MIND MEDICINE AUSTRALIA

6 August 2025

Therapeutic Goods Administration
PO Box 100
Woden
ACT 2606
Australia

Dear Sir/Madam

Re: **Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions**

Thank you for your invitation to make a submission in response to your targeted invitation in relation to the above review. Our response document is attached for your consideration. Please let me know if you require any further information.

Yours sincerely

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Submission to the Therapeutic Goods Administration in response to the targeted external consultation paper dated July 2025 titled:

"Review of Authorised Prescriber Scheme to allow access to MDMA and psilocybine for use with psychotherapy in mental health conditions"

6 August 2025

Mind Medicine Australia Limited

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1. Introductory Comments

Mind Medicine Australia (MMA) welcomes the TGA's invitation to provide our views on how to improve key aspects of the Authorised Prescriber scheme in relation to the use of MDMA and psilocybine as part of psychotherapy. Please note that in this submission we use the terms "psilocybine" and "psilocybin" interchangeably as both appear in the literature.

MMA is a registered mental health promotion charity. MMA is focused on the development of new treatments (appropriately supported by safety and efficacy data) to deal with the worsening mental health epidemic in Australia, the lack of effectiveness of current treatments for many people and the enormous suffering that this gives rise to. Please see www.mindmedicineaustralia.org.

We would encourage the reader to look at the calibre of our Advisory Panel (https://mindmedicineaustralia.org.au/advisory-board/) which includes many World-leading clinicians and researchers in the application of psychedelic-assisted therapies from both Australia and overseas. We consult regularly with members of our Advisory Panel to ensure that we are at the forefront of knowledge in relation to the safe and effective clinical application of psychedelic-assisted therapies.

In 2023 MMA's applications to the TGA led to the rescheduling of MDMA and psilocybin as part of psychotherapy. MMA's applications were supported by over 13,000 submissions from clinicians, researchers, patients and other members of the public which were over 96% in favour of the rescheduling. These submissions and the Delegate's Final Decision all recognised that current treatments either don't work or work inadequately for a large number of Australians and that there is a need for treatment innovation in the sector. The Delegate specifically acknowledged "*the current lack of options for patients with specific treatment-resistant mental illnesses.*"

As the TGA will be aware, current pharmaceuticals and/or conventional therapies generate remission rates for depression of only about 35% and for PTSD under 20%. Whilst response rates are higher, the

pharmaceuticals often prescribed (particularly SSRIs) can have difficult adverse patient side effects, create challenges for patients seeking to withdraw from them and overall relapse rates remain high. This failure of the system leads to enormous patient suffering (sometimes over decades and lifetimes) and unfortunately, in some cases, suicide.

Since the rescheduling decision, Mind Medicine Australia has played a central role in developing the logistics to safely enable psilocybin and MDMA assisted therapies to be made available to suitable patients across Australia within the constraints laid down by the Delegate and the TGA.

We have done this through:

- Awareness building and education.
- Clinician training (our Certificate in Psychedelic-Assisted Therapies (CPAT)) course is widely regarded by clinicians and researchers as the best course of its kind in Australia and one of the best in the World, with a global Faculty of leading researchers and clinicians – see https://cpat.mindmedicineaustralia.org.
- Providing underwriting arrangements for the importation of GMP quality medicines that conform to the TGA Quality Standards for MDMA (TGO 112) and psilocybine (TGO 113) through an appropriately licensed pharmacist that satisfy TGA and ODC requirements.
- Funding the Australian National University's Registry to collate real world evidence from the clinical application of these therapies.
- Working with clinics around Australia to help them to manage the complex logistics involved with this form of intensive therapy (based on the availability of 2-3 practitioners including a psychiatrist with Authorised Prescriber status and up to 70 hours of clinician time over a relatively short intensive period of patient therapy).
- Working with governments around Australia on areas of regulatory friction which unnecessarily increase patient costs and act as barriers to patient access but don't improve patient safety. An example of the work that we do in this area is the recent changes in NSW which allow psilocybin and MDMA assisted psychotherapies to now take place in outpatient clinics. Prior to our submissions to the

NSW Department of Health these therapies could only be conducted in private hospitals, which presented patients with unnecessary cost and access problems.

- Developing a Patient Support Fund to subsidise treatments for patients who demonstrably can't afford these therapies (see https://mindmedicineaustralia.org.au/psf-application/) and making representations to potential funders such as Medibank, other medical insurers, workers compensation insurers, the Department of Veterans Affairs and the Medical Services Advisory Committee to support patient funding.

As an organisation we have consistently focused on patient safety and making sure that rollout strategies are consistent with patient safety. We also dealt with the importance of patient safety at length in our rescheduling applications with detailed results from clinical trials highlighted.

To date we estimate that there have been over 150 patients accessing these therapies. We have received very positive feedback from the psychiatrists involved in terms of treatment outcomes and the absence of serious adverse events. Importantly, outcomes to date have been consistent with the positive outcomes achieved in clinical trials. See for example the Emyria/PAX Centre announced patient results and six month follow up with MDMA assisted therapy – https://announcements.asx.com.au/asxpdf/20250429/pdf/06j4m328c8k0z5.pdf and https://emyria.com/announcements/6976806.

2. The Stated Objective of the TGA's Consultation Process

The stated objective of the TGA's consultation process is to improve clarity for stakeholders and ensure alignment between the TGA and Human Research Ethics Committees (HRECs) (*see page 4 of the TGA's consultation paper*).

Given this objective, we would like to raise four important preliminary issues with the TGA which are increasing patient costs and making access for patients more challenging, without simultaneously improving patient safety.

Issue 1. Risk of Compromising the Role of the HRECs

In our view, HREC's should be more than capable of assessing the quality and content of applications from psychiatrists for Authorised Prescriber status. HREC's are central to the clinical trial approval process in Australia and have a strong focus on patient safety. Under the TGA's notification scheme applicants for most clinical trials only need to notify the TGA that they have HREC approval rather than go through a second set of requirements which the TGA is currently insisting on under the Authorised Prescriber scheme for MDMA and psilocybin assisted therapy.

Our concern is that the TGA, by insisting upon more rigorous standards than those required by the HRECs, is putting pressure on the HRECs to also tighten their own standards to a level which they wouldn't otherwise require. This is leading to a situation where we believe TGA is starting to seriously compromise the independent views of the HRECs and make the application process to become an Authorised Prescriber much more arduous and time consuming than it should be. It also leads to double handling and rework between the TGA, the HREC and the submitting psychiatrist. The people that are suffering from these delays are the patients seeking access to these therapies who have not benefitted from conventional treatments.

For instance, we have seen responses from the TGA regarding a proposed psychedelic-assisted therapy protocol put forward by a psychiatrist undergoing the Authorised Prescriber process that contradict the

treatment delivery framework that had already been approved by the HREC.

We respectfully submit that the TGA's approach amounts to regulatory overreach to the disadvantage of suffering patients who could otherwise benefit from these therapies. This is particularly seen in the TGA's attempts to regulate the psychotherapy components of psychedelic-assisted therapies.

An example of this is the TGA's requirement that the therapy team (if not led by the prescribing psychiatrist) **must involve a clinical psychologist**. We deal with this in detail below, but the point we want to make here is that this is not a normal HREC requirement for clinical trials in Australia. Furthermore, this approach is not normally followed by clinical trials around the world and there is no evidence to suggest that clinical psychologists achieve better patient outcomes (as measured by safety and efficacy) than other trained and experienced mental health therapists.

Another example is the recent requirement from the TGA that **the prescribing psychiatrist must be physically present at the clinic throughout a patient's dosing sessions (which can last as long as 8-10 hours)**. This requirement hasn't been part of the TGA's published guidance to date. It also hasn't been a requirement of the HRECs provided a medical practitioner or nurse is physically present at the clinic with appropriate training to deal with medical emergencies. Unfortunately, the "physical presence" requirement of the TGA is now likely to be followed by HREC's in the future as they seek to align themselves with the TGA's evolving position rather than work from first principles.

The net effect of the TGA approach is that it risks losing the benefit of the independent thinking, qualifications and experience of the HRECs on these sorts of matters as HREC's endeavour to align themselves with TGA thinking. In our view this state of affairs adversely affects patient access without additional safety benefits by limiting the number of psychiatrists operating in this area, making logistics harder than they should otherwise be and unnecessarily driving up patient costs.

Issue 2. Not Properly Recognising the Expertise of Psychiatrists

Another issue, not specifically dealt with by the TGA in its consultation paper, is the TGA's failure to properly recognise that the prescribing psychiatrist is in the best possible position to form a judgment on matters such as the quality of the therapist team and whether the psychiatrist needs to be physically present at the clinic during the treatment process. This is because of the expertise and professional training of the psychiatrist (as reviewed by the HREC), the psychiatrist's knowledge of the specific patient and the preferred therapists, and the fact that the treating psychiatrist is obliged to professionally assess:

- the appropriateness of this form of treatment for a particular patient.
- the quality and expertise of the proposed therapists.
- the quality of the clinicians available at the clinic and the appropriateness of their operating procedures.
- the protocols, rescue medicines, medical devices and clinicians available at the clinic in the unlikely event that an intervention is necessary.

While psychiatrists may not routinely deliver psychotherapy themselves, they are uniquely trained to assess complex mental illness, determine treatment suitability, prescribe restricted medicines and evaluate risk. In our view, these skills mean that psychiatrists who have been trained in these therapies are best placed to select and oversee appropriately trained therapists for psychedelic-assisted therapy and to determine whether they need to be present at the clinic on the medicine dosing days.

This oversight should not necessitate continuous physical presence during all therapy sessions. Just as psychiatrists commonly oversee multidisciplinary mental health care teams in community or hospital settings, they are able to provide effective oversight of psychedelic-assisted therapy by ensuring therapist competence, reviewing session reports and intervening where necessary without compromising patient safety.

We therefore respectfully submit that the TGA needs to be particularly sensitive about introducing new requirements or continuing with requirements that are additional to those required by the HREC that has been involved in assessing the psychiatrist's application to become an Authorised Prescriber. Unnecessary regulatory creep disadvantages patients who can be suffering terribly (and may be suicidal) by increasing costs and restricting patient access without any attendant safety benefits for the patient.

Issue 3. The Need for an Open Dialogue and Transparency in Decision Making

One of the impressive things about the TGA's rescheduling process was its transparency. Applications, submissions in response and the reasoning behind the Delegate's decision were all made public.

This current review by the TGA will directly impact on patient accessibility and costs. Given the vulnerable nature of this population, and in the interests of transparency and patient safety, we believe that the TGA should make all submissions from interested parties public and publish the reasoning behind decisions made by the TGA in relation to the matters covered by the consultation paper.

Issue 4. Risk of Regulatory Creep

We also note that the TGA's legislative mandate is the regulation of medicines and poisons. We believe that when the TGA gets involved in specifying rules for the conduct of non-medical interventions (such as where integration sessions can be conducted and by whom) the TGA is staying beyond that legislative mandate. Integration doesn't involve a patient taking medicine or in any way being in an altered state. Why is the TGA making a distinction between this form of "talk" therapy and the "talk" therapy that a patient may have when taking other psychiatric medicines (often on the same day as the "talk" therapy)?

3. Comments on the TGA's First Recommendation: Psychiatrist Experience

We agree with the stated rationale supporting the TGA's recommendation that ***"****the psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have initial supervision by an Australian registered psychiatrist that has experience in conducting psychedelic-assisted psychotherapy"*.

Whilst this requirement has led to delays in the treatments becoming available because of the small number of psychiatrists who initially met the supervision criteria, this requirement is getting easier to manage over time as more psychiatrists gain experience in these modalities.

4. Comments on the TGA's Second Recommendation: Therapy 'Dyad' Qualifications

We strongly disagree with the TGA's view that if the AP psychiatrist is not to be part of the therapy dyad one of the therapists involved must be a clinical psychologist. As discussed below, there is ***no evidence*** that we have been able to find in any of the literature to suggest that the presence of a clinical psychologist rather than another mental health expert enhances patient safety and/or treatment effectiveness. In our view the focus should be on the expertise and experience of the mental health practitioner and their capacity to develop a trusted relationship with the patient.

In addition, the TGA's position will have an ***adverse impact*** on both patient costs and patient access to these treatments. This adverse impact will further exacerbate the worsening mental health crisis that we have in Australia without having any attendant safety benefits.

Psychedelic-assisted therapy (irrespective of whether the medicine involved is MDMA or psilocybin) involves several distinct stages:

- Review of the patient for appropriateness of treatment (including discussion of any other available treatments, any requirement for

tapering of existing psychiatric medicines and whether there are any contraindications).
- Patient informed consent.
- Selection of therapists in consultation with the patient and therapy timetable agreed with the patient.
- Prescribing of medicines.
- Preparation.
- Medicine dosing days.
- Integration sessions following each medicine dosing day.
- Final review of treatment outcomes with the patient and way forward.

It should be noted that the actual dosing days account for a minority of the therapeutic time involved (around one third with most protocols (Horton, Morrison & Schmidt, 2021)).

In our view, it is imperative that the psychiatrist is directly and personally involved in the initial patient assessment and discussion with the patient of alternative treatments, the patient's informed consent, the selection of the therapists, the prescribing of the medicines and the final patient review. In addition, if not physically present during the preparation, medicine dosing and integration stages, we also believe that it is imperative that the prescribing psychiatrist is regularly updated by the lead therapist on the patient's progress and any significant issues that may arise.

In selecting a lead therapist and a supporting therapist the psychiatrist must pay particular attention to the experience, training and expertise of the therapists proposed.

In assessing experience, training and expertise we see no reason why, in the absence of the psychiatrist from the therapist dyad, one of the therapists involved has to be a clinical psychologist. In our view all that this achieves is to make patient access harder and more expensive with no attendant safety benefits or improved treatment outcomes in and of itself.

We substantiate our views with the following supporting evidence:

(i) Acute shortage of mental health professionals in Australia

There is an acute shortage of mental health professionals in Australia, and this shortage is even more acute with psychiatrists and clinical psychologists (Department of Health and Aged Care, 2023a). In many cases these professionals have closed their books to new patients and in other cases waiting times can be as long as 6-12 months.

Latest estimates are that Australia has about:

- **4,300 registered psychiatrists** (https://www.aihw.gov.au/mental-health/topic-areas/workforce)
- **12,890 clinical psychologists**; (www.psychologyboard.gov.au/About/Statistics.aspx)
- **26,827 registered psychologists excluding clinical psychologists (**www.psychologyboard.gov.au/About/Statistics.aspx**);** and
- **7,375 psychotherapists who are registered with PACFA** (www.pacfa.org.au)

In other words, clinical psychologists represent only 25% of psychologists and registered psychotherapists who provide therapy for mentally ill patients.

These numbers also significantly overstate the number of practitioners available in each category in the private sector because many of these practitioners are working in government, academia and state care institutions and some are only working part time.

A 2020 study on Australia's mental health workforce showed that, whilst an estimated 85% of psychiatrists worked full-time (page A-16), that figure was only 55% for psychologists (A-19) further exacerbating workforce shortages (Australian Government Department of Health, 2023).

Given the shortage of mental health practitioners in Australia and the worsening state of mental health in this country, we believe that it is

imperative that any decision by the TGA that insists on the involvement in the therapeutic dyad of a clinical psychologist (if the prescribing psychiatrist chooses not to be involved) must be evidence-based.

(ii) The AP psychiatrist is the party best placed to determine the calibre of the therapists for PAT treatment

To become an Authorised Prescriber of psilocybin or MDMA as part of psychotherapy, the psychiatrist has to convince a Human Research Ethics Committee that – amongst other things – the psychiatrist has relevant patient experience, has appropriate diagnostic training and experience, has completed training in these modalities and will use appropriate protocols. The applying psychiatrist must also advise the HREC of the training and experience required for therapists that will work as part of the therapy dyad.

In our view, given these strenuous but appropriate requirements, the AP psychiatrist is best placed to determine the calibre of the therapists to be used for the dosing sessions by drawing from a pool of therapists with appropriate patient experience and training in these modalities as set out in the psychiatrist's protocols approved by the HREC involved.

We believe that the TGA's insistence that one of the therapists in the therapeutic dyad must (in the absence of the prescribing psychiatrist) be a clinical psychologist undermines the professional judgement of the psychiatrist about which trained therapist is best for a particular patient. Quality and expertise do not reside only in clinical psychologists.

(iii) Lack of evidence to support the TGA's position venerating clinical psychologists above other experienced clinical disciplines

We might have a different view if there was clear evidence that the use of clinical psychologists would lead to better patient outcomes in terms of both safety and efficacy but there is no available evidence that we have

been able to find to support such a contention. What research there is suggests that, despite their specialist training, clinical psychologists do not perceive themselves as achieving superior therapy outcomes (Parker & Waller, 2015). The research also suggests that the therapeutic alliance (the quality of relationship between therapist and patient) rather than the qualifications of the therapist is one of the most significant predictors of treatment outcomes (McCabe & Priebe, 2004).

Indeed, the findings set out in table A16.1 of the *Medicare Better Access Initiative Evaluation Report Appendices* (Australian Government Department of Health and Aged Care, 2022, p. 63) indicates that there is no strong evidence that seeing a clinical psychologist led to better outcomes than seeing a general psychologist. Whilst the Department of Health and Aged Care Annual Report 2022-23 (Department of Health and Aged Care, 2023b) refers to the Medicare Better Access Evaluation Report as a basis for mental health system reform it does not elaborate on the report's specific findings regarding psychologist outcomes.

The best article that we could find on this subject shows no statistical difference in treatment outcomes for depression (in fact, it shows a slight preference for registered psychologists over clinical psychologists) – see Pirkis et al. (2011)

In our view, the prescribing psychiatrist is in a far better position to assess the quality of a therapist, their ability to deal with a specific patient and the likely quality of the therapeutic alliance. There is no evidence that we can find that suggests that the use of clinical psychologists improves patient outcomes and safety. All that this requirement does is to adversely impact patient costs and access to these potentially life-saving treatments (given the higher rates of suicidality in these populations).

(iv) Published Clinical Trial Protocols Do Not Require a Clinical Psychologist in the Therapy Dyad

Clinical trial protocols *do not* support the TGA's position that one of the two therapists in the therapeutic dyad (in the absence of the treating psychiatrist) must be a clinical psychologist (Horton, Morrison & Schmidt, 2021). We have extensively reviewed the protocols used in psychedelic-

assisted therapy clinical trials around the world and spoken to many of the practitioners involved. None of these experts have supported the TGA's mandatory requirement for the involvement of a clinical psychologist in the therapeutic dyad in the absence of the prescribing psychiatrist.

(v) TGA's position creates unnecessary barriers to access for patients

The net effect of the TGA's mandatory requirement in relation to the involvement of clinical psychologists is more challenging clinic logistics because of the limited number of clinical psychologists available for these therapies and the tendency of clinical psychologists to charge higher fees (Department of Health and Aged Care, 2023a). In our view the TGA's current position adversely affects patient access and increases patient costs for no patient benefit.

(vi) TGA's position also makes critical shortages even more acute

Finally, as mentioned above, there is a critical shortage of mental health practitioners (and particularly psychiatrists and clinical psychologists) in Australia. To insist upon their involvement in the therapeutic dyad for psychedelic-assisted therapy, in the absence of any evidence that patient outcomes and safety is improved, means that the TGA is making the shortages of these practitioners for general consultation and therapy even more acute.

Concluding Comments on TGA's Second Recommendation

The TGA, in its consultation document, seeks to justify the mandatory requirement for a clinical psychologist to be present (in the absence of the treating psychiatrist) by reference to the need for formal clinical oversight by a national board. It notes that clinical psychologists satisfy this requirement because these clinicians have regulatory oversight by the Psychology Board of Australia. However, the Psychology Board of Australia also has the same oversight of all registered psychologists (i.e. not just clinical psychologists).

As far as psychotherapists are concerned, we recognise that the title of a psychotherapist is not protected under Australian law. However, PACFA (the Psychotherapy and Counselling Federation of Australia), acts as the self-regulating body for this profession and is a highly respected, professional organisation.

We therefore believe that the TGA should expand its requirement that a clinical psychologist be involved (in the absence from the therapeutic dyad of the prescribing psychiatrist) to include other registered psychologists and psychotherapists registered with PACFA. A clinician from any of these professions would also need to demonstrate to the prescribing psychiatrist that they had been trained in the application of psychedelic-assisted therapies and had experience of treating patients with the relevant mental illnesses, namely depression or PTSD (as the case may be).

We note the comment in the TGA's consultation paper that the external guidance of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) is that the practitioners involved in psychedelic-assisted therapy should hold registration with AHPRA. The RANZCP fails to explain their rationale for excluding psychotherapists from the therapy dyad who are registered with PACFA.

It's ironic that the current regulatory settings allow for very disturbed, mentally ill patients to access psychotherapists for therapeutic treatments, but the TGA seeks to exclude psychotherapists from the lead therapeutic role in psychedelic-assisted therapy. This is despite the involvement of the treating psychiatrist in assessing the specific therapist for relevant training and experience, and the overall responsibility of the prescribing psychiatrist for the course of treatment (something that doesn't occur when a mentally ill patient just seeks the help of a therapist).

We therefore believe that the TGA should remove its requirement that where the AP psychiatrist chooses not to be part of the therapy dyad a clinical psychologist must be present. We see no evidence to support the position that the TGA is taking from either a patient safety or outcomes perspective and believe that the best person to apply professional judgment on the makeup of the therapist team should be

the prescribing psychiatrist. This accords with the emphasis placed on the psychiatrist in the Delegate's rescheduling decision.

We also believe that, at the very least, the TGA's current requirement that a clinical psychologist must be involved in the therapy dyad (in the absence of the treating psychiatrist) should be expanded to include other registered psychologists and psychotherapists registered with PACFA. Under this approach the HREC involved with the psychiatrist's Authorised Prescriber application would still be required to consider the training and experience of all of the therapists involved in the treatment.

5. Comments on the TGA's Third Recommendation: Level of AP Oversight

We agree with the TGA's view that the AP psychiatrist must be responsible for initial patient screening and obtaining informed patient consent. However, the requirement that the AP psychiatrist must be present onsite and involved in the ongoing psychotherapeutic management makes no sense to us. All this requirement achieves is to reduce the number of psychiatrists seeking to become Authorised Prescribers, reduce patient access and increase patient costs.

It needs to be recognised that psychiatrists do not have the monopoly in Australia on providing psychotherapy for a person suffering from mental illness. Many psychiatrists don't get involved with psychotherapy but refer patients instead to psychologists, psychotherapists, counsellors or other mental health professionals.

Psychotherapy also has the smallest membership base of any of the specialty groups of the RANZCP as the peak body for psychiatrists (Royal Australian and New Zealand College of Psychiatrists, 2019).

There is no evidence that the TGA's requirement that the psychiatrist needs to be onsite will improve patient safety if the members of the therapy dyad have the requisite training and experience, appropriate safety protocols are in place for the medicine dosing sessions (as reviewed by the HREC involved) and a medical practitioner or nurse is on hand to provide rescue

medicines and/or use medical devices in the highly unlikely circumstance that these medicines are necessary.

It's also critical in our view that the TGA differentiate between the medicine dosing sessions that must take place in an appropriate medically controlled environment and the non-medicated preparation and integration sessions with the patient. **There is absolutely no reason that we have been able to identify that explains why preparation and integration sessions need to take place in the same location as the medicine dosing sessions.**

During preparation and integration sessions the patient is not in an altered state under the influence of MDMA or psilocybin (as the case may be). Preparation and integration sessions are, by definition, psychotherapy sessions without medication (the patient is not in an altered state). These non-medicated sessions should be able to take place at professional consulting rooms and, as an option, by teleconferencing for remoter patients if the psychiatrist and lead therapist involved believe that this is acceptable.

All the TGA is achieving (if it insists that both medicated and non-medicated therapeutic sessions must all take place in the same clinic) is the creation of an unnecessary barrier to patient access and increased patient costs.

The TGA's position would also make it highly challenging for people outside of the major cities to have the benefit of psychedelic-assisted therapy. Coming into the city for 2 – 3 medicine dosing sessions might be possible but adding in potentially up to 10 non-medicated therapeutic sessions would make the therapy much more challenging for patients and add significantly to patient costs without any attendant patient safety benefits.

In other words, the TGA's position discriminates against patients and therapists who don't live close to the clinic where the medicine dosing sessions occur, unnecessarily inconveniences the therapists and patients involved and does not provide any clear safety benefits.

To summarise our views about the appropriate level of AP psychiatrist oversight during the preparation, medicine dosing and integration sessions:

1. **In relation to the medicine dosing sessions** -The AP psychiatrist *should not be required* to be physically present on site during the medicine dosing session (if the psychiatrist chooses not to be) provided that:

   i. The psychiatrist is available at all times by phone to provide any advice sought by the therapists involved:
   ii. The clinic has appropriate safety procedures in place to deal with a medical emergency; and
   iii. If the psychiatrist is not at the clinic an appropriately trained medical practitioner or nurse is on hand in the unlikely event that a medical emergency occurs.

2. **In relation to the preparation and integration sessions** -There is no reason why these sessions need to take place at the clinic where the dosing sessions occur or for the psychiatrist to be in the same physical location at the therapist conducting these sessions. Why is a distinction being made by the TGA between non-medicine therapy sessions for psychedelic-assisted therapy and other forms of non-medicalised therapy? Stating that the preparation and integration sessions should take place in a professional environment accessible by both the therapist involved and the patient should be sufficient. This could for example be the therapist's professional consulting rooms or a more conveniently located non–specialised clinic or via telehealth for patients from regional and rural areas.

3. **When the AP psychiatrist is not physically involved in the preparation, medicine and integration sessions, we believe an appropriate level of oversight would require the psychiatrist to ensure that**:

   i. The lead therapist for each session provides the psychiatrist with regular written updates of each therapeutic session (preparation, dosing and integration, as the case may be) focusing on whether any significant issues arose for the patient and any safety issues that were identified during the session.
   ii. The medical practitioner or nurse in attendance at the clinic during each medicine dosing session provides the psychiatrist with written advice on whether any safety issues arose and the patient's vital signs before, at appropriate intervals during, and immediately after the medicine dosing sessions.
   iii. The psychiatrist is directly involved in the final session where outcomes are discussed with the patient and plans and recommendations are made about the patient's future.

6. Comments on the TGA's Fourth Recommendation; Appropriate Site Location

Most published late phase clinical trials to date have shown that MDMA and psilocybin can be administered to patients in medically controlled environments with a high level of safety (Goodwin et al., 2022; Mitchell et al., 2023).

It is important to recognise the unique aspects of psychedelic-assisted therapy. The medicine dosing sessions, as developed in clinical trials, involve the patient taking capsules containing the medicine (either MDMA or psilocybin) with two therapists present at all times and a doctor or nurse on hand. This medicine dosing session takes place within a single

appropriately furnished room with easy access to toilet facilities, given sessions can last 6-8 hours.

The key point that we would ask the TGA to recognise is that from a patient safety perspective, this treatment doesn't need to be part of a substantial facility to support the delivery of these medicines.

What is necessary is that the clinic where the medicine dosing sessions are to occur has in place:

i. An appropriately furnished and quiet room to enhance the comfort of the patient and to avoid distractions.
ii. Appropriate safety protocols in place approved by the AP psychiatrist to deal with an emergency, however unlikely.
iii. A commitment to support the treatment protocols that were approved as part of the psychiatrist's application to become an AP.
iv. Appropriate storage facilities for Schedule 8 medicines as per state/territory requirements.
v. Rescue medication and medical devices on hand to deal with any patient emergencies in the unlikely event that this occurs.
vi. A medical practitioner or nurse on hand with appropriate training to deal with medical emergencies and to monitor the vital signs of the patient at regular intervals.
vii. Proximity to an accredited healthcare facility with an emergency department for potential episodes of acute deterioration (which hasn't been necessary to date in any of the clinical trials around the World).
viii. The required permits to operate from the State/Territory Authorities if mandatory

As discussed in Section 5:

a) We see no reason why the AP psychiatrist (if not part of the therapy dyad) needs to be onsite during the medicine dosing sessions provided that the requirements that we recommend in that section are followed.

b) We also don't see any rationale for insisting that preparation and integration sessions have to occur at the same place as the medicine dosing sessions.

It should also be recognised by the TGA that hospital environments can feel overly clinical and impersonal and they can even be triggering for patients with trauma-related conditions. Community-based settings, when appropriately equipped, can offer a more calming and therapeutic environment better suited to intensive psychotherapy.

Insisting that treatments should only occur at public or private hospitals will severely disadvantage patients and clinicians by making access to these therapies much harder for many patients and significantly increasing costs. Indeed, the NSW Government originally adopted such a requirement after the rescheduling of MDMA and psilocybin was announced. However, the NSW Government removed this requirement last year in response to representations from Mind Medicine Australia and other interested parties, thereby allowing dosing sessions to occur in NSW in outpatient clinics with the appropriate facilities (see above). A copy of our submission to NSW Health is available to the TGA on request.

7. Other Matters

There are three other matters that we would like to raise with the TGA that relate directly to patient access and patient costs:

(i) Number of therapists for each therapeutic session

In order to safeguard the patient, best practice requires two therapists to be in the therapy room with the patient during the medicine dosing session and for these sessions to be video recorded. This is to minimise any risk of inappropriate conduct by a therapist which breaches professional boundaries and to have a record if any allegations are subsequently raised.

This requirement is based upon the fact that during the medicine dosing session the patient is in an altered state and therefore more vulnerable.

Given the long nature of the medicine dosing sessions there may also be a patient benefit from a therapeutic perspective with having two therapists present.

However, we see no reason to insist that two therapists must participate in the preparation and integration sessions. This is simply because during those sessions the patient *is not* in an altered state. Patients (some with very serious mental illnesses) routinely receive conventional therapy from only one therapist. Why should the preparation and integration sessions associated with psychedelic-assisted therapy be any different and why is the TGA seeking to regulate it in this way?

It seems to us inappropriate to differentiate the requirements for non-medicated therapy which is part of psychedelic-assisted therapy from non-medicated therapy outside of this treatment modality. All that such a requirement achieves is increased patient costs, worse patient accessibility and an overuse of therapist time when there is an acute shortage of therapists in Australia.

(ii) Use of distance videoconferencing for preparation and integration sessions

Videoconferencing (where patients and their mental health practitioner are in different physical locations) has become a normal part of psychotherapy sessions in Australia today. In our view there is nothing to differentiate preparation and integration sessions as part of psychedelic-assisted therapy from other forms of psychotherapy that currently utilise the convenience of video conferencing or telehealth.

Any requirement that preparation and integration sessions must take place in person and at the clinic where the medicine dosing sessions occur will severely disadvantage patients that don't live in geographic proximity to the clinic and the therapists involved. It would dramatically increase patient costs and accessibility, particularly with patients who have to journey into the clinic for the medicine dosing sessions from country areas.

Requiring preparation and integration sessions to take place on-site at the same clinic being used for the dosing sessions is not, in our view, evidence-based. Many of the clinical trials to date have utilised videoconferencing for preparation and integration.

We believe that the decision on whether preparation and integration sessions should be in person or by videoconferencing should be one for the AP psychiatrist and lead therapist to make based upon the circumstances of the patient.

(iii) Length of Time being taken by the TGA to review HREC approved applications by Psychiatrists to become Authorised Prescribers

Finally, we would ask the TGA to evaluate its own internal review processes as we believe that it is taking too long for the TGA to review HREC approved authorised prescriber applications from psychiatrists. Given that these applications have already been subjected to the rigour of a HREC approval process we believe that the TGA processes could be significantly quicker. We say this within the context of the dreadful patient suffering (and in some cases suicide) that we are seeing in the mental health area in Australia, the failure of current treatments for many patients and the need for a step-change in the way that patients are treated.

8. Peer Review and Further Information

8.1 Peer Review

In accordance with our practice when making submissions to regulatory bodies we have provided this document to the following experts, all of whom have provided their support:

Professor David Nutt – Head of Neuropsychology at Imperial College London for many years and one of the leading researchers in the World in Psilocybin and MDMA assisted therapies. In addition to his work as a researcher, Professor Nutt has also worked as a psychiatrist in the United Kingdom.

Dr Ted Cassidy – Chairman of Monarch Mental Health and one the leading psychiatrists practicing in the field of psychedelic-assisted therapies in Australia today. He is a graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies.

Dr Eli Kotler – A leading Melbourne based psychiatrist, a member of MMA's Board of Directors, co-leader of MMA's Certificate Course in Psychedelic-Assisted Therapies (https://cpat.mindmedicineaustralia.org.au/#faculty) and an Authorised Prescriber of MDMA and psilocybin practising in the field of psychedelic assisted therapy.

Dr Stephen Proud – A leading Western Australian psychiatrist with both hospital and outpatient clinic experience, a member of MMA's Board of Directors, an Authorised Prescriber of MDMA and psilocybin practising in the field of psychedelic assisted therapy. He is also a part of the faculty of MMA's CPAT training.

Dr Michael Winlo – Chief Scientific Officer and Executive Director of Emyria, which is pairing frontline clinical care with the development of psychedelic-assisted therapies guided by real-world data via their Empax Centre network operating in both community settings and private hospitals.

He holds a Bachelor of Medicine and Surgery from the University of Western Australia and an MBA from Stanford Graduate School of Business.

Dr Cliff Baxter – Psychiatrist based in the Northern Rivers Region with a speciality in treating addiction. Cliff is trained to deliver Psychedelic-Assisted Therapies and is a graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies course.

Dr Geri Dyer – A veteran psychiatrist with a strong background in public health and a focus on culturally and socially informed mental healthcare. She has worked extensively with diverse populations, including Aboriginal and Torres Strait Islander communities and refugees in international conflict zones. A Fellow of the Royal Australian and New Zealand College of Psychiatrists, she holds additional qualifications in child and adolescent psychiatry. Dr Dyer has been recognized for her contributions to Indigenous mental health with the RANZCP Mark Sheldon Award. She is also trained in the delivery of psychedelic-assisted therapies through MMA's CPAT course.

Dr Julian Dodemaide – Fellow of the Royal Australian and NZ College of Psychiatrists with extensive experience in forensic, addiction, and adult psychiatry. He holds a Certificate of Advanced Training in Forensic Psychiatry and is an active member of the Queensland Mental Health Review Tribunal. He has worked in various clinical settings, including high-security and prison mental health services, and specialises in medico-legal reports, risk assessment and providing expert evidence for the courts. Julian is qualified in the delivery of psychedelic-assisted therapies through MMA's CPAT course.

Dr James Heaney – A General Adult Psychiatrist with special interests including Mood disorders, Neurodivergence, Anxiety Disorders and Addictions. James is qualified in the delivery of psychedelic-assisted therapies through MMA's CPAT course.

Dr Arthur Hokin – Highly experienced psychiatrist with over 35 years of practice in both international and Australian settings. A Fellow of the Royal Australian and New Zealand College of Psychiatrists, he has worked extensively with a wide range of conditions, including treatment-resistant illnesses, personality disorders, anxiety, and depression. Dr Hokin is trained to deliver Psychedelic-Assisted Therapies and is a graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies course.

Dr. Claire King -Psychiatrist and co-director of the Daintree Clinic in Cairns, Australia. Dr King is trained to deliver Psychedelic-Assisted Therapies and is a graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies course. She specialises in general adult psychiatry with a focus on addiction treatment and difficult-to-treat mood disorders, such as treatment-resistant depression (TRD). The Daintree Clinic is a provider of psychedelic-assisted therapies. She is a Fellow of the Royal Australian and New Zealand College of Psychiatrists (FRANZCP) and holds an advanced certificate in addiction psychiatry.

Dr Lana Lubimoff – Psychiatrist with nearly 20 years of clinical practice, working with children, adolescents, and adults. Her areas of expertise include trauma, ADHD, anxiety, depression, autism, mood disorders, addiction, and women's mental health. She offers both medication-based and client-centred therapy, tailoring life management strategies to individual needs. Lana is a registered psychiatrist qualified to provide assessments for early superannuation release on compassionate mental health grounds. Dr Lubimoff holds a Bachelor of Medicine from UNSW, advanced training in child and adolescent psychiatry, and is a registered clinical psychotherapist and accredited supervisor with PACFA. She is also listed as an expert in psychiatry with the International Criminal Court and is a member of the Royal Australian and New Zealand College of Psychiatrists. Lana is trained to deliver Psychedelic-Assisted Therapies and is a graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies course.

Dr Paul Meens – Child & Adolescent Psychiatrist, has been working in mental health since 2006. He is an alumnus of MMA's CPAT training and is qualified to deliver Psychedelic-Assisted Therapies.

Dr Kevin Ong – Consultant forensic psychiatrist with 17+ years' experience leading teams in provision of quality care to high-risk and complex consumers in both in-patient and community settings. Proven track record of effective leadership in consumer care, developing teams, quality improvement, and providing innovative solutions to complex problems. He is a recent graduate of Mind Medicine Australia's Certificate in Psychedelic-Assisted Therapies.

Dr Matthew Ritson – A medical doctor, psychiatrist, and psychotherapist based in the Adelaide Hills. He specialises in Systemic Constellation work, a method for addressing the hidden origins of trauma in individuals, families, and organisations. He also facilitates nature-based constellations, exploring ancestral connections to the land, and offers services for both individuals and groups. Dr Ritson is trained to deliver Psychedelic-Assisted Therapies and is a graduate of MMA's CPAT training program.

Associate Professor Dr Jörg Strobel – Previously the Acting Clinical Director of Country Health SA Mental Health Services. He is a psychiatrist and psychotherapist with a background in forensic psychiatry and has over 30+ years of clinical experience. Dr Strobel is also an innovator in the field, having co-founded a software company that develops mobile-friendly self-management tools to enhance patient participation and empowerment. Dr Strobel has graduated from Mind Medicine Australia's Certificate in Psychedelic-Assisted therapies training program.

8.2 Further Information

Please contact Peter Hunt, Chairman of MMA, if you require any further information or if you would like us to arrange for you to meet with clinical members of our Board and Advisory Panel. Details of these researchers and clinicians can be found below:

- MMA Board
- MMA Advisory Panel

Peter Hunt can be contacted:

- By phone; 0419 271 483
- By email; peter@mindmedicineaustralia.org

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