# Australian regulatory perspective of psychedelic drugs in psychiatry

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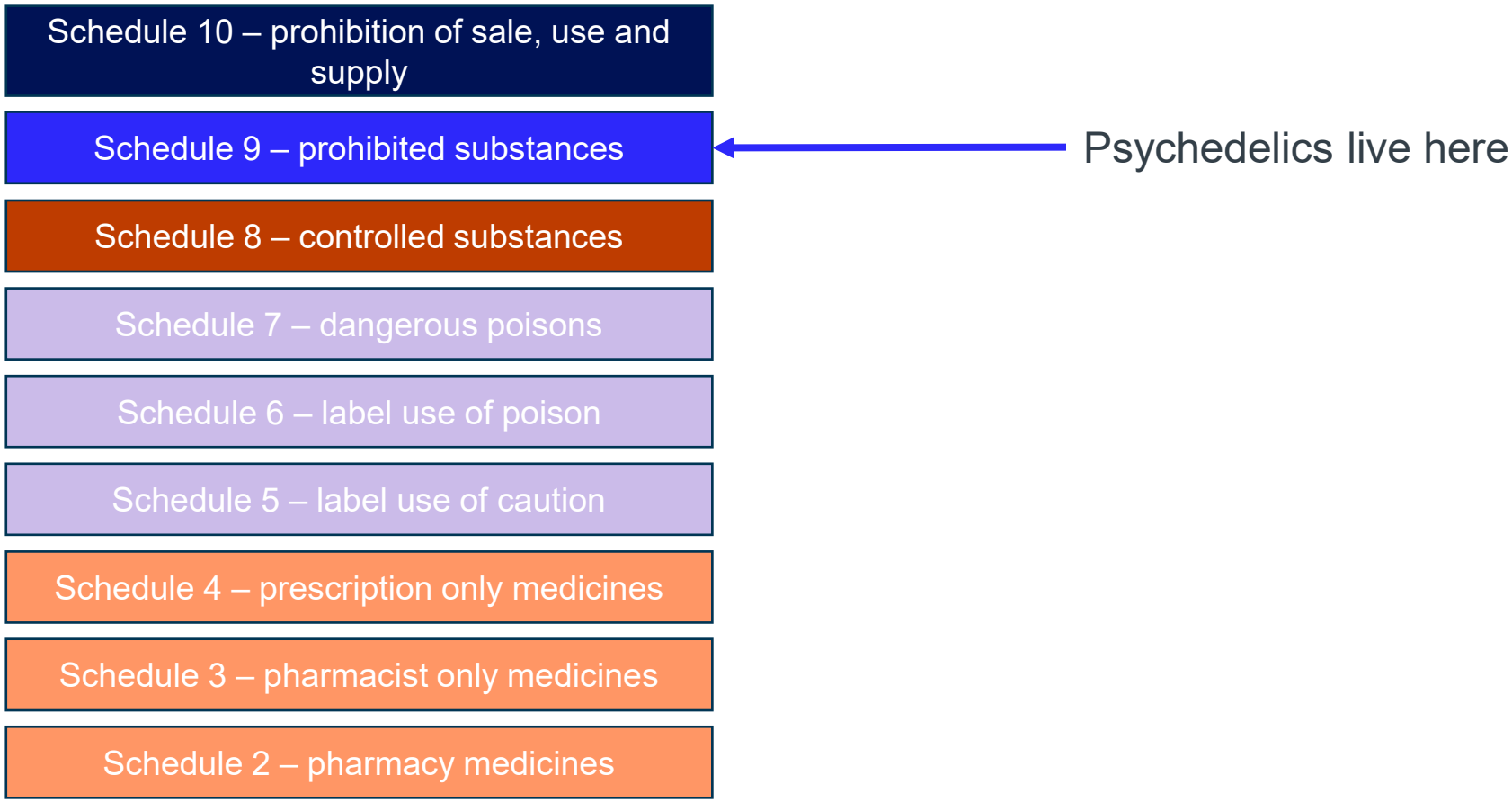
# To summarise..

- Down-scheduling of MDMA and psylocibin for the psychotherapy assisted treatment of PTSD and treatment resistant depression respectively as of July 1 2023.

- Allowed access to use by experienced psychiatrists under prescription, noting several restrictions are in place

- MDMA and psylocibin are NOT registered, but being prescribed through an unapproved goods pathway – the Authorised Prescriber pathway

# Scheduling Policy Framework




https://www.tga.gov.au/resources/resource/guidance/ahmac-scheduling-policy-framework-medicines-and-chemicals/scheduling-factors

# Scheduling Policy Framework

Schedule 10 – prohibition of sale, use and supply

Schedule 9 – prohibited substances

Schedule 8 – controlled drugs

Schedule 7 – dangerous poisons

Schedule 6 – label use of poison

Schedule 5 – label use of caution

Schedule 4 – prescription only medicines

Schedule 3 – pharmacist only medicines

Schedule 2 – pharmacy medicines

**S9 factors:**

- The substance has **no currently established therapeutic value** and is likely to present a high risk of dependency, abuse, misuse or illicit use.
- A high level of control is required through prohibition of manufacture, possession, sale or use to prevent abuse, misuse or diversion into illicit activities.
- The benefits of use are substantially outweighed by the risks, and dangers are such as to warrant limiting use to strictly controlled medical and scientific research.

**S8 factors:** The substance has an **established therapeutic value** but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.

**For Both:** The substance is included in Schedule I or II of the UN Single Convention on Narcotic Drugs 1961 or in Schedule II or III of the UN Convention on Psychotropic Substances 1971.

https://www.tga.gov.au/resources/resource/guidance/ahmac-scheduling-policy-framework-medicines-and-chemicals/scheduling-factors

# Rescheduling of MDMA and Psylocibin in PAT Decision making process - over two years

Two applications (2020 and 2022)

- Public submissions (over 13,000 submissions)
- Meeting of Advisory Committee on Medicines Scheduling
- Independent expert panel report – 15 Dec 2021
- Earlier decision (not to change scheduling) – 15 Dec 2021 and 21 Oct 2022

Further public consultation (almost 7,000 submissions)

Newer publication on psilocybin for major depression (NEJM Nov 2022)

Final decision – the poison's schedule was amending to down-schedule (Schedule 8). 3 February 2023

*The Delegate was satisfied that sufficient controls on access to the substances as Schedule 8 drugs for particular purposes could be included*

*These controls are more restrictive than what was proposed in the application to the TGA but are consistent with the clinical evidence supporting the therapeutic use of the substances*

# The Authorised Prescriber Scheme

Under the AP scheme, TGA grants a medical practitioner authority to prescribe a **specific unapproved medicine** for **particular indications** to a **class of patients** in their **immediate care**

To become an AP, **a medical practitioner must first obtain approval from a HREC** to prescribe the product under a protocol, including full consent process

Once a medical practitioner becomes an Authorised Prescriber, they must only report to the TGA the number of patients treated with the unapproved product twice yearly

There is **no application fee**

# What controls were in place?

- Only **Australian Registered Psychiatrists, FRANZCP,** with the relevant experience, can apply to be an Authorised Prescriber
- **approval from a Human Research Ethics Committee**
  - Clinical protocol – aligned with those from published studies
  - Consent form (including the specifics of the AP responsibilities)
  - Demonstrate a therapeutic relationship with the patient
  - Make-up of the remainder of the clinical team, relevant expertise.
- **authorised by the TGA to be an Authorised Prescriber. The TGA;**
  - encourages the use of products included in the ARTG
  - determines whether there are emerging safety concerns that would make approval or endorsement inappropriate
  - determines whether the requirements for authorisation as an Authorised Prescriber have been met
- **Comply with relevant State/Territory requirements re possession and supply**

# Obtaining psilocybin and MDMA

Although the scheduling of MDMA and psilocybin in the Poisons Standard has changed, except for prescription for Authorised prescribers, these substances remain as Schedule 9 (prohibited drugs).

The import, manufacture, possession and supply of these goods are prohibited under the Commonwealth Criminal Code, unless authorised under a law of the Commonwealth or a State or Territory.

This applies to all those involved in manufacture, possession and supply of goods containing MDMA and psilocybin. In addition to complying with Commonwealth laws, all those involved must also comply with state and territory legislation that applies to these goods.


**Note that**

- possession of the substances without authority (e.g. legal prescription) is illegal
- For other indications they remain as S9 prohibited substances (clinical trials only)
- Approval is not granted for protocols which enable the patient to be dispensed medicines containing these substances to take home

# Authorised Prescriber responsibilities

**Medical practitioners who become Authorised Prescribers must:**

- remain informed about changes to the benefits and risks of the good as they arise
- consider the potential benefits and risks of the ‘unapproved’ for each patient it is prescribed for
- obtain written informed consent from each patient before prescribing
- arrange supply of the goods directly through a sponsor or pharmacy
- monitor the patient during and after use of the ‘unapproved’ good
- provide the TGA with a six monthly report for the periods 1 January to 30 June and 1 July to 31 December. These reports must be supplied to TGA within one calendar month after the reporting period ends
- inform the TGA of adverse events associated with use of the good
- meet any conditions the TGA, HREC or specialist college applies to the approval or endorsement
- comply with relevant State or Territory legislation governing the supply of therapeutic goods. Approval as an Authorised Prescriber does not override State or Territory legislation

# Clinical guidance – the RANZCP

Clinical Memorandum

**Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression**

The Royal Australian & New Zealand

Your Health

| | |
|---|---|
| **Authorising Committee/Department:** | Psychedelic-A |
| **Responsible Committee/Department:** | Practice, Poli |
| **Document Code:** | **CM PPR The treatment re** |

**Key messages**

- Current evidence for PAT is drawn from research trials that feature psychotherapy as a core component of the treatment model. PAT is the use of a psychedelic drug as a tool to support or assist psychotherapy.
- The evidence base for PAT with either MDMA or psilocybin is limited and emerging. Patient safety is paramount and PAT carries unique risks that necessitates careful clinical judgement and clear communication with potential patients. The use of PAT with either MDMA or psilocybin is only recommended for those for whom established psychiatric treatment methods have been attempted without lasting success.
- Treatment protocols must be carefully designed and led by psychiatrists with appropriate training in PAT, including prior experience in treating at least one patient with PAT using the same psychedelic drug for the same indication in a clinical trial or in a clinical setting; failing this, the treating psychiatrists must be closely supervised by a psychiatrist who has prior experience with PAT.[2]
- The delivery of PAT using either MDMA or psilocybin must occur under highly controlled conditions and include the careful monitoring and reporting of efficacy and safety outcomes. Data, including on adverse events, must be collected systematically and longitudinally.

https://www.ranzcp.org/getmedia/0cf57ea2-0bd7-4883-9155-d2ba1958df86/cm-therapeutic-use-of-mdma-for-ptsd-and-psilocybin-for-treatment-resistant-depression.pdf

# Advertising controls

Prescription medicines and unapproved therapeutic goods such as MDMA or psilocybin are **prohibited by law from being advertised to the public**

**it is illegal** for Authorised Prescribers or healthcare facilities to indicate that they can prescribe and/or supply MDMA and/or psilocybin. But:

- MDMA and psilocybin may be advertised exclusively to health professionals provided there are means to prevent access to the advertisement by the public
- Information provided by a health practitioner to a patient during consultation or treatment is not subject to the advertising rules
- Presenting factual, balanced information about MDMA or psilocybin (e.g. at medical conferences) is unlikely to be considered advertising, but it depends on the context of the presentation

# AP reporting to date..

**16th April 2024**

9 individual psychiatrists approved to prescribe MDMA for PTSD, or psylocibin for TRD, or both for psychotherapy-assisted psychotherapy.

3 for MDMA use alone

3 for psylocibin alone

3 for both

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

**Six monthly report – supply of unapproved therapeutic goods by an authorised prescriber**

Six monthly report required under regulation 47B(1)(b) of the *Therapeutic Goods Regulations 1990*.

**Please complete only one form per doctor, per product, per reporting period.**

**Details of Authorised Prescriber**

| | |
|---|---|
| Name of Authorised Prescriber | |
| AHPRA number of Authorised Prescriber | |
| Unapproved product | |
| Authorised Prescriber approval number | |

**Reporting period for the six months**

(Select the period for which this report applies and complete the year.)

☐ 1 January – 30 June 20__

**OR**

☐ 1 July – 31 December 20__

**Number of patients**

| | |
|---|---|
| Number of new patients commenced on treatment or number of devices supplied | |
| Number of total patients treated during this period | |

Signature _____ Date _____

as public by the European Medicines Agency

# **We need clinical trials to continue**, especially for other indications - and the Schedule 9/CTN pathway enables this

**TGA receives a notification**, and **the HREC reviews** the scientific validity of the trial design, risk versus harm, ethical acceptability, and approves the trial protocol and monitoring trial conduct.

**Substances being imported or used for the trial** still require TGA/ODC approval/ permit

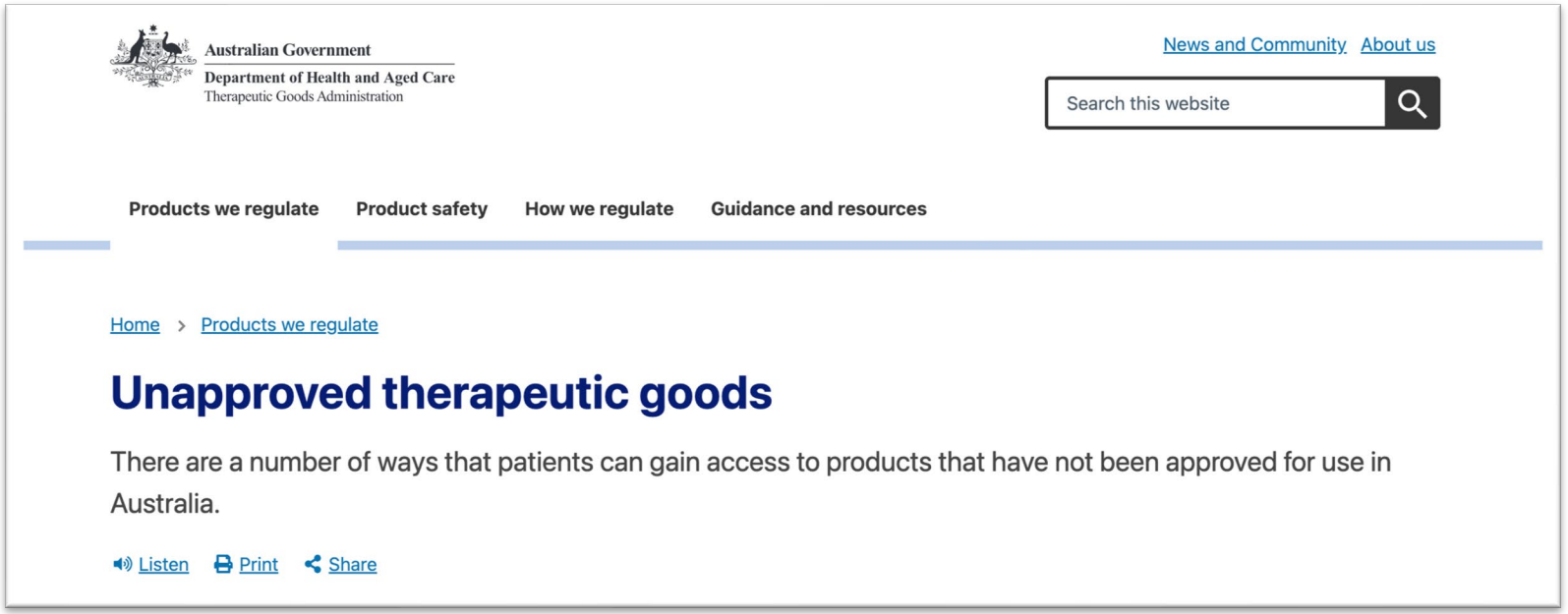
**Some current / approved Australian trials**

- Psilocybin – Treatment-resistant depression, Generalised Anxiety Disorder, Depression/ Anxiety in life-threatening illness, Substance use disorder, Motor symptoms in neurological disorders
- MDMA – Mood and anxiety in advanced cancer, PTSD,  Obsessive compulsive disorders

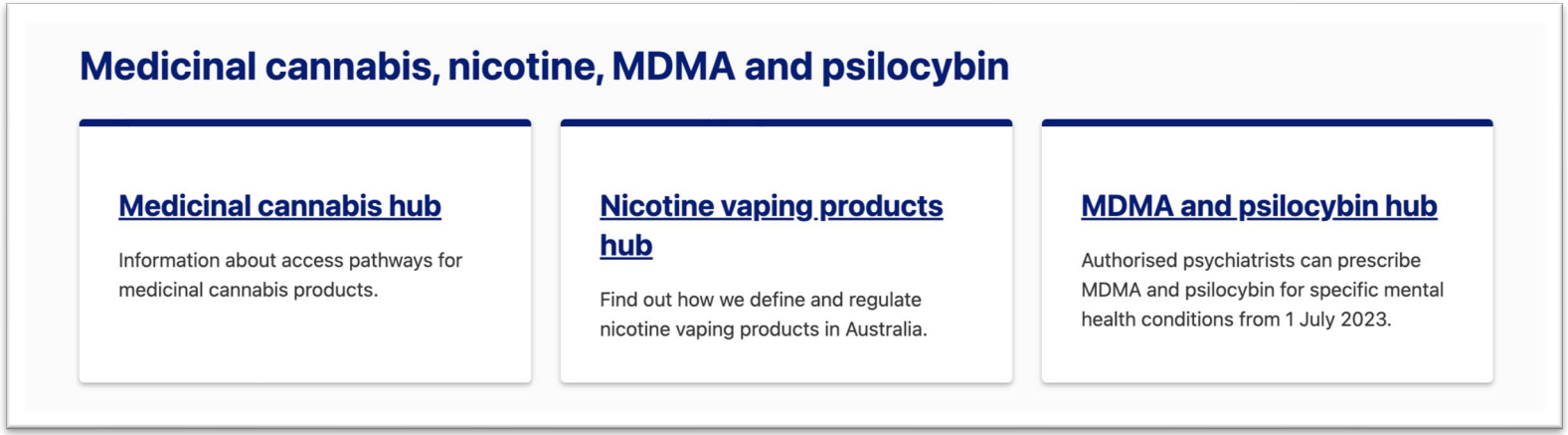
**Additional indications being trialled internationally** e.g. for psilocybin on clinicaltrials.gov

- Alcohol use disorder, cocaine use, tobacco addiction, smoking cessation
- Borderline personality disorder, Bipolar, Body dysmorphic disorder, suicidal ideation, autism spectrum disorder, binge eating, anorexia nervosa, obsessive compulsive disorder
- Parkinsons disease, early Alzheimers, migraine, chronic low back pain, fibromyalgia

# Resources




https://www.tga.gov.au/products/unapproved-therapeutic-goods

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