From: Peter Hunt
To: SKERRITT, John
Cc: NOYEN, Benjamin; Nutt, David J; arthur.christopoulos@monash.edu; Peter Hunt; tania@mindmedicineaustralia.org
Subject: RE: OUR MEETING ON MONDAY 21st NOVEMBER 2022 [SEC=OFFICIAL]
Date: Sunday, 27 November 2022 11:04:19 PM
Attachments: image001.png

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Dear John

Thank you for your quick reply on the technical point of whether a meeting of the ACMS will occur. However, there was a lot of other considered information in my email and attached submission. Could I please ask that you ensure that both are copied to the Delegate so that he/she understands the points that we are making and our view that the Delegate needs to hear from experts in this field, either directly or through presentations that our proposed experts are able to make to the ACMS.

I was also very surprised to hear that the ACMS may not be meeting again given the importance of the rescheduling decision to so many suffering people and their families and the importance which the present government is placing on reducing the currently high and increasing levels of suicide across Australia. The presence of Mrs Vanessa Bortolin at our meeting and the accompanying video about the suicide of her husband should have highlighted in the starkest of ways why it's so important for this rescheduling to happen

The fact that ACMS may not meet again wasn't raised by you with us last Monday when we discussed the benefit of organising a presentation to the ACMS from leading experts in this field. This is not a normal rescheduling decision because the determination of the Delegate will have a direct impact on the suicide risks and suffering of so many treatment resistant patients. In these circumstances we would have thought that the Delegate would want to consult with the ACMS again and receive expert advice from leading experts in the field.

If, despite our comments above, the Delegate doesn't want further advice from the ACMS then we believe that it becomes even more important for the Delegate to meet directly with our proposed experts. This goes directly to the soundness of the process, public confidence in the system and the normal rights of interested parties to be properly heard and the best advice being made available.

This is really all about leadership.

I would also ask you to direct the Delegate to the Appendices in our submission and in particular the letters from Vanessa Bortolin and Graham Daniels about the inadequacy of current treatments for some patients and the need for workable compassionate access schemes.

I am not sure I understand your point about the "expert review team" and I disagree with your reference to the report being an independent report for the reasons given in our recent

submission.   All I was saying was that the information in the Experts Report was sufficiently positive that it could have been used by the ACMS and the Delegate to support a rescheduling decision.

All the more reason for the process to be seen as demonstrably robust.

I hope these comments are helpful.

Yours faithfully

Peter
Peter Hunt AM
Mob 0419 271 483

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Sunday, 27 November 2022 8:20 PM
To: Peter Hunt <peter@phunt.com.au>
Cc: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>; Nutt, David J <d.nutt@imperial.ac.uk>; arthur.christopoulos@monash.edu; Peter Hunt <peter@mindmedicineaustralia.org>; tania@mindmedicineaustralia.org
Subject: RE: OUR MEETING ON MONDAY 21st NOVEMBER 2022 [SEC=OFFICIAL]

Peter

Thanks for your email and providing the submission.

It is not clear whether the Advisory Committee will meet again prior to the delegate making her/his final decision; in an overwhelming majority of cases the Committee only meets a single time to consider a rescheduling proposal. It is up to the delegate to consider whether they need to seek further advice from the committee prior to making her/his final decision. If the ACMS does reconvene to discuss the final decision AND the chair of ACMS wishes to invite the experts you have nominated the ACMS secretariat will get back in touch with you.

I believe your interpretation of the role of the independent expert review team is quite incorrect. They were not taken on by the TGA to do what is frankly the role of the Advisory Committee ie to provide advice on whether the two substances " met the standards required for Schedule 8" so it is important that you do not misrepresent this as having been the case.

Regards

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
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From: Peter Hunt <peter@phunt.com.au>
Sent: Sunday, 27 November 2022 8:09 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>; Nutt, David J <d.nutt@imperial.ac.uk>; arthur.christopoulos@monash.edu; Peter Hunt <peter@mindmedicineaustralia.org>; tania@mindmedicineaustralia.org
Subject: OUR MEETING ON MONDAY 21st NOVEMBER 2022

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Dear Professor Skerritt

Thank you for arranging the meeting last Monday at which Professor David Nutt presented the background and the scientific data associated with the medical use of MDMA and psilocybin as part of therapy. You will recall that his conclusions showed that MDMA and psilocybin could be used safely and effectively as part of therapy in medically controlled environments for the treatment of depression and post- traumatic stress disorder (and potentially other classes of mental illnesses in the future).

Professor David Nutt also made it very clear that he believed that these two substances, when used as proposed in our rescheduling applications, met the Schedule 8 test of "established therapeutic value". Medicinal cannabis was moved from Schedule 9 to Schedule 8 of the Poisons Standard with much less trial data in support than the trial data associated with the medical use of psilocybin and MDMA.

We lodged our submission in response to the Delegate's Interim Decisions with the TGA last Thursday and a copy is attached for your convenience.

As you saw from the presentation of Mrs Vanessa Bortolin, the Delegate's Final Decision is incredibly important to the lives of patients with treatment resistant depression and treatment resistant post- traumatic stress disorder. These people do not (by definition) benefit from current treatments and, unfortunately (like Vanessa's husband, Franco), some of these people in their desperation will take their own lives. The rates of suicide amongst these people, including the dreadful suicide rates for ADF Veteran and First Responder populations, are truly terrible.

The proposal that we have put forward is very conservative and has lots of protections built in (see Section 3 of our attached submission and our summary below).

At the meeting you raised the views of the Royal Australian and New Zealand College of Psychiatrists (RANZCP). We mentioned that many psychiatrists supported our proposal, the

RANZCP's decision-making processes were opaque (the writers of their clinical memorandum were not named, and review processes aren't described) and their membership base was not consulted. The RANZCP has a history of being unduly conservative (witness its historical opposition to the use of medicinal cannabis and TMS). The purpose of RANZCP is also to act for its members. Under its Constitution it has not been set up to act for patients. Conflicts within RANZCP are also not declared.

We also note that in July of this year the RANZCP authored a clinical memorandum that accepted the utility of the anaesthetic ketamine being used off-license for the treatment of treatment resistant-depression. We would contend that the evidence base for psilocybin and MDMA are at least as good (if not better) than the evidence in mental health treatments for the ketamine. Moreover, both psilocybin and MDMA require many fewer sessions than ketamine to work and have significantly reduced abuse liability risks.

It should also be noted that RANZCP opposed the rescheduling of medical cannabis and yet medicinal cannabis was moved by the TGA to Schedule 8 of the Poisons Standard. Here is an extract from a medicinal cannabis report from RANZCP published in 2021 (in other words several years after the rescheduling of the medical use of cannabis):

"Further research is required to ascertain the potential risks and benefits of the targeted use of medicinal cannabis. Further high-quality studies directly examining the effect of medicinal cannabis on treating mental disorders are needed. There is a role for psychiatrists in contributing to this research, as well as supporting other medical colleagues in providing advice on potential risks in using medicinal cannabis for other medical conditions. The RANZCP supports legislation that facilitates the research and, where backed by sufficient evidence, appropriate regulation of medical cannabis. These products should follow the same approval process as other new pharmaceuticals to ensure these standards are met before they are accessible."

At our meeting we also discussed the possibility of **Professor David Nutt** and **Professor Arthur Christopoulos,** together with a practising Australian psychiatrist such as **Dr Eli Kotler** presenting to the Advisory Committee on Medicines Scheduling before it finalises its advice to the Delegate. We believe that this is an incredibly important part of due process for the following reasons:

1. It is not apparent from the TGA website that any members of the Committee have any expertise in the mental health sector either as practising psychiatrists or as neuropharmacologists. There appears to be a clear absence of mental health expertise at this level on the Committee.
2. From your recent comments in Senate Estimates it also appears that the Delegate does not have this level of necessary expertise.
3. **Professor David Nutt** is both a psychiatrist and a world - leading neuropsychopharmacologist. Just as importantly Professor Nutt is one of the world's leading experts in the use of MDMA and psilocybin assisted psychotherapies for treatment resistant mental illnesses, such as depression and PTSD.
4. **Professor Arthur Christopoulos** is Dean of the Faculty of Pharmacy and Pharmaceutical Sciences (ranked No 1 in the World), is one of Australia's leading neuropharmacologists and he is recognised globally as a leader in this field. He has a specific focus in his own research work on the brain receptors involved with these medicinal therapies.

5. **Dr Eli Kotler** is a leading Australian trauma and addiction psychiatrist (he can be joined on the day by other leading Australian psychiatrists such as **Professor Paul Fitzgerald** who is doing work in this area if that is your wish).
6. The Expert Report referred to by both the Delegate and the ACMS did not meet the standards for being an independent expert report for the reasons set out in our submission, the members of the expert panel did not specifically address the question of whether the medical use proposed of psilocybin and MDMA met the standards required for Schedule 8 and the data in their report could have easily been used by the Delegate to justify a decision to reschedule.
7. The overwhelming support for rescheduling, on the limited basis that we have proposed, from the 13,155 people and organisations that lodged public submissions with the TGA. These were overwhelmingly in favour of rescheduling on the basis proposed (including virtually all Health Sector Experts and professional researchers who lodged submissions).
8. The failure of current treatments to work for treatment resistant patients and the pain and suffering that this can lead to and, in some cases, suicides.

If you are agreeable to this proposal, we would please request that time be set aside for questions after the presentations, that a recording of the meeting be made available and that, if possible, the presentation and the Q and A session that follows should be able to be observed by members of the public.

We would suggest that the same presentation team should also present to the Delegate (with an obligation to preserve the Delegate's anonymity if that is desired) or (less desirably) the Delegate could be present at the ACMS meeting but not identified

I look forward to hearing from you as soon as possible with proposed dates and times to ensure that the proposed members of the presentation team are available for the meeting.

Yours sincerely

Peter

Peter

Peter Hunt AM
Chair
Mind Medicine Australia
Mob 0419271483

Overview of MMA's Rescheduling Proposal

For each treatment resistant patient seeking this treatment:

a). The treating psychiatrist has been trained in whichever medicine is to be used.

b). The treating psychiatrist's patient diagnosis and treatment plan is approved by two independent psychiatrists.

c). Medicine treatment is given to standard protocols including preparation and

integration sessions.

d). Medicine sessions take place in medically controlled environments with patients never being allowed to take the medicines home.

e). For the whole period of the medicine treatment session two health care professionals are present with the patient at all times.

f). The medicine treatment session could also be filmed for safety reasons and (if the patient agrees) training purposes.

g). The patient has given fully informed consent.

In addition, all patients will be entered into a register of patients set up at Monash University. The register will contain:

a). Pre-and post-treatment data including standard measures of illness severity.

b). Data on adverse effects.

c). Patient-reported outcomes especially quality of life and other relevant outcomes e.g. sleep and wellness scores.

d). Provide an independent report in a regular fashion on outcomes and safety data to key stakeholders.

e). Clinical efficacy could also be evaluated using Bayesian methods that have been shown within another compassionate-use clinical-register programme to provide most optimal statistical evidence of efficacy.

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