



LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

QON No. 12

SELECT COMMITTEE ON ESTIMATES 2024-2025

Ms Nicole Lawder MLA (Chair), Ms Suzanne Orr MLA (Deputy Chair),
Miss Laura Nuttall MLA

ANSWER TO QUESTION ON NOTICE

Asked By: Dr Marisa Paterson MLA

Addressed to: Minister for Mental Health

Reference:

Hearing Date: 23/07/2024

In relation to: Canberra Health Services and Patient access to MDMA/psilocibin treatments in the ACT

QON lodgement Date: 25/07/2024

Answer Due date: 01/08/2024

- (a) What conditions are approved for patients to access MDMA and psilocibin for treatment in the ACT?
- (b) What is the process for people in the ACT suffering PTSD should go through to access MDMA and psilocibin treatment?
- (c) It has been reported that eligible patients in the ACT are not able to access this treatment in the ACT, what is the ACT Government doing to ensure equitable access to this treatment for ACT residents?
- (d) Since the TGA approved these treatments last year, what work has the ACT Government done to ensure adequate training was undertaken by pharmacists, general practitioners, and psychiatrists in relation to the availability of these treatment options?
- (e) How many people in the ACT are being treated with MDMA, Psilocibin and Ketamine?
- (f) Can you provide a breakdown of the answer to Question 5 by treatment type and condition?
- (g) What work is the ACT Government doing to ensure that particular cohorts of the community that may be more prone to conditions such as PTSD - such as veterans, have access to this treatment?

Minister Emma Davidson: The answer to the Member's question is as follows:

- (a) Psychiatrists who are Authorised Prescribers (AP) under the Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme, hold Human Research Ethics Committee (HREC) approval and have completed training in psychedelic-assisted therapy can apply to the ACT Chief Health Officer (CHO) to prescribe:

- MDMA for the treatment of post-traumatic stress disorder (PTSD)
- Psilocybin for treatment-resistant depression (TRD)

Psilocybin is a Schedule 8 controlled medicine for treatment-resistant depression only. MDMA is a Schedule 8 controlled medicine for PTSD only. All other uses fall under Schedule 9 as a Prohibited substance.

ACT Health also assists psychiatrists, through education of their legislative requirements and the provision of research licences under the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act), to enable clinical trials to be conducted. Clinical trials may be undertaken to investigate MDMA or psilocybin used for conditions other than those approved within Schedule 8, or the clinical benefits of ketamine-assisted psychotherapy for treatment resistant depression.

- (b) Patients with a diagnosis of PTSD or TRD should visit their general practitioner and obtain a referral to a psychiatrist. They will need to be referred to a psychiatrist for whom the use of psychedelic-assisted psychotherapy is within their scope of practice, and who have completed the requirements under the TGA to become an AP and conform to the requirements in the ACT under the MPTG Act.

The psychiatrist would need to be an AP through the TGA Authorised Prescriber Scheme, hold HREC approval and have completed training in psychedelic-assisted therapy to be able to prescribe MDMA for PTSD, or psilocybin for TRD. The psychiatrist must then apply for a Category 7A CHO approval to prescribe to a patient in the ACT.

- (c) The down-scheduling MDMA for PTSD and psilocybin for TRD occurred on 1 July 2023. After this date, psychiatrists must complete a lengthy program of clinical study, prior to being able to prescribe these substances for patients, and seek HREC approval of their clinical protocols. It is expected it may take some time before any prescriber completes the training and is competent within their scope of practice to provide these new therapies.

Treatment with psychedelic-assisted psychotherapies with psilocybin, MDMA and/or ketamine, are not funded by the Commonwealth under the Pharmaceutical Benefits Scheme (PBS) as they are unapproved therapeutic goods on the Australian Register of Therapeutic Goods (ARTG), and there is currently limited research available to inform safety and efficacy. In Australia, the Commonwealth Government must balance access to new medicines against the cost to the Pharmaceutical Benefits Scheme.

It is anticipated that psychedelic-assisted psychotherapy may be associated with extensive costs due to the usage of unapproved medicines and the associated costs to provide repeated treatment sessions with a number of clinicians.

- (d) ACT Health supports prescribers (GPs and psychiatrists) to ensure they understand their obligations under the Controlled Medicines Prescribing Standards, prior to prescribing MDMA and psilocybin.

Psychiatrists must prescribe consistently under the Royal Australian and New Zealand College of Psychiatry (RANZCP) guidelines. Access to this treatment requires expertise that is led by psychiatrists with appropriate, specialist and experiential training in psychedelic-assisted treatments.

- (e) As at 29 July 2024, ACT Health has not received any applications to prescribe MDMA or psilocybin under Schedule 8 for PTSD or TRD, respectively. However, there are a limited number of clinical trials being undertaken by prescribers under Schedule 9.

Ketamine is currently indicated as the sole anaesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, for the induction of anaesthesia

and to supplement low potency agents. All other purposes for ketamine require approval under the MPTG Controlled Medicines Prescribing Standards. ACT Health is currently reviewing the usage of ketamine in the ACT, to ensure clinically appropriate access, and regulatory oversight to protect the community and reduce the incidence of harms.

It is difficult to provide a distinct number of patients receiving ketamine as usage within surgical procedures does not need to be reported to ACT Health, and other uses of psilocybin and MDMA within clinical trials are minimal.

(f) See above.

(g) The RANZCP guideline regarding these treatments specifies that the field is developing with treatments remaining experimental, and patient safety a primary concern.

The ACT is consistent with other jurisdictions in respect to utilising psychedelic-assisted treatments in psychiatric care. For further information about the RANZCP guideline can be found at <https://www.ranzcp.org/clinical-guidelines-publications/in-focus-topics/psychedelics>.

The Australian National University has a Psychedelic Assisted Psychotherapy Research Registry which provides further information about current clinical trials in the ACT.

ACT Health is aware that Department of Veteran Affairs (DVA) is supporting veterans to access psychedelic-assisted psychotherapy, however, as DVA is a Commonwealth agency, ACT Health does not have access to this data.

Approved for circulation to the Select Committee on Estimates 2024-2025

Signature: *Emma Davidson*

Date: 5 August 2024

By the Minister for Mental Health, Emma Davidson MLA