From: To: Cc: Subject: Date: NOYEN. Be

SKERRITT, John; Tania de Jong AM; Peter Hunt AM; Peter Hunt (gmail); Ilan Ha

RE: Public Subn ions [SEC=OFFICIAL] rc: Public Submissions [SEC=OFFICIA] Tuesday, 25 October 2022 9:11:06 PM image001.png image002.png

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Hi Ben

To be clear I didn't actually assert in my email to you that "the decision making or the process is opaque and a failure." But as you have raised the issue I have to say that the process is opaque. We don't know who the decision-maker is and we don't know how individual members of the Committee voted and the reasons for their individual votes. We also can't appeal the Delegate's decision. This makes the process vulnerable to undisclosed pressures.

For people who are suffering from treatment resistant mental illnesses this lack of openness and therefore accountability is not very reassuring.

I hope you understand that we appreciate our dialogue with you and your colleagues and we realise the restrictions on you as public servants working within a prescribed framework. We are motivated only by the interests of all the people who could benefit from these therapies and who don't benefit from current treatments. We are not pushing these therapies on anyone. We just believe that psychiatrists and their patients should be given the option of accessing them under controlled conditions.

On the 6500 submissions you must have already reviewed them to properly brief the Advisory Committee on Medicines Scheduling and the Delegate.

With best wishes

Peter

Peter Hunt AM

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

Sent: Tuesday, 25 October 2022 8:08 PM

To: Peter Hunt AM <pthe decision making process is opaque and a failure"eter@mindmedicineaustralia.org>

Cc: SKERRITT, John < John. Skerritt@health.gov.au>; Tania de Jong AM < tania@mindmedicineaustralia.org>; Peter Hunt (gmail) < peterhunt407@gmail.com>; Ilan Hayman <ilan@mindmedicineaustralia.org>

Subject: RE: Public Submissions [SEC=OFFICIAL]

Thanks for you email. With respect, I disagree with your assertion that the decision making or the process is opaque and a failure

As I explained over the phone, the TGA needs to review over 6500 submissions in relation you this application. This will take some time as it may be necessary to redact some information, whether consent is provided or not in relation to a submission. For example, it would not be appropriate to release some personal information relating to particular applications in the public domain.

Work has commenced in relation to publishing the submissions and it will not be necessary to courier submissions to you. I will respond to you by the end of the week with further information.

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.

Ben

Ben Noven Regulatory Engage ment 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 [F: Benjamin Noyen@health.gov.au PO Box 100, Woden ACT 2606, Australia

From: Peter Hunt AM <peter@mindmedicineaustralia.org>

Sent: Tuesday, 25 October 2022 7:00 PM

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

Cc: SKERRITT, John < John. Skerritt@health.gov.au>; Tania de Jong AM < tania@mindmedicineaustralia.org>; Peter Hunt (gmail) < peterhunt407@gmail.com>; Ilan Hayman <ilan@mindmedicineaustralia.org>

Subject: RE: Public Submissions

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Hi Ben

Just following this up further because the more that I think about the TGA's failure to publish the public submissions in a timely way the more concerned that I am becoming. As you know we are totally patient focused and too many people in Australia with treatment resistant conditions are suffering. It's critical for the TGA process to be both fair and

The TGA's submissions form that was made available on the TGA website to enable members of the public to give their views on our rescheduling applications during the first public submissions period was quite clear that the TGA would publish the submissions.

At the end of the form, there was a specific field that asked for consent to publish one's submission on the TGA website (see screenshot):

Consent

I consent to the collection, use or disclosure of my personal information as set out in the privacy notice and select the following option regarding the publication of my submission:

A user could then select options, including:

- Publish my response, including both my name and organisation's name
- 2. Publish my response, without my name or my organisation's name (anonymously)

It should be obvious that the whole purpose of publishing submissions on the TGA website is to ensure that interested parties who want to lodge a submission in relation to the Delegate's interim decision can review those submissions. People have given their specific consent to their submissions being published.

As mentioned the TGA has had months to organise this and if the TGA (for reasons I don't understand) is unable to scan these submissions on to its website then we are more than happy to organise and pay for a courier to pick up hard copies from you.

I would be grateful if you could advise me on this as soon as possible.

With best wishes

Peter Peter Hunt AM Chair Mind Medicine Australia Mob 0419 271 483

Peter Hunt AM Chairman

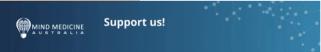
0.

e: peter@mindmedicineaustralia.org

Working Hours:
Mind Medicine Australia
Level 1 | 10 Dorcas St, Southbank







From: Peter Hunt AM

Sent: Monday, 24 October 2022 7:46 PM

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

 $\textbf{Cc:} \ SKERRITT, John < \underline{John.Skerritt@health.gov.au} >; \underline{tania@mindmedicineaustralia.org}$

Subject: Public Submissions

Dear Ben

Good to talk today.

As discussed, I was very concerned to hear from you that the public submissions in response to our rescheduling applications weren't going to be available on the TGA's website anytime time soon. Parties interested in making submissions in relation to the Delegate's Interim Decision should be able to view the submissions already made to better inform their own submissions (as happened with our last rescheduling applications). We need to properly understand the arguments in support that the Delegate rejected, the precise levels of support, the arguments against and the calibre of the people making the submissions. This is integral to our ability to make the best submission possible in relation to the Delegate's interim decision and timing is tight.

We don't understand why its so hard to put these submissions on the TGA's website in a timely way given that submissions closed months ago. In any event, if this is not possible could you please copy the submissions and we will arrange a courier to pick them up straightaway. The Delegate's decision making process and credentials is already very opaque and this failure of process makes it worse.

Given the worsening levels of depression and PTSD across Australia, the failure of current treatments for so many people, the unbearable suffering that this can cause and the risk of suicide for some sufferers it seems to us that the Delegate would want to receive the most informed submissions and particularly from the party that lodged the rescheduling applications.

I await your response as a matter of urgency.

With best wishes

Peter Peter Hunt AM Chair Mind Medicine Australia 0419271483

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