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Victorian Government Proposes Controversial Regulatory Change Amidst Worsening Mental Health Crisis

The Victorian Government has proposed a controversial change in health regulations to take away its current ability to issue permits for the clinical use of pharmaceutical grade MDMA and Psilocybin as part of psychotherapy for treatment resistant patients. This move will deny 'at-risk' patients the opportunity to access treatments recommended by their psychiatrists which have been shown to be safe and highly effective in medically controlled environments.

The proposal comes in the middle of an Appeal in the Melbourne Magistrate's Court against the refusal of the Victorian Department of Health and Human Services (DoH) to issue a psychiatrist with a permit to provide MDMA-assisted therapy to an 'at-risk' patient with treatment resistant post-traumatic stress disorder (PTSD).

Once implemented, the change would prevent the DoH from issuing the permits despite the fact that the treatment for a specific patient has been approved by the federally administered Therapeutic Goods Administration (TGA).

The change could also result in the cessation of the Appeal, which will allow the Court to review the safety and efficacy evidence for the use of MDMA-assisted therapy as an unregistered medicine under the TGA's Special Access Scheme and hear from leading international experts in this field.

According to the leading Australian advocate on the development of safe and effective psychedelic-assisted therapies to cure a range of mental illnesses, Mind Medicine Australia (MMA), the Victorian Government is abrogating its responsibility to assist mental health patients on a case-by-case basis, where the treatment has been recommended by the patient's psychiatrist.

"The Victorian Government holds itself out to be the most progressive government in Australia when it comes to actioning improvements in the care of patients suffering from mental illnesses. This was highlighted when Premier Andrews confirmed that his government would implement all of the recommendations of the 2021 Royal Commission into Victoria's Mental Health System," said MMA chairman Peter Hunt.

"Allowing Victorian public servants to abrogate the Government's existing right to issue permits to enable a patient to benefit from an approval already given by the TGA under its Special Access Scheme without any proper public consultation or meaningful dialogue with the Victorian Minister for Health is a backward step in the treatment of mental illness."

MMA is one of several organisations and individuals that have lodged submissions to the DoH outlining key reasons why the proposed regulatory change should not proceed. MMA has outlined seven issues:



1. *It would lead to the continuation of unbearable suffering for many people with treatment resistant PTSD and/or treatment resistant depression who, by definition, are not benefiting from current treatments (in the worst cases these treatment resistant mental illnesses can lead to suicidal ideation and, in some cases, actual suicide).*
2. *It would be unconscionable to pre-empt the court appeal process already commenced which is an opportunity to examine all of the evidence and hear from World leading experts.*
3. *It would be inconsistent with the progressive, innovative, and pragmatic approach of the Victorian Government to improving mental health outcomes.*
4. *It would be inconsistent with the international conventions that Australia has committed to, and which Victoria should therefore observe.*
5. *It would be inconsistent with the National Scheduling Policy Framework for Medicines and Poisons.*
6. *Restricting the availability of Schedule 9 permits for the medical use of MDMA and Psilocybin as part of psychotherapy to ethics-approved clinical trials is not a viable solution for a treatment resistant 'at-risk' patient.*
7. *Removing the availability of Schedule 9 permits for the medical use of MDMA and Psilocybin would lead to perverse, and indeed heartless, results.*

MMA is promoting innovation in the treatment of mental illnesses because outcomes remain poor for many patients across Australia.

Prior to the COVID-19 pandemic lockdowns, 1 in 5 Australians were estimated to have a chronic mental illness and 1 in 8 Australians were on antidepressants (including 1 in 4 older people). Anecdotal evidence shows that these figures are now considerably worse in Victoria and Premier Daniel Andrews has described the mental health system as “broken” on multiple occasions.

Only about 35% of patients with depression go into remission with current treatments and a further 30% are estimated to get some benefit (but often with significant adverse side effects and with high relapse rates). This leaves roughly 35% of depression sufferers who don't benefit from existing treatments (these patients are often described as “treatment resistant”).

The percentages for PTSD are much worse than this (less than 10% with PTSD are estimated to go into remission, a further 20% get some positive response, whilst the balance receive very little, if any, benefit from current treatments). These treatment failures are highlighted by the fact that there has been minimal treatment innovation in the mental health sector in Australia for over 50 years and treatment outcomes haven't improved over that period.

“Given the extent of systemic treatment failure in Victoria, why is the Victorian Government seeking to abrogate its rights to issue permits to psychiatrists who already have approvals from the TGA to use Psilocybin and MDMA-assisted therapies to treat consenting patients with treatment resistant depression and treatment resistant PTSD in controlled medical environments.? Issuing permits in these circumstances is clearly within the limited medical exemption contained in the United Nations Convention on Psychotropic Substances and is therefore consistent with Australia's international obligations”, said Mr Hunt.



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“Treatment resistant depression and treatment resistant post-traumatic stress disorder are serious illnesses and cause enormous suffering. By definition, current treatments aren’t working for these patients. MDMA and psilocybin assisted therapies have been shown to be safe and effective in overseas trials and are already being used in a number of countries with expanded access schemes or regulatory exemptions (such as Canada, Switzerland, Israel, Holland and the United States).

“It must be asked why the Victorian State Government is so resistant to these therapies being used in controlled medical environments by trained psychiatrists and therapists when the psychiatrists involved believe they are appropriate, and the proposed treatment resistant patient has given fully informed consent.”

“Allowing doctors and their treatment resistant patients who have given fully informed consent to access treatments which could offer respite and healing from debilitating illnesses should be a basic human right. It is cruel for a government to stand in the way and prevent this, when the controls proposed ensure that the treatments will be confined to a medically controlled environment and patients will never be able to take the medicines home.”

The Victorian Government’s consultation document seeking submissions and Mind Medicine Australia’s submission to the Victorian Government can be found here:

<https://mindmedicineaustralia.org.au/submissions/>

For further information please call or email:

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Visit: www.mindmedicineaustralia.org

About Us: [Mind Medicine Australia](http://www.mindmedicineaustralia.org) is Australia’s leading not-for-profit organisation focused on developing the ecosystem for the use of medicinal psilocybin and MDMA-assisted therapies within the medical system to treat a range of mental illnesses. Mind Medicine Australia exists to help alleviate the suffering caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients. Our focus is wholly clinical.