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

Notice of final decisions to amend the current Poisons Standard

25 September 2026

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Notice of final decisions to 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 regulation 42ZCZS a, this notice publishes:

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

This web publication also contains decisions made by the Delegate pursuant to subsection 52D(2) of the *Therapeutic Goods Act, 1989* (the Act).

Defined terms

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

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

Final decision in relation to 6-methylnicotine

Proposal

The Department of Health, Disability and Ageing proposed creating a Dangerous Poison (Schedule 7) entry for 6-methylnicotine in the current Poisons Standard. 6-Methylnicotine has been reported to be present in several e-cigarette liquids being sold in Australia that are advertised as nicotine-free or a nicotine-alternative.[2] There is evidence that 6-methylnicotine is also being added to preparations such as oral pouches. The proposal was initiated to mitigate the potential public health risks arising from 6-methylnicotine.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to 6-methylnicotine as follows.[3]

Schedule 9 – New entry

6-METHYLNICOTINE

Index – New entry

6-METHYLNICOTINE

cross-reference: CAS No. 13270-56-9

Schedule 9

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to 6-methylnicotine (the **Proposal**)
- the 163 public submissions, with 9 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**)
- the interim decision relating to 6-methylnicotine and the materials considered as part of the interim decision
- One public submission received in response to the public consultation on the interim decision

[2] Jenkins C, Kelso C, Morgan J. 6-Methylnicotine: a new nicotine alternative identified in e-cigarette liquids sold in Australia. Med J Aust. 2024;221(7):333-335. https://doi.org/10.5694/mja2.52423.

[3] 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.

- 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
- pursuant to paragraph 52E(2)(a) of the Act, 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 6-methylnicotine. The decision is to classify 6-methylnicotine as a Prohibited substance (Schedule 9).

One public submission was received on the interim decision which supported the decision in agreement with Committee's advice that stronger regulatory controls are warranted to manage the significant public health risks posed by 6-methylnicotine and to urgently prevent the growing spread of misleading claims.

My reasons for making the final decision are those set out in the interim decision. The main concerns are the substance's acute toxicity; risks of use in unapproved consumer products such as oral pouches and vaping liquids; misleading marketing claims ("nicotine-free" alternatives); and risk of dependence, particularly among vulnerable populations. There are no identified therapeutic benefits, and the risks outweigh any claims of safety. I agree with the Committee advice that classifying 6-methylnicotine as a Dangerous Poison (Schedule 7) does not provide sufficient regulatory controls to manage the risks. Classification as a Prohibited substance (Schedule 9) offers a stronger legal framework, enabling more effective enforcement through higher penalties for unlawful supply and possession under the Commonwealth and jurisdictional drug laws and can help address the serious health risks from 6-methylnicotine.

6-methylnicotine is a high-risk substance with no therapeutic value and currently there are no lawful products in Australia that would be affected by this decision. Therefore, I have decided to immediately implement my decision to classify 6-methylnicotine as a Prohibited substance.

Implementation date

1 October 2026

Final decision in relation to somatrogon, lonapegsomatropin and somapacitan

Proposal

The Department of Health, Disability and Ageing has proposed creating new Prescription only medicine (Schedule 4) entries for somatrogon and lonapegsomatropin in the Poisons Standard.

Somatrogon and lonapegsomatropin are human growth hormone analogues primarily used for the treatment of growth failure in paediatric patients, caused by inadequate endogenous growth hormone production. Somapacitan is a functional analogue of these 2 substances but is also used as a replacement therapy in adults with growth hormone deficiency. While somapacitan is currently scheduled as a Prescription only medicine (Schedule 4), somatrogon and lonapegsomatropin are currently not explicitly scheduled. Due the similarities in their function and therapeutic use, all 3 substances have been considered together.

Additional controls on the possession and supply of somatrogon, lonapegsomatropin and somapacitan through inclusion of all 3 substances in Appendix D was also proposed.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to somatrogon, lonapegsomatropin and somapacitan as follows.[4]

Schedule 4 – New entry

SOMATROGON

Schedule 4 – New entry

LONAPEGSOMATROPIN

Schedule 4 – Amend entry

SOMAPACITAN

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SOMATROGON

Schedule 4

Appendix D, clause 5

LONAPEGSOMATROPIN

Schedule 4

Appendix D, clause 5

SOMAPACITAN

Schedule 4

Appendix D, clause 5

Appendix D, clause 5 – Additional controls on possession or supply of poisons included in Schedule 4 or 8 – New entry

Item	Poison
26	LONAPEGSOMATROPIN
34	SOMATROGON
35	SOMAPACITAN

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to somatrogon, lonapegsomatropin and somapacitan (the **Proposal**)
- the 2 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)

[4] 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 advice received from the 47th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)
- the interim decision relating to somatrogon, lonapegsomatropin and somapacitan and the materials considered as part of the interim decision, as published on 9 June 2026
- 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
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

Note: No public submission was received on the public consultation on the interim decisions in relation to somatrogon, lonapegsomatropin and somapacitan.

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 somatrogon, lonapegsomatropin and somapacitan. My reasons for making the final decision are those set out in the interim decision, the main ones being the need for medical supervision in diagnosing and treating growth hormone deficiency, the importance of correct dosing, the risk of adverse events from overdose and the misuse potential of all 3 substances.

Implementation date

1 October 2026

Amendment to the Poison Standard in relation to New Chemical Entities (NCE)

The New Chemical Entity (NCE) listed below will be included in the new Poisons Standard that will come into effect on 1 October 2026.

BEMPEDOIC ACID

Schedule 4 – New Entry

BEMPEDOIC ACID

Index – New Entry

BEMPEDOIC ACID

Schedule 4

EFANESOCTOCOG ALFA

Schedule 4 – New Entry

EFANESOCTOCOG ALFA

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EFANESOCTOCOG ALFA

Schedule 4

EPLONTERSEN

Schedule 4 – New Entry

EPLONTERSEN

Index – New Entry

EPLONTERSEN

cross reference: EPLONTERSEN SODIUM

Schedule 4

GADOQUATRANE

Schedule 4 – New Entry

GADOQUATRANE

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GADOQUATRANE

Schedule 4

GEPOTIDACIN

Schedule 4 – New Entry

GEPOTIDACIN

Index – New Entry

GEPOTIDACIN

cross reference: GEPOTIDACIN MESILATE

Schedule 4

OLUTASIDENIB

Schedule 4 – New Entry

OLUTASIDENIB

Index – New Entry

OLUTASIDENIB

Schedule 4

TAPINAROF

Schedule 4 – New Entry

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TAPINAROF

Schedule 4

TEPLIZUMAB

Schedule 4 – New Entry

TEPLIZUMAB

Appendix L – New Entry

TEPLIZUMAB

Warning statements

Do not use during pregnancy and do not use for at least 30 days prior to planned pregnancy.

Do not breastfeed during treatment and for at least 30 days after the last dose.

Index – New Entry

TEPLIZUMAB

Schedule 4

Appendix L

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