

4 March 2020

Advisory Committee on Medicines Scheduling (ACMS)  
Therapeutic Goods Administration

By email to: [medicines.scheduling@health.gov.au](mailto:medicines.scheduling@health.gov.au)

Dear Secretariat

**Re: Public consultation on interim decisions to amend the Poisons Standard –  
November 2020 ACMS/ACCS meetings**

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide input on the interim decision to amend the Poisons Standard made at the Therapeutic Goods Administration (TGA) Advisory Committee on Medicines Schedule (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS) meetings in November 2020.

The RANZCP is responsible for training, educating and representing psychiatrists in Australia and New Zealand. The RANZCP has more than 6700 members, including around 5000 fully qualified psychiatrists. In developing this submission, the RANZCP consulted widely with members, including the Faculty of Addiction Psychiatry, Faculty of Psychotherapy, and Committee for Evidence-based Practice. The RANZCP is well positioned to provide assistance and advice about issues that relate to mental disorders due to the breadth of academic, clinical, and service delivery expertise it represents.

The RANZCP wishes to provide comment on items 2.4 and 2.5.

## **2.4 Psilocybin**

The RANZCP supports the interim decision not to amend the current Poisons Standard in relation to psilocybin. As outlined in its original submission, the RANZCP supports that research into the clinical use of psilocybin should only occur under research trial conditions that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.

While trials have provided encouraging results, it is the RANZCP's position that it is important to recognise that the evidence available is limited and insufficient to comprehensively assess the efficacy, safety, and effectiveness of psilocybin to inform future potential use in psychiatric practice at this point. In particular phase 3 data from trials for psilocybin-assisted psychotherapy is not yet available.

The RANZCP recognises that further research, referenced in the interim decision, has been undertaken since the RANZCP published its *2020 Clinical Memorandum: The therapeutic use of psychedelic substances*. The RANZCP has reviewed this further research, including recent meta-analyses, and maintains its position. The RANZCP will ensure to carefully review any further research evidence when updating its clinical memorandum in 2021.

The RANZCP further supports that, in addition to better safety and efficacy data, there is a need to ensure safe and ethical use, prior to any decision to down-schedule psilocybin. Of particular concern to the RANZCP is the need to recognise that psilocybin is not a treatment in itself and that the presence of psychological support is an essential component of the psychedelic treatment model. This mandates carefully designed trials within safe and comfortable settings led by researchers with appropriate psychiatric and psychotherapy training, including specific training in psychedelic psychotherapy. Presently only a limited number of professionals are currently trained to provide psilocybin-assisted psychotherapy putting patients at risk of potential harm if used outside of research trials. Therefore, a move to Schedule 8 would be premature and, further, limit the ability for data to be recorded and evaluated as part of a formally constituted research trial to inform appropriate treatment methodologies.

### **2.5 N, $\alpha$ -Dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA)**

The RANZCP supports the interim decision not to amend the current Poisons Standard in relation to MDMA. As outlined in its original submission, the RANZCP supports that research into the clinical use of MDMA should only occur under research trial conditions that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.

The RANZCP recognises the emerging evidence for the use of MDMA for people with PTSD, noting that the trials provide encouraging results that provide initial evidence of safety and efficacy, but support that more rigorous follow-up is required in phase III trials. In particular 'Breakthrough Therapy Designation' that has been granted by United States Food and Drug Administration (FDA), indicates that the therapy shows promise, but does not equate to FDA approval that is equivalent in category to Schedule 8.

The RANZCP recognises that further research, referenced in the interim decision, has been undertaken since the RANZCP published its *2020 Clinical Memorandum: The therapeutic use of psychedelic substances*. The RANZCP has reviewed this further research, including recent systematic reviews and meta-analyses, and maintains its position. The RANZCP will ensure to carefully review any further research evidence when updating its clinical memorandum in 2021.


As outlined above in response to 2.4 (psilocybin), only a limited number of professionals are currently trained to provide MDMA-assisted psychotherapy, and premature down-scheduling may put patients at increased risk of harm and limit opportunities for recording and evaluating data.

Whilst the RANZCP acknowledges that under Schedule 8, the prescribing of both psilocybin and MDMA would be subject to controls under TGA's Special Access Scheme (SAS) pathway B or Authorised Prescriber Scheme, the RANZCP supports the view that the ethical, legal and training framework to provide appropriate safeguards to psychedelic-assisted therapy is currently insufficient and underdeveloped to support down scheduling at this time.

The RANZCP further notes that its position on the need for further evidence prior to expanding the use of psilocybin and MDMA into clinical practice is no different from that of any other therapy or intervention that requires further research, and is in line with other relevant international psychiatry bodies, including the American Psychiatric Association (see: [Psychedelics for Psychiatric Disorders: More Research Needed | Psychiatric News \(psychiatryonline.org\)](#) and the Royal College of Psychiatrists (UK). As previously stated, should the evidence for safety and efficacy sufficiently advance, we would be pleased to reconsider our position at that point.

To discuss any of the issues raised in this letter, please contact Rosie Forster, Executive Manager, Practice, Policy and Partnerships Department via [rosie.forster@ranzcp.org](mailto:rosie.forster@ranzcp.org) or by phone on (03) 9601 4943.

Yours sincerely



Associate Professor John Allan  
**President**

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