



Media Alert: 8<sup>th</sup> of April 2021

## **TGA Seeks Independent Review on Rescheduling of Psilocybin and MDMA as Part of Therapy in Medically Controlled Environments**

Yesterday, the TGA announced (<https://www.tga.gov.au/node/937114>) that the Scheduling Delegate has decided to seek further advice in relation to Mind Medicine Australia's applications to reschedule [psilocybin and MDMA](#) as part of therapy in medically controlled environments from Schedule 9 (prohibited substances) to Schedule 8 (controlled medicines) of the Poisons Standard.

This comes following thorough and evidence-backed submissions from Mind Medicine Australia which were prepared in response to the Interim Decision not to reschedule these substances.

The TGA went on to say that:

*"This will include an independent expert review into the therapeutic value, risks and benefits to public health outcomes for these substances as well as seeking additional advice from the Advisory Committee on Medicines Scheduling following the review."*

*"The final decision [about MMA's rescheduling applications] will not be announced on 22 April 2021. Amended timing on the scheduling process will be published on the TGA website following the completion of the independent review."*

In commenting on the TGA announcement, the Chairman of Mind Medicine Australia, Peter Hunt AM said that:

*"We are delighted with this development because we have become increasingly concerned about the process to date and the quality of the arguments that were used by the Delegate to justify rejecting our applications at the interim stage."*

*"We have the ridiculous situation in Australia where the TGA is authorising applying medical practitioners to use these medicines as part of therapy in medically controlled environments for patients suffering from treatment resistant PTSD and treatment resistant depression but the wrongful scheduling of these medicines in Schedule 9 of the Poisons Standard is preventing these medical practitioners from obtaining the consents of the State and Territory Governments where the treatment would be carried out."*

The Executive Director of Mind Medicine Australia, Tania de Jong AM stated that:

*"We have terrible rates of mental illness in Australia with too many people suffering from debilitating treatment resistant depression. The current system is failing those people. Medical grade MDMA and psilocybin have been shown in overseas trials to be safe and non-addictive and lead to high remission rates when used as part of*



# MIND MEDICINE A U S T R A L I A

*psychotherapy in medically controlled environments and only requires 2-3 dosed sessions with the medicines. We must put the patient first rather than be held back by bias and stigma.”*

Mr Hunt went on to say that:

*“It is critical that the Independent expert be independent of the Royal Australian and New Zealand College of Psychiatrists given the College’s Memorandum on the Therapeutic Use of Psychedelic Medicines which they published in May 2020 and which contained many errors and misleading statements and which the College to date has refused to acknowledge.”*

*“We would also encourage the Independent expert to seek advice from World leading experts in this field rather than just depend on local and, in many cases, uninformed advice.”*

Mind Medicine Australia's submissions opposing the TGA's Interim Decision, and more information can be found here - <https://mindmedicineaustralia.org/tga/>

An amended timing on the scheduling process for these substances will now be published on the TGA website following the completion of this independent review.

Mind Medicine Australia exists to help alleviate the suffering caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients.

**For more information please visit: [www.mindmedicineaustralia.org](http://www.mindmedicineaustralia.org)**

**Please note the following are available for interview:**

- **Peter Hunt AM (MMA Chair)**
- **Tania de Jong AM (MMA Executive Director)**
- **The Hon. Andrew Robb AO (MMA Director)** - Board Director of MMA and former Trade Minister to Australia who has had treatment resistant depression for 43 years.
- **Chris Barrie AC** - Board Director of MMA and former Head of the Armed Forces who says these treatments are the only hope for Veterans and others suffering with PTSD.

**For further information, or to arrange an interview, please contact Ilan Hayman [ilan@mindmedicineaustralia.org](mailto:ilan@mindmedicineaustralia.org) or Tania de Jong AM [tania@mindmedicineaustralia.org](mailto:tania@mindmedicineaustralia.org)  
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