From: NOYEN, Benjamin
To: Peter Hunt AM

Cc: Tania de Jong AM; Ilan Hayman; Peter Hunt (gmail)

Subject: Notice of Final Decision [SEC=UNOFFICIAL]

Date: Friday, 3 February 2023 12:12:00 PM

Attachments: <u>image002.png</u>

image003.png image004.png image006.png

Hi Peter,

The scheduling decisions relating to your application has been published today.

- Media release
- Questions and answers
- Final decisions

Kind regards,

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: Benjamin.Noven@health.gov.au

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 AM <peter@mindmedicineaustralia.org>

Sent: Monday, 23 January 2023 7:19 PM

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

Cc: SKERRITT, John < John. Skerritt@health.gov.au>; Tania de Jong AM

<tania@mindmedicineaustralia.org>; Ilan Hayman <ilan@mindmedicineaustralia.org>; Peter Hunt

(gmail) <peterhunt407@gmail.com>

**Subject:** RE: Touching Base [SEC=UNOFFICIAL]

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Dear Ben

Thanks for coming back to me on this.

I assume that you have also provided to the Delegate Professor David Nutt's presentation that was given to the TGA in November 2022 as well as the MAPS preliminary announcement earlier this month (which I forwarded to you at the time) of the second Phase 3 results and a detailed breakdown of the public submissions. I know that David would be very happy to speak to the

Delegate if the Delegate has any queries or requires any more information. I am sure that Professor Christopoulos would also make himself available.

Without access to these therapies people suffer and the risk is that some of these people will take their own lives.

The MAPS announcement is again attached for your information - - <u>Prior Positive Results</u>

<u>Confirmed in MAPS-Sponsored, Philanthropy-Funded Phase 3 Trial - Multidisciplinary Association</u>
for Psychedelic Studies - MAPS

I would also be very disappointed if our own response – dated  $24^{th}$  November 2022 - to the interim decision was not provided to the Delegate.

It seems to me that the role of the TGA and the Department of Health is to focus first and foremost on needs of patients within the regulatory framework provided. I am therefore attaching two short videos of people who have experienced the suicide of a loved one with treatment resistant PTSD and/or depression. The current system completely failed these people. Why treatment resistant at- risk patients are being denied a workable regulatory pathway to these therapies in the very conservative manner that we have proposed is completely beyond me.

The two short videos can be found here;

Vanessa Bortolin - short video: <a href="https://www.youtube.com/watch?v=pDSI2SOTQ2w">https://www.youtube.com/watch?v=pDSI2SOTQ2w</a>
Brian Walker MP - 2 min video: <a href="https://www.youtube.com/watch?v=46G3tsRAhSs">https://www.youtube.com/watch?v=46G3tsRAhSs</a>

Thank you again for communicating with me.

Yours sincerely

Peter Peter Hunt AM Mob 0419 271 483

Peter Hunt AM Chairman

o:

e: peter@mindmedicineaustralia.org

Working Hours:
Mind Medicine Australia
Level 5 | 468 St Kilda Rd, Melbourne, 3004
www.mindmedicineaustralia.org







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

**Sent:** Thursday, 19 January 2023 9:30 AM **To:** Peter Hunt peter@phunt.com.au>

Cc: SKERRITT, John < John. Skerritt@health.gov.au >; Tania AM (tania@mindmedicineaustralia.org)

<tania@mindmedicineaustralia.org>; llan Hayman <ilan@mindmedicineaustralia.org>

**Subject:** RE: Touching Base [SEC=UNOFFICIAL]

Hi Peter,

The Delegate has all the information they need to make an informed decision, including but not limited to your application, additional information you've provided, independent report, advice from the Advisory Committee on Medicine Scheduling, and other expert advice, research and information.

The scheduling decision will be published on 8 February.

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: Benjamin.Noyen@health.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: Peter Hunt < peter@phunt.com.au > Sent: Wednesday, 18 January 2023 11:43 AM

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

Cc: SKERRITT, John < John. Skerritt@health.gov.au >; Tania AM (tania@mindmedicineaustralia.org)

<tania@mindmedicineaustralia.org>; Ilan Hayman <ialign@mindmedicineaustralia.org>

Subject: Touching Base

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe. Hi Ben

Happy new year.

Could you please give me an update on the rescheduling decision and whether the Delegate is agreeable to a presentation and Q an A session with experts in the field. There are too many people unnecessarily suffering for this not to take place.

Best

Peter

Peter Hunt AM

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