Why Have We Lodged New Rescheduling Applications with the TGA?

Mind Medicine Australia has recently lodged new applications with the TGA to reschedule the medical use of MDMA-assisted therapy for treatment resistant post-traumatic stress disorder (commonly referred to as **PTSD**) and psilocybin assisted therapy for treatment resistant depression from Schedule 9 to Schedule 8 of the Poisons Standard.

Our MEDIA RELEASE can be found **here.**

The key reason that we are lodging new applications is the worsening mental health crisis that we have in Australia. We believe that one of the key reasons that rates of mental illness are so high is that the available treatments for illnesses like depression and PTSD don't work (or don't work very well) for a large number of sufferers. Remission rates are only around 35% for patients suffering from depression and less than 10% for patients suffering from **PTSD**. Furthermore, treatment resistant mental illness is one of the main causes of suicidality and suicide across Australia.

In contrast, MDMA assisted therapy and psilocybin assisted therapy are showing outstanding results in overseas trials with high levels of safety. We desperately need these innovative treatments in Australia to help people suffering from treatment resistant PTSD and treatment resistant depression where both the psychiatrist involved (and two reviewing psychiatrists) and the patient (properly informed) believe that these therapies could positively assist the patient's treatment outcome.

Background

Our NEW APPLICATIONS can be found **here**.

In Australia responsibility for medical treatments in our health system is shared between the Commonwealth Government and the State or Territory Government where the proposed treatment is to occur.

Medicines are scheduled in what is referred to as **the Poisons Standard**, which determines how medicines and poisons are made available to the public. Substances are classified into Schedules according to the assessed level of regulatory control required to protect public health and safety.

Scheduling is initially determined at the Commonwealth level (through a TGA administered process) and then incorporated by States and Territories around Australia into their own regulatory frameworks on a cooperative basis. Scheduling is important because it determines who can authorise the provision of a medicine and the basis for that authorisation.

For historical reasons associated with the War on Drugs, the medical use of psilocybin and MDMA is in Schedule 9 of the Poisons Standard (where substances are described as "prohibited substances"). Mind Medicine Australia believes that this scheduling is inappropriate given the strong safety and efficacy data that has been generated from clinical trials around the World when these medicines are used as part of therapy for treatment resistant depression and treatment PTSD. These are very

debilitating illnesses and directly affect the quality of life of the person suffering from the illness as well as families and friends caring for that person.

Mind Medicine Australia has therefore applied for the rescheduling of the medical use of MDMA and psilocybin as part of therapy to Schedule 8 of the Poisons Standard (where substances are described as "controlled medicines"). This is the second time that we have lodged rescheduling applications with the TGA. Our first applications were lodged in July 2020.

Our first applications were ultimately rejected by the decision – maker in the TGA administered process, an anonymous person referred to as the Delegate. The Delegate is appointed for this purpose by the Secretary of the Department of Health. However, the benefit that we gained from participating in this process was the detailed reasoning published by the Delegate explaining the reasons for the rejection. This published reasoning – which can be found **here** - has enabled Mind Medicine Australia to address each concern raised by the Delegate in a very targeted and factual way in our new applications.

Why is Rescheduling So Important?

Put simply, rescheduling is important because a large number of patients in Australia suffering from depression and/or PTSD are treatment resistant. In other words, current treatments aren't working for them. This leads to an enormous amount of suffering across Australia and in the worst cases can lead to patient suicidality and suicide.

Trial results to date have shown high safety levels and high efficacy rates associated with psilocybin and MDMA assisted therapies. However, the current Scheduling of these medicines in Schedule 9 of the Poisons Standard is preventing medical practitioners from being able to treat consenting patients with these therapies.

In Australia there are broadly two types of medicines; medicines that are registered and medicines that are not registered on the Australian Register of Therapeutic Goods.

The registration of a medicine is normally sponsored by a pharmaceutical company which funds supporting research (normally Phase 1, Phase 2 and Phase 3 clinical trials) to convince the TGA that it should register the medicine. This is an expensive process, and the pharmaceutical company will normally seek patent protection for the medicine giving it a monopoly over its use for 20 years. The benefit of registration for medical practitioners and patients is that medical practitioners can prescribe the medicine without seeking individual patient approvals from the regulatory authorities.

However, the TGA recognises that a patient may be treatment resistant meaning that current registered medicines are not properly treating the patient's condition. In these circumstances medical practitioners can apply to the TGA on a patient specific basis under what is referred to as the Special Access Scheme to be able to prescribe an unregistered medicine for the patient's condition. In some circumstances a medical practitioner can also become an authorised prescriber which means that the medical practitioner can prescribe an unregistered medicine to a particular

class of patients without being required to first make individual patient specific applications to the TGA each time for approval.

As mentioned above, the problem that we have with key mental illnesses in Australia such as depression and PTSD in Australia is that current treatment doesn't work for a large percentage of patients, and this causes enormous suffering in our communities. Existing medical treatments can also have significant side effects and withdrawal from medication can sometimes be challenging.

The TGA has recognised this problem by granting individual medical practitioner's approvals under the Special Access Scheme to prescribe MDMA-assisted therapy for treatment resistant PTSD and psilocybin-assisted therapy for treatment resistant depression. Most approvals are being given by the TGA within 72 hours of receipt of the individual application.

In other words, at the TGA level, the system is working well.

Unfortunately, the problem that we have in Australia is that State and Territory Governments don't recognise that MDMA and psilocybin can be used as medicines because of their listing as prohibited substances in Schedule 9 of the Poisons Standard. This means that a medical practitioner who received approval from the TGA to prescribe psilocybin or MDMA assisted therapy for a treatment resistant patient and who sought to use either substance as part of the treatment would be criminally liable under the recreational drug laws of that State or Territory. There are no Schedule 9 permit processes available in States and Territories around Australia (with the possible exception of Victoria – which the Victorian State Government currently isn't acknowledging) which would enable a medical practitioner to avoid criminal liability by first seeking approval for the use of the treatment at the State or Territory level.

By moving the Scheduling of these substances as part of therapy into Schedule 8 of the Poisons Standard permit systems will become available in all States and Territories of Australia. This will lead to State and Territory Governments developing policies for granting approvals.

This is broadly what occurred when medicinal cannabis was rescheduled from Schedule 9 to Schedule 8 of the Poisons Standard. Initially the system was quite unwieldly with medical practitioners having to apply for approvals from both the TGA and their local State or Territory Health Departments. However, the system has now become much more efficient and streamlined with over 100,000 patient approvals being given to date.

The other benefit of rescheduling is that we will start to get data back from the actual use of these therapies in practice which will complement the data that is being obtained from clinical trials. This should lead to even better results being achieved over time as new ways of administering the therapies are developed.

MIND MEDICINE AUSTRALIA

The Rescheduling Timetable

The rescheduling process takes nearly a year. We have the broad timeline from the TGA website, but specific dates will shortly be announced by the TGA when it publishes our applications on its website**. We will update this part of our website for these specific dates as soon as they are announced by the TGA.**

The broad timeline is set out below:

Our New Rescheduling Applications

We lodged our new rescheduling applications on 4th March 2022 before the deadline for the current round of applications and the TGA has acknowledged receipt.

In our new applications we have made the proposed rescheduling more restricted in response to comments made by the Delegate in rejecting our earlier applications.

We are proposing that the medical use of MDMA and psilocybin as part of therapy will only become Schedule 8 medicines in the following restricted circumstances.

1. As an unregistered medicine, the treating psychiatrist will only be able to prescribe pharmaceutical grade psilocybin or pharmaceutical grade MDMA as a Schedule 8 controlled medicine if the psychiatrist first obtains approval from the TGA under its Special Access Scheme-B to use these substances as part of psychotherapy. To obtain such an approval, the psychiatrist will have to demonstrate to the TGA that the patient is treatment resistant and "at risk".
2. The treating psychiatrist will need to have received specific training in the use of the proposed medicine- assisted psychotherapy.
3. The psychiatrist's patient diagnosis and treatment plan will have to be confirmed by two other psychiatrists.
4. The Government of the State or Territory where the treatment is to occur will also need to approve the proposed treatment for the specified patient under its own Schedule 8 permit procedures.

Importantly the new Neuromedicines Discovery Centre at Monash University has agreed to host an independent registry to collate treatment data from the treating psychiatrists and their patients.

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This will significantly add to our knowledge base about the translation of these therapies into clinical practice.

In structuring our limited rescheduling applications, we have carefully responded to issues raised by the Delegate, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and the Australian Medical Association.

Whilst our rescheduling applications are necessarily detailed because of the enormous amount of developments that we are seeing in this field, the following provides a brief summary (references below are to the Psilocybin Application but the same points are made in both documents):

1. **The limited nature of the rescheduling proposed** (Part 1 Section 1 on page 6).
2. **The strong supporting safety data** (Part 1 Section 2.3 starting on page 11 which includes the latest trial research data and Part 2.1 Section (B) 3(4) starting on page 71 which compares psilocybin when used as part of therapy with other well-known medicines from the perspective of both safety and therapeutic index).
3. **Our response to specific issues raised by the Delegate in its Final Decision announced in December 2021 and in particular whether the established therapeutic value test has been satisfied, translation risk and diversion risk** (Part 1 Section 3.2 starting on page 17).
4. **Our response to matters raised by RANZCP and the AMA in their submissions in response to our first applications** (Part 1 Section 3.3 starting on Page 21). This section also includes the offer by Monash University's Neuromedicines Discovery Centre to host the independent registry.
5. **The desperate need for new and improved treatments for treatment resistant patients** (Part 1 Section 3.5 starting on page 25).
6. **The strong evidence supporting efficacy** (Section 3.6 starting on page 29 and Part 2.1 Section (A) 3.1 starting on page 41).
7. **The fact that seeking to participate in trials is not a solution for a treatment resistant "at risk" patient and can be very cruel** (Part 1 Section 3.10 starting on page 33).
8. **The importance of supporting the psychiatrist-patient relationship where appropriate controls are in place** (Part 1 Section 3.11 on page 34).
9. **The high calibre of health practitioner training now being offered in this field** (Part 1 Section 4 starting on page 38 and Part 2.1 Section (F) 3 starting on page 81).

Our applications also specifically deal with recommendations in an article which appeared in RANZCP's own journal in 2021, the Australian and New Zealand Journal of Psychiatry. In that article the writers (many of whom are leading Australian psychiatrists and psychologists) acknowledged that a Special Access Scheme pathway may be appropriate for these medicinal therapies "in judicious cases". The limited down-scheduling that we are proposing is even more constrained than the pathway proposed in this article. However, as mentioned above, whilst the TGA is already giving approvals for the use of these therapies on a case-by-case basis, the Special Access Scheme is unworkable at the State and Territory level whilst the medical use of these substances remains in Schedule 9 of the Poisons Standard.

You can find THIS ARTICLE **here**

Key Next Steps

The next steps in the medicines rescheduling process are:

1. **Early April 2022** – The TGA will publish our applications on the TGA website and publicly invites submissions from interested parties.
2. **May 2022** – The public submissions period will end.
3. **21-23 June 2022** - Meeting of the TGA's Advisory Committee on Medicines Scheduling which will advise the Delegate on our rescheduling proposal.
4. **September 2022** – The TGA will publish the Delegate's interim decision and publicly invites further submissions from interested parties.
5. **October 2022** – The second public submissions period will end.
6. **November 2022** – The TGA will publishes the Delegate's final decisions.
7. **February 2023** – Effective date for any changed scheduling.

CALL TO ACTION – LODGING A SUBMISSION

If you agree with us that the use of psilocybin and MDMA as part of therapy should be rescheduled to Schedule 8 of the Poisons Standard to make Australia's Special Access Scheme workable, we will ask you to lodge a submission in support with the TGA during the public submission period in late April/May. The actual closing date for submissions will be announced shortly.

As soon as the TGA publishes our applications on its website we will publish a **Guide on How to Make a Submission to the TGA** to make it easier for you to prepare and lodge your submission. Please watch out for this.

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