27 May 2022

Medicines Scheduling
Therapeutic Goods Administration

Dear Advisory Committee on Medicines and Chemicals Scheduling

Re: Public consultation on proposed amendments to the Poisons Standard - Advisory Committees on Medicines and Chemicals Scheduling, June 2022

Thank you for seeking the views of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) on the proposals to amend the Poisons Standard to be discussed at the June 2022 meetings of the Advisory Committee on Medicines Scheduling. The RANZCP is responding to applications 2.3, 2.4 and 3.3.

Application 2.3 N,α-Dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA)
The RANZCP does not support amending the Poisons Standard for MDMA to allow Schedule 8 entry for restrictive medical use in the circumstances outlined.

Application 2.4 Psilocybine (psilocybin[1])
The RANZCP does not support amending the Poisons Standard to reschedule psilocybin to allow Schedule 8 entry for restrictive medical use in the circumstances outlined.

Comments in relation to applications 2.3 and 2.4

Evidence for MDMA and psilocybin

For up-to-date evidence relating to the use of both MDMA and psilocybin the RANZCP refers to existing systematic literature reviews and meta-analyses on the mental, behavioural or developmental disorders, including the Systematic literature review of the therapeutic value, benefits and risks of MDMA and psilocybin for the treatment of mental health conditions report prepared for the Therapeutic Goods Administration (TGA) which has subsequently been updated and published in the Australian and New Zealand Journal of Psychiatry. [1, 2]

In addressing the issue of the established therapeutic value of MDMA, the applicant states that further evidence for the use of this substance in the treatment of mental health conditions, including PTSD, has emerged since the previous MDMA decision. In particular, the applicant cites a phase 3 study published in June 2021. [3]

In addressing the issue of the established therapeutic value of psilocybin, the applicant states that further evidence for the use of this substance in the treatment of mental health

[1] It is noted that application 2.4 refers to the chemical name psilocybine. The RANZCP uses the synonym psilocybin throughout its response as the term referred to most commonly in literature.

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conditions, including treatment resistant depression, has emerged since the previous psilocybin decision. In particular, the applicant cites two separate phase 2 studies published in May 2021 and November 2021. [4, 5] With the exception of the study released by Compass, these studies were previously reviewed within the TGA report where the overall evidence for MDMA and psilocybin was rated being low to very low, and formed the basis of the TGA's decision not to reschedule these substances. This therefore does not constitute updated evidence. The further study by Compass has not been peer reviewed with the data published as an investor and media release statement. [5] This statement omits to mention that there was no significant difference between the active and control arms in terms of protocol defined remission at 12 weeks, which is different from the outcome reported where there was a significant difference.

Restrictive medical use

It is recognised that the applicant has proposed a more limited basis for use under Schedule 8 listings particularly in regard to training, and the requirement for independent psychiatrists' review of treatment plan. Whilst the RANZCP supports safeguards, in practice there are not yet adequate protocols in place to support translation from clinical trial setting to the community setting. [6] As outlined in the final TGA decision, the potential for poor clinical practice is significant which needs to be addressed prior to any change in regulation. [7]

There is an ongoing need to collect efficacy and adverse event data systematically and longitudinally in a manner that allows aggregated analyses. At this stage, this can best be achieved through formal research channels, and efforts to promote research are encouraged. The RANZCP looks forward to the outcome of trials within Australia, including those funded under the 2021 Innovative Therapies for Mental Illness grants offered as part of the Medical Research Future Fund (MRFF) Clinical Trials Activity Initiative and through initiatives such as the The Clinical Psychedelic Research Lab at Monash University.

In addition to collating further data on efficacy, the RANZCP supports ongoing collaboration within the psychiatry community to establish appropriate safeguards and protocols to ensure that, as evidence develops sufficiently, formal frameworks are in place to support practice. The RANZCP understands the urge to fast-track approval of novel treatments which are showing promise, but is concerned about rushing to expand access without the necessary frameworks in place. The RANZCP supports continued dialogue between relevant organisations as to how the use of these substances can best translate from research to community clinics, as the evidence continues to develop through research trials.

In view of the above the RANZCP supports maintaining the decision made by TGA to not amend the current Poisons Standard for psilocybin and MDMA until further research has more clearly determined the therapeutic value benefits and risks, and the development of best practice frameworks for clinical use have been subsequently developed.

Application 3.3 N,α-Dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and 3,4-methylenedioxyamfetamine (MDA)

This proposal from a private applicant requests to reference the international non-proprietary names (INNs) for MDMA and MDA as midomafetamine and tenamfetamine respectively, with retention of the original names as cross-references in the respective index entries for each substance.

It is suggested that the proposed change may be most relevant from a marketing perspective where the application may wish to distance the agents from the possible association or stigma of being called MDMA and MDA, which may be seen as Illicit recreational substances. The RANZCP does not have a strong position on this proposed change, but would seek to ensure that any name change be accompanied by clear communication to the community to avoid confusion and misinterpretation.

If you would like to discuss any of the issues raised, please contact Nicola Wright, Senior Manager, Policy and Practice and nicola.wright@ranzcp.org or by phone on (03) 9601 4943.

Yours sincerely

Associate Professor Vinay Lakra
President

Ref: 2995

References

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7. Therapeutic Goods Administration. Notice of final decision to not amend the current Poisons Standard - Psilocybin and MDMA available at: https://www.tga.gov.au/sites/default/files/notice-final-decisions-amend-or-not-amend-current-poisons-standard-relation-psilocybin-and-mdma.pdf. December 2021.