Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

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Contents

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

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

- the decisions made by a delegate[1] of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to regulations 42CZR, 42ZCZU AND 42ZCZW
- the reasons for those final decisions and
- the date of effect of those decisions.

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 #45, June 2024)

Final decision in relation to sildenafil

Proposal

The applicant proposed to create a new Pharmacist only (Schedule 3) entry for sildenafil. The proposed amendment would include divided preparations containing 50 mg of sildenafil for oral use, in packs of 4 or fewer dosage units, in Schedule 3 and a new entry for sildenafil in Appendix H to permit advertising of Schedule 3 preparations. Sildenafil is currently included in Prescription Only medicines (Schedule 4).

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to sildenafil.

Materials considered

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

- the application to amend the current Poisons Standard with respect to sildenafil (the **Application**)
- the 4 public submissions, with 4 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 45th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**)[2]
- the interim decision relating to sildenafil and the materials considered as part of the interim decision, as published on 19 September 2024
- the one submission received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations
- subsection 52E(1) of 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; and (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health
- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

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

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

I have made a final decision to confirm my interim decision and not amend the current Poisons Standard with respect to sildenafil. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material in the interim decision and the public submission from the Pharmacy Guild of Australia (PGA), which was received through public consultation on the interim decision.

I have considered the main points raised by PGA in opposition of the interim decision. The submission states that including sildenafil as a Pharmacist Only Medicine (Schedule 3) would reduce importation of unregulated products and eliminate the need to visit a doctor, which can dissuade some patients from seeking medical treatment for the condition. Whilst I agree there is evidence of unregistered product importation which remains a concern, I am of the view that there is insufficient evidence of a net positive health benefit to support making sildenafil available as a Pharmacist Only Medicine (Schedule 3). Chiefly that the ailments or symptoms that the substance is used for requires medical intervention to ensure adequate medical assessments and diagnosis, and to promote medical assistance in treating any underlying causational health conditions. Furthermore, I note that sildenafil has the potential to interact with several medicines used in groups of people with higher rates of erectile dysfunction. In considering the SPF factors, I remain of the opinion that the seriousness or severity and frequency of the interactions of the substance (medicine-medicine) are such that oversight and prescribing is required by a medical practitioner.

Final decisions on proposed amendments referred to the Advisory Committee on Chemicals Scheduling (ACCS #39, June 2024)

Final decision in relation to allyl esters

Proposal

The Delegate proposed an amendment to the Poisons (Schedule 6) entry for allyl esters to include allyl phenoxyacetate; allyl amyl glycolate; allyl (2-methylbutoxy)acetate; and allyl (cyclohexyloxy)acetate. The proposal was initiated following a recommendation by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS; now known as the Australian Industrial Chemicals Introduction Scheme, AICIS) in their evaluation of allyl esters of acetic acid ethers published in June 2019. These substances are currently captured in the Poisons Standard under the Dangerous poisons (Schedule 7) and Appendix J entries for allyl alcohol.

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to confirm the interim decision and not to amend the current Poisons Standard in relation to allyl amyl glycolate or allyl (2-methylbutoxy)acetate, which will continue to be captured under the Schedule 7 and Appendix J entries for allyl alcohol. The delegate has also made a decision to amend the current Poisons Standard in relation to allyl phenoxyacetate and allyl (cyclohexyloxy) acetate, as follows:[3]

Schedule 6 – Amend Entry

ALLYL ESTERS (excluding derivatives) being:

(a) ALLYL CYCLOHEXANEACETATE (CAS No. 4728-82-9); or

(b) ALLYL CYCLOHEXANEPROPIONATE (CAS No. 2705-87-5); or

(c) ALLYL HEPTANOATE/ALLYL HEPTYLATE (CAS No. 142-19-8); or

(d) ALLYL HEXANOATE (CAS No. 123-68-2); or

(e) ALLYL ISOVALERATE (CAS No. 2835-39-4); or

(f) ALLYL NONANOATE (CAS No. 7493-72-3); or

(g) ALLYL OCTANOATE (CAS No. 4230-97-1); or

(h) ALLYL PHENYLACETATE (CAS No. 1797-74-6); or

(i) ALLYL TRIMETHYLHEXANOATE (CAS No. 68132-80-9); or

(j) ALLYL PHENOXYACETATE (CAS No. 7493-74-5); or

(k) ALLYL (CYCLOHEXYLOXY)ACETATE (CAS No. 68901-15-5);

[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.

in preparations containing 0.1% or less of free allyl alcohol by weight of allyl ester except in preparations containing 5% or less of allyl esters with 0.1% or less of free allyl alcohol by weight of allyl esters.

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ALLYL ESTERS (excluding derivatives)

Schedule 6

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to allyl phenoxyacetate, allyl amyl glycolate, allyl (2-methylbutoxy) acetate, and allyl (cyclohexyloxy) acetate (the **Proposal**)
- that there were no public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 39th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**)
- the interim decision relating to allyl esters and the materials considered as part of the interim decision, as published on 19 September 2024
- the one submission 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
- 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 not amend the current Poisons Standard with respect to allyl amyl glycolate or allyl (2-methylbutoxy)acetate, which will continue to be captured under the Dangerous poisons (Schedule 7) and Appendix J entries for allyl alcohol. I have also made a final decision to amend the current Poisons Standard in relation to allyl phenoxyacetate and allyl (cyclohexyloxy)acetate. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material in the interim decision and the one public submission received through public consultation on the interim decision.

I have considered the public submission received in opposition of the interim decision. The submission notes that allyl esters have more in common with each other than with allyl alcohols, and that the Poisons (Schedule 6) entry should be amended to capture all allyl esters, including those currently listed in the Schedule 6 entry. I acknowledge that the current scheduling would require provision of an application for each allyl ester to be included in Schedule 6, placing a burden on industry. However, I remain of the view that default inclusion of allyl esters under the Schedule 7 entry for allyl alcohol is appropriate for two reasons. Firstly, allyl esters can form toxic metabolites, including through hydrolysis to allyl alcohol and subsequent metabolism of allyl alcohol to acrolein in the liver. Thus,

supporting inclusion of allyl esters under the group entry for allyl alcohol. Secondly, each allyl ester exhibits differences in toxicity, as evidenced by the 4 allyl esters considered in this decision. As no new evidence has been provided to support that broadly allyl ester substances meet the SPF factors associated with Schedule 6, I remain of the view that each allyl ester warrants individual consideration to support down scheduling from Schedule 7.

I have decided on an implementation date of 1 February 2025 as the decision to down-schedule allyl phenoxyacetate and allyl (cyclohexyloxy)acetate, and maintain the current scheduling of allyl amyl glycolate and allyl (2-methylbutoxy)acetate, should not adversely impact industry.

Implementation date

1 February 2025

Final decision in relation to glyoxylic acid

Proposal

The Delegate proposed the creation of a Poisons (Schedule 6) entry for glyoxylic acid. The proposal was initiated following a recommendation by the Australian Industrial Chemicals Introduction Scheme (AICIS) in their evaluation of glyoxylic acid published in December 2022. The recommendation proposed to create a new Schedule 6 entry in the Poisons Standard, similar to the entry for glycolic acid, except for cosmetic preparations containing over 12% glyoxylic acid and when featuring warning labels. This substance is not currently captured in the Poisons Standard.

Final decision

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

Schedule 6 – New Entry

GLYOXYLIC ACID (including its salts and esters) in cosmetic products.

Appendix E, clause 3 (First aid instructions for poisons) – New Entry

Item	Poison	Statement code (and statement)
138a	GLYOXYLIC ACID	A (For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).) G3 (If swallowed, do NOT induce vomiting.) E2 (If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes.)

[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.

Appendix F, clause 4 (Poisons that must be labelled with warning statements and safety directions) – New Entry

Item	Poison	Warning statement item number (and statement)	Safety direction item number (and statement)
160a	GLYOXYLIC ACID	79 (Will irritate eyes)	1 (Avoid contact with eyes) 5 (Wear protective gloves when mixing or using) 6 (Wash hands after use) 10 (Ensure adequate ventilation when using.) 31 (Do not use on broken skin)

Index – New entry

GLYOXYLIC ACID

Schedule 6
Appendix E, clause 3
Appendix F, clause 4

Materials considered

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

- the proposal to amend the current Poisons Standard with respect to glyoxylic acid (the **Proposal**)
- that there were no public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 39th meeting of the Advisory Committee on Chemicals Scheduling (the **Committee**)
- the interim decision relating to glyoxylic acid and the materials considered as part of the interim decision, as published on 19 September 2024
- the two submissions 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
- 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 glyoxylic acid. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material in the interim decision and the two public submissions received through public consultation on the interim decision.

I note that both public submissions received were in partial support of the interim decision. One public submission recommended including a low concentration exemption to the Poisons (Schedule 6) entry as some low concentration preparations not used in hair straightening products pose a low risk of consumer exposure and toxicity. However, I am not satisfied that there is sufficient evidence regarding substance toxicity to reasonably establish a concentration cutoff. I also note that one of the public submissions expressed support for an extended implementation timeline of 24 months, though did not support implementing additional labelling requirements due to lack of reported adverse effects and limited benefit for consumers who are unlikely to have access to the product container. However, as noted by the Committee, there are multiple emerging case studies that have reported kidney injury or failure in patients linked to exposure to ‘formaldehyde-free’ hair straightening products containing glyoxylic acid derivatives. Given the potential for toxic byproducts being produced at high temperatures during high straightening, I remain of the view that additional warning statements promoting adequate ventilation will help reduce inhalation exposure risks, particularly among workers and end-use consumers of these products.

I have decided on an implementation date of 1 June 2026 allow industry adequate response time to implement the labelling changes and to avoid disruption to the supply of glyoxylic acid containing products.

Implementation date

1 June 2026

Final decisions on proposed amendments referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #37, June 2024)

Final decision in relation to sulfonamides

Proposal

The Delegate has proposed amendments to the current Prescription only medicine (Schedule 4) entry for sulfonamides. The proposal is intended to clarify the status of sulfonamides when used in a variety of settings, including therapeutically and industrially. The proposal follows a referral from the Australian Industrial Chemicals Introduction Scheme (AICIS) evaluation of sulfonamides published in January 2022.

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 sulfonamides as follows:[5]

Schedule 4

SULFONAMIDE ANTIBIOTICS **except**:

(a) when separately specified in this~~is~~ese Schedules~~; or~~

(b) ~~when included in Schedule 3, 5 or 6; or~~

(c) ~~when packed and labelled solely for use as a herbicide~~

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SULFONAMIDES
cross reference: SULFACETAMIDE, SULPHANILAMIDE

Schedule 4

Materials considered

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

- the application to amend the current Poisons Standard with respect to sulfonamides (the **Application**)
- the 1 public submission, with no written component was received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations (the **Submissions**)
- the advice received from the 37th meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (the **Committee**)

[5] 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 interim decision relating to sulfonamides and the materials considered as part of the interim decision, as published on 19 September 2024
- the one submission received in response to the public consultation on the interim decision under regulation 42ZCZP of the Regulations
- 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 sulfonamides. 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 submission received in response to the public consultation on the interim decision.

The submission was in partial support of the interim decision. The submission was supportive of specifically capturing therapeutic uses of sulfonamides under Schedule 4, rather than all sulfonamide preparations. However, the submission raised concerns that the current entry may allow for sulfonamides with antibiotic properties (not being used for this purpose), to not be captured under Schedule 4, leading to potential misuse and antibiotic resistance. I am, however satisfied that intent of the schedule entry for ‘sulfonamide antibiotics’ will capture all sulfonamide preparations with antibiotic properties no matter the intended usage, unless otherwise specified in the Poisons Standard.

I have decided on an implementation date of 1 February 2025 as the amended entry for sulfonamides should not adversely impact industries manufacturing or selling products containing either antibiotic or non-antibiotic sulphonamides.

Implementation date

1 February 2025

Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZU and 42ZCZW

In my capacity as a delegate of the Secretary for the purpose of regulations 42ZCZU and 42ZCZW of the Regulations, I have made final decisions under regulations 42ZCZU and 42ZCZW with respect to the following substances:

- fluoride
- molidustat
- desloratadine

Final decision in relation to fluoride

Background

Fluoride plays a major role in prevention of tooth decay and has several applications including fluoridated water, toothpaste, and fluoride varnishes. While fluoride is safe to use when applied according to its instructions, there can be adverse effects if used excessively or incorrectly.

Fluoride varnish was initially developed in 1964 to prevent dental caries and is still widely used in the dental industry today.[6] It is typically applied by a professional 2-4 times a year depending on the patients' requirements and is the most used preventative measure taken for dental caries, particularly in high-risk children.[7]

Current Scheduling

Fluorides are currently captured in Schedules 2, 3, 4, 5 and 6 of the Poisons Standard as set out below:

Schedule 6

FLUORIDES **except**:

(a) when included in Schedule 5; or
(b) in preparations for human use; or
(c) in preparations containing 15 mg/kg or less of fluoride ion.

Schedule 5

FLUORIDES in preparations containing 3% or less of fluoride ion **except**:

(a) in preparations for human use; or
(b) in preparations containing 15 mg/kg or less of fluoride ion.

Schedule 4

FLUORIDES in preparations for human use **except** when included in or expressly excluded from Schedule 2 or 3.

[6]Fluoride Varnishes for Preventing Occlusal Dental Caries: A Review https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8229232/

[7] Fluoride and Caries Prevention https://www.sciencedirect.com/science/article/abs/pii/B9780323554848000253

Schedule 3

FLUORIDES for human topical use:

(a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure except when included in or expressly excluded from Schedule 2; or

(b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion **except**:

(i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the required advisory statements for medicine labels; or

(ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect:

(A) Do not swallow; and

(B) Do not use [this product/name of product] in children six years of age or less; or

(iii) in preparations for supply to registered dental professionals or by approval of an appropriate authority.

Schedule 2

FLUORIDES for human use:

(a) in preparations for ingestion containing 0.5 mg or less of fluoride ion per dosage unit; or

(b) in liquid preparations for topical use containing 1000 mg/kg or less of fluoride ion, in a container with a child-resistant closure:

(i) for therapeutic use when compliant with the requirements of the required advisory statements for medicine labels **except** in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride when fitted with a child-resistant closure and compliant with the requirements of required advisory statements for medicine labels; or

(ii) for non-therapeutic use when labelled with warnings to the following effect:

(A) Do not swallow; and

(B) Do not use [this product/insert name of product] in children 6 years of age or less;

except in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride, when fitted with a child-resistant closure and labelled with warnings to the following effect:

(C) Do not swallow; and

(D) Do not use [this product/insert name of product] in children 6 years of age or less;

except in preparations containing 15 mg/kg or less of fluoride ion or preparations for supply to registered dental professionals or by approval of an appropriate authority.

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FLUORIDES
cross reference: SILICOFLUORIDES
Schedule 6
Schedule 5
Schedule 4
Schedule 3
Schedule 2
Appendix E, clause 3
Appendix F, clause 4
Appendix H, clause 1

Appendices

Appendix E, clause 3

Item	Poison	Statement code	First aid instructions
132	FLUORIDES **except** when separately specified – when included in Schedule 6	A, G1, G3, E2, S1	**A** - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once).
			G1 - Urgent hospital treatment is likely to be needed (not – the words "at once" to be added to instruction A.
			G3 - If swallowed DO NOT induce vomiting.
			E2 - If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes
			S1 - If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, clause 4

Item	Poison	Statement code for safety directions	Safety direction
152	FLUORIDES (including silicofluorides) when included in Schedule 5 or 6 **except** when separately specified	1, 4	1 - Avoid contact with eyes 4 - Avoid contact with the skin

Appendix H, clause 1

Item	Medicines permitted to be advertised
17	FLUORIDES

Scheduling history

Fluorides were originally entered in the Poisons Standard in Schedule 4 by the Poisons Scheduling Committee (PSC) in May of 1956. Since its initial entry into the Poisons Standard, the scheduling of fluorides has been discussed several times with a Fluorides Working Party (FWP) which was established in 2007 to assist with the reconstruction of the scheduling of fluorides.

In February 2008, the National Drugs and Poisons Scheduling Committee (NDPSC) amended the wording of the Schedule 2 and 3 exemptions for fluorides to address a consequence of a previous decision that provided a potential avenue for diversion of the substance. The amended wording clarified that the products were only unscheduled when supplied directly for registered dental professionals.

In December of 2018 a Delegate-only decision was made to create an Appendix H entry for fluorides, permitting Schedule 3 preparations of the substance to be advertised.

Proposal

The applicant proposed that the wording in the Schedule 3 exemption for supply of non-liquid preparations containing 5,500 mg/kg or less of fluoride ion be amended from 'in preparations for supply to registered *dental* professionals or by approval of an appropriate authority' to 'in preparations for supply to registered ~~dental~~ health professionals or by approval of an appropriate authority' (the **Proposal**). The amendment would permit the non-liquid preparations containing 5,500 mg/kg or less of fluoride to be supplied directly to *any* registered health professional.

Final Decision

Pursuant to regulation 42ZCZW of the Regulations, a Delegate of the Secretary has made a final decision not amend the current Poisons Standard in relation to fluoride. The detailed reasons for the decision are provided within.

Materials considered

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

- The application to amend the current Poisons Standard with respect to fluorides (the **Application**)
- Subsection 52E(1) of the Act, in particular (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; f) any other matters that the Secretary considers necessary to protect public health.
- The applicant response to the interim decision provided on the 17 November 2023
- the Scheduling Policy Framework 2018 (the **SPF**), and
- the Scheduling handbook: Guidance for amending the Poisons Standard (the **Handbook**).

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

Interim decision reasons

I have made an interim decision not to amend the current Poisons Standard (the **Standard**) in relation to fluorides. The detailed reasons for my decision are as follows:

My decision not to amend the Poisons Standard with respect to fluorides was formed based on 3 key rationales:

- there are no controls on supply to specific groups when amending the entry to read all registered health professionals. For example, there is nothing to stop direct supply of the substance to someone outside of the oral health industry.
- there are already mechanisms in place through state and territory legislation to increase access and supply to specific health professional working groups, and
- the Poisons Standard is not the appropriate instrument by which to increase access for specific health practitioner groups.

The insertion of 'health' professional and the removal of 'dental' professional opens direct access of fluorides to all health professionals registered under the Australian Health Practitioners Regulation Agency (AHPRA). I acknowledge the applicant's response to the interim decision stating that it is reasonable that any registered health practitioners whose scope of practice is irrelevant to oral health promotion in primary health care is unlikely to seek obtain and supply fluoride varnish. This is regarding both lack of clinical relevance and negligible financial incentives, given fluoride varnish is only a reimbursable service through the Department of Veterans' Affairs dental program, Child Dental Benefits Scheme, and state/territory dental programs.

I am of the view that the direct supply of fluorides being available to any registered health professional is inappropriate. I do not feel there is a compelling argument regarding the purchase of fluoride varnish being well controlled by oral health industry. There are no mechanisms by which to ensure that direct supply is to an appropriate authority and cannot also be freely supplied to people outside of the oral health profession.

Turning to 52E(1)(b) and (c) of the Act, I note that fluorides when applied and used as directed can provide protection against dental caries. However, I am of the view that the direct supply of fluorides to an untrained health professional may result in misuse or incorrect application of the substance and, therefore, result in toxicity from excess exposure. Further, the Scheduling Handbook states that exemptions of substances from scheduling must be determined to be supplied with reasonable safety. Assessment of contraindications, particularly ulcerative gingivitis or stomatitis may be missed by a health professional not trained in oral health.

With regard to 52E(1)(f), I note that in February of 2008, the National Drugs and Poisons Scheduling Committee (NDPSC) amended the wording of the Schedule 2 and 3 exemptions for fluorides from 'preparations supplied to registered dental professionals' to instead read 'preparations *for* supply to registered dental professionals' to mitigate unauthorised on-supply. The proposed amendment to insert 'health' professionals instead of 'dental' professionals reverts this risk mitigation strategy to prevent unauthorised re-distribution.

I note the applicant has indicated that the existing mechanisms to gain access through state and territory legislation is lengthy and cumbersome. I do acknowledge the disparity in access to early intervention dental care between various communities. However, as mentioned in the Application, there are already state and territory mechanisms in place in all states to expand access to specific healthcare workers. Currently, Queensland, Western Australia and Victoria have amended their regulations to extend access to fluoride varnish for a select group of non-dental health professionals. As there are already mechanisms to achieve the increased access as proposed in the application, any

potential benefits to amending the Poisons Standard entry for fluorides to include all registered health professionals, are not outweighed by the risks to public health of unauthorised use of the substance.

In acknowledgment that the Poisons Standard is given legal effect through state and territory medicines and poisons legislation, I am of the view that the Poisons Standard is not the appropriate mechanism to increase access for specific health practitioner groups.

Based on the above reasons, I am of the opinion that the existing scheduling entry for fluoride, is appropriate and aligns with the relevant factors listed in the SPF. Extension of access to fluoride varnish has been successfully implemented and managed within Queensland, Western Australia and Victoria state and territory legislation, verifying that this is an equitable and viable delivery approach to authorise specifically approved healthcare professionals when required.

Final decision reasons

I have made a final decision to not amend the current Poisons Standard (the **Standard**) in relation to fluoride. The detailed reasons for my decision are as outlined in the interim decision.

Final decision in relation to molidustat

Final Decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to molidustat as follows.

Schedule 4 – New Entry

MOLIDUSTAT

Index – New Entry

MOLIDUSTAT

Schedule 4
Appendix D, clause 5

Appendix D, clause 5 – New Entry – Poisons for which possession without authority is illegal.

Item	Poison
26	MOLIDUSTAT

Materials considered

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

- the application to amend the current Poisons Standard with respect to molidustat (the **Application**)
- 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 Human Health Risk Assessment (HHRA) technical report on molidustat and a related product.

- 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)

In determining that this matter will be a delegate-only decision I have taken into account the information provided in the Application from the applicant, the Australian Pesticides and Veterinary Medicine Authority (APVMA), and the matters outlined under s 52E of the Act and the SPF. I note that:

- The Application proposes that molidustat be included in Schedule 4 of the Poisons Standard. The ailments or symptoms that the substance is used for requires veterinary intervention. Molidustat is currently not included in the Poisons Standard.
- In relation to s 52E(1)(a) and (b) of the Act, the proposed amendment to the Poisons Standard is to include an entry for molidustat in Schedule 4 based upon molidustat is proposed for treating anaemia associated with chronic kidney disease (CKD) in cats. The proposed molidustat-containing product is for use in companion animals and is not intended for use in food-producing animals. The risks to humans from potential exposure to molidustat product are low when used for this purpose.
- Regarding s 52E(1)(d) of the Act, the intended product will contain 25 mg/mL of molidustat sodium in a solution. The product will be available in 30 mL glass bottles fitted with a tamper proof child resistant closure, and a 3 mL oral dosing syringe. The product is intended to be a prescription veterinary medicine for oral administration by veterinary professionals and cat owners to be administered once per day for 28 days. This is consistent with the SPF factors for Schedule 4, as products containing molidustat will require veterinary diagnosis and oversight to ensure appropriate and safe use.
- In relation to s 52E(1)(c) of the Act, I have considered the Human Health Risk Assessment (HHRA) provided by the applicant for both the active ingredient and the intended product formulation containing molidustat sodium at 25 mg/mL. The HHRA indicated that the risks to human health and safety posed by this substance were acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act 1994*. However, in accordance with the cascading principle for veterinary medicines, the product formulation is intended for veterinary use only and should therefore be captured under Schedule 4, despite the relatively low toxicity profile befitting a Schedule 5 classification.
- In reviewing the HHRA, I find that the acute oral (LD_{50}) toxicity of molidustat in both rats and mice is low (> 2000 mg/kg bw). I note that no information was provided on the acute dermal and inhalation toxicity. The 25 mg/mL product formulation is neither a skin irritant *in vitro* nor a skin sensitiser in mice. Studies on the product formulation indicate that it has low potential to cause either eye or skin irritation and is unlikely to be a skin sensitiser. I consider that the risk to human health and safety would be sufficiently mitigated, as the 25 mg/mL oral formulation will only be available following professional advice from a veterinarian, where careful adherence to the label instructions will be emphasised.
- Repeat-dose, short-term and sub-chronic toxicity studies conducted in rats, mice and dogs, induced adverse haematologic effects (regenerative anaemia), and liver and/or bile duct lesions (rats only). These effects were common across all species, with mice being the most sensitive. Males tended to be more susceptible than females across the various species.
- In reference to reproductive toxicity in rats, no adverse effects were shown in male or female fertility toxicity studies with high, repeat doses. In reference to developmental toxicity studies, an increased incidence of ocular malformations in rat foetuses was observed at a maternal toxic dose (30 mg/kg bw/day), whereas no maternal toxicity or effects on foetal development in

rabbits was observed at the highest dose tested (20 mg/kg bw/day). No significant effects on fertility and reproduction were observed. The HHRA noted that there were no teratogenic findings at 10 mg/kg bw/day in rats.

- Molidustat was considered to be unlikely to be genotoxic based on a range of *in vivo* and *in vitro* studies. Studies in mice and rats indicated that molidustat was not a carcinogen at the highest doses tested (mice: 5 mg/kg bw/d; and rats: 1.1 mg.kg bw/day). There was no evidence of neurotoxicity from repeat-dose or specific acute neurotoxicity studies.
- Regarding the risk to humans through accidental exposure to molidustat, I consider that the risk to human health and safety can be adequately mitigated at the time of product registration. For the purposes of s 52E(1)(d) of the Act, I am satisfied that, the APVMA, as the regulator of all veterinary products, will consider the dosage, formulation, labelling, packaging and presentation of molidustat-containing products.
- In relation to s 52E(1)(e) of the Act, I have considered that the substance's pharmacological activity (hypoxia-inducible factor (HIF) prolyl-hydroxylase (PH) inhibitor) has the potential pose a risk of abuse, misuse, or diversion into illicit use in humans. The applicant noted that similar substances, erythropoietins (EPOs), pose a similar risk of potential abuse as performance enhancing drugs in humans or misuse in the animal racing industry. These substances often have additional access restrictions imposed on them through inclusion in Appendix D of the Poisons Standard. With this in mind it would be prudent to include molidustat in Appendix D to address molidustat's potential for misuse or abuse.
- Further, the application also provided information that molidustat is currently under development for use as a human therapeutic drug. It already has as approved usage in human in Japan[8] and has obtained conditional approval from US FDA. In this case, the entry under S4 of the Poisons Standard should not be limited to veterinary use only but allow for appropriate control of the therapeutic substance irrespective of its use in animals and humans.

Based on the above considerations and the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out above. The proposed amendment was not referred to an expert advisory committee.

Implementation date

1 February 2025

[8] Information for Approved Products in Japan. Pharmaceuticals and Medical Devices Agency (pmda.go.jp)

Final decision in relation to desloratidine

Final Decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to desloratadine as follows:[9]

Schedule 4

DESLORATADINE **except**:

(a) when included in Schedule 2; or
(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, when:
    i. in a primary pack containing 10 dosage units or less; and
    ii. labelled with a recommended daily dose not exceeding 5 mg of desloratadine.

Schedule 2 – Amend Entry

DESLORATADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis when:

(a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over; and
(b) labelled with a recommended daily dose not exceeding 5 mg of desloratadine.

Appendix F, clause 4 – Poisons that must be labelled with warning statements and safety directions

Item	Poison	Warning statement item number
23	ANTIHISTAMINES not separately specified in this Appendix **except** the following: (a) dermal, ocular, parenteral and paediatric preparations; (b) oral preparations of astemizole, azelastine, bilastine, cetirizine, desloratadine, fexofenadine, loratadine, or terfenadine; (c) nasal preparations of azelastine or olopatadine; (d) preparations for the treatment of animals	**39** – This medication may cause drowsiness. If affected, do not drive a vehicle, or operate machinery. Avoid alcohol. Or **40** – This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery

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DESLORATADINE
Schedule 4
Schedule 2

Materials considered

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

- the application to amend the current Poisons Standard with respect to desloratidine (the **Application**)

[9] 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 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.
- 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 amend the current Poisons Standard in relation to desloratadine to allow supply on general sale as proposed by the applicant. The applicant proposed for desloratadine to be scheduled in line with loratadine (except the labelled recommended daily dose) due to a comparable safety and efficacy profile.[10] Loratadine is exempt from scheduling when in divided preparations for oral use for the treatment of seasonal allergic rhinitis when:

(a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over; and
(b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Desloratadine has a higher potency than loratadine with 5 mg being a typical adult dose.

In relation to s 52E(1)(a) and (b) of the Act, desloratadine is a second-generation antihistamine first approved for use in Australia in 2003 to treat seasonal allergic rhinitis and perennial allergic rhinitis. Allergic rhinitis is a condition that affects the membrane lining of the nose induced by inflammation from the immune system. This causes symptoms such as nasal congestion, sneezing and nasal itching.[11] Allergic rhinitis affects almost 20% of the Australian population and can have a considerable impact on quality of life.[12]

In considering s 52E(1)(a) and (c) of the Act, the safety and toxicity of desloratadine is well established. There is 20 years of approved desloratadine use in Australia as a Pharmacy medicine (Schedule 2). The 2023 Organon periodic safety update report (PSUR) for desloratadine reports approximately 47,485,607 cumulative patient-years of treatment worldwide with desloratadine from 1998 until July 2023.[13] Most adverse events reported with the recommended daily dose of 5 mg were not serious and included dry mouth, fatigue and headache. I note more serious adverse events, like anaphylaxis, are very rare. I have also reviewed the Database of Adverse Event Notifications (DAEN) for desloratadine. While two reported cases were in relation to cardiac arrest, these cases involved prescription medicines, rocuronium and sugammadex, which have a known potential to cause cardiac arrest.[14, 15]

The proposed scheduling changes for desloratadine aligns 'with reasonable safety' in the Handbook:

- Allergic rhinitis is readily self-diagnosed by consumers.
- The risks to health from desloratadine are small as it has a well-established safety profile and does not interact with commonly used drugs, food or alcohol.[16] Desloratadine products would

[10] untitled (researchgate.net)

[11] Clinical practice guideline: Allergic rhinitis - PubMed (nih.gov)

[12] Optimising the management of allergic rhinitis: an Australian perspective - PubMed (nih.gov)

[13] Desloratadine Company Core Data Sheet 2023 (Appendix 20.1 – Organon. Desloratadine. Periodic Safety Update Report (PSUR). Organon LLC, USA 2023)

[14] ESMERON (tga.gov.au)

[15] pdf (tga.gov.au)

[16] Australian Medicines Handbook (amh.net.au)

remain subject to labelling that cautions consumers to check with their pharmacist or doctor if they are pregnant or breastfeeding.[17]

- There is no evidence to indicate desloratadine has potential for abuse or dependency.
- There is little need to take any special precautions in handling as desloratadine is a low-risk medicine and the proposal is for oral use and in divided preparations.[18] Products on the ARTG that are proposed to be exempt from scheduling have standard storage conditions.[19]

Based on the above reasons, I am of the opinion that greater access to desloratadine should provide a net public health benefit. The proposal presents an acceptable level of risk and will further enable consumers to readily treat allergic rhinitis. I have therefore made a final decision to amend the Poison Standard with regards to desloratadine in the manner set out above. The proposed amendment was not referred to an expert advisory committee.

Implementation date

1 February 2025

[17] Federal Register of Legislation - Therapeutic Goods (Medicines Advisory Statements) Specification 2021

[18] Divided preparations for the purposed of the Poisons Standard means a preparation manufactured and packed as discrete pre-measured dosage units prior to supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

[19] Australian Register of Therapeutic Goods (ARTG) | Therapeutic Goods Administration (TGA)

Amendments to the Poison Standard in relation to New Chemical Entities (NCEs)

The NCEs listed below will be included in the new Poisons Standard that will come into effect on 1 February 2025.

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Momelotinib

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Cipaglucosidase alfa

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Inebilizumab

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Palopegteriparatide

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Garadacimab

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Sodium citrate dihydrate

Schedule 4 – New Entry

Sodium citrate dihydrate for therapeutic use in dialysis, diafiltration, or total plasma exchange

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Sodium citrate dihydrate

Schedule 4

Version history

Version	Description of change	Effective date
1.0	Original publication	16 December 2024
2.0	p12: the sentence under heading ‘Reasons for the final decision (including findings on material questions of fact)’ incorrectly stated “…to not amend the current Poisons Standard.” The word ‘not’ has been removed to accurately reflect the final decision.	2 April 2026

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