

Subject: Invitation to consultation outcomes discussion meeting – Authorised Prescriber scheme for MDMA and Psilocybine

Location: Microsoft Teams Meeting

Start: Wed 19/11/2025 10:00 AM

End: Wed 19/11/2025 2:00 PM

Recurrence: (none)

Meeting Status: Meeting organiser

Organiser: LANGHAM, Robyn

Required Attendees: s22 @ahpra.gov.au'; s22 @ahpra.gov.au'; 'admin@pacfa.org.au'; 'policy@ranzcp.org'; 'aca@theaca.net.au'; 'marketing@psychology.org.au'; 'ceo@aasw.asn.au'; 'acthealth-hrec@act.gov.au'; 'Research@monashhealth.org'; 'RamsayHREC.WA-SA@ramsayhealth.com.au'; 'aps@niim.com.au'; 'SMHS.HREC@health.wa.gov.au'; 'research.ethics@svhm.org.au'; 'TSV-Ethics-Committee@health.qld.gov.au'; 'HPSB.MEDICAL.ALLIED.HEALTH.PROGRAMS@dva.gov.au'; 'HPS@act.gov.au'; 'dpcs@health.vic.gov.au'; 'ChiefHealthOfficer.DoH@nt.gov.au'; 'mprb@health.wa.gov.au'; Pharmaceutical Services Branch; 'MOH-S8Auth@health.nsw.gov.au'; 'MARU@health.qld.gov.au'; DAVISON, Sophie; 'enquiries@acmhn.org'; s22 @ahpra.gov.au'; 'psychologyboard@ahpra.gov.au'; s22 @ahpra.gov.au'; s22 @acmhn.org'; s22 @gmail.com'; s22 .com'; 'reception@s22 .com'; s22 @ramsayhealth.com.au'; s22 .com.au'; s22 @ahpra.gov.au'; s22 @ahpra.gov.au'; s22 @theaca.net.au; s22 @theaca.net.au; s22 ; ranzcp@ranzcp.org; s22 .com.au'; 'admin@aapi.org.au'; s22 @health.qld.gov.au'; s22 @ahpra.gov.au'; s22 .com.au'; s22 .com'; s22 @monash.edu; s22 (Ministry of Health); 'ahpra.secretariat@ahpra.gov.au'; 'Health.OfficeoftheChiefPharmacist@sa.gov.au'; s22 @ranzcp.org'; s22 @nt.gov.au; s22 (Health); s22 (South Eastern Sydney LHD); s22 (Health); s22 (Health); s22 DOH Medicines and Poisons Regulation Branch Policy; s22 com.au; s22 (Health); s22 @health.wa.gov.au; s22 ; AASW CEO

Categories: NFA

Dear stakeholder,

The Therapeutic Goods Administration (TGA) recently conducted a consultation on the application process under the Authorised Prescriber scheme for the use of 3,4-methylenedioxymethamphetamine (MDMA) and psilocybine in psychedelic-assisted psychotherapy.

To support informed decision-making and reflect the diverse perspectives of stakeholders, the TGA is convening a chaired discussion of the consultation outcomes. This meeting will bring together key representatives to help finalise the outcomes, which will inform future application processes and be reflected in TGA's publicly available guidance.

The discussion will be chaired by TGA's Chief Medical Advisor, Prof Robyn Langham, and will include participants from peak bodies, regulators, national boards, state and territory health departments, and Human Research Ethics Committees (HRECs). A detailed agenda will be shared ahead of the meeting.

The consultation outcomes paper will be sent to attendees with the agenda shortly, prior to the discussion meeting. The TGA actions in the summary document will be used to guide the discussion. (Updated Agenda and Summary Document attached [18/11/2025]) – Please treat the attached papers as confidential.

Meeting Details

Date: Wednesday, 19 November 2025

Time: 10:00 AM – 2:00 PM (AEDT)

Location: Virtual (Microsoft Teams link provided)

Please confirm your attendance by accepting this meeting invite (using the 'send response' option) no later than Friday, 14 November 2025.

We look forward to your valuable contribution to this important discussion.

Kind regards,

s22

Executive Assistant to Prof. Robyn Langham, Chief Medical Advisor

Health & Safety Representative

Therapeutic Goods Administration

Australian Government Department of Health, Disability and Ageing

T: s22 @health.gov.au

This email comes to you from Ngunnawal Country

Location: Gulgana Office – 27 Scherger Dr, Canberra Airport, ACT, 2609

PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing 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.

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Subject: PsyBA - TGA consultation paper - Authorised Prescriber scheme for MDMA and Psilocybine

Location: Microsoft Teams Meeting

Start: Fri 27/02/2026 9:00 AM

End: Fri 27/02/2026 9:15 AM

Recurrence: (none)

Meeting Status: Accepted

Organiser: PsyBA-calendar

Categories: Red Category

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.

Dear Prof Langham

The Psychology Board of Australia (PsyBA) would like to invite you to join their board meeting on Friday 27 February 2026 at 09:00-09:15 AEDT to speak to the paper.

Teams link to join the meeting online is below.

Thank you.

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Phone conference ID: 930 684 05#

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Kind regards

s22

Board Officer

Psychology Board of Australia

Phone | s22

Email | s22@ahpra.gov.au

Web | www.ahpra.gov.au

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 s22 @mindmedicineaustralia.org; hello@mindmedicineaustralia.org; admin@mindmedicineaustralia.org;
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 HealthDrugsofDependenceUnit@sa.gov.au; ChiefHealthOfficer.Doh@nt.gov.au; mprb@health.wa.gov.au;
 Pharmaceutical Services Branch; MOH-S8Auth@health.nsw.gov.au; MARU@health.qld.gov.au;
 HealthOfficeoftheChiefPharmacist@sa.gov.au; MOH-PharmaceuticalServices@health.nsw.gov.au
Subject: Therapeutic Goods Administration (TGA) - targeted consultation paper - July 2025 [SEC=OFFICIAL]
Date: Monday, 21 July 2025 3:00:26 PM
Attachments: [image001.png](#)
[Targeted consultation paper - AP scheme for psychedelics - July 2025.pdf](#)

Good morning,

The Therapeutic Goods Administration (TGA) is seeking your feedback on the attached targeted consultation paper.

This consultation focuses on reviewing the application processes for accessing MDMA and psilocybine under the Authorised Prescriber (AP) Scheme. Your insights will help us better understand stakeholder perspectives and inform any future decisions about the regulatory process.

Please provide a response by COB Wednesday 6th August 2025.

Should you have any questions, please get in contact with us at SAS.Support@health.gov.au using REFERENCE: Psychedelic Consultation.

Kind regards,

Admin Officer
Unapproved Medicines Support Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health and Aged Care

E: SAS.Support@health.gov.au

Location: Gulbana Building, Fairbairn
 PO Box 100, Canberra ACT 2601, 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.

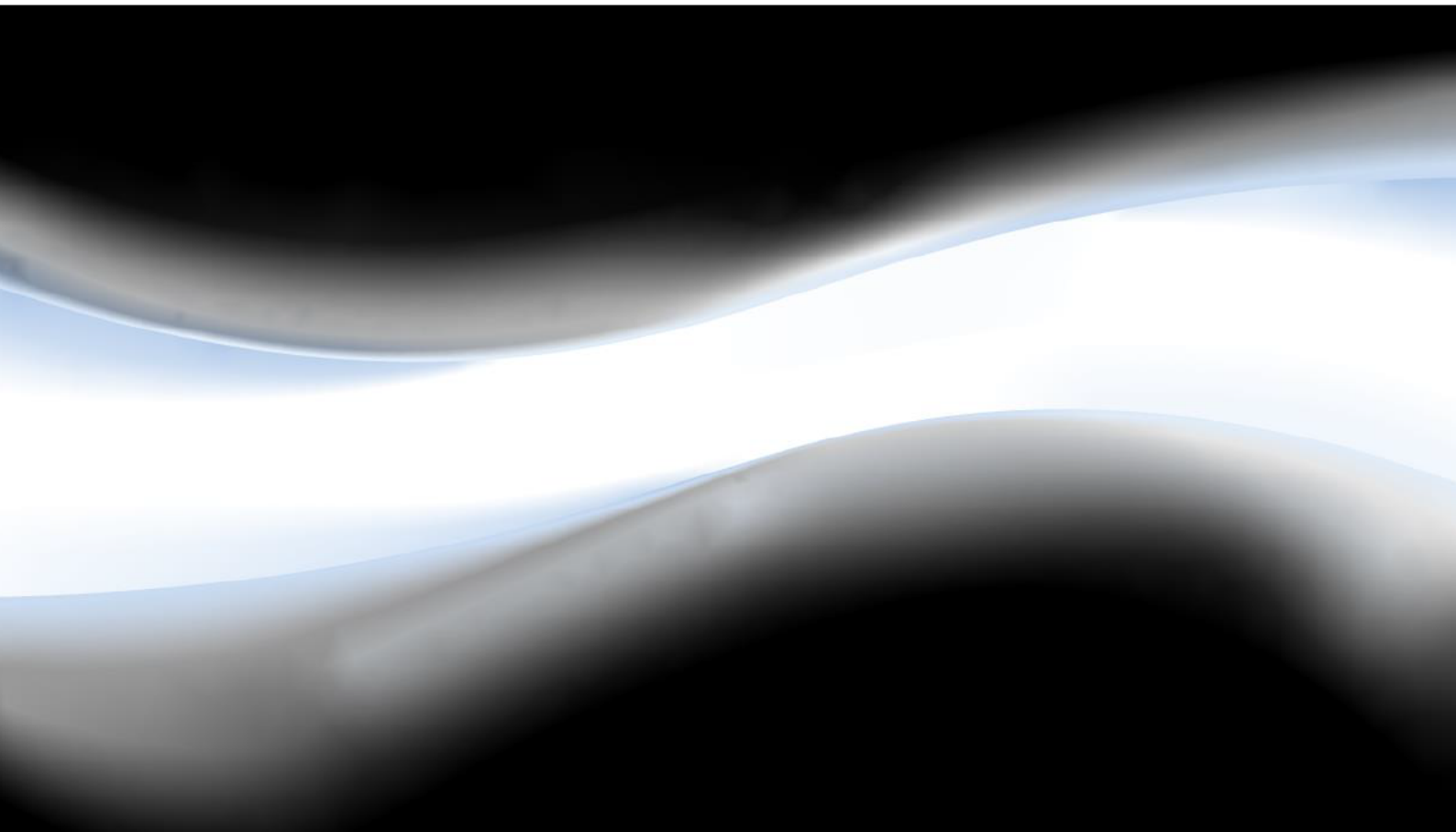


Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions

Targeted external consultation paper



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Introduction

Purpose and scope

Since 1 July 2023, psychiatrists authorised under the Authorised Prescriber (AP) scheme have been permitted to prescribe MDMA for the treatment of post-traumatic stress disorder (PTSD) and psilocybine for treatment-resistant depression in patients undergoing psychotherapy.

To support the effective continuation of MDMA and psilocybine access, a review of the application processes is currently underway. The objective is to improve clarity for stakeholders and ensure alignment between the Therapeutic Goods Administration (TGA) and Human Research Ethics Committees (HRECs).

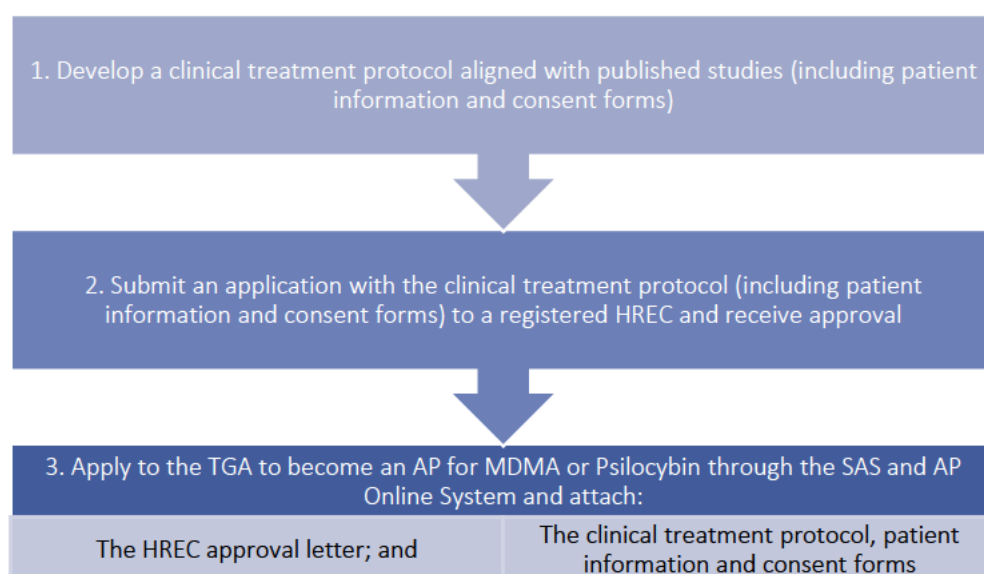
This review involves a targeted consultation with selected Authorised Prescribers, peak professional bodies, state and territory health departments, and HRECs.

Background

Psychedelic-assisted psychotherapy (PAT or PAP) involves combining pharmacological and psychological treatment which occurs in a controlled, supportive setting with trained therapists. Psychedelic therapy typically involves a structured dosing regimen that is accompanied by specialised forms of psychotherapy before, during and after each drug session.

Authorisation to prescribe MDMA and psilocybine as part of PAT is restricted to registered psychiatrists who have obtained HREC approval and have also been authorised by the TGA to be an AP.

An application to the TGA must be made using the Special Access Scheme (SAS) & Authorised Prescriber (AP) Online System and be accompanied by a site-specific clinical treatment protocol, patient information and consent form, HREC approval and other supporting documents. The site-specific treatment protocol should include details specified in the prescriber's checklist ([Attachment 1](#)). A renewal application checklist is also available, which specifies the updated information that is required to be provided to the TGA in the treatment protocol ([Attachment 2](#)).



The delegates of the Secretary of the Department of Health, Disability and Ageing who review and provide outcomes on AP applications for MDMA and psilocybine are registered medical practitioners and senior medical officers. In addition to ensuring the applying practitioner complies with all AP requirements, the delegate must be satisfied of the prescriber's clinical justification for the treatment regimen, confirm the prescriber will have oversight of the treatment process, and that there are suitable measures to protect patients, such as records of informed consent.

The Review

Why are we conducting a review of recommendations?

It has been 2 years since the changes were made to the [Poisons Schedule](#) to allow access to MDMA and psilocybine outside clinical trials. Since this time, a number of inconsistencies in expectations and procedures have been identified between applicants, HRECs and the TGA. Additionally, practical issues have arisen that were not anticipated when the products were re-scheduled.

Recommendations

Recommendation 1: Psychiatrist experience

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have initial supervision by an Australian registered psychiatrist that has experience in conducting psychedelic-assisted psychotherapy.

Rationale

The delegate assessing an AP application must be satisfied that the psychiatrist has the training and expertise appropriate for the condition being treated and the proposed use of the product. Considering the unapproved nature of MDMA and psilocybine and that psychedelic-assisted psychotherapy is still a novel treatment outside of clinical trials in Australia, the TGA considers prior experience or initial supervision to demonstrate the required expertise is critical.



Questions:

1. Do you agree that the psychiatrist must have prior psychedelic-assisted psychotherapy clinical trial experience or requires initial supervision by an Australian-registered psychiatrist with experience in psychedelic-assisted psychotherapy'?
2. If not, then please outline what experience or qualifications you believe are appropriate and your rationale to support your response.

Recommendation 2: Therapy ‘dyad’ qualifications

The psychedelic-assisted psychotherapy sessions to be attended by at least one of the following:

- psychiatrists who are registered with a specialist registration by the Medical Board of Australia; OR
- clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology.

The training and experience of other therapists involved in the sessions, and any other supporting staff, is the responsibility of the HREC to approve.

Rationale

There are inconsistencies and confusion about the required qualifications of the therapists that make up the ‘therapy dyad’, or pair of clinical practitioners typically involved in psychedelic-assisted psychotherapy.

The role of the TGA in the AP scheme is to provide medical practitioners with lawful access to supply ‘unapproved’ therapeutic goods. The TGA does not have a role in regulating health professionals or clinical practice. The HREC reviewing the treatment protocol is responsible for considering the training and experience of all staff involved in the treatment.

However, given psychedelic-assisted psychotherapy is a treatment providing access to an ‘unapproved’ medicine coupled with a clinical intervention, it is appropriate that both the medicine and the practitioners involved in the psychotherapy sessions are subject to regulatory oversight. Due to the vulnerability of patients and until further data is available to demonstrate the safety risks, the TGA expects that the clinical practice of members of the treatment team would be subject to formal clinical oversight. In a situation where the authorised prescriber of the ‘unapproved’ medicine is not directly involved in the psychotherapy sessions, oversight of the therapy should be by a health practitioner regulated by a national board. Currently the TGA has limited this to a registered clinical psychologist, understanding these clinicians have regulatory oversight by the Psychology Board of Australia. This gives the general public assurance that the therapists will be held accountable for high competency, safety, and ethical standards, protecting the public from unqualified or unsafe healthcare providers.

Current TGA Guidance for psychiatrist prescribers ([Attachment 3](#)) states: “The TGA expects that the HREC reviewing the treatment protocols would consider the training and experience of all staff involved in the treatment. It is likely that a minimum standard of training of others involved in patient oversight would be that of clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology or equivalent.”

External guidance published by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) ([Attachment 4](#)) requires practitioners involved with psychedelic-assisted psychotherapy to hold registration with Ahpra.

The TGA has received requests that other Ahpra-registered health professionals and therapists trained in psychedelic-assisted psychotherapy be considered for the lead therapist role.



Questions:

3. Should Ahpra-registered and qualified therapists trained in psychedelic-assisted psychotherapy, other than the following, be considered for the lead therapist role within a therapy dyad?
 - a. Specialist psychiatrists registered with Ahpra; OR

- b. Clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology
- 4. If so, what types of health practitioners should be considered for the lead therapist role and why?

Recommendation 3: Level of AP oversight

The AP psychiatrist must be responsible for initial patient screening and obtaining informed consent. Additionally, they need to be present on site and involved in the on-going psychotherapeutic management.

Rationale

An authorised prescriber can supply an AP-approved product directly to a specified patient under their immediate care provided they have a therapeutic relationship with the patient. Authorised prescribers are responsible for monitoring their patient during and after use of an unapproved therapeutic good.

The Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors of unapproved therapeutic goods further highlights medical practitioner requirements under the AP scheme ([Attachment 5](#)).

The current TGA Guidance for psychiatrist prescribers ([Attachment 3](#)) states: *“The AP psychiatrist must be responsible for assessment and on-going psycho-therapeutic management before and after administration of appropriately supervised dosing of the patient in an appropriate setting.”*

Prescribers are not clear on what this level of oversight means practically, or in some cases whether they need to be on site at clinics.



Questions:

- 5. Do you agree that, to provide the appropriate level of oversight to their patient, the AP psychiatrist must be physically on-site at the treatment location?
- 6. If not, what oversight structure do you consider to be appropriate, why and does this structure meet the requirements of an approved AP?

Recommendation 4: Appropriate site location

The prescriber should include details of the site, demonstrating the location is an appropriate supervised environment. The treatment site should be reviewed by the HREC, in accordance with state/territory requirements (prescriber's responsibility to check), as part of their approval of the treatment protocol according to specific criteria as outlined below:

- a. **Equipment and appropriately trained staff on-site to provide comprehensive clinical care, monitoring and emergency resuscitation;**
- b. **Appropriate storage facilities for Schedule 8 medicines as per state/territory requirements;**

- c. **Approved Authorised Prescriber available on-site to treat any complications that arise;**
- d. **Readiness to address treatment emergent adverse events and rescue medications available on-site;**
- e. **Close monitoring of patients during medication administration by appropriately trained staff;**
- f. **Proximity to an accredited healthcare facility with an emergency department for potential episodes of acute deterioration; and**
- g. **Practice has or is seeking accreditation, if required, from the state/territory.**

The TGA Delegate will determine if the treatment location is appropriate to adequately store, administer and monitor treatment, but the HREC's review and approval is taken into consideration.

Rationale

Initial advice provided to the TGA included a recommendation that psychedelic-assisted therapy should only be conducted in an 'accredited facility' to minimise potential safety risks to patients.

It was raised with the TGA that it would be highly unlikely for a drug and therapeutics committee of a public hospital to take on the large cost of treatment and any associated indemnity risk and therefore, in most cases, private hospitals and clinics would be the only option.

Issues around equity have been raised in terms of access to psychedelic-assisted psychotherapy in different geographical locations (i.e. remote areas within Australia). A private or public hospital facility may not be available.



Questions:

7. Should sites other than day hospitals or inpatient settings be considered appropriate for an AP to provide the service of psychedelic-assisted psychotherapy through this scheme?
8. If so, please provide comments on appropriate criteria that would ensure a site is appropriate.

Consultation instructions

Please provide to the TGA responses to each question as detailed under each recommendation.

Answers can be provided in the form of a written response on a company letterhead and sent by email to SAS.Support@health.gov.au by close of business on **6th August 2025**. In your submission, please provide your name, email address, and your organisation name.

Consent

The TGA will collect your personal information in this consultation to:

- Contact you if we need to clarify issues raised in your feedback and help provide context about your feedback.
- Personal information means information or an opinion about another person whose identity can be easily guessed based on the information provided.

- Please do not include personal information about other people in your feedback. The TGA will not publish personal information without consent unless authorised or required by law.

Attachments

- **Attachment 1:** [Checklist for prescribing psychiatrists of MDMA and psilocybine](#)
- **Attachment 2:** [Renewal checklist](#)
- **Attachment 3:** [Accessing MDMA \(3,4-methylenedioxy-methamphetamine\) and psilocybine as a psychiatrist](#)
- **Attachment 4:** [Therapeutic use of MDMA for PTSD and psilocybine for treatment resistant depression | RANZCP](#)
- **Attachment 5:** [Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors of unapproved therapeutic goods](#)

Consultation on Psychedelics AP review

Stakeholder information		Response Details				Reccomendation 1		Recomendation 2		Recomendation 3		Recomendation 4		Additional comments			
Stakeholder Name	Email address	Stakeholder Type	Organisation	Email sent	Read rec'd	Respon	TRIM link	Comments on	Question 1.	Question 2.	Question 3.	Question 4.	Question 5.	Question 6.	Question 7.	Question 8.	Comments provided outside questions
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OFFICIAL

[illegible]

From: [SAS.Support](#)
To: ["AHPRA Secretariat"](#)
Subject: RE: Therapeutic Goods Administration (TGA) - targeted consultation paper - July 2025 - Psychedelic Consultation [SEC=OFFICIAL]
Date: Tuesday, 5 August 2025 4:05:04 PM
Attachments: [image002.png](#)
[image003.png](#)

Dear **s22**,

Thank you for your email.

We are happy to provide an extension until COB 13th August 2025.

If you have any questions in the meantime, please do not hesitate to contact us at SAS.Support@health.gov.au.

Kind regards,

Project Officer
Unapproved Medicines Support Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health and Aged Care

E: SAS.Support@health.gov.au

Location: Gulgana Building, Fairbairn

PO Box 100, Canberra ACT 2601, Australia

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From: AHPRA Secretariat <AHPRA.Secretariat@ahpra.gov.au>
Sent: Tuesday, 5 August 2025 4:02 PM
To: SAS.Support <SAS.Support@health.gov.au>
Subject: RE: Therapeutic Goods Administration (TGA) - targeted consultation paper - July 2025 - Psychedelic Consultation [SEC=OFFICIAL]

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Good afternoon

Thank you for the opportunity to respond to the TGA's targeted consultation on the AP scheme for psychedelics.

Would it be possible to obtain an extension to next Wednesday 13 August? We have a handful of items we still need to consider internally.

Many thanks

s22

Ahpra Secretariat

Government Relations
Strategy and Policy

Phone | s22

Email | ahpra.secretariat@ahpra.gov.au

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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From: SAS.Support <SAS.Support@health.gov.au>

Sent: Tuesday, 5 August 2025 1:01 PM

Subject: Therapeutic Goods Administration (TGA) - targeted consultation paper - July 2025 - Psychedelic Consultation [SEC=OFFICIAL]

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Good afternoon,

Please note this is an email reminder for the request for feedback on the attached external consultation.

TGA has requested that this feedback is provided by close of business Wednesday 6th August 2025.

If you don't wish to provide feedback, please advise by return email.

Should you have any questions, please get in contact with us on SAS.Support@health.gov.au.

Kind regards,

Administrative Team



Business Improvement and Compliance Section | International Regulatory Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

PO Box 100, Canberra ACT 2606

www.tga.gov.au

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From: s22
To: SAS.Support
Cc: s22
Subject: FW: Feedback on TGA consultation [SEC=OFFICIAL]
Date: Monday, 11 August 2025 2:48:47 PM
Attachments: ~WRD0003.jpg
 image001.png

FYI – Ahpra have asked for an extension until 18 August.

From: s22
Sent: Monday, 11 August 2025 2:44 PM
To: s22
Cc: s22
Subject: RE: Feedback on TGA consultation [SEC=OFFICIAL]

Hi s22

Thanks for reaching out.

We can accommodate your request for an extension until next Monday.

Myself and s22 are happy to catch up with you this week to assist with your questions.

Would this Thursday 14 August work? I have time available at 11am or 2pm that day.

Kind regards,

s22

A/g Director – Unapproved Medicines Access Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health, Disability and Ageing
 s22 @health.gov.au
 Location: 27 Scherger Drive, Level 1
 PO Box 100, Canberra ACT 2601, Australia

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From: s22 @ahpra.gov.au>

Sent: Monday, 11 August 2025 1:22 PM

To: s22 @health.gov.au>

Cc: SAS.Support <SAS.Support@health.gov.au>

Subject: FW: Feedback on TGA consultation [SEC=OFFICIAL]

Hi s22

I was forwarded the psychedelics consultation last week from our government relations team, and advised the date for response is 13 August. I'm coordinating feedback from a couple of teams, and wondering if it's possible to have a brief extension until next Monday?

If possible, it would also be great to understand some further background to the consultation, to support Ahpra and National Boards consideration about the proposed changes. Would there be a good time to discuss in the next couple of days?

Many thanks

s22

National Manager, Multiprofession policy – Rapid Regulatory Response
 Office | Level 7, 111 Bourke Street, Melbourne
 Email | s22 @ahpra.gov.au
 Web | www.ahpra.gov.au
Australian Health Practitioner Regulation Agency
 G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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From: s22
To: [SAS.Support](#); s22
Cc: s22
Subject: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions
Date: Thursday, 21 August 2025 5:18:04 PM
Attachments: [2025-08 - Letter - TGA - targeted consultation paper - AUGUST 2025 - final - CR signed 21.08.2025.pdf](#)

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Hi s22

Thank you again for your time last week to discuss this consultation, and also appreciate the additional time to finalise a response.

Please find attached a response from Ahpra and National Boards. As flagged when we discussed, we are not in a position to comment directly on the proposals in the consultation paper and would welcome the opportunity for further discussions with the TGA and others.

I'm working with our internal teams on a list of some of the questions we have about the current framework, so I'll aim to share this in the next week or so to inform our future discussions.

Please let me know if you have any questions.

Many thanks

s22

National Manager, Multiprofession policy – Rapid Regulatory Response

Office | Level 7, 111 Bourke Street, Melbourne

Email | [s22@ahpra.gov.au](#)

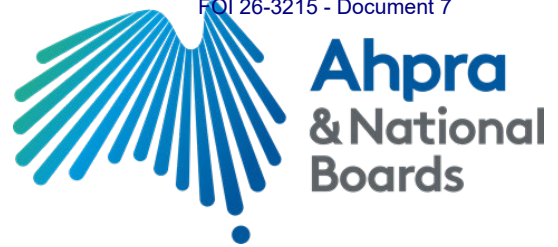
Web | www.ahpra.gov.au

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21 August 2025

Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration
PO Box 100
Canberra ACT 2606

Via email: SAS.Support@health.gov.au

Dear Department of Health, Disability and Ageing, Therapeutic Goods Administration (TGA)

Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions

The Australian Health Practitioner Regulation Agency (Ahpra) and the National Boards welcome the opportunity to provide feedback on this targeted consultation.

Ahpra and National Boards are monitoring the framework and uptake of prescribing of methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy, given the vulnerable patient group involved. Experience with medicinal cannabis shows that easier access can lead to misuse, risking patient harm and undermining important mental health research.

Ahpra and National Boards do not develop clinical guidance and have not been involved in any previous expert discussions about the psychedelics access regime. The consultation questions ask about the training and experience required for the therapy team providing treatment, and specifically reference Ahpra and National Board registration requirements. To assess proposed changes, we need more information on how the framework currently operates, including access patterns and existing risk controls. We are particularly keen to understand the inconsistencies that have occurred between HRECs and who has raised concerns.

Given the complexity and multiple stakeholders with an interest, we suggest the TGA convene a round table or expert group to discuss the current framework and proposed changes with Ahpra, National Boards, together with jurisdictions and HREC representation.

We note there is another consultation currently underway by Monash University on a new [national Clinical Practice Guideline for the appropriate use of methylenedioxymethamphetamine-assisted psychotherapy \(MDMA-AP\) to treat post-traumatic stress disorder \(PTSD\)](#), which further highlights the need for a coordinated approach access frameworks and practitioner guidance to ensure patient safety.

Other comments

We also note the recommendations from the recent independent [scope of practice review](#) led by Professor Mark Cormack encourage initiatives that enable the health workforce to work to full scope of practice. This is another consideration relevant to the proposed changes, that we can discuss further.

We look forward to hearing your thoughts on our proposal. For further discussion and any questions, please contact [s22](#), National Manager Strategic Policy at [s22](#) [@ahpra.gov.au](mailto:s22@ahpra.gov.au).

Yours sincerely

A handwritten signature in blue ink, appearing to read "Chris Robertson".

Chris Robertson

Executive Director, Strategy, Policy and Health Workforce

Australian Health Practitioner Regulation Agency
National Boards

GPO Box 9958 Melbourne VIC 3001 Ahpra.gov.au 1300 419 495

Ahpra and the National Boards regulate these registered health professions: Aboriginal and Torres Strait Islander health practice, Chinese medicine, chiropractic, dental, medical, medical radiation practice, midwifery, nursing, occupational therapy, optometry, osteopathy, paramedicine, pharmacy, physiotherapy, podiatry and psychology.

[illegible]

From: [LANGHAM, Robyn](#)
To: s22; [ahpra.secretariat@ahpra.gov.au](#);
 s22@ahpra.gov.au; s22@ahpra.gov.au; [admin@pacfa.org.au](#); [ranzcp@ranzcp.org](#);
 s22@ranzcp.org; [policy@ranzcp.org](#); [aca@theaca.net.au](#); [marketing@psychology.org.au](#);
 s22.com.au; [admin@aapi.org.au](#); [ceo@aasw.asn.au](#); [acthealth-hrec@act.gov.au](#);
[Research@monashhealth.org](#); [RamsayHREC.WA-SA@ramsayhealth.com.au](#); [aps@niim.com.au](#);
[SMHS.HREC@health.wa.gov.au](#); [research.ethics@svhm.org.au](#); [TSV-Ethics-Committee@health.qld.gov.au](#);
 s22@health.qld.gov.au; [HPSB.MEDICAL.ALLIED.HEALTH.PROGRAMS@dva.gov.au](#); [HPS@act.gov.au](#);
[dpcs@health.vic.gov.au](#); [Health.OfficeoftheChiefPharmacist@sa.gov.au](#);
[HealthDrugsofDependenceUnit@sa.gov.au](#); [ChiefHealthOfficer.DoH@nt.gov.au](#); [mprb@health.wa.gov.au](#);
[Pharmaceutical Services Branch](#); [MOH-S8Auth@health.nsw.gov.au](#); [MARU@health.qld.gov.au](#);
 s22@gmail.com; [DAVISON, Sophie](#); [enquiries@acmhn.org2](#); s22@ahpra.gov.au;
 s22@ahpra.gov.au; [psychologyboard@ahpra.gov.au](#); s22@ahpra.gov.au; s22

Subject: Invitation to consultation outcomes discussion meeting – Authorised Prescriber scheme for MDMA and Psilocybine

Attachments: [image001.gif](#)

Dear stakeholder,

The Therapeutic Goods Administration (TGA) recently conducted a consultation on the application process under the Authorised Prescriber scheme for the use of 3,4-methylene-dioxymethamphetamine (MDMA) and psilocybine in psychedelic-assisted psychotherapy.

To support informed decision-making and reflect the diverse perspectives of stakeholders, the TGA is convening a chaired discussion of the consultation outcomes. This meeting will bring together key representatives to help finalise the outcomes, which will inform future application processes and be reflected in TGA's publicly available guidance.

The discussion will be chaired by TGA's Chief Medical Advisor, Prof Robyn Langham, and will include participants from peak bodies, regulators, national boards, state and territory health departments, and Human Research Ethics Committees (HRECs). A detailed agenda will be shared ahead of the meeting.

Please review the consultation outcomes summary document attached to assist in your preparation for the meeting. The TGA actions in the summary document will be used to guide the discussion.

Meeting Details

Date: Wednesday, 19 November 2025

Time: 10:00 AM – 1:00 PM (AEDT)

Location: Virtual (Microsoft Teams link provided)

Kindly confirm the names and email addresses of one to two representative attendees by replying to this email no later than Wednesday, 15 November 2025.

We look forward to your valuable contribution to this important discussion.

Kind regards,

s22

A/g Executive Assistant to Prof. Robyn Langham, Chief Medical Adviser

Email: s22@health.gov.au <mailto:s22@health.gov.au>
 Therapeutic Goods Administration
 Australian Government, Department of Health, Disability and Ageing
 PO Box 100
 Woden ACT 2606
[www.tga.gov.au](#)

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Meeting ID: 451 439 283 585 2

Passcode: AC9Gx6S2

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Phone conference ID: 862 154 740#

Join on a video conferencing device

Tenant key: health-au@m.webex.com

Video ID: 139 628 613 2

More info <<https://www.webex.com/msteams?confid=1396286132&tenantkey=health-au&domain=m.webex.com>>

For organisers: Meeting options <https://teams.microsoft.com/meetingOptions/?organizerId=1e1a1e91-5a86-4fdf-8ee0-cac264b56646&tenantId=34a3929c-73cf-4954-abfe-147dc3517892&threadId=19_meeting_OGIxM2FkNmItYzg2Yy00OGUwLWEyOTktYWVhNjg0ZTE4MTI3@thread.v2&messageId=0&language=en-GB> | Reset dial-in PIN <<https://dialin.teams.microsoft.com/usp/pstnconferencing>>

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From: s22
To: s22
Cc: s22
Subject: RE: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions [SEC=OFFICIAL]
Date: Friday, 24 October 2025 5:01:17 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)

OFFICIAL

Dear s22

As you may have seen, an invite for a roundtable discussion on the psychedelics consultation has been sent out by the office of our Chief Medical Advisor (Prof Robyn Langham).

As follow-up to the emails from yourself and s22, I can confirm that Professor Langham is keen to have representation from Ahpra and the National Boards, particularly those professions whose scope of practice intersects with psychedelic prescribing and psychotherapy (e.g. Medical, Nursing, Psychology).

An outcomes paper will be circulated ahead of the meeting. In the meantime, I wanted to flag a few key issues that have emerged:

- Oversight of psychotherapy sessions: Questions have been raised about whether therapists must be Ahpra-registered, or if non-Ahpra psychotherapists could be considered.
- Supervising psychiatrists: Concerns were raised over the level of experience of supervising psychiatrists and how psychiatrists could demonstrate competence after initial supervision.
- AP oversight: The required level of on-site presence received varying responses, particularly in relation to remote practice and raised flags about the appropriateness of remote practice and telehealth.

Given the nature of these discussions, your initial suggestion of 2–3 representatives from Ahpra and 2–3 from the Boards seems appropriate.

Please let me know if you're happy to forward the invite internally, or alternatively, feel free to send through the names and email addresses of any relevant contacts we may have missed.

Please let me know if you have any further questions.

Kind regards

s22

**Senior Pharmacist – Unapproved Medicines Access Section
International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

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Location: Gulgana Building, Fairbairn
PO Box 9848, Canberra ACT 2601, Australia

www.tga.gov.au

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OFFICIAL

From: s22

Sent: Tuesday, 16 September 2025 2:11 PM

To: s22

Subject: RE: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions [SEC=OFFICIAL]

Dear s22

Thanks for the update on the consultation, and advice about the proposed round table.

Are you able to provide any further information about dates and other attendees? This would help us identify the right people, as we may have interest from a couple of the Board in having a representative (possibly Medical, Psych and Pharmacy), as well as some senior Ahpra staff. For example previously for some round table discussions about telehealth prescribing we've had 2-3 Ahpra reps covering policy and operations, and 2-3 Board reps, but appreciated that might be too many for this discussion!

Happy to set up a time to discuss if that's helpful.

Many thanks

s22

National Manager, Multiprofession policy – Rapid Regulatory Response

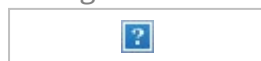
Email | s22 @ahpra.gov.au

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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From: s22 @Health.gov.au>

Sent: Monday, 15 September 2025 2:52 PM

To: s22 @ahpra.gov.au>; s22 @health.gov.au>

Cc: s22 @ahpra.gov.au>

Subject: RE: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions [SEC=OFFICIAL]

OFFICIAL

Dear s22

Thank you for your follow-up email.

We are currently reviewing the consultation responses and drafting a summary of the outcomes. Once this is complete, we intend to hold a roundtable discussion to help determine whether the proposed outcomes are appropriate. To allow sufficient time for consideration, it would be preferable to defer any discussions on the results until after the roundtable. In the meantime, could you please nominate Ahpra representatives to attend the discussion?

Regarding your questions on prescribing volumes and compliance with reporting requirements, I will consult with our support team to clarify any limitations on the information we can share and will follow up with you shortly.

To initially address the questions in the attached response, “*we need more information on how the framework currently operates, including access patterns and existing risk controls. We are particularly keen to understand the inconsistencies that have occurred between HRECs and who has raised concerns*”, the following guidance document published on our website provides the background and controls in place for the Authorised Prescriber scheme for psychedelics: [Accessing MDMA \(3,4-methylenedioxy-methamphetamine\) and psilocybine as a psychiatrist | Therapeutic Goods Administration \(TGA\)](#). Please let me know if there are any further specific questions you have that are not addressed in the guidance document. Access remains very limited, which will be evident in the patient reporting data if we are able to release this.

We can explore the issues that prompted the consultation further during the roundtable. However, as for any medicine, review processes vary between HRECs. The TGA does not regulate the review processes of HRECs. However, unlike other unapproved medicines, a TGA medical officer additionally reviews the treatment protocol for the use of psychedelic medicines. The consultation aims to ensure that the policies the medical officers use to review treatment protocols are consistent and appropriate and they are published clearly in our guidance.

We look forward to continuing the discussion.

Kind regards

s22

Senior Pharmacist

Medicinal Cannabis and Psychedelics Team | Unapproved Medicines Access Section
International Regulatory Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

T: s22 @health.gov.au

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Location: Gulgana Building, Level 1, South, Fairbairn
PO Box 9848, Canberra ACT 2601, Australia

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OFFICIAL

From: s22 [redacted] <[redacted]@ahpra.gov.au>

Sent: Monday, 15 September 2025 1:22 PM

To: s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted]

[redacted] <[redacted]@health.gov.au>

Cc: s22 [redacted] <[redacted]@ahpra.gov.au>; SAS.Support

<SAS.Support@health.gov.au>

Subject: FW: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions

Hi s22 [redacted],

I am writing to follow up on the response provided from Ahpra and National Boards (copy attached) to the recent TGA consultation, and hope that we can organise to meet again with you on the next steps?

Further to the questions in our letter of response, and the suggestion to convene a roundtable, we've also worked with our internal teams on a list of questions about the current framework.

These questions include:

- The volume of prescribing from the current Approved Prescribers?
- Compliance of Approved Prescribers in submitting the 6 monthly reports on their prescribing?
- Any mechanisms that could be built in for Ahpra to be notified of non-compliance?

We'd also be very interested to hear about the consultation results to-date and analysis, and your thoughts on the impact of the new national Clinical Practice Guideline being developed by Monash. Would you have availability for a catch-up this week or next week?

Many thanks s22 [redacted]

Manager, Strategic Policy - Multiprofession

Health Workforce

Email | s22 [redacted] <[redacted]@ahpra.gov.au>

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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From: s22 [redacted] <[redacted]@ahpra.gov.au>

Sent: Thursday, 21 August 2025 5:17 PM

To: SAS.Support@health.gov.au; s22 [redacted] <[redacted]@health.gov.au>;

s22 [redacted] <[redacted]@health.gov.au>

Cc: s22 [redacted] <[redacted]@ahpra.gov.au>

Subject: Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions

Hi s22 [redacted]

Thank you again for your time last week to discuss this consultation, and also appreciate the additional time to finalise a response.

Please find attached a response from Ahpra and National Boards. As flagged when we discussed, we are not in a position to comment directly on the proposals in the consultation paper and would welcome the opportunity for further discussions with the TGA and others.

I'm working with our internal teams on a list of some of the questions we have about the current framework, so I'll aim to share this in the next week or so to inform our future discussions.

Please let me know if you have any questions.

Many thanks

s22

National Manager, Multiprofession policy – Rapid Regulatory Response

Office | Level 7, 111 Bourke Street, Melbourne

Email | s22@ahpra.gov.au

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Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Psychedelics consultation outcomes discussion meeting

Wednesday 19 November 2025
10:00AM – 2:00PM AEDT

AGENDA

Agenda item	Topic	Presenter/ lead	Time
1.	Introduction Welcome, acknowledgement of country, housekeeping, introductions	TGA Chief Medical Advisor Prof Robyn Langham	10:00AM
2.	Outcomes summary Brief presentation on background to psychedelics access and feedback from the targeted consultation	Unapproved Medicines Access Section (UMAS)	10:15AM
3.	Discussion of recommendation 1: Psychiatrist experience Discussion points 1. <i>When would an Authorised Prescriber, who was not initially involved in a clinical trial, be considered to have sufficient experience to be a supervisor of other Authorised Prescriber's?</i> 2. <i>Alternatively, should this be a decision governed by the TGA or should the experience of the supervisor be assessed on a case-by-case basis by the HREC?</i> 3. <i>Should the experience of the supervisor be governed by the standards of a peak body?</i>	s22 A/g Principal Medical Officer Pharmacovigilance Branch	10:30AM
4.	Discussion of recommendation 2: Therapy Dyad Qualifications Discussion Points: 1. <i>Should the therapy dyad be limited to specific Ahpra registered health practitioners?</i> 2. <i>Should therapists with oversight by a professional body other than Ahpra (such as PACFA) replace the need for an Ahpra registered practitioner? Would there be adequate mechanisms for oversight of scope of practice and managing professional misconduct?</i> 3. <i>HRECs have advised the TGA to remove the statement indicating that oversight of practitioner qualifications and experience falls within their remit. Considering this, which regulatory or professional</i>	s22 A/g Principal Medical Officer Pharmacovigilance Branch	11:00AM

	bodies are responsible for ensuring that practitioners involved in the AP scheme possess the appropriate qualifications and experience?		
Lunch Break (30 mins)			12:00PM
5.	Discussion of Recommendation 3: Level of AP oversight Discussion Points: - The TGA updated this recommendation to establish an expectation for physical presence at the administration of the medication only, where "administration" is defined as the patient ingesting the medication, rather than encompassing the entire dosing day. Do you believe this approach provides sufficient flexibility for Authorised Prescribers (APs) to manage immediate adverse events without compromising patient safety? - Additionally, in practices where multiple APs are present, should the physical presence of any AP be considered sufficient, or is it necessary for the AP who conducted the individual assessment to be present during administration?	s22 A/g Principal Medical Officer Pharmacovigilance Branch	12:30PM
6.	Discussion of Recommendation 4: Appropriate site location Discussion Points: This recommendation is the current practice followed by the medical officer delegates when reviewing whether a site is appropriate. Are there any comments on whether this criterion is sufficient?	s22 A/g Principal Medical Officer Pharmacovigilance Branch	1:20PM
7.	Other matters	s22 A/g Principal Medical Officer Pharmacovigilance Branch	1:40PM
Meeting close			2:00PM

From: [Authorised Prescribers](#)
To: s22
Subject: RE: Invitation to consultation outcomes discussion meeting – Authorised Prescriber scheme for MDMA and Psilocybine [SEC=OFFICIAL]
Date: Friday, 21 November 2025 2:09:10 PM
Attachments: [image001.png](#)
[Psychedelics consultation discussion meeting presentation.pdf](#)
[image002.png](#)

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Dear all

Thank you for your valuable contributions to the discussion meeting on Wednesday. We are very appreciative of the expertise that was shared.

I have attached the slides from the presentation for those who were interested. We are in the process of summarising the Minutes from the meeting and finalising the recommendations based on the feedback from the discussions. We hope to provide an update as soon as possible.

Please don't hesitate to contact us if you have any further questions or feedback.

Kind regards

s22

**Senior Pharmacist – Unapproved Medicines Access Section
 International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

This email comes to you from Ngunnawal
 Location: Gulgana Building, Fairbairn
 PO Box 9848, Canberra ACT 2601, Australia
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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.

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-----Original Appointment-----

From: LANGHAM, Robyn

Sent: Friday, 24 October 2025 3:58 PM

Subject: Invitation to consultation outcomes discussion meeting – Authorised Prescriber scheme for MDMA and Psilocybine

When: Wednesday, 19 November 2025 10:00 AM-2:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.

Where: Microsoft Teams Meeting

Dear stakeholder,

The Therapeutic Goods Administration (TGA) recently conducted a consultation on

the application process under the Authorised Prescriber scheme for the use of 3,4-methylene-dioxymethamphetamine (MDMA) and psilocybine in psychedelic-assisted psychotherapy.

To support informed decision-making and reflect the diverse perspectives of stakeholders, the TGA is convening a chaired discussion of the consultation outcomes. This meeting will bring together key representatives to help finalise the outcomes, which will inform future application processes and be reflected in TGA's publicly available guidance.

The discussion will be chaired by TGA's Chief Medical Advisor, **Prof Robyn Langham**, and will include participants from peak bodies, regulators, national boards, state and territory health departments, and Human Research Ethics Committees (HRECs). A detailed agenda will be shared ahead of the meeting.

The consultation outcomes paper will be sent to attendees with the agenda shortly, prior to the discussion meeting. The TGA actions in the summary document will be used to guide the discussion. (**Updated Agenda and Summary Document attached [18/11/2025] – Please treat the attached papers as confidential.**)

Meeting Details

Date: Wednesday, 19 November 2025

Time: 10:00 AM – 2:00 PM (AEDT)

Location: Virtual (Microsoft Teams link provided)

Please confirm your attendance by accepting this meeting invite (using the 'send response' option) no later than **Friday, 14 November 2025.**

We look forward to your valuable contribution to this important discussion.

Kind regards,
s22

Executive Assistant to Prof. Robyn Langham, Chief Medical Advisor
Health & Safety Representative

Therapeutic Goods Administration

Australian Government Department of Health, Disability and Ageing

s22 @health.gov.au

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Location: Gulgana Office – 27 Scherger Dr, Canberra Airport, ACT, 2609

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Psychedelics targeted consultation outcomes

s22

Senior Pharmacist, Unapproved Medicines Access Section
Therapeutic Goods Administration (TGA)

Psychedelics consultation outcomes discussion – 19 November 2025



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Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.



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Department of Health, Disability and Ageing
Therapeutic Goods Administration

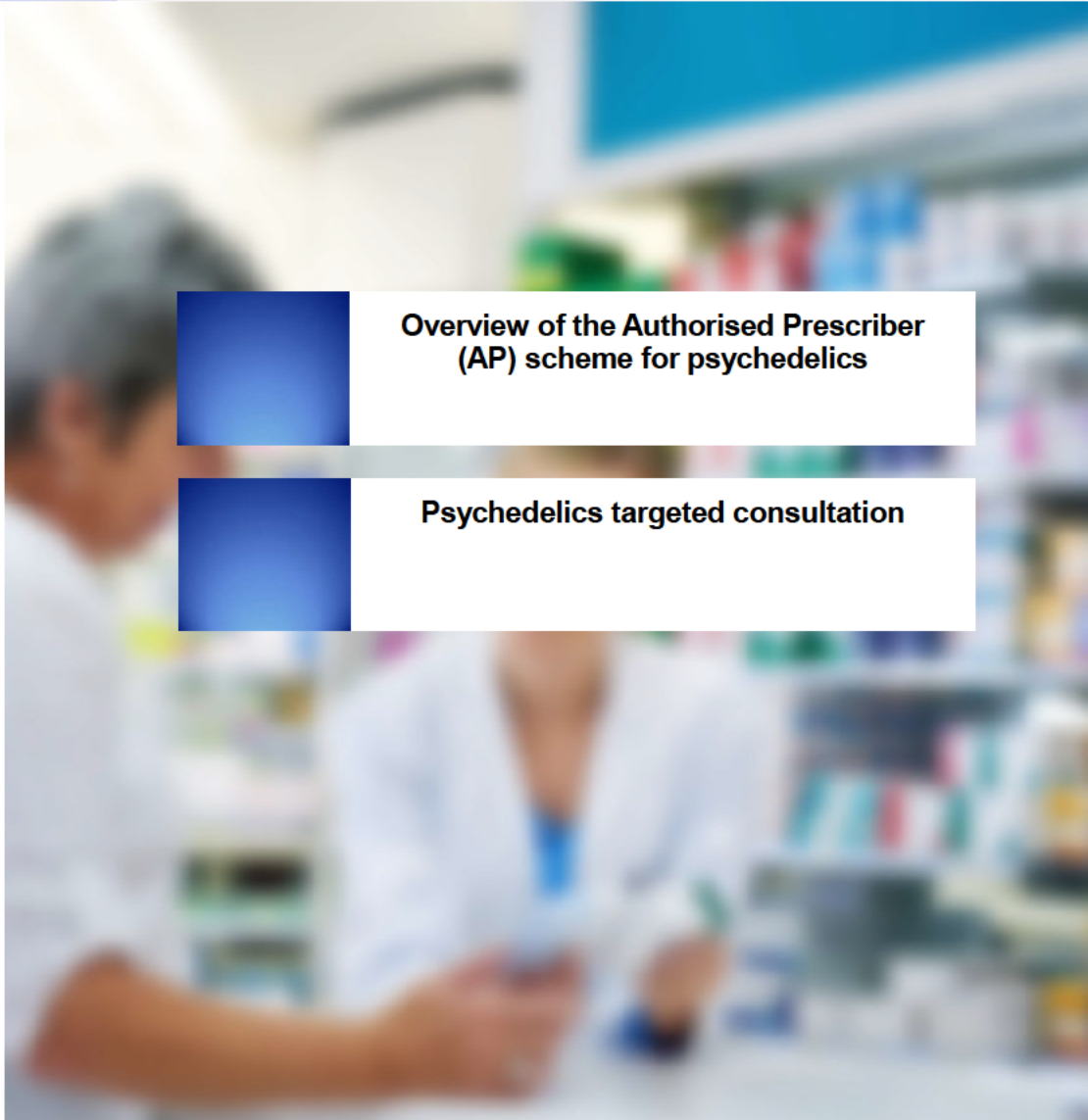
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Contents

- 1. Overview of the Authorised Prescriber (AP) scheme for psychedelics**
 1. Re-scheduling of MDMA and Psilocybine
 2. Unapproved therapeutic good basics
 3. Authorised Prescriber scheme
 4. Roles of the TGA, AP and HREC
- 2. Psychedelics targeted consultation**
 1. Rationale for consultation
 2. Response and recommendations
 3. Other issues
 4. Next steps



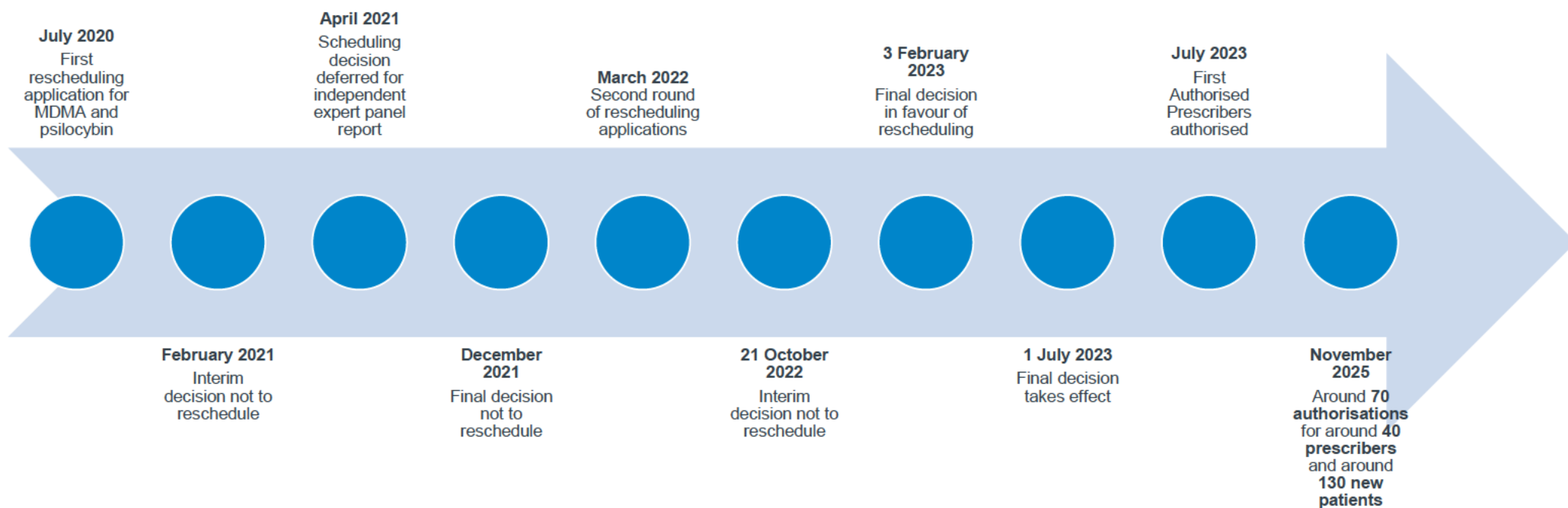
Overview of the Authorised Prescriber (AP) scheme for psychedelics

Psychedelics targeted consultation

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Overview of the AP scheme for psychedelics

Rescheduling of MDMA and psilocybine



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Overview of the AP scheme for psychedelics

'Unapproved' therapeutic good basics



The Therapeutic Goods Act 1989 provides a national framework for regulating therapeutic goods



Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) to be supplied in Australia



Therapeutic goods not in the ARTG are 'unapproved' therapeutic goods



Unapproved goods have not been evaluated for quality, safety, efficacy or performance



An exemption, approval or authorisation from TGA is needed to access unapproved goods for patients

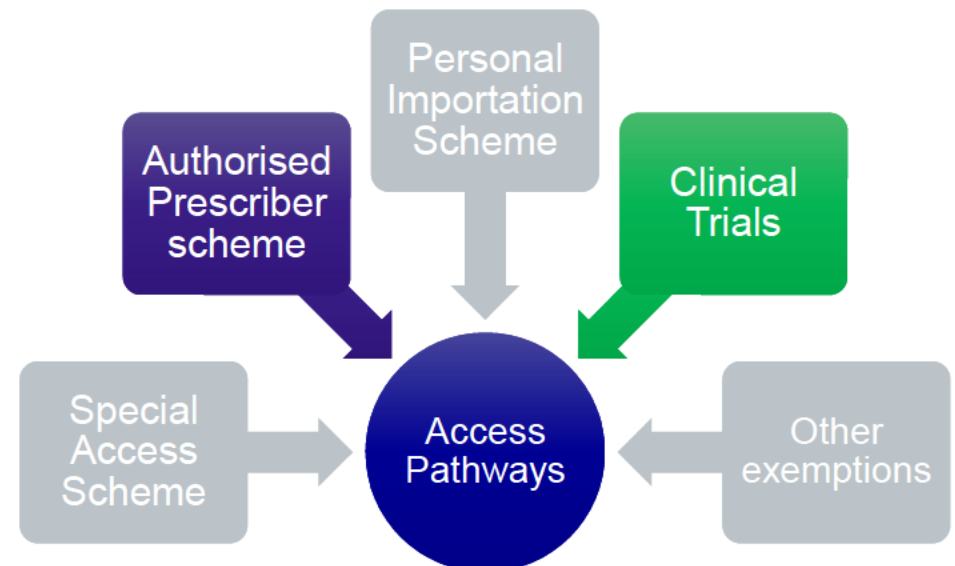
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Overview of the AP scheme for psychedelics

Unapproved therapeutic good basics

- The TGA encourages the use of therapeutic goods included in the ARTG
- There are pathways in the TG legislation that allow access to unapproved products in certain situations
- The TGA cannot guarantee the quality, safety efficacy and/or performance of 'unapproved' therapeutic goods
- The prescriber is responsible for deciding to use an unapproved product and for any risks/adverse outcomes
- Only the AP scheme and clinical trials are applicable pathways to access MDMA and psilocybine



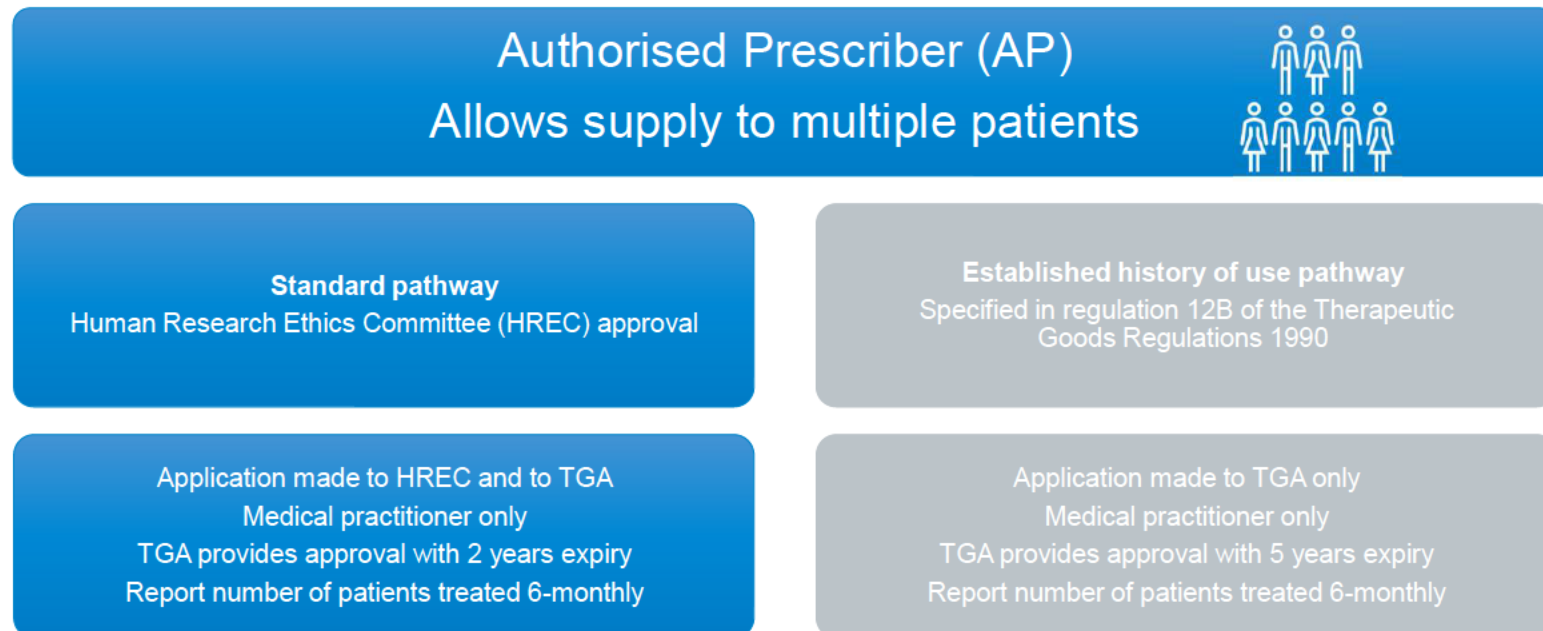
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Overview of the AP scheme for psychedelics

Authorised Prescriber scheme

Did you know? The regulatory framework for the AP scheme, including the requirement for HREC approval, commenced in 1991 with the scheme operational in the early 1990's.



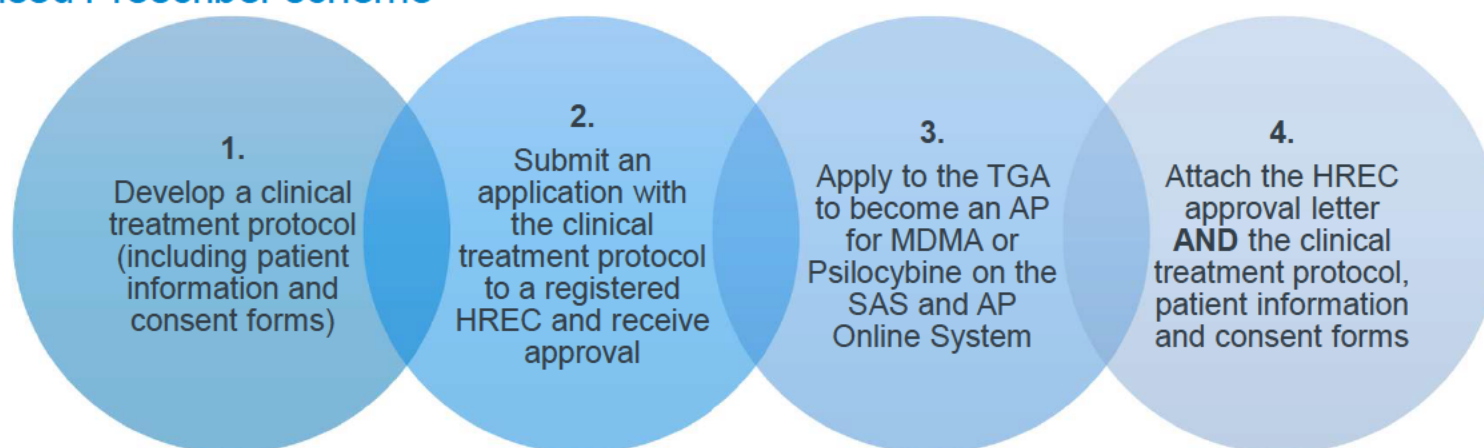
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Overview of the AP scheme for psychedelics

Authorised Prescriber scheme



Why does TGA review the treatment protocol for MDMA and psilocybin?

- These are psychoactive substances with limited long-term safety and efficacy data
- Patients are psychologically vulnerable
- Require a controlled supply chain and administration in tightly controlled therapeutic settings

This review ensures alignment with TGA expectations to safeguard patient wellbeing while still allowing access for patients with an unmet clinical need.

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Overview of the AP scheme for psychedelics

Medical practitioner role

- **Determine** whether suitable alternatives are in the ARTG
- **Apply** for approval from a HREC and authorisation from TGA
- **Review** the potential benefits and risks for each patient
- **Obtain** written informed consent from each patient
- **Arrange** supply through a sponsor or pharmacy
- **Monitor** the patient during and after use of the unapproved good
- **Report** the number of new and total patients to the TGA every six months
- **Report** adverse events and defects
- **Meet any conditions** the TGA or HREC applies
- **Comply** with relevant state or territory and Commonwealth legislation

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Overview of the AP scheme for psychedelics

HREC role

- **Review** submissions to access unapproved goods
- **If approved/endorsed**, provide the medical practitioner with a letter of approval/endorsement
- **Monitor** the use of the 'unapproved' goods to ensure continued endorsement is appropriate

TGA role

- **Review** a clinical treatment protocol, patient information and consent forms (for psilocybine and MDMA only)
- **Authorise** medical practitioners to lawfully supply an unapproved therapeutic good, as reviewed by a HREC
- **Receive** prescriber and sponsor reports
- **Receive** information from prescribers and sponsors regarding adverse events and emerging safety concerns

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Overview of the AP scheme for psychedelics

Delegate review process

1	Prescriber qualifications	Check
	Provide evidence you are registered as a specialist psychiatrist with the Medical Board of Australia.	☐
2	Treatment protocol	Check
	Treatment protocols are required for both the HREC application and the TGA Authorised Prescriber application. Aspects of the treatment protocol are likely to be very similar to the protocols that have been used in Australia and internationally in clinical trials of these substances. To include but not limited to:	
	(a) Medical practitioner details The psychiatrist should provide evidence of specific clinical experience and training applicable to the proposed use of the product.	☐
	(b) Practice location Evidence the psychiatrist will conduct administration and monitoring of the treatment in an appropriate supervised environment (i.e. accredited facility, either day hospital or inpatient setting).	☐
	(c) Clinical justification and evidence for use of the unapproved product (i) Consideration of Australian Register of Therapeutic Goods (ARTG) registered products: psychiatrists must specify that only patients who have unsuccessfully trialled ARTG registered products for the indication will be considered for treatment. (ii) Evidence: to support the use of the unapproved product for the intended indication along with sources of evidence to support the use of the unapproved good (i.e. RCTs).	☐

(d) Product Active ingredient, strength, dosage form, trade name, manufacturer/sponsor details. Access and storage. (i) Products other than pharmaceutical grade psilocybine and MDMA will not be approved by the TGA. (ii) Products manufactured at Good Manufacturing Practice (GMP) licenced sites strongly preferred. (iii) Declare products conform with the relevant Therapeutic Goods Order (see: Complying with the quality requirements for MDMA and psilocybine). (iv) Extracts of mushrooms will not be approved.	☐
(e) Use and monitoring Definition of the specified indication, concomitant medications, number of dose sessions required, rescue medications, assessment of efficacy, assessment of outcome measures, completion of therapy and follow up.	☐
(f) Efficacy and safety Any known/expected adverse effects, risks including but not limited to how patient vulnerability will be managed, safety measures and related toxicology.	☐
(g) Participant selection Screening for eligibility, inclusion and exclusion criteria and patient withdrawal process.	☐
(h) Consent process (please attach consent form with the clinical protocol) Details of the consent process, the purpose of the treatment and what is involved, the medical risks involved with the drug and in using an unapproved drug, psychological risks and physical risks during the session.	☐
(i) Psychotherapy Psychoeducation and preparation for the dose sessions, anxiety management strategies, strategies to monitor mental state and wellbeing, supporting staff management.	☐
(e) Supporting clinical therapists Supporting therapists are expected to be properly trained on evidence-informed protocols for psychedelic-assisted psychotherapy and should hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology or equivalent.	☐

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Psychedelics targeted consultation

Why was a consultation conducted?

- Since 1 July 2023, several procedural and practical challenges have emerged for AP applicants, Human Research Ethics Committees (HRECs), and the Therapeutic Goods Administration (TGA).
- To address these concerns a review of the application process is underway.
- Outcomes from this consultation will be discussed, to guide decision-making and support updates to TGA's external guidance.
- Twenty-nine of the 83 invited stakeholders provided feedback on four proposed recommendations.

Stakeholder group	Total	Percentage
State health department	7	24.1%
Authorised Prescriber psychiatrists	6	20.7%
Peak bodies	8	27.6%
Human Research Ethics Committees (HRECs)	4	13.8%
Other	4	13.8%
Total	29	100%

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Recommendation 1: Psychiatrist experience

Responses

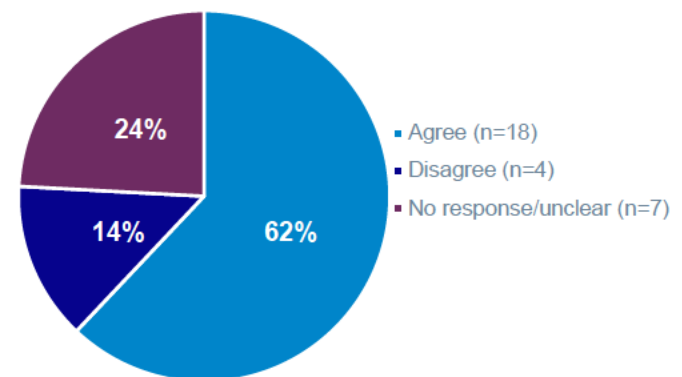
Most respondents supported the requirement for either clinical trial experience or developing competence through supervision by an experienced AP (where the level of experience of the supervisor is defined).

Emphasis for clear criteria for supervision. However, this aspect falls outside the regulatory scope of the TGA.

It is noted the Royal Australian and New Zealand College of Psychiatrists (RANZCP) published their 'Psychedelic training framework for psychiatrists' in June 2025 ([Psychedelic training framework for psychiatrists | RANZCP](#)).

This recommends supervision and membership in a psychiatric peer review network. Further advice on which professional body or regulator could take on the role of further defining the criteria for supervision is necessary.

Psychiatrist should have prior PAT clinical trial experience or initial supervision



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Post consultation recommendation 1: Psychiatrist experience

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with RANZCP's 'Psychedelic training framework for psychiatrists', including supervision and ongoing peer support.

Discussion points

1. When would an Authorised Prescriber, who was not initially involved in a clinical trial, be considered to have sufficient experience to be a supervisor of other Authorised Prescriber's?
2. Alternatively, should this be a decision governed by the TGA or should the experience of the supervisor be assessed on a case-by-case basis by the HREC?
3. Should the experience of the supervisor be governed by the standards of a peak body?

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Recommendation 2: Therapy 'dyad' qualifications

Responses

Confusion about the TGA's expectations for the composition of the therapy 'dyad' (or pair of therapists) in PAT.

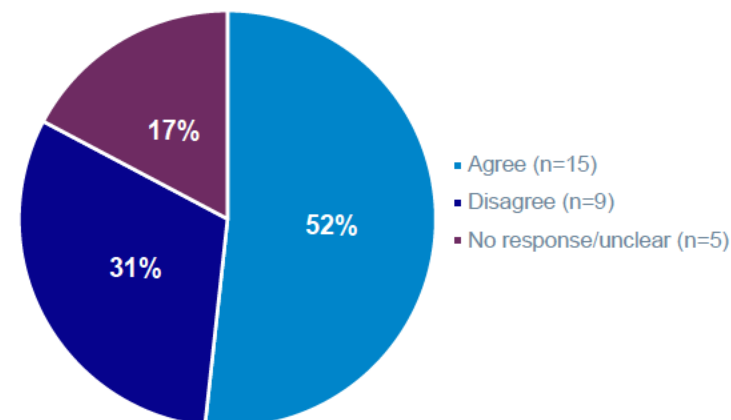
Most respondents advocated for the broader inclusion of other types of therapists in place of a clinical psychologist or psychiatrist, including those not registered with the Australian Health Practitioner Regulation Agency (Ahpra).

HRECs mentioned they do not have the expertise to review qualifications of therapists.

Other clinical practice bodies should provide guidance on the suitability of their professional groups.

The responsibility for choosing therapists should be placed with the Authorised Prescriber.

Other health practitioners should be considered for the lead therapist role



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Post consultation recommendation 2: Therapy ‘dyad’ qualifications

The PAT dyad must include at least one therapist who is registered with a National Board that with regulatory oversight of psychotherapy, specifically, the Psychology Board, Medical Board, or Nursing and Midwifery Board. Oversight of the qualifications and experience of any additional therapists participating in sessions is guided by the determination of the Authorised Prescriber.

Discussion Points:

1. Should the therapy dyad be limited to specific Ahpra registered health practitioners?
2. Should therapists with oversight by a professional body other than Ahpra (such as PACFA) replace the need for an Ahpra registered practitioner? Would there be adequate mechanisms for oversight of scope of practice and managing professional misconduct?
3. HRECs have advised the TGA to remove the statement indicating that oversight of practitioner qualifications and experience falls within their remit. Considering this, which regulatory or professional bodies are responsible for ensuring that practitioners involved in the AP scheme possess the appropriate qualifications and experience?

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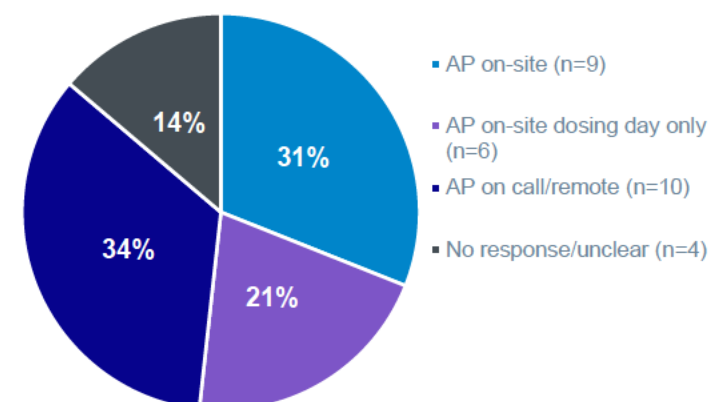
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Recommendation 3: Level of AP oversight

Responses

- Most stakeholders supported the requirement for the AP to be physically present on-site for some period of time.
- Respondents justified this requirement by noting that PAT remains experimental with direct, on-site oversight by the AP necessary for patient safety.
- There were comments that having the AP on-site is onerous and restricts access in rural and regional areas.
- Some states/territories also require the APs involvement in administration of the product.

AP must be physically on-site at the treatment location



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Post consultation recommendation 3: Level of AP oversight

The AP psychiatrist should be physically present during at least patient screening, consent and medicine administration (dosing).

It is expected the AP be physically present during the administration of the psychedelic (this does not need to be the full dosing day). This presence ensures the AP is readily available to manage any immediate issues and severe adverse events that may occur.

Discussion Points:

1. The TGA updated this recommendation to establish an expectation for physical presence at the administration of the medication only, where "administration" is defined as the patient ingesting the medication, rather than encompassing the entire dosing day. Do you believe this approach provides sufficient flexibility for Authorised Prescribers (APs) to manage immediate adverse events without compromising patient safety?
2. Additionally, in practices where multiple APs are present, should the physical presence of any AP be considered sufficient, or is it necessary for the AP who conducted the individual assessment to be present during administration?

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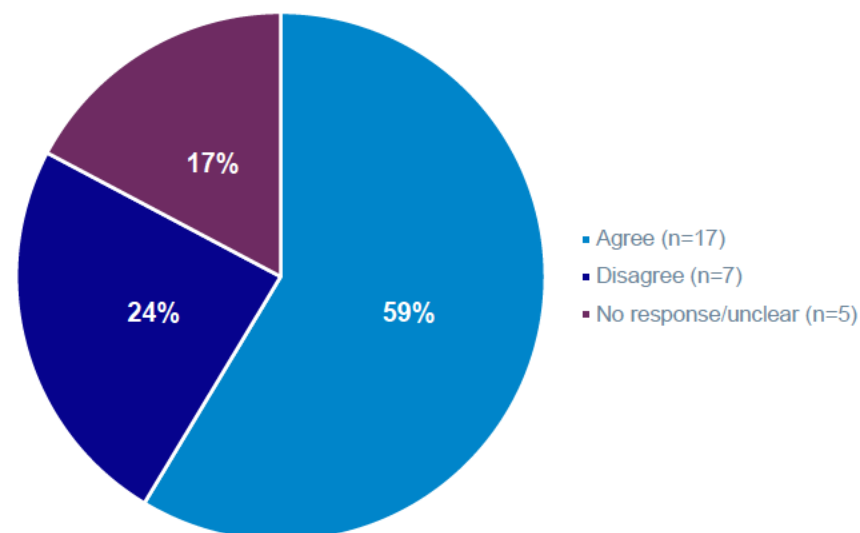
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Recommendation 4: Appropriate site location

Responses

- There was a majority view from respondents who supported sites other than day hospitals or inpatient settings to be considered appropriate.
- Based on this feedback, the TGA considers that the original recommendation, allowing the use of private clinics with appropriate emergency management processes, to be the right balance between access and safety.
- This is also the current policy in use by TGA delegates and has been internally approved until the review is complete.

Sites other than day hospitals or inpatient settings should be considered appropriate for PAT



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Post consultation recommendation 4: Appropriate site location

Prescribers must provide details of the treatment site to demonstrate it is a suitable and supervised environment. The prescriber must verify the site meets all state and territory requirements. The HREC is responsible for reviewing the appropriateness of the site in line with the following criteria:

Have equipment and trained staff for clinical care, monitoring, and emergency resuscitation.

Provide secure storage for Schedule 8 medicines as per jurisdictional regulations.

Be prepared to address treatment-emergent adverse events, with rescue medications on hand.

Be located near an accredited healthcare facility with an emergency department.

Hold or be seeking accreditation if required by the relevant state or territory.

Discussion Points:

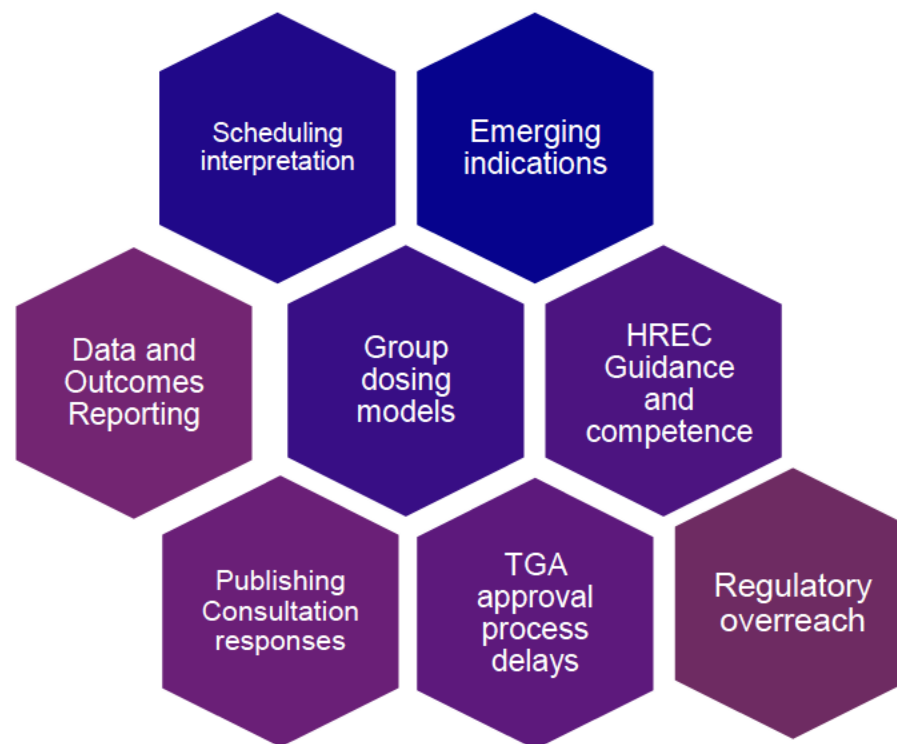
This recommendation is the current practice followed by the medical officer delegates when reviewing whether a site is appropriate. Are there any comments on whether this criterion is sufficient?

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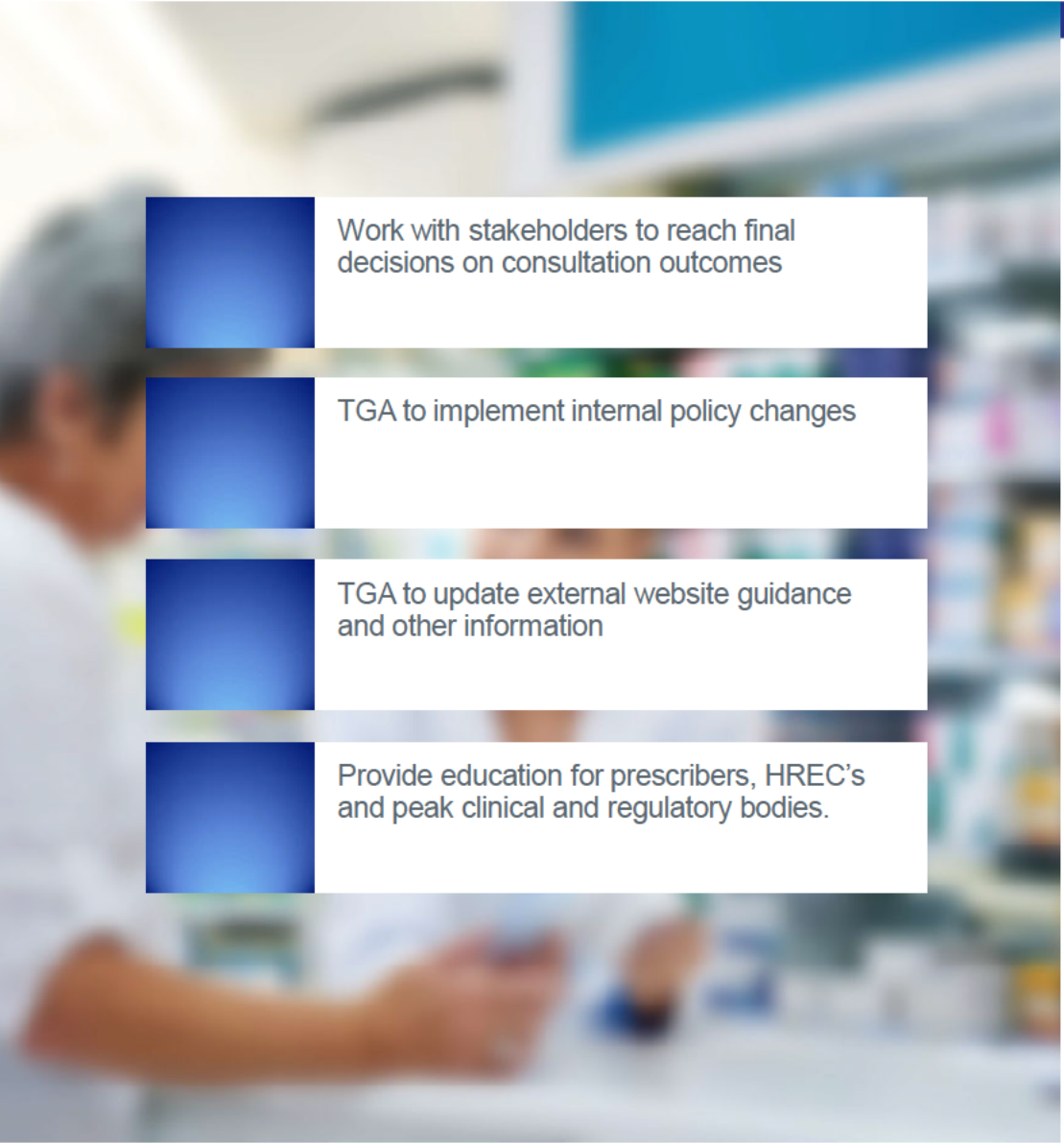
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Psychedelics targeted consultation

Other issues



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Work with stakeholders to reach final decisions on consultation outcomes

TGA to implement internal policy changes

TGA to update external website guidance and other information

Provide education for prescribers, HREC's and peak clinical and regulatory bodies.

Next steps

- Outcomes from this consultation will be discussed, to guide decision-making and support updates to the Authorised Prescriber Scheme for psychedelics.

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Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

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From: [Authorised Prescribers](#)
Bcc: [LANGHAM, Robyn](#) s22 [DAVISON, Sophie](#) s22
 s22 [i@act.gov.au](#); s22 [@health.nsw.gov.au](#);
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Subject: Final meeting minutes – psychedelics consultation outcomes discussion
Date: Wednesday, 24 December 2025 2:37:47 PM
Attachments: [image002.png](#)
[image003.png](#)
[Authorised Prescriber Scheme Psychedelics Consultation Outcomes Discussion Minutes.pdf](#)

Dear Attendees,

Thank you for your valuable participation in the discussion on outcomes of the TGA's psychedelics consultation held on Wednesday, 19 November. We greatly appreciate the expertise and insights shared during the session.

A final version of the meeting minutes is attached.

We are actively addressing the issues raised since MDMA and psilocybine were rescheduled, allowing access through the Authorised Prescriber scheme. Finalising the consultation recommendations remains a priority, and we are working to complete this process as efficiently as possible.

We appreciate your patience as we gather some final essential feedback from key stakeholders. The timeline for publishing the recommendations is dependent on this process, therefore we are unable to confirm a date at this stage.

Once the recommendations are approved, the TGA website and guidance will be updated, and education emails will be distributed to keep all stakeholders informed.

Thank you for your continued engagement and support. Please do not hesitate to reach out if you have any questions.

Kind regards,

**The TGA will close from 3pm Wednesday 24 December 2025 until 9am
 Friday 2 January 2026. All enquiries will be responded to as soon as possible
 upon our return**



Pharmacist Team
Unapproved Medicines Access Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

This email comes to you from Ngunnawal
Location: Gulgana Building, Fairbairn
PO Box 9848, Canberra ACT 2601, Australia
www.tga.gov.au

The Department of Health, Disability and Ageing 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.

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Review of the Authorised Prescriber scheme for psychedelics

Targeted consultation outcomes discussion

Meeting Minutes

Wednesday, 19 November 2025

10:00AM – 2:00PM AEDT

Microsoft Teams

Attendance

Department of Health, Disability and Aged Care	
s22	Chair & Medical Officer Delegate, Therapeutic Goods Administration
Prof Robyn Langham	Chief Medical Advisor, Therapeutic Goods Administration
s22	Medical Officer Delegate, Therapeutic Goods Administration
	Director, Unapproved Medicines Access Section, Therapeutic Goods Administration
	Senior Pharmacist, Therapeutic Goods Administration
	Pharmacist, Therapeutic Goods Administration
	Pharmacist, Therapeutic Goods Administration
	Chief Medical Advisor Unit, Therapeutic Goods Administration
	Chief Medical Advisor Unit, Therapeutic Goods Administration
	Chief Psychiatrist
	Director, Scheduling and Chemicals Policy Section
	Delegate, Chief Nursing and Midwifery Office
Department of Veterans Affairs	
s22	Senior Medical Officer
	Chief Health Officer
	Specialist Mental Health Adviser
States and Territories	
s22	Deputy Chief Pharmacist, Pharmaceutical Services Section, ACT Health and Community Services Directorate
	Pharmacist Manager, Medicines and Poisons Regulation Branch, WA Department of Health
	Medicines and Poisons Regulation Branch, WA Department of Health
	Director, Medication Services Queensland, Queensland Health
	Medication Services Queensland, Queensland Health
	Principal Pharmaceutical Officer, Pharmaceutical Services, NSW Ministry of Health
	Chief Pharmacist, NT Health
	Director Clinical Regulation, Public Health Division, SA Health
	Senior Pharmacist, Pharmaceutical Services Branch, Tasmanian Department of Health
	Manager, Permits and Licensing Team 2, Victorian Department of Health
	Director, Regulatory Services, Victorian Department of Health
	Chief Mental Health Alcohol and Other Drugs Officer, Chief Psychiatrist, Queensland Health
Peak bodies & Organisations	

s22	Psychiatrist, The Royal Australian & New Zealand College of Psychiatrists
	Appointed Director, Trainee, The Royal Australian & New Zealand College of Psychiatrists
	Director, Indigenous Psychedelic-Assisted Therapies (IPAT)
	Indigenous Psychedelic-Assisted Therapies (IPAT)
	Chair, Australian Multidisciplinary Association for Psychedelic Practitioners
	Partnership Liaison Advisor, Psychotherapy and Counselling Federation of Australia (PACFA)
	CEO, Psychotherapy and Counselling Federation of Australia (PACFA)
	Australian Counselling Association
	CEO, Australian Counselling Association
	Co-chair, Psychedelic-assisted Psychotherapy Interest Group, Australia Association of Psychologists Inc (AAPi)
	Co-chair, Australian Association of Psychologists Inc (AAPi) Psychedelic Assisted Therapy interest group and committee member of the Australian Psychological Society (APS) Psychedelic Assisted Therapy interest group
	General Manager, Australian Association of Social Workers (AASW)
Ahpra & National Boards	
s22	Chair, Medical Board of Australia
	Chair, Pharmacy Board of Australia
	Chair, Psychology Board of Australia
	Executive Officer, Medical Board of Australia
	Executive Officer, Psychology Board of Australia
	National Director, Policy and Accreditation, Australian Health Practitioner Regulation Agency
	Manager, Clinical Input (Pharmacy), Notifications, Australian Health Practitioner Regulation Agency
	Manager, Multiprofession Policy, Australian Health Practitioner Regulation Agency
Ethics Committees	
s22	Chair, Townsville Hospital and Health Service HREC
	Chair, ACT Human Research Ethics Committee
	Senior Manager, Research Ethics and Governance Office, Canberra Health Services
	Research Ethics and Governance Office, Canberra Health Services
	HREC Secretariat for Ramsay Health Care HREC A and Ramsay Health Care WA and SA HREC.
Prescribers & clinics	
s22	Director, s22
	Project Manager, s22
	Clinical Governance, s22
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist

Apologies	
	Australian College of Mental Health Nurses
	National Institute of Integrative Medicine HREC
	South Metropolitan Health Service HREC
	Australian Psychology Society
	St Vincents Hospital Melbourne HREC
	Monash Health HREC
	Nursing and Midwifery Board of Australia

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Meeting outcomes

1. Preliminary

1.1 Welcome and introductions

The Therapeutic Goods Administration (TGA) Chief Medical Advisor opened the meeting by welcoming the attendees, delivering an Acknowledgment of Country and providing housekeeping instructions. It was clarified that the purpose of the discussion was not to review the efficacy or safety of psychedelic treatments but to discuss recommendations for changes to the Authorised Prescriber (AP) application process for psychiatrists applying to access psychedelic medicines.

2. Discussion of recommendations

2.1 Outcome summary presentation

The TGA's Unapproved Medicines Access Section (UMAS) provided a presentation outlining the role of the section in reviewing Authorised Prescriber applications, background to the re-scheduling decision, 'unapproved' medicines access, the Authorised Prescriber scheme and a summary of responses from the targeted consultation.

3. Discussion of Recommendation 1: Psychiatrist experience

3.1 Introduction of recommendation 1

The Chair introduced recommendation 1 below:

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with The Royal Australian and New Zealand College of Psychiatrist's (RANZCP's) ['Psychedelic training framework for psychiatrists'](#), including supervision and ongoing peer support.

The Chair then invited attendees to participate in an open discussion of Recommendation 1.

3.2 Discussion

Guidance from professional bodies

Stakeholders supported deferring clinical guidance and credentialing to professional bodies. It was noted that decisions should be guided by these bodies to maintain standards and avoid risks

associated with low-quality clinical services under vertical integration models, which could increase public health burden.

Competency and supervised practice

Participants advocated for supervised practice pathways based on competency criteria, including minimum case numbers and observed sessions. There was agreement on recognising structured, real-world experience alongside clinical trial experience when assessing competency. It was suggested prescriber competency could be evaluated on a case-by-case basis where evidence of experience in a structured program exists. Input from relevant professional colleges and cross-professional collaboration were considered essential for defining standards and establishing benchmarks.

Regulatory roles

It was clarified that Human Research Ethics Committees (HRECs) do not serve as credentialing bodies; their role is limited to assessing applications against the [National Health & Medical Research Council \(NHMRC\) National Statement](#).

Additionally, the Medical Board of Australia does not regulate a practitioner's scope of practice but in responding to a notification about a medical practitioner would need standards to refer to. The TGA operates under the *Therapeutic Goods Act 1989* and is limited to medicine regulation.

Certification and training framework

Stakeholders agreed on the importance of linking the recommendation to the Royal Australian and New Zealand College of Psychiatrists (RANZCP) Psychedelics Training Framework, which includes prescribing and psychotherapy components, supervision, peer support, case logging, and clinical governance. A certification process was proposed, drawing on models such as electroconvulsive therapy (ECT) and Gastroenterological Society of Australia (GESA) endoscopy certification. Development of a consensus framework by the College was suggested, although it was noted that the College is not resourced to monitor or endorse specific training courses.

Supervision criteria

Recommendations for supervision criteria included prescriptive guidance on minimum case numbers, case discussions, and observed sessions. Some applications already include peer support arrangements documented in written plans. A decentralised approach was suggested, leveraging existing Authorised Prescribers and sites. Additionally, a "train-the-trainer" model was proposed, requiring applicants to participate in at least one MDMA treatment with an Authorised Prescriber who would sign off on their involvement. Clarification was sought on whether "supervision" refers to workplace or professional oversight and whether peer support qualifies as professional supervision.

Practical challenges

Concerns were raised that current policy makes it difficult for psychiatrists to begin prescribing psychedelics, as requirements for hands-on training and supervised treatment are impractical for many clinicians starting out. While standards are essential, stakeholders stressed the need to balance these with practical pathways to achieve Authorised Prescriber status.

Actions

- As a clinical body was seen to be an appropriate organisation to provide clarity on supervision criteria or a consensus opinion, the TGA will consult with RANZCP to further clarify the recommendation prior to finalisation.

4. Discussion of Recommendation 2: Therapy Dyad

4.1 Introduction of recommendation 2

The **Chair** introduced recommendation 2 below:

The PAT dyad must include at least one therapist who is registered with a National Board with regulatory oversight of psychotherapy, specifically, the Psychology Board, Medical Board, or Nursing and Midwifery Board. Oversight of the qualifications and experience of any additional therapists participating in sessions is guided by the determination of the Authorised Prescriber.

The Chair clarified the requirement for therapy dyads to include at least one therapist registered with a National Board is to ensure regulatory oversight of psychotherapy. This acknowledges a multidisciplinary approach while maintaining oversight. The policy has shifted slightly, leaving assessment of additional therapists' qualifications to the AP. Regulatory oversight must come from a regulatory body with oversight of psychotherapy. TGA discussions with HRECs confirmed that practitioner qualification oversight is outside a HREC's remit.

The Chair then invited attendees to participate in an open discussion of Recommendation 2.

Note: reference to "Ahpra-registered" below refers to practitioners registered with a National Board and administered by the Australian Health Practitioner Regulation Agency (Ahpra).

4.2 Discussion

Multidisciplinary input

Stakeholders emphasised the importance of multidisciplinary perspectives, including cultural and faith-based considerations, and noted that qualifications alone do not guarantee psychotherapeutic competency. Collaboration between Australian Multidisciplinary Association for Psychedelic Practitioners (AMAPP) and the Psychotherapy and Counselling Federation of Australia (PACFA) was suggested to co-create psychotherapy training guidelines. Concerns were raised about mandating the use of a clinical psychologist in the therapy dyad, as this is not internationally standard and may be culturally unsafe. Models were proposed where the Authorised Prescriber provides oversight as a regulated practitioner, with other team members approved by ethics committees. The role of social workers and psychotherapists was highlighted. Clearer wording from TGA on this recommendation was requested to avoid confusion.

Workforce challenges

The role of counsellors and psychotherapists in addressing workforce shortages was highlighted. It was argued that advanced credentials among non-Ahpra registered practitioners pose less risk than some Ahpra-registered professions. Workforce constraints were identified as a major barrier to treatment access, with calls to broaden eligibility to include psychotherapists, social workers, and occupational therapists.

Regulatory oversight and accountability

Some stakeholders cautioned against excluding professions that already have established roles in mental health facilities, such as social workers (who are not Ahpra-registered) and occupational therapists (who are Ahpra-registered). Suggestions included linking Authorised Prescribers and lead therapists to regulatory bodies, while secondary therapists could be approved by credentialing committees.

PACFA's role as a registration and quality assurance body for psychotherapists was outlined. It was clarified that registration with PACFA required criteria such as tertiary qualifications in counselling, indemnity insurance and completion of Continuing Professional Development (CPD).

It was explained that the Australian Association of Social Workers (AASW) has a robust complaint mechanism allowing families or participants to lodge complaints if the social worker is a member. The AASW investigates complaints, shares information with the relevant Healthcare Complaints Commissioner when relevant and removes membership if the social worker fails to comply with the code of ethics and standards.

Removing distinctions between clinical and other psychologists was raised, as regulatory oversight is the same. Accountability measures were discussed, including peak body oversight, Authorised Prescriber responsibility, and site clinical governance. Mechanisms for complaints of non-Ahpra

registered professionals through Healthcare Complaints Commissions and professional associations were highlighted.

Other stakeholders disagreed with the recommendation, supporting therapy dyads with two Ahpra-registered practitioners for accountability, while allowing non-registered professionals in other supporting roles. The importance of being able to control non-compliant individuals through the national health practitioner regulation framework was highlighted. Challenges with lack of legal recourses and service design issues across the regulatory landscape for scheduled medicines was raised. Emphasis was placed on logistical safety checks, such as nurse or pharmacist checks. It was also emphasised that Ahpra provides clear pathways for jurisdictions and the Commonwealth to act decisively if issues arise. However, recognising the essential role of non-Ahpra registered practitioners in care delivery is still necessary. There is a need for minimum standards and strong oversight to ensure safe, controlled care, given the experimental nature of these medicines. Safeguards should remain until sufficient evidence supports safety and efficacy, at which point restrictions could be eased.

Cultural competency and inclusion

Concerns were raised that requiring registration with Ahpra would exclude Aboriginal and Torres Strait Islander healing practitioners, limiting culturally safe access. Ahpra provides registration for Aboriginal and Torres Strait Islander Health Practitioners that meet certain qualification and competency requirements. There are also credentialling and registration pathways through other peak bodies, such as the Australian Council for International Development (ACFID), however, these are still inaccessible for non-clinical practitioners. Stakeholders also stressed the need for cultural competency within therapy dyads and inclusion of diverse practitioners to reduce risks and improve client safety. It was noted that registered practitioners may not always feel culturally safe for clients. It was clarified these practitioners would work within a team, under an Authorised Prescriber for oversight and accountability.

Credentialing and supervision

Recommendations included developing a credentialing pathway with minimum supervision and training requirements, noting this responsibility does not sit with TGA or HRECs. Stakeholders emphasised that training should apply to the entire therapy dyad, not just the Authorised Prescriber, and highlighted the need for ongoing credentialing and cultural safety considerations. Support was provided for developing competency standards and an endorsement framework for training.

Professional indemnity insurance

Stakeholders raised the issue of professional indemnity insurance, stating that some practitioners are not eligible for insurance coverage and that there were legal ramifications for the Authorised Prescriber if conducting psychedelic-assisted therapy while uninsured.

Actions:

- TGA to refine the recommendation based on additional feedback in the meeting to potentially include further practitioners in the recommendation.

5. Discussion of Recommendation 3: Level of AP oversight

5.1 Introduction of recommendation 3

The Chair introduced recommendation 3 below:

The Authorised Prescriber psychiatrist should be physically present during at least patient screening, consent and medicine administration (dosing).

It is expected the Authorised Prescriber be physically present during the administration of the psychedelic (this does not need to be the full dosing day). This presence ensures the

Authorised Prescriber is readily available to manage any immediate issues and severe adverse events that may occur.

The Chair described the post-consultation position that the Authorised Prescriber psychiatrist should be physically present for screening, dosing, and consent, but not for the entire dosing day. The rationale for this being that it allows flexibility while the Authorised Prescriber should still be available to manage issues. He emphasised the need to consider state and territory legislation and that TGA applications must include details about access to emergency procedures.

The Chair then invited attendees to participate in an open discussion of Recommendation 3.

5.2 Discussion

Presence of Authorised Prescriber

It was noted that a person authorised under medicines and poisons legislation must be present to administer medicines. Several participants preferred that the Authorised Prescriber remain on-site for the full dosing day to enable prescribing of rescue medications and management of adverse events. Others supported flexibility, suggesting that additional medical practitioners or nurses on-site could provide safety coverage or that prescribers could remain nearby and available rather than continuously present, while ensuring accountability for screening, consent, and medication administration.

Questions were raised about whether the original prescriber must oversee the first dose or if another Authorised Prescriber could manage subsequent dosing. It was discussed that Authorised Prescribers should be readily available and able to reach the site within 30 minutes, questioning the need for Authorised Prescriber presence during initial dosing (for example, in hospital orders can be given over the phone).

Concerns were raised about the term “physically present,” with calls for clearer guidance on what constitutes “on-site.” Participants emphasised the need for precise wording in recommendations and contingency planning for prescriber unavailability due to leave or illness.

Telehealth and consent

Stakeholders highlighted the benefits of telehealth for initial screening and consent, particularly to address cost and travel burdens and improve rural access. It was suggested consent could be revisited during preparation or on the first dosing day. A regulator advised that the prescriber must conduct the consent process face to face, which can occur via initial telehealth discussions and be revisited during dosing. Multiple opportunities for consent were recommended to ensure clarity and defensibility in this experimental setting.

Safety and risk management

Discussions addressed how adverse events would be managed if the prescriber was not immediately available. It was noted that nurses can often manage dosing based on patient risk, but prescribers retain legal responsibility. Stakeholders stressed the importance of understanding legal implications and accountability when delegating tasks. Jurisdictional requirements were highlighted, including rules governing authority to possess, administer, and dispose of medicines.

Jurisdictional requirements

Specific expectations were outlined for psychedelic-assisted psychotherapy in some jurisdictions, such as New South Wales, including requirements for prescriber presence throughout treatment sessions, proper supervision, environmental risk assessments, and capacity to manage behavioural or medical emergencies. Patients must be informed that the product is unapproved and has not been assessed for safety or efficacy, with clear explanation of potential risks. It was also noted that regulation should remain adaptive as evidence develops.

Actions

- TGA to clarify state and territory requirements to further refine the recommendation.

6. Discussion of Recommendation 4: Appropriate site location

6.1 Introduction of recommendation 4

The Chair introduced recommendation 4 below:

Prescribers must provide details of the treatment site to demonstrate it is a suitable and supervised environment. The prescriber must verify the site meets all state and territory requirements. The HREC is responsible for reviewing the appropriateness of the site in line with the following criteria:

- *Have equipment and trained staff for clinical care, monitoring, and emergency resuscitation.*
- *Provide secure storage for Schedule 8 medicines as per jurisdictional regulations.*
- *Be prepared to address treatment-emergent adverse events, with rescue medications on hand.*
- *Be located near an accredited healthcare facility with an emergency department.*
- *Hold or be seeking accreditation if required by the relevant state or territory.*

The Chair outlined the post-consultation position above and the criteria. The Chair then invited attendees to participate in an open discussion of Recommendation 4.

6.2 Discussion

Accreditation and safety standards

Stakeholders emphasised that patients in altered states require strong protections and accredited facilities with medical oversight and governance. Recommendations included applying [National Safety and Quality Health Service Standards](#) (NSQHS) to outpatient mental health settings and mandating accreditation to prevent poor practices. While safe facilities are essential, therapist quality and rapport were noted as critical to successful treatment.

Role of HRECs

It was clarified that evaluating site appropriateness is outside the role of HRECs whose responsibility is limited to reviewing information against the NHMRC National Statement.

Cost and accessibility

Concerns were raised that psychiatric hospital accreditation is extremely costly and could prohibit clinics, with costs passed to consumers. Some participants supported private clinics operating safely under appropriate policies and procedures. Others stressed balancing safety with accessibility, noting that care should remain locally available to avoid interstate travel and maintain continuity with patients' existing therapists. It was noted that there have been no adverse events to justify higher accreditation levels. One stakeholder highlighted the need for clear guidance on what "near an accredited healthcare facility with an ED" means e.g. defining acceptable travel times

Systemic inequities and cultural safety

Stakeholders highlighted systemic inequities that limit access to treatment, particularly for First Nations people and marginalised groups. Hospital or clinic settings were described as potentially traumatic due to lack of privacy, shared spaces, and inappropriate staff interactions. The importance of set and setting was also highlighted. Recommendations included culturally safe spaces such as Aboriginal and Torres Strait Islander medical centres, outdoor or nature-integrated facilities, and cultural competency training for therapists. Pathways to reach remote and isolated communities were also emphasised.

Jurisdictional challenges and evidence gaps

Concerns were raised that responsibility falls on jurisdictions when adverse events occur. Accreditation was seen as a way to mitigate risks and maintain service quality, drawing parallels with other regulated sectors. Jurisdictions face challenges determining appropriate settings without clear data on therapy risks. More clinical evidence on adverse outcomes is needed before expanding beyond hospitals or inpatient environments. Concern that responsibility falls on jurisdictions when something goes wrong.

Regulatory limitations

It was noted that TGA cannot regulate facilities. Registered medicines benefit from multiple layers of regulation, which do not apply in the context of unapproved medicines. Access issues may be easier to resolve once products are registered.

The TGA would welcome a sponsor submitting a dossier of safety and efficacy data to include treatments in the ARTG, but the AP scheme operates outside of this. The AP scheme requires prescribers to report adverse events to TGA; none have been reported to date. Lack of reported adverse events should not be taken as proof of safety for these medicines. Ongoing monitoring is essential.

Actions

- TGA to clarify state and territory requirements to further refine the recommendation.

7. Other matters

7.1 Registries

Registry participation

Stakeholders strongly supported the use of the [Australian National University \(ANU\) Registry](#) for data collection to strengthen the evidence base. It was suggested that Authorised Prescriber applications should be contingent on registry participation, although it was acknowledged that this is currently voluntary.

TGA position

The TGA highlighted that the Authorised Prescriber scheme relates to unapproved medicines and the need to distinguish these from registered products, which have established safety and regulatory frameworks. It was noted that clinical trials remain the standard for generating evidence on efficacy and safety required for product registration in the ARTG.

It was clarified that there is no legislative basis to mandate registry participation, and therefore the TGA does not have the legislative power to enforce this requirement. It was emphasised that the Authorised Prescriber scheme is an access pathway for unapproved products and noted the expectation that submission of a clinical evidence package through the registration process will eventually enable broader use once safety and efficacy are demonstrated.

Practical and systemic challenges

Questions were raised about practical barriers to mandating outcome data submission, including uncertainty around whether sponsors will seek product registration. Concerns were expressed that current regulatory systems may not deliver a registered product soon due to financial and systemic constraints. Stakeholders emphasised the importance of evidence collection through registries and cautioned against relying on the Authorised Prescriber scheme as a long-term supply pathway.

The Chair closed the meeting at **2:00pm AEDT**.

7.2 Key meeting chat contributions

1. Accountability and oversight

- Questions were raised regarding accountability of the AP, especially regarding use of non-registered practitioners in therapy dyads.
- Consideration of implications for indemnity, insurance, and professional misconduct regulation.
- Emphasis on clarity in TGA documentation and guidance to ensure indemnity and compliance.

2. Practitioner registration and competency

- Debate on whether non-Ahpra registered practitioners should be permitted in dyads; if allowed, this must be explicitly stated in guidelines.
- National Standards for Counsellors and Psychotherapists will introduce minimum competency requirements.
- Multiple comments stressed that competency and cultural suitability can be more critical than formal qualifications or Ahpra registration.
- Risks associated with assuming Ahpra registration equates to suitability for PAT were highlighted.
- Difficulty recruiting clinical psychologists with trauma expertise noted; other disciplines (e.g., mental health social workers, counsellors) may offer better therapeutic outcomes.
- Importance of matching therapeutic skills to patient needs rather than relying solely on qualifications.

3. Cultural safety and equity

- Concerns that peak body registration excludes Aboriginal and Torres Strait Islander healing practitioners, widening health outcome gaps.
- Advocacy for culturally safe treatment spaces and pathways for remote communities.
- Recommendation for lived experience and community consultation in next steps.

4. Regulatory framework and risk management

- Current complaints handling for self-regulated practitioners relies on Health Care Complaints Commissions; proposals for a unified scheme across Ahpra and non-Ahpra professions noted.
- Jurisdictional variations in site requirements were discussed:
 - New South Wales (NSW): Approvals issued by NSW Health to Authorised Prescriber psychiatrists will include a condition that the treatment is provided in an appropriately supervised healthcare setting where an environmental risk assessment has been conducted and incidents of behavioural and/or medical emergencies can be adequately managed.
 - Victoria (VIC): No additional restrictions on settings for PAT.
 - Australian Capital Territory (ACT): No restrictions on setting; however, medicines and poisons legislation requires secure storage and limits administration to authorised medical practitioners and nurse practitioners.
 - Queensland (QLD): No additional setting restrictions currently in place.
 - South Australia (SA): Controlled substances regulations mandate administration of MDMA/psilocybine by the Authorised Prescriber in an approved treatment centre or authorised community mental health facility under the Mental Health Act 2009.
 - Western Australia (WA): Authorisations require dosing at the clinic specified in the AP's application; some clinics may need licensing under private hospital legislation depending on services offered.
 - Tasmania (TAS): Similar to ACT requirements for storage and administration.
- Medicines and poisons legislation governs possession, supply, and administration of psychedelics; secure storage requirements apply.

5. Consent and telehealth

- Telehealth widely accepted for informed consent; flexibility needed for remote and rural access. Consent should be ongoing and relational.
- Practical suggestions included GP involvement for physical examinations and investigations when remote screening is used.

6. Registries

- Strong support for ANU Registry and similar initiatives to collect safety and efficacy data.
- Transparency of registry funding and governance raised as a concern.

7.3 *Next steps*

1. Finalise recommendations based on meeting feedback for TGA internal approval
2. Publish a summary of final recommendations and justification
3. Update TGA internal review processes and external guidance material
4. Provide communication on update external guidance material

From: s22
To: s22
Subject: Summary of meeting with Ahpra and National Boards – Psychedelic-Assisted Therapy [SEC=OFFICIAL]
Date: Friday, 30 January 2026 3:44:27 PM
Attachments: [image003.png](#)

OFFICIAL

Hi s22

Below is a summary of the discussion from our meeting on Friday with Ahpra and the relevant National Boards regarding psychedelic-assisted therapy (PAT).

Key discussion points

- **Credentiailling and training requirements:**

There was a strong focus on the need to clearly articulate what training would be required for practitioners involved in PAT. In particular, the boards emphasised the distinction between a practitioner's *base professional training* and any *additional, specific training* required to safely and appropriately deliver PAT. – Robyn clarified this was out of TGA scope

- **Role clarity within the dyad:**

Ahpra and the boards were keen to understand the different roles within the dyad model, including whether one or both practitioners are supervising, and in what capacity (e.g. acting as a therapist). They noted this role clarity is essential to inform both credentiailling expectations and the nature of any required additional training. Robyn clarified this was out of TGA scope

- **Appropriate professions:**

It was noted that general psychologists would be an appropriate professional group to participate in PAT. There was also support for the position that both members of the dyad should be Ahpra-registered, to ensure appropriate regulatory oversight. Robyn stated hard to do when this already isn't the current requirement

- **Importance of clarity for regulatory consideration:**

Overall, the boards highlighted that clear articulation of roles, responsibilities, and training pathways is critical for them to meaningfully consider the proposal, particularly given the novel nature of PAT and the need to manage risk.

Action for you

Ahpra and each of the three National Boards requested separate, direct emails outlining our proposal for recommendation 2. They have asked that:

- Each email clearly sets out the background and context for the proposal,
- Ask specific questions about suitability of professions and each board's

willingness to support the recommendation and

- The time sensitivity is made clear, noting that they would like to consider the proposal at their end-of-February board meetings.

I emphasised the timing during the meeting so they are expecting correspondence shortly.

s22 – please add to this if you think there is anything further.

Please let me know if it would be helpful to workshop the key questions or background framing before the emails are sent.

Thanks,

s22

s22

**Director – Unapproved Medicines Access Section
International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

s22 [@health.gov.au](mailto:s22@health.gov.au)

Location: 27 Scherger Drive, Level 1
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The Department of Health, Disability and Ageing acknowledges 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.

OFFICIAL

From: s22
To: s22
Cc: s22; LANGHAM, Robyn; s22
Subject: RE: FOLLOW-UP - RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]
Date: Monday, 23 March 2026 12:57:05 PM
Attachments: [image001.png](#)
[image002.png](#)

Dear s22

Following a further discussion with Professor Langham this morning, we were wondering whether you could share an indicative timeframe for the Boards' final advice?

This would assist with managing stakeholder expectations, although we appreciate the due process involved.

Kind regards

s22

Senior Pharmacist – Unapproved Medicines Access Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

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From: s22 @ahpra.gov.au
Sent: Thursday, 12 March 2026 1:08 PM
To: s22 @Health.gov.au
Cc: s22 @ahpra.gov.au; s22 @ahpra.gov.au; s22 @ahpra.gov.au; s22 @health.gov.au;
 LANGHAM, Robyn <Robyn.LANGHAM@Health.gov.au>; s22 @ahpra.gov.au; s22 @ahpra.gov.au;
 s22 @health.gov.au
Subject: RE: FOLLOW-UP - RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

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.

Dear s22,

Thank you for checking in.

We are currently working with Boards to finalise their advice and will come back to you on the expected timeframes, to assist in planning the next stages of work.

Kind regards s22

From: s22 <[redacted]@Health.gov.au>

Sent: Thursday, 12 March 2026 12:54 PM

To: s22 <[redacted]@ahpra.gov.au>

Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@ahpra.gov.au>;

s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>;

s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>;

s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>;

s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>;

Subject: FOLLOW-UP - RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

OFFICIAL

Dear s22

We understand that the four Board meetings with Professor Langham have now concluded. We are writing to check whether the Boards have finalised their advice on our recommendation regarding the qualifications of the psychotherapy dyad.

Could you please provide an update on the expected timeframe for receiving the Boards' responses, to assist us in planning the next stages of work?

We had originally anticipated completing this work by the end of March.

Thank you for your assistance.

Kind regards

s22

**Senior Pharmacist – Unapproved Medicines Access Section
International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

This email comes to you from Ngunnawal
Location: Gulgana Building, Fairbairn

PO Box 9848, Canberra ACT 2601, Australia
www.tga.gov.au

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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.

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OFFICIAL

From: s22 <[REDACTED]@health.gov.au>
Sent: Thursday, 12 February 2026 11:54 AM
To: s22 <[REDACTED]@ahpra.gov.au>
Cc: s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings
 [SEC=OFFICIAL]

OFFICIAL

Dear s22

Thank you again for the opportunity for Professor Langham to present at the National Board meetings. Please find attached the four Board papers for circulation. Each Board paper is also accompanied by two Attachments.

Board paper	Attachments	Timing of Professor Langham's attendance
Occupational Therapy Board of Australia	● Attachment A: Consultation paper ● Attachment B: Summary of consultation outcomes	9.00am, Tuesday 24 th Feb
Medical Board of Australia	● Attachment A: Consultation paper ● Attachment B: Summary of consultation outcomes	10.30am, Wednesday 25 th Feb Confirmed with s22
Nursing and Midwifery Board of Australia	● Attachment A: Consultation paper ● Attachment B: Summary of	12:00pm, Thursday 26 th Feb

	consultation outcomes	
Psychology Board of Australia	• Attachment A: Consultation paper • Attachment B: Summary of consultation outcomes	9.00am, Friday 27 th Feb

Please feel free to contact if you have any questions.

Kind regards,

s22

OFFICIAL

From: s22 @ahpra.gov.au>

Sent: Wednesday, 11 February 2026 12:20 PM

To: s22 @health.gov.au>

Cc: s22 @ahpra.gov.au>; s22 @ahpra.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Thank you s22

We will liaise with these Boards on the times provided and will come back to you to confirm details.

We've also now heard from the Medical Board, with the proposal of 1.30pm on Wednesday 25 Feb, if that could work for Professor Langham?

Kind regards s22

From: s22 @health.gov.au>

Sent: Wednesday, 11 February 2026 11:22 AM

To: s22 @ahpra.gov.au>

Cc: s22 @ahpra.gov.au>; s22 @ahpra.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Dear s22,

Thank you for the chat yesterday and granting the additional time for the agenda papers. It is greatly appreciated.

We have identified the following available times in Robyn's calendar for her attendance at the National Board meetings:

- **9:00am, Tuesday 24th** – Occupational Board meeting

- **12:00pm, Thursday 26th** – Nursing and Midwifery Board meeting
- **9:00am, Friday 27th** – Psychology Board meeting

Grateful if you could confirm whether these times are suitable. We will await further details regarding the Medical Board meeting on Wednesday 25th, as well as the official calendar invites with login information.

Many thanks,

s22

From: s22 <[redacted]@ahpra.gov.au>
Sent: Wednesday, 11 February 2026 10:22 AM
To: s22 <[redacted]@health.gov.au>
Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>
Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Hi s22,

Further to below, we can share these Board meeting start–finish times:

- Occupational Therapy Board of Australia – **Tuesday 24 February, 8.30am-3.30pm (AEDT)**
- Nursing and Midwifery Board of Australia – **Thursday 26 February, 10am-3pm (AEDT)**

Please can confirm that Professor Langham has availability for these days/meetings? – and we will aim to come back with specific time slots.

With thanks s22

From: s22 <[redacted]>
Sent: Tuesday, 10 February 2026 6:07 PM
To: s22 <[redacted]@health.gov.au>
Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>
Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Hi s22

Thank you for this update, and our phone call just now.

We appreciate you letting us know about the delay and understand the pressures this week with Senate Estimates.

We look forward to receiving the papers, if possible by tomorrow (Wednesday), or by Thursday morning.

As discussed, we are working with our Boards to schedule potential time slots for Professor

Langham to speak to the paper.

This offer is very much appreciated, and we will send through proposed times from each Board as soon as they confirm.

For the Psychology Board **on Friday 27 February**, could you please let us know if any of the following could work for 15 minutes:

- between 09:00 – 09:45 AEDT
- between 10:30 – 11:45 AEDT
- 12:45 – 13:00 AEDT

We will come back you as soon as possible on the other Board meetings:

- Occupational Therapy Board of Australia – Tuesday 24 February
- Medical Board of Australia – Wednesday 25 February
- Nursing and Midwifery Board of Australia – Thursday 26 February, 10am-3pm

Please let me know if you have any queries.

Kind regards,

s22

From: s22 <[redacted]@health.gov.au>

Sent: Tuesday, 10 February 2026 4:45 PM

To: s22 <[redacted]@ahpra.gov.au>

Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]

<[redacted]@ahpra.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Hi s22

I am just flagging that we may not be able to meet the deadline for the Board papers. Unfortunately, it is a busy week with Senate Estimates for our Executives which has delayed clearance times.

Please be reassured that we are working to get the papers to you as soon as possible.

Please give me a call if you have any concerns.

Kind regards,

s22

s22

Chief Medical Adviser Unit

Health Products Regulation Group

Australian Government, Department of Health, Disability and Ageing

s22 <[redacted]@health.gov.au>

Location: 27 Scherger Drive, Level 2

PO Box 100, Woden ACT 2606, Australia

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From: s22 <[REDACTED]@ahpra.gov.au>
Sent: Friday, 6 February 2026 11:44 AM
To: s22 <[REDACTED]@health.gov.au>
Cc: s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Thank you s22

We appreciate that we can anticipate the paper next week.

Meanwhile, we are liaising with the four National Boards on time slots for Professor Langham and we will aim to come back to you as soon as possible with information.

Kind regards

s22

From: s22 <[REDACTED]@health.gov.au>
Sent: Thursday, 5 February 2026 10:40 AM
To: s22 <[REDACTED]@ahpra.gov.au>
Cc: s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Hi s22,

Thank you very much for supporting the meeting last Friday and also organising the logistics for the National Board meetings.

We are working swiftly to prepare the agenda item paper for the four National Board meetings and will aim to provide these to you by COB Tuesday 10 February.

We would very much appreciate if you could share the time slots for our agenda item as soon as they are available. Professor Langham has limited availability that week, but we will do our best to accommodate a 15-minute slot on the four days.

Kind regards,

s22

s22

Chief Medical Adviser Unit

Health Products Regulation Group

Australian Government, Department of Health, Disability and Ageing

s22

[@health.gov.au](mailto:s22@health.gov.au)

Location: 27 Scherger Drive, Level 2

PO Box 100, Woden ACT 2606, Australia

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From: s22 [@ahpra.gov.au](mailto:s22@ahpra.gov.au)>

Sent: Wednesday, 4 February 2026 4:44 PM

To: s22 [@health.gov.au](mailto:s22@health.gov.au)>

Cc: s22 [@ahpra.gov.au](mailto:s22@ahpra.gov.au)>; s22

[@ahpra.gov.au](mailto:s22@ahpra.gov.au)>; s22 [@Health.gov.au](mailto:s22@Health.gov.au)>; s22

[@health.gov.au](mailto:s22@health.gov.au)>; s22 [@Health.gov.au](mailto:s22@Health.gov.au)>; s22

[@Health.gov.au](mailto:s22@Health.gov.au)>

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings

Hi s22

Thank you again for last Friday's meeting. It was agreed that the TGA would prepare a paper for the advice of Boards on the proposed Final Recommendations together with background and specific discussion points, for consideration at their upcoming February meetings.

As discussed, it will be very helpful for Boards to have clarity on the roles and responsibilities of the treating team, to consider the recommendations and provide their advice.

To meet Board paper deadlines, we will need the TGA's paper, and any supporting information, **by COB Tuesday 10 February**.

We also appreciate the offer for Professor Langham to join the Board meetings to speak to the paper. While we have yet to confirm which Boards would like Professor Langham to join their meetings, we're providing the meeting dates of the various Boards below for your information, and we will confirm the meeting times as soon as possible.

We could anticipate Professor Langham would be needed for approximately 15 - 30 minutes on each day, and attendance can be virtual.

Occupational Therapy Board of Australia	Tuesday 24 Feb
Medical Board of Australia	Wednesday 25 Feb

Nursing and Midwifery Board of Australia	Thursday 26 Feb
Psychology Board of Australia	Friday 27 Feb

Please let me know if you have any queries or concerns with timeframes,

Kind regards, s22

From: s22

Sent: Friday, 30 January 2026 12:43 PM

To: s22 <@health.gov.au>; s22 <@ahpra.gov.au>; s22 <@ahpra.gov.au>

Cc: s22 <@ahpra.gov.au>; s22 <@Health.gov.au>; s22 <@health.gov.au>; s22 <@Health.gov.au>; s22 <@Health.gov.au>

Subject: RE: Psychedelics Consultation - updated list of National Board and Ahpra attendees for today's meeting

HI s22

Thanks so much for organising the meeting today for the discussion and the next steps. Meanwhile I am sending through for your records the list of attendees for today from our end - as a couple of changes.

With thanks s22

National Boards and Ahpra attendees

Medical Board of Australia

s22 - Policy Manager

Psychology Board of Australia

s22 - Chair

Nursing and Midwifery Board of Australia

s22 - Senior Policy and Project Officer

OT Board of Australia

s22 - Executive Officer

Ahpra

s22 - National Director, Policy and Accreditation

s22 - Manager, Multiprofession Policy

From: s22

Sent: Friday, 30 January 2026 9:30 AM

To: s22 <@health.gov.au>; s22 <@ahpra.gov.au>

Cc: s22 <@ahpra.gov.au>; s22 <@Health.gov.au>; s22 <@health.gov.au>; s22 <@Health.gov.au>; s22 <@Health.gov.au>

Subject: Psychedelics Consultation - National Board and Ahpra attendees for today's meeting

Hi s22

Thanks again for organising the meeting for today.
We've forwarded the meeting on and below is the list of Board representatives and Ahpra attendees.
Please let me know any queries, with thanks s22

National Boards and Ahpra attendees

Medical Board of Australia

s22 - Policy Manager

Psychology Board of Australia

s22 - Chair (for part of the meeting)

s22 - Executive Officer

Nursing and Midwifery Board of Australia

s22 - Policy Manager

OT Board of Australia

s22 - Executive Officer

Australian Health Practitioner Regulation Agency

s22 - National Director, Policy and Accreditation

s22 - Manager, Multiprofession Policy

From: s22 <s22@health.gov.au>

Sent: Tuesday, 27 January 2026 10:23 AM

To: s22 <s22@ahpra.gov.au>; s22

<s22@ahpra.gov.au>

Cc: s22 <s22@ahpra.gov.au>; s22

<s22@Health.gov.au>; s22 <s22@health.gov.au>; s22

<s22@Health.gov.au>; s22 <s22@Health.gov.au>

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion
[SEC=OFFICIAL]

Hi s22,

I've sent the MS Teams invite for Friday at 11 am. You're welcome to forward it to the Board representatives, or if it's easier, please feel free to send through the list and I can add them directly.

Kind regards,

s22

From: s22 <s22@ahpra.gov.au>

Sent: Friday, 23 January 2026 9:05 AM

To: s22 <s22@health.gov.au>; s22

<s22@ahpra.gov.au>

Cc: s22 <s22@ahpra.gov.au>; s22

<s22@Health.gov.au>; s22 <s22@health.gov.au>; s22

<s22@Health.gov.au>

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion
[SEC=OFFICIAL]

Thank you s22

Friday 11am-12 pm, 30 January sounds good – and we will aim to be in contact on Tues/Wed next week to confirm the attendees.

Kind regards s22

From: s22 <[redacted]@health.gov.au>

Sent: Thursday, 22 January 2026 1:46 PM

To: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@ahpra.gov.au>

Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion
[SEC=OFFICIAL]

Hi s22

Yes, thank you.

Shall we lock in 11am – 12pm on Friday 30 January?

I'll send out the invite once we have the attendees from your end confirmed.

Many thanks,

s22

From: s22 <[redacted]@ahpra.gov.au>

Sent: Thursday, 22 January 2026 12:21 PM

To: s22 <[redacted]@health.gov.au>; s22 <[redacted]@ahpra.gov.au>

Cc: s22 <[redacted]@ahpra.gov.au>; s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion
[SEC=OFFICIAL]

Hi s22

Thank you for offering the alternate date of Friday 30 January, from 10.30am

We are in the process of confirming availability with the relevant National Boards, and with a number of people on leave until early next week, Friday is looking like the best option at this stage.

Would this day/time still work for you and others at the TGA?

Kind regards, s22

From: s22 <[REDACTED]@health.gov.au>
Sent: Friday, 16 January 2026 4:54 PM
To: s22 <[REDACTED]@ahpra.gov.au>
Cc: s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

Hi s22

There is certainly some flexibility. We could also look at moving the meeting to 30 January. Robyn is available any time after 10.30am on that day.

Enjoy your leave next week and I hope you have something exciting planned. Thank you again for coordinating the relevant people.

Thanks,

s22

From: s22 <[REDACTED]@ahpra.gov.au>
Sent: Friday, 16 January 2026 1:13 PM
To: s22 <[REDACTED]@health.gov.au>
Cc: s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@ahpra.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>
Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

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Hi s22

Apologies for the slow response! Yes the week of 28 January will definitely be easier to set up and we are just canvassing availability for the proposed time. I have conflicting meetings at that time so it would be great to know if there are any other windows that work at the TGA end – but if not I should be able to join for part.

Thanks so much for the further background on discussion points for the meeting, and this will help us canvass some views in advance.

I will be on leave next week but back on 27 Jan, and s22 will touch base next week to confirm availability and attendees at our end.

Many thanks

s22

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Monday, 12 January 2026 4:15 PM
To: s22 [redacted] <[redacted]@ahpra.gov.au>
Cc: s22 [redacted] <[redacted]@ahpra.gov.au>; s22 [redacted] <[redacted]@ahpra.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>
Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

Hi s22 [redacted],

No worries around the timely. That is completely understandable.

Do you think **Wednesday 28 January at 11am – 12.30pm** is more achievable on your end?

In terms of discussion points, we would like to seek input from the Boards on the involvement of certain healthcare practitioners in the PAT dyad. As you know, the current policy limits participation in the PAT dyad to psychiatrists and clinical psychologists. Feedback received during consultation suggested that the range of eligible practitioners could be expanded to include nurses, occupational therapists, and other psychologists (not limited to clinical psychologists).

We are keen to explore this feedback further with the individual Boards. We would also like to discuss the use of telehealth models in MDMA and psilocybin-assisted therapy, particularly during the dosing phase.

Many thanks,
s22 [redacted]

From: s22 [redacted] <[redacted]@ahpra.gov.au>
Sent: Monday, 12 January 2026 12:59 PM
To: s22 [redacted] <[redacted]@health.gov.au>
Cc: s22 [redacted] <[redacted]@ahpra.gov.au>; s22 [redacted] <[redacted]@ahpra.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>
Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

Hi s22 [redacted]

Happy new year! I had a lovely break thanks, and hope you did too.

Thanks for reaching out about a further catch up, and we are very keen to be involved in further discussions about the psychedelics framework.

We won't be able to make the proposed time work unfortunately as I'll be in transit and we'll need some more notice to get together reps from these Boards who can provide advice about qualifications relevant to participation in the treatment dyad. Are there some other times in the next week or two that would work?

Also, if you're able to share any further detail about what is proposed in terms of qualification requirements that would be helpful for us to share with Board teams so they can consider and discuss

in advance of a meeting.

Happy to discuss if helpful.

Many thanks

s22

s22

Acting National Director, Policy and Accreditation

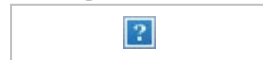
Email s22@ahpra.gov.au

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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From: s22@health.gov.au

Sent: Monday, 12 January 2026 10:39 AM

To: s22@ahpra.gov.au

Cc: s22@ahpra.gov.au; s22@ahpra.gov.au; s22@ahpra.gov.au; s22@ahpra.gov.au

s22@Health.gov.au; s22@Health.gov.au; s22@Health.gov.au; s22@Health.gov.au

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

Hi s22

Happy New Year. I hope you had a lovely and restful break.

As you are aware, the TGA recently undertook a two-step consultation process on the Authorised Prescriber policy for MDMA and psilocybin, which included a targeted consultation and a targeted roundtable discussion. Feedback from stakeholders is currently being reviewed.

One of the key issues raised through the consultation relates to qualification requirements for practitioners involved in the PAT dyad. In light of this, we are seeking to convene a meeting with Ahpra and relevant National Boards, specifically the Nursing and Midwifery Board, the Occupational Therapy Board and the Psychology Board, to discuss qualification and scope of practice considerations for health practitioners participating in the PAT dyad.

I would be grateful if you could please provide details of appropriate key staff from each of these Boards to attend the meeting.

At this stage, we are hoping to schedule the meeting for **Wednesday 14 January from 2pm –**

3.30pm.

Please feel free to call to discuss anytime.

Kind regards,

s22

s22

Chief Medical Adviser Unit

Health Products Regulation Group

Australian Government, Department of Health, Disability and Ageing

s22 @health.gov.au

Location: 27 Scherger Drive, Level 2

PO Box 100, Woden ACT 2606, Australia

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From: s22 @ahpra.gov.au>

Sent: Monday, 22 December 2025 5:53 PM

To: Authorised Prescribers <Authorised.Prescribers@health.gov.au>; s22 @health.gov.au>

Cc: s22 @ahpra.gov.au>; s22 @ahpra.gov.au>

Subject: RE: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion [SEC=OFFICIAL]

OFFICIAL

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.

Dear s22 and TGA Pharmacist Team,

Thank you for the opportunity to participate in the discussion on Wed 19 November on this important topic, and for the opportunity to review the draft meeting minutes.

Please see below in the table for our feedback to-date from Ahpra and National Boards, and note we may also have some further feedback in the new year from our Board reps who attended.

We would be interested to meet again with you and the team to discuss in January. We have also been exploring the potential for a standing Ahpra/TGA meeting about medicines related issues so have copied in s22 in case this topic would be a topic to include in a broader meeting.

Until then, our best wishes for the holiday season. I am heading on leave today until 6 Jan, but touch base with s22 if any questions.

Many thanks

s22

s22

Acting National Director, Policy and Accreditation

Email | s22@ahpra.gov.au

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.ahpra.gov.au

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Page/section	Feedback
Page 2 Attendees – Ahpra and National Boards	Please list s22, Executive Officer, Medical Board of Australia
Page 4: Regulatory roles	Please change text to 'Additionally, the Medical Board of Australia does not regulate a practitioner's scope of practice but in responding to a notification about a medical practitioner would need standards to refer to.'
Page 5 Regulatory oversight and accountability	There is an error in the first sentence - occupational therapists are an Ahpra registered profession.
Page 6 Cultural competency and inclusion	The first sentence of this section needs clarifying and terminology confirmed regarding registration with peak bodies. It may be helpful to clarify/provide an example of a peak body, being different entities from Ahpra, and noting that Ahpra does register Aboriginal and Torres Strait Islander Health Practitioners. The text refers to Aboriginal and Torres Strait Islander Healing Practitioners – query is this terminology accurate?
Page 10 Cultural safety and equity	The first dot point in this section refers to Aboriginal and Torres Strait Islander practitioners – it is unclear whether this is Aboriginal and Torres Strait Islander Health Practitioners, who are

	registered with Ahpra, or another type of profession/practitioner?– eg the Healing Practitioners– page 6.
--	---

OFFICIAL

From: Authorised Prescribers <Authorised.Prescribers@health.gov.au>

Sent: Friday, 12 December 2025 10:39 AM

Subject: Draft meeting minutes for review – Psychedelics Consultation Outcomes Discussion
[SEC=OFFICIAL]

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

OFFICIAL

Dear attendees,

Thank you for your valuable participation in the discussion on outcomes of the TGA's psychedelics consultation held on Wednesday, 19 November. We greatly appreciate the expertise and insights shared during the session.

A draft version of the meeting minutes is attached for review. We kindly ask that you provide any comments by **Monday, 22 December 2025**. Once all input has been incorporated, a final copy of the minutes will be shared with you.

We are actively addressing the issues raised since MDMA and psilocybine were rescheduled, allowing access through the Authorised Prescriber scheme. Finalising the consultation recommendations remains a priority, and we are working to complete this process as efficiently as possible.

We appreciate your patience as we gather some final essential feedback from key stakeholders. The timeline for publishing the recommendations is dependent on this process, therefore we are unable to confirm a date at this stage.

Once the recommendations are approved, the TGA website and guidance will be updated, and education emails will be distributed to keep all stakeholders informed.

Thank you for your continued engagement and support. Please do not hesitate to reach out if you have any questions.

Kind regards

Pharmacist Team

**Unapproved Medicines Access Section
International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

This email comes to you from Ngunnawal
Location: Gulgana Building, Fairbairn
PO Box 9848, Canberra ACT 2601, Australia
www.tga.gov.au

The Department of Health, Disability and Ageing 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.

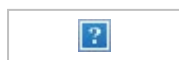
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Ahpra acknowledges the Traditional Owners of Country throughout Australia and the continuing connection to lands, waters and communities. We pay our respect to Aboriginal and Torres Strait Islander cultures and Elders past and present.



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Review of the Authorised Prescriber scheme for psychedelics

Targeted consultation outcomes discussion

Meeting Minutes

Wednesday, 19 November 2025

10:00AM – 2:00PM AEDT

Microsoft Teams

Attendance

Department of Health, Disability and Aged Care	
s22	Chair & Medical Officer Delegate, Therapeutic Goods Administration
Prof Robyn Langham	Chief Medical Advisor, Therapeutic Goods Administration
s22	Medical Officer Delegate, Therapeutic Goods Administration
	Director, Unapproved Medicines Access Section, Therapeutic Goods Administration
	Senior Pharmacist, Therapeutic Goods Administration
	Pharmacist, Therapeutic Goods Administration
	Pharmacist, Therapeutic Goods Administration
	Chief Medical Advisor Unit, Therapeutic Goods Administration
	Chief Medical Advisor Unit, Therapeutic Goods Administration
	Chief Psychiatrist
	Director, Scheduling and Chemicals Policy Section
	Delegate, Chief Nursing and Midwifery Office
Department of Veterans Affairs	
s22	Senior Medical Officer
	Chief Health Officer
	Clinical Psychologist/ Principal Research Fellow, GMRF Veteran Mental Health Research Unit
States and Territories	
s22	Deputy Chief Pharmacist, Pharmaceutical Services Section, ACT Health and Community Services Directorate
	Pharmacist Manager, Medicines and Poisons Regulation Branch, WA Department of Health
	Medicines and Poisons Regulation Branch, WA Department of Health
	Director, Medication Services Queensland, Queensland Health
	Medication Services Queensland, Queensland Health
	Principal Pharmaceutical Officer, Pharmaceutical Services, NSW Ministry of Health
	Chief Pharmacist, NT Health
	Director Clinical Regulation, Public Health Division, SA Health
	Senior Pharmacist, Pharmaceutical Services Branch, Tasmanian Department of Health
	Manager, Permits and Licensing Team 2, Victorian Department of Health
	Director, Regulatory Services, Victorian Department of Health
	Chief Mental Health Alcohol and Other Drugs Officer, Chief Psychiatrist, Queensland Health
Peak bodies & Organisations	

s22	Psychiatrist, The Royal Australian & New Zealand College of Psychiatrists
	Appointed Director, Trainee, The Royal Australian & New Zealand College of Psychiatrists
	Director, Indigenous Psychedelic-Assisted Therapies (IPAT)
	Indigenous Psychedelic-Assisted Therapies (IPAT)
	Chair, Australian Multidisciplinary Association for Psychedelic Practitioners
	Partnership Liaison Advisor, Psychotherapy and Counselling Federation of Australia (PACFA)
	CEO, Psychotherapy and Counselling Federation of Australia (PACFA)
	Australian Counselling Association
	CEO, Australian Counselling Association
	Co-chair, Psychedelic-assisted Psychotherapy Interest Group, Australia Association of Psychologists Inc (AAPi)
	Co-chair, Australian Association of Psychologists Inc (AAPi) Psychedelic Assisted Therapy interest group and committee member of the Australian Psychological Society (APS) Psychedelic Assisted Therapy interest group
	General Manager, Australian Association of Social Workers (AASW)
Ahpra & National Boards	
s22	Chair, Medical Board of Australia
	Chair, Pharmacy Board of Australia
	Chair, Psychology Board of Australia
	Executive Officer, Psychology Board of Australia
	National Director, Policy and Accreditation, Australian Health Practitioner Regulation Agency
	Manager, Clinical Input (Pharmacy), Notifications, Australian Health Practitioner Regulation Agency
	Manager, Multiprofession Policy, Australian Health Practitioner Regulation Agency
Ethics Committees	
s22	Chair, Townsville Hospital and Health Service HREC
	Chair, ACT Human Research Ethics Committee
	Senior Manager, Research Ethics and Governance Office, Canberra Health Services
	Research Ethics and Governance Office, Canberra Health Services
	HREC Secretariat for Ramsay Health Care HREC A and Ramsay Health Care WA and SA HREC.
Prescribers & clinics	
s22	Director, s22
	Project Manager s22
	Project Manager, s22
	Clinical Governance, s22
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist, s22
	Psychiatrist
	Psychiatrist

Apologies	
	Australian College of Mental Health Nurses
	National Institute of Integrative Medicine HREC
	South Metropolitan Health Service HREC
	Australian Psychology Society
	St Vincents Hospital Melbourne HREC
	Monash Health HREC
	Nursing and Midwifery Board of Australia

This document contains information intended solely for meeting participants. Do not distribute, copy, or disclose without prior written authorisation.

Meeting outcomes

1. Preliminary

1.1 Welcome and introductions

The Therapeutic Goods Administration (TGA) Chief Medical Advisor opened the meeting by welcoming the attendees, delivering an Acknowledgment of Country and providing housekeeping instructions. It was clarified that the purpose of the discussion was not to review the efficacy or safety of psychedelic treatments but to discuss recommendations for changes to the Authorised Prescriber (AP) application process for psychiatrists applying to access psychedelic medicines.

2. Discussion of recommendations

2.1 Outcome summary presentation

The TGA's Unapproved Medicines Access Section (UMAS) provided a presentation outlining the role of the section in reviewing Authorised Prescriber applications, background to the re-scheduling decision, 'unapproved' medicines access, the Authorised Prescriber scheme and a summary of responses from the targeted consultation.

3. Discussion of Recommendation 1: Psychiatrist experience

3.1 Introduction of recommendation 1

The Chair introduced recommendation 1 below:

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with The Royal Australian and New Zealand College of Psychiatrist's (RANZCP's) ['Psychedelic training framework for psychiatrists'](#), including supervision and ongoing peer support.

The Chair then invited attendees to participate in an open discussion of Recommendation 1.

3.2 Discussion

Guidance from professional bodies

Stakeholders supported deferring clinical guidance and credentialing to professional bodies. It was noted that decisions should be guided by these bodies to maintain standards and avoid risks

associated with low-quality clinical services under vertical integration models, which could increase public health burden.

Competency and supervised practice

Participants advocated for supervised practice pathways based on competency criteria, including minimum case numbers and observed sessions. There was agreement on recognising structured, real-world experience alongside clinical trial experience when assessing competency. It was suggested prescriber competency could be evaluated on a case-by-case basis where evidence of experience in a structured program exists. Input from relevant professional colleges and cross-professional collaboration were considered essential for defining standards and establishing benchmarks.

Regulatory roles

It was clarified that Human Research Ethics Committees (HRECs) do not serve as credentialing bodies; their role is limited to assessing applications against the [National Health & Medical Research Council \(NHMRC\) National Statement](#).

Additionally, the Medical Board of Australia's role is reactive, focusing on compliance rather than defining scope of practice.

The TGA operates under the *Therapeutic Goods Act 1989* and is limited to medicine regulation.

Certification and training framework

Stakeholders agreed on the importance of linking the recommendation to the Royal Australian and New Zealand College of Psychiatrists (RANZCP) Psychedelics Training Framework, which includes prescribing and psychotherapy components, supervision, peer support, case logging, and clinical governance. A certification process was proposed, drawing on models such as electroconvulsive therapy (ECT) and Gastroenterological Society of Australia (GESA) endoscopy certification. Development of a consensus framework by the College was suggested, although it was noted that the College is not resourced to monitor or endorse specific training courses.

Supervision criteria

Recommendations for supervision criteria included prescriptive guidance on minimum case numbers, case discussions, and observed sessions. Some applications already include peer support arrangements documented in written plans. A decentralised approach was suggested, leveraging existing Authorised Prescribers and sites. Additionally, a "train-the-trainer" model was proposed, requiring applicants to participate in at least one MDMA treatment with an Authorised Prescriber who would sign off on their involvement. Clarification was sought on whether "supervision" refers to workplace or professional oversight and whether peer support qualifies as professional supervision.

Practical challenges

Concerns were raised that current policy makes it difficult for psychiatrists to begin prescribing psychedelics, as requirements for hands-on training and supervised treatment are impractical for many clinicians starting out. While standards are essential, stakeholders stressed the need to balance these with practical pathways to achieve Authorised Prescriber status.

Actions

- As a clinical body was seen to be an appropriate organisation to provide clarity on supervision criteria or a consensus opinion, the TGA will consult with RANZCP to further clarify the recommendation prior to finalisation.

4. Discussion of Recommendation 2: Therapy Dyad

4.1 Introduction of recommendation 2

The **Chair** introduced recommendation 2 below:

The PAT dyad must include at least one therapist who is registered with a National Board with regulatory oversight of psychotherapy, specifically, the Psychology Board, Medical Board, or Nursing and Midwifery Board. Oversight of the qualifications and experience of any additional therapists participating in sessions is guided by the determination of the Authorised Prescriber.

The Chair clarified the requirement for therapy dyads to include at least one therapist registered with a National Board is to ensure regulatory oversight of psychotherapy. This acknowledges a multidisciplinary approach while maintaining oversight. The policy has shifted slightly, leaving assessment of additional therapists' qualifications to the AP. Regulatory oversight must come from a regulatory body with oversight of psychotherapy. TGA discussions with HRECs confirmed that practitioner qualification oversight is outside a HREC's remit.

The Chair then invited attendees to participate in an open discussion of Recommendation 2.

Note: reference to "Ahpra-registered" below refers to practitioners registered with a National Board and administered by the Australian Health Practitioner Regulation Agency (Ahpra).

4.2 Discussion

Multidisciplinary input

Stakeholders emphasised the importance of multidisciplinary perspectives, including cultural and faith-based considerations, and noted that qualifications alone do not guarantee psychotherapeutic competency. Collaboration between Australian Multidisciplinary Association for Psychedelic Practitioners (AMAPP) and the Psychotherapy and Counselling Federation of Australia (PACFA) was suggested to co-create psychotherapy training guidelines. Concerns were raised about mandating the use of a clinical psychologist in the therapy dyad, as this is not internationally standard and may be culturally unsafe. Models were proposed where the Authorised Prescriber provides oversight as a regulated practitioner, with other team members approved by ethics committees. The role of social workers and psychotherapists was highlighted. Clearer wording from TGA on this recommendation was requested to avoid confusion.

Workforce challenges

The role of counsellors and psychotherapists in addressing workforce shortages was highlighted. It was argued that advanced credentials among non-Ahpra registered practitioners pose less risk than some Ahpra-registered professions. Workforce constraints were identified as a major barrier to treatment access, with calls to broaden eligibility to include psychotherapists, social workers, and occupational therapists.

Regulatory oversight and accountability

Some stakeholders cautioned against excluding non-Ahpra professions such as social workers and occupational therapists with already established roles in mental health facilities. Suggestions included linking Authorised Prescribers and lead therapists to regulatory bodies, while secondary therapists could be approved by credentialing committees.

PACFA's role as a registration and quality assurance body for psychotherapists was outlined. It was clarified that registration with PACFA required criteria such as tertiary qualifications in counselling, indemnity insurance and completion of Continuing Professional Development (CPD).

It was explained that the Australian Association of Social Workers (AASW) has a robust complaint mechanism allowing families or participants to lodge complaints if the social worker is a member. The AASW investigates complaints, shares information with the relevant Healthcare Complaints Commissioner when relevant and removes membership if the social worker fails to comply with the code of ethics and standards.

Removing distinctions between clinical and other psychologists was raised, as regulatory oversight is the same. Accountability measures were discussed, including peak body oversight, Authorised Prescriber responsibility, and site clinical governance. Mechanisms for complaints of non-Ahpra

registered professionals through Healthcare Complaints Commissions and professional associations were highlighted.

Other stakeholders disagreed with the recommendation, supporting therapy dyads with two Ahpra-registered practitioners for accountability, while allowing non-registered professionals in other supporting roles. The importance of being able to control non-compliant individuals through the national health practitioner regulation framework was highlighted. Challenges with lack of legal recourses and service design issues across the regulatory landscape for scheduled medicines was raised. Emphasis was placed on logistical safety checks, such as nurse or pharmacist checks. It was also emphasised that Ahpra provides clear pathways for jurisdictions and the Commonwealth to act decisively if issues arise. However, recognising the essential role of non-Ahpra registered practitioners in care delivery is still necessary. There is a need for minimum standards and strong oversight to ensure safe, controlled care, given the experimental nature of these medicines. Safeguards should remain until sufficient evidence supports safety and efficacy, at which point restrictions could be eased.

Cultural competency and inclusion

Concerns were raised that requiring registration with peak bodies could exclude Aboriginal and Torres Strait Islander healing practitioners, limiting culturally safe access. Stakeholders stressed the need for cultural competency within therapy dyads and inclusion of diverse practitioners to reduce risks and improve client safety. It was noted that registered practitioners may not always feel culturally safe for clients. It was clarified these practitioners would work within a team, under an Authorised Prescriber for oversight and accountability.

Credentialing and supervision

Recommendations included developing a credentialing pathway with minimum supervision and training requirements, noting this responsibility does not sit with TGA or HRECs. Stakeholders emphasised that training should apply to the entire therapy dyad, not just the Authorised Prescriber, and highlighted the need for ongoing credentialing and cultural safety considerations. Support was provided for developing competency standards and an endorsement framework for training.

Actions:

- TGA to refine the recommendation based on additional feedback in the meeting to potentially include further practitioners in the recommendation.

5. Discussion of Recommendation 3: Level of AP oversight

5.1 Introduction of recommendation 3

The Chair introduced recommendation 3 below:

The Authorised Prescriber psychiatrist should be physically present during at least patient screening, consent and medicine administration (dosing).

It is expected the Authorised Prescriber be physically present during the administration of the psychedelic (this does not need to be the full dosing day). This presence ensures the Authorised Prescriber is readily available to manage any immediate issues and severe adverse events that may occur.

The Chair described the post-consultation position that the Authorised Prescriber psychiatrist should be physically present for screening, dosing, and consent, but not for the entire dosing day. The rationale for this being that it allows flexibility while the Authorised Prescriber should still be available to manage issues. He emphasised the need to consider state and territory legislation and that TGA applications must include details about access to emergency procedures.

The Chair then invited attendees to participate in an open discussion of Recommendation 3.

5.2 Discussion

Presence of Authorised Prescriber

It was noted that a person authorised under medicines and poisons legislation must be present to administer medicines. Several participants preferred that the Authorised Prescriber remain on-site for the full dosing day to enable prescribing of rescue medications and management of adverse events. Others supported flexibility, suggesting that additional medical practitioners or nurses on-site could provide safety coverage or that prescribers could remain nearby and available rather than continuously present, while ensuring accountability for screening, consent, and medication administration.

Questions were raised about whether the original prescriber must oversee the first dose or if another Authorised Prescriber could manage subsequent dosing. It was discussed that Authorised Prescribers should be readily available and able to reach the site within 30 minutes, questioning the need for Authorised Prescriber presence during initial dosing (for example, in hospital orders can be given over the phone).

Concerns were raised about the term “physically present,” with calls for clearer guidance on what constitutes “on-site.” Participants emphasised the need for precise wording in recommendations and contingency planning for prescriber unavailability due to leave or illness.

Telehealth and consent

Stakeholders highlighted the benefits of telehealth for initial screening and consent, particularly to address cost and travel burdens and improve rural access. It was suggested consent could be revisited during preparation or on the first dosing day. A regulator advised that the prescriber must conduct the consent process face to face, which can occur via initial telehealth discussions and be revisited during dosing. Multiple opportunities for consent were recommended to ensure clarity and defensibility in this experimental setting.

Safety and risk management

Discussions addressed how adverse events would be managed if the prescriber was not immediately available. It was noted that nurses can often manage dosing based on patient risk, but prescribers retain legal responsibility. Stakeholders stressed the importance of understanding legal implications and accountability when delegating tasks. Jurisdictional requirements were highlighted, including rules governing authority to possess, administer, and dispose of medicines.

Jurisdictional requirements

Specific expectations were outlined for psychedelic-assisted psychotherapy in some jurisdictions, such as New South Wales, including requirements for prescriber presence throughout treatment sessions, proper supervision, environmental risk assessments, and capacity to manage behavioural or medical emergencies. Patients must be informed that the product is unapproved and has not been assessed for safety or efficacy, with clear explanation of potential risks. It was also noted that regulation should remain adaptive as evidence develops.

Actions

- TGA to clarify state and territory requirements to further refine the recommendation.

6. Discussion of Recommendation 4: Appropriate site location

6.1 Introduction of recommendation 4

The Chair introduced recommendation 4 below:

Prescribers must provide details of the treatment site to demonstrate it is a suitable and supervised environment. The prescriber must verify the site meets all state and territory

requirements. The HREC is responsible for reviewing the appropriateness of the site in line with the following criteria:

- Have equipment and trained staff for clinical care, monitoring, and emergency resuscitation.
- Provide secure storage for Schedule 8 medicines as per jurisdictional regulations.
- Be prepared to address treatment-emergent adverse events, with rescue medications on hand.
- Be located near an accredited healthcare facility with an emergency department.
- Hold or be seeking accreditation if required by the relevant state or territory.

The Chair outlined the post-consultation position above and the criteria. The Chair then invited attendees to participate in an open discussion of Recommendation 4.

6.2 Discussion

Accreditation and safety standards

Stakeholders emphasised that patients in altered states require strong protections and accredited facilities with medical oversight and governance. Recommendations included applying [National Safety and Quality Health Service Standards](#) to outpatient mental health settings and mandating accreditation to prevent poor practices. While safe facilities are essential, therapist quality and rapport were noted as critical to successful treatment.

Role of HRECs

It was clarified that evaluating site appropriateness is outside the role of HRECs whose responsibility is limited to reviewing information against the NHMRC National Statement.

Cost and accessibility

Concerns were raised that psychiatric hospital accreditation is extremely costly and could prohibit clinics, with costs passed to consumers. Some participants supported private clinics operating safely under appropriate policies and procedures. Others stressed balancing safety with accessibility, noting that care should remain locally available to avoid interstate travel and maintain continuity with patients' existing therapists. It was noted that there have been no adverse events to justify higher accreditation levels. One stakeholder highlighted the need for clear guidance on what "near an accredited healthcare facility with an ED" means e.g. defining acceptable travel times

Systemic inequities and cultural safety

Stakeholders highlighted systemic inequities that limit access to treatment, particularly for First Nations people and marginalised groups. Hospital or clinic settings were described as potentially traumatic due to lack of privacy, shared spaces, and inappropriate staff interactions. The importance of set and setting was also highlighted. Recommendations included culturally safe spaces such as Aboriginal and Torres Strait Islander medical centres, outdoor or nature-integrated facilities, and cultural competency training for therapists. Pathways to reach remote and isolated communities were also emphasised.

Jurisdictional challenges and evidence gaps

Concerns were raised that responsibility falls on jurisdictions when adverse events occur. Accreditation was seen as a way to mitigate risks and maintain service quality, drawing parallels with other regulated sectors. Jurisdictions face challenges determining appropriate settings without clear data on therapy risks. More clinical evidence on adverse outcomes is needed before expanding beyond hospitals or inpatient environments. Concern that responsibility falls on jurisdictions when something goes wrong.

Regulatory limitations

It was noted that TGA cannot regulate facilities. Registered medicines benefit from multiple layers of regulation, which do not apply in the context of unapproved medicines. Access issues may be easier to resolve once products are registered.

The TGA would welcome a sponsor submitting a dossier of safety and efficacy data to include treatments in the ARTG, but the AP scheme operates outside of this. The AP scheme requires prescribers to report adverse events to TGA; none have been reported to date. Lack of reported adverse events should not be taken as proof of safety for these medicines. Ongoing monitoring is essential.

Actions

- TGA to clarify state and territory requirements to further refine the recommendation.

7. Other matters

7.1 Registries

Registry participation

Stakeholders strongly supported the use of the [Australian National University \(ANU\) Registry](#) for data collection to strengthen the evidence base. It was suggested that Authorised Prescriber applications should be contingent on registry participation, although it was acknowledged that this is currently voluntary.

TGA position

The TGA highlighted that the Authorised Prescriber scheme relates to unapproved medicines and the need to distinguish these from registered products, which have established safety and regulatory frameworks. It was noted that clinical trials remain the standard for generating evidence on efficacy and safety required for product registration in the ARTG.

It was clarified that there is no legislative basis to mandate registry participation, and therefore the TGA does not have the legislative power to enforce this requirement. It was emphasised that the Authorised Prescriber scheme is an access pathway for unapproved products and noted the expectation that submission of a clinical evidence package through the registration process will eventually enable broader use once safety and efficacy are demonstrated.

Practical and systemic challenges

Questions were raised about practical barriers to mandating outcome data submission, including uncertainty around whether sponsors will seek product registration. Concerns were expressed that current regulatory systems may not deliver a registered product soon due to financial and systemic constraints. Stakeholders emphasised the importance of evidence collection through registries and cautioned against relying on the Authorised Prescriber scheme as a long-term supply pathway.

The Chair closed the meeting at **2:00pm AEDT**.

7.2 Key meeting chat contributions

1. Accountability and oversight

- Questions were raised regarding accountability of the AP, especially regarding use of non-registered practitioners in therapy dyads.
- Consideration of implications for indemnity, insurance, and professional misconduct regulation.
- Emphasis on clarity in TGA documentation and guidance to ensure indemnity and compliance.

2. Practitioner registration and competency

- Debate on whether non-Ahpra registered practitioners should be permitted in dyads; if allowed, this must be explicitly stated in guidelines.

- National Standards for Counsellors and Psychotherapists will introduce minimum competency requirements.
- Multiple comments stressed that competency and cultural suitability can be more critical than formal qualifications or Ahpra registration.
- Risks associated with assuming Ahpra registration equates to suitability for PAT were highlighted.
- Difficulty recruiting clinical psychologists with trauma expertise noted; other disciplines (e.g., mental health social workers, counsellors) may offer better therapeutic outcomes.
- Importance of matching therapeutic skills to patient needs rather than relying solely on qualifications.

3. Cultural safety and equity

- Concerns that peak body registration excludes Aboriginal and Torres Strait Islander practitioners, widening health outcome gaps.
- Advocacy for culturally safe treatment spaces and pathways for remote communities.
- Recommendation for lived experience and community consultation in next steps.

4. Regulatory framework and risk management

- Current complaints handling for self-regulated practitioners relies on Health Care Complaints Commissions; proposals for a unified scheme across Ahpra and non-Ahpra professions noted.
- Jurisdictional variations in site requirements were discussed:
 - New South Wales (NSW): Approvals issued by NSW Health to Authorised Prescriber psychiatrists will include a condition that the treatment is provided in an appropriately supervised healthcare setting where an environmental risk assessment has been conducted and incidents of behavioural and/or medical emergencies can be adequately managed.
 - Victoria (VIC): No additional restrictions on settings for PAT.
 - Australian Capital Territory (ACT): No restrictions on setting; however, medicines and poisons legislation requires secure storage and limits administration to authorised medical practitioners and nurse practitioners.
 - Queensland (QLD): No additional setting restrictions currently in place.
 - South Australia (SA): Controlled substances regulations mandate administration of MDMA/psilocybine by the Authorised Prescriber in an approved treatment centre or authorised community mental health facility under the Mental Health Act 2009.
 - Western Australia (WA): Authorisations require dosing at the clinic specified in the AP's application; some clinics may need licensing under private hospital legislation depending on services offered.
 - Tasmania (TAS): Similar to ACT requirements for storage and administration.
- Medicines and poisons legislation governs possession, supply, and administration of psychedelics; secure storage requirements apply.

5. Consent and telehealth

- Telehealth widely accepted for informed consent; flexibility needed for remote and rural access. Consent should be ongoing and relational.
- Practical suggestions included GP involvement for physical examinations and investigations when remote screening is used.

6. Registries

- Strong support for ANU Registry and similar initiatives to collect safety and efficacy data.
- Transparency of registry funding and governance raised as a concern.

7.3 *Next steps*

1. Finalise recommendations based on meeting feedback for TGA internal approval
2. Publish a summary of final recommendations and justification
3. Update TGA internal review processes and external guidance material
4. Provide communication on update external guidance material

From: s22
To:
Cc:
Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]
Date: Thursday, 12 February 2026 11:54:12 AM
Attachments: [image001.png](#)
[image002.png](#)
[Medical Board paper - TGA review of the Authorised Prescriber scheme for MDMA and psilocybine - 25 February 2026.DOCX](#)
[Nursing and Midwifery Board paper - TGA review of the Authorised Prescriber scheme for MDMA and psilocybine - 26 February 2026.DOCX](#)
[Occupational Therapy Board paper - TGA review of the Authorised Prescriber scheme for MDMA and psilocybine - 24 February 2026.DOCX](#)
[Psychology Board paper - TGA review of the Authorised Prescriber scheme for MDMA and psilocybine - 27 February 2026.DOCX](#)

Dear s22,

Thank you again for the opportunity for Professor Langham to present at the National Board meetings. Please find attached the four Board papers for circulation. Each Board paper is also accompanied by two Attachments.

Board paper	Attachments	Timing of Professor Langham's attendance
Occupational Therapy Board of Australia	• Attachment A: Consultation paper • Attachment B: Summary of consultation outcomes	9.00am, Tuesday 24 th Feb
Medical Board of Australia	• Attachment A: Consultation paper • Attachment B: Summary of consultation outcomes	10.30am, Wednesday 25 th Feb Confirmed with Dr Katsoris
Nursing and Midwifery Board of Australia	• Attachment A: Consultation paper • Attachment B: Summary of consultation outcomes	12:00pm, Thursday 26 th Feb
Psychology Board of Australia	• Attachment A: Consultation paper • Attachment B: Summary of consultation outcomes	9.00am, Friday 27 th Feb

Please feel free to contact if you have any questions.

Kind regards,

s22

From: s22

Sent: Wednesday, 11 February 2026 12:20 PM

To: s22

Cc: s22

Subject: RE: Psychedelics Consultation - TGA paper for National Board meetings [SEC=OFFICIAL]

Thank you s22,

We will liaise with these Boards on the times provided and will come back to you to confirm details. We've also now heard from the Medical Board, with the proposal of 1.30pm on Wednesday 25 Feb, if that could work for Professor Langham?

Kind regards s22



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

**Review of Authorised Prescriber Scheme to allow access
to 3,4-methylenedioxy-methamphetamine (MDMA) and
psilocybine for use with psychotherapy in mental health
conditions**

Targeted external consultation paper

Version 1.0, July 2025



Therapeutic Goods Administration

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Introduction

Purpose and scope

Since 1 July 2023, psychiatrists authorised under the Authorised Prescriber (AP) scheme have been permitted to prescribe MDMA for the treatment of post-traumatic stress disorder (PTSD) and psilocybine for treatment-resistant depression in patients undergoing psychotherapy.

To support the effective continuation of MDMA and psilocybine access, a review of the application processes is currently underway. The objective is to improve clarity for stakeholders and ensure alignment between the Therapeutic Goods Administration (TGA) and Human Research Ethics Committees (HRECs).

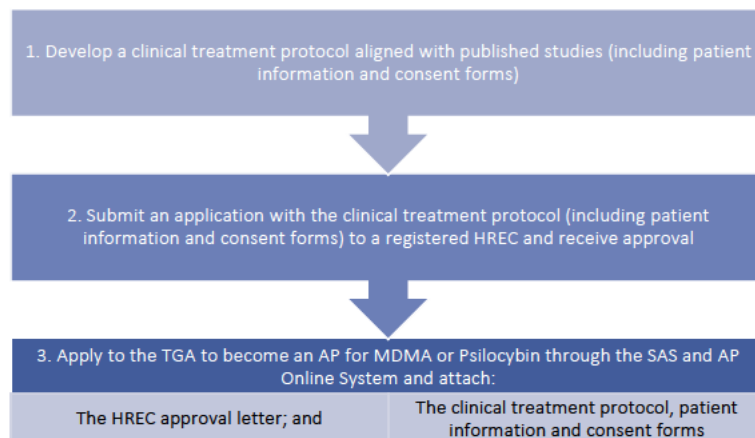
This review involves a targeted consultation with selected Authorised Prescribers, peak professional bodies, state and territory health departments, and HRECs.

Background

Psychedelic-assisted psychotherapy (PAT or PAP) involves combining pharmacological and psychological treatment which occurs in a controlled, supportive setting with trained therapists. Psychedelic therapy typically involves a structured dosing regimen that is accompanied by specialised forms of psychotherapy before, during and after each drug session.

Authorisation to prescribe MDMA and psilocybine as part of PAT is restricted to registered psychiatrists who have obtained HREC approval and have also been authorised by the TGA to be an AP.

An application to the TGA must be made using the Special Access Scheme (SAS) & Authorised Prescriber (AP) Online System and be accompanied by a site-specific clinical treatment protocol, patient information and consent form, HREC approval and other supporting documents. The site-specific treatment protocol should include details specified in the prescriber's checklist ([Attachment 1](#)). A renewal application checklist is also available, which specifies the updated information that is required to be provided to the TGA in the treatment protocol ([Attachment 2](#)).



The delegates of the Secretary of the Department of Health, Disability and Ageing who review and provide outcomes on AP applications for MDMA and psilocybine are registered medical practitioners and senior medical officers. In addition to ensuring the applying practitioner complies with all AP requirements, the delegate must be satisfied of the prescriber's clinical justification for the treatment regimen, confirm the prescriber will have oversight of the treatment process, and that there are suitable measures to protect patients, such as records of informed consent.

The Review

Why are we conducting a review of recommendations?

It has been 2 years since the changes were made to the [Poisons Schedule](#) to allow access to MDMA and psilocybine outside clinical trials. Since this time, a number of inconsistencies in expectations and procedures have been identified between applicants, HRECs and the TGA. Additionally, practical issues have arisen that were not anticipated when the products were re-scheduled.

Commented s22 Suggest providing link:

[Therapeutic Goods \(Poisons Standard—June 2025\) Instrument 2025 - Federal Register of Legislation](#)

Recommendations

Recommendation 1: Psychiatrist experience

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have initial supervision by an Australian registered psychiatrist that has experience in conducting psychedelic-assisted psychotherapy.

Rationale

The delegate assessing an AP application must be satisfied that the psychiatrist has the training and expertise appropriate for the condition being treated and the proposed use of the product. Considering the unapproved nature of MDMA and psilocybine and that psychedelic-assisted psychotherapy is still a novel treatment outside of clinical trials in Australia, the TGA considers prior experience or initial supervision to demonstrate the required expertise is critical.

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Questions:

1. Do you agree that the psychiatrist must have prior psychedelic-assisted psychotherapy clinical trial experience or requires initial supervision by an Australian-registered psychiatrist with experience in psychedelic-assisted psychotherapy?
2. If not, then please outline what experience or qualifications you believe are appropriate and your rationale to support your response.

Recommendation 2: Therapy 'dyad' qualifications

The psychedelic-assisted psychotherapy sessions to be attended by at least one of the following:

- psychiatrists who are registered with a specialist registration by the Medical Board of Australia; OR
- clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology.

The training and experience of other therapists involved in the sessions, and any other supporting staff, is the responsibility of the HREC to approve.

Rationale

There are inconsistencies and confusion about the required qualifications of the therapists that make up the 'therapy dyad', or pair of clinical practitioners typically involved in psychedelic-assisted psychotherapy.

The role of the TGA in the AP scheme is to provide medical practitioners with lawful access to supply 'unapproved' therapeutic goods. The TGA does not have a role in regulating health professionals or clinical practice. The HREC reviewing the treatment protocol is responsible for considering the training and experience of all staff involved in the treatment.

However, given psychedelic-assisted psychotherapy is a treatment providing access to an 'unapproved' medicine coupled with a clinical intervention, it is appropriate that both the medicine and the practitioners involved in the psychotherapy sessions are subject to regulatory oversight. Due to the vulnerability of patients and until further data is available to demonstrate the safety risks, the TGA expects that the clinical practice of members of the treatment team would be subject to formal clinical oversight. In a situation where the authorised prescriber of the 'unapproved' medicine is not directly involved in the psychotherapy sessions, oversight of the therapy should be by a health practitioner regulated by a national board. Currently the TGA has limited this to a registered clinical psychologist, understanding these clinicians have regulatory oversight by the Psychology Board of Australia. This gives the general public assurance that the therapists will be held accountable for high competency, safety, and ethical standards, protecting the public from unqualified or unsafe healthcare providers.

Current TGA Guidance for psychiatrist prescribers ([Attachment 3](#)) states: *"The TGA expects that the HREC reviewing the treatment protocols would consider the training and experience of all staff involved in the treatment. It is likely that a minimum standard of training of others involved in patient oversight would be that of clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology or equivalent."*

External guidance published by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) ([Attachment 4](#)) requires practitioners involved with psychedelic-assisted psychotherapy to hold registration with Ahpra.

The TGA has received requests that other Ahpra-registered health professionals and therapists trained in psychedelic-assisted psychotherapy be considered for the lead therapist role.



Questions:

3. Should Ahpra-registered and qualified therapists trained in psychedelic-assisted psychotherapy, other than the following, be considered for the lead therapist role within a therapy dyad?
 - a. Specialist psychiatrists registered with Ahpra; OR

- b. Clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology
- 4. If so, what types of health practitioners should be considered for the lead therapist role and why?

Recommendation 3: Level of AP oversight

The AP psychiatrist must be responsible for initial patient screening and obtaining informed consent. Additionally, they need to be present on site and involved in the on-going psychotherapeutic management.

Rationale

An authorised prescriber can supply an AP-approved product directly to a specified patient under their immediate care provided they have a therapeutic relationship with the patient. Authorised prescribers are responsible for monitoring their patient during and after use of an unapproved therapeutic good.

The Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors of unapproved therapeutic goods further highlights medical practitioner requirements under the AP scheme ([Attachment 5](#)).

The current TGA Guidance for psychiatrist prescribers ([Attachment 3](#)) states: *"The AP psychiatrist must be responsible for assessment and on-going psycho-therapeutic management before and after administration of appropriately supervised dosing of the patient in an appropriate setting."*

Prescribers are not clear on what this level of oversight means practically, or in some cases whether they need to be on site at clinics.



Questions:

- 5. Do you agree that, to provide the appropriate level of oversight to their patient, the AP psychiatrist must be physically on-site at the treatment location?
- 6. If not, what oversight structure do you consider to be appropriate, why and does this structure meet the requirements of an approved AP?

Recommendation 4: Appropriate site location

The prescriber should include details of the site, demonstrating the location is an appropriate supervised environment. The treatment site should be reviewed by the HREC, in accordance with state/territory requirements (prescriber's responsibility to check), as part of their approval of the treatment protocol according to specific criteria as outlined below:

- a. **Equipment and appropriately trained staff on-site to provide comprehensive clinical care, monitoring and emergency resuscitation;**
- b. **Appropriate storage facilities for Schedule 8 medicines as per state/territory requirements;**

- c. **Approved Authorised Prescriber available on-site to treat any complications that arise;**
- d. **Readiness to address treatment emergent adverse events and rescue medications available on-site;**
- e. **Close monitoring of patients during medication administration by appropriately trained staff;**
- f. **Proximity to an accredited healthcare facility with an emergency department for potential episodes of acute deterioration; and**
- g. **Practice has or is seeking accreditation, if required, from the state/territory.**

The TGA Delegate will determine if the treatment location is appropriate to adequately store, administer and monitor treatment, but the HREC's review and approval is taken into consideration.

Rationale

Initial advice provided to the TGA included a recommendation that psychedelic-assisted therapy should only be conducted in an 'accredited facility' to minimise potential safety risks to patients.

It was raised with the TGA that it would be highly unlikely for a drug and therapeutics committee of a public hospital to take on the large cost of treatment and any associated indemnity risk and therefore, in most cases, private hospitals and clinics would be the only option.

Issues around equity have been raised in terms of access to psychedelic-assisted psychotherapy in different geographical locations (i.e. remote areas within Australia). A private or public hospital facility may not be available.



Questions:

- 7. Should sites other than day hospitals or inpatient settings be considered appropriate for an AP to provide the service of psychedelic-assisted psychotherapy through this scheme?
- 8. If so, please provide comments on appropriate criteria that would ensure a site is appropriate.

Consultation instructions

Please provide to the TGA responses to each question as detailed under each recommendation.

Answers can be provided in the form of a written response on a company letterhead and sent by email to SAS.Support@health.gov.au by close of business on **6th August 2025**. In your submission, please provide your name, email address, and your organisation name.

Consent

The TGA will collect your personal information in this consultation to:

- Contact you if we need to clarify issues raised in your feedback and help provide context about your feedback.
- Personal information means information or an opinion about another person whose identity can be easily guessed based on the information provided.

- Please do not include personal information about other people in your feedback. The TGA will not publish personal information without consent unless authorised or required by law.

Attachments

- **Attachment 1:** [Checklist for prescribing psychiatrists of MDMA and psilocybine](#)
- **Attachment 2:** [Renewal checklist](#)
- **Attachment 3:** [Accessing MDMA \(3,4-methylenedioxy-methamphetamine\) and psilocybine as a psychiatrist](#)
- **Attachment 4:** [Therapeutic use of MDMA for PTSD and psilocybine for treatment resistant depression | RANZCP](#)
- **Attachment 5:** [Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors of unapproved therapeutic goods](#)



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Review of Authorised Prescriber scheme to allow access to 3,4-
methylenedioxymethamphetamine (MDMA) and psilocybine for use with
psychotherapy in mental health conditions
Targeted consultation outcomes summary

Version 1.0, October 2025

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Executive summary

Background and purpose

On 1 July 2023, the Poisons Standard was amended to allow access to MDMA for the treatment of post-traumatic stress disorder (PTSD) and psilocybine for treatment-resistant depression (TRD) by psychiatrists who are specifically authorised under the Authorised Prescriber (AP) scheme. Since this time, several procedural and practical challenges have emerged for AP applicants, Human Research Ethics Committees (HRECs), and the Therapeutic Goods Administration (TGA).

To address these concerns and support the continued safe and effective use of psychedelic-assisted psychotherapy (PAT or PAP), a review of the application process is underway. The first step involved a targeted consultation (**Attachment A**) with prescribers, peak professional bodies, state and territory health departments, and HRECs. Outcomes from this consultation will be further discussed in a roundtable meeting, chaired by the Chief Medical Advisor, to guide decision-making and support updates to TGA's external guidance materials.

Twenty nine of the 83 invited stakeholders provided feedback on four proposed recommendations. The breakdown of stakeholder groups and their representation is in Table 1 below.

Table 1 – Targeted stakeholder groups

Stakeholder group	Total	Percentage
State health department	7	24.1%
Authorised Prescriber psychiatrists	6	20.7%
Peak bodies	8	27.6%
Human Research Ethics Committees (HRECs)	4	13.8%
Other	4	13.8%
Total	29	100%

Recommendation 1: Psychiatrist experience

Most respondents supported the requirement for either clinical trial experience or developing competence through supervision by an experienced AP (where the level of experience of the supervisor is defined). They emphasised the need for clearly defined criteria for supervision. However, this aspect falls outside the regulatory scope of the TGA. It is noted the Royal Australian and New Zealand College of Psychiatrists (RANZCP) published their 'Psychedelic training framework for psychiatrists' in June 2025 ([Psychedelic training framework for psychiatrists | RANZCP](#)). This recommends supervision and membership in a psychiatric peer review network. Further advice on which professional body or regulator could take on the role of further defining the criteria for supervision is necessary.

Post consultation recommendation

The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with RANZCP's 'Psychedelic training framework for psychiatrists', including supervision and ongoing peer support.

Recommendation 2: Therapy 'dyad' qualifications

Consultation feedback revealed widespread confusion about the TGA's expectations for the composition of the therapy 'dyad' (or pair of therapists) in PAT. Most respondents advocated for the broader inclusion of other types of therapists in place of a clinical psychologist or psychiatrist, including those not registered with the Australian Health Practitioner Regulation Agency (Ahpra). One rationale for this is that only a small proportion of clinical psychologists are trained in psychotherapy.

However, it is still the preference of the TGA that at least one therapist in the dyad must be a psychiatrist/clinical psychologist due to the scope of practice and regulatory oversight provided by the National Boards. Given that HRECs advised it is not their role to assess therapist qualifications, a revised recommendation will be presented to the group proposing that responsibility for choosing therapists shift to the AP.

Post consultation recommendation

The PAT dyad must include at least one therapist who is registered with a National Board with regulatory oversight of psychotherapy, specifically, the Psychology Board, Medical Board, or Nursing and Midwifery Board. Oversight of the qualifications and experience of any additional therapists participating in sessions is guided by the determination of the Authorised Prescriber.

Recommendation 3: Level of AP oversight

Most stakeholders supported the requirement for the AP to be physically present on-site during at least the administration of the psychedelic medicine. Respondents justified this requirement by noting that PAT remains experimental with direct, on-site oversight by the AP necessary for patient safety. There were comments that having the AP on-site is onerous and restricts access in rural and regional areas. Some states/territories also require the APs involvement in administration of the product.

Post consultation recommendation

The AP psychiatrist should be physically present during at least patient screening, consent and medicine administration (dosing).

It is expected the AP be physically present during the administration of the psychedelic (this does not need to be the full dosing day). This presence ensures the AP is readily available to manage any immediate issues and severe adverse events that may occur.

Recommendation 4: Appropriate site location

There was a majority view from respondents who supported sites other than day hospitals or inpatient settings to be considered appropriate. Based on this feedback, the TGA considers that the original recommendation, allowing the use of private clinics with appropriate emergency management processes, to be the right balance between access and safety. This is also the current policy in use by TGA delegates and has been internally approved until the review is complete.

Post consultation recommendation

Prescribers must provide details of the treatment site to demonstrate it is a suitable and supervised environment. The prescriber must verify the site meets all state and territory requirements. The HREC is responsible for reviewing the appropriateness of the site in line with the following criteria:

- *Have equipment and trained staff for clinical care, monitoring, and emergency resuscitation.*
- *Provide secure storage for Schedule 8 medicines as per jurisdictional regulations.*
- *Be prepared to address treatment-emergent adverse events, with rescue medications on hand.*
- *Be located near an accredited healthcare facility with an emergency department.*
- *Hold or be seeking accreditation if required by the relevant state or territory.*

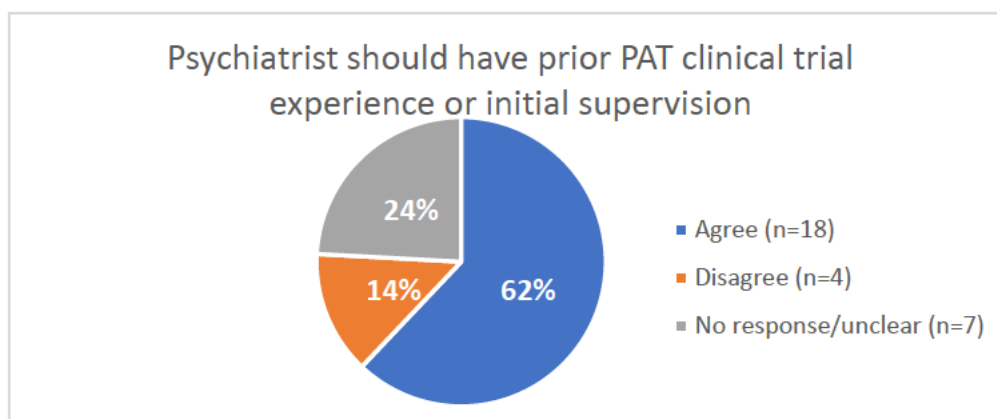
Consultation responses

Recommendation 1: Psychiatrist experience

Consultation questions:

1. Do you agree that the psychiatrist must have prior psychedelic-assisted psychotherapy clinical trial experience or requires initial supervision by an Australian-registered psychiatrist with experience in psychedelic-assisted psychotherapy?
2. If not, then please outline what experience or qualifications you believe are appropriate and your rationale to support your response.

Figure 1. Respondents who agreed/disagreed the psychiatrist should have clinical trial experience or initial supervision



General support for supervision requirements

The majority of stakeholders supported the recommendation that psychiatrists prescribing PAT should either have prior clinical trial experience or be supervised by an experienced psychiatrist until competence is demonstrated. This was viewed as a reasonable safeguard to ensure clinical competence and patient safety for an emerging treatment modality. There were a variety of opinions on the required level of experience of the supervisor, requirements to demonstrate competence and frequency and length of supervision. A strong emphasis was placed on the need for clear definitions and guidance around supervision requirements.

Some stakeholders suggested specific supervision structures. A peak body recommended oversight for the first five patients and 10 to 20 hours. Others recommended flexible models of supervision via video conferencing, supervision based on experience level or allowing overseas-based psychiatrists to act as supervisors.

Several stakeholders emphasised that supervision should not be overly onerous or restrictive, particularly for experienced psychiatrists. One respondent mentioned that all APs should be subject to supervision whether they have clinical trial experience or not.

There was strong interest in establishing formal training pathways and accreditation mechanisms. A few responses called for formal accreditation through RANZCP. While some felt supervision was unnecessary where adequate training was provided, others advocated for a combination of training and supervision. Respondents recommended that the TGA establish a clear list of training and experience requirements such as accredited PAT training, supervised practice, peer review and continuing professional development (CPD), however, this is outside the remit of the TGA as a therapeutic goods regulator.

Concerns and alternative proposals

Respondents highlighted that only a limited number of psychiatrists have participated in Australian PAT clinical trials, and that requiring such experience may restrict access particularly for practitioners in rural and regional areas. Some respondents did not agree with the TGA imposing the requirement for supervision and note the HREC should be responsible for assessing supervision plans.

TGA response and actions

The TGA notes that the availability of Australian psychiatrists with experience in Australian PAT clinical trials is limited and the recommendation has moved away from requiring the supervisor to have clinical trial experience, but rather demonstrated experience in PAT. However, considering that PAT is still a novel treatment outside of clinical trials in Australia, the TGA considers prior clinical trial experience or initial supervision is critical to demonstrate the required expertise. We propose the following updated recommendation to the discussion group, to include reference to the RANZCP's framework ([Psychedelic training framework for psychiatrists | RANZCP](#)).

As a regulator of medicines, the TGA does not have a role in providing guidelines regarding supervision criteria and appropriate training and we suggest any further detailed criteria could potentially be the role of a professional body or regulator. These guidelines could then be used by HRECs to review individual supervision plans.

Post consultation recommendation

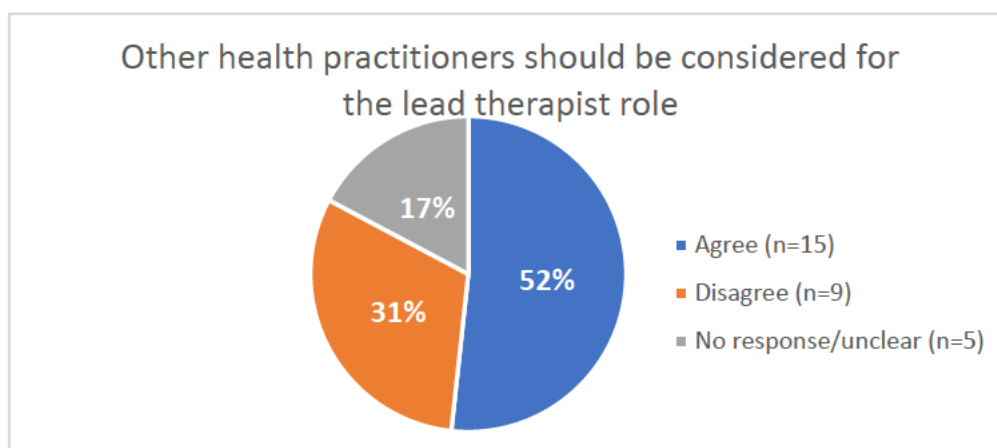
The psychiatrist must have demonstrated experience in psychedelic-assisted psychotherapy clinical trials OR have complied with RANZCP's 'Psychedelic training framework for psychiatrists', including supervision and ongoing peer support.

Recommendation 2: Therapy 'dyad' qualifications

Consultation questions:

3. Should Ahpra-registered and qualified therapists trained in psychedelic-assisted psychotherapy, other than the following, be considered for the lead therapist role within a therapy dyad?
 - a. Specialist psychiatrists registered with Ahpra; OR
 - b. Clinical psychologists who hold general registration with the Psychology Board of Australia and an endorsement in the area of practice of clinical psychology
4. If so, what types of health practitioners should be considered for the lead therapist role and why?

Figure 2. Respondents agreed/disagreed that other health practitioners should be considered for the lead therapist role



General support for more flexible therapist requirements

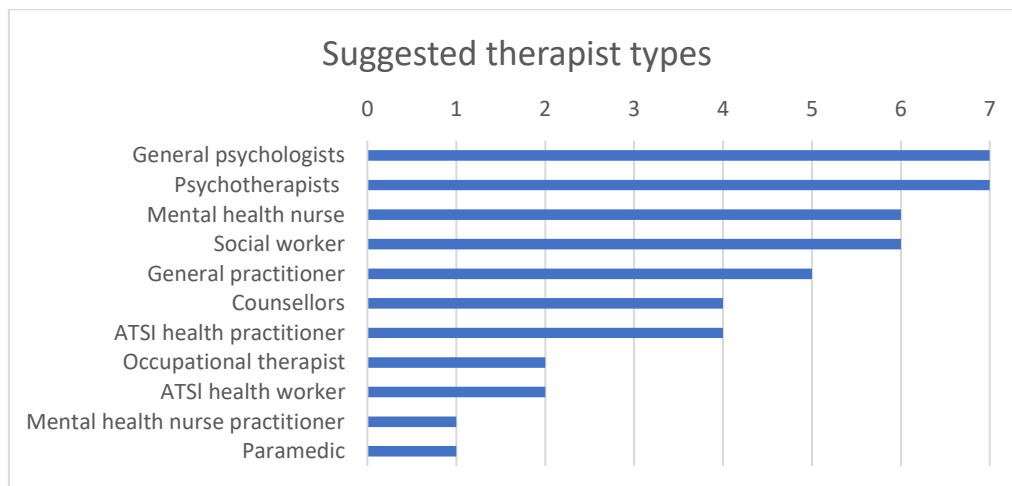
Around half of respondents advocated for removing the requirement for one of the therapy dyad to be a psychiatrist or clinical psychologist. Some respondents misunderstood that the therapy dyad is not only restricted to psychiatrists and clinical psychologists and other members of the therapy team can be determined by the HREC. Although, an ethics committee expressed concern that the HRECs role is to assess the ethical acceptability of the treatment protocol and not the qualifications of individual practitioners. There was variation in whether respondents felt any of the therapy dyad required Ahpra registration.

The rationale for opening this up to other therapists included concerns regarding limited access in rural and regional areas. Respondents noted that other qualified health professionals, such as, general practitioners and general psychologists were subject to the same code of conduct as psychiatrists and clinical psychologists.

There was advocacy for psychotherapists to replace the role of a clinical psychologist in therapy sessions due to their highly specific training in psychotherapy models and the oversight of the Psychotherapy and Counselling Federation of Australia (PACFA). Additionally other non-AHPRA registered therapists fall under the oversight of bodies such as the Australian Counselling Association and the Australian Association of Social Workers. It was noted there should be an emphasis on experience over professional designation or discipline.

To support the growth of PAT in Australia, it was also proposed that psychiatrists registered overseas may be lead therapists under strict conditions. This approach allows access to international expertise while ensuring patient safety and adherence to regulatory standards. As there is no Australian clinical oversight of internationally registered psychiatrists this approach will not be considered.

Figure 3. Other types of therapists who could be considered for the therapy dyad



Lack of support for current model

Only around one third of respondents supported the current therapy dyad model, where the therapy dyad must be made up of at least a psychiatrist or clinical psychologist. State health departments highlighted regulatory limitations, noting that clinical psychologists are not authorised to handle Schedule 8 substances under current legislation. Clinical psychologists (and not general psychologists) were viewed by one respondent as the only psychology professionals with appropriate competencies for treating complex mental health conditions.

TGA response and actions

Due to the vulnerability of patients and until further data is available to demonstrate the safety risks, the TGA expects that the clinical practice of members of the therapy team would be subject to formal clinical oversight. In a situation where the authorised prescriber of the 'unapproved' medicine is not

directly involved in the psychotherapy sessions, oversight of the therapy should be by a health practitioner regulated by a national board.

While most respondents agreed that a clinical psychologist or psychiatrist does not need to be part of the therapy dyad, the TGA notes that there is widespread confusion about the required qualifications of the therapists that make up the 'therapy dyad', or pair of clinical practitioners typically involved in PAT. We feel that further communication is necessary to address that the training and experience of other therapists involved in the sessions, and any other supporting staff, is not the role of the TGA.

The TGA noted apprehension about the level of responsibility placed on HRECs, especially in reviewing the qualifications and training of health professionals involved in prescribing and administering of psychedelic substances and associated psychotherapy. There was also criticism of the TGA's limited recognition of the prescribing psychiatrist's clinical judgement particularly regarding the suitability of the therapist team.

As HRECs have pointed out they do not have the expertise in reviewing the appropriate qualifications of the other therapists, we propose that other clinical practice bodies provide guidance on the suitability of their professional groups for conducting psychotherapy and update the recommendation to the below.

Post consultation recommendation

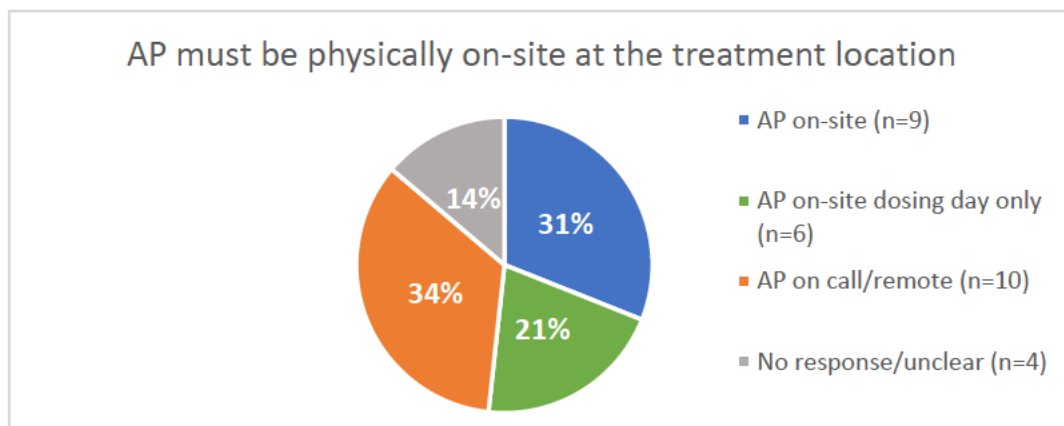
The PAT dyad must include at least one therapist who is registered with a National Board that with regulatory oversight of psychotherapy, specifically, the Psychology Board, Medical Board, or Nursing and Midwifery Board. Oversight of the qualifications and experience of any additional therapists participating in sessions is guided by the determination of the Authorised Prescriber.

Recommendation 3: Level of AP oversight

Consultation questions:

5. Do you agree that, to provide the appropriate level of oversight to their patient, the AP psychiatrist must be physically on-site at the treatment location?
6. If not, what oversight structure do you consider to be appropriate, why and does this structure meet the requirements of an approved AP?

Figure 4. Respondents who agreed/disagreed the AP must be physically on-site



General support for some on-site presence

Respondents who supported on-site presence, noted that AP psychiatrists must oversee both psychotherapy and medication safety, being able to be immediately available during emergencies. However, responses varied in the level of on-site presence necessary (for example, many supported

the AP being on-site just during the dosing day). There were ethical concerns raised, where delegating oversight or relying on emergency services who were unfamiliar with PAT may be inappropriate and risky. Respondents rationalised that PAT is still experimental, requiring direct on-site oversight by the prescriber.

Government departments mentioned regulatory requirements, raising state legislation mandates that the AP psychiatrist retrieve and oversee administration of Schedule 8 substances in some cases. A member of a HREC raised risks of Hallucinogen Persisting Perception Disorder (HPPD) justifying the psychiatrist's presence during even the integration sessions.

Concerns and alternative options

Respondents that did not agree with on-site physical presence preferred that authorised prescribers could be available in an 'on-call' manner, meaning they are available via phone, for emergency consults and physically attend in a short amount of time (for example, 15 minutes). The rationale was that on-site presence increases logistical challenges and costs, especially in rural and remote areas with limited psychiatrist availability. Reducing the on-site requirement could ease pressure on limited specialist resources without compromising safety.

Concerns have been raised about models in which prescribing psychiatrists are not involved beyond the initial assessment in PAT. To address this, a peak body recommended that psychiatrists participate in the therapeutic dyad for the first four patients they prescribe for and maintain ongoing involvement with at least two patients per calendar year thereafter.

Other considerations included hybrid models involving the initial assessment and consent to be done in person, first patient dosing session to be attended by the AP psychiatrist, the use of other medical practitioners, AP psychiatrist available within 15 minutes, secure live video monitoring for remote oversight and integration sessions scheduled at key milestones or after adverse events.

TGA response and actions

Strict screening, monitoring and dose control is considered necessary due to the vulnerability of patients and until further data is available to demonstrate the safety risks. However, the TGA acknowledges that the AP's continuous presence would limit availability for other tasks such as assessments, reviews, and clinical governance. Mandating the APs continuous on-site presence may impose barriers to equitable access, especially in regional settings.

Availability for medication administration means that the management of adverse events can be directly overseen by the AP psychiatrist who is physically on-site during administration of the psychedelic medicine. This aligns with state/territory Schedule 8 handling requirements that prohibit direct dispensing of psychedelic medicines to patients or other therapists and require the prescriber to maintain custody and oversight of the medicine. Additionally, some jurisdictions do not allow administration of the psychedelic medicine to be delegated to another health practitioner. Therefore, the TGA proposes the recommendation be amended to the below.

Post consultation recommendation

The AP psychiatrist should be physically present during at least patient screening, consent and medicine administration (dosing).

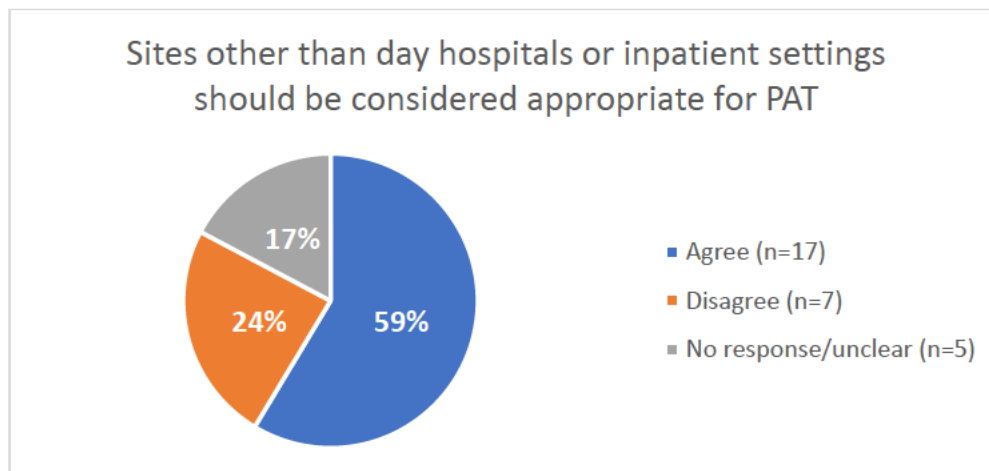
It is expected the AP be physically present during the administration of the psychedelic (this does not need to be the full dosing day). This presence ensures the AP is readily available to manage any immediate issues and severe adverse events that may occur.

Recommendation 4: Appropriate site location

Consultation questions:

7. Should sites other than day hospitals or inpatient settings be considered appropriate for an AP to provide the service of psychedelic-assisted psychotherapy through this scheme?
8. If so, please provide comments on appropriate criteria that would ensure a site is appropriate.

Figure 5. Number of respondents who agreed/disagreed that sites other than day hospitals or inpatient settings should be considered appropriate for PAT



General support for treatment in private outpatient clinics

There was a majority view from respondents who supported sites other than day hospitals or inpatient settings to be considered appropriate for PAT. These clinics were seen as less 'clinical', creating a more therapeutic and comfortable environment for psychotherapy. They were noted to be more culturally safe for Aboriginal and Torres Strait Islander patients, who may distrust hospital settings, and more accessible in rural and regional settings. Respondents noted that already established transcranial magnetic stimulation or ketamine clinics could meet TGA safety criteria, including patient stabilisation and emergency transfer capabilities.

Suggestions for alternative settings include considering GP clinics, community mental health centres and hospital outpatient units.

Concerns

Some stakeholders disagreed with the recommendation, stating that more clinical data is required before considering locations other than hospitals or inpatient settings or that it was unethical to leave the patient in a situation where they do not have timely access to the AP. Concerns included the need for stringent monitoring and response in an emergency. It was noted that clinical psychologists cannot prescribe/administer medications.

TGA response and actions

It was raised with the TGA that it would be highly unlikely for a drug and therapeutics committee of a public hospital to take on the large cost of treatment and any associated indemnity risk and therefore, in most cases, private hospitals and clinics would be the only option. Therefore, the TGA's view is that the recommendation provides a balance between access and safety in having the appropriate emergency management processes in place. The TGA also acknowledges that a private or public

hospital facility may not be available in certain geographical locations. As such, the TGA proposes the recommendation to remain as below.

Post consultation recommendation

Prescribers must provide details of the treatment site to demonstrate it is a suitable and supervised environment. The prescriber must verify the site meets all state and territory requirements. The HREC is responsible for reviewing the appropriateness of the site in line with the following criteria:

- *Have equipment and trained staff for clinical care, monitoring, and emergency resuscitation.*
- *Provide secure storage for Schedule 8 medicines as per jurisdictional regulations.*
- *Be prepared to address treatment-emergent adverse events, with rescue medications on hand.*
- *Be located near an accredited healthcare facility with an emergency department.*
- *Hold or be seeking accreditation if required by the relevant state or territory.*

Summary of other feedback

Emerging indications for psilocybine use

One respondent supported expanding the approved indications for psilocybine, citing emerging evidence of its effectiveness in alleviating end-of-life anxiety in palliative care settings.

The TGA notes that indications for psilocybine to be used under the AP pathway can only be extended if an application is received with the appropriate justification and evidence through the medicines Scheduling process. Other indications can still be researched under the clinical trials pathways.

Consideration of group dosing models

A respondent recommended that group dosing be considered, noting its potential to significantly reduce treatment costs and enhance therapeutic outcomes.

Treatment protocols must align with those from published clinical trials. To date there does not appear to be any published trials on group therapy.

Concerns about regulatory overreach

Some stakeholders raised concerns about the TGA imposing more stringent standards than those typically required by HRECs. This may inadvertently pressure HRECs to align with TGA expectations, potentially compromising their independence and flexibility in ethical review.

Respondents called for increased transparency in TGA decision-making processes. Additionally, concerns were raised about the TGA potentially exceeding its remit by prescribing rules for non-medical aspects of care, such as the location and facilitation of integration sessions. Stakeholders emphasised that such decisions should remain within the scope of clinical and therapeutic discretion.

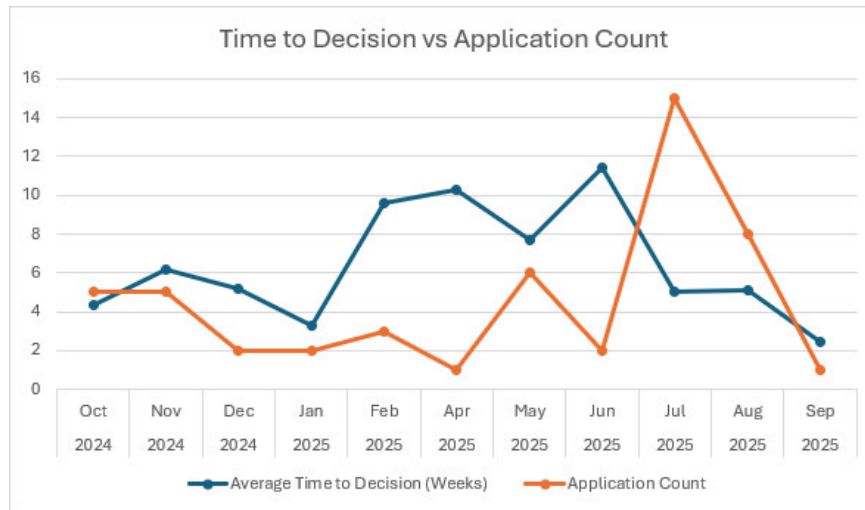
One of the aims of TGA conducting this review is with the hope to better align expectations with HRECs, increase transparency and clarity about decision making and ensuring the role of the TGA extends to the safe use of medicines and not clinical practice.

TGA approval process delays

A stakeholder reported that the process of establishing clinics for psychedelic-assisted therapy was significantly delayed, taking 18 months for psilocybin and 9 months for MDMA. While some delays were attributed to the TGA the respondent felt that certain questions posed during the approval process were post ethics committee approval and not directly relevant, such as enquiries about treatment pricing.

The TGA has been able to significantly cut down the approval process since the initial APs were authorised. Now that the process is more established, although the TGA is now receiving an increase in application numbers, it has become more efficient and streamlined.

Figure 6. AP approval timeframe for psychedelics vs applications received



Data and outcomes reporting

Stakeholders endorsed the inclusion of a requirement for clinics to contribute de-identified outcome data to a national registry. This would support ongoing safety monitoring and enable health-economic analysis, ensuring evidence-informed development of PAT.

The TGA does not have a role in mandating the use of clinical registries however, this may be a point of interest for clinical practice bodies such as RANZCP.

HREC guidance and competence

A HREC expressed a need for clear guidance from the TGA regarding expectations for ethics review, including required documentation, approval timeframes, and assessment criteria. To date, HRECs state they have received minimal direction, and many lack the expertise and structural capacity to adequately assess PAT applications, as they were not established for this purpose.

It has also been suggested that the TGA contact the National Health and Medical Research Council (NHMRC) to determine which HRECs have the expertise and no conflicts to review PAT applications.

HREC approval and review of a clinical treatment protocol has always been a requirement of the standard AP pathway for medicines. HRECs have expressed concern about not having processes in place or guidance to review AP applications as they are set-up to approve the ethical acceptability of clinical trials. The TGA also acknowledges the PAT space is emerging and one of the purposes of the review is to improve clarity in role delineation with HRECs and provide clearer guidance.

The TGA does not have regulatory authority over HRECs. While the TGA requires HREC approval as part of AP processes and clinical trial notifications, it does not oversee or enforce HREC processes and decisions.

HRECs are institutionally governed and guided by NHMRC standards, and function independently of the TGA's regulatory oversight. The TGA may consider HREC reviews in its decision-making but does not intervene in HREC governance or disciplinary actions.

Concern regarding Scheduling interpretation

Stakeholders reported inconsistent interpretations of the Poisons Standard across jurisdictions. In the ACT, substances are treated as Schedule 9 until a valid prescription is received, then reclassified as Schedule 8, while other states apply different approaches. Despite unchanged risk profiles, this variation creates regulatory confusion.

The TGA acknowledges the Schedules in the Poisons Standard are implemented by each state/territory and this creates variation in interpretation. APs are directed by the TGA to ensure that they conform with state/territory requirements as Commonwealth requirements do not override these.

Publishing consultation responses

A small number of respondents requested for the consultation responses and reasons for any decisions and outcomes to be published externally. The TGA decided on a targeted consultation for this review to encourage thorough and open feedback from respondents. The TGA will consider publishing the reasons for decisions or changes that arise from the consultation.

Therapeutic Goods Administration

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<https://www.tga.gov.au>



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Board of Australia – Agenda Paper

Date: 25 February 2026

Sponsor: Prof Robyn Langham, Chief Medical Advisor, Therapeutic Goods Administration (TGA)

Subject: TGA Review of the Authorised Prescriber (AP) application process for MDMA and Psilocybine

1. Key issues

- The TGA is finalising its first policy review on access to MDMA and psilocybin for use in psychedelic-assisted psychotherapy under the Authorised Prescriber (AP) scheme, following commencement of the program in July 2023. The consultation paper and summary of consultation outcomes are provided at *Attachment A* and *Attachment B*.
- Access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression is distinct from other unapproved therapeutic goods. These substances can only be used in conjunction with structured psychotherapy, forming the combined treatment modality known as psychedelic-assisted therapy (PAT).
- The current TGA policy for psychotherapists involved with PAT was that at least one of the psychotherapists present during PAT should be either the AP (a registered specialist psychiatrist) or a registered psychologist with an endorsement as a clinical psychologist. Our understanding is that it is generally uncommon for specialist psychiatrists to be involved in psychotherapy, with the result being that dyad most often composed of the clinical psychologist and one other. The AP and the Human Research Ethics Committee (HREC) are responsible for ensuring the appropriate training and experience of any therapists involved.
- A specific focus of the consultation process focused on the question of whether the inclusion criteria for the lead psychotherapist should be broadened. Most respondents advocated for broader inclusion. The rationales for expanding eligibility included challenges in rural and regional access, workforce shortages of clinical psychologists trained in trauma therapy, and the need to accommodate culturally safe models of care. Many participants considered that, under the oversight of an AP psychiatrist, any practitioner could form part of the therapy dyad, yet others wanted the reassurance of oversight by a relevant regulator.
- The TGA and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) remain concerned about broadening eligibility for the therapeutic dyad. Given patient vulnerability, the limited safety data available for MDMA and psilocybine treatments, and the absence of statutory powers for self-regulating professional bodies, the TGA considers it necessary to maintain restrictions on who may form part of the dyad. Specifically, the TGA expects that at least one member of the therapy team must be a health practitioner registered with a National Board that has relevant oversight of a practitioner undertaking psychotherapy.
- The questions we are asking the Board regarding medical practitioners relate only to those who are considered suitable for the psychotherapy team, and not to the nature of registration and

training of the AP. The requirement is for the AP to be an Australian registered specialist psychiatrist approved by the TGA and a registered HREC.

- The TGA notes that decisions regarding practitioner eligibility under this policy fall within the remit of a number of individual National Boards. Accordingly, the TGA is seeking review of the proposal of practitioner eligibility from the Medical Board of Australia, the Psychology Board of Australia, the Nursing and Midwifery Board of Australia, and the Occupational Therapy Board of Australia in February 2026.

2. Questions for the MBA – expanding criteria of lead psychotherapist

- Which other specialist or medical practitioners with general registration would be considered appropriate to act as the primary psychotherapist within the therapy dyad, noting that the AP legislation is clear that the AP psychiatrist retains overall responsibility for the treating team and patient care?
 - Does the Board consider that other registration types (provisional/limited) could be considered suitable?
- Would the Board expect any minimum competency requirements, including qualifications, psychotherapy training, supervised practice expectations and Continuing Professional Development (CPD) obligations? *Note that the RANZCP has a training framework applicable to the psychiatrist AP ([Psychedelic training framework for psychiatrists | RANZCP](#)).*
- Does the Board have any additional concerns, risks, or recommended safeguards regarding the implementation of the proposal to broaden psychotherapist eligibility, specifically, the requirement that **at least one member of the therapy team** be a health practitioner registered with a National Board that provides appropriate oversight of practitioners undertaking psychotherapy (including medical practitioners, registered psychologists, registered mental health nurses, and registered occupational therapists).

3. Background

- On 1 July 2023, amendments to the Poisons Standard enabled access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression outside clinical trials. Prescribing is restricted to Australian registered specialist psychiatrists with HREC approval and AP status with the TGA. Further information on the access scheme is available on the TGA website at <https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybine/access-pathways/access-mdma-or-psilocybine-consumers>.

4. Attachments

- **Attachment A:** Consultation paper
- **Attachment B:** Summary of consultation outcomes



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Nursing and Midwifery Board of Australia – Agenda Paper

Date: 26 February 2026

Sponsor: Prof Robyn Langham, Chief Medical Advisor, Therapeutic Goods Administration (TGA)

Subject: TGA Review of the Authorised Prescriber (AP) application process for MDMA and Psilocybine

1. Key issues

- The TGA is finalising its first policy review on access to MDMA and psilocybin for use in psychedelic-assisted psychotherapy under the Authorised Prescriber (AP) scheme, following commencement of the program in July 2023. The consultation paper and summary of consultation outcomes are provided at *Attachment A* and *Attachment B*.
- Access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression is distinct from other unapproved therapeutic goods. These substances can only be used in conjunction with structured psychotherapy, forming the combined treatment modality known as psychedelic-assisted therapy (PAT).
- The current TGA policy for psychotherapists involved with PAT was that at least one of the psychotherapists present during PAT should be either the AP (a registered specialist psychiatrist) or a registered psychologist with an endorsement as a clinical psychologist. Our understanding is that it is generally uncommon for specialist psychiatrists to be involved in psychotherapy, with the result being that dyad most often composed of the clinical psychologist and one other. The AP and the Human Research Ethics Committee (HREC) are responsible for ensuring the appropriate training and experience of any therapists involved.
- A specific focus of the consultation process focused on the question of whether the inclusion criteria for the lead psychotherapist should be broadened. Most respondents advocated for broader inclusion. The rationales for expanding eligibility included challenges in rural and regional access, workforce shortages of clinical psychologists trained in trauma therapy, and the need to accommodate culturally safe models of care. Many participants considered that, under the oversight of an AP psychiatrist, any practitioner could form part of the therapy dyad, yet others wanted the reassurance of oversight by a relevant regulator.
- The TGA and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) remain concerned about broadening eligibility for the therapeutic dyad. Given patient vulnerability, the limited safety data available for MDMA and psilocybine treatments, and the absence of statutory powers for self-regulating professional bodies, the TGA considers it necessary to maintain restrictions on who may form part of the dyad. Specifically, the TGA expects that at least one member of the therapy team must be a health practitioner registered with a National Board that has relevant oversight of a practitioner undertaking psychotherapy.
- The questions we are asking the Board regarding registered nurses relate only to those who are considered suitable for the psychotherapy team, and not to the nature of registration and

training of the AP. The requirement is for the AP to be an Australian registered specialist psychiatrist approved by the TGA and a registered HREC.

- The TGA notes that decisions regarding practitioner eligibility under this policy fall within the remit of a number of individual National Boards. Accordingly, the TGA is seeking review of the proposal of practitioner eligibility from the Medical Board of Australia, the Psychology Board of Australia, the Nursing and Midwifery Board of Australia, and the Occupational Therapy Board of Australia in February 2026.

2. Questions for the Nursing and Midwifery Board – expanding criteria of lead psychotherapist

- Which categories of registered nurses or nurse practitioners (such as registered nurses with specific mental health endorsement or those with advanced practice experience in psychotherapy) does the Board consider appropriate to act as the primary psychotherapist within the therapy dyad, noting that the authorised psychiatrist will retain overall responsibility for the treating team and patient care under the AP legislation?
- Would the Board expect any minimum competency or credentialing requirements for nurses undertaking psychotherapy within this model, including qualifications, psychotherapy-specific training, supervised practice expectations, or Continuing Professional Development (CPD) obligations? *Note that the RANZCP has a training framework applicable to the psychiatrist AP ([Psychedelic training framework for psychiatrists | RANZCP](#)).*
- Does the Board have any additional concerns, risks, or recommended safeguards regarding the implementation of the proposal to broaden psychotherapist eligibility, specifically, the requirement that **at least one member of the therapy team** be a health practitioner registered with a National Board that provides appropriate oversight of practitioners undertaking psychotherapy (including medical practitioners, registered psychologists, registered mental health nurses, and registered occupational therapists).

3. Background

- On 1 July 2023, amendments to the Poisons Standard enabled access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression outside clinical trials. Prescribing is restricted to Australian registered specialist psychiatrists with HREC approval and AP status with the TGA. Further information on the access scheme is available on the TGA website at <https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybine/access-pathways/access-mdma-or-psilocybine-consumers>.

4. Attachments

- **Attachment A:** Consultation paper
- **Attachment B:** Summary of consultation outcomes



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Occupational Therapy Board of Australia – Agenda Paper

Date: 24 February 2026

Sponsor: Prof Robyn Langham, Chief Medical Advisor, Therapeutic Goods Administration (TGA)

Subject: TGA Review of the Authorised Prescriber (AP) application process for MDMA and Psilocybine

1. Key issues

- The TGA is finalising its first policy review on access to MDMA and psilocybin for use in psychedelic-assisted psychotherapy under the Authorised Prescriber (AP) scheme, following commencement of the program in July 2023. The consultation paper and summary of consultation outcomes are provided at *Attachment A* and *Attachment B*.
- Access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression is distinct from other unapproved therapeutic goods. These substances can only be used in conjunction with structured psychotherapy, forming the combined treatment modality known as psychedelic-assisted therapy (PAT).
- The current TGA policy for psychotherapists involved with PAT was that at least one of the psychotherapists present during PAT should be either the AP (a registered specialist psychiatrist) or a registered psychologist with an endorsement as a clinical psychologist. Our understanding is that it is generally uncommon for specialist psychiatrists to be involved in psychotherapy, with the result being that dyad most often composed of the clinical psychologist and one other. The AP and the Human Research Ethics Committee (HREC) are responsible for ensuring the appropriate training and experience of any therapists involved.
- A specific focus of the consultation process focused on the question of whether the inclusion criteria for the lead psychotherapist should be broadened. Most respondents advocated for broader inclusion. The rationales for expanding eligibility included challenges in rural and regional access, workforce shortages of clinical psychologists trained in trauma therapy, and the need to accommodate culturally safe models of care. Many participants considered that, under the oversight of an AP psychiatrist, any practitioner could form part of the therapy dyad, yet others wanted the reassurance of oversight by a relevant regulator.
- The TGA and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) remain concerned about broadening eligibility for the therapeutic dyad. Given patient vulnerability, the limited safety data available for MDMA and psilocybine treatments, and the absence of statutory powers for self-regulating professional bodies, the TGA considers it necessary to maintain restrictions on who may form part of the dyad. Specifically, the TGA expects that at least one member of the therapy team must be a health practitioner registered with a National Board that has relevant oversight of a practitioner undertaking psychotherapy.

- The questions we are asking the Board regarding registered OTs relate only to those who are considered suitable for the psychotherapy team, and not to the nature of registration and training of the AP. The requirement is for the AP to be an Australian registered specialist psychiatrist approved by the TGA and a registered HREC.
- The TGA notes that decisions regarding practitioner eligibility under this policy fall within the remit of a number of individual National Boards. Accordingly, the TGA is seeking review of the proposal of practitioner eligibility from the Medical Board of Australia, the Psychology Board of Australia, the Nursing and Midwifery Board of Australia, and the Occupational Therapy Board of Australia in February 2026.

2. Questions for the Occupational Therapy Board – expanding criteria of lead psychotherapist

- Which specific categories of registered OTs (such as registered psychologists with specific mental health endorsement or those with advanced practice experience in psychotherapy) does the Board consider appropriate to act as the primary psychotherapist within the therapy dyad, noting that the authorised psychiatrist will retain overall responsibility for the treating team and patient care under the AP legislation?
- Would the Board expect any minimum competency or credentialing requirements for OTs undertaking psychotherapy within this model, including qualifications, psychotherapy-specific training, supervised practice expectations, or Continuing Professional Development (CPD) obligations? *Note that the RANZCP has a training framework applicable to the psychiatrist AP ([Psychedelic training framework for psychiatrists | RANZCP](#)).*
- Does the Board have any additional concerns, risks, or recommended safeguards regarding the implementation of the proposal to broaden psychotherapist eligibility, specifically, the requirement that **at least one member of the therapy team** be a health practitioner registered with a National Board that provides appropriate oversight of practitioners undertaking psychotherapy (including medical practitioners, registered psychologists, registered mental health nurses, and registered occupational therapists).

3. Background

- On 1 July 2023, amendments to the Poisons Standard enabled access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression outside clinical trials. Prescribing is restricted to Australian registered specialist psychiatrists with HREC approval and AP status with the TGA. Further information on the access scheme is available on the TGA website at <https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybine/access-pathways/access-mdma-or-psilocybine-consumers>.

4. Attachments

- **Attachment A:** Consultation paper
- **Attachment B:** Summary of consultation outcomes



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Psychology Board of Australia – Agenda Paper

Date: 27 February 2026

Sponsor: Prof Robyn Langham, Chief Medical Advisor, Therapeutic Goods Administration (TGA)

Subject: TGA Review of the Authorised Prescriber (AP) application process for MDMA and Psilocybine

1. Key issues

- The TGA is finalising its first policy review on access to MDMA and psilocybin for use in psychedelic-assisted psychotherapy under the Authorised Prescriber (AP) scheme, following commencement of the program in July 2023. The consultation paper and summary of consultation outcomes are provided at *Attachment A* and *Attachment B*.
- Access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression is distinct from other unapproved therapeutic goods. These substances can only be used in conjunction with structured psychotherapy, forming the combined treatment modality known as psychedelic-assisted therapy (PAT).
- The current TGA policy for psychotherapists involved with PAT was that at least one of the psychotherapists present during PAT should be either the AP (a registered specialist psychiatrist) or a registered psychologist with an endorsement as a clinical psychologist. Our understanding is that it is generally uncommon for specialist psychiatrists to be involved in psychotherapy, with the result being that dyad most often composed of the clinical psychologist and one other. The AP and the Human Research Ethics Committee (HREC) are responsible for ensuring the appropriate training and experience of any therapists involved.
- A specific focus of the consultation process focused on the question of whether the inclusion criteria for the lead psychotherapist should be broadened. Most respondents advocated for broader inclusion. The rationales for expanding eligibility included challenges in rural and regional access, workforce shortages of clinical psychologists trained in trauma therapy, and the need to accommodate culturally safe models of care. Many participants considered that, under the oversight of an AP psychiatrist, any practitioner could form part of the therapy dyad, yet others wanted the reassurance of oversight by a relevant regulator.
- The TGA and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) remain concerned about broadening eligibility for the therapeutic dyad. Given patient vulnerability, the limited safety data available for MDMA and psilocybine treatments, and the absence of statutory powers for self-regulating professional bodies, the TGA considers it necessary to maintain restrictions on who may form part of the dyad. Specifically, the TGA expects that at least one member of the therapy team must be a health practitioner registered with a National Board that has relevant oversight of a practitioner undertaking psychotherapy.

- The questions we are asking the Board regarding registered psychologists relate only to those who are considered suitable for the psychotherapy team, and not to the nature of registration and training of the AP. The requirement is for the AP to be an Australian registered specialist psychiatrist approved by the TGA and a registered HREC.
- The TGA notes that decisions regarding practitioner eligibility under this policy fall within the remit of a number of individual National Boards. Accordingly, the TGA is seeking review of the proposal of practitioner eligibility from the Medical Board of Australia, the Psychology Board of Australia, the Nursing and Midwifery Board of Australia, and the Occupational Therapy Board of Australia in February 2026.

2. Questions for the Psychology Board – expanding criteria of lead psychotherapist

- Which specific categories of registered psychologists (such as registered psychologists with specific mental health endorsement or those with advanced practice experience in psychotherapy) does the Board consider appropriate to act as the primary psychotherapist within the therapy dyad, noting that the authorised psychiatrist will retain overall responsibility for the treating team and patient care under the AP legislation?
- Would the Board expect any minimum competency or credentialing requirements for psychologists undertaking psychotherapy within this model, including qualifications, psychotherapy-specific training, supervised practice expectations, or Continuing Professional Development (CPD) obligations? *Note that the RANZCP has a training framework applicable to the psychiatrist AP ([Psychedelic training framework for psychiatrists | RANZCP](#)).*
- Does the Board have any additional concerns, risks, or recommended safeguards regarding the implementation of the proposal to broaden psychotherapist eligibility, specifically, the requirement that **at least one member of the therapy team** be a health practitioner registered with a National Board that provides appropriate oversight of practitioners undertaking psychotherapy (including medical practitioners, registered psychologists, registered mental health nurses, and registered occupational therapists).

3. Background

- On 1 July 2023, amendments to the Poisons Standard enabled access to MDMA for post-traumatic stress disorder and psilocybine for treatment-resistant depression outside clinical trials. Prescribing is restricted to Australian registered specialist psychiatrists with HREC approval and AP status with the TGA. Further information on the access scheme is available on the TGA website at <https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybine/access-pathways/access-mdma-or-psilocybine-consumers>.

4. Attachments

- **Attachment A:** Consultation paper
- **Attachment B:** Summary of consultation outcomes

From: s22
To: s22
Cc:
Subject: RE: Correspondence from Ahpra to TGA regarding Review of Authorised Prescriber Scheme
Date: Thursday, 2 April 2026 9:43:28 AM
Attachments: [image002.png](#)
[image003.png](#)

Dear s22

Thank you for providing the response from Ahpra. We are in the process of reviewing the response to feed into our final recommendations for the consultation process.

We appreciate the input and collaboration with Ahpra and the National Boards.

Kind regards

s22

Senior Pharmacist – Unapproved Medicines Access Section
International Regulatory Branch

Medicines Regulation Division | Therapeutic Goods Administration
 Health Products Regulation Group
 Australian Government, Department of Health, Disability and Ageing

E: Medicinal.cannabis@health.gov.au | SAS@health.gov.au | Authorised.Prescribers@health.gov.au

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 PO Box 9848, Canberra ACT 2601, Australia
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The Department of Health, Disability and Ageing 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.

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.

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From: s22
Sent: Tuesday, 31 March 2026 4:38 PM
To: s22 @Health.gov.au>
Cc: s22 @ahpra.gov.au>; s22
 s22

Subject: Correspondence from Ahpra to TGA regarding Review of Authorised Prescriber Scheme

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.

Dear s22

Please find attached correspondence from Helen Townley, Executive Director Health Workforce, Ahpra, regarding the *Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxymethamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions*.

For further discussion and any questions please contact s22 [REDACTED] National Manager Strategic Policy at s22 [REDACTED] [@ahpra.gov.au](mailto:s22@ahpra.gov.au).

Thank you and kind regards,

s22 [REDACTED]

National Business Coordinator, Health Workforce

Email | s22 [REDACTED] [@ahpra.gov.au](mailto:s22@ahpra.gov.au)

Web | www.ahpra.gov.au

Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Hobart TAS 7001



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It's available for anyone participating in our processes.

🔗 **Ahpra's website** offers links to practitioner, student and general support services.

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Ahpra acknowledges the Traditional Owners of Country throughout Australia and the continuing connection to lands, waters and communities. We pay our respect to Aboriginal and Torres Strait Islander cultures and Elders past and present.



31 March 2026

Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration
PO Box 100
Canberra ACT 2606
Via email: s22@Health.gov.au

Dear [s22](#)

Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxymethamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions.

The Australian Health Practitioner Agency (Ahpra) and the National Boards welcome the opportunity to provide further information on this targeted consultation. We would also like to thank Professor Robyn Langham for her attendance at Board meetings throughout February and discussion of this consultation.

As you will be aware, Ahpra and the National Boards are monitoring the framework and uptake of prescribing of MDMA and psilocybine for use with psychotherapy given the vulnerable patient group involved and the experimental nature of these treatments. Experience with medicinal cannabis shows that easier access can lead to a significant uptake in demand with potential for misuse and risk to patients. With this risk in mind and the particular vulnerability of the patient population seeking psychedelic assisted therapy (PAT), we are pleased to note that there is no consideration to alter the role of a registered psychiatrist as authorised prescriber (AP) within PAT and that the AP, along with the Human Research Ethics Committee (HREC) will maintain all current responsibilities, including ensuring any therapists involved in providing psychotherapy as part of PAT have appropriate training and experience.

We are happy to provide the following information and responses to specific questions in relation to the TGA's exploration of broadening the type of registered health practitioners to lead psychotherapy provided as part of PAT.

National Board's role in relation to scope of practice

As you will be aware, National Boards do not regulate scope of practice. In line with their relevant Code of Conduct for their profession, all practitioners are expected to possess the necessary skills, training and competency for the scope of their practice, noting:

- what is appropriate training and education to practise safely and competently in a particular area will vary depending on the individual practitioner and profession, and
- competency is not merely the ability to carry out a task within a particular area of practice but includes having the knowledge and skills to judge the appropriateness of treatment, the individual risk of harm, knowledge of any potential risks or complications and the ability to manage these risks and complications should they arise.

Before a practitioner moves to a new area of practice, they are expected to ensure they have or undertake appropriate training and education, along with sufficient knowledge and skills to practise safely in this new area. When National Boards receive a notification (complaint) about the practice of a registered health practitioner they consider whether the practitioner was practising within their scope of practice having regard to the training, education and experience of the individual practitioner.

Some Boards recognise an extended scope of practice through a particular type of registration, such as specialist registration as a psychiatrist, and/or a practice endorsement, such as clinical psychologist,

Australian Health Practitioner Regulation Agency
National Boards

GPO Box 9958 Melbourne VIC 3001 Ahpra.gov.au 1300 419 495

Ahpra and the National Boards regulate these registered health professions: Aboriginal and Torres Strait Islander health practice, Chinese medicine, chiropractic, dental, medical, medical radiation practice, midwifery, nursing, occupational therapy, optometry, osteopathy, paramedicine, pharmacy, physiotherapy, podiatry and psychology.

which indicate an extended scope of practice in a particular area because the practitioner has an additional qualification that is approved by the National Board.

National Board feedback on proposed changes to access framework

Feedback from individual National Boards to the specific questions asked is attached.

In summary:

- the Medical, Nursing and Midwifery and Occupational Therapy Boards supported the involvement of additional practitioners from their professions to be the primary practitioner to provide PAT psychotherapy, and
- all Boards highlighted the need for health practitioners involved in this treatment to be suitably trained, noting no National Board has an approved program of study, endorsement or category of registration that is specifically designed to adequately train and educate practitioners to provide psychotherapy for PAT. Some practitioners may have received adequate training and education to provide PAT psychotherapy; others are unlikely to have received sufficient training and education through their foundational qualification and would need to undertake significant training and education before they could be considered safe and competent to provide PAT psychotherapy.
- all Boards noted the TGA's advice that the AP and the HREC are responsible for ensuring appropriate training and experience of any therapist involved.

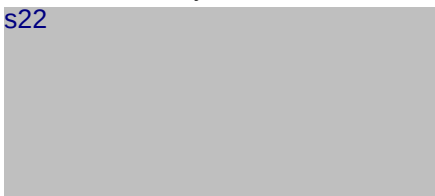
Monitoring impact of changes to the framework

As noted earlier, our experience with medicinal cannabis has indicated that increasing access and reducing barriers to treatment by medicines which are also popular illicit drugs carries risk of increased nontherapeutic use. We are keen to monitor how any changes to the access framework may impact practice and update, and to receive any data the TGA may be able to share that would assist in monitoring trends of health practitioner involvement in this treatment.

We hope that this information is useful. For further discussion and any questions please contact [s22](#), National Manager Strategic Policy at [s22@ahpra.gov.au](#)

Yours sincerely

[s22](#)



Executive Director, Health Workforce

National Board responses: TGA review of the Authorised Prescriber (AP) application process for MDMA and Psilocybine.

Question	Medical Board of Australia (the MBA)	Nursing and Midwifery Board of Australia (the NMBA)	Occupational Therapy Board of Australia (the OTBA)	Psychology Board of Australia (the PsyBA)
Question One: Which specific types/categories of practitioners would be considered appropriate to act as the primary psychotherapist within the therapy dyad?	The MBA considered that in addition to the primary role of the AP, other medical practitioners with general or specialist registration, who possessed the appropriate training and experience in psychotherapy should participate in the treatment dyad as primary psychotherapist	The NMBA noted within Australia there are no 'mental health nurses', however there are registered nurses with mental health experience. The NMBA recommended a suitably experienced, educated, confident and competent registered nurse or nurse practitioner may be appropriate as a member of the therapy dyad.	The OTBA advised that it does not regulate advanced scopes of practice nor area of practice endorsement. Occupational therapists involved in the delivery of psychedelic-assisted psychotherapy need to have a scope of practiced in psychotherapy and be suitable trained and experienced in psychotherapy. The OTBAs code of conduct provides guidance and would be referred to in the case of any notification. The OTBA noted that OT Australia offers a mental health endorsement, but most occupational therapists who work in public mental health, including psychotherapy, would not have mental health endorsement.	The Psychology Board of Australia (the PsyBA) considered registered psychologists with an area of practice endorsement in clinical psychology were the appropriate members of the psychology profession to act as primary psychotherapists within the therapy dyad. The PsyBA noted that patients undertaking PAT are likely to have very complex clinical presentations with longstanding illness and considered that it was important then that the primary psychotherapist not only had specific training in PAT but also in treating severe mental health conditions such as PTSD and treatment resistant depression. The PsyBA suggested therefore that, until evidence base grows, psychiatrists and clinical

Australian Health Practitioner Regulation Agency

National Boards

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Ahpra and the National Boards regulate these registered health professions: Aboriginal and Torres Strait Islander health practice, Chinese medicine, chiropractic, dental, medical, medical radiation practice, midwifery, nursing, occupational therapy, optometry, osteopathy, paramedicine, pharmacy, physiotherapy, podiatry and psychology.

Question	Medical Board of Australia (the MBA)	Nursing and Midwifery Board of Australia (the NMBA)	Occupational Therapy Board of Australia (the OTBA)	Psychology Board of Australia (the PsyBA)
				psychologists are appropriate primary psychotherapists.
MBA only Does the Board consider that other registration types (provisional/limited) could be considered suitable?	The Board did not support medical practitioners with limited or provisional registration to be involved in the therapy dyad.	N/A	N/A	N/A
Question two: Would the Board expect any minimum competency requirements, including qualifications, psychotherapy training, supervised practice expectations and Continuing Professional Development (CPD) obligations? <i>Note that the RANZCP has a training framework applicable to the psychiatrist AP (Psychedelic training framework for psychiatrists RANZCP).</i>	All Boards expect practitioners to possess the necessary skills, training and competency for the scope of their practice, noting that what is appropriate training and education to practise safely and competently in a particular area will vary depending on the individual practitioner and profession. No National Board has an approved program of study, endorsement or category of registration that is specifically designed to adequately train and educate practitioners to provide psychotherapy for PAT. All Boards noted the TGA's advice that the AP and the HREC are responsible for ensuring appropriate training and experience of any therapist involved.			
	The Board expects that medical practitioners with general or specialist registration involved in the therapy dyad to have appropriate psychotherapy training and experience and to complete annual CPD that	The NMBA noted that a psychiatrist remains the approved prescriber and is responsible for assessing the suitability of the participants in the therapy dyad.	The OTBA noted as above that the Board does not regulate advanced scopes of practice nor area of practice endorsement. OT Australia offers a mental health endorsement, but the OTBA considered it was more geared towards occupational therapists who wish to offer private mental health services under a range of	The PsyBA does expect minimum competency and credentialing requirements for psychologists undertaking psychotherapy within the PAT model.

Question	Medical Board of Australia (the MBA)	Nursing and Midwifery Board of Australia (the NMBA)	Occupational Therapy Board of Australia (the OTBA)	Psychology Board of Australia (the PsyBA)
	supports their scope of practice.		government funding schemes. The OTBA does not expect the OT Australia endorsement as a requirement for occupational therapists to undertake psychotherapy within the PAT.	
Question three: Does the Board have any additional concerns, risks, or recommended safeguards regarding the implementation of the proposal to broaden psychotherapist eligibility, specifically, the requirement that at least one member of the therapy team be a health practitioner registered with a National Board that provides appropriate oversight of practitioners undertaking psychotherapy (including medical practitioners, registered psychologists, registered mental health nurses, and registered occupational therapists).	The MBA noted that the Board does not have the expertise to define what competencies are required for psychotherapy however noted that the prescribing of MDMA and psilocybine should remain within the human ethics research framework until there is a better alternative to ensure there continues to be appropriate reporting and evaluation mechanisms.		The OTBA has no specific concerns, noting that adequate supervision, ongoing training and compliance with professional Codes of Conduct act as safeguards. The Board noted that occupational therapists participating in psychotherapy need to clearly link the goal of therapy as supporting re-engagement with occupations that are meaningful to the client and with occupational performance, not secondary to symptom relief.	The PsyBA refrains from commenting on other practitioners and health providers.

Thank you for your contribution to the TGA's targeted consultation on the Authorised Prescriber (AP) scheme for psychedelic-assisted therapies. We appreciate the time and expertise provided by stakeholders across clinical, regulatory and research settings.

Your feedback, together with additional stakeholder roundtable meetings and communications, has informed refinements to the scheme to address early implementation challenges while maintaining patient safety.

The outcomes of the consultation and subsequent roundtable meetings are available [here](#).

Key outcomes

The final recommendations support appropriate access to MDMA and psilocybine as unapproved and emerging therapies with strong safeguards, including:

- **Psychiatrist experience** – Psychiatrists must demonstrate experience through participation in a clinical trial involving psychedelic therapy or through supervision by an Authorised Prescriber experienced in psychedelic assisted psychotherapy, recognising current workforce constraints while supporting competency development. Psychiatrists should refer to appropriate guidance from the Royal Australian and New Zealand College of Psychiatrists (RANZCP) regarding specific supervision and supervisor experience criteria.
- **Therapy dyad composition** – Requirements now allow greater flexibility in the therapy team.
 - The psychedelic assisted psychotherapy dyad must include at least ONE therapist who holds the following registration with one of the following National Boards:
 - Psychology Board with endorsement as a clinical psychologist

- Medical Board with general registration
- Nursing and Midwifery Board with mental health experience
- Occupational Therapy Board
- Health practitioners must demonstrate appropriate skills, training, and competence relevant to psychedelic assisted psychotherapy, as determined by the AP psychiatrist and subject to HREC oversight.
- The AP psychiatrist is responsible for determining the qualifications and experience of any ADDITIONAL practitioners.
- **Authorised Prescriber oversight** – The Authorised Prescriber will remain responsible for patient screening, informed consent, and must be physically present during administration of the psychedelic medicine to manage safety risks.
- **Treatment site requirements** – Clarified minimum expectations for a medically supervised setting, including emergency preparedness, Schedule 8 compliance, and proximity to emergency care, without mandating formal accreditation.

What happens next

Until registered products become available, psychedelic-assisted psychotherapy remains an unapproved treatment under the AP scheme, with access strictly controlled while the evidence base develops.

- The TGA will **update external guidance materials and prescriber checklists** to reflect these changes.
- Final recommendations will be **incorporated into internal procedures** and implemented administratively.

Thank you again for your engagement and patience throughout this process.

Should you require further information, please contact the Authorised Prescribers team at authorised.prescribers@health.gov.au.

Kind regards,

**Unapproved Medicines Access Section
International Regulatory Branch**

Medicines Regulation Division | Therapeutic Goods Administration
Health Products Regulation Group
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The Department of Health, Disability and Aging 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.