Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

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

22 January 2026

Copyright

© Commonwealth of Australia 2026
This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to tga.copyright@tga.gov.au.

Contents

Notice of final decision to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS, this notice publishes:

- the decision made by a delegate[1] of the Secretary of the Department of Health, Disability and Ageing (the **Delegate**) pursuant to regulation 42CZR
- the reasons for the final decision and
- the date of effect of the decision.

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).

Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #47, June 2025)

Final 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.

This would mean that adrenaline intranasal preparations could be made available for sale as Pharmacist Only (Schedule 3) medicines and as an alternative to auto injector adrenaline pens currently used in anaphylaxis. Under the current scheduling, adrenaline intranasal preparations would be considered to fall under the Schedule 4 entry of the Poisons Standard and therefore require a prescription for access.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has decided to confirm the interim decision and amend the current Poisons Standard in relation to adrenaline as follows:[2]

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.

Index

ADRENALINE

Schedule 4

Schedule 3

Appendix H, clause 1

Materials considered

In making this final decision, the Delegate considered the following materials:

[2] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

- The proposal to amend the current Poisons Standard with respect to adrenaline (the **Proposal**)
- 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**)[3]
- The interim decision and the materials considered as part of the interim decision, as published on 19 December 2025
- The 4 public submissions, all included a written component, received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, 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; and (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- The SPF, and
- The Handbook.

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

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to adrenaline. My reasons for making the final decision are those set out in the interim decision.

In making my final decision, I have considered the material in the interim decision, and the submissions received in response to the public consultation on the interim decision. I have considered that recently two adrenaline intranasal preparations were registered for use in Australia by the Therapeutic Goods Association (TGA) and are expected to be available early 2026 (date yet to be confirmed). In the absence of a Schedule 3 entry for intranasal adrenaline preparations, they would be classified under Schedule 4 (Prescription Only medicine). To ensure equitable access options for consumers facing anaphylaxis, I have carefully considered that the benefits outweigh the risks of this dosage formulation.

I have considered all submissions received in response to the interim decision, all of which were from organisations (peak professional bodies), of these 3 responses were in support of the interim decision and one submission was in partial support. Respondents were given the choice of replying with or without written justification, and all submissions received had accompanying written justification. The submission in partial support, whilst expressing some concerns, did not provide written justification relevant to the proposed scheduling. No responses were received opposing the interim decision.

The submissions in support of the interim decision emphasised that the primary risks associated with accidental exposure to adrenaline auto-injectors are due to the formulation and the delivery device. Accidental injection into a digit can result in a local reaction that may impair circulation, potentially requiring further evaluation and management in a hospital setting. This issue does not arise with intranasal formulations.

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

In 2024, for all intranasal dosage form medicines, the NSW Poisons Information Centre (PIC) recorded only 6 cases involving children under 10 years of age administering an intranasal device in a manner that constituted accidental exposure. No serious outcomes were reported in any of these cases. This provides some reassurance regarding the risk of accidental actuation of this dosage form by children or toddlers.

Allergy & Anaphylaxis Australia emphasised that consumers should be able to access various adrenaline delivery methods when clinically appropriate. Furthermore, they highlighted the importance of strong advocacy to ensure proper training and consumer education, so that the benefits of intranasal administration outweigh its potential risks.

The submission from Consumer Healthcare Product Australia raised concerns about the number of registered products mentioned in the pre-meeting public notice and questioned why this clarification was not included in the interim decision. The submission noted that, according to the Australian Register of Therapeutic Goods (ARTG) as of April 2025 there were 52 medicines containing adrenaline as an active ingredient (rather than 13), with several classified as Pharmacist Only Medicines (Schedule 3). I clarified that the count of 13 products refers specifically to those adrenaline listings with a matching CAS number (51-43-4). Products such as adrenaline acid tartrate and adrenaline hydrochloride were not included in this count since their CAS numbers differed from the CAS number cited in the application.

The Committee was informed prior to the 47th meeting of the ACMS that the number of products on the ARTG and reports to Database of Adverse Event Notifications (DAEN) were specific to adrenaline, and not inclusive of hydrochloride nor tartrate preparations. When making recommendations, they considered other adrenaline products, including those available as Schedule 3 medicines, and I took these concerns into account when reaching the final decision.

Furthermore, I have noted that Neffy® 2mg and Neffy® 1mg adrenaline nasal spray devices have been listed on the ARTG; both of which were listed on 8 December 2025. Internationally, intranasal preparations of adrenaline are already available with no reports of harm.[4]

In conclusion, I acknowledge that adrenaline for anaphylaxis is currently restricted to intramuscular injection dosage forms. Intranasal adrenaline offers a non-invasive, rapid-delivery option that increases accessibility to anaphylaxis treatment, particularly for individuals with needle phobia, in emergency situations.

The inclusion of intranasal formulations containing 2 mg or less per dose within Schedule 3 will not affect the availability of auto-injectors while continuing to uphold public safety and accessibility. Although paediatric and adult intranasal products require different dosages, this is similar to the auto injectors already available on the market and can be addressed through pharmacist counselling at point of provision. Additionally, pharmacist oversight at the point of supply, provides an important safeguard against inappropriate use. In consideration of the lower barriers to use of intranasally administered adrenaline compared to autoinjectors[5], and the fact there are two products already registered on the ARTG, I have decided that this amendment will come into effect with the next Poisons Standard update on 1 February 2026.

Implementation date

1 February 2026

[4] UK EMC (2025) EURneffy 2 mg nasal spray, solution in single-dose container - Summary of Product Characteristics (SmPC) - (emc) | 101346

[5] Treudler R, Brockow K, Beyer K, Klimek L, Lange L, Schnadt S, Ring J, Worm M. Adrenaline nasal spray in emergency management: An initial expert opinion. Allergol Select. 2025 Sep 4;9:80-85. doi: 10.5414/ALX02590E.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au