MIND MEDICINE AUSTRALIA

Ms Caroline Felstead
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Medicines and Poisons Regulation
Department of Health and Human Services
Victorian Government
50 Lonsdale Street,
Melbourne, Victoria

26 August 2022

Dear Ms Felstead

Consultation Document – Proposal to Restrict Permits for Schedule 9 Poisons for Human Therapeutic Use under the Drugs, Poisons and Controlled Substances Regulations 2017 to Clinical Trials Approved by a Human Research Ethics Committee

I am writing to you in response to your consultation document emailed to me on 15th August 2022 and specifically in relation to the use for medical purposes of two substances that are currently in Schedule 9 of the Poisons Standard, namely **pharmaceutical grade MDMA** and **pharmaceutical grade Psilocybin.**

Our response is confined to psychiatrists prescribing these substances as part of psychotherapy in medically controlled environments for patients 'at-risk' who are suffering from **treatment resistant post-traumatic stress disorder (PTSD) (in the case of MDMA**) or **treatment resistant depression (in the case of Psilocybin).** These are serious and debilitating illnesses. There is also a third category of illness which we discuss where a single dose of **Psilocybin** is used to give relief to a patient suffering from **depression and anxiety associated with a terminal diagnosis**. In each case we are dealing with situations where the patient is suffering and no currently used medical or therapeutic intervention is working for that patient.

I would ask you and your colleagues to review this letter in the context of:

- ***the terrible suffering of people in Victoria with treatment resistant PTSD, treatment resistant depression and/or depression and anxiety associated with a terminal diagnosis; and***
- ***the failure of the current health system to provide these people with treatments that relieve their suffering.***

As you are aware the TGA has given a number of approvals to psychiatrists to use MDMA and Psilocybin assisted psychotherapy treatments pursuant to its Special Access Scheme. This accords with Australia's obligations under ***the UN Convention on Psychotropic Substances*** (discussed in Section 4 below). The TGA's Special Access Scheme enables medical practitioners with approval from the TGA on a case-by-case basis to use unregistered medicines for patients suffering from treatment resistant illnesses, including medicines in Schedule 9 of the Poisons Standard if any necessary State or Territory approvals are also obtained.

In our view it would be completely inappropriate and cruel for the Victorian Government to proceed with the proposed regulatory change for seven key reasons:

1. The proposed change would lead to the continuation of unbearable suffering for many people with treatment resistant PTSD and/or treatment resistant depression, who by definition are not benefiting from current treatments (these treatment resistant mental illnesses can, for some suffering patients, lead to suicidal ideation and, in some cases, actual suicide).
2. The proposed change would be unconscionable in the context of an appeal process already commenced against the refusal of the Department of Health and Human Services (**DoH**) to issue a psychiatrist with a permit to provide MDMA assisted therapy to an 'at-risk' patient with treatment resistant PTSD.
3. The proposed change would be inconsistent with the progressive, innovative and pragmatic approach of the Victorian Government to improving mental health outcomes.
4. The proposed change would be inconsistent with the international conventions that Australia has committed to, and which Victoria should therefore observe.
5. The proposed change would be inconsistent with the National Scheduling Policy Framework for Medicines and Poisons.
6. Restricting the availability of Schedule 9 permits for the medical use of MDMA and Psilocybin as part of psychotherapy to ethics-approved clinical trials is not a viable solution for a treatment resistant 'at-risk' patient.
7. Removing the availability of Schedule 9 permits for the medical use of MDMA and Psilocybin would lead to perverse, and indeed heartless, results.

1. The Proposed Change Would Lead to the Continuation of Unbearable Suffering for Patients with Serious Treatment Resistant PTSD and/or Treatment Resistant Depression who are not, by Definition, Benefitting from Current Treatments

1.1 Victoria's Mental Health System is Failing Many People

Australia has some of the worst mental health statistics in the World and levels of mental illness in this country are getting worse. This is particularly the case in Victoria because of the unprecedented length of the lockdowns experienced in this State. Even before the pandemic 1 in 5 Australian adults were estimated to have a chronic mental illness and 1 in 8 Australians were on anti-depressants (including 1 in 4 older people). At that time Australia had the second worst mental illness statistics of all OECD nations (Iceland being the worst). Whilst these figures are terrible (and continue to deteriorate), they are much worse for members of key groups such as Australian Defence Force Veterans (where the 1 in 5 across the population becomes 1 in 2 and suicidal ideation increases 10-fold) and First Responders (where the 1 in 5 across the population becomes 1 in 3 and suicidal ideation is twice the rate of adults in the general population).

One of the key problems with our current mental health system is lack of treatment efficacy for many people. There have been no major effective innovations in the mental health sector now for over 50 years and treatment outcomes over the last 50 years haven't improved. In the case of depression only 35% of sufferers are estimated to experience remission with current treatments (pharmacotherapy and/or psychotherapy) and relapse rates are as high as 80% when treatments stop. In the case of PTSD, remission rates are estimated to be less than 10%. Even where pharmaceuticals provide relief, they can also give the patient nasty side effects and lead to dependency making withdrawal extremely difficult.

It is true that response rates are higher, perhaps another 30% for depression and another 20% for PTSD amongst the general population but much lower than this for ADF Veterans and First Responders because of their higher level of co-morbidities. However, this still leaves a large percentage of sufferers who are classified as "treatment resistant". In other words, current treatments aren't working for them. This group understandably has a much higher level of suicidal ideation and suicide than patients who get some benefit from existing treatments.

It is within a mental health system that is failing so many people that access to MDMA-assisted therapy for treatment resistant PTSD and Psilocybin-assisted therapy for treatment resistant depression, on a controlled basis through the medical system and with proper safeguards in place, becomes so important and urgent.

1.2 MDMA when used as part of psychotherapy is safe and effective as measured by the standards required for an unregistered medicine

Under our therapeutic goods framework in Australia MDMA satisfies the safety and efficacy requirements for medical use as an unregistered medicine on the basis proposed.

MDMA was first synthesised by pharmaceutical company Merck in 1912 (in other words over 100 years ago) so we know a lot about its safety when used in controlled environments. Up until prohibition in the 1980s (prohibition was part of the War on Drugs and had nothing to do with medical merit or safety) over **500,000** doses were used legally by practitioners across 20 years as part of psychotherapy – see the letter from Drug Science in the UK on page 42 of our second MDMA rescheduling application lodged with the TGA in March 2022 which can be found here - https://mindmedicineaustralia.org.au/tga/.

You will note that the Drug Science letter is signed by Professor David Nutt, the Head of Neuropsychopharmacology at Imperial College London, and one of the leaders in clinical research in this field globally. In addition, a total of 1,799 research participants have been exposed to MDMA in clinical or research studies so we have a lot of data available to support its safety and when used with appropriate medical protocols..

The safety and efficacy of pharmaceutical grade MDMA as an unregistered medicine and when used in a medically controlled environment with proper medical protocols has been confirmed by:

- **The Independent Expert Panel** in its report to the TGA on the therapeutic value, risks and benefits of MDMA and Psilocybin for the treatment of mental. behavioural or developmental disorders dated November 2021 where the Panel confirmed, amongst other things, the safety aspects of the medical use of MDMA in controlled settings. According to the Panel **"***MDMA was well tolerated in all the studies*" and *"Serious events such as suicidal ideation were rare and occurred almost entirely in the placebo arm or were otherwise unrelated to the therapy"*.
- **The TGA's Final Decision** against rescheduling announced in December 2021 where the Delegate acknowledged that "*The risks of individuals undergoing MDMA-assisted psychotherapy in a highly controlled environment are not high"* (note that as a Schedule 9 medicine use would be highly controlled given that approvals would be required from both the TGA and the Victorian DoH on a patient specific basis).
- **All clinical trials conducted to date** including the MAPS Phase 2 trials and the current MAPS Phase 3 trials.
- **The affidavits lodged by independent experts Professor David Nutt and Professor Jennifer Mitchell** in the current appeal against the Victorian Government's decision not to issue a permit to psychiatrist Dr Eli Kotler seeking to provide MDMA-assisted psychotherapy to a patient 'at-risk' with treatment resistant PTSD (discussed in section 2 below).
- **The letters of support** attached to our Rescheduling Submission (see link below) from **Drug Science** in the United Kingdom and from Australia's leading psychopharmacologist, **Professor Arthur Christopoulos,** who is also the Dean of the Faculty of Pharmaceutical Sciences at Monash University (this faculty is now ranked number 1 in this discipline in the World).

The efficacy of MDMA assisted psychotherapy is clearly documented in the MAPS Phase 2 trials and the first of two stages of the MAPS Phase 3 trials. In the MAPS Phase 2 trials with 105 participants, all with treatment resistant PTSD for an average of 18 years, remission rates were 52% immediately after the trial and 68% after 12 months. In the current Phase 3 trials remission rates were 67% immediately after completion of the first stage trial. Adverse events were minor in the MDMA group but significantly worse in the placebo group. I would encourage you to read about the Phase 3 trial results – see https://www.nature.com/articles/s41591-021-01336-3

For more details on the safety and efficacy of MDMA assisted therapy, please see our detailed rescheduling submission lodged with the TGA in March 2022 - see https://mindmedicineaustralia.org.au/wp-content/uploads/TGA-MDMA-rescheduling-submission_FINAL_030322.pdf.

1.3 <u>Psilocybin Assisted Therapy is safe and effective as measured by the standards required for an unregistered medicine.</u>

Under our therapeutic goods framework in Australia Psilocybin satisfies the safety and efficacy requirements for medical use as an unregistered medicine on the basis proposed.

Psilocybin is a naturally occurring substance that is found in over 200 species of fungi. Psilocybin was first synthesised by a pharmaceutical company in 1963. Therefore, as with MDMA, a lot is known about safety and appropriate medical dosage levels for psilocybin in controlled environments

The safety and efficacy of pharmaceutical grade Psilocybin as an unregistered medicine and when used in medically controlled environments with proper protocols has been confirmed by:

- **The Independent Expert Panel** in its report to the TGA on the therapeutic value, risks and benefits of MDMA and Psilocybin for the treatment of mental, behavioural or developmental disorders dated November 2021 where the Panel confirmed amongst other things that from a safety perspective "*Psilocybin was … well tolerated in all the studies. The main [adverse] effects were anxiety, headache and transient increases in blood pressure."*
- **All 51 clinical trials conducted to date** with a total of 3,091 participants including the recent Compass Phase 2b multi-site trial, the Imperial college Phase 2 trial and trials conducted at Johns Hopkins and New York University in the United States.
- **The letters of support** attached to our Rescheduling Submission from Drug **Science** in the United Kingdom and from Australia's leading psychopharmacologist, **Professor Arthur Christopoulos**, who is also the Dean of the Faculty of Pharmaceutical Sciences at Monash University (now ranked number 1 in this discipline in the World).
- The 14 long-term follow up studies of 232 participants which have shown sustained efficacy in a significant portion of participants with no psychosis, HPPD, or other health complications.
- People taking psilocybin as part of therapy in countries such as the Netherlands, Jamaica, the Bahamas and a number of South America countries (where the laws permit usage) and under compassionate access schemes in Canada, the United States, Switzerland and Israel.
- Significant media and online anecdotal evidence from people who have taken psilocybin assisted therapy outside of the legal medical system.

Although there have been over 51 psilocybin trials in total, we will focus on the two most recent ones in this letter as these were placebo controlled and randomised.

Compass Pathways released its Phase 2b results in November 2021. This was a multi-site parallel, randomised, double-blinded, placebo controlled trial with 216 participants taking either a 25 or 10 mg active dose of psilocybin as part of psychotherapy vs a 1

mg active placebo in patients with treatment-resistant depression. According to Drug Science the sample size was demonstrably statistically relevant with an effect size of over 0.5 and the trial was of high quality. The results were robust and confirmed the results achieved in earlier trials.

Key findings of the Compass trial included in relation to the Psilocybin group that:

- Response levels were more than twice that of the placebo group.
- Remission rates were more than 4 times as high as the placebo group.
- Adverse events were manageable and significantly worse in the placebo group.

The Imperial College trial also showed that psilocybin was well tolerated with remission rates twice as high in the psilocybin group than the group taking a leading SSRI, escitalopram.

For more details on the safety and efficacy of psilocybin-assisted therapy please see our detailed rescheduling submission lodged with the TGA in March 2022 – https://mindmedicineaustralia.org.au/wp-content/uploads/TGA-psilocybin-rescheduling-submission_FINAL_030322.pdf

1.4 Why would the Victorian Government Regulate Itself out of being able to Issue permits for these treatments?

Given the strong safety and efficacy results achieved to date from these medicinal therapies how could it be conscionable for the Victorian Government to regulate away its ability to provide a psychiatrist with a permit to provide these therapies to a treatment resistant patient in Victoria in a medically controlled environment? The consequences of such a decision are the denial of what should be a patient's right to access this therapy on the advice of the patient's psychiatrist if the patient is treatment resistant and at risk (discussed further in Section 4 below).

It's worth pointing out that the Victorian Government currently permits the use of other psychiatric medicines which are far more dangerous than MDMA or Psilocybin, even when Psilocybin and MDMA are used recreationally. This is evident from the recently published report by the Coroner's Court of Victoria on Victorian Overdose Deaths 2011-2020 published in July 2021 (see particularly Tables 7 and 8) – see https://www.coronerscourt.vic.gov.au/sites/default/files/2021-07/CCOV%20-%20Overdose%20deaths%20in%20Victoria%202011-2020%20-%2029Jul2021.pdf.

All of the clinical trials involving the use of MDMA and Psilocybin (and the clinical use before prohibitions) demonstrate that these substances can be used with a high level of safety in medically controlled environments.

2. **<u>The Proposed Change would be Unconscionable in the Context of a legally provided Court Appeal Process that has Already been Commenced Against the Department of Health's Refusal to issue a Permit to Enable a Psychiatrist with Special Access Scheme Approval to provide MDMA assisted therapy to an 'at-risk' patient with treatment resistant PTSD.</u>**

Why is the Victorian Government seeking to avoid its refusal to issue a Schedule 9 permit for the medical use of MDMA as part of psychotherapy for an 'at-risk' patient suffering from treatment resistant PTSD from being tested in Court?

The Appellant's lawyers have arranged for two of the leading researchers in the World in this field (**Professor David Nutt** from Imperial College London and **Professor Jennifer Mitchell** from The University of California, San Francisco) to give expert independent testimony on the safety and efficacy of MDMA when used by trained therapists in medically controlled environments.

Why would the Victorian Government seek to disrupt this appeal process and seek to prevent the views of expert witnesses from being heard in an open Court by changing the regulations?

The patient in this case has suffered from severe treatment resistant PTSD since 2015. According to the treating psychiatrist: *"The disorder has caused the patient to be significantly disabled and she suffers with flashbacks, constant nightmares and disturbed sleep, irritability, constant worry and panic, constant feelings of impending doom and feelings of powerlessness".* Furthermore she *"has sought treatment via multiple treatment modalities without success, including high-dose trials of selective serotonin inhibitors (SSRIs), serotonin and norepinephrine uptake inhibitors (SNRIs), mood-stabilisers, benzodiazepines and anti-psychotic medications. She has also been treated with family therapy, cognitive behaviour therapy (CBT), acceptance and commitment therapy (ACT), cognitive processing therapy (CPT), dialectical behaviour therapy (DBT), acupuncture, group therapy, yoga and art therapy. Despite the patient's concerted effort to treat her PTSD, she continues to suffer with the disorder which adversely affects her life".*

Given the severe treatment resistant nature of the patient's PTSD, her treating psychiatrist applied for and received Special Access Scheme approval from the TGA on 19 February 2021 to treat the patient with MDMA as part of therapy. The treating psychiatrist made it clear in his application that he proposed to treat the patient in a controlled hospital environment in which he and two other experienced therapists would be present.

Following the receipt of the TGA's approval the psychiatrist applied to the **DoH** on 25 March 2021 pursuant to **Section 33A of the Victorian Drugs, Poisons and Controlled Substances Act 1981 (the Act))** for a permit to treat the patient with

pharmaceutical grade MDMA as part of therapy. Further requested information was then supplied by the psychiatrist to the DoH on 27 May, 7 July and 9 August 2021.

On 25 August, Dr Stefan Tulloch, Acting Chief Officer, Medicines and Poisons Regulation, who works for the **DOH,** wrote to the treating psychiatrist declining the application to use pharmaceutical grade MDMA to treat the patient. Our understanding is that Dr Tulloch has no expertise in mental health treatments or human psychopharmacology. The reasons for refusal given by Dr Tulloch are also misconceived, based as they are on the refusal of the TGA to reschedule MDMA to Schedule 8 of the Poisons Standard and the fact that MDMA is not a registered medicine (both of these reasons are irrelevant given the application was for the use of an unregistered Schedule 9 medicine).

On 6 October 2021 the applicant filed an application pursuant to Section 37 of the Act appealing this decision to refuse the application.

Since lodging the appeal the Government's lawyers (Minter Ellison) have endeavoured at every stage to slow down the appeal process and have tried to have the evidence of the applicant's independent expert witnesses in this case struck out.

The case was originally going to be heard in the Magistrate's Court, as provided for in the Act, in July 2022 but was deferred until October 2022 due to the illness of the Applicant's senior barrister. Due to the submissions of the DOH's lawyers seeking to strike out the Applicant's Independent Expert Witnesses and the DoH's proposal to change the regulations so that applications for permits to use Schedule 9 substances would no longer be possible, the Court case has been deferred yet again to early in 2023. The DoH lawyers are using the DoH's proposal to take away its discretion to issue Schedule 9 permits to argue that the Court should not hear the appeal on the basis that if the DoH's proposal was implemented the lack of discretion to issue a Schedule 9 permit would become retrospective.

To put all of this into perspective: We have a young person suffering from severe treatment resistant PTSD who has tried a wide range of treatments all of which have failed. The person is suffering terribly. The psychiatrist involved (supported by two other psychiatrists) has applied for a permit to treat his patient with MDMA-assisted therapy which has been widely used in trials, in countries such as Holland and through Special and Compassionate Access pathways and exemptions in Switzerland, the USA, Canada and Israel. All treatments to date have been shown to be safe and highly effective when done in medically controlled environments. The treating psychiatrist has received Special Access Scheme approval from the TGA.

Looking at all of this from a compassionate perspective, why would the DoH oppose this matter being heard on appeal? The DoH's actions amount to severe cruelty. To keep a suufering patient like this strung out for nearly 18 months after the patient's psychiatrist has received TGA approval for this form of medicinal therapy, and then to attempt to strike out expert witnesses who are

leading global experts in this field, and then to try to avoid the DoH's actions being examined in Court by proposing to close the permit avenue – why would the DoH do this? The evidence supporting the safety and efficacy of the medical use of MDMA is actually far stronger than the evidence that was available to support the medical use of cannabis when the DoH started to issue permits for this substance.

3. The Proposed Change would be Inconsistent with the Victorian Government's Progressive, Innovative and Pragmatic Approach to Improving Mental Health Outcomes

The Victorian Government is probably the most progressive government in Australia when it comes to innovation in the health sector. For example, the Victorian Government led the way with the use of medicinal cannabis and with euthanasia laws.

The Victorian Government has also been the most outspoken government in Australia about the failure of the mental health system to provide the necessary support for patients. The Premier, Mr Daniel Andrews, has described the mental health system as "*broken*". This led to the Government appointing a Royal Commission into the mental health system and committing to implementing all of its recommendations. The Andrews State Government is to be commended for its acknowledgement of the magnitude of the problem and its progressive approach.

To emphasise the stance of the Victorian Government, Premier Daniel Andrews at the Rural Press Club in June 2022 commented that*: "The broken mental health system makes things worse not better for those at their lowest point."*

The Victorian Government's Schedule 9 permit system is the most progressive in Australia and recognises that the medical use of Schedule 9 substances can be justified and that medical use can be distinguished from recreational use. Because of the reasons that we set out in our rescheduling submissions, diversion risks are minimal and translation risks occur with every medicine which moves from clinical trials into the medical domain.

So why would the DoH remove the ability to issue Schedule 9 permits when the TGA has approved the use of an unregistered medicine for a treatment resistant patient.? This is not putting the patient first which the Victorian Government has declared is the central part of its mental health strategy.

4. The Proposed Change would be Inconsistent with International Conventions that Australia has Signed, and which Victoria should therefore observe

Article 7 of the United Nations Convention on Psychotropic Substances 1971 provides a specific medical exemption for Schedule 1 substances (Schedule 1 of the UN Convention is mirrored by Schedule 9 of the Australian Poisons Standard). This medical exemption in the UN Convention specifically supports the ability of medical practitioners to apply for approvals to use MDMA or Psilocybin as part of therapy under the TGA's Special Access Scheme and the ability of the Victorian Government to issue permits under **Section 33A of the Victorian Drugs, Poisons and Controlled Substances Act 1981.**

Article 7 of the UN Convention is extracted below:

"Article 7: SPECIAL PROVISIONS REGARDING SUBSTANCES IN SCHEDULE I

In respect of substances in Schedule I [equivalent to Schedule 9 of our Poisons Standard, the Parties shall:

*a) Prohibit all use except for scientific **and very limited medical purposes** by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments **or specifically approved by them;***

b) Require that manufacture, trade, distribution and possession be under a special licence or prior authorization;

c) Provide for close supervision of the activities and acts mentioned in paragraphs a) and b);

d) Restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;

e) Require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein; and

f) Prohibit export and import except when both the exporter and importer are the competent authorities or agencies of the exporting and importing country or region, respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose. The requirements of paragraph 1 of article 12 for export and import authorizations for substances in Schedule II shall also apply to substances in Schedule I..."

There are also other 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 rights to "*the enjoyment of the highest standard of physical and mental health*").

So why would the Victorian Government seek to constrain its current ability to issue a Schedule 9 permit for the use of MDMA or Psilocybin as part of therapy, and in doing so set up a regulatory regime that is more constrictive that a 50 year old UN Convention focused on the recreational use of these substances that Australia has signed up to? How can this be in the interests of patients with treatment resistant PTSD or treatment resistant Depression?

5. The Proposed Change would be Inconsistent with Australia's National Scheduling Policy Framework for Medicines and Poisons

The Consultation Document makes an inaccurate claim on page 3 when it states that *"The purpose of the proposed regulations [i.e. to restrict Schedule 9 permits to clinical trials] is to ensure that access to Schedule 9 poisons in Victoria is in accordance with the national Scheduling Policy Framework for Medicines and Poisons".*

As discussed in Section 4, the application of Schedule 9 of the Poisons Standard to MDMA and Psilocybin followed Australia's signing of the UN Convention on Psychotropic Substances. That Convention contains a specific exemption for restricted medical use. The TGA has interpreted this exemption as giving it the authority to issue approvals on a case-by-case basis to medical practitioners under the Special Access Scheme to enable MDMA and Psilocybin to be used as part of therapy for the treatment of patients with treatment resistant PTSD (MDMA) and treatment resistant depression (PTSD). Over 30 such approvals have been given by the TGA to date.

This UN Convention and the approach of the TGA clearly justifies the current ability of the Secretary of the DoH to issue a psychiatrist with a Schedule 9 permit ***outside of a clinical trial environment.***

So if the patient really does come first as the Victorian Government would have us believe, why would the DoH try to take away its ability to issue a Schedule 9 permit when the TGA itself believes that such an issue would be consistent with Australia's national policy framework for medicines and poisons*?*

6. Limiting the Availability of Schedule 9 permits for the Medical Use of MDMA and Psilocybin as part of Therapy to Ethics Approved Clinical Trials is not a Solution for a Treatment Resistant 'at-risk' Patient.

Clinical trials in Australia have very limited places available for people suffering from treatment resistant mental illnesses. These trials tend to take at least four years at a minimum from inception of the idea through funding, ethics approval, patient selection, patients actually being treated, and the research findings being written up. Patient selection is highly selective (for example in the recent MAPS Phase 3 trial the investigators reduced 1,331 applications to just 90 participants) and participants have to fall within narrow and singular categories of illness. Trial requirements (often supported by limited funding) don't enable treatments to be tailored to a patient's specific needs.

In contrast, patients being treated by psychiatrists in their clinical practices often have several co-morbidities and are therefore normally ineligible for clinical trials.

Furthermore, the funding of clinical trials is expensive and, to date, traditional pharmaceutical companies have not shown any interest in funding these trials. The

challenge with the business model of a pharmaceutical company is that MDMA and Psilocybin-assisted therapies only requires two to three medicine dosing sessions rather than years of taking a medicine on a daily basis, as often occurs with SSRI's and most other psychiatric medicines. Furthermore, patents (which give commercial monopolies), are not available for these substances.

Mind Medicine Australia recognises the importance of ongoing clinical trial work in Australia to support the development of medical knowledge and the improvement of outcomes. Our advocacy directly led to the previous Federal Government in Canberra announcing a $15 million grant round for trials of psychedelic medicinal therapies (the largest government grant from any government in the World to date). However, the suffering that people with treatment resistant mental illnesses go through (with some committing suicide) combined with the strong safety and efficacy data mentioned in Section 2 above supports the need for the Victorian Government to maintain the discretion of the Secretary of the DoH to be able to issue Schedule 9 permits in the limited circumastances proposed. In other words, to enable a psychiatrist with TGA approval through the Special Access Scheme to prescribe MDMA or Psilocybin assisted therapy to a treatment resistant patient in a medically controlled environment.

Why would the Victorian Government seek to take away this discretion to issue a Schedule 9 permit if the patient really does come first?

7. Removing the availability of Schedule 9 permits for the medical use of MDMA and Psilocybin would lead to perverse – and indeed heartless - results.

It would lead to the bizarre outcome that a patient with a terminal illness could apply under Victoria's euthanasia laws to legally kill themselves but couldn't legally access Psilocybin as part of psychotherapy to treat the depression and anxiety associated with a terminal illness. Trial outcomes overseas, and outcomes in Canada where regulatory exemptions have been used in these circumstances, have shown remarkable psychological improvements for patients with a terminal illness from just a single dose of Psilocybin.

I am attaching a letter from Mr Thomas Hartle, a patient with a terminal illness who was the first patient in Canada to legally access psilocybin for end-of-life distress. In the letter Mr Hartle highlights how positive and life changing the experience was for him.

Why would the Victorian Government seek to take away its discretion to issue a Schedule 9 permit to a person in Mr Hartle's situation. Why should a Canadian in these circumstances have more rights than a person living in Victoria?

Conclusion

We can arrange for World leading experts in this field to be available to the Victorian Government's DoH to discuss the veracity of the views that we have expressed in this letter. In the interests of patients and all Victorians and their families we would encourage the DoH to take up this offer.

At a time when countries like Canada and the United States are opening up their Special Access Schemes for the medical use of MDMA and Psilocybin as part of psychotherapy for doctors and their treatment resistant patients it would be a huge backward and severely detrimental step for the Victorian Government to restrict Schedule 9 permits just to clinical trials.

It is imperative that the Premier and the relevant Ministers in Victoria are properly briefed on all of this in a balanced way. If the patient truly does come first, the Victorian Government will not proceed with this proposal.

Please do not hesitate to reach out to me with any further questions.

Yours sincerely

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Chair
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