Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of interim decisions to amend (or not amend) the current Poisons Standard

21 October 2022

TGA Health Safety Regulation

appropriately in Australia. It is my view that the Proposal would contravene the QUM's approach to using medicines safely with respect to the use of budesonide. The addition of a Schedule 3 entry would also be inconsistent with international regulations, with the USA, Canada, Ireland and New Zealand all regulating inhalational budesonide products as prescription only medicines.

I have also noted the submissions from the Royal Australian College of General Practitioners, the Australian Medical Association, and Asthma Australia. All expressed their concerns in relation to the Proposal, citing the importance of appropriate diagnostic tools, monitoring of any disease progression and the ability to check patient history to properly diagnose asthma.

Having considered the need for medical practitioner oversight and the risks to consumers due to the lack of patient review and follow up, and the increased risk of inappropriate use, I have decided that the current scheduling of budesonide is appropriate.

2.3 Interim decisions in relation to psilocybine and MDMA

This section contains two independent interim decisions in respect to (i) psilocybine and (ii) MDMA (the **substances**). Given the current scheduling and the proposed amendments to the Poisons Standard in relation to the substances are identical, and their nature and intended uses provided by the proposed amendments are highly similar, the reasons for making the interim decision for each substance are substantially the same. As such, these reasons have been consolidated to assist the reader.

Proposals

Psilocybine

The applicant proposed the creation of a Schedule 8 entry for the use of psilocybine in combination with psychotherapy for treatment resistant mental illness in medically controlled environments in certain circumstances (the **current psilocybine proposal**). Psilocybine is currently included in Schedule 9, which limits its use to authorised research and analytical purposes only.

MDMA

The applicant has proposed the creation of a Schedule 8 entry for the use of MDMA in combination with psychotherapy for treatment resistant mental illness in medically controlled environments in certain circumstances (the **current MDMA proposal**). MDMA is currently included in Schedule 9, which limits use to authorised research and analytical purposes only.

Interim decisions

Pursuant to regulation 42ZCZN of the *Therapeutic Goods Regulations 1990* (Cth) (the **Regulations**), a delegate[3] of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made the following two interim decisions (the **present decisions**):

(i) to not amend the current Poisons Standard in relation to psilocybine.
(ii) to not amend the current Poisons Standard in relation to MDMA.

The Delegate's detailed reasons for the present decisions follow.

Materials considered

In making the present decisions, the Delegate considered the following material.

In relation to psilocybine:

- The application to amend the current Poisons Standard with respect to psilocybine (the **psilocybine application**);
- The 6,650 public submissions on the current psilocybine proposal, including 2,332 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **psilocybine submissions**);
- The advice concerning the Psilocybine Application received from the 38th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**); and
- The Delegate's final decision to not amend the Poisons Standard in relation to psilocybine on 15 December 2021 (the **previous psilocybine decision**) and the materials they considered in making those decisions.

In relation to MDMA:

- The application to amend the current Poisons Standard with respect to MDMA (the **MDMA application**);
- The 6,505 public submissions on the current MDMA proposal, including 2,068 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **MDMA submissions**);
- The advice concerning the MDMA Application received from the 38th meeting of the Committee; and
- The Delegate's final decision to not amend the Poisons Standard in relation to MDMA on 15 December 2021 (the **previous MDMA decision**) and the materials they considered in making that decision.

In relation to both Substances:

- The Independent expert panel report on *an evaluation of the therapeutic value, benefits and risks of methylenedioxymethamphetamine (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders* (the **Expert Report**);
- The Royal Australian and New Zealand College of Psychiatrists' (RANZCP) clinical memorandum on the therapeutic use of psychedelic substances published in July 2022;
- The international regulatory status of the Substances and access pathways;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework for medicines and chemicals 2018 (the **SPF**); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of Committee advice to the Delegate

The Committee individually considered the psilocybine application and the MDMA application and recommended that the current scheduling for each substance remains appropriate.

Members agreed that the matters under Section 52E(1) of the Act relevant to both substances are: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is

to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.

The Committee was of the view that there was insufficient additional evidence of the therapeutic value of either psilocybine or MDMA provided in the respective applications, compared to that considered in making the previous psilocybine or MDMA decisions, to now consider that the therapeutic value of either substance has been established. As such, the Committee considered that there was no basis on which to depart from its advice provided at its 36th meeting in November 2021 to not vary the scheduling of psilocybine and MDMA, and its reasons provided at that meeting are equally applicable to the present application.

Psilocybine

The reasons for the Committee's advice with respect to psilocybine included:

g) the risks and benefits of the use of a substance;

Risks:

- Can cause transient increase in blood pressure and tachycardia. Trials suggest some risk of suicidal ideation, although it is not clear at this stage if this is attributable to the treatment or illness. Some risk of psychosis in at-risk individuals.
- Extensive exclusion criteria for clinical trials limits generalisability to the wider population.

Benefits:

- The benefits include emerging evidence of efficacy in treating depression with demonstrated low risk of adverse events with short-term use in controlled settings.
- Possible, albeit less convincing, benefit in treating other mental health conditions.

h) the purposes for which a substance is to be used and the extent of use of a substance;

- For use as an adjunct to psychotherapy (in psychedelic-assisted psychotherapy) for treatment-resistant depression.
- Clinical trials are underway for treatment of other conditions in similar settings.

i) the toxicity of a substance;

- based on animal studies, the lethal dose is extrapolated to 6 g in humans, equivalent to 300 times the typical therapeutic dosage.

j) the dosage, formulation, labelling, packaging and presentation of a substance;

- Trialled dosage includes 25 mg capsule (for patients up to 90 kg bw), 30 mg capsule (90 -115 kg) and 35 mg (>115 kg).
- Dosage forms are likely to be compounded by a pharmacist.
- It is unclear at this stage how the medication will be dispensed to a practitioner. No product for registration.

k) the potential for abuse of a substance;

- Low risk of addiction.

- Potential for diversion for recreation use. This is manageable in the clinical setting through Schedule 8 requirements, but concerns of diversion at other points throughout distribution still exist.

l) any other matters considered necessary to protect public health;

- Increased risk of use beyond the conditions for which there is clinical trial evidence of therapeutic benefit.
- Emerging evidence of therapeutic value, but not yet established as required by scheduling policy framework for Schedule 8.
- The risks and benefit of the substance not solely dependent on the substance but also on the skill of the therapist guiding patient through altered state of consciousness.
- Concerns with using down-scheduling as a mechanism to bypass the processes for clinical trials, by inserting specific requirements (to mirror a clinical trial environment) in the entry to allow it to fit a lower schedule.

MDMA

The reasons of the Committee with respect to MDMA included:

a) the risks and benefits of the use of a substance;

Risks:

- Acute effects include high blood pressure and pulse rate, faintness and panic attacks. In severe cases, MDMA can cause loss of consciousness and seizures.
- Secondary effects include involuntary jaw clenching, lack of appetite, depersonalisation, illogical or disorganised thoughts, restless legs, nausea, hot flashes or chills, headache, sweating and muscle/joint stiffness.
- Long-term use can result in sleep disturbances, difficulties with concentration, depression, heart disease, impulsivity and decreased cognitive function.

Benefits:

- There is limited but emerging evidence that MDMA-assisted psychotherapy may have therapeutic benefits in the treatment of PTSD in closely supervised clinical settings with intensive professional support. These benefits are currently under investigation in clinical trials.

b) the purposes for which a substance is to be used and the extent of use of a substance;

- For use as an adjunct to psychotherapy (psychedelic-assisted psychotherapy) for post-traumatic stress disorder.
- MDMA-assisted psychotherapy sessions typically last 6 - 8 hours, relying on two trained specialists. The regime consists of 1 - 3 psychedelic-assisted therapy sessions, usually supplemented with 'integrative' therapy sessions where MDMA is not used.

c) the toxicity of a substance;

- The lethal dose is estimated at 10-20 mg/kg bw
- Due to the novel nature of the treatment, the adverse effects in the context of psychotherapy, outside of the acute effects, are largely unknown.

d) the dosage, formulation, labelling, packaging and presentation of a substance;

- Optimal dosages have not been established, especially outside of clinical trials for the treatment of PTSD.
- A typical dose in the context of psychotherapy ranges from 30-125 mg. This is often followed by an optional half-dose 1.5 to 2.5 hours into the session.

e) the potential for abuse of a substance;

- It is not clear whether MDMA causes dependence. However, it affects many of the same neurotransmitter systems in the brain that are targeted by drugs with an abuse and dependence liability, and some studies report symptoms of dependence in users.

f) any other matters considered necessary to protect public health;

- There remains significant doubt regarding the degree to which the psychedelic/psychotherapy interaction is dependent on the specific type of psychotherapy administered. This raises the question as to the stringency with which protocols need to be followed and the practicality for implementing these in clinical practice outside of the highly controlled clinical trial environment.
- There are currently no medicines containing MDMA proposed for inclusion or already included in the ARTG.
- There are significant benefits to waiting for the results of clinical trials. MDMA-assisted psychotherapy may prove to be safe and efficacious, but the evidence does not yet suggest this - especially for conditions outside of PTSD.
- It will take time to develop a curriculum and accredited training process for psychiatrists. To protect public health and prevent inappropriate use, MDMA should not be down-scheduled until all necessary safeguards have been established and implemented.
- A substantial evidence base will be required to inform a curriculum and accredited training process for psychiatrists. To protect public health and prevent inappropriate use, MDMA should not be down-scheduled until all necessary safeguards have been established and implemented.
- There is a high risk of diversion for misuse, even in conjunction with Schedule 8 controls.
- Scheduling is not an appropriate mechanism for establishing clinical governance of the therapeutic use of MDMA.

Reasons for the interim decisions (including findings on material questions of fact)

I have made the present decisions because I am of the view that retaining the current entries for these substances in Schedule 9 ensures appropriate control over their access. In reaching this view, I am satisfied that both psilocybine and MDMA meet the scheduling factors for Schedule 9 in the SPF, and the currently limited evidence of benefit for both substances is outweighed by the risks to patients and public health from any increased access. Insufficient new information or clinical evidence for either substance has been presented by the applicant since I made the previous psilocybine and MDMA decisions to depart from those decisions. The detailed reasons for my present decisions follow.

I agree with the Committee's findings on the relevant provisions of section 52E of the Act. Paragraph 52E(2)(a) provides that in exercising the power under subsection 52D(2), I must comply with the SPF.

The SPF sets out the factors to consider for Schedule 8, which are:

1. The substance is included in Schedule I or II of the *United Nations Single Convention on Narcotic Drugs 1961* or in Schedule II or III of the *United Nations Convention on Psychotropic Substances 1971*.

2. 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. The substance has an established therapeutic value but by reason of its novelty or properties carries a substantially increased risk of producing dependence.

The factors to consider for Schedule 9 are:

1. The substance is included in either Schedule IV to the *United Nations Single Convention on Narcotic Drugs 1961* or in Schedule I of the *United Nations Convention on Psychotropic Substances 1971*.

2. The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use.

Pursuant to paragraph 52E(1)(a) and in view of the SPF, I note that my previous psilocybine and MDMA decisions turned in significant part on the lack of established therapeutic value of the substances, and by extension the uncertain benefit from their use in patients. I considered that these substances did not meet the Schedule 8 scheduling factors and the risks outweighed the benefits from down-scheduling them.

In this context, in relation to those completed studies that were before me in making my previous psilocybine and MDMA decisions, I am not persuaded by the applicant's arguments in the current psilocybine and MDMA applications that my concerns about the quality of these studies were unfounded. In this regard I have attached significant weight to the analysis and findings of the Expert Report.

I note evidence has been presented in the current psilocybine and MDMA applications that is additional to what was before me, including in the previous applications by the same applicant, when I made the previous psilocybine and MDMA decisions. Before turning to my consideration of this evidence, I acknowledge the applicant's arguments about the definition of 'established' therapeutic value. I agree with the applicant that therapeutic value of a substance may be 'established' for the purposes of the SPF, despite there being insufficient efficacy evidence to support the inclusion of a product containing that substance in the Australian Register of Therapeutic Goods (ARTG). However, I am of the view that for the therapeutic value to be 'established' the evidence must, contrary to the applicant's arguments, go beyond the mere existence of completed clinical trials and an apprehension of therapeutic value based on a small number of promising trial results.

Turning to the additional evidence, in relation to psilocybine, one phase II trial[5] has been completed that has not yet completed its final analysis of all data and endpoints nor been peer reviewed or published. I acknowledge that this study indicates significant improvement in outcomes for patients with treatment resistant depression who were administered a dosage of 25 mg, but not for 1 mg or 10 mg, of psilocybine. The details of an additional published study were also included in the psilocybine application, which was a 12-month follow up of 24 patients who were given two doses of psilocybine at 25 mg or 30 mg two weeks apart with assisted psychotherapy. The results showed that two doses of psilocybine for major depressive disorder produced large and stable antidepressant effects throughout a 12-month follow-up period in a select number of patients. Specifically, that there was a decrease in the depression score (GRID-

[5] Compass Ph2b clinical trial results: https://ir.compasspathways.com/static-files/0f9fbce8-2619-438b-a6ba-5bbe2ba08cf6

Hamilton Depression Rating Scale (GRID-HAMD)). Further high and stable rates of response and remission occurred throughout the follow-up period.[6]

While these studies represent increasing evidence of the long-term benefits of even small doses of psilocybine in conjunction with psychotherapy, I remain of the view and agree with the Committee that this is insufficient to consider that the therapeutic value of psilocybine is *established*. I share the Committee's concerns regarding: the broadness of the indication (treatment-resistant mental illness) included in the current psilocybine proposal, as this appears to be much broader than the indications for which there is emerging evidence (such as treatment-resistant depression); the lack of phase III trials; and the problems associated with the translation from a clinical trial setting to clinical practice. All of these concerns raise significant doubt about the established therapeutic value of psilocybine and the benefits likely to be realised were the current psilocybine proposal to be adopted.

In relation to MDMA, a phase III trial (MAPP1) referenced by the applicant in the MDMA application had previously been considered in the Expert Report. A second phase III study, MAPP2,[7] is listed as active (not recruiting) at the time of the MDMA application, with results anticipated in March 2023. The MAPP2 study protocol is not yet publicly available. As such, I am of the view that there is no new evidence in the MDMA application compared to that before the Committee and myself in connection with the previous MDMA decision to now consider that the therapeutic value of MDMA is established.

In considering paragraph 52E(1)(a) of the Act, I agree that there seems to be emerging evidence of the benefits of MDMA-assisted psychotherapy in the treatment of post-traumatic stress disorder (PTSD). However, I remain of the view that further research is required in this area. As I have stated above in relation to psilocybine, I have concerns regarding the broadness of the indication (treatment-resistant mental illness) included in the current MDMA proposal, the lack of the further phase III trial results, and the problems associated with the translation from a clinical trial setting to clinical practice.

In relation to each substance, I have considered the Royal Australian and New Zealand College of Psychiatrists (RANZCP) updated clinical memorandum released in July 2022,[8] which states that:

> *There is limited but emerging evidence that psychedelic therapies may have therapeutic benefits in the treatment of a range of mental illnesses.*

The RANZCP memorandum also states that:

> *Further research is required to assess the efficacy, safety, and effectiveness of psychedelic therapies to inform future potential use in psychiatric practice.*
>
> *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.*

A principal factor against down-scheduling each of these substances is therefore still that they do not meet the Schedule 8 factor in the SPF for established therapeutic value, the corollary of

[6] Natalie Gukasyan, Alan K Davis, Frederick S Barrett, Mary P Cosimano, Nathan D Sepeda, Matthew W Johnson, Roland R Griffiths, 2022 (sagepub.com), Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up.

[7] MAPS Second Phase 3 Trial of MDMA-Assisted Therapy for PTS: https://maps.org/2022/05/09/maps-completes-enrollment-as-planned-for-the-confirmatory-phase-3-trial-of-mdma-assisted-therapy-for-ptsd/

[8] RANZCP Clinical Memorandum on the therapeutic use of psychedelic substances https://www.ranzcp.org/files/resources/college_statements/clinical_memoranda/cm-therapeutic-use-of-psychedelics.aspx

which is limited therapeutic benefit to patients (there being evidence only of potential therapeutic value) for the purposes of paragraph 52E(1)(a) of the Act.

I note that the current psilocybine and MDMA proposals incorporate, in the schedule entry and in Appendix D, a number of proposed controls on the substances when in Schedule 8 that were not part of the amendments previously proposed by the applicant in relation to which I made the previous psilocybine and MDMA decisions. The applicant has proposed these controls in response to the concerns expressed by the Committee, myself as the Delegate, and the authors of the Expert Report in relation to the previous applications. These additional proposed controls include requiring certain practitioner expertise and training, and procedures and standards for treatment of patients with the substances.

These additional controls could theoretically ensure the benefit for treated patients is realised despite there only being evidence of potential therapeutic value, and mitigate safety and public health risks. The RANZCP memorandum highlighted the need for guidelines for preparing patients undergoing psychedelic therapy and addressing issues regarding accreditation of training programs prior to regulatory controls being explored. Considering paragraphs 52E(1)(b) and (f) of the Act, I am of the view that the suitability and control of the treatment setting (such as a clinic), led by researchers with appropriate psychiatric and psychotherapy training (including specific training in psychedelic psychotherapy), are crucially important to mitigate the risks associated with psychedelic therapy. These risks include the vulnerability under which patients are placed by psychedelic agents that alter one's state of consciousness, such as psilocybine and MDMA, which requires appropriate oversight before, during and following the administration of either substance.

However, I am not satisfied that these controls that are purported to support a favourable benefit-risk balance will have the desired effect and support the proposed down-scheduling of the substances. This is due to how they would potentially operate in practice under State and Territory legislation. The Poisons Standard is not implemented by the States and Territories in a manner that is intended to give effect to highly specialised restrictions on clinical practice in situations where therapeutic value of a substance in Schedule 8 has not been established. This is because regulation of Schedule 8 substances under State and Territory legislation aligns with the corresponding scheduling factors in the SPF.

I accept the Committee's view that States and Territories do not have established mechanisms to give effect to the controls in the current psilocybine and MDMA proposals relating to training, including accreditation by an appropriate body, or to oversee the requirement for review by two additional psychiatrists. As such, I am of the view that many of the additional requirements included in the current psilocybine and MDMA proposals are not reasonably able to be administered or enforced at State and Territory level. This particularly poses an issue in relation to preparations containing the substances that are not included in the ARTG. Substances of this nature should remain in Schedule 9, where therapeutic use is largely restricted to clinical trials, until adequate evidence of their therapeutic value has been demonstrated and there are appropriately accredited training programs for the personnel involved.

Turning to paragraphs 52E(1)(d), (e) and (f) of the Act, I recognise that the risk of diversion of the substances is low in a controlled medical environment, yet I remain of the view that there are significant risks of their diversion at other points in the supply chain. In addition, not dispensing the substances from a pharmacy due to the lack of registered products would bypass the nationally implemented real-time prescription monitoring system, hence limiting oversight and governance. These issues argue for both substances to remain in Schedule 9, consistent with the relevant scheduling factors in the SPF.

I agree with the applicant that the *United Nations Convention on Psychotropic Substances 1971* permits exemptions to be granted for limited medical use and therefore the inclusion of psilocybine and MDMA in the Convention is not a barrier to the current proposals. However, I agree with the Committee that the regulation of access to the substances for therapeutic use

abroad is consistent with the controls associated with Schedule 9 of the Poisons Standard. In the case of MDMA, expanded patient access schemes have been instituted in countries including the United States, Israel and Switzerland under compassionate grounds for the treatment of PTSD. These are analogous to the current use of the Special Access Scheme in Australia, which allows patient access to Schedule 9 substances with approval under particular circumstances. In the case of psilocybine, I note its "Breakthrough Therapy" status in the USA, designated by the Food and Drug Administration (FDA), relating to treatment-resistant depression (TRD) only and not the broader indication included in the current psilocybine proposal. Moreover, this status is not connected to controls over access, but rather pathways to promote research and to market products. There are still no approved therapeutic products containing either substance anywhere in the world.

I note that a very large number of psilocybine and MDMA submissions were received from members of the public with the majority in favour of the current proposals, citing a clinical need (in relation to PTSD in the case of MDMA) and low risk of diversion of the substances. However, I note that both the Australian Psychological Society (APS) and RANZCP were against the proposals to down-schedule psilocybine and MDMA.

The APS indicated that until additional evidence is available from phase III clinical randomised controlled trials, there is insufficient evidence to endorse widespread adoption of psychedelic-assisted therapy. In the view of the APS there was insufficient data regarding the efficacy, safety, potential for abuse and tolerability of both substances in vulnerable patient populations. The RANZCP stated that until further research is available to clearly determine the therapeutic value, benefits and risks, and the development of best practice frameworks for clinical use have been subsequently developed, down-scheduling psilocybine and MDMA should not occur.

In summary, insufficient new evidence has been provided in either the psilocybine or MDMA application to establish the therapeutic value and benefits of the substances in psychedelic-assisted therapy in clinical practice. As such, I am of the view that the current psilocybine and MDMA proposals are inconsistent with the SPF and pose an unfavourable balance of the risks and benefits to the public. I have therefore decided to not amend the existing scheduling for either psilocybine or MDMA in the Poisons Standard.

2.4 Interim decision in relation to apronal (allylisopropylacetylurea)

Proposal

A proposal was initiated by a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) to clarify the appropriate scheduling for apronal and allylisopropylacetylurea, which are currently in Schedule 4 and Schedule 10 of the Poisons Standard respectively. These entries represent the same substance.

Interim Decision

Pursuant to regulation 42ZCZN of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made an interim decision to amend the current Poisons Standard in line with their proposal as follows:

Schedule 4 – Delete entry

~~APRONAL~~

Index – Delete entry

Proposed implementation date

1 February 2023

3.3 Interim decisions in relation to MDMA and MDA nomenclature

This section contains two independent interim decisions in respect to the nomenclature of (i) MDMA and (ii) MDA (the **Substances**). Given the current scheduling and the proposed amendments to the Poisons Standard in relation to the substances are similar, the reasons for making the interim decisions for both substances are substantially the same. As such these reasons have been consolidated to assist the reader.

Proposals

MDMA

The applicant proposed amendment of the current Schedule 9 entry for N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) to reference the international non-proprietary name (INN) midomafetamine (the **MDMA Proposal**). The original name for the substance would be included as a cross-reference in the index entry for the substance.

MDA

The applicant proposed amendment of the current Schedule 9 entry for 3,4-methylendioxyamfetamine (MDA) to reference the INN tenamfetamine (the **MDA Proposal**). The original names for the substance would be included as a cross-reference in the index entry for the substance.

Interim Decision

Pursuant to regulation 42ZCZN of the Therapeutic Goods Regulations 1990 (Cth) (the **Regulations**), a delegate[3] of the Secretary of the Department of Health and Aged Care (the **Delegate**) has made the following interim decisions:

(i) to not amend the current Schedule 9 listings for MDMA in the Poisons Standard.
(ii) to not amend the current Schedule 9 listings for MDA in the Poisons Standard.

Instead, the INNs for these substances are to be entered as cross references to MDMA and MDA in the index as follows:

> **Index - Amend Entry**
>
> **N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA).**
> cross reference: 3,4- METHYLENEDIOXY-N-α-DIMETHYLPHENYLETHYLAMINE, MDMA, MIDOMAFETAMINE
>
> **3,4-METHYLENEDIOXYAMFETAMINE *(MDA).**
> cross reference: 3,4-METHYLENEDIOXYAMPHETAMINE, MDA, TENAMFETAMINE.

Materials considered

In making these interim decisions, the Delegate considered the following material:

- The applications to amend the current Poisons Standard with respect to the nomenclature of MDMA and MDA (the **Applications**);

- The 5,350 public submissions,[4] including 2 with a written component, received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**);
- The advice received from the 31st meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Summary of Committee advice to the Delegate

The Committee recommended that no change be made regarding the existing scheduling entries for MDMA and MDA, however agreed that the INNs for each substance should be included as cross-references in the respective index entries.

In making this recommendation the Committee members considered the main issues regarding the renaming of MDMA and MDA to be familiarity and recognition of the current names, as they are known to many organisations, industry, and the wider community.

The Committee acknowledged that at this time the substances MDMA and MDA are only listed in Schedule 9, and the names in Schedule 9 are the names that law enforcement and other agencies use, therefore including the INNs in the index as cross-references may avoid confusion.

Regarding the implications for State and Territory drug and poisons legislation, the Committee considered the fact that amending the index by adding the INNs as cross references to the existing entries would not adversely affect their legislative instruments.

Inconsistencies in international treaties and legislative documents with reference to these substances' nomenclature was also considered by the Committee.

The Committee also recommended an implementation date of **1 February 2023**.

Reasons for the interim decision (including findings on material questions of fact)

I have made interim decisions to retain the names for MDMA and MDA as presently listed in the Poisons Standard. However, I have decided to include the INNs midomafetamine and tenamfetamine in the index as cross-references for MDMA and MDA respectively. The detailed reasons for my decision follow.

I note that the current Poisons Standard conventionally uses INNs in the absence of a name approved by an appropriate authority such as the TGA, and there are no registered products containing MDMA or MDA in Australia. In making this decision I have considered the Committee's advice regarding the inconsistencies in international treaties and legislative documents with reference to these substances. For example, I recognise the inconsistent naming of these substances in the United Nations Convention on Psychotropic Substances 1971, which uses the chemical name for MDMA as is listed in the Poisons Standard, but conversely, uses the INN for MDA (tenamfetamine). Additionally, it has been noted that the United States Food and Drug Administration (FDA) uses the INNs for both substances in the FDA's Global Substance Registration System.[9]

The current nomenclature for MDMA and MDA as used in Schedule 9 of the Poisons Standard is familiar to stakeholders such as law enforcement and customs officials, as well as the general public. I recognise that changing the nomenclature in the Schedule 9 entries may cause confusion for these bodies, and I agree with the Committee that including the INNs in the index

[9] FDA Global Substance Registration System https://precision.fda.gov/uniisearch

as cross-references may be preferable. I also acknowledge the Committee's advice that amending the index by adding the INNs as cross references to the existing entries would not adversely affect the relevant legislative instruments of the States and Territories.

I have also taken into consideration the two written submissions on the Proposal. In particular, the submission received from the Royal Australian & New Zealand College of Psychiatrists opposed the proposal, citing that clear communication would need to be provided to all sectors involved to avoid any confusion regarding these substances. The other written submission was by the Pharmacy Guild of Australia who supported the Applications, however I note that no reasons were provided.

The matters listed in section 52E of the *Therapeutic Goods Act 1989* were not considered in making these interim decisions, as the MDMA Proposal and MDA Proposal involved consideration of the nomenclature of the substances only and no other factors.

Proposed implementation date

1 February 2023