From:	Peter Hunt
To:	NOYEN, Benjamin
Cc:	Tania; Ilan Hayman; Peter Hunt
Subject:	Re: Your correspondence to the Treasurer, the Hon Jim Chalmers MP was referred to the Minister for Health and Aged Care, the Hon Mark Butler MP [SEC=UNOFFICIAL]
Date:	Tuesday, 20 December 2022 11:33:35 AM
Attachments:	image002.png
	image002.png

Hi Ben

Thanks for this note. I must admit to being somewhat confused because under section 52E of the Therapeutic Goods Act it's the Secretary that actually has responsibility for making the decision. I understand that as a matter of process the Secretary appoints a delegate to make the decision for him but it's still actually the Secretary's decision.

Likewise under our democratic system it's the Minister that has to account to Parliament and through Parliament to all of us for matters relating to health and suicide prevention.

Please let me know if I am missing something. The TGA can't be an island ?

Best

Peter

Peter Hunt AM Mob 0419271483

On 19 Dec 2022, at 5:00 pm, NOYEN, Benjamin <Benjamin.Noyen@health.gov.au> wrote:

Thanks Peter for your email. I will arrange to inform the delegate that you may be able to provide access to additional information and expertise should the delegate need it. Please remember that scheduling decisions are made by a senior medical officer in the TGA and are independent of the Secretary and Minister.

Thanks,

Ben.

Ben Noyen Assistant Secretary Regulatory Engagement Branch

Therapeutic Goods Administration Regulatory Practice and Support Division | Health Products Regulation Group Australian Government, Department of Health and Aged Care T: +61 2 6289 7214 | E: <u>Benjamin.Noyen@health.gov.au</u> PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Peter Hunt <peter@phunt.com.au>
Sent: Monday, 19 December 2022 5:06 PM

To: NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>

Cc: Tania <tania@taniadejong.com.au>; Ilan Hayman <ilan@mindmedicineaustralia.org>; Peter Hunt <peter@mindmedicineaustralia.org>

Subject: Your correspondence to the Treasurer, the Hon Jim Chalmers MP was referred to the Minister for Health and Aged Care, the Hon Mark Butler MP [SEC=UNOFFICIAL]

Dear Ben

Thank you for writing to us.

It does seem to us that the best way for the Delegate and members of the Advisory Committee on Medicines Scheduling to make a fully informed decision is to hear from and debate the application of the rescheduling criteria with World leading experts. We have suggested Professor Arthur Christopoulos and Professor David Nutt but we can organise other experts as well. Given the Government's focus on suicide prevention we believe that this should be an attractive proposition for the Delegate and the TGA.

Given the importance of the decision to so many people (as evidenced by the number of submissions the TGA has received) and the pain and suffering that leads to and is caused by suicide and treatment resistant mental illnesses (not to mention the enormous economic costs) we also believe the Secretary of the Department of Heath, representatives from the Minister's office and the President of RANZCP should also be present.

We look forward to hearing from you

Peter Hunt AM Chair Mind Medicine Australia Mob 0419271483

On 19 Dec 2022, at 3:03 pm, Mind Medicine Australia <<u>admin@mindmedicineaustralia.org</u>> wrote:

From: Regulatory Engagement <<u>RegulatoryEngagement@health.gov.au</u>>
Date: Monday, 19 December 2022 at 2:10 pm

To: Mind Medicine Australia <<u>admin@mindmedicineaustralia.org</u>>, Tania de Jong AM <<u>tania@taniadejong.com.au</u>>

Subject: Your correspondence to the Treasurer, the Hon Jim Chalmers MP was referred to the Minister for Health and Aged Care, the Hon Mark Butler MP [SEC=UNOFFICIAL]

Dear Ms De Jong and Mr Hunt

Please find attached a response to your correspondence to the Treasurer, the Hon Jim Chalmers MP which was referred to the Minister for Health and Aged Care, the Hon Mark Butler MP.

<u>Please do not respond to this email</u>. If you wish to contact the TGA about this or any other matter, please email us at: <u>info@tga.gov.au</u>.

Kind regards

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care T: 1800 020 653 | E: <u>info@tga.gov.au</u> PO Box 100, Woden ACT 2606, Australia Web: <u>www.tga.gov.au</u>

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met. The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering. https://www.mailguard.com.au/mg

Report this message as spam

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering. https://www.mailguard.com.au/mg

Report this message as spam

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering. https://www.mailguard.com.au/mg

Report this message as spam

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering. https://www.mailguard.com.au/mg Report this message as spam



Australian Government

Department of Health and Aged Care

Ref No: MC22-022020

Mr Peter Hunt Ms Tania De Jong Mind Medicine Australia admin@mindmedicineaustralia.org tania@taniadejong.com.au

Dear Mr Hunt and Ms de Jong

I refer to your correspondence of 21 November 2022 to the Treasurer, the Hon Jim Chalmers MP, regarding the TGA's interim decision on MDMA and psilocybin. Your correspondence has been referred to the Minister for Health and Aged Care, the Hon Mark Butler MP. The Minister has asked me to reply.

I note that you also wrote to other Parliamentarians on this matter. That correspondence has also been referred to the Minister.

I acknowledge your concerns about mental illness and the rates of suicide in the Australian community. I can assure you that these matters have been front of mind of the members of the Advisory Committee on Medicines Scheduling (ACMS), and the delegate of the Secretary of the Department of Health and Aged Care who have considered your applications to down-schedule MDMA and psilocybin.

As you are aware, a final decision has not yet been made in relation to your applications. I do wish to take this opportunity to reassure you that the delegate is considering the submissions made on your proposal and the delegate's interim decision, and the information presented by Professor Nutt and yourselves at the meeting hosted by the TGA that over 120 TGA staff attended. We will continue to afford Mind Medicine Australia ample opportunity to put all relevant information and evidence before the ACMS and the delegate before it makes its decision.

Thank you for writing on this matter.

Yours sincerely

Ben Noyen Assistant Secretary Regulatory Engagement Branch Health Products Regulation Group 19 December 2022