



The Commissioners  
Australian Productivity Commission

20 January 2020

Dear Commissioners

**Submission to the Mental Health Inquiry**

**Lack of Effective Treatment Options for Major Mental Illnesses and the Need for Innovation**

One of the central tenets of the Productivity Commission's Interim Report is summed up in the following quote from that report:

*"In any year, approximately one in five Australians experiences mental ill-health. Whilst most people manage their health themselves, many who do seek treatment are not receiving the level of care necessary." (page 2)*

Whilst the one in five ratio represents an average across the Australian population, the position is significantly worst for distinct groups such as Australian Defence Force Veterans, First Responders and Indigenous people.

	<b>General Population*</b>	<b>ADF Veterans</b>
<b>Criteria (over 12-month period) for:</b>	%	%
<b>Mental Disorders</b>	20	46
<b>PTSD</b>	6.4	17.7
<b>Depression Episodes</b>	4.1	11.2
<b>Alcohol Disorder</b>	4.3	12.9
<b>Suicidal Ideation (Plans or Attempts)</b>	2.2	21.7
<b>Co-Morbidity</b>	8.5	55.2

\*above 16 years of age  
Veterans Information- Mental Health Prevalence: Department of Veterans Affairs 2018  
General Population- 2007 National Survey of Mental Health & Wellbeing (ABS)



10% of **First Responders** are also estimated to have PTSD with 1 in 3 suffering from high psychological distress. First Responders are estimated to have suicidal thoughts at two times the rate of adults in the general population and one First Responder takes his or her own life every 6 weeks. ( Source; Beyond Blue)

In our view the big gap in the Interim Report is the lack of focus on:

1. **the inadequacy of current treatment options** that are available to medical practitioners and their patients in Australia to deal with major mental illnesses such as Depression and Post Traumatic Stress Disorder (“PTSD”); and
2. **the lack of treatment innovation** given that current treatment options in relation to these mental illnesses haven’t improved much for decades.

As a result, despite all the massive investment by Federal and State Governments into the health sector and the efforts of our medical practitioners, treatment outcomes also haven’t improved.

The mental health statistics in Australia are some of the worst in the World. Given that we are one of the wealthiest countries in the World with one of the best health systems our poor statistics must be due, at least in part, to a lack of treatment innovation. Unless we face up to this and focus more resources on innovation with a changed mindset, we face the risk that Government initiatives flowing from your final report will only lead (at best) to incremental improvements.

### **Mind Medicine Australia**

Mind Medicine Australia is an Australian registered charity (with DGR-1 status) seeking to broaden the treatment paradigm available to Medical Practitioners and their patients in Australia for mental illness and to improve treatment effectiveness. We are seeking to achieve this through the introduction of safe, accessible and effective Medicine-Assisted Psychotherapy for major mental illnesses in this Country.

Our primary focus is on the use of medicinal psilocybin (for **Depression**) and medicinal MDMA (for **Post-Traumatic Stress Disorder (PTSD)**) because of the strong overseas clinical results that support these forms of psychotherapy and the fact that both forms of therapy have been



granted Breakthrough Therapy Designation by The Food and Drug Administration (“FDA”) in the United States. This designation highlights the FDA’s anticipation that these therapies may offer substantial advantages over current treatments.

Medicine-Assisted psychotherapies may also be available in the future to help people with other mental illnesses such as **Anorexia, Substance Abuse, Dementia** and **Obsessive-Compulsive Disorder** but the clinical evidence supporting treatment for these conditions is at an earlier stage.

MMA’s Board, Management team, Ambassadors, and Advisory Panel members consist of leading practitioners in the applied treatment of mental illness, medical research into the use of medicine-assisted psychotherapies, health strategies, ethics, law, business and other relevant fields from both Australia and overseas. These include:

- ***Applied treatment of Mental Illness: Professor David Castle*** (Professor of Psychiatry, University of Melbourne and St Vincent’s Hospital; **Dr Ben Sessa** (adult and adolescent psychiatrist based in the UK, lead of MDMA – assisted psychotherapy medical research team); **Dr Nigel Strauss** (practicing Melbourne based psychiatrist); **Professor David Forbes** (Director, Phoenix Australia Centre for Post-traumatic Mental Health) and **Professor John Tiller** (Professor Emeritus of Psychiatry, University of Melbourne)
- ***Medical Research into the use of Medicine-Assisted Psychotherapies: Professor David Nutt*** (Head of Neuropsychopharmacology at Imperial College London and lead on multiple clinical research trials); **Dr Rick Doblin** (Founder of the Multidisciplinary Association of Psychedelic Studies in the US which is sponsoring the FDA-approved Phase 3 Trials for MDMA-assisted psychotherapy for PTSD); **Professor Roland Griffiths** (Research psychiatrist at the John Hopkins University School of Medicine, and lead on multiple clinical psilocybin research trials); **Professor Jayashri Kulkarni** (Professor of Psychiatry at The Alfred and Monash University); **Dr Robin Carhart-Harris** (Director of the Centre for Psychedelic Research at Imperial College London), **Dr James Rucker** (Consultant psychiatrist at Kings College London) and **Dr Martin Williams** (pharmacologist and President of Psychedelic Research In Science and Medicine)



- **Health Strategy: Professor Jane Burns** (Chair of the Centre for Mental Health at Swinburne University)
- **Ethics: Dr Simon Longstaff AO** (Executive Director of the Ethics Centre and one of Australia's leading ethics practitioners).
- **Therapist Training: Professor Janis Phelps** (Founder and Director of the California Institute of Integral Studies Centre for Psychedelic Therapies and Research); **Dr Rosalind Watts** (Lead of the Imperial College, London Psilocybin and Depression Study) and **Sean O'Carroll** (Psychotherapist and psychotherapy course designer based in Melbourne).
- **Business, Government and the Social Sector: Peter Hunt AM** (Investment Banker, Engaged Philanthropist, co-founder of MMA), **Tania de Jong AM** (Founder of Creative Universe, Creativity Australia, Creative Innovation Global, co-founder of MMA), **The Honorable Andrew Robb AO** (Australia's former Minister for Trade, Investment and Tourism) and **Admiral Chris Barrie AC** (former head of the Australian Armed Forces)

For further information, please see [www.mindmedicineaustralia.org](http://www.mindmedicineaustralia.org)

### The Inadequacy of Current Treatment Options

Only an estimated 40% to 60% of people with **Depression** in the general Australian population respond to current **Chemical Therapies** or **Psychotherapies**, with the majority experiencing ongoing symptoms and between 50% to 80% relapsing after treatments stop. In addition, psychotherapy can lead to dependence and chemical therapies are usually associated with considerable adverse side-effects and withdrawal risks.

**Anti-depressants** are often stated to help up to 60% of depression sufferers. However, the placebo effect could be as high as 50% of this figure and the chemicals used can often have nasty side effects (diarrhoea, weight gain, mood swings, anxiety and loss of libido - to name a few). In addition, actual remission figures from anti-depressant usage (including people who would have got well anyway and the significant placebo effect) are only about 35%.

Reversion rates when people come off their anti-depressants are as high as 80%. Withdrawal symptoms can often be nasty. Despite the massive increased use of anti-depressants in Australia (now 1 in 8



Australians and 1 in 4 older Australians - up by 95% over the last 15 years) the precise way that anti-depressants impact the brain remains unclear.

**PTSD** is even harder to treat and is often co-morbid with other disorders and illnesses such as anxiety, depression, obesity, hypertension and immune dysfunction. It's estimated that current pharmacotherapy treatments achieve relief from symptoms in only about 20-30% of sufferers. For psychotherapy, PTSD sufferers exhibit low retention rates, with only around 30% completing treatment. Only about 50% of sufferers show some response to existing treatments and remission rates are much lower.

Without significant treatment innovation the incidence of mental illness across Australia is, in our view, actually likely to get worse as technology (and particularly automation and robotics) increases employment uncertainty, existing jobs are made redundant and there is constant pressure on people to retrain and add new skills. There is also evidence that other aspects of modern life including increasing reliance on social media and perceived risks from climate change are exacerbating this situation. In addition, natural disasters including our current bushfire crisis, are likely to significantly increase the incidence of PTSD and other mental illnesses.

Simply doing more of the same or making only incremental changes to the current system is not going to solve our mental health problem and relieve the suffering of so many Australians. To create positive change, we need to be innovative and to broaden the tools available to our medical practitioners and qualified therapists working in this area.

### **The Effectiveness and Safety of Medicine-Assisted Therapies**

There has been a massive increase in the research of Medicine-Assisted Therapies, particularly using psilocybin for depression and MDMA for PTSD, over the last 15 years in clinical trials at major clinical centres in the United States and Europe with high remission rates being achieved. 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 Autònoma de Barcelona.



Large FDA approved multi-site Phase 2b (psilocybin) and Phase 3 (MDMA) trials have already commenced overseas and have been granted Breakthrough Therapy Designation by the FDA to fast-track the approval process. In addition, several countries such as Israel, Switzerland, Canada and the United States (pending) are using Compassionate or Expanded Access Schemes (similar to our Special Access Scheme) to expedite access to these therapies for patients in need who aren't benefiting from current treatments.

Most effective treatments for mental illness show effect sizes (using Cohen's d values) in the order of  $d = 0.5$  (where 0.2 is small, 0.5 is medium and 0.8 represents a 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  $d=1.17 - 1.24$  and psilocybin-assisted psychotherapy for Depression had even higher effect sizes of  $d = 2.0 - 3.1$ .

Remarkably, these results are being achieved with only 2-3 dosed sessions in contrast to conventional treatments which usually require daily medications and/or weekly psychotherapy over extended timeframes.

Medicinal psilocybin and medicinal MDMA have a strong safety record when used in a medically controlled environment and the medicines themselves are non-addictive. Importantly all treatments occur in medically controlled environments and patients are not allowed to take these medicines home.

More information about the effectiveness and safety of Psilocybin-Assisted Therapy and MDMA-Assisted Therapy can be found on our website ([www.mindmedicineaustralia.org](http://www.mindmedicineaustralia.org)) and in the attached presentation.



## **Proposals to Fast-Track Treatment Innovation**

We believe that the Productivity Commission should explicitly recognise the lack of treatment innovation in its Final Report and make at least the following two recommendations to Government:

### **Recommendation 1 - Establishment of a Steering Group to Advise the Government on the Application of Medicine-Assisted Psychotherapy**

Under this proposal the Government would establish a Steering Committee with representation from Government, leading Australian clinicians and other relevant parties. The Steering Group would seek advice from leading researchers and clinicians from around the World with specific expertise in the application and safety of Medicine-Assisted Psychotherapies.

The task of the Steering Committee would be to make recommendations to Government about the benefits and safety of Medicine-Assisted Psychotherapies, cost effectiveness, treatment protocols, required medical training, preferred legal implementation framework and rollout strategies.

### **Recommendation 2 - Support For The Establishment of a Centre of Excellence in Medicine-Assisted Psychotherapies**

In order to maximise and extend our understanding of Medicine-Assisted Psychotherapies a Centre of Excellence would be established with an affiliation to a major Australian University. The Centre of Excellence would focus on, among other things:

- (1) Research into the practical use of Medicine-Assisted Psychotherapies in areas such as depression, PTSD, early stage dementia, anorexia nervosa, chronic pain, the treatment of addiction and potentially bipolar disorder and related diseases including mechanistic studies;
- (2) The development of local trials and participation in global multi-site trials;



- (3) The development of an agricultural base in Australia for the supply of medicinal psilocybin as a natural medicine for medical purposes;
- (4) The development of secure medicinal MDMA manufacturing capabilities and/or sources of supply and manufacturing expertise for the supply of GMP certified pharmaceutical grade psilocybin and other psychedelic medicines to domestic and international markets; and
- (5) The education of health sector professionals and medical schools around Australia.

We envisage that the Centre of Excellence would be funded jointly by Philanthropists and Governments with in-kind support from the affiliated University.

This Centre of Excellence would be one of the first in the World (the other two being at Imperial College London and Johns Hopkins in the United States) and would be regionally focus on Australia and the Asia Pacific Region.

### **Concluding Remarks**

We believe that the lack of treatment innovation in Australia is a critical part of any assessment of how the Government can improve mental health outcomes for Australians. Medicine-Assisted Psychotherapies would be able to help an enormous number of people if the high remission rates currently being achieved in the overseas clinical trials are able to be maintained as these treatments are rolled out. High remission rates would also release an enormous amount of resources to help and support Australians with more intractable mental illnesses and to invest in prevention.





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

We are, of course, available to answer any questions that you may have and we would be delighted to arrange for local and overseas experts in this field to be available to you.

Yours faithfully,

Peter Hunt AM  
Chair

Tania de Jong AM  
Executive Director

Attached: Mind Medicine Presentation on Medicine-Assisted  
Psychotherapy