



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Notice of interim decision to amend (or not amend) the current Poisons Standard in relation to adrenaline

19 December 2025

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Notice of interim decisions made under Regulation 42ZCZN of the Therapeutic Goods Regulations 1990

This web publication constitutes a notice for the purposes of regulation 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations). In accordance with regulation 42ZCZP, this notice sets out:

- the interim decision made by a delegate of the Secretary of the Department of Health, Disability and Ageing responsible for scheduling of medicines and chemicals (the **Delegate**)¹ under regulation 42ZCZN in relation to proposed amendment to the current Poisons Standard which was referred to an expert advisory committee² under subdivision 3D.2 of the Regulations in June 2025;
- the proposed date of effect of the proposed amendment.

In accordance with regulation 42ZCZP, interested persons (including the applicant requesting the amendment) are invited to make submissions to the Secretary in relation to this interim decision on or before 12 January 2026.

Submissions should be provided through our [consultation hub](#). Submissions will be considered by the Delegate in making the final decision.

Please note that in accordance with subregulation 42ZCZQ (4) of the Regulations, the Secretary must publish all relevant submissions received, unless the Secretary considers the information to be confidential information.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the *Therapeutic Goods Act 1989* (Cth) (the Act)
- the Scheduling Policy Framework 2018 (the SPF)
- the Scheduling handbook: Guidance for amending the Poisons Standard (the Handbook), and
- the Therapeutic Goods Administration (the TGA).

Note: additional terms are also defined for individual decisions.

¹ For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth)

² Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

Interim decision on a proposed amendment referred to the Advisory Committee on Medicines Scheduling (ACMS #47, June 2025)

Interim decision in relation to adrenaline

Proposal

The applicant proposed to amend the current Poisons Standard in relation to adrenaline. Under the proposal, intranasal preparations containing 2% or less of adrenaline would be included as a Pharmacist Only (Schedule 3) medicine. While there are no current intranasal adrenaline products in the Australian market, if one were introduced it would be a Prescription Only medicine (Schedule 4) under the current Poisons Standard.

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, the Delegate has, in relation to the proposed amendment, made an interim decision to amend the current Poisons Standard in relation to adrenaline as follows:

Schedule 4

ADRENALINE in:

- (a) topical preparations for the treatment of wounds in humans; or
- (b) all other preparations containing adrenaline **except** when included in or expressly excluded from Schedule 3.

Schedule 3 – Amend Entry

ADRENALINE in:

- (a) preparations containing 1% or less of adrenaline; or
- [\(b\) intranasal preparations containing 2% or less of adrenaline](#)

except in preparations that are not for injection containing 0.02% or less of adrenaline.

Appendix H

Clause 1 – Schedule 3 medicines permitted to be advertised.

ADRENALINE

Materials considered

In making this interim decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to adrenaline (the **Application**)
- The 173 [public submissions](#), with 7 including a written component, received in response to the [pre-meeting consultation](#) under regulation 42ZCZK of the Regulations (the **Submissions**)
- The advice received from the 47th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)
- Subsection 52E(1) of the Act, in particular (a) 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 that the Secretary considers necessary to protect public health

- The [Scheduling Policy Framework \(SPF\)](#), and
- The [Scheduling Handbook](#).

Summary of Committee advice to the Delegate

The Committee recommended that the Poisons Standard be amended in relation to adrenaline as follows:

Schedule 3 – Amend Entry

ADRENALINE in:

(a) preparations containing 1% or less of adrenaline; or

[\(b\) intranasal preparations containing 2% or less of adrenaline.](#)

except in preparations that are not for injection containing 0.02% or less of adrenaline.

The Committee also recommended an implementation date of **1 October 2025**.

Members agreed that the relevant matters under subsection 52E(1) of the Act included: (a) 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 that the Secretary considers necessary to protect public health.

The reasons for the advice included:

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

Risks:

- Common adverse effects include tachycardia, hypertension, headache, anxiety, apprehension, palpitations, diaphoresis, nausea, vomiting, weakness and tremors.
- Risk of adverse effects far outweighed by risk of death due to anaphylaxis from non-administration.
- Some data provided for ocular exposure (a common accident for nasal devices), but not in humans.

Benefits:

- Benefits outweigh risk of harm, with ASCIA recommending the administration of adrenaline even if there is doubt as to whether the condition to be treated is anaphylaxis.
- Effective, non-injectable treatment of anaphylaxis, great for patient use.
- Adrenaline works by quickly reducing swelling in the throat, opening up airways and preventing blood pressure from falling too low.
- Works within minutes and the effects last around 10 to 20 minutes.
- Adrenaline is an endogenous substance that is rapidly cleared after administration.
- Even when administered for the treatment of severe allergy or anaphylaxis, adrenaline levels remain in the normal physiological range that occurs during strenuous activity, exercise or fear.

- Less risk of administration errors when used by other people to administer to a person requiring treatment.

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

- Medicine of choice in the emergency treatment of severe acute anaphylactic reactions, including anaphylactic shock.
- Existing products in the requested schedule for the same indication.
- Adrenaline has a well-established history of use as a Schedule 3 medicine in anaphylaxis.

c) the toxicity of a substance

- Similar side effect profile to existing products when used appropriately.

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

- The application proposes a 2% adrenaline nasal spray, in a 2 pack – matching existing adrenaline treatments for anaphylaxis.
- A similar delivery device (containing naloxone) has a good history of use here in Australia.
- Dosage is one spray administered into one nostril. In absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose in the same nostril with a new nasal spray starting 5 minutes after the first dose.

e) the potential for abuse of a substance

- Low potential for abuse in small quantities/single dose units.

f) any other matters that the Secretary considers necessary to protect public health

- Lack of history for safety data in Australia regarding this dose and method of administration.
- Increases accessibility to emergency anaphylaxis treatment by introducing a different formulation that may be more accepted by patients (e.g. needle phobia).

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

I agree with the Committee's findings on the relevant provisions of section 52E of the Act.

I have made an interim decision to amend the current Poisons Standard in relation to adrenaline to include intranasal preparations containing 2 mg or less per dose as a Pharmacist Only (Schedule 3) medicine. Although there are different doses for children's and adult intranasal products, this can be managed through the product registration process and does not require separate scheduling entries.

In Australia, for the treatment of anaphylaxis, adrenaline is currently available as a Pharmacist-only (Schedule 3) intramuscular injection.

I have considered the 7 written public submissions received during the pre-meeting consultation period. Four written responses received were fully supportive of the applicant's proposal, 2 partially supportive and 1 opposed. Interested parties were also given the choice to select from options to indicate their support or opposition to the proposed amendment without providing a written component – 166 responses were received, with 152 supportive, 14 partially supportive. These respondents did not provide reasons for their support or opposition and as a result, the extent of my consideration is limited to noting that the majority of submissions were generally in favour of the scheduling proposal.

I note that most written submissions highlighted that intranasal adrenaline is a non-invasive, patient-friendly, rapid alternative, especially beneficial for those with needle phobia and for use in emergency situations such as anaphylaxis.

I have considered the issue of accidental exposures involving adrenaline auto-injectors, as highlighted in the submissions from NSW Poisons Information Centre. I note that an intranasal device may be just as accessible to children and may result in inadvertent self-dosing.

In relation to section 52E(1)(a) and (f) of the Act, I agree with the Committee that there is limited historical safety data for this specific dose and method of administration in Australia. However, I agree that the common adverse effects associated with adrenaline must be weighed against the potential risk of death resulting from non-administration in cases of anaphylaxis.

A concern raised by the Committee with reference to 52E(1)(a) of the Act regarding accidental eye exposure, a known risk of nasal delivery devices was noted. I determine that the overall benefit-risk profile is considered acceptable.

In relation to s 52E(1)(b), (c) and (d) of the Act, I acknowledge that adrenaline is a naturally occurring hormone in the body and has been safely used for a long time as a Pharmacist-only medicine (Schedule 3), particularly for treating severe, acute allergic reactions (anaphylaxis). It is the preferred emergency treatment for opening airways, helping with breathing, and stabilising blood pressure during allergic reactions. For the proposed product, a typical dose would involve up to 2 sprays (requiring 2 devices) of the 2% formulation. Therapeutic dosage levels are within natural endogenous levels and are for short timeframes only as adrenaline acts quickly and doesn't stay in the body for long. Given that therapeutic and intranasal exposures (250–400 pg/mL) fall within the range that bodies can naturally produce adrenaline, further toxicity studies for adrenaline are unnecessary for this decision.

One of the challenges with using the proposed delivery device is that it does not require priming, unlike more familiar nasal sprays such as those used for the treatment of allergic rhinitis. This carries a small risk that unfamiliar users could discharge the only dose trying to prime the spray. However, I consider this to be a similar risk to administration errors that might occur from the use of single, fixed-dose autoinjectors. The risks of incorrect use can be mitigated through pharmacist advice and clear instructions on the label.

I note that the US Food and Drug Administration (FDA) has approved 2 different strengths of adrenaline nasal spray. For patients aged 4 years and over who weigh at least 15 kg, the recommended dose depends on body weight: those weighing 30 kg or more should use one spray of the 2 mg formulation, while those between 15 kg and less than 30 kg should use one spray of the 1 mg nasal spray. As the proposed scheduling requires consultation with a pharmacist, the most appropriate product can be dispensed depending on the needs of the consumer.

Regarding s 52E(1)(e) of the Act, I note that the product presents minimal risk of misuse or abuse. It mimics endogenous adrenaline and is used in small quantities or single doses. Use of these devices should also involve immediate subsequent medical attention with users recommended to call an ambulance if administering. Additionally, pharmacist oversight at the point of supply, provides an important safeguard against inappropriate use.

With regards to s 52E(1)(f) of the Act, I agree with the Committee that the proposed intranasal preparation improves accessibility, especially for children and people with needle phobia, and offers an option equivalent to intramuscular administration, enabling more patients to receive timely emergency treatment.

In conclusion, I acknowledge that the current evidence indicates that intranasal adrenaline is a safe and effective option for the emergency management of anaphylaxis when used in accordance with appropriate instructions. The pharmacokinetic and safety profiles of the intranasal formulations are comparable to those of existing intramuscular preparations, supporting their inclusion as Pharmacist Only medicine (Schedule 3).

Proposed implementation date

1 February 2026

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