MIND MEDICINE AUSTRALIA

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Use of Psychedelic Therapies for Treatment Resistant Patients Again Rejected by Government, Despite Strong Supporting Safety and Efficacy Data, Massive Public Support and Australia's Worsening Mental Health Crisis

Mind Medicine Australia (**MMA**) will prepare a detailed submission to the Therapeutic Goods Administration (**TGA**) following the Delegate's "disappointing" decision not to include the limited medical use of MDMA and Psilocybin therapies in Schedule 8 of the Poison's Standard, despite strongly supporting safety and efficacy results from overseas trials and strong controls. The Delegate's Interim Decision can be found here - https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/notice-interim-decisions-proposed-amendments-poisons-standard-acms-38-accs-34-joint-acms-accs-31-june-2022.

The rescheduling of these medicines, on the basis proposed by Mind Medicine Australia, would have allowed psychiatrists to apply to the TGA and the relevant State or Territory Government to use these therapies for specific patients with treatment resistant mental illnesses on a highly controlled basis.

The arguments used by the Delegate were all comprehensively dealt with in our rescheduling applications which can be found here.

There were **6,650** public submissions lodged in relation to our psilocybin application and **6,505** public submissions lodged in relation to out MDMA application (representing more than a 10 fold increase in the number of public submissions lodged in response to our previous applications made in July 2020 which were overwhelmingly in favour of rescheduling). A full analysis of the public submissions will be announced as and when the TGA gives us access to them.

During the next stage of the process the public have the opportunity of giving the TGA their views on the Interim Decision with the consulting period ending on 24th November 2022. The Final Decision is then expected to be made by the Delegate sometime in December 2022.

MMA Executive Chairman **Peter Hunt AM** said that he was confident that health public servants and Health Ministers around Australia would eventually agree to make MDMA and Psilocybin controlled medicines under Schedule 8 of the Poisons Standard but delay would lead to unnecessary suicides and unbearable suffering.

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Mr Hunt also stated how saddened he was by the interim decision: *"We believe that we had convincingly addressed all of the concerns raised by the TGA's Delegate when it rejected our first rescheduling applications in December 2021. Governments around Australia keep reiterating that the patient should be at the centre of the mental health system. But these same governments keep refusing to allow psychiatrists and their patients to use these therapies in highly controlled environments, despite the high levels of safety and efficacy being achieved in overseas trials."*

Mr Hunt noted that the Delegate had acknowledged the emerging evidence of efficacy of Psilocybin in treating depression, with demonstrated low risk of adverse events with short-term use in controlled settings. The Delegate also found that there was possible benefit in treating other mental health conditions.

The Delegate also acknowledged the emerging evidence that MDMA-assisted psychotherapy may have therapeutic benefits in the treatment of Post-Traumatic Stress Disorder (PTSD) in closely supervised clinical settings with intensive professional support.

Mr Hunt explained that: "*Both medicines are at a more advanced stage of research than cannabis was when it was rescheduled by the TGA to Schedule 8."*

"We acknowledge and agree with the Delegate's view that ongoing research is required but that's the same with almost all medicines (whether registered or unregistered), and even for medicines that have been used for decades such as antidepressants. However, the priority should be to save lives now with medicines that many leading health sector experts believe are safe to administer in a secure medical environment by properly qualified clinicians."

"*But the Delegate's statement that the regulation of access to these substances for therapeutic use abroad is consistent with the controls in Australia associated with Schedule 9 of the Poisons Standard and that the Special Access Scheme in Australia allows patient access to Schedule 9 substances is highly misleading. The application of the Special Access Scheme to the medical use of these substances in this country is unworkable (in contrast to similar schemes that operate in countries like Canada, the United States, Switzerland and Israel). There are no States or Territories in Australia with permit systems in place which would enable psychiatrists with approval from the TGA under the Special Access Scheme (and a number of TGA approvals have already been given) to legally administer these medicines to their patients in controlled settings."*

MMA's rescheduling applications were overwhelmingly supported by thousands of Australians and recognised experts in this field, including Australia's leading psychopharmacologist **Professor Arthur Christopoulos** of Monash University and Drug Science in the UK Chaired by world-leading neuropsychopharmacologist **Professor David Nutt** who heads up the Centre for Psychedelic Research at Imperial College London.

MMA's conservative rescheduling applications were based on these medicines ***only*** being accessed by a specifically trained psychiatrist on a case-by-case basis

under the TGA's Special Access Scheme; two other psychiatrists confirming the patient diagnosis and treatment plan; the State or Territory Government where the treatment would take place issuing a permit on a patient specific basis; the medicinal session only being conducted in a medically controlled environment and two qualified therapists being with the patient at all times. Importantly (and unlike most psychiatric medicines), the patient would never be allowed to take the medicines home.

The TGA's Special Access Scheme ***only*** applies to treatment resistant 'at-risk' patients where, by definition, no other treatments are working. Without effective treatments these people experience enormous – and at times unbearable - suffering. For some people unbearable suffering can lead to suicidal ideation and in some cases actual suicide.

Vanessa Bortolin said: *"My daughter, Zara, at 11, lost her papa to suicide last year. He tried everything the current mental health system both private and public have to offer, including TCM therapy, 16 different antidepressants from all major classes of drugs, and a staggering 94 Electroconvulsive Therapy treatments over 3 years. I cared for him full time and I left no stone unturned in trying to find him the best psychiatric treatment to treat him.*

I'm convinced psychedelic treatments could have helped my beautiful loving husband, Franco and that he would still be here if he had been able to access them."

Dr Brian Walker MLC, who is a member of the Legislative Council of the Western Australia Parliament and a medical practitioner by profession, said: "*We urgently need these treatments to be available through the medical system on the conservative basis suggested by Mind Medicine Australia. My son Kayvan Walker, who was also a medical practitioner, suffered from mental illness and committed suicide in March this year. I am convinced that had these therapies been available in Australia through our medical system my son would still be alive today. It is my hope that no one else experiences the unnecessary pain I have felt because of short-sighted fears of psychedelic medicines."*

The medical use of both MDMA (which is currently in Phase 3 trials) and Psilocybin (which is about to go into Phase 3 trials) has been shown to be safe in clinical environments, with minimal adverse events and with large positive effect sizes.

In the past 20 years about **1800 people** have gone through MDMA assisted therapy trials with a further estimated **4000 people** going through clinical trials up to the mid-1980s, when the War on Drugs (which was targeted at recreational use) had the unfortunate side effect of also prohibiting medical use. In the case of Psilocybin, the comparable clinical trial patient numbers are **1,131** in the last 20 years with a further **1,960** before the War on Drugs.

Medical use outside of clinical trials before prohibition massively increases these patient numbers. Data sets and safety data can also be drawn from recreational use studies. A lot more is known about the safety and effectiveness of these substances than for many other unregistered medicines accessible under the Special Access Scheme which are in Schedule 8 of the Poisons Standard.

The effectiveness of MDMA when used as part of therapy for treatment resistant patients is highlighted by the recent MAPS Phase 3 trial. 67% of patients in the MDMA group who were suffering with severe, chronic PTSD for an average duration of 14 years no longer qualified for a PTSD diagnosis at the end of the trial. A further 21% of patients experienced a positive response. Study participants included patients with PTSD caused by combat-related events, accidents, abuse and sexual harm. Adverse events were markedly greater in the placebo group highlighting the relative, as well as absolute, safety of this therapy.

In recent Phase 2 trials using psilocybin assisted therapy for Depression, sponsored by Imperial College London and by Compass Pathways, remission rates after only one to two dosing session were twice as high in the psilocybin group compared to the placebo group.

In Schedule 8 of the Poisons Standards there are medicines already listed that are much more dangerous than Psilocybin and MDMA. However, in contrast to the restrictions which are contained in our rescheduling applications, patients are allowed to take these medicines home. Examples include highly addictive opiates such as fentanyl and oxycodone and stimulants such as dexamphetamine and methylphenidate.

"*We do find it deeply disappointing that there is so much resistance within governments around Australia to the medical use of pharmaceutical grade MDMA and Psilocybin by trained professionals in medically controlled environments, despite the strong evidence supporting their use as unregistered medicines on the limited basis proposed. The controls proposed are much tighter than the controls in place for many current Schedule 8 medicines, combined with the strong safety data associated with these substances",* said Mr Hunt.

According to the Executive Director of MMA, **Tania de Jong AM,** the TGA's decision making process lacks transparency: "*The identity of the Delegate is kept secret and only known to key people within government. Half the members of the key advisory body (the Advisory Committee on Medicines Scheduling) are appointed by the States and Territories, and these are all public servants and therefore subject to political direction. However, the opaqueness of the process means that we are never told how they each vote and the individual rationale for that vote. We therefore can't determine the extent to which individual decisions are based on science, political concerns or simply prejudice, stigma and bias. The enabling legislation provides that applicants can't appeal the Delegate's decision. This means that there is minimal public accountability and transparency in the system, despite its impact on so many suffering people. It is urgent that we focus on data and science and the immense avoidable suffering in this nation. Why should Australians have to go overseas to legally access these safe and effective treatments?"*

The Delegate's arguments in its Interim Decision and the summary responses of Mind Medicine Australia are set out in Attachment 1 to this Media Release. The failure of the current mental health system to provide effective treatments for many sufferers is summarised in Attachment 2.

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POSTSCRIPT:

On Thursday 27 October 22, the TGA released a breakdown of the survey responses received during the public submissions period that closed 27 May 2022. They are overwhelmingly in favour of rescheduling.

We lodged our first applications to reschedule the medical use of psilocybin and MDMA as part of therapy in July 2020. During the public consultation period there were:

1. For **Psilocybin**; 575 submissions lodged of which **96% were supportive and a further 2% gave qualified support** (e.g. they wanted additional controls) giving a total support level of 98%.
2. For **MDMA**; 478 submissions were lodged of which **95% were supportive and a further 3% gave qualified support** giving a total support level of 98%.

With our second rescheduling application lodged in **March 2022** the numbers have **increased more than 10 - fold**:

1. For **Psilocybin**; **6,650 submissions were lodged of which 98.2% were in favour and a further 1.2% gave qualified support giving a total support level of 99.4%**.
2. For **MDMA; 6,505 submissions were lodged of which 95.2% were in favour and a further 4.1% gave qualified support giving a total support level of 99.3%.**

Like last time we believe that many the supporting submissions will have come from Health practitioners.

We understand this is the most submissions ever lodged in relation to the proposed rescheduling of a medicine. It is also significantly higher than the number of submissions lodged for the successful medical cannabis rescheduling.

We believe this level of support can be attributed to the enormous levels of mental illness that we have in Australia, the positive trial results being achieved for these therapies in overseas trials and the failure of current treatments (mainly pharmaceuticals and unaided psychotherapies) to help so many sufferers.

The raw numbers can be found on the TGA website here - https://consultations.tga.gov.au/tga/proposed_admendments_june-2022/user_uploads/all-substance-tally-final.pdf

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Attachment 1 – Key Arguments Used by the Delegate in the Interim Report and our Summary Responses (more detailed information appears in our Rescheduling Applications).

1. **There was insufficient evidence that MDMA or Psilocybin when used as part of psychotherapy has an established therapeutic value as required by the Schedule 8 policy guidelines**

As detailed in the main release there is actually much more evidence to support the established therapeutic value of MDMA and psilocybin when used as part of psychotherapy then there was for the medical use of **cannabis** when it was rescheduled to Schedule 8 of the Poisons Standard in 2016.

PTSD and Depression are both notoriously hard to treat with current treatments and the failure rate is unacceptably high. Current treatments (which primarily consist of pharmaceuticals and/or psychotherapy) are only estimated to achieve remission rates in less than 10% of PTSD patients and only one-third of Depression patients. In contrast remission rates in the first MAPS Phase 3 trial using MDMA assisted therapy were 67% which compared to 52% after the Phase 2 trials (increasing to 68% after 12 months). Remission rates in the Psilocybin Phase 2 trials were much higher than in the placebo or antidepressant groups. In all the Psilocybin and MDMA trials adverse events have been minor and easily managed.

The views in our rescheduling applications that the established therapeutic value requirement has been satisfied were supported by leading experts in the field including Australia's leading psychopharmacologist **Professor Arthur Christopoulos** of Monash University and Drug Science in the UK Chaired by World leading neuropsychopharmacologist **Professor David Nutt** who heads up the Centre for Psychedelic Research at Imperial College London.

2. **Risks and Benefits**

This section of the Delegates reasoning was confusing because all the risks mentioned have been managed well in the trials. Furthermore, the Committee advising the Delegate acknowledged that with Psilocybin the trials indicated "low risk of adverse events with short term use in controlled settings". The safety data from the MDMA trials is even more compelling. The risks associated with long term use which were mentioned by the Delegate don't apply to these therapies because patients only take the medicines two to three times in a controlled setting. There is no evidence of addiction.

3. **The Optimal Dose has not been established**

This argument ignores the Phase 3 and Phase 2 trial results for MDMA and the Phase 2 trial results for Psilocybin where the dosage levels used led to positive outcomes with minimal adverse side effects.

4. **Risk of Dependence**

There is no supporting evidence from any of the trials to date that the medical use of MDMA in the manner proposed can lead to dependence. With Psilocybin the Advisory Committee acknowledge that there is "low risk of addiction". This low risk should be compared against the high risks of opioid dependence associated with a number of current pharmaceutical medications, many of which are in Schedule 8 of the Poisons Standard.

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5. **<u>There are significant benefits to waiting for more clinical trial results</u>**

Benefits to whom? The current treatments paradigm is failing many people suffering from mental illness. This can cause unbearable suffering. The trials to date have shown very positive results with minimal adverse events. These medicines were extensively used before prohibition. Unbearable suffering can lead to people self-medicating or taking their own lives. Who actually benefits from delaying access to these treatments?

6. **<u>It will take time to develop a Training Regime for Psychiatrists and Therapists</u>**

There has been no attempt by the Delegate, government representatives or peak bodies to investigate the quality of Mind Medicine Australia's training programme, our extensive use of recognised World experts in this field and the strong testimonials received from participating psychiatrists, doctors and psychologists. We have already trained 240 health practitioners including psychiatrists, psychologists, general practitioners, specialist physicians, counsellors, mental health nurses, social workers and psychotherapists. There seems to be no urgency or even planning in this area by the Delegate, the Advisory Committee, or relevant peak bodies despite the tragic and worsening mental health statistics in Australia and the failure of current treatments for so many people.

7. **<u>The fact the States and Territories don't have established mechanisms to give effect to the controls proposed in our applications</u>**

The obvious response to this argument is for State and Territory Governments to show some urgency by establishing the required review mechanisms. This is exactly what the Provincial Government of Alberta in Canada and the State Government of Oregon in the United States have done. All State and Territory governments in Australia say that they have a major focus on reducing the incidence of mental illness and yet don't appear to be doing any tangible forward planning in this area.

8. **<u>There is a Risk of Diversion for Misuse in the Supply Chain</u>**

In the Interim Decision the Delegate recognised that "*the risk of diversion of the substances is low in a controlled setting"* but then went on to say that "*yet I remain of the view that there are significant risks of their diversion at other points of the supply chain".* This is difficult to understand given that there are far more dangerous substances in Schedule 8 of the Poisons Standard and these more dangerous substances use comparable supply chains. MDMA and Psilocybin are already readily available in Australia on the Black Market (and in the case of Psilocybin simply by picking certain mushrooms that grow in nature). The Australia Institute in Canberra (one of Australia's most influential think tanks) made it clear in its submission to the TGA that diversion risk was low.

The Delegate's argument that the supply chain would "*bypass the nationally implemented real-time prescription monitoring system, hence limiting oversight"* ignores the fact that permits would have to be issued for supply of these medicines on a case by case basis, an authorised pharmacist will always have to be involved and that the obvious solution to this concern is to make the supply subject to the real-time monitoring system if this is required. If we start with the needs of the patient these types of issues are all manageable.

9. **<u>The current regulation of these substances for therapeutic use abroad is consistent with the controls associated with Schedule 9 of the Poisons Standard in Australia.</u>**

This ignores the dual Federal/State nature of Australia's health system where the Special Access Scheme in Australia is unworkable for these medicines whilst they remain in Schedule 9. Whist the TGA has already given multiple approvals for the use of these substances as part of therapy under its Special Access Scheme, there are no permit access procedures available for these medicines in any State or Territory of Australia whilst they remain in Schedule 9. This leads to the perverse outcome that a psychiatrist with TGA approval who used this medicinal therapy for a treatment resistant patient would be criminally liable under existing State/Territory recreational drug laws if the psychiatrist proceeded to conduct the treatment.

Why is it that a number of overseas countries like Canada, the United States, Israel and Switzerland can develop a workable regulatory system but Australia cannot?

10. **<u>Scheduling is not an appropriate mechanism for establishing clinical governance and in the case of Psilocybin rescheduling would bypass the processes for clinical trials.</u>**

This is a remarkable statement in the context of a lack of action on the part of governments and peak bodies to develop "appropriate mechanisms", the large number of trials completed to date which have established successful protocols, the slow nature of further trials which normally take 3-4 years, the worsening mental health crisis in Australia and the failure of current treatments to help a large number of sufferers (in some cases leading to suicide). Where is the sense of urgency or the indication of any plan to address the appalling lack of effective treatment options in Australia for so many people?

11. **<u>Reliance on the Views of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and the Australian Psychological Society (APS)</u>**

Both RANZCP and APS are membership-based organisations and neither represent the interests of patients suffering from mental illnesses. RANZCP has been notoriously slow in supporting new treatments, such as the use of medicinal cannabis and transcranial magnetic stimulation. Thousands of psychiatrists and psychologists support rescheduling and both RANZCP and APS represent members with a range of diverse views. A large number of their members consistently report to us and others that they urgently need access to treatments that will get more of their patients well and out of the system.

The psychiatrists who wrote the RANZCP clinical memorandum, referred to by the Delegate, are not named in the RANZCP memorandum, there are no conflict declarations and there is no indication of whether the document was peer reviewed (and if so by whom) and put out for discussion amongst the RANZCP members. There is also no indication by RANZCP that they have any urgency in developing the guidelines that they refer to, despite the failure of current treatments for so many people.

Most unregistered medicines in Schedule 8 of the Poisons Standard haven't completed Phase 3 trials. Had they successfully completed Phase 3 trials they would be likely to have been registered on the Australian Register of Therapeutic Goods. This is exactly why the TGA has a Special Access Scheme to support the use of unregistered medicines.

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Attachment 2 - Failure of the Current Mental Health System to Provide Effective Treatments for Many Sufferers

The levels of mental illness in Australia, already at very high levels, have become much worse because of the Covid pandemic. At the same time, the current treatment paradigm remains ineffective for many sufferers and, in the case of pharmaceuticals, can lead to adverse side effects, abuse and long-term dependence.

Before the Covid pandemic began in early 2020 it was estimated that I in 5 Australians suffered from mental illness, with 1 in 8 being on antidepressants (including 1 in 4 older people). For Australian Defence Force veterans and First Responders the incidence of mental illness and suicide is much worse than for the general population (with nearly 1 in 2 veterans having a mental disorder and 10% of First Responders and 1 in 3 Veterans suffering from severe psychological distress). Veterans have suicidal ideation at 10 times the rate of the general population and a First Responder commits suicide every 6 weeks.

These terrible statistics are made worse by the failure of the mental health system to provide effective treatments for so many people, with no substantive improvement in treatment outcomes and minimal treatment innovation in the last 50 years. Specifically, only about 35% of Depression sufferers experience remission from current treatments and the primary treatment (an antidepressant) has low effect size and can cause nasty side effects, long term dependence and challenging withdrawal symptoms. With PTSD remission rates are estimated to be less than 10%.

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