charity founded by social entrepreneurs Tania de Jong AM and Peter Hunt AM to facilitate the introduction into Australia of psychedelic-assisted psychotherapies, to provide patients and medical practitioners with better treatment options and to tackle the accelerating mental health epidemic.

MMA operates as a nexus between medical practitioners, academics, governments, regulatory bodies, philanthropists, patients and other stakeholders in Australia's mental health system. MMA is building the ecosystem for these treatments through educating interested stakeholders, the production of a major International Summit in Melbourne, as soon as the current pandemic is over, the development of the first accredited practitioner training course for these therapies in the Southern Hemisphere, developing an Asia-Pacific Centre of Excellence, providing funding for relevant clinical trials, developing an appropriate legal and ethical structure for discussion with regulators and producing reliable sources of pharmaceutical grade medicines in Australia.

MMA's focus is wholly clinical. MMA does not advocate for recreational use of psychedelics, MDMA, or any other prohibited substances, nor do we advocate for any changes to the law with respect to recreational use.

The MMA Board comprises:



Peter Hunt AMInvestment Banker & Engaged Philanthropist
Chair



Tania de Jong AM

Social Entrepreneur, Business Woman, Global

Speaker and Soprano

Deputy Chair



Admiral Chris Barrie AC

Past Chair of the Australian Defence Force (1998-2002)

and Strategic Leadership Consultant

Director



Professor Jane Burns
Chair, Centre for Mental Health at Swinburne
University and Health Strategist
Director



Dr Simon Longstaff AOExecutive Director of the Ethics Centre

Director



Monojit (Mono) Ray
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Partner
Director



Hon Andrew Robb AO

Australia's Minister for Trade and Investment
(2013-2016). Chair of AsiaLink
Director



Nicholas Smedley
Investment Banker & Business Entrepreneur.
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Director



Dr Eli KotlerPsychiatrist and Director of Medicine at Malvern

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Ambassadors

Dr Rick Doblin (USA) BSc, PhD, Founder and Executive Director of the Multidisciplinary Association for Psychedelic Studies (MAPS)

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Dr Ted Cassidy Psychiatrist and Co-Founder of TMS Australia

Dr Mark Cross Psychiatrist, SANE Board Director

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Young leaders

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Dr Jesse Schnall MBBS (HONS), Medical Doctor and co-author of Medicinal Use of Psilocybin:
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