Public consultation on proposed amendments to the Poisons Standard - ACMS & Joint ACMS-ACCS, June 2025

May 2025

Introduction

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice clinics to realise their full potential. We are the peak body committed to forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha is committed to supporting improved access to evidence-based medicines for all consumers, ensuring that treatments are safe, effective, and aligned with contemporary clinical practice.

As part of this commitment, AdPha convenes a range of Specialty Practice Groups comprising clinicians with expertise in:

- Palliative Care
- Voluntary Assisted Dying
- Paediatrics and Neonatology
- Emergency Medicine

These expert groups provide critical insights drawn from frontline clinical experience, with their contributions instrumental in informing and shaping AdPha's position and response, outlined below, to the proposed amendments 1.1 psilocybine and 1.2 adrenaline.

If you have any queries or would like to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy at jyik@adpha.au.

1.1 Psilocybine

AdPha does **not support** the proposed amendment to the Controlled drugs (Schedule 8) entry of psilocybine to include a new indication for existential distress towards end of life for the reasons outlined below:

Requirement for specialist psychiatric input: The safe and effective use of psilocybin requires expert psychiatric or psychological assessment, supervision, and follow-up. Such specialist input is not routinely available within most palliative care settings, and the lack of integrated mental health support limits the feasibility of implementation.

Impracticality in end-of-life care: The tightly regulated nature of Schedule 8 substances, combined with the requirement for psychiatric specialist involvement, makes psilocybin use logistically and clinically impractical for many palliative care patients, particularly those nearing the end of life.

Outside the remit of palliative care practice: The proposed use of psilocybin falls outside the established scope of practice and standard prescribing patterns within palliative care. It is unclear what training or frameworks the applicant anticipates palliative care teams would use to safely administer and monitor treatment. No formal training pathways or competency standards have been identified.

Lack of local evidence base: While international studies may indicate some potential, current research remains experimental and is not sufficiently mature to justify regulatory change. There is a notable absence of robust, peer-reviewed, Australian-based clinical studies demonstrating efficacy and safety for this indication. AdPha maintains a strong commitment to evidence-based medicine and cannot support interventions without a solid evidentiary foundation.

Insufficient engagement with the palliative care sector: AdPha is concerned about the limited consultation with, and involvement of, the palliative care community in the development of this proposal. Any change of this nature requires broad sector engagement to ensure safe, appropriate, and sustainable implementation across care settings.

1.2 Adrenaline

AdPha **supports** the proposal to include intranasal preparations containing 2% or less of adrenaline as a Pharmacist Only Medicine (Schedule 3), for the reasons outlined below, some of which align with those presented by the applicant:

Alignment with existing adrenaline delivery options: If the intranasal spray is intended to serve as an alternative to intramuscular adrenaline auto-injectors (e.g. EpiPens or Anapens), it should be scheduled in the same way to ensure equitable access and consistency in treatment options for patients at risk of anaphylaxis.

Improved Accessibility and Usability: A needle-free intranasal adrenaline option addresses barriers to timely administration, including fear of needles, administration errors, and portability issues. Allowing intranasal adrenaline to be obtained from community pharmacies

aligns with how similar medicines are accessed for anaphylaxis management. While this may be considered beyond the immediate scope of the policy submission, it is important to acknowledge the real-world implications—particularly the risk that patients may not follow up with their GP for repeat prescriptions. This is a pattern observed in Emergency Departments. Providing access through pharmacies offers a practical safety net and ensures continuity of care without unnecessary delays.

Clinical and Practical Advantages: The proposed product offers benefits such as ease of use, improved safety profile, higher likelihood of being carried, and enhanced stability and device reliability.

Proven Use and Pharmacokinetics: The intranasal delivery method has a history of effective use in emergency settings and achieves adrenaline blood levels comparable to injection-based methods.

Established Safety and Market Reception: The safety profile aligns with known risks of adrenaline, with pharmacist involvement ensuring appropriate use; early adoption in the US has been positive with no new safety concerns.