

TGA blocks use of MDMA, magic mushrooms trials for mental health

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Psychedelic drugs cannot be used to treat mental health conditions, the Therapeutic Goods Administration has ruled, rejecting a bid to have MDMA and magic mushrooms reclassified as controlled substances.

An application with the TGA sought to amend current poisons regulations to downscale psilocybin (the active ingredient in magic mushrooms) and MDMA from Schedule 9 prohibited substances, cracking open the door for their use in approved medical environments.

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



But the TGA has decided the drugs will not be rescheduled, pointing to the risk that psilocybin and MDMA (aka methylenedioxymethamphetamine) might be abused outside strictly controlled medical and scientific research settings.

Peter Hunt, chair of Mind Medicine Australia, and the lead on the rescheduling application, criticised the opaque TGA process and said the response shows a failure to understand the existing mental health crisis in Australia.

“It’s a shocking process,” Mr Hunt said. “Sadly, someone up high in the health department didn’t have the courage to follow the science and the data and many people will continue to suffer.”

Mr Hunt said a rescheduling would still require psychiatrists to get TGA and state government approval for each individual case.



Tania de Jong and Peter Hunt, co-founders of Mind Medicine Australia. **James Alcock**

“This was never going to open the floodgates, the government would still have control in the process,” he said.

“We need registered doctors and health practitioners involved, now the risk is desperate people will go underground and get underground therapy. It’s the worst of both worlds.”

In an anonymously authored report, the TGA 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.”

Despite the ruling of the TGA, Australia has a fledgling psilocybin industry that is mirroring the tentative growth of the cannabis industry before it was recognised by the TGA in 2018.

ASX-listed companies Bionomics (backed by ATAI Life Sciences), Incannex Health and Emyria are local biotechnology firms with clinical trials involving psilocybin underway.

On the start-up side, Enosis Therapeutics is a Melbourne-based start-up building out a clinical trial to use virtual reality technology with psilocybin-use to help treat trauma.

Sydney-based Psylo recently raised \$1.1 million to boost its plans to develop a shorter acting version of psilocybin. The round was led by Chris Hitchen’s global micro-VC fund Possible Ventures, and had participation from a range of angel investors including AirTree chairman and philanthropist Daniel Petre.

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