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TGA blocks bid to have MDMA, magic mushrooms used to treat mental health conditions

By political reporter Claudia Long

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The TGA was considering whether to change the regulation of Psilocybin, which is found in magic mushrooms. *(Supplied: Caine Barlow)*

Australia's medicines regulator has rejected a call to legalise psychedelic drugs for use in mental health settings.

The Theraputic Goods Administration (TGA) has rejected an application to amend current poisons regulations to allow for psilocybin — also known as magic mushrooms — and MDMA (methylenedioxymethamphetamine) to be used in medically controlled environments.

Following research findings here and abroad, the application sought to have the drugs used as part of psychotherapy treatment for mental illnesses, depression and post-traumatic stress disorder.

TGA's decision means the drugs will not be downscaled from Schedule 9 drugs, which are prohibited substances, to Schedule 8 drugs which are controlled substances.

The TGA's stance is the same as its earlier interim decision.

Key points:

- The TGA is concerned changing the rules could lead to misuse of psilocybin and MDMA
- An independent review found the drugs may show promise for therapeutic use
- A number of clinical trials have been investigating the potential of psychedelics in mental health treatment

"I am satisfied that psilocybin poses a high danger for both acute and long-term effects if abused or misused by way of access outside of strictly controlled medical and scientific research settings," the author of the final decision, who is not named, said.

"Given this increased risk to individuals of acute and long-term effects, a high level of control across the supply chain commensurate with Schedule 9 is warranted."

Earlier this year, an expert panel review commissioned by the TGA found that psychedelics could possibly be used to manage treatment-resistant mental illnesses in closely supervised medical settings.

"I agree with the committee that the preliminary findings from clinical trials — although still in early phases — evaluated by the panel are promising," the decision's author said.

"However, given the extent and issues with the quality of the completed studies detailed by the panel, I reiterate my statement in my interim decision that I consider that evidence is still emerging, and the therapeutic value of psilocybin has not been established.

"I am of the view that ensuring administration of psilocybin — according to the strict protocols used in clinical trials that have showed promise of efficacy to date — would be hard to achieve outside a clinical trial framework."

On the use of MDMA in clinical settings, the TGA's decision outlined similar concerns to those it had about psilocybin.

"I consider that the benefits of MDMA have not been fully established, although there is emerging evidence in treating PTSD, with [a] demonstrated low risk of adverse events in controlled settings," the decision said.

"I am concerned with how, in accordance with the qualification included in the expert report's conclusion about the promise of MDMA in highly selected populations, namely the controlled clinical trial environment, can be replicated in real-world settings.

"I have considered the impacts on public health, were access to MDMA to be increased through an entry in Schedule 8 of the Poisons Standard ... I am of the view that there would be an increased risk of misuse by individuals outside of a highly controlled environment or diversion for illicit purposes."