

## MEDIA ALERT: 17 February 2021

### Mind Medicine Australia challenges TGA Interim Decision

#### **CALL TO ACTION**

**We URGENTLY Need Your Support to ensure the Rescheduling Applications for the Medicinal Use of Psilocybin and MDMA are Approved by the Government in Canberra.**

**On 3<sup>rd</sup> February, the Delegate for the Secretary of the Department of Health in Canberra made an interim decision NOT to reschedule these medicines from Schedule 9 to Schedule 8 of the Poisons Standard.** The rescheduling applications were lodged last July and supported by over 80 leading psychiatrists, psychologists, pharmacologists, researchers and other medical practitioners and another 30 leading scientists and clinicians from DrugScience UK. The public submissions were also overwhelmingly in favour of the rescheduling of these medicines and over 50% of these submissions came from Health Sector Experts.

In commenting on the interim decisions, the Chairman of Mind Medicine Australia, Peter Hunt AM, said that: *“Whilst we are disappointed, we have to remember that these are only interim decisions. The enormous benefit that we now have is that the Delegate of the Secretary of the Department of Health has had to publish the Delegate’s reasons for making these interim decisions. Under the rescheduling process we now have the opportunity to address each of those stated reasons in our final submissions.”*

Executive Director Tania de Jong said: *“[Mind Medicine Australia](#) has now analysed all the submissions. The responses given to the TGA about our rescheduling submissions were overwhelmingly supportive. Over 50% of the support came from medical professionals and health sector researchers. The balance came from consumers including those with lived experience of mental illness. In addition, our applications were endorsed by over 110 named experts including many of the World’s leading researchers in this field.*

This included support from the leading researchers in the medicinal use of both Psilocybin (including Professor Roland Griffiths, Professor David Nutt and Dr Robin Carhart-Harris) and MDMA (including Dr Rick Doblin and Dr Ben Sessa) as part of therapy who have completed many trials with these medicines. There are no researchers in Australia with anything like this experience.

Peter Hunt said: *“For the Delegate to suggest that few of the submissions addressed the factors relevant to rescheduling and few of the submissions were from psychiatrists is simply wrong and fails to acknowledge the quality and expertise of the many experts who supported our rescheduling submissions.”*

The numbers are quite startling:

- In the case of medicinal psilocybin there were 575 responses of which 553 (or 96%) were supportive, 11 partially supportive and only 11 opposed.
- In the case of medicinal MDMA, there were 478 responses of which 453 (or 95%) were supportive, 14 partially supportive and 11 opposed.

Of the 11 opposing submissions (about 2% of the total submissions), 3 appear to have been written by the same person who chose to retain anonymity. This lack of preparedness to be identified means



that any conflicts of interest affecting that person (such as involvement in a trial sponsored by a pharmaceutical company whose commercial interests are against these medicines becoming more accessible until the trial is completed) is also not identified. Good governance requires disclosure of conflicts and members of the public are entitled to know this information.

Research from a large number of overseas trials indicates that the medicines are safe and non-addictive when administered within a medically-controlled environment and can lead to remissions in 60-80% of patients after just 2-3 medicinal sessions in combination with psychotherapy. There have been no adverse events in any of the trials, involving over 3000 patients. Psychiatrists are trained to screen out at-risk individuals in order to safely prescribe conventional drugs. It is somewhat ironic in this context that in contrast to medicinal psilocybin and medicinal MDMA anti-depressants have been associated with some cases of psychosis and suicide.

Pre-Covid 1 in 5 people in Australia were suffering from a mental illness. At least 1 in 8 adults, 1 in 4 older adults in 1 in 30 children are on anti-depressant medications currently, and often without disclosure of potential side effects. Additionally, the long-term effects of anti-depressants have never been studied. There has been no innovation in existing treatments for 5 decades. The lack of effective treatments has most certainly contributed to Australia's devastating mental health statistics, which position Australia as second worst amongst all OECD nations, only ahead of Iceland. With mental illness accelerating throughout the community as a result of the Covid-19 pandemic this makes the need for innovation even more urgent.

Both psilocybin and MDMA have been granted **Breakthrough Therapy Status** by the FDA in the USA to fast-track their approval. This designation is only given to medicines which may prove to be vastly superior to existing treatments.

The [Clinical Memorandum published by the RANZCP](#) in May 2020 which argues against these medicines being made available through our medical system at the present time was noted in the Delegate's Interim Decision. A number of psychiatrists (as reported in [The Australian last week](#)) believe that the Memorandum is poorly researched and contains many errors and misleading statements. They also question why the Clinical Memorandum didn't go through the normal peer review process and whether the authors had any affiliations with pharmaceutical companies. A Critique of the errors and misleading statements in the RANZCP Clinical Memorandum, which was authored by 9 researchers, appears here <http://ssrn.com/abstract=3757891>.

The AMA in their submissions to the TGA confused the TGA's Special Access Scheme-B pathways with trial pathways. They suggested that these medicines could be available through the Special Access Scheme-B pathway whilst not acknowledging that the Schedule 9 classification means that most States do not have a medical exemption system in place to allow Doctors to use the medicines as part of therapy for patients residing in those States.

Veteran and psychiatrist, Dr Stuart Saker from NSW, has received 12 SAS-B approvals from the TGA to treat seriously unwell patients with Psilocybin or MDMA assisted therapies depending on their specific condition. Due the Schedule 9 classification of these medicines he is unable to treat his patients who are all Veterans. **They deserve a chance to get better.**

**The TGA is inviting comments about the Interim Decision.** Mind Medicine Australia has prepared a "How-to Guide" which can be found [HERE](#). To maximise the prospects of the Delegate authorising the rescheduling of medicinal Psilocybin and medicinal MDMA in the Delegate's Final Decision,



**submissions need to be lodged through the [TGA's portal](#) **OPPOSING** the Delegate's Interim Decision by no later than 5pm on March 4th. The final decision will be announced on April 22.**

Thank you for your support for creating positive change in Australia and helping so many people suffering from debilitating mental illnesses in this country.

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

- Peter Hunt AM (MMA Chair)
- Tania de Jong AM (MMA Executive Director)
- Dr Simon Longstaff AO, Executive Director of The Ethics Centre (MMA 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 suffering with PTSD.
- Dr Jamie Rickcord - who received the first SAS-B approval for a GP to treat a patient with psilocybin-assisted therapy in northern NSW.
- Michael Raymond - Veteran in Canberra who has healed through these treatments
- Shane Hill and his daughter Angelique - who have recovered from serious mental illnesses through these treatments – based in Shepparton VIC.

**For further information, or to arrange an interview, please contact Ilan Hayman  
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