# Submission
# from the Supporting Applicant

## Opposing

# The Delegate's Interim Decision Not to amend the Poisons Standard To Enable the Controlled Drugs (Schedule 8) entry of Psilocybine to include Existential Distress towards End of Life.

27 July 2026

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# 1. INTRODUCTION

## 1.1. Our Position

Mind Medicine Australia **(MMA)** is a registered health charity focused on alleviating human suffering through the development and clinical rollout across Australia of psychedelic assisted therapies for key mental illnesses *where the evidence in relation to safety and efficacy favours their use* – see www.mindmedicineaustralia.org.au.

MMA embarked on this mission in 2019 because it was very clear that current treatments did not work or did not work adequately for so many people who suffer from debilitating mental illnesses. It was also clear that the medications used by the medical profession could have serious side-effects for many patients (including in the case of SSRIs, nausea, sexual dysfunction, withdrawal challenges, dependence and, in some cases, suicidality) (Carvalho et al., 2016; Moret et al., 2009; Pannu and Goyal, 2025).

MMA was the successful applicant for the 2023 rescheduling of psilocybine as part of therapy for treatment resistant depression (**TRD**). MMA is supported by an extraordinary group of global experts in treating mental illness and in the research and clinical application of psychedelic assisted therapies - see:

- https://mindmedicineaustralia.org.au/ambassadors/
- https://mindmedicineaustralia.org.au/advisory-board/

MMA agreed to be named as the supporting applicant in the application made by palliative care group End Wise (www.endwise.au) for the extension of the Schedule 8 listing of psilocybine to cover existential distress towards end-of-life (**the Rescheduling Application**). We did this because of the enormous suffering of people with existential distress towards end of life and because we believed that the requirements for a Schedule 8 listing of psilocybine for this condition were clearly satisfied.

Endwise lodged this application with MMA's support in March 2025 (i.e. over 18 months ago). End Wise is a not-for- profit organisation which represents palliative care practitioners who understand the terrible existential distress that patients can go through as they face the end of their lives with the associated loss of identity, purpose, autonomy and connection.

Despite the Delegate's comments in the Interim Decision about lack of diagnostic criteria for existential distress towards the end-of-life, the symptoms are obvious to any practitioner working in the palliative care sector and include depression, anxiety and a loss of meaning as death draws near (Geber-Júnior, 2026; Graham, 2011; Horowitz et al., 2024). This condition is made worse by the fact that it can damage a patient's ability to interact harmoniously and positively with family members and friends during the remaining time that they have left.

We set out detailed diagnostic criteria for this condition in Section 2.2.2 (ACMS Proposition 2) below.

We believe that compassion (which is central to the existence of the TGA's compassionate access scheme) requires us all to help a person suffering from existential distress to find peace and harmony as they approach the closing stages of their lives. Compassion also extends to the person's family and close friends who can be traumatised by the patient's suffering.

This degree of suffering places a heavy onus on the Secretary of the Department of Health and Aged Care, the Delegate (acting for the Secretary) and the TGA (providing research support) to base their decision on an accurate and compassionate assessment of the supporting data.

**For the reasons given in this submission we respectfully disagree with the Delegate's Interim Decision. We firmly believe that there is sufficient evidence to justify extending the Schedule 8 listing of psilocybine to patients suffering from existential distress towards end-of-life.**

## 1.2. The Delegate's "on balance" decision and the principle of patient autonomy in end-of-life decisions.

The Delegate's interim decision to oppose the extension of the rescheduling to cover existential distress towards end-of-life was expressed by the Delegate to be an "*on balance*" decision. On page 14 of the Interim Decision the Delegate states that "*On balance, I agree that the current evidence base is not sufficient to support the proposal.*"

Both the Advisory Committee on Medicines Scheduling (**ACMS**) and the Delegate acknowledged that existential distress associated with end of life is a unique form of psychological distress (TGA, 2026b: 7). They also acknowledged that psilocybine is well tolerated (TGA, 2026b: 8).

However, the ACMS provided the Delegate with some extraordinary and ironical advice (which the Delegate appears to have accepted without questioning) that *"patient autonomy in end-of – life decisions is acknowledged through Voluntary Assisted Dying (VAD) (which is currently available across Australia in 7 jurisdictions) and is consistent with patients' rights in modern palliative care for choice over palliative treatments"* (TGA, 2026b: 7).

In other words, what the ACMS advised (and the Delegate appears to have accepted) is that our Government and Health Authorities believe that:

1. ***It is acceptable*** for a patient suffering intolerably from existential distress as they approach the end of their lives to be given medications that have low efficacy, can cause nasty side effects and blunt the patient's emotions and sense of self; and
2. ***It's also acceptable*** for a patient to voluntarily kill themselves if they meet the required VAD criteria outlined in Appendix A;
3. ***BUT It's not acceptable*** for a **fully informed and consenting patient** suffering from existential distress towards end of life to take psilocybine as part of therapy in a clinical environment watched

over by trained clinicians even though both the ACMS and the Delegate acknowledge

(a) the tolerability and safety of psilocybin (TGA, 2026b: 8); and

(b) the positive results achieved in a number of clinical trials (TGA, 2026b: 9–11).

***This is a very strange interpretation of patient autonomy in end-of-life decisions.***

The Delegate (advised by the ACMS) acknowledges in the Interim Decision:

(i) The importance of patient autonomy in end-of-life decisions.

(ii) That psilocybine is well tolerated.

(iii) That there are clinical trials that have been conducted at major institutions overseas and in Australia that indicate that psilocybine -assisted therapy can relieve existential distress towards end-of-life.

(iv) That an integral part of the Rescheduling Application was the professional judgement of palliative care specialists and the patient giving fully informed consent to receiving the treatment.

Given these acknowledgements our question to the Delegate, the Secretary of the Department of Health and Aged Care (who the Delegate acts for) and the TGA is this:

*Shouldn't compassion for people suffering from existential distress at an incredibly vulnerable time in their lives lead to the Delegate making a decision to enable properly informed and consenting patients to access this treatment in a clinical environment? Doesn't compassion and patient treatment autonomy demand this?*

## 1.3. The Need for Flexibility because People are Suffering

In the Interim Decision both the ACMS and the Delegate raised several "*technical*" barriers to extending the Schedule 8 psilocybine entry to existential distress towards end-of-life. We deal with each of these "*technical*" barriers in detail later in this submission but summarise them here:

(i) Limited evidence of therapeutic efficacy and safety of psilocybine-assisted therapy in the treatment of existential distress towards end-of-life.

(ii) Lack of clarity regarding diagnostic criteria for existential distress towards end -of- life, treatment protocols, product and dosage levels.

(iii) Lack of clarity in relation to the accreditation process for specialist prescribers and identification of reviewing practitioners.

(iv) Lack of clarity in relation to the mechanisms for controlling the dispensing of psilocybine.

(v) Lack of clarity in relation to the regulatory impact of implementing the decision in each State and Territory of Australia.

(vi) Concerns over the potential for abuse.

(vii) The need for input from key stakeholders.

With the exception of diagnostic criteria, all of the above issues were also considered to be issues by the then Delegate when the Interim Decision in relation to the psilocybine rescheduling application for treatment resistant depression was publicly released in October 2022. However, each one of these issues was dealt with satisfactorily in the Final Decision because the then Delegate recognised the suffering of people with treatment resistant depression and was prepared to be proactive in finding solutions. In particular, the use in the Final Decision of the TGA's Authorised Prescriber Scheme was an innovation driven by the TGA itself and not by the Applicant.

**These so called "*technical barriers*" are all capable of being solved as we discuss later in this submission. All that's required is for the Delegate, the Secretary of the Department of Health and Aged Care and the TGA to have the right mindset. We provide the solutions in Sections 2 and 3 below.**

In the Interim Decision, the Delegate argued that

(i) there was limited evidence to support the therapeutic efficacy and safety of psilocybine-assisted therapy in the treatment of end-of-life distress states; and there was a need for input from key stakeholders.

As we will see in Sections 2 and 3 below, the evidence supporting the therapeutic efficacy and safety of psilocybine-assisted therapy for end- of-life distress is actually at least as good as (and in some cases better) than the evidence that the then Delegate relied on to support the original 2023 psilocybine rescheduling decision.

The key stakeholders have had plenty of time to input into this process given that the Rescheduling Application was lodged in March 2025. People who are suffering from existential distress as they approach the end of their lives simply do not have the luxury of time.

## 1.4. Comparison with the VAD Requirements which enable people suffering intolerably to legally kill themselves

Voluntary assisted dying (VAD) is now lawful in every State of Australia and will shortly be available in the ACT. In every one of these jurisdictions, the parliament has entrusted medical practitioners with the authority to prescribe, and in some circumstances administer, medication for the purpose of intentionally ending a patient's life (see **Appendix A**).

Although each jurisdiction differs slightly, VAD legislation uniformly requires strict eligibility criteria, including that the patient is an adult with decision-

making capacity, has an advanced, incurable and progressive illness expected to cause death within a prescribed timeframe, is experiencing suffering they consider intolerable, and makes repeated voluntary and informed requests free from coercion. The process requires independent medical assessments, documentation, mandatory statutory safeguards and ongoing regulatory oversight.

Importantly, the patient's suffering may include existential or psychological suffering arising from their terminal illness, not merely physical pain. These regimes therefore recognise that end-of-life suffering extends beyond physical symptoms and may justify access to highly regulated (and deadly) medical interventions.

The significance of these legislative schemes is not to compare psilocybin-assisted therapy with VAD as equivalent interventions. Rather, they demonstrate that Australian governments have already accepted that, where patients are approaching the end of their lives and appropriate safeguards exist, clinicians can be entrusted with making profoundly significant treatment decisions, including prescribing medication that intentionally ends life.

Against that background, it is difficult to accept that alleged "*technical barriers*" should prevent access to a treatment that does not end life but instead seeks to alleviate existential distress and therefore enhance the remaining part of a person’s life. The regulatory and clinical safeguards required for psilocybin-assisted therapy are considerably less complex than those already operating successfully within Australia's VAD frameworks. If governments have demonstrated the capacity to establish safe and effective systems for VAD, there is no principled reason why solutions cannot be implemented for psilocybin-assisted therapy.

## 1.5. The Enormous Support Received by the TGA for the Rescheduling Application

### 1.5.1. <u>The High Calibre of Researchers and Clinicians Specifically Named in the Rescheduling Application as Supporters of the Proposal</u>

The Rescheduling Application lodged by End Wise received direct support noted in the document from leading researchers and practitioners from around the world.

These included;

(i) 24 psychedelic and palliative care professionals from Switzerland where psilocybin-assisted therapy has been judiciously used in palliative care for many years (See letter attached to the Rescheduling Application)

(ii) Leading psychedelic assisted therapy researchers from the United States (including Dr William (Bill) Richards and Dr Bessel van der Kolk) and from the UK (including Professor David Nutt and David Erritzoe).

### 1.5.2. <u>The Enormous Support Given to the Rescheduling Application in Australia by Experts in this Field, People with Lived Experience and Members of the Public</u>

In the Interim Decision the Delegate states that there were 595 public submissions that were lodged with the TGA before the closing date of which 590 were in favour of the Rescheduling Application, 3 submissions were partly in favour and only 2 submissions were against.

***In other words, according to the Delegate's own numbers, over 99% of the submissions lodged supported the Rescheduling Application. This was even higher than the extraordinary 97% support level that was received for the successful 2023 psilocybine rescheduling application.***

The Delegate went on to say in the Interim Decision that of the 595 submissions lodged, 316 provided written justification including the two that were not in favour. The Delegate also made it clear that both the Advisory Committee on Medicines Scheduling (**ACMS**) and the Delegate had considered these public submissions - as they are required to do under their governing legislation - as part of their decision-making process.

The TGA has only published 534 of the 595 submissions received on its website, meaning that 61 submissions have been held back from public access by the TGA (for reasons which haven't been explained).

Our analysis shows that of the 534 published submissions, 12 didn't address the psilocybine rescheduling application in any way. These 12 submissions only commented on other substances being assessed by the TGA in the same rescheduling assessment period. Of the balance of 522 published submissions 515 supported, 3 partially supported and 4 opposed the psilocybine Rescheduling Application.

Given the comments made by the Delegate about the level of support received we have to assume that all of the 61 submissions that haven't been published by the TGA supported the psilocybine rescheduling application.

As shown in **Table 1** below, our analysis therefore suggests slightly different numbers to the numbers published by the Delegate in the Interim Decision. **But the numbers are still overwhelmingly (99%) in favour of the Rescheduling Application**.

As you will see from Table 1 below, 183 respondents, equal to 35% of the published submissions, were from **registered healthcare professionals**. These people are at the frontline in dealing with mental illness in Australia and understand the degree of suffering and the failure of current treatments for so many people. 181 of the 183 were fully supportive of the rescheduling application and 2 were partially supportive (but didn't provide an explanation of what partial support meant).

A further 27 or 5% of the published submissions were from **professional researchers.** These people should be perfectly capable of analysing the

research data on the use of psilocybin-assisted therapy for existential distress towards end of life and they were all in favour of the proposal.

**Table 1. Breakdown of Psilocybine Submissions Received by Respondent Type**

| Respondent Type | Support | Partially Support | Oppose | Total | % of Disclosed Respondents |
|---|---|---|---|---|---|
| Registered healthcare professional | 181 | 2 | 0 | **183** | 35% |
| Consumer / patient | 67 | 0 | 0 | **67** | 13% |
| Professional researcher | 27 | 0 | 0 | **27** | 5% |
| Organisation | 11 | 1 | 4 | **16** | 3% |
| None of the above / I am responding out of personal interest | 229 | 0 | 0 | **229** | 44% |
| **Total Published By TGA** | **515** | **3** | **4** | **522** | **100%** |
| Not Publicly Disclosed | 61 | — | — | 61 | — |
| **Total Received By TGA** | **576** | **3** | **4** | **583** | — |

### 1.5.3. Partial Support for the Rescheduling Application.

The **Australia and New Zealand Society of Palliative Medicine** (**ANZSPM**) (a palliative care peak body) only partially supported the psilocybine rescheduling proposal.

In its submission to the TGA, **ANZSPM** expressed the belief that psilocybin-assisted therapy had the potential *"...to significantly benefit patients at the end of life"*. However, they described the data available to demonstrate safety and efficacy as "limited", something that we disagree with as described in Sections 2.2 (ACMS Proposition 1) and Section 3 (Analysis of the Delegate's Advice) below.

ANZSPM go on to say that because of this evidentiary issue, their support for extending the Schedule 8 listing of psilocybine to existential distress towards end-of-life came with 4 four "critical" qualifications;

(1) The treatment should initially only be continued within a research framework.
(2) Prescription rights should be restricted to psychiatrists or palliative care specialists who have undergone specific training in this area.
(3) Rigorous safeguards must be put in place.
(4) A strong clinical governance framework must be put in place.

We strongly agree with points (2), (3) and (4) above. In our view, these issues can all be managed under the TGA's Authorised Prescriber Scheme, as they have already been with the use of psilocybine for treatment resistant depression. With the Authorised Prescriber Scheme the Human Research Ethics Committee involved reviews the proposed prescriber's protocols, adequacy of training, experience, clinical governance and so on. It's also worth noting that the same arguments were raised in relation to our original application for the rescheduling of psilocybin for treatment resistant depression and the outcomes to date have been exemplary.

ANZSPM's first point above has massive implications because it would deny virtually all end-of-life patients suffering from existential distress access to psilocybine-assisted therapy treatments. Clinical trials take a long time to conduct and being able to access a clinical trial when a patient is approaching death would be akin to winning a lottery. As we discuss in Sections 2.2 (ACMS Proposition 1) and Section 3 below, the data supporting the use of psilocybine-assisted therapy for existential distress towards end of life is far more advanced than the ANZSPM suggests.

## 1.6. Opposition to the Rescheduling Application

The four organisations that opposed the Rescheduling Application consisted of three pharmacy peak bodies and one palliative care peak body:

(1) The Pharmacy Guild of Australia;
(2) The Pharmaceutical Society of Australia;
(3) Advanced Pharmacy Australia; and
(4) Palliative Care Australia.

At the heart of the **Pharmacy Guild's** reasoning was that they didn't support "*...measures that promote increased access to unapproved medicines [which] potentially disincentivise sponsors to register their products with the necessary supporting evidence base".* This is an argument against the use of compassionate access schemes which are available in most jurisdictions around the world to allow patient access to unapproved medicines on compassionate grounds precisely because of the absence of available registered medicines that can adequately deal with a patient's illness.

The Pharmacy Guild give medical cannabis as an example of the problems associated with giving patients access to unapproved medicines but the Pharmacy Guild fails to recognise that patients seek to access medical cannabis precisely because the existing registered medicines aren't working for them. They also fail to recognise that psilocybine-assisted therapy is very different to prescribing cannabis because the psilocybine dosing session will only take place in medically controlled environments. Furthermore, unlike medicinal cannabis, there will be two clinicians with the patient at all times during the dosing session and the patient will never be allowed to take the medicine home.

The Pharmacy Guild seems to also completely ignore the pain and suffering of the patient and the principle of patient treatment autonomy in palliative care situations.

**The Pharmaceutical Society of Australia** has clearly not read the underlying clinical trials which we list in Table 3 of Section 2.2.1 below and

like the Pharmacy Guild express the belief that *"access is better facilitated through a clinical trial (or similar arrangement) under the S9 entry"*. Given that there have only been two clinical trials in Australia in this area in the last 10 years (compared to multiple clinical trials overseas) what this comment fails to acknowledge is that the chances of a patient who is suffering existential distress towards end of life of being able to access a clinical trial is virtually zero.

**Advanced Pharmacy Australia (APA)** and **Palliative Care Australia** (**PCA)** each base their opposition to the Rescheduling Application on three broad arguments:

**(i)** **Practicalities**. A lack of clarity in the Rescheduling Application around clinical and implementation issues (including qualifications and the training of the proposed prescribers and the other clinicians involved and the model of care to be used).

**(ii)** **Evidence.** A belief that whilst the evidence from clinical trials was promising it wasn't sufficiently established to justify extending the application of the current Schedule 8 listing of psilocybin to existential distress towards end-of life.

**(iii)** **Engagement.** A lack of sufficient engagement to date with the palliative care sector to ensure safe, appropriate and sustainable implementation across care settings

Our response to each of these broad areas is set out below.

**(i)** **Practicalities.** The nature of innovation is always that new ways of doing things have to be developed and this is exactly what has occurred in Australia since psilocybin became a Schedule 8 treatment in 2023 for patients suffering from treatment resistant depression. MMA has itself trained ove 700 clinicians in the use of these therapies (see https://cpat.mindmedicineaustralia.org), our course has been recognised by the Australian Medical Association CPD Standards as well as other qualifying organisations (https://cpat.mindmedicineaustralia.org.au/#course-accreditation) and the testimonials that we have received from

clinicians have been outstanding (see https://cpat.mindmedicineaustralia.org.au/#testimonials. New medicine supply lines have been developed through the pharmacy network, protocols and standard operating procedures have been rigorously reviewed by Human Research Ethics Committees, specialist clinics have been rolled out across Australia, over 100 patients have been treated with psilocybin-assisted therapy, reported outcomes from psychiatrists have been excellent and there have been no severe adverse events reported to the TGA (TGA, 2026a).

If the Delegate approves the proposed extension of the Schedule 8 listing of psilocybine to existential distress towards end-of-life the health system will adapt under the watchful stewardship of the Human Research Ethics Committees involved, the TGA and the relevant peak bodies.

**(ii). Evidence.** The lack of a solid evidentiary base to support the proposed rescheduling is simply not correct (see Section 2.2.1 below).

**(iii). Engagement.** Engagement with the palliative care sector is inherent in the rollout of these therapies (as it has been with the equivalent peak bodies in the rollout of psilocybin-assisted therapy for treatment resistant depression and MDMA assisted therapy for PTSD).

**The critical question** that neither APA nor PCA address in their submissions is this. Is it appropriate to deny a fully informed and consenting patient suffering from existential distress towards the end-of-life access to psilocybin-assisted therapy when:

- the patient has been properly assessed by a trained clinician;
- the dosing session will take place in a medically controlled environment, with two trained clinicians in attendance at-all-times;
- the safety data supporting these therapies is strong (see Section 2.2.1); and

- the protocols to be followed and the experience and training of the authorised prescriber will have been vetted by a Human Research Ethics Committee?

### 1.5.5 Summary

In summary, the Delegate received overwelming support for the Rescheduling Application. We believe that the arguments outlined above that have been used to justify opposing the rescheduling or only giving the rescheduling qualified support can all be adequately dealt with by the Delegate through the Authorised Prescriber Scheme (just as they were for psilocybine for treatment resistant depression). It all depends upon the compassion and preparedness to act of the Delegate, the TGA and the Department of Health and Aged Care. If the Delegate, the TGA and the Department of Health and Aged Care want these medicinal therapies to be available to patients going through enormous suffering they have the same authorised prescriber methodology available to them which the then Delegate used to support the 2023 rescheduling of psilocybin.

## 1.6 Ethical considerations

Ethical considerations should be a critical part of the Delegate's decision on whether to extend the rescheduling of psilocybine so that it can be made available as part of therapy to fully informed and consenting patients suffering existential distress towards the end of their lives.

We deal below with all of the "technical barriers" raised by the ACMS (and accepted b y the Delegate) to an extension of the Schedule 8 listing. In our view, all of these "technical barriers" can be adequately dealt with.

In our view the best person to comment on the ethical issues involved with the proposed rescheduling is Dr Simon Longstaff, the Executive Director of the Ethics Centre and Australia's pre-eminent ethicist. Dr Longstaff

explained his position eloquently in his submission to the TGA in relation to our original psilocybin rescheduling application for treatment resistant depression when he said the following (which is directly applicable to the current application):

***"In summary: the alleviation of human suffering cannot always await the attainment of perfect knowledge. The greater the suffering, the greater the requirement to apply a test of sufficiency. Or, perhaps, to sharpen the point – there is a prima facie ethical obligation to alleviate avoidable suffering. That obligation can only be set aside in the face of compelling evidence that the means available to relieve suffering would cause more harm than the suffering itself. The current evidence does not support such a conclusion when it comes to the clinical use of MDMA and psilocybin."***

**(**https://mindmedicineaustralia.org.au/wpcontent/uploads/Submission-TGA-Interim-Decisions_FINAL_241122.pdf page 12**).**

## 2. ANALYSIS OF THE ACMS ADVICE

### 2.1. Relevant Experience

We note at the outset that the ACMS, which is advising the Delegate on the Rescheduling Application, doesn't appear have any expertise in mental health treatments and palliative care. There appear to be no psychiatrists, psychologists or palliative care clinicians on the Committee.

We also have not been told whether the Delegate (an unnamed person) has any expertise in mental health treatments and palliative care.

Given the overwhelming support that the Rescheduling A-pplication received we believe that it's critical that the Delegate specify exactly where the Delegate is getting expert advice from and the content of that advice.

Public confidence in the TGA depends in large part on the transparency of the decision-making process.

**As mentioned in Section 1.1 above, MMA benefits from a World-leading expert advisory panel. We would be very happy to arrange for members of the panel to present to the Delegate and the ACMS on the therapeutic value of psilocybine when used as part of therapy for existential distress towards end-of-life and methodology issues**

## 2.2. Analysis of the 7 ACMS Propositions

The ACMS advice to the Delegate, (as reported by the Delegate in the Interim Decision) was based on seven propositions.

1. Limited evidence of therapeutic efficacy and safety of psilocybine-assisted therapy in the treatment of end -of -life distress.
2. Lack of clarity regarding diagnostic criteria for existential distress at end of life, treatment protocols, product and dosage.
3. Lack of clarity in relation to the accreditation process for specialist prescribers and identification of reviewing practitioners.
4. Lack of clarity for the mechanisms for controlling dispensing of psilocybine.
5. Lack of clarity of the regulatory impact of implementing the decision in each State and Territory of Australia.
6. Concerns over the potential for abuse.
7. The need for input from key stakeholders.

We analyse the ACMS arguments for each proposition below.

### 2.2.1. ACMS PROPOSITION 1: Limited evidence of therapeutic efficacy and safety of psilocybine-assisted therapy in the treatment of end -of -life distress.

As we are dealing with an unregistered medicine, rescheduling does not require us to meet the standards prescribed by the TGA for registration of a medicine on the Australian Register of Therapeutic Goods (ARTG).

Furthermore, the policy criteria set out in the Scheduling Policy Framework for Medicines and Chemicals approved by the Australian Health Ministers' Advisory Council (December 2017) is a "best fit" approach. In the present case the question to be answered is this. Is the "best fit" for the use of psilocybine for existential distress towards end-of- life the criteria in Schedule 8 or the criteria in Schedule 9 of the Poisons Standard?

Schedule 8 states that "*The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use*".

Schedule 9 states that "*The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use*".

We deal with "*dependency, abuse, misuse and illicit use"* in ACMS Proposition 6 below. Suffice to say that there is no evidence from any of the approximately 100 psilocybine clinical trials that have been completed over the last 20 years that psilocybine produces dependency when given in clinical environments (Lowe et al., 2021; Passie et al., 2002; Studerus et al., 2011). This is also true when psilocybine is used in the recreational domain (Martinotti et al., 2018; Murrie et al., 2020). The risks of misuse and abuse are far greater for substances such as ketamine and morphine that are already in Schedule 8 of the Poisons Standard than they are for psilocybine (van Amsterdam et al., 2015; Bonomo et al., 2019; Nutt et al., 2010).

In the 2023 rescheduling decision the Delegate had to answer the question about which scheduling criteria was most appropriate in relation to the use

of psilocybine for treatment resistant depression (**TRD**). The Delegate concluded that "*the therapeutic value of psilocybine was not yet fully established"* but that the best fit for psilocybine for TRD was Schedule 8.

Since the 2023 psilocybine rescheduling decision for TRD, Compass Pathways (**Compass**) has published the results of its Phase 2b trial, Usona has published the results of its Phase 2 trial and Compass has finished its Phase 3 trials and published the headline results. All of these results demonstrate the therapeutic value of psilocybine in a statistically significant way ((A. L. Back et al., 2024; Compass Pathways 2026).

Compass announced a headline summary of its Phase 3 trial results on February 17, 2026 and stated clearly that the results demonstrated a "*clinically meaningful effect, with a generally well tolerated and safe profile'* (Compass Pathways, 2026). Compass expanded on this statement in its May investor presentation in the manner set out in **Table 2**.

**Table 2. Key Takeaways Highlighted by Compass from its Phase 3 TRD Psilocybine Trials (May 2026)**

| Rapid Onset | Deep and Durable Clinical Effects | Well-tolerated safety profile |
|---|---|---|
| Statistically significant improvement demonstrated from the day immediately following administration and maintained at all measured timepoints through Week 6 in both clinical trials | 25% of participants in COMP005 (Phase 3 Trial 005) achieved a clinically meaningful reduction in MADRS*** at Week 6 with durability through to at least 26 weeks following 1 or 2 doses of 25 mg | COMP360 (psilocybin medication) was generally well-tolerated, with a safe profile, with majority of AEs resolving on the day of treatment |
| | >40% of those that had a clinically meaningful reduction in MADRS who had not remitted by Week 6 achieved remission after a 2nd dose in COMP005 Part B | |
| | 39% of participants in COMP006 (Phase 3 Trial 006) achieved clinically meaningful reduction in MADRS at week 6 | |

*****Clinically meaningful reduction in MADRS defined as a >25% reduction from baseline in MADRS total score**

Source:https://s204.q4cdn.com/927483861/files/doc_presentations/2026/May/13/FINAL_CMPS-investor-presentation_MAY2026-1.pdf

On 7th July 2026 Compass announced its 6 month follow up data and stated that the data *"...demonstrates durable benefits through at least 6 months validating [psilocybine's] differentiated product profile in highly chronic TRD..[and] continues to demonstrate a generally well-tolerated and safe profile with no new safety findings"* (Compass Pathways, 2026).

All of this evidence that has emerged since the March 2003 Rescheduling decision should resolve, for the current Delegate, any ambiguity in the 2023

Delegate's assessment of the therapeutic value of psilocybine for TRD in favour of established therapeutic value. Surely there can no longer be any doubt about this in relation to the use of psilocybine for TRD.

Our view that the therapeutic value of psilocybine has been established is reinforced by the results being achieved in the clinical roll out in Australia of psilocybine-assisted therapy for TRD. The feedback to date in relation to efficacy has again been positive for most patients and the safety profile reported in clinical trials has been confirmed in clinics across Australia.

The Delegate justifies its decision not to extend this evidence to the current rescheduling application because of the Delegate's view that there have been only three trials using psilocybine-assisted therapy to treat existential distress towards end of life.

**However, this view of the Delegate is not accurate.**

The published literature records:

(i) at least nine completed clinical trials in international settings, plus one Australian trial at St. Vincent's Hospital Melbourne, using psilocybine to treat existential distress towards end of life;

(ii) a systematic review and a meta-analysis, and

(iii) two long-term follow-up studies.

The three trials that the Delegate appears to be relying on (John Hopkins, New Your University and St Vincent's Hospital) include two of the earliest and most cited clinical trials (Johns Hopkins and New York University), but the evidence base has grown substantially since the time that those studies were conducted. The methodology used and results achieved in all the ten clinical trials mentioned above have been broadly consistent, with high safety levels and large effect sizes. A summary of the published literature is set out in **Table 3** below.

## Table 3. Summary of Published Literature on Use of Psilocybine for Existential Distress Towards End-of-Life

| Results Published | | Study Details | | | | Participant Details | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Author** | **Link** | **Type** | **Masking** | **Control** | ***n*** | **Location** | **Population Group** | **Health Condition(s)** | **Dose** | **Key Outcomes** |
| Yu et al. (2026) | DOI | Medical Access | — | — | 1603 | US | End-of-Life Care | Existential Distress | not specified | Medical access survey of 1,603 individuals receiving psilocybin-assisted therapy for end-of-life existential distress; real-world outcomes reported. |
| Back et al. (2026) | PMID: 42058096 | Clinical Trial | Open | None | 15 | US | Metastatic Cancer | Cancer-Related Anxiety | 35 mg w optional 10 mg booster | Psilocybin-assisted therapy was feasible and well tolerated in patients with metastatic cancer and cancer-related anxiety. |
| Beaussant et al. (2026) | PMID: 41184102 | Clinical Trial | Open | None | 15 | US | Palliative Hospice Care Cancer | Demoralisation | 25 mg | Single-dose psilocybin-assisted therapy was feasible and acceptable for hospice patients experiencing demoralisation. |
| Dwyer et al. (2026) | PMID: 41418682 | Follow Up | — | — | 10 | AU | Life-Threatening Illness | Depression and Anxiety | 25 mg | Follow-up analysis demonstrated durability of improvements in depression and anxiety following psilocybin-assisted therapy. |
| Downar et al. (2026) | PMID: 41617652 | Clinical Trial | Open | None | 20 | CA | Palliative Care | Psychological and Existential Distress | 1–3 mg | Psilocybin microdosing was feasible and acceptable in palliative care patients with psychological and existential distress. |
| Matos et al. (2026) | PMID: 41410211 | Secondary Research | — | — | 6 | PT | Palliative Care | Depression, Anxiety, Existential Distress | — | Systematic review concluded that psilocybin-assisted therapy shows promise for reducing depression, anxiety and existential distress in palliative populations. |

| Results Published | | Study Details | | | | Participant Details | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Author** | **Link** | **Type** | **Masking** | **Control** | ***n*** | **Location** | **Population Group** | **Health Condition(s)** | **Dose** | **Key Outcomes** |
| Ross et al. (2025) | PMID: 40858059 | Clinical Trial | Quadruple | Yes | 35 | AU | Life-Threatening Illness | Depression and Anxiety | 25 mg | Significant reductions in depression and anxiety were observed; 71% improved and 54% achieved remission four weeks after treatment. |
| Youngblood and Zarrabi (2025) | ScienceDirect | Clinical Trial | Open | None | 11 | US | Palliatice Care Cancer | Demoralisation | | Psilocybin-assisted therapy demonstrated potential for reducing demoralisation in palliative cancer care. |
| Back et al. (2024) | PMID: 40051480 | Clinical Trial | Open | None | 52 | US | Metastic Cancer | Depression, Anxiety | 25 mg | Psilocybin-assisted therapy was associated with reductions in depression and anxiety in patients with metastatic cancer. |
| Schipper et al. (2024) | PMID: 39260823 | Secondary Research | — | — | 2 | UK | Life-Threatening Illness | Depression, Anxiety, Existential Distress | — | Review identified emerging evidence supporting psilocybin-assisted therapy for psychological and existential distress associated with life-threatening illness. |
| Patchett-Marble et al. (2022) | PMID: 36376043 | Expanded Access | — | — | 1 | CA | Palliative Lung Cancer | Existential Distress | 5 g dried *psilocybine cubensis* | Case report described marked improvement in existential distress and psychological wellbeing following psilocybin use in palliative lung cancer. |
| Yu et al. (2021) | PMID: 34619818 | Secondary Research | — | — | 5 | TW | Life-Threatening Illness | Anxiety | — | Meta-analysis found psilocybin-assisted therapy was associated with reductions in anxiety among patients with life-threatening illness. |

| Resulted Published | | Study Details | | | | Participant Details | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Author** | **Link** | **Type** | **Masking** | **Control** | ***n*** | **Location** | **Population Group** | **Health Condition(s)** | **Dose** | **Key Outcomes** |
| (Ross et al., 2021) | PMID: 33860185 | Follow Up | Open | None | 11 | US | Life-Threatening Cancer | Psychiatric and Existential Distress | 0.3–0.35 mg/kg ≡ 21–24.5/70kg | Long-term follow-up suggested sustained improvements in psychiatric and existential distress after psilocybin-assisted therapy. |
| (Anderson et al., 2020) | PMID: 33150319 | Clinical Trial | Open | None | 30 | US | Palliative Care AIDS | Existential Distress and Grief | 0.3–0.35 mg/kg ≡ 21–24.5/70kg | Pilot study found psilocybin-assisted therapy may reduce demoralisation, grief and existential distress in long-term AIDS survivors. |
| Patchett-Marble et al. (2022) | PMID: 36376043 | Expanded Access | — | — | 4 | CA | Life-Threatening Cancer | Existential Distress | — | Expanded-access experience reported feasibility of psilocybin use in palliative care settings. |
| (Agin-Liebes et al., 2020) | PMID: 31916890 | Follow Up | Quadruple | Yes | 29 | US | Life-Threatening Cancer | Depression, Anxiety | 0.3 mg/kg ≡ 21 mg/70kg | Benefits observed in the original trial remained durable for several years after treatment. |
| (Ross et al., 2016) | PMID: 27909164 | Clinical Trial | Quadruple | Yes | 29 | US | Life-Threatening Cancer | Anxiety, Psychosocial Distress | 0.3 mg/kg ≡ 21mg 70 kg | High-dose psilocybin produced substantial and sustained reductions in anxiety, depression and psychosocial distress associated with life-threatening cancer. |
| (Griffiths et al., 2016) | PMID: 27909165 | Clinical Trial | Quadruple | Yes | 51 | US | Life-Threatening Cancer | Depression, Anxiety | 22; 30 mg/70 kg | Psilocybin produced rapid, substantial and enduring decreases in depression and anxiety in patients with life-threatening cancer. |
| (Grob et al., 2011) | PMID: 20819978 | Clinical Trial | Quadruple | Yes | 12 | US | Advanced-Stage Cancer | Anxiety | 0.2 mg/kg ≡ 14 mg/70kg | Pilot study demonstrated preliminary evidence of safety and reductions in anxiety in patients with advanced-stage cancer. |

Importantly the qualitative feedback from patients in the Australian clinical trial reported in Dwyer et al. (2026) has also been broadly consistent – see Table 5 below.

In terms of safety, the results of psilocybine trials for both TRD and existential distress towards end-of-life have all reinforced the safety of psilocybine when used in a clinically controlled environment. In the case of TRD, this has also been confirmed by authorised prescribers in Australia in their reporting back of patient outcomes to the TGA. The Delegate also acknowledges in the Interim Decision the safety of using psilocybine in a clinically controlled environment by noting that "*psilocybine is well tolerated"* (TGA, 2026b: 10).

Given the above we believe that there is sufficient data available for the Delegate to conclude that the use of psilocybine for existential distress towards end of life meets the Schedule 8 criteria of "*established therapeutic value*". If the Delegate in the 2023 rescheduling decision was persuaded, why haven't the ACMS and the Delegate for the current rescheduling application also been persuaded?

In addition, there are at least three further considerations which, in our view, the ACMS and Delegate have not given proper weight to:

(i) Schedule 9 is reserved for substances with "*no currently established therapeutic value*", yet the Delegate's own reasons accept a growing body of promising research, acknowledge clinically meaningful improvements in anxiety, depression and existential distress in key trials, note that psilocybine is "*well tolerated*" in controlled settings, and record that no serious treatment-emergent adverse events have been observed in those settings. Once those matters are accepted, it is difficult to maintain that psilocybine has "*no*" established therapeutic value for this indication.

(ii) The methodological limitations relied upon by the Delegate – particularly difficulties with blinding – are intrinsic to psychedelic-assisted therapy but not defects unique to

psilocybine trials. If a classical double-blind standard is applied without adaptation to medicines whose psychoactive effects are inherently obvious, the regulatory bar will be set at a level that is practically impossible to meet, regardless of actual patient outcomes.

(iii) The "*more research is needed*" position takes on a different ethical complexion in the context of terminal illness. Patients with a prognosis of months rather than years are unlikely to be able to survive long enough to benefit from future large trials. To rely on the possibility of future research as a reason to deny carefully controlled access now, in the face of substantial suffering and a reassuring safety profile in supervised settings, risks turning a general research mantra into a de facto prohibition for the very group who have the least time to wait.

(iv) There is another critical consideration factor here. Given end of life distress is NOT an illness outlined in DSM 5 there may be NO incentive for a company to develop psilocybin or any other medicine for this indication. In other words if psilocybine is not rescheduled for existential distress towards end-of-life patients may NEVER gain access to a medicine that we know can relieve existential distress towards end of life when used as part of therapy (see the information in **Table 2** above).

### 2.2.2. <u>ACMS PROPOSITION 2: Lack of clarity regarding diagnostic criteria for existential distress towards end of life, treatment protocols, product and dosage.</u>

We deal with each below.

#### (i) <u>Diagnostic criteria for existential distress</u>

Although DSM-5 is the predominant psychiatric classification system used in the United States, it is not synonymous with clinical validity (Jablensky, 2016; Pickersgill, 2014). DSM-5 diagnoses are based largely

on expert consensus and descriptive symptom clusters rather than objective biological markers. Critics have argued that some DSM-5 categories demonstrate only modest reliability and uncertain construct validity (Kendell and Jablensky, 2003). Importantly, the absence of demoralisation syndrome from DSM-5 does not preclude its recognition as a clinically meaningful condition (Regier et al., 2013). The ICD-11 is another diagnostic tool that is validated and recognised in Australia (AIHW, 2026a). Demoralisation is recognised within ICD-11 (MB22.2 Demoralization; https://www.findacode.com/icd-11/code-1581226979) and is supported by a substantial body of psychiatric, psycho-oncology, and palliative care research. (Harrison et al., 2021).

Moreover, existential distress of a patient toward end-of-life has always been obvious to most doctors and even more so to palliative care specialists. Do we really have to depend on a group of psychiatrists in an overseas country arguing over the constituent elements of existential distress as part of revisions to the DSM manual? Are we that lacking in confidence and trust in the judgement of our own medical professionals?

Existential distress towards end of life is rarely characterised by a single moment of panic that fades away but leaves a feeling of dread in the patient. More often this condition can show up as a slow, omnipresent uneasiness associated with a terminal diagnosis that's hard to name and even harder to shake off. It can affect the patient's emotions, thought patterns, physical well-being, and behaviour.

In our view a workable definition of existential distress towards end-of-life for diagnostic purposes is set out in **Table 4** below.

## Table 4. Diagnostic Criteria for Existential Distress Towards End of Life (Philipp et al., 2025; Lo et al., 2017)

| Domain | Sign or Symptom | Clinical Description |
|---|---|---|
| Emotional | **Dread** | A persistent sense of uneasiness, apprehension, or existential fear that adversely affects the patient's quality of life. |
| Cognitive | **Ongoing, intrusive thoughts about death** | Recurring and unwanted thoughts about death, dying, the afterlife, mortality, and the inevitability of separation from loved ones. |
| Cognitive / Existential | **Difficulty finding meaning in things** | The patient experiences a diminished sense of purpose, meaning, or value in daily activities, relationships, achievements, or future goals. |
| Emotional | **Emotional numbness** | A sense of disconnection from positive emotions such as joy, excitement, fulfilment, or engagement with life. |
| Behavioural / Cognitive | **Paralysis and indecision** | Difficulty making decisions or committing to actions because activities, goals, or choices no longer feel meaningful or worthwhile. |
| Cognitive | **Rumination** | Repetitive and persistent focus on existential concerns, unanswered questions, regrets, or worries without reaching resolution or relief. |
| Physical / Psychological | **Sleep disturbances** | Difficulty initiating or maintaining sleep due to distressing thoughts, anxiety, or persistent existential concerns. |
| Social / Behavioural | **Social withdrawal** | Reduced engagement with family, friends, or social supports due to feelings that relationships are temporary, burdensome, or lacking meaning. |
| Physical | **Physical symptoms** | Manifestations of distress including muscle tension, fatigue, chest tightness, gastrointestinal discomfort, nausea, or other somatic symptoms. |
| Dissociative | **Depersonalisation** | Feelings of detachment from oneself, one's experiences, or one's life, as though observing events from a distance or from outside oneself. |

The key diagnostic components of existential distress towards end-of – life therefore become:

1. The patient receiving a terminal diagnosis with death expected within no more than 2 years.
2. One or more of the signs and symptoms mentioned in **Table 4** above adversely affecting the patient's quality of life to a significant extent and related in the mind of the patient to that terminal diagnosis.

The very nature of existential distress is that it's a subjective experience of a particular patient. But the subjective nature of the experience doesn't mean that it's not a real and debilitating condition for that patient or that an experienced clinician can't diagnose this state of mind for the purposes of qualifying the patient for treatment with psilocybine - assisted therapy.

**(ii) Treatment Protocols**

If the Authorised Prescriber Scheme methodology is adopted by the Delegate in the Final Decision, then treatment protocols, product quality and dosage levels will all have to be submitted for review to a Human Research Ethics Committee as part of the accreditation process. In doing this the applying psychiatrists and palliative care specialists will be able to draw upon material from both the completed existential end of life trials and the completed TRD trials. This is no different from the methodology approved by the then Delegate in the 2023 psilocybine rescheduling decision.

**(iii) Product Quality**

This has already been determined by the TGA through the TGA's Quality Standards in relation to psilocybine through the *Therapeutic Goods (Standard for Psilocybine) (TGO 113) Order 2024* (TGA, 2024),

**(iv) Dosage Levels**

Protocols for dosage levels have become relatively standardised. In five existential distress end-of life trials a 25 mg standard dose was used (Beaussant et al., 2026; Ross et al., 2025; Back et al., 2024; Anderson et al., 2020; Youngblood and Zarrabi, 2025), and for non-responders a 30 mg dose with an optional 10 mg booster (Back et al., 2026; Griffiths et al., 2016). This is equivalent to the Australian Authorised Prescriber approvals which typically provide for a dose of 25 mg of psilocybine for treating TRD, with an optional 30 or 35 mg for non-responders.

ACMS Proposition 2 should therefore not be used by the Delegate to deny patients suffering from existential distress access to psilocybine as part of therapy if the patient has given informed consent and the patient's prescribing medical practitioner believes that this treatment is appropriate.

### 2.2.3. ACMS PROPOSITION 3: Lack of clarity in relation to the accreditation process for specialist prescribers and identification of reviewing practitioners.

This could be easily clarified in relation to the proposed Schedule 8 entry by stating that the prescriber must be:

1. Either a psychiatrist or a treating palliative care medical specialist involved in the management of the patient's condition; and
2. The practitioner must also be an Authorised Prescriber for this purpose under the TGA's Authorised Prescriber Scheme.

The TGA's Authorised prescriber scheme gives adequate protection because the psychiatrist or palliative care medical specialist would have to persuade a Human Research Ethics Committee that they had:

- Adequate experience of treating patients struggling from existential distress towards the end of their lives.

- A clear understanding of the requirements for diagnosing existential distress towards end-of-life.
- Appropriate treatment protocols including minimum qualifications and experience of other clinicians who will be involved in providing the treatment.
- The minimum features of the clinical environment where the dosing session will take place.
- A clear understanding of patient contraindications and the means of assessing whether those contraindications exist.
- A clear approach to patient assessment and to patient informed consent with appropriate documentation.
- A clear understanding of the quality of the psilocybine to be used, the TGA Quality Standards and the proposed dosage range.

In our view this provides for the same level of clarity that the then Delegate accepted in making the 2023 rescheduling decision in relation to the use of psilocybine as part of therapy for treatment resistant depression.

The Delegate will be able to draw comfort from the position of other major jurisdictions around the World:

- **Canada** has provided for compassionate use of psilocybine for patients suffering from existential distress towards end-of-life (Patchett-Marble et al., 2022). A letter from the first patient who underwent this form of medicinal therapy in Canada, Thomas Hartle, in 2021 is attached in **Appendix B**.
- **The United States** has federally permitted the use of medicinal psilocybine in end-of-life care under the *Right to Try Clarification Act* (United States) (Brinzei, 2025)
- **The Czech Republic** has recently allowed for the use of medicinal psilocybine for existential distress towards end of life (European Union, 2026)

- In **Germany** medicinal psilocybine can be used "*for administration to patients with a seriously debilitating disease or whose disease is life-threatening and who cannot be treated satisfactorily with an authorised medicinal product"* under section 21(2)(3) of the Arzneimittelgesetz (Germany) [Medicinal Products Act] (Brinzei, 2026).
- In **Switzerland**, the Federal Office of Public Health may grant treating physicians time-limited, patient-specific exceptional authorisations for the medical use of otherwise prohibited substances, including psilocybin, under article 8(5) of the Federal Act on Narcotics and Psychotropic Substances (Brinzei, 2026). This limited medical-use pathway is available where the patient has a serious, generally incurable or treatment-resistant condition, the proposed treatment may alleviate the patient's suffering, and available alternatives are absent or have been used without sufficient benefit. Psilocybin has been available through this pathway since 2021, including for patients experiencing severe depression, anxiety, or other psychiatric suffering associated with serious illness (Liechti et al., 2025).
- In the **State of New Mexico** in the **United States** a *"regulated programme [allows for] approved healthcare providers to administer psilocybin in licenced settings. The programme permits access for qualifying patients, including minors if deemed medically appropriate by a licenced provider, who are diagnosed with specified conditions such as treatment-resistant depression, post-traumatic stress disorder, substance use disorders, and* ***end-of-life distress****."* (Brinzei, 2026).
- In the **State of Oregon** in the **United States** psilocybin has been prescribed hundreds of times for end-of-life care (Bellman, 2024; Yu et al., 2026).

An additional safeguard could be a detailed TGA prescriber approval process after the medical practitioner receives ethics approval as part of the Authorised Prescriber Scheme although this would become cumbersome,

time consuming and (in our view) not a great use of the TGA's limited resources. We believe the better approach would be for the approval process to mirror the notification requirements of the TGA's Clinical Trial Notification Scheme.

### 2.2.4. ACMS PROPOSITION 4: Lack of clarity in relation to the mechanisms for controlling the dispensing of psilocybine.

Psilocybine is already being dispensed through the pharmacy system for the treatment of patients with TRD in a way that complies with all Schedule 8 requirements. The pharmacy system is used to dispensing Schedule 8 medicines. Why would psilocybine for existential distress towards end-of – life be any different and present a greater risk than psilocybine for TRD and for highly addictive Schedule 8 medicines such as morphine?

### 2.2.5. ACMS PROPOSITION 5: Lack of clarity in relation to the regulatory impact of implementing the decision in each State and Territory of Australia

After the 2023 rescheduling decision all States around Australia quickly established their own processes for implementing the decision in their jurisdiction or relied on their existing Schedule 8 processes. Why would it be any different in this case?

### 2.2.6. ACMS PROPOSITION 6: Concerns over the potential for abuse.

We dealt with this extensively in our 2023 rescheduling application and submission in response to the Delegate's Interim decision (MMA, 2022: 77–79).

Why has the potential for abuse suddenly emerged as an issue again when it was, in the view of the TGA and the then Delegate, dealt with satisfactorily as part of the positive 2023 psilocybine rescheduling decision?

### 2.2.7. ACMS PROPOSITION 7: The need for input from key stakeholders.

We are dealing with people suffering from existential distress as they face the end of their lives. The relevant peak bodies have had plenty of time to put in submissions given that the Rescheduling Application was lodged nearly 18 months ago and has been publicly available on the TGA website for nearly all of that period. In our experience Peak and Regulatory Bodies can often find treatment innovation challenging unless it is sponsored by a pharmaceutical company. This can compromise their ability to give objective advice on alternative approaches to treatment innovation in a system dominated by pharmaceutical companies.

The TGA and the then Delegate had the confidence in 2023 to lead rather than wait for the peak bodies to do the work themselves and catch up with the outcomes of clinical trials and developments around the world. We would hope that on this occasion the TGA and the Delegate would also have this confidence to lead.

We should add that the principal stakeholders with an unapproved medicine are the patient (who must give informed consent), the medical practitioners (who must demonstrate to an ethics committee appropriate training, experience, protocols etc), ethics committees (who consider authorised prescriber applications), the clinics involved (who must have appropriate levels of governance) and regulators (who administer the authorised prescriber scheme).

## 3. ANALYSIS OF THE DELEGATE'S VIEWS

The Delegate's Interim Decision against extending the Schedule 8 entry for psilocybine to existential distress towards end of life is based on the same propositions or alleged "technical" barriers set out by the ACMS in its advice to the Delegate (see Section 2 above).

Additional comments by the Delegate on its stated rational are set out below with quotes taken directly from the Delegate's Interim Decision.

1. **Delegate Comment ID page 9 "*... psychedelic substances such as psilocybine ... have been associated with clinical and ethical risks*"**

What clinical risks is the Delegate referring to?

All medicines carry clinical risks, even non- prescription medicines such as Panadol which are widely available and used across Australia.

Unlike most prescribed medicines, psilocybine under the TGA's Authorised Prescriber Scheme for TRD, can only be used in a clinical environment with trained specialists present and caring for the patient at all times. The patient is never allowed to take the medicine home and therefore can't overdose. (even if that were possible, which it isn't). We believe that these restrictions are equally appropriate to the use of psilocybine as part of therapy for existential distress towards end of life.

The Delegate also admits that psilocybine is "well tolerated" (TGA, 2026b: 10), and this view of safety is supported by both the clinical trials that have taken place to date and the real-world evidence from treating psychiatrists and their patients from the clinical rollout of psilocybine-assisted therapy in Australia for TRD.

What ethical risks is the Delegate referring to?

We would have thought that it was unethical for the Delegate not to allow a patient suffering from existential distress as they approach the end of their

life access to an appropriately controlled medicinal therapy that the Delegate seems to agree can be safely used and where there is evidence of strong effect size.

Furthermore, if its "*ethical*" for people to legally kill themselves under VAD legislation how can it possibly not be ethical to provide a psilocybine treatment to a fully informed and consenting patient in a medically controlled environment that has been shown to relieve existential distress in patients going through enormous suffering?

People who have taken psilocybine in a controlled environment commonly speak of the experience as being akin to a spiritual experience where the person comes out of the altered state feeling "connected "to everything.

We have set out a number of the participant statements from the St Vincent's Hospital existential distress towards end-of-life psilocybine trial in **Table 5** below as well as comments from the authors (Dwyer et al., 2026):

**Table 5 - Patient Feedback and Author Commentary - Phase 2b St Vincent's Psilocybin Trial for Existential Distress Towards End-of-Life**

| **Domain – Mood** | |
|---|---|
| **Representative Participant Feedback** | **Author Interpretation / Theme Summary** |
| PN11: "It made me feel a bit calmer… everything is as it should be right now." | Participants described a shift from fear, overwhelm, and distress toward calmness, acceptance, and emotional stability. |
| PN6: "I haven't had any panic attacks… obsessive thoughts, angst and despair have given way to a range of personally affirming emotions." | Anxiety, panic, despair, and intrusive thoughts diminished, allowing more positive emotional experiences. |
| PN34: "There's more to life than just the illness. I'm more open to everything that's going on." | Illness remained present but no longer dominated participants' emotional worlds. |
| PN3: "I feel happier… I'm really excited about life; I've joined a choir." | Participants reported renewed joy, engagement, and enthusiasm for life. |
| Theme Summary | Emotions increasingly affirmed life still to be lived. While illness and mortality remained |

| Domain – Mood | |
|---|---|
| **Representative Participant Feedback** | **Author Interpretation / Theme Summary** |
| | realities, they no longer dominated the emotional landscape. |

| Domain – Temporality | |
|---|---|
| **Representative Participant Feedback** | **Author Interpretation / Theme Summary** |
| PN22: "I was just suppressing everything… now I don't give a shit … or I'll say something." | Participants re-engaged with previously suppressed aspects of themselves and became more authentic in daily life. |
| PN3: "I feel like I've given myself some freedom to be all those things that I shut down so long ago." | The past was revisited and integrated, allowing personal growth and self-reclamation. |
| PN14: "We still make plans for travelling… we still look forward to what's ahead of us." | The future became imaginable and meaningful again despite life-limiting illness. |
| PN24: "I'm much more relaxed about it and more mindful of living in the moment." | Participants became more present-focused and less constrained by fears about the future. |
| PN19: "Planning for the future has become a huge part of our lives." | Hope and future-oriented thinking re-emerged. |
| Additional observations | Some participants pursued new educational goals, hobbies, music, and personal projects for their intrinsic value rather than achievement alone. |
| Theme Summary | The past was reclaimed, the future became available, and participants re-entered the flow of life. Time was no longer experienced primarily as a countdown to death. |

| Domain – Lifeworld | |
|---|---|
| **Representative Participant Feedback** | **Author Interpretation / Theme Summary** |
| PN1: "I look at the world around me and it's just sparkling and beautiful. The colours are intense." | Participants described heightened appreciation, beauty, wonder, and connection with the world. |

| Domain – Lifeworld | |
|---|---|
| **Representative Participant Feedback** | **Author Interpretation / Theme Summary** |
| PN19: "More connected to myself, more connected to other people… more connected to nature." | Experiences of connectedness expanded across self, relationships, work, nature, and future aspirations. |
| PN29: "Life's much more abundant and free now." | Life was experienced as richer, more meaningful, and less constrained by illness. |
| PN10: "It gives me fresh perspective… to go out and be sexual and sensual and it's ok." | Participants described renewed embodiment, sensuality, and comfort with their physical selves. |
| PN3: "What my body wanted was exactly the opposite. It wants me to tend to it." | Relationships with the body shifted from avoidance and fear toward acceptance and care. |
| PN4: "It affirmed that I was going in the right direction of decreasing medical intervention and just letting nature take its course." | Participants often engaged with healthcare decisions from a renewed sense of personal wholeness and agency. |
| PN22: "It literally has changed both of us… we had this huge breakthrough." | Relationships deepened through greater emotional openness, authenticity, and communication. |
| Theme Summary | Participants reconstructed their lifeworld on their own terms. The world became more expansive, connected, meaningful, and vibrant, with ordinary experiences often described as extraordinary encounters. |

We believe that if the Delegate is going to use the argument of clinical and ethical risks then it's incumbent on the Delegate to explain exactly what risks the Delegate is referring to, to listen to the experience of trial participants and to draw parallels with VAD requirements and the requirements for Schedule 8 medicines more broadly.

2. **Delegate Comment ID page 9 – "*In Australia research involving prohibited psychedelic substances may nonetheless be lawfully undertaken where approval is granted through the TGA's clinical trials framework*"**

This is not a very comforting statement for a patient suffering from existential distress towards end-of – life. Clinical trials take many years to put together and complete and participation in a clinical trial is a lottery for a suffering patient. The one thing that a patient facing death does not have is time.

It should be noted that the 2023 TGA approval of psilocybine for treatment-resistant depression was largely based on data acquired from outside Australia that has since been validated by local practice.

3. **Delegate Comment ID page 9 – "*Public submissions overwhelmingly in favour of making psilocybine available as part of therapy for patients suffering from existential distress towards end-of-life*"**

We have covered this in detail in Section 1.5.2 above.

4. **Delegate Comment ID page 9 "*...Palliative Care Australia raised concerns...*"**

We have also responded tin detail o the views of Palliative Care Australia in Section 1.6 above.

5. **Delegate Comment page 10 – "*I note that while there is emerging evidence suggesting potential therapeutic use is alleviating distress around end-of-life, the current research base remains limited and inconclusive. Clinical trials to date have involved small participant numbers and lack standardised treatment protocols, dosage regimens or definitions of existential distress, making validity and reproducibility***

*challenging… To date, clinical trial findings…have yielded mixed and inconclusive results"*

We deal with each of the Delegate's claims in turn

(i) **First Delegate Claim – The research base is small and inconclusive with only small participant numbers.**

As mentioned in Section 2.2, we believe that the evidence today supporting the use of psilocybine-assisted therapy for existential distress towards end of life is as good as the evidence reviewed by the then Delegate in making the Final Decision in relation to the use of psilocybine for TRD in early 2023 (see the detailed comparison in Table 9 below).

The full list of clinical trials using psilocybine for existential distress towards end of life is extensive and much greater than the number suggested by the ACMS (see Table 3 above). The positive safety and efficacy outcomes are also much more consistent than suggested by the Delegate and the ACMS.

**(ii). Second Delegate Claim – There is a lack of standardised treatment protocols.**

This is also not an accurate statement as all psilocybine trials involve:

- Assessing the patient for inclusion in the clinical trial including screening the patient against a list of contraindications.
- Informed patient consent.
- Preparation sessions.
- Dosing sessions with two clinicians being with the patient at all times;
- Active dosage levels of around 25 mg in palliative care studies (Ross et al., 2025), replicating similar or the same dosage levels used for TRD (Erritzoe et al., 2024; Goodwin et al., 2023).
- Integration and final assessment sessions.

Furthermore, the protocols used for the existential trials are at least as well developed as the protocols used for the TRD trials so why can't a Human Research Ethics Committee deal with this as part of an authorisation process under the TGA's Authorised Prescriber Scheme?

(i) **Third Delegate Claim – There is a lack of standardised dosage regimens:** This is not true and we have already covered this in Section 2.2 (ACMS Propostion 2) above.

(ii) **Definitions of Existential Distress.** We have already dealt with this is Section 2.2 (ACMS Proposition 2) above. Is the Delegate really suggesting that an experienced medical practitioner is incapable of identifying in a patient the signs of existential distress towards end of life? The Delegate explains the indication perfectly by stating that "*Symptoms of existential distress relate to meaning, mortality, identity, dignity, and freedom*" (ID page 6). The fact that

there is not *a "validated, internationally accepted diagnostic tool for existential suffering or distress" (given that the indication is not defined in DSM -5)* doesn't mean that the indication isn't real to the patient. It shouldn't thererore be a reason for denying patients suffering from the symptoms of existential distress access to psilocybine-assisted therapy. See also the discussion in Section 2.2 (ACMS Proposition 2) above.

6. **Delegate Comment ID page 10 – "*The systematic review concluded that "No severe negative side-effects of psychedelic assisted therapy were reported in the studies*"**

We believe that this statement from the Delegate should be at the heart of the Delegate's analysis There is good evidence that psilocybin-assisted therapy can help patients with existential distress towards end of life and that psilocybin given in a clinical environment is well tolerated. If the Delegate really believes in the palliative care principle of patient autonomy, how can the Delegate ethically deny patients in these circumstances the right to choose this treatment if they pass their clinical assessment with no (or manageable) contraindications and they have given fully informed consent?

7. **Delegate Comment ID page 11 – "*Using GRADE criteria, the study authors judged the certainty of evidence to be low or very low*"**

The Delegate places substantial reliance on a 2024 systematic review which concluded that the certainty of evidence was low to very low under the GRADE framework. Respectfully, that conclusion requires careful interpretation and should not be considered determinative of the present application.

Most importantly, low-certainty evidence is not synonymous with evidence of no benefit. Under the GRADE framework, certainty ratings may be

downgraded for reasons including risk of bias, inconsistency, indirectness, imprecision, and publication bias (Zhang et al., 2019). A low or very-low certainty rating indicates that confidence in the estimated effect is limited and that future studies may alter the estimate. It does not indicate that an intervention is ineffective.

The review relied upon by the Delegate reported that psychedelic-assisted therapy may improve anxiety, depression, and existential distress in individuals with life-threatening illness (Schipper et al., 2024). Importantly, the review identified statistically significant improvements in demoralisation among participants receiving psilocybin-assisted therapy. Demoralisation is a central component of existential distress and is characterised by hopelessness, loss of meaning, helplessness, and diminished purpose. The finding is therefore directly relevant to the present application.

In the review relied upon by the Delegate, the principal reasons for downgrading certainty were methodological rather than clinical. These included concerns regarding functional unblinding, small sample sizes, and resulting imprecision. Functional unblinding is an acknowledged limitation throughout psychedelic medicine research because therapeutically effective doses of psilocybin produce noticeable subjective effects. While this may increase the risk of expectancy bias, it does not negate observed clinical outcomes. If functional unblinding were regarded as sufficient to dismiss efficacy findings altogether, then much of the psychedelic medicine literature would become incapable of meeting conventional evidentiary standards irrespective of the magnitude or durability of the therapeutic effect. Such a position would also be difficult to reconcile with Australia's existing Schedule 8 access pathways for psilocybin-assisted therapy in treatment-resistant depression and MDMA-assisted therapy in post-traumatic stress disorder, both of which are subject to similar methodological limitations.

Furthermore, the review relied upon by the Delegate pooled evidence from different psychedelic substances, including psilocybin, LSD, and MDMA. This introduces a significant issue of indirectness. MDMA is pharmacologically distinct from psilocybin and is not the subject of the

present application. Likewise, historical LSD studies are of limited relevance to contemporary psilocybin-assisted therapy protocols. Pooling heterogeneous substances, patient populations and treatment paradigms inevitably reduces the applicability of the conclusions specifically to psilocybin.

More importantly, the Delegate's analysis does not appear to consider the substantially expanded body of psilocybin-specific evidence that has emerged since the literature search underpinning the earlier review was conducted.

A recent systematic review examining psilocybin-assisted therapy specifically within palliative care settings identified six eligible studies involving 74 participants with serious and life-limiting illness (Matos et al., 2026). Unlike broader psychedelic reviews, this review focused exclusively on psilocybin and on populations directly relevant to the present application.

The review found that psilocybin-assisted therapy produced clinically significant reductions in depression and anxiety across both randomised and open-label studies. Between 57% and 79% of participants achieved at least a 50% reduction in symptom severity on validated outcome measures, including the Hamilton Depression Rating Scale (HAM-D), Hamilton Anxiety Rating Scale (HAM-A), Beck Depression Inventory (BDI) and State-Trait Anxiety Inventory (STAI). Importantly, these benefits were not merely transient. Improvements were sustained for six to eight months in most studies, and one long-term follow-up study reported durable benefits persisting for up to 4.5 years following treatment.

The review further concluded that psilocybin-assisted therapy demonstrated a favourable safety profile. Reported adverse effects were generally mild and transient, consisting primarily of nausea, vomiting and temporary increases in blood pressure and heart rate. No serious adverse events were reported.

The conclusions of this more recent review are notable. The authors found that psilocybin-assisted therapy consistently demonstrated efficacy and safety in reducing depression and anxiety symptoms among patients receiving palliative care. The review also reported improvements in existential and psychological suffering, quality of life and emotional wellbeing. While the authors appropriately called for further research regarding implementation, feasibility and health-system integration, the overall direction of evidence was consistently positive.

Accordingly, the evidence before the Delegate is materially broader than the three clinical trials identified in the Interim Decision. The current literature includes multiple randomised controlled trials, long-term follow-up studies, open-label studies, hospice and palliative care studies, systematic reviews, meta-analyses and real-world clinical evidence. The most recent psilocybin-specific palliative care systematic review demonstrates clinically meaningful and durable benefits together with an acceptable safety profile under supervised clinical conditions.

When viewed in its entirety, the evidence does not support a conclusion that psilocybin-assisted therapy remains merely speculative or unsupported for existential distress associated with life-threatening illness. Rather, it supports the conclusion that there is now a growing and increasingly consistent body of evidence demonstrating clinically meaningful benefit, manageable risk and sufficient justification for tightly controlled Schedule 8 access through the Authorised Prescriber Scheme.

The question before the Delegate is not whether psilocybin has satisfied the evidentiary threshold for unrestricted marketing approval on the Australian Register of Therapeutic Goods. Rather, the question is whether the available evidence demonstrates sufficient safety and clinical utility to justify access under a highly restricted specialist prescribing framework. On the current evidence, we believe that threshold has been met.

8. **Delegate Comment ID page 7 – "*further research is needed to establish therapeutic value*"**

We have already argued in Section 2.2.1 that the use of psilocybine for existential distress towards the end-of-life satisfies the Schedule 8 test of established therapeutic value. The need for further research applies to all psychiatric medicines. This is repeatedly recognised by researchers in their analysis of clinical trial data for psychiatric medicines published in medical journal articles. It's become a mantra and for good reason.

The way virtually all psychiatric medicines work in the human brain is not well understood and researchers are always seeking more research funding. But psychiatric medications are widely used despite this lack of mechanistic understanding because, in a particular circumstance, they may offer the best treatments available for a particular psychiatric illness.

In the present case, we have patients suffering intolerably from existential distress as they approach the end of their lives, we know that psilocybine treatment is well tolerated and there is evidence from clinical trials that psilocybine-assisted therapy can alleviate existential distress with large effect sizes. We believe it is unethical and immoral to repeat this "needs more research" argument to deny a properly informed and consenting patient approaching their own death the right to access these treatments

9. **Delegate Comments ID pages 11 and 12, which refer to some "*up and coming*" trials**

(i) **The PSYCHED-PAL study (NCT04754061):** Contrary to the view expressed by the Delegate, this study has already been completed, with peer-reviewed published results (Downar et al., 2026). This study was a Phase 1/2 open-label, single-arm feasibility study and involved 20 participants. The results demonstrate that psilocybin ***microdosing*** (1–3 mg) was feasible and well tolerated, with preliminary signals of efficacy. However, the absence of a control

group and the small sample size mean the study could not establish microdosing treatment efficacy. More importantly this study is not relevant to the current rescheduling application as the study investigated ***microdosing*** rather than the ***full doses*** associated with the treatment of existential distress towards end of life (Downar et al., 2026).

(v) **The PSYCHED-PAL-RCT study (NCT07063862):** This is a larger Phase 3 randomised controlled trial but likewise investigates psilocybin ***microdosing*** rather than the ***full dosing*** associated with the present rescheduling application. As such, it has limited relevance to the present application. The study remains ongoing, with results not expected before 2027 at the earliest.

(vi) **The Psilocybin Therapy in Advanced Cancer Trial (NCT05398484):** This is the only study cited by the Delegate that directly evaluates full-dose psilocybin-assisted psychotherapy (25 mg) and is therefore relevant to the current application. However, the study remains actively recruiting with meaningful results not expected to be announced until probably early 2028.

Is the Delegate really seeking to argue that patients approaching the end of their lives and suffering horribly from existential distress must wait for further trial results when all the evidence to date suggests that psilocybine-assisted therapy can help to treat existential distress and the Delegate agrees that psilocybine is "well tolerated".

10. **Delegate's Comment ID page 12 – "*The completion of additional Phase 3 studies with larger participant cohorts will enable the collation of more robust evidence…*"**

This is obviously a fair statement, but the existence of Phase 3 trial results ***was not*** a requirement of the then Delegate in 2003 when psilocybine was rescheduled for TRD. In March 2023 when the final decision was announced

there were no Phase 3 studies using psilocybine for TRD (the Delegate was mistaken when the Delegate asserted this).

Scheduling does not require the same evidence base that is required for registering a medicine on the ARTG. More objective evidence is always good, but this argument doesn't justify denying patients suffering from existential distress towards end-of-life access to these treatments when there is positive safety and efficacy evidence available, the patient has given their fully informed consent, and the patient may die before further trial results are announced.

11. **Delegate Comment ID Page 12 – "*...the risk and efficacy of psychotherapies are intrinsically linked to the context of care and skills of the providing practitioner. Practitioner training, care setting and patient vulnerability all play significant role in both efficacy and safety outcomes*"**

We agree and this was exactly the position faced by the Delegate when the Delegate made the rescheduling decision for psilocybine for TRD in March 2023. TRD is a serious illness and patients who suffer from TRD have a much higher level of suicidal ideation than the public generally (McIntyre et al., 2023). However, with both the rescheduling of psilocybine for TRD and this proposed rescheduling for existential distress towards end of life, Human Research Ethics Committees are more than capable of assessing the adequacy of practitioner training, practitioner experience, care settings and patient management.

The comparison with VAD requirements around Australia is directly relevant because the two independent assessors can come from a range of medical disciplines with, in most cases, at least one of the two assessors having expertise and experience in the disease, illness or condition expected to cause the person's death. The same would be the case if the Delegate agreed to reschedule the use of psilocybine for existential distress towards the end of life.

12. **Delegate's Comment ID page 12 – "*This raised concerns around the credentials of approved practitioners and what bodies could offer a robust and independent means of credentialing. The [ACMS] advised that the proposed amendment to authorise the prescribing and supply to a 'treating palliative care specialist' is not clearly defined. The applicant seeks such authorisation to be broader than the specialist palliative medicine physician (under the Medical Board of Australia's listed specialists) and to include oncologist and GPs with palliative are training. This would be a broader authorisation than currently permitted for treatment resistant depression, which is currently limited to specialist psychiatrists*"**

Our responses to the Delegate's views are set out below:

(i) One of the differences between TRD and existential distress towards end of life is, in the latter case, the interaction between the condition likely to cause death and the existential distress. It seems to us that limiting prescribers to specialist psychiatrists would ignore this link. We need the specialist involved in treating the patient's physical condition to be involved in (or at the very least aware of) the proposed treatment of the patient's existential distress with psilocybine-assisted therapy.

(ii) Restricting palliative care specialists to Specialist Palliative Medicine Physicians would make timely access to these physicians very challenging (if not impossible) for most patients given that:

- by definition, the one thing such patients may not have is the luxury of time;
- the best current national estimate that we have is that Australia has only 358 Specialist Palliative Medicine Physicians, equivalent to only 335 full time positions; and

- only about 15% of these specialists work in rural and regional Australia (AIHW, 2026b).

(iii) The VAD requirements around Australia don't restrict the assessor to one particular medical profession. The general requirement is for two independent trained practitioners. The terminology changes between jurisdictions but the process of assessment and sign off is broadly similar.

The obvious way of dealing with this issue of prescriber credentials is for the prescriber to be either:

(i) A medical practitioner with experience in treating the patient's medical condition as they approach the end of their life and with specific training in palliative care; or

(ii) A specialist psychiatrist with experience of treating patients suffering from existential distress towards end of life.

Given that the specialist treating the patient's medical condition is unlikely to also be a specialist psychiatrist then, in our view, two further conditions are necessary;

(i) The prescriber would need to be an Authorised Prescriber under the TGA's Authorised Prescriber Scheme so that the clinician's experience, protocols, training etc are properly assesses by a Human Research Ethics Committee. We have already dealt with this in more detail in Section 2.2.3 (ACMS Proposition 3) above.

(ii) If the patient is also suffering from an assessed mental illness, then a psychiatrist should also be consulted.

Given the circumstances of a patient suffering from existential distress and the importance of effective treatments being available to that patient, this credentialling issue is solvable if the Delegate, the TGA and the Secretary of the Department of Health and Aged Care have the "will' to solve it (as they did for the 2023 rescheduling of psilocybine for TRD).

13. **Delegate's Comment ID page 12 – "*The submissions report that no serious adverse events have been reported in controlled clinical environments, but the lack of standardisation and the uncertain evidence base underscores the need for caution. Whilst the submissions highlight compassionate and ethical motivations for access, the risks, particularly in unregulated or poorly supervised settings must be carefully weighed against the currently unproven therapeutic claims. These risk considerations provide important context for evaluating the proposed therapeutic use and presentation of the substance*"**

We have commented on the Delegate's assertion of a lack of standardisation and uncertain evidence base in Section 2.2.2 (ACMS Proposition 2) above. Suffice to repeat here that there is a lot of standardisation already in psilocybin-assisted therapy trials, the evidence base doesn't need to be at the same level as that required to register a medicine on the Australian Register of Therapeutic Goods and the evidence supporting the use of psilocybine for existential distress towards end of life is broadly consistent, with high levels of safety and large effect sizes.

Also, we are ***not*** proposing that the medicine dosing sessions take place in unregulated or poorly supervised settings. This is an irrelevant consideration. The whole reason for suggesting that the Delegate amend the Schedule 8 entry by reference to the TGA's Authorised Prescriber Scheme is to bring in the rigour of Human Research Ethics Committee involvement and a regulated environment.

14. **Delegate Comment ID page 12 – "*However, the actual extent of therapy sessions, use in clinical or compassionate settings remains unknown*"**

This wasn't highlighted as a barrier in the 2023 rescheduling decision because it will be covered as part of the practitioner's ethics submission. The broad outline of therapy sessions is known; assessment is followed by

preparation sessions, which are followed by the medicine dosing session which are followed by integration sessions. The number of preparation and integration sessions will depend upon the practitioner's assessment of what the patient needs. The medicine dosing sessions will take place either in a hospital or in a clinic depending upon the prescribing practitioner's assessment of the patient's condition. The place where the assessment, preparation and integration sessions will take place will also depend on practitioner's assessment of the patient's condition and the patient's preferences.

There is nothing "unknown" here and proposed locations will all be vetted by the Human Research Ethics Committee involved.

15. **Delegate's Comment ID page 12 – "*This absence of regulator listing and product standardisation presents challenges for consistent clinical application, quality assurance and oversight…[this] highlights the need for caution and further development of appropriate governance frameworks*"**

The lack of regulatory listing is precisely why the TGA introduced a compassionate access scheme. The involvement of a Human Research Ethics Committee and the TGA's oversight of the Authorised Prescriber Scheme deals directly with clinical application, quality assurance and the governance framework. We note that the issue of consistent clinical application and oversight also applies to many registered medicines such as SSRIs whereby definition there isn't an ethics committee involved and rates of prescribing appear to be out of control. The TGA has already dealt with the issue of psilocybin medicine quality by issuing the *Therapeutic Goods (Standard for Psilocybine) (TGO 113) Order 2024* (TGA, 2024).

16. ***Delegate's comment page 12 – "Finally, under section 52(E)(1)(e) and (f), concerning the potential for abuse and other public health considerations, I note emerging concerns that warrant attention"***

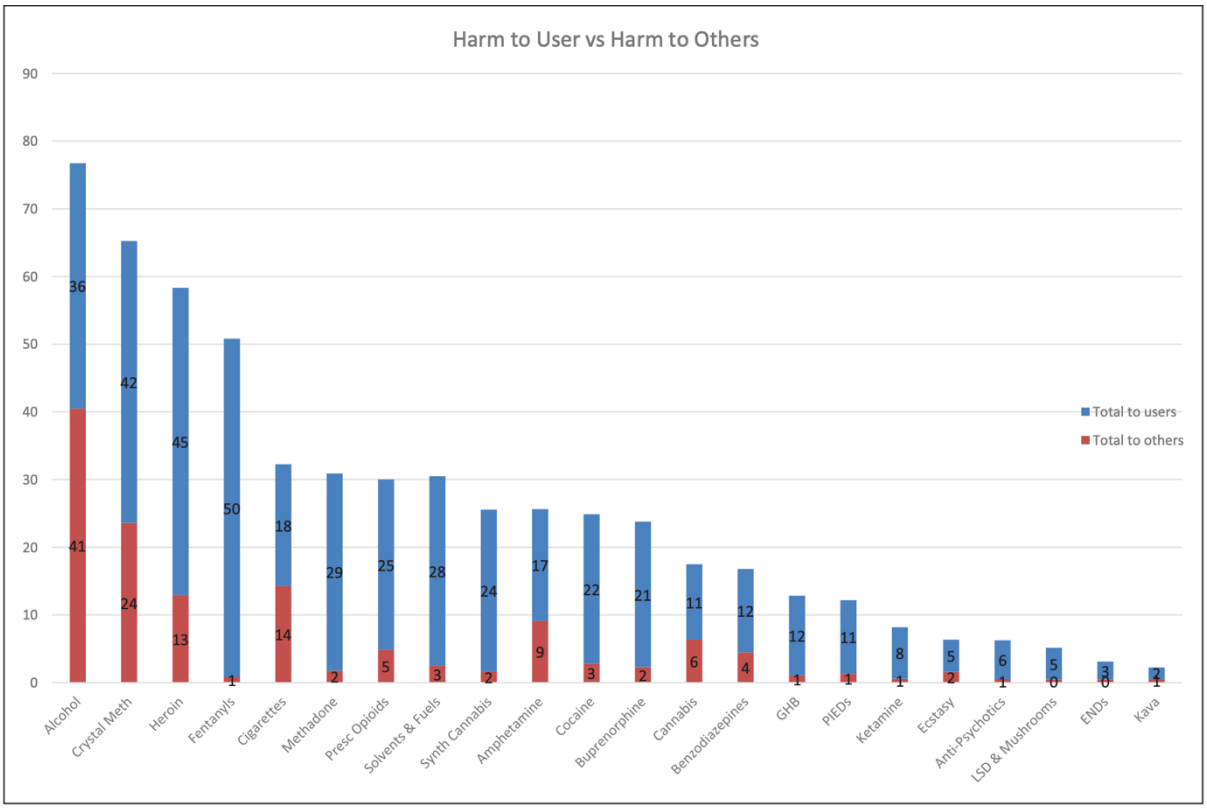
What are these emerging concerns?

The Delegate's reference to regulatory controls being relaxed in the United States with a documented increase is harm is presumably a reference to recreational schemes such as the scheme in Oregon. That scheme has far less controls than those envisaged in our submission and yet outcomes from a safety perspective have been very positive with reported significant use and symptom reduction using psilocybine for end-of-life distress(Bellman, 2024; Yu et al., 2026).

The link to individuals attempting self-treatment outside of clinical settings arises precisely because this treatment is ***not*** broadly available in clinical settings in the United States. Whether or not the Delegate supports the amended Schedule 8 listing that we are seeking in its Final Decision won't stop self -treatment attempts. Indeed, we would argue that the risks are much greater if the Delegate rules against the Rescheduling Application.

We dealt with the "abuse" argument at length in our 2022 response to the Delegate's interim decision in relation to the use of psilocybine for TRD (MMA, 2022: 77–79). Given that our views on "abuse" were accepted by the Delegate in that case we are at a loss at to why the subject of abuse is being raised again by the Delegate in the Interim Decision. All medicines are capable of being abused. Psilocybine, even when used illegally in the recreational domain, is actually one of the safest recreational substances\ available (see Tables 6,7 and 8 below).

## Table 5. Drug Harms in Australia – Safety of Psilocybin Relative to Other Drugs Across Broad Populations (Bonomo et al., 2019)




## Table 6. Drug Harms in United Kingdom – Safety of Psilocybin Relative to Other Drugs Across Broad Populations (Nutt et al., 2010)

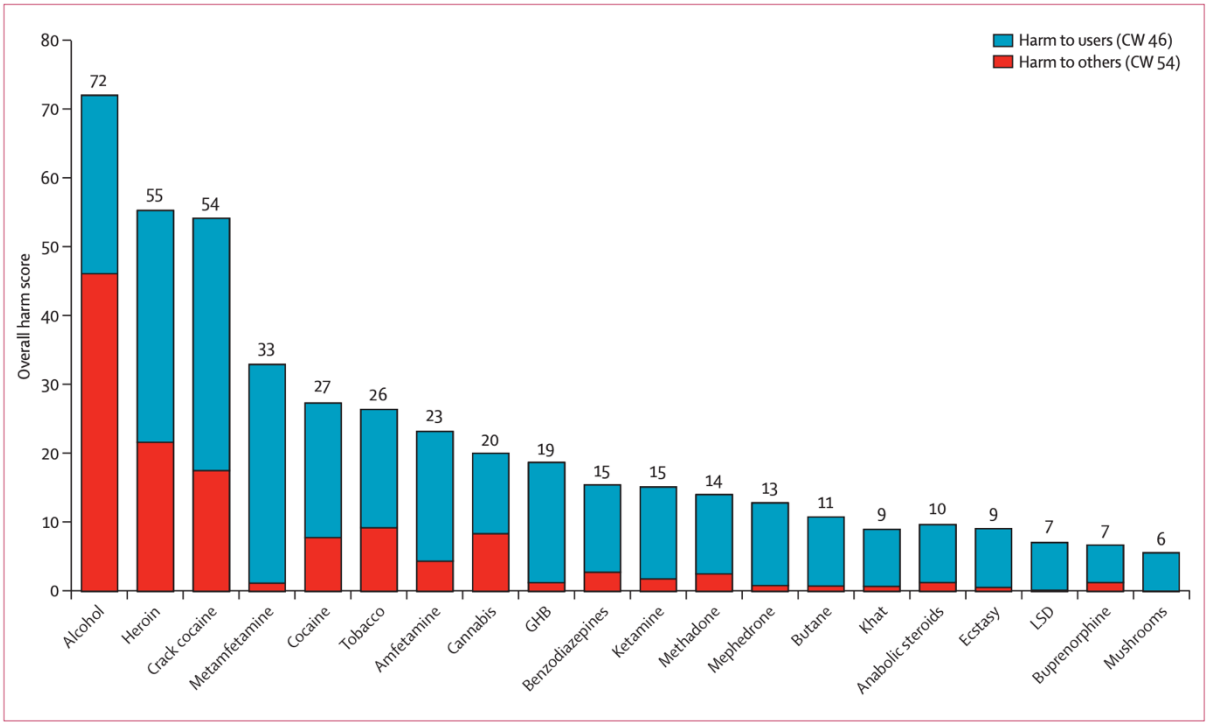
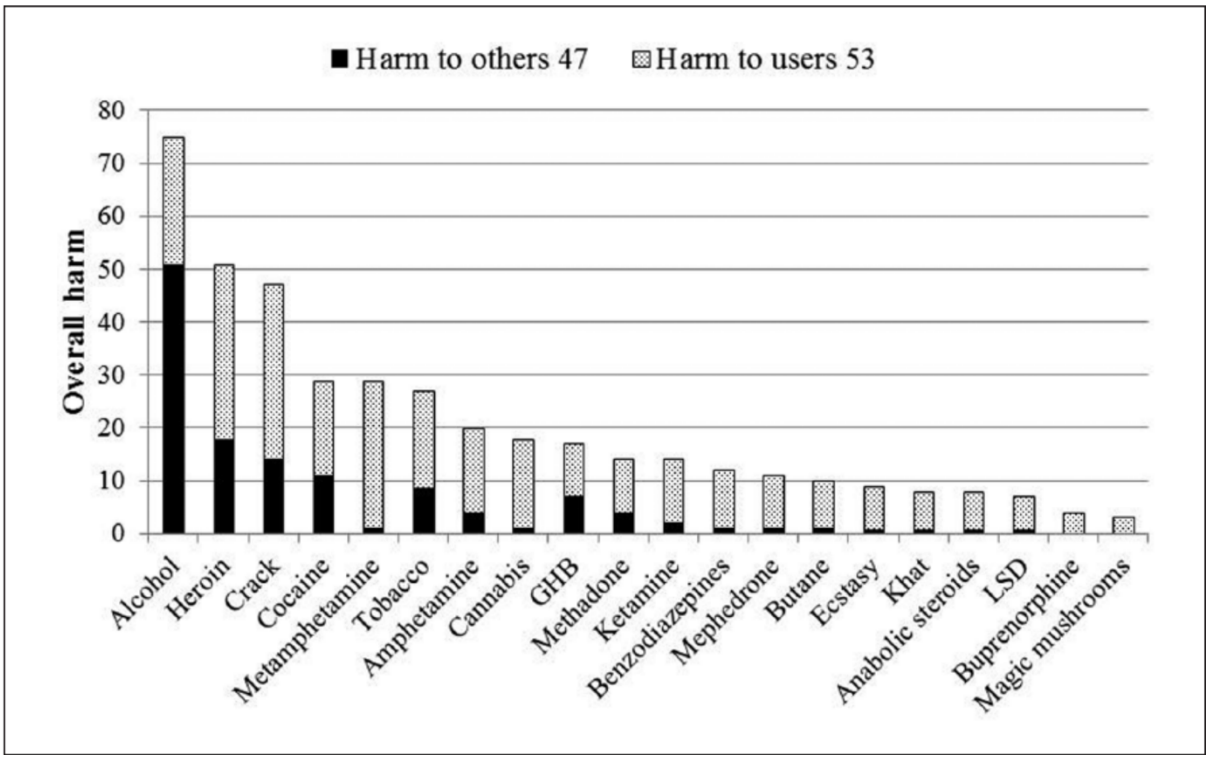


**Table 7. Drug Harms in Europe – Safety of Psilocybin Relative to Other Drugs Across Broad Populations (van Amsterdam et al., 2015)**




17. **Delegate Comment ID page 13 – "*Whilst the proposed amendment to Schedule 8 seeks to enable controlled therapeutic use, it presents significant clinical and implementation issues surrounding diagnosis*"**

As mentioned already in Section 2.2.2 (ACMS Proposition 2) above in relation to the ACMS advice, we would have thought that the existence of existential distress in a patient toward end-of-life was obvious to any experienced medical practitioner and even more so to psychiatrists and palliative care specialists. Do we really have to depend on a group of psychiatrists in an overseas country mulling over its constituent elements as they rewrite and add to the DSM? As the Delegate quite rightly say *"Its core concerns relate to meaning, mortality, dignity and loss of self -worth reflecting broad palliative care constructs rather than psychiatric pathology*" (ID page 13).

Are we really so lacking in confidence and trust in the judgement of our medical professionals?

Do we ignore the palliative care principles of patient autonomy and the wishes of fully informed patients as they approach the end of their lives in favour of a diagnostic debate? So what if the identification of existential distress is, in the Delegate's words "*inferential, contextual and culturally mediated*" (ID page 13). Is our compassion and faith in our medical practitioners so restrained that these arguments should deny a patient suffering from existential distress access to psilocybine-assisted therapy. A treatment that can be given with high levels of safety and which offers that person the prospect of peace and acceptance as they approach their own death.

What is the safeguard to public health that the Delegate is seeking in these circumstances? Surely the Authorised Prescriber scheme can deal with all of this?

## 18. Delegate Comment ID page 13 – Need for input from the relevant peak bodies

The fact that a number of relevant peak bodies haven't yet responded does raise the question of whether these organisations are "fit for purpose". The TGA put out invitations to respond to respond to the Psilocybine Rescheduling Application for Existential Distress towards End-of-Life in April 2025 (i.e. over 16 months ago). The patients that need the option of being able to access these treatments don't have the luxury of time. They are approaching death, and they are suffering. If this doesn't motivate a peak body into providing a detailed written assessment of the Rescheduling Application how can the Delegate and the TGA justify waiting for the comments of that peak body?

With the 2023 rescheduling decision the Delegate and the TGA had the courage to reschedule psilocybine for TRD in the face of opposition from the

Royal Australian and New Zealand College of Psychiatrists (but not opposition from many of its members who put in written submissions supporting the rescheduling). The rescheduling finally galvanised the RANZCP into action, they appointed a psychedelic medicine committee and published an explanatory memorandum which was in the most part helpful and included a supervision requirement which we support.

19. **Delegate Comment ID page 13 – "*Given the complexity of the therapeutic context and the potential for unintended consequences, I am of the view that a cautious, whole of system approach is essential to public health*"**

We trust that we have dealt with the Delegate's issues above. There is a clear pathway to implementation and a road map provided by the 2023 Delegate's approach to the original rescheduling of psilocybine. Being cautious is fine but denying people who are dying access if they so choose to a treatment that has achieved outstanding results in clinical trials is in our view simply cruel.

20. **Delegate comment page 13 – "*Regarding patient vulnerability, the committee raised concerns that end-of-life patients (especially in late stages) may be vulnerable to active promotion of these therapies*"**

This was the argument used by people and peak bodies that opposed VAD legislation in jurisdictions around Australia but there is no evidence that this has occurred since the VAD laws came into effect (National Seniors Australia, 2025).

It's also a perverse argument. Is the Delegate and the TGA seriously going to oppose the Rescheduling Application and deny patients that are suffering

the opportunity to access these therapies when the giving of fully informed patient consent is a standard and a well – trodden path in modern medicine.

21. **Delegate Comment ID page 13 – "*...any use of psilocybine for patients with a terminal illness should currently continue within a clinical research framework*"**

Two points to make here:

1. The Authorised Prescriber scheme adopts much of the "clinical research framework" because the experience and training of the lead practitioner, the protocols to be used, the logic and evidence for the proposed treatment, the environment where the dosing session is to occur and the quality of the medicine to be used are all assessed by a human research ethics committee (i.e. the same entity that vets the same information for clinical trial submissions).
2. Clinical trials are notoriously hard to fund and can take years to set up and implement. People who are dying do not have the luxury of time to wait and hope that a clinical trial emerges that they can gain access to. Using this as an argument is simply cruel.

22. **Delegate comment page 14 – "*Whilst the proposal seeks to improve quality of life for patients at the end of life and alleviate severe psychological distress where existing interventions have been insufficient, major stakeholders including Palliative Care Australia, have advised to await the outcomes of more advanced clinical trials before considering further amendments to the current regulatory settings*"**

We have already covered this in Section 1.6 above.

23. **Delegate Comment ID page 14 – "*...the risks and uncertainties in implementation of a Schedule 8 entry for the indication outweigh the benefits with the current limited evidence*"**

We have commented on the evidence base above. In our view (see Section 2.2 (ACMS Proposition 1) above) there is just as much evidence to support this indication than there was at the start of 2023 when then then Delegate issued a final deion in favour of rescheduling psilocybine for TRD. There is also a significant amount of evidence from the Oregon Scheme in the United States (Bellman, 2024; Yu et al., 2026). In the context of suffering patients and the strictures of the Authorised Prescriber Scheme, it's not clear to us how the "risks and uncertainties" can be of such a magnitude that they would deny a fully informed and consenting patient the ability (subject to assessment and practitioner support) to access psilocybine-assisted therapy for existential distress as their life draw to a close.

The risks and uncertainties argument were all dealt with by the then Delegate who made the 2023 psilocybine rescheduling decision for TRD.

It really is ironic that regulators can feel comfortable implementing VAD around Australia but struggle with a treatment that has the potential to give a suffering person meaning and peace as they approach the end of their lives.

24. **Delegate Comment ID page 14 – "*I am not satisfied that the factors which supported the 2023 amendments apply in equal force to the current proposal*"**

The Delegate's statement relies on the following factors;

(i) **The Delegate's view that TRD related to a well – characterised underlying psychiatric condition whereas existential distress towards end of life does not:** Does anyone really doubt the existential distress towards end-of-life amounts to an underlying

psychiatric condition? The Delegate in the Interim Decision actually describes the underlying psychiatric condition quite well.

(ii) **The Delegate's view that TRD has clear diagnostic criteria whereas existential distress towards end of life does not:** See our comments in Section 2.2 (ACMS Proposition 2) above. The failure of psychiatrists to incorporate a definition of existential distress towards end life in DSM-5 should not be a reason to deny suffering patients access to therapies that have been shown, in clinical trials, to bring peace and meaning (with large effect sizes).

(iii) **The Delegate's view that the evidence base was stronger for the use of psilocybine-assisted therapy for TRD in early March 2023 because there was a growing body of clinical evidence including later phase clinical trials (including Phase 3) is simply wrong:** The Delegate has made a mistake. The first completed Phase 3 clinical trial using psilocybine for TRD didn't report its findings until 2026 (Compass Pathways, 2026), well after the psilocybine TRD rescheduling decision was announced in March 2023. We have six phase 2 trials supporting our current application for end-of-life distress (Back et al., 2024; Downar et al., 2026; Griffiths et al., 2016; Grob et al., 2011; Lewis, 2026; Ross et al., 2025), compared to two phase 2 trials supporting our TRD application in 2023 (Davis et al., 2021; Carhart-Harris et al., 2021). In each case the evidence shows strong effect sizes.

We summarise the comparable evidence for the use of psilocybine for TRD in 2023 with the current evidence for the use of psilocybine to treat existential distress towards end of life in Table 9 below.

## Table 9. Evidence Base Comparison | Psilocybine for TRD (2023 Decision) vs Psilocybine for Existential Distress (2026 Application)

| Factor | Psilocybine for TRD \| 2023 Decision | Psilocybine for Existential Distress \| 2026 Application |
|---|---|---|
| Phase of completed trials at time of decision | Phase 1 and 2. No completed Phase 3 data existed at the time of the March 2023 final decision. | Phase 1 and 2. No completed Phase 3 data. Directly comparable position. |
| Number of completed clinical trials | Multiple completed trials (but primarily Carhart-Harris et al. 2021; Goodwin et al. 2022 Phase 2b). | 10+ completed trials across institutions in the US, Australia, and Canada. |
| Key trials | Carhart-Harris et al. (2021), NEJM; Goodwin et al. (2022), NEJM (Phase 2b, n=233). | Ross et al. (2016); Griffiths et al. (2016); Ross et al. (2025) St Vincent's Melbourne Phase 2b RCT; Downar et al. (2026) PSYCHED-PAL. |
| Total participants across completed trials | Approximately 300+ across Phase 2 trials available at time of decision. | 260+ across all completed end-of-life and palliative trials. Exceeds 400 when secondary analyses and follow-up cohorts are included. Additional over 1,600 patients treated in Oregon, US for existential distress at end-of-life. |
| Effect sizes | Large. MADRS reduction of approximately 6-8 points vs comparator in Goodwin et al. (2022). Secondary outcomes favoured psilocybine in Carhart-Harris et al. (2021). | Large. SMD -1.05 (95% CI -1.46 to -0.63) for depression; SMD +0.88 (95% CI 0.29 to 1.47) for quality of life (Marchi et al. 2024 meta-analysis). Downar et al. (2026): Cohen's d -0.91 depression; -1.44 anxiety; -0.73 demoralisation. |
| HADS outcomes | HADS used as secondary outcome in multiple trials. Consistent reductions in both subscales. | HADS used as primary outcome in St Vincent's Phase 2b trial (Ross et al. 2025). HADS improvement also reported in Downar et al. (2026): 54% achieved >50% improvement. University of Washington trial (NCT05847686, n=52) used HADS as primary outcome. |

| Factor | Psilocybine for TRD \| 2023 Decision | Psilocybine for Existential Distress \| 2026 Application |
|---|---|---|
| Safety profile | Well tolerated. No serious adverse events in clinical settings. Transient cardiovascular effects, nausea, headache. No physical dependence or withdrawal. | Well tolerated. No serious adverse events in any completed clinical trial. Adverse events transient and manageable within therapy session. Identical profile to TRD trials. This was accepted by the Delegate in the Interim Decision itself. |
| DSM-5 diagnostic category | TRD is not a standalone DSM-5 diagnosis. It is defined operationally by treatment failure criteria. The Delegate accepted this in 2023. | Existential distress is not a DSM-5 diagnosis. However, the Delegate's own Interim Decision describes its constituent elements clearly. Existing validated measures (HADS, HAM-D, DS-II) plus terminal illness confirmation by two practitioners provides a workable diagnostic threshold. |
| Secondary research available | Systematic reviews and meta-analyses. Cochrane review available. | Cochrane systematic review (Schipper et al. 2024); network meta-analysis (Marchi et al. 2024); meta-analysis (Yu et al. 2021); systematic review (Matos et al. 2026). |
| Australian clinical experience | None at time of 2023 decision. Australian TRD rollout was proposed on the basis of international evidence only. | Active St Vincent's Hospital Melbourne Phase 2b RCT completed and published (Ross et al. 2025). Australian clinical experience exists and confirms the international safety profile. |
| Proposed access mechanism | Authorised Prescriber Scheme with HREC oversight. Restricted to specialist psychiatrists. | Authorised Prescriber Scheme with HREC oversight. Proposed prescribers: treating specialist in relevant physical condition plus psychiatrist where required. Identical governance structure. |
| Phase 3 data available at time of decision | No. The first Phase 3 psilocybine trial (COMP005) did not report until June 2025, more than two years after the March 2023 final decision. The Delegate's Interim Decision incorrectly states Phase 3 evidence existed. | No. Phase 3 trials in end-of-life populations are recruiting but have not yet reported. Directly comparable evidentiary position to TRD in 2023. |

| Factor | Psilocybine for TRD \| 2023 Decision | Psilocybine for Existential Distress \| 2026 Application |
|---|---|---|
| Population vulnerability | TRD patients have substantially elevated suicidal ideation (15% vs 1% general population; Voineskos et al. 2020). This was accepted as manageable under HREC oversight in 2023. | End-of-life patients face existential distress but do not present with suicidal pathology as a defining feature. Lower acute safety risk than TRD population. The same HREC oversight framework applies. |
| Overall conclusion | Delegate concluded that whilst (in the Delegate's view) the evidence was not fully established the balance of benefits and risks favoured limited Schedule 8 access, through the use of the Authorised Prescriber Scheme as the governing framework. | The evidence base is structurally comparable to TRD in 2023 on every material dimension. The same governance framework is proposed. The Delegate's reasoning for treating the two situations differently does not survive this comparison. |

(iv) **The Delegate's view that the authorised prescriber scheme in 2023 could be used to operationalise diagnostic criteria and treatment protocols with oversight from a HREC whilst it couldn't be applied to existential distress towards end of life in 2026:** Why can't the same approach be applied to existential distress towards end of life? Existential distress is perfectly capable of being defined in the protocols vetted by the HREC involved.

Given the above we believe that a failure by the Delegate to support an extended Schedule entry for psilocybine to cover existential distress towards end of life would be inconsistent with the then Delegate's approach in the 2023 rescheduling of psilocybine for TRD.

It would also be perverse. Under VAD legislation a person suffering from existential distress and satisfying the VAD criteria is legally allowed to kill themselves but under the Delegate's approach the same person isn't allowed to receive a treatment that could bring peace and meaning to them as they approach the end of their life

## 4. CONCLUSIONS

We believe that there is more than sufficient evidence to justify a decision by the Delegate to extend the Schedule 8 listing of psilocybine so that it can be prescribed as part of therapy pursuant to the TGA's Authorised Prescriber Scheme to treat patients suffering from existential distress towards end-of -life. The evidence that we have set out in this submission and its application to the specific Schedule 8 tests in our opinion requires such a decision.

Regulators play a critical role in our Health System but sometimes saying "no" becomes the default position. In this case the Delegate, the TGA and the Department of Health and Aged Care (led by the Minister and the Secretary) have the opportunity to reduce the suffering of patients as they enter the final stages of their lives. What could be more satisfying to a

regulator and government leaders than this. Evidence, government leadership, regulatory structures and compassion all coming together to provide our clinicians with better treatment options to reduce human suffering.

Medicines always benefit from more clinical trials (and this statement is also true for registered medicines) but there comes a point where there is enough data available to justify controlled use of an unapproved medicine under the Authorised Prescriber provisions of the TGA's Compassionate Access Scheme.

Extending the rescheduling of psilocybine so that it can be prescribed to patients suffering from existential distress towards end-of-life if both the prescribing clinician and the patient believe that its appropriate and the patient gives informed consent doesn't mean widespread access. Under the TGA's Authorised Prescriber Scheme and Schedule 8 regulatory controls in all States and Territories of Australia there will be plenty of checks and balances.

It is simply not acceptable for members of the ACMS representing State and Territory Governments to argue about process when patients with existential distress in the last stages of their lives are suffering terribly. It's even worse when those same regulators administer VAD regulatory rules that allow patients to use substances to legally kill themselves. All that these governments need to do is to develop appropriate policy controls, something that was efficiently done for the original Schedul8 8 listing of psilocybine for treatment resistant depression and has been routinely done for all other Schedule 8 medicines.

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## APPENDIX A. VOLUNTARY ASSISTED DYING REQUIREMENTS IN AUSTRALIA

The table below summarises the eligibility requirements for Voluntary Assisted Dying (VAD) in each Australian jurisdiction where it is currently lawful, as of July 2026. All jurisdictions additionally require that the person be an adult with decision-making capacity, that their suffering (which may be physical, psychological or existential) cannot be relieved in a way they consider tolerable, that their request is voluntary and enduring, and that they be independently assessed by at least two trained medical practitioners.

| Jurisdiction | VAD Commenced | Prognosis Timeframe | Residency Requirement | Distinctive Feature |
|---|---|---|---|---|
| Victoria | 19 June 2019 | 6 months (12 months if neurodegenerative) | Citizen/PR; Victorian resident 12 months | Practitioners cannot raise VAD first |
| Western Australia | 1 July 2021 | 6 months (12 months if neurodegenerative) | Citizen/PR; WA resident 12 months | Doctors and nurse practitioners may raise VAD proactively |
| Tasmania | 23 October 2022 | 6 months (Commission may grant exemption) | Citizen/PR or 3-yr Australian residency; Tas resident 12 months | Only state allowing a formal exemption from the timeframe |

| Jurisdiction | VAD Commenced | Prognosis Timeframe | Residency Requirement | Distinctive Feature |
|---|---|---|---|---|
| Queensland | 1 January 2023 | 12 months (single timeframe, all conditions) | Citizen/PR or 3-yr Australian residency; Qld resident 12 months | Broadest prognosis window of any jurisdiction |
| South Australia | 31 January 2023 | 6 months (12 months if neurodegenerative) | Citizen/PR; SA resident 12 months | Objection right extends to private hospitals, not aged care |
| New South Wales | 28 November 2023 | 6 months (12 months if neurodegenerative) | Citizen/PR or 3-yr Australian residency; NSW resident 12 months | Non-doctors may raise VAD if referring to a doctor |
| Australian Capital Territory | 3 November 2025 | No fixed timeframe – 6/12-month rule does not apply | Citizen/PR or 3-yr Australian residency (period set by regulation) | Only jurisdiction with no fixed prognosis timeframe |
| Northern Territory | Not yet available | N/A | N/A | Bill expected to be tabled in 2026 |

Sources: Voluntary Assisted Dying Act 2017 (Vic); Voluntary Assisted Dying Act 2019 (WA); End-of-Life Choices (Voluntary Assisted Dying) Act 2021 (Tas); Voluntary Assisted Dying Act 2021 (Qld); Voluntary Assisted Dying Act 2021 (SA); Voluntary Assisted Dying Act 2022 (NSW); Voluntary Assisted Dying Act 2024 (ACT); End of Life Law in Australia (QUT); healthdirect.gov.au. This summary is provided for comparative purposes only, is not legal advice, and should be verified against the current legislation before reliance.

## Appendix B. Letter from Canadaian Terminally ill Patient Administered Psilocybin To Treat Existential Distress

TO: The Secretariat
Medicines Rescheduling Unit
Therapeutic Goods Administration
Canberra
Australia

FROM: Thomas Hartle
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DATE: Feb 28, 2021

First, I would like to say thank you for the opportunity to speak about my patient experience with you. My name is Thomas Hartle, and I am a Canadian who has been dealing with stage 4 colon cancer for the past 5 years. I have undergone a significant number of different treatments and therapies as part of my condition. These therapies include medical procedures, naturopathic procedures, and several natural supplements. I am the first person in Canada to legally use psilocybin to treat the anxiety I have experienced as a result of my terminal cancer.

What we are considering here is not a discussion of the recreational use of a drug, which is a completely different matter from the use of any drug in a controlled clinical setting with medical supervision. I'm including here a copy of the section 56 exemption that was granted to me by the Minister of health and the Office of Controlled Substances here in Canada so that you have an idea of the restrictions that are placed on the usage of psilocybin that ensure that safety is a primary concern.

Some of you may be familiar with the kind of devastating physical effects that having stage 4 cancer can cause, but like so many things concerning mental illness, we often do not speak about the mental and emotional toll that cancer also imparts. We seem to be more comfortable talking about topics like death than we are to address issues like anxiety. Mental health is somehow a taboo subject that makes people feel they are somehow weak or ashamed to seek help. My cancer has put me in a position where I simply do not have time left to ignore things the way that more healthy people are able to. When you have a terminal illness, hearing talk about studies that may (or may not) produce any outcome in 3 or more years' time is the equivalent of saying that nothing will be done for the rest of your life. Nothing will improve for the rest of your life. You will not get any relief from the anxiety or depression for the rest of your life, so every minute that you have left will likely be one where you are suffering. With a hopeless prognosis like this, it isn't surprising to find that many opt for suicide instead of the extended suffering that a lack of options guarantees. My personal experience is that this suffering can be alleviated effectively and with almost no side effects or risk.

For someone like myself, factors such as the small possibility for a negative reaction from a psychedelic such as psilocybin are trivial in the face of the absolute certainty that stage 4 cancer kills nearly everyone who has it, often within 18 months. Equally, as someone with a terminal diagnosis, I assure you that the possibility of experiencing some discomfort because of a "bad trip" is also almost laughable if you understand the level of daily discomfort cancer causes. This daily discomfort for me was greatly compounded by the anxiety I experienced over the uncertainty my life now has.

The most common question I am asked about my experience with psilocybin is usually concerning how a psychedelic substance could have any effect on something seemingly unrelated like anxiety. I can offer you the comparison of my experience between a traditional anti-depressant and psilocybin.

In a nutshell, the anti-depressant suppresses feelings for the duration that the drug is in effect. It removed the depths of negative feelings to some degree, but it also removed a proportionate amount of the peaks of happiness and wellbeing. Without the drug, everything returned to its original state with the same busy thoughts that are inherent to having anxiety and depression. The use of this drug is a lifetime commitment. For some, this is an acceptable option, but for me, it was not OK to trade the rest of my life with anxiety for the rest of my life feeling numb.

By comparison, the psilocybin gave me a different perspective on my circumstances. It did not only change the way I was feeling, but it also changed the way that I thought about what was happening to me. I have used psilocybin twice, and at this point, I don't feel any need to use it again. My results are typical, and as someone who has been extremely public about what most people would consider a personal matter, I have been approached by numerous people who have shared their experiences with me on the therapeutic use of this medicine. This perspective shift and the life changing result it has had for me is a theme that I have heard repeated by every patient I have spoken to. Every experience is different, and some are certainly challenging from an emotional point of view. We have anxiety because we are dealing with difficult things. Dealing with difficult things is not easy no matter what mode of treatment you take.

I will not try to tell you that this is somehow a cure all for mental illness. Of course, it isn't, and anyone who says so certainly does not understand how it works any more than someone who says that it has no medicinal value. Information on the toxicity of psilocybin is readily available, as are studies by highly reputable universities. There is a large body of research that is available from the 60s prior to the criminalization of the entire class of drugs. Many of the claims made against psilocybin such as its addictive potential are simply not supported by actual research. For myself, my doctors, and my government, this was sufficient to give me the opportunity to see if it would also work for me in the same way that it worked for 80% or people in the studies.

I am grateful that my government representatives were not only well informed, but also acted in a way that showed real human compassion. It would have been a simple matter for them to just say no and wait for me to die and no longer present a problem for them. Instead, they demonstrated that in medical matters, life changing medical decisions such as this are best left between a patient and their doctor. While the government in no way condones or promotes the use of psilocybin for any purpose, they had the decency to recognise that I am an informed and intelligent adult, capable of making choices about my treatment.

It is my hope that my positive treatment outcome, and the positive outcomes of others would be enough to convince you that the possibility of alleviating the suffering of the terminally is worth exploring. I would suggest that it could also be a mechanism to provide the research data that would show that this is in fact an effective treatment. Simply allow people who are terminally ill and who wish to use this treatment based on their own informed research to provide you with the evidence of their experience as recorded by their supervising medical practitioner. Allow them to use this medicine with protocols that have been established in other studies and treat that as your starting point in the development of protocols that reflect your own medical practices. If it does not deliver a result like I have experienced, they are no further behind than before they started. If they get even a fraction of the relief I have, you will give them at least the chance to be present with their loved ones instead their illness. There is nothing more precious to a family with a terminally ill member than quality time together.

Thank you for your consideration,

Thomas Hartle.