28 September 2020

Advisory Committee on Medicines Scheduling (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS)
Therapeutic Goods Administration

By email to: medicines.scheduling@health.gov.au

Dear Secretariat

Re: Proposed amendments to the Poisons Standard – November 2020 Joint ACMS/ACCS meetings

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide input into proposed amendments Poisons Standard to be discussed at the Therapeutic Goods Administration (TGA) Joint ACMS/ACCS meetings in November 2020.

The Royal Australian and New Zealand College of Psychiatrists (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 and the 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 is providing comment on applications 1.2, 1.5 and 1.6.

- **1.2 Cannabidiol**

The RANZCP's clinical memorandum in relation to the medicinal use of cannabinoids supports more research into the use of cannabinoids for medical treatment. It is important to ensure that ongoing, long-term research is continued to ensure safety and best outcomes with the use of all cannabinoids, including cannabidiol (CBD) products. The RANZCP does not support the inclusion of synthetic or semi-synthetic CBD within Schedule 4 as listed in the application. Synthetic CBD products currently represent an inconsistent market; there are concerns about the 2% impurity rate, including evidence that synthetic CBD may have psychoactive potential that would not be found in plant-derived CBD. [1]

- **1.5 Psilocybin**
- **1.6 N, α-Dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA)**

The RANZCP notes that these applications are for the rescheduling of psilocybin and MDMA for medicinal use from Schedule 9 (Prohibited Substances) to Schedule 8 (Controlled Medicines). The RANZCP is responding to these applications collectively as the issues

309 La Trobe Street, Melbourne VIC 3000 Australia
T +61 3 9640 0646 F +61 3 9642 5652
ranzcp@ranzcp.org www.ranzcp.org
ABN 68 000 439 047

raised in this submission are relevant to both applications. When using the term 'psychedelics' in this submission, this refers to both psilocybin and MDMA.

In summary the RANZCP does not support the rescheduling of psychedelics from Schedule 9 to Schedule 8 at this time. Whilst accepting that, under Schedule 8, psychedelics would be available only under medically controlled situations, the RANZCP is necessarily conservative given the history of emerging psychiatric practices being approved without the required level of evidence or necessary safeguards in place. The RANZCP is supportive of further research and clinical trials in this area as way of developing the evidence base to inform future discussions about the TGA scheduling of psychedelic therapies.

Evidence and safety

In May 2020 the RANZCP published a clinical memorandum on the therapeutic use of psychedelic substances. This memorandum states that:

- There is limited but emerging evidence that psychedelic therapies may have therapeutic benefits in the treatment of a range of mental illnesses.
- Further research is required to assess the efficacy, safety and effectiveness of psychedelic therapies to inform their future potential use in psychiatric practice.
- Research into the clinical use of psychedelic substances 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.

When rescheduling a substance, we understand that the TGA takes into account a range of factors including risks and benefits, purpose and extent to be used, toxicity and safety, dose, formation and packaging, and potential for misuse.

The RANZCP acknowledges the evidence and safety information provided within the applications for the potential use of psychedelics in the treatment of non-psychotic disorders, particularly psilocybin for people with depression and anxiety and MDMA for people with PTSD. These trials have provided encouraging results that provide initial evidence of safety and efficacy, although most have not been appropriately designed to demonstrate this conclusively.

Whilst the RANZCP encourages and is open to better and more effective treatments, it is important to recognise that the evidence available is limited and insufficient to comprehensively assess the efficacy, safety and effectiveness of psychedelic therapies to inform future potential use in psychiatric practice at this point. [2] In particular sample sizes within the trials have generally been very small, and more research is needed to examine whether there are any long-term benefits or harms.

There is a range of effective and evidence-based treatments currently available in psychiatry for the treatment of mental disorders, and the RANZCP supports their ongoing use whilst simultaneously expanding the evidence-base for psychedelics via clinical trials.

Regulatory controls and education

The rationale for this application is that, as a Schedule 8 controlled medicine, psychiatrists and specialist addiction physicians will be able to more easily access these medicines for

use in patients with specific mental disorders. The RANZCP recognises that research into the therapeutic potential of psychedelic substances has been limited by legal restrictions and practical difficulties. Currently there is the option for psychiatrists to apply to prescribe psychedelics under the TGA's Special Access Scheme (SAS) pathway B or through the authorised prescriber scheme. However, as Schedule 9 substances, additional state or territory permissions are required to allow these to be prescribed outside clinical trials that are rarely, if ever, granted.

Whilst including psychedelics under Schedule 8 would remove some of these barriers, this move would be premature and potentially adversely impact the development of the greater scientific evidence-base that is required. In particular there is an ongoing need to collect outcomes and adverse event data systematically in a manner that allows aggregated analyses. Opening access to psychedelic therapy outside of clinical trials may impact the ability to recruit patients for clinical trials of psychedelic therapies to contribute further to this dataset. Whilst acknowledging that these data may be recorded and evaluated outside of clinical trials, the RANZCP suggests that appropriate treatment methodologies, adequate training, and an ethical and legal framework that provides appropriate safeguards are not sufficiently developed to inform this.

The RANZCP is further conscious that, given the use of psychedelics as recreational drugs, these substances are of significant political and public interest. They have not yet been regulated for therapeutic use in any country. The RANZCP suggests therefore that consideration be given to societal risks, given rescheduling could be interpreted as messaging that psychedelics are 'safe and good for you' and encourage recreational use, outside of medically controlled use, with potential detrimental effects. It is suggested that impartial public and medical practitioner education that reflects the current state of knowledge and contextualises the use of psychedelics is also required prior to any rescheduling of these substances.

The RANZCP would like to emphasise the importance of regulating cannabinoids and psychedelics using the same rigor and safeguards as other pharmaceuticals and ensuring that any changes in relation to accessibility is based in the most up-to-date, sound research and evidence.

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 or by phone on (03) 9601 4943.

Yours sincerely

Associate Professor John Allan
President

Ref: 1919

References

1. Therapeutic Goods Administration. Safety of low dose cannabidiol. April 2020: https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf

2. Reiff CM, Richman EE, Nemeroff CB, Carpenter LL, Widge AS, Rodriguez CI, Kalin NH, McDonald WM, Work Group on Biomarkers and Novel Treatments, a Division of the American Psychiatric Association Council of Research. Psychedelics and psychedelic-assisted psychotherapy. American Journal of Psychiatry. 2020 May 1;177(5):391-410.