Media Alert: 15 December 2021 - TGA says NO again to psychedelic-assisted therapies

Mind Medicine Australia's Response to the Announcement of the TGA NOT to Reschedule the Medical Use of MDMA for Treatment Resistant PTSD and the Medical Use of Psilocybin for Treatment Resistant Depression as Part of Therapy.

Australia has some of the worst mental health statistics in the World and these are getting significantly worse. According to the Productivity Commission 1 in 5 Australians pre-covid were suffering from a mental illness and 1 in 8 Australians (including 1 in 4 older people) were on antidepressants. Recent evidence indicates that mental health in Australia has significantly deteriorated because of the fears and constraints associated with the covid pandemic.

In contrast to other areas of health there has been minimal treatment innovation in the mental health sector for decades and treatment outcomes haven't improved over that period. As a result, remission rates for common and debilitating classes of mental illness such as depression and post-traumatic stress disorder remain low and many people that seek healing from our medical system remain treatment resistant.

According to the Chairman of Mind Medicine Australia (**MMA**), Mr Peter Hunt AM:

"We are bitterly disappointed by the TGA's decision because, in our view, the medical use of both psilocybin and MDMA within controlled medical environments by trained professionals should come squarely within Schedule 8 of the Poisons Standard. This is a view echoed by the many researchers and medical practitioners who supported our rescheduling applications. There are so many people suffering from treatment resistant depression and treatment resistant PTSD in Australia who will be in despair because of this decision."

We also respectfully believe that there are many errors and inconsistencies in the Delegate's published reasons for refusing these applications. Here is a link to their decision: https://www.tga.gov.au/scheduling-decision-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-relation-psilocybin-and-mdma

A full analysis of the Delegate's decision will be published by MMA in the next few days.

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At the point we simply want to highlight that Australia has missed an extraordinary opportunity to help people suffering from treatment resistant PTSD and treatment resistant Depression and to become one of the global leaders in this area.

Central to MMA's rescheduling application was the fact that:

1. The medicines would only be used in medically controlled environments when prescribed by psychiatrists or specialist addiction physician as part of therapy. Under our application the medicines would never be available for patients to take home.
2. To prescribe these medicines the treating psychiatrist or specialist addiction physician would still need to obtain specific permission on a per patient basis from both the TGA and the Health Department of the State or Territory where the treatment was to occur.
3. The trial data clearly show that in these circumstances the medicines are safe to use as part of psychotherapy and generate high remission rates. It also needs to be emphasised that very positive results were recently released in relation to a major Phase 3 trial in the US using medical grade MDMA for treatment resistant PTSD and in relation to a major Phase 2b trial using medical grade psilocybin for treatment-resistant depression. Most of the sources referred to by the Delegate were published in 2020 before these results were published and none of them support retention of a Schedule 9 listing (with the exception of the RANZCP clinical memorandum which is now badly out of date and contains many errors).
4. The TGA has already recognised MDMA and psilocybin assisted therapies as medicines by providing a significant number of approvals to treating psychiatrists and other specialist physicians on a case-by-case basis under Special Access Scheme-B for the past 18 months.

The Delegate refers to concerns about abuse or misuse. In other words, the Delegate is suggesting that our medical system doesn't have appropriate controls to keep Schedule 8 substances secure. Given that many Schedule 8 medicines used in clinical environments are far more dangerous than psilocybin or MDMA if abused or misused (e.g. opiates and medical cocaine) this rationale doesn't make any sense to us. Furthermore, this decision will undoubtedly push many more desperate people into the underground for treatment because this is their last hope.

A related argument used by the Delegate is that somehow these medicines could find their way into the recreational drug scene. We would encourage all readers to think about this. Psilocybin is readily available for free simply by picking psilocybin containing mushrooms which grow plentifully in many gardens and country areas. Recreational MDMA is easily accessible through the black market. Medical grade MDMA and

medical psilocybin are synthesised by pharmaceutical companies and are therefore much more expensive. Under Schedule 8 of the Poisons Standard, they would have to be kept in a safe when not used and accounted for by medical establishments in regular lodgements with the TGA.

In closing the Executive Director of MMA, Tania de Jong AM said that:

"Our hearts go out to all those suffering from treatment-resistant depression and PTSD. All the evidence shows that these substances, when used as part of therapy in medically controlled environments, are safe and remission rates are very high. We are also devastated for all those treating practitioners who desperately need to help their patients. They urgently need access to these medicinal therapies in a controlled medical environment under the supervision of caring practitioners. We have an increasing shadow pandemic of mental illness in this country and our wonderful and caring practitioners do not have the tools to treat the immense suffering and suicidal ideation. Furthermore, Australia has lost a massive opportunity to be a leader in this field with this decision."

MMA will be lodging fresh applications for the rescheduling of these medicines as soon as possible, when used as part of therapy with the TGA.

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