

Media Alert: 3 February 2023 – Melbourne, Australia

Breaking News: The TGA Announces the Delegate's Final Decision to Reschedule the Use of Psilocybin and MDMA for Medical Purposes

Earlier today, the Therapeutic Goods Administration (TGA) <u>announced</u> that - from the 1st July 2023 - the medical use of MDMA and Psilocybin will be rescheduled from Schedule 9 (prohibited substances) to Schedule 8 (controlled medicines) of the Poisons Standard. This will enable authorised psychiatrists to prescribe these substances for treatment resistant depression and treatment resistant post-traumatic stress disorder.

All other uses of MDMA and Psilocybin will remain in Schedule 9.

The TGA's decision to reschedule these substances for medical purposes for use by authorised psychiatrists is in response to Mind Medicine Australia's rescheduling application lodged in March 2022 (and earlier application lodged in July 2020) and the enormous number of Australians who lodged their submissions in support.

You can read the TGA's full announcement and the Delegate's Final Decision here - https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists

In commenting on the decision, the Chairman of Mind Medicine Australia, Peter Hunt AM said that: "We are delighted with the decision which will be welcomed by so many suffering Australians. The decision specifically recognises the current lack of options for patients with specific treatment resistant mental illnesses and the supporting evidence of safety and efficacy from clinical trials. Whilst not yet a medicine registered on the Therapeutic Goods Register, this decision will enable appropriately screened patients with treatment resistant depression and treatment resistant post-traumatic stress disorder to access these medicinal therapies through authorised psychiatrists."

The Executive Director of Mind Medicine Australia, Tania de Jong AM commented: "We want to express our enormous gratitude to the tens of thousands of people who have made this breakthrough possible including the TGA, the Delegate, the members of the TGA's Medicines Scheduling Advisory Committee and all of the psychiatrists, psychologists, other mental health professionals, world leading experts and all of the people who put in submissions of support.

The support that we have had throughout this process has been incredible and overwhelming. We were also delighted that the work of Professor David Nutt who presented to the TGA last November was specifically recognised by the Delegate in the Final Decision.

Finally, our hearts go out to all those Australians suffering from treatment resistant depression and treatment resistant post-traumatic stress disorder. They now have the opportunity of accessing this breakthrough treatment with their mental health professionals, which has shown such positive safety and efficacy results internationally."



See the TGA's FINAL Decision to SUPPORT rescheduling here -

https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma

Mind Medicine Australia is Australia's leading not-for-profit organisation working on the use of medicinal psilocybin and MDMA-assisted therapies to treat a range of mental illnesses. Mind Medicine Australia exists to help alleviate the suffering and suicides caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients. Visit: https://www.mindmedicineaustralia.org

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