

# **ACNEM**

**TRANSFORMING GLOBAL HEALTH**

## **APPLICATION TO RESCHEDULE PSILOCYBIN FROM SCHEDULE 9 TO SCHEDULE 8 OF THE POISONS STANDARD**

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Australasian College of Nutritional and Environmental Medicine  
Level 5, 111 Cecil Street, South Melbourne 3205

### Applicants Details

1. **Applicants Name:** Australasian College of Nutritional and Environmental Medicine
2. **Applicants Address:** Level 5, 111 Cecil Street South Melbourne VIC 3205
3. **Business Name:**
4. **Date of Submission:** September 28 2020
5. **Contact Person:** Andrea Lott
6. **Email Address of Contact Person:** andrea@acnem.org
7. **Postal Address of Contact Person:** As above
8. **Phone Number of Contact Person:** 03 9583 1320
9. **Fax Number of Contact Person:** N/A

This application has been made in support of Mr Peter Hunt, the Chairman of Mind Medicine Australia and his application for psilocybin to be rescheduled from Schedule 9 of the Poisons Standard to Schedule 8 of the Poisons Standard.

## 1) Proposed Rescheduling of the Poisons Standard

ACNEM requests the rescheduling of psilocybin or psilocybin from Schedule 9 to Schedule 8 of the Poisons Standard.

### Overview

#### Description

Psilocybin is a member of the tryptamine chemical family and presents as a white crystalline solid. It is stable over extended periods at room temperatures. It is a major psychoactive constituent in mushrooms of the *Psilocybe* genus. Psilocybin is classed as a psychedelic, sometimes called a hallucinogen, although this name is advised against in modern scientific literature as psychedelics do not generally induce true hallucinations. Psychedelics are chemical compounds which temporarily create changes in brain function including shifts in perception, thinking, and feeling, which temporarily produces an 'altered state of consciousness'.

#### Toxicity

The toxicity of psilocybin is very low. Based on the results of animal studies, the lethal dose of psilocybin has been extrapolated to 6 g in humans (Gable 2004, p. 690); which is 300 times the typical therapeutic dose of 20 mg. The lethal doses are below: > LD50 (mouse) = 285 mg/kg > LD50 (rat) = 280 mg/kg > LD50 (rabbit) = 12.5 mg/kg.

#### Effects in Humans

Therapeutic Psychological Effects (Carhart-Harris and Goodwin, 2017; Roseman et al., 2018; Kraehenmann, 2017; Passie et al., 2002)

- Enhancement of emotions
- Enhanced ability for introspection
- Increased awareness of sub-conscious processes
- Induction of hypnagogic experience and dream-like experiences
- Synaesthesia
- Labile brain state
- Alterations of thought and sense of time
- Enhances emotional breakthroughs

### **Possible Adverse Effects**

No drug related serious adverse events (SAE) have been reported from any previous research investigating psilocybin's effects in healthy participants (Aday, 2020).

All adverse effects in the studies were appropriately managed with safeguards in a clinical setting. The most common psychological adverse experiences have been anxiety and negative mood. The most common physical adverse events are cardiovascular (mild to moderate increases in blood pressure and heart rate), occasional nausea and headache.

### **Range of Use**

The following are taken from completed or current clinical studies:

- Major depression
- Treatment-resistant depression
- Anxiety disorders
- Addiction
- Anorexia nervosa
- Body-dysmorphic disorder
- Cluster and migraine headaches
- OCD (obsessive compulsive disorder)

### Why is rescheduling important?

#### Why is rescheduling so important?

The rescheduling will enable psychiatrists and specialist addiction physicians to more easily access these medicines to augment therapy for patients suffering from key mental illnesses such as depression, PTSD and the depression and anxiety often associated with a terminal illness diagnosis (and possibly in the future for substance abuse, OCD, anorexia and early stage dementia).

It will also relieve a significant part of the regulatory burden associated with undertaking trials with these medicines in Australia. Rescheduling is critical for a number of major reasons:

#### **a) To expand the medical treatment paradigm in Australia**

Trials to date have shown that these medicines when used with proper protocols in a medically controlled environment:

- can provide high remission rates for key classes of mental illness when compared to current treatments (such as antidepressants and conventional therapy)
- require only 2 -3 dosed sessions with the medicines (in contrast to a permanent or long-term use of pharmaceutical substances such as antidepressants)
- have minimal side effects (again in contrast to pharmaceuticals such as antidepressants).

#### **b) To educate Australians**

Rescheduling will educate all key stakeholders in our medical system (eg. medical practitioners, other health workers, politicians, regulators, people suffering from mental illness and other members of the general public) these substances can be used positively and safely in a medically controlled environment to broaden the treatment paradigm for mental illnesses in Australia and substantially reduce the incidence of mental illness in our community.

#### **c) To remove stigma**

To help the general community understand the prohibition of psychedelics was not based on any scientific or medical rationale and the failure of our system to recognise these substances can be used effectively as medicines in a medically controlled environment is detrimental to the health and welfare of a huge number of Australians.

### What does rescheduling mean?

Psilocybin are currently Schedule 9 substances under the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (often referred to as the Poisons Standard). This standard is designed to create a national system in Australia by classifying medicines and poisons into schedules for inclusion into relevant State and Territory legislation. At the moment psilocybin are classified in the Poisons Standard as Schedule 9 substances.

Schedule 9 substances are described as; “Prohibited substances - substances that may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except where required for medical or scientific research, or for analytical teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities”. This designation doesn’t acknowledge these substances can be used as medicines and as a consequence, makes it much harder and more expensive for our medical practitioners and researchers to access these substances.

ACNEM is seeking to have psilocybin medicines rescheduled to Schedule 8 of the Poisons Standard. Schedule 8 substances are described as; “Controlled Drug - Substances which should be available for use but require restriction on manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence”. The proposed rescheduling will make it easier for clinical trials to take place in Australia and for patients to access these medicines through their psychiatrists and specialist addiction physicians in a medically controlled environment under proper supervision. Moving the medicines to Schedule 8 will acknowledge these substances can be used as medicines. Many of the medicines prescribed by medical specialists are Schedule 8 medicines.

### 2) Why psilocybin should be in Schedule 8

Psilocybin shows therapeutic benefit for individuals who have been previously unsuccessful with traditional forms of treatment. Given the therapeutic benefits and high remission rates in clinical trials, the FDA’s designation of Breakthrough Therapy status and international “Expanded Access Schemes”, psilocybin does not fit into the requirements of a Schedule 9 substance and more closely reflects the requirements of Schedule 8.

Currently the Schedule 9 classification of psilocybin places additional hurdles on research (cost, stigma and ease of access) and on its medical use in a medically controlled environment. Reclassifying psilocybin as a Schedule 8 substance will reduce cost and improve ease of access for researchers and specialist medical practitioners working for individuals who seek relief for their treatment resistant conditions via the Special Access Scheme.

This treatment is only to be used in clinical settings under the guidelines of a Schedule 8 controlled substance in the Poisons Standards and in accordance with strict safety protocols in supplying psilocybin assisted therapy through health care providers in a medically controlled environment.

Ibogaine, another psychedelic compound, is currently Schedule 4 in Australia. Ibogaine has a far narrower therapeutic index, greater range of risk factors and is substantially less researched than psilocybin (Brown 2013). Reclassifying psilocybin as a Schedule 8 substance will ameliorate some of this discrepancy and reflect an evidence-based approach to drug policy.

Psilocybin containing mushrooms have limited abuse, misuse or overdose potential internationally as outlined in [MIND Medicine Australia's July 2020 TGA submission](#).

Further, there are no adverse reports within Australia. Current antidepressants and benzodiazepines hold far greater abuse, misuse or potential overdose as discussed in [MIND Medicine Australia's July 2020 TGA submission](#). With the noted breakthrough therapeutic potential publicly available for discussion we believe psilocybin should be rescheduled to Schedule 8.

### 3) Conclusion

Australia is in the midst of a mental health crisis, which has only been exacerbated by the current pandemic. The key diseases, depression, anxiety, PTSD, and addiction can be crippling for the individual, and also for communities. Unfortunately, the existing medications for these conditions are not effective in a substantial amount of people, and often have unacceptable side effects such as emotional numbing and increased suicidality. ACNEM believes there is an urgent need to explore other treatment modalities, including pharmacotherapies, which are showing to be effective in supporting mental health.

With the strong results and efficacy of psilocybin for anxiety and depression and for substance abuse and its very low toxicity and abuse potential in a medically controlled setting, it would be detrimental for suffering Australians not to have medically supervised access to this breakthrough medicine. There would not only be a large saving in the Australian economy through getting more people suffering from mental illness into remission but an improvement in the quality of life of Australians suffering from these illnesses.

This would have profound and vastly positive societal implications. We acknowledge and accept the premise that the use of psilocybin should only be authorised by psychiatrists or specialist addiction physicians and only used under medical supervision in a medically

controlled environment. We therefore believe that it is reasonable to reschedule psilocybin from being a Schedule 9 drug to being a Schedule 8 drug under the above conditions.

ACNEM would also like to declare their support of the Mind Medicine Australia Limited application to the Therapeutic Goods Administration to amend Poisons Standard by rescheduling psilocybin from Schedule 9 (prohibited substance) to Schedule 8 (Controlled Drug).

### Bibliography

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